

**The Specialist Pharmacist and Quality Indicators
of Medication Use in the Care of People with
Intellectual Disabilities and Behaviour Disorders**

A thesis submitted for the degree of Doctor of Philosophy

by

Bernadette Flood, M.P.S.I., B.Sc. Pharm, M.Sc. Primary Healthcare

DECLARATION

I declare that this thesis has not been submitted as an exercise for a degree at this or any other university and it is entirely my own work.

I agree to deposit this thesis in the University's open access institutional repository or allow the library to do so on my behalf, subject to Irish Copyright Legislation and Trinity College Library conditions of use and acknowledgement.

Bernadette Flood

SUMMARY

Quality Medication Use and the Population with Intellectual Disabilities and Behaviour Disorders. A Modified Delphi Technique to develop Quality Indicators and a Grounded Theory approach to information provided by people with Intellectual Disabilities.

In healthcare, the process of medication use is a means to produce value for the patient with intellectual disability and to maintain or improve their health. This process is of varying quality in the vulnerable population with intellectual disabilities and behaviour disorders. To address the evident health inequities in this population the medication use process should be made predictable with only chance causes of variation left in the process. Quality Indicators (QIs) are explicitly defined and measurable items referring to the structures, processes or outcomes of care that infer a judgement about the quality of care provided. This thesis describes a two part project that aimed to improve the quality of the medication use process for people with intellectual disabilities and behaviour disorders. Two separate applications were made to the university research ethics committee for approval to undertake each part of the project.

The Delphi process has been widely used for QI development in healthcare. Part 1 of this project involved a Modified Delphi Technique (MDT); a structured process involving a series of questionnaires or 'rounds' to gather information. Candidate QIs were developed using narrative literature and guideline review and expert evaluation. The candidate QIs were submitted to a 32-member panel of multidisciplinary experts, from Ireland and the UK. The MDT panel included psychiatrists, pharmacists, nursing personnel, speech and language therapists, geriatricians, psychologists and representation from academia, regulation and administration. Over two rounds the QIs were rated for importance, scientific soundness and feasibility on a 9 point Likert scale. Consensus criteria were preset. Participants were chosen based on their willingness to participate and knowledge of the population with intellectual disabilities. A total of 38 candidate QIs underwent Delphi scoring. QIs addressed patient experience, access to care, continuity of care, equity, patient safety, effectiveness, appropriateness and assessment. Following round one, 23 QIs were accepted, none were rejected and 15 were equivocal. A total of 30 candidate QIs were accepted following round two. Selection criteria were raised to differentiate the hierarchy of the final list. The following six crucial QIs were identified, rated by 90% or more of the panel as important: Medication Review, General Health Review, Restrictive Practice, Excessive Dose Anti-Psychotics, Gradual Dose Reduction and Dementia Anti-Psychotic Medication.

The experience of all patients in healthcare is an accepted arm of quality. Patients say that they care about their experience of care as much as clinical effectiveness and safety. Six people with intellectual disabilities were interviewed in Part 2. The aims of this qualitative study, using Grounded Theory were to discover how informed the participants with intellectual disabilities are about their medication and to identify key factors relating to their experiences and understanding of the medication use process.

Grounded Theory highlights the importance of developing an understanding of human behaviour through a process of discovery and induction. It aims to enquire and state how participants interpret reality and is attentive to how theory emerges from the subjective experiences of the participants. Six people with intellectual disabilities supported by a national voluntary support organisation consented to participate. Pat, a diabetic, was identified as the index case in the analysis and his situation is analysed in detail in the thesis document. The main theory developed in Part 2 of this project is that there is a role and need for 'specialist pharmacists' in the healthcare of vulnerable people with intellectual disabilities. A significant sub theory was that 'self determination' by the person with intellectual disabilities in the medication use process poses difficulties and may not ensure the highest quality care.

Quality of care can be defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge". The medication use process in this population is of vital importance as it will have an impact on the health status of the population and on healthcare costs. Pharmacists and others can only be sure to improve what they can actually measure and quality cannot be measured without QIs. QIs developed in the project have a potential impact on health, they are meaningful and susceptible to being influenced by the health system and/or a pharmacist or other health professional. The implicit notion in selecting the QIs in this project is that there is a significant quality gap in the medication use process in this vulnerable population group that needs to be addressed.

This project was the first attempt to develop QIs for the medication use process in people with intellectual disabilities and behaviour disorders. They infer a judgement about the quality of care provided in the medication use process. They are important definitions of quality care for people with intellectual disabilities and behaviour disorders and will support 'specialist pharmacists' and others involved in quality improvement in the medication use process in this vulnerable population.

ACKNOWLEDGEMENTS

I would like to thank and gratefully acknowledge the following people:

The people with intellectual disabilities with whom I have worked for the past fifteen years who have enriched my life and inspired me.

The dedicated carers of people with intellectual disabilities who live in long term care.

My supervisor, Dr. Martin Charles Henman, for giving me the opportunity to undertake this research.

The members of the 'pilot' group who gave constructive criticism and encouragement at the start of the Delphi process in Part 1 of this project.

The members of the 'expert panel' in the Modified Delphi process who gave of their expertise and time.

The C.E.O., Clinical Director and Counsellor of the National Support Organisation for People with Intellectual Disabilities who facilitated Part 2 of this project.

The interview participants; Pat, Alex, Keelan, Gabrielle, Jamie and Frances who shared their experiences of the medication use process.

To Sharon Wilson for sharing her expertise during the formatting of this thesis document.

The research community who strive to reduce health inequities and health inequalities in the vulnerable population with intellectual disabilities.

My parents, family and friends.

And finally Dermot, John, Aileen, Cormac and Maeve for your ongoing love, support and patience.

PUBLICATIONS AND COMMUNICATIONS FROM THIS THESIS

JOURNAL PUBLICATIONS

Bernadette Flood, Martin Henman. British Journal of Learning Disabilities, Advance article DOI 10.1111/bld.12121. *Case study: hidden complexity of medicines use: information provided by a person with intellectual disability and diabetes to a pharmacist.*

Bernadette Flood, Martin Henman, International Journal of Developmental Disabilities Advance article Print ISSN: 2047-3869 Online ISSN: 2047-3877. *Building quality indicators for medication use in people aging with intellectual disabilities and behaviour disorders.*

Bernadette Flood. Irish Pharmacy News Feb 2014. Invited CPD article *Intellectual disabilities: An introduction for pharmacists.*

Bernadette Flood, Martin Henman. Journal of Applied Research in Intellectual Disabilities 2014, 27, 297-328. Abstract: *Quality Indicators of the medication use process in adults with intellectual disabilities and behaviour disorders: an opportunity to address health inequities.*

Bernadette Flood, Martin Henman. Journal of Applied Research in Intellectual Disabilities 2014, 27, 297-328. Abstract: *People with intellectual disabilities and the medication use process. Grounded theory analysis of information from interviews with six people.*

Bernadette Flood, Martin Henman. Pharmacoepidemiology and Drug Safety 3428. 2013. Prescribing and Research in Medicines Management (UK & Ireland) Conference 2013 London 2013 “Intelligent Poly-pharmacy... It's not all about the number”. Abstract: *Multiple Medication Use in People Ageing with Intellectual Disability (PAWID) and Behaviour Disorders. Poly pharmacy not a superior quality indicator.*

Bernadette Flood. Clinical Pharmacist 2013 5:8:231 Invited article: *How to improve health outcomes for patients with learning disabilities.*

Bernadette Flood, Martin Henman. Irish Journal of Medical Science, Sept 2013. Vol 182. Supplement 6, S250, P60. Abstract: *Quality Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders*.

Bernadette Flood. Irish Pharmacy Union Review, Dec 2013/Jan 2014. Invited article: *People with Intellectual Disabilities and Behaviour Disorders are Complex Patients*.

Bernadette Flood. College of Mental Health Pharmacists Bulletin. March 2013. Invited article: *Tackling health inequalities. Improving medicines use for people with intellectual disabilities*.

Bernadette Flood, Martin Henman. The International Pharmacy Journal, Vol 27, No 3, Dec 2011. *The Intellectually Disabled. A neglected group who need pharmacists' help*.

Bernadette Flood, Martin Henman. The Irish Pharmacy Journal, Jan-March 2010, Page 166-167. *An invisible profession: Pharmacists and the population with intellectual disability*.

ORAL PRESENTATIONS

Bernadette Flood, Martin Henman. International Association for the Scientific Study of Developmental Disabilities, IASSIDD, Vienna, 2014. Oral presentation. *People with intellectual disabilities and the medication use process. Grounded Theory analysis of information from interviews with six people*.

Bernadette Flood, Martin Henman, IASSIDD, Vienna, 2014. Oral presentation. *Quality Indicators of the Medication Use Process in Adults with Intellectual Disabilities and Behaviour Disorders: An opportunity to address health inequities*.

Bernadette Flood, Martin Henman. Prescribing & Research In Medication Management Conference 2014, London. Invited Presentation – Abstract winner 2013. *The medication use process. What we can learn from people with intellectual disabilities*.

Bernadette Flood, Martin Henman. 14th Healthcare Interdisciplinary Conference, Trinity College Dublin 2013. *People with intellectual disabilities as 'experts' in the medication use process*.

Bernadette Flood. Hospital Pharmacists Association of Ireland, Mental Health Special Interest Group. 2013. St Mary's Hospital, Phoenix Park, Dublin, Nov 29th. Invited presentation. *Health Inequalities and People with Intellectual Disabilities.*

Bernadette Flood, Martin Henman. Seattle Club Conference, Cardiff, 2013. Oral presentation. *The Medication Use Process and People with Intellectual Disabilities.*

Bernadette Flood, Martin Henman. International Pharmaceutical Federation, FIP World Congress, Dublin 2013, August 2013. Oral presentation. *The Medication Use Process in People Ageing with Intellectual Disabilities and Behaviour Disorders. What is Quality? A Modified Delphi Technique to develop Quality Indicators.*

Bernadette Flood, Martin Henman. Prescribing and Research In Medication Management Conference Jan 2013, London. Oral presentation. *Multiple Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders. PolyPharmacy not a superior Quality Indicator.*

Bernadette Flood, Martin Henman. All Ireland Pharmacy Conference, Dundalk. Nov 2012. Oral Presentation. *The Use of a Modified Delphi Technique to identify Quality Indicators for Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders.*

Bernadette Flood. Pharmacy Law and Ethics Association, Trinity College Dublin, Dublin. 2012. Invited oral presentation. *Vulnerable People in Healthcare.*

Bernadette Flood, Martin Henman. College of Mental Health Pharmacists Conference, Hinckley, England. 2012. Oral presentation. *The Use of a Modified Delphi Technique to identify Quality Indicators for Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders.*

Bernadette Flood, Martin Henman. 11th Annual Interdisciplinary Research Conference, School of Nursing and Midwifery, Trinity College Dublin, 2010. Oral presentation. *Medication use and health Inequalities. Quality Indicators for medication use in people ageing with intellectual disability and behaviour disorders: a Delphi study.*

POSTER PRESENTATIONS

Bernadette Flood, Martin Henman. The International Association of Gerontology and Geriatrics European Region Congress 2015, April, Dublin. Poster: *Medication Use for People Ageing with Intellectual Disabilities and Behaviour Disorders: 'Advocacy' Not a High Level Indicator of Quality.*

Bernadette Flood, Martin Henman. The International Association of Gerontology and Geriatrics European Region Congress 2015, April, Dublin. Poster: *'Restrictive Practice' is a killer indicator of quality in the medication use process in people ageing with intellectual disabilities and behaviour disorders.*

Bernadette Flood, Martin Henman. All Ireland Pharmacy Conference 2015, Dundalk, Ireland. Poster: *People with intellectual disabilities and the medication use process. Grounded theory analysis of information from interviews with six people.*

Bernadette Flood, Martin Henman. Prescribing and Research In Medication Management Conference 2015, London. Poster: *Optimisation of medication use in people with intellectual disabilities: We need to listen to what they can tell us.*

Bernadette Flood. Hospital Pharmacists Association of Ireland Annual Conference Dublin, April 2014. Poster: *Safety of people with intellectual disabilities in general hospitals in Ireland.*

Bernadette Flood, Martin Henman. Irish Gerontological Society Conference, Croke Park Dublin, Sept 2013. Poster, P60. *Quality Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders.*

Bernadette Flood, Martin Henman. CARDI International Training Programme on Ageing, Sept 2013, Dublin. Poster: *The Medication use Process in People Ageing with Intellectual Disability and Behaviour Disorders. What is Quality? A Modified Delphi Technique to develop Quality Indicators.*

Bernadette Flood, Martin Henman. Hospital Pharmacists Association of Ireland Annual Conference Dublin, April 2013. Poster: *Health Inequalities and People with Intellectual Disabilities.*

Bernadette Flood, Martin Henman. Royal College of Psychiatrists Conference, Liverpool, 2012. Poster: *The Use of a Modified Delphi Technique to identify Quality*

Indicators for Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders.

Bernadette Flood, Martin Henman. 5th All Ireland Pharmacy Healthcare Conference, Dundalk, Feb. 2011. Poster: *Quality Indicators for medication use in people ageing with intellectual disability and behaviour disorder: A proposed Delphi study.*

Bernadette Flood, Martin Henman. Hospital Pharmacists Association of Ireland Annual Educational Conference, Dublin, 2010. Poster: *Quality medication use in people Ageing with Intellectual Disability and Behaviour Disorders: A proposed study to identify Quality Indicators.*

AWARDS

Bernadette Flood. Irish Pharmacy News Dec 2014, *Dynamic 100 Pharmacist 2014.*

Bernadette Flood. Irish Pharmacy News Dec 2013, *Dynamic 100 Pharmacist 2013.*
The Dynamic 100 have been nominated by their peers, colleagues and those who these individuals inspired.

Bernadette Flood, Martin Henman. Prescribing & Research In Medication Management Conference Jan 2013, London. *Hugh McGavock Bursary Award for the Best Research Abstract presented at the Prescribing and Research in Medicines Management (PRIMM) Annual Scientific Meeting in London 2013.*

BOOK CHAPTER

Invitation to contribute chapter to book: COMMUNITY LIVING, INCLUSION AND INTELLECTUAL DISABILITY. Publication is scheduled for Autumn 2016. The publisher is Floris Books of Edinburgh.

ABBREVIATIONS

<i>Abbreviation</i>	<i>Meaning</i>
AADE	American Association of Diabetes Educators
ACOVE	Assessing Care of Vulnerable Elders
AEDs	Anti-Epileptic Drugs
ACSCs	Ambulatory Care Sensitive Conditions
ADRs	Adverse Drug Reactions
AHRQ	Agency for Healthcare Research and Quality
ASD	Autism Spectrum Disorder
BPSD	Behavioural and Psychological Symptoms of Dementia
CBT	Cognitive Behaviour Therapy
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CHAP	Comprehensive Health Assessment Programme
CMHP	College Mental Health Pharmacists
CPD	Continuing Professional Development
CQC	Care Quality Commission
CRPD	UN Convention on the Rights of Persons with Disabilities
CYP	Cytochrome P
DC-LD	Diagnostic Criteria for Psychiatric Disorders for Use with Adults with Learning Disabilities
DD	Dual Diagnosis
DH	Department of Health
DIA	Disability Impact Assessment
DOHC	Department of Health and Children
DisDAT	Disability Distress Assessment Tool
DRPs	Drug Related Problems
DSM	Diagnostic and Statistical Manual of Mental Disorders
EAMHMR	European Association for Mental Health in Mental Retardation
ECHR	European Convention for the Protection of Human Rights and Fundamental Freedoms
EFHIA	Equity Focused Health Impact Assessment
EPS	Extra-Pyramidal Side Effects

EU	European Union
FDA	Food and Drug Administration – USA
FIP	International Pharmaceutical Federation
FREDA	Fairness, Respect, Equality, Dignity and Autonomy
GP	General Medical Practitioner
HbA1c	Glycated Haemoglobin
HCQI	Health Care Quality Indicator
HDAT	High Dose Anti-Psychotics
HEF	Health Equalities Framework
HIA	Health Impact Assessment
HIQA	Health Information and Quality Authority
HSCIC	Health and Social Care Information Centre
HSE	Health Service Executive
HWBs	Health and Wellbeing Boards
IASSIDD	International Association for the Scientific Study of Intellectual and Developmental Disabilities
ICD	International Statistical Classification of Diseases and Related Health Problems
ID	Intellectual Disabilities
IDS-TILDA	Intellectual Disability Supplement - The Irish Longitudinal Study on Ageing
IloP	Irish Institute of Pharmacy
IOM	Institute of Medicine
IQ	Intelligence Quotient
IQR	Inter Quartile Range
KPIs	Key Performance Indicators
LD	Learning Disability
LHO	Local Health Office
MAOI	Mono-Amine Oxidase Inhibitor
MDS	Monitored Dosage System
MDT	Modified Delphi Technique
MHT	Mental Health Trusts
MI	Mental Illness

MI	UN Principles for the Protection of Persons with Mental Illness and the
PRINCIPLES	Improvement of Mental Health Care
MRR	Medication Regimen Review
MURs	Medication Use Reviews
NCBDDD	National Center on Birth Defects and Developmental Disabilities
NDA	National Disability Authority
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIDD	National Intellectual Disability Database
NMC	National Midwifery Council
NPSA	National Patient Safety Agency
NSP	National Service Plan
OECD	The Organisation for Economic Co-operation and Development
OTC	Over the Counter
PBS	Positive Behavioural Support
PCP	Person Centred Planning
PharmCP	Pharmaceutical Care Plan
PIL	Patient Information Leaflet
PIM	Potentially Inappropriate Medication
PLEA	Pharmacy Law and Ethics Association
PNA's	Pharmaceutical Needs Assessments
POMH-UK	Prescribing Observatory for Mental Health UK
PRN	"pro re nata" – 'when necessary', 'when the thing is needed'
PSI	Pharmaceutical Society of Ireland
PwSIs	Practitioners with Special Interests
QI	Quality Indicator
QOF	Quality outcomes Framework
QUIPP	Quest for Quality and Improved Performance
RAND	RAND Corporation
RCGP	Royal College of General Practitioners
RCT	Randomised Controlled Trial
RPS	Royal Pharmaceutical Society
RQIs	Robust Quality Indicators

RTE	Raidió Teilifís Éireann, Ireland's National Public Service Broadcaster
SI	Statutory Instruments
SNRIs	Selective Norepinephrine Reuptake Inhibitors
SPC	Summary of Product Characteristics
SSRIs	Selective Serotonin Re-uptake Inhibitors
SD	Standard Deviation
TILDA	The Irish Longitudinal Study on Ageing
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
UMS	Universal Medication Schedule
UN	United Nations
UNESCO	United Nations Educational Scientific and Cultural Organisation
USA	United States of America
UTIs	Urinary Tract Infections
VFM	Value for Money
WGCS	Working Group on Congregated Settings
WHO	World Health Organisation

TABLE OF CONTENTS

DECLARATION	ii
PUBLICATIONS AND COMMUNICATIONS FROM THIS THESIS	vi
JOURNAL PUBLICATIONS	vi
ORAL PRESENTATIONS	vii
POSTER PRESENTATIONS	ix
AWARDS	x
BOOK CHAPTER.....	x
ABBREVIATIONS.....	xi
TABLE OF CONTENTS.....	xv
CHAPTER 1	1
INTRODUCTION	1
PEOPLE WITH INTELLECTUAL DISABILITIES AND BEHAVIOUR DISORDERS: QUALITY IN THE MEDICATION USE PROCESS	1
Preamble	2
1.1 Human Rights.....	2
1.1.1 Introduction	2
1.1.2 Right to Health	5
1.1.3 Capacity and Consent	8
1.2 Background	11
1.2.1 Pharmacy.....	11
1.2.2 Introduction to the Population with Intellectual Disabilities	12
1.2.3 Complex Environment	13
1.2.4 Personal Background	15
1.2.5 Expanding Knowledge.....	16
1.2.6 The Field	16
1.3 Healthcare	18
1.3.1 Human Rights Issues in Healthcare in Ireland and People with Intellectual Disabilities.....	18
1.3.2 Language Use.....	19
1.3.3 Health and Social Care Environment.....	20
1.3.4 Healthy Ireland	22
1.3.5 HSE National Service Plan.....	22
1.3.6 The Health Information and Quality Authority	24
1.3.7 The Patient Charter	24
1.3.8 Recession	25

1.3.9 Public Service	26
1.3.10 Health Inequalities.....	26
1.3.11 Quality of Healthcare for People with Intellectual Disabilities.....	27
1.3.12 Advocacy	30
1.4 Mental Health	32
1.4.1 Introduction	32
1.4.2. Mental Health Promotion.....	33
1.4.3 Mental Health and Inequalities	34
1.4.4 Behaviour Disorders and Intellectual Disability.....	35
1.4.5 Medication Use	36
1.5 Medication Use.....	37
1.5.1 Multiple Medication Use	37
1.5.2 Psychotropic Medication Use and People with Intellectual Disability ...	39
1.5.3 Medication Use and Human Rights	40
1.5.4 Pharmacy.....	41
1.6 Healthcare and People with Intellectual Disabilities	43
1.6.1 Introduction	43
1.6.2 Health Indicators	45
1.7 This Project	47
1.7.1 Evidence of Need.....	47
1.7.2 Difficulties	48
1.7.3 Quality Healthcare.....	51
1.8 Aim	51
CHAPTER 2.....	55
NARRATIVE LITERATURE REVIEW	55
2.1 Introduction.....	56
2.1.1 What is a Narrative Literature Review?	56
2.2 Intellectual Disability	60
2.2.1 Definition.....	60
2.2.2 Demographic Information	61
2.2.3 Residential Circumstance.....	61
2.2.4 Those Who Provide Care	63
2.2.5 Ageing and Intellectual Disability.....	64
2.2.6 Human Rights and Advocacy	65
2.2.7 Healthcare	69
2.2.8 Health Literacy	70
2.2.9 Pain	72

2.2.10 Inequalities and Inequities	73
2.2.11 Physical Health.....	76
2.3 Behaviour Disorders	77
2.3.1 Introduction	77
2.3.2 Assessment of Behaviour Disorders.....	80
2.3.3 Determinants of Behaviour Disorders	81
2.3.4 Health and Behaviour Disorders.....	82
2.3.5 Meta-analysis for Interventions for Challenging Behaviour	83
2.3.6 Restrictive Practices	84
2.3.7 Consent and Capacity	87
2.4 Medication Use.....	89
2.4.1 Introduction	89
2.4.2 Psychotropic Medication.....	90
2.4.3 Potentially Inappropriate Medication Use	92
2.4.4 Medication Classes	95
2.4.5 Medication Regimen Review	101
2.4.6 Medication Side Effects	103
2.4.7 Dementia.....	108
2.4.8 Dysphagia	109
2.4.9 The Medication Use Process.....	110
2.4.10 Pharmaceutical Care	113
2.4.11 Medication Use and People Ageing with Intellectual Disabilities.....	116
2.4.12 Medication Reconciliation.....	117
2.5 Quality	120
2.5.1 Introduction	120
2.5.2 Experience of Quality	121
2.5.3 Healthcare Quality.....	123
2.5.4 Dimensions of Quality	123
2.5.5 Medication Use and Quality.....	124
2.5.6 Culture	126
2.5.7 National Patient Safety Agency Priorities	129
2.5.8 Covert Medication	131
2.5.9 Complex Processes	133
2.5.10 Non Pharmacological Interventions	134
2.5.11 Quality Indicators.....	135
2.5.12 Vulnerable Groups	139
2.6 Discussion	143

2.7 Conclusion.....	144
CHAPTER 3.....	145
MODIFIED DELPHI TECHNIQUE	145
3.1 Introduction.....	147
3.1.1 Background.....	149
3.1.2 Definition.....	151
3.1.3 Objectives	152
3.1.4 Appropriateness of MDT	153
3.1.5 Ethical Considerations	153
3.1.6 Validity of the process.....	155
3.1.7 Pilot.....	155
3.1.8 Appearance of Survey.....	157
3.2 Modified Delphi Technique	158
3.2.1 Introduction	158
3.2.2 Background.....	158
3.2.3 Panel Composition	159
3.2.4 Candidate Quality Indicators	162
3.2.5 Email Survey.....	164
3.2.6 Deadline.....	166
3.2.7 Demographic Information	167
3.2.7.1 Heterogeneity of Panel	168
3.2.7.2 Pharmacists.....	169
3.2.8 Opinion of Participants	170
3.2.9 Validity of Quality Indicators	173
3.2.10 Procedure	175
3.2.11 Consensus.....	176
3.2.12 Initial Results.....	178
3.2.13 Feasibility and Consensus	179
3.2.14 No Answer	180
3.3 Modified Delphi Technique Analysis: Stage 1	181
3.3.1 Introduction.....	181
3.3.2 Descriptive Statistical Analysis.....	182
3.3.2.1 Introduction.....	182
3.3.2.2 Median Values.....	182
3.3.2.3 Mean and Standard Deviation Values.....	185
3.3.2.4 Inter-Quartile Range	186
3.3.3 Inferential Statistics.....	188

3.3.4 Qualitative Data.....	189
3.3.4.1 Background.....	189
3.3.4.2 Pharmacy	190
3.3.4.3 General Comments.....	191
3.3.5 Round 2	192
3.3.5.1 Introduction.....	192
3.3.5.2 Round 2 Survey Procedure.....	193
3.3.5.3 Round 2 Analysis.....	194
3.3.5.4 Robust Quality Indicators.....	195
3.3.6. Survey Outcome.....	198
3.3.6.1 Response Rates	198
3.3.6.2 Participation Rates.....	198
3.3.6.3 Non-Response.....	199
3.3.6.4. Partial.....	200
3.3.6.5 Co-operation.....	200
3.4 Modified Delphi Technique Analysis: Stage 2	201
3.4.1 Introduction	201
3.4.2 Cross Tabulation	202
3.4.3 Quality Criteria	205
3.4.4 Crucial or 'Killer' Quality Indicators.....	207
3.4.5. Grading of Quality Indicators	210
3.5. Discussion	212
3.5.1 Background.....	212
3.5.2. Modified Delphi Process.....	212
3.5.3 Validity of Quality Indicators	213
3.5.4 'Experts' by Experience	214
3.5.5 Advantages of this Modified Delphi Process.....	214
3.5.6 Difficulties with Modified Delphi Process	215
3.5.7 Research Personnel.....	216
3.5.8. Dimensions of Quality.....	216
3.5.9 For the Future	216
3.6 Conclusion.....	217
CHAPTER 4.....	219
PEOPLE WITH INTELLECTUAL DISABILITIES AS 'EXPERTS BY EXPERIENCE' IN THE MEDICATION USE PROCESS	219
4.1 Introduction.....	220
4.2 Background	220

4.2.1 Communication	220
4.2.2 Health Literacy	220
4.3 Project	224
4.3.1 Aim of This Project	224
4.3.2 The Researcher	224
4.3.3 Ethical Issues	224
4.3.3.1 Non-maleficence	225
4.3.3.2 Beneficence	225
4.3.3.3 Autonomy	226
4.3.3.4 Justice	226
4.3.4 The Participants	227
4.3.5 Capacity and Consent	228
4.3.6 Pharmacist Researchers	228
4.4 Methodology	229
4.4.1 Background	229
4.4.2 Interview Type	229
4.4.3 Recruitment of Participants	230
4.4.4 The Interview Process	231
4.4.5 The Interview Tool	231
4.4.6 The Interview Procedure	232
4.4.7 Interview Recording	232
4.4.8 After the Interview	233
4.5 Data Analysis	234
4.5.1 Grounded Theory	234
4.5.1.1 Background	234
4.5.1.2 Data Collection	235
4.5.1.3 Participants	237
4.5.2 Participants and Memos	240
4.5.2.1 Participant Pat	240
4.5.2.2 Participant Alex	241
4.5.2.3 Participant Keelan	242
4.5.2.4 Participant Gabrielle	243
4.5.2.5 Participant Jamie	244
4.5.2.6 Participant Frances	245
4.6 Theory Generation	246
4.6.1 Stage 1: Background to Theory Generation	246
4.6.1.1 Axial Coding	250

4.7 Literature Review – Theory Generation: Stage 2	252
4.7.1 Health of Population with Intellectual Disabilities	252
4.7.2 Medication Use in the Population with Intellectual Disabilities	254
4.7.2.1 Republic of Ireland	255
4.7.2.2 Holland	255
4.7.2.3 Norway	256
4.7.2.4 USA	256
4.7.2.5 New Zealand.....	256
4.7.3 Medication Use Issues Identified Following Interviews	257
4.7.3.1 Adherence and Concordance	257
4.7.3.2 Health Literacy	260
4.7.3.2.1 Introduction	260
4.7.3.2.2 Communication and Health Literacy	261
4.7.3.2.3 Pharmacy Health Literacy	261
4.7.3.3 Medication Side Effects	263
4.7.3.4 Provision of Information	265
4.7.3.4.1 Medication Labeling	266
4.7.4 Health Outcomes.....	267
4.7.4.1 Pathway: Health Literacy and Health Outcomes	267
4.7.4.2 Sentinel Events.....	270
4.7.5 The Person with Intellectual Disability	270
4.7.5.1 Self Determination	270
4.7.5.2 Autonomy	273
4.7.5.3 Adherence with Medication	274
4.7.6 Diabetes.....	276
4.7.6.1 Background.....	276
4.7.6.2 Ambulatory Care	276
4.7.6.3 Diabetes Distress.....	277
4.7.6.4 Understanding of Diabetes and People with Intellectual Disabilities	278
4.7.6.5 Education.....	279
4.7.6.6 Diabetes and Risk.....	280
4.7.7 Pharmacy and Medication Management	282
4.7.7.1 Background.....	282
4.7.7.2 Medication and Health Inequalities	283
4.7.7.3 Ambulatory Care Sensitive Conditions	284
4.7.7.4 Repeat Dispensing.....	284

4.8 Theory	285
4.8.1 Introduction	285
4.8.2 Theory Generation	286
4.8.2.1 Background	287
4.8.2.2 Integrated Care.....	288
4.8.2.3 Education	291
4.8.2.4 Mental Health	292
4.8.2.5 Reasonable Adjustments and Pharmacy	294
4.8.2.6 Health Literacy.....	296
4.8.2.7 Pharmacists' Interventions.....	297
4.8.2.8 Outcomes and People with Intellectual Disabilities	298
4.8.2.9 Goal Setting.....	300
4.8.2.10 Policy Context.....	302
4.8.3 Self Determination.....	304
4.8.3.1 Background	304
4.8.3.2 Accessible Information.....	306
4.8.3.3 Risk Assessment	307
4.8.3.4 Patient Safety	308
4.9 Advantages, Disadvantages and Limitations of Grounded Theory.....	311
4.9.1 Background.....	311
4.9.2 Advantages of Grounded Theory	311
4.9.3 Disadvantages	312
4.9.4 Limitations.....	312
4.9.5 Conclusions	313
4.10 Discussion	314
CHAPTER 5.....	321
DISCUSSION	321
5.1 Introduction.....	322
5.1.1 Background.....	322
5.1.2 Aims.....	322
5.1.3 Medication Use Process.....	324
5.1.4 Population Interventions.....	325
5.2 Care Environment.....	326
5.2.1 Ethics.....	326
5.2.2 Capacity in Ireland	327
5.2.3 Residential Care	328
5.2.3 Deinstitutionalisation	328

5.2.4 Experts by Experience	333
5.2.5 Audit of Intellectual Disabilities Services.....	335
5.3 Quality Indicators	336
5.3.1 Identification of Crucial Quality Indicators.....	336
5.3.2 Medication Review Crucial Quality Indicator.....	337
5.3.3 General Health Review Crucial Quality Indicator	342
5.3.4 Restrictive Practice Crucial Quality Indicator	344
5.3.5 Excessive Dose Crucial Quality Indicator	347
5.3.6 Gradual Dose Reduction Crucial Quality Indicator.....	349
5.3.7 Dementia Anti-Psychotic Medication Crucial Quality Indicator.....	350
5.3.8 Feasibility Problems	352
5.3.9 Advantages and Disadvantages of the Modified Delphi Approach.....	353
5.4 Quality	354
5.4.1 Quality Improvement	354
5.4.2 Implementation of the Quality Indicators in Healthcare.....	356
5.4.3 Medicines Management	358
5.4.5 Pharmacy.....	366
5.4.6 Specialist Intellectual Disability Pharmacist	369
5.5 Priority Areas	371
5.5.1 Introduction	371
5.5.2 Pharmacy Priorities	374
5.5.3 Healthcare Priorities	377
5.5.4 Future Research.....	380
5.6 Complexity of Care	380
REFERENCES.....	383
APPENDICES	433
APPENDIX 1	434
List of Round 1 Candidate Quality Indicators.....	434
APPENDIX 2	444
Research Ethics Committee Approval for Quality Indicators Project.....	444
APPENDIX 3	445
Quality Indicator Project – Information for Delphi Panel Participants.....	445
APPENDIX 4	448
APPENDIX 4A.....	448
Demographic Options for Round 1 Panel Members	448
APPENDIX 4B.....	449
Demographic Information Supplied by Round 1 Panel of Expertise.....	449

APPENDIX 4C.....	450
Demographic Characteristics Provided by Round 1 Panel Members	450
APPENDIX 5	451
APPENDIX 5A.....	451
Pharmacists' Rating of Round 1 Candidate Quality Indicators	451
APPENDIX 5B.....	452
Psychiatrists' Rating of Round 1 Candidate Quality Indicators	452
APPENDIX 6	453
APPENDIX 6A.....	453
Round 1 Candidate Quality Indicators: First Analysis.....	453
APPENDIX 6B.....	454
Quality Indicators with High Level Round 1 Consensus	454
APPENDIX 7	455
Ranked Mean for Importance Round 1 Quality Indicators	455
APPENDIX 8	456
Round 1 Quality Indicators Mean, Median, Mode and Standard Deviation.	456
APPENDIX 9	457
List of Round 2 Candidate Quality Indicators	457
APPENDIX 10	461
APPENDIX 10A.....	461
Round 2 Quality Indicators Survey Results	461
APPENDIX 10B.....	462
Round 2 Quality Indicators Importance Ranking	462
APPENDIX 10C.....	463
Round 2 Quality Indicators Scientific Soundness Ranking	463
APPENDIX 10D.....	464
Round 2 Quality Indicators Feasibility Ranking	464
APPENDIX 11	465
Round 2 Quality Indicators: Mean, Median, Mode and Standard Deviation	465
APPENDIX 12	466
Survey Participation: Round 1 'Partials'	466
APPENDIX 13	467
Panel Members who Consented to be Identified	467
APPENDIX 14	471
APPENDIX 14A.....	471
Participant Information Sheet.....	471
APPENDIX 14B.....	475

Participant Consent Form.....	475
APPENDIX 14C.....	476
Information Leaflet for Support Organisation Personnel	476
APPENDIX 14D.....	479
Information Leaflet for Family Members	479
APPENDIX 15	481
APPENDIX 15A.....	481
Letter from CEO National Support Organisation for People with Intellectual Disabilities.....	481
APPENDIX 15B.....	482
Letter from Medical Director National Support Organisation for People with Intellectual Disabilities	482
APPENDIX 16	483
Research Ethics Approval for Interviews with People with Intellectual Disabilities.....	483
APPENDIX 17	484
Semi Structured Interview Tool	484
APPENDIX 18	492
Feedback to Counsellor	492
APPENDIX 19	507
Information for Participants Post Interviews.....	507
APPENDIX 20	509
The Health Equalities Framework	509
APPENDIX 21	511
Grounded Theory: Inductive Theories	511
APPENDIX 22	513
The Leeds Health and Social Care Transformation Programme:.....	513
Clinical Values in Prescribing – Cross Sector Project.....	513
APPENDIX 23	514
Self Management of Medication - Person with Intellectual Disabilities.....	514
APPENDIX 24	516
Theories: Grounded Theory Approach to Interviews with People with Intellectual Disabilities.....	516
APPENDIX 25	519
Quality Indicators – Graded.....	519
APPENDIX 26	530

Principles of Good De-prescribing during Medication Review in the Population with Intellectual Disabilities and Behaviour Disorders.....	530
APPENDIX 27	531
Statutory Instrument (S.I.) No. 367/2013 Reference to Medicines and Pharmaceutical Service	531

TABLE OF FIGURES

Figure 1.1 Approaches to Disability Over Time.....	3
Figure 1.2 Linkage Between Health and Human Rights	6
Figure 1.3 Determinants of Health.....	14
Figure 1.4 Structure of Literature Review Chapter 2.....	52
Figure 2.1 Themes in Literature Review	58
Figure 2.2 Intellectual Disability: Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders.....	60
Figure 2.3 Behaviour Disorders: Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders.....	77
Figure 2.4 Health and Intellectual Disabilities and Behaviour Disorders	82
Figure 2.5 Medication Use: Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders.....	89
Figure 2.6 Medication Use Process for People with Intellectual Disabilities.....	112
Figure 2.7 Quality: Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders.....	120
Figure 2.8 Framework for the Analysis of Factors Influencing the Person with Intellectual Disabilities Experience of Healthcare	122
Figure 2.9 Quality Indicator Structure	138
Figure 3.1 Process of Building Quality Indicators for Medication Use in People Ageing with Intellectual Disabilities and Behaviour Disorders.....	147
Figure 3.2 Example of Pilot Likert Scale	156
Figure 3.3 Process Leading to Crucial Quality Indicator Identification	209
Figure 4.1 Essential Grounded Theory Methods	237
Figure 4.2 Coding Process Grounded Theory Approach - Participant Pat	240
Figure 4.3 Coding Process Grounded Theory Approach - Participant Alex.....	241
Figure 4.4 Coding Process Grounded Theory Approach - Participant Keelan.....	242
Figure 4.5 Coding Process Grounded Theory Approach - Participant Gabrielle	243
Figure 4.6 Coding Process Grounded Theory Approach - Participant Jamie	244
Figure 4.7 Coding Process Grounded Theory Approach - Participant Frances.....	245
Figure 4.8 'Self Determination' as a Theory.....	248
Figure 4.9 'The Quality of the Medication Use Process' as a Theory.....	249
Figure 4.10 Person with Intellectual Disability is Vulnerable in Medication Use Process in Healthcare – Axial Coding	251
Figure 4.11 Pharmacy and the Medication Use Process for Vulnerable People with Intellectual Disabilities – Axial Coding	252

Figure 4.12 Five Countries in which Medication Use is Reviewed	254
Figure 4.13 Health Literacy and Health Outcomes	269
Figure 4.14 Self Determination Scale for Participants	271
Figure 4.15 Adherence Scale for Participants	275
Figure 4.16 Process of Theory Generation.....	285
Figure 4.17 Factors Necessary to Improve Health Outcomes	299
Figure 4.18 Goal Setting – Participants in this Project.....	301
Figure 4.19 Risk Stratification-Support Needs and Cost.....	308
Figure 5.1 The Complexity of the Medication Use Process	325
Figure 5.2 Priorities.....	373

TABLE OF TABLES

Table 1.1 Sequelae for Intellectual Disability: Severity Levels, Definitions and Lay Description	13
Table 1.2 System Wide Priority Areas. HSE National Service Plan	23
Table 1.3 Health Inequalities in People with Intellectual Disabilities	27
Table 1.4 European Health Indicators	46
Table 1.5 Proposed Health Indicators – USA	47
Table 2.1 Candidate Quality Indicators (QIs).....	59
Table 2.2 Main Residential Circumstance in 2012.....	62
Table 2.3 Advocacy Issues for People with Intellectual Disabilities.....	67
Table 2.4 Possible Causes of Poorer Health Experienced by People with Intellectual Disabilities	69
Table 2.5 Function of Psychiatrist in Delivering Healthcare to People with Intellectual Disabilities	75
Table 2.6 Combined use of Antipsychotics, Antidepressants and Anxiolytics, IDS-TILDA.....	96
Table 2.7 Performance Against Standard for Monitoring of Side Effects.....	105
Table 2.8 Factors Shaping Person’s Experience at Individual Level.....	123
Table 2.9 NPSA Priority Areas for People with Intellectual Disabilities	130
Table 3.1 Modified Delphi Process for Developing Quality Indicators for Medication Use in People Ageing with Intellectual Disabilities and Behaviour Disorders.	148
Table 3.2 Candidate Quality Indicators and Quality Criteria.....	163
Table 3.3 Use of Email in a Survey: Advantages and Disadvantages.....	164
Table 3.4 Round 1: Informational Transfer Candidate Quality Indicator Importance Rating.....	171
Table 3.5 Round 1 Feasibility Ratings for Advocate Candidate Quality Indicator.	172
Table 3.6 Round 1 Candidate Quality Indicators rated 7-8-9 ‘important’ by less than 75% of Round 1 Panel	178
Table 3.7 Round 1 Candidate QIs rated 7-8-9 by less than 75% of the Round 1 Panel	179
Table 3.8 Round 1 Quality Indicators rated 7-8-9 for Feasibility by Less than 50% of Round 1 Panel	180
Table 3.9 Round 1 Panel Use of ‘No Answer’ Option	181
Table 3.10 Round 1 Quality Indicators Median Values – Panel Ratings	183
Table 3.11 Median Values for Twenty-three Quality Indicators that Achieved Consensus in Round 1	184

Table 3.12 Inter-Quartile Range Example from Round 1 Statistical Analysis.....	187
Table 3.13 Number of Comments made by Round 1 Panel Members.....	190
Table 3.14 Sample Results Round 1 Demographic Work – Pharmacy.....	191
Table 3.15 Response Rate Round 1 and Round 2.....	193
Table 3.16 Importance Ranking of 30 Robust QIs.....	196
Table 3.17 Survey Outcome Rates for Consented Panel Members.....	200
Table 3.18 Cross Tabulation 30 Robust Quality Indicators: Importance v Scientific Soundness.....	203
Table 3.19 Robust Quality Indicators: Rated by > 80% Panel Members as Important and Scientifically Sound.....	204
Table 3.20 Robust Quality Indicators Cross Tabulation: Importance and Scientific Soundness versus Feasibility.....	205
Table 3.21 14 Higher Level Quality Indicators and Quality Criteria.....	206
Table 3.22 Higher Level Quality Indicators Importance Rating by Panel.....	207
Table 3.23 Crucial or ‘Killer’ Quality Indicators.....	208
Table 3.24 Crucial Quality Indicators, Mean, Standard Deviation and Median.....	208
Table 3.25 Grade 1: Quality Indicators - Eight.....	210
Table 3.26 Graded Quality Indicators.....	211
Table 4.1 Criteria for Assessing Quality of Grounded Theory Research.....	235
Table 4.2 Participant Information.....	239
Table 5.1 Aims of This Project.....	323
Table 5.2 Pharmacy Priorities.....	375
Table 5.3 Healthcare Priorities.....	378

TABLE OF BOXES

Box 1.1 Healthcare Value Equation.....	49
Box 2.1 Medication Recommendation - People who Challenge: Practice and Services	86
Box 2.2 Psychotropic Medication - Commissioning Action.....	90
Box 2.3 Psychotropic Medication Use	106
Box 2.4 Medication Use Linked to Care Delivery.....	111
Box 2.5 Strategy for Improving Capacity of Disability Services to Meet the Needs of People with a Disability by Improving Health Outcomes	114
Box 2.6 NPSA Patient Safety Issue 2	118
Box 2.7 Dimensions of Healthcare Performance	124
Box 2.8 Recommendation 4.5 Madden Report	126
Box 2.9 Implication for Policy and Practice: Mental Health	133
Box 2.10 Mental Health and Intellectual Disabilities: Addressing the Mental Health Needs of People with Intellectual Disabilities.....	134
Box 2.11 Example of a RAND Quality Indicator for Assessing the Reasons for Falling	137
Box 2.12 Experiences of People with Intellectual Disabilities of the Medication Use Process	140
Box 2.13 NHS Quality Indicator Relating to Effectiveness of Care for Those with Intellectual Disability.....	142
Box 2.14 Examples of NHS Quality Indicators that Appear Relevant to the Population with Intellectual Disabilities and Behaviour Disorders.....	142
Box 3.1 Strategies for Mitigating Risks Associated with a Modified Delphi Study	150
Box 3.3 The Delphi Technique: Key Features of Design, Administration and Analysis of the Data	152
Box 3.3 Survey Monkey Questionnaires.....	157
Box 3.4 What Does a RAND Quality Indicator Look Like?	165
Box 3.5 What does a Quality Indicator Look Like in this Survey?	166
Box 3.6 Demographic Information Question – Appearance in Survey Monkey	167
Box 3.7 Panel Member Comments to Round 1 Inter-Intra Class Poly-pharmacy Candidate Quality Indicator	170
Box 3.8 Round 1 Panel Member Comment on Residential Care Quality Indicator.....	186
Box 3.9 Round 1 Informational Transfer Quality Indicator: Panel Members Comments	187
Box 3.10 General Comments from Round 1 Panel Members	191

Box 3.11 Panel Member Comment on ‘Fatigue’ in Postal Delphi Survey.....	192
Box 3.12 Panel Members Comments on 30 Robust QIs – Sample.....	197
Box 3.13 One Panel Member’s Comment on Robust QIs.....	201
Box 3.14 Example of Different Criteria in One Modified Delphi Technique	202
Box 4.1 Simple Strategies to Improve Concordance	259
Box 4.2 Universal Medication Schedule	267
Box 4.3 Practical Tips for Minimizing Pain During Injection	280
Box 4.4 Participation Facilitation Requirements in Population with Intellectual Disabilities.....	291
Box 4.5 Planning to Involve People With Intellectual Disabilities and Mental Health Difficulties	293
Box 4.6 What Primary Care for People with Intellectual Disabilities and Mental Health Problems Might Look Like: Pharmacist and Primary Care for People with Intellectual Disabilities and Mental Health Problems	294
Box 4.7 Pharmacy Staff Communication Skills.....	296
Box 4.8 What People with Intellectual Disabilities Want from Contact with Mental Health Services.....	298
Box 4.9 Matters for Consideration when Making Pharmaceutical Needs Assessments	304
Box 4.10 What can be Learnt from Incidents in the Mental Health and Learning Disabilities Sector?	310
Box 4.11 Synopsis of Grounded Theory.....	313
Box 4.12 Summary of Competencies for a Practitioner with Special Interest in Learning Disabilities.....	318
Box 5.1 What People with Intellectual Disabilities have said about Pharmacists	331
Box 5.2 Crucial Quality Indicators	337
Box 5.3 Medication Review Crucial Quality Indicator	337
Box 5.4 Level 3 Room for Review Medication Review.....	338
Box 5.5 National Standards for Residential Services for Children and Adults with Disabilities, HIQA Standard 4.3.....	339
Box 5.6 General Health Review Crucial Quality Indicator.....	343
Box 5.7 Family Carers’ Experiences of Assessment and Treatment Units	344
Box 5.8 Restrictive Practice Crucial Quality Indicator.....	345
Box 5.9 Excessive Dose Crucial Quality Indicator	348
Box 5.10 Gradual Dose Reduction Crucial Quality Indicator.....	350
Box 5.11 Dementia Anti-Psychotic Medication Crucial Quality Indicator.....	351
Box 5.12 Question to be Asked when Antipsychotic Medication Requested.....	352

Box 5.13 Comments on: National Clinical Strategy for Older People, Specialist Geriatric Services Model of Care, Part 3: Mental Health Service Provision, Draft Document..... 360

CHAPTER 1

INTRODUCTION

PEOPLE WITH INTELLECTUAL DISABILITIES AND BEHAVIOUR DISORDERS: QUALITY IN THE MEDICATION USE PROCESS

Preamble

Census 2011 in Ireland showed that 57,709 people, or 1.3 per cent of the population, suffered from an intellectual disability. More than four out of five (81.3%) of those with an intellectual disability suffered from a second disability. The most common of which was a difficulty with learning, remembering or concentrating which was indicated by 40,550 people (70.3%) in this group. One in three also indicated a psychological disability with 19,329 persons experiencing both of these disabilities (Central Statistics Office, 2012).

People with intellectual disabilities remain among the most neglected - the most “invisible” - members of our communities (Hunt, 2005). Their neglect is reflected in society at large, among the health professions such as pharmacy, and in the human rights community. They are often especially vulnerable in healthcare due to their varying ability to protect their own interests without assistance. Improving the lives of people with intellectual disabilities by enhancing the quality of health and social care services is a concern that should be shared by professionals, staff, families and carers. The process of medication use is a means to produce value for the patient with intellectual disability, but is of varying quality. Quality measurement and feedback are important aspects of improving the delivery of health care.

[Different terms such as ‘learning disability’, ‘learning difficulty’ and ‘mental retardation’ are used in different countries. In Ireland the term ‘intellectual disability’ is used and for the sake of consistency the terms ‘intellectual disability’ and ‘intellectual disabilities’ are used throughout the thesis that follows except where a direct quote warrants otherwise. When writing or speaking about people with disabilities The National Disability Authority has emphasised the importance of putting the person first (NDA, 2011b) and this shall be done throughout this document].

1.1 Human Rights

1.1.1 Introduction

The World Health Organisation has long recognised that the needs of adults ageing with intellectual disabilities requires special attention (Janicki, 2000). The health needs and causes of death differ for people with intellectual disabilities and it is a concern that

most current health policies and public health initiatives will widen rather than close this health inequality gap (Cooper et al., 2004). People with intellectual disabilities are vulnerable in healthcare, they bear an unfair proportion of health problems and will depend on assistance from others, such as pharmacists interested in their care.

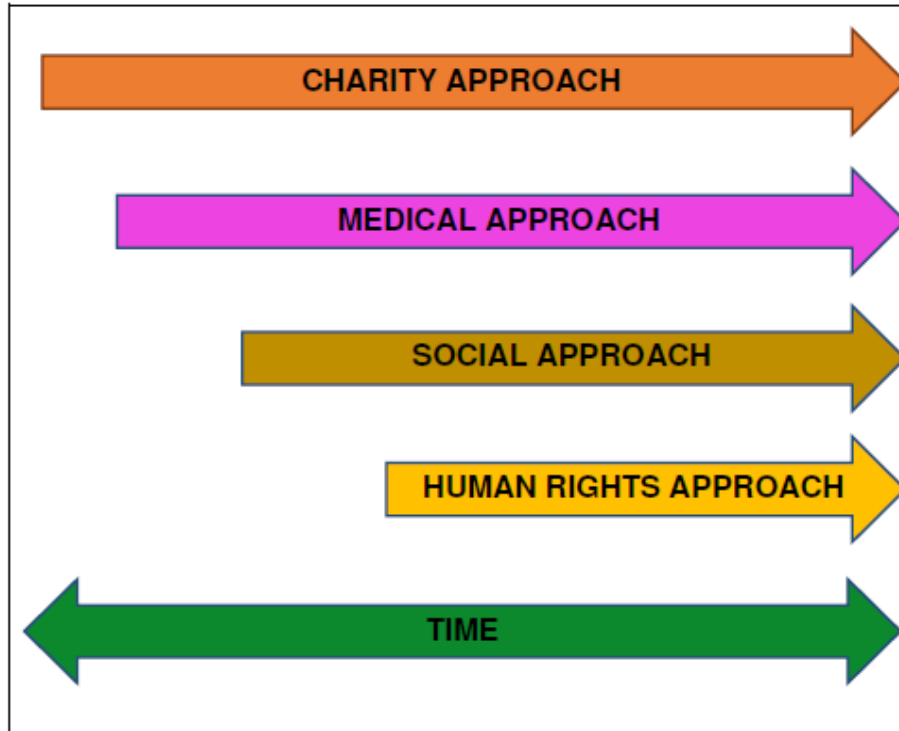


Figure 1.1 Approaches to Disability Over Time

Over time the approach to disability has changed from the charity model, to the medical model to the social model (Office of the High Commissioner for Human Rights, 2012). This is illustrated in Figure 1.1 above. In the charity model persons with disabilities cannot take care of themselves, they inspire compassion and they are objects of benevolence. In the medical approach they need to be cured, they play a passive role, they are considered abnormal and they are unable to live independently. In the social model disability is seen as the result of an incorrect way of organizing society, which causes people with disabilities to face bias and barriers that prevent their equal participation. In the human rights approach people with disabilities are ensured full and equal enjoyment of all human rights. This approach also promotes respect for their dignity. In this approach people are viewed as rights holders.

States are obliged in the case of vulnerable or disadvantaged groups to

'give appropriate preferential treatment to people with disabilities in order to achieve the objectives of full participation and equality within society for all person with disabilities' (Harnois and Saraceno, 2007).

Listening to the voice and experiences of people with intellectual disabilities, their carers and advocates will ensure that human rights are placed at the heart of the way healthcare services are designed and delivered for people with intellectual disabilities. Chapter 4 of this thesis details some experiences of people with intellectual disabilities in relation to medication use where rights, respect and responsibility converge.

Human rights are acknowledged (Gearty, 2006) as

"one of the great civilising achievements of the modern era"

The British Institute of Human Rights has articulated the need to make human rights

"a living, breathing tool that can be used by people who are delivering services and also people who are on the receiving end of them".

The former Irish Ombudsman, Emily O Reilly, has stated that human rights should become part of the process or

"rules of the game"

of government and political life and secondly, that human rights should become part of public consciousness (O Reilly, 2010). This consciousness must extend to healthcare and the medication use process in particular.

It is only in relatively recent times that the words 'human rights' and 'intellectual disabilities' appear in the same sentence even though the right to the highest attainable standard of health is not optional for people ageing with intellectual disabilities. Their right to health depends upon the interventions and insights of doctors, pharmacists, allied health professionals, social care staff, families, nurses and public health. It includes an entitlement to a system of health protection, including health care and medication. Care and support services - as well as healthcare - play a vital role in ensuring the health and dignity of people with intellectual disabilities.

Ensuring a human rights based approach to health which pays equal attention to process (how the rights of people with intellectual disabilities are respected within the

health system) as well as outcome (the goal of improving health) is vital for people ageing with intellectual disabilities. Pharmacists and others proactively promoting human rights can drive up quality, improve outcomes for people with intellectual disabilities and staff and reduce cost pressures. The right of people with intellectual disabilities to the highest attainable standard of health is concerned with both the processes and the outcomes of healthcare. This means that it is interested in not only what a health system does but also how well it does it. The quality of the medication use system is therefore of importance.

The Universal Declaration of Human Rights (UDHR) which was adopted in 1948 lays out the foundation for the '*right to health*'. The '*right to health*' is a legal instrument that is a crucial and constructive tool for the health sector to provide the best care for patients and to hold national governments, and the international community, to account (Lancet, 2008). In 2000 the United Nations (UN) Committee on Economic, Social and Cultural Rights adopted General Comment 14, which states that in addition to access to health care, the right to health also includes underlying determinants of health, freedom from discrimination, participation and accountability (CESCR, 2000).

1.1.2 Right to Health

Health is a resource for everyday life for people with intellectual disabilities. Health is a positive concept emphasising social and physical resources as well as physical and mental capacity and our understanding of 'health' for people ageing with intellectual disabilities depends on the many different contexts in which their lives are lived and their health is perceived. The right to adequate health is a prerequisite to all other human rights recognized in treaties. To deny someone with intellectual disabilities health care is to deny or damage all that person's rights. Individuals who may lack adequate health care such as people ageing with intellectual disabilities can lose some or all ability to exercise fully the civil, political, economic, social and cultural rights they possess. Violations of the right to health can occur through the direct action of states or others such as healthcare providers and individual professionals, such as pharmacists, insufficiently regulated by states.

The right to health is a legal instrument. It is a crucial and constructive tool to be used by the health sector to provide the best care for patients with intellectual disabilities and to hold national governments, and the international community, to account. The Special Rapporteur (Hunt, 2006) on the right to health defines it as the

“right to an effective and integrated health system, encompassing healthcare and the underlying determinants of health, which is responsive to national and local priorities and accessible to all”.

Health professionals and health workers, health policy makers, and all who care about the health of individuals, groups, and the global population, should incorporate the right to health as a

‘valuable and practical tool’

in their everyday practice (Lancet, 2008). Healthcare staff should address health issues and human rights in all settings of care and there is a recognised linkage between health and human rights, illustrated in Figure 1.2 below (Talbot and Verrinder, 2014).

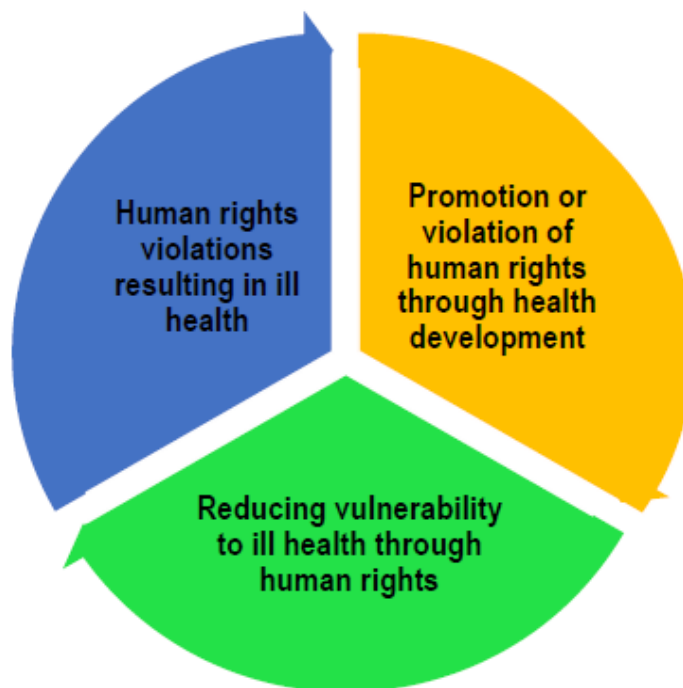


Figure 1.2 Linkage Between Health and Human Rights

Vulnerability to ill health in the population with intellectual disabilities can be reduced by taking steps to respect, protect and fulfil human rights such as the right to health. The right to health for people with intellectual disabilities contains entitlements and freedoms, including freedom from discrimination. Overt or implicit discrimination

against people with intellectual disabilities violates one of the fundamental principles of human rights and often lies at the root of the poor health status of many people with intellectual disabilities. This discrimination may be direct or indirect. Direct discrimination occurs when an intellectually disabled person experiences exclusion when she is not offered health screening or is treated less fairly than another person on grounds of her membership of the population with intellectual disability. This is usually overt and involves intent. Indirect discrimination is less visible and does not always involve intent. It is most visible in terms of the outcomes for particular groups such as the population with intellectual disabilities in relation to healthcare services. Indirect discrimination refers to the differential impact of the same treatment where the differential is not justified, for example not including 'reasonable adjustments' when providing pharmaceutical care.

'In situations where discrimination occurs we either deliberately refuse to see it or whitewash out its very existence by pretending it is other than what it actually is - we see the victims as lesser, as not quite fully human and therefore undeserving of our full protection' (O Reilly, 2009b).

If the human rights approach is to have any impact, then it needs to reach out first and foremost to those who are the most marginalised and excluded within our society (House of Commons and House of Lords, 2007) such as people ageing with intellectual disabilities and behaviour disorders. The UDHR articulates the right to adequate health in Article 25 –

"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care..." (UN, 1948).

UDHR Article 25 contends that states must also take action to ensure that all citizens enjoy an adequate standard of living. It recognizes food, clothing, housing, health care and social services as essential components of a standard of living adequate for health and well-being.

Human rights impact assessments which are a relatively new phenomenon are based on a framework of international legal obligations to which governments have agreed. They provide opportunity to make government policy making more coherent across departments, as the framework applies to all departments of government. They should result in more effective policies, as the policies would be more coherent and be

supported by legal obligations and they would be adopted through processes that respect human rights (Hunt and McNaughton, 2006). The right to health for people with intellectual disabilities would provide an excellent case study for human rights impact assessment that focuses on ensuring that Irish government policy as it affects the population with intellectual disabilities alleviates rather than contributes to health poverty and health inequalities.

Consent to treatment is one of the most important human rights issues relating to intellectual disabilities. While the issue is often considered in relation to the right to liberty and security of the person, as well as the prohibition against inhuman and degrading treatment, it is less frequently considered in the context of the right to health. States should refrain from applying coercive medical treatments other than on an exceptional basis for the treatment of mental illness or for the prevention and control of communicable diseases (Irish Human Rights Commission, 2010). Connected closely with a vital element of the right to health is the freedom to control one's health and body which will include the consumption of medication. Paul Hunt, the Special Rapporteur, has recommended that this important 'right to health' issue is given urgent reconsideration with a view to better protecting, at the international and national levels, the right to informed consent (Hunt, 2005).

1.1.3 Capacity and Consent

Capacity and consent are complicated in people with intellectual disabilities by literacy problems, communication difficulties and unsubstantiated assumptions by some professionals, as well as by the fact that some people with intellectual disabilities will not be competent to make some decisions regarding medication use.

The test of capacity currently applied in the Irish Courts is the 'C test' which is in three parts all of which must be fulfilled for the patient to be deemed competent to make the decision they are being asked to consider:

1. Does the person comprehend and retain treatment information?
2. Does the patient believe that information?
3. Does the patient weigh that information, balancing risks and needs, to arrive at a choice?

The underlying principles (Bernal, 2006), that can be applied to medication use are:

- Assume capacity. All adults have capacity unless and until they are shown not to. If the decision is a complex one it may be useful to consider the ethical issues.
- Capacity refers to the ability to make a particular decision at a particular time. It is wrong to refer to a person as having or lacking capacity for all decisions.
- Capacity can vary in the same person for different decisions and can fluctuate over time. Capacity is decision specific.
- A person with capacity has the right to refuse treatment. People have the right to make bad decisions. If a person does not consent, the reasons for this should be explored.
- A health professional such as a pharmacist has a duty of care to patients. A person should not be denied treatment that is necessary to them merely because they are not competent to consent.
- If an adult lacks capacity the health professional has a duty to provide treatment and care in the best interests of that adult, even if the person does not agree.
- In Irish Law nobody can consent on behalf of another adult.
- If you force treatment on a person who has capacity you may be assaulting them.
- If you deny treatment to a person who lacks capacity you may be neglecting them.
- The professional giving the treatment is responsible for assessing the patient's capacity, and for asking for any assistance they need to do so. It is the responsibility of the health professional who will be performing the intervention to make sure the patient understands in broad terms what the intervention is for, the main risks and benefits of the intervention and what may happen if the patient does not have the treatment.
- Capacity depends on understanding.
- Understanding depends on effective communication and accessible information as well as cognitive abilities.

- Even people who lack capacity may want and have the right to receive information. Health professionals such as pharmacists need to give people permission to disagree with the “expert” without withholding expertise.
- Consent obtained by force (under duress) is not valid. The differences in power between patients and health professionals as well as between cared for and care-giver are a common, perhaps inevitable, part of these relationships.
- Consent can be shown behaviourally, for example a person with intellectual disability may pull up his sleeve to allow the administration of an injection or a person with intellectual disability may scream and pull away when the injection is about to be given.

The medication use process in the population with intellectual disabilities contains a tension between the desire of professional staff, prescribers, pharmacists, social workers and others to promote choice and independence in relation to medication use on one hand, and on the other hand to protect people with intellectual disabilities from abuse and neglect in relation to medication use that may result from excessive use, underuse, inappropriate use and poor monitoring. The reality of the risk concerning medication use in the lives of people with intellectual disabilities, that comes with having control of medication use vested in other persons who provide support, must be recognised. It must also be recognized that people with intellectual disabilities may be overly controlled through risk management approaches which ineffectively acknowledge their right to self determination in the medication use process in an effort to keep them safe.

The Assisted Decision-Making (Capacity) Bill (2013) (formerly referred to as the Mental Capacity Bill) that was published in July 2013, contains proposals to provide a modern statutory framework supporting decision-making by adults who have difficulty in making decisions unaided. It will repeal the Marriage of Lunatics Act 1811 and cause the Lunacy Regulation (Ireland) Act 1871 to cease to have effect. The replacement of the Wards of Court system for adults is provided for in the Bill. The Wards of Court System is the existing mechanism for managing the affairs of persons whose capacity is impaired. The Bill will be a key step in enabling ratification of the UN Convention on the Rights of Persons with Disabilities (DJ&E, 2014) and should impact on many aspects of medical care in the Irish state including medication use in people with intellectual disabilities and behaviour disorders.

The Irish Human Rights Commission has however included the following observations on the Assisted Decision-Making (Capacity) Bill 2013 that should be of interest to those pharmacists and others concerned with human rights in the care of people with intellectual disabilities in Ireland.

‘The distinction between legal capacity and mental capacity be clarified within the Bill, so as to ensure a person’s legal capacity is guaranteed and is not infringed on the basis of their having diminished or impaired mental capacity’ (IHRC, 2014).

1.2 Background

1.2.1 Pharmacy

The implementation of the 2007 Pharmacy Act in Ireland must ensure protection of the most vulnerable in society and enable pharmacists to meet the challenge of an increasingly complex and evolving therapeutic environment. When speaking at a lecture to mark the Pharmaceutical Society of Ireland (PSI) Council's first meeting in its capacity as regulator, Dr Mary Keys, issued a call to action

“Any new legislation must increase the focus on the vulnerable individual and should have a positive influence on the human rights of patients”.

People with intellectual disabilities are a population group that pharmacists may find ‘hard to see’ and ‘hard to hear’. There is no more complex population group being cared for by pharmacists in a continually evolving therapeutic and social environment than the population with intellectual disabilities.

Pharmacists are recognised as highly skilled and autonomous professionals (Oliver, 2013). However the contribution of pharmacists to the care of people with intellectual disabilities is often hidden, overlooked or potentially undervalued. Pharmacists may be invisible in the healthcare processes of people with intellectual disabilities and attempts have been made to alert the wider pharmacy community to this state of affairs (Flood and Henman, 2010). Pharmacists must engage with the quality of medication use in this population group and pharmaceutical care is discussed in more detail in Chapter 2 of this thesis.

1.2.2 Introduction to the Population with Intellectual Disabilities

The population with intellectual disabilities is a heterogeneous one. In almost half of cases of intellectual disability, the cause is not identified. An identifiable etiology is present in up to 70% of children with severe intellectual disability but in only 24% of children with mild intellectual disability (WHO, 2013). The causes can be environmental or genetic. Down Syndrome is a common genetic cause of intellectual disability. The common environmental causes include birth asphyxia and trauma, intrauterine growth retardation, maternal infection, malnutrition, iodine deficiency and lead exposure.

For those pharmacists and others who are unfamiliar with this vulnerable population it is important to note that intellectual disability is an International Classification of Diseases and Health Related Problems (ICD) - 10 classification. Five sequelae in Table 1.1 have been identified for intellectual disability (WHO, 2013) and these may help those unfamiliar with the population group to gain some insight into the people who are members of this vulnerable population. In the narrative literature review that follows in Chapter 2 of this thesis, there is a detailed look at the population with intellectual disabilities from various perspectives.

Table 1.1 Sequelae for Intellectual Disability: Severity Levels, Definitions and Lay Description

Sequelae for Intellectual Disability: Severity Levels, Definitions and Lay Description		
Severity Level	Definition	Lay Description
Borderline ICD-10	IQ range 70-84	This person does not do well in school, has some difficulty doing complex or unfamiliar tasks, has trouble concentrating. The person may also have behavioural problems.
Mild ICD-10	IQ range 50-69	This person has low intelligence and is slow in learning at school. As an adult, the person can work at simple supervised jobs and live independently, but often needs help to raise children.
Moderate ICD-10	IQ range 35-49	This person has low intelligence and is slow in learning to speak and do simple tasks. As an adult, the person requires a lot of support to work productively, live independently and raise children.
Severe ICD-10	IQ range 20-34	This person has low intelligence and cannot speak more than a few words, needs help with most basic daily activities and can do only simple tasks under close supervision.
Profound ICD-10	IQ range <20	This person has low intelligence, cannot understand basic requests or instructions and requires constant assistance for nearly all activities.

1.2.3 Complex Environment

Those working and providing care to people with intellectual disabilities may not be immediately aware of the complexity of the environment in which people with intellectual disabilities live. However, over time they will become aware of many ethical and practical challenges and difficulties inherent in providing care to a vulnerable population group, many of whom live in long term residential care. Working in this area

challenges professionals and others to learn more about themselves, their core ethical values and healthcare in general.

Pharmacists and others caring for people with intellectual disabilities are often challenged to let go of familiar patterns of thought and behaviour. The vulnerabilities of people with intellectual disabilities requires new ways of being in a relationship with oneself, the community in the work environment and the wider health and social care landscape. Personal development and a heightened awareness of the communication needs and the rights of people with intellectual disabilities is required. A sense of professional responsibility to the population is often engendered and speaking

'with passion on the experiences of people with an intellectual disability as 'experts' in the medication use process' (Griffiths and Doyle, 2013)

can be the result.

Social circumstances in vulnerable populations are shaped by the distribution of money, power and resources at global, national and local levels. The social determinants of health are mostly responsible for 'health inequities' which are the unfair and avoidable differences in health status seen within and between countries. The determinants of health can be seen in Figure 1.3 (Dahlgren and Whitehead, 1998).



Figure 1.3 Determinants of Health

The social and economic conditions and their effects on the lives of people with intellectual disabilities determine their risk of illness and the actions taken to prevent them becoming ill or to treat illness when it occurs. Efforts have been made to alert mental health and other pharmacists to health inequalities, health inequities and the determinants of health in an invited article '*Tackling health inequalities. Improving medicines use for people with intellectual disabilities*' (Flood, 2013c).

The 'ethical' position of pharmacists and others involved in the care of people with intellectual disabilities should be recognised as a very significant factor in the quality of healthcare they receive. When a person is a member of a vulnerable group, their health in part depends on the ethical standards applied by those charged with providing healthcare (Noonan Walsh, 2011).

1.2.4 Personal Background

I am a pharmacist with fifteen years experience working with people ageing with intellectual disabilities. In 2005 I completed a Certificate in Counselling Skills with First Class Honours at the National University of Ireland in Maynooth. The course was aimed to give participants a range of skills that included a deeper appreciation of the emotional impact of life events on individuals and an understanding of the importance of being present to others in their difficulties. Participation in this course enabled me to recognise that change in oneself is challenging when and wherever it occurs.

Following completion of this Counselling Skills course, a Masters Degree in Primary Healthcare in the Royal College of Surgeons in Ireland was undertaken. Participants on this course were introduced to The Alma-Ata Declaration (WHO, 1978) that emerged as a major milestone of the twentieth century in the field of public health. They were also introduced to varying influences on the health profiles of different population groups, Figure 1.3. My focus obviously was healthcare in the population with intellectual disabilities, in particular those people with intellectual disabilities with whom I spend my working day.

The course content for the M.Sc. in Primary Health Care included an introduction to the social determinants of health, which are the conditions in which people are born, grow, live, work and age. This was my 'eureka moment'. My interest in health and healthcare now extended beyond medication to the primary health care of each individual person with intellectual disabilities and included a need to understand health

inequities, which are explored later in this Chapter and in the literature review in Chapter 2.

Becoming a founding member of the Pharmacy Law and Ethics Association (PLEA), I gave an invited presentation at the PLEA in October 2010, drawing the attention of the audience to the need for an understanding of 'ethics' and health inequalities in the population with intellectual disabilities. 'Ethics' was defined as 'principled sensitivity to the rights of others'.

As my education broadened and as background reading for this thesis deepened, I was able to look at many healthcare situations with new eyes. I became aware of ethical challenges in the population particularly in relation to medication use. At one lecture, the presenter suggested that there was 'no point' in doing a PhD, if when a PhD student saw something 'wrong' she did not try to right it. This advice has 'stuck' with me and I have tried to live up to that ideal in my professional life.

1.2.5 Expanding Knowledge

As mentioned at the start of this chapter, pharmacists may find people with intellectual disabilities 'hard to see' and 'hard to hear'. Many pharmacists may have no direct experience of communicating with a person with intellectual disabilities. In community pharmacies, it is often the paid or family carer who will communicate with the pharmacy staff and/or the pharmacist. In secondary care, it is very rare that there is a designated pharmacist available with the skills and time to facilitate communication with people with intellectual disabilities who live in residential care settings in Ireland. In hospital care, pharmacists may be unaware of the person with intellectual disability on a ward and may communicate only with the nursing staff and/or doctor when discussing medication related issues. Pharmacists have been alerted to the safety issues for people with intellectual disabilities by the presentation of a poster '*Safety of people with intellectual disabilities in general hospitals. How the pharmacist can help reduce inequalities*' presented at the Hospital Pharmacists Association of Ireland Annual Educational Conference (Flood, 2014b) and at the 7th All Ireland Pharmacy Healthcare Conference 2015.

1.2.6 The Field

The scope and nature of pharmacy practice in Ireland and internationally continues to evolve and expand beyond traditional practice experiences. A number of non-

traditional pharmaceutical care practice areas exist that provide unique practice opportunities for pharmacists. One of these areas is in the pharmaceutical care of people with intellectual disabilities.

There has been a scarcity of pharmacists publishing research articles or opinion pieces concerning the pharmaceutical care of people with intellectual disabilities in Ireland. In the UK, Dr David Branford, who was an 'expert' panel member in the Delphi Process described in Chapter 3 of this thesis, has led the way. Dr Branford and others have published *'New Ways of Working for Mental Health Pharmacists and Other Pharmacy Staff'* (Branford, 2007). This document provided a vision for pharmacy staff members many of whom supplied services to people with intellectual disabilities. He is also the author of a study of prescribing for people with learning-disabilities living in the community and in national-health-service care (Branford, 1994) and has described factors associated with the successful or unsuccessful withdrawal of antipsychotic drug therapy prescribed for people with intellectual disabilities (Branford, 1996).

Dr Branford was re-elected as chairman of the English Pharmacy Board in 2013. Prior to his re-election Dr Branford described the two pivotal events of 2013 as being the *'Now or Never'* report and the National Health Service (NHS) England call to action for community pharmacy.

"Now or Never encourages us to adopt a higher profile and persuade providers and the public of the benefits that pharmacists can bring to healthcare. We have spent far too much time talking to ourselves and need to focus on the external environment" (Pharmaceutical Journal, 2014).

Dr Branford could have been speaking specifically about the need for pharmacists to become visible in the care of people with intellectual disabilities and to engage with other practitioners in the field.

In Ireland in recent times, the supervisor of this thesis Dr Martin Henman, has alerted pharmacists to the need to give special focus to the care of vulnerable people. At the International Pharmaceutical Federation FIP Conference 2014, in a session organised by the FIP Community Pharmacy Section and the FIP Social and Administrative Pharmacy Section, he spoke on *'Health needs of vulnerable patients in the 21st century'*. Ms Maire O' Dwyer, MPSI, a PhD candidate, under the supervision of Dr Henman, in the School of Pharmacy and Pharmaceutical Sciences in Trinity College

Dublin has co authored a paper '*Epidemiology of Epilepsy in Older Adults With an Intellectual Disability in Ireland: Associations and Service Implications*' (McCarron et al., 2014b).

In Ireland currently, research in the area of intellectual disabilities is largely dominated by the Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing project, IDS-TILDA (IDS-TILDA), which is a longitudinal study researching ageing in Ireland among people with an intellectual disability aged 40 and over. This study is the first of its kind in Europe, and the only study able to directly compare the ageing of people with intellectual disability with the general ageing population. Dr Mary McCarron and her team of researchers have many publications issuing from that project that is based on self reports from people with intellectual disabilities. The IDS-TILDA Wave 2 Report, entitled *Advancing Years, Different Challenges*, looked at how the ageing process is affecting the physical wellbeing and mental health of people in Ireland with an intellectual disability. Dr McCarron has said that the findings of the Wave 2 Report raise serious concerns for the planned movement from congregated settings of older adults with more severe and profound levels of intellectual disabilities and higher levels of ill health, (McCarron, 2014).

"We promised that movement to the community would improve the quality of people's lives. Unless the community is truly organised and resourced to support ageing people with ID when there are complex health issues, their experience may instead be one of social isolation, loneliness and new forms of institutionalisation".

1.3 Healthcare

1.3.1 Human Rights Issues in Healthcare in Ireland and People with Intellectual Disabilities.

The Irish Human Rights Commission carried out an enquiry that focused on the experience of a group of persons with a severe to profound intellectual disability in one residential centre. The commission considered their experience against the law and practice relevant to persons with a severe to profound intellectual disability in the Irish State (Irish Human Rights Commission, 2010). The individuals who were the subject of the enquiry and others with intellectual disabilities had difficulty communicating and were mostly or wholly reliant on others for their care and well being.

The following are some findings of the enquiry (Irish Human Rights Commission, 2010): (italics in text that follows are author's own)

- The agreements and arrangements between the Health Service Executive (HSE) and the service providers, do not confer any specific entitlement on individuals with intellectual disability, who are largely *objectified* within agreements and dealt with as *units of service* provision rather than individuals with differing needs. This lack of emphasis or attention to individual needs is a serious deficiency of the current system and has resulted in clear detriment to the individuals in the Centre.
- The medical needs of the individuals as a group are extremely complex.
- Individuals in the Centre were not in a position to provide formal consent to the administration of medication and there was no system of determining their capacity to consent.
- In the Centre, 'restrictive practices' were part of a reactive strategy in the case of a severe incident of challenging behaviour and appropriate procedures were in place to govern its exceptional use.
- Issues arise in relation to the protocols governing capacity and consent to medication insofar as there are no established system by which the decision making capacity of individuals is assessed.
- International standards on ill treatment place emphasis on the importance of ensuring that proper safeguards are in place to avoid situations of ill treatment arising. Where a resident is subject to 'restrictive practices', international standards must be in place.

1.3.2 Language Use

Language use in healthcare is a means of communication, an integral part of social and professional life and exerts hidden power that may not be detected by the vulnerable in society and by those with less power. The particular meaning we attach to words reveal the underlying values and attitudes we hold about the things or people we are referring to. Institutionalized 'jargon' reflects prevailing ideological, political and economic interests, and thus maintains existing power relations. The Human Rights Commission as previously mentioned found that people were '*objectified*' and dealt

with as *'units of service'* rather than as individual people with differing needs (Irish Human Rights Commission, 2010).

In many intellectual disabilities services in the Republic of Ireland the term *'service user'* is used to describe the people with intellectual disabilities who use and are cared for by services. The *'service user'* may be viewed only as a 'consumer' of services, by the healthcare service provider and healthcare professionals working for the service provider. The term *'service user'* is one reluctantly used by many healthcare professionals. People with intellectual disabilities who are 'patients' have the right to expect that biological factors of their illness are fully considered and, where appropriate, evidence-based interventions, such as prescribed medications are delivered. Pharmacists and other should note that the language of *'service user'* or *'user'* may be acceptable at the political level, but may be potentially detrimental to those it labels in healthcare and may arguably be damaging to the underlying ethical practices of many healthcare professions, such as pharmacy.

Healthcare is given to *'the person'*. Article 6 of the UDHR, states that

'Everyone has the right to recognition everywhere as a person before the law' (UN, 1948).

Being recognized as a person is crucial in the everyday lives and in healthcare for people with intellectual disabilities. For pharmacists, a focus on the person in the medication use process and their relationships inspires a priority for their vulnerabilities and gives rise to an ethic of responsibility in society and healthcare.

1.3.3 Health and Social Care Environment

The National Intellectual Disability Database (NIDD), managed by the Health Research Board on behalf of the Department of Health and Children, is an information set that outlines the specialised health services currently used or needed by people with intellectual disability in the Republic of Ireland (Health Research Board, 2015). The database informs the regional and national planning of these services in Ireland by providing information on trends in demographics, current service use and future service need.

Disability services in Ireland are wholly or partly funded from Vote 40 (HSE), including the statutory and non-statutory sectors. This system of funding disability services in

Ireland is guided by the National Disability Databases. The responsibility to provide health and personal social services in Ireland is delegated from the Department of Health and Children to the HSE. The disability budget is currently disbursed by the HSE to the 32 HSE Local Health Offices (LHO) nationwide, or directly to some of the larger non-statutory voluntary service providers at regional level. Section 38 documentation relates to the Agencies provided with funding under Section 38 of the Health Act, 2004. This is limited to 25 non-acute agencies and 16 voluntary acute hospitals currently within the HSE Employment Control Framework.

In 2010, the budget for disability services delivered directly by HSE amounted to €450 million, while the budget for services delivered via non-statutory voluntary bodies was €1.026 billion. The breakdown of the Revised Estimates for the 2010 disability budget indicated that the majority of this funding, €858 million, was allocated to intellectual disability and autism spectrum disorder services. Approximately three quarters of the entire disability expenditure in 2009 was spent in two key areas, residential supports (48%) and adult day care services (26%). Recent reports examining resource allocation models across the wider Irish Health Sector call for a system that is based on need, is equitable and promotes individualised care solutions (NDA, 2011b).

1.3.3.1 Value for Money and Policy Review of Disability Services

The Department of Health review on the *Value for Money* (VFM) and Policy Review of Disability Services Programme was published in 2012 (DH, 2012e). The objectives of the review were to look at how effective and efficient the disability services funded by the HSE are, and to review and make recommendations about policy in relation to services. The report suggested that there should be a move towards person-centred service provision with individually chosen supports, and that funding should follow people and not places. The issue of how to ensure a quality medication use process was not addressed in this review.

1.3.3.2 Time to Move on from Congregated Setting: A Strategy for Community Inclusion

In June 2011, a report prepared by the HSE titled '*Time to move on from Congregated Setting: a Strategy for Community Inclusion*' was published (Working Group on Congregated Settings, 2011). The authors of the report outlined how people who live in congregated settings should move into community living. The report made thirty one

recommendations without specific mention of quality healthcare and/or the medication use process.

1.3.3.3 Health Services Reform

In 2012, the Minister for Health published *Future Health – A Strategic Framework for Reform of the Health Service 2012 - 2015* (DH, 2012c). This represented one of the most significant programmes for reform in the history of the Irish Health Service. Delivery of the first phase of the reform of health structures has commenced with the establishment of the Health Service in July 2013, as the precursor to the Healthcare Commissioning Agency. Services are now organised into Divisions covering acute hospitals, primary care, social care, mental health, and health and wellbeing services.

1.3.4 Healthy Ireland

During 2013, the Irish government published a major policy, *Healthy Ireland, a Framework for Improved Health and Wellbeing 2013 - 2025* (DH, 2013a).

Healthy Ireland sets the government and cross sectoral approach to addressing the challenges of an ageing population, together with the demands being placed on health services resulting from the growth in the incidence of chronic illness. Healthy Ireland supports action to:

- Increase the proportion of people who are healthy at all stages of life.
- Reduce health inequalities.
- Protect the public from threats to health and wellbeing.
- Create an environment where individuals and sectors of society can play their part in achieving a healthy Ireland.

1.3.5 HSE National Service Plan

The HSE National Service Plan (NSP) 2014 is the first annual plan presented by the Directorate of the Health Service, following the enactment of the Health Service Executive (Governance) Act 2013 (HSE, 2013). It sets out the type and volume of services, as required under legislation, which will be provided within the funding provided by Government. HSE Service Priorities 2014 have been identified and a sample of the priority areas relevant to this project are shown in Table 1.2.

Table 1.2 System Wide Priority Areas. HSE National Service Plan

System Wide Priority Areas	
Quality and Patient Safety	National Clinical Strategy and Programmes
Patient experience Medication Management	Quality Patient flow Chronic disease prevention and management Demographic planning
Service Priority Areas	
Social Care	
<p>Disability Services</p> <ul style="list-style-type: none"> • Implementation Framework – Value for Money and Policy Review • People moving from institutional settings to homes in the community • Reconfiguration of day services and young people leaving school/rehabilitation programme • Disability services for children and young people (0 – 18s) • Service user involvement and quality in the development of services • Management and information systems 	

The HSE Service Plan confirms that quality and patient safety, as service priorities, are seen to be the responsibility of all staff and core to service provision. The HSE patient charter, *You and Your Health Service* (HSE, 2012), indicates the commitment to inform and empower people to actively look after their own health and to influence the quality of healthcare in Ireland. Two key focus areas in the HSE Plan relevant to this thesis are:

- The development and use of a comprehensive set of *quality and safety indicators* to measure the quality and safety of our services and take appropriate action to improve poor performance including medication safety.
- Ensuring that there is *robust risk assessment* (from a patient safety perspective) of any reconfiguration of services required to meet financial and staffing constraints.

In 2014, the HSE focus was to be on supporting people with disabilities to achieve their full potential, including living as independently as possible. The aim was to ensure that

people with disabilities were heard and involved in all stages of the process to plan and improve services. Peoples' strengths and personal goals were to inform the development of their care plans and their decisions will be supported by the provision of clear information and advice. The HSE envisages that eventually, people with disabilities will have increased control of their own resource through a 'money follows the patient' approach. This will have an impact on pharmaceutical care provision to people with intellectual disabilities.

1.3.6 The Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established in May 2007 to drive continuous improvement in Ireland's health and social care services. HIQA reports directly to the Minister for Health and the Minister for Children and Youth Affairs. Its role is to promote quality and safety in the provision of health and personal social services for the benefit of the health and welfare of the public.

In May 2013, HIQA published standards that set out what a good quality, safe residential service for people with disabilities should be (HIQA, 2013c). Since November 1st 2013, HIQA is responsible for the regulation of residential and residential respite services for children and adults with disabilities provided by the HSE, private organisations or voluntary bodies. By the end of August 2014, HIQA had carried out 491 inspections of residential centres for adults and children with disabilities since they started inspections of these services in November 2013. As of the end of August 2014, there were 88 providers, 908 designated centres, comprising 1361 residential units.

Quality in disability services has been defined by HIQA as

'meeting the assessed needs and expectations of service users by ensuring the provision of efficient and effective management and processes' (HIQA, 2009b).

To measure the quality of medication use, quality indicators will be required.

1.3.7 The Patient Charter

The patient charter, *You and Your Health Service* (HSE, 2012), indicates a commitment to inform and empower people who use services to actively look after their own health and to influence the quality of healthcare in Ireland. The HSE indicates that

the voice of the patient and the voice of staff will be central to all that the organisation sets out to achieve. Some key focus areas for quality relevant to this thesis are:

- Commitment to supporting the development of an open and transparent culture with defined accountability for quality and safety.
- Improving the patient experience within health services.
- Supporting quality improvement throughout the health system to improve outcomes and reduce patient harm.
- The development and use of a comprehensive set of quality and safety indicators to measure the quality and safety of our services and take appropriate action to improve poor performance including medication safety.
- Ensuring that there is robust risk assessment (from a patient safety perspective) of any reconfiguration of services required to meet financial and staffing constraints.

Some Key Priorities for Actions to deliver in 2014 for the Disability Services include:

- Streamline governance arrangements and maximise optimum efficiency.
- Continue to drive migration towards a person-centred model of services and supports.
- Build on the mechanisms employed in the National Consultative Forum structures to ensure enhanced service user involvement in the development of disability services.
- Enhance the quality of services used by people with disabilities.
- Improve management and information systems for disability services.

1.3.8 Recession

History shows that services for people with intellectual disabilities with minimally adequate resources may be cut back until they reach unacceptable levels. In times of recession, decisions may be made to reduce disability infrastructure. This can be short sighted, as a neglected under-resourced disability service will not be in a position to respond to inevitable recovery and growth in the economy. Reimbursement strategies designed to save money may be detrimental to patients and may actually result in higher overall health care costs (Soumerai et al., 1994). There is an historical deficit in

the level of services available to people with disabilities since the 1980s in Ireland. This has resulted in little scope to cut back further, though 'value for money' may be needed in disability sector spending. Some reorganisation of services may be needed and is currently being suggested under the banner of 'personalized budgets'.

1.3.9 Public Service

Public servants and those working in public healthcare must be guided by fundamental values - fairness, equality, integrity and a recognition of the notion of the common good - that have informed public services, including healthcare, since the foundation of the Irish State. Efficiency and cost-effectiveness are and should be key elements which all public servants including those providing health and social care must offer to the population with intellectual disabilities.

However, it must never be forgotten that, unlike patients in the private sector, the person with an intellectual disability using public services seldom has a choice of an alternative competitive supplier. Fair treatment is vital and must not be lost sight of when efficiency measures are being introduced (O Reilly, 2009c).

'Public bodies begin to go wrong when they forget why they were put there in the first place, when they put their own needs above the needs of those who they are there to support and to serve' (O Reilly, 2009a)

1.3.10 Health Inequalities

People ageing with intellectual disability experience inequalities in health and healthcare. Inequalities often represent an

'inequality in quality' (AHRQ, 2003)

and can only be interpreted within the context of inequalities in healthcare. Eliminating inequalities in health care is a logical method for eliminating associated inequalities in health. The population with intellectual disabilities is one of the most medicated groups in society. The quality of the medication use process for this vulnerable population must be assessed and monitored to help tackle health inequalities and deficiencies in this aspect of health care provision. This is a principle underlying this thesis.

People with intellectual disabilities have significantly higher rates of mortality and morbidity than their non-disabled peers. Many international reports have drawn

attention to the need for healthcare to consciously address the health inequalities experienced by people with intellectual disabilities. People with intellectual disabilities experience a different level of health than their non-disabled peers (Kerr, 2004), illustrated in Table 1.3 below. This health differential may be considered as a health inequality and is costly for the individual with intellectual disability, service providers and for society. Inequalities in health are easily identified when there is a clear reference point for what is appropriate and reasonable to expect.

Table 1.3 Health Inequalities in People with Intellectual Disabilities

Health Inequalities in People with Intellectual Disabilities	
Area of Inequality	Example in Intellectual Disability
Increased mortality	Lower life expectancy
Increased morbidity	High levels of epilepsy, sensory impairment and behavioural disorder
Increase in negative determinants of health	High levels of obesity and underweight; low employment; fewer social connections and meaningful relationships
Access to services	Lower rates of uptake of health promotion
Quality of services	High prescription rate of antipsychotic medication with no evidence of psychosis; high rates of unrecognized disease identified on health screening

The problem of health inequality has been recognized as an issue in Ireland and is embodied in framework health policy documents. People with intellectual disabilities often have health needs that go unrecognised and untreated. This may be because of difficulties in communication, diagnostic overshadowing, discrimination or indifference. There is concern that public health measures aimed at reducing the main health risks in the whole population will not address these issues for people with intellectual disabilities and may preferentially widen the inequality gap that already exists (O Hara et al., 2010).

1.3.11 Quality of Healthcare for People with Intellectual Disabilities

The quality of health care for people with intellectual disabilities is dependent on the knowledge and skills of individual providers, particularly their capacity to engage these vulnerable patients in their own health care, and also on systemic factors. These factors include monitoring the utilization of health care services and health outcomes for people with intellectual disabilities and correcting deficiencies in the quality of their

care. These deficiencies may involve medication use, medication safety incidents, underutilization of services, and failure to interact effectively with patients and their family members or paid carers.

On 31 May 2011, an undercover investigation by the BBC's Panorama programme revealed criminal abuse by staff of patients at Winterbourne View Hospital near Bristol in England. People with intellectual disabilities at Winterbourne View experienced serious and sustained abuse, ill-treatment and neglect that represented an extreme failure of the health and care system in England (DH, 2012g). Winterbourne View was a private hospital owned and operated by Castlebeck Care Limited. It provided accommodation for 24 people aged 18 years and over in two separate wards, and was registered as a hospital providing assessment, treatment and rehabilitation for people with intellectual/learning disabilities.

The English Government set up a Review, led by the Department of Health (DH, 2012g) to:

- investigate the failings surrounding Winterbourne View,
- understand what lessons that should be learnt to prevent similar abuse,
- explore and recommend wider action to improve quality of care for vulnerable groups.

The Review drew the following conclusions:

- Patients stayed at Winterbourne View for too long and were too far from home.
- The rate of 'physical intervention' was extremely high with more than 500 reported cases of restraint in a 15 month period.
- Multiple agencies failed to pick up on key warning signs of nearly 150 separate incidents - which could and should have raised the alarm.
- There was clear management failure at the hospital - with no Registered Manager in place, substandard recruitment processes and limited staff training.
- A 'closed and punitive' culture had developed - families and other visitors were not allowed access to the top floor wards and patient bedrooms, offering little chance for outsiders to see daily routines at the hospital.

Subsequent Care Quality Commission (CQC) inspections in England showed that people with intellectual/learning disabilities or autism who also have mental health conditions or challenging behaviour in specialist hospital or residential care settings continue to be at high risk of poor quality care. Government intervention has been deemed necessary in England because commissioners of services lack knowledge and expertise about poor quality care for people with intellectual disabilities and there is little feedback or information, including poor regulatory oversight and poor quality provision.

Poor quality of care provided to people with intellectual disabilities may reflect information problems. All healthcare systems are subject to a double problem of asymmetric information:

- the provider for example, a healthcare professional, knows more about the quality of services provided than the care recipient who may be a person with intellectual disability/carer and the commissioner of the service/provider organization,
- the care recipient with intellectual disabilities may know more about their needs and the outcomes of care than either the provider, for example the healthcare professional or the commissioner, because data and information on this subset of the population and their care pathway is sparse.

In England, a Concordat (DH, 2012f) which has been agreed with key partner organisations, including The Royal Pharmaceutical Society, represents a commitment to a programme for change to transform health and care services and improve the quality of care for people with intellectual disabilities and autism and challenging behaviour.

The aim of the Concordat is to make sure that:

- people can access high quality local support near their family and friends and can live fulfilling lives in the community,
- people are not sent to inpatient services where it is not necessary,
- people spend the minimum time in inpatient services where they need assessment and treatment,
- the quality of care improves and that progress is monitored and measured.

The National Institute for Health and Clinical Excellence (NICE) will publish Quality Standards and Clinical Guidelines on challenging behaviour in intellectual disability in Summer 2015 and on mental health and intellectual disability in Summer 2016 (NICE, 2015a).

As mentioned previously, in the Republic of Ireland, HIQA has published *National Standards for Residential Services for Children and Adults with Disabilities*, including people with intellectual disabilities (HIQA, 2013c). The HIQA Standards outline to providers what they must do to ensure safe and effective care is provided to people with disabilities, including those with intellectual disabilities, living in, or using, residential and residential respite services.

The original definition and assessment of quality in healthcare was from the view of healthcare professionals and health service researchers. It is important to recognise that definitions of quality are constantly evolving and there is growing acknowledgement that the views and preferences of the patient, the family, the public and other key stake holders are also relevant. Ascertaining the views of the population with intellectual disabilities will prove more difficult to undertake. In recognition of this, the author interviewed six people with intellectual disabilities to determine their knowledge and views of medication and the medication use process. The results of these interviews are detailed in Chapter 4.

1.3.12 Advocacy

A system of quality assessment such as that undertaken by HIQA, based on compliance with guidelines and auditing alone may be

‘unlikely to uncover the more subtle abuses which appear in people with intellectual disabilities everyday lives, due to its concentration on the measurement of the existence of policy and procedure at the expense of measuring individual satisfaction with the quality of services. The abuse and neglect of highly marginalised and vulnerable people is less likely to be uncovered within a complaints based system, unless that person has a staunch advocate’ (Robinson and Chenoweth, 2011).

The Public Health Alliance for the Island of Ireland recognises that advocacy is a powerful tool in public health, central to protecting and promoting health and well being for all (Public Health Alliance, 2007).

The key principles central to public health advocacy are:

- Human Rights - recognizing health as the basis for public health advocacy.
- Equity - advocating for equality of access, participation and outcomes in health and health service utilization and for the reduction of inequalities in health.
- Democracy - enabling people, communities and organizations to participate in decision making which impacts on health.
- Inclusion - working in partnership with people, communities and organizations to ensure inclusion across sectors, communities, individuals and representative organizations.

Advocacy is crucial to reduce abuse. Health professionals such as pharmacists have a major responsibility to act as advocates for health at all levels of society and in all population groups so that the healthier choice is the easier choice for all and that quality health and social care is provided.

Healthcare for people with intellectual disabilities is under the microscope worldwide. In the UK, the independent inquiry *'Healthcare for All'* and the *'Six Lives'* investigation by the Parliamentary and Health Services Ombudsman and Local Government Ombudsman highlighted failings in health and social care services that led to premature and avoidable deaths of people with intellectual disabilities. Services in the NHS and Strategic Health Authorities in the UK have been asked to ensure that services are 'making reasonable adjustments' for people with intellectual disabilities. The National Director for Learning Disabilities in England (Williams, 2010a) has recommended that organizations should urgently review:

- The effectiveness of the systems that they have in place to enable them to understand and plan to meet the full range of needs of people with intellectual disabilities.
- The capacity and capability of the services they provide and/or commission for their local populations to meet the additional and often complex needs of people with intellectual disabilities.

1.4 Mental Health

1.4.1 Introduction

Mental health is a fundamental component of the health assets, capabilities, resilience and positive adaptation that enable people to cope, to flourish and to experience good health and social outcomes (Friedle, 2009). Poor mental health is a cause of and a consequence of the experience of social, economic and environmental inequalities. Improving mental health can lead to substantial benefits for health and quality of life, for individuals with intellectual disabilities and for the communities in which they live.

The World Health Organisation describes mental health as a state of wellbeing whereby people recognize their abilities, are able to cope with the normal stresses of life, work productively and fruitfully, and make a contribution to their communities. Like physical health status, people experience a wide range of mental health difficulties which may range from stress or anxiety to mental illness. Levels of mental distress among population groups need to be seen as a response to relative deprivation and social injustice, which erode the emotional, spiritual and intellectual resources essential to psychological wellbeing (Friedle, 2009).

A Vision for Change, the Irish Mental Health Policy, sets out a comprehensive policy framework for mental health services in Ireland (DOH&C, 2006). It proposes a holistic view of mental illness and recommends an integrated multidisciplinary approach to addressing biological, social and psychological factors that contribute to mental health problems. The key recommendations of the policy include:

- mental health promotion should be available for all age groups, to enhance protective factors and decrease risk factors for developing mental health problems,
- service provision should be prioritised and developed where there is greatest need, this should be done equitably and across all service user groups,
- involvement of service users and their carers should be a feature of every aspect of service development and delivery.

The introduction to Chapter 14 of the policy recognises that individuals with intellectual disability are more vulnerable to environmental factors that influence mental health, as

they are less able to adapt and respond to features in their environment and to changes in it, and services need to be sensitive to this vulnerability (DOH&C, 2006).

It has long been acknowledged that the physical health and well being of people with mental health problems is of lower quality than in the general population (World Federation for Mental Health, 2004). A systematic review of the literature of health inequalities and health care provision experienced by people with intellectual disabilities identified the educational needs of health care workers, the need for comprehensive health screening and the need for health promotion campaigns targeting fitness among people with intellectual disabilities as common themes (Fischer, 2004). It is of interest that only relatively recently the conceptual difference between disability and ill health has been identified as up to relatively recently illness and disability were presumed to be equivalent (Krahn, 2003).

1.4.2. Mental Health Promotion

Mental health promotion in the population ageing with intellectual disability can be seen as a set of activities directed at strengthening the determinants of mental health and their maintenance. The promotion of mental health involves a broad range of issues, but it includes those strategies which contribute towards the prevention of mental illness and promote and maintain an individual's mental well-being. Psycho-biological studies provide growing evidence of how chronic low level stress gets 'under the skin' through neuro-endocrine, cardiovascular and immune systems, influencing hormone release. The WHO recognizes that health-damaging behaviours and violence (in all population groups) may be survival strategies in the face of multiple problems, anger and despair related to poverty, poor housing, exclusion, occupational insecurity and other indicators of low status (Friedle, 2009).

The promotion and maintenance of mental well being should ideally be an integral part of service provision within intellectual disability services. Positive mental health confers considerable protection and advantage, but it does so predominantly among those with equal levels of resources. There is evidence for health promotion effectiveness as mental health promotion programmes not only improve mental health and quality of life, but also reduce the risk for mental disorder (Hosman and Jane-Lopis, 2002). There is a need for multi-disciplinary involvement in mental health promotion to the population with intellectual disability and the WHO recognizes that

‘modern psychiatry cannot abdicate responsibility for “promotional and prevention aspects of mental health” (Rutz, 2003).

In Ireland there is recognition by the government that the promotion and maintenance of mental well being should be an integral part of service provision within intellectual disability services (DOH&C, 2006). Optimum healthcare for the elderly with intellectual disability must be individualised and highly variable. This must encompass the existence of multiple chronic conditions; the impact of psychological, social and environmental factors; the risk/benefit ratio of interventions, including medications; and variable individual differences and preferences.

1.4.3 Mental Health and Inequalities

The Irish health system is generally rendered accessible for people with disabilities only with considerable support from friends and relatives and from informal goodwill of individual health workers who try to personally compensate for the deficiencies, inefficiencies and injustices of the system (D'Eath et al., 2005). D'Eath and colleagues in their report, *“The Experience of People with Disabilities in Accessing Irish Health Services: Do Inequalities Exist?”*, found that people with intellectual disabilities, sensory disabilities and sometimes those with a dual diagnosis, may be particularly disadvantaged with respect to mental health care. The publication also concluded that people with a hearing impairment or who were deaf were one of the groups most likely to be subject to layers of different and compounding inequality.

The evidence base of the mental health needs of the population ageing with intellectual disability is growing and with it the need to ensure the full range of psychotherapies available to the general population are made available to people with intellectual disabilities. There is evidence that people with intellectual disabilities have more frequent and negatively perceived life events than the general population. In the second report from IDS-TILDA, two thirds of respondents self reported that they had experienced multiple life events in the preceding twelve months, with the most frequently reported changes relating to change of key-worker or other staff (McCarron et al., 2014a). An increase in the prevalence of depression and anxiety symptoms has been associated with the accumulation of life events (Hermans and Evenhuis, 2012) which have also been identified as a predictive factor for later psychological dysfunction (Hulbert-Williams et al., 2014) in older people with intellectual disabilities.

Cognitive Behaviour Therapy (CBT) is now a widely accepted and effective form of psychotherapy for many mental health problems. However the evidence base is scant with a paucity of methodologically sound clinical trials on the effectiveness with the intellectually disabled population (Hassiotis and Hall 2008). To close the inequality gap the model needs to be applied differently for this group to take account of their cognitive impairment, decreased verbal ability and health support needs.

1.4.4 Behaviour Disorders and Intellectual Disability

All behaviour has a meaning and the behaviour of a person ageing with an intellectual disability can be a method to communicate their needs and wants. Healthcare professionals need to understand what the person is trying to communicate through their behaviour. The behaviour of people with intellectual disabilities can offer 'challenges' to carers and service providers. A positive approach to challenging behaviour by healthcare professionals involves changes to the environment - internal and external - to achieve a better 'fit' with the needs and characteristics of the person. This requires getting to know a person, their unique qualities, their personal history and their living environment (Kissane and Guerin, 2009).

People with intellectual disabilities frequently contend with a lifetime of adversity, inadequate social supports and poor coping skills. These factors contribute to increased vulnerability to stressful life events (Cooray and Bakala, 2005) as described above, which may trigger behaviour disorders. The 'challenge' for the healthcare provider and health care professionals is to establish a process of care that will respond effectively to the needs of people with intellectual disabilities who present with behaviour disorders. Frequently, they exhibit 'challenging behaviour' as a means of coping with frustration, anxiety and stress (Menolascino, 1977). When anxiety cannot be expressed, especially in people with more severe degrees of intellectual disability, it might manifest as a behaviour disorder (Matson et al., 1997).

Considerable care needs to be taken in appropriately accommodating persons with intellectual disability and challenging behaviour (Carter, 2006). The primary focus has to be the needs of the individual person and the circumstances of accommodation in which that persons behaviour can best be addressed. This means that a number of options have to be available, or provided, which will facilitate the most effective response. Studies showed that grouping together residents with severely challenging behaviour produces worse outcomes than supporting residents in homes where there is a mix of resident needs, and that any greater expertise that staff within these

settings have, or develop, is not easily observed in their care practices (Mansell and Beadle-Brown, 2004).

Many authors have expressed concerns around the use of psychotropic medications in the population ageing with intellectual disabilities. The 'culture' of the organisation providing care for the person ageing with intellectual disability may have an influence on the prescribing and administration of psychotropic medication. Culture in this situation would include - the way things are judged, understood and valued, shared beliefs, attitudes, values and norms of behaviour and

'the way we do things around here'.

International consensus guidance, *Problem Behaviour in Adults with Intellectual Disabilities: International Guide for Using Medication*, suggests that the lack of adequate or available non-medication based interventions should not be the reason for use of medication (World Psychiatric Association, 2008). Psychiatrists saying 'no' to the staff, parents, and other professionals who request psychotropic medication in situations where they are not indicated, will force the staff, parents and others to be creative in developing appropriate interventions (Tsiouris, 2010) for the patient ageing with intellectual disability.

1.4.5 Medication Use

The UN Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care ("UN Principles") provide, inter alia, for proper determination procedures for mental illness, that are prescribed by law and that medication

'shall meet the best health needs of the patient ... and be given ... for therapeutic or diagnostic purposes and ... never be administered as a punishment or for the convenience of others', the administration of medication being of known or demonstrable efficacy only' (UN, 1991).

Medication use is a complex process in all population groups. It includes several components including prescribing, dispensing, administration and monitoring. The complexity of the process in the population with intellectual disabilities is discussed further in Chapters 2 and 5 of this thesis.

The introduction to this thesis so far has attempted to illuminate some background issues in the healthcare of people with intellectual disabilities. The medication use process in this population is another complex process in an already complex care environment (McCarron et al., 2014a). In a population group where the quality of care is under scrutiny, medication use does provide an opportunity for monitoring quality of care. Medication use is a major therapeutic intervention in this population (Nøttestad and Linaker, 2003). The systematic surveillance of the quality of medication use is one of the most promising approaches to improving a process that is amenable to direct action by those involved in the medication use process.

Medications are approved for use on the basis of benefits outweighing risks and not because there is a complete lack of risk. The ageing population with intellectual disabilities, because of inclusion and exclusion criteria of clinical trials for medication, are typically excluded - along with vulnerable elders - from clinical trials and other evidence based research studies. The overall incidence of adverse reactions to medications in the intellectually disabled population is therefore unknown. Medications can have considerable toxicity in older patients with intellectual disability who are major recipients of health care, often for several conditions at once, and often delivered across the boundary between primary and secondary care. Many adverse reactions to medications in the population with intellectual disabilities are never recognised because it is not easy to determine if the patient is experiencing an adverse reaction or what type of adverse reaction is occurring. The use of psychotropic medication in this population is reviewed in detail in Chapter 2 of this thesis.

1.5 Medication Use

1.5.1 Multiple Medication Use

The use of multiple medications is recognized as an increasingly serious issue in the healthcare of people with intellectual disability (McCarron et al., 2014a). This issue of multiple medication use, particularly in ageing people with intellectual disabilities, is a complex one and the potential risks of multi medication use are obvious. However, the benefits to patients when medications are combined to cure, slow the progression, or reduce the symptoms of disease are also obvious. Balancing the risks and benefits of using multiple medications in people ageing with intellectual disabilities is challenging for prescribers, carers and other professionals, including pharmacists. Education and strategies which enable healthcare professionals providing care to people ageing with

intellectual disabilities, to optimise multi medication use and avoid poor quality multi medication use must be identified and disseminated. What is required is an evidence based patient-centred care model for multi-morbidity in people ageing with intellectual disabilities. Knowledgeable and skilled pharmacists should ideally be involved in multi-morbidity case management training programmes in this vulnerable population group. Policy-makers are becoming increasingly aware of the challenge of multi-morbidity in the general population (Struckmann et al., 2014). However national policies and strategies focusing on multi-morbid patients with intellectual disabilities have not yet been developed.

There is no consensus existing in the medical literature on the definition for poly-pharmacy and to complicate the situation, the term 'poly-pharmacy' is taken to describe negative, inappropriate medication use in some areas of the literature. Twenty four distinctly different definitions emerged following a literature review designed to evaluate and clarify terminology currently used in the medical literature to describe multiple medication use in the older adult (Bushardt et al., 2008). Poly-pharmacy (defined as taking more than five medications, prescription and non-prescription) was observed in 59.1% of the IDS-TILDA sample (McCarron et al., 2011a), almost three times the level (21%) found for the general Irish population.

Medication-related side effects can have adverse effects on the quality of life of a person ageing with intellectual disability and would interfere with their ability to complete activities of daily living and/or have negative effects on their behaviour. Multiple medication use which increases the risk for the development of substance-induced impairment and for other adverse drug reactions is common in ageing populations. Prescription medications may cause a range of cognitive impairments from confusion to delirium, and may even mimic dementia. The use of multiple medications with anti-cholinergic effects can increase patients' total anti-cholinergic burden with clinical signs such as dry mouth, sedation, confusion and hallucinations and delirium. All these effects may be associated with behaviour disorders in people ageing with intellectual disability.

Monitoring the use of the multiple medications used in the treatment of people ageing with intellectual disability, is very important. The main reasons for this monitoring are to track progress towards the identified therapeutic goal for the individual, to detect the emergence or presence of any consequences of the use of the medication and to protect the human rights of the person with intellectual disability. Effective monitoring of

medication for physical and mental health conditions relies on understanding the indications and goals for using the medication, identifying baseline information, identifying the criteria for evaluating the benefits of the medication, and recognizing and evaluating adverse consequences. Any resultant impairment of cognitive and psycho-motor abilities may have profound implications for behaviour and general functioning (Cooray and Bakala, 2005).

1.5.2 Psychotropic Medication Use and People with Intellectual Disability

In Ireland, the National Disability Authority (NDA, 2003) has noted that some fundamental issues exist in relation to the medication use process in the population with intellectual disability and have been identified over time:

- The vast majority of people with intellectual disability who reside in community accommodation, and who may be receiving medication or other psychiatric treatment to which they do not have the capacity to consent, are not subject to any formal independent monitoring.
- The vast majority of people with intellectual disability who are receiving psychiatric treatment are outside the remit of the protective legislation.
- There is little empirical evidence to demonstrate the efficacy of drugs 'per se'.

Antipsychotics are estimated to comprise 30 - 50% of all the psychotropic medication prescribed for persons with intellectual disabilities, although the prevalence of psychotic disorders is only 3% in this population (Tsiouris, 2010). There is widespread concern over the use of antipsychotic medications in elderly patients without psychosis, as the trial evidence indicates a poor benefit to risk balance. The U.S. Food and Drug Administration (FDA) has issued several warnings and has mandated a 'black box' warning (the strongest available to the FDA) on use in the elderly in the prescribing information for all antipsychotic medications in 2008 (FDA, 2008a).

Medication compliance in different population groups prescribed psychotropic medications is a complex, prevalent and clinically severe problem. The rate of non-compliance with medication use for people with schizophrenia in the general population has been estimated to be from 40 - 60%. The following reasons have been proposed for this non-compliance - side effects of neuroleptics, lack of insight and severe psychotic symptoms. A Japanese study found that the most frequent reason for non-compliance was 'distressed by side effects' (Yamada et al., 2006).

Depending on their residence and their level of ability, medication for people with intellectual disabilities may be self administered, administered by family members, administered by paid care staff or administered by nursing staff. The level of non-compliance with prescribed psychotropic medication in people with intellectual disabilities is unknown and will in turn depend on the residence and the person responsible for administration. Care staff have demonstrated an array of concerns in relation to medication use such as the negative impact upon client quality-of-life, the ethical implications of the medications' regime, the relationship perceived by care staff with the organisation management and a significant lack of training (Martorell and Tsakanikos, 2008). Also in one study, a disproportionate number of parents expressed a negative attitude to medications in comparison with professional carers (Rasaratnam et al., 2004). All these would be expected to have an effect on compliance with psychotropic medication in people with intellectual disabilities and behaviour disorders. Chapter 4 of this thesis provides some insight into the prescribing and administration of psychotropic medication to some people with intellectual disabilities who were interviewed for this thesis.

1.5.3 Medication Use and Human Rights

The starting point for the development of a human-rights based approach to medication use in people with intellectual disability and behaviour disorders is that people with intellectual disability and behaviour disorders are full human beings who are entitled to rights (Flood, 2013b). Considering mental health in terms of human rights would call for changes in the medication use process that go beyond quality of care to include both legal and services reforms for the population with intellectual disability and behaviour disorders.

People with mental illness are not always in a position to assert their rights. Amnesty International urges the Irish government to acknowledge and respect the right of all people with mental illness to the best available mental health care (Amnesty International, 2003). There are however very few, if any, measures of mental health or well being in the population with intellectual disabilities. Pharmacists can help improve the physical and mental health of this vulnerable patient group and support them to take their medicines (Flood, 2013b).

1.5.4 Pharmacy

Pharmacy in many ways has become an isolated profession. However its ability to break out of this isolation will largely determine the success or otherwise of its public health role in the future (Anderson, 2007).

Pharmacists should have and should also look for a role in the care of vulnerable people with intellectual disabilities. It has been suggested that they should challenge themselves to develop and implement realistic health plans to reduce health inequalities in people with intellectual disabilities. The involvement of pharmacists is key, as medicine use is a major therapeutic intervention in this population. Some opportunities for pharmacists to help improve the quality of the medication use process have been identified (Flood, 2013c):

- Providing medicines in a form suitable for patients with dysphagia.
- Ensuring that carers are confident in using any prescribed epilepsy rescue medicines.
- Providing accessible medicines information for patients or their carers.
- Monitoring for changes in body mass index if antipsychotic medicines are being taken.
- Ensuring that patients on antiepileptic medicines have their bone mineral density monitored.
- Ensuring the effectiveness of any prescribed and “over the counter” medicine.
- Monitoring for side effects of psychotropic medication, the misinterpretation of which can, in turn, lead to increases in the use of psychotropic medicines.

Many people with intellectual disabilities and high support needs live in residential centres in Ireland. However, patients in these centres rarely have access to full time pharmaceutical care and do not currently use pharmacists to a substantial degree or at all. This is in part the result of current financial models for payment in Ireland which do not make it easy for providers to justify employing pharmacists in residential care settings for people ageing with intellectual disability. To establish the value that pharmacists can bring to the care of people with intellectual disabilities, information on service provision will be required. Following the publication of the first IDS-TILDA Report, contact was made with the lead author on the report and a suggestion made that the Wave 2 questionnaire include a question about pharmacy. Consequently, the

Wave 2 Report of IDS-TILDA contained a question about pharmacy, and replies indicated that pharmacy services were one of the top four health and social care services used by respondents (McCarron et al., 2014a). The others were chiropody, residential and day services. General Medical Practitioner (GP) visits, however, were recorded for more than 90% of the respondents. It would be expected that the vast majority of GP visits by people with intellectual disabilities result in the prescribing of medication. This may throw some doubt on the accuracy of self-reported use of pharmacy service by just 58% of the respondents. It may also indicate that people with intellectual disabilities living in residential care did not have access to a pharmacist.

A number of other multi-disciplinary professionals and allied health professionals justifiably feel that they are playing important roles in the care of people ageing with intellectual disability, such as nurses, social workers, psychologists, care coordinators, dietitians, speech and language therapists and others. These groups will be competing for scarce resources in the care of people ageing with intellectual disability. Pharmacists must get involved to justify their role in the care of vulnerable populations and should aggressively promote research in this area. A former Irish Ombudsman, Emily O Reilly has suggested that

'We all have to prove that the outcomes we achieve justify our existence and we all have a duty to make the public aware of what our contribution is' (O Reilly, 2009a).

The NIDD, mentioned previously, has been silent in relation to the need for pharmaceutical care for the vulnerable population with intellectual disability in Ireland (Flood and Henman, 2010).

In England, The Spread Programme was designed to engage a number of service providers across England in testing, developing and implementing new, changed or extended ways of working in mental health pharmacy that deliver impacts on components of medicines management (Branford, 2007). Some key points identified following the Spread Programme were that although significant changes to roles within pharmacy can achieve some improved services to service users, major changes are dependent on the capacity of a pharmacy workforce. The Spread Programme demonstrated a wide range of potential impacts on service user care and treatment that can be achieved by the various grades of pharmacy staff and recommended that most Mental Health Trusts (MHTs) need to develop a pharmacy strategy with a clear developmental programme that ensures increased staffing and service provision over a

3 - 5 year period. In England, a work force survey identified that for most MHTs, the pharmacy workforce is too small to provide effective medicines-related services to service users with mental health and intellectual disabilities (Taylor and Sutton, 2006) with subsequent clinical governance issues (Taylor and Sutton, 2009). This situation is likely to be replicated in the Republic of Ireland.

The Irish Mental Health Policy, *A Vision for Change* (DOH&C, 2006), identifies the mental health professionals who should comprise the core multidisciplinary team to deliver mental health services to adults with intellectual disability and a mental health problem and/or challenging behaviour: one consultant psychiatrist, one doctor in training, two psychologists, two clinical nurse specialists (CNS) and registered nurses with specialist training, two social workers, one occupational therapist and administration support staff.

The policy does suggest that other mental health professionals and health professionals such as creative therapists, speech and language therapists should be brought in as required to address other needs. However that need for a pharmacist in a population group where medication use is the main therapeutic intervention is not recognized. This situation was also replicated in a recent draft document, *National Clinical Programme for Older People Specialist Geriatric Services Model of Care Part 3: Mental Health Service Provision*, that was open for public consultation.

1.6 Healthcare and People with Intellectual Disabilities

1.6.1 Introduction

Patients with multi-morbidities are the norm rather than the exception in healthcare. This applies in particular to the population ageing with intellectual disabilities, where there is a different picture of prevalence of varying diseases (McCarron et al., 2014a). Management of patients with intellectual disabilities with several chronic diseases, who may have behaviour disorders, is now an important task facing health services in developed countries. This will present a fundamental challenge to the single-disease focus that currently pervades medicine, pharmacy and many guidelines.

It must be recognised that clinical guidelines are likely to further widen the health inequities experienced by persons with intellectual disabilities by being preferentially advantageous to the general population (Mizen et al., 2012). Clinicians, such as pharmacists, must be aware that there is a need to systematically incorporate methods

to consider vulnerable population groups into the processes used to develop clinical guidelines. This issue was raised with Dr Aine Carroll, National Director of Clinical Strategy and Programmes in April 2013, to ensure she was aware that the proposed Clinical Strategies and Programmes may not take account of the particular needs and difficulties for vulnerable populations such as the population with intellectual disabilities. Dr Carroll's reply offered reassurance that the Clinical Strategy and Programmes directorate's aim is to improve quality, access and value for all Irish citizens with equality in all these areas.

Multi-morbidity does not only affect 'old' people with intellectual disabilities. People with intellectual disabilities age at a quicker rate than people in the general population though there is no consensus on when old age starts in the population with intellectual disabilities. Quality of care measurements used for the general old age population if used in an intellectually disabled population may yield an incomplete assessment of care for the intellectually disabled population. They may ignore other conditions and aspects of health and social care that are of equal and even greater importance to the population ageing with intellectual disabilities and/or their carers. The health needs and causes of death differ for people with intellectual disabilities and most current health policies and public health initiatives will widen rather than close the health inequality gap (Cooper et al., 2004).

As the population with intellectual disabilities ages so the proportion of people with intellectual disabilities and coexisting medical problems and behaviour disorders is increasing. Expenditure on health care rises with the number of chronic conditions that an individual has. Multi-morbidity and/or behaviour disorders generates financial pressures for service providers. Current models of treatment for people with intellectual disabilities and multi-morbidities and/or behaviour disorders may lead to duplication of care provision. It will become necessary to manage these complex patients in more efficient ways with increased collaboration between all health professionals, including pharmacists, who are aware of 'health indicators' in this population.

1.6.2 Health Indicators

A 'health indicator' was defined by the WHO as

'A characteristic of an individual, population or environment which is subjected to measurement and can be used to describe one or more aspects of the health of an individual or population quality, quantity or time' (WHO, 2004).

Health indicators yield data to identify health conditions, plan interventions and compare populations or segments of the population. They are tools for gathering reliable, valid and comparable health information when it is important to monitor trends or to determine what interventions are effective (Murray, 2007). When people with intellectual disabilities are compared with their peers in the general population, disparities in health determinants, outcomes and use of health services are evident (Ward et al., 2010). Indicators can gather comparable health information with the general population and thus identify health inequalities.

A search for evidence in the published literature; consultation with advocates, family members and health professionals; and analysis of national and international databases were part of a European process of intellectual disability 'health indicator' development. Indicators were selected if appraised as important, useful, and measurable and if their application would yield comparable data about the health of people with intellectual disabilities and that of the general population. The set of eighteen indicators, illustrated in Table 1.4, was operationalized and applied in Pomona II, to survey the health of about one thousand three hundred adults in fourteen European countries (Van Schroyen Lantman-de Valk et al., 2007). Challenging behaviour and psychotropic medication use were identified as two health determinants in this process.

Table 1.4 European Health Indicators

EUROPEAN HEALTH INDICATORS	
Demographics:	Determinants:
1.1 Prevalence 1.2 Living Arrangements 1.3 Daily Occupation 1.4 Income/Socio-Economic Status 1.5 Life Expectancy	3.1 Physical Activity 3.2 Challenging Behaviour 3.3 Psychotropic Medication Use
Health Status	Health Systems
2.1 Epilepsy 2.2 Oral Health 2.3 Body Mass Index 2.4 Mental Health 2.5 Sensory 2.6 Mobility	4.1 Hospitalisation and Contact with Health Care Professionals 4.2 Health Check 4.3 Health Promotion 4.4 Specific Training for Physicians

The feasibility of conducting population surveillance of the health status of adults with intellectual disabilities in the United States of America (USA) was considered in 2009 by the Centers for Disease Control and Prevention (CDC) and the National Center on Birth Defects and Developmental Disabilities (NCBDDD). Health indicators that were key variables of health and quality of healthcare required to answer questions about health status, risks and access were identified. It was acknowledged in this survey that obtaining data about and from people with intellectual disabilities is very challenging as surveys sometimes rely on proxy respondents that can present challenges of accuracy and permissions. Under-medication or over-medication (e.g., with psychotropic drugs) were some of the health indicators proposed, as seen in Table 1.5.

Table 1.5 Proposed Health Indicators – USA

PROPOSED HEALTH INDICATORS - USA	
1.	Health and participation: health status, chronic conditions, health behaviors, participation in meaningful activities and socialization, and quality of life.
2.	Health care and health promotion: access to health care, quality of health care, quality of health promotion, and health systems.
3.	Associated and secondary conditions: indicators uniquely important for people with intellectual disabilities, such as under-medication or over-medication (e.g., with psychotropic drugs), access to advocacy, communication supports, emergency room visits and hospitalizations, screening for vision and hearing, and conditions associated with disabilities or syndromes.
4.	Demographic variables: race/ethnicity, age, sex, etiology of ID when known, and type of residential setting.

1.7 This Project

1.7.1 Evidence of Need

The health and strength of a society can be measured by how well it cares for its most vulnerable members (Michael and Richardson, 2008). People with intellectual disabilities, as we have seen, are vulnerable in healthcare. People with intellectual disabilities and behaviour disorders are particularly vulnerable. This issue is explored in the literature review that follows in Chapter 2. There is a recognised need to transform the quality of services provided to this population group.

The rate of behaviour disorders in the population with intellectual disabilities is high (Deb et al., 2001b). These behaviours may include aggression, hyperactivity, impulsivity, self-injury and destruction of property (Unwin and Deb, 2011). Behaviour disorders burden the individual with intellectual disability, increase strain on families (Irazabal et al., 2012) and caregivers (Hassiotis et al., 2012), impair social interactions, increase the risk of restrictive practices being used (Australian Psychological Society, 2011), increase the risk of out of home placements (McConkey et al., 2011) and they are costly for the service provider (Knapp et al., 2005c).

There is no clarity to date to identify what the most successful treatment for behaviour disorders is. Psychotropic medication is commonly used, but this is one of the most

controversial areas in current mental health (Deb, 2012). Psychotropic medications in the main are not licensed for use in the management of behaviour disorders, they have potential to cause adverse effects, particularly if used over an extended period of time and when prescribed, these medications are difficult to withdraw. The benefit-risk of any psychotropic medication depends on numerous factors such as: the profile of the patient, the disease/condition to be treated, the therapeutic alternatives and existing knowledge about the medication (EMEA, 2009). Medication use is a major intervention in the population ageing with intellectual disabilities in Ireland (McCarron et al., 2011b, McCarron et al., 2014a) and the medication use process in the population ageing with intellectual disabilities is complex. A skilled pharmacist with experience of working with people with intellectual disabilities is ideally placed to begin the process of developing Quality Indicators for medication use in this population. To review the quality of the medication use process, Quality Indicators will be necessary.

When developing Quality Indicators of medication use in consultation with my supervisor, this body of work was further focused on a subgroup of the population, being people ageing with intellectual disabilities and challenging behaviours. This project focused on the development of Quality Indicators of medication use in this group. As was identified earlier in this chapter, psychotropic medication use and challenging behaviour have both been identified as determinants of health for people with intellectual disabilities in the European context. Both of these determinants are looked at in detail in the literature review in Chapter 2 of this thesis.

The quality of the entire medication use process in this population is of interest. The literature review described in Chapter 2 gives a 'bird's eye view' of medication use as 'a process' in this vulnerable population. It extends beyond what medication was prescribed, to gaining an understanding of why the prescription was written, how the medication was administered, what were the immediate and long term outcomes of medication use and the human rights background to care in this area. It is no longer acceptable that little is known about the quality of the medication use process in this vulnerable group. The 'medication use process' is explored in Chapter 2 and discussed further in Chapter 5 of this thesis.

1.7.2 Difficulties

There are complexities in all health care systems and particularly in the delivery of health and social care services to people with intellectual disabilities. They are a heterogeneous population and they receive care in many different environments.

Healthcare given to this population group can be unpredictable. There is occupational differentiation and interdependence among healthcare clinicians and systems responsible for providing health and social care to this group. It is acknowledged that this will make measuring quality difficult.

There are three distinct drivers that can encourage service provider organisations to improve the quality and safety of the care they provide to people with intellectual disabilities. These are professionalism, regulation and market forces.

With regard to professionalism, members of a profession such as pharmacy, establish and maintain standards for its membership through a system of governance. In regulation, the Irish government and independent regulators such as the HIQA establish standards to which everyone must comply, resulting in an overall increase in the quality of services provided to people with disabilities. In the general population through market forces, patients as consumers influence improvement in quality and safety by selecting those organisations that have desirable quality and safety records. This last avenue is often not open to the population with intellectual disabilities.

In health care for people with intellectual disabilities, the overarching goal for service providers, professionals such as pharmacists as well as for every other stakeholder, must be improving value for patients and/or their carers. Value is defined as the health outcomes achieved that matter to patients relative to the cost of achieving those outcomes. To understand outcomes from the person with intellectual disabilities' stand point it is firstly important to develop an understanding of their views and knowledge of medication use and the medication use process. Chapter 4 of this thesis describes a Grounded Theory approach to the analysis of interviews with six people with intellectual disabilities. A semi structured interview tool is used to gain insight into the participants' views and knowledge of medication use.

When discussing healthcare value, the Porter equation where value is equal to quality over cost can help (Porter, 2010). We know that healthcare costs are increasing so we must improve the quality of healthcare in order to improve value.

$$\text{Value} = \text{Quality}/\text{Cost}$$

Box 1.1 Healthcare Value Equation

What this equation makes clear, is that we must markedly improve the quality of healthcare for people with intellectual disabilities in order to improve value for the patient. Healthcare for people with intellectual disabilities must move away from a supply-driven health care system organized around what physicians, pharmacists and others do and toward a patient-centered system organized around what patients with intellectual disabilities need. As mentioned earlier in this chapter, people with intellectual disabilities must be seen as people and not only as 'service users'. Professor James Mansell reiterates this point in the report, *Services for people with learning disabilities and challenging behavior or mental health needs*, when he revised and brought it up to date in 2007. In paragraph 12 of that report he states that people with behaviour problems

'have the same needs as anyone else, in addition to special needs for help to overcome the problems their behaviour presents. They do not surrender their needs for personal relationships, for growth and development or for anything else because their behaviour presents a challenge to services. They have the same human and civil rights as anyone else' (Mansell, 2007)

Commissioners in England have been advised to:

- Give priority to improving services for people with intellectual/learning disabilities whose behaviour presents challenges to services.
- Demonstrate value for money through improvements in the outcomes such as rights, inclusion, independence and choice, as well as on the specific treatment of challenging behaviour.
- Demonstrate value for money by a low number of placement breakdowns and of out-of-area placements.
- Replace low-value high-cost services with better alternatives.
- Avoid increasing the burden on family carers by reducing levels of service.

1.7.3 Quality Healthcare

Quality health care is defined as

“the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (Lohr, 1990).

To measure and understand the quality of care provided to people with intellectual disabilities in the medication use process, we need to develop Quality Indicators and we also need to hear the voice of the person with intellectual disabilities. People with intellectual disabilities who use health services can no longer be viewed as passive recipients of care but must be active co-producers of their own health.

Focusing on medication use in the population with intellectual disabilities and behaviour disorders for the development of Quality Indicators ensures a focus on the most vulnerable population, where care provision is complex and that experiences health inequities. To provide quality healthcare to all we must ensure quality care to the most vulnerable in society.

‘The rising tide lifts all boats’

Improving the quality of care for the most vulnerable should also improve quality of care for all.

The monitoring of the quality and safety of healthcare is becoming increasingly important internationally and many countries use Quality Indicators to monitor the performance of their health services and to highlight issues that need further exploration in relation to quality and safety.

1.8 Aim

The overarching aim of this PhD project is to improve the quality of care for people with intellectual disabilities and behaviour problems in the medication use process. This aim is to be achieved by:

1. Developing Quality Indicators of medication use in people with intellectual disabilities and behaviour disorders.
2. Gaining insight into the medication use process in this vulnerable population.

Quality improvement assumes that health care providers to the population with intellectual disabilities are concerned about doing a good job and want to do the best job possible.

Chapter 2 of this thesis is a narrative literature review of the field of quality and medication use in people with intellectual disabilities and behaviour disorders, illustrated in Figure 1.4 below. No study exists that systematically compares different methodological approaches to quality indicator development with respect to their ability to generate Quality Indicators that improve the quality of the particular healthcare aspects they were designed for (Kotter et al., 2012). Among working groups specializing in guideline and quality indicator development, a wide variety of methodological approaches are used (Blozik et al., 2010).

A thematic review of the literature under the following headings – intellectual disability, behaviour disorders, medication use and quality, identified 38 candidate Quality Indicators. It is felt that this approach provided a broader basis for the subsequent development of Quality Indicators in Chapter 3, as it bore the potential to produce a balanced set of Quality Indicators, it carried a reduced risk of selection bias, and increased content validity.

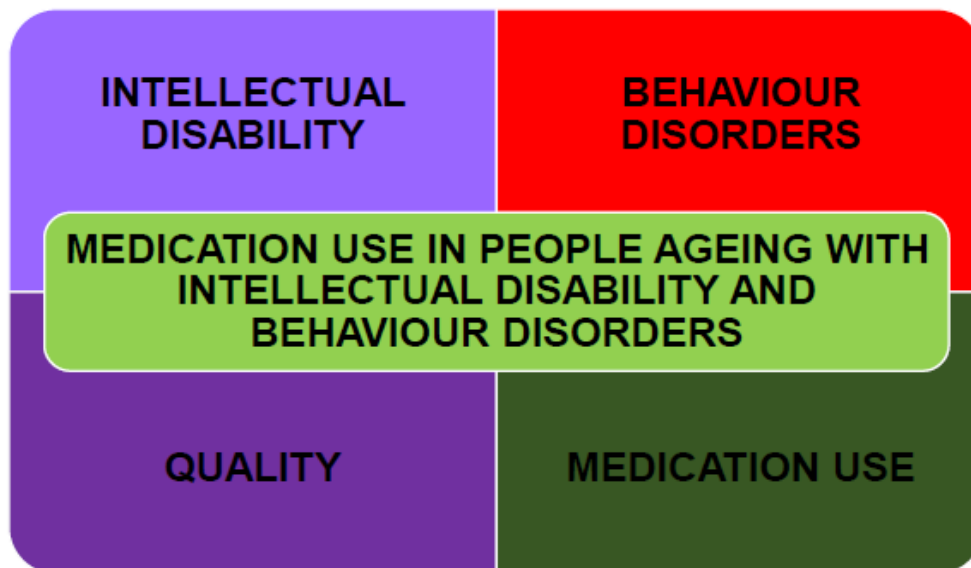


Figure 1.4 Structure of Literature Review Chapter 2

Chapter 3 describes a modified Delphi Technique which was designed as a group communication process which aimed to achieve consensus on the candidate Quality Indicators for medication use identified in Chapter 2. A multidisciplinary panel with 28 members participated in the first email round and 25 panel members in the second email round. Consensus was achieved following Round 1 and Round 2 of this Delphi process. The participants in the Delphi study brought a wide range of direct knowledge and experience to the decision-making processes. Robust Quality Indicators were identified and graded during this process which led to the identification of 6 'Crucial' Quality Indicators (Flood and Henman, 2015c).

Chapter 4, details interviews with six people with intellectual disabilities analysed using a Grounded Theory approach. The experience of all patients in healthcare is an accepted arm of quality. It is therefore important to 'hear the voice' of people with intellectual disabilities, represented by the six participants in this project, who take medication. People with intellectual disabilities have unique perspectives of healthcare processes such as the medication use process, that might not be considered by others and they may often be 'hard to hear' and 'hard to see'.

Chapter 5 considers the results of this body of work as a whole and discusses them in the context of national and international developments.

CHAPTER 2

NARRATIVE LITERATURE REVIEW

2.1 Introduction

This Chapter details a narrative literature review undertaken prior to a modified Delphi process designed to develop Quality Indicators for the medication use process in people ageing with intellectual disabilities and behaviour disorders. This narrative review attempted to explain diverse studies and papers concerning the medication use process in people with intellectual disabilities and behaviour disorders. It is qualitative, is not 'systematic' and summarised primary studies. Contributing to the review of available literature were the reviewers' own experience as a pharmacist working with people with intellectual disabilities and discussions between the reviewer and the supervisor, an international expert in pharmacy practice and existing theories and models.

The search for relevant studies and guidelines covered a wide range of sources including key databases, websites of international government bodies, health policy organisations and research centres worldwide, medical, pharmacy, health services research and journals in the field of quality improvement, and a search of the publications of key individuals writing in the field of medication use in the population with intellectual disabilities. Synthesis of the various sources sought to understand quality improvement in the medication use process in people with intellectual disabilities and behaviour disorders.

2.1.1 What is a Narrative Literature Review?

Narrative literature reviews, such as the one that follows, are valuable when one is attempting to link together many studies on different topics. They are a valuable theory building technique, and may also be used to generate opinion (Baumeister and Leary, 1997) and they have the potential to unearth and report minority experience and viewpoints in healthcare studies (Jones, 2004). These types of review do not list the types of databases and methodological approaches used to conduct the review nor the evaluation criteria for inclusion of retrieved articles during databases search (Cronin et al., 2008). This review is therefore selective in the material it uses, although the criteria for selecting specific sources for review may not always be apparent to the scholar accessing the review.

When developing the 'candidate' Quality Indicators at the start of this project, an attempt was made to provide levels of evidence for the panel members in the modified

Delphi process. However this attempt was found to be largely unsuccessful because the systems in use depend on large group studies. Small group studies and single subject designs prevail in intellectual disability research. Glassheim, in her report into evidence based practices in intellectual disabilities draws attention to the fact that

'A comprehensive list of evidence-based interventions for individuals with developmental disabilities is lacking' (Glassheim, 2009).

Guidelines for evaluating the relevance of the evidence are just emerging in the intellectual disability field and were not available for use in this project.

Evidence-based medicine has been described as a systematic approach to clinical problem solving which allows the integration of the best available research evidence with clinical expertise and patient values (Sackett et al., 2000). The most appropriate match between clinical conditions in people ageing with intellectual disabilities and behaviour disorders and medications cannot be defined by guideline recommendations, potentially inappropriate medication tools and best practices, but by how medication treatment for behaviour disorders will help the patient with intellectual disability attain the goals of care in their individualized care plan and quality of life.

It is recognised that the extraction process in the translation of guideline text research articles, government documents and other literature into recommendations manageable as potential Quality Indicators is a potential source of bias. It is not easy to translate a whole paragraph of text or a research paper into a potential Quality Indicator without cutting out potentially relevant information. No randomized controlled or other comparative studies investigating the issue of Quality Indicator development in the healthcare of people with intellectual disabilities and behaviour disorders exists.

The following, Figure 2.1, illustrates the themes in the Literature Review. The candidate Quality Indicators identified following this Literature Review, seen in Table 2.1, provided the basis for the modified Delphi process described in Chapter 3 of this document. They are provided here at the start of the literature review to inform the reader during the comprehensive narrative literature review that follows. Where appropriate during the review the author has indicated the candidate Quality Indicator (QI) number to which the information discussed could apply, for example QI 1 – refers to candidate QI Number 1 – Informational Transfer. The details of each candidate QI are available in Appendix 1.

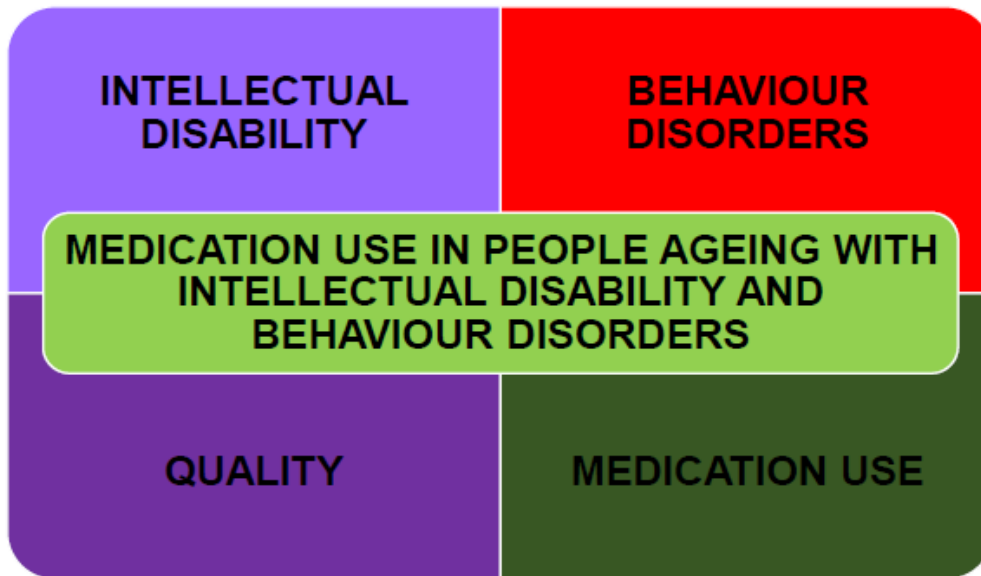


Figure 2.1 Themes in Literature Review

Table 2.2 Candidate Quality Indicators (QIs)

QI NUMBER	CANDIDATE QUALITY INDICATORS
1	Informational Transfer
2	Communication
3	General Health Review
4	Geriatric Syndromes
5	Non Pharmacological Interventions
6	External Environment and Behaviour Disorders
7	Pharmacist and Specialist Team
8	Acute Behaviour Disorder
9	Residential Care
10	Medication Reconciliation
11	Advocacy
12	Medication Regimen Review
13	Restrictive Practices
14	Covert Medication Use
15	Adverse Drug Reactions
16	Multiple Medication Use/Poly-Pharmacy
17	Inter - Intra Class Multiple Medication Use/Poly Pharmacy
18	Psychotropic Medication Side Effects
19	Psychotropic Medication - Physical Side Effects
20	Anti-Cholinergic Medication
21	Neuroleptic Side Effects
22	Anti-Epileptic Medication
23	Anti-Depressant Medication and the Serotonin Syndrome
24	Off Label Prescribing Anti-Psychotic Medication
25	Excessive Dose Anti-Psychotic Medication
26	Gradual Dose Reduction
27	As Required [PRN] Prescribing of Anti-Psychotic Medication
28	Dysphagia
29	Gastro-Intestinal Disorders
30	Dementia and Cholinesterase Inhibitors
31	Dementia and Anti-Psychotic Medication
32	Dementia, Anti-Cholinergic Medication and Cholinesterase Inhibitors
33	Sleep and Behaviour Disorders
34	Insomnia Treatment
35	Pain
36	Infection
37	Autistic Spectrum Disorders
38	Dental - Oral Health

2.2 Intellectual Disability

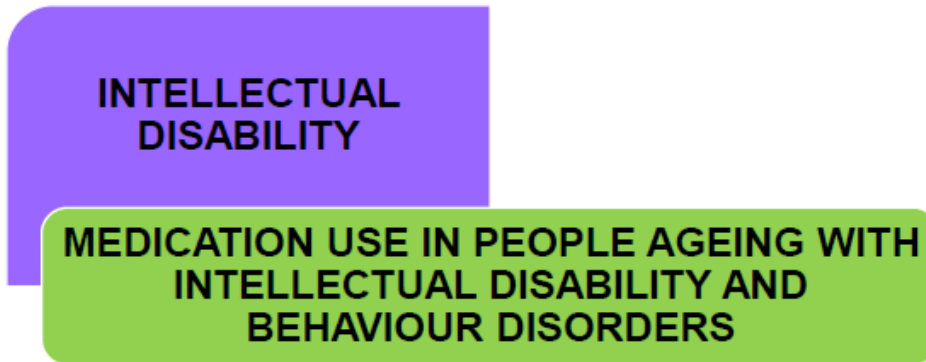


Figure 2.2 Intellectual Disability: Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders

2.2.1 Definition

The term 'intellectual disability' is the preferred term used in Ireland for a condition that has been referred to as 'mental retardation' in the United States and 'learning disability' in the United Kingdom. Intellectual disability was referred in the past throughout Europe as 'mental handicap'. There were 27,691 people registered on the National Intellectual Disability Database at the end of December 2013 (Kelly and O'Donohue, 2014). The NIDD definition is based on the WHO International Classification of Diseases, Tenth Edition (ICD-10) (WHO, 2011a).

Intellectual disability is a disability characterized by significant limitations both in intellectual functioning and in adaptive behaviour, which covers many everyday social and practical skills (American Association on Intellectual and Developmental Disabilities, 2010). This disability originates before the age of 18. An IQ test is one criterion used to measure intellectual functioning with an IQ test score of around 70 or as high as 75 indicating a limitation in intellectual functioning. Standardized tests can also determine limitations in adaptive behaviour, which comprises three skill types:

- Conceptual skills - language and literacy; money, time, and number concepts; and self-direction.
- Social skills - interpersonal skills, social responsibility, self-esteem, gullibility, naïveté (i.e., wariness), social problem solving, and the ability to follow rules/obey laws and to avoid being victimized.
- Practical skills - activities of daily living (personal care), occupational skills, healthcare, travel/transportation, schedules/routines, safety, use of money, use of the telephone.

2.2.2 Demographic Information

Intellectual disability is the most common developmental disability and it will have an immense effect on the individual, family and community as most individuals are affected from an early age. The ICD-10 is the most widely used classification system across all member countries of the World Health Organization. Using ICD-10, the levels of severity are mild (IQ of 50-69), moderate (35-49), severe (20-34) and profound (<20). Prevalence estimates using standard diagnostic systems find that among adults, the rates vary between 3-6/1000 and among children the rates are between 3-14/1000. The 27,691 people registered on the NIDD at the end of December 2013 represents a prevalence rate of 6.04 per 1,000 population (Kelly and O'Donohue, 2014). The prevalence rate for mild intellectual disability was 2 per 1,000, and the rate for moderate, severe or profound intellectual disability was 3.54 per 1,000. There were more males than females registered with an intellectual disability in all age groups, except the 55-years-and-over group, with an overall ratio of 1.38 to 1.

In the past 38 years there has been an increase in numbers registered on the NIDD confined largely to the two older age groups, the 35–54 year age group and the 55-years-and-over age group. A number of factors contributed to this increase, including the general population increase in these age groups during the period, improved standards of care and an increase in the lifespan of people with intellectual disability.

2.2.3 Residential Circumstance

The NIDD dataset 2013 (Kelly et al., 2013) consisted of information in relation to 27,691 individuals with intellectual disability. The majority, 18,498, 67% of people with intellectual disabilities in Ireland lived with their families. 7,972 individuals (29.2%) lived in full-time residential services, mainly in community group homes, residential centres,

psychiatric hospitals, and intensive placements such as those for challenging behaviour.

Table 2.2 Main Residential Circumstance in 2012

Main Residential Circumstance in 2012	
Home setting	9360 (50.6%)
Independent setting	1157 (6.3%)
Community group homes	4147 (22.4%)
Residential centres	2536 (13.7%)
Other full time services	1269 (6.9%)
No fixed abode	13 (0.1%)
Insufficient information	17 (0.1%)

A report published in 2011 by the Working Group on Congregated Settings (WGCS) set up by the HSE, identified that 3,759 people with intellectual disabilities lived in 'congregated settings' (Working Group on Congregated Settings, 2011) and that over half of those with intellectual disability living in congregated settings were found to have a severe or profound disability (compared to about one in five of those registered on the NIDD). The report identified that more than 75% of people in congregated settings have lived there for more than fifteen years, that residents were mainly middle aged and that about half of those with intellectual disability were in the age range 40-60 years.

The WGCS has proposed a new model of support in the community for people with disabilities in Ireland. The philosophy of the Working Group (Working Group on Congregated Settings, 2011) was that neither funders nor providers 'own' people with disabilities nor should they exercise control over their lives on the basis that they are service users. The report identified that there was a spend of approximately 417 million euro on congregated settings, which equated to 34% of the total Disability Budget for approximately 13% of the population of people with disabilities and an average cost of 106,000 euro per person per annum, of which 83% represented pay. Not surprisingly, the level of dependency was identified as significant, with greater than 80% of residents whose primary disability was intellectual having some other condition.

Locations of care provided to people with intellectual disabilities are not homogenous whether they are family settings, institutional settings or congregated settings. It is recognized that institutionalization can and does arise within community and other

settings when brought in by staff that are themselves moving from hospital or institutional jobs to community based roles. [QI 2, QI 6, QI 9]

2.2.4 Those Who Provide Care

Carers of people with intellectual disabilities can be family members or paid carers and all are central and pivotal individuals in the lives and healthcare of people with an intellectual disability. The “care” in the carer (Lennox and Edwards, 2001) is influenced by the attitudes, skills and confidence of those providing care to people with intellectual disabilities. Recommendation 5, of the *Lessons from the Labyrinth Report* which is a general resource on the health and well-being of adults with an intellectual disability, is that direct care staff must be supported

‘to meet both advocacy and duty of care obligations in relation to the healthcare needs’

of people with intellectual disability (Lennox and Edwards, 2001).

Carers, if paid or family members, often have a significant role within the psychiatric/mental health assessment process, as assessments of the mental state of people with intellectual disabilities are in the main carer-led (Lindsey, 2002). Agitation, aggression, self injury and other symptoms of behaviour disorder that are exhibited by the person with intellectual disability often prove to be the biggest caregiver stressor. The stress associated with caring for a person with an intellectual disability and behaviour disorders will take its toll on the care giver, whether they are family members (Jacques, 2003) or paid care givers (White et al., 2006). [QI 6]

The authors of some chapters in the *DM-ID: A Textbook of Diagnosis of Mental Disorders in Persons with Intellectual Disability* (Fletcher et al., 2007) examine and explore the role of carers during the mental health diagnostic process and the information they can provide during consultations. In the chapter on Schizophrenia and Other Psychotic Disorders, it is acknowledged that use of carers as observers of behaviours suggestive of hallucinations and delusions, can be very effective due to the skills and familiarity the carers may have with the people with intellectual disability that they support. It is heartening to observe that the recognition of carers’ role in the diagnosis process in this textbook, suggests value being placed on the role of each professional for the experience and ability they have and the contributions they can

make to the process of diagnosis and the healthcare of people with intellectual disabilities.

Wilson and colleagues (Wilson et al., 2008), who designed a study to understand how professionals actually provide ethical services with people with intellectual disability found that

'Emotional sensitivity to people with intellectual disability and making ethical judgements within the context of these enduring and intimate relationships, rather than reference to 'external' and abstract guidelines, were emphasised by professionals'

who had been interviewed. Some implications for those providing care identified by the authors following this study were:

- the experiences of vulnerability, anxiety and fear of retribution evoked by ethical issues need to become legitimate topics of discussion for all care staff,
- making task definition more realistic is likely to reduce the anxiety felt by professionals and help them to realise greater job satisfaction,
- the stressful and strenuous nature of the work described by professionals strongly suggests that staff in intellectual disability services also need their efforts to be valued and recognised (Wilson et al., 2008).

This research had examined the subjective experience of professionals who had taken responsibility for an ethical issue concerning a person with intellectual disability and in some way demonstrated the ethical dimensions involved in the care of people with intellectual disability and behaviour disorders. [Q1 1, Q1 2, Q1 6, Q1 11]

2.2.5 Ageing and Intellectual Disability

People with intellectual disability experience the same changes, medical problems and mental health problems associated with ageing as the general population. However chronological age may not always be an appropriate measure of ageing in the population with intellectual disability (Williamson and Harvey, 2007). When addressing the issue of ageing, Williamson and Harvey confirmed that age-related changes can occur at an earlier age in people with intellectual disability.

At the systems level, people with a disability are more likely to experience poor health outcomes, social isolation and poverty when entering the ageing life stage compared to people without a disability (Disability Federation of Ireland, 2005). At a personal level, some types of disability increase the likelihood of early onset ageing (and associated complications) such as the prevalence of early onset dementia in some people with Down Syndrome or the lifelong impact of significant physical disability and early onset secondary disabilities or health complications associated with ageing (Bigby, 2004).

In Ireland, a paper outlining key trends in specialised health service use and need by those aged 50 years and over who were registered on the NIDD confirmed that

'there is no generally accepted chronological point in life at which old age can be said to begin in the population of people with intellectual disability; recent reports have focused on the age of 50 years as the chronological point for determining age related change' (Kelly et al., 2009).

For the purpose of that paper, those on the NIDD who were aged 50 years or over were selected for review. Following the decision of the NIDD, 50 years and over has also been selected as a definition of older age in people with intellectual disability in this project.

2.2.6 Human Rights and Advocacy

Human rights provide a worldwide and developing framework for rethinking how people with intellectual disabilities are supported, included and respected in health and social care. The former Irish Ombudsman had stated that:

'No public body, professional organization or healthcare provider can hope to defend itself against a claim, formulated in terms of a human rights violation, if that body has not even considered human rights implications in the course of risk assessment' (O Reilly, 2007). [QI 11]

Human rights are important as a driver of good public services. However in the United Kingdom (UK), the introduction of the Human Rights Act 1998 has not led to widespread knowledge and understanding of human rights in patient and carer groups, healthcare professionals or at an organisational level. This knowledge deficit has been recognised and has led to the introduction of a bottom-up human rights-based approach that can be used in everyday practice. This process by which human

rights can be protected in healthcare involves adherence to underlying core values of fairness, respect, equality, dignity and autonomy, or FREDAs (Curtice and Exworthy, 2010).

Failures of the health system in the UK to meet the human rights of people with intellectual disability have been highlighted in *'Treat me right - better health care for people with a learning disability'* (Mencap, 2004), *'Equal Treatment: Closing the Gap'* (Kerr et al., 2005) and *'Death by Indifference'* (Mencap, 2007). Mencap's *'Death by Indifference'* report published in March 2007 contained evidence that people with an intellectual disability were

'dying unnecessarily due to institutional discrimination in the NHS'.

When Mencap published the results of an opinion poll it commissioned that was carried out on one thousand NHS staff (Mencap, 2010), the results indicated among other findings that:

- more than a third of health professionals (35%) have not been trained in how to make reasonable adjustments for patients with an intellectual disability, which can often mean the difference between life and death,
- more than half of doctors (53%) and over two thirds of nurses (68%) said they needed specific guidelines on how care and treatment should be adjusted to meet the needs of those with an intellectual disability. **[QI 6, QI 8, QI 10, QI 13]**

Advocacy has always existed in human relationships and for people with intellectual disability. An important way that human rights are brought into everyday life is through the efforts of advocacy. Supporting people with intellectual disabilities in expressing preferences and making choices has been recognised as a core value in positive behaviour support and a method of protecting human rights. The results of a meta-analysis (Shogren et al., 2004) have indicated that facilitating individuals with disability to make choices significantly reduced problem behaviour to below baseline rates of behaviour. The results suggested that when individuals with disability increase their self determination, behavioural problems can reduce. A person with disability should have choice about his/her life or if the person cannot make this choice clearly, he should have an advocate (DoH&C, 2010). **[QI 11]**

An Irish review (MacCann, 2008) of case files of 54 residents receiving the services of an advocate, referred from two service providers, one statutory and one voluntary, highlighted a number of issues/difficulties for residents, itemized in Table 2.3.

Table 2.3 Advocacy Issues for People with Intellectual Disabilities

Advocacy Issues for People with Intellectual Disabilities	
List of Issues	% (n = 54)
Privacy Issues	48%
Support at PCP Meetings	37%
Holiday Entitlements	35%
Family Visits	28%
Accommodation Issues	28%
Assessment of Need	26%
Day Services	23%
Speech Therapy	15%
Multisensory Services	13%
Educational Services	12%
Management of Money	12%
Behavioural Assessment	12%
Health Care	9%
Human Rights Issues	8%

The review of the files in this Irish review identified the primary concerns for people as revolving around very fundamental needs such as privacy, accommodation and links to families. The highlighting of healthcare by only 9% of residents may result from the lack of involvement or the expected lack of involvement by people with intellectual disability in decisions about their own healthcare. Access to advocacy has been proposed in a White Paper as one of a series of health indicators for the population with intellectual disability in the USA (CDC and NCBDDD, 2009). Information and advocacy are linked as it is not possible to make a case for oneself or someone else without accurate and up to date information (Weafer, 2003). **[QI 1, QI 2, QI 11]**

Advocates and others involved with people ageing with intellectual disability and behaviour disorders may

'experience a sense of confusion and uncertainty when considering the more precise nature and associated limitations of their roles' (King and Anderson, 2004).

People with an intellectual disability may require support to ensure they get relevant medical advice and may need to be supported to effectively communicate all their symptoms. Ensuring the person is accompanied to healthcare encounters by someone who knows them well can be very important. The authors of a literature review for the National Disability Service of Western Australia acknowledge that people with a disability may require support to ensure they get valuable medical advice and that they effectively communicate all their symptoms (Williamson and Harvey, 2007). They identified that advocacy should be provided on such matters as:

- dissatisfaction with diagnosis or treatment,
 - accessing regular comprehensive health assessments, **[QI 3]**
 - ensuring health care plans are developed, where appropriate,
 - seeking further medical advice when required such as referral to a specialist.
- [QI 11]**

Consideration must also be afforded to healthcare professionals as often professionals working in services for people with intellectual disabilities feel 'vulnerable' as has been illustrated by Wilson and colleagues who interviewed nine professionals about their experience of addressing an ethical issue within their work in intellectual disability services (Wilson et al., 2008). Professionals have felt at times that they had negligible power to make changes in the lives of people with intellectual disability. Support workers and professionals who advocate for people with intellectual disabilities can be placed in vulnerable positions with their employing organizations (Jorgensen et al., 2009). This has the potential to make advocacy very variable in all settings in which vulnerable people are cared for. **[QI 11]**

People with intellectual disabilities experience health inequalities. Advocacy has the potential to be used as a strategy for addressing and improving the determinants of health for members of this population group. Advocacy can be used as a strategy to promote and achieve the right to health and all interconnected rights of people with intellectual disability (Brolan et al., 2012).

2.2.7 Healthcare

Healthcare is becoming increasingly patient-centered, and individualized, with the patient/person becoming an active subject rather than a mere object of healthcare. Patient-centred care is recognised as a dimension of high-quality health care in its own right and is identified as one of the six quality aims for improving care (Committee on the Quality of Healthcare in America, 2001). It has long been recognised that clinical decisions and recommendations concerning medication, must attend to best available evidence and also to the values and preferences of the informed patient/carer (Montori and Guyatt, 1992). [QI 2, QI 11]

People ageing with intellectual disabilities experience poorer health than their peers without intellectual disabilities and this poorer health can be attributed to a number of factors illustrated in Table 2.4 (Williamson and Harvey, 2007).

Table 2.4 Possible Causes of Poorer Health Experienced by People with Intellectual Disabilities

Possible Causes of Poorer Health Experienced by People with Intellectual Disabilities
<ul style="list-style-type: none">• Inexperience of general practitioners (and other specialists) in understanding the needs of people with a disability.• Effects of the long term usage of some medications.• Poor physical access to some health services.• Low rates, compared to the general population, of health screening (for example lower rates of screening for cervical and breast cancer in women, and prostate cancer in men).• Communication barriers that make it difficult to identify pain and symptoms required for accurate diagnosis of ill health.• Observations by care givers sometimes are not given proper credit as they are not 'health professionals'.• An inability by disability services and staff to advocate adequately for people with a disability in the health sector.• Inability of both health and disability workers to communicate an issue effectively (both professional and non professional staff).• Lack of experiences, among medical professionals, about how to facilitate medical exams with a person with a disability and limited time for

consultation (standard 15 minutes).

- Health complications associated with disability.
- A tendency to attribute health related issues to the pre existing disability rather than looking for other causes.
- Late/delayed recognition of health related symptoms by care givers exacerbated by a tendency for people with a disability to not complain about symptoms due to their lack of capacity to do so.

In a Cluster Randomised Controlled Trial (RCT) (Lennox et al., 2007) which was the first RCT of a health assessment in adults with intellectual disabilities performed by their general practitioner, Lennox and his co authors found that use of the Comprehensive Health Assessment Programme (CHAP), in general practice in Australia identified a substantial increase in GPs' attention to the health needs of adults with intellectual disability with disease detection. The approach used sought to further enhance communication and knowledge retention and transfer especially in the long term. The authors found that the CHAP produced increased health promotion/disease prevention activities and a trend to increased case finding and that the health assessment process was acceptable to those involved. **[QI 1, QI 3]**

It has been recognised for some time that poor communication can act as a barrier to high quality health care for patients with intellectual disabilities (Lennox et al., 1997). Double consultation time (Perez, 2002) may be required and it is important for all clinicians to create time, and be generous with their time, so that the decision-making of people with intellectual disabilities is facilitated and supported, and their consent to treatment is achieved by a reflective and informed process. **[QI 2, QI 3, QI 12]**

2.2.8 Health Literacy

Health literacy is fundamental to patient engagement with healthcare and the medication use process. If people with intellectual disability do not have the capacity to obtain, process and understand basic health information, they will not be able to look after themselves effectively or make appropriate health decisions.

A Quest for Quality and Improved Performance (QQUIP) research initiative of the Health Foundation (Coulter and Ellins, 2006) that examined patient focused interventions has reported that patients with low health literacy:

- have poorer health status,
- are at greater risk of hospitalisation and have longer hospital visits,
- have higher rates of admission to emergency services,
- are less likely to adhere to prescribed treatments and self-care plans,
- have more medication and treatment errors,
- have less knowledge of disease management and health-promoting behaviours,
- have decreased ability to communicate with healthcare professionals and share and in decision-making,
- are less able to make appropriate health decisions,
- make less use of preventive services,
- incur substantially higher healthcare costs.

Like other patient groups, people with intellectual disability are known to have limited knowledge of medication. Strydom and Hall tested a specially designed information leaflet intended to improve knowledge of psychotropic medication in patients with intellectual disability (Strydom et al., 2001). The trial demonstrated that written medication information with verbal prompts can be difficult for people with intellectual disability to use. However, the authors do not believe that this group should be excluded from written resources. They recommend that carers and health professionals should assist people with intellectual disabilities to use such resources and help them to align new knowledge with previous knowledge. A more recent study has raised concerns about the generalised use of text and picture formats for all people with intellectual disabilities as there is scant evidence supporting the effectiveness of using both (Hurtado et al., 2014). **[Q1 1, Q1 2]**

Mansoor and Dowse examined the impact of pictogram information on the acquisition and comprehension of drug information in low literacy patients (Mansoor and Dowse, 2003). Sixty participants were randomly allocated to a group either receiving text only information or text and pictogram information. They were then asked to read a patient information leaflet (PIL) and medicine label for nystatin suspension which is used in the prevention and treatment of thrush. The group receiving the pictograms demonstrated significantly greater comprehension of the PIL and medicine label. Patients also

showed a clear preference for the pictogram information. [QI 1, QI 2, QI 3, QI 11, QI 15, QI 21]

2.2.9 Pain

Joanna Bourke (Bourke, 2012) draws attention to the following

'...when suffering, people in pain are often highly creative in expressing their suffering - sometimes in words, other times in images and art, and still other times in gestures, ritual utterances, symbols, posture, and performance. By paying careful attention to languages of pain, medical professionals and patients alike can cooperate more successfully in the healing process'. [QI 2, QI 3, QI 35]

People with intellectual disability are at increased risk for chronic pain (McGuire et al., 2010) and under-treatment of physical pain may occur if psychotropic medications are prescribed as they may mask the signs of physical pain. Any physical problems that causes pain or distress can also cause difficulty in focusing attention, sleeping and eating, as well as psychomotor agitation and may be mistaken for a behaviour disorder. If administered, Kovach et al. acknowledge that psychotropic drugs may actually mask the signs of physical pain and contribute to under-treatment in dementia. They provide an example where a psychotropic drug may decrease calling out or fidgeting behaviour, which are common signs of physical pain in people with late-stage dementia (Kovach et al., 1999). [QI 18, QI 21, QI 24, QI 27, QI 35]

Efforts to create a pain scale for persons with intellectual disabilities have revealed a wide range of indicators and differences in expression and manifestation of pain based upon level of intellectual disability. The addition of dementia symptoms to communication difficulties in intellectual disability, is likely to make pain assessment both more necessary and more complex (McCallion and McCarron, 2004). *The Disability Distress Assessment Tool* has been developed to assess and document a wide range of signs and behaviours of distress and contentment in patients with a profound intellectual disability and severely limited communication. The tool has been found to adequately reflect a person with intellectual disabilities distress communication as identified by a range of carers, and to provide carers with evidence for their intuitive observations of distress (Regnard et al., 2007).

Many carers have difficulty identifying dental problems in those with an intellectual disability, and often rely on detection of changes in the individual's behaviour or demeanour (McKelvey et al., 2014). In recognition of the particular needs of people with intellectual disabilities The Royal College of Surgery, Faculty of Dental Surgery has published guidelines that focus on oral health for people with intellectual disabilities (Faculty of Dental Surgery, 2012). The guidelines note the major challenge there is to improving the poor oral health of people with intellectual disabilities and they highlight the significant contribution that oral health makes to the quality of life of people with intellectual disabilities. **[QI 3, QI 38]**

2.2.10 Inequalities and Inequities

People with intellectual disabilities experience health inequalities (Emerson et al., 2011). Among the population with intellectual disabilities those with behaviour disorders experience more health inequalities than their peers who do not have behaviour disorders (Emerson et al., 2012). The impact of these inequalities on the health of people with intellectual disabilities is serious, with research indicating that people with moderate to serious intellectual disabilities are three times as likely to die early than the general population.

Five key determinants of health inequalities have been identified (Emerson and Baines 2010):

- 1) Greater risk of exposure to social determinants of poorer health such as poverty, poor housing, unemployment and social disconnectedness.
- 2) Increased risk of health problems associated with specific genetic and biological causes of intellectual disabilities.
- 3) Communication difficulties and reduced health literacy.
- 4) Personal health risks and behaviours such as poor diet and lack of exercise.
- 5) Deficiencies relating to access to healthcare provision.

A vital step in the effort to eliminate health care inequalities is the systematic collection and analysis of health care data. Inequalities in health care can only be interpreted within the context of disparities in health. Reducing and eventually eliminating inequalities in health care is a logical method for eliminating associated inequalities in health.

Equity, as envisioned by the Institute of Medicine is

'the provision of health care of equal quality based solely on need and clinical factors' (AHRQ, 2003).

Whitehead argues that not all differences in health status are inequities, but that where differences are unnecessary, avoidable, unfair and unjust, then inequity exists (Whitehead, 1991). Northway, when concluding an article that highlights problems encountered by people with intellectual disabilities when they seek to access healthcare, stated that the aim must be to promote equity of access and that would require healthcare provision to be responsive to the additional needs which people with intellectual disabilities may experience. Northway identified that reasonable adjustments are required along with action at a range of levels involving all key stakeholders (Northway, 2011).

The National Healthcare Disparities Report 2003 (AHRQ, 2003) provides seven key findings to policymakers, clinicians, health system administrators and community leaders who seek to improve health care services for all populations and would appear to be particularly relevant to the population with intellectual disabilities:

- 1) Inequality in quality persists.
- 2) Disparities come at a personal and societal price.
- 3) Differential access may lead to disparities in quality.
- 4) Opportunities to provide preventive care are frequently missed.
- 5) Knowledge of why disparities exist is limited.
- 6) Improvement is possible.
- 7) Data limitations hinder targeted improvement efforts.

Kerr has made the premise that the general health of people with intellectual disabilities can be improved by addressing those areas in which disparities in health and in health care provision are evident and in this regard he identifies the functions and necessary competencies of the psychiatrist (Kerr, 2004) detailed in Table 2.5. Kerr notes that of particular importance in the population with intellectual disability is the presentation of physical disease through psychiatric symptoms.

Table 2.5 Function of Psychiatrist in Delivering Healthcare to People with Intellectual Disabilities

Function of Psychiatrist in Delivering Healthcare to People with Intellectual Disabilities		
Function	Health Improvement	Clinical Competencies
Psychiatric illness - <ul style="list-style-type: none"> • Treatment and assessment of all psychiatric illness • Treatment and assessment of challenging behaviour 	Reduced morbidity in individuals and carers	<ul style="list-style-type: none"> • Knowledge of presentation of mental illness in those with communication deficits • Assessment of behaviour disorder • Knowledge of pharmacological, behavioural and psychotherapeutic treatment
Interface between epilepsy and psychiatric illness - <ul style="list-style-type: none"> • Diagnostic assessment • Treatment of epilepsy • Treatment of mental illness coexistent with epilepsy 	<ul style="list-style-type: none"> • Reduced seizure related morbidity and mortality • Reduce inaccurate diagnosis • Identified and treated comorbid mental illness 	<ul style="list-style-type: none"> • Knowledge of seizure types and their presentation as behaviour disorder or mental illness • Knowledge of epilepsy treatment • Knowledge of diagnostic standards for epilepsy • Knowledge of behavioural assessment
<ul style="list-style-type: none"> • Health care organization • Recognition of psychiatric symptoms as presentation of physical morbidity • Appropriate referral to health care speciality through GP 	<ul style="list-style-type: none"> • Reduction in inappropriate psychiatric diagnosis and treatment • Decrease in physical ill health 	<ul style="list-style-type: none"> • Knowledge of patterns of unrecognized physical ill health in people with intellectual disability • Knowledge of appropriate referral pathways

[QI 1, QI 2, QI 3, QI 6, QI 9, QI 29, QI 35]

2.2.11 Physical Health

The highest priorities for the majority of people with intellectual disabilities internationally are identified as basic health care, adequate nutrition and housing, education, civil rights, and political, social and economic stability (Evenhuis et al., 2001).

Health guidelines were developed by individual members of the Special Interest Research Group on Physical Health, on behalf of the International Association for the Scientific Study of Intellectual and Developmental Disabilities (IASSID) which relate to the health disorders that are most prevalent in people with intellectual disability (Prasher and Janicki, 2002). These disorders are listed below with associated QIs from this project.

1. Dental health [**QI 3, QI 5, QI 38**]
2. Sensory impairment: vision, hearing [**QI 1, QI 2, QI 3**]
3. Nutrition [**QI 3, QI 5**]
4. Constipation [**QI 3, QI 15, QI 16, QI 17, QI 20, QI 36**]
5. Epilepsy [**QI 3, QI 8, QI 12, QI 15, QI 18, QI 19, QI 22**]
6. Thyroid disease [**QI 3**]
7. Mental health [**QI 3, QI 12, QI 15, QI 17, QI 18, QI 19**]
8. Gastroesophageal reflux disease and helicobacter pylori [**QI 3, QI 28, QI 29**]
9. Osteoporosis [**QI 3, QI 5, QI 12**]
10. Medication review [**QI 12**]
11. Immunisation status [**QI 3, QI 36**]
12. Physical activity and exercise [**QI 3, QI 5**]
13. Comprehensive health assessments [**QI 3**]
14. Genetics [**QI 3**]
15. Women's health [**QI 3, QI 5, QI 11, QI 12**]

2.3 Behaviour Disorders



Figure 2.3 Behaviour Disorders: Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders

2.3.1 Introduction

The narrative review of behaviour disorders that follows firstly examines the following terms used often interchangeably in the literature and in clinical practice:

- Problem Disorders
- Challenging Behaviour

2.3.1.1 Problem Disorders

In Ireland and the UK, psychiatrists have adopted consensus diagnostic criteria for mental and behavioural disorders in intellectual disabilities. *Diagnostic Criteria for Psychiatric Disorders for Use with Adults with Learning Disabilities* (DC-LD) provides appropriate operationalised diagnostic criteria within a classification system specifically designed for use with adults with intellectual disabilities, and is complementary to ICD-10 (Royal College of Psychiatrists, 2001). It has been acknowledged that the development of *DC-LD* addressed the following issues (Cooper, 2003):

- the pathoplastic* effect of increasing severity of intellectual disabilities on psychopathology,
- limitations in eliciting psychopathology from informant histories (and hence the increased likelihood of inaccuracy introduced by the extensive sub-classifications within ICD-10 main categories),
- inconsistencies within ICD-10 and DSM-IV regarding classification of problem behaviours, features that are recognized as part of a behavioural phenotype, and use or otherwise of the 'organic' categories,
- the need to distinguish between features due to level of intellectual disabilities, cause of intellectual disabilities, developmental disorders, mental illness, personality disorders and problem behaviours.

* 'Pathoplasticity' is the term used to describe how pathology is altered by specific factors. It is recognised that intellectual disability has a pathoplastic effect on psychopathology, the presentation of mental illness.

DC-LD introduced a hierarchical approach to improve clinical practice and reduce the risks of 'diagnostic overshadowing'. It provides further information on assessment and classification of mental disorders in adults with intellectual disabilities. It aims to make a positive contribution to the lives of people with intellectual disabilities by systematic identification and description of these behaviours, with resultant improvements in understanding and identification of opportunities for intervention.

Uniquely, *DC-LD* includes problem behaviour as a diagnosis. This reflects the common occurrence of behaviour problems among people with intellectual disabilities which pose substantial clinical challenges, but which are not included in conventional psychiatric classification systems. In *DC-LD*, only behaviours which have adverse consequences for the lives of the individuals and/or those in their immediate vicinity are considered. O' Brien documents that the adoption of problem behaviour as a diagnosis, set in a strict hierarchy allows added opportunities for clarification of the extent and nature of problem behaviour among people with intellectual disabilities (O'Brien, 2003). Tully et al., who applied *DC-LD* to a sample of a population with intellectual disability in Ireland to investigate its usefulness in the clinical setting, found considerable discrepancy between the rates of psychiatric diagnoses after application of *DC-LD* and rates of previously documented diagnoses within the sample (Tully et al., 2012).

2.3.1.2 Challenging Behaviour

A number of studies have attempted to describe the extent or prevalence of challenging behaviour. The Irish Mental Health Policy document, *A Vision for Change*, suggests that evidence would indicate that over three thousand people with intellectual disability in Ireland (approximately 12% of those on the NIDD) exhibit challenging behaviour (DOH&C, 2006). However the term 'challenging behaviour' is socially defined, and what is registered as extremely challenging in one environment and for one set of staff, may not be defined as such in any other. The term represents an interaction between individual and environmental factors and the relationship between them. 'Challenging behaviour' is not currently a recognised medical diagnosis. This results in definitional differences between studies into its prevalence and leads to confusion in the literature and in healthcare provision. [QI 6, QI 8, QI 9, QI 13, QI 17, QI 18, QI 21]

A modified definition, which builds on an original definition, has been suggested by the Royal College of Psychiatrists, The British Psychological Society and the Royal College of Speech and Language Therapists, in their 2007 report *Challenging Behaviour: a Unified Approach*:

'Behaviour can be described as challenging when it is of such an intensity, frequency or duration to threaten the quality of life and/or the physical safety of the individual or others and is likely to lead to responses that are restrictive, aversive or result in exclusion' (Royal College of Psychiatrists et al., 2007).

This definition puts the responsibility for change with the environment around the individual with the quality of life and physical safety of the person and those around them being the focal concept of this definition. Following on from this it is advocated that the actual nature of the behaviours such as self injury, assault, socially inappropriate behaviour, is defined (Healthcare Commission, 2007). Using the modified definition of challenging behaviour, which focuses on services and systemic responses, the prevalence of challenging behaviour can be examined using parameters such as:

- Service responses including – seclusion, restraint, locked doors, abuse.
- Clinical responses including – inappropriate prescribing of drug treatments, punitive and aversive behavioural interventions, risk avoidance rather than risk management (Royal College of Psychiatrists et al., 2007).

Thorough assessment prior to medication administration was recommended by the authors of a comprehensive systematic review (Deb et al., 2007) which was part of the guideline (Deb et al., 2006) development process for the '*Guide to using psychotropic medication for the management of behaviour problems among adults with intellectual disability*'. Following the review process the authors found that the evidence available at that time for the effectiveness of antipsychotic medication in the management of behaviour problems among adults with intellectual disability is primarily based on case studies and they recognized the difficulty in carrying out RCTs involving adults with intellectual disability, particularly because of securing consent in adults who lack capacity (Deb et al., 2007).

2.3.2 Assessment of Behaviour Disorders

There is a potentially complex interrelationship between psychiatric disorder and mental health that results in difficulties in producing definitive statements on prevalence (Allen and Davies, 2007) of behaviour disorders in this population.

The European Association for Mental Health in Mental Retardation (EAMHMR) supported a project to produce a series of Practice Guidelines for those working with people with intellectual disability to encourage and promote evidence-based practice. The first publication of the series was titled *Practice Guidelines for the Assessment and Diagnosis of Mental Health Problems in Adults with Intellectual Disability* (Deb et al., 2001a). They were based on evidence on the subject and consensus opinion from clinicians working in the field at that time.

Ranges in the prevalence of behaviour disorders differ greatly depending on location and the severity of behaviours that are included as well as age of the person with intellectual disabilities. Following a rapid review of literature (Slevin et al., 2011) relating to support for people with intellectual disabilities and their family carers when the person has: behaviours that challenge and/or mental health problems; or they are advancing in age the authors reported the following ranges of behaviours:

- between 7% in community services and up to 30% in institutional settings (Hassiotis and Hall 2008), [QI 9]
- between 2-20% of people with an intellectual disability have been reported to display aggressive behaviour (Allen, 2000),
- for the most severe types of behaviour problems 7-15% is the estimate (Emerson, 2001, Emerson et al., 2001),
- 19% display some degree of behavioural challenge (Joyce et al., 2001).

2.3.3 Determinants of Behaviour Disorders

Behaviour disorders displayed by some people with intellectual disabilities are often a response to social, biological and environmental factors, particularly the behaviours and attitudes of carers (Deb et al., 2001a). The nature of staff interactions with people with intellectual disabilities often depends on the education and training staff have received (Windley and Chapman, 2010) and the degree of stress they experience (Lambrechts et al., 2008), as well as on the design and culture of services (Hastings and Brown, 2000). Carer behaviour defines key dimensions of the social environment of individuals with intellectual disability and behaviour disorders. Carers' reactions to behaviours are frequently counter-habilitative and it is often thought that they contribute to the development and maintenance of these behaviours through positive or negative reinforcement, thus making them more likely to reoccur (Totsika et al., 2008). [QI 1, QI 6, QI 9, QI 11]

In his literature review, O' Brien identified a number of factors that were of established importance as causes of problem behaviour among people with intellectual disorders (O'Brien, 2003):

- Problem behaviour is dependent to a powerful extent upon the individual's overall severity of intellectual/learning disability.
- Prevalence rates of problem behaviour among people with intellectual/learning disability vary with age.
- A gender effect is apparent with, especially, more outwardly directed, aggressive and severe forms of problem behaviour being more prevalent among men than women with intellectual/learning disability.

- The cause of intellectual/learning disability has a substantial bearing upon the occurrence of problem behaviour among people with intellectual/learning disability.
- Physical health problems are important precipitants to problem behaviour among people with intellectual/learning disability, notably epilepsy, toothache and any febrile illness. [QI 36, QI 38]

Environment figures prominently as a predisposing and precipitating factor to problem behaviour. A very broad array of specific changes in the individual's immediate personal environment can be an important precipitant to behavioural change. Studies on aggression and self-injury stress that the extent to which a behaviour is a problem lies in consideration of the individual's environment. [QI 6, QI 9]

2.3.4 Health and Behaviour Disorders

There is ongoing concern in the literature concerning the complex relationship between people with intellectual disabilities who exhibit behaviour disorders and their health status.

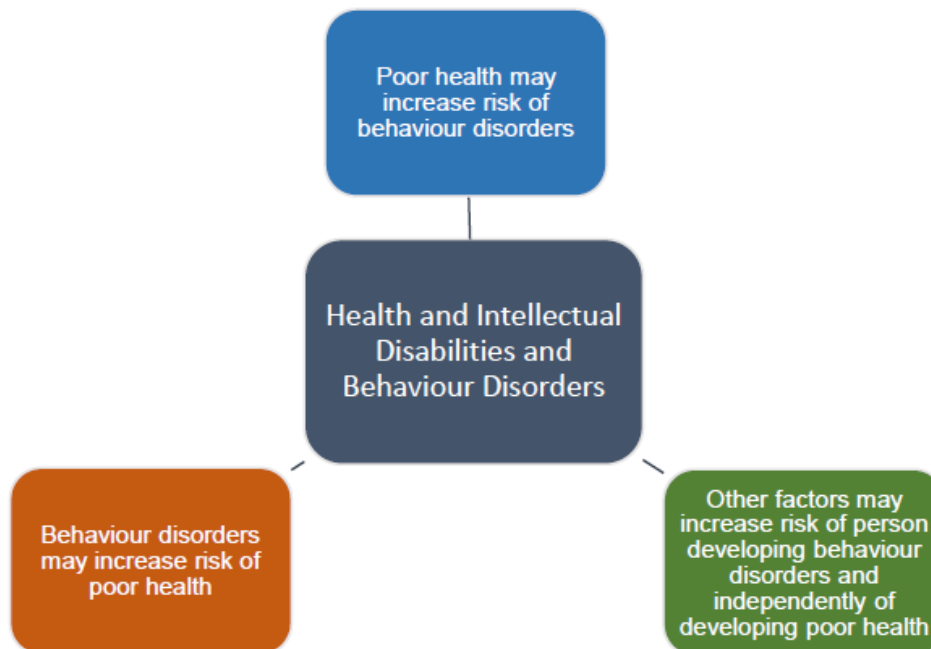


Figure 2.4 Health and Intellectual Disabilities and Behaviour Disorders

Reports following the exposure of serious abuse received by people with intellectual disabilities have recently redirected attention to this issue. Evidence is available of poor quality of care, poor care planning, lack of meaningful activities to do in the day, and too much reliance on restraining people with intellectual disabilities and behaviour disorders (DH, 2012a). Emerson and colleagues found no population based research that directly examined the health status differences between people with intellectual disabilities who do and do not exhibit behaviour disorders (Emerson et al., 2012). To gain some insight on this issue they extracted data from the UK's Millenium Cohort study on the prevalence of health conditions and impairments among two groups of seven year old children: children with intellectual disabilities with behaviour disorders and children with intellectual disabilities with no evidence of behaviour disorders. They found that for thirteen of a possible sixteen health indicators children with intellectual disabilities and behaviour disorders had poorer health/or greater exposure to risk for poor health, than children with intellectual disabilities with no behaviour disorder (Emerson et al., 2012). [QI 3, QI 6, QI 9]

2.3.5 Meta-analysis for Interventions for Challenging Behaviour

Distinct biological, psychotherapeutic and contextual interventions that are applied to treat challenging behaviour among persons with intellectual disability were reviewed in a meta-analysis of thirty articles that contained sufficient data (Heyvaert et al., 2010). A quality assessment was carried out for each study included and the moderating role of study quality was examined for reported intervention effectiveness. Of the thirty articles, eighteen described a biological, thirteen a psychotherapeutic and nine a contextual intervention, with sometimes more than one implemented treatment discussed in a single article. [QI 5, QI 12]

For the biological treatments, atypical antipsychotic medications (risperdone and olanzapine) were studied (9), next to typical antipsychotics (2) and other biological interventions (5). Combined effect sizes and their standard errors computed for all 30 articles were presented by the authors of the meta-analysis with the 30 selected articles, representing 1444 participants. For each article, challenging behaviours shown by participants, interventions used to target these challenging behaviours, assessment of the articles' quality, and gender, level of intellectual disabilities and number of participants are reported.

In this meta-analysis of articles 'describing rigorous quantitative empirical studies of intervention effects on challenging behaviour among persons with intellectual

disability', effect sizes (standardised mean differences) from 0.223 to 1.411 were found. The effect sizes varied between a small and a very large, all indicating positive treatment effects. The combined effect size over all studies was 0.671, with a 95% confidence interval of 0.570 to 0.771, which is a medium to large effect. The implemented sensitivity analysis revealed that this effect is robust. Analyses of variance showed no significant different treatment effects for biological, psychotherapeutic and contextual interventions. Differences between uni-modal and multimodal treatments turned out to be not significant as well.

The authors of the meta-analysis concluded that there is evidence for the effectiveness of pharmacological, psychotherapeutic and contextual interventions, used alone or in combination. They found no indications for the superiority of one of the treatment approaches or combination types (Heyvaert et al., 2010). In contrast to claims in the literature that the evidence for one or another intervention is still rather limited, Heyvaert et al., found that the effects in their study were robust and convincing and claimed that they showed that challenging behaviour among individuals with intellectual disability can be successfully treated by diverse biological, psychotherapeutic and contextual interventions. However they noted that it is still not very clear how and why each of these interventions works, either when applied alone or combined. **[QI 1, QI 5, QI 18]**

2.3.6 Restrictive Practices

The use of restrictive practices can be a threat to quality of care and individual human rights. A paper that reviewed physical/mechanical and chemical restraint and the factors that may result in the use and maintenance of restraint found that the rate, type and intensity of behaviours that challenge, and the age of the individual with intellectual disability and the type of residential placement have been found to be the major factors that put people with intellectual disability at risk for restraint (Matson and Boisjoli, 2009).

Various international instruments are of relevance to the use of restrictive practices. These are the United Nations Convention on the Rights of Persons with Disabilities (CRPD/Disability Convention) (UN, 2006), the European Convention on Human Rights (ECHR) and the Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care ('MI Principles') (UN, 1991). Due regard should always be given to the need to respect the right of the person with intellectual disability to dignity, bodily integrity, privacy and autonomy, which is in line with the requirements

of Article 8 of ECHR (European Court on Human Rights and Council of Europe, 1950).
[QI 2, QI 8, QI 11, QI 13]

The right to respect for private life in Article 8 of the European Convention on Human Rights, includes a person's physical and psychological integrity i.e. what happens to our bodies and our minds. The objective of Article 8 is to

“protect against unjustified interference with personal integrity”.

Medical treatment without consent will not be an interference under Article 8 with private and family life if the State can convincingly show that it was necessary and the individual was not in a position to give informed consent – due to incapacity. However, the Courts have said that

“the position of inferiority and powerlessness which is typical of patients confined in psychiatric hospitals calls for increased vigilance in reviewing whether the Convention has been complied with.”

The Convention reflects the principle of proportionality requiring that any interventions in a person's life must be in proportion to the aim to be achieved, also known as the least restrictive alternative, both of which are important human rights principles (Keys, 2007). **[QI 7, QI 11, QI 12, QI 13, QI 12, QI's 14 - 28, QI 31, QI 32, QI 37]**

The Irish Mental Health Commission has issued a *Code of Practice Guidance for Persons working in Mental Health Services with People with Intellectual Disabilities* which defines 'restrictive practices' as including, but not limited to 'the use of mechanical restraint, physical restraint, psychotropic medication as restraint and seclusion' (Mental Health Commission, 2009). A European Union Green Paper '*Improving the Mental Health of the Population*', emphasised the urgent need to

‘improve the quality of life of people with mental ill health or disability through social inclusion and the protection of their rights and dignity’
(European Commission, 2005). **[QI 13]**

Chemical restraint has been defined as:

‘... both deliberate and incidental use of pharmaceutical products to control behaviour and/or restrict freedom of movement, but which is not required to treat a medically identified condition. These drugs may be

purposively administered to sedate a patient as a means of convenience. Convenience is any action not in the patient's best interests, to control or manage behaviour' (Mott and Poole, 2005).

However it should be noted that many clinicians consider the term 'chemical restraint' pejorative, since it does not reflect the possibility that 'forced' medication may be clinically necessary. [QI 8, QI 11, QI 13, QI 14]

A rapid review (Slevin et al., 2011) undertaken using a framework adapted from the NHS Centre for Reviews and Dissemination and the Rapid Review Methodology aimed to search for, evaluate and prioritise studies or other robust literature that have focused on people who challenge and others. One recommendation only in relation to medication use was made by the authors, Box 2.1.

Medication Recommendation - People who Challenge: Practice and Services
Medications should only be used when indicated for the treatment of physical causes of behavioural problems or treatment of psychiatric illness and be used to supplement other interventions rather than as a stand-alone treatment.

Box 2.1 Medication Recommendation - People who Challenge: Practice and Services

In the discussion of these review findings, Slevin and colleagues state that

'With respect to interventions the review found some expected outcomes that have remained unchanged for a number of decades. Medications are a highly used treatment for people who challenge but there are now clearer guidelines on use for behavioural management. Behavioural interventions, based on a positive behavioural support (PBS) model have been found most effective in supporting people with intellectual disability who have behaviours that challenge' (Slevin et al., 2011). [QI 5, QI 6]

The incidence of restraint in Australia (23-28%) is considered high compared with the UK where it is reported that between seven and seventeen percent of adults with a disability are subjected to restraint. A practice guide has been prepared by the Australian Psychological Society, the aim of which is to reduce restrictive practices in the disability sector by increasing the use of positive behaviour support programs (Australian Psychological Society, 2011). The Queensland Government had developed

a *Restrictive Practice Identification Tool* and has recently produced *Amendments to restrictive practices in Queensland* with changes that focus on ensuring a robust system of effective safeguards for adults subject to restrictive practices and reducing red tape for disability service providers so they can focus on supporting people (Queensland Government, 2014).

The results of a cross sectional study (Emerson et al., 2000) investigated aspects of the treatment and management of challenging behaviour among adults with intellectual disabilities receiving various forms of residential supports included the following:

- 1) 53% of participants were reported to have shown at least one 'moderately serious' or 'severe' form of challenging behaviour in the previous month;
- 2) The most commonly employed management strategies were physical restraint (44%), sedation (35%); seclusion (20%) and mechanical restraint (3%);
- 3) The most commonly employed 'treatment strategies' were goal setting within individual programme plans (used with 62% of people showing challenging behaviour), antipsychotic medication (49%), written intervention programmes (23%) and written behaviourally orientated intervention programmes (15%).

In the discussion of their results, the authors noted that residents with challenging behaviour are over three times more likely to receive antipsychotic medication than they are to receive behavioural support. They further note that

'such an inequitable pattern of provision clearly violates the principle of evidence based practice'.

In this sample, the receipt of antipsychotic medication was not predicted by the presence of psychiatric disorder, but by factors which included the severity of challenging behaviour and the setting. [QI 5, QI 9, QI 13]

2.3.7 Consent and Capacity

Consent and capacity are complicated in people with intellectual disabilities (Arscott et al., 1999) by literacy problems, communication problems and unsubstantiated assumptions by some professionals as well as by the fact that some people with intellectual disabilities will not be competent to make some decisions regarding medication use.

Clinical responses to behaviour disorders that have been identified (Deb et al., 2007) and are connected to consent and capacity that are of relevance to this project include:

- inappropriate prescribing of drug treatments,
- punitive and aversive behavioural interventions,
- risk avoidance rather than risk management.

Shogren and colleagues examined the efficacy of the use of choice-making as an intervention for reducing problem behaviour through a meta-analysis of single-subject research studies using choice-making as an intervention (Shogren et al., 2004). They found that providing choice opportunities resulted in clinically significant reductions in the number of occurrences of problem behaviour. **[QI 1, QI 2, QI 11]**

2.4 Medication Use



Figure 2.5 Medication Use: Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders

2.4.1 Introduction

The population with intellectual disabilities are thought to be one of the most medicated groups in society (Matson et al., 2003, Nøttestad and Linaker, 2003). The highest predictor of a prescription for a psychotropic medication in this population group is not mental illness but is behaviour disorders (Matson et al., 2003, Matson and Neal, 2009, Hess et al., 2010) and the most common response to behaviour disorders is the use of psychotropic medication. This medication use has become commonplace as it can be a 'quick fix' (Thomas et al., 2010) to a potentially difficult or dangerous circumstance (McGillivray and McCabe, 2006, Deb et al., 2007, Heyvaert et al., 2010).

Guidance is available for those people with responsibility for commissioning services for people with intellectual disabilities about ways to increase access to and improve healthcare (Turner, 2011). The guidance document draws attention to inequality in service provision and outcomes and Box 2.2 has suggested commissioning action in relation to the prescribing of psychotropic medication in England.

Psychotropic Medication - Commissioning Action

- A very high proportion of people with learning disabilities are receiving prescribed psychotropic medication, most often anti-psychotic drugs, to control for challenging behaviours. This is despite a lack of evidence for their effectiveness in treating challenging behaviours and evidence of considerable harmful side effects.
- Commissioners should instigate a review of anti-psychotic medication used with people who challenge as well as ensuring that people with learning disabilities, their family and paid carers as well as relevant professionals understand the side effects of different types of medication.
- Medication reviews can also result in cost savings. There is accessible information about medication on the Easy Health website. A quick reference guide on prescribing such medication is also available.

Box 2.2 Psychotropic Medication - Commissioning Action

Reliable measures of behaviour disorders are required if interventions such as psychotropic medication use, aimed at reducing these behaviour disorders among people with intellectual disability, are to be evaluated for effectiveness. Psychotropic medications are an integral part of the care of many of the intellectually disabled population and are prescribed, dispensed and administered to try to achieve various outcomes. The use of antipsychotics for the management of behavioural problems in people with intellectual disability is common with rates varying across studies from 20% to 50% (Branford, 1994, Stolker et al., 2002, Tyrer et al., 2008). **[QI 12, QI 17, QI 18, QI 20, QI 22, QI 23, QI 25]**

2.4.2 Psychotropic Medication

The regular review of psychotropic medication for people with intellectual disabilities has been advocated (Thomas et al., 2010) along with regular monitoring of physical health and side effects (Griffiths, 2012, Edelson et al., 2014). In the main, psychotropic medications are not licensed for use in the management of behaviour disorders, they have the potential to cause adverse effects particularly if used over a long period of time, once prescribed they are difficult to withdraw and overall there is very little good quality evidence available to support the use of medications under these circumstances (Deb, 2012). **[QI 24, QI 26]**

High rates of use of psychotropic medications in both community and inpatient environments for people with intellectual disabilities have been found (McGillivray and McCabe, 2005). Psychotropic medication is used frequently in adults with intellectual disabilities, with between 20 and 45% overall being prescribed psychotropic medication, of which 14 - 30% are to control behaviour disorders (Deb and Fraser, 1994). In England, the Department of Health heard

'deep concerns'

about over-use of antipsychotic and anti-depressant medicines in people with intellectual disabilities in their review of the Winterbourne View Hospital scandal (DH, 2012d).

Psychotropic medications have a range of potential side effects and the frequency of side effects in people with intellectual disabilities has received little systematic attention (Reiss and Aman, 1997). In the treatment of a psychiatric condition or a behaviour disorder, the use of psychotropic medications may produce some side effects that may not be recognised as being related to the medication with the possibility that these side effects may in fact be diagnosed as further psychiatric illness or a further behaviour disorder (Royal College of Psychiatrists et al., 2007). There is also a concern about the difficulty in communicating any potential side effects of psychotropic medication to the person with intellectual disability before any treatment starts. People with intellectual disabilities and their carers must get the opportunity to have as much understanding as possible of the medication they will be consuming and any potential side effects it may bring (Thomas et al., 2010). This is a patient safety issue. The precise target symptoms for which any psychotropic medication is being prescribed should be stated to the person and their carer. This should clarify what exactly is it hoped that this medication will achieve for example:

"patient will hit others less frequently"

rather than

"patient will be less disruptive" (Einfeld, 2001).

Matson and Wilkins have identified the use of antipsychotics for self injurious behaviour or aggression as

'one of the most controversial issues in mental health.' (Matson and Wilkins, 2008).

Matson underscores the vulnerability of this population of individuals and urges more research in the area of assessment and treatment with behavioral and interventions with medications (Antonacci et al., 2008). A retrospective study (Ruedrich et al., 2008) suggests that atypical antipsychotics reduce aggression but not self-injurious behaviour while a randomized controlled trial (Tyrer et al., 2008) could not distinguish atypical or traditional neuroleptic antipsychotics from placebo for effects on aggression. Tyrer and his co authors observed that

'patients given placebo showed no evidence at any time points of worse response than did patients assigned to either of the antipsychotic drugs'.

There are also a number of other reasons why psychotropic medications may be prescribed in the population with intellectual disabilities and behaviour disorders. Potential reasons for this prescribing have been identified as, limited resources - financial and personnel, lack of clinical psychology input, inability to change environment - internal and external - meaningfully, lack of suitably trained staff, pressure from nursing staff and other professionals for immediate resolution of problems (Bhaumik and Michael, 2004). [QI 9]

Antipsychotics and anti-epileptics were the most commonly used prescription medications in the IDS-TILDA sample (McCarron et al., 2011a). [QI 5, QI 12, QI 14, QI 16, QI 17, QI 19, QI 21, QI 22, QI 24, QI 25]

2.4.3 Potentially Inappropriate Medication Use

In Ireland in 2005, 11 - 13% of the population was over the age of 65 years but they consumed 47% of all prescription medications (Barry et al., 2006). Medicines that are potentially inappropriate in older people, either have no clear evidence-based indication, carry a substantially higher risk of adverse side-effects compared to younger people or are not cost-effective (O'Mahony and Gallagher, 2008). Multiple medication use is prevalent in the ageing intellectually disabled population and it may be contributed to by the use of medications used to correct medication induced conditions and adverse drug events and to manage behaviour disorders. The key to recognising an adverse drug reaction in a person with intellectual disability may be to recognise a change in the patient's functioning or behaviour, which can be an early

sign of an adverse drug reaction. The need for comprehensive, evidence-based, easily applicable inappropriate prescribing criteria has been identified (O'Mahony and Gallagher, 2008).

Deb and Unwin in *'Guide to using psychotropic medication for the management of behaviour problems among adults with intellectual disability'* drew attention to the following

'because of the small number of individuals included in the studies, mixed populations studied, dearth of use of validated outcome measures and the potential for publication bias, no specific recommendation can be made to support prescribing medication in adults with an intellectual disability and behaviour problems' (Deb and Unwin, 2006a).

However the authors also observed that

'the fact that good-quality evidence is sparse does not mean that there is evidence to show that medication is ineffective' (Deb and Unwin, 2006a).

[QI 4, QI 7]

A comparative overview of explicit criteria that have been developed since 2003 for inappropriate prescribing in older adults and to contrast these newer criteria with the Beers criteria, published in 2003, concluded that research to validate the several newer criteria in various practice settings and to explore the effect of adhering to the guidelines on patient outcomes is warranted (Levy et al., 2010). Therefore before applying such tools to the population with intellectual disability much care is required. In a paper that recognised that the health needs of people with intellectual disabilities are different, the authors suggest questions that could be asked by all involved in the use of potentially inappropriate prescribing criteria:

- How might this affect specifically people with intellectual disabilities?
- Could it possibly disadvantage some people with intellectual disabilities?
- What additional supports or reasonable adjustments are required so that it equally benefits people with intellectual disabilities? (Cooper et al., 2004). **[QI 7]**

Prescribing of medication for behaviour disorders in patients with intellectual disability requires an understanding of the efficacy of the medication in frail older people with

intellectual disability, assessment of the risk of adverse drug events in the population, discussion of the harm:benefit ratio with the patient/carer, a decision about the dose regime and careful monitoring of the patient's response (Hilmer et al., 2007). This requires evaluation of evidence from clinical trials, if available, that included people ageing with intellectual disability. Application of the evidence to frail older people with intellectual disability through an understanding of changes in pharmacokinetics and pharmacodynamics, and attention to medication use issues specific to the population group are also required to ensure patient safety and quality of care. **[QI 12, QI 15, QI 16, QI 17, QI 18, QI 19]**

Sergei and colleagues have recognised that comprehensive geriatric assessment has proved effective in reducing the number of prescriptions and daily drug doses for patients by facilitating discontinuation of unnecessary or inappropriate medications (Sergi et al., 2011). Multidimensional and multidisciplinary efforts are needed to tackle poly-pharmacy related problems in frail patients ageing with intellectual disability. The most appropriate medication regimen should combine existing evidence-based clinical practice guidelines with data gathered from comprehensive geriatric assessment, including social and economic considerations. **[QI 4]**

Psychotropic medications such as antipsychotics, antidepressants, anti-anxiety drugs including benzodiazepines, buspirone and beta blockers, mood stabilisers such as lithium and some antiepileptic medications, psychostimulants, opioid antagonists and also vitamins and diets are received by a high proportion of people with intellectual disability (Deb, 2007).

The authors of a systematic review designed to establish the frequency and characteristics of people with intellectual disability included in RCTs on antipsychotic treatment for behavioural problems and to investigate the quality of these RCTs identified limitations in its design. It was reported that although they included several terms (disruptive behaviour, aggression, violence, anger, hostility, acting-out, impulsiveness, self-injurious behaviour and agitation) and allowed for behavioural problems to be a primary, secondary or post hoc outcome, they could have missed studies depending on the terminology used to describe behavioural problems (Scheifes et al., 2011). The authors concluded that studies in which people with intellectual disability are included are of a sufficient quality, but of a small size. The heterogeneity in the characteristics of the intellectual disability population included as well as in the

applied assessment instruments made performing meta-analyses unfeasible (McCarron et al., 2011a).

The World Psychiatric Association in its international guidelines (WPA, 2008) gives the following suggestions for situations in which medication use may be considered in a person with intellectual disability and behaviour disorders:

- failure of non-medication based interventions,
- risk evidence of harm/distress to self,
- risk evidence of harm/distress to others or property,
- high frequency/severity of problem behaviour,
- to treat an underlying psychiatric order or anxiety,
- to calm the person to enable implementation of non-medication based interventions,
- good previous response to medication,
- person/carer choice. [QI 2, QI 8, QI 11, QI 12]

2.4.4 Medication Classes

There are few accepted guidelines for using psychotropic medication in behaviour disorders, despite this being common practice. The high rate of antipsychotic prescribing with no evidence of psychosis is an identified area of inequality in the population with intellectual disabilities (Kerr, 2004).

In the first report of the IDS –TILDA study (McCarron et al., 2011a), poly-pharmacy, defined as using five or more medicines or supplements, was observed in 445 participants or in 59.1% of the sample, almost three times the level (21%) found for the general Irish population (Cronin et al., 2011). The level of poly-pharmacy increased with age; from 50.4% of those aged 40-49 to 57.8% among the 50-64 age group and to 80.6% among those 65 years and older. Poly-pharmacy was identified for 24% of those living independently or with family, 51.5% of those living in the community and 77.8% of those living in residential centres. Antipsychotics, antidepressants and anxiolytics were among those medicines with the highest cognitive impairment side effects, Table 2.6. The authors acknowledge that this effect is more powerful when a combination of those medicines is used and that research is needed to examine the

impact of the anticholinergic and sedative impact on cognitive function for people with intellectual disability. [QI 7, QI 12 - 27, QI 32]

Table 2.6 Combined use of Antipsychotics, Antidepressants and Anxiolytics, IDS-TILDA

Combined Use of Antipsychotics, Antidepressants and Anxiolytics				
Age Group (years)	Antipsychotics Antidepressants Antianxiety	Antipsychotics Antidepressants	Antipsychotics Antianxiety	Antidepressants Antianxiety
40-49	5.5%	13.1%	15.0%	8.0%
50-64	9.0%	19.5%	18.0%	9.0%
65+	5.2%	20.9%	14.9%	9.0%
All	7.0%	17.4%	16.4%	8.6%

2.4.4.1 Antipsychotic Medication

A Cochrane Review in 2004, found that antipsychotic medications have been used to modify challenging behaviours in people with intellectual disability, but that there was no randomised controlled trial-based information that suggested that antipsychotic medication was either helpful or harmful for adults with intellectual disability and challenging behaviour (Brylewski and Duggan, 2004). Only nine randomised controlled trials could be included in this Cochrane review and these provided no evidence of whether antipsychotic medication helps or harms adults with intellectual disability and challenging behaviour.

A systematic review, identified only 22 papers suitable for data extraction and quality assessment (Deb and Unwin, 2006b). There was evidence in that review from good-quality RCTs to show that risperidone is effective in improving behaviour problems among adults and children with an intellectual disability with or without autism. However, most RCTs have shown that using this medication can result in a high rate of adverse effects such as weight gain and somnolence. The evidence from case studies and small trials that focus on the treatment of particular behaviour problems was inconclusive. However, studies directly comparing the use of different medication to manage specific behaviour problems were absent. Therefore, the authors decided that it was not possible to recommend any specific medication for any specific behaviour problem.

A more recent randomized controlled trial that compared flexible doses of haloperidol, risperidone, and placebo, in the treatment of aggressive challenging behaviour found that 'antipsychotic medications should no longer be regarded as acceptable routine treatment for aggressive challenging behaviour in people with intellectual disability' (Tyrrer et al., 2008). However there were some methodological difficulties with the study in that it did not include a placebo run in and the outcome measure depended on behaviour reporting by carers.

The use of antipsychotic drugs in people with intellectual disabilities has received intensive scrutiny and attempts are being made to reduce it. The clinical implications of the results of a RCT designed to investigate factors influencing antipsychotic drug reduction among people with intellectual disabilities prescribed antipsychotics for behavioural problems were:

- An encouragingly large proportion of people with intellectual disability can have their antipsychotic drug dosages decreased when prescribed for behavioural purposes.
- Dosage reduction can be achieved without extra support in ordinary clinical practice.
- If a drug is reinstated, any deterioration in behaviour is reversed; behaviour returns to that at baseline (i.e. prior to drug reduction) (Ahmed et al., 2000).

Where differences on the variables measured were apparent between participants for whom psychotropic medication reduction was successful or unsuccessful, they were identified as mainly in staff and environmental characteristics. In particular, the reinstatement of medication in this RCT was associated with greater restriction and adaptation of the setting, less conducive staffing arrangements in certain respects and less well developed policies and poorer staff training concerning responding to difficult behaviour. The confidence of clinicians and carers to cope with possibly transient fluctuations in behaviour seemed to be an important factor in the determination necessary to see whether any initial adverse reactions to withdrawal can be tolerated and drug reduction sustained. Staff attitudes and apprehension may play important roles in determining psychotropic medication reduction outcome. **[QI 2, QI 9, QI 11, QI 13]**

A systematic review, showed that people with intellectual disability were included in 27% of RCTs concerning management of behavioural problems with antipsychotics

(Scheifes et al., 2011). Most studies were found to be of sufficient quality. However, when the authors looked at the number of patients included in those trials, only 11% of the population studied in the 100 trials were patients with intellectual disability. It is of note that in 10 RCTs, people with intellectual disability were explicitly excluded and 63 studies did not mention either inclusion or exclusion of people with intellectual disability. The authors concluded that there was not sufficient evidence available to assess the effects of antipsychotic drugs for behavioural problems in people with intellectual disability, although in this population group this class of medication is commonly used in clinical practice.

2.4.4.2 Antiepileptic Drugs

The pooled analysis of 199 clinical trials involving eleven antiepileptic drugs (AEDs) as either monotherapy or as adjuvant therapy showed that 0.43% of patients receiving an antiepileptic had suicidal behaviour/ideation compared to 0.24% of patients receiving placebo. As a result of the findings, the FDA has required that the product labelling of the entire class of anti-epileptics include a warning concerning the risk of suicidal behaviour or ideation and a medication guide be developed informing patients of this risk (FDA, 2009b).

Antiepileptic/anticonvulsant medications can be used in three different situations in people ageing with intellectual disability - as an anticonvulsant, for neuropathic pain and as a mood stabilizer. A systematic review (Deb and Unwin, 2007) of the literature found that anticonvulsants are the second most common psychotropic medication class prescribed in this population. Although improvement was seen with the use of anticonvulsant medications in this review, the overall quality of evidence for the use of anticonvulsant medications for aggression was not high. AEDs are not the only option for treatment for psychiatric disorders, behavioural problems and pain in this population group. The FDA advised healthcare professionals that all patients who currently are taking or starting on any antiepileptic drug for any indication should be monitored for notable changes in behaviour that could indicate the emergence or worsening of suicidal thoughts or behaviour or depression. It would be advisable for the prescriber and/or the dispensing pharmacist to alert the person with intellectual disability and/or their carer to the possibility of the emergence of behaviour changes in people with intellectual disability and behaviour disorders prescribed AEDS. [QI 7, QI 12, QI 22, QI 26]

The relationship between epilepsy and behaviour disorders is complex and no substantial evidence exists to draw any definitive conclusions about the mode of action of the mood stabilizers in improving behaviour problems in adults with intellectual disability. A systematic review (Deb et al., 2008) designed to determine the evidence base for the effectiveness of mood stabilizers in the management of behaviour problems among adults with intellectual disability found that although improvement was seen with the use of some antiepileptic medication, the overall evidence in their support was not of high quality in this systematic review. The authors noted also that no systematic approach was adopted to assess the side effects of many of the medications used within the studies. [QI 2, QI 16, QI 22]

2.4.4.3 Anti Depressant Medication

Antidepressant medications, specifically selective serotonin re-uptake inhibitors (SSRIs), have been suggested as being potentially useful in the treatment of aggression and self-injury, partly due to the observation that irritability is often associated with aggressive behaviour. Sohanpal et al, undertook a systematic review (Sohanpal et al., 2007) of the literature to establish the current evidence base regarding the effectiveness of antidepressants for management of behaviour problems in adults with intellectual disability. They observed that the evidence for efficacy was scant and concluded that SSRIs improve aggression and self-injury on average in less than 50% of cases and patients with underlying anxiety or obsessions and compulsions may benefit the most.

The FDA issued an alert in 2006 concerning the potential for life-threatening serotonin syndrome (a syndrome of changes in mental status, autonomic instability, neuromuscular abnormalities and gastrointestinal symptoms) in patients taking 5-hydroxytryptamine receptor agonists (triptans) and SSRIs or selective serotonin/norepinephrine reuptake inhibitors (SNRIs) concomitantly (FDA, 2006). The FDA advised that healthcare professionals consider the following issues that are all pertinent to the care of people ageing with intellectual disability and behaviour disorders:

- Weigh the potential risk of concomitant SSRI/SNRI and triptan use with the benefit expected from using each drug, prior to prescribing these drugs together.

- When prescribing an SSRI or a triptan, physicians should discuss the possibility of serotonin syndrome with patients if an SSRI and a triptan will be used concomitantly.
- Healthcare providers should keep in mind that triptans are often used intermittently, and that the SSRI, SNRI, or triptan may be prescribed by a different healthcare provider.

Healthcare providers should be alert to the highly variable signs and symptoms of serotonin syndrome in people with intellectual disabilities. Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g. hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhoea). If concomitant treatment with an SSRI or SNRI and triptan is clinically warranted, the patient should be carefully observed, particularly during treatment initiation and dose increases. [QI 2, QI 3, QI 7, QI 12, QI 23]

2.4.4.4 Lithium Carbonate

Lithium carbonate has been used for behaviour problems in non-bipolar individuals with intellectual disability. A high proportion of the patients treated with lithium have shown improvement in target behaviours. [QI 7, QI 9, QI 11, QI 19]

2.4.4.5 Benzodiazepines

Anxiety could be a precipitating factor for problem behaviours in people with intellectual disability. Anti-anxiety medications such as benzodiazepines, buspirone and also beta-blockers have been used for the management of problem behaviour in people with intellectual disability, although evidence in support of their effectiveness is lacking (Deb and Unwin, 2007). [QI 12, QI 13, QI 19]

An alert published by the office of an American Ombudsman for Mental Health and Developmental Disabilities (Hanzel and Kalachnik, 2006) noted that behavioural side effects associated with benzodiazepines such as clonazepam, diazepam and lorazepam can be an easily overlooked and under-recognized problem for people who have intellectual disability and can be inadvertently confused with other behavioural or psychiatric conditions. The alert pointed out that this is especially important because

many individuals with intellectual disability cannot effectively communicate the presence of these side effects and are, for the most part, dependent upon others for detecting and recognizing these side effects. The alert considered that benzodiazepine behavioural side effects included: aggression, agitation, anger, depression, hostility, hyperactivity, irritability, property destruction, self-injurious behaviour, socially inappropriate behaviour (e.g., disrobing in public) and temper tantrums. [QI 15]

Kalachnik et al in their literature review (Kalachnik et al., 2002), found that behavioural side effects occurred for 13.0% of 446 individuals with intellectual disability who were prescribed benzodiazepines for either behavioural or psychiatric conditions (n = 138, 17.4%), epilepsy (n = 208, 15.4%), or other medical conditions such as myoclonus or cerebral palsy (n = 100, 2.0%). Behavioural side effects for individual benzodiazepines for which data were available ranged from 11.4% to 25.0%. The alert mentioned earlier calls attention also to the fact that the display of benzodiazepine behavioural side effects can take one of two forms. A side effect may increase or worsen i.e. “behavioural exacerbation.” A side effect may occur for the first time i.e. “behavioural disinhibition” (Hanzel and Kalachnik, 2006). [QI 7, QI 12, QI 17, QI 18, QI 19]

2.4.5 Medication Regimen Review

Inadequate medication review (Beange et al., 1995) has long been an acknowledged problem in the population with intellectual disabilities. The *IASSID Health Guidelines for Adults with Intellectual Disability* include the following

‘Prescribers need to acknowledge the inherent difficulties with monitoring and ensure that the patient and carers safely and reliably administer medication, are able to recognise adverse effects, monitor the efficacy of the medication and are aware of the review process’ (IASSID, 2002). [QI 7, QI 12]

One of the health targets developed by The Physical Health Special Interest Group of IASSIDD is

‘Review medications at frequent intervals, ideally at least every three months’.

A medication regimen review (MRR) includes preventing, identifying, reporting and resolving medication related problems, medication errors, or other irregularities and

collaborating with other members of the inter-disciplinary team' (DHHS, 2007) and would facilitate meeting the target set by the IASSID. Nishtala et al, the authors of a literature review designed to evaluate the evidence pertaining to the impact of medication reviews and/or educational interventions on psychotropic drug use in long-term care facilities, concluded that medication reviews and/or educational interventions are effective at reducing psychotropic drug prescribing (Nishtala et al., 2008). However, the authors noted that research on the benefits of these interventions in reducing psychotropic drug use on total health care costs and resident health outcomes is lacking. **[QI 12, QI 9]**

In an audit of 382 sets of notes examined (89% of case-load) in a community intellectual disability service, Marshall found that 102 patients were receiving regular medication for challenging behaviour (26.7%). (This did not include those receiving as required (PRN or 'pro re nata) medication only), (Marshall, 2004). The most common coexisting diagnoses were autism in thirty patients (29%) and epilepsy in 29 patients (28%). A wide range of different classes of drugs were used to control behaviour but antipsychotic drugs predominated, with 98 patients (96%) receiving one or more of these medications. Antidepressants, anti-epileptics, lithium, beta-blockers and antilipid drugs were also used. The most common types of challenging behaviour described in the audit were physical aggression (79%), self-injury (42%), destructiveness (34%), verbal aggression (26%), sexually inappropriate behaviour (17%) and absconsion (12%). Benefit in the audit was determined by carer impression (89%), by rating scale (8%) and by direct recording of behaviour (1.5%). In 1.5% of cases there was no apparent criterion for the perceived benefit. In discussion the author stated that

'Psychotropic medication is frequently prescribed for challenging behaviour, often for many years, and poly-pharmacy is common. The frequency and severity of the behaviour are poorly described and the continued use of this medication is not routinely reviewed' (Marshall, 2004). **[QI 12, QI 13, QI 16, QI 17]**

The impact of pharmacist-conducted clinical medication review was measured in a study of elderly care home residents and found that a total of 75.6% (565/747) of pharmacist recommendations were accepted by a general practitioner; and 76.6% (433/565) of accepted recommendations were implemented (Zermansky et al., 2006). Greater pharmacist involvement has been shown in a systematic review to increase

physicians' and nurses' knowledge and awareness about medication in nursing home settings. [QI 7, QI 12, QI 15, QI 19]

Matson and Wilkins recognised that minimizing psychotropic medication usage in people with intellectual disabilities and behaviour disorders on a large scale may be difficult to achieve (Matson and Wilkins, 2008). They suggested that the following reasons for this state of affairs:

- unfamiliarity of medical personnel with psychologically based treatments,
- insufficient numbers of trained staff,
- the attraction of sedating violent individuals as opposed to engaging them with psychological interventions,
- the fact that psychological interventions may produce gradual versus dramatic changes which can occur with sedation,
- monitoring treatment efficacy can be difficult,
- the potential for physical injury to staff and/or allegations of client abuse with psychological interventions is greater than for medication use.

2.4.6 Medication Side Effects

Empowerment in safeguarding involves risk management that is based on understanding the person, understanding the autonomy of the person and how they or their carer view the risks they face (Sussex Multi Agency, 2011). However it may not be possible or even desirable to eliminate all risk with respect to medication use in the population with intellectual disabilities and behaviour disorders.

The identification of side effects to psychotropic and other medications causes difficulties in the population with intellectual disabilities. The international consensus process on psychopharmacology and intellectual disability in 1997 identified that this may be because:

- the patient's functional handicap may be confused with certain symptoms,
- many people with intellectual disability are unable to report the presence of subjective side effects,
- some features frequently seen in the population with intellectual disability may be difficult to disentangle from movement disorders,

- the population with intellectual disability may be at greater risk of side effects to medications occurring (Reiss and Amam, 1997). [QI 3, QI 7, QI 9, QI 12, QI 15, QI 19, QI 21]

The results of an observational study comparing 138 antipsychotic-treated and 64 antipsychotic-naive participants with intellectual disability in one National Health Service Trust with general population controls suggested that antipsychotics at the low doses routinely prescribed for people with intellectual disability are

'generally safe in relation to metabolic adverse effects, even if efficacy remains poorly defined' (Frighi et al., 2011b).

A UK study, published in 2011, was designed to identify the range of indications for which antipsychotic drugs are prescribed in people with intellectual disability and to audit clinical practice against three recognised standards. The three standards were:

- 1) The indication for treatment with antipsychotic medication should be documented in the clinical records.
- 2) The continuing need for antipsychotic medication should be reviewed at least once a year.
- 3) Side effects of antipsychotic medication should be reviewed at least once a year, and this review should include assessment for the presence of extra-pyramidal side effects, and screening for the four aspects of the metabolic syndrome: blood pressure, obesity, glycaemic control and plasma lipid profile.

Following the audit of data for 2,319 patients the authors concluded that

'In clinical practice, most prescriptions for antipsychotic drugs in people with intellectual disability are consistent with the evidence base and the overall quality of prescribing practice, as measured against recognised standards, is good, although in some patients potentially remedial side effects may not be detected and treated' (Paton et al., 2011).

The standard in relation to side effects described in this study, was only applied to the subsample of patients who had been prescribed antipsychotic medication for a year or more and the results for this standard are presented here in Table 2.7.

Table 2.7 Performance Against Standard for Monitoring of Side Effects

Performance Against Standard for Monitoring of Side Effects	
<ul style="list-style-type: none"> • General statement in the clinical records that side effects were either present or not present 	1378 (69%)
<ul style="list-style-type: none"> • Patients treated for at least a year 	<ul style="list-style-type: none"> • No documented evidence of any EPS assessment in 1165 (59%). • No assessment of <ol style="list-style-type: none"> a. weight/body mass index in 883 (44%) b. blood pressure 1257 (63%) c. blood glucose 791 (40%) d. lipid profile 848 (43%)
<ul style="list-style-type: none"> • No documented evidence of assessment of any of these specific side effects was found, nor any general statement about the presence or absence of side effects 	247 (12%)
<ul style="list-style-type: none"> • Statement that side effects were present/not present had been recorded in the case notes 	<ul style="list-style-type: none"> • 72% of those with borderline/mild intellectual disability • 66% of those classified as severe/profound intellectual disability

The data presented in this audit did not suggest that patients with more severe intellectual disability were more likely to be targeted for side effect review (Paton et al., 2011). A previous audit revealed that less than 15% of adults with intellectual disability prescribed second generation antipsychotic medications had all the parameters of metabolic syndrome monitored on a regular basis (Devapriam et al., 2009).

Frigi and colleagues, Box 2.3, found that 138 (68%) were on antipsychotics and 64 (32%) were antipsychotic naïve (Frigi et al., 2011b). 80 participants (58%) in the antipsychotic-treated group had challenging behaviour, which was the commonest reason for the prescription. There were more men (59%) in the antipsychotic-treated and more women (61%) in the antipsychotic-naïve group. In the whole study group,

27% of the participants had a diagnosis of challenging behaviour only, in the absence of psychiatric disorders.

Psychotropic Medication Use (n = 202)
97% were on one or more psychotropic agents, with a mean of 2.0 drugs per participant. (Mean = 1.4 per participant excluding anti-epileptics)
In total 68% were on antipsychotics, 42% on antidepressants, 39% on anti-epileptics, 25% on benzodiazepines (generally 'as required' rather than regularly), 2% on non-benzodiazepine hypnotics and 1% on lithium.
Of the 138 antipsychotic-treated participants, 48% were on risperidone, 18% on olanzapine, 10% on thioxanthenes, 9% on chlorpromazine or other first-generation phenothiazines, 9% on quetiapine, 7% on amisulpride or 4% on sulpiride.

Box 2.3 Psychotropic Medication Use

Comparisons with the general population showed that glucose and lipid parameters were on average the same or even more favourable in the intellectual disability group. In women with intellectual disability, prevalence of overweight/obesity and of Type 2 diabetes were markedly higher in the intellectual disability group. The relatively small number of people in the study taking olanzapine and clozapine, which are antipsychotics with the highest potential metabolic impact, and the low doses prescribed could account for the absence of any effect in relation to glucose and lipid parameters. In their summary, the authors identified that the findings of the *Oxford Learning Disabilities Study* provides an initial evidence base underpinning the safe use of antipsychotic drugs in the intellectual disability population (Frighi et al., 2011a). The study identified hyperprolactinaemia as the commonest side-effect in people with intellectual disability administered antipsychotic medications and hyperprolactinaemic hypogonadism as a complication of risperidone and amisulpride treatment, leading to bone loss in a population already at risk for osteoporosis and fractures.

Frighi et al., noted that antipsychotics continue to be consistently used for challenging behaviour and advise that this practice would be difficult to defend in such a population group if it led to major metabolic side-effects. However their findings offered significant reassurance in relation to cardiovascular and metabolic risk in the population with intellectual disability. They did however caution that there may be potential problems in a susceptible subgroup and that regular monitoring of blood glucose, lipids and weight

should be instituted when prescribing antipsychotics to people who may already have risk factors for diabetes, and when using antipsychotics with a high metabolic impact (Frigi et al., 2011a).

The results of a longitudinal study with random sampling and selection which commenced in Melbourne, Australia in 1994, were suggestive that advice on medications may be forgotten over time by an older cohort, so that the importance of regular monitoring and reinforcement by doctor and pharmacist is needed (Thomson et al., 2010). The important role of doctors and pharmacists as educators was emphasized by another study that found starting a new medication, cessation of a medication or changes to prescribed and over the counter (OTC) medications were associated with an increased risk of medication side effects (van den Brent et al., 2000). Doctors in prescribing, and pharmacists in dispensing, have an important role in detection and education. Greater awareness and knowledge of health professionals including doctors and pharmacists as well as patients is also important. Identified risk factors for medication side effects, identified in the Melbourne study were increased education level, co-morbidities and health service factors including recency of visiting the pharmacist, attending younger doctors and their doctor's awareness of their medications (Thomson et al., 2010). **[QI 7, QI 12, QI 19, QI 21]**

People with mental illness and mental illness and intellectual disability would be expected to report numerous complaints associated with the medications they take and the oculo-visual anomalies they exhibit during the initial case history and the review. A retrospective analysis (Donati et al., 2009) of all medical records for patients (n = 202) with intellectual disabilities or intellectual disability and mental illness (MI) i.e., Dual Diagnosis (DD) and who were prescribed psychotropic medications was undertaken to determine the frequency of ocular anomalies, drugs taken, and complaints reported by patients during the initial review of systems. The most common documented side effects for the targeted drug types were decreased or blurred vision (near or far), visual hallucinations, decreased accommodation, and eyelid/conjunctiva irregularities. The most frequently encountered complaints for the patients were no complaints (45.16% MI and 46.84% DD), blurry vision (17.74% MI and 17.72% DD) and need new glasses (11.29% MI and 17.72% DD). The data from this study suggest that only about 50% of those who should have complaints actually report them. This would confirm the wider experience that people with intellectual disabilities have difficulties describing side effects of medications. **[QI 15, QI 19, QI 21]**

2.4.7 Dementia

Due to language and other communication difficulties experienced by people with intellectual disabilities, screening and other diagnostic measures for dementia used for the general population have limited potential in the population ageing with intellectual disabilities. The authors of a literature review noted that agreed prevalence and incidence figures of dementia in people ageing with intellectual disabilities are not available and that estimates ranged from a low of 6% for persons with intellectual disabilities over age 60 in one state in the USA, to a high of 21.6% for persons over age 65 in a UK study (McCallion and McCarron, 2004). It is agreed that there is a higher prevalence of dementia in persons with Down Syndrome than in persons with other intellectual disabilities and the general population (Bush and Beail, 2004).

Consensus guidelines suggest that in people with intellectual disabilities undergoing dementia assessment, medications require specific focus, as the risks associated with multiple medication use and the involvement of multiple prescribing physicians increases as people age (Moran et al., 2013). Special attention should be given to any newly prescribed medications, particularly those that are psychoactive, antiepileptic, or anticholinergic, and those with sedating properties. Medications with anticholinergic effects are important causes of urinary retention, impaired cognitive function, confusion, and delirium in older people, and are generally considered inappropriate for the elderly. Many medications commonly prescribed in the population with intellectual disabilities have anticholinergic effects - antiemetics, antispasmodics, bronchodilators, antiarrhythmic drugs, antihistamines, analgesics, anti-hypertensives, anti-parkinsonian agents, corticosteroids, skeletal muscle relaxants, ulcer drugs and psychotropic drugs. **[QI 7, QI 12, QI 20]**

The research evidence on anti-dementia drugs in people with intellectual disability is sparse at present, consisting of small trials and case reports on side effects with most of the evidence in this population relating to studies in people with Down Syndrome (Strydom et al., 2009). Caregivers need training in awareness of side effects and their management. These side effects have been reported as urinary incontinence, agitation and aggression, abdominal pain and diarrhoea in various studies. **[QI 7, QI 12, QI 20, QI 30, QI 32]**

In the general population, concomitant use of anticholinergic drugs and cholinesterase inhibitors is common among older adults with the use of anticholinergic drugs being

associated with poor psychological well-being (Teramura-Grönblad et al., 2011). **[QI 12, QI 15, QI 30, QI 31, QI 32]**

A Pharmacist's/Prescriber's Letter detailed the risk of adverse effects (e.g., cognitive dysfunction, delirium) in the elderly (Therapeutic Research Center, 2011). The Letter also highlighted the following:

- Anticholinergics also interact with other drugs to reduce their effectiveness (e.g., cholinesterase inhibitors like donepezil or increase the risk of adverse effects (e.g., increased gastrointestinal irritation with oral potassium tabs).
- Drugs with low anticholinergic activity may be good alternatives to drugs with more anticholinergic activity. For example, SSRIs with lower anticholinergic activity are preferred over tricyclics for treatment of depression in the elderly. However, it's not just the use of single drugs with significant anticholinergic activity that can cause trouble.
- Individuals who take multiple meds with low anticholinergic activity may also have increased risk of adverse effects. In fact, even small increases in so-called anticholinergic burden or load increase the risk of morbidity and mortality in older individuals.

Psychiatric patients and people with intellectual disabilities prescribed psychotropic medications are especially at risk of suffering anticholinergic effects. Psychotropic medications have been shown to be particularly likely to demonstrate anticholinergic activity (Chew et al., 2008). Anticholinergic toxicity is a common problem in older people with effects ranging from dry mouth, constipation, and visual impairments (peripheral effects) to confusion, delirium, and severe cognitive decline (central nervous system effects). Cumulative anticholinergic burden results from the use of multiple medications and metabolites rather than of a single compound (Tune, 2001). **[QI 18, QI 19, QI 30, QI 31, QI 32]**

2.4.8 Dysphagia

Dysphagia is a serious chronic condition that affects the health and quality of life of many people with intellectual disabilities. Risks associated with having dysphagia include aspiration, dehydration, poor nutritional status and asphyxiation and choking. The true consequences of unmanaged dysphagia in people ageing with intellectual disability are difficult to ascertain (Chadwick and Jolliffe, 2009). A retrospective cohort

study aimed to examine the rate of dysphagia recommendation omissions in hospital discharge summaries for high-risk subacute care (i.e., skilled nursing facility, rehabilitation, long-term care) populations, found that 47% (88/186) of patients with speech and language pathologists' dietary recommendations, 82% (93/114) with postural, 100% (16/16) with rehabilitation, 90% (69/77) with meal pacing, 95% (21/22) with medication, and 79% (96/122) with provider/supervision recommendations had these recommendations completely omitted from their discharge summaries (Kind et al., 2011). The need to ensure that each patient with dysphagia has an individualized medication regimen, and that the formulation of the medicine is as important for people with dysphagia as the active ingredients has been recognised (Kelly et al., 2010). **[QI 1, QI 7, QI 9, QI 10, QI 28]**

2.4.9 The Medication Use Process

The disability sector accounted for 8.6% of all medication related adverse events reported in Ireland in 2012 and medication related incidents represented 4.1% of all adverse incidents reported by the disability sector in that year (Oglesby, 2013). For the population ageing with intellectual disability there are many components in the medication use process that are very unlikely to have been tested in clinical trials. They may however be important and may form a basis for measuring quality of care in this vulnerable population. Having information on the process leading up to the prescribing, dispensing and administration of medication to people with intellectual disability is vital to establishing the quality of care. **[QI 1, QI 2, QI 7, QI 9, QI 10, QI 14, QI 15]**

Medication use has provided an opportunity for monitoring the quality of care in ageing populations (Knight and Avorn, 2001a) and provides an opportunity for monitoring quality of care in the ageing intellectually disabled population with behaviour disorders. Several steps have been identified in the medication use process:

- 1) prescribing,
- 2) transcribing and documenting,
- 3) dispensing,
- 4) administering and
- 5) monitoring (US Pharmacopeia, 2004).

Medication use is the main therapeutic intervention in the population ageing with intellectual disability and the medication use process involves some very complex

activities, each of which requires oversight and co-ordination to ensure that the patient with intellectual disability receives each of their medications in a safe manner that maximises effectiveness and reduces risk (LTCPLC, 2008), Box 2.4. Because of the complexity of the medication use process for people with intellectual disabilities and the inability to correct all of the problems at once, the rational approach would appear to be to seek meaningful interventions that will target portions of the risk chain. **[QI 1, QI 2, QI 6, QI 10, QI 12, QI 16, QI 17]**

The medication use process in the person ageing with intellectual disability and behaviour disorders includes a 'pre prescribing step' consisting of 2 elements of the care delivery process described in Box 2.4 i.e. recognition/assessment and diagnosis/cause identification (LTCPLC, 2008). These are vital components of the medication use process in this population with communication difficulties, in which 'diagnostic overshadowing' (Walker and Spengler, 1995, Jopp and Keys, 2001) and 'healthcare by proxy' (Cooper et al., 2006) are significant factors. Direct care workers have a very critical role as advocates for health for the people with intellectual disabilities in their care (Lennox and Edwards, 2001) and their attitudes, skills and confidence will have an impact on the 'pre prescribing' stage and other stages of the medication use process in this population group.

Medication Use Linked to Care Delivery	
Care Delivery Process	Medication Use Process
Recognition/Assessment	
Diagnosis/Cause Identification	
Selecting Interventions/Delivering Care	Prescribing Transcribing/Documenting Dispensing Administering
Monitoring	Monitoring

Box 2.4 Medication Use Linked to Care Delivery

One barrier to healthcare in this population is the reliance of people with intellectual disabilities on health management 'by proxy' which involves numerous steps (Cooper et al., 2006), Figure 2.6. Underreporting of risk factors for ill health may occur among people with intellectual disabilities for many reasons, including compromised ability of the person with intellectual disability to report illness or medication side effects. People with intellectual disabilities and their carers may be the first to notice any observable problem that arises from a medication adverse event. However the 'expertise' of the carer is often not acknowledged in healthcare encounters.

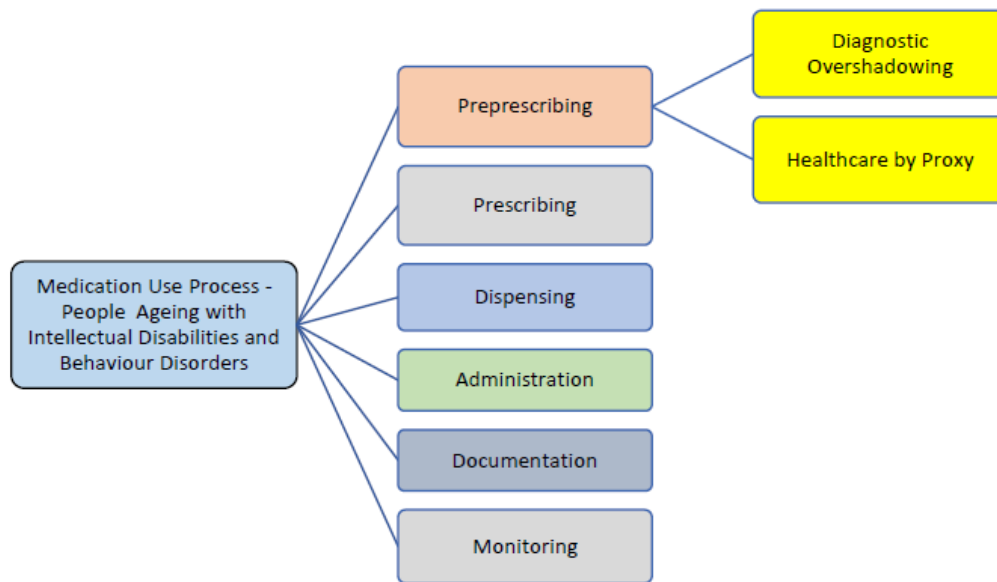


Figure 2.6 Medication Use Process for People with Intellectual Disabilities

Healthcare for people with intellectual disabilities contains an overshadowing bias when the presence on one impairment such as intellectual disabilities results in a reduced likelihood that another existing impairment will be identified. This 'diagnostic overshadowing' is a significant barrier to people with intellectual disabilities receiving quality healthcare, Figure 2.6. 'Diagnostic overshadowing' has been recognised by the National Patient Safety Agency (NPSA) in the UK as a patient safety priority for people with intellectual disabilities (NPSA, 2004c).

Quality issues exist at every stage of the medication use process for people ageing with intellectual disability. We need to adopt a whole system approach as there can be cumulative loss of quality at each consecutive stage of the medicine use process for people ageing with intellectual disability. The systematic surveillance of the quality of medication use is one of the most promising approaches to improving the quality

process of care that is amenable to direct action by those involved in medication use (Knight and Avorn, 2001b).

2.4.10 Pharmaceutical Care

The ageing of the intellectually disabled population, as described in reports of the NIDD over the years, should have a major effect on the future practice of pharmacy with that population group. This increase in the older population with intellectual disability and increasing utilization of medications will pose new demands for expertise in the area of medication therapy management for this population. To date, the need for specialised pharmaceutical care for the ageing population with intellectual disability has not been widely recognised (Flood and Henman, 2010). Poor knowledge and attitudes of healthcare professionals have been cited as one of the reasons why the healthcare needs of people with intellectual disabilities are frequently unmet (Kerr, 2004). Flood and Henman have identified that the Annual Report of the NIDD Committee 2008 and all previous reports of the committee have been silent about the need for pharmaceutical care provided by pharmacists for this vulnerable population (Flood and Henman, 2010). **[QI 7]**

In 1990, a new way to look at the responsibilities of the pharmacist and pharmacy services was identified and the term “pharmaceutical care” was used to describe this concept of pharmacists' services (Hepler and Strand, 1990). The philosophy of pharmaceutical care focuses on the responsibility of the pharmacist to meet all of the patient's drug related needs, be held accountable for meeting those needs and assist the patient in achieving his or her medical goals through collaboration with other health professionals (McGivney et al., 2007). In an article proposing a redefinition of pharmaceutical care, Blackburn and colleagues have proposed that “the current definition of pharmaceutical care and its associated care processes need to be modified to ensure the activities of pharmacists are being focused on high-priority patients on a consistent basis’ (Blackburn et al., 2012). They argued that the philosophy of pharmaceutical care (and its associated care processes) should be expanded to make pharmacists accountable to populations of patients at high risk for drug- or disease-induced morbidity. One such population is the population ageing with intellectual disability and behaviour disorders. Williamson and Harvey in a Literature Review/Scoping paper identified some considerations and strategies for improving capacity of disability services to meet the needs of people with a disability in improving

health outcomes (Williamson and Harvey, 2007). One such strategy related to pharmacists, Box 2.5.

Strategy for Improving Capacity of Disability Services to Meet the Needs of People with a Disability by Improving Health Outcomes
Pharmacist <ul style="list-style-type: none">• Developing a sound relationship with a pharmacist can benefit people with a disability by being an avenue for advice. People with a disability may regularly require medication and often will require more than one medication.• The need for medication can increase with age. Advice from a pharmacist can provide a safeguard against interaction of medication and side effects.• The pharmacist can support the person and service provider to provide a regular assessment and monitoring of medication (both prescribed and over the counter) to identify risks of adverse interaction.

Box 2.5 Strategy for Improving Capacity of Disability Services to Meet the Needs of People with a Disability by Improving Health Outcomes

Pharmaceutical care, rational medication use and effective medicines supply management are key components of an accessible, sustainable, affordable and equitable healthcare system, which ensures the efficacy, safety and quality of medicines. HIQA in its *National Quality Standards for Residential Care Settings for Older People in Ireland* states in Criteria 15.2 of Standard 15: Medication Monitoring and Review,

‘the condition of the resident on medication is monitored and subject to review at three monthly intervals or more frequently where there is a significant change in the resident’s care or condition’.

Criteria 15.6 also states that

‘each resident on long term medication is reviewed by his/her medical practitioner at least on a three monthly basis, in conjunction with nursing staff and the pharmacist’.

These criteria are the supporting statements that set out how a service can be judged as to whether the standard is being met or not. In contrast, the HIQA *National Quality*

Standards: Residential Services for People with Disabilities (HIQA, 2009b) in which there is no mention of the pharmacist, states in Standard 9: Health, Criteria 9.14 that

“the individual’s medication is monitored and subject to review at regular intervals, appropriate to the individual’s needs”.

The difference in standards expected here is a concern.

The most recent Canadian *Consensus Guidelines for Primary Care of Adults with Developmental Disabilities* did not include a pharmacist in the consensus process. Among the 39 participants were practitioners in family medicine, nursing, paediatrics, psychiatry, psychology, occupational therapy and speech-language pathology (Sullivan et al., 2011). This should be a cause for concern for people with intellectual disabilities, their carers and their pharmacists.

Pharmacists and pharmaceutical care are components of the medication use process. Deirdre Madden in her report, *Building a Culture of Patient Safety*, recognised that health services are provided by professionals who are dependent on each other to deliver safe, high quality care and treatment to patients (Madden, 2008). Berta and colleagues, who conducted a systematic review of the literature followed by a 2-round modified Delphi consensus process to identify elements of data that have been shown to contribute to continuity of information between primary care providers and medical specialists providing care to adult asthma patients, observed that,

‘The quality of decision making by clinicians is profoundly affected by informational continuity which refers to the use, transfer, and management of patient information’ (Berta et al., 2008).

Good informational continuity is achieved with the accurate assimilation, timely transfer, and sharing of essential patient information among care providers that includes relevant information on past events and on patients’ personal circumstances (Haggerty et al., 2003). To practice effectively pharmacists require adequate information. **[QI 1, QI 2, QI 7, QI 10, QI 12]**

The authors of the *Lessons from the Labryinth Report* acknowledged that quality issues at any stage of healthcare are notably significant for people with intellectual disabilities, because the impact of poor quality may have serious repercussions for them when compared to people without disabilities (Lennox and Edwards, 2001). It is

important that care is right for people with intellectual disabilities whose behaviour challenges and *The Winterbourne View Update Report* raised questions about whether people with intellectual disabilities were being given the right medications to improve their condition, or whether they were being over-medicated for the benefit of staff (DH, 2013c). There is consequently a perceived need to improve the quality of the medication use process in this population group.

2.4.11 Medication Use and People Ageing with Intellectual Disabilities

The prescription and administration of medication is an area where people with intellectual disabilities experience lack of control and disempowerment. In their Grounded Theory qualitative study, Crossley and Withers organized and analysed data from interviews conducted with eight adults with intellectual disabilities about their experiences of antipsychotic medication. Their results indicated that respondents had little knowledge about their medication, beyond knowing their regime and that despite participants experiencing side effects, they were accepting of these effects. A 'model of compliance' was generated from the analysis (Crossley and Withers, 2009). **[QI 2, QI 7, QI 11, QI 15]**

Interest in comparative quality measurement and evaluation has grown considerably over the past two decades because of factors such as the recognition of widespread variation in clinical practice, the increased availability of evidence about medical effectiveness, and increasing concern about the cost and quality of health care (Kelley et al., 2006) and also because of the recognition that there are vulnerable population groups in healthcare who experience health inequalities. The most recent Canadian *Consensus Guidelines for Primary Care for adults with developmental disabilities* (Sullivan et al., 2011) contain a strong recommendation that inappropriate long term use of antipsychotic medications to address behavioural issues is avoided. The Technical Document for the '*Guide to using psychotropic medication for the management of behaviour problems among adults with intellectual disability*' identified some issues of particular concern when using psychotropic medication in this population group (Deb and Unwin, 2006a). These include concerns in relation to high dose, off label prescriptions, multiple medication use and 'prn' or 'as required' medications. Communication between professionals, carers and people with intellectual disability and the sharing of information is an underlying thread of this guideline and the authors acknowledged that communication forms a very important

principle of care when managing people with behaviour problems and intellectual disability (Deb and Unwin, 2006a). **[QI 1, QI 7, QI 10, QI 12]**

Stakeholders have different perspectives about quality of care (Campbell et al., 2002). Patients ageing with intellectual disabilities, and their carers/families may have very different views than multidisciplinary clinicians about a quality medication use process. It is acknowledged that patient centeredness, the aspect of quality related to patient self-management and engagement in medical decision making, can only be defined from a patient's perspective (AHRQ, 2009). This area is addressed in Chapter 4 of this thesis where data from interviews with people with intellectual disabilities are explored. **[QI 2]**

2.4.12 Medication Reconciliation

Transitions of care - admissions and discharges - are complex events for the person with intellectual disability and their carers. Comprehensive and reliable information transfer decreases readmission rates, improves health outcomes and ensures quality transitions. The highest category of medication adverse events incidents reported in Ireland in 2012 was in relation to incorrect reconciliation of medication on admission/discharge/transfer at 21.8% (Oglesby, 2013). Medication reconciliation is the process of obtaining a complete and accurate list of each patient's current medications from all available sources at all points of contact and verifying and reconciling medications to reduce medication errors (Madden, 2008). In order to succeed, medication reconciliation must be a formal, standardised process that is built into the system of care. This is of particular importance for people ageing with intellectual disability who may not be able to communicate for themselves in relation to medication use. Each time a patient moves from one setting to another, clinicians must compare previous medication orders with new orders and plans for care and reconcile any differences. **[QI 1, QI 2, QI 10, QI 28, QI 29]**

The NPSA, has highlighted areas of vulnerability for people with intellectual disabilities in healthcare (NPSA, 2004c) and has considered the vulnerability of people with intellectual disabilities in general hospitals as a Patient Safety Issue, Box 2.6. The NPSA has indicated that people with intellectual disability and higher support needs are the most vulnerable group of patients.

NPSA Patient Safety Issue 2

People with learning disabilities may be more at risk of things going wrong than the general population, leading to varying degrees of harm being caused whilst in general hospitals

Box 2.6 NPSA Patient Safety Issue 2

Medication reconciliation was named as 2009 National Patient Safety Goal Number 8 by the Joint Commission in the USA (Joint Commission, 2009). The Joint Commission's announcement called on organizations to

“accurately and completely reconcile medications across the continuum of care”.

An addendum was subsequently added that is significant in the care of people with intellectual disabilities:

‘When the patient is unable to actively or fully participate in the medication reconciliation process and has requested assistance from another person(s) (e.g., family member, significant other, surrogate decision maker), involve the authorized person(s) in the medication reconciliation process. This involvement should occur at all interfaces of care, and on admission to and discharge from the facility’.

This addendum recognized that many patients may be too ill, injured, young, or disabled to actively participate themselves in the medication reconciliation process.

In 2014 HIQA, defined medication reconciliation as:

‘the process of creating and maintaining the most accurate list possible of all medications a person is taking – including drug name, dosage, frequency and route – in order to identify any discrepancies and to ensure any changes are documented and communicated, thus resulting in a complete list of medications’ (HIQA, 2014).

The guidance document does not address the specific medication management issues for the population with intellectual disabilities but does acknowledge that ‘there may be other requirements relevant to particular services that are not addressed in this

guidance and it is for service providers to identify the regulations, standards and best available evidence relevant to their service'. [QI 1, QI 9, QI 10]

Professionals must try to communicate unbiased and understandable accessible information related to medication use and medication non use to people with intellectual disabilities and behaviour disorders and/or their carers. This information should include benefits, harms, monitoring requirements and any uncertainties. This is an ethical imperative and

'failure to provide this should be taken as evidence of poor quality care'
(Coulter and Collins, 2011).

Support workers/carers have recognised their need for specific information regarding the side effects of psychotropic medication and its alternatives (Donley et al., 2012). From a human rights perspective, it is a concern that people with intellectual disabilities are not always involved in decision-making about their medications as this may mean that some patients are

'unfairly denied of their autonomy' (Huneke et al., 2012).

2.5 Quality



Figure 2.7 Quality: Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders

2.5.1 Introduction

Inequalities often represent an

'inequality in quality'

The average age at death of 1120 people with an intellectual disability in Ireland who died between 1996 and 2001 was 45.68 years with a more severe level of intellectual disability predicting shorter lifespan (Lavin et al., 2006). It is of concern that the lifespan among this sample of people with intellectual disability was considerably lower (45.68 years) than the average lifespan among the general population in Ireland (75.75 years) (Central Statistics Office 1996). Inequalities are most easily identified when there is a clear reference point such as mortality, for what is appropriate and reasonable to expect (AHRQ, 2003). The results of one European study suggest that inequities in access to good-quality health care have a role in generating inequities in mortality (Mackenbach et al., 2008).

Getting quality health care can enable people with intellectual disability stay healthy and recover faster when they become sick. It is acknowledged that the single, most

important thing any person with or without intellectual disability can do to ensure they get high-quality health care is to find and use health information and take an active role in making decisions about their own health and social care (AHRQ, 2005). This provides obvious challenges for people ageing with intellectual disability and their carers. The Agency for Healthcare Research and Quality (AHRQ) recognises quality health care as:

- Doing the right thing (getting the health care services that are needed).
- At the right time (when needed).
- In the right way (using the appropriate test or procedure).
- To achieve the best possible results.

The AHRQ recognises that providing quality health care for all population groups means striking the right balance of services by:

- Avoiding underuse (for example, not screening a person for diabetes).
- Avoiding overuse (for example, performing tests that a patient doesn't need).
- Eliminating misuse (for example, providing medications that may have dangerous interactions).

The way a patient is treated as a person has for some time been seen as a cornerstone of quality and the quality of every patient's experience is at the heart of what health care is about. Lord Darzi's report, *'High Quality Care for All'*, highlighted the importance of the person's entire experience within the NHS, ensuring people are treated with compassion, dignity and respect within a clean, safe and well-managed environment (Darzi, 2008). Unfortunately there is unease about the most important characteristic of any health system - how patients are treated - not in the sense of which medical intervention is offered, but how they are cared for, how they are looked after (Goodrich and Cornwell, 2008), as too often patients feel marginalised rather than empowered and involved in their own care.

2.5.2 Experience of Quality

The experience of quality by any person ageing with intellectual disability is shaped, directly and indirectly, by organisational and human factors interacting in dynamic and complex ways at four levels as illustrated in Figure 2.8, and Table 2.8.

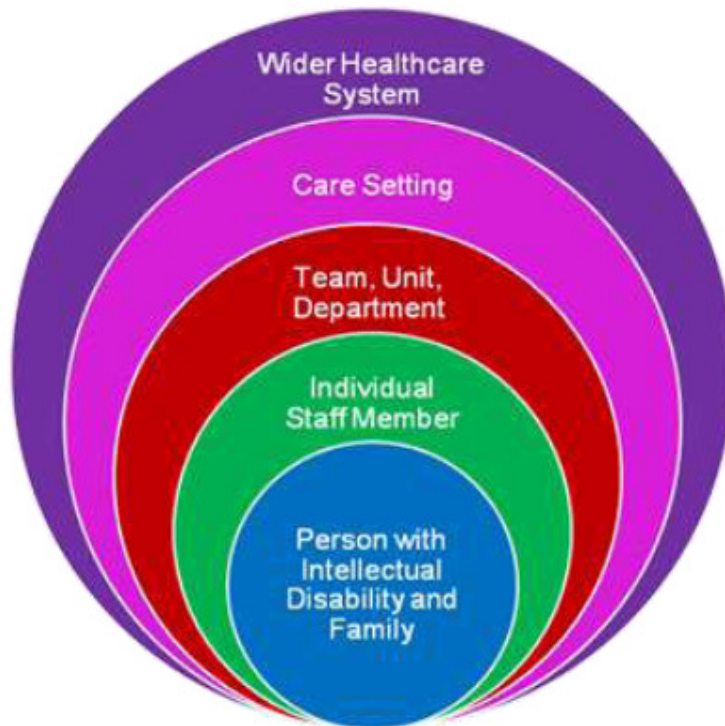


Figure 2.8 Framework for the Analysis of Factors Influencing the Person with Intellectual Disabilities Experience of Healthcare

Goodrich and Cornwell recognised that in healthcare, people with intellectual disabilities are less powerful than others (Goodrich and Cornwell, 2008) and that their experience of healthcare is shaped by many diverse factors illustrated in Figure 2.8 above and Table 2.8.

Table 2.8 Factors Shaping Person’s Experience at Individual Level

Factors Shaping the Person’s Experience at Individual Level		
Organisational Factors	Human Factors	
Staff	Staff	Person with Intellectual Disability
<ul style="list-style-type: none"> • Education, training, qualifications • Induction, preparation • Job description • Accountability • Delegated responsibilities • Permanent, temporary status • Support • Supervision, appraisal 	<ul style="list-style-type: none"> • Morale • Experience • Health status • Tiredness, stress, well- being • Professional and personal attitudes, values • Support • Spoken English 	<ul style="list-style-type: none"> • Clinical need • Mental and physical capacity • Ability to speak for self • Language use • Age • Social status • Active family or other support • Depression, anxiety, fear

2.5.3 Healthcare Quality

‘Improving the lives of people with intellectual disability by enhancing the quality of services is a concern shared by professionals, staff and carers’ (Clegg, 2008)

In a briefing paper for the NHS, Emerson and Baines identified that people with an intellectual disability tend to experience poor health outcomes compared to the general population (Emerson and Baines 2010).

Increasing demands are being placed upon the medical profession internationally for high quality services which will only be achieved through a collaborative approach that extends beyond the traditional doctor:patient boundary (Lennox and Edwards, 2001) for people ageing with intellectual disabilities and behaviour disorders. This raises the question, how are quality services to be identified?

2.5.4 Dimensions of Quality

There are many commonly used performance dimensions in different countries and by different agencies (Arah et al., 2006), identified in Box 2.7.

Dimensions of Healthcare Performance
<ul style="list-style-type: none"> • Acceptability • Accessibility • Appropriateness • Care environment and amenities • Competence or capability • Continuity • Effectiveness or improving health or clinical focus • Expenditure or cost • Efficiency • Equity • Governance • Patient-centeredness or patient focus or responsiveness • Safety • Sustainability • Timeliness

Box 2.7 Dimensions of Healthcare Performance

2.5.5 Medication Use and Quality

Medication management has emerged as the greatest problem area for social care providers, according to English CQC inspectors (CQC, 2012b). Social care services are facing increasing challenges because of the significant growth in recent years in service users presenting with multiple health problems and requiring complex drug treatment. The CQC National Pharmacy Manager Brian Brown, highlighted that in relation to ‘prn’ or ‘as required’ medications, there is often a lack of a clear plan to indicate how the decision to administer these medicines is to be made or what the desired/expected outcome should be. He said that the inspectors also found that a person may be prescribed several similar medicines and there is no clear direction to indicate how to decide which of the medicines is to be administered and in what circumstances. Problems that were highlighted in the report included the administration of medicines not being properly recorded, storage not being monitored in line with providers’ policies, a lack of staff training and inadequate information about medicines being given to staff and service users (CQC, 2012b). **[QI 1, QI 9, QI 10, QI 12]**

Medication use in residential care is one of the most complex circumstances in all medicine and may also be one of the most difficult environments in which to improve the quality of medication use (Tjia et al., 2012). The whole residential care facility can be identified as a system that creates 'a prescribing culture'. Evidence from a single site multipronged intervention has suggested that antipsychotic use might be reduced by providing combinations of resident-centred activities, prescribing guidelines and educational rounds to improve nursing home dementia care. Some studies have suggested that differences in organisational culture might explain the wide variation in the use of antipsychotics in nursing homes that were unexplained by patient case mix and organisational or market characteristics (Tjia et al., 2012). **[QI 7, QI 13, QI 19]**

A cross-sectional study of medical and pharmaceutical records in a population living in residential settings of three care providers for persons with intellectual disability in the Netherlands (n = 2373) investigated antipsychotic drug prescription practice of Dutch intellectual disability physicians. The authors concluded that there was a

'continuing lack of evidence-based psychopharmacological treatment in mental health care for persons with intellectual disabilities' (De Kuijper et al., 2010).

Difficulties presented in the care of people with intellectual disabilities with feeding, eating, drinking and swallowing difficulties is one area that is challenging to the carers/families of people ageing with intellectual disability. These difficulties can have a significant impact on the health of a person with intellectual disabilities, resulting in problems such as aspiration pneumonia and frequent upper respiratory infections, under-nutrition, difficulties taking medications and dehydration. The authors of a multi-centre observational study (Kelly et al., 2011) to describe the interventions used by nurses when administering oral medicines to patients with and without dysphagia to quantify the appropriateness of these interventions and the medicine administration error rate, concluded that the administration of medicines to patients with dysphagia is complex and potentially more error prone because of the need to match the medication's formulation to the swallowing ability of the patient. Guidelines and advice are available to guide the administration of medication to patients unable to take solid dosage forms (UKMi, 2013). Kelly and colleagues (Kelly et al., 2010) who reported a study that explored the experiences of taking medication for older people with dysphagia, concluded that all healthcare professionals involved with medicine management must ask patients if they have swallowing difficulties. In the case of

community pharmacists, this will often mean asking the carer who is collecting the prescription. The authors also noted that it would

'seem vital that doctors, pharmacists and nurses do not just consider the active ingredients of medicines, but also the formulation, and that they make patients aware that liquid alternatives do exist'.

In order for patients with intellectual disability and their carers to be effectively advised, methods of communication must be developed between members of the multi-disciplinary team and the patient/carer (Cornish, 2005). [QI 1, QI 2, QI 7, QI 12, QI 28]

2.5.6 Culture

A high quality health service can only be delivered if there is a focus on three critical dimensions of quality: clinical effectiveness, safety and patient experience. In times of economic challenge it is crucial not to change this focus. At the heart of quality healthcare is the culture of healthcare environment in which the person/patient finds themselves.

Deirdre Madden in her report *'Building a Culture of Patient Safety'*, observed that what is required is a culture where patients are put first and at the centre of their care, staff are suitably skilled and developed, behaviours are respectful, relationships are built on trust, team working is effective and active and open and effective communication is the norm (Madden, 2008), Box 2.8.

Recommendation 4.5 Madden Report
<ul style="list-style-type: none">• Healthcare organisations must ensure an environment that allows for patients and their families to raise issues at the point of care.• Communications and behaviours need to be reinforced to facilitate this and patients should be informed at first point of contact that it is the policy of the organisation that raising concerns about their care will not negatively affect their care or their experience while under care and they should be reassured as necessary throughout their treatment that this is the case.

Box 2.8 Recommendation 4.5 Madden Report

Staff issues are central to the quality of care provided to people with intellectual disability and behaviour disorders. Those providing direct care are of critical importance in the health care of people with intellectual disabilities and play a pivotal role as they are responsible for health related decisions ranging from diet and nutrition, to exercise obtained and use of medication (Lennox and Edwards, 2001). However, it is a concern that those providing direct care are at 'the bottom' of organizational hierarchies in services providing care to people with intellectual disabilities. Individual health care professionals can become socialised into

'ways of doing and behaving'

that may be at odds with their professional education and their initial reasons for becoming a doctor, nurse or therapist (Maben, 2008). This situation may have serious implications for people ageing with intellectual disability and behaviour disorders and other vulnerable population groups.

Research consistently finds that the most important indicator of the culture of an organisation is the leadership style of the most senior person in the organisation and his or her team. Patricia Noonan Walsh has noted that

'people's health in part depends on the ethical standards applied by those charged with providing healthcare' (Noonan Walsh, 2011).

Senior organisational members act as powerful role models through their behaviour for what is and what is not acceptable behaviour within the organization (Alban-Metcalf, 2008) providing care to people with intellectual disability. The Madden Report identified that

'One of the recurrent deficiencies is that of inadequate leadership by managers or clinicians, characterised by a lack of vision, an inability to develop shared or common objectives, a management style which can be weak or bullying and a reluctance to tackle known problems even in the face of extensive evidence' (Madden, 2008).

Legislation and policy can institute change but the translation involves the action of an individual. The reliance of people with intellectual disabilities upon individual carers and individual professionals makes this relationship critical to their health and well being. Residential care workers are largely invisible and hidden behind the complex layers of

disability services. The *Lessons from the Labyrinth* report explored the perceptions of Residential Care Workers about the health care of Disability Services Queensland clients with an intellectual disability whom they supported in community accommodation (Lennox and Edwards, 2001). The report highlights the importance of attitudes, skills and confidence of direct care workers, who take on the very critical role of health advocates in their efforts to obtain comprehensive health assessment for their clients.

Although healthcare professionals are committed to providing high quality care for their patients within the constraints of the environment they work in, little evidence that they engage in systematic quality improvement initiatives has been found (Wilkinson et al., 2011). Wilkinson and co-workers believe that an enhanced model of professionalism is required and one that has a number of components. This model places a stronger emphasis on accountability, recognises the benefits of creating a different dynamic between patients and professionals, and assumes a stronger sense of responsibility for how the wider health system works and for all dimensions of quality. The model promotes a constant drive to improve what clinicians do and accepts change as a virtue rather than a threat. It commits to using a range of different approaches to develop and mobilize knowledge about how to improve care and build the formal evidence base which is the basis for improvement (Wilkinson et al., 2011).

Safety and quality of patient care is dependent on teamwork, communication and a collaborative work environment (Hughes, 2008). The Joint Commission has issued a Sentinel Event Alert '*Behaviours that Undermine a Culture of Safety*' that identifies that intimidating and disruptive behaviours can foster medical errors, contribute to poor patient satisfaction and to preventable adverse outcomes, increase the cost of care, and cause qualified clinicians, administrators and managers to seek new positions in more professional environment (Joint Commission, 2008). To assure quality and to promote a culture of safety, health care organizations providing care to people with intellectual disabilities must address the problem of behaviours that threaten the performance of the health care team. Many patients and/or their carers are able to safeguard their own interests and protect themselves from neglect, harm or abuse in healthcare. However, some adults, such as those ageing with intellectual disabilities are in vulnerable situations and are less able to protect themselves or make decisions about their safety in healthcare and in particular in the medication use process.

High profile inquiries have identified recurrent themes in the failures of care:

- patients are not empowered to make choices about their care and protection,
- patient's voice is not heard,
- neglect and abuse arise in the absence of effective prevention and early warning systems,
- neglect and abuse are not always recognised by health care staff,
- lack of transparency and openness in investigation – incidents are not well managed through multi agency safeguarding adults procedures,
- safeguarding adults is seen as the responsibility of others (Social Care Policy, 2011). [QI 1, QI 2, QI 3, QI 6, QI 9]

Many interventions in relation to medication use in people with intellectual disabilities and in other population groups target the prescriber in isolation from the 'prescribing culture' (Tjia et al., 2012) in which the medication is prescribed and administered. The prescription and administration of medication is an area where people with intellectual disabilities and/or their carers experience lack of control and disempowerment. Despite participants in one study experiencing side effects to antipsychotic medications, they were accepting of these effects and the authors generated a

'model of compliance'

from the analysis of interview data (Crossley and Withers, 2009). This emphasises the need for carers involved in the administration of psychotropic medication to have up-to-date knowledge about the expected effects of each specific medication administered, as well as the possible effects, contraindications, dose parameters and potential interactions (Devine and Taggart, 2008). [QI 12, QI 15, QI 16]

2.5.7 National Patient Safety Agency Priorities

People with intellectual disabilities have more health concerns and more problems accessing health services and finding out what is wrong with their health. They are sometimes treated differently to those without an intellectual disability (DH, 1999). The NPSA undertook three separate pieces of work to understand the patient safety issues of people with intellectual disability using healthcare services which consisted of a literature review, *Speaking Up!* Workshops and staff focus groups. These confirmed that people with intellectual disabilities are more at risk of being involved in a patient

safety incident than the general population. The breadth of information received suggested that the diverse needs of people with intellectual disabilities, the range of different agencies involved in their care and the long term nature of the relationship with the NHS may make them more vulnerable (NPSA, 2004c). Using the NPSA's prioritisation framework and independent advice, the NPSA has identified priority areas for people with intellectual disabilities, Table 2.9.

Table 2.9 NPSA Priority Areas for People with Intellectual Disabilities

Priority Areas for People with Intellectual Disabilities in Healthcare	Patient Safety Issue
Inappropriate use of physical intervention (control and restraint)	People with intellectual disabilities may be receiving injuries and being harmed when physical restraint is used inappropriately.
Vulnerability of people with learning disability in general hospitals	People with intellectual disabilities may be more at risk of things going wrong than the general population, leading to varying degrees of harm being caused whilst in general hospitals.
Swallowing difficulties (dysphagia)	Swallowing difficulties are more common in people with intellectual disabilities. If not managed safely they can lead to respiratory tract infections, a leading cause of early death for people with intellectual disability.
Lack of accessible information	Harm may result if a person with an intellectual disability is unable to understand information relating to illnesses, treatment or interventions.
Illness or disease being mis- or undiagnosed	Access to treatment is often delayed because symptoms are not diagnosed early enough. This could lead to undetected serious health conditions and avoidable deaths.

2.5.8 Covert Medication

When the behaviour of people with intellectual disabilities challenges carers and services, complex and competing human rights issues may emerge (Bailey et al., 2010). One such issue is 'covert medication' which is the use of any medical treatment in disguised form (Mental Welfare Commission for Scotland, 2006). This usually involves disguising medication and administering it in food or drink and as a result the person with intellectual disability is unknowingly taking the medication. Consensus agreement has been reached that it should never be given to someone capable of deciding about medical treatment and that:

- it is generally unlawful to administer medication without consent,
- where the individual is incapable of giving consent it could still be regarded as an assault unless done properly,
- the rights of the individual need to be protected,
- those prescribing, dispensing or administering covert medication need protection (Mental Welfare Commission for Scotland, 2006). **[QI 9, QI 7, QI 12, QI 14]**

A cross-sectional survey of mainly older adults, who were inpatients at a UK tertiary referral centre, found that of the 110 patients, 34 (30.9%) were receiving medication mixed with food or drink, although for only 52.9% was the procedure documented in the patient's care plan and for 64.7% was it documented on the medication chart (Haw and Stubbs, 2010a). In their conclusions, the authors Haw and Stubbs state that before administering medication covertly it is important to discuss the matter with the multidisciplinary team and, where appropriate, with the patient's relatives. It is also important to ensure that supporting documentation has been completed in order to avoid medico-legal difficulties. **[QI 14]**

The following important treatment issue in relation to covert medication has been identified by Canadian Psychiatric Patient Advocates:

'The experience of each patient in taking a particular medication is important in deciding whether a treatment is effective and should be continued or discontinued. An individual patient receiving 'covert medication' will not be able to report on side effects that may be experienced and the prescriber and clinical team will have to rely on other

sources of information to answer questions regarding the effectiveness and potential side effects of medication administered covertly. The prescriber may need to consult with the pharmacist to determine if there are any potential interactions between foods or beverages and the proposed medication' (Psychiatric Patient Advocate Office, 2009).

Form change of medication, for example by splitting or crushing tablets or opening capsules as an alternate route to administer medications, is not without its problems and in general is carried out outside licence or 'off label'. It has been described as prudent and professionally responsible to always consult a pharmacist regarding the safety of crushing a tablet or opening a capsule to mix the medication in food or a liquid (Gill et al., 2012). **[Q1 7]**

There is little systematic research to establish how widespread the use of covert medication actually is and the practice is not well described in the psychiatric literature. Whitty and Devitt observed that fear of professional censure results in minimal discussion or recording in patients' case notes, which serves to compound the atmosphere of secrecy and suspicion (Whitty and Devitt, 2005).

A cross sectional study in Norway (Kirkevold and Engedal, 2005) where data was collected by structured interview, found that 11% of patients in regular nursing home units and 17% of patients in special care units for dementia were covertly administered drugs at least once, and in 95% the practice was routine. The results showed that patients with severe cognitive impairment, reduced function in activities of daily living or aggressive behaviour were more often subjected to covert administration and that the practice of covert drug administration was poorly documented in the patients' records. The replication of this situation could be expected in healthcare settings for people ageing with intellectual disabilities and behaviour disorders.

Staff education and training and local audit are needed to improve standards and safeguard vulnerable patients in institutions (Haw and Stubbs, 2010b). Medication administration in people ageing with intellectual disability is a complex, invasive healthcare intervention. The results of the intervention often lead to changes in the person's care and it is important for all those involved in making recommendations about medications to be fully informed about the processes that are being implemented. It is obvious that many complex ethical issues in law and medicine exist, that there are no absolutes and no one response will suit every situation (Welsh and Deahl, 2002).

2.5.9 Complex Processes

Complex interactions between biological, psychological or behavioural and social factors, together with often limited communication skills makes the process of assessment, and therefore treatment selection, particularly difficult in people with intellectual disabilities and behaviour disorders. In 2001, the Mental Health Special Interest Group of IASSID had identified implications for policy and practice in the complex area of mental health treatment in the population with intellectual disabilities (Mental Health Special Interest Group, 2001), Box 2.9. [QI 1, QI 2]

Implication for Policy and Practice: Mental Health
<ul style="list-style-type: none">• The treatment of mental ill-health and behaviour disorders must be based on a thorough assessment and formulation that may require, and often benefits from, the expertise of more than one discipline.• Treatment interventions must be based on this formulation and the effects of any intervention must be reviewed regularly to inform future intervention and management strategies.

Box 2.9 Implication for Policy and Practice: Mental Health

For people ageing with intellectual disabilities and spoken language ability, medication regimen reviews which include reporting by the patient may be possible. However for others, information from informants/carers may be crucial. In *'Mental Health and Intellectual Disabilities; Addressing the Mental Health Needs of People with Intellectual Disabilities'*, the Mental Health Special Interest Research Group of the IASSID, identifies concerns with diagnosis and formulation that guides intervention in people with intellectual disabilities and behaviour disorders, box 2.10. [QI1, QI 2, QI 3, QI 6, QI 12]

**Mental Health and Intellectual Disabilities:
Addressing the Mental Health Needs of People with Intellectual Disabilities**

- This process is often sadly lacking when the person involved has an intellectual disability, and as a consequence medication is prescribed to modify particular behaviours rather than to treat a mental disorder, such as depression or a psychotic illness.
- Anecdotal evidence suggests that psychotropic medication may be administered without consent to suppress behaviours that others do not like without any attempt to identify possible underlying causes (including mental illness), and without adequate provision for accompanying therapies or treatments.
- There is evidence that the risk of motor side effects from neuroleptic medication is greater among those with pre-existing brain abnormalities, and that such medication has an adverse effect on cognitive functioning.
- Whether, when improvements are noted, an acquired mental disorder was in fact present which responded to treatment and resulted in a reduction in the prevalence of challenging behaviour, has not been considered.

Box 2.10 Mental Health and Intellectual Disabilities: Addressing the Mental Health Needs of People with Intellectual Disabilities

2.5.10 Non Pharmacological Interventions

Emerson and colleagues designed a cross sectional study to investigate aspects of the treatment and management of challenging behaviour among five hundred adults with intellectual disabilities receiving various forms of residential supports in the UK (Emerson et al., 2000). Their findings indicate that residents with challenging behaviour are over three times more likely to receive antipsychotic medication than they are to receive behavioural support. When discussing their results the authors felt that

‘Such an inequitable pattern of provision clearly violates the principle of evidence-based practice’ (Emerson et al., 2000). [QI 5, QI 6]

A review of reports of aggressive challenging behaviour in individuals with intellectual disability indicated that greater access to effective, non-medication treatments is needed (Benson and Brooks, 2008). Cognitive behaviour therapy (CBT) is the

treatment of choice for common mental health problems and is recommended by NICE for this purpose. It is only recently that CBT has been adapted for people with intellectual disabilities and the evidence of its effectiveness in this population consists largely of case studies and case series (Willner et al., 2011). [QI 5]

Hassiotis and Hall conducted a systematic review that concluded that there was scant evidence for the efficacy of cognitive behavioural and behavioural interventions on outwardly directed aggression in children and adults with intellectual disabilities. They found a lack of methodologically sound clinical trials and noted that given the impact of such behaviours on the affected person with intellectual disability, his or her carers and on service providers, effective interventions are essential. The authors also recognized the importance of investigating the cost efficacy of treatment models against existing treatments. They recommended that randomised controlled trials of sufficient power are carried out using primary outcomes of reduction in outward directed aggression, improvement in quality of life and cost efficacy as measured by standardised scales are carried out (Hassiotis and Hall 2008).

2.5.11 Quality Indicators

Quality improvement is part of the daily routine of many healthcare professionals working with this vulnerable population such as GPs, psychiatrists, pharmacists, speech and language therapists, nurses, social care workers and others. However, professionals can only be sure to improve what they can actually measure (Darzi, 2008) and quality cannot be measured without Quality Indicators. Quality Indicators are explicitly defined and measurable items referring to the structures, processes or outcomes of care (McGlynn and Asch, 1998) that infer a judgement about the quality of care provided (Lawrence and Olesen, 1997).

Relatively few quality measures exist that specifically address disability-related issues and the body of research to inform quality metric development for persons with disabilities is limited (AHRQ, 2010d). Examples of indicators that do exist focus primarily on biomedical aspects of underlying disabling conditions rather than on functioning, wellness, quality of life and the broad range of environmental concerns. Common health conditions that can be profoundly disabling include some, such as diabetes and heart failure, that generally are widely accepted and used. Most of these Quality Indicators reflect processes of care (e.g., measurement of glycated haemoglobin (HbA1c) levels, ophthalmologic examinations, prescriptions for certain

medications). These Quality Indicators do not address considerations relating to disability (AHRQ, 2011).

The surveillance of health care quality is greatly aided by the use of relevant Quantitative Indicators (Mainz, 2003). Many people ageing with intellectual disabilities live in long term care (Kelly, 2012) and it has been noted that safety is the most neglected dimension of quality in relation to long term care in European institutional care organisations (Dandi and Casanova, 2012). However, patient safety has been identified by member countries of the Organisation for Economic Co-operation and Development (OECD) as one of the five priority areas for improving data systems (Armesto et al., 2007).

Shield et al. designed a modified Delphi survey to identify a generic set of face valid Quality Indicators for primary care mental health services which reflected a multi-stakeholder perspective and could be used for facilitating quality improvement. The background information they provided included an acknowledgement that there are few indicators available for quality assessment of primary mental health care, and few that can be applied at the system level - for example, practice or primary care organisation - rather than at the level of the diagnostic group (such as depression or anxiety) or that reflect the views of key stakeholders in the primary mental health setting, particularly patients and carers (Shield et al., 2003).

2.5.11.1 Assessing Care of Vulnerable Elders Quality Indicators

The quality of care of vulnerable elders in the general population in the USA has been assessed by using processes rather than outcomes in *the Assessing Care of Vulnerable Elders (ACOVE) Project* (Shekelle et al., 2001a). In all, 236 Quality Indicators covering four domains of health care:

- Prevention,
- Diagnosis,
- Treatment,
- Follow up.

were developed in the ACOVE Project.

An observational study, in which the authors applied the ACOVE Quality Indicators to a sample of vulnerable older patients in two large managed care organizations in the USA, concluded that better performance on process quality measures is strongly associated with better survival among community-dwelling vulnerable older adults (Higashi et al., 2005). Overall, the 372 participants in the observational study had a mean quality score of 53%, SD 11% (range 22% to 88%), indicating that they received on average, 53% of the care recommended in the ACOVE Quality Indicators. The receipt of better quality care was causally linked with improvement in 3-year mortality in the sample of community dwelling vulnerable older adults. This study was described by the authors as the first to show predictive validity of a broad-based, process-of-care quality measurement system using patient survival among community dwelling older persons.

ACOVE determined that twenty two conditions accounted for the majority of health care received by older adults in the general population (Higashi et al., 2005). A Quality of Care Indicator for each topic was developed, that is the minimum standard of acceptable care. ACOVE 3 later revised and expanded Quality Indicators to update and increase the comprehensiveness of the ACOVE Quality Indicators for the medical care provided to vulnerable elders in the general population. ACOVE 3 expanded the conditions to twenty six and contains three hundred and ninety two Quality Indicators covering fourteen different types of care processes. ACOVE 3 indicators will be used to guide the design of future interventions aimed at improving the quality of care that vulnerable elders receive (RAND, 2008), an example is seen in Box 2.11.

Example of a RAND Quality Indicator for Assessing the Reasons for Falling
<p>If a patient reports two or more falls in the past year, or one fall with injury requiring medical care;</p> <p>Then a “falls evaluation” should be performed, including history and physical exam;</p> <p>Because some reasons for falling can be treated, which can reduce the risk for future falls.</p>

Box 2.11 Example of a RAND Quality Indicator for Assessing the Reasons for Falling

2.5.11.2 Quality Indicator Structure in Use

The Quality Indicators in the ACOVE Project were structured with an

IF – THEN – BECAUSE

format, as seen in Figure 2.9.

The **IF** clause indicating eligibility of the patient for consideration of the Quality Indicator,

the **THEN** clause representing the required intervention and,

the **BECAUSE** clause referring to the expected health impact if the indicator is performed.

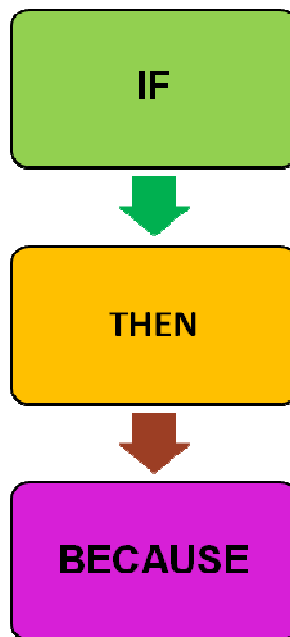


Figure 2.9 Quality Indicator Structure

When the ACOVE researchers applied the indicators to assess the quality of care received by vulnerable elderly who were living on their own and, not in nursing facilities, they found that, on average, this group receives about half of the care that is recommended for their conditions. For conditions that affect primarily the elderly, such as impaired mobility (difficulty getting around, which can lead to falls), urinary incontinence, and impaired cognitive function, elders received less than one-third of recommended care (RAND, 2008).

The authors of a systematic review that was designed to identify and uniformly describe studies employing the ACOVE Quality Indicators within a comprehensive thematic model that reflects how the indicators were used, observed that the ACOVE framework has mainly been used to assess care rather than to achieve the ultimate goal of the Quality Indicators, that of improving the quality of care (Askari et al., 2012).

2.5.11.3 Quality Indicators and Medication Use

One in four ACOVE indicators in the USA related to medication management – the prescription of drugs – for the various ACOVE conditions (RAND, 2004b). The Quality Indicators for medication management were divided into four categories of medication management behaviour:

- 1) Prescribing medication recommended for the condition,
- 2) Avoiding inappropriate medications,
- 3) Educating patient, documenting prescription and any adverse drug reactions,
- 4) Adequate monitoring – laboratory tests.

Nineteen Quality Indicators for medication use in vulnerable elders have been judged to be valid for use in a community dwelling elderly general population (Castelino et al., 2009). It is of note, with reference to this project, that no pharmacist participated in the expert panel that established this set of Quality Indicators of pharmacological care in the USA. The authors state that

'future iterations should include this discipline' (i.e. pharmacists).

2.5.12 Vulnerable Groups

Measurement strategies and methods are particularly challenging for vulnerable populations because:

- numbers of subgroup members in any single data set may be too small for significant differences to be detected,
- identifying the groups through existing data systems may be difficult,
- qualitative information may be lacking about quality problems these groups face (Agency for Health Care Policy and Research, 1998).

Effective health care provision is dependent on good communication between all stakeholders and leads to an inclusive and dignified experience. Many people with intellectual disabilities will have significant communication needs and it is essential that clinicians adapt their service delivery to accommodate this. This includes implementing larger organisational changes, such as providing a range of accessible information, to preparing appropriately for one-on-one interactions (RCN, 2013a). Some positive and not so positive experiences of people with intellectual disability relating to medication use are illustrated in Box 2.12 below. [QI 2]

Experiences of People with Intellectual Disabilities of the Medication Use Process	
Positive Experiences	Areas for Improvement in Relation to Dignity
<ul style="list-style-type: none"> • My nurse gave me a leaflet about the medication. • The leaflet was easy to read. It used words that I knew. • It also had pictures that helped. • We read through it together and she answered my questions. • I told the doctor that I would take the medication. 	<ul style="list-style-type: none"> • I was at the doctors and he started to write a prescription. • He hadn't told me what the prescription was for. • He didn't ask if I wanted the tablets.

Box 2.12 Experiences of People with Intellectual Disabilities of the Medication Use Process

Paton and colleagues audited prescribing practice for antipsychotics against recognised standards (Paton et al., 2011) using data collected from the clinical records of individuals with intellectual disability who were under the care of mental health services in the UK and prescribed an antipsychotic drug. The study sample comprised two thousand three hundred and nineteen patients from thirty-nine clinical services. The three standards used in the study were:

- The indication for treatment with antipsychotic medication should be documented in the clinical records,
- The continuing need for antipsychotic medication should be reviewed at least once a year,

- Side effects of antipsychotic medication should be reviewed at least once a year and this review should include assessment for the presence of extra-pyramidal side effects (EPS), and screening for the four aspects of the metabolic syndrome: blood pressure, obesity, glycaemic control and plasma lipid profile.

In the discussion of their results the authors state that ‘with respect to efficacy, the effects of treatment were closely and actively monitored’. They noted also that

‘side effects had been reviewed over the previous year in 7 out of every 10 patients, in 6 out of every 10 patients there was no documented evidence that EPS had been assessed’.

With regard to metabolic side effects they found that

‘blood pressure had not been measured in 6 out of 10 individuals, and for 4 out of every 10 there was no evidence that they had been weighed, or that blood glucose or lipids had been checked’.

The data collected during the Paton study did not suggest that patients with more severe intellectual disability were more likely to be targeted for side effect review and this is a cause for concern. [QI 7, QI 15, QI 16]

2.5.12.1 Quality Indicators NHS

In the report *High Quality Care for All*, Lord Darzi set out commitments for making quality the organising principle of the NHS (Darzi, 2008). His vision is that all NHS staff will measure what they do as a basis for improving quality. Quality Indicators primarily intended for use by staff to inform quality improvement activities, supported by appropriate statistical techniques to analyse and interpret the data, have been identified by the Information Centre for Health and Social Care and the Department of Health (HSCIC, 2009) in England. The list is evolving and has one indicator that relates specifically to intellectual disability (learning disabilities), seen in Box 2.13 and some others that would also apply to this population group are available in Box 2.14.

NHS Quality Indicator Relating to Effectiveness of Care for Those with Intellectual Disability
<p>Quality Outcomes Framework (QOF)* Learning Disabilities</p> <p style="text-align: center;"><i>'The practice can produce a register of patients with learning disabilities'.</i></p> <p>The rationale for this indicator is <i>'The idea of a learning disability register for adults in primary care has been widely recommended by professionals and charities alike'</i> (Mencap, 2004).</p> <p>*The QOF rewards general practices for how well they care for patients.</p>

Box 2.13 NHS Quality Indicator Relating to Effectiveness of Care for Those with Intellectual Disability

Examples of NHS Quality Indicators that Appear Relevant to Population with Intellectual Disabilities and Behaviour Disorders
<ul style="list-style-type: none"> • The percentage of patients diagnosed with dementia whose care has been reviewed in the previous 15 months [QOF Dementia]. • The percentage of patients on lithium therapy with a record of lithium levels in the therapeutic range within the previous 6 months [QOF Mental Health]. • The percentage of patients on the register who have a comprehensive care plan documented in the records agreed between individuals, their family and/or carers as appropriate [QOF Mental Health]. • The percentage of patients age 18 and over on drug treatment for epilepsy who have a record of seizure frequency in the previous 15 months. [QOF Epilepsy].

Box 2.14 Examples of NHS Quality Indicators that Appear Relevant to the Population with Intellectual Disabilities and Behaviour Disorders

2.6 Discussion

Quality improvement is a multidisciplinary, systems-focused, data-driven method of understanding and improving the efficiency, effectiveness and reliability of health processes and outcomes of care (McPheeters et al., 2012). Valid health information is essential for improving health care processes and the health of people ageing with intellectual disabilities. People with intellectual disabilities and behaviour disorders are some of the most vulnerable people in society.

Medication use is one of the main therapeutic interventions in the population ageing with intellectual disabilities and behaviour disorders. Both psychotropic medication use and 'challenging behaviour' are identified determinants of health in this population group (Van Schrojenstein Lantman-de Valk et al., 2007). Many individuals with behaviour disorders are prescribed multiple, long-term medications and 'as required' medications and it is challenging to ensure these people ageing with intellectual disabilities get the maximum benefit with minimal harm from their medication regimen. Principles for medication review (Family Practitioner Unit, 2003) in this population group should include:

- all patients with intellectual disabilities and/or their health facilitator/carer should have a chance to raise concerns and highlight any difficulties with their medicines,
- the medication review endeavours to improve or optimise the impact of treatment with medication for the individual patient with intellectual disabilities and behaviour disorders,
- the medication review must be systematic and undertaken by a person with competence in providing healthcare to people with intellectual disabilities and who is aware of the many ethical, legal and professional issues involving medication use in this vulnerable population group,
- any changes made following the medication review must be communicated to and agreed with the patient with intellectual disabilities and/or their family/carer,
- documentation of the review should be evident in the patient notes and should be documented legibly in any health communication passport and communicated clearly and legibly to other professionals for example pharmacists,

- the effect of any change in medication and/or behaviour should be monitored by the patient/family/carer and the prescriber, and ideally the pharmacist.

An individualised and flexible approach which can provide for and targets the person with intellectual disabilities' specific needs and the circumstances of the current situation is a vital element in a quality medication use process of care and support for any person with intellectual disability and behaviour disorders and their carer. Suitably educated, experienced and skilled professionals, including pharmacists with developed expertise, should be available to efficiently respond 'with or without' medication use as appropriate, to the individual needs of the person with intellectual disability and behaviour disorders. The use of medication as a 'restrictive practice' should only be supported when the medication use is part of a specific individualised behaviour and support plan which will be of benefit to the person with intellectual disability and behaviour disorders and which will assist in the achievement of the aims of the support plan. Professionals including pharmacists involved in the medication use process for people ageing with intellectual disabilities must 'move to a world in which people are

"worked with, rather than worked on" (Cribb, 2011).

Many professional organizations support the limited or rare use of restraint if it is in the best interests of the person with intellectual disability and behaviour disorders (Williams, 2010b). These organizations expect that all staff supporting the person will be properly trained and supervised to ensure that the potential for injuries and abuse during the use of a medication as a 'restrictive practice' are limited.

2.7 Conclusion

This narrative literature review supports the need for Quality Indicators for medication use in people ageing with intellectual disabilities and behaviour disorders.

Quality Indicators developed in the project should have a potential impact on health, they should be meaningful and susceptible to being influenced by the health system and or a health professional. The medication use process is influenced by prescribers, pharmacists, nurses, support staff and others. The implicit notion in selecting a Quality Indicator in this project should be that there is a significant quality gap in the medication use process in this vulnerable population group that needs to be addressed.

CHAPTER 3

MODIFIED DELPHI TECHNIQUE

*'Common surveys try to identify "what is",
whereas the Delphi Technique attempts to
address "what could/should be"' (Miller, 2006).*

3.1 Introduction

The modified Delphi Technique described in this chapter has been published in the International Journal of Developmental Disabilities (Flood and Henman, 2015c).

The process of Building Quality Indicators for Medication Use in People Ageing with Intellectual Disabilities and Behaviour Disorders undertaken in this project is illustrated below in Figure 3.1 and in Table 3.1.

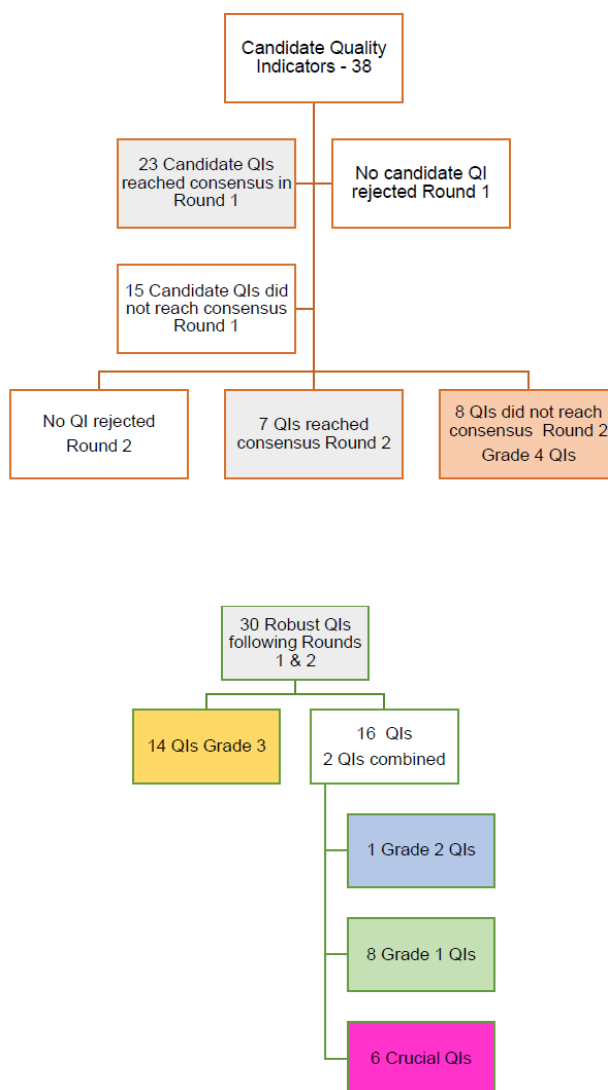


Figure 3.1 Process of Building Quality Indicators for Medication Use in People Ageing with Intellectual Disabilities and Behaviour Disorders

Table 3.1 Modified Delphi Process for Developing Quality Indicators for Medication Use in People Ageing with Intellectual Disabilities and Behaviour Disorders.

CRITERIA		ROUND 1	ROUND 2
Panel Composition	Panel Size	49 invited 35 accepted 32 consented 28 commenced 25 completed in full	28 invited 24 completed in full
	Geographic Representation	Republic of Ireland and UK	Republic of Ireland and UK
	Expertise/ Heterogeneity	Pharmacists, Psychiatrists, Psychologists Nursing, Speech and Language, Academia, Regulation, Other	Pharmacists, Psychiatrists, Psychologists, Nursing, Speech and Language, Academia, Regulation, Other
Panel Member Motivation	Written Consent	Before Round 1	
	Deadline	Yes	Yes
	Reminders	Yes	Yes
	Comments	132 comments	38 comments
	Response Rate	25 of 32 completed full survey	24 of 28 completed full survey
	Demographic Information	25 supplied	
Issue Exploration	QIs based on existing literature and guidelines, expert opinion, discussion. 9 point Likert scale		
	38 candidate QIs		15 candidate QIs
	No candidate QIs rejected		
Consensus – Robust QIs	Importance and Scientific Soundness 75%. Feasibility 50%		Importance and Scientific Soundness 75%. Feasibility 50%
	Consensus for 23 candidate QIs		Consensus for 7 candidate QIs
Anonymity	Yes		Yes
Feedback	List of 30 Final QIs sent to 28 Round 2 panel members		
	Comments received from 7 Round 2 panel members		
Resources	Time	Each round took approximately 3 months to complete. Researcher's time in literature review/controlling Delphi. Panel members' time. Supervisor's time.	
	Financial	Survey Monkey. SPSS. Researchers and supervisor's time - no charge. Panel members' time - no charge	
	Human	Researcher. Supervision.	
	Chanel	Email	Email
Permission to Publish Panel Identity	24 panel members gave permission when process complete		

3.1.1 Background

Formal consensus development methods such as the Delphi process are ways of obtaining and combining views of experts, opinion leaders and other stakeholders. They use a wider range of information than is common in statistical methods. Where published information is inadequate or non-existent, these methods provide a means of using the insights of appropriate experts to enable judgements to be made. They allow a greater role for the qualitative assessment of evidence as they are mainly concerned with producing quantitative estimates through qualitative approaches (Jones and Hunter, 1995a).

The Delphi process has been used widely in business, industry and health care research with a variety of methodological interpretations and 'modifications'. It is a flexible and adaptable tool that was developed by Dalkey and colleagues at the RAND Corporation in the 1950's. The technique is designed as a group communication process which aims to achieve a convergence of opinion on a specific real-world issue. In the structured process, experts are required to respond to non-leading, unambiguous statements with the aim of achieving convergence. There are numerous variations of formats of the Delphi Technique and it has been described as an ever adapting process (Keeney et al., 2001).

Little guidance is available to researchers who wish to use the Delphi Technique, even though aspects of its methodology can be interpreted in a variety of ways (Sinha et al., 2011). Delphi comes in different guises and it is considered acceptable to use *modifications* of the Delphi Technique to fit various research scenarios, but it is advised that care must be taken to avoid risks which would undermine the effectiveness of the technique and usefulness of results. Strategies to mitigate the risks are detailed in Box 3.1 (Snyder-Halperm et al., 2000).

Strategies for Mitigating Risks Associated with a Modified Delphi Study

1. Recruit a representative panel of experts.
2. Obtain agreement to serve on the panel.
3. Explain the Delphi procedure completely.
4. Make questionnaires easy.
5. Avoid over structuring or under structuring questionnaires.
6. Be reasonable with the number of questions.
7. Explore areas of disagreement.
8. Avoid inserting moderator opinions into collection process used.
9. Avoid underestimating panel response burden and fatigue factors.
10. Plan enough turnaround time between rounds.
11. Avoid over generalization of results.

Box 3.1 Strategies for Mitigating Risks Associated with a Modified Delphi Study

A Modified Delphi Technique (MDT) as described in this Chapter, may be used to determine the extent of agreement on an issue. A panel of experts are invited to take part in a series of rounds to identify, clarify and finally gain consensus on the particular issue. The MDT is similar to the full Delphi in terms of procedure (i.e., a series of rounds with selected experts) and intent (i.e., to arrive at consensus). The major modification consists of beginning the process with a set of carefully selected items which may be drawn from various sources including reviews of the literature, guidelines and expert opinion. The primary advantages of this modification to the Delphi is that it (a) typically improves the initial round response rate, and (b) provides a solid grounding in previously developed work (Custer et al., 1999). Other advantages relating to the use of a MDT include reducing the effects of bias due to group interaction, assuring anonymity, reducing the effect of noise where communication which occurs in a group process can both distort the data and deal with group/individual interests rather than focusing on problem solving and providing controlled feedback to participants (Hsu and Sandford, 2007).

3.1.1.1 Healthcare Quality Indicators

The OECD Health Care Quality Indicators (HCQI) Project, initiated in 2002, aims to measure and compare the quality of health service provision in the different countries. The HCQI Project has revealed substantial interest in information on the quality of care that can be used to compare the performance of different health systems. The experience of the expert panels of the HCQI Project demonstrates that consensus can be achieved internationally in how to measure the quality of care in various priority areas (Mattke et al., 2006).

The HCQI Project has identified mental health care as a priority area for further quality of care indicator development, to build on the existing indicators relating to health workforce (e.g. psychiatrists) and health status (e.g. suicide) (OECD).

No studies are reported in the literature on the use of the Delphi Technique in developing Quality Indicators for use in the population ageing with intellectual disability and behaviour disorders. This project is a first attempt to do so. However, a study published in 2011 described the use of a MDT in the identification of ambulatory care sensitive conditions that are applicable to people with an intellectual disability (Balogh et al., 2011) and a previous MDT (Caplin et al., 2006) identified 30 potential indicators for evaluating the care provided to paediatric patients with epilepsy.

3.1.2 Definition

The definition of the Delphi Technique presented by Linstone and Turoff (1975) is adopted in this study. The Delphi Technique is defined as –

a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem.

The flexibility of the Delphi approach presents a considerable challenge but this has not prevented researchers from using it (Hasson and Keeney, 2011). Key features of the design, administration and analysis of data in this and other MDTs are detailed in Box 3.2.

The Delphi Technique	
Key Features of Design, Administration and Analysis of the Data	
<p><u>Group Composition</u></p> <p>Expertise Heterogeneity Representation of geographic regions, disciplines and stakeholders Panel size</p> <p><u>Participant Motivation</u></p> <p>Written consent Reminders Clarity of the questions Response rate</p> <p><u>Problem Exploration</u></p> <p>Problem exploration/questionnaire development Scale</p> <p><u>Consensus</u></p> <p>Consensus definition</p>	<p><u>Feedback</u></p> <p>Method of feedback Individual verses group feedback Interpretation of the questions Comments allowed</p> <p><u>Number of Rounds</u></p> <p>Optimal number of rounds To reach consensus To retain the participants</p> <p><u>Anonymity</u></p> <p>Anonymity</p> <p><u>Resources</u></p> <p>Time Financial resources Chanel</p>

Box 3.2 The Delphi Technique: Key Features of Design, Administration and Analysis of the Data

3.1.3 Objectives

The objectives of this MDT are as follows:

- to gain consensus concerning indicators of quality that take account of key aspects of the medication use process for people ageing with intellectual disabilities and behaviour disorders,
- to gain consensus about QIs that will facilitate comparisons between the medication use process for people ageing with intellectual disabilities and behaviour disorders in different settings and healthcare environments,
- to gain consensus about QIs for medication use in people ageing with intellectual disabilities and behaviour disorders that meet key quality criteria.

The terms consensus and agreement are essentially two different ideologies (Keeney et al., 2011) and consensus is what is under discussion in this project. It is important to note that the extent to which participants agree with each other does not mean that consensus exists nor does it mean that the 'correct' answer has been found.

The efficient structuring of a group communication process is considered the primary aim of this MDT.

3.1.4 Appropriateness of MDT

Sometimes reliance on intuitive judgment is not just a temporary expedient but in fact a mandatory requirement (Kroger et al., 2007).

Delphi has been described as a method of last resort in dealing with extremely complex problems for which there are no adequate templates. An overriding factor in the selection of the Delphi Technique in this project was the appropriateness of the technique for the particular study. Two circumstances where Delphi Techniques are most appropriate have been identified (Linstone, 1978):

- the problem does not lend itself to precise analytical techniques but can benefit from subjective judgments on a collective basis;

and

- individuals who need to interact cannot be brought together in a face-to-face exchange because of time or cost.

3.1.5 Ethical Considerations

This project received approval from Faculty of Health Sciences Health Sciences Ethics Committee, Trinity College, May 17th 2010, Appendix 2.

The adoption of a Delphi Technique to identify a set of Quality Indicators for medication use in people ageing with intellectual disability and behaviour disorders was considered ethical by the researcher. A MDT would facilitate the engagement of more expertise than any other group method with the resources available. This MDT facilitated 'fair' representation of the views of each participant on the panel because each panel member had an equal opportunity to have their views taken into account.

The potential for harm in this study was relatively low, because panel members were mature professional adults and as each were chosen on the basis of their expertise, they were not considered vulnerable.

Other ethical issues revolving around consent, privacy and confidentiality of data were also considered during the design stage of this study. The Participant Information Leaflets informed the panel members about the purpose of the study, the procedures to be followed and contact details for the Principal Investigator if they wished to ask any questions about the study. Further information was provided by email. Participants were free to withdraw from the study at any time, Appendix 3.

In the research context, every effort was and will be made to protect the privacy of the participants. Two recognised ways of protecting privacy are through confidentiality and anonymity.

Participants in almost all studies expect that confidentiality will be protected. Assurances of confidentiality were provided to all participants in this study. At the outset of the MDT, a code number was allocated to each participant. Completed questionnaires were identifiable by code number and the key for the code is held in a locked filing cabinet by the researcher. The codes are accessible only to the researcher and the project supervisor. Questionnaires and other data collected will be held in a secure location after the study but will then be destroyed. Requirements under data protection legislation will be complied with.

The essence of anonymity is that information provided by participants should in no way reveal their identity and such anonymity is a central feature of this MDT. All interactions with each panel member in this study are anonymous to the rest of the panel. This is important as those participating were not making a public statement about their position on any issue. They were therefore freer to propose a position that could later turn out to be naïve or otherwise embarrass the author (de Meryick, 2003). They were also able to further change their position as they did not have to defend their initial comments.

This MDT endorsed the principles of mutual respect, non-coercion and non-manipulation, the support of democratic values, and the belief that every research act implies moral and ethical decisions. These principles were used to guide each part of this study and at all stages, issues relating to consent, privacy and confidentiality were key features considered by the researcher.

It is noted in this MDT that the researcher cannot be certain that the nominated individual is the person who completed the questionnaire or whether it has been the focus of discussion with other individuals. It is also impossible to know whether panel members responded with honesty or responded according to what they thought was expected.

3.1.6 Validity of the process

Validity of the MDT process depends on the careful and systematic application of procedures for initial competency selection (Custer et al., 1999) (for example, reviewing the literature, conducting a pilot test, etc.). This careful selection process is necessary in order to (a) avoid biasing panellists by including inappropriate or unnecessary items, and (b) increase the probability that consensus can be achieved in an efficient and timely manner.

The extent to which the Delphi process is capable of achieving consensus is a function, not only of the quality of the initial competency selection process, but also of the degree of controversy or clarity that exists in a given subject area or professional group. Factors that can threaten the validity of any Delphi are:

- a) a lack of expertise on the panel,
- b) lack of clear content definition, and
- c) a poorly developed initial data set at the start of a Modified Delphi.

3.1.7 Pilot

Delphi researchers rarely report undertaking pilot tests before implementation. This may be because the situation around pilot testing prior to the main study is unclear and it is also unclear how many pilot tests should be undertaken. Powell, argues that 'pilot testing is optional although it may be useful to identify ambiguities and improve the feasibility of administration' (Powell, 2003).

In this project the initial survey was produced in Microsoft Word document format for sending via email. Piloting the proposed email survey was undertaken to provide an opportunity for discovery of possible technical problems in managing the volumes of data being returned and to improve wording on the questionnaire if necessary.

In view of the possible importance of this study to future policy-making and developments around medication use in the vulnerable population ageing with intellectual disability, substantial pilot testing of the first round questionnaire was undertaken with two participants who were not to be involved in the final study. An email based pilot questionnaire was trialled with these two volunteers – one an academic pharmacist/university lecturer and the other a practising mental health pharmacist. The two people in the pilot group used a version of the questionnaire that proved to be very cumbersome and complicated. One difficulty identified during the pilot was that the normal Likert scale, when presented horizontally across the screen, could not be guaranteed to appear appropriately when received by a variety of email systems. An example of a horizontal 7 Point Likert scale is given below in Figure 3.2.

<i>Strongly Disagree</i>	<i>Disagree</i>	<i>Slightly Disagree</i>	<i>Neither Disagree nor Agree</i>	<i>Slightly Agree</i>	<i>Agree</i>	<i>Strongly Agree</i>
1	2	3	4	5	6	7

Figure 3.2 Example of Pilot Likert Scale

Also because of the length of the survey in this project it may have been necessary to subdivide the questionnaire into sections and to use separate emails because of size limitations in many email systems. The results of the pilot highlighted a number of issues of importance and these were addressed in the final design of the first round questionnaire for the main study which was eventually distributed using Survey Monkey via email.

Using technology such as the internet and email can makes the MDT process inexpensive and allows for the involvement of panel members who are geographically dispersed. The advantages of technology in this MDT were:

- 1) storage, processing and speed of transmission capabilities of computers were exploited,
- 2) respondents remained anonymous from each other,
- 3) potential for rapid feedback,
- 4) email technology enabled the message to follow the recipient and to wait for a convenient time for them to act on it.

It has been found that questionnaires that ask for evaluations of health care in terms of *satisfaction* or *dissatisfaction* show less discrimination than questionnaires that use terms such as *good* and *bad* or *agree* and *disagree* with concrete aspects of care (Wensing et al., 1994). *Agree* and *disagree* were used in the pilot for this study and appeared to show discrimination and so were used in the final questionnaire.

3.1.8 Appearance of Survey

The appearance of email surveys can have a large impact on the percentage of responses received. The researcher in this project was asking the panel members to volunteer their time to fill out the electronic questionnaire for which they would receive no instant response, benefit or gratification. If the survey design makes the task difficult by providing an unattractive design or form with poor directions or including confusing questions, the panel member would be more likely to choose not to donate their time “to the cause” (Schreuren, 2004).

Due care was therefore taken with the survey design to ensure a design that would indicate professionalism, quality and attractiveness. The use of a web-based survey platform, with structure and questionnaires designed with Survey Monkey, has been found to simplify the MDT and has allowed ready tracking and analysis (Thomson et al., 2009), Box 3.3. The final questionnaire for this project was developed and designed using Survey Monkey (www.surveymonkey.com) as the platform. Survey Monkey is an online tool that enables users to create professional online surveys quickly and easily.

Survey Monkey Questionnaires
Design questionnaires using a dozen types of questions
Control mandatory responses
Customise look and feel
Skip logic is enabled
Collect responses via Web or email
Browse, search, filter and download results reports
(www.surveymonkey.com)

Box 3.3 Survey Monkey Questionnaires

The final version of the Round 1 survey was distributed in a ‘sea green’ colour which it was hoped would be ‘easy on the eye’ and relaxing to undertake.

3.2 Modified Delphi Technique

3.2.1 Introduction

The key to a successful Delphi study lies in the selection of participants (Gordon, 2009) as the MDT is only as good as the panel members it includes. There is no strong evidence supporting particular size, composition or selection of participants (Keeney et al., 2011). The term 'expert' itself can be challenged and it has been suggested that this title is misleading (Hanafin and Brooks, 2005). In this MDT, the terms 'panel of expertise' and 'participants' are used rather than 'experts'.

Most studies use panels of 15 to 35 people and it has been advised that the length of the invitation list should anticipate an acceptance rate of between 35 and 75 percent (Gordon, 2009). The specific interest participants have in the topic determines the success of the recruitment process (Balogh et al., 2011). Delphi Techniques have been undertaken with many panel sizes, with the sample size in Delphi studies being both researcher and situation specific (Akins et al., 2005). Convenience samples have been chosen regularly that depended on availability of participants and resources.

It is recognized that the panel in this survey were just a fraction of the population being studied who had an interest or role in the medication use process for people ageing with intellectual disability and behaviour disorders.

3.2.2 Background

The purposeful selection of the 'panel of expertise' is the most important step in the entire Delphi process as it directly relates to the quality of the results generated (Millar, 2001). There is, however, no criterion listed in the literature concerning the selection of Delphi panel participants but panel members must be proficient in their field in order to yield more accurate results and must also be capable of contributing helpful inputs.

Ideally Delphi study panel members should be highly trained and competent within the specialised area of knowledge related to the target issue (Hsu and Sandford, 2007). The varying levels of knowledge and varying expertise that participants in this study have about the use of medication in people with intellectual disability with behaviour disorders requires collection of data indicating the panel members' frame of reference.

Multi-specialty groups have the potential to take into account a wider range of opinions (Hutchings and Raine, 2006). To account for the interdisciplinary approach that is commonly used in the clinical care of people ageing with intellectual disability, members of the respondent group in this Delphi Technique study were selected from the following disciplines - psychiatry, psychology, behaviour support, nursing, pharmacy, speech and language therapy and also administration in the HSE, HIQA, residential care administration and academia.

During the identification of a target panel, consideration was given by the researcher and the project supervisor to relevant publications in the literature, the identification of positional leaders and/or identifying individuals who have first hand relationships with the target issue, in this instance medication use in people ageing with intellectual disability and behaviour disorders. Some knowledgeable persons were identified through literature searches and some were recommended by institutions such as the HSE and HIQA. Some identified panel members were those who may have had something to contribute from their experience but have not published.

Due to constraints on time and resources, the panel of expertise in this study was charged with reviewing and evaluating Quality Indicators as identified in the literature review and guidelines review described in Chapter 2, rather than undertaking development of indicators *de novo*. The advantages of using a pre-established set of statements in the first round are as follows:

- 1) It saves time that would otherwise be needed to collate and edit the usual first round responses and prepare the output that becomes the second round questionnaire,
- 2) It cuts down on the dropout rate of panellists completing the open-ended, needs-assessment type survey and not participating in the rest of the study,
- 3) It assures that important statements were included by the researcher that otherwise might have been omitted,
- 4) Panel members genuinely appreciate a completed instrument on which to respond.

3.2.3 Panel Composition

The intent of this Delphi survey was to develop Quality Indicators for medication use in people ageing with intellectual disability and behaviour disorders. Ten broad groups

(categories) who hold expertise/interest in the area of medication use in people ageing with intellectual disability and behaviour disorders were identified at the start of this project and these are:

- People ageing with intellectual disability and behaviour disorders and their carers*,
- Medical personnel prescribing medication for people ageing with intellectual disability and behaviour disorders,
- Pharmacists dispensing medication for people ageing with intellectual disability and behaviour disorders,
- Nurses administering/prescribing medication for people ageing with intellectual disability and behaviour disorders,
- Psychologists and behaviour support therapists,
- Speech and language therapists advising on feeding, eating, drinking and swallowing issues for people ageing with intellectual disability and behaviour disorders,
- Statutory policy-makers and service providers,
- The Health Information & Quality Authority – HIQA,
- The Health Service Executive – HSE,
- Researchers, academics and others with experience in specific areas not covered above.

[* The views of people with intellectual disability, who are the real 'experts' with respect to medication use in their population group will be explored in Chapter 4 of this thesis.

It has been identified that clinical services and programs are often evaluated only on the basis of what matters most to physicians (symptom reduction) or payers (costs) rather than what matters most to patients and families (functioning and quality of life) (Burnam, 2005).]

The recommended size of the Delphi panel is variable with very little actual empirical evidence on the effect of the number of participants on the reliability or validity of consensus processes. Ten to fifteen panellists have been suggested if the background

of the panellists is homogeneous. If various reference groups are to be involved, as in this Delphi study, then it is expected that more panellists are needed. Approximate sizes of panels is generally less than fifty, with the majority of Delphi studies using between fifteen and twenty panellists (Hsu and Sandford, 2007). The Delphi does not call for panels of expertise to be representative samples for statistical purposes as representativeness is assessed on the qualities of the expert panel rather than its numbers (Powell, 2003).

Purposive sampling in which participants are deliberately selected to capture a range of specified group characteristics was used at the start of this MDT. This form of sampling is based on the premise that the researcher's knowledge of the population can be used to carefully select participants to be included in the sample (Polit and Hungler, 1997). Due to many complexities in identifying and contacting different panel participants a snowball sampling approach was adopted. An information letter was sent via email to 42 potential panel members soliciting their interest in study participation. Seven of the original 42 were unable to participate themselves and nominated other possible participants. These seven were therefore substituted. In total 49 individuals, including substitutions, were invited to participate. Some individuals were unable to participate/felt they did not have the required expertise/did not reply. Agreement was received from thirty two individuals who formally consented to become panel members by signing consent forms for participation in this project prior to the commencement of the study. The advantages of this type of recruitment process were:

- commitment was gained from eligible individuals to be panel members,
- written agreement to participate in the study was obtained,
- data collection time and costs associated with sending random mailings to individuals who were not interested in participating in this study were minimised.

Following countersigning, a paper copy of the consent forms was returned to each individual participant before the survey was distributed.

Some Delphi studies use more than one panel. This project used a single panel of expertise which was derived by a two stage process. Firstly, eligible participants for inclusion in the study were identified and then those within the eligible group who were willing to take part were identified. A single panel of expertise was used as this

approach protected against fragmentation and lack of coherence within the indicator set (Hanafin, 2004) .

The initial questionnaire was divided into two parts. Part 1 was concerned with the quality indicator development and Part 2 asked respondents to provide their demographic and 'expertise' characteristics. All panel participants remained anonymous to each other during the rating process. No incentives were provided to potential participants at the invitation stage or during this study.

Gordon and his fellow authors in a report for the Millennium Project indicated that in their experience a response rate from 40 to 75 percent of the participants can be anticipated (Gordon, 2009) in a Delphi study.

3.2.4 Candidate Quality Indicators

Following the literature and guidelines review described in Chapter 2, and expert discussion between the researcher, a pharmacist working full time with people ageing with intellectual disabilities and the supervisor of this project, an international expert in the area of pharmacy practice, thirty eight candidate QIs were identified as seen in Table 3.2. Details of each individual QI are available in Appendix 1.

Table 3.2 Candidate Quality Indicators and Quality Criteria

Candidate Quality Indicators and Quality Criteria (n = 38)
<p style="text-align: center;">Patient Experience and Access to Care and Continuity of Care and Equity</p> <p>Informational Transfer Communication General Health Review Geriatric Syndromes Non Pharmacological Interventions External Environment and Behaviour Disorders Pharmacist and Specialist Team Acute Behaviour Disorder Residential Care Medication Reconciliation Advocacy Medication Regimen Review Restrictive Practices Covert Medication Use</p>
<p style="text-align: center;">Patient Safety and Effectiveness</p> <p>Adverse Drug Reactions Multiple Medication Use/Poly-Pharmacy Inter – Intra Class Multiple Medication Use/Poly Pharmacy Psychotropic Medication Side Effects Psychotropic Medication – Physical Side Effects Anti-Cholinergic Medication Neuroleptic Side Effects Anti-Epileptic Medication Anti-Depressant Medication and the Serotonin Syndrome Off Label Prescribing Anti-Psychotic Medication Excessive Dose Anti-Psychotic Medication Gradual Dose Reduction As Required [PRN] Prescribing of Anti-Psychotic Medication Dysphagia</p>
<p style="text-align: center;">Appropriateness and Assessment</p> <p>Gastro-Intestinal Disorders Dementia and Cholinesterase Inhibitors Dementia and Anti-Psychotic Medication Dementia and Anti-Cholinergic Medication and Cholinesterase Inhibitors Sleep and Behaviour Disorders Insomnia Treatment Pain Infection Autistic Spectrum Disorders Dental – Oral Health</p>

3.2.5 Email Survey

A Delphi response rate of 40-50% (Linstone and Turoff, 1975) is recommended and to enhance responses in Delphi rounds it is critical that participants realise and feel that they are partners in the study (Keeney et al., 2011). Recruiting letters for this study included an explanation of the study, anticipated number of rounds, Appendix 3, and a consent form to take part in the study. The Round 1 survey using Survey Monkey as the frame was sent to each consented panellist by email. The advantages and disadvantages of the use of email in a survey (Snyder-Halperm et al., 2000) such as this are detailed in Table 3.3 below.

Table 3.3 Use of Email in a Survey: Advantages and Disadvantages

Advantages and Disadvantages of Email Use	
Advantages	Disadvantages Mainly technological and include
Recruitment cheap and quick	Unexpected changes of email application
Cost saving	Unreliability of panellists email capabilities, resulting in some panellists being unable to participate in some rounds
Legibility of responses	Some respondents unable to retrieve email attachments in their original format
Ease of data entry, resulting in decreased data entry time and efforts	Some respondents had incompatibility with Excel or MS word applications
Decrease in response turnaround time	Problems with mine encryption
Ability to track transmission status	

Approximately one month after the first email containing the Survey Monkey Round 1 (R1) questionnaire was distributed, a follow-up email message was sent to remind panellists who had not replied up to that date to return their survey. It is recognised that notoriously low response rates for questionnaire surveys can be minimised by ensuring that respondents are fully informed about the study and that reminders are issued. A final reminder for that round was then sent by the researcher some weeks later. Care was exercised when contacting non-responders to Round 1 as it was important that respondents did not feel forced into returning the questionnaire, even though they may have wished to withdraw from the study.

The following issues were given consideration:

- 1) The number of indicators to be included: in general, MDT indicator sets have had between 25 and 35 indicators and it was the researchers intention to approximate to this number
- 2) Question content: this has been informed by the extensive review of the literature and guidelines already undertaken in Chapter 2
- 3) Question wording: the questionnaire was to take the form

IF - THEN - BECAUSE

as described previously in the literature (Sinha et al., 2011) and in the literature review for this project in Chapter 2:

IF refers to the clinical characteristics that describe persons eligible for the quality indicator;

THEN indicates the actual process that should or should not be performed;

and

BECAUSE refers to the expected health impact if the indicator is performed (Shekelle et al., 2001b).

An example of a QI developed by the RAND Corporation (RAND, 2004a) is shown in Box 3.4 and Box 3.5 shows a QI from this project.

What Does a Rand Quality Indicator Look Like?
<p>Quality Indicator 1 for Dementia:</p> <p><i>Cognitive and Functional Screening</i></p> <p>IF a vulnerable elder is admitted to a hospital or is new to a physician practice, THEN multidimensional assessment of cognitive ability and assessment of functional status should be documented BECAUSE screening for dementia can lead to early detection and initiation of treatment that may delay further progression.</p>

Box 3.4 What Does a RAND Quality Indicator Look Like?

What does a Quality Indicator Look Like in This Survey?

Round 1 Candidate QI Communication

IF a person with intellectual disability exhibits a behaviour disorder **THEN** all clinicians/carers should try to optimize communication with the person with intellectual disability before medication is prescribed, dispensed or administered **BECAUSE** people with intellectual disabilities need to be encouraged and empowered to communicate/speak for themselves and the way medication is prescribed and the need for accessible information have been identified by people with intellectual disability as an area of concern.

Box 3.5 What does a Quality Indicator Look Like in this Survey?

3.2.6 Deadline

Conducting a MDT and participating in a Delphi panel can be time consuming. When the instrument of a Delphi study consists of a large number of statements such as the thirty-eight statements in Round 1 of this project, the participants may need to dedicate large blocks of time to complete the survey questionnaires.

It is necessary to set a deadline for participants to respond in all kinds of research inquiry. Delphi panellists can be unavailable to respond to a questionnaire for various reasons. Even when the given deadline set has passed, it is still advisable to contact the non-respondents. This was attempted in this study at each round because if the researcher failed to contact them in a timely manner, participants could feel that their responses were no longer important and/or necessary to the study outcome.

It has been noted that if participants 'drop out' in Round 1, then having them continue to participate in further iterations may become improbable and, as a result, response rates will suffer. The use of email contacts and follow-up reminders enabled the researcher in this MDT to directly and promptly communicate with non-respondents for the purpose of expediting the process of data collection and ultimately maintaining a high response rate. The Round 2 survey was started by 28 of the 32 consented panel members (87.5%) and was completed in full by 24 of the 32 panel members. The four panel members who did not reply to Round 1 were excluded from Round 2 of this process.

Email reminders created an open communication opportunity between the researcher and non-respondents. Email was also used by the panel members to communicate any difficulties they had to the researcher.

3.2.7 Demographic Information

Panel members in this MDT were not equivalent in knowledge or experience of the medication use process for people ageing with intellectual disability and behaviour disorders. The expertise of the panel would be unevenly distributed and some panellists may have in-depth knowledge of certain areas of the topic. The need to include a survey of panellists to establish their experience of working with people with intellectual disabilities and their professional qualifications was identified. This information was obtained from them voluntarily rather than looking for their ‘expert’ opinion only.

The panel members who were sent Round 1 of the survey were given the option of supplying demographic information by answering seven questions with preset optional answers. This was achieved using the ‘*Matrix of drop down menus*’ under Question Type in Survey Monkey. Participants were also offered the opportunity to provide any comments they wished to make in free text, Box 3.6.

Demographic Information Question – Appearance in Survey Monkey

Option answers are available in drop down menus under each heading.
If you do not wish to answer any question please use the No Answer option

	Principal	Current	Academic	Work with	Experience
Age	Gender	Work	Position	Intellectual	Since
	Setting		Qualifications	Disability	Qualifying

If you have any comments please add them in the following space

Comments:

Box 3.6 Demographic Information Question – Appearance in Survey Monkey

Demographic information was supplied by 25 panel members (89.29%) who started the Round 1 survey. Demographic information was not supplied by three panel members, Table 3.5. In total, demographic information was not available for seven or 21.8% of the consented Round 1 panel members. These 25 panel members were not the same 25 panel members who completed the Round 1 survey in full.

Individuals on Delphi panels can differ in their age, gender, educational background, knowledge base, profession or tenure e.g. length of time working with people with intellectual disabilities, Appendix 4a. Panel members can also be diverse in relation to their ethical values, attitudes and awareness of human rights. This diversity was not captured in the demographic information.

A framework was developed for the differentiation in this Delphi panel and for the purposes of the project heterogeneity was judged by both professional background and the knowledge base that can be associated with working with people with intellectual disabilities over a period of time. These two dimensions are shaded in Appendix 4b, Q3 and Q6.

3.2.7.1 Heterogeneity of Panel

It is recognised that panellists who have less in-depth knowledge of certain areas of the topic are unable to specify the most important statements which have been identified by those panellists who possess in-depth knowledge concerning the target issue, which in this project is the medication use process in this vulnerable population group. In total, 20% of the panel identified that they worked 'not at all' with people with intellectual disability and therefore may not have a full realisation of many of the issues relevant to the medication use process.

The demographic information collected in Round 1 of this MDT, indicated that of the 25 panel members who provided demographic information, the majority (60%) were in the age range of 40-59 years. 24% of panel members described themselves as a '*Practitioner with ID*', 36% worked full time with people with intellectual disability and 48% either worked full or part time with people with intellectual disabilities. However on examination of the data it was noted that one pharmacy panel member identified themselves as a '*Practitioner with ID*' and that they worked 'not at all' with people with intellectual disability. This would appear to indicate some confusion.

The qualifications of the members of the expert panel is one of the key aspects of the expertise of the panel. The information from the panel indicated that 76% of the panel had a Master's or a PhD qualification, 24% indicated 'consultant' as their present position and these included nursing, psychology, psychiatry and geriatric medicine. Regulation, administration or other was described by 12% as their principal work and 56% had between 20-39 years experience since qualifying, Appendix 4c. Panellists were not asked for their location (in Ireland, or UK) as this could have identified them.

All participants in the healthcare community at large such as patients, consumers, caretakers, healthcare practitioners, pharmacists, healthcare systems, health insurers, drug manufacturers, FDA and other agencies have a role to play in managing medication risks and reducing preventable harm from medication (FDA, 2009a). A previous modified Delphi study (Nigam et al., 2008) designed to develop a set of Canadian consensus-based indicators for the safe use of medication for both in-patient and outpatient settings, used a panel that consisted of experts in medication safety representing medicine, nursing, pharmacy, research and decision-makers in hospital and community settings across Canada. The panel members in this Modified Delphi study, who provided demographic information broadly represented the categories of expertise described in the Canadian Modified Delphi study.

There is increasing recognition that the degree to which sampled respondents differ from the survey population as a whole (i.e. non-response bias) is central to evaluating the representativeness of a survey, rather than response rates per se (Johnson and Wislar, 2012). If a non-response variable is correlated with the phenomenon of interest in the research, results will be biased. A difficulty in this Round 1 survey relates to the non provision of demographic information by three panel members who did provide answers to survey questions. There is a potential for bias in this study as respondents may be more interested in/knowledgeable about medication use in people ageing with intellectual disabilities and behaviour disorders or have other unmeasured characteristics that differ from those who did not respond.

3.2.7.2 Pharmacists

There was a 100% response to the Round 1 survey by five pharmacists who consented to participate. This response rate may have been due to collegiality in that the researcher is a pharmacist and also the concern/interest pharmacists have in the topic under discussion. Previous examination of pharmacist non-response to surveys in the USA identified that the main reasons for pharmacist not responding to the survey

were that it was too long or that it was too intrusive (Mott et al., 2001). This did not become an issue in this project.

3.2.8 Opinion of Participants

The opinions of each member of the panel in this study are given equal weight. This is because ‘experts’ with knowledge of all questions posed on medication use may not exist, and even if these ‘experts’ did exist, their answers should not carry more weight than ‘non-experts’. (If ‘experts’ could answer the questions associated with medication use in the population with intellectual disabilities, for example, why have they not already been answered?). Also ‘non-experts’ with good and useful opinions/suggestions/comments could be dissuaded from contributing since they might have to admit a self-deprecating level of ignorance of the issue under consideration. One panel member response to a Round 1 candidate QI concerning Inter-Intra Class Poly-Pharmacy is available in Box 3.7 below.

Round 1 Panel Member Comments on Inter-Intra Class Poly Pharmacy Candidate Quality Indicator
<i>‘My answers here are best guesses as I do not have the knowledge to assess our existing knowledge base but it seems to make logical sense’.</i>

Box 3.7 Panel Member Comments to Round 1 Inter-Intra Class Poly-pharmacy Candidate Quality Indicator

Except for participant specialty, there is little generalisable evidence for how the characteristics of participants and groups influence the judgments produced in formal consensus development methods. Multi-specialty groups have been identified as being preferable to single-specialty groups because of their potential for taking account of a wider range of opinions (Hutchings and Raine, 2006).

There was no variation of opinion in relation to the importance of eight Round 1 candidate QIs. To illustrate this, the unanimity of the panel in relation to rating the Round 1 Informational Transfer candidate QI is illustrated in Table 3.4.

Table 3.4 Round 1 Informational Transfer Candidate Quality Indicator Importance Rating

Round 1 Informational Transfer Candidate QI: Importance Rating				
Demographic	Work		Frequency	Percent
Pharmacy	Valid	7-9	5	100
Psychiatry	Valid	7-9	4	100
Geriatric Medicine	Valid	7-9	1	100
Psychology	Valid	7-9	3	100
Speech and Language	Valid	7-9	2	100
Nursing	Valid	7-9	3	100
Academia	Valid	7-9	4	100
Admin	Valid	7-9	1	100
Regulation	Valid	7-9	1	100
Other	Valid	7-9	1	100

In contrast, there was a wider diversity of opinion in the panel rating of other Round 1 QIs illustrated by the *feasibility* ratings for the Round 1 Advocate QI detailed in Table 3.5 in which 15 different opinions were identified.

Table 3.5 Round 1 Feasibility Ratings for Advocate Candidate Quality Indicator

Round 1 Feasibility Ratings for Advocate Candidate QI				
Demographic	Work		Frequency	Percent
Pharmacy	Valid	4-6	4	80.0
		7-9	1	20.0
Psychiatry	Valid	4-6	3	75.0
		7-9	1	25.0
Geriatric Medicine	Valid	1-3	1	100.0
Psychology	Valid	7-9	3	100.0
Speech and Language	Valid	4-6	1	50.0
		7-9	1	50.0
Nursing	Valid	4-6	1	33.3
		7-9	2	66.7
Academia	Valid	4-6	2	50.0
		7-9	2	50.0
Admin	Valid	7-9	1	100.0
Regulation	Valid	1-3	1	100.0
Other	Valid	1-3	1	100.0

This diversity of opinion was also reflected in the panel comments to the Round 1 Advocate QI. The Round 1 Advocate QI was rated 7-8-9 for *feasibility* by only 39.3% of the 25 panel members who replied to that question.

This was the lowest rating achieved by any candidate QI under any heading i.e. *importance, scientific soundness or feasibility* and represents the most diversity of opinion. Diversity of panel membership leads to better performance as this allows for the consideration of different perspectives and a wider range of alternatives (Murphy et al., 1998b). The diversity of panel membership in this MDT allowed for the consideration of the different perspectives of the multi-disciplinary panel and the wider range of alternative opinions that exist in relation to 'advocacy' for people ageing with intellectual disability. Stakeholders in healthcare for people ageing with intellectual disability have diverse views of quality of care in relation to medication use and the value or benefit of advocacy and these differences translate into how they rate Quality Indicators that relate to advocacy.

There was close correlation in the main between the ratings provided by both psychiatrists and pharmacists to many of the candidate QIs, Appendix 5a and 5b. However differences were obvious in relation to some QIs, for example, Residential Care. Only three of five pharmacists rated the Residential Care QI as being *important* while all four psychiatrists rated this QI as *important*. All psychiatrists rated the Gastrointestinal Tract QI as being *important*, *scientifically sound* and *feasible*. This QI was rated *important* and *scientifically sound* by two pharmacists and *feasible* by three. These differences in rating would appear to indicate more in-depth knowledge by psychiatrists of the issues in the population with intellectual disabilities that could contribute to behaviour disorders. In contrast, all five pharmacists rated the Medication Review QI as *important* while only two psychiatrists rated it *important*. This could relate to pharmacists more in-depth knowledge of medication side effects and their possible association with behaviour disorders.

Dentists were not recruited in a recent study designed to identify ambulatory care sensitive conditions that are applicable to persons with an intellectual disabilities (Balogh et al., 2011). It is of note that dentists were also not recruited for this study. This was an oversight during the design stage of this project and dentists should be used in the future to evaluate the appropriateness and quality of care for dental conditions for people ageing with intellectual disabilities and behaviour disorders.

3.2.9 Validity of Quality Indicators

Validity is defined as the extent to which the characteristics of the indicator are appropriate for the concept being assessed (Boukdedid et al., 2011). Generally, this criterion is used when the objective is to develop new indicators in a given field. Indicators selected via consensus methods such as the Delphi procedure have high *face validity*, which is a prerequisite for any QI.

In a critique of the Delphi Technique (Goodman, 1987), Goodman stated that if the panels participating in the study are representative of the group or the area of knowledge, then *content validity* can be assumed (Keeney et al., 2001). The original 32 member representative panel of expertise who consented to participate in Round 1 of this MDT consisted of five pharmacists, four psychiatrists and one psychiatric registrar, four psychologists and one trainee psychologist, two speech and language therapists, one behaviour support specialist, one nurse prescriber, one Director of Nursing, two Professors of Nursing, one nurse consultant in Learning Disabilities, three consultant

geriatricians, three nurse lecturers, one HSE employee, one HIQA employee and one medical school lecturer.

Internal validity exists when sufficient scientific evidence is present such that the measured variable is helpful for the quality assessment of health care aspects. The Round 1 panel supported the scientific soundness of 23 of the Round 1 candidate QIs. In Round 1, only 15 candidate QIs were rated 7-8-9 for *scientific soundness* by less than 75% of the Round 1 panel. The internal validity depends on the integrity of the study design and is a prerequisite for the applicability of the study results in routine care.

External validity is present, when by comparison of the measurement and the given reference ranges, the medical care of the target group, for example, people with intellectual disabilities and behaviour disorders, and their outcomes are improved. The external validity relates to the transferability and applicability of the results of the MDT to patients with intellectual disabilities and behaviour disorders in routine care. This is for further evaluation.

It is vital that Delphi investigators achieve a desirable response rate in the initial round of the Delphi process and also that a high response rate is maintained in any following iterations. There are no specific guidelines for an acceptable response in Delphi studies. However a number of authors have suggested that a 70% response rate must be maintained between rounds to ensure the rigor of the process. If a desirable response rate is not achieved this can jeopardize the validity of a Delphi study.

In this project a QI was considered to be valid if:

- adequate scientific evidence or professional consensus supported a link between the medication use process and a (health) benefit to the patient with intellectual disability,
- a clinician involved in the medication use process with high rates of adherence to the indicator would be considered a higher-quality provider,
- a clinician or service provider influenced a majority of factors that determine adherence to the indicator.

3.2.10 Procedure

In the email questionnaire the frame and stem was repeated for every question which was provided in an identical format, to avoid recipients having to scroll backwards and forwards. This could have given the impression of a very lengthy questionnaire as 38 questions with accompanying background information were provided. Each statement required a response to be indicated on a nine point Likert scale. There was also an unnumbered option '*Not able to answer*'. If the participant felt that they really could not answer the question then the '*No answer*' option was used. Also, each question had a comment option and comments could be added by participants when answering each individual question.

Following the literature review in Chapter 2, 38 candidate Quality Indicators were identified for Round 1 of this project. In keeping with procedure adopted in a project undertaken as part of the OECD QI Project (McLoughlin et al., 2006), candidate QIs were then rated against three key criteria by the panel of expertise in this project. These criteria were:

- 1) their ***importance*** to patient safety,
- 2) their ***scientific soundness***,
- 3) their potential ***feasibility***.

The panel were given the following advice to guide their understanding of the criteria:

- *Important*: Quality assurance is conducted by defining key areas of importance associated with expected benefit. A QI is a key concept in the context of quality assurance and is defined as follows: a specially selected measure or attribute that may indicate and point to good or poor quality.
- *Scientifically sound*: The standards of good clinical practice in this investigation are based on best scientific evidence when present; otherwise, they were based on consensus of a panel of experts where available and/or relevant guidelines.
- *Feasibility* of measurement can relate to chart review or interview. The level of documentation is, in itself, an indicator of performance; poor documentation may represent poor quality patient care.

(Feasibility here does not relate to feasibility of implementation e.g. due to staff shortages).

These three key criteria were also described in an article which developed a conceptual framework for the OECD's HCQI Project. This article noted that

'conceptual concerns, indicator selection and prioritization of health areas can undermine a performance framework if care is not taken to define the selection and prioritization criteria beforehand' (Arah et al., 2006).

3.2.11 Consensus

Consensus has been viewed as a term that embodies a decision-making process rather than the resulting feeling in the group. The approach to measuring consensus is the least-developed component of the Delphi Method and it varies from study to study.

Consensus methods include the RAND Appropriateness Method and the Delphi Technique (Campbell et al., 2004). The Delphi Technique was used in the survey described in this document. Von der Gracht, in his paper dedicated to how consensus has been measured since the Delphi Technique's emergence in the 1960s and which criteria have been used, concluded that a general standard of how to measure consensus in Delphi studies does not yet exist (von der Gracht, 2012). He found that researchers have applied subjective criteria as well as descriptive and inferential statistics to measure consensus and convergence.

Round 1 panel members in this project were asked to base their assessment of *importance* and *scientific soundness* on background information provided by the researcher, and their own sources and personal and professional knowledge of the field, and to provide an explicit rating of the measures on a scale from 1 to 9 for each dimension.

- Ratings of 7-8-9: labelled agree/somewhat agree/strongly agree were taken to indicate *support* of a measure.
- Ratings of 4-5-6: labelled slightly disagree/neutral/slightly agree indicated *ambiguity*.
- Ratings of 1-2-3: labelled strongly disagree/somewhat disagree/disagree indicated *rejection*, using the criteria of *importance* and *scientific soundness*.

Panellists may have had only limited knowledge about data availability and comparability across different healthcare settings and countries, so their assessment of probable *feasibility* was therefore subjective.

- A rating of 7-8-9 was taken to indicate '*likely*' *feasibility*.
- A rating of 4-5-6 was taken to indicate '*possible*' *feasibility*
- A rating of 1-2-3 was taken to indicate '*unlikely*' *feasibility*.

Standards for consensus in Delphi research have never been rigorously established. The aim of the Delphi Technique is to achieve consensus but this is not a straightforward concept and is generally poorly explained in studies. Failure to offer an interpretation of the meaning of consensus is an important omission in many examples of Delphi studies (Powell, 2003). Consensus has been identified as one of the most contentious components of the Delphi Method, and debates have centred on the position of consensus in the overall study (Hanafin, 2004). In 1998, the NHS Health Technology Assessment group produced a detailed report on the requirements of effective consensus development methods yet could not identify an appropriate statistical measure for reporting a move towards consensus, identified by central tendency in Delphi (Holey et al., 2007). It is recognised that the monitoring team has to define criteria for each Delphi process individually (von der Gracht, 2012).

In this study consensus in Round 1 was defined as 75% or more of replies rating 7-8-9 for importance and scientific soundness and 50% rating 7-8-9 for feasibility.

The use of 75% cut off, (which is in line with McKenna et al (McKenna et al., 2000) and Kilroy and Driscoll (Kilroy and Driscoll, 2006)) was taken to differentiate the consensus and non-consensus results for *importance* and *scientific soundness*. The use of 75% cut off was also found to clearly differentiate the consensus and non-consensus results in the first methodological study to assess the Delphi Technique in developing international infectious disease policies (Syed et al., 2009).

It has been recommended that qualitative research should supplement quantitative analyses to understand participants' underlying thought processes within consensus techniques and this is done in this project through inclusion of panel member comments.

3.2.12 Initial Results

The results of the First Analysis of the Round 1 survey are detailed in Appendix 6a. Of the original 38 Round 1 candidate Quality Indicators, 13 achieved a rating of 7-8-9 by 75% or more of panel members for all three criteria following Round 1 i.e. rated 7-8-9 on the 9 point Likert scale for *importance*, *scientific soundness* and *feasibility*.

There was a high level of consensus achieved around 13 Round 1 candidate QIs, Appendix 6b. However the original consensus criteria for this project was defined as 75% or more of replies rating 7-8-9 for *importance* and *scientific soundness* and 50% rating 7-8-9 for *feasibility*. Consensus was achieved by 23 Round 1 QIs.

Only four of the 38 Round 1 QIs were rated 7-8-9 for *importance* by less than 75% of the Round 1 panel and are detailed in Table 3.6. This demonstrated the level of importance of the candidate QIs identified in the initial guideline and literature review stage of this project. The Round 1 panel supported the *importance* of 34 of the 38 Round 1 candidate QIs.

Table 3.6 Round 1 Candidate Quality Indicators rated 7-8-9 ‘important’ by less than 75% of Round 1 Panel

Round 1 Candidate QIs rated 7-8-9 ‘Important’ by less than 75% of Round 1 Panel		
<i>Round 1 Quality Indicator (Number and abbreviated title)</i>	<i>This QI is Important</i>	<i>Number</i>
17. Inter-Intra Class Poly-Pharmacy	74.1%	27
30. Dementia Cholinesterase Inhibitors	70.4%	27
32. Dementia Cholinesterase Inhibitors Anti-Cholinergic Medications	74.1%	27
37. Autistic Spectrum Disorder	59.3%	27

In contrast, 15 of the R1 candidate QIs were rated 7-8-9 for *scientific soundness* by less than 75% of the Round 1 panel, Table 3.7. The Round 1 panel supported the *scientific soundness* of 23 of the Round 1 candidate QIs. *Scientific soundness* proved to be the ‘deciding factor’ in the decision to support or not support the Round 1 candidate QIs, as the 15 R1 candidate QIs that were not supported for *scientific soundness* were those QIs that were used in the Round 2 QIs survey.

Table 3.7 Round 1 Candidate QIs rated 7-8-9 by less than 75% of the Round 1 Panel

Round 1 QIs rated 7-8-9 for Scientific Soundness by less than 75% of Round 1 Panel		
<i>Round 1 Quality Indicator (Number and abbreviated title)</i>	<i>This QI is Scientifically Sound</i>	<i>Number</i>
4. Geriatric Syndromes	67.9%	28
7. Pharmacist/Specialist team	60.7%	28
8. Acute Behaviour	71.4%	28
11. Advocate	42.9%	28
12. Medication Regimen Review	71.4%	28
14. Covert Medication	71.4%	28
17. Inter-IntraClass Poly-Pharmacy	70.4%	27
22. Anti-Epileptic Medications	74.1%	28
24. Off Label Anti-Psychotic Medications	74.1%	28
29. Gastro-Intestinal Tract	74.1%	28
30. Dementia Cholinesterase Inhibitors	55.6%	28
32. Dementia Cholinesterase Inhibitors Anti-Cholinergic Medications	74.1%	28
36. Infections	70.4%	26
37. Autistic Spectrum Disorder	40.7%	27
38. Dental Oral Health	61.5%	27

3.2.13 Feasibility and Consensus

Data availability would present initial feasibility problems with the use of QIs for medication use in people ageing with intellectual disabilities and behaviour disorders. There can be strong disincentives for disclosing quality information in this area of healthcare, such as fear of litigation and shame. Even when there are medication safety incident reporting systems, there can be under reporting of actual incidents and 'near misses'. Feasibility issues arise because administrative data commonly lack the detail and completeness to capture quality information, and the use of chart reviews and nursing and medical notes can be limited by cost concerns.

Another feasibility problem is that a set of QIs may include events that are very rare, difficult to document and that may also be under-reported in administrative data. At an

individual health systems level, a medication process event might not occur with a sufficient frequency and variance to draw inferences from it about differential quality of care.

Only three of the Round 1 candidate QIs were rated 7-8-9 for *feasibility* by less than 50% of the R1 panel, Table 3.8. This translated to the Round 1 panel considering that 35 of the 38 R1 candidate QIs were *likely* to be *feasible*. The Round 1 result for the Advocate QI of 39.3% for *feasibility* represented the lowest score of any QI in Round 1 or Round 2 of this survey.

Table 3.8 Round 1 Quality Indicators rated 7-8-9 for Feasibility by Less than 50% of Round 1 Panel

Round 1 Quality Indicators Rated 7-8-9 for Feasibility by Less than 50% of the Round 1 Panel		
	<i>This QI is Feasible</i>	<i>Number</i>
7. Pharmacist/Specialist Team	46.4%	28
11. Advocate	39.3%	28
37. Autistic Spectrum Disorder	48.1%	27

3.2.14 No Answer

The panel members in Round 1 had the availability of a '*No answer*' option for each criteria for each individual candidate QI. This option was used very rarely during this survey, Table 3.9. There were 1,140 opportunities for use of the '*No answer*' option in Round 1 of the survey. The '*No answer*' option was used only 15 times. This represented 1.3 % usage of the '*No answer*' option during Round 1.

Table 3.9 Round 1 Panel Use of ‘No Answer’ Option

Round 1 Panel Use of ‘No Answer’ Option						
<i>QI (Number and Abbreviated Title)</i>	<i>This QI is Important</i>	<i>Number</i>	<i>This QI is Scientifically Sound</i>	<i>Number</i>	<i>This QI is Feasible</i>	<i>Number</i>
8. Acute Behaviour	3.6%	28	3.6%	28	3.6%	28
9. Residential Care	7.1%	28	7.1%	28	7.1%	28
14. Covert Medication	3.6%	28	3.6%	28	3.6%	28
36. Infections	3.7%	27	3.7%	27	3.8%	26

3.3 Modified Delphi Technique Analysis: Stage 1

3.3.1 Introduction

Statistics is a branch of mathematics used to summarize, analyze and interpret what is observed - to make sense or meaning of the observations. There are two general types of statistics:

Descriptive statistics: statistics that summarize observations.

Inferential statistics: statistics used to interpret the meaning of descriptive statistics.

Data from the MDT questionnaire in this project was entered into a database and statistical analysis was undertaken using the IBM SPSS software version 19. Statistical analysis allows for impartial and objective analysis and summarization of the collected data which reduces the potential of group pressure for conformity. Statistical analysis can ensure that opinions generated by each participant of a Delphi panel are well represented in the final iteration because at the end of the process there will still be a significant spread of individual opinions.

Because the number of respondents is usually small, Delphi's do not and are not intended to produce statistically significant results. The results provided by any one panel of expertise do not predict the response of a larger population or even a different Delphi panel. They represent the synthesis of opinion of the particular group, no more, no less.

3.3.2 Descriptive Statistical Analysis

3.3.2.1 Introduction

Descriptive statistics are procedures used to summarize, organize and make sense of a set of scores or observations. Descriptive statistics are typically presented graphically, in tabular form (tables), or as summary statistics (single values). The major descriptive statistics used in this Delphi study are measures of central tendency - means, medians - and level of dispersion (standard deviation and inter-quartile range) in order to present the collective judgements of respondents. The mode however is also presented here because the Delphi process has a tendency to produce convergence of opinion.

Agreement has two forms, which need to be distinguished from each other:

- the extent to which each respondent agrees with the issue under consideration (typically rated on a numerical or categorical scale), and
- the extent to which respondents agree with each other, the consensus element of these studies (typically assessed by statistical measures of average and dispersion) (Jones and Hunter, 1995b).

The mean or median are used to represent group opinion and the standard deviation used to indicate the level of agreement (Keeney et al., 2011) in Delphi studies where the scale on which the expert panel are asked to indicate their opinion is considered to have interval properties.

3.3.2.2 Median Values

The median is a good measure of central tendency as it picks up the score in the middle of the distribution i.e. it is the score which cuts the list into two halves. The median values achieved for *importance*, *scientific soundness* and *feasibility* seen in Table 3.10 showed a pattern of descending convergence of opinion at the high end i.e.

median = '9', from *importance* to *scientific soundness* to *feasibility*. The median value, for *importance* was '9' for 32 of the 38 Round 1 candidate QIs. The median value for *scientific soundness* was '9' for 16 of the 38 Round 1 QIs and the median value for *feasibility* was '9' for nine of the 38 Round 1 QIs. This descending convergence highlights the difficulty of developing scientifically sound and feasible Quality Indicators for medication use in people ageing with intellectual disabilities that are agreed to be *important*.

Table 3.10 Round 1 Quality Indicators Median Values – Panel Ratings

Round 1 Quality Indicators Median Values - Panel Ratings			
Median Value	Importance	Scientific Soundness	Feasibility
6.0		2	3
7.0	2	7	12
7.5		1	1
8.0	4	11	11
8.5		1	2
9.0	32	16	9
Total	38	38	38

The use of median score based on Likert type scale is strongly favoured in some of the literature. Jacobs, quoted in (Keeney et al., 2011) stated

'considering the anticipated consensus of opinion and the skewed expectation of responses as they were compiled, the median would inherently appear best suited to reflect the resultant convergence of opinion' (Jacobs, 1996).

The median is an indicator of the most typical value if a set of scores has an outlier, which is an extreme value that differs greatly from other values. In the analysis of the Round 1 candidate QIs that achieved consensus, the median of 9 was achieved for *importance* for all 23 Round 1 QIs, for *scientific soundness* for 19 Round 1 QIs and for *feasibility* for 17 Round 1 QIs, Table 3.11. This indicated very few outliers.

Table 3.11 Median Values for Twenty-three Quality Indicators that Achieved Consensus in Round 1

Median of Twenty-three Candidate Quality Indicators that Achieved Consensus in Round 1				
No	Quality Indicator Abbreviated Title	Important Median	Scientifically Sound Median	Feasible Median
1	Informational Transfer	9	7	9
2	Communication	9	8	8
3	General Health Review	9	9	8.5
5	Non-Pharmacological Interventions	9	9	8
6	External Environment	9	8	9
9	Residential Care	9	9	8.5
10	Medication Reconciliation	9	9	7.5
13	Restrictive Practice	9	8	9
15	Adverse Drug Reactions (ADRs)	9	9	7
16	Poly-Pharmacy	9	9	9
18	Psychotropic Medication	9	9	9
19	Psychotropic Med Physical Side Effects	9	9	9
20	Anti-Cholinergic Medication	9	9	9
21	Neuroleptic Side Effects	9	9	9
23	Anti-Depressants/Serotonin Syndrome	9	9	9
25	Excessive Dose Anti-Psychotic Medication	9	9	9
26	Gradual Dose Reduction	9	9	9
27	'PRN' As Required Anti-Psychotic Medication	9	9	9
28	Dysphagia	9	9	9
31	Dementia Anti-Psychotics	9	9	9
33	Sleep Behaviour Disorders	9	9	9
34	Insomnia Treatment	9	9	9
35	Pain	9	9	9

3.3.2.3 Mean and Standard Deviation Values

When the sample size is large and does not include outliers, the mean score usually provides a better measure of central tendency. An examination of the mean values for the Round 1 QIs showed that 20 of the 23 Round 1 QIs that achieved consensus were ranked 1-20 when the mean values, for *importance*, of the Round 1 candidate QIs were ranked in order, Appendix 7.

The amount of convergence and therefore the strength of agreement is indicated by a comparison of standard deviation (SD) (strength of aggregate judgement) and range (larger ranges being indicative of outliers views) (Holey et al., 2007). The mean, mode, median and SD results from statistical analysis of the Round 1 survey are available in Appendix 8.

The SD (a measure of spread), can be understood as a representation of the amount of disagreement within the panel. If the SD is low, then the Delphi panel is in agreement. If the SD is high, the panel is in disagreement.

The SD in Round 1 for importance ranged from 0.956 (Communication) to 2.603 (Residential Care). This represents a high level of agreement in relation to *importance* for the Communication QI and a high level of disagreement for the *importance* of the Residential Care QI. The SD for *scientific soundness* ranged from 1.315 (Gradual Dose Reduction) to 2.706 (Residential Care). The SD for *feasibility* ranged from 1.418 (Psychotropic Meds) to 2.690 (Residential Care).

The residential care QI, in Appendix 8, accounted for extreme variation in SD and therefore most disagreement for all three criteria i.e. *importance*, *scientific soundness* and *feasibility*. The comments of the Round 1 panel members to the Residential Care QI throw some light on this variation. One comment in Box 3.8 from a panel member in relation to the Round 1 Residential Care QI would appear to indicate that was made by a researcher rather than a practitioner in the intellectual disability field. Professionals working in and familiar with residential care settings for people ageing with intellectual disability would be aware that the culture of the particular setting and the prescribing practices of those prescribing is highly influential in relation to the quality of medication use.

Round 1 Panel Member Comment on Residential Care Quality Indicator
<i>“Is the quality of prescribing specific to the individual or their place of residence?”</i>

Box 3.8 Round 1 Panel Member Comment on Residential Care Quality Indicator

In relation to the 15 Round 1 candidate QIs that did not achieve consensus, the ‘average’ or mean varied from 6.7 (SD 2.00) to 8 (SD 1.21) for *importance*, from 6.19 (SD 2.22) to 7.52 (SD 1.85) for *scientific soundness* and from 6.25 (SD 2.03) to 7.44 (SD 1.42) for *feasibility*.

The median is a measure of central tendency and is the score that comes in the middle of a list when it is ordered from lowest to highest. The median values in this project simply picked up the score in the middle position and cut the list of scores into two halves. The median did not take account of the value of all the scores. Nine of the QIs that did not achieve consensus had a median of 9 for importance, Appendix 8 and if used alone the median would not have explained the results.

In a systematic examination of consensus development methods and their use in clinical guideline development, Murphy et al. have argued that the median and the inter-quartile range are more robust than the mean and SD (Murphy et al., 1998a). However, as noted earlier, there is confusion concerning the statistics to be reported in relation to Delphi studies. For the sake of completeness in this study both approaches have been examined.

3.3.2.4 Inter-Quartile Range

The calculation of quartiles allows examination of the spread of results with quartiles cutting the data into groups. A sophisticated measure of spread of the range is the Inter-Quartile Range (IQR), which is the difference between the third and the first quartile. This is the range of half the scores, those 50% in the middle of the distribution. The value of the IQR is that it is not affected by one particularly high or low score and it may represent the spread of the distribution appropriately. The closer the clustering of values around the median, the smaller the IQR. The higher the IQR, the more spread out the data points.

The value of the IQR is important when two sets of similar data are compared, for example when comparing the results for two QIs. An IQR of less than one means that

more than 50% of all opinions fall within one point on the scale. The range of the IQR actually depends on the number of response choices. The more points there are on the scale, the larger the IQRs that can be expected. The IQR for the Round 1 Informational Transfer QI for *importance* was equal to zero which indicated that the scores were clustered around the median which was nine.

The Informational Transfer QI survey question was answered by 28 panel members. The IQR for this QI for *scientific soundness* was three, for *feasibility* was two and for *importance* was zero. This would suggest that while there was no divergence of opinion in relation to *importance* and therefore the QI was recognised as being *important*, there was most diversity of opinions in relation to *scientific soundness*. An example of the IQRs is provided below in Table 3.12.

Table 3.12 Inter-Quartile Range Example from Round 1 Statistical Analysis

Inter Quartile Examples from Round 1 Statistical Analysis					
Round 1 QI	Criteria	IQR	Quartiles (%)		
			25	50	75
Informational Transfer	Importance	0	9	9	9
	Scientific Soundness	3	6.25	7	9
	Feasibility	2	7	9	9

This concern in relation to *scientific soundness* is well illustrated by comments from members of the Round 1 panel of expertise, Box 3.9.

Round 1 Informational Transfer Quality Indicator: Panel Members Comments
<p><i>“This is too subjective to be scientifically sound but I am unsure if any of the measures we use for assessment can be considered to be scientifically rigorous”</i></p> <p><i>“If the information is fragmented and incorrect, diagnosis and intervention plans can have a significantly negative effect on the person with ID.”</i></p>

Box 3.9 Round 1 Informational Transfer Quality Indicator: Panel Members Comments

3.3.3 Inferential Statistics

The true value of the Delphi Method concerns the generation of ideas rather than the determination of statistically significant results that can be generalized to a larger population. There may be a difference between the extent to which each participant agrees with the *issue* under consideration and the extent to which participants agree with each other (Keeney et al., 2011).

As mentioned earlier, the Delphi Method has been used when the complexity or ambiguity associated with a particular problem exceeds the intellectual capabilities of a single decision-maker or speciality group. The underlying assumption of this Delphi Technique is that the informed, collective judgment of a group of 'experts' is more accurate and reliable than individual judgment where effective decision-making for medication use in people ageing with intellectual disability and behaviour disorders is dependent on the knowledge and expertise of different disciplines.

Inferential statistics are procedures used that allow researchers to infer or generalize observations made with samples to the larger population from which they were selected. It has been thought by some that the reliance on small, non-representative samples associated with most Delphi investigations prohibits the utilization of inferential statistics (Gordon, 2009).

Inferential statistics are statistics that help to establish relationships among variables and draw conclusions from them. The application of such statistical tests depends on the level of data and whether this data conforms approximately to a normal distribution. If the latter is the case and the data is interval/ratio-scaled, parametric tests can be used. Nonparametric tests, on the other hand, can be used on nominal- or ordinal-scaled data not conforming to a normal frequency distribution. Both parametric and nonparametric tests have been used in Delphi research for consensus measurement and stability/convergence between rounds, but most often for the comparison of subgroups (von der Gracht, 2012).

The main method advocated in the recent literature for determining stability across responses is the use of Kappa statistics (Holey et al., 2007). Stability refers to the 'within-subject' level of agreement in the expert panel member's responses to two rounds. It does not refer to the level of agreement between expert panel members (Keeney et al., 2011). In this project the Round 1 QIs that did not achieve consensus were changed and/or renamed to reflect the comments of the panel and/or advances in

the literature. The Round 2 candidate QIs were therefore different to those presented in Round 1. In this situation it was not possible to assess the 'within subject' level of agreement between rounds.

Reductions in the number of subjective comments reinforce the quantitative observations of convergence (Holey et al., 2007). This reduction is described in the following section.

3.3.4 Qualitative Data

3.3.4.1 Background

Of the 28 panel members who started Round 1, 19 (67.86%) made at least one comment during the MDT process, Table 3.13. The range of comments made by individual panel members was 0-26. One panel member commented on 26 of the 38 (68.42%) Round 1 candidate Quality Indicators. This demonstrated an exceptional level of commitment and involvement in the process.

No comments were received for the following three Round 1 QIs: Anti-Epileptic Drugs, (QI No 22), Anti Depressant Medications (QI No 23) and Dementia Anti-Psychotics (QI No 31). The highest number of comments were received for Round 1 Communication QI and supports the finding that 96.4% of respondents to Round 1 gave this candidate QI a rating of 7-8-9 on the 9 point Likert scale for the *importance* criteria.

QIs 1-14 were concerned with the following dimensions of quality - Patient Experience, Access to Care, Continuity of Care and Equity. These first 14 QIs received 56.82% of the Round 1 comments. QIs 15-28 were concerned with Patient Safety and Effectiveness and received 36 (27.27%) of the Round 1 comments. QIs 29-38 were concerned with Appropriateness and Assessment and received 21 (15.91%) of the comments.

Table 3.13 Number of Comments made by Round 1 Panel Members

Number of Comments made by Round 1 Panel Members	
Number of Comments	Number of Panel Members who made Comments (n = 28)
0	9
1	3
2	3
3	2
4	0
5	1
6	2
7	0
8	0
9	2
10	3
11	0
12	0
13	2
14-25	0
26	1

3.3.4.2 Pharmacy

Participants in Delphi studies from the specialities whose performance is being assessed have been found to rate more critically than participants from other specialities. Pharmacists would be expected to have particular knowledge or opinion in relation to the value of a pharmacist, the need for a medication review or the issue of poly-pharmacy in the population with intellectual disabilities and behaviour disorders. Table 3.14 shows the results from the five pharmacist participants on the Round 1 panel in relation to these three QIs. Of particular note is the divergence of opinion of the pharmacists in relation to the poly-pharmacy candidate QI and the pharmacist/specialist team QIs.

Table 3.14 Sample Results Round 1 Demographic Work – Pharmacy

Sample Results Round 1 Demographic Work – Pharmacy			
Criteria	Pharmacist Specialist Team QI	Medication Regimen Review QI	Poly-Pharmacy QI
Importance Rating			
4-6	1		1
7-9	4	5	4
Scientific Soundness Rating			
1-3			1
4-6	3		1
7-9	2	5	3
Feasibility Rating			
1-3			1
4-6	3	3	1
7-9	2	2	3

3.3.4.3 General Comments

Panel members who provided demographic information were invited to provide general comments on the process and any other comment they wished to offer. Some general comments provided by panellists are documented below, Box 3.10.

General Comments Round 1 Panel Members
<p><i>‘Good luck with study - this phase was very long and in parts required an expertise that I did not have - sorry. However you have reinforced my belief that the fewer medications people are given the better it is for everyone!’</i></p> <p><i>‘As I am not an expert on medication/pharmacological issues I am responding to this survey in the context of supporting a strengthened high quality evidence base for policy in relation to individuals ageing with a disability (and ageing in general). Therefore I found it hard to disagree with any of the statements which clearly have a strong evidence base.’</i></p>

Box 3.10 General Comments from Round 1 Panel Members

Panel participant 'fatigue' is a contributing factor in how participants rate indicators, and panellists may not make judgements in the same way at the end of the questionnaire as at the beginning. This situation is illustrated by the comments provided in Box 3.11 by a panel participant in a MDT that included a two round postal Delphi Technique. One objective of that MDT was to describe differences in panel ratings on the quality of primary mental health care services by patient, carer, professional and managerial panels within a Delphi procedure (Campbell et al., 2004).

Panel Member Comment on 'Fatigue' in Postal Delphi Survey

'I think it got to the point that I felt really fed up with it. But then I thought no, I am determined to finish it..... so I might not have been making judgements in the same way as I was at the beginning. At the beginning I was obviously enthusiastic. I think towards the end I wanted to get it finished.'

Box 3.11 Panel Member Comment on 'Fatigue' in Postal Delphi Survey

3.3.5 Round 2

3.3.5.1 Introduction

The iteration characteristics of some Delphi's can potentially enable researchers to mould opinions of the panel of expertise. Subtle pressure to conform with group ratings can occur in some Delphi studies.

Delphi investigators have been advised to be cognisant, exercise caution and implement prior safeguards when considering feedback. The researcher in this study was cognizant of this issue and so no feedback was provided following Round 1, to ensure proper safe guards in dealing with the issue of group pressure.

The written comments (qualitative data) provided by the respondents following Round 1 were examined and the questionnaire for Round 2 was based on the results and comments received in Round 1. Candidate QIs which reached consensus in Round 1 were excluded from Round 2. Unclear and confusing QIs from Round 1 were rephrased and/or retitled. The Round 2 panel consisted of those 28 Round 1 panel members who started the Round 1 survey.

In keeping with the methodology used in the Delphi study to identify performance indicators for emergency medicine (Beattie and Mackway-Jones, 2004), only those 15 candidate QIs that had not reached consensus in Round 1 were returned to the panel for reconsideration in Round 2, Appendix 9. This decision was made to encourage the panel members to maintain their interest in the survey by avoiding a too repetitive iterative process and to avoid the development of panel member fatigue. One disadvantage of this decision was that if all QIs from Round 1 were kept for Round 2 of this MDT, every statement would get an equal chance to gain the highest importance rating and level of consensus as each other.

3.3.5.2 Round 2 Survey Procedure

The validity of a Delphi study may be affected by response rates and successive Delphi rounds may lead to fatigue and/or dropout of participants before it is completed (Keeney et al., 2011). High drop out rates in Delphi studies may result in non-response bias, a situation where the final results are based upon an unrepresentative subsample of the original sample. In order to maintain rigour, a 70% minimum response rate should be achieved and this was achieved in Round 2 of this MDT where the percentage response rate was 85.7%, Table 3.15.

Table 3.15 Response Rate Round 1 and Round 2

Response Rate Round 1 and Round 2		
	Response Rate	% response
Round 1	28 of 32	87.50%
Round 2	24 of 28	85.72%

The Round 2 survey was sent via email to each of the 28 consented panellists who started Round 1 and the Round 2 panel members individually rated each indicator. The selection criteria did not change between the two Rounds of this MDT. The three selection criteria for QIs that were set at start of this MDT project were used in Round 2. The QIs must:

- 1) capture *important* aspects of care,
- 2) be *scientifically sound*, and
- 3) be potentially *feasible*.

Survey Monkey with the same appearance was used in both Rounds. The Round 2 survey was completed by 24 of the 28 Round 2 panel members who rated each of 15 Round 2 QIs on a 9 point Likert scale for *importance*, *scientific soundness* and *feasibility*. Ratings of 7-9 were taken to indicate support of a measure, ratings of 4-6 ambiguity and ratings of 1-3 rejection, using the criteria of *importance* and *scientific soundness*.

In both Rounds, *feasibility* was given less weight in the analysis of the results. Panellists may have had only limited knowledge about data availability and comparability across different healthcare settings and countries, so their assessment of probable *feasibility* was subjective.

A rating of 7-9 was taken to indicate 'likely' *feasibility*, a rating of 4- 6 'possible' *feasibility* and a rating of 1-3 as 'unlikely' *feasibility*.

In total, seven indicators in Round 2 received a rating of 7-8-9 by $\geq 75\%$ Round 2 panellists for both *importance* and *soundness* and a rating of 7-8-9 by $> 50\%$ of panellists for *feasibility* and were taken to be robust Round 2 indicators.

QI rankings based on *importance*, *scientific soundness* and *feasibility* of the Round 2 survey results are available in Appendices 10a, 10b, 10c and 10d. The Round 2 candidate QI for Medication Regimen Review QI, in bold type in Appendix 10a was ranked first for all three criteria.

Eight Round 2 QIs were ranked *scientifically sound* by less than 75% of the Round 2 panel and did not become part of the 30 robust QIs identified following Round 1 and Round 2.

3.3.5.3 Round 2 Analysis

The mean, median, mode and SD for the Round 2 QIs are shown in Appendix 11. SD in Round 2 for *importance* ranged from 0.61 (Medication Review) to 2.25 (Advocate). This represents a high level of agreement in relation to importance for the Medication Review QI and a high level of disagreement for the *importance* of the Advocate QI. SD for *scientific soundness* ranged from 1.33 (Dental - Oral Health) to 2.73 (Inter - Intra class poly-pharmacy). SD for *feasibility* ranged from 1.685 (Infections) to 2.637 (Advocate).

The Round 2 panel made 40 comments on the 15 Round 2 QIs.

3.3.5.4 Robust Quality Indicators

Following Round 2, the candidate QIs that reached consensus in Round 1 were combined with the QIs that reached consensus in Round 2. These are considered to be Robust QIs and will be termed Robust QIs in the information that follows. The importance ranking of the Robust QIs is shown in Table 3.16.

This list of 30 Robust QIs that achieved consensus following Round 1 and Round 2 were sent to the Round 2 panel members for comment. A selection of the panellists' comments are available in Box 3.12.

Table 3.16 Importance Ranking of 30 Robust QIs

Ranking Based on Importance 30 Robust QIs (RQIs) that Achieved Consensus				
	<i>Abbreviated Quality Indicator</i>	<i>This QI is Important</i>	<i>This QI is Scientifically Sound</i>	<i>This QI is Feasible</i>
1	Medication Review	100.0%	91.7%	83.3%
2	Informational Transfer	96.4%	75.0%	83.0%
3	Communication	96.4%	78.6%	71.4%
4	As Required 'PRN' Psychotropic Medications	96.2%	76.9%	80.8%
5	Dementia Cholinesterase Inhibitors	95.8%	75.0%	75.0%
6	Pharmaceutical Care	95.8%	75.0%	58.3%
7	Dental-Oral Health	95.8%	79.2%	79.2%
8	General Health Review	92.9%	82.1%	75.0%
9	Restrictive Practices	92.9%	85.7%	75.0%
10	Excessive Dose Anti-Psychotic Medications	92.6%	85.2%	74.1%
11	Gradual Dose Reduction	92.6%	85.2%	74.1%
12	Dementia Anti-Psychotic Medications	92.6%	88.9%	77.9%
13	Pain	92.3%	76.9%	69.2%
14	Infections	91.7%	79.2%	79.2%
15	Geriatric Syndromes	91.7%	83.3%	58.3%
16	Non-Pharmacological Interventions	89.3%	78.6%	78.6%
17	External Environment	89.3%	75.0%	82.1%
18	Poly-Pharmacy	88.9%	85.2%	70.4%
19	Insomnia Treatment	88.9%	88.9%	76.0%
20	Psychotropic Medication Physical Side Effects	88.9%	77.8%	74.1%
21	Anti-Cholinergic Medication	88.9%	81.5%	77.8%
22	Anti-Depressant Medications Serotonin Syndrome	88.9%	81.5%	74.1%
23	Psychotropic Medication	88.0%	85.2%	77.8%
24	Medication Reconciliation	85.7%	78.6%	75.0%
25	Neuroleptic Side Effects	85.2%	81.5%	81.5%
26	Sleep Behaviour Disorder	85.2%	81.5%	74.1%
27	Dysphagia	85.2%	81.5%	80.8%
28	Dementia Cholinesterase Inhibitors and Anti-Cholinergic Medications	83.3%	83.3%	75.0%
29	Residential Care	78.6%	75.0%	71.4%
30	Adverse Drug Reactions	77.0%	77.8%	63.0%

Round 2 Panel Members Comments on 30 Robust Quality Indicators - Sample

Question 1....If you have any comments/observations to make on the final set of Quality Indicators please do so in the box below

'Dear researcher Having gone through this process I wonder whether you could be even more proscriptive and divide them more into categories Killer indicators - these are what every regulator is looking for - a bit like a core symptom - are there 3 or 4 indicators that everyone agreed were important High level indicators - next stage down - these are indicators that most people agree are probably important Medium level indicators - one you may want to consider if the ones above are not indicating there is a good performance.'

'The complexity of medical conditions experienced by persons with an intellectual disability presents a major challenge to the determination of standards.'

'It is disappointing to see that the feasibility of advocates is rated at 33.3% while its importance is rated at 83.83%. Having an advocate should be a cheap and easy service to provide when compared to the some of the other Quality Indicators. The expert panel perhaps do not view this as feasible to implement.'

Question 2..... If you have any general comments/observations to make on the Modified Delphi Technique process please do so in the box below

'It took quite a while to review them and I did wonder whether you might suffer some rater fatigue. It is likely that the ratings of the last ten may not have done as thoroughly as the first 10.'

If you wish to comment further please do so in box below

'All the Quality Indicators outlined appear of high clinical relevance, academic relevance for further research/exploration and practically of high importance.'

Box 3.12 Panel Members Comments on 30 Robust QIs – Sample

3.3.6. Survey Outcome

3.3.6.1 Response Rates

The validity of a Delphi study can be affected by response rates. As mentioned previously, the successive Delphi rounds can lead to fatigue with dropout of participants before the process is completed. High dropout rates may result in nonresponse bias where the final results are based upon the unrepresentative subsample of the original panel. In order to maintain rigour, a 70% minimum response rate should be achieved. In Round 2 of this project the response rate was 85.72% as seen in Table 3.15.

Response rates are used as a common metric for evaluating survey quality with the understanding that a higher response rate will produce findings that are more representative of the population of interest (Johnson and Wislar, 2012). The Journal of the American Medical Association in its *Instructions for Authors* section states that survey studies should have sufficient response rates (generally at least 60%) and appropriate characterization of non-responders to ensure that non-response bias does not threaten the validity of the findings. If there is more than one questionnaire, it is advised that the survey should report response rates for each questionnaire separately (AAPOR, 2011).

3.3.6.2 Participation Rates

The number of panel members who consented to participate in this two round survey, and the number who responded and who completed the survey, are known. The participation rate, which is defined as the number of respondents who have provided a usable response divided by the total number of initial personal invitations requesting participation can be calculated.

The participation rate may serve as a useful indicator of panel efficiency (AAPOR, 2011). Using a narrow definition of survey participants the Round 1 participation rate was 0.875 i.e. the number of respondents who provided a usable response, 28 divided by the number of panellists who consented to participate and who were sent the original survey 32.

The Round 2 participation rate was 0.096 and reflects the removal of the inactive Round 1 panel members from the panel for the Round 2 survey.

It is recognised that because of varying practices in panel management, the participation rate may have little utility as a comparative measure across panels (AAPOR, 2011).

3.3.6.3 Non-Response

Addressing non-response error is particularly critical when designing and conducting a Delphi study. This is because qualified subjects can be difficult to find and often the number of panellists can be small. Specifically identified persons in the sampling frame in this project were the sampling unit and only the named individual was the appropriate respondent e.g., another person who has replaced the respondent in healthcare/academic hierarchy was not acceptable in this email survey. This was queried by one potential participant following the issuing of the initial invitations but no proxies were allowed.

The Round 1 survey was sent via email to each of the 32 consented panellists. 28 panel members commenced Round 1 of the process and individually rated each indicator on a Likert scale of 1-9 for *importance, scientific soundness and feasibility*. The Round 1 survey was completed in full by 24 panellists. Responses were received in full for 14 of the 38 Round 1 QIs from the 28 Round 1 respondents.

The list of the original 32 Round 1 panel members and their email addresses was assumed to be accurate as the researcher had issued the invitations to participate in this project to each panel member using a valid current email address from which a response to the original invitation was received. As the list was both accurate and current at that time, it can be assumed that all those from whom 'no response' was received must be treated as non-respondents.

It must be remembered that email may be successfully delivered to the address, but never seen by the addressee because of spam filters, inboxes that are too full or other technical reasons. Nothing is known about whether the mailed questionnaire ever reached, or could have reached, the address and thus the person to which it was mailed in three of the four non response instances. These represent an 'unknown eligibility' subset of the panel. In the case of the fourth non-responder, the researcher made face to face contact with the panel member after the initial deadline who 'promised' to complete the survey. However this did not occur and so this panel member is represented by 'no returned questionnaire'.

3.3.6.4. *Partials*

In an Internet survey such as in this project, there are many levels of completion of the survey instrument. At one extreme, the respondent provides an answer to every one of the items and submits the completed questionnaire via the Internet. Some respondents may only get partway through the questionnaire and then, for various reasons, fail to ever complete it. These cases are typically referred to as - abandonments, break-offs, drop-outs or partials. Other respondents may read, or at least view, every question in the questionnaire and submit the instrument after reaching the final question, but decline to answer all of the questions. These may also be viewed as partials, or as completes with missing data (AAPOR, 2011). Partial became an issue after Q1 14 in Round 1 of this survey, Appendix 12.

Numerous outcome rates are commonly cited in survey reports and in the research literature. The same names are used to describe fundamentally different rates and different names are sometimes applied to the same rates. As a result, survey researchers are rarely doing things in a comparable manner and frequently are not even speaking the same technical language (AAPOR, 2011). Several response rates have been described in the literature. In this survey the minimum response rate is used. The minimum response rate, is the number of complete interviews divided by the number of interviews (complete plus partial) plus the number of non-interviews (refusal and break-off plus non-contacts plus others) plus all cases of unknown eligibility (unknown if housing unit, plus unknown, other) , Table 3.17.

Table 3.17 Survey Outcome Rates for Consented Panel Members

Survey Outcome Rates for Consented Panel Members		
	Round 1	Round 2
Participation Rate	0.875	0.096
Minimum Response Rate	0.781	0.857
Refusal Rate	0.219	0.038

3.3.6.5 *Co-operation*

In the original efforts to recruit panel members some prospective panel members identified by the researcher and supervisor declined the invitation to participate as they felt that they did not have the expertise to partake in the panel. They were unable to cooperate.

3.4 Modified Delphi Technique Analysis: Stage 2

3.4.1 Introduction

Quality is complex and multidimensional. Too few Quality Indicators for medication use in people ageing with intellectual disability and behaviour disorders could risk the charge of oversimplification and neglect of unmeasured aspects of care; too many could confuse or lead to apathy in clinical use situations. Clusters of QIs around specific themes or dimensions of quality should encourage their application and increase their effectiveness in the care of people ageing with intellectual disabilities and behaviour disorders. On the basis that measures of quality, must of themselves, be of high quality, then *'less is more'* has been identified in terms of the numbers of QIs in this project.

With this philosophy in mind and with awareness of the suggestions from one panel member in Box 3.13 below, more rigorous criteria for consensus were established to differentiate the 30 Robust QIs that achieved consensus following Round 1 and Round 2. This was done with the view of producing a manageable list of QIs for use in practice and having 'levels' or 'grades' of QIs.

Panel Member's Comment on 30 Robust QIs

'Having gone through this process I wonder whether you could be even more proscriptive and divide them more into categories. Killer indicators - these are what every regulator is looking for - a bit like a core symptom - are there 3 or 4 indicators that everyone agreed were important.'

'High level indicators - next stage down - these are indicators that most people agree are probably important.'

'Medium level indicators - one you may want to consider if the ones above are not indicating there is a good performance.'

Box 3.13 One Panel Member's Comment on Robust QIs

The new criteria that was required for the inclusion of a Robust QI as a higher level QI in the final set was: A rate of 7-8-9 for *importance* and *scientific soundness* by $\geq 80\%$ Round 1 or Round 2 panel.

This new stricter criteria was in keeping with a project where 2 levels of criteria were used in two different rounds of a MDT (Shield et al., 2003) to identify a generic set of face valid Quality Indicators for primary care mental health services which reflect a multi-stakeholder perspective and can be used for facilitating quality improvement, Box 3.14.

Example of Different Criteria in One MDT
Round 1: 60% or more of ratings within a panel fell within the region 7-9.
Round 2: 75% or more of ratings within a panel fell within the region 7-9.

Box 3.14 Example of Different Criteria in One Modified Delphi Technique

Figure 3.1 at the start of this chapter illustrates the process undertaken for this MDT.

3.4.2 Cross Tabulation

Cross tabulations are a quantitative research method appropriate for analysing the relationship between two or more variables, for example *importance* and *scientific soundness* in this project. Cross tabulations are data tables that present the results of the entire group of panel members, as well as results from sub-groups of survey respondents. Cross tabulations enable examination of the relationships within the data that might not be readily apparent when analysing total survey responses.

Cross tabulation of *importance* and *scientific soundness* for the 30 Robust QIs (Table 3.18) identified 16 QIs that met these stricter criteria for identification as possible Higher Level QIs.

Table 3.18 Cross Tabulation 30 Robust Quality Indicators: Importance v Scientific Soundness

30 Robust Quality Indicators Cross Tabulation Importance v Scientific Soundness						
					≥ 95%	Scientific Soundness Rating by Panel of Expertise
				QI 10	90-94.9%	
		QI 16, QI 34 QI 18	QI 13, QI 25 QI 26, QI 31		85-89.9%	
	QI 32	QI 20, QI 23 QI 21, QI 33 QI 28	QI 3 QI 4		80-84.9%	
QI 9 QI 15		QI 5, QI 6 QI 19, QI 10	QI 35 QI 36	QI 1, QI 2 QI 30 QI 7 QI 38, QI 27	75-79.9%	
75-79.9%	80-84.9%	85-89.9%	90-94.9%	≥ 95%		
Importance Rating by Panel of Expertise						
<i>Example: ≥ 95 % of panel of expertise rated QI 10 important and between 90-94% of panel of expertise rated this QI as scientifically sound</i>						

The grey area shaded in Table 3.18 visually represents the 16 Robust QIs that were rated by 80% or more of the Round 1 or Round 2 panel to be *important* and *scientifically sound*. These higher level QIs are identified in Table 3.19.

Table 3.19 Robust Quality Indicators: Rated by > 80% Panel Members as Important and Scientifically Sound

Robust Quality Indicators: Rated by > 80% Panel Members as Important and Scientifically Sound	
1	QI 12 Medication Review
2	QI 3 General Health Review
3	QI 13 Restrictive Practices
4	QI 25 Excessive Dose Anti-Psychotic Medication
5	QI 26 Gradual Dose Reduction
6	QI 31 Dementia Anti-Psychotic Medications
7	QI 4 Geriatric Syndromes
8	QI 16 Poly-Pharmacy
9	QI 34 Insomnia Treatment
10	QI 20 Anti-Cholinergic Medications
11	QI 23 Anti-Depressant Medications - Serotonin Treatment
12	QI 18 Psychotropic Medication
13	QI 21 Neuroleptic Side Effects
14	QI 33 Sleep Behaviour Disorder
15	QI 28 Dysphagia
16	QI 32 Dementia Cholinesterase Inhibitors and Anti-Cholinergic Medications

To ensure that it would be feasible to apply these 16 QIs, the list was cross tabulated with *feasibility* as rated by the Round 1 or Round 2 panel of expertise. The new stricter criteria for acceptance was that $\geq 70\%$ of the Round 1 or Round 2 panel rated the QI to be *feasible*, Table 3.20. The 15 Robust QIs, shaded in Table 3.20, fulfilled the new criteria.

Table 3.20 Robust Quality Indicators Cross Tabulation: Importance and Scientific Soundness versus Feasibility

Robust QIs Rated Important and Scientifically Sound by > 80% Members of Panel of Expertise	Feasibility Rating by % R1 or R2 Panel
	>95%
	90-94.9%
	85-89.9%
QI 12, QI 21, QI 28	80-84.9%
QI 3, QI 13, QI 31, QI 34, QI 20, QI 18, QI 32	75-79.9%
QI 25, QI 26, QI 16, QI 23, QI 33	70-74.9%
	65-69.9%
	60-64.9%
QI 4	55-59.9%

3.4.3 Quality Criteria

It is important that quantitative measures of quality are capturing meaningful information and that any problems with the measures in use will be identified. It is better to measure a few important dimensions of quality well than to measure a limitless number less optimally (Walter et al., 2004). To identify the quality criteria represented by the 15 QIs that met the new criteria, they were categorised in relation to quality criteria in Table 3.21 below.

Two Higher Level QIs related to similar issues: Insomnia (QI 34) and Sleep Behaviour Disorder (QI 33). It was decided to develop one QI that would take account of the both of these issues. This resulted in a final list of 14 Higher Level QIs, Table 3.21.

Table 3.21 14 Higher Level Quality Indicators and Quality Criteria

Stage 2 - Fourteen Higher Level Quality Indicators and Quality Criteria
Patient Experience/Access to Care/Continuity of Care/Equity
Medication Review General Health Review Restrictive Practice
Patient Safety/Effectiveness
Excessive Dose Anti-Psychotics Gradual Dose Reduction Poly Pharmacy/Multiple Medication Use Anti-Cholinergic Medication Anti-Depressant Medication Psychotropic Medications Neuroleptic Side Effects Dysphagia
Appropriateness/Assessment
Dementia Anti-Psychotic Medication Insomnia Treatment and Sleep Behaviour Dementia Cholinesterase Inhibitors – Anticholinergic Medication

The Round 1 and Round 2 panel rating of these 14 QIs was then examined and it was noted that the *importance* rating these QIs achieved ranged from 83.3% to 100%, Table 3.22.

Table 3.22 Higher Level Quality Indicators Importance Rating by Panel

Higher Level Quality Indicators and Quality Criteria	% of Panel that Rated this QI Important
Patient Experience/Access to Care/Continuity of Care/Equity	
Medication Review	100.0% R2 panel
General Health Review	92.9% R1 panel
Restrictive Practice	92.9% R1 panel
Patient Safety/Effectiveness	
Excessive Dose Anti-Psychotics	92.6% R1 panel
Gradual Dose Reduction	92.6% R1 panel
Poly-Pharmacy/Multiple Medication Use	88.9% R1 panel
Anti-cholinergic Medication	88.9% R1 panel
Anti-depressant Medication	88.9% R1 panel
Psychotropic Medications	88.0% R1 panel
Neuroleptic Side Effects	85.2% R1 panel
Dysphagia	85.2% R1 panel
Appropriateness/Assessment	
Dementia Anti-Psychotic Medication	92.6% R1 panel
Insomnia Treatment and Sleep behaviour	88.9% and 85.2% R1 panel Average: 87.05%
Dementia Cholinesterase Inhibitors – Anticholinergic Medication	83.3% R2 panel

Only two of the Round 2 survey QIs were incorporated into the list of Higher Level QIs. The Medication Review QI was rated by 100% of the Round 2 panel as being *important*. The Dementia Cholinesterase and Anticholinergic Medication QI was rated by 83.3% of the Round 2 panel as *important*.

3.4.4 Crucial or ‘Killer’ Quality Indicators

When given the opportunity to comment on the original list of 30 Robust QIs, one panel member made the suggestion in Box 3.13 above that ‘Killer’ indicators be identified.

To identify these ‘Killer or ‘Crucial’ indicators stricter criteria were now set. It was decided that ‘Crucial/Killer indicators’ were those Higher Level QIs that achieved a

rating of 90% or more for *importance* by either the Round 1 or Round 2 panel, Table 3.23 (Flood and Henman, 2015c).

Table 3.23 Crucial or ‘Killer’ Quality Indicators

Crucial or ‘Killer’ Quality Indicators	
Rated by More than 90% Round 1 or Round 2 Panel as Important	
Patient Experience/Access to Care/Continuity of Care/Equity	
Medication Review	100.0% R2 panel
General Health Review	92.9% R1 panel
Restrictive Practice	92.9% R1 panel
Patient Safety/Effectiveness	
Excessive Dose Anti-Psychotics	92.6% R1 panel
Gradual Dose Reduction	92.6% R1 panel
Appropriateness/Assessment	
Dementia Anti-Psychotic Medication	92.6% R1 panel

Following discussions between the researcher and supervisor it was decided to use the term ‘Crucial’ QI rather than ‘Killer’ QI as the use of the term ‘Killer’ might be confusing in healthcare and social care settings. The mean, standard deviation and median for the six ‘Crucial’ QIs is shown in Table 3.24.

Table 3.24 Crucial Quality Indicators, Mean, Standard Deviation and Median

Crucial Quality Indicators					
Abbreviated Title	% of Panel Rated this QI Important	Mean	Standard Deviation	Coefficient Of Variation	Median
Medication Review	100.0%	8.75	0.61	0.06948	9
Health Review	92.9%	8.54	1.14	0.13325	9
Restrictive Practice	92.9%	8.50	1.17	0.13776	9
Excessive Dose Antipsychotics	92.6%	8.44	1.19	0.14076	9
Gradual Dose Reduction	92.6%	8.37	1.15	0.11947	9
Dementia Antipsychotic Medication	92.6%	8.30	1.24	0.16319	9

The median for all 6 was 9. The narrowest variation in response was achieved by the Medication Review QI and the widest variation by the Dementia Antipsychotic Medication QI. The coefficient of variation is smallest for the Medication Review QI, showing great uniformity with respect to the mean and agreement among the sample. The coefficient of variation was widest for the Excessive Dose Antipsychotics QI.

A flow chart of the MDT process that resulted in the identification of the Crucial QIs is available below in Figure 3.3.

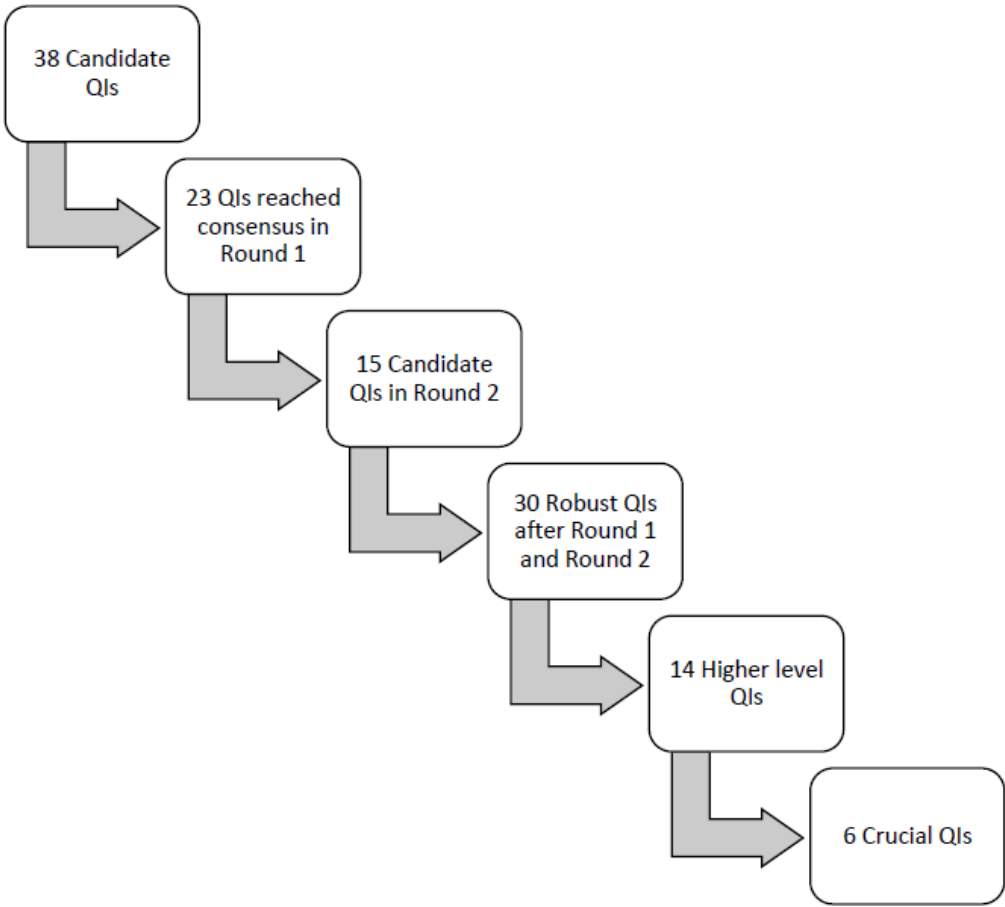


Figure 3.3 Process Leading to Crucial Quality Indicator Identification

3.4.5. Grading of Quality Indicators

No candidate QI was rejected in this Delphi process. The breakdown of the graded QIs is as follows:

- 1) Crucial QIs – 6, Table 3.23
- 2) Grade 1 QIs – 8, Table 3.25
- 3) Grade 2 QIs – 1, Table 3.26
- 4) Grade 3 QIs – 14, Table 3.26
- 5) Grade 4 QIs – 8, Table 3.26

Table 3.25 Grade 1: Quality Indicators - Eight

8 GRADE 1 Quality Indicators - Quality Criteria	Rated by more than 80% and <90% R1 or R2 panel as Important
Patient Experience/Access to Care/Continuity of Care/Equity	
Patient Safety/Effectiveness	
Poly-Pharmacy/Multiple Medication Use	88.9% R1 panel
Anti-Cholinergic Medication	88.9% R1 panel
Anti-Depressant Medication	88.9% R1 panel
Psychotropic Medications	88.0% R1 panel
Neuroleptic Side Effects	85.2% R1 panel
Dysphagia	85.2% R1 panel
Appropriateness/Assessment	
Insomnia Treatment and Sleep Behaviour	88.9% and 85.2% R1 panel Average: 87.05%
Dementia Cholinesterase Inhibitors – Anticholinergic Medication	83.3% R2 panel

The final graded list of QIs with the related quality criteria is available in Table 3.26.

Table 3.26 Graded Quality Indicators

Quality Indicators n = 37 2 Candidate QIs Combined during MDT Process	Panel Rating
<p style="text-align: center;">Crucial QIs</p> <p>Medication Review General Health Review Restrictive Practice Excessive Dose Anti-Psychotics Gradual Dose Reduction Dementia Anti-Psychotic Medication</p>	<p>90% or more of panel rated important 80% or more of panel rated scientifically sound 70% or more of panel rated feasible</p>
<p style="text-align: center;">Grade 1 QIs</p> <p>Multiple Medication Use/Poly-Pharmacy Anti-Cholinergic Medication Anti-Depressant Medication Psychotropic Medications Psychotropic/Neuroleptic Side Effects Dysphagia Insomnia Treatment and Sleep Behaviour Dementia Cholinesterase Inhibitors – Anticholinergic Medication</p>	<p>80% of panel rated important and scientifically sound 70% or more of panel rated feasible</p>
<p style="text-align: center;">Grade 2 QI</p> <p>Geriatric Syndromes</p>	<p>80% or more of panel rated important and scientifically sound 50% or more of panel rated feasible</p>
<p style="text-align: center;">Grade 3 QIs</p> <p>Informational Transfer Communication Medication Reconciliation Residential Care Pharmaceutical Care/Pharmacist Non-pharmacological Interventions External Environment Dementia Cholinesterase Inhibitors Dental-Oral Health Pain Infections As Requires 'PRN' Psychotropic Medications Psychotropic Medication Physical Side Effects Adverse Drug Reactions</p>	<p>70% or more of panel rated important and scientifically sound 50% of panel rated feasible</p>
<p style="text-align: center;">Grade 4 QIs</p> <p>Acute Behaviour Advocate Covert Administration of Medication Inter-Intra-class Psychotropic Multiple Medication Use/Poly-Pharmacy Anti-Epileptic Medications Off Label Psychotropic Medications Gastro-intestinal Disorders Autism Spectrum Disorder</p>	<p>Importance: rates R2 panel 57%-96% Scientific soundness: rates R2 panel 50%-79% Feasibility: rates R2 panel 33%-75%</p>

3.5. Discussion

3.5.1 Background

The rationale for the use of this MDT to develop Quality Indicators for medication use in people ageing with intellectual disability and behaviour disorders is that RCTs, which are the “gold standard” for evidence-based medicine, often are either not available in this population group or cannot provide evidence at a level of detail sufficient to apply to the range of patients with intellectual disabilities and behaviour disorders seen in everyday clinical practice by psychiatrists, pharmacists, other healthcare clinicians and service providers (Flood and Henman, 2015c).

The MDT process has been used previously in healthcare situations. The first step in this MDT was a narrative literature review designed to review and synthesise the literature on quality and medication use in the population ageing with intellectual disabilities and behaviour disorders. The literature review confirmed that the medication use process in this population is very complex. To measure quality we need Quality Indicators which are explicitly defined and measurable items referring to the structures, processes or outcomes of care. They infer a judgement about the quality of care provided. The literature review identified thirty eight candidate Quality Indicators representing various dimensions of quality, Table 3.2.

3.5.2. Modified Delphi Process

This Modified Delphi process consisted of a pilot round, two email rounds and feedback for comment on the final robust Quality Indicators. Twenty-eight panel members participated in the first email round and twenty-four panel members in the second email round. Consensus was achieved following Round 1 and Round 2 of this MDT. The participants in the Delphi study brought a wide range of direct knowledge and experience to the decision-making processes.

The draft questionnaire was sent for pilot testing to two external experts and the survey structure and format were edited based on their replies. The final Round 1 Survey Monkey questionnaire used a 9-point Likert-scale, in which written labels were used for all categories. The panel members were asked to rate the QIs under three criteria - *importance*, *scientific soundness* and *feasibility*. The replies to the statements on a 9-point Likert scale, under *importance* and *scientific soundness* were grouped into three sub-categories for analysis (1 to 3 - rejection i.e. total disagreement, 4 to 6 - ambiguity

i.e. neither agree/nor disagree and 7 to 9 - support i.e. completely agree. The three sub-categories for analysis for *feasibility* were 1 to 3 - unlikely i.e. total disagreement, 4 to 6 - possible i.e. neither agree/nor disagree and 7 to 9 - likely i.e. completely agree.

Consensus in this project was defined as 75% or more of replies falling either in the 7-8-9 i.e. completely agree for *importance* and *scientific soundness* and 50% or more for *feasibility*. The written comments (qualitative data) provided by the respondents were individually analysed. The response rate was 87.5% to the Round 1 questionnaire. The questionnaire for Round 2 was based on the results and comments received in Round 1. The panel members made 132 comments during Round 1 of this MDT. Questions which had reached consensus in Round 1 were excluded from Round 2. The Round 2 panel consisted of those 28 Round 1 panel members who started the Round 1 survey. The 15 QIs indicators that had not reached consensus in Round 1 were returned to the panel, for reconsideration in Round 2. The two MDT rounds produced consensus among the panel of expertise for 30 of the original 38 QIs. No candidate QI was rejected. Details of the final 30 robust QIs were fed back to the Round 2 panel. Few comments were received.

Stricter criteria were applied to the 30 QIs that reached consensus to differentiate their position in the hierarchy of QIs. A flow chart describing the process is available as Figure 3.1. Following this process six Crucial QIs were identified. These QIs were identified as *important* by 90% or more of the panel, as *scientifically sound* by 80% or more of the panel and *feasible* by 70% or more of the panel.

Panel members were guaranteed that no comment would be attributed to any one individual. At the end of the process permission to publish their names was received from the majority of the panel members, Appendix 13.

3.5.3 Validity of Quality Indicators

Indicators selected via consensus methods such as the Delphi procedure have high face validity, which is a prerequisite for any quality indicator. The original 32 member panel who consented to participate in Round 1 consisted of five pharmacists, four psychiatrists and one psychiatric registrar, four psychologists and one trainee psychologist, and other clinicians, with one Health Service Executive employee, one Health Information and Quality Authority employee and one medical school lecturer. In this project 28 of the 32 consented panel members started Round 1 of the survey and 24 of the 28 Round 2 panel started Round 2.

Internal validity exists when sufficient scientific evidence is present such that the measured variable is helpful for the quality assessment of health care aspects. The Round 1 panel supported the *scientific soundness* of 23 of the Round 1 candidate QIs. In Round 1 only 15 candidate QIs were rated 7-8-9 for *scientific soundness* by less than 75% of the R1 panel. The internal validity depends on the integrity of the study design and is a prerequisite for the applicability of the study results in routine care.

External validity is present, when by comparison of the measurement and the given reference ranges, the medical care of the target group, people with intellectual disabilities and behaviour disorders and their outcomes are improved. The external validity relates to the transferability and applicability of the results of the MDT to patients with intellectual disabilities and behaviour disorders in routine care. This is for further evaluation.

3.5.4 'Experts' by Experience

In Chapter 4 of this PhD thesis, data from interviews with six people with intellectual disabilities is presented. People with intellectual disabilities were interviewed to gain an understanding of their views and knowledge of medication use as they are the real 'experts' by their life experience.

Research conducted in the general population suggests that clinicians and researchers may not realise that certain outcomes are very important for patients. The perspective of patients is now routinely incorporated into the work conducted by OMERACT (Outcome Measures in Rheumatology) which is an independent initiative of international health professionals interested in outcome measures in rheumatology. (Sinha et al., 2011). This is reflected by the inclusion of people with intellectual disabilities as 'experts' in the medication use process in Chapter 4 of this thesis.

3.5.5 Advantages of this Modified Delphi Process

Advantages of using a Modified Delphi Technique in this project were:

- Panel members were anonymous which prevented mutual influence and ensured that clinicians 'higher up' in the hierarchy in the medication use process for people with intellectual disabilities and behaviour disorders did not unduly influence the process.

- Communication via email removed geographical obstacles and took less time for the researcher and panel members. Information sent to participants via email was quick, which resulted in the high number of participants remaining with the process and having a positive effect on the results achieved. Panel members were able to contribute to the group communication process when it was convenient for them to do so.
- High level of professionalism of the members of the multidisciplinary panel that participated in this MDT study, exemplified through their prompt and thorough responses and the detailed and numerous comments provided. The comments and ratings provided by these experts from different clinical backgrounds were a good indication of the fact that the study was considered to be of high importance by the multi-disciplinary panel members and that the MDT process was also of high quality.
- The data distribution and gathering was achieved using Survey Monkey and email which functioned very well and provided an efficient and effective method.

3.5.6 Difficulties with Modified Delphi Process

- It is only when developing and managing the process that one understands the difficulties involved in the process.
- The results of this MDT offer a snapshot of expert opinion, at a particular time, which can be used to inform thinking, practice or theory. As such, the QIs developed in this MDT should be compared with other relevant evidence and guidelines in the field of intellectual disability. They should be validated with further research to enable findings to be tested against observed data to enhance their use in the medication use process in the population with intellectual disabilities and behaviour disorders.
- It is not clear for a researcher exactly how methodological rigour should be established as each Delphi study's design, sample and consensus process is unique.
- As in all other judgemental methods the MDT can produce false accuracy, reflecting errors introduced by the method.
- This MDT was resource consuming for both researcher and panel members from a time perspective. It was labour intensive from the researcher's, supervisor's and panel members' perspective requiring on going thought,

expertise and effort. The MDT was restricted to two rounds due to the labour and time intensity of each additional round.

3.5.7 Research Personnel

This project was carried out by a pharmacist who has worked for many years in a long term care setting with people ageing with intellectual disabilities in the Republic of Ireland. This project was supervised by an international expert and specialist in the area of Pharmacy Practice.

3.5.8. Dimensions of Quality

Quality is complex and multidimensional. Too few indicators of quality for the medication use process in people ageing with intellectual disability and behaviour disorders could risk the charge of oversimplification and neglect of unmeasured aspects of the medication use process in this vulnerable population. Having too many could confuse or lead to apathy in clinical use situations. Clustering these QIs around dimensions of quality should encourage their application and increase their effectiveness in the care of people ageing with intellectual disabilities and behaviour disorders. It is important that quantitative measures of quality in this population group capture meaningful information and it is better to measure a few important dimensions of quality well than to measure a limitless number less optimally (Flood and Henman, 2015c).

Desirable attributes of QIs are *importance*, *scientific soundness*, and *feasibility* and these were used in this project. Healthcare organizations providing care to people with intellectual disabilities would be expected to seek to maximise these attributes and also seek measures that are representative of the highly diverse health care systems in which this vulnerable population group receive health and social care. Dimensions of this diversity in this project include such domains of quality as patient experience, access to care, continuity of care and equity, patient safety and effectiveness and appropriateness and assessment, Table 3.2.

3.5.9 For the Future

Further research and guidance will be required to determine which QIs to include in a core set and how to measure them. Once core outcomes are agreed upon, potential instruments to measure them must be identified. A more detailed review of the possible

approaches to this question of how to measure the chosen outcomes is beyond the scope of this project but will be the basis for further study.

Medication use is a condition with high prevalence, morbidity and possibility for intervention in this population group. Management of behaviour disorders may include both pharmacological and non pharmacological interventions. There are many clinical settings across the continuum of care provided to people with intellectual disabilities and behaviour disorders. It must, of course, be recognised that there are tensions among those involved in the medication use process in this vulnerable population group, in the many settings in which care is provided. Further research will be necessary to determine any 'trade-offs' in measure selection that will be required.

3.6 Conclusion

The Delphi Method has been used when the complexity or ambiguity associated with a particular problem exceeds the intellectual capabilities of a single decision-maker or speciality group. The underlying assumption of this MDT is that the informed, collective judgment of a group of multidisciplinary 'experts' is more accurate and reliable than individual judgement. Effective decision-making in the medication use process in people ageing with intellectual disability and behaviour disorders is dependent on the knowledge and expertise of different disciplines. Process Quality Indicators are especially useful when quality improvement, in this case of the medication use process, is the goal of the measurement process. QIs can also explain why some service providers and clinicians achieve particular outcomes.

This was a successful Modified Delphi Process as it achieved consensus in the development of Quality Indicators for medication use in people ageing with intellectual disability and behaviour disorders. The QIs identified were *important, scientifically sound* and *feasible* to implement. It is the thought that this project is the first methodological study to assess a Modified Delphi Technique in developing Quality Indicators for use in people with intellectual disabilities and behaviour disorders. This project exemplifies some crucial issues in applying a Modified Delphi Technique to the identification of Quality Indicators for medication use. The major strength of the Modified Delphi Technique used was its ability to ascertain expert opinions on the process of medication use and the continuity of panel members from Round 1 to Round 2. A major weakness of this MDT was that the panel members represented only

two European countries. The use of pre-existing information to generate the original quality indicators increased the effectiveness of the Modified Delphi process.

CHAPTER 4

PEOPLE WITH INTELLECTUAL DISABILITIES AS 'EXPERTS BY EXPERIENCE' IN THE MEDICATION USE PROCESS

4.1 Introduction

The experience of all patients in healthcare is an accepted arm of quality. Patients say that they care about their experience of care as much as clinical effectiveness and safety (NHS, 2013). In recognition of this, people with experience of intellectual disability are contributing to Care Quality Commission inspections in the UK as 'experts by experience' (Salman, 2013). People with intellectual disabilities and their carers know the complexity of their needs and they alone know the real gaps in healthcare that can occur in services provided to them. Communicating these gaps may however present a problem.

Grounded Theory investigates their experience, the actualities in the real world and analyses the data with no preconceived ideas or hypothesis. This chapter describes a Grounded Theory Approach to interviewing people with intellectual disabilities to establish their views and knowledge of medication use.

4.2 Background

4.2.1 Communication

Communication is essential for the effective delivery of healthcare for people with intellectual disabilities. There is, however, often a mismatch between the healthcare clinician's level of communication and the level of comprehension of the person with intellectual disability or their carer. The role of communication in caring for a person with an intellectual disability is to ensure that the person and/or their carer provides that healthcare professional with the information the professional needs to formulate a treatment plan, and that the person with an intellectual disability and/or their carer has all the information required to follow the treatment plan. Improving health care communication reduces health care costs and increases the quality of health care. To obtain optimal health outcomes, people with intellectual disabilities and their carers may need healthcare access, health knowledge and some behaviour change.

4.2.2 Health Literacy

Health literacy, which is the ability to obtain, process and understand health information and services needed to make appropriate health decisions and follow

instructions for treatment (Committee on Health Literacy, 2004) is limited in the population with intellectual disabilities.

People with intellectual disabilities experience health inequalities and they and others with limited health literacy skills have poorer health status than the rest of the population. People with low health literacy have been found to be less likely to get influenza injections, to understand medical labels and instructions and to have an increased likelihood of taking medicines incorrectly compared with adults with higher health literacy (Bennett et al., 2009).

The healthcare environment in which people with intellectual disabilities receive care and are prescribed medication is increasingly complex. It has been suggested that some people with an intellectual disability face a situation of 'double jeopardy' where they are at risk of receiving second rate services from both the disability and health service because they are seen to be the primary responsibility of neither (Bland et al., 2003). In healthcare locations and situations, people with intellectual disabilities and/or their carer are often faced with complex information and treatment decisions. Some of the specific tasks people with intellectual disabilities and/or their carers are required to carry out in the medication use process may include:

- evaluating information on medication for credibility and quality,
- analyzing relative risks and benefits of any medication use,
- calculating dosages of medications e.g. insulin, liquid antibiotics,
- interpreting test results, e.g. blood sugar levels,
- locating accessible and appropriate medication and health information e.g. 'easy to read' medication leaflets.

In IDS-TILDA, which is a large scale nationally representative study of people with an intellectual disability aged 40 years and over in Ireland, more than half (56.5%) of participants reported they had never received 'easy to read' leaflets on keeping healthy and three quarters said they had never received 'easy to read' information leaflets on healthcare services (McCarron et al., 2011a).

Shared decision-making which is encouraged in many healthcare settings, is a process in which clinicians such as pharmacists and patients work together to decide about interventions based on clinical evidence and the patient's informed preferences (D&TB, 2012). This shared decision making will raise difficulties for people with intellectual

disabilities because in order to accomplish these tasks, the individual with an intellectual disability and/or their carer may need to be able to:

- understand graphs or other visual information,
- operate a computer,
- obtain and apply relevant information,
- calculate or reason numerically (National Network of Libraries of Medicine, 2014).

Seeking medical care, taking medications correctly and following prescribed treatments requires that people with intellectual disabilities and their carers understand how to access and apply health information. The results of a national health literacy survey in Ireland found that 17.5% of those surveyed (n=1005) had difficulty understanding medication leaflets (Doyle et al., 2012). This survey did not indicate any involvement of people with intellectual disabilities, although people with intellectual disabilities are not likely to meet current standards of health literacy.

Health literacy issues and ineffective communications place people with intellectual disabilities at greater risk than the general population of preventable adverse events involving medication use in healthcare. Oral language skills are important in health and social care for people with intellectual disabilities as patients need to articulate their health concerns and describe their symptoms or side effects of medication accurately. Pertinent questions must be asked by the person with intellectual disabilities and/or their carer, and they need to understand spoken medical advice, directions for taking prescribed medications or treatment directions. If a person with an intellectual disability and/or their carer does not understand the implications of the medical diagnosis and the importance of prevention and treatment plans, or cannot access health care services because of communications problems, a safety event may occur (The Joint Commission, 2007). If pharmacists and other healthcare staff can engage patients with intellectual disabilities and help them feel involved, they are more likely 'to hear' the advice they are given about medication and to act on it, so treatment is more effective and safer.

Pharmacists and others must be aware that people with limited literacy such as people with intellectual disabilities are less likely to:

- ask questions during a healthcare encounter,
- seek health information from print resources,
- understand medical and/or healthcare terminology and jargon (AHRQ, 2010b).

A number of studies have indicated that people with limited health literacy have difficulty understanding written information, including medication dosage instructions and warning labels, discharge instructions, consent forms for treatment and basic health information about diseases, nutrition, prevention and health services (AHRQ, 2010b). Health literacy difficulties can affect the person with intellectual disabilities understanding of healthcare advice, how to take medication in a correct and safe manner, how to participate in self care activities and how to make informed decisions about their healthcare.

People with intellectual disabilities are unlikely to seek information about their medication and if they are given information they are likely to experience difficulties with both understanding and remembering what has been told to them about their medication. Even if they do possess some information, people with intellectual disabilities may experience difficulties in communicating about side-effects of their medication and they may have difficulties reporting adverse effects such as 'blurred vision' or feeling 'dizzy'. It is also likely that carers may have only a limited knowledge of the medications which their clients are taking and of the possible side-effects (Arscott et al., 2010).

Too often, clinical services and programs are examined only on the basis of what matters most to the medical or other healthcare professionals. Their concerns may relate to reduction of symptoms. Service providers concerns may relate to costs. What matters most to people with intellectual disabilities and their carers may be functioning and quality of life. Currently, in Ireland, there is a dearth of research representing what is actually happening in the lives of people with intellectual disabilities in relation to medication use. Grounded Theory methodology, which will be used in this project, is particularly suited to looking at rarely explored phenomena where extant theory would not be appropriate.

4.3 Project

4.3.1 Aim of This Project

Gaining insight into vulnerable patient knowledge, understanding, views and perceptions on medication use are paramount to the practice of pharmacy and may be a potential starting point for pharmacists and others, to think of ways of improving care of vulnerable population groups such as the population with intellectual disabilities.

The aims of this qualitative study, using Grounded Theory, were to discover how informed the participants with intellectual disabilities (ID) are about their medication and to identify key factors relating to their experiences and understanding of the medication use process.

4.3.2 The Researcher

The skills and knowledge gained in the workplace by the pharmacist researcher facilitated good communication with people with intellectual disabilities. This ensured that the individual characteristics of the participants, the topic of the research project and any potential difficulties were considered and addressed in advance. This preparation was necessary to ensure the validity of the interviews and to ensure that the person involved in the interview was not demeaned (NFVB, 2005).

Following contact with a national support organisation this project was supported by the organisation. The Chief Executive Officer (CEO), Medical Director and Counsellor/ Drama-therapist agreed to facilitate the project once approval had been received from the Faculty of Health Sciences Ethics Committee, Trinity College. The organisation will not be identified in this thesis to protect the identity of the participants in the interviews. All possible identifying information will be removed from the relevant appendices.

4.3.3 Ethical Issues

Ethical issues in research relates to the protection of human participants to ensure the possibility of harm, anxiety, discomfort or trauma is absent or lessened. If any piece of research is to be representative, people, regardless of disability or other aspects of human diversity, should be equally eligible to participate as research subjects.

Qualitative research projects such as this project involve the concepts of relationships and power between researchers and participants. This research project therefore

followed the National Federation of Voluntary Bodies fundamental ethical principles for conducting research with people with intellectual disabilities. The four ethical principles (NFVB, 2008) guiding this research project with people with intellectual disabilities are:

1. Non-maleficence – the research must not cause harm to the participants with intellectual disabilities and to people in general.
2. Beneficence – the research should make a positive contribution towards the welfare of people with intellectual disabilities.
3. Autonomy – research must respect and protect the rights and dignity of participants with intellectual disabilities.
4. Justice – the benefits and risks of research should be fairly distributed among people.

4.3.3.1 Non-maleficence

During the interview process the Counsellor was involved to ensure that the participants were not physically or psychologically harmed. The Counsellor who was well known to the participants facilitated communication and interpretation during the interviews when necessary. Prior to the interviews it was agreed that in the event that a participant became distressed at any stage, the interview would be terminated and support sought from the Counsellor. It was not necessary to terminate any interview ahead of schedule.

The topic of medication use might be a difficult one for some of the participants. During the interviews they were all listened to attentively. Questions were posed in a caring manner with more probing questions were only used when it was deemed necessary.

It is common in qualitative research to use audio tape recordings to ensure that full attention is paid to the participant and to note non-verbal behaviour. However the support organisation did not allow audio taping of the interviews in this project. Therefore permission was sought and granted from the Faculty of Health Sciences Ethics Committee, Trinity College, solely for written recording of the interviews.

4.3.3.2 Beneficence

Beneficence is a fundamental ethical principle in research with the onus on researchers to minimise harm and maximise benefits for the participants themselves, other individuals or society as a whole. Researchers pledge to promote good, by

creating new knowledge or providing some benefit to subjects, when they accept public support for their work.

It was important to give consideration to maximizing the benefits and reducing the risks that might occur from this research investigation for the individual participant with intellectual disability. In this project it is thought that the benefits may accrue to the individual subjects or, through the development of generalized knowledge, to society, perhaps in the form of better health care for people with intellectual disabilities. Risks, however, are borne by individual subjects.

All the risks and benefits of this research project are not known. It is, however, justifiable to seek certain benefits despite the risks involved. During the process of informed consent the risks of participation in this research project were disclosed to the participants.

4.3.3.3 *Autonomy*

All participants in this project were given clear unambiguous information regarding the research project, Appendix 14a. They indicated that they understood the information and that the option to consent or decline participation was voluntary. Informed consent was sought from each participant individually. The participants were informed they have the right to withdraw from the study at any time.

The consent form was clear, concise and easy to read with no jargon, Appendix 14b. Each participant signed the consent form prior to each interview. A copy of the consent form signed by the participant and the researcher was posted to each participant after the interviews. The original signed consent forms will be stored in a locked press which only the researcher has access to.

Information was also supplied for the staff of the support organisation, Appendix 14c and the family/supporter of the person with intellectual disability, Appendix 14d.

4.3.3.4 *Justice*

Understanding and applying the principle of justice in this qualitative research study required recognition of the vulnerability of the participants and their contributions to the study.

This research proposal did not include a therapeutic component.

It was decided to include participants with intellectual disabilities less burdened than other classes of persons with intellectual disabilities, such as those people with intellectual disabilities residing in long term care. It is thought unfair that certain populations such as those with intellectual disabilities residing in long term care who are dependent on public health care constitute a pool of preferred research subjects if more advantaged populations such as those who live in the community, are likely to be the recipients of the benefits.

4.3.4 The Participants

People with intellectual disabilities can raise points of satisfaction or concern about their healthcare that are sometimes new ones. Their views and knowledge of medication use and the medication use process are of fundamental importance. Their experiences of the care that they receive in the medication use process may often be unknown. This is despite the fact, as illustrated in Chapter 2, that adults with intellectual disabilities have multiple comorbidities, are at a higher risk for health problems than the general population and medication use is the major therapeutic intervention in the population.

IDS-TILDA recognized that people with intellectual disabilities may wish to participate in research and are able to independently give consent (McCarron et al., 2009). In the project described in this chapter, participants with intellectual disabilities were those capable of giving consent for themselves.

The inclusion criteria for participation by people with intellectual disabilities in this project were as follows:

- person has an intellectual disability,
- known to the support organisation,
- taking medication,
- over 40 years of age preferably,
- who have agreed to participate in this project,
- with ability to communicate verbally,
- with capacity to consent for themselves to participating in this project.

The exclusion criteria were that people with intellectual disability were:

- not known to support organisation,
- not taking medication,
- who have not agreed to participate in this project.

4.3.5 Capacity and Consent

Participants in this project are those people with intellectual disabilities who have capacity to consent for themselves. 'Capacity to consent' has changed from a status approach towards a functional point of view over the recent past. A person gives consent if he/she agrees by choice, and has the freedom and capacity to make that choice. Asking a person to participate in this research project was an individual exercise and a voluntary decision in that the person was given to understand that they had a choice. They had the ability to say 'yes' and 'no' and to communicate their choice.

The following details were supplied to the Faculty of Health Sciences Ethic Committee, Trinity College:

- the purpose of the study and the purpose for seeking the person's participation,
- the procedures for obtaining the informed consent and included the identification of those responsible for obtaining this consent and the time frame in which it would occur,
- the written information to be given to the participants, their relatives and support organisation personnel,
- the content and wording of the informed consent form.

4.3.6 Pharmacist Researchers

Qualitative health research is focused on the experiences of people in relation to health and illness. Pharmacist researchers undertaking qualitative research can find that their roles as researchers and as clinicians may be in conflict. Once in the research field, pharmacists may experience ethical dilemmas or come across ethical issues that may not have been anticipated in the original research proposal or plan. Each research approach and every study has its own ethical implications.

4.4 Methodology

4.4.1 Background

The CEO and Clinical Director of a national voluntary organisation supporting people with intellectual disabilities indicated that the organisation would facilitate this project once permission for the project was granted by the University, Appendix 15a and 15b.

Application was initially made to the Faculty of Health Sciences Ethics Committee, Trinity College in February 2012 for permission to undertake this study. Numerous adjustments to the initial application were required over the following months. Final permission to undertake the project was granted in November, approximately nine months after the original application. Despite these ethical challenges this research project was pursued, as it has the potential to improve the lives of people with intellectual disabilities who are participants in the medication use process. Analysis of the results of a research project, that conducted individual interviews and focus groups with 16 adults with intellectual disabilities to examine their perspectives on participating in research, found that adults with intellectual disabilities want to engage in research to improve their quality of life and to have greater access to a worthwhile activity through more active participation (McDonald et al., 2013). The final application was approved by the Faculty of Health Sciences Ethics Committee, Trinity College, Appendix 16.

The principles of the Data Protection Acts of 1988 and 2003 (amendment) were adhered to in this research proposal. Pseudonyms were given to each participant in this project to reduce the risk of personal data being compromised.

All data will be stored in a locked safe. This storage will remain in place for the requisite time of one to five years, as this is in keeping with the recommendations of the Data Protection Acts. After this time, all electronic data will be overwritten and all manual data will be shredded, in accordance with the Data Protection Acts.

4.4.2 Interview Type

Individual semi-structured interviews were thought to be appropriate in this project as the topic of medication use is sensitive and respondents with intellectual disabilities may not have been willing to speak about some aspect of their experience of medication use in front of others. The semi-structured individual face-to-face interviews as used in this project were similar to structured interviews in that the topics or

questions to be asked were planned in advance, but instead of using closed questions, these semi-structured interviews were based on open-ended questions.

Each semi-structured interview allowed attention to be paid to non-verbal behaviour and allowed the establishment of a rapport over a period of time. The purpose of the interview was explained and the participant was thanked for their co-operation. Questions were clarified, any misunderstandings corrected, prompts offered, responses probed and new ideas followed up. Each face-to-face interview was very labour intensive. Each interview was also enriching and humbling.

One of the key determinants that directly influence the qualitative research process are the questions used to collect data and the questions asked of the data during the analysis. A practising pharmacist brought her own mix of theoretical, academic, professional and personal knowledge into the particular research field.

4.4.3 Recruitment of Participants

The CEO, Clinical Director and a senior staff member of a national support organisation for people with intellectual disabilities were contacted in an effort to generate potential interviewees. This approach had the advantage that it appeared to provide a good supply of possible research participants with verbal communication skills. However, it is recognized that this approach may have led to bias if the selection by staff members in the organization was based on their judgment of who was appropriate to participate.

Information in an accessible form and consent forms were distributed by the staff member to people with intellectual disabilities who were known to the support organisation. Information was also supplied for the family/supporter of the person with intellectual disability and the staff of the support organisation, Appendix 14c. Contact details for participants who wished to ask further questions were supplied on the information form. Only one family member made direct contact prior to the interviews.

Six people with intellectual disabilities agreed to participate in this research project and signed consent forms prior to the interviews, which were held on three separate days in two locations.

4.4.4 The Interview Process

Qualitative research involves the collection of detailed, rich and complex data, and aims to generate in-depth understanding and explanation of processes and situations. It was decided not to use focus groups in this project due to the possible sensitivity of the issue of medication use. Semi-structured interviews were the format used in this project as a primary data gathering method to collect information from individuals with intellectual disabilities about their own practices, beliefs or opinions around aspects of the medication use process. The semi-structured interviews could also be used to gather background information or to tap into the expert knowledge of an individual with intellectual disability in relation to medication use.

The informed consent of each person with intellectual disability was obtained prior to any involvement in this research process. When meeting each participant, the researcher clearly identified herself and established a good rapport with the participant, using incidental conversation to break the ice (for example transport methods, weather) before starting the interview proper. The participant was encouraged to trust and share accurate information on medication and the medication use process.

4.4.5 The Interview Tool

Up to 80% of people with an intellectual disability have communication difficulties with 50% having significant difficulties. Verbal over-loading in some interview tools pose challenges for people with intellectual disabilities and limited verbal skills. A semi-structured interview schedule was used to guide the interviews with the participants. Previous literature regarding the knowledge that people with intellectual disabilities have about their health and medication (Crossley and Withers, 2009) and the literature review described in Chapter 2 assisted with compiling the categories of questions for the tool. The participants were asked open questions that included questions around administration, type and name of medication and side effects.

The semi-structured interview questions were phrased as simply as possible using concrete concepts and were pitched at a level that would facilitate understanding by the participant with an intellectual disability. The sentences were kept short and each sentence dealt with only one topic. Each question was set to have a short answer. The tool is available in Appendix 17.

4.4.6 The Interview Procedure

At the start of each interview:

- The project was described to the participant including the benefits for them as participants and the discomforts/risks/inconveniences, if any, involved.
- No undue pressure was placed on the individuals in order to ensure their participation. There would be no negative consequences for those that refused to participate. The consent of the person with intellectual disability was genuinely voluntary.
- Confidentiality and anonymity were explained.
- The right of the participant to refuse to participate or to continue to participate at any stage of the interview was highlighted.
- The on-going process nature of consent was explained.
- How the information would be collected i.e. by note-taking during the interviews was explained.
- Participants were facilitated to consider their decision in a full, free and informed manner to continue to review the consent process in all its stages.
- What would happen with the findings of the project was explained.
- Participants were reminded that the counsellor, who was known to them, was available to support them during the interview if they desired.

The researcher must be able to engage with the interviewees in a setting that is relaxed and familiar to them, free from distractions and conducive to a conversation to allow the participant to talk freely about possibly emotional and confidential matters.

The interviews in this project took place in the accommodation of the support organisation familiar to each participant.

4.4.7 Interview Recording

The interviews in this project were not audio or video recorded as this was not allowed by the support organisation. This fitted well with the use of Grounded Theory in that Glaser does not encourage the use of tape recording (Glaser, 1998) when using Grounded Theory. Glaser contends that recording is unnecessary because the researcher is after important concepts and patterns, not precise 'word-for-word'

accounts as in other more descriptive methods. The actual words spoken are therefore not highly significant, as they are part of a process and are not required for conceptualisation purposes. Recording can also be time consuming and inefficient as tapes are often taken to be transcribed and then corrected with resultant analysis of many non-important parts.

Written notes taken during the interviews were compiled and the resultant document was sent to the counsellor who had been present at each interview, for confirmation that they were an accurate representation of what was said at each interview, Appendix 18. The counsellor confirmed the accuracy of the document. The accuracy of the notes may reflect the sensitivity of the researcher who has professional experience of the population and knowledge of the field under study, which is medication use.

4.4.8 After the Interview

Sufficient time at the end of the interview was provided to allow the participant with an intellectual disability to ask any questions they had. All questions and answers were clarified with the participant to ensure understanding of the question by the participant and understanding of the answer by the researcher. Participants were provided with contact details following the completion of the interview to facilitate clarification of any other concerns that they might have a later time. No contact was made.

Following each interview a copy of the signed consent form and a 'Thank You' card was posted to each participant.

An accessible information sheet for participants showing the results of the interviews was prepared, this is available as Appendix 19. This was given to the counsellor to confirm the language used was accessible to the participants and that the document was accurate. The counsellor confirmed the accessibility and accuracy of the participant information document.

Participants were invited to inform the researcher if they had any concern with the information in the participant information document or if they suggested any changes. There was no request for changes.

A second card was sent to each participant thanking them again for their participation in this research project.

Early project results were presented at the IASSIDD Scientific Conference in Vienna in 2014. The abstract was sent to the CEO, Clinical Director and the Counsellor of the support organisation with a copy of the participant accessible information.

4.5 Data Analysis

4.5.1 Grounded Theory

4.5.1.1 Background

The current focus of Irish service delivery when working with and for people with intellectual disabilities is Person Centred Planning (PCP). PCP has been defined by the National Disability Authority (NDA, 2011a) as a way of discovering:

- how a person wants to live their life,
- what is required to make that possible.

Grounded Theory methodology fits comfortably with some of the principles of person centred planning, as it focuses on explaining the person's main issue of concern and how the person continually resolves this concern. Grounded Theory, which was used to analyse the interviews in this project, allows the generation of new theory from data, as opposed to testing existing theory.

Grounded Theory is

'an inductive theory discovery methodology that allows the researcher to develop a theoretical account of the general features of the topic, while simultaneously grounding the account in empirical observation of data' (Glaser and Strauss, 1967).

It is a qualitative research design which allowed for flexibility in this project, and for decision-making to take place as the research process proceeded. Grounded Theory aims to enquire and state how participants interpret reality and is attentive to how theory emerges from the subjective experiences of the participants. Data generation in this project showed that participants provided additional direct and indirect data next to the data gathered through semi-structured interviews, which was the main source of data. This additional data included lists of prescribed medications in three interviews, 'brown bag' medication and emotional impact of diagnosis and life situations.

Everything is data to the grounded theorist which allows the flexibility of utilizing different data sources.

4.5.1.2 Data Collection

The Grounded Theory approach used in this project was a ‘package’ of research methods that included the use of concurrent data collection and constant comparative analysis, theoretical sampling and memoing. These methods were an integral part of the systematic and rigorous research approach of Grounded Theory and were not ‘add ons’ (Elliott and Lazenbatt, 2005).

Table 4.1 Criteria for Assessing Quality of Grounded Theory Research

Criteria for Assessing Quality of Grounded Theory Research	
Original Criteria	Strauss and Corbin’s Criteria
<ul style="list-style-type: none"> • Fit • Work • Relevance • Modifiability (Glaser, 1998)	Two sets of criteria <ul style="list-style-type: none"> • Research process • Empirical grounding of findings (Strauss and Corbin, 1998, Corbin and Strauss, 1990)

Grounded Theory highlights the importance of developing an understanding of human behaviour through a process of discovery and induction rather than from the more traditional quantitative research process of hypothesis testing and deduction. No extensive literature review was undertaken prior to this study because pre-conceptualising the problem, theoretical framework, or concepts that would follow from extensive literature review would have the potential to contaminate the emerging theory. The literature was treated like another source of data and was woven into the theory in the constant comparative process.

Semi-structured interviews were chosen for data generation, due to the explorative nature of the study and good access to research participants. Participants were selected based on their ‘expertise’, because they met the inclusion criteria for this project, and were willing to participate. The complexity of the data generated here varied among the participants.

The interviews were transcribed and analysed using the Grounded Theory approach. Working for fourteen years as a pharmacist with adults with intellectual disabilities provided a knowledge base that gave credibility when analysing and interpreting the

data. This professional knowledge and experience allowed a deeper insight into the issues discussed by the participants of the research. It is acknowledged that the attitude towards the investigated topic is shaped by professional experience and influences the way the data is seen and heard. In this exploratory qualitative study, the data was carefully read and reread following the interviews to look for trends, themes or ideas.

Each researcher's level of theoretical sensitivity (Glaser and Strauss, 1967) is deeply personal and reflects the researcher's level of insight into both herself and the area that she is researching. The level of theoretical sensitivity exhibited will reflect intellectual history, the type of theory that has been read, absorbed and is now used in day to day thought processes. All researchers are a sum of all they have experienced and this is acknowledged and accounted for in this research project. It is expected that as a grounded theorist becomes immersed in their research data, their level of theoretical sensitivity to analytical possibilities will increase.

Memoing is a significant component of the Grounded Theory methodology. Throughout the study, case-based memos and conceptual memos were used. After each interview, a case-based memo that reflected on what was learned from that interview was prepared. They contained impressions about the participants' experiences and the researcher's reactions. They were also used to systematically question some pre-existing ideas in relation to what had been said in the interview. A sample of the memos are detailed over the following pages.

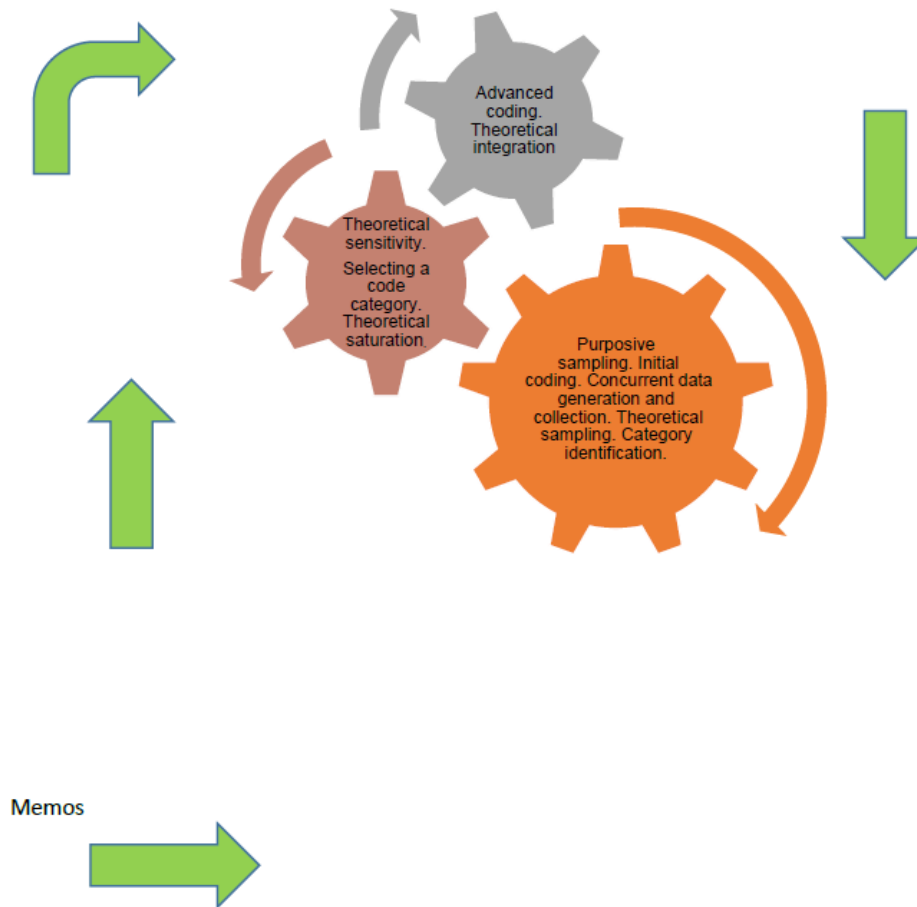


Figure 4.1 Essential Grounded Theory Methods

In Figure 4.1 writing memos lubricate the cogs as they rotate around each other.

4.5.1.3 Participants

Six people with intellectual disabilities supported by a national voluntary support organisation consented to participate in this research project. Three participants were male and three were female. Two were younger than 30 years of age and four were aged between 30 and 35 years. No participant who consented was over 40 years of age which was one of the original criteria for participation. However, due to the difficulties of having access to a population group who fully met the criteria, it was decided that the research project would continue with those participants who consented to participate.

All were very personable and pleasant interviewees and they appeared to be happy to participate in the process. Their knowledge of their medication varied from moderate in the main to very little. Pseudonyms are used throughout the following pages.

Pat was identified as the index case in the analysis and his situation is analysed in detail in the information that follows. Raw data only for the other five participants is presented in the following sections.

Table 4.2 has tabulated information provided by the six participants.

Table 4.2 Participant Information

Participant Information - Not their real names - * = 'as required'/'prn'						
Participant	Pat	Alex	Keelan	Gabrielle	Jamie	Frances
Lives at Home with Parents	Yes	Yes	Yes	Yes	Yes	Yes
Age Group	30-35	25-30	30-35	20-25	30-35	30-35
Gender	Male	Male	Male	Female	Female	Female
Home Address	Outside Dublin	Outside Dublin	Outside Dublin	Outside Dublin	Dublin area	Dublin area
Diabetic	Yes	No	No	No	Yes	No
Prescribed Medications	Yes	Yes	Yes	Yes	Yes	Yes
Insulin Injections	Yes	No	No	No	Yes	No
Oral Hypo-glycaemics	0	0	0	0	Glucophage [®]	No
Eltroxin	Yes	No	No	Yes	No	No
Antidepressant	No	Lexapro [®]	No	No	No	No
Antipsychotic	No	Stelazine [®]	No	No	No	Abilify [®]
Gastrointestinal	Nexium [®]	0	0	0	0	0
Cardiovascular	Coversyl [®]	0	Aspirin	0	Cozaar [®]	0
Gout	0	Allopurinol	Purinol	0	0	0
Hypnotic	0	Zimovane [®] 7.5*				
Anti-diarrhoeal	Imodium	0	0	0	0	0
Non-Prescription Medications	Yes	No	Yes	Yes	No	Yes
Analgesic	Solpadeine ^{®*}	0	0	0	0	Feminax ^{®*}
Vitamins/ Minerals etc	No	No	Vit B+C Zinc	Vit B Cod Liver Oil	No	No
Anti-diarrhoeal	Arret ^{®*}	No	No	0	No	No
Skin	0	0	0	Moisturisers	0	0
GIT	Motilium ^{®*}	0	0	0	0	0

4.5.2 Participants and Memos

4.5.2.1 Participant Pat

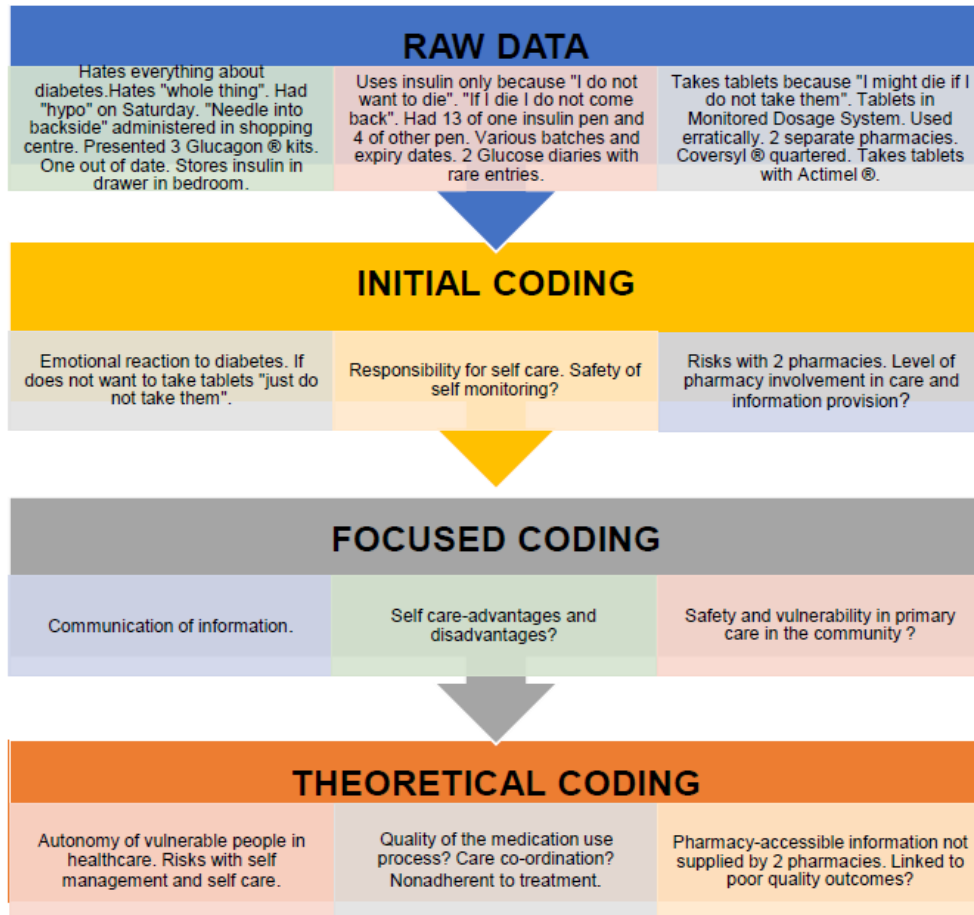


Figure 4.2 Coding Process Grounded Theory Approach - Participant Pat

4.5.2.2 Participant Alex

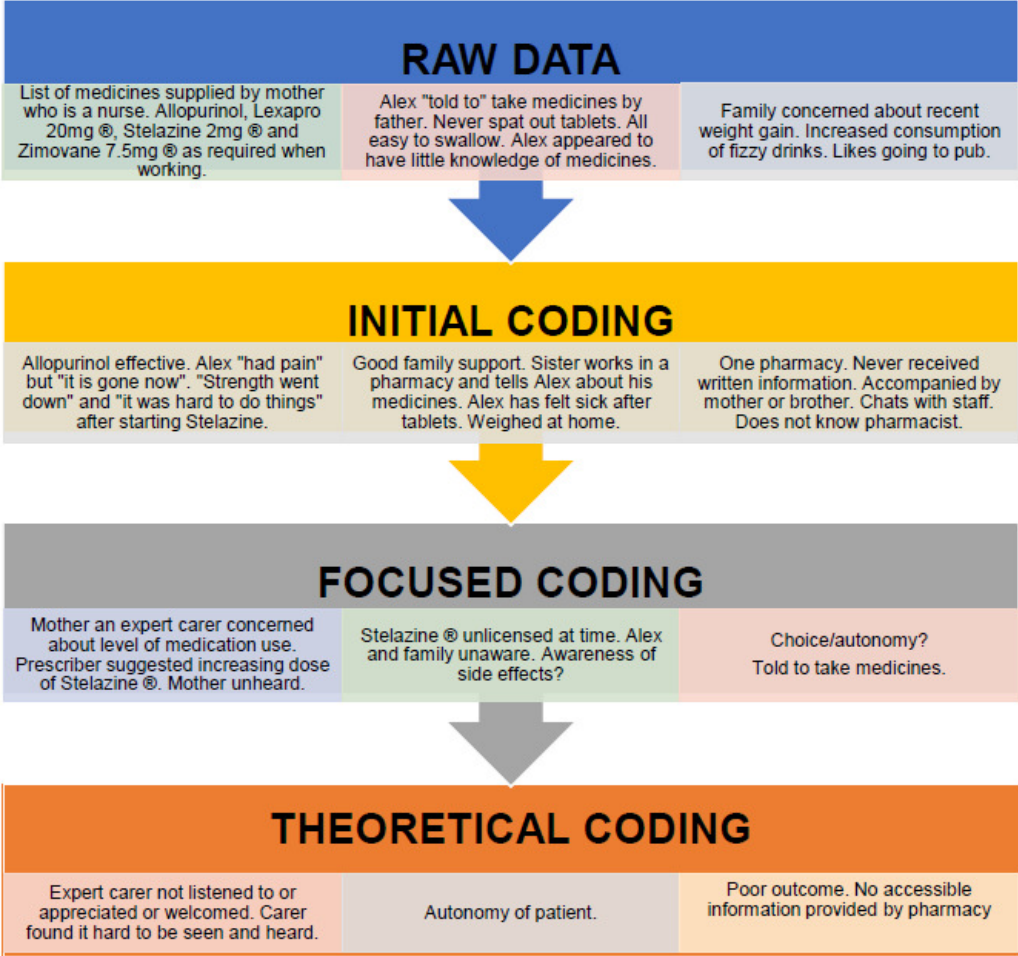


Figure 4.3 Coding Process Grounded Theory Approach - Participant Alex

4.5.2.3 Participant Keelan

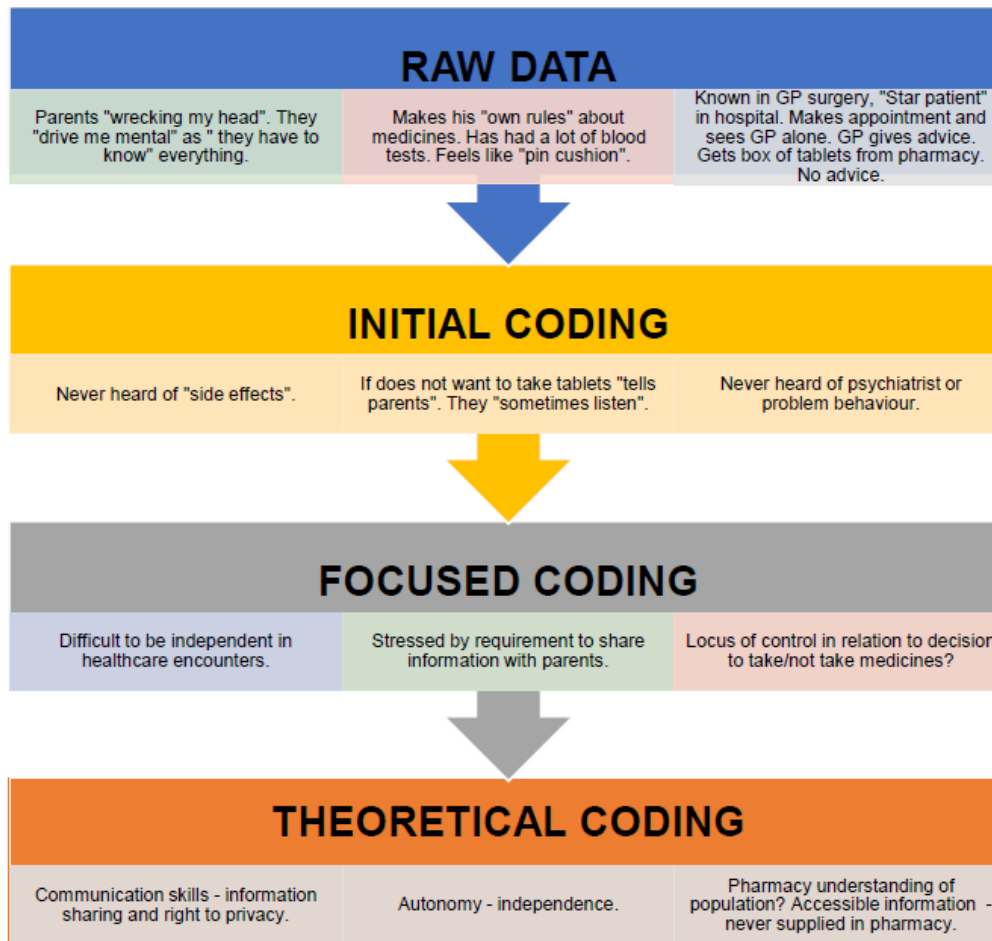


Figure 4.4 Coding Process Grounded Theory Approach - Participant Keelan

4.5.2.4 Participant Gabrielle

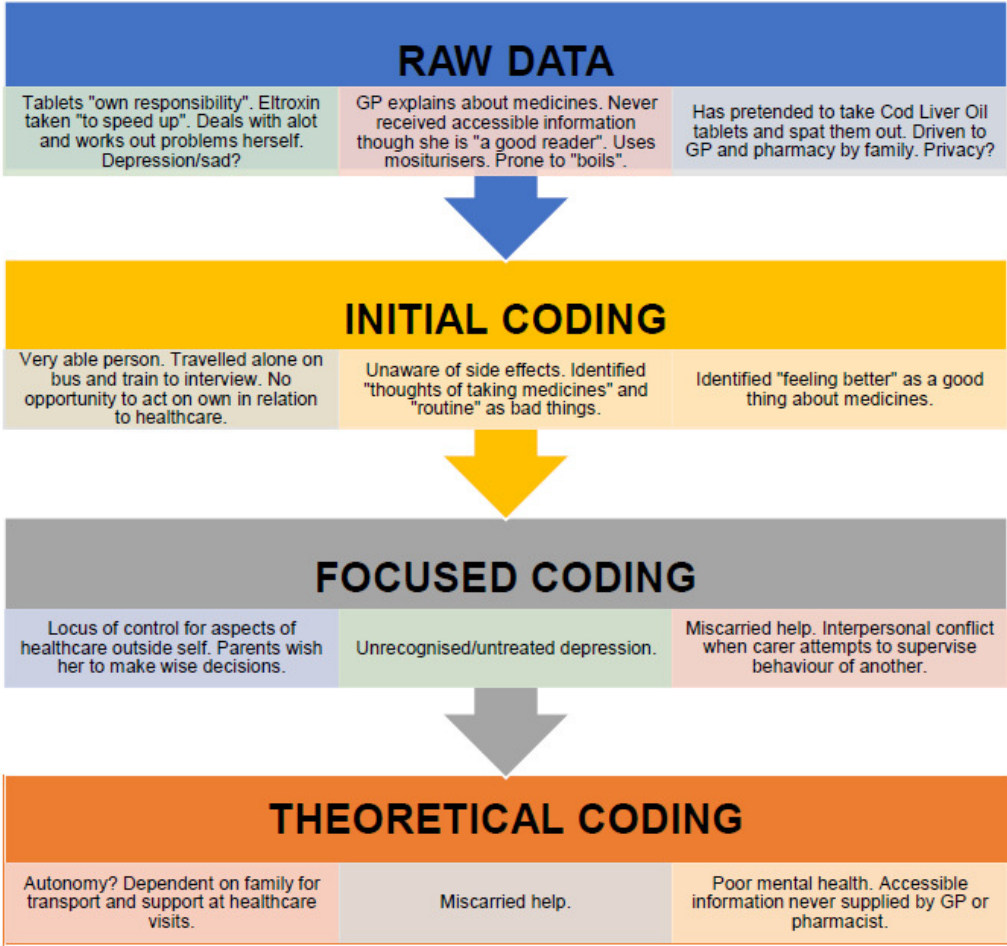


Figure 4.5 Coding Process Grounded Theory Approach - Participant Gabrielle

4.5.2.5 Participant Jamie

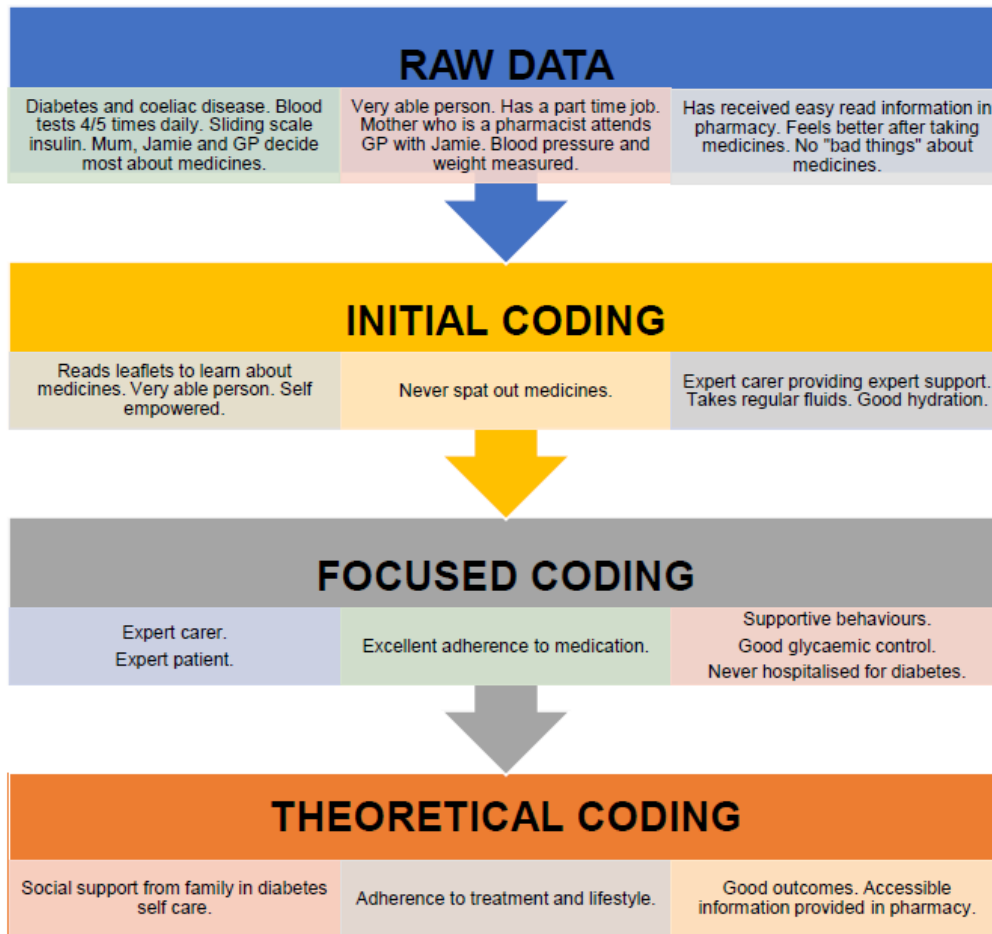


Figure 4.6 Coding Process Grounded Theory Approach - Participant Jamie

4.5.2.6 Participant Frances

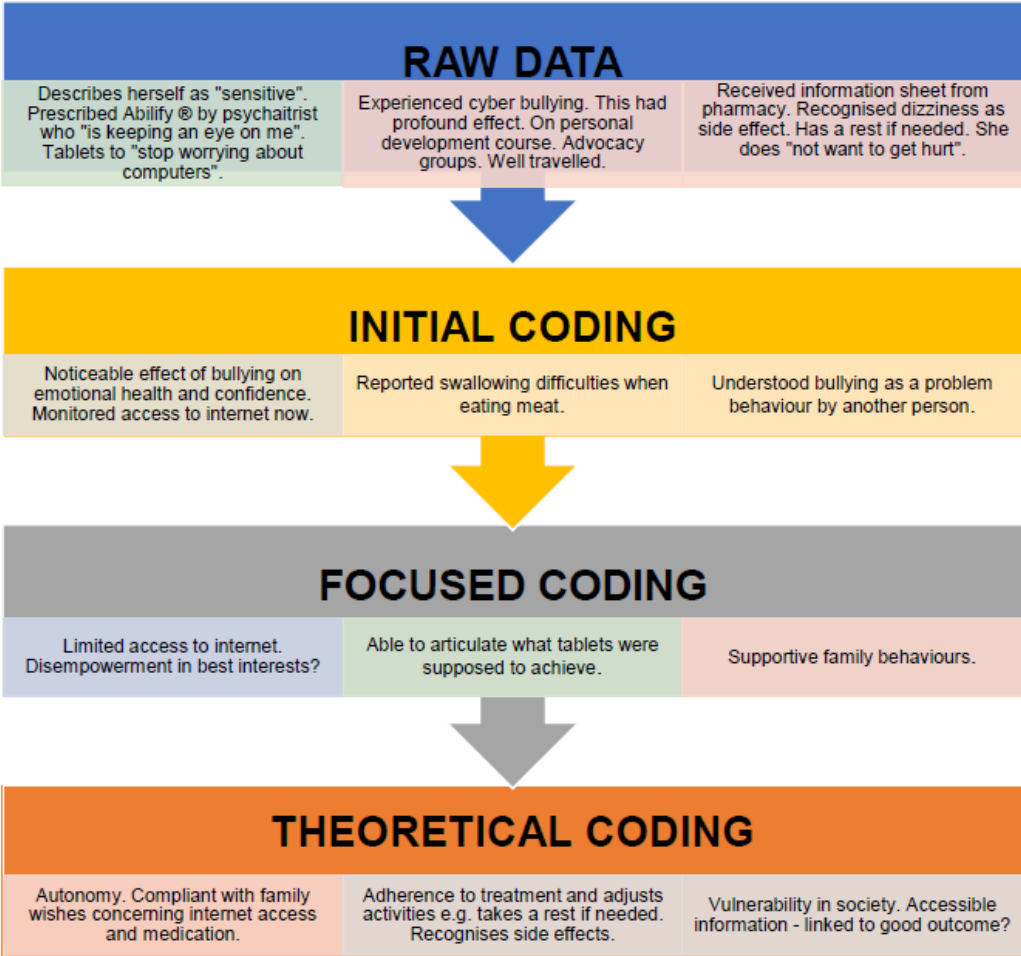


Figure 4.7 Coding Process Grounded Theory Approach - Participant Frances

4.6 Theory Generation

4.6.1 Stage 1: Background to Theory Generation

This project did not start with a theory to prove or disprove. Avoiding misconceptions is paramount when doing Grounded Theory in that the bulk of the literature review is conducted after the emergence of substantive theory. It is then, and not before, that data from the extant literature contributes to the study.

A rigorous and constant literature review process that took place at two levels:

- constant reading in other substantive areas to increase theoretical sensitivity,
- conceptual emergence forced the review of convergent and diverging literature in the field.

One of the dangers in research of this nature is that sampling will be too superficial. However Participant 'Pat' was identified as a foundation case who was the 'richest vein' and most relevant source of data. This richness, combined with the data from the other participants and the literature review, allowed conceptual saturation and closure of the Grounded Theory study.

The objective of the research was to generate theory

'that accounts for the patterns of behaviour which is relevant and problematic for those involved'.

The theories that emerged which included '*self determination*' and '*the quality of the medication use process*' drove the literature review that follows and so the extant literature is incorporated into this study as data.

Self Determination



Quality of the Medication Use Process



The initial theories are illustrated in Figure 4.8 and Figure 4.9.



Figure 4.8 'Self Determination' as a Theory



Figure 4.9 'The Quality of the Medication Use Process' as a Theory

4.6.1.1 Axial Coding

The aim of axial coding was to compile the memo data in a way that enabled a more precise and complex explanation of the researched phenomenon. In this project axial coding was undertaken from two perspectives: that of the person with intellectual disabilities and that of the pharmacy perspective. This resulted in the generation of two explanations for what was discovered during the interview process.

Explanation 1: The person with intellectual disability is vulnerable in the medication use process and self determination in the medication use process in health care by people with intellectual disabilities:

- Is problematic for the person and their family.
- Is difficult to achieve but can be achieved with adequate support networks.
- May not ensure quality healthcare.
- May lead to poor outcomes.
- May increase risk of adverse events.
- May increase vulnerability in medication use process.

It is also important to note that the population with intellectual disabilities is heterogeneous with respect to abilities and disabilities. Also, there are different intervening conditions in each living environment; family dynamics that will include education, health literacy, resources and the knowledge base of the healthcare provider i.e. the pharmacist.

This explanation is illustrated in Figure 4.10.

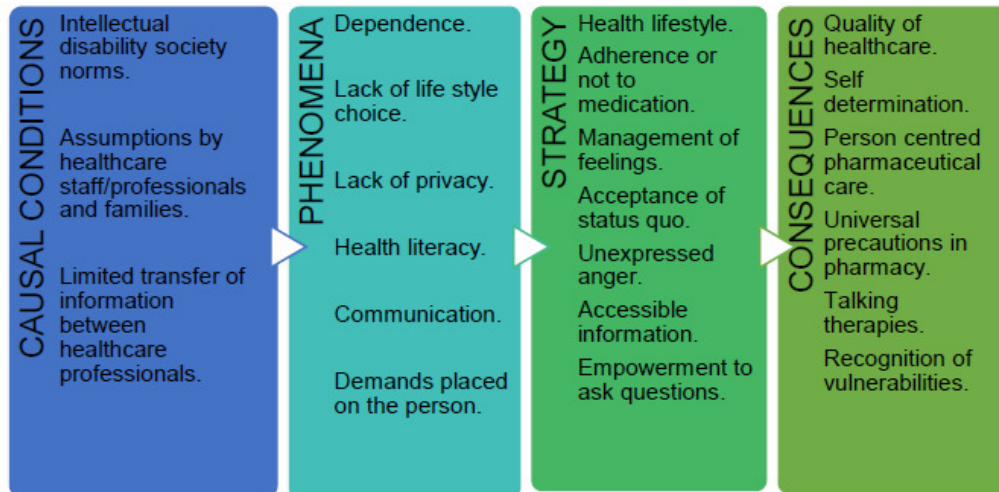


Figure 4.10 Person with Intellectual Disability is Vulnerable in Medication Use Process in Healthcare – Axial Coding

Explanation 2: Knowledgeable and interested pharmacists are pivotal in ensuring a quality medication use process for this - and other - vulnerable populations.

Pharmacists may be unaware of the vulnerabilities of people with intellectual disabilities in healthcare. Pharmacists need to develop a relationship with the person with intellectual disability and/or their carer and a level of expertise of working with this population group. The following processes may not be in the best interest of the person with intellectual disability:

- Repeat dispensing without question of diabetic and other products.
- Use of MDS in population with intellectual disabilities.

The context in which this explanation is considered is:

- Government policy to deinstitutionalize the population with intellectual disabilities.
- A countrywide network of community pharmacies.

The relevant intervening conditions include:

- Patients at increased risk if not supported by knowledgeable carer.
- Quality of information transfer between patient/carer and pharmacist, GP and pharmacist, clinics and pharmacist and intellectual disability service provider organization and pharmacist.

This second explanation is illustrated in Figure 4.11 below.

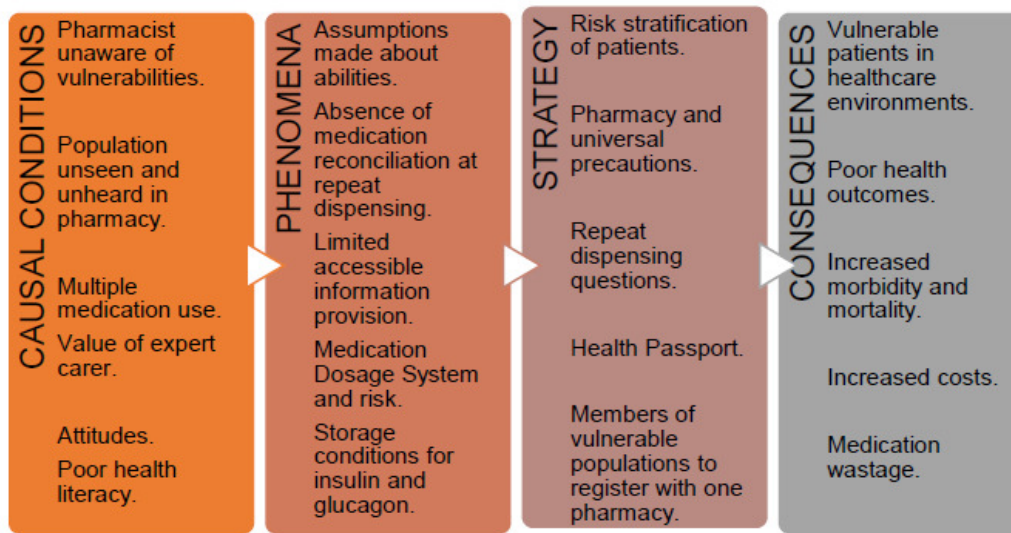


Figure 4.11 Pharmacy and the Medication Use Process for Vulnerable People with Intellectual Disabilities – Axial Coding

4.7 Literature Review – Theory Generation: Stage 2

A literature review was undertaken post interviews and Grounded Theory Stage 1. As mentioned previously, avoiding preconceptions is paramount in doing Grounded Theory. This point, which seems clear to the researcher grounded theorist can puzzle the observer. The Grounded Theory literature emphasizes that the critical factor is that the research does not start with a theory to prove or disprove. When the initial theories become dense with explanations for the behaviour identified during the interviews and enriched by relevant extant literature, only then has the researcher 'discovered' a substantive theory.

Substantive theories are applicable to the particular area of empirical enquiry from which they emerged.

4.7.1 Health of Population with Intellectual Disabilities

The people interviewed in this project had mild-moderate intellectual disabilities and their healthcare was provided in the main in primary care with referral to specialist services, for example mental health and diabetic care. The literature review in Chapter 2 describes in some detail aspects of the health and healthcare of people ageing with

intellectual disabilities. There is a need to protect the health of people with intellectual disabilities and to respond to this need the Department of Health in England (Addington et al., 2005) has made the following recommendations:

- Better training in intellectual disability for all healthcare staff.
- Longer and more flexible appointments.
- Accessible information to be provided in all health care settings.
- All screening programmes to ensure that people with an intellectual disability have the same access rate as others.
- Identification on health records that someone has an intellectual disability.
- Tackle health inequalities by ensuring a Health Equity Audit to address how well people with an intellectual disability are accessing mainstream services and propose action to reduce the gap in life expectancy.
- Annual health checks should be offered to all people with an intellectual disability.
- Hospitals to fulfill their legal duty of care and provide appropriate levels of support to clients with an intellectual disability.
- An inquiry into premature deaths should be conducted.

The Health Review QI developed in Chapter 3 of this thesis was identified by the 'expert' panel as a 'Crucial QI'. However, the results of a survey carried out by the Down Syndrome Association in England to find out how many members had received an annual health check and how thorough it had been (Heslam, 2011) showed that:

- Uptake of annual health checks remains patchy.
- Health checks are not being conducted in line with the RCGP protocol.
- Sufficient time is not always being given to conducting a thorough health check.
- Basic checks that are critical for the health of people with Down Syndrome are being missed.

In healthcare, the process of medication use is a means to produce value for the patient with intellectual disability and to maintain or improve their health. This process is of varying quality but the process should be made predictable with only chance causes of variation left in the process (Bergman et al., 2011). It is important that people

with intellectual disabilities are included in decisions about their own healthcare of which medication use is a major component. If people with intellectual disabilities do not possess information on the medication they are consuming, then it is questionable whether they can truly be said to have given their informed consent to treatment with medication (Anthony, 2012).

The following sections of this literature review were informed by the interviews and Grounded Theory process to date and illustrate the literature available in relation to aspects of the medication use process highlighted by the interview data.

4.7.2 Medication Use in the Population with Intellectual Disabilities

The literature review in Chapter 2 illustrated the complexity of medication use in the population with intellectual disabilities. Some issues particular to the population with intellectual disabilities in five countries are reviewed at the start of this section. These issues presented in different geographical locations may have general applicability.

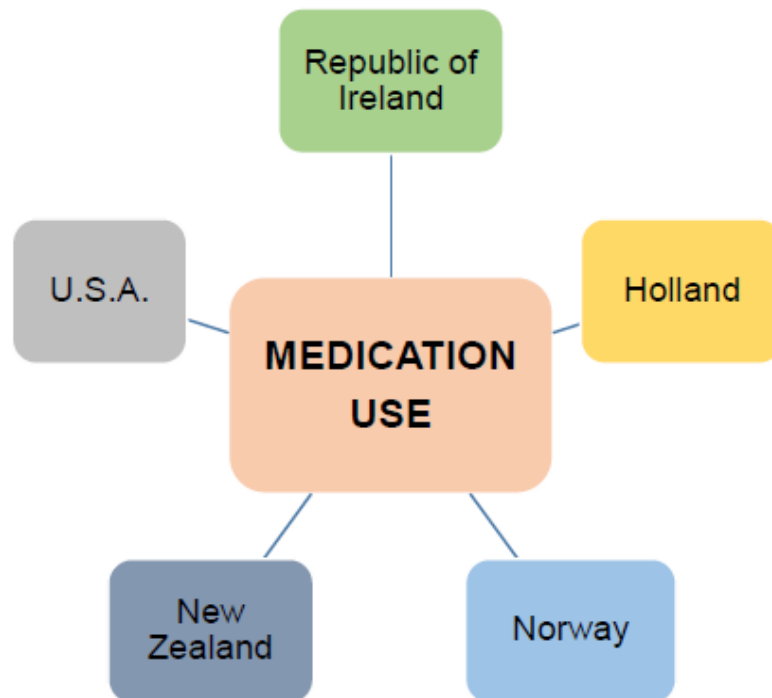


Figure 4.12 Five Countries in which Medication Use is Reviewed

4.7.2.1 Republic of Ireland

The results of the IDS-TILDA longitudinal study that is researching ageing in Ireland among people with an intellectual disability aged 40 and over, have indicated that nine out of ten participants were taking at least one (prescription or non-prescription), medicine (McCarron et al., 2011a). Poly-pharmacy was defined in the report as taking more than five medications (prescription and non-prescription). It was observed in 59.1% of the participants and was almost three times the level (21%) found for the general Irish population and was higher for those living in residential centres compared to those living in community, independently or with their family. Antipsychotics and antiepileptic medications were the most commonly used prescription medications. Both groups were used by 30% of the participants. Some participants in the study used up to five medicines classed as antiepileptic medications. Anxiolytics including benzodiazepines were used by 25% of respondents and antidepressants were also used by 25% of respondents. The use of one hypnotic was reported by 20% of respondents with 13% reporting the use of two or more hypnotics concurrently.

4.7.2.2 Holland

In the Dutch National Survey of General Practice, people with intellectual disabilities presented a variety of health problems at a rate of 1.7 times more than those without intellectual disabilities (Straetmans et al., 2007). Seventy-five per cent of people with intellectual disabilities received medication, compared to 59% in the control group. People with intellectual disabilities received almost four times as many repeat prescriptions as the control group, particularly chronic psychiatric medication and anticonvulsants. Straetmans et al. found that Dutch people with intellectual disabilities in primary care received an average of 4.3 prescriptions, compared with 3.1 prescriptions for people without intellectual disability during consultations. The most frequently prescribed medications were psycholeptics (63%), antibacterials (36.8%), anticonvulsants (26.7%), anti-inflammatory and antirheumatic products (26.7%), and sex hormones and modulators of the genital system (25.8%). People with intellectual disabilities received an average of 5.4 repeat prescriptions, usually for the same types of medication, compared with an average of 1.6 repeat prescriptions for people without intellectual disability.

4.7.2.3 Norway

The authors of a Norwegian qualitative study based on in-depth interviews with parents of children with intellectual disability and a broad range of associated health problems suggested that focus needs to be directed at GPs who prescribed medication without a personal examination. It is recognized that information from people who know the child with an intellectual disability is important, but can not fully replace the GP's own observations of this 'hard to hear' group (Fredheim et al., 2011). It was a concern that participants in this study described situations where medication for acute or more permanent problems was prescribed for people with intellectual disabilities by GPs who did not consider it necessary to see the person or carry out a physical examination. In addition, none of the parents were instructed on how to evaluate the possible effects of the medication in the child with an intellectual disability.

4.7.2.4 USA

The presence of medical diagnoses and medication utilisation in 187 adults with Down Syndrome in the USA using retrospective chart review identified 24 categories of prescribed medications (Kerins et al., 2008). The review of medication use in this sample of adults with Down Syndrome identified the presence of thyroid supplementation, anti-anxiety and antidepressant medications and anticonvulsants as common and appropriate. Multivitamins were used at least a third of the time and Vitamin E is used by over 50% of adults in this sample. Calcium with Vitamin D (30%) and Fosamax (22%) were also common.

4.7.2.5 New Zealand

In the year to 30 June 2008, people with intellectual disability in New Zealand were dispensed an average of 5.8 different medications from community pharmacies (Ministry of Health NZ, 2011). This was nearly twice as many as for people without intellectual disability. The number dispensed increased with age, as it does for people without intellectual disability. There were only small differences between sexes and different ethnic sub-groups.

4.7.3 Medication Use Issues Identified Following Interviews

The interview data identified the following medication use issues:

- Adherence and Concordance.
- Health Literacy.
- Medication Side Effects.
- Provision of Information.
- Health Outcomes.
- The Person with Intellectual Disability.
- Diabetes.
- Pharmacy and Medication Management.

4.7.3.1 Adherence and Concordance

Adherence to medication is a multidimensional phenomenon. In an Irish survey, 18% of participants reported that they are not fully adherent all of the time, with the number rising to 23% in men only; 23% in ≤ 35 years individuals; 30% in people with high cholesterol and 31% in people with asthma and diabetes (Al-Lawati, 2014). In this survey, the most common patient-related factor leading to missing medications was simple forgetfulness. This study demonstrated that patients (even the adherent ones) benefit from regular engagement with their healthcare professionals, where the need and benefits of their prescribed medication can be explained fully and repeatedly. A more active role was identified for pharmacists and nurses in this area as the survey indicated that healthcare professionals, especially the patients' doctors, are influencers towards improving patient adherence. The outcomes of the analyzed studies in a systematic review indicate that pharmacists could have an influential and important role to improve adherence in patients taking oral medication for type 2 diabetes (Antoine et al., 2014).

Eussen et al., in a study to implement a pharmaceutical care program to improve medication adherence in new users of statins, found that the pharmacist has an important role to play in ensuring that drug therapy is appropriate and effective (Eussen et al., 2010). When the researchers compared discontinuation rates of statin therapy over time between patients in a pharmaceutical care and usual care groups,

they found that patients in the pharmaceutical care group were more likely to persist with treatment compared to patients in the usual care group.

Interventions to improve adherence should be specified according to the type of disease, patient population, healthcare provider, etc. and must be individualized to the individual patient's needs (WHO, 2003) for example intellectual disability, poor health literacy. Patients who have difficulty maintaining adequate adherence need more intensive strategies than patients who have less difficulty with adherence, a more simple medication regimen, or both. Innovative approaches can include reducing complex medical regimens and smart dispensing of medications (Al-Lawati, 2014).

Concordance is the degree to which clinical advice and health behaviour agrees (Mitchell and Selmes, 2007) and simple strategies can improve concordance, Box 4.1. In some patients, counselling or cognitive behavioural therapy may be needed, especially for patients with chronic conditions such as arthritis or diabetes. For example, a recent study of 87 patients demonstrated significant benefits of cognitive behavioural therapy on adherence as well as patient outcomes in type 2 diabetes patients with depression (Safren et al., 2013).

Simple Strategies to Improve Concordance

Basic Communication

- Establish a therapeutic relationship and trust
- Identify the patient's concerns
- Take into account the patient's preferences
- Explain the benefits and hazards of treatment options

Strategy-Specific Interventions

- Adjusting medication timing and dosage for least intrusion
- Minimise adverse effects
- Maximise effectiveness
- Provide support, encouragement and follow-up

Reminders

- Consider adherence aids such as medication boxes and alarms
- Consider reminders via mail, email or telephone
- Home visits, family support, counselling

Evaluating Adherence

- Ask about problems with medication
- Ask specifically about missed doses
- Ask about thoughts of discontinuation
- With the patient's consent, consider direct methods: pill counting, measuring serum or urine drug levels
- Liaise with general practitioners and pharmacists regarding prescriptions

Box 4.1 Simple Strategies to Improve Concordance

It is important to remember that in the population with intellectual disabilities securing adherence, compliance and concordance with treatment may involve other agencies, and may rely on carers or care staff who have no 'health service background' (NPSA, 2004b).

The index case Pat in this project, demonstrated poor adherence to his medication regimen. The researcher is unaware what, if any, advice he had received from the prescriber or dispensing pharmacist concerning self administration of medication. The researcher is unaware what, if any, 'risk assessment' of self administration of medication by Pat was undertaken. It was unclear how much support was available in his living environment. It is to be hoped that he received healthcare advice at some

stage that would have included advice on storage of medication including insulin and glucagon and the proper usage of a Monitored Dosage System (MDS). It would appear from observation only that he also demonstrated poor concordance, poor compliance and poor adherence.

4.7.3.2 Health Literacy

4.7.3.2.1 Introduction

Literacy demands are placed upon all patients in the increasingly complex health care system. Those people who are functionally illiterate or marginally literate are likely to have low health literacy skills. Health literacy refers to the set of skills needed to read, understand and act on basic health care information. People with low health literacy skills have limited ability to read and understand the instructions contained on prescriptions or medicine bottles, appointment slips, informed consent documents, insurance forms, and health educational materials (National Academy on an Aging Society). The results of *the European Health Literacy Survey* showed that almost half of the people have risk of limited health literacy and will have difficulties in accessing, understanding, appraising and applying information to take decisions in terms of health (HLS-EU Consortium, 2012). In certain groups the vulnerability was higher than 60%. In certain sub-groups of the populations there were higher risks, such as among elderly, among people with low levels of education, among people with low socio-economic status and among people considered to have bad health. No study has directly measured the health literacy of the population with intellectual disabilities in Ireland or internationally.

There are varied approaches to improving health literacy in the population with intellectual disabilities. In Ireland the National Adult Literacy Agency has produced guidelines intended to

'provide a clear and helpful framework which individual literacy schemes, in conjunction with the relevant agencies, can fine tune to meet their particular needs and preferences and those of the student'

(Rush and Kelly, 1999) with intellectual disability.

People with low to moderate healthcare literacy skills are unable to assume positive self management. Their care has been found to result in higher medical costs due to more medication and treatment errors, more frequent hospitalizations, longer hospital stays, more visits to their healthcare provider and a lack of necessary skills to obtain needed services (National Academy on an Aging Society).

4.7.3.2.2 Communication and Health Literacy

Communication difficulties and reduced health literacy have been identified as a determinant of health in people with intellectual disabilities (Emerson et al., 2011). Health literacy should be seen as a “systems issue” (Rudd, 2010), reflecting the complexity of both the presentation of health information accessible to people with intellectual disabilities and navigation of the health and social care system. Research on interventions and approaches that may build health literacy are required (Ministry of Health NZ, 2011) to improve the health literacy of people with intellectual disabilities and their carers/family. The emphasis must be shifted from the literacy skills of the public which include people with intellectual disabilities, to the activities of health systems and health care professionals, highlighting the importance of removing literacy-related barriers to health (Office of Disease Prevention and Health Promotion, 2010). Despite apparent access to health professionals, one in three adults with an intellectual disability in Ireland reported that they found it difficult to make themselves understood when speaking with health professionals (McCarron et al., 2011a).

4.7.3.2.3 Pharmacy Health Literacy

Pharmacy health literacy is the degree to which individuals are able to obtain, process and understand basic health and medication information and pharmacy services needed to make appropriate health decisions (AHRQ, 2014). Pharmacists have a responsibility to ensure that all patients, including those with intellectual disabilities, obtain the maximum positive health outcomes from their medications. Pharmacists in Ireland and worldwide care for a wide variety of patients. Patients may have varied educational and income levels. Patients may present with hidden difficulties that may be sensory, psychological or intellectual. Patients may have varied communication abilities and speak multiple languages. Members of all these groups may have limited health literacy. Medication safety incidents are likely to be higher with patients with limited health literacy as they are more likely to misinterpret the prescription label information and auxiliary labels.

Studies document an association between low literacy and poor health outcomes (Doyle et al., 2012). Low health literacy may predict medication adherence in patients with cardiovascular related conditions (Gazmararian et al., 2006).

Three levels of health literacy have been described (Nutbeam, 2000) that can be applied to pharmacy:

- *Functional health literacy* where having accurate information will lead to a basic understanding of what the pharmacist desires the recipient both to know and to do. Functional health literacy is a vital first step to realizing improvements in many health-related outcomes.
- *Interactive health literacy* refers to the personal capacity to build skills and “act independently” when armed with factual information about medicines.
- *Critical health literacy* is the empowerment of an individual to be his or her own health advocate despite difficult economical or social situations, even to the point of working to establish changes in those circumstances through community action.

In October 2011, the Cabinet Secretary for Health, Wellbeing and Cities Strategy announced a review of NHS Pharmaceutical Care of Patients in the Community in Scotland. In this review (Wilson and Barber, 2013) patients described what they wanted from their pharmacist and pharmacy:

- continuity and consistency of professional input and care from an individual pharmacist,
- easily understood information about their medicines adapted to the needs of the individual,
- appropriate support and advice,
- greater ownership of their own care,
- accessible services in a suitable environment, which allowed privacy and confidentiality when required.

They also expressed a desire that the relevant information needed to deliver high quality care would be shared between the professionals involved. Many would also welcome some form of patient held information (paper or electronic) about diagnoses, medication and allergies. They said that they would often ask a pharmacist questions

about their medication which they were unwilling to ask of their GP. They also expected the overall system to be safe and error free, and that their pharmacist would act as the “*guardian*” of their medicines.

Research has highlighted the association between low health literacy and treatment misunderstanding, including medication names, indications and instructions. Studies among adults found those with limited literacy had higher rates of misunderstanding their directions for medications provided by either the physician or pharmacist (Fischhoff et al., 2011).

People with intellectual disabilities are unlikely to seek information about their medication and it is the responsibility of health professionals to make such information readily available. Even if they do possess adequate information, people with intellectual disabilities may experience difficulties in communicating about side-effects of their medication and may find it hard to report adverse effects such as ‘blurred vision’ or feeling ‘dizzy’. Therefore, health care providers must be receptive to the possible side-effects which people may experience. People with less education are those who have been found to desire more information during refill dispensing in pharmacies (Kreuger and Hermansen-Kobulnicky, 2011).

4.7.3.3 Medication Side Effects

The frequency of side-effects to medications may be greatly underestimated by doctors (Smith et al., 2002, Roose, 2003). Adverse effects are a problem for at least half of those taking psychotropic medication and they may be a rational reason for the patient choosing to discontinue medication (Lambert et al., 2004). There is evidence that clinicians prescribing antidepressants only ask roughly one in five patients how well the drugs are working and only one in ten whether they are experiencing any side-effects (Sleath et al., 2003, Young et al., 2006). These questions may be even more rarely asked of patients in vulnerable population groups such as minority ethnic groups (Lewis-Fernández et al., 2005) and people with intellectual disabilities. It was identified by Hess et al. that individuals with intellectual disabilities and autism spectrum disorder prescribed psychotropic medications across multiple classes experienced the most side effects with those prescribed only one class of psychotropic medication still displaying side effects (Hess et al., 2010). Griffiths, in a study that reviewed prescribing practice of antipsychotics by a UK Intellectual Disability Psychiatry Department in accordance with standards adapted from nationally recognised

guidelines, found that there was lack of documentation of physical health and side effect monitoring (Griffiths, 2012).

Epilepsy is more common in people with an intellectual disability than in the general population with one third of the population having this condition. For some people with intellectual disabilities, it can be difficult to understand how and why they need to take their anti-epileptic medications and they may need help from health professionals and people involved in their care (Epilepsy Society, 2013). The Epilepsy Society website indicates that people with an intellectual disability may be more likely to have side effects to anti-epileptic drugs, which may include feeling drowsy, feeling sick, having problems with vision or changes in behaviour. Side effects can be difficult to tell apart from behaviour related to an intellectual disability. The Epilepsy Society website also draws attention to the fact that if someone with an intellectual disability is not able to express what they are feeling or the side effect that they are experiencing, they may be withdrawn, or show aggression or other challenging behaviour. This could be mistaken for a side effect of their antiepileptic medications (Epilepsy Society, 2013).

Consumer and carer education on the use of medication in the population with intellectual disabilities is important in ensuring compliance, recognising side effects and maximising efficacy (IASSID, 2002). IASSID Health Guidelines for Adults with an Intellectual Disability suggest that continuing re-evaluation should ensure the least effective dose of medication, that medication side effects should be monitored and ineffective drugs discontinued.

The recognition of side effects and drug interactions experienced by a person with intellectual disabilities will require a skilled and knowledgeable carer and/or professional. It is not known if the side effects reported by the participants in this project were previously reported to any other healthcare professional. Alex reported that his 'strength went down' and that he found it 'hard to do things' when taking trifluoperazine. This would appear to indicate akinesia which relates to loss of drive and energy and of having slowed down. Frances reported feeling dizziness and having to get up slowly when taking aripiprazole. She also reported having to cut meat in to small pieces and to chew well before swallowing which may indicate a swallowing difficulty. The Abilify Summary of Product Characteristics states that:

'Oesophageal dysmotility and aspiration have been associated with antipsychotic treatment, including ABILIFY. Aripiprazole and other antipsychotic active substances should be used cautiously in patients at risk for aspiration pneumonia'

Pat brought numerous packets of loperamide to the interview. Diarrhoea is a less common side effect of levothyroxine administration.

4.7.3.4 Provision of Information

Limited provision of medicines information in accessible format was reported by participants in this project. Communication of information to people with intellectual disabilities is complex and person specific and each person with intellectual disability will have a different receptive communication capacity and communication strategies must be individualised. In the expressive communication of individuals with intellectual disabilities there is a significant reliance on non-verbal communication, often to a greater degree than a typical adult in the general population would require. The communication abilities and needs of individuals with intellectual disabilities and/or psychiatric illness are highly heterogeneous (Schalick et al., 2012).

Heslop, in a study of 21 people with intellectual disabilities and their carers and prescribers living in four different regions of England, found that that few of the people with intellectual disabilities were fully informed about their treatment (Heslop et al., 2005). Many of their carers said that although they knew how to administer the medication, they knew little about why the person was taking it and what the implications might be. Heslop and her colleagues found the current provision of information to people with intellectual disabilities and carers to be poor. This finding was echoed in this project.

Four key strategies to support people with intellectual disabilities in obtaining information about medication have been identified - spending more time providing and reiterating key information; providing accurate, up-to-date, accessible information about medications; providing training for carers in wider aspects of medication usage; and tailoring information to each person's individual needs (Heslop et al., 2005).

Of the population with intellectual disabilities, individuals with Down Syndrome have a lower incidence of mental health problems overall, however, they are at particular risk of developing dementia. Individuals with Down Syndrome (24.1%) were less likely to

report that they had an emotional or mental health disorder, other than dementia, compared with those with an intellectual disability from other causes (McCarron et al., 2011a). People also identified services they would benefit from but were not currently receiving. These included dietician, chiropody services and education. Regarding the latter, one participant's supporter noted,

'literacy services, he/she would love to be able to read and write, very embarrassed that he/she cannot'.

If people with intellectual disabilities do not come forward, it can be difficult for the health system and health care professionals to help them and to provide information. People with intellectual disabilities visit their GP with similar frequency to the general population. However there is evidence that they have greater health needs and so would be expected to access primary care services and healthcare professionals and to require information more frequently than the general population. Collaboration between GPs, primary health care teams and specialist services for people with intellectual disabilities is generally regarded as poor and is a cause for concern internationally. In particular, adults aged over 60 with intellectual disabilities are less likely to receive a range of health services compared to younger adults with intellectual disabilities (IHAL and NDTi, 2013).

4.7.3.4.1 Medication Labeling

One participant in this study reported finding labels on medicine containers difficult to read. Other participants in the study were administered medicines by their carers. It is questionable if the index case Pat was able to read the directions on the MDS in which his medication was provided. His use of the MDS was erratic and it was impossible to determine when the first or last dose had been taken.

To ensure good health outcomes from the use of medication there is a need for a standard uniform approach to delivering health information. Healthcare professionals such as pharmacists and health systems should coordinate their efforts to ensure patients and families have multiple access points to receive the same content. In a document published by the FDA the use of a universal medication schedule (UMS) Box 4.2, has been proposed to standardize the way physicians prescribe medicines in the most patient-centered manner and to equally request pharmacies to use the same instructions and information when labeling and dispensing medicines (Fischhoff et al., 2011). This represents 'joined up' thinking.

Universal Medication Schedule	
Take...1 pill in the morning	Morning 6-8am Noon 11-1pm Evening 4-6pm Bedtime 9-11pm
Take....1 pill in the morning	
1 pill in the evening	
Take....1 pill in the morning	
1 pill at noon	
1 pill in the evening	
Take.....1 pill in the morning	
1 pill at noon	
1 pill in the evening	
1 pill at bedtime	

Box 4.2 Universal Medication Schedule

4.7.4 Health Outcomes

Outcome relates to the state of health of the individual with intellectual disability or the population with intellectual disabilities resulting from their interaction with the healthcare system. It can include lifestyle improvements, emotional responses to illness or its care, alterations in levels of pain, morbidity and mortality rates and increased level of knowledge (Mainz, 2003).

Poor outcomes were demonstrated by the index case Pat, who experienced regular ‘hypos’, did not take his medications and insulin as prescribed, appeared to be distressed with having diabetes and fearful of death. Similarly, Alex’s carer reported weight gain following the prescribing of trifluoperazine. Gabrielle reported that she deals ‘with a lot’ herself, that she ‘works out problems’ herself and appeared to be ‘depressed’.

4.7.4.1 Pathway: Health Literacy and Health Outcomes

Studies document an association between low literacy and poor health outcomes. For the person with intellectual disabilities ‘health literacy skills may be the first step in a chain of factors impacting on their health status’ (Osborn et al., 2011). Health literacy must always be examined in the context of the specific tasks that need to be accomplished, for example blood glucose measurement, administration of insulin,

adequate nutritional intake. Health literacy includes not only a person's ability, but also the complexity of the tasks at hand (Paasche-Orlow and Wolf, 2007).

Certain causal pathways, Figure 4.13, have been proposed (Paasche-Orlow and Wolf, 2007) in which it would be plausible to assume how limited literacy and health literacy skills affect health outcomes in the population with intellectual disabilities. Using the literature, Paasche-Orlow and Wolf argue that social, cognitive/physical and demographic factors determine health literacy skills. They illustrate how limited health literacy might impact health outcomes at three distinct points along a continuum of health care, focusing on access and use of health care provider-patient interactions and patient self-care. Limited health literacy could negatively influence a patient with intellectual disabilities motivation, problem-solving ability self-efficacy and/or knowledge required to accurately perform self-care behaviours in relation to diabetes and other chronic illnesses.

The NPSA in England recognized that people with intellectual disabilities face a dynamic interplay of disadvantage and discrimination which lead them to be excluded from certain forms of treatment or to receive less than optimum care. Dysphagia is a particular risk in this population that has negative health consequences such as asphyxiation and/or choking episode, aspiration incidents, dehydration and poor nutritional status (NPSA, 2007). These factors are not related to the severity of the dysphagia itself but to other intrinsic and extrinsic factors which may exacerbate dysphagia risks. Participant Frances in this study was prescribed aripiprazole which has been found to be effective in treating depression but has relevant side effects. Frances reported getting up slowly in morning. Fatigue is a common side effect of aripiprazole. Frances related difficulties swallowing meat and the need to cut up/chew well. Dysphagia, oesophageal dysmotility and aspiration have been associated with antipsychotic treatment, including aripiprazole.

In Chapter 2 of this thesis, concerns in relation to psychotropic medication use in people with intellectual disabilities and behaviour disorders were explored. Antipsychotic medication consumption has been associated with the unintended health outcome of the development of diabetes. A recent study of Medicaid expenditure data found that people with intellectual disabilities were six times more likely to have type II diabetes than people without intellectual disabilities, as well as having an average of four other chronic health problems (Reichard and Stolze, 2011).

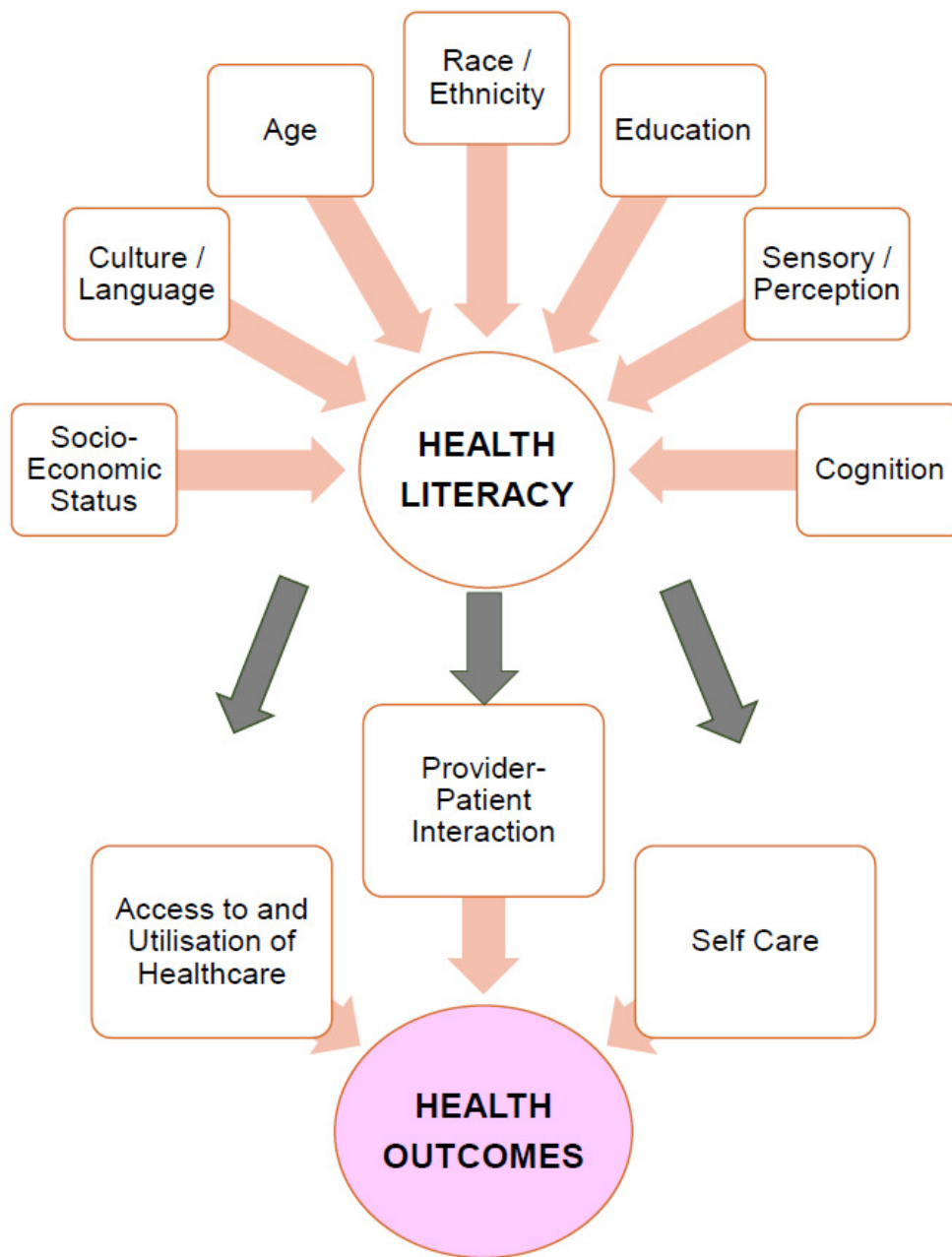


Figure 4.13 Health Literacy and Health Outcomes

4.7.4.2 Sentinel Events

Gravestock used the term “sentinel” events to describe those adverse outcomes, which specifically affect people with intellectual disabilities and/or dual diagnoses and which should always result in further enquiries to determine possible avoidable factors (Gravestock, 1994). The examples he spells out include:

- deaths due to status epilepticus, dementia, suicide or challenging behaviour,
- lithium or anti-convulsant toxicity and tardive dyskinesia,
- physical, sexual or emotional abuse,
- frequent or failed admissions and discharges,
- service user complaints.

Health literacy-sensitive interventions should aim to enhance disease-specific knowledge that, in turn, will enhance self-efficacy, so that self-efficacy will, in turn, promote the performance of self-care behaviours needed for desirable health outcomes (Osborn et al., 2011).

4.7.5 The Person with Intellectual Disability

Human Rights and the population with intellectual disabilities were introduced in Chapter 1 of this thesis and also explored in relation to advocacy in the literature review in Chapter 2. During the interviews the researcher was brought face to face with ‘rights, respect and responsibility’ in relation to medication. A sample of the literature in this complex area is presented below.

4.7.5.1 Self Determination

Self determination is at the core of the CRPD along with the concepts of participation and inclusion. Self determination refers to a characteristic of a person that leads them to make choices and decisions based on their own preferences and interests, to monitor and regulate their own actions and to be goal-oriented and self-directing. There is a growing literature base relating to self determination and people with intellectual disabilities. Research has shown that people with intellectual disabilities have many fewer opportunities to make choices and express preferences across their daily lives. A review of the literature found that choice-making opportunity is a strong predictor of self determination with evidence that the environments in which adults

with intellectual disabilities live or work limit opportunities to make choices and restrict personal autonomy (Werner, 2012).

The participants in this project reflected various levels of self determination ranging from Alex who was 'told' to take his medication to Pat who appeared to be in total control of his medication and insulin. If Pat did not want to take his tablets or insulin he did not take them.

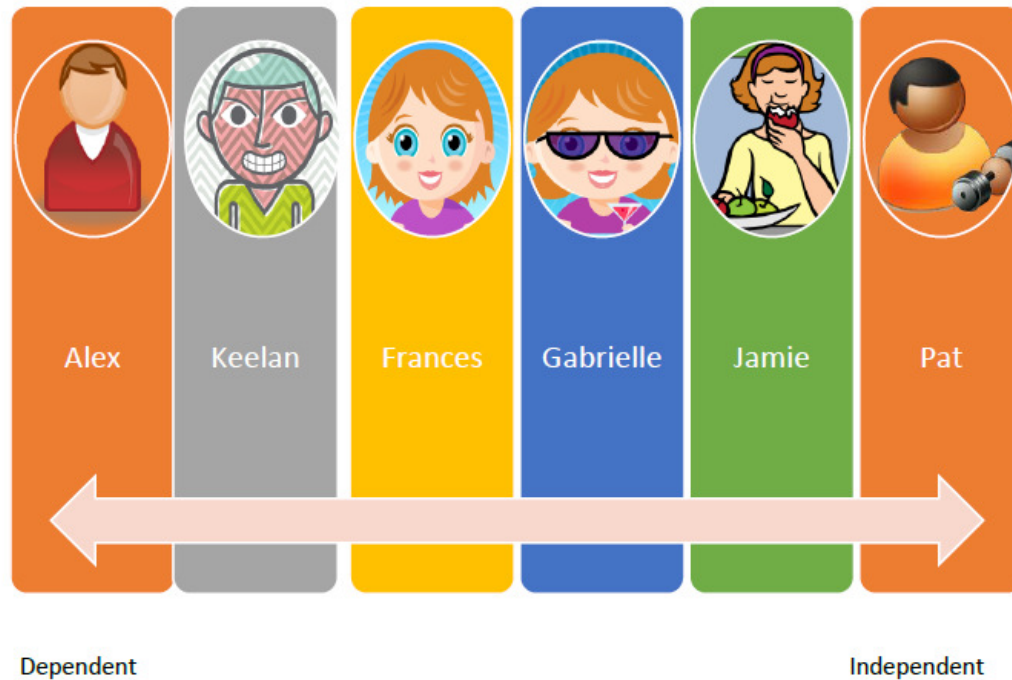


Figure 4.14 Self Determination Scale for Participants

Health care strategies to deal with health inequalities have tended to focus on better training for primary care physicians, dentists and other health care providers (Corbin et al., 2005). The use of checklists by practitioners to identify unmet health needs has also been advocated (Robertson et al., 2011). Promoting self determination in health has also been suggested as being a key strategy in reducing health inequalities (Scheepers et al., 2005). The health literacy of the population is a barrier to quality healthcare in the population and 'functional health literacy' has been described for people with intellectual disabilities who have reduced potential for achieving health literacy.

Adults with disabilities themselves rank self determination as more important than do professionals and parents/family members. People with intellectual disabilities

themselves and their families have identified opportunities for better health self-management, self-advocacy and self-direction in their current experiences with the health care system (O Hara, 2012). To advocate for their health people need education to take charge of their health, for example healthy lifestyle, setting goals, developing a health plan. Knowing one's own health history and understanding their own health and healthcare needs and being a self advocate by preparing for healthcare appointments and speaking up for good health and healthy activities (Vitale, 2012) will be required.

Self determination in health has only recently been explored as a means of reducing the ongoing and significant health inequalities experienced by people with intellectual disabilities. Crossley and Withers in a study that used Grounded Theory qualitative methodology of interviews with eight people with intellectual disabilities, found that participants had very limited information about their antipsychotic medication, beyond knowing the regime (Crossley and Withers, 2009). The authors identified that despite the apparent lack of information and understanding that the people with intellectual disabilities had about their medication, they were extremely compliant. They also noted that despite participants with intellectual disabilities experiencing side effects, they were accepting of these effects. A *'model of compliance'* was generated from the analysis.

People with intellectual disabilities rely on their carer for assistance and support across many aspects of their life and life style (Lennox and Edwards, 2001). It has been reported that for over 50% of individuals with intellectual disabilities, others make health care decisions and choices for them (Wehmeyer and Metzler, 1995, Shogren et al., 2006). Therefore family and paid carers can have a major impact on the health of people with intellectual disabilities and this is an area that requires attention as people with intellectual disabilities might have capacity to make simple decisions about their own health (Arscott et al., 2000, Goldsmith et al., 2008) and healthcare. However Arscott, when he investigated the amount of knowledge that people with intellectual disabilities have about their medication, found that participants appeared to find questions regarding the side-effects of their medication, alternatives to medication and other medications which they should not take in conjunction with their prescribed medications the most difficult to answer (Arscott et al., 2010).

Huneke et al., carried out an audit to determine whether people with intellectual disabilities were receiving the information they require, in a form that they can understand, to make informed decisions about their medication (Huneke et al., 2012).

The results of the audit showed that medication knowledge was poor, with people with intellectual disabilities scoring less than 50% in all but one of the areas assessed. In particular, the people with intellectual disabilities showed a lack of knowledge about the proposed duration of their treatment with medication, possible disadvantages and names of their medications. However Huneke et al., when they reported that overall, intellectually disabled patients' knowledge of their medications is poor, recognised that their finding may not be representative of intellectually disabled patients as a whole, due to the number of profoundly disabled patients present in their audit, who lacked the capacity to make healthcare decisions.

4.7.5.2 Autonomy

Agich describes the importance of not striving for an ideal state of autonomy as in independence (Agrich, 1993). Instead, autonomy should be seen as something all individuals can develop as it is a personally unique characteristic which exists in different degrees, depending on a person's circumstances.

It is important that people with intellectual disabilities are included in decisions about their own healthcare of which medication use is a major component. Cleary and colleagues interviewed 40 patients in acute inpatient mental health settings regarding their experience of, and views about, receiving 'as required' or pro re nata (PRN) medication (Cleary et al., 2012). In that project, patients identified that interactions surrounding the immediate administration of PRN medication were inadequate, as half of the interviewees were simply *told to* take the medication, and three-quarters said that, in their experience, formal consent was not commonly sought.

Medication is a core part of the healthcare of many people with intellectual disabilities. The right to consent to medical treatment, which includes medication use, is a critical first step in promoting self determination in health. It is therefore important to investigate the amount of knowledge people with intellectual disabilities have about their medication. The NPSA in England has highlighted the lack of information about medication that people with intellectual disabilities have been prescribed as an area of concern (NPSA, 2004c). In psychiatric settings, most people prescribed antipsychotics do not feel involved in treatment decisions and state that they take medication only because they are told to (Gray et al., 2005). People reported that they had not been given written information about their treatment or warned about side effects and stated that alternative non-pharmacological interventions had not been offered.

Quality therapeutic relationships that reflect clear communication, choice and empathy have been identified as being vital in developing trust in mental health services in one NHS trust (Maidment et al., 2011). Maidment and colleagues found that cognitively impaired and/or isolated people may not be able to access accurate information and that although GPs were particularly vital in providing information to mental health service users, appropriate support was not always available. Unfortunately, people who use mental health services did not trust clinicians to tell them the whole truth about prescribed medications and in particular adverse events.

With regard to people with disabilities in the Republic of Ireland, the Equal Status Acts (Equality Authority, 2014) require that providers of goods and services:

- do not discriminate (including indirect discrimination by association and discrimination by imputation) against people with a wide range of disabilities, including people with mobility, sensory, mental health and intellectual impairments,
- accommodate the needs of people with disabilities through making reasonable changes in what they do and how they do it where, without these changes, it would be very difficult or impossible for people with disabilities to obtain those goods or services – unless it costs more than a nominal cost.

4.7.5.3 Adherence with Medication

The participants in this project exhibited various levels of adherence with their prescribed medications. Jamie appeared to be fully adherent because she understood her condition and the value of medication. Alex took his medication because he was told to. Frances took her medication because it helped her to cope. Pat who was 'self caring' appeared to be the least adherent.

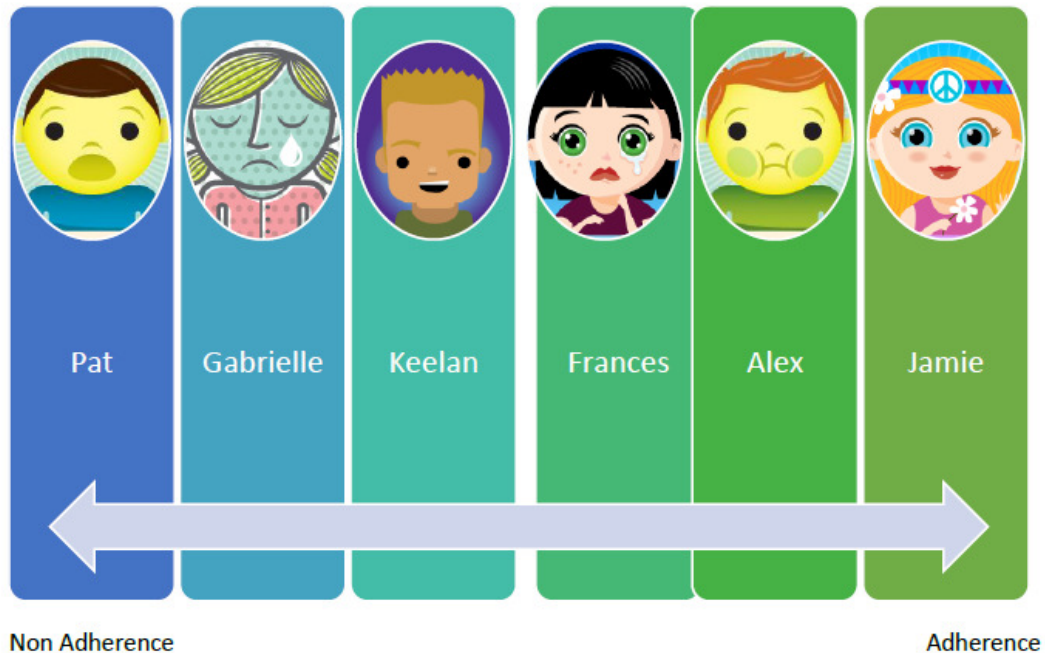


Figure 4.15 Adherence Scale for Participants

The adherence of people with intellectual disabilities who live in community care with prescribed medication and treatment should be monitored carefully as many factors may affect adherence. Adherence problems were evident in the life of Participant Pat in this study. He used a MDS erratically and it was impossible to tell when the first or most recent dose was taken. In the past the IASSID *Health Guidelines for People with Intellectual Disabilities* suggested that some type of MDS for prepackaging doses for community based patients should be considered to maximize compliance (IASSID, 2002). However the Royal Pharmaceutical Society recognizes that

'the use of multi-compartment compliance aids has become regarded as a panacea for medicines use and is often integrated into practice and service policy without giving due consideration to the alternatives available' (RPS, 2013).

Information is now available on the suitability of solid dose forms for transfer from the manufacturers' original packaging to multi-compartment compliance aids (Beswick and Barrett, 2014).

Psycho-education, particularly informing people about indications, contraindications and adverse effects of the treatment may be useful in improving adherence in certain

cases (Deb et al., 2009). It has been suggested that more work needs to be done with family carers than with professional carers to improve adherence with medication in people with intellectual disabilities (Rasaratnam et al., 2004).

4.7.6 Diabetes

4.7.6.1 Background

Diabetes is a progressive, life-long, complex high risk medical condition that requires regular review. Two participants in this study were diagnosed with diabetes and it is assumed by the researcher that this diagnosis related to diabetes mellitus. The recognised goal of diabetes management is to enable the person with diabetes to be able to 'self-care' (Harkins, 2008) and those people with diabetes who self-care must monitor their diet and blood glucose levels, take medication and/or inject insulin. They must also understand the correct storage conditions for insulin and glucagon that are high risk medications. The complexities of diabetes management are intensified in people with an intellectual disability (Rey-Conde and Lennox, 2007) and in many cases to reduce risk, the person's carer takes charge of the daily diabetes management. Therefore it is vitally important that all family and paid carers should have good diabetes knowledge and skills. Pharmacists are ideally placed to provide information. However the value of pharmacists in the care of people with intellectual disabilities has not been widely recognised to date (Flood and Henman, 2010).

4.7.6.2 Ambulatory Care

Pharmacists ideally should engage in routine health assessment interviews, maintaining a health record or providing routine monitoring services (Knapp et al., 2005a). Ambulatory care sensitive conditions (ACSCs) have been defined as conditions which, given 'effective management' at the primary care level, should not normally result in an admission to hospital. The most common ACSC in Ireland in 2008 was diabetes with complications (29.8%) (Sheridan et al., 2012). People with intellectual disabilities are more likely to be hospitalised for ACSCs than people without (Balogh et al., 2010). Crude rate of admissions for ACSCs is 76 admissions per 1000 per year for adults with intellectual disability associated conditions (Glover and Evison, 2013). This is roughly five times the rate for other people (15 per 1000). Strategies to avoid these hospitalizations in all population groups may target after-hours care, optimal use of ambulatory services, intensified monitoring of high-risk patients,

initiatives to improve patients' willingness and ability to seek timely help, as well as patients' medication adherence (Freund et al., 2013).

Diabetes is an ACSC which should be treatable in primary care. People with intellectual disabilities and diabetes are more likely to be admitted as an emergency admission for diabetes related complications and this raises a red flag to a potential weakness in primary care services for people with an intellectual disability (Turner and Emerson, 2013). People with intellectual disabilities and diabetes must have access to information on their diabetes and how it is treated, and health promotion activities, in a person centred accessible form such as verbal, written, pictorial, video, aural. However there is very little comprehensive education material available regarding diabetes education for adults with intellectual disabilities (Kelly, 2011).

A recent study of Medicaid expenditure data found that people with intellectual disabilities were six times more likely to have type 2 diabetes than people without intellectual disabilities, as well as having an average of four other chronic health problems (Reichard and Stolze, 2011). Medication adherence is an important issue in this population.

Devon Local Pharmaceutical Committee have produced a Diabetes Medicines Use Review (MURs) Toolkit designed to help improve the confidence of community pharmacy to provide high quality MURs for patients taking diabetes medicines (Devon Local Pharmaceutical Committee, 2012). Good diabetes management can have a significant impact on morbidity and mortality. The United Kingdom Prospective Diabetes Study showed that better management of patients with an average glycated haemoglobin (HbA1c) of 53 mmols/mol (7%) can achieve a decrease in diabetes-related mortality, reduction in heart attacks and decrease in microvascular complications (Holman et al., 2008).

4.7.6.3 Diabetes Distress

The Royal College of Psychiatrists acknowledge that for some people, the emotional impact of a serious physical illness can be overwhelming and that it can be difficult asking for help with anxiety and depression when one is physically ill, because the person can feel the doctors and nurses are more interested in their physical problems than their emotional ones (Royal College of Psychiatrists, 2013).

People with intellectual disabilities are more likely to get diabetes than their non-disabled peers. They face many challenges when perceiving and coping with their illness (Dysch et al., 2012b) and may develop 'diabetes distress'. The best way for professionals to manage diabetes distress may simply be to have brief, direct and ongoing conversations with patients (Gonzalez et al., 2011). Balfe and colleagues recognise that finding the time to do so may be difficult in the context of a typical clinical appointment in the Irish healthcare system (Balfe et al., 2013).

Diabetes is a severe and complex condition. Diabetes distress is a general term that refers to the emotional burdens, stressors and frustrations that stem from managing diabetes (Egede and Dismuke, 2012, Fisher et al., 2012). It is recognised that individuals in the second phase of young adulthood can experience significant diabetes-related emotional struggles (Balfe et al., 2013) and distress is associated with poor clinical outcomes in many patients (Gonzalez et al., 2011). One strategy that has been identified for managing diabetes-related distress is obtaining diabetes-related social support from three main sources: healthcare professionals, family members and peers with diabetes. Peers with intellectual disabilities and diabetes may help those with diabetes to regulate negative emotions. Peer-led education and user-friendly resources are recommended to achieve lifelong education and support (Hale et al., 2011).

A survey which included 500 patients with diabetes has identified that 33% of patients have some level of dread associated with daily insulin injections and 57% of patients intentionally skip insulin injections (Peyrot et al., 2010). In general, 4 mm needles can be used in almost all individuals, including children/adolescents and obese patients (American Association of Diabetes Educators, 2011). There are safety and tolerability advantages for shorter needles (i.e., 4 mm, 5 mm, and 6 mm) and they are now recommended for use in children or adults, regardless of body mass index (Frid et al., 2010).

People with intellectual disabilities and their carers will require longer appointment times and services and professionals such as pharmacists must make 'reasonable adjustments' (Turner and Robinson, 2011).

4.7.6.4 Understanding of Diabetes and People with Intellectual Disabilities

There is a difference in the self-management skills of people with intellectual disabilities and diabetes when compared to people without intellectual disabilities

(Cardol et al., 2012). Patients in the general population may ask questions and express concerns about their medications which will provide the professional with an opportunity to tailor medication information to the patients' needs and level of understanding. When the patient has an intellectual disability they may not ask questions and this opportunity is often not presented to the professional. Pharmacists in their communication with patients, will require skills that relate to achieving a patient centred communication style (Swenson et al., 2004), i.e., active listening behaviour with use of open ended and feedback questions.

A study in New Zealand involving 14 participants with intellectual disabilities and type 1 or type 2 diabetes identified three categories of understanding of diabetes: (1) those who had a good understanding of the disease; (2) those who had some knowledge but their actual understanding was limited; and (3) those who demonstrated only a very basic knowledge (Hale et al., 2011). Information, training and education must be provided to persons with intellectual disabilities in order to help them develop better decision-making skills in relation to diabetes self care and to minimise any distress the illness may cause. This process should include pharmacists and others teaching them elements of diabetes goal planning and self-regulation in relation to insulin and medication use, nutritional intake and physical exercise. In a policy brief, written for the WHO European Ministerial Conference on Health Systems 2008, the WHO recognizes that well-designed training courses can improve the communication skills of doctors, nurses and pharmacists (Coulter et al., 2008).

4.7.6.5 Education

A questionnaire-based survey in Northern Ireland reported that the extent to which quality of diabetes care indicators were achieved was variable (Taggart et al., 2013). The results of the survey suggest that for many people with intellectual disabilities and diabetes the indices were not met, that glycaemic control was poor, that only a quarter were of normal weight, that many were hypertensive and that almost a quarter had no record of their lipid level.

People who use services have said that they want the information they need, when they need it. Information on diabetes and medications needs to be accurate and up to date, from trusted providers. Practical tips on minimizing pain during injection, such as those in Box 4.3 are examples of information that is needed to minimize 'insulin dread' (American Association of Diabetes Educators, 2011).

Practical Tips for Minimizing Pain During Injection

- Wait until the insulin reaches room temperature before injecting
- Inspect area to be injected, swab with alcohol wipe and wait for area to dry
- Use a new needle for each injection
- Insert the needle quickly
- To reduce leakage, keep the needle in the injection site for 10 seconds with pen needles and for 5 seconds with syringes
- Avoid shifting needle while in injection site, carefully draw needle out through the same path

Box 4.3 Practical Tips for Minimizing Pain During Injection

4.7.6.6 Diabetes and Risk

The two participants with diabetes in this project showed clearly that no two people with intellectual disabilities and diabetes are the same. Pharmacists and other members of the health and social care team should recognise that the degree of difficulty or risk that people with an intellectual disability and diabetes experience when using a healthcare diabetic product, health care diabetic service or health or social care environment can vary as follows (Fischhoff et al., 2011):

- The person may have no significant problems but would appreciate a well-designed accessible and usable healthcare product, service or environment.
- The person has little difficulty with all features.
- The person has difficulty with some features e.g. blood glucose testing, insulin dose calculation.
- The person has trouble with most features e.g. written information, medical “jargon”.
- The person may be unable to use the product at all e.g. profound intellectual disability.

Interventions to address medication use risk may have an impact on health inequalities in this vulnerable population group. Repeat prescribing and dispensing systems have evolved rather than been designed and are, therefore, subject to local variations (National Prescribing Center, 2008). They normally rely on the patient with intellectual

disabilities and/carer prompting the continuity of supply and this has serious drawbacks if the patient is non-compliant. They do not, normally, include any provision for regular checks on the patient's concordance with their medication or instructions (Strath, 2001). Pharmacists usually dispense the diabetic medicines and insulin by installments for the duration of an original repeatable prescription as this:

- enables community pharmacists to dispense regular diabetic medicines to patients, without the direct involvement of the GP surgery on each occasion a repeat medicine is required,
- can save time and improve choice and convenience for patients/carers who do not have to order/collect monthly prescriptions,
- can help reduce the risk of medicine-related problems eg regular supply.

Health professionals such as pharmacists should get insight into challenges faced by people with intellectual disabilities and diabetes to encourage them to work together more effectively and provide appropriate support (Dysch et al., 2012a). Advice that is applicable to the general population, such as maintaining a diet that is rich in high-fibre, low glycaemic-index sources of carbohydrate, etc., should be emphasised (Lewis, 2009) to those with intellectual disabilities and diabetes. A combination of interventions of medication review, modification of containers, medication education and a drug reminder chart are all important components of a medication management program for older adults in the general population (Hughes et al., 2008) and may also be appropriate aids to minimize risk for some people with intellectual disabilities.

Interviews with people with intellectual disabilities who have diabetes show that they also have needs related to dealing emotionally with the illness and that they have questions about their future (Cardol et al., 2012). Diagnosis of a serious/chronic illness can make people feel sad, frightened, worried or angry. This may be because they:

- may feel out of control of their body and the situation generally,
- may feel that there is nothing that they can do,
- feel lonely and isolated from family and friends,
- may find it difficult to talk about the illness with those close to them (RCPsych, 2014b).

Many people living with a chronic illness such as hypothyroidism may not experience significant obvious impact on their lives or planning. However, for many people with diabetes the impact will be significant, and for a number of people with type 1 insulin dependent diabetes, the impact will become the focus of their lives and planning (Clarke and Forde, 2006). Diabetes involves an unrelenting management plan that requires daily adherence to dietary and exercise plans, home blood glucose monitoring and oral medications and/or insulin therapy (Diabetes Ireland, 2014). The presence of diabetes markedly alters the lives of individuals (Diabetes Spectrum, 2000) with intellectual disabilities and their carers/families. Studies in people without intellectual disabilities show that individuals who perceive their illness to have serious consequences experience greater distress and have more difficulties in coping (Hagger and Orbell, 2003).

4.7.7 Pharmacy and Medication Management

4.7.7.1 Background

In all population groups people may want to make decisions about everyday and significant moments in their lives and at other times they may want others to decide for them or at least advise them (Clegg, 2008). The latter is more likely when people are ill, confused or lack crucial knowledge.

Research has shown that 20 to 30% of medication prescriptions are never filled and that, on average, 50% of medications for chronic disease are not taken as prescribed (Peterson et al., 2003). Pharmacists are regularly seen as the most accessible source of information because they were typically available when patients needed information (Nair et al., 2002). In New Zealand there are a number of areas where work is progressing to help support the health sector to better respond to the needs of people with intellectual disabilities and includes improving pharmacy services for people with intellectual disabilities who live in community residences with an emphasis on obtaining the clinical support they need with their medicines to achieve better health results (Ministry of Health NZ, 2011). It is likely that carers may have only a limited knowledge of the medications which their clients are taking and of the possible side-effects (Arscott et al., 2010).

Health literacy in relation to medication use is not a constant but is dynamic and will change with each situation and new diagnosis. To address the need for relevant and

accessible medication and health information it is advisable that healthcare providers including pharmacists:

- Maintain a small collection of patient education materials on topics most relevant to their practice.
- Select or develop the materials themselves.
- Are familiar with the content of the materials they use.
- Ensure that materials are integrated into the patient's plan of care.
- Make materials available through a central database or internal website (Wizowski et al., 2014).

Community pharmacies are a valuable and underutilized resource for the disease management of diabetes (Mitchell et al., 2011). In a survey that sought to determine patient views of pharmacist effectiveness and impact on health care delivery, 96% of respondents reported benefits, including improved disease management outcomes, increased return on investment and increased access to patient care (Giberson et al., 2011). To be effective, pharmacists should of course acknowledge unique patient considerations such as education level, cultural beliefs, literacy, native language and physical and mental capacity in all individual patient assessments (FIP and WHO, 2012).

4.7.7.2 Medication and Health Inequalities

In 2005, the Department of Health in England, identified and listed in its public health strategy "*Choosing Health Through Pharmacy*", a number of ways in which pharmacists can improve public health (DH, 2005). Of relevance to this thesis, the document suggested that pharmacy could contribute to the care of people with long-term conditions, e.g. heart disease, diabetes and asthma, by encouraging the effective use of medicines; promoting healthy lifestyles; supporting self care; carrying out medication reviews; managing disease systematically within multi-professional teams; and working in partnership with case managers.

Interventions by pharmacists to tackle health inequalities must target the most vulnerable (Flood, 2014a). Pharmacists must aim to help improve the health of those that suffer most health and healthcare inequalities. 'Targeted interventions' include

ensuring that services can meet the complex needs of vulnerable people (Crombie et al., 2005) including the population with intellectual disabilities.

Pharmacists and others interested in addressing health inequalities, can use *The Health Equalities Framework* (HEF), which is an outcomes framework based on the determinants of health inequalities. This framework can be used by all services with regard to their effectiveness in tackling health inequalities for people with intellectual disabilities. The developers of the framework hope that it will result in a clearer understanding of the impact of the determinants of health on the lives of people with intellectual disabilities, and is a shared way of tackling these determinants (IHAL and NDTi, 2013). Determinant 2 of the framework can be used by pharmacists as a guide to inform medication management in this population group, Appendix 20.

4.7.7.3 Ambulatory Care Sensitive Conditions

Improving the quality of medication management may help decrease the number of ACSC hospitalisations. Pharmaceutical care requires that the pharmacist have a thorough understanding of the patient and his/her condition or disease and its treatment (APA, 2014). Barriers to good health and good healthcare outcomes include poor access to quality medical products, lack of access to trained health professionals and care, an inadequate health workforce, unaffordable cost of care and poor standards of education of health-care professionals. There is also increasing recognition that providing patients with medicines alone is not sufficient to achieve the treatment goals (WHO, 2011b). To address medication-related needs, the WHO recognizes that pharmacists will need to accept greater responsibility for the outcomes of medicines use and to evolve their practices to provide patients with enhanced medicines-use services.

4.7.7.4 Repeat Dispensing

To be effective pharmaceutical care requires good communication and shared understanding with patients and local prescribers (Wilson and Barber, 2013). Once stabilised on their medication, patients normally obtain continuing supplies through the repeat prescription process operated by their GP practice and dispensed by their community pharmacy. Repeat prescriptions account for approximately 75% of all prescribed items and represent roughly 80% of all primary care expenditure on medicines (Strath, 2001). Many repeat prescribing and dispensing systems have evolved over time rather than been designed and are, therefore, subject to local

variations. Changes in the remuneration system in the Republic of Ireland have recognised the value of pharmacists being free to 'not dispense' an item where that item is not required and remunerated them appropriately. The repeat dispensing of insulin to Participant Pat in this project was identified as a risk situation.

4.8 Theory

4.8.1 Introduction

The aim of Grounded Theory is to generate or discover a theory, Figure 4.16. In this project theory generation involved inductive reasoning which moved from specific observations to broader generalizations and theories. Medication use as an aspect of social life was observed and then patterns that may point to relatively universal principles were sought.

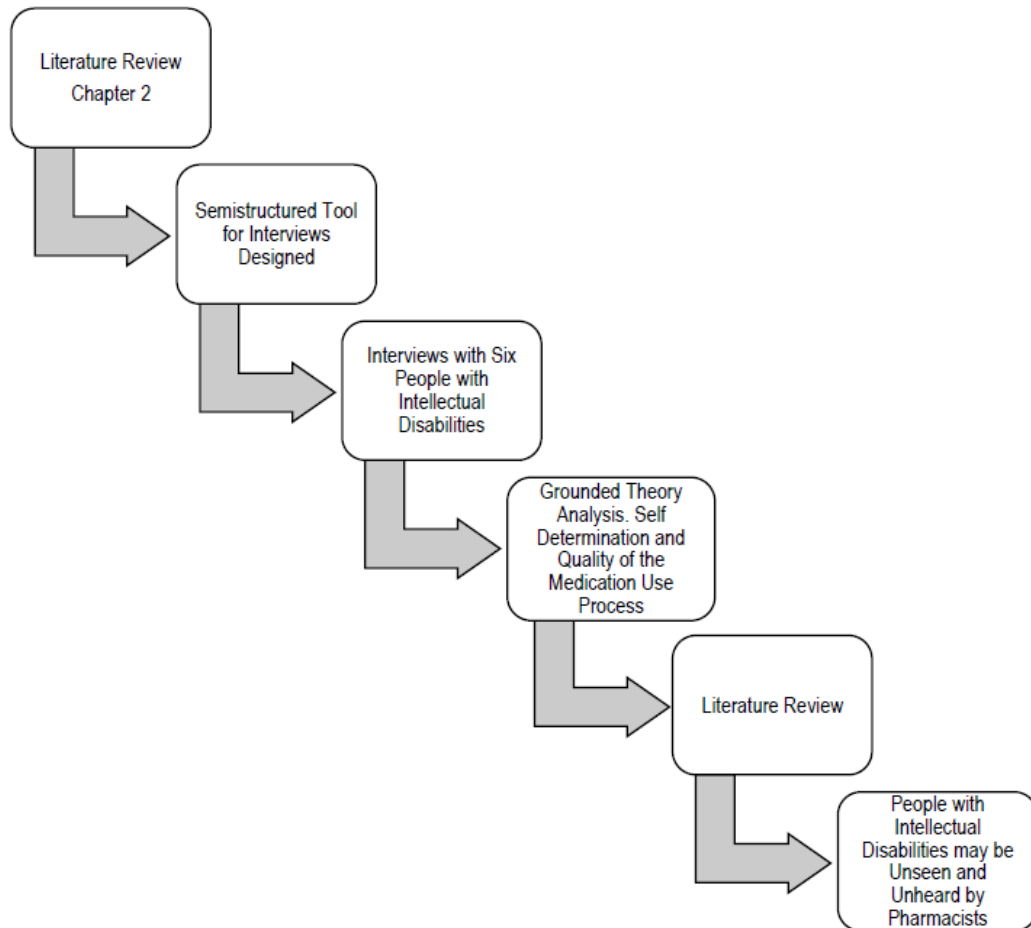


Figure 4.16 Process of Theory Generation

People with intellectual disabilities were interviewed to determine their views and knowledge of medication use. Following immersion in the data ‘theoretically sensitivity’ was achieved by immersion in the data from the interviews, the Chapter 2 narrative literature review and the literature review in this chapter. Understanding what the participants with intellectual disabilities and the research community see as being significant and important issues or difficulties for medication use in this vulnerable population group was the aim. It was important to discover patterns that may point to relatively universal principles in relation to the phenomenon of medication use in the population with intellectual disabilities.

4.8.2 Theory Generation

The main inductive theory developed during this Grounded Theory project that involved research and literature review was that the vulnerabilities of people with intellectual disabilities may be ‘unheard’ and ‘unseen’ by pharmacists. This vulnerable population will therefore require the expertise of a ‘specialist’ pharmacist in intellectual disability to ensure their safety in the medication use process. This is discussed in section 4.8.3 below.

Self determination poses difficulties for the person with intellectual disability and their carer in the medication use process and may not be associated with quality outcomes. This was a significant sub theory. This is discussed in section 4.8.4.

The main theory, sub theory and other theories, depicted in Appendix 21, are based on the fact that in promoting access to healthcare three important principles underpin best practice and apply to pharmacists and all other healthcare staff in contact with people with intellectual disabilities and their carers:

- The need of people with intellectual disabilities are greater and more complex and often present differently from those of the general population.
- People with intellectual disabilities are more likely to have impaired communication and therefore require special consideration.
- People with intellectual disabilities have the right to access health services and these should be provided within current legislative and professional frameworks.

4.8.2.1 Background

In the Republic of Ireland, community pharmacists and many hospital pharmacists are generalists in their knowledge of medicines. Each community pharmacy and most hospital pharmacies have a very mixed case load of patients for whom they provide professional care. Internationally, concerns about the basic competencies and level of training of all healthcare staff who care for people with intellectual disabilities have been raised (Disability Rights Commission, 2006, Michael and Richardson, 2008, Scholte, 2008). Patient safety issues in healthcare have also been raised by people with intellectual disabilities (NPSA, 2004a). In Scotland the process of formalising links between intellectual disability and hospital services to improve the quality of care and hospital experiences for people with intellectual disabilities has begun.

The supply of medicines to people with intellectual disabilities is important. However this stage of the medication use process should become a trigger point for the establishment of a more meaningful clinical encounter between the patient with intellectual disability and pharmacist (Wilson and Barber, 2013). This should encourage the opportunity for greater patient involvement in their own care and improved understanding of what the medicines are intended to achieve, how and when they should be taken and how to resolve any concerns.

It will be important to build capacity in the pharmacy workforce in Ireland to ensure pharmacists can intervene positively to improve the quality of medication use process and health outcomes in the population with intellectual disabilities. Pharmacists must be encouraged to learn how to respond effectively to vulnerable people (Pharmaceutical Journal, 2009). Specialist pharmacists and/or 'pharmacist champions' of vulnerable people are needed (NHS Wales, 2015). Pharmacists in primary and secondary care who are attempting to make reasonable adjustments will need support from a variety of sources including clinicians with specialist knowledge in intellectual disabilities or autism (NDTi et al., 2013). They may also need advice from speech and language therapists in relation to swallowing problems and medication administration.

An initial attempt to increase awareness among pharmacists of the safety risk to patients with intellectual disabilities in general hospitals in Ireland (Flood, 2014b) and the existence of health inequalities in the population (Flood and Henman, 2011, Flood, 2013c) have been made. Pharmacists need to be integrated into the care process for people with intellectual disabilities, to be recognized for the skills and knowledge they possess and valued for their expertise.

Raidió Teilifís Éireann (RTE), Ireland's National Public Service Broadcaster aired a programme, *Inside Bungalow 3*, on December 9th 2014. This focused the attention of the Irish nation on the care given to people with intellectual disabilities (RTE, 2014). The undercover report showed some residents at a unit of Áras Attracta Care Centre in Swinford, Co Mayo, maltreated through being force-fed, slapped, kicked, physically restrained and shouted at. This care crisis could provide an opportunity for pharmacists to become involved in improving the care given to these vulnerable people. To do this it will be important that pharmacy in Ireland and internationally begins to look outwards so that the profession will not miss vital opportunities to be part of wider healthcare service plans and priorities. However, in the UK, the Royal Pharmaceutical Society (RPS) drive towards a broader role for pharmacists has been undermined by the continuing divided leadership of the profession, and a tendency to look inwards, missing vital opportunities to be part of wider NHS plans and priorities (Nuffield Trust, 2014).

Pharmacists in Ireland appear to be 'invisible' to the care system for people with intellectual disabilities (Flood and Henman, 2010). The first report of the IDS-TILDA study failed to acknowledge the level of utilization of pharmacies by the population. Many services utilized by adults with intellectual disabilities were identified, ranging from general practitioner to 'meals on wheels' (McCarron et al., 2011a). This IDS-TILDA report was silent about pharmacies and pharmacists.

4.8.2.2 Integrated Care

Integration of pharmacists into the care of people with intellectual disabilities may mean different things to different people. Fundamentally, care integration can be defined as an approach that seeks to improve the quality of care for individual patients, services and carers by ensuring that services are well co-ordinated around their needs. To achieve integrated care for people with intellectual disabilities, those involved with planning and providing services must impose the user's perspective as the organising principle of service delivery (Shaw et al., 2011) to ensure their 'voice' is heard.

No single 'best practice' model of integrated care exists. What matters most is clinical and service-level integration that focuses on how care can be better provided around the needs of individuals with intellectual disabilities, especially where this care is being given by a number of different professionals and organisations. Formalized integrated care is not needed for all people or all forms of care but must be targeted at those vulnerable groups who stand to benefit most or who are at most risk.

The PSI, the independent statutory regulator established by the Pharmacy Act 2007 recognises that the provision of pharmaceutical care and medication management by pharmacists is an essential element of the multidisciplinary care of vulnerable patients with additional needs, such as those related to mental health, dementia or intellectual disability (PSI, 2010). Internationally, attempts have been made to increase provider skills, over the recent past which included the publication of population specific guidelines which are of benefit to all healthcare staff, including general practitioners (RCGP, 2010, Hoghton et al., 2011, Hoghton and RCLD Group, 2013) and carers (Bowers et al., 2013).

The IASSID has adopted five basic standards for healthcare for people with intellectual disabilities (Scholte, 2008) that have relevance for pharmacists:

- Accessibility of mainstream health service with primary care playing a central role. This means adequate support in communication when needed, no barriers to using mainstream services and the provision of accessible health information and health promotion.
- Health professionals in mainstream services will have competencies in intellectual disability (attitudinal and communication skills being seen as important as clinical skills).
- Professionals specialised in the specific health needs of people with intellectual disabilities are available as back up to mainstream health services to advise, treat and take over (a part of) medical care for people with intellectual disabilities if needed.
- A multidisciplinary approach to specific health assessments and/or treatment if needed.
- A proactive approach with a right to national screening programmes, implementation of health monitoring programmes and the right to aetiological investigations.

Standard 3 identifies the need for

'Professionals specialised in the specific health needs of people with intellectual disabilities'

which supports the theory developed in this Grounded Theory project that there is a need for '*specialist pharmacists*' in the area of intellectual disabilities to provide support to those pharmacists working at the coalface in primary, secondary or tertiary care.

People with intellectual disabilities pose specific challenges for clinicians and health and social care services. In Great Britain it is recognised that there is a need for General Practitioner and Pharmacist Practitioners with a Special Interests (PwSIs) - in Learning Disabilities. The RCGP and the RPS have produced a guidance document detailing the specific training and accreditation needs of general practitioners and pharmacists seeking accreditation as PwSIs in Learning Disabilities (RCGP et al., 2009). The document recognises that many GPs and pharmacists may not consider themselves to be special interest practitioners but are currently providing services within their practice or locality. The framework is for those doctors and pharmacists who wish to extend their competences and skills within a formally accredited PwSI framework. It is envisaged that the PwSI will be a practising professional with personal responsibility for a number of patients with learning disabilities. In addition to this generalist role, the PwSI will be expected to provide support and management advice to other practitioners in the local area. The Pharmacist PwSI could deliver the following different services (Alzheimer's Society, 2011):

- Clinical services, for example provide specialist pharmaceutical care for patients with learning disabilities and their carers and provide clinical medicines management support to residential and supported housing for people with intellectual/learning disabilities.
- Liaison services, for example in collaboration with specialist health and social services contribute to the co-ordination, oversight and auditing of health care issues and initiatives particular to learning disabilities, such as uptake of health checks, development of health action plans, psychotropic drug use and access to health services applicable to the general population (such as the uptake of breast screening).
- Educational services in partnership with others to develop the skills and knowledge in primary care to manage the health needs of patients with intellectual/learning disabilities. This partnership to include specialist learning disabilities professionals, Post Graduate Dean, psychiatrists working in Learning Disability (LD) and, in particular, people who use services and their carers.

- Leadership services, for example provide support to general practitioners and other health care professionals to improve the “health experience” and health outcomes for patients with intellectual/learning disabilities.

To integrate pharmacists effectively and meaningfully into the care of people with intellectual disabilities will require planning and time. This involvement does not happen over night and it may require that ‘expert’ people with intellectual disabilities and physical health or mental health difficulties, be supported to meet together for a period of time to develop their agenda for change before they are asked to contribute to development planning for increased pharmacy involvement. Pharmacists and pharmacy organisations also need to take actions that support people to participate and communicate, such as suggested in Box 4.4 below (NDTi et al., 2013).

Participation Facilitation Requirements in Population with Intellectual Disabilities
<ul style="list-style-type: none"> • Using plain language • Listening carefully and valuing people’s contribution • Talking one to one, in private, if someone with intellectual disabilities prefers • Using visual and audio formats to aid communication • Having easy to read summaries of written documents • Funding support workers • Giving people adequate information and time to prepare their response • Going at a pace that allows people with intellectual disabilities to take part • Creating a relaxed and comfortable atmosphere in meetings, with regular breaks • Paying people with intellectual disabilities and their support workers for their time and meeting their expenses

Box 4.4 Participation Facilitation Requirements in Population with Intellectual Disabilities

4.8.2.3 Education

Health care providers, including staff in medical schools, often report that there is inadequate training in medical schools for doctors working with people with intellectual disability. Medical schools have been found to provide adequate training on knowledge of intellectual disability, but the training on the skills and attitudes required for working

with this vulnerable population can be inadequate. Surveys have found a willingness among GPs to increase their skill levels.

The findings of an Australian study to gain an understanding of the perceptions of individual pharmacists in relation to their role in the provision of healthcare for people with intellectual disabilities highlighted factors such as education, training and experience in the field of intellectual disabilities to be among the most significant barriers to the provision of healthcare to people with intellectual disabilities (Di Blasi et al., 2006).

To date, many schools of pharmacy focus on knowledge and skills and may not develop pharmacists as people who will act as patient centred pharmacists. There is a great challenge for pharmacist educators to prepare pharmacists to take responsibility for their decisions, rather than deferring responsibility to others in the health team, regardless of their practice context (Anderson et al., 2012). This will be particularly relevant to the pharmaceutical care of vulnerable population groups. The QIs developed in Chapter 3 of this thesis will enable pharmacists to take responsibility for and to monitor the quality of the medication use process in the vulnerable population with intellectual disabilities and behaviour disorders.

4.8.2.4 Mental Health

There is insufficient experience among many healthcare clinicians in the diagnosis and treatment of psychiatric disorder in people with intellectual disability. The result of this is that symptoms are often attributed to the intellectual disability rather than an additional psychiatric disorder. This phenomenon is known as '*diagnostic overshadowing*' and is explored in Chapter 2. In England, a Green Light toolkit for improving mental health support services for people with intellectual/learning disabilities was written for the Department of Health in 2004 (FPLD, 2004). This toolkit shows what good mental health support services for people with intellectual/learning disabilities look like and provides a method of assessing how well local services measure up to it. The toolkit identified specific areas to address when pharmacists and other clinicians plan to involve people with mental health problems who have intellectual/learning disabilities, see Box 4.5. These ideas could be adapted for involving all groups with intellectual disabilities, those with or without mental health problems.

**Key Things to Consider when Planning How Best to Involve People with
Mental Health Problems and Learning Disabilities.**

- People with intellectual/learning disabilities involved in regular self-advocacy groups may have little personal experience of 'mental health problems'.
- It may take time to identify, locate and bring together a group of people with significant experience of mental health support, including those with experience of mainstream mental health service provision, to get their perspective.
- The concepts 'mental health', 'mental health problems' and 'mental illness' are complex. They may not have been explored very much previously with people who have intellectual/learning disabilities, people may need time and help to think about what they mean. Finding the right words to use, that mean something to people, is a critical starting point.
- Including people in mixed discussion forums with clinicians, professionals and carers before they have had much chance to consider the issues and what they want to say may effectively 'exclude' them from making an effective contribution.
- People need time to feel comfortable in groups and to think about the issues being discussed.
- The picture will evolve and become more comprehensive and informative over time.
- People from ethnic minority groups who have mental health problems and intellectual/learning disabilities may have had different experiences that are important to capture and learn from.
- Groups will need facilitators who can use approaches and techniques that get the most out of people. The facilitators will need knowledge and skills around mental health as well as how best to support people with intellectual/learning disabilities to communicate and contribute their views.

Box 4.5 Planning to Involve People With Intellectual Disabilities and Mental Health Difficulties

The Mental Health National Service Framework highlighted seven standards that local mental health services were working to achieve. Standard 2, in Box 4.6 below, contained reference to a '*specialist community pharmacist*' with a specific information and quality monitoring brief in the population with intellectual disabilities and mental health difficulties. The QIs, from Chapter 3 of this thesis will provide a framework for the monitoring process.

<p style="text-align: center;">What Primary Care for People with Intellectual Disabilities and Mental Health Problems Might Look Like: Pharmacist and Primary Care for People with Intellectual Disabilities and Mental Health Problems</p>
--

<p>A community pharmacist with a specific information and quality monitoring brief around effective use of medication for people with mental health problems who have learning disabilities.</p>
--

Box 4.6 What Primary Care for People with Intellectual Disabilities and Mental Health Problems Might Look Like: Pharmacist and Primary Care for People with Intellectual Disabilities and Mental Health Problems

4.8.2.5 Reasonable Adjustments and Pharmacy

In Ireland, the Equal Status Acts 2000 to 2004 prohibit discrimination, harassment and victimisation in the provision of goods and services, education and accommodation on the following grounds: gender, marital status, family status, sexual orientation, religion, age, disability, race and membership of the Traveller community. With regard to people with disabilities, providers of goods and services must:

- not discriminate (including indirect discrimination, discrimination by association and discrimination by imputation) against people with disabilities,
- accommodate the needs of people with disabilities through making reasonable changes in what they do and how they do it where, without these changes, it would be very difficult or impossible for people with disabilities to obtain those goods or services, unless this special treatment or special facilities cost more than a nominal cost.

There is evidence from this research project and other projects that services and clinicians such as pharmacists fail to adequately address communication issues and to understand the complex social networks on which people with intellectual disabilities

often rely. The pharmacists who supplied the insulin and MDS to Pat, may have been unaware that he was 'self caring' and that he may not fully have understood the working on a MDS or the proper storage requirements for insulin and glucagon.

When there is little understanding of the social networks and communication difficulties in the vulnerable population with intellectual disabilities, mainstream services can have difficulty in instituting successful treatment and management packages. This can result in mainstream or primary care services and clinicians being reluctant to engage with people with intellectual disabilities.

Pharmacists' roles of providing patient education and physician education has been supported by the existing literature but areas of direct patient care activities in vulnerable population groups require further study. A recent narrative literature review found that the limited evidence available in the literature suggests that pharmacists can make positive interventions in relation to the quality of the medication use process, in collaboration with other healthcare professionals, carers and patients with intellectual disabilities (O'Dwyer et al., 2015). The provision of written/pictorial information to support understanding of medication use by some people with intellectual disabilities and/or their carers can be vital to ensure optimisation of medication. In this project only two of the participants – Jamie and Frances – reported having ever received accessible information. Guidelines for pharmacists and others are available to support making written information accessible for people with intellectual disabilities (DH, 2010).

For pharmacists in Ireland, reasonable adjustments involve providing special treatment or special facilities. It is the law and is not discretionary. The Irish Pharmacy Union and the Equality Authority have produced a joint guidance document to support and stimulate quality and accessible services in the pharmacy sector for customers with disabilities (Gilbert, 2008). For pharmacists, specific and/or innovative methods of communication may be needed to ensure that issues such as medication, dosage, potential drug therapy problems or side effects are explained in a manner that makes reasonable accommodation for customers with disabilities. Gilbert and colleagues recognize that good communications skills for pharmacists and pharmacy staff are essential to provide person centred, reasonably adjusted care for people with intellectual disabilities and their carers. Advice on communication is available in Box 4.7.

Pharmacy Staff Communication Skills

- Make sure that all staff use simple, direct sentence structure and straightforward language. Terms like “placebo” and “regular application” may seem obvious to staff but are not to everyone else. A term like “at mealtimes” is ambiguous: does this mean before the meal, with the meal, after the meal? The same is true of “three times a day”: does a day mean 24 hours, or daytime...?
- Demonstrate where possible. How much is “sparingly”, for example?
- Explain possible side-effects in simple terms and reassure customers that they can come back if they have a problem. Advise people to return to talk to pharmacist about it, rather than to stop taking the medication.
- Be specific. If you are vague, your words can be interpreted in more than one way.
- Listen carefully to what people say and have patience with them. Getting flustered increases everyone’s anxiety and impairs comprehension.
- Observe carefully. Some people with intellectual disabilities will give you what they hope is the right answer, as opposed to the truth.
- Ask about people’s preferences and concerns. For example, liquid medicines may be easier to swallow.

Box 4.7 Pharmacy Staff Communication Skills

4.8.2.6 Health Literacy

Health literacy, which was explored in Chapter 2 of this document, in the population with intellectual disabilities is not a constant but is dynamic and will change with each healthcare situation. It has been recommended that healthcare providers:

- Maintain a small collection of patient education materials on topics most relevant to their practice.
- Select or develop the materials themselves.
- Are familiar with the content of the materials they use.
- Ensure that materials are integrated into the patient’s plan of care.
- Make materials available through a central database or internal website (Wizowski et al., 2014).

In pharmacies, time is often in short supply during healthcare interviews and interactions. The current business model of community pharmacy in Ireland forces pharmacist owners to maximize the number of patients they and their staff see each day. When time is limited, and patients with intellectual disabilities do not feel comfortable communicating in a rushed, busy environment, it can be very difficult for the pharmacist to determine what the patient does not understand and to address this knowledge gap adequately. Pharmacists should aim to evaluate patient comprehension of important 'to do' items for example storing insulin in the fridge until opened, indicating date on box when glucagon is removed from fridge, if two insulins are in use why they are different etc. In this project Pat stored his insulin in a drawer in his bedroom. There was no indication on any of the insulin pens and glucagon kits of the date they were removed from the fridge.

4.8.2.7 Pharmacists' Interventions

Pharmacists' interventions can range from the provision of written or oral information and counselling at the time of dispensing, to more complex interventions involving counselling, monitoring and support of patients' self management over a number of visits. Some studies have demonstrated the potential of pharmacists to identify individuals at risk and motivate them to participate in preventive health education programs which result in behaviour change. One of the objectives of patient education and counselling is to improve patient adherence to medication. Pharmacists must develop a communication style that is a more patient centered approach in order to take greater account of patients' perspectives and experiences in using their medication (Blom and Krass, 2011). Patients' understanding of the necessity of the medication treatment may be viewed as a starting point to develop concordance and so ensure adherence. Pharmacists and others making healthcare interventions in the care of people with intellectual disabilities should be mindful of the issues that are of interest to the population (FPLD, 2004), detailed in Box 4.8.

What People with Intellectual Disabilities Want from Contact with Mental Health Services
<ul style="list-style-type: none"> • to be given information and be told what's happening • to be asked what they want and for people to listen • help to understand why they are unwell • help so they feel better • someone to talk to about themselves • good advice and help to make decisions • people to do what they say they are going to do • people to respect their religious beliefs • to be treated well

Box 4.8 What People with Intellectual Disabilities Want from Contact with Mental Health Services

During the development of a mental health service for people with intellectual disabilities in the London area, it was decided to allocate specialist beds for people with mild intellectual disabilities within a mainstream acute psychiatric ward. There was a recognition that ‘specialist’ staff should play an active role in the care and support of people with intellectual disabilities admitted to the unit (Hall et al., 2006). It was arranged for ‘specialist’ psychology, occupational therapy, *pharmacy* and speech therapy to be available from the intellectual disability services and new posts were created or were added to existing posts to achieve this. Hall and colleagues recognised also that primary care services are more important for the long term support of people with intellectual disabilities. A ‘Virtual Team’ was created in the community that comprised of psychiatrists, psychologists, occupational therapist, *pharmacists* and nurses with care managers and support workers.

4.8.2.8 Outcomes and People with Intellectual Disabilities

Barriers to good health in the population with intellectual disabilities include poor access to quality medical products, lack of access to trained health professionals and care, an inadequate health workforce, unaffordable cost of care and poor standards of education of health-care professionals. Factors necessary to improve health outcomes have been identified (AHRQ, 2010c), Figure 4.17. As was mentioned previously,

providing people with intellectual disabilities, such as Pat, with medicines alone is not sufficient to achieve the treatment goals. To address their medication-related needs, pharmacists need to accept greater responsibility for the outcomes of medicines use and should evolve their practices to provide their high risk patients with intellectual disabilities with enhanced medicines-use services. Pharmacists must recognise, acknowledge and accommodate unique patient considerations in this population such as education level, cultural beliefs, health literacy, language skills and physical and mental capacity in all individual patient assessments.

The entire support and clinical network plays an important part in recognising need and navigating access to appropriate services for people with intellectual disabilities. People with health problems who have intellectual disabilities and their carers, know better than most what needs to change and their perspectives, as obtained in this project, can be very helpful when setting the priorities.

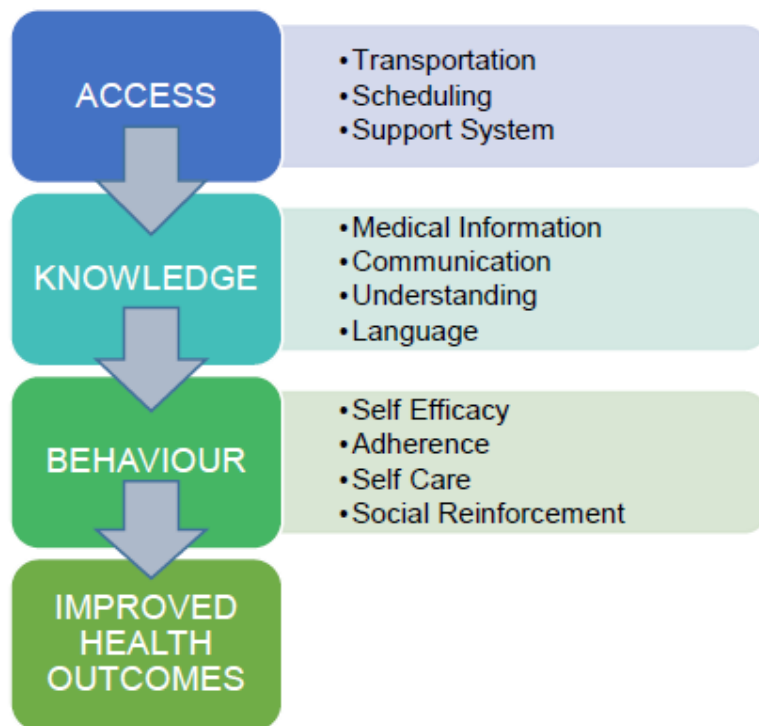


Figure 4.17 Factors Necessary to Improve Health Outcomes

To improve outcomes during healthcare encounters, healthcare professionals including pharmacists should assume that everyone may have difficulty understanding health information or have limited health literacy. An environment where patients and carers of all literacy skills can thrive should be created, (AHRQ, 2010a). Changes that will be necessary for promoting health literacy in any healthcare setting include:

- Improve spoken communication.
- Ensure supportive nonverbal communication.
- Improve written communication.
- Improve self management and empowerment.
- Improve supportive systems.

Many aspects of the care people with intellectual disabilities receive from pharmacists have not been examined. However in a project designed to test innovative ways to improve the cost effectiveness of medicines use within the city of Leeds, clinical pharmacist led medication reviews for care residents with learning disabilities, dementia or mental health needs were examined and interim results of the project published in October 2012 are available in Appendix 22 (Nelson, 2012). Pharmacists made an average of 3.4 recommendations per patient with the average number of medicines prescribed reducing from 6.0 to 5.3, with a cost saving of £107,000 annually to the primary care prescribing budget.

In Scotland, the term “*Named Pharmacist*” has been used by many patients to describe a relationship with a pharmacist, supported by a system of registration. The Scottish Government, in the report *Prescription for Excellence*, has agreed to explore the utilisation of caseloads to ‘*Named Pharmacists*’ to contribute to the clinical management of Long Term Conditions by developing the concept for registration with a ‘*Named Pharmacist*’ for all pharmaceutical care needs throughout the patient journey (Scottish Government, 2013). This is described as a fundamental principle of care and it is recommend that this should be reflected in the future arrangements for pharmaceutical care in Scotland.

4.8.2.9 Goal Setting

Goal setting is a process whereby the patient is often required to learn and master an entirely new cognitive skill (such as problem identification, setting attainable and

realistic goals), while at the same time to develop mastery over changing entrenched habits. Getting a diagnosis of diabetes exemplifies this situation, where the person may have to monitor their blood glucose levels and change their dietary habits of a lifetime. In this project Pat and Jamie have a diagnosis of diabetes. When patients such as Pat and Jamie, and/or their carers, are given choice in self-management of a chronic condition such as diabetes they are likely to focus on those aspects of self-management which are of most personal importance or relevance to them. Jamie appeared to have very good understanding of the need to adhere to her medication and insulin regimen, monitor her blood glucose and maintain a diet appropriate for a person with both coeliac disease and diabetes. In contrast, Pat did not appear to have set goals and this was exemplified by his erratic use of the MDS, his accumulation of many insulin pens and his incorrect storage habits for insulin and glucagon. His experience of having many occasions when glucagon was administered demonstrates a gap in his care and goal setting.

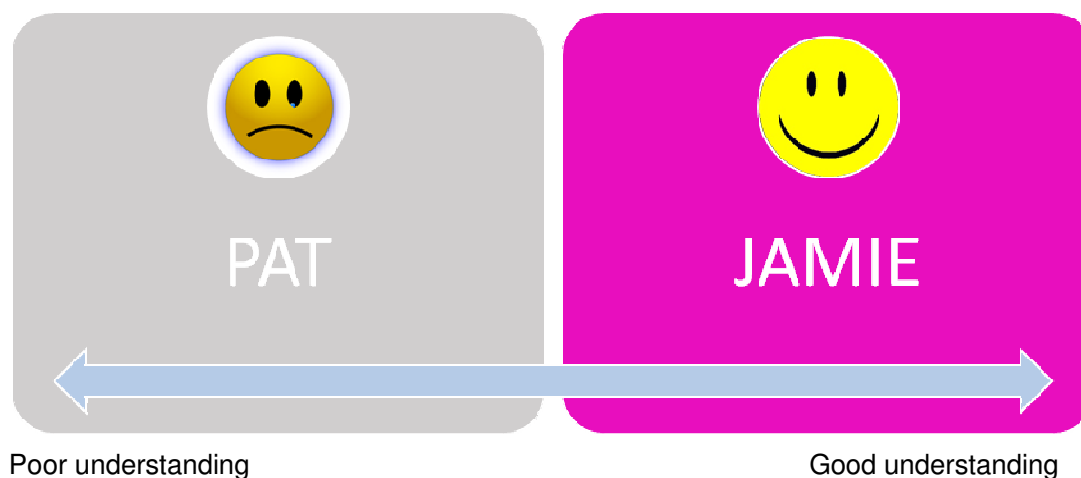


Figure 4.18 Goal Setting – Participants in this Project

The goal of self-management support is to assist and sustain the ability of the patient with intellectual disability to engage in self-management behaviours that fit within their own life patterns, and prepare them to make effective health decisions day-to-day. The agreed-upon goal must be the patient's own goal and be something that the person wants to do to improve their symptoms, function, coping or well-being. In one study in Northern Ireland, the extent to which the quality of diabetes care indicators were achieved for a population with intellectual disabilities was variable (Vitale, 2012), but results suggest that for many people the indices were not met, that glycaemic control was poor, that only a quarter were of normal weight, that many were hypertensive and

that almost a quarter had no record of their lipid levels. These are all areas in which pharmacists could make a significant impact (Wubben and Vivian, 2008) to assure realistic goal setting.

4.8.2.10 Policy Context

In the Republic of Ireland, the objectives of the *Value for Money Review* (DH, 2012e) were to look at how effective and efficient the disability services funded by the HSE are and to review and make recommendations about policy in relation to services. Of relevance to this project, the report made clear that there were no additional resources available and there was no lifting of the moratorium on recruitment.

A report prepared by the HSE titled *Time to move on from Congregated Setting: a Strategy for Community Inclusion* was published in June 2011 and referenced in Chapter 2. The report outlined how people who live in congregated settings should move into community living. The report made 31 recommendations, one of which was that

'A model should be designed for movement to community settings that goes beyond an examination of accommodation'.

When considering any policy change proposal, a *Disability Impact Assessment* should be applied at the earliest possible stage (DJ&E, 2012). *Disability Impact Assessment* is the process used for carrying out disability proofing. It involves a comprehensive examination of how any proposed policy, legislation, programme or service impacts on a person with a disability. The analysis should consider all potential impacts, both positive and negative. Carrying out a *Disability Impact Assessment* helps to ensure that decisions are taken with full awareness of the impact of those decisions on persons with disabilities. A *Disability Impact Assessment* supports mainstreaming, which essentially means ensuring that people with disabilities can take their place in society.

The impact of disability on health and healthcare and the medication use process was not considered in the *Value for Money* review or the *Time to Move on from Congregated Setting: a Strategy for Community Inclusion* document. The IDS –TILDA Report (McCarron et al., 2011b) found that key determinants of continued good health include healthcare access and healthcare utilisation. Unfortunately it did not look at any contact the population with intellectual disabilities had with their pharmacist. This report

suggested that healthcare utilisation by people with intellectual disabilities increased with age and that those living in residential centres were more likely to have accessed medical and therapy services than people living in any other living arrangement. This raises a concern in relation to the *Time to Move on from Congregated Setting: a Strategy for Community Inclusion* document, which aims to move people from residential settings into community living arrangements and also in relation to the government's responsibilities in relation to vulnerable people being 'deinstitutionalised' from an area where they have access to specialised healthcare to primary care where the access and expertise may not be available.

The various reports of the NIDD have neglected to capture the involvement of people with intellectual disabilities with their pharmacists whether they are living in the community with their families, in community residential services, in long term care, in psychiatric hospitals or other living arrangements. The invisibility of pharmacists has been identified (Flood and Henman, 2010) and is a concern. With moves towards community and primary care based services, there will be a greater reliance of people with intellectual disabilities and society on care providers and families supporting people with intellectual disabilities with their healthcare and medication use. The results of this study should motivate health care policy makers, thought leaders and funding agencies to support further research in the important area of pharmacist interventions in this vulnerable population group. There are many cost constraints in today's Irish health care environment. However it is particularly important that multi-centre studies evaluate the cost-effectiveness of specialist pharmacists providing pharmaceutical care to the population with intellectual disabilities.

Public health policies and health economics policies are part of the socioeconomic environment. In volatile economic times challenges to the provision of quality healthcare to vulnerable population groups are bound to occur. Concern has been expressed that budget cuts may lead to rationing of health services.

“Will it be perceived that longevity has a price too high when allocating costly care to older people with intellectual disabilities?”
(Noonan Walsh and McConkey, 2009).

The full benefits to patient centred care for people with intellectual disabilities will not be realised until pharmacists in Ireland are part of and integrated into the HSE system of sharing information. In New Zealand there are a number of areas where work is progressing to help support the health sector to better respond to the needs of people

with intellectual disabilities and includes improving pharmacy services for people with intellectual disabilities who live in community residences with an emphasis on obtaining the clinical support they need with their medicines to achieve better health results (Ministry of Health NZ, 2011).

In England, The Health and Social Care Act 2012 transfers responsibility for the developing and updating of *Pharmaceutical Needs Assessments* (PNAs) to Health and Wellbeing Boards (HWBs). An information pack is available that is intended to support local authority HWBs in a practical way in understanding and implementing the requirements (DH, 2013b) with attention to the specific needs of vulnerable groups being highlighted, Box 4.9.

Matters for Consideration when Making Assessments - Possible Factors to be Considered in Terms of the Benefits of Sufficient “Choice”
Is there a need for specialist or other services, which would improve the provision of, or access to, services such as for specific populations or vulnerable groups?

Box 4.9 Matters for Consideration when Making Pharmaceutical Needs Assessments

It is important that the meaning of self management or self-care in the context of people with intellectual disabilities who cannot or do not wish to exercise some control over their physical health requirements and medication management, needs to be explored in the Irish context. Self management may be too often associated with the idea of independence which does not fit the reality of many people with intellectual disabilities and chronic illnesses such as diabetes. In both self-care/self management by patients with intellectual disabilities and care by informal caregivers, safety and quality standards may not be understood or achieved.

4.8.3 Self Determination

4.8.3.1 Background

One of the keys to managing this high-risk population and intervening to address health inequalities and address poor quality care processes involves making efforts to understand the person with intellectual disabilities’ situation more fully. Clinicians such as pharmacists, must try to understand the person’s social and economic situation which will significantly impact how a patient fares in the healthcare system, as well as

when it comes to managing his or her health outside the system, in their living environment. To develop effective interventions, clinicians such as pharmacists must understand the patient's situation. Does the person manage their own healthcare or does their carer 'take charge'? In this project, Participant Gabrielle reported that her tablets were her 'own responsibility' while Participant Alex reported that he was 'told' by his father to take his medicines. The positioning of the six participants on a Self Determination scale is seen in Figure 4.14.

We understand self determination to refer to a characteristic of a person that leads them to make choices and decisions based on their own preferences and interests, to monitor and regulate their own actions and to be goal-oriented and self-directing, (National Gateway to Self Determination, 2012). Self determination poses challenges for people with intellectual disabilities as the abilities of the person and the opportunities presented by the environment contribute to the degree of self determination that can be expressed by any individual with intellectual disabilities.

The lives of most people with intellectual disabilities incorporate a culture of interdependency in that many people with intellectual disabilities live their entire lives relying on their family members and/or multiple professionals for support (Taggart and Cousins, 2014). This may be most obvious in accessing different aspects of healthcare such as GP and pharmacy visits. In this project the participants depended on their families for transport to and from their doctors' surgeries and their local pharmacies. Many of them also depended on their family member for support during healthcare encounters, for example when bringing the prescription to the pharmacy. However, Participant Keelan reported that although he sees the doctor alone, his family were 'wrecking my head' as they 'have to know' everything.

The people interviewed in this project all lived at home with family members. Rights, respect and responsibility interact at all stages in the lives of people with intellectual disabilities. Each home was different and so care was provided in unique situations. People with intellectual disabilities who live 'at home' often have a greater role in determining how and even if certain interventions in healthcare will be implemented. For example, in a residential care setting, nurses, physicians and pharmacists may all play a role in ensuring that the patient with intellectual disabilities receives antibiotics at therapeutically appropriate intervals. At home, however, the patient with intellectual disability may choose, for a variety of reasons, to take the medication at irregular times, despite advice about the importance of a regular antibiotic schedule.

Interventions by pharmacists and others to promote patient safety and quality care in the medication use process must account for the fact that patients will sometimes choose to act in ways that are inconsistent with the relevant evidence and the pharmacist's best efforts may not result in desired outcomes. Participant Keelan makes 'his own rules' about medicines. However many patients with intellectual disabilities receive assistance or support from family members or other informal caregivers. Professional clinicians such as pharmacists have no authority over these caregivers.

Opportunities to directly observe the 'self determined' patient and their informal caregivers in the medication use process are limited. Many people with intellectual disabilities are 'invisible' to pharmacists. This will hinder efforts to quickly determine the etiology of any medication safety incident that occurs. If a person with intellectual disabilities presents at a healthcare encounter with bruises that the patient can't explain, is the cause a fall resulting from hypotension caused by antipsychotics, physical abuse or a blood dyscrasia? It must be recognised that there may be situational variables that present risks to patients with intellectual disabilities who are 'self determined' that may be difficult or impossible for the clinician to eliminate. Participant Pat did not take medication when he did not want to and Participant Gabrielle has pretended to take medicine on occasions and has then spat it out.

4.8.3.2 Accessible Information

It is the responsibility of health professionals to make information on medication readily available to people with intellectual disabilities and their carers. The need for accessible information has been identified by people with intellectual disabilities as an area of concern (NPSA, 2004a). Four of the six participants in this project reported that they have never received accessible information from the doctor or the pharmacist.

However, even when information is provided to the person and/or their carer, this does not guarantee that an individual patient/carers has understood and accepted the information they have received. The written drug information presented in patient leaflets and patient package inserts, or published on websites, may not be accessible to people with intellectual disabilities and may be misinterpreted by the person and/or their carers with limited health literacy skills. In particular, the frequencies of drug side effects are often misunderstood, especially by consumers with low numeracy skills which will include most people with intellectual disabilities.

People need information in a language they can understand. People with intellectual disabilities may not understand 'side effects'. In this project the participants were able to identify 'good' and 'bad' things about medicines. Keelan had never heard of 'side effects'. Participant Gabrielle, who was unaware of side effects identified 'feeling better' as a 'good' thing about medicines. Participant Alex said that his 'strength went down' and that 'it was hard to do things' after starting Stelazine (Flood and Henman, 2015a).

4.8.3.3 Risk Assessment

Patient independence and engagement with their treatment should be encouraged and pharmacists must pay close attention to at-risk patients such as people with intellectual disabilities. Groups at increased risk of medication safety incidents within the population with intellectual disabilities will include those who self manage their own health, those with high risk illnesses such as diabetes, those taking high risk medications such as insulin and those for whom reasonable accommodations were not provided by clinicians including prescribers and pharmacists. Accurate documentation and review of medications during each patient encounter in this vulnerable group is important. The evidence suggests that frequent medication reviews and collaboration with members of the health care team, especially pharmacists, will improve care and help to prevent adverse events associated with poor medication management (Ellenbecker et al., 2008). In England, the sharing of relevant information can on occasion be as important as the duty to respect patient confidentiality (HSCIC, 2013).

To protect people with intellectual disabilities in the medication use process it is important that a risk assessment is undertaken to ensure that medication use will be of high quality, that it is safe, appropriate, cost effective, etc. Pharmacists must discharge their professional responsibility to confirm that patients with intellectual disabilities are 'competent' to self administer medications for example, from MDS and/or insulin injections and that they are aware of storage conditions for certain products such as insulin and glucagon. Participant Pat in this project stored his insulin in a drawer in his bedroom. He had 13 Lantus insulin pens removed from their original packaging. He also had three Glucagen Hypokits with no indication of when they had been removed from the fridge. He used a MDS erratically with no medications used in Week 1.

Work has been undertaken by the RPS in England in relation to the safety of Home-Care Treatments (RPS, 2014). An adaptation for use in the population with intellectual disabilities is available in Appendix 23 and risk stratification is illustrated in Figure 4.19.

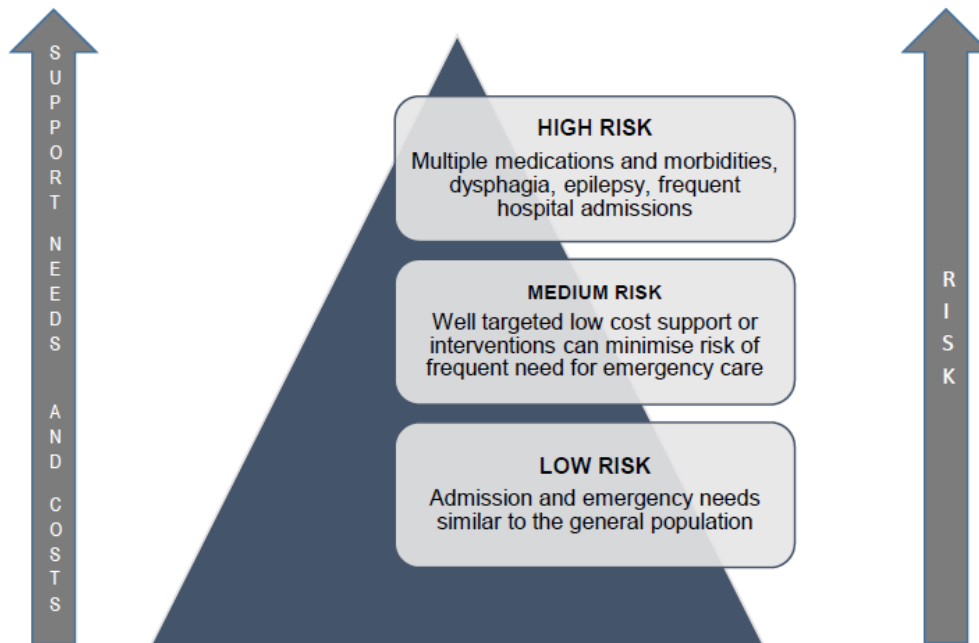


Figure 4.19 Risk Stratification-Support Needs and Cost

4.8.3.4 Patient Safety

Improving patient safety and the quality of care by educating and assisting caregivers (families and providers) is an approach that has been tested in several RCTs (Ellenbecker et al., 2008). Reporting of medication safety incidents and near misses should be encouraged (IMSN, 2014) from all 'home' environments of people with intellectual disabilities. This is required to establish the quality of current processes. To improve processes, people with intellectual disabilities and/or their paid or family carers should be encouraged to report medication safety incidents. Incident reporting and effective incident management allows healthcare service providers the opportunity to learn from medications safety incidents. Medication safety incidents should be recorded as a basis for investigation, analysis and learning with the investigation taking a systems approach to error occurrence. Analysis should include the classification of the incident to facilitate standardisation and comparison across clinical settings and should allow identification of the patient as a person with intellectual disabilities.

The potential of medication errors among the home health care population is greater than in other health care settings because of the unstructured environment and unique communication challenges in the home health care system (Marek and Antle, 2008).

Many patients in primary care have been found to take medications in ways that deviated from the prescribed medication regimen (Ellenbecker et al., 2004). Participant Pat gave evidence of this by his non-compliance with the MDS in which his medications were supplied. Recently non-adherence to anti-epileptic medications has been identified as a potential medical risk for individuals with intellectual disabilities that is significantly impacted by the type of community living arrangement (Hom et al., 2015).

Analysis of large numbers of incidents allows the detection of trends which should prompt the issuing of patient safety alerts such as those published by the NPSA in England. Analysis at national level may lead to recommendations for changes to clinical practice. The NPSA noted that more information is needed about medication incidents occurring in mental health and intellectual disability services to enable national learning to be derived. The NPSA found that some incidents related to confusion over what medicines patients had self-administered, possibly as a result of inadequate supervision or a lack of continued assessment of the patient's suitability for self-administration (NPSA, 2009).

**What can be Learnt from Incidents in the
Mental Health and Learning Disabilities Sector?**

- Omission in the administration of anti-convulsant medicines was the most frequent type of incident reported by the learning disabilities sector.
- Medicines reconciliation across the primary - secondary care interface was identified as a high risk.
- Modern mental health services are predominantly based in the community, however, very few reported incidents were from the community sector of services.
- New approaches to the provision of modern mental health services have increased the number of interfaces requiring communication/transfer of information, hence increasing the potential for medication errors.
- Steps should be taken to increase the reporting of, and learning from, medication incidents that occur in the mental health sector and should enable the improvement of medicines management systems.
- There are fewer pharmacy resources in mental health services than in acute care and this may increase the risk of medication errors.

Box 4.10 What can be Learnt from Incidents in the Mental Health and Learning Disabilities Sector?

In the future, with the move towards community and primary care based services, there will be a greater reliance of people with intellectual disabilities and society on care providers and families supporting people with intellectual disabilities with their healthcare and medication management. This may not be easy for the person with intellectual disabilities and may cause conflicts in the home setting. Participant Keelan reported that his parents were 'wrecking my head' and that 'they have to know' what the doctor has said. Care givers such as family members, may be bothered by the dilemma between providing good care such as preventing a person with intellectual disability and diabetes from unhealthy eating and providing person centred care and respecting the autonomy of the person with intellectual disability and diabetes. This may have been the case for Participant Pat who appeared to have the sole responsibility for his medication and insulin administration.

As this vulnerable population ages in the community, experiences more complex health problems and takes more medication, medication management practices will require systematic monitoring by 'expert' pharmacists and other 'experts' in the area e.g. speech and language therapists, psychiatrists, psychologists, general practitioners and behaviour support therapists.

It has been acknowledged internationally that a discrepancy exists between the number of adverse events reported versus the actual number of adverse events. In Ireland it is recognised that there is a significant level of under reporting of clinical adverse events. However medication adverse events were within the top three adverse events reported in 2012 and represent 7.8% of all events reported (Oglesby, 2013). The disability sector accounted for 8.6% of all medication related adverse events, 49.2% of all reports of violence/harassment and aggression and 11.8% of all falls reported. Understanding the underlying system factors that lead to patient harm in the disability sector and intervening to fix them will lead to improved safety for people with intellectual disabilities in all living environments.

4.9 Advantages, Disadvantages and Limitations of Grounded Theory

4.9.1 Background

Grounded Theory, as used in this project, was based upon the goal of deriving theory from the ground up. This limited the imposition of a priori assumptions on the data derived from interviews with six people with intellectual disabilities and literature review. Along with other researchers using this approach, this researcher did not use the whole approach, but made pragmatic use of the analytical tools in the approach.

4.9.2 Advantages of Grounded Theory

The main advantages of using Grounded Theory in this project included:

- its intuitive appeal as an approach because it allowed immersion in the data,
- the approach fostered creativity because it avoided preconceived theoretical data,
- it allowed concept development and the separation of the relevant from the irrelevant,

- as a systematic approach to data analysis it used a systematized set of procedures to develop and inductively derive Grounded Theory about the phenomenon of medication use in this vulnerable population,
- it allowed the researcher to gather rich data, to make sense of the data and to refine it to generate insight into the world of the participants with intellectual disabilities,
- there is always something new to discover from people who are 'hard to hear',
- the ability to reveal high level concepts and theories that are not specific to a particular participant with intellectual disability or setting.

4.9.3 Disadvantages

The main disadvantages of using Grounded Theory in this project included:

- as a novice Grounded Theory researcher, the author had to avoid becoming inundated at the different levels that were time consuming, tiring and labour intensive,
- it was not always easy to abstract and encompass concepts,
- the need for the researcher to avoid becoming absorbed in the process that would result in losing sight of the task that was the discovery of theory, ideas and themes that were emerging from the data,
- it is not a simple task and cannot be hurried as it took months to fine tune the emerging theories.

4.9.4 Limitations

A limitation of this study is that it only targeted the most able (and verbal) people within the population with intellectual disabilities and thus omitted the views and experiences of medication use of a large proportion of less able people with intellectual disabilities. It does, however, raise the question of how less able, non-verbal people with intellectual disabilities would manage some of the more negative feelings of medication use described by participants within this study and the impact of this on their behaviour in relation to medication use and their health based quality of life.

A further limitation is that only people living in the community with their families were interviewed. People ageing with intellectual disabilities living in long term care or supported accommodation away from their families were not interviewed.

The participants were not in the older group of people ageing with intellectual disabilities and in the main were not prescribed significant quantities of psychotropic medications.

It is not possible to be 'purely objective' but the aim is to 'maximise objectivity'. Personal bias may have been introduced.

The interviewer knew that it was necessary to probe deeper and to get the interviewee to elaborate or broaden the topic of discussion. However, due to the vulnerabilities of the participants, great care was required to ensure they were not upset or anxious about the subject matter.

This research was governed by the practicalities of human resources. In particular, time was a limited resource as the researcher was engaged in full time employment while carrying out the entire Grounded Theory process.

4.9.5 Conclusions

Synopsis of Grounded Theory
<p>The phenomenon observed in this research project was that some people with intellectual disabilities who live in the community are vulnerable in the medication use process.</p> <p>Risks were identified in the medication use process.</p> <p>Theories identified during the Grounded Theory approach in this project are:</p> <ul style="list-style-type: none">• there is a need for 'specialist' or 'expert' pharmacists with knowledge of the vulnerabilities of people with intellectual disabilities in healthcare• 'self determination' may not ensure quality medication use or best outcomes in people with intellectual disabilities who have high risk illnesses and who take high risk medications.

Box 4.11 Synopsis of Grounded Theory

4.10 Discussion

This research is the first attempt by a pharmacist in Ireland to understand the experience of people with intellectual disabilities in the medication use process. How the data presented was heard and interpreted will have been influenced by the experience of working as a pharmacist in a residential centre for people ageing with intellectual disabilities in the Dublin area.

Pharmacists have a unique insight into the medication use process that will be different from that of a physician, psychiatrist, nurse etc. The perspective of a pharmacist working at the 'point of care' with people ageing with intellectual disabilities will be different again from that of a community pharmacist or a pharmacist working in secondary care.

Six people with intellectual disabilities were interviewed to ascertain their views and knowledge of medication. The project was facilitated by a national support organisation for people with intellectual disabilities and received approval from the Faculty of Health Sciences Ethics Committee, Trinity College. People with intellectual disabilities in this project consented to participate themselves and were pleased to be recognised as the 'experts' of the medication use process in their population group. They provided valuable information and insight into medication use in this population. The six people were welcoming, interested, informative and polite with definite opinions and observations of their own.

The aim of Grounded Theory used in this research project was to 'generate or discover a theory' (Glaser and Strauss, 1967). Grounded Theory was chosen as it is ideal for exploring integral social relationships and the behaviour of groups where there has been little exploration of the contextual factors that affect individual lives (Crooks, 2001). One such little explored area is medication use in the population with intellectual disabilities. Grounded Theory enables the researcher to 'get though and beyond conjecture and preconception to exactly the underlying processes of what is going on, so that professionals can intervene with confidence to help resolve the participant's main concerns' (Glaser, 1978). To the Grounded Theorist, '*all is data*'.

A semi structured interview tool was used to collect data, from which components of a theory were developed. Theoretical sensitivity was achieved over time by immersion in the data and attempting to understand what was significant and important in relation to medication use to the lives of the people interviewed. Efforts were made to avoid

predetermined ideas. However, the literature review described in Chapter 2 of this thesis and the day-to-day working environment could also be used to inform rather than direct the development of theory and the analysis. The following questions were used to ensure the process was always active:

- What is actually happening here?
- Under what conditions does this happen?
- What is this data a study of?
- What category does this incident indicate? (Glaser, 1978)

Memoing was used as an intermediate step. Two core categories were identified that were grounded in the data:

1. Person with intellectual disabilities is vulnerable in the medication use process in healthcare.
2. Pharmacy and the medication use process in the vulnerable population with intellectual disabilities.

Vulnerable populations can be defined as those at greater risk for poor health status and healthcare access, experience significant disparities in life expectancy, access to and use of healthcare services, morbidity and mortality. Their health needs are complex and they intersect with the social and economic conditions they experience in their environment. Unfortunately health care initiatives to reduce the barriers to healthcare created by vulnerability rarely recognize that risk factors often overlap. While the role of pharmacists as members of the health care team has expanded beyond conventional medication dispensing internationally, pharmacists in all practice settings and locations may lack exposure to this vulnerable population group. Once a diagnosis is made in a person with intellectual disabilities, patient care relies on pharmacologic interventions as the major form of therapy. Data suggest that medications are currently the cornerstone of chronic disease therapy in all population groups. Medication is the major therapeutic intervention in the population with intellectual disabilities. However, the pharmacist is often 'invisible' in the care process for people with intellectual disabilities (Flood and Henman, 2010). People with intellectual disabilities are also invisible to pharmacists as they are a group of people that are 'hard to hear' and 'hard to see'.

Pharmacists can make a valuable contribution to the care of patients in all groups. In a report to the USA Surgeon General that focused on improving health care delivery through utilisation of the pharmacist, Giberson et al. state that one of the most evidence-based decisions to improve the health system is to maximize the expertise and scope of pharmacists and minimize expansion barriers of an already existing and successful health care delivery model (Giberson et al., 2011). The authors of a comprehensive systematic review of 298 research studies to examine the effects of pharmacist-provided direct patient care on therapeutic, safety and humanistic outcomes, concluded that integrating pharmacists into direct patient care results in favourable outcomes across health care settings and disease states (Chisholm-Burns et al., 2010). The vital role undertaken by pharmacists in the areas of medication safety and management, as well as the value of pharmacist-physician collaboration in patient care is recognised by the Institute of Medicine (Adams and Corrigan, 2003). According to the Institute of Medicine (IOM)

'To close the gaps between best practice and usual care ... will require the collective expertise of a vast array of doctors, nurses, pharmacists, allied health professionals, social workers, and vested laypersons'.

The main theory developed in this project is that there is a role and need for 'specialist pharmacists' in the healthcare of vulnerable people with intellectual disabilities, Appendix 24. A significant sub-theory related to the main theory was that self determination by the person with intellectual disabilities in the medication use process poses difficulties and may not ensure the highest quality care. Other minor but interlinked theories directly related to the main theory and the sub-theory were: patient centred care, reasonable accommodations, health literacy, communication and accessible information, health inequalities, vulnerabilities, the right to health, peer learning, health promotion, staff attitudes, equal health outcomes, government policy, pharmacists' responsibility, transfer of information, expert patient and expert carer, health in quality of life, risk stratification, quality of the medication use process, medicines optimization and regulatory and standards bodies.

Guidance has been produced in Ireland to support and stimulate quality and accessible services in the pharmacy sector for people with disabilities (Gilbert, 2008). In England the Green Light toolkit for improving mental health support services for people with learning disabilities indicates that the ideal primary care for people with intellectual disabilities and mental health problems might include a community pharmacist with a

‘specific information and quality monitoring brief around use of medication for people with mental health problems who have learning disabilities’ (FPLD, 2004).

Pharmacists have been identified as a specialist staff member required to play an active part in the care and support of people with intellectual disabilities in an acute psychiatric ward (Hall et al., 2006). In Leeds, clinical pharmacist led medication reviews for care residents with intellectual disabilities, dementia or mental health needs resulted in 2,309 recommendations to GPs, i.e. an average of 3.4 per patient, to improve the quality or cost effectiveness of prescribing and a decrease in the average number of medicines prescribed from 6.0 to 5.3 (Nelson, 2012). An increase in the prescribing of bone health medication resulted from an Irish pharmacist’s interventions following falls in an ageing population with intellectual disabilities in long term care (Flood, 2013a).

Effective patient care services related to medication management by pharmacists and others can lower total health care costs. Although initial medication costs may rise due to improved medication adherence, it has been shown that hospital and emergency room visits are reduced (PCPCC Medication Management Task Force, 2010). Diabetes is an ACSC i.e. it is a condition which can normally be treated effectively in primary care. Admission to hospital for ACSCs indicates potential weaknesses in primary care that need addressing. People with intellectual disabilities are more likely than the general population to be admitted to hospital as an emergency with complications of diabetes (Turner and Emerson, 2013).

The Executive Director of the Irish Institute of Pharmacy, Dr Caitriona Bradley, has said that a lack of understanding of the role of pharmacists is the ‘biggest challenge’ the profession of pharmacy faces (Kelly, 2014). Dr Bradley recognises that there are many examples around Ireland of pharmacists working, both as part of multi-disciplinary teams and alone, to improve patient outcomes. She notes that initiatives for advanced practice generally come about as the result of great personal effort on the part of pharmacists and that it doesn’t often feel like the Irish healthcare system makes it easy. Dr Bradley advocates establishing an evidence base for pharmacy practice in Ireland that can be communicated to ‘the right people’ with its implications need to be clearly understood. Concentrating on establishing a research base initially on high risk patients, such as those with intellectual disabilities, with chronic high risk illnesses e.g. diabetes, who are prescribed high risk medications e.g. insulin, may offer an

opportunity of a 'win - win' situation for the vulnerable patient and the pharmacy profession.

The RCGP has produced information for those interested in the specific training and accreditation needs of GPs and pharmacists seeking accreditation as Practitioners with Special Interests in Learning Disabilities (RCGP et al.). Pharmacists are expected to have the relevant competences dependent on the requirements of the service. While some competences are similar to those listed below in Box 4.12, the prime focus of the contribution of the PwSI pharmacist to the care of patients with intellectual disabilities will relate to medication and integrating with other relevant services.

Summary of Competencies for a Practitioner with Special Interest in Learning Disabilities
<ul style="list-style-type: none">• History taking and diagnosis• Referral for people with learning disabilities• Clinical management of people with learning disabilities• Management of drug therapy for people with learning disabilities• Legal issues pertaining to the care of people with learning disabilities

Box 4.12 Summary of Competencies for a Practitioner with Special Interest in Learning Disabilities

This project brought to the fore difficulties in the medication use process in this vulnerable population. These included difficulties for the patients, their families and for clinicians providing healthcare interventions. The index case in this project was that of Participant Pat, who was a diabetic. Poor co-ordination of care and the need to integrate the pharmacist into the care process for people with intellectual disabilities were evident. This project identified risk in Pat's care that were associated with poor outcomes e.g. regular hypoglycaemic episodes. Health literacy difficulties resulted in incorrect use of a MDS. Incorrect storage conditions for insulin and glucagon were evident. A CPD article of pharmacists that draws attention to some issues in this population, including diabetes, that pharmacists should be aware of is available (Flood, 2014a).

QIs for GPs in England include the need for close co-operation between the GP practice and community pharmacy to be demonstrated (Duerden et al., 2011). Ideally each practice should have regular meetings with the pharmacies that are most closely related to them and where pharmacists flag up significant medication issues they

should be given feedback on how these have been dealt with. Also when GPs encounter dispensing errors or where inappropriate advice has been given to patients, there should be a frank and open discussion.

Some people with intellectual disabilities have reported that they had very helpful pharmacists who helped them understand their medication. However, the picture was often of prescribed tablets with limited information (NPSA, 2004a). Efforts by pharmacists to improve health literacy are essential for effective self-management and collaborative care. For example, diabetics with poor health literacy, unable to read and/or comprehend directions on their pill bottles were found to have worse blood sugar control and higher rates of preventable vision impairment (Schillinger et al., 2002). Pharmacists devising strategies to improve health literacy both at the micro level where patients and pharmacists interact when medication is being dispensed, and at the macro level, where the population health of people with intellectual disabilities and diabetes is the target, would not only improve diabetes outcomes, but also form part of a package of improvements for nearly all currently inadequate aspects of health care.

Pharmacists are one of the most accessible professionals who provide healthcare and addressing literacy is identified as an important quality improvement intervention. People with intellectual disabilities must have access to accessible information and this is closely related to communication channels. Pharmacist must use language accessible to each individual. The term 'side effects' may not be known to people with intellectual disabilities. As demonstrated in this project, it may be more appropriate to discuss 'bad things' and 'good things' about medication with a person with intellectual disabilities. This is important because without accessible information the individual will have no basis to process messages to improve health outcomes and will not be in a position to give informed consent.

The introduction of 'specialist pharmacists' with knowledge of this vulnerable population will bring value to the care of people with intellectual disabilities and support the theory developed in this Grounded Theory research project.

CHAPTER 5

DISCUSSION

5.1 Introduction

5.1.1 Background

Internationally, there is opportunity to improve the quality and performance of health-care systems, as well as growing awareness and public pressure to do so. There is also a growing field of research concerning evidence for quality service that emphasises the requirement of a more scientific and systematic approach to the use of information concerning interventions on quality.

The focus of this project is on the quality of the medication use process in the population with intellectual disabilities and behaviour disorders and on the outcomes produced by the process. People ageing with intellectual disabilities experience health and health care inequalities. Medication use is the main therapeutic intervention in this vulnerable population. The quality of the medication use process must be reviewed and improved to ensure medication use contributes to the improvement in health and the narrowing of the health inequality and inequity gap between the population with intellectual disabilities and the general population.

Assessing the quality and safety of care has become increasingly important. Unless we actually measure the quality and safety of care in this vulnerable population, we cannot determine if improvements are being made.

To improve quality and outcomes in health systems there must be a starting point. Some understanding of what is meant by 'quality' will be necessary in the design of interventions and measures used to improve outcomes. To provide quality healthcare, health systems should seek to make improvements in various dimensions of quality, that have been mentioned throughout this thesis - effectiveness, efficiency, accessibility, acceptability, patient-centredness, equity and safety - that are associated with the QIs developed in Chapter 3, Appendix 25.

5.1.2 Aims

The overall aim of this project is to improve the quality of care for the population with intellectual disabilities and behaviour disorders. The two part project described in this thesis and seen in Table 5.1 involved:

- The successful development of QIs for medication use in people with intellectual disabilities and behaviour disorders as described in Chapter 3. A multidisciplinary and international group was recruited and took part in a MDT that agreed 37 QIs. The QIs were graded and six Crucial QIs that were identified related to various dimensions of quality.
- Interviews with six people with intellectual disabilities to gain insight into the medication use process in the population with intellectual disabilities by hearing ‘the voice’ of people with intellectual disabilities who are the ‘experts’ in relation to medication use in their population. As described in Chapter 4 of this thesis, a Grounded Theory approach to the analysis identified key themes arising from the participants experiences.

Table 5.1 Aims of This Project

AIM	OUTCOME	THESIS
Identify candidate QIs for medication use in people with intellectual disabilities and behaviour disorders	A narrative literature review identified 38 candidate QIs.	Chapter 2
Develop QIs for medication use in people with intellectual disabilities and behaviour disorders	A multidisciplinary and international group was recruited and took part in a successful MDT. 37 QIs were agreed. 6 Crucial QIs were identified and remainder of QIs graded for importance.	Chapter 3
Obtain views and knowledge of people with intellectual disabilities of the medication use process	6 people with intellectual disabilities interviewed using semi-structured tool. Interview data analysed using Grounded Theory. Themes identified. Theories developed – Specialist Intellectual Disability <ul style="list-style-type: none"> • Specialist Pharmacist • Self determination 	Chapter 4

5.1.3 Medication Use Process

Specific determinants of health identified for the population with intellectual disabilities are challenging behaviour, psychotropic medication use and physical activity (Van Schrojenstein Lantman-de Valk et al., 2007). Much of this thesis relates to challenging behaviour and psychotropic medication that are linked in the care of many people with intellectual disabilities. The QIs developed in Chapter 3 reflect this linkage. The framework for Chapter 2 of this thesis, a literature review linking these two determinants with medication use and quality is illustrated in Figure 2.1. The quality of the 'real life' experience of the medication use process was examined in Chapter 4.

The medication use process in the population ageing with intellectual disabilities and behaviour disorders is very complex and the quality of the process will vary depending on the location in which it occurs, the processes, and the personnel involved. Quality issues exist at every stage and a whole system approach to quality improvement is necessary as there can be cumulative loss of quality at each consecutive stage of the medicine use process. Furthermore, medication use provides an ideal opportunity for monitoring quality of care in vulnerable older people (Knight and Avorn, 2001a).

The complexity of the medication use process in this vulnerable population is illustrated in Figure 5.1 which expands Figure 2.6 in Chapter 2. The literature review in Chapter 2 of this thesis, illustrated how the medication use process in this population starts before medication is prescribed, with a 'pre-prescribing' stage. This stage includes both '*diagnostic overshadowing*' and '*healthcare by proxy*'. The importance of this stage must be recognised by policy makers, government, service providers, clinicians, pharmacists, direct care givers, people with intellectual disabilities and their advocates and carers.

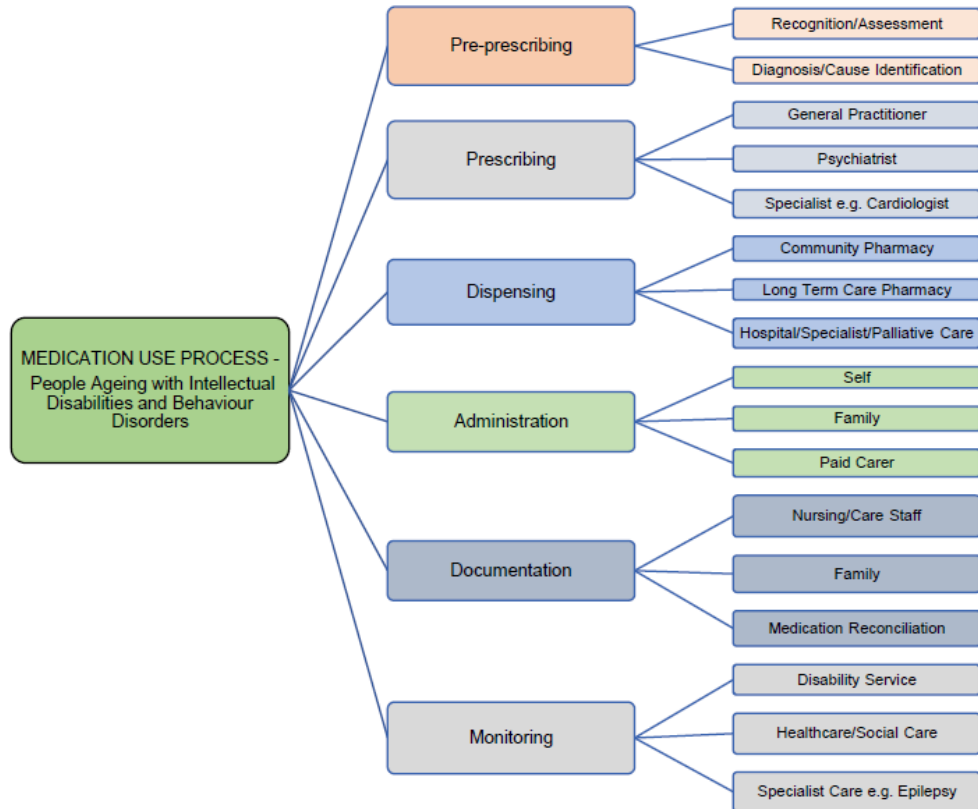


Figure 5.1 The Complexity of the Medication Use Process

5.1.4 Population Interventions

Population-based medication management projects potentially have the highest impact on improving patient care and decreasing healthcare costs compared to many other types of pharmacy interventions (Kennedy and Biddle, 2014). Population-based projects involve looking at a patient population, such as the population with intellectual disabilities, as a whole and determining the number of patients who are not achieving specific quality care measures. Once a group of patients, e.g. people with behaviour disorders, or quality measures similar to the QIs developed in this project are identified, quality improvement interventions can be developed and implemented.

5.2 Care Environment

5.2.1 Ethics

The health of people with intellectual disabilities is in part dependant on the ethical standards applied by those charged with providing healthcare (Noonan Walsh, 2011). Ethics can be defined as

'principled sensitivity to the rights of others'.

However, concentration by pharmacists on rights alone without regard to respect and responsibility can place people with intellectual disabilities in the position of making potentially unwise and unhealthy decisions in relation to medication use/non-use and other healthcare decisions. This was illustrated by the experience of Participant Pat in Chapter 4 of this thesis, who appeared to have responsibility for his own self care and medication use (Flood and Henman, 2015d). His 'right' to autonomy was recognised but there would be concerns about the 'respect' shown to him as a person deserving of the highest quality of healthcare and the 'responsibility' of clinicians including pharmacists to protect his 'right to health'. The apparent disconnect between universal human rights and the heterogeneous limitations of people with intellectual disabilities has caused concern (Fyson and Cromby, 2013).

In many ethical frameworks autonomy is seen as the most important ethical principle, but this can be a limiting point of view when considering medication use. Autonomy is not an isolated phenomenon. The life circumstances of a person with intellectual disability such as Pat will have a significant effect on how they experience any sense of autonomy and of being in control of their life and their medication use. The evidence available from Pat showed that there may be practical difficulties in maximising a person's autonomy and ensuring safety in the medication use process. For people with intellectual disabilities, autonomy can only be made possible by the social infrastructure that supports each person. All the participants interviewed for this thesis lived with their families but, as illustrated in Chapter 4, they had varying experiences of autonomy in relation to medication use decisions and they also experienced varying health related outcomes.

The situation of vulnerable staff, including pharmacists, who have 'ethical concerns' while working in services for people with intellectual disabilities must also be acknowledged. Some difficulties have been illustrated by Wilson and colleagues who

interviewed nine professionals about their experience of addressing an ethical issue within their work in intellectual disability services (Wilson et al., 2008). Professionals have felt at times that they had negligible power to make changes in the lives of people with intellectual disability and support workers and professionals who advocate for people with intellectual disabilities can be placed in vulnerable positions with their employing organizations (Jorgensen et al., 2009). This has the potential to make advocacy very variable in all settings in which vulnerable people are cared for, this was supported by the results achieved by the Advocacy QI in the MDT described in Chapter 3 of this thesis. This QI was rated to be important by 66.79% of the Round 2 panel, to be scientifically sound by 41.7% and feasible by only 33.3%. This was the lowest rating for feasibility for all QIs. One panel member commented

'it is disappointing to see that feasibility of advocates is rated at 33.3%'.

5.2.2 Capacity in Ireland

The issue of capacity and lack of capacity is central to the complexity of the medication use process in this population. Pharmacists and others must keep in mind that for many people with intellectual disabilities the following may be true

'entitlement to ID services is an implicit recognition that an individual - to a greater or lesser extent - lacks capacity to make meaningful choices'
(Fyson and Cromby, 2013).

The health related quality of life outcomes achieved by medication use or medication non use may not be appreciated by some people with intellectual disabilities and Schelly describes a situation where some people with intellectual disabilities

'cannot think in the ways necessary to make choices that would improve [their] quality of life' (Schelly, 2008).

Consistent with these points, self determination was generated as a significant sub-theory following Grounded Theory analysis in Chapter 4. This analysis illustrated that difficulties posed by self determination for the person with intellectual disability and their carer may not always be associated with quality healthcare outcomes. These difficulties arise in particular when the person with intellectual disability has a high risk illness such as diabetes and is prescribed high risk medications such as insulin.

5.2.3 Residential Care

5.2.3.1 Care Quality Commission

In England inspection reports of the CQC have highlighted common issues of poorer performance across health and social care settings (CQC, 2012b). There were particular concerns where safe management of medicines was being compromised by a lack of information given to those taking medicines or those caring for them. The inspectors also noted that increasing strain was being placed on social care environments by more complex treatment with medicines and significant growth in co-morbidity.

5.2.3.2 Health Information and Quality Authority

In Ireland, HIQA has published *Guidance on Developing Key Performance Indicators (KPIs) and Minimum Data Sets to Monitor Healthcare Quality*. HIQA states that:

'specific KPIs are related to a specific service user population and measure particular aspects of care related to those service users'.

KPIs as described by HIQA, are closely related to the QIs developed in Chapter 3 of this thesis that provide a solid base for the development of these vital KPIs.

To assist designated centres in meeting regulations and implementing standards HIQA has published guidance documents including *Guidance on End-of-Life Care* and *Guidance on Food and Nutrition*. To date HIQA has not published specific guidance or KPIs in relation to the medication use process in people with intellectual disabilities and behaviour disorders.

5.2.3 Deinstitutionalisation

5.2.3.1 Introduction

The Irish government has a deinstitutionalization strategy for people with intellectual disabilities (Working Group on Congregated Settings, 2011) but concern has been expressed in relation to this strategy being associated with poor community integration (McCarron et al., 2014a). The HSE provided funding for transitioning 150 people from congregated settings to the community. However, as of September 2014, only some 25 people had been moved. A number of reasons have been given for delays in

moving people with intellectual disabilities into the community; namely non-availability of social housing, funding, stakeholders not in agreement and HIQA regulations. It is becoming evident that people who live in institutions must go through long processes before they can live independently (NFVB, 2014). It is also a concern that in the Wave 2 IDS-TILDA report, most individuals who moved to a new location reported not having being part of the decision to move (McCarron et al., 2014a).

After the exposure of abuse of patients with intellectual disabilities at the Winterbourne View Hospital, the English Department of Health set out its action plan in the *Winterbourne View Concordat* published in December 2012 (DH, 2012f). The Government had set a central goal of moving people with intellectual disabilities and challenging behaviour out of hospital by 1st June 2014. However it is now recognised in England that the complexity and level of challenge in meeting these commitments was underestimated and the goal was not achieved. The Wave 2 IDS-TILDA report in Ireland noted that participants who moved to more restrictive settings were more likely to use multidisciplinary services including occupational and physiotherapy and dental services (McCarron et al., 2014a).

The information gained during the interviews described in Chapter 4 of this thesis should raise particular concerns for Irish pharmacists. If the government proceeds with the current deinstitutionalisation strategy there will be many more vulnerable people living in communities accessing their medications through community pharmacies. It will be important that their families and/or paid supporters have adequate training and education to ensure the safe and effective use of medications and high risk treatments such as insulin.

Community pharmacists will also require access to clinical pharmacists with expertise in this complex area of health and social care (NHS Fife, 2015). Concern has been expressed in England that people with mild, moderate or severe intellectual disabilities with multi-morbidity may be cared for by support staff (if they receive care or support at all) that are ill-equipped to effectively help them coordinate, manage and proactively address their health needs (Heslop et al., 2014b). This is a wake-up call for all providing healthcare to this vulnerable population in social care settings in Ireland.

5.2.3.2 Accessibility

Healthcare professionals including pharmacists must make reasonable adjustments to their practice that will make them as accessible and as effective as they would be for

people without intellectual disabilities (Turner and Emerson, 2013). Ideally pharmacists and others should ensure 'anticipatory' adjustments (IHAL et al., 2012). Pharmacists should consider in advance the adjustments people with intellectual disabilities will require, rather than waiting until people with intellectual disabilities experience problems using medication, insulin, MDS and other aspects of health services provided by pharmacists.

People with intellectual disabilities living in the community with low health literacy may work hard to hide the fact that they have trouble understanding something they are told about medication or given to read. To compound this difficulty many people with intellectual disabilities may not see the same pharmacist each time they seek care which makes it challenging for pharmacists to develop and maintain good relationships and to become skilled communicators with members of this population group. The need for 'specialist' and/or named pharmacists in this area was highlighted in Chapter 4 of this thesis.

Accessibility is a fundamental right; Article 9 of the CRPD states that

'States Parties shall take appropriate measures to ensure persons with disabilities access, on an equal basis with others ... to information and communications' (UN, 2006).

In Ireland, the Equal Status Acts 2000 to 2005 and the Disability Act 2005 uphold our rights to an accessible society and specifically to accessible information.

The Disability Act which makes specific reference to the accessibility of information for people with intellectual disabilities states:

'The head of a public body shall ensure, as far as practicable, that information published by the body, which contains information relevant to persons with intellectual disabilities, is in clear language that is easily understood by those persons'.

A sub-theory identified following the Grounded Theory analysis related to reasonable accommodation. Pharmacists and others need to take into account the impact of cognitive and sensory abilities and disabilities, and should match the accommodation to the learning style, skills and abilities of the individual with intellectual disabilities. Specialist Pharmacists will raise awareness of the requirement for 'anticipatory'

reasonable accommodations (IHALL et al., 2012) and ensure that pharmacy environments are well designed with accessibility and usability in mind for people with intellectual disabilities. Pharmacists will need to consider in advance what accommodations people with intellectual disabilities will require, rather than waiting until people with intellectual disabilities attempt to use pharmacy services to put reasonable accommodations into place.

5.2.3.3 What People with Intellectual Disabilities have said about Pharmacists

In institutional settings the medication use process may have involved qualified nursing staff and input from pharmacists with experience and/or specialist knowledge of the medication related issues in this population. The movement of people with intellectual disabilities into the community from such settings requires knowledge transfer and acceptance by the community pharmacies of this high risk population. Challenging issues about pharmacists were raised in a NPSA report (NPSA, 2004a) on healthcare concerns identified by people with intellectual disabilities and their carers, Box 5.1.

What People with Intellectual Disabilities Have Said About Pharmacists
<p>Lots of people had stories of being given the wrong medication. This ranged from big tablets given to someone with cerebral palsy who cannot swallow easily, to medication being given that had nasty side-effects:</p> <p><i>“Sometimes they give me the wrong tablets. I have to take some three times a day for my arthritis, and I have to take the red ones for my sugar diabetes.”</i></p> <p><i>“And sometimes they give me the wrong tables.”</i></p> <p><i>“When I take the wrong tablets they make me feel terrible, they make me feel tired.”</i></p>
<p><i>“If I could change health services, I would have bigger labels on medicine bottles, especially for people with learning difficulties who can’t read them properly. It might say for instance: take two in the morning, one in the evening, but sometimes it is very difficult. You could miss your dose.”</i></p> <p><i>“Instructions for taking tablets need to be explained to people who cannot read.”</i></p>

Box 5.1 What People with Intellectual Disabilities have said about Pharmacists

5.2.3.4 Health Literacy

It is the responsibility of health professionals including pharmacists to make information on medication readily available to people with intellectual disabilities and their carers. This was done with varying levels of success in the lives of the six people interviewed in Chapter 4 with only one participant reporting being happy with *'easy read'* information. One participant had never been offered accessible written information even though she described herself as *'a good reader'*.

However even when written and/or verbal information is provided to the person and/or their carer, this does not guarantee that an individual patient with an intellectual disability has understood and accepted the information they have received. The written drug information presented in patient leaflets and patient package inserts, or published on websites, may not be accessible to people with intellectual disabilities and may be misinterpreted by the person and/or their carers. In particular, the frequencies of drug side-effects are often mis-understood, especially by consumers with low numeracy skills which will include most people with intellectual disabilities. Wave 2 of IDS-TILDA reported that two thirds of respondents (66.3%) had trouble with reading, writing, numeracy and money management (McCarron et al., 2014a).

A *'specialist'* pharmacist, with the patient and with the patient's carers and other healthcare providers as necessary, will develop a medication therapy plan with recognised *'outcomes'*. In regard to chronic high risk diseases, the pharmacist must carefully consider the psycho-social aspects of the disease. Participant Pat, a person with diabetes, demonstrated evidence of both *'insulin dread'* (Peyrot et al., 2010) and *'diabetes distress'* (Fisher et al., 2012, Egede and Dismuke, 2012) during the interviews described in Chapter 4. The essential elements of the plan, including the patient's and or carer's responsibilities, must be carefully and completely explained to the patient with intellectual disability and/or carer. Information should be provided to the patient at a level the patient will understand.

The Wave 2 IDS-TILDA Report showed that 69% of the participants were taking five or more medicines and supplements and that 34% were taking ten or more medicines and supplements (McCarron et al., 2014a). Despite this high use of medicines, only 58% reported having contact with a pharmacy. This may reflect a situation where the carer and not the patient makes contact with the pharmacy. It may also reflect a situation where there is no pharmacist presence in residential care settings. Data from one residential care setting in Ireland where a pharmacist was employed full time and

dispensed all medications to 127 residents with intellectual disabilities, have indicated a very high usage of medications (Flood, 2015) and highlighted the situation where medication dispensing and administration is 'not a simple process' in long term care.

Pharmacists and other professionals working in and familiar with residential care settings for people ageing with intellectual disabilities are aware that the culture of the particular setting and the prescribing practices of those prescribing are highly influential in relation to the quality of medication use. In Round 1 of the MDT described in Chapter 3 of this thesis, a panel member asked the question on Residential Care QI

'Is the quality of prescribing specific to the individual or their place of residence?'

5.2.3.5 Communication

The difficulties for pharmacists of communicating information to vulnerable patients particularly when caring for patients taking mental health medicines has been recognised as a problem (The Pharmaceutical Journal, 2014). A specialist pharmacist will require excellent communication skills; ideally knowledge of autism or intellectual disability will be included as a 'desirable' characteristic in every person specification for every specialist post (NDTi et al., 2013). There is an 'art' in this communication and that includes speaking, listening and non-verbal communication. No pharmacist can communicate with people with autism or severe intellectual disability unless they 'try to see the world through their eyes' (Caldwell and Horwood, 2007).

5.2.4 Experts by Experience

5.2.4.1 'Expert' Patients

Inequalities exist in the provision of healthcare to people with intellectual disabilities and numerous international reports mentioned throughout this thesis have revealed a high level of unmet needs. This has resulted in less effective treatment and in some instances led to premature death (Heslop et al., 2014a).

There is now a growing interest in conducting research that includes the experience of vulnerable people including people with intellectual disabilities in relation to all aspects of health care. Chapter 4 of the thesis reports on interviews the researcher had with people with intellectual disabilities who are the 'experts by experience' on the medication use process in their population. A Grounded Theory approach, which was

attentive to how theory emerged from subjective experiences was used in this work. Everything is data to the Grounded Theorist and this allowed flexibility of utilizing different data sources. In this study the main source of the data was semi-structured interviews and participants provided additional direct and indirect data. This additional data included lists of prescribed medications in three interviews and 'brown bag' medication and the observed emotional impact of diagnosis and life situations. Fourteen years experience working as a pharmacist with adults ageing with intellectual disabilities provided the researcher with credibility when analysing and interpreting the data.

One limitation of the Grounded Theory approach described in Chapter 4 was that it involved only one interview with each participant. The interview time therefore involved time spent building rapport with the participant and making them feel as comfortable as possible with the interviewer. A second interview would have given the interviewer an opportunity to ask follow up questions and explore the information gleaned from the original interviews. A second interview would also have allowed the participant time to process and think about the interview process and to ask any follow up questions they may have had.

The use of focus groups could have been used as an alternative to the one-to-one interviews and the semi structured questionnaire. Focus groups would have provided the advantages of a group dynamic that would build confidence and peer support and validation among people with intellectual disabilities

5.2.4.2 The 'Expert Carer'

It is a limitation of this thesis that it does not incorporate the views of 'expert carers'. The panel of expertise in the MDT described in Chapter 3 was a 'professional' panel and those people interviewed in Chapter 4 were people with intellectual disabilities. Efforts will be made to obtain the views of carers in future research.

However the family carer of Participant Alex in Chapter 4, who accompanied Alex to the interview location and requested to meet with the researcher, expressed frustration that her concerns were not considered by the prescriber of her son's anti-psychotic medication. This echoes the situation found in a recent UK audit where carers voiced their anger at having to constantly fight for adequate care and expressed considerable anger at not being taken seriously by healthcare professionals (RC Psych et al., 2014). Carers in that audit shared examples of being ignored by professionals to the detriment

of their children and also the NHS as it resulted in wasted resources and missed appointments. Carers talked about being frustrated with expectations that they should conduct care duties that are the responsibility of healthcare professionals. Carers said they did not trust the healthcare system and had concerns about leaving their children unattended in hospital.

Participant Jamie was herself an 'expert patient' who had access to an 'expert carer' in the person of her mother who was a pharmacist. Jamie had a diagnosis of coeliac disease and diabetes. She appeared to be aware of the issues and to be in control of both conditions. She reported never having been admitted to hospital in connection with her diabetes.

Participant Keelan appeared to have 'expert carers' who were very involved in his care. However this caused him difficulties as he reported that they are 'wrecking my head'. It appeared to be frustrating for Keelan that his parents 'have to know' and he reported that 'they drive me mental'.

The information obtained from the interview data in this project highlight the difficulties for carers supporting people with intellectual disabilities in the medication use process. If they step away, as evidenced in the situation of Participant Pat, and allow the person to exercise complete autonomy there are risks for the safety of the person. If they become involved they can be seen as controlling by the person with intellectual disabilities. However, Jamie illustrates that a harmonious relationship can also be the result.

5.2.5 Audit of Intellectual Disabilities Services

The complexity of the medication use process in this vulnerable population has been described in Chapters 2 and 4 of this thesis and illustrated in Figure 5.1 of this Chapter.

NHS England National Clinical Director for Learning Disability Dominic Slowie has said that collecting reliable data on healthcare experiences and outcomes for people with an intellectual disability is

'key to improving outcomes for them' (Slowie, 2014).

In the UK, a feasibility study that focussed on the mental and physical care of people with intellectual disabilities, demonstrated that it is possible to collect data on

healthcare that people with intellectual disabilities receive in both primary and secondary care (RCPsych et al., 2014). The study identified extensive variation in practice and quality of care across sites, indicating the importance of reliable audit tools and standards. This may be particularly true in relation to the complexity of the medication use process previously described in Chapters 2 and 4 of this thesis. However, when stakeholders were asked for their comments on the Feasibility Study, The Faculty of Intellectual Disabilities of the Royal College of Psychiatrists stated that

'Audit standards should be more specific to people with learning disabilities'.

The use of the QIs developed following the MDT described in Chapter 3 of this thesis will ensure any future audit of intellectual disability services in the UK or Ireland is more specific for people with intellectual disabilities.

5.3 Quality Indicators

Specific medication issues of concern in this vulnerable sector were highlighted in a *Learning Disability Census* that was commissioned in England in response to the abuse at Winterbourne View Hospital. The Census collected information on inpatients receiving treatment or care in facilities registered with the CQC as provider of mental or behavioural healthcare. Results have shown that 2,345 (73%) patients in 2014 received antipsychotic medication either regularly or through PRN in the 28 days prior to census day compared with 2,220 (68%) patients in 2013 (HSCIC, 2015).

A similar issue was raised in Ireland as in the IDS-TILDA sample antipsychotics and antiepileptic medications were the most commonly used prescription medicines: 50% of the sample used one of these groups of medications and 30% used medications from both medication groups (McCarron et al., 2011a). The QIs described in the following section will provide a framework for addressing some of the concerns highlighted.

5.3.1 Identification of Crucial Quality Indicators

Following the literature review in Chapter 2 of this thesis, 38 candidate QIs of the medication use process in people ageing with intellectual disabilities and behaviour disorders were identified, Table 2.1 and Appendix 1. In Chapter 3 of this thesis a two round MDT with a panel of multidisciplinary 'experts' resulted in the development of 37

final QIs (Flood and Henman, 2015b). This comprehensive list of QIs was graded according to their rating for *importance* by the panel, Appendix 7. No QI was rejected during the process. However, it was recognised that there was a need for a shorter list of crucial QIs. Six were identified that are of very particular relevance to medication use in this population and will be discussed in detail in the following sections, Box 5.2.

Crucial Quality Indicators	
Title of Quality Indicator - Abbreviated	Criteria
Medication Review	90% or more of panel rated important
General Health Review	80% or more of panel rated scientifically sound
Restrictive Practice	
Excessive Dose Anti-Psychotics	70% or more of panel rated feasible
Gradual Dose Reduction	
Dementia Anti-Psychotic Medication	

Box 5.2 Crucial Quality Indicators

5.3.2 Medication Review Crucial Quality Indicator

5.3.2.1 Introduction

Medication review can mean different things to different stakeholders. It can range from a pharmacist opportunistically reviewing the dose of an antibiotic prescribed by a doctor for a patient with intellectual disability and a urinary tract infection, to a multidisciplinary review of behaviour problems with the patient with intellectual disability and/or their carer/advocate present.

Medication Review Crucial Quality Indicator
<p>IF a person ageing with intellectual disability and a behaviour disorder is prescribed medication(s) THEN the medication regimen of the patient should be reviewed by qualified multidisciplinary personnel, preferably on site (if living in a residential setting), at least 3 monthly BECAUSE medication review will ensure thorough evaluation of the medication used by a vulnerable patient, and medication review is increasingly seen as a cornerstone of medicines management.</p>

Box 5.3 Medication Review Crucial Quality Indicator

The Medication Review Crucial QI developed in this project received the highest rating for *importance* of any candidate QI during the two round Delphi process, Box 5.3.

The QI was rated important by 100% of the R2 panel in the Delphi process. The *importance* of medication review for people with intellectual disabilities was also identified in *Room for Review*, which is a guide to medication review in which people with intellectual disabilities were identified as a special population group in need of special consideration (Task Force on Medicines Partnership and Programme, 2002).

A Level 3 Medication Review identified in *Room for Review* supports the Medication Review Crucial QI developed in this project, Box 5.4.

Level 3 Room for Review Medication Review
Full, structured medication review with the patient's full medical notes
Patient present
Can be a single health professional or multidisciplinary
Example: review of all medicines prescribed

Box 5.4 Level 3 Room for Review Medication Review

HIQA in the National Standards for Residential Services for Children and Adults with Disabilities also acknowledge the need for regular medication review in this population (HIQA, 2013c), Box 5.5.

**National Standards for Residential Services for
Children and Adults with Disabilities. HIQA Standard 4.3**

Each person's health and wellbeing is supported by the residential service's policies and procedures for medication management.

Some features to meet the requirements of this standard include:

4.3.5

Staff actively promote each person's understanding of their medication and health needs. Each person is advised, as appropriate, about the side effects of prescribed medicines and is given access to information leaflets provided with medicines. Each person is afforded the opportunity to consult the pharmacist or other appropriate independent healthcare professional about medicines prescribed as appropriate.

4.3.6

Medication is reviewed at regular specified intervals as documented in the personal plan. Special consideration is given to the use of: antipsychotic medication, sedative medication, anticonvulsant medication, medication for the management of depression, analgesic medications, and different medications and their potential interactions.

Box 5.5 National Standards for Residential Services for Children and Adults with Disabilities, HIQA Standard 4.3

In Ireland HIQA standards require that medication review is undertaken in residential care every three months in the general population (HIQA, 2009a). As mentioned previously in this thesis, it is a concern that the review of medication in the population with intellectual disabilities living in similar residential settings, is only to be 'at regular specified intervals' (HIQA, 2013b). People with intellectual disabilities are exposed to multiple medication use (McCarron et al., 2011a, McCarron et al., 2014a).

The medications used in the population with intellectual disabilities are similar though often used in more significant quantities than in the general population. The HIQA standards in this area would appear to indicate a lack of awareness on the part of HIQA of the safety profile for many psychotropic medications (FDA, 2006, FDA, 2008b, FDA, 2008a), the anticholinergic burden in this population (O'Dwyer et al., 2014) and

the need for regular monitoring. It is not clear why people with intellectual disabilities are to be afforded less protection in relation to medication use than the general population. People with intellectual disabilities and behaviour disorders require equitable care that is not discriminatory. The QIs described in the following section will provide a framework for addressing some of the concerns highlighted above.

5.3.2.2 Medication Optimisation

Medication reviews in the population with intellectual disabilities should pay particular attention to people with behaviour disorders as this section of the population offer the potential for cost and clinical benefit. There should be a clear purpose for the review that should ideally be carried out by the most competent health professional with a skill and knowledge base in the area. During any medication review it will be important to consider the following adapted from the NICE Draft Medicines Optimisation Guideline document (NICE, 2014):

- the person with intellectual disabilities' (and/or the family members' or carers', as appropriate) views and understanding about their medicines,
- the person with intellectual disabilities' (and/or their family members' or carers') concerns, questions or problems with the medicines,
- all prescribed, over-the-counter and complementary medicines that the person with intellectual disability is taking or using, and what these are for,
- how safe the medicines are, how well they work, how appropriate they are, and whether their use is in line with evidence based guidance in the population with intellectual disabilities,
- any monitoring tests that are needed.

5.3.2.3 Structured Medication Review

Interest has been recently shown in using a 'structured medication review' in this vulnerable population group. Scheifes and colleagues in Holland, designed a review process to improve pharmacotherapy in people with intellectual disability and behavioural problems (Scheifes et al., 2015). They prepared a pharmaceutical care plan (PharmCP) with the physician, nurse, pharmacist and patient. The primary outcome of the study were the frequency and type of drug related problems (DRPs) documented in the PharmCP. The most prevalent DRP identified was lack of indication

or unclear indication in two thirds of the DRPs. The DRP adverse event/side effects were not mentioned at all by the psychiatrist and pharmacist in the PharmCPs, although patients did mention them in a pharmaceutical anamnesis with a nurse. The authors described this as an 'extraordinary finding'. It was unclear in this study how much experience the psychiatrist and pharmacist had of providing pharmaceutical care in this population. The authors concluded that the structured medication review process increased awareness, clarified indications, caused cessation of unnecessary medications, caused adjustment to dosage schedules and

'a structured medication review should become standard procedure in the care of people with an intellectual disability and behavioural problems'.

This supports the Medication Review Crucial QI identified in this project.

5.3.2.4 Interview Data

Data from the interviews in Chapter 4 of this thesis document support the need for the person with intellectual disabilities to be involved in any Medication Review. It is important to learn of the 'real life' experience that people with intellectual disabilities have of the medication use process. One participant in the interviews described how she spat her tablets out when she did not want to take them. Another described how his 'strength went down' after taking antipsychotic medication. Another participant told the researcher that he stored his insulin in a drawer in his bedroom. The evidence from the MDS used by this participant indicated that he did not take his medication in a systematic manner and that he may not have understood how to use the MDS system.

It is evident from these Chapter 4 interviews, that the person with intellectual disability can be a valuable resource in the Medication Review process (Flood and Henman, 2015d). Many people with intellectual disabilities may also wish to be active participants in their own healthcare. Participant Jamie was a very knowledgeable participant who managed having diabetes and coeliac disease. She reported never having been admitted to hospital for complications of her diabetes. To include and involve people with intellectual disabilities in Medication Reviews will require further research, patience, co-operation and the development of appropriate and accessible patient decision aids. Scheifes and colleagues in Holland also recognise that

'patient participation in the medication review process is essential'
(Scheifes et al., 2015).

A systematic review of interventions such as educational programs, in-reach services, medication review and multicomponent interventions to reduce inappropriate prescribing of antipsychotic medications to people with dementia resident in care homes, found that these interventions may be effective in the short term (Thompson Coon et al., 2014). However, little information was available on the sustainability of the interventions and the authors concluded that to reduce prescribing levels in long term, the culture and nature of care settings and the availability and feasibility of nondrug alternatives needs to be addressed.

5.3.2.5 Appropriate Prescribing

It is important to note that any change to the number of medications prescribed following a Medication Review is not in itself an indicator of quality. Medication can be started or stopped following a review when managing behaviour disorders or when managing or treating medical conditions. It is important that the outcomes for the patient's health related quality of life are monitored and reported following any change to the medication regimen. It is interesting to note that the study by Scheifes described above was a technical measurement only, without information on clinical outcomes or patient satisfaction (Scheifes et al., 2015).

Appropriate prescribing and de-prescribing for patients ageing with intellectual disabilities and behaviour disorders requires a thorough understanding of the individual person, their therapeutic goals, the benefits and risks of all of their medicines, medical ethics and health determinants in the population group. Clinical guidelines rarely provide recommendations for people ageing with intellectual disabilities with multiple morbidities and behaviour disorders and it has been suggested that all

'older adults need healthcare that can count past one' (Banerjee, 2015).

5.3.3 General Health Review Crucial Quality Indicator

People with intellectual disabilities and behaviour disorders are more likely than people with intellectual disabilities without challenging behaviours to experience a range of health conditions or impairments (Emerson et al., 2012). There is a complex link

between poor health and challenging behaviours which involves three causal pathways, illustrated in Figure 2.2, Chapter 2.

The General Health Review Crucial QI developed in this project raises awareness of the many factors that can influence the behaviour being presented, Box 5.6. If these factors are not assessed carefully there is a risk of inappropriate prescribing and administration of medications.

General Health Review Crucial Quality Indicator
<p>IF psychotropic medication use is considered for a person ageing with intellectual disability and a behaviour disorder, THEN prior to medication use, consideration should be taken of possible underlying medical (UTIs, dental problems, congestive heart failure, idiosyncratic reaction to medication or other medication side effects), environmental or psychosocial stressors and any available laboratory results, BECAUSE the use of any psychotropic medication should occur after multidimensional interdisciplinary communication and the development of a coordinated plan for treatment and follow up.</p>

Box 5.6 General Health Review Crucial Quality Indicator

The introduction of annual health checks for people with intellectual disabilities can lead to the detection of unmet, unrecognised and potentially treatable health conditions and targeted actions to address health needs (Robertson et al., 2011). However there have been failures of health systems to appropriately respond to identified treatable morbidity detected during health checks. This is a failure of the system and poor quality care. Stakeholder feedback reported in the *Report on the National Audit of Learning Disabilities Feasibility Study* (RCPsych et al., 2014) included the following

'It's not good enough just to document your incompetence as a clinician...that people would record poor health, and then not act on it...what interventions came as a result of that? That's the more interesting information' National Clinical Director of Learning Disabilities, NHS England.

Concerns expressed by family carers (DH, 2012b) relevant to this Crucial Quality Indicator are illustrated in Box 5.7.

Family Carers' Experiences of Assessment and Treatment Units
Doctors are often inexperienced and don't understand learning disabilities and challenging behaviour. Levels of medication can be very high and can affect behaviour. Use of medication must be appropriate. Sufficient time should be given for the assessment of a person with mental health issues especially where medication is involved.

Box 5.7 Family Carers' Experiences of Assessment and Treatment Units

The participants interviewed in Chapter 4 of this thesis experienced varying levels of healthcare. Jamie who had diabetes and coeliac disease was an 'expert patient' supported by an 'expert carer' who reported no physical or mental health problems. Participant Pat who appeared to exhibit both 'diabetes distress' and 'insulin dread' provided verbal and non verbal information on deficiencies in healthcare provision. He reported numerous 'hypos' and gave evidence of not using a MDS as intended.

5.3.4 Restrictive Practice Crucial Quality Indicator

HIQA recognises that everyone has a fundamental right to freedom but that at times some people with intellectual disabilities may behave in a way that heightens risks to themselves or others (HIQA, 2013a). When restrictive procedures of any type are used, they must always be legitimate, safe and minimal. The CEO of HIQA has stated that HIQA's inspection findings across differing provider organisations indicated fundamental breaches in regulations and standards and particularly in the human rights of individuals (Quinn, 2015). In many cases staff did not appear able to distinguish between what is an acceptable and unacceptable standard of care and in these situations there is a danger of over use of restrictive practices. Environmental, interpersonal and contextual factors influence variations in the use of restrictive practices (RCN, 2013b). The following have all been implicated in the use of restrictive practices: unclear policy and guidelines, overcrowding, poor care environments, low or inflexible staff numbers, inexperienced staff, poor staff retention, poor information sharing and acuteness of the person's presentations (Allen et al., 2009).

When the behaviour of people with intellectual disabilities challenges carers and services, complex and competing human rights issues may emerge (Bailey et al., 2010). The Restrictive Practice Crucial QI developed in this project supports the need

for the human rights of the individual to be protected when medication is used as a restrictive practice, Box 5.8.

Restrictive Practice Crucial Quality Indicator
IF psychotropic medication is used as a restrictive practice for a person ageing with intellectual disability and behaviour disorders, THEN this should only be done in the best interest of the person, protecting their human rights and in the context of a comprehensive policy on the management of behaviour disorders, BECAUSE restrictive practices (including psychotropic medication use), should only be used when the person with intellectual disability poses an immediate threat of physical harm to self or others and they should only be used as a last resort.

Box 5.8 Restrictive Practice Crucial Quality Indicator

The highest predictor of a prescription for a psychotropic medication in this population group is not mental illness but is behaviour disorders and the most common response to behaviour disorders is the use of psychotropic medication. The use of antipsychotics for self-injurious behaviour or aggression has been described as one of the most controversial issues in mental healthcare. However, a RCT (Tyrer et al., 2008) could not distinguish atypical or traditional neuroleptic antipsychotics from placebo for effects on aggression and the authors observed that

'patients given placebo showed no evidence at any time points of worse response than did patients assigned to either of the antipsychotic drugs'.

The World Psychiatric Association identifies situations in which medication use may be considered in a person with intellectual disability and behaviour disorders (WPA, 2008), which supports the Restrictive Practice Crucial QI described here:

- Failure of non-medication based interventions
- Risk evidence of harm/distress to self
- Risk evidence of harm/distress to others or property
- High frequency/severity of problem behaviour
- To treat an underlying psychiatric order or anxiety

- To calm the person to enable implementation of non-medication based interventions
- Good previous response to medication
- Person/carer choice.

The use of restrictive practices can be a threat to quality of care and individual human rights. A paper that reviewed physical/mechanical and chemical restraint and the factors that may result in the use and maintenance of restraint, identified multiple factors that put people with intellectual disabilities at risk of restraint. These included: the rate, type and intensity of behaviours that challenge, the age of the individual with intellectual disability and the type of residential placement (Matson and Boisjoli, 2009). Pharmacists caring for people with intellectual disabilities and behaviour disorders and/or using the Restrictive Practice Crucial QI will require an understanding of the particular context and narrative of any given situation where medication is prescribed to determine a balance between rights, respect and responsibility.

Slevin and colleagues reported on a rapid review (Slevin et al., 2011) which aimed to search for, evaluate and prioritise studies that focused on people who challenge made the following recommendation in relation to medication use

‘Medications should only be used when indicated for the treatment of physical causes of behavioural problems or treatment of psychiatric illness and be used to supplement other interventions rather than as a stand-alone treatment’.

A cross sectional study that investigated aspects of the treatment and management of challenging behaviour among adults with intellectual disabilities receiving various forms of residential supports noted that (Emerson et al., 2000) residents with challenging behaviour are over three times more likely to receive antipsychotic medication than they are to receive behavioural support. They further noted that

‘such an inequitable pattern of provision clearly violates the principle of evidence based practice’. In this sample the receipt of antipsychotic medication was not predicted by the presence of psychiatric disorder, but by factors which included the severity of challenging behaviour and the setting’.

There will be occasions when the use of restraint will be lawful and justifiable. However, by definition, restraint is a limitation of a person's autonomy and freedom of movement. Therefore, pharmacists and others must ensure that the use of pharmacological restraint should be a matter of last resort, only used when there is no less restrictive option available which would promote the rights of the person to be restrained.

The Restrictive Practice Crucial QI identified in this project is supported by the Department of Health's Policy document *Towards a Restraint Free Environment in Nursing Homes* (DoH, 2011). This identifies restrictive practices as a serious and potentially hazardous intervention that should only be used as an option of last resort in response to a serious risk to people's safety and welfare.

5.3.5 Excessive Dose Crucial Quality Indicator

The identification of an Excessive Dose Anti-Psychotic Medication QI as a Crucial QI in this project supports a recent consensus statement from the Royal College of Psychiatrists on the risks and benefits of high doses of anti-psychotic medications, Box 5.9. While there is little convincing evidence that off-label prescription of antipsychotic medication above the licensed dosage range has any therapeutic advantage in any clinical setting, there is clear evidence for a greater side-effect burden and the need for appropriate safety monitoring (RCPsych, 2014a). The consensus group that included a pharmacist, made no specific recommendations in relation to the population with intellectual disabilities, but did advise that clinicians should be aware that prescribing high doses of antipsychotics might worsen already compromised cognitive function in their patients.

Excessive Dose Crucial Quality Indicator

IF a person ageing with intellectual disability and a behaviour disorder is prescribed an ‘excessive dose’ (i.e. giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer’s recommendations, clinical practice guidelines, evidence based studies from medical/pharmacy journals or standards of practice for the patient’s age and condition) of an antipsychotic medication, **THEN** the prescriber must document a clinically pertinent rationale for the prescription that should only be used in exceptional circumstances after full discussion with all the relevant stakeholders under appropriate safeguards and regular reviews, **BECAUSE** an excessive dose may be inappropriate and ‘unlicensed’, may have the potential to cause harm to the patient and may not be supported by medical-legal frameworks.

Box 5.9 Excessive Dose Crucial Quality Indicator

Recent *Guidelines for the Use of High Dose Antipsychotics* (HDAT) have been published and remind prescribers that the use of PRN or “as required” antipsychotic medication should also be taken into account if given on a regular/semi-regular basis (Henry, 2015b). (The PRN/‘As Required’ QI was identified as being a Grade 3 QI in this project). The Prescribing Observatory for Mental Health-UK (POMH-UK) a national quality improvement programme open to all UK specialist mental health services, has published an *Antipsychotic Dosage Ready Reckoner* (Henry, 2015a) which could be used in combination with the Restrictive Practice Crucial QI developed in this project to improve the quality of antipsychotic use in the population with intellectual disabilities.

The British Pharmacological Society recommends that health-care professionals who prescribe medicines should do so based on ten principles, which underpin safe and effective use of medicines (British Pharmacological Society, 2010). These have been adapted in this thesis, Appendix 26, and can be applied when considering excessive dose prescribing and gradual dose reduction and/or de-prescribing in the vulnerable population with intellectual disabilities and behaviour disorders. The difficulties with deprescribing were mentioned by one panel member during the MDT described in Chapter 3

'Sadly, it seems the easiest route is simply to go on prescribing without questioning the reasons for the continued use of such agents. Once an agent is prescribed it becomes difficult to "unprescribe". In a hierarchical system where GPs rarely question psychiatrists' therapeutic interventions errors and harms are perpetuated '.

Participant Alex, who was interviewed in Chapter 4 of this project, was prescribed Stelazine and Lexapro. Alex's 'expert carer', his mother who was a nurse, described her frustrations when she was not listened to by the prescriber. She was concerned about Alex's increased weight, increased consumption of fizzy drinks, the current level of medication prescribed and a suggestion by the prescriber that the dose of Stelazine would be increased in the future. Alex's 'expert carer' found it hard to be heard in the medication use process. Alex himself described how his '*strength went down*' and that it was '*hard to do things*' when taking his medications.

5.3.6 Gradual Dose Reduction Crucial Quality Indicator

There is some evidence that individuals with neurological damage are more prone to the adverse side effects of antipsychotic medication than non-brain damaged comparison populations. There is also an argument that in people with aggressive behaviour and intellectual disabilities but no psychosis, the benefits of antipsychotics may not balance out their potential harms (Tyrer et al., 2008). It is important therefore that gradual dose reduction is attempted in this population.

However, caution should be exercised when attempting to withdraw antipsychotic medication among people with intellectual disabilities, particularly when withdrawing antipsychotics from individuals with a more severe degree of intellectual disability, those who are taking high doses and particularly those who have been on such medication for a long period of time (Matthews and Weston, 2003). *The Principles of Good De-prescribing*, Appendix 26, should also apply.

A recent analysis of the 2013 *Learning Disability Census*, commissioned in response to events at Winterbourne View Hospital published by the Health and Social Care Information Centre (HSCIC) provided information on inpatients with intellectual disabilities in England being treated in specialist units. The Census showed that two thirds of the inpatients (68% or 2,220) had been given anti-psychotic medication in the 28 days preceding the census. Of these, 93% (2,064) had been given them on a regular basis (HSCIC, 2014).

The Gradual Dose Reduction Crucial Quality Indicator developed in this project should allow examination of the efforts made to reduce the doses of anti-psychotics in this population, Box 5.10. Participant Frances interviewed in Chapter 4, described herself as being ‘*very sensitive*’ and that her medication, aripiprazole, made her feel ‘*more relaxed*’ and that her tablets help her ‘*to be positive*’. However Frances reported side effects such as the need to get up slowly in the morning and that she had difficulty swallowing certain foods which must be cut up and chewed well before swallowing. She also reported dizziness. It was not evident from discussion with Frances if the prescriber had discussed side effects and the risk/benefit of her medication with her or her carer.

Gradual Dose Reduction Crucial Quality Indicator
<p>IF a person ageing with intellectual disability is prescribed regular antipsychotic medication for a behaviour disorder, THEN gradual dose reduction must be attempted (unless contraindicated) with implementation of behavioural interventions to enable reduction or discontinuation, BECAUSE prolonged antipsychotic medication therapy may result in functional decline, somnolence, lethargy, tremors, increased falling, or impaired ambulation.</p>

Box 5.10 Gradual Dose Reduction Crucial Quality Indicator

5.3.7 Dementia Anti-Psychotic Medication Crucial Quality Indicator

Many health care professionals and families believe that dementia behaviours are abnormal and that they require treatment. Antipsychotic medications are often seen as effective in the management of behaviours associated with dementia. Despite this, current HIQA Guidelines in this area make no specific reference to anti-psychotic medications (HIQA, 2015). However, it acknowledges that a holistic assessment includes an understanding of medication needs and that care plans should include assessment and review of all medications. Two of the aspects of care that HIQA states are particularly relevant to people with dementia include medication management and behavioural and psychological signs and symptoms of dementia. This is consistent with the Dementia Anti-Psychotic Medication Crucial Quality Indicator, Box 5.11.

Dementia Anti-Psychotic Medication Crucial Quality Indicator

IF a person ageing with intellectual disability and dementia presents with a behaviour disorder, **THEN** any prescribed antipsychotic medication should be monitored and reviewed regularly, **BECAUSE** an increased long-term risk of mortality in patients with Alzheimer’s disease who are prescribed antipsychotic medication has been identified and the risk should be considered within the context of medical need for the drugs, efficacy evidence, medical co-morbidity and the efficacy and safety of alternatives.

Box 5.11 Dementia Anti-Psychotic Medication Crucial Quality Indicator

In 2013, the American Medical Directors Association was involved in identifying the top five items that physicians and patients should question in the long-term care setting as part of the American Board of Internal Medicine Foundation's Choosing Wisely Campaign. Item 4 on this list which supports the Crucial QI, discussed here, Box 5.11, was

‘Don't prescribe antipsychotic medications for behavioral and psychological symptoms of dementia (BPSD) in individuals with dementia without an assessment for an underlying cause of the behaviour’ (Vance, 2013).

Some strategies to reduce antipsychotic use that have been identified include training staff on interacting with people with dementia and intellectual disabilities and developing policies on minimising the use of medications with dementia residents. Education of families on the policy, consistent assessment and comparing facility off-label antipsychotic use to other settings and learning from other facilities are also important. This last strategy will be facilitated by use of the Dementia Anti-Psychotic Medication Crucial QI developed in this project. Staff and families could be asked the following questions (Gifford, 2012) in Box 5.12 when medication is requested to manage behaviours associated with dementia in people with intellectual disabilities.

Question to be Asked when Antipsychotic Medication Requested
What did you do to try and figure out why the resident was doing <fill in the blank>?
What is resident trying to communicate to us about their <fill in blank>?
What is reason for resident doing <fill in blank>? Unacceptable answer (Dementia or sun-downing)?
What did you try before requesting medications?

Box 5.12 Question to be Asked when Antipsychotic Medication Requested

The involvement of 'specialist' pharmacists using QIs as a framework will facilitate the following recommendations in relation to longer term care settings caring for people with dementia (Mental Welfare Commission for Scotland, 2014):

- Medication should be used as a last, not first, resort in management of stressed and distressed behaviours.
- People with dementia on multiple psychotropic medications should be prioritised for multi-disciplinary review, including pharmacy, to ensure the continued use is appropriate.
- All people with dementia receiving psychotropic medication should have their continuing need for this reviewed every three months. Where the benefit of medication is not clear, it should be gradually withdrawn with appropriate monitoring of target symptoms.
- Full multi-disciplinary reviews should be carried out at least annually, proxies and carers should be actively encouraged to participate in this. Pharmacy should be included as a core discipline within the unit multi-disciplinary team.

5.3.8 Feasibility Problems

There are difficulties developing scientifically sound and feasible QIs for medication use in people ageing with intellectual disabilities that are agreed to be important. Data availability would present initial *feasibility* problems with the use of some of these QIs. There are strong disincentives for disclosing quality information in this area of healthcare, including fear of litigation or shame. Even where there are incident monitoring systems for medication safety incidents, safety events and 'near misses' may be under-reported.

5.3.9 Advantages and Disadvantages of the Modified Delphi Approach

In Chapter 2 of this thesis a narrative literature review was used to identify candidate QIs for consideration by the MDT panel. In Chapter 3, ethical issues, the multidisciplinary panel of expertise, the number of rounds, the establishment of consensus, the development of the questionnaire, the distribution method of the questionnaire, data collection, response rate, maintaining panel involvement, feedback and analysis of the results were described. No candidate QI was rejected by the panel thus confirming the value of the initial narrative literature review.

For QIs to effectively guide quality improvement efforts in the care of people ageing with intellectual disabilities, they must be developed, evaluated, maintained, and implemented using rigorous evidence-informed practices. As was seen in the literature review in Chapter 2 there are very limited RTCs in this area. This area is also under represented in pharmacy practice research (Bell et al., 2015) but a recently published narrative review noted that the limited evidence in this population suggests that pharmacists can make a positive intervention in relation to the quality of the medication use process (O'Dwyer et al., 2015).

The advantages of the Modified Delphi Technique described in Chapter 3 of this thesis are:

- guaranteed anonymity thus ensuring no peer pressure,
- iterative approach,
- questionnaire captured wide range of variables,
- feedback informed the final QIs,
- respondents able to reply in own time thus decreasing burden and inconvenience,
- crucial indicators met criteria for importance, scientific soundness and feasibility,
- MDT allowed for process management by one person.

Difficulties with the Delphi Technique have been recognised over time with the reliability, validity and credibility of Delphi as a research methodology being questioned. All groups working to gain consensus run the risk of diluting individual opinion. Some methodological issues concerning panel expertise, number of rounds,

survey questionnaire development, analysis and consensus achievement have been identified.

5.4 Quality

5.4.1 Quality Improvement

5.4.1.1 Financial Cost

This thesis did not explore the considerable cost of managing behaviour problems in adults who have an intellectual disability. It has been reported that those with exceptional need, typically defined as 'extremely' challenging behaviour most often in combination with autism spectrum disorder and mental health difficulties, are responsible for high costs often in excess of €150,000 per annum (Linehan et al., 2014). These costs can result from significant use of medications, breakdowns in community care and consequent admission to hospital or specialist settings. Higher care costs have been associated with more severe intellectual disabilities and more challenging behaviours and sector and scale of residence have also been found to influence cost in complex ways (Knapp et al., 2005b). Healthcare costs in all sectors are increasing. The QIs developed in this project will improve the quality of healthcare supplied to people with intellectual disabilities and so ensure value for the patient and the healthcare system.

5.4.1.2 Implementation of Quality Improvement

A sound evidence base is necessary but not sufficient to ensure engagement and implementation of quality improvement initiatives (Health Foundation, 2012). The Health Foundation has noted that quality standards that appear relatively well established in scientific terms may be open to contest if they do not align well with people's own reasoning, if they threaten people's interests or if they cause too many conflicts of priorities. Consequently, when considering the implementation of the QIs developed in this work, it is important to recognise that professional consensus may not be reached. Moreover, attempts to achieve unanimity may waste time and energy and prevent necessary improvements in quality. Different forms of evidence may have different degrees of credibility with different professional and administrative groups. What has been accepted as best practice in one profession or discipline has been disputed in others. However no candidate QI identified in Chapter 2 of this project was

rejected and the Crucial QIs developed in the project, were rated by 90% or more the multidisciplinary panel as important, Section 5.3.

5.4.1.3 People with Intellectual Disabilities and Medication

It was observed in this project that there are people with intellectual disabilities living in the community who have responsibility for their own medication. This raises concerns if the person has a high risk illness like diabetes and is prescribed high risk medications such as insulin (Flood and Henman, 2015d). In this project, difficulties for some people with intellectual disabilities and poor health literacy skills, carers of people with intellectual disabilities and pharmacists were identified. People ageing with intellectual disabilities may also live in residential care where they may or may not have access to a pharmacist.

There is an urgent need for pharmacists in all locations to become aware of this vulnerable population group (Flood and Henman, 2011). Government policy is causing change in the locations in Ireland where health and social care is provided to people ageing with intellectual disabilities (Working Group on Congregated Settings, 2011) and the way in which this sector is funded. In all settings and care locations each person with intellectual disability must be regarded as an individual. Each encounter with a person with intellectual disability should matter and result in improved quality of mental or physical health care.

In England, concerns have been expressed about management of medicines where 17% of all locations inspected were not meeting the relevant standard (CQC, 2012b). The inspectors observed a worrying number of examples where safe management of medicines was compromised, often by a lack of information given either to those taking the medicines or those caring for them. It was also noted that more complex drug treatments and significant growth in co-morbidity were being observed and that this put an increasing demand on social care environments in particular. In a community mental health survey in England, over a quarter of those prescribed new medication in the last 12 months said that they were not told about possible side-effects and over a tenth said that they were not given information about it in a way that was easy to understand (CQC, 2012a). In the interviews described in Chapter 4 of this thesis, the participants were in the main unfamiliar with the term '*side effects*' but could describe both '*bad things*' and '*good things*' about medicines. As mentioned in the literature review in Chapter 2, CQC's National Pharmacy Manager has highlighted that in relation to 'PRN' or 'As Required' medications there is often a lack of a clear plan to

indicate how the decision to administer these medicines is to be made or what the desired/expected outcome should be. The 'As Required/PRN' QI and other QIs developed in this project will support attempts to improve the quality of the medication use process and in particular the transfer of information in relation to medication use. The Informational Transfer QI developed in this project was identified as a Grade 3 QI.

How pharmacies review and dispense medication, and the need for a good relationship between care home and pharmacists has been identified (Barber et al., 2009). Barber and colleagues in the Care Home Use of Medicines Study (CHUMS) report also indicated an urgent need for research into the effectiveness of MDS. Difficulties with MDS were also highlighted during this project and these will be of interest to pharmacists, pharmaceutical organisations, patient support groups, service providers and policy makers.

5.4.2 Implementation of the Quality Indicators in Healthcare

Measuring performance is central to quality improvement because it provides information on current and past performance that can help guide future improvement efforts. Performance and quality measures, such as QIs, can distinguish between good and substandard performance. Accordingly, the development and application of performance measurement is essential to improving the quality of care. It is one of the

'first steps in the improvement process and involves the selection, definition, and application of performance indicators formal evidence base which is the basis for improvement' (Wilkinson et al., 2011).

To obtain the maximum information from the use of the QIs developed in this thesis, tools will be developed to collect data from inpatient services, primary care, social care, secondary care and other settings where people with intellectual disabilities receive health and social care. These tools will enable comparisons across the various care settings and include:

- Organisational checklist.
- Case note audit tool.
- Staff questionnaire.
- Patient questionnaire.
- Carer questionnaire.

Researchers who undertake audit using QIs may have to trawl through mounds of information to answer questions and the quality of case notes in this area can be extremely variable (RCPsych et al., 2014). Questionnaires based on the QIs will be devised for use with people with intellectual disabilities and their carers. Exploration of the experience of the person with intellectual disability in the medication use process was commenced in Chapter 4 of this thesis. It is important to continue to explore the patient experience for vulnerable population groups and to attempt to 'see' and 'hear' their experiences of care and medication use.

Although not explored in this project, it will be important to develop a tool for carers of people with intellectual disabilities, i.e. both family carers and paid carers. Their experience of quality care in the medication use process will include whether they were satisfied with their level of involvement in healthcare and treatment decisions that involved medication use for the person being cared for or supported. Carers can give an insight into where the medication use process is failing, performing well and where improvement is necessary. Carers will be encouraged to think critically and consider that the information they provided could be used to help raise care standards in health and social care services for people with intellectual disabilities. Carers will be encouraged to identify any important relevant information that is not currently obtained.

It will not be enough to simply gather information on the QIs from whatever source. It will also be necessary to ensure that any suggested improvements in the process of medication use are followed through. It will not be enough to note that the medication use process is failing, or that the medication use process is unsafe or that there is no access to relevant skilled professional advice, such as specialist pharmacists.

It is important to note that any results obtained during quality analysis using QIs will be contextual. Evidence requires local interpretation by those involved in planning for quality. Diversity in practice makes published evidence heavily contextual. QIs will therefore be used with care, because the data on which many are based are not collected for research purposes or for measuring quality of care. This data are relatively inexpensive to collect, convenient to use and represent a rich source of information that provides valuable insights. If QIs are used in isolation they may provide only one view of the multi-dimensional concept of quality in the medication use process in people with intellectual disabilities and behaviour disorders.

5.4.3 Medicines Management

5.4.3.1 Introduction

The QIs for the medication use process in people ageing with intellectual disabilities and behaviour disorders fit neatly into the landscape of care where many different instruments are being developed to ensure quality care in this vulnerable population. At the time of submission of this thesis, HIQA are in consultation phase of producing guidelines on medication management. A submission was made by the researcher at the consultation stage of the *Draft Guidance for Providers - Medication Management* that included concerns in relation to less rigorous medication review required in the population with intellectual disabilities than in the general population.

Information is needed to guide workforce planning at local and national levels and to ensure that vulnerable population groups such as the population with intellectual disabilities and behaviour disorders and their direct carers have access to appropriate professional pharmaceutical support at 'the point of care'. This will include specialist pharmacists as identified in Chapter 4 of this thesis and as recognised in the NHS in Fife (NHS Fife, 2015).

It is, however, interesting to note that while the Pharmaceutical Care QI in the MDT in Chapter 3 was rated as *important* by 95.8% of the panel, as *scientifically sound* by 75% of the panel it was only rated as *feasible* by 58.3% of the panel. This issue will be explored in future research.

5.4.3.2 Guidelines

It is of utmost importance that there are appropriate national good practice guidelines for the medication management of behaviour problems in adults with an intellectual disability with or without dementia. The development of such guidelines, with multidisciplinary input from the pharmacy profession and specialists in the area of intellectual disabilities, will ultimately aid in the process of safe integration of people with intellectual disability within the wider society, where appropriate.

The work of the Irish Clinical Strategy and Programmes Directorate is based on three main objectives:

- to improve the quality of care delivered to all users of HSE services,
- to improve access to all services,
- to improve cost effectiveness.

Following contact with Dr Aine Carroll, National Director of Clinical Strategy and Programmes in April 2013, Dr Carroll offered re-assurance that the Clinical Strategy and Programmes directorate's aim is to improve quality, access and value for all Irish citizens with equality in all these areas. However to date in June 2015, there has been no specific public acknowledgement of the vulnerabilities of minority groups which include people with intellectual and other disabilities and their need for equitable health and social care.

An Irish Guidance Document on Dementia in Persons with Intellectual Disability suggests that medications for behavioural correlates of dementia such as transient psychosis, sleep disorder and aggressive behaviour should only be considered if there is a clear risk benefit analysis and a lack of response to other interventions (Faculty of Learning Disability Psychiatry, 2014). This document details the members of the multidisciplinary team that should include a consultant psychiatrist in intellectual disability, a clinical psychologist, a social worker and specialist nurses with access to occupational therapy, physiotherapy, and speech and language therapy. Unfortunately there is no mention of the value a pharmacist can bring to the care of this population in the document and concerns in relation to this were brought to the attention of the authors.

At the time of completion of this thesis, the researcher responded to a call for submissions on the National Clinical Strategy for Older People, *Specialist Geriatric Services Model of Care, Part 3: Mental Health Service Provision* draft document. A sample of the comments submitted are available in Box 5.13.

Comments on: National Clinical Strategy for Older People, Specialist Geriatric Services Model of Care, Part 3: Mental Health Service Provision Draft Document

- No mention of special position of people ageing with intellectual disabilities, mental health difficulties, multiple co-morbidities and multiple medication use.
- Medication use is currently the main therapeutic intervention in all population groups who have mental health difficulties.
- There is no pharmacist on the proposed teams.
- The input of a 'specialist pharmacist' with expertise/interest/experience of the specific medication issues in the population ageing with intellectual disabilities is required.
- Behaviour management with medication in the population ageing with intellectual disabilities is an area of concern and controversy.
- Psychotropic medication use and behaviour problems are two recognised determinants of health in the population with intellectual disabilities.
- An interdisciplinary approach incorporating a specialist pharmacist with expertise/interest in the physical and mental states of the population with intellectual disabilities will be the most effective way of addressing all health issues in this population where medication use is high.
- Optimal care of patients with intellectual disabilities requires integration of divergent concepts about health and disease, as well as people and providers across numerous disciplines, including pharmacy. For both the treatment and prevention of illness, the tendency to see medical and psychiatric conditions as separate and unrelated should be avoided.

Box 5.13 Comments on: National Clinical Strategy for Older People, Specialist Geriatric Services Model of Care, Part 3: Mental Health Service Provision, Draft Document

5.4.3.3 UN Convention on the Rights of Persons with Disabilities

The UN CRPD is an international agreement that has been signed by Ireland but it is not yet a part of Irish law as Ireland needs to also ratify the agreement for it to have effect.

Areas in the CRPD of particular interest to this thesis and pharmacists are the following:

- Equal Recognition (Article 12) refers to equal recognition before the law. This section affirms that persons with disabilities are entitled to enjoy legal capacity on an equal basis with others and that they should have access to the supports required to enjoy legal capacity.
- Access to Information (Article 21) states that state parties should take measures so that persons with disabilities receive information in a format accessible to them. State parties should urge private entities to make information accessible.
- Health (Article 25) outlines that there should not be any discrimination on the basis of disability. Health services that are required by a person with a disability should be provided as early as possible and should be local to their community.

Employment of the QIs developed in this project will enable pharmacists to support efforts to ensure that people with intellectual disabilities get the supports they need in relation to medication use. The QIs recognise the CRPD and their use will highlight the need for medication use process reasonable accommodations in all living environment; this may be in a residential care setting, in a general hospital in a community or social care setting or with a family.

5.4.3.4 Assisted Decision-Making (Capacity) Bill

In Ireland, the Assisted Decision-Making (Capacity) Bill 2013 contains proposals to provide a modern statutory framework supporting decision-making by adults who have difficulty in making decisions unaided, such as many people with intellectual disabilities. It will repeal the Marriage of Lunatics Act 1811 and cause the Lunacy Regulation (Ireland) Act 1871 to cease to have effect. The Bill provides for a range of legal options on a continuum of intervention levels to support people in maximising their decision-making capability. The Bill will be a key step in enabling ratification of the

UN CRPD. Use of the Communication QI and others developed in this project will ensure involvement of the person with intellectual disabilities in the medication use process is monitored.

5.4.3.5 HIQA

HIQA published *National Standards for Residential Services for Children and Adults with Disabilities* in 2013, all of which are important in the lives of people with intellectual disabilities living in residential care in Ireland. Those standards of particular relevance to this thesis, to pharmacy and the QIs developed in the project described include the following:

- Standard 1.5 Each person has access to information, provided in a format appropriate to their communication needs.
- Standard 1.6 Each person makes decisions and has access to an advocate and consent is obtained in accordance with legislation and current best practice guidelines.
- Standard 3.3 People living in the residential service are not subjected to a restrictive procedure unless there is evidence that it has been assessed as being required due to a serious risk to their safety and welfare.
- Standard 3.4 Adverse events and incidents are managed and reviewed in a timely manner and outcomes inform practice at all levels.
- Standard 4.2 Each person receives a health assessment and is given appropriate support to meet any identified need.
- Standard 4.3 Each person's health and wellbeing is supported by the residential service's policies and procedures for medication management.
- Standard 6.1 The use of available resources is planned and managed to provide person-centred effective and safe residential services and supports to people living in the residential service.
- Standard 8.1 Information is used to plan and deliver person-centred, safe and effective residential services and support.
- Standard 8.2 Information governance arrangements ensure secure record-keeping and file-management systems are in place to deliver a person-centred, safe and effective service.

In relation to Standard 6.1, undersupply of appropriate professional staff, such as pharmacists, results in a scarcity of professional expertise; this may negatively affect outcomes, quality of care and the patient experience of the medication use process. It is important to note that although there is limited evidence available in the literature, what evidence exists suggests that pharmacists can make positive interventions in relation to the quality of the medication use process in the population with intellectual disabilities (O'Dwyer et al., 2015).

HIQA has also published *Guidance for Designated Centres Restrictive Procedures* (HIQA, 2013a) where the first principle of care is identified as

'Restrictive practices are a serious and potentially hazardous intervention and should only be used as an option of last resort in response to a serious risk to people's safety and welfare'.

The Restrictive Practice Crucial QI and other QIs provide a framework for specialist pharmacists and others to monitor the performance of the medication use process in designated centres and support the principle of care identified above.

5.4.3.7 Health Act 2007

Statutory Instrument (S.I.) No. 367/2013 - Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013, makes reference to medicines and pharmaceutical service, Appendix 27.

This S.I. recognises the medicines management role of pharmacists in the care of people with disabilities and supports the Pharmaceutical Care Grade 3 QI developed in this project. All QIs identified in this project will provide guidance for specialist pharmacists and others providing pharmaceutical care to vulnerable people with intellectual disabilities and behaviour disorders in designated centres and other health and social care environments.

5.4.3.8 Patient Experience

Care of those people who are unable to care for themselves and compassion towards people who are vulnerable has been a basic doctrine of medicine since ancient times. The way a patient is treated as a person has for some time been seen as a cornerstone of quality. Policy-makers, politicians and the HSE (HSE, 2013) have made

patients' experience a national priority. The HSE has specifically targeted the enhancement of the quality of services used by people with disabilities.

The National Standards for Safer Better Healthcare describe a vision for high quality, safe healthcare for all (HIQA, 2012). As seen throughout this thesis, quality in healthcare is a multifaceted concept with dimensions such as patient-centredness, safety, effectiveness, efficiency, access, timeliness, equity and promoting better health. Two of the main attributes of high quality, safe healthcare identified by HIQA are:

- service providers put service users' needs and preferences at the centre of all their activities,
- service users have access to the right care and support at the right time.

Pharmaceutical services should be designed for reliability, thus minimising inconsistency, variation in provision and the likelihood of things going wrong in relation to medication management. A quality and safety culture ensures that quality and safety of the medication use process is fundamental to every person working within that service including clinical and nonclinical staff, healthcare managers and the board or equivalent of an organisation. This culture places the interests of patients and service users at the centre of care and supports behaviours that are respectful of patients, service users and others. The dimensions of quality described by HIQA and illustrated below from a 'specialist' pharmacy perspective are:

- Person-centred care and support – how specialist pharmacy services place the patient at the centre of their delivery of pharmaceutical care. This includes the concepts of access, equity and protection of rights supported by the QIs.
- Effective care and support – how specialist pharmacy services deliver best achievable outcomes for patients with intellectual disabilities in the context of that service, reflecting best available evidence and information and monitoring using the QIs. This includes the concepts of service design and sustainability.
- Safe care and support – how specialist pharmacy services avoid, prevent and minimise harm to patients with intellectual disabilities during the medication use process and learn from when things go wrong.
- Better health and wellbeing – how specialist pharmacy services identify and take opportunities to support patients with intellectual disabilities in increasing control over improving their own health and wellbeing as appropriate.

HIQA recognises that delivering improvements within these quality dimensions depends on service providers having capability and capacity in four key areas, one of which relates to workforce: planning, recruiting, managing and organising a workforce with the necessary numbers, skills and competencies. The implementation principles for these National Standards include the following:

'Steps taken to meet one National Standard by the service provider should not cause a breach of any other of the National Standards for Safer Better Healthcare'.

There is a need for a joined-up approach to overseeing and managing the medication use process in all care environments. It is important to recognise the clinical and financial importance of developing a specialist pharmacy workforce that is fit for purpose in this vulnerable population.

5.4.3.9 NICE Guidelines

In May 2015, NICE published the following guideline, *Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges (NG11)* (NICE, 2015b), which covers the support and interventions that should be available for family members and carers of people with an intellectual difficulty and behaviour that challenges. Antipsychotic medication should only be used in particular circumstances and not as a first resort. The *Interventions for Behaviour That Challenges* section includes the following medication use recommendations:

Consider antipsychotic medication to manage behaviour that challenges only if:

- psychological or other interventions alone do not produce change within an agreed time, or
- treatment for any coexisting mental or physical health problem has not led to a reduction in the behaviour, or
- the risk to the person or others is very severe (for example, because of violence, aggression or self-injury).

Only offer antipsychotic medication in combination with psychological or other interventions.

These recommendations and others in this comprehensive guideline reflect the narrative literature review data described in Chapter 2 of this thesis and importance of the graded QIs identified following the MDT described in Chapter 3.

5.4.5 Pharmacy

5.4.5.1 Professionalism

An enhanced model of professionalism has been suggested that places a stronger emphasis on accountability, recognises the benefits of creating a different dynamic between patients and professionals and assumes a stronger sense of responsibility for how the wider health system works and for all dimensions of quality (Wilkinson et al., 2011). The model promotes a constant drive to improve what clinicians such as pharmacists do and accepts change as a virtue rather than a threat. It commits to using a range of different approaches to develop and mobilize knowledge about how to improve care and ensure quality care. Building a formal evidence base for the value of specialist pharmacist involvement in the care of people ageing with intellectual disabilities will be the basis for improvement. QIs can be used to both increase knowledge and the evidence base for the integration of specialist pharmacists into care processes. In Ireland, it is envisaged that a quality assured Continuing Professional Development (CPD) system will assure the competence of the *entire pharmacy profession* in order to achieve consistent standards of service and quality of care for all patients including those who are most vulnerable.

However, the need for a pharmacist with a 'specialist' role in the care of people with intellectual disabilities was identified in Chapter 4 of this thesis. In the literature presented below, there is evidence of pharmacist involvement in ensuring quality in various healthcare environments.

5.4.5.2 Pharmacy and People with Intellectual Disabilities in the Community

In rural Victoria, Australia, ten community pharmacists perceived their main role in the care of patients with intellectual disabilities to be in medication management (Di Blasi et al., 2006). They acknowledged there was a need to spend additional time counselling a patient with intellectual disabilities and that the patient's carers had an important role in conveying information. Time resources, education and training and experience in the area of intellectual disabilities were identified as barriers to optimal provision of care, as were inadequate professional collaboration and ability to

communicate effectively with these patients. Solutions identified by the pharmacists included education and training in this field (particularly in the area of communication skills), increasing staffing and increasing inter-professional collaboration in the care of these patients.

The need for inter-professional collaboration was also identified during the interviews with the participants in Chapter 4 of this thesis as was the apparent lack of contact by the participants with a pharmacist. The care provided to Participant Pat (Flood and Henman, 2015d) raised many concerns with consequent worrying outcomes. He exhibited a lack of understanding in relation to MDS management, poor adherence with insulin administration and storage, poor diabetes control, diabetes distress and insulin dread.

In a study that aimed to determine where 21 patients with intellectual disabilities sourced medication information, the authors found that 50% of participants used doctors as a source of information relating to their medication (Strydom et al., 2001). Only two patients (10%) only used the community pharmacist as a source of information.

Variations in medication information provision were described in Chapter 4 of this thesis. Alex had no memory of ever receiving easy read information. Keelan received advice from his doctor on medicines and never received any advice from his pharmacy. Gabrielle had never received accessible information from her GP or pharmacy. Jamie, whose mother was a pharmacist reported that she had received easy read information from her pharmacy. Frances also reported having received a separate sheet of information on her medication.

5.4.5.2 Pharmacy and People with Intellectual Disabilities in the Intermediate Care

Based on the pharmacotherapy suggestions made by consultant pharmacists, 12% (29) of a group of 241 people with intellectual disabilities in intermediate care in the USA received anti-retrosorptive therapy with alendronic acid 10 mg once daily (Schmidt et al., 2004).

5.4.5.3 Pharmacy and People with Intellectual Disabilities in the Long Term Care

Study 1:

A fulltime pharmacist working on site in a designated centre for people ageing with intellectual disabilities in Ireland obtained reports of falls from staff and undertook a medication review for each individual who had participated in the reported fall. Where appropriate, the pharmacist made recommendations to the prescriber to consider calcium and vitamin D and/or a bisphosphonate for the individual. Advice was also provided on the suitability of various calcium and vitamin D formulations and on the correct administration technique for bisphosphonates. After four years the pharmacist audited the prescribing of bone health medications. The number of residents in the centre for whom calcium and vitamin D were dispensed rose from 23.2% to 81.3%. Medications used to treat osteoporosis rose from 8.4% to 46% of residents (Flood, 2013a).

Study 2:

An intervention in an institution for people with intellectual disabilities in Holland, which consisted of advice on medication administration through enteral feeding tubes by the pharmacist, a training programme and introduction of a 'medication through tube' box containing proper materials for crushing and suspending tablets was shown to be effective. Before the intervention, 158 (64.5%) medication administration errors were observed, and after the intervention, this decreased to 69 (30.1%) (Idzinga et al., 2009).

5.4.5.4 Pharmacy and People with Intellectual Disabilities in a Specialist Unit

A dedicated pharmacist who was available in a four bed specialist facility for people with intellectual disabilities within a 16 bed psychiatric ward in an inner city London hospital distributed specialised written material to the patient and verbally counselled the patients about their prescribed medications. Patients demonstrated a greater knowledge of their prescribed medications and mentioned how useful they found the special information leaflets about the medicines (Parkes et al., 2007). Over half the participants understood the importance of taking their medications.

5.4.6 Specialist Intellectual Disability Pharmacist

The need for pharmacists to focus on the most vulnerable people has been identified (Keys, 2008). In an era of rapidly accelerating change in health care delivery, the roles of pharmacists are constantly being redefined, as roles, competency, and training requirements change (Anderson and Roy, 2012). The main inductive theory developed in Chapter 4 of this project was that the vulnerabilities of people with intellectual disabilities may be 'unheard' and 'unseen' by pharmacists. This vulnerable population will therefore require the expertise of a 'specialist' pharmacist in intellectual disability to ensure their safety in the medication use process. This new role will require competency and training. It will be important that the 'specialist' pharmacist supporting people with intellectual disabilities and behaviour disorders and their carers will be familiar with the QIs and the 'real life' data from the interviews in this thesis.

As the level of complexity in health care increases, the need for 'specialist pharmacist' or 'area expert pharmacist' roles was recognised in a recent report in Irish community pharmacy by the Leading Edge Group (Leading Edge Group, 2012). The report recognised that such specialisation may ensure each area has access to high quality services using the most up to date best practice.

In NHS Fife, there are already Clinical Pharmacist members of the Community Learning Disability Teams. The role of the Clinical Pharmacist in NHS Fife is to identify and assist in meeting the pharmaceutical needs of people with an intellectual disability, thereby maintaining and enhancing quality of life.

The need for a specialist pharmacist in the Irish context was explored in detail in Section 4.8 of this document and has been illustrated in Appendix 24. The following documents, mentioned previously, lend support:

- The Pharmaceutical Care of People with Learning Disabilities, NHS Scotland 2014.
- Prescription for Excellence. A Vision and Action Plan for the right pharmaceutical care through integrated partnerships and innovation (Scottish Government, 2013).
- Guidance and Competencies for the Provision of Services using Practitioners with Special Interests [PwSIs]. Learning Disabilities (RCGP et al., 2009).

- Green Light Toolkit 2013. A guide to auditing and improving your mental health services so that it is effective in supporting people with autism and people with learning disabilities (NDTi et al., 2013).

The development of the role of 'specialist' or 'named' pharmacists in the area of intellectual disabilities in the pharmacy profession in Ireland will require support from three different stakeholder groups.

It will be particularly important for the pharmacy profession and individual pharmacists to help the average person with intellectual disability and their carer understand what pharmacists can do and the value they bring to complex care situations. Disability support organisation such as the organisation that supported the project described in Chapter 4 of this thesis will be vital advocates for this new role for pharmacists. As mentioned by a former Irish Ombudsman (O Reilly, 2009a)

'we all have a duty to make the public aware of what our contribution is'

Two other key stakeholder groups, physicians and other health professionals with whom pharmacists work and from who they receive prescriptions and referrals, and third-party payers that provide reimbursement for services etc. will have different goals and perspectives. A recent narrative review of the literature suggests that pharmacists can make positive interventions in relation to the quality of the medication use process, in collaboration with other healthcare professionals, carers and patients with intellectual disabilities (O'Dwyer et al., 2015). Pharmacists and the pharmacy profession will also need support from the patient with intellectual disability, other professionals, service providers, the HSE and government to assign a positive value to their service to this vulnerable population.

Pharmacists, prescribers and others do not always understand the complexity of the tasks they ask their patients with intellectual disabilities and their carers to do. There is a recognised need to improve clinical outcomes of patients with intellectual disabilities and in many areas of health and social care for people with intellectual disabilities there may be 'consultation overload'. It is important in the Irish context to make use of relevant information that has already been gathered from international research. The situation in Ireland for people with intellectual disabilities and their carers and those in healthcare and social care is unlikely to be very different from that that exists internationally. There should be no need 'to reinvent the wheel'.

5.5 Priority Areas

5.5.1 Introduction

The monitoring of all aspects of the quality and safety of healthcare provided to people ageing with intellectual disabilities and behaviour disorders is becoming increasingly important internationally. Many countries use QIs to monitor the performance of various aspects of their health and social care services and to highlight issues that need further exploration in relation to quality and safety.

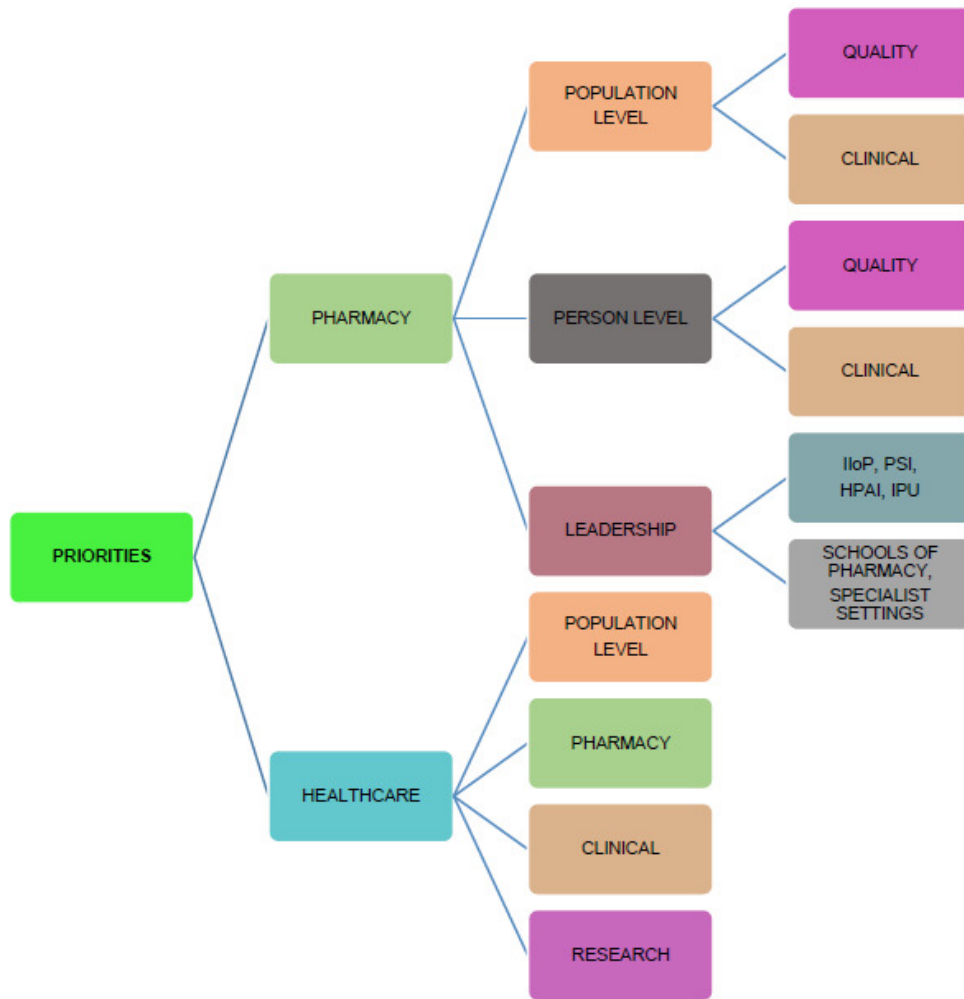
Medication use in people with intellectual disabilities and behaviour disorders is at the complex interface between the individual's rights, the law and ethics and the care the person is receiving. The interconnection between rights, respect and responsibility in the care of people with intellectual disabilities is crucial in the care of this vulnerable population. The development of QIs for medication use in people ageing with intellectual disabilities and behaviour disorders and their publication and dissemination, will raise the consciousness of professionals, carers, family members, service providers, policy makers and government to the many and varied issues relating to medication use in this vulnerable population group.

It is vital that service providers have accurate data about complex issues, such as the medication use process in vulnerable populations, to help them to develop their understanding and improve their services for vulnerable patients with intellectual disabilities. QIs will shine a light in this complex area.

Preventing people with intellectual disabilities and behaviour disorders from suffering avoidable harm during the medication use process and ensuring that people experience a quality medication use process will enhance the quality of their lives. This will require that pharmacy and healthcare respond to the priorities detailed in the following sections. The value that pharmacy can bring to the lives of people ageing with intellectual disabilities and behaviour disorders needs to be realised.

Healthcare and pharmacy must prioritise the most vulnerable in society, Figure 5.2, Table 5.2 and Table 5.3 and three important principles identified in Chapter 4 of this thesis should inform best practice in this area:

- The needs of people with intellectual disabilities are greater and more complex and often present differently from those of the general population.
- People with intellectual disabilities are more likely to have impaired communication and therefore require special consideration.
- People with intellectual disabilities have the right to access health services and these should be provided within current legislative and professional frameworks.



IloP = Irish Institute of Pharmacy

HPAI = Hospital Pharmacists Association of Ireland

IPU = Irish Pharmacy Union

Figure 5.2 Priorities

5.5.2 Pharmacy Priorities

Pharmacy has a responsibility to the population with intellectual disabilities. Priority areas were identified for pharmacy from the two literature reviews that informed this project, the MDT that was used to develop QIs and Grounded Theory analysis of the interviews with six people with intellectual disabilities. The priorities are at the population level, the level of the person with intellectual disability and at the leadership level of the pharmacy profession, Table 5.2. Pharmacy must unite to ensure that this vulnerable population receive the highest quality healthcare service and that each individual receives maximum value from the medication use process.

Table 5.2 Pharmacy Priorities

Pharmacy Priorities		
Population Level	Person with Intellectual Disability Level	Leadership of the Pharmacy Profession
Quality	Quality	IloP PSI HPAI IPU
<p>Improve outcomes in the population</p> <ul style="list-style-type: none"> • Acknowledge vulnerabilities in ID population • Awareness of determinants of health in ID • Multiple medication use in ID • Integrate pharmacists into ID teams • ACSC in ID e.g. epilepsy, diabetes • Health Passport • Unique patient identifier 	<p>Awareness of each individual's</p> <ul style="list-style-type: none"> • communication skills • strengths and weaknesses • self care or carer management • 'real life' – social and clinical networks • swallowing ability • preferences for medication form e.g. liquid or tablets • evidence for behavioural support before medications <p>Medication Review - only use tools validated in population e.g. no PIM validated in population with ID. Use QIs to monitor the medication use process.</p>	<p>Establish need for integration of 'Specialist Pharmacists' into professional networks as a strategy for tackling health inequalities and inequities in people with intellectual disabilities.</p> <ul style="list-style-type: none"> • Evolve practice of pharmacy to include Specialist Pharmacist in Intellectual Disabilities role in all settings. • QIs to be used to inform practice of pharmacy in ID population. <p>Consult people with intellectual disabilities and their carers and support organisations to ask what they need from pharmacy.</p>
<p>Ethics – principled sensitivity to the rights of others. Human Rights – right to health.</p>	<p>Each person with ID to be treated with dignity and respect. FREDA principles ensure human rights protected by adherence to underlying core values of fairness, respect, equality, dignity and autonomy.</p>	<p>Support pharmacists protecting human rights and ethical care in population with ID. Support pharmacist 'whistleblowers'. Support use of HIA, EIA and DHIA in all health related policies, guidelines etc.</p>
<p>Design medication use process for reliability. Use QIs to monitor quality of the medication use process in ID population with behaviour disorders.</p>	<p>Encourage annual health check. Pharmacist involved in risk assessment and assessment of capacity of each resident in LTC to take responsibility for his or her own medication.</p>	<p>Encourage pharmacists to partake in CPD in relation to most vulnerable populations i.e. population with ID and behaviour disorders</p>
<p>Communication e.g plain English, medicine labels. Information provision e.g. appropriate/'easy read', verbal, visual. 'Anticipatory' reasonable accommodations e.g. more time, 'specialist' pharmacist Health Literacy e.g. measure insulin. System navigation e.g. transport to doctor, attend numerous clinics.</p>	<p>Issues in long term care –</p> <ul style="list-style-type: none"> • 'Prescribing culture' • Culture of service provider • Multiple morbidities • Multiple medication use • Staff turnover • Deinstitutionalisation 	<p>Ensure pharmacy representation on the National Clinical Strategy Programmes – including those relating to disability issues. Develop training packages and resource materials on the population with intellectual disabilities to support pharmacists in all areas of healthcare.</p>
<p>Widespread use MDS to be examined – must be appropriate for every ID patient, every medication and every living environment.</p>	<p>Transitions of care hazardous Medication reconciliation</p>	<p>Examine widespread use and safety profile of MDS to ensure appropriate for each patient, medication and living environment. DHIA of MDS.</p>

Clinical	Clinical	Schools of Pharmacy Specialist ID Settings
Pharmacy accept responsibility for vulnerable ID population.	Pharmacist's practice of her profession must be directed to maintaining and improving the health, wellbeing, care and safety of each patient with intellectual disability.	Raise profile vulnerable population during undergraduate and post graduate teaching. Include 'experts by experience' i.e. people with ID in teaching programmes.
Register of all vulnerable patients including ID. Risk register highlighting most vulnerable e.g. ID patients with behaviour disorders. Use QIs to inform pharmaceutical care.	Agree outcomes for medication use with the patient and/or carer. Home medication use review as appropriate. Awareness of deprescribing issues in ID.	Inter-professional education opportunities
Contribute to national health policy, guidelines etc. development groups.	Acknowledge 'expert patient' and 'expert carer'. Side effects can be overlooked - be alert to and report changes in behaviour and or mental/physical health indicated by the person/carers.	Increase sensitivity of profession to ethical and human rights issues in ID population.
People with ID particular risk in general hospitals.	People with ID and behaviour disorders more vulnerable – medication used as a restrictive practice. Use QIs to monitor medication use process. Monitor use 'prn' medications as psychotropic medications in particular.	Establish evidence base for specialist pharmacist involvement in care of population with intellectual disabilities.
Specialist Pharmacists in ID in primary, secondary and tertiary care.	Multiple prescribers and clinicians involved. Use Health Passport – include Pharmacy contact details	Research 'prescribing culture' for medication in all care settings – involve local pharmacists. Research safety issues arising from 'repeat dispensing' of high risk medications.
Co-operation with prescribers and other clinicians	Health promotion – people with ID may not be aware of the long term implications of life style choices i.e. diet, not undertaking blood glucose testing, poor opportunities for physical exercise.	Develop Structured Medication Review tool in conjunction with pharmacists who are 'experts by experience' in the population.
Understand patient journey – multiple prescribers, carers, pharmacies.	Refer to Peer Support and Support organisations as appropriate.	Establish clinical and financial evidence base for specialist pharmacist involvement 'at point of care' in residential care settings.
Examine medication safety incidents in sector - many people with ID unable to protect themselves in the medication use process.	Ensure person aware of correct administration technique for insulin etc. and how to undertake blood glucose monitoring.	Develop medication accessible information resources.

HPAI = Hospital Pharmacists Association of Ireland

IPU = Irish Pharmacy Union

EIA = Equity Impact Assessment

DHIA = Disability Health Impact Statement

5.5.3 Healthcare Priorities

The Irish government and healthcare system seeks to ensure a healthy population with the most cost-effective use of health resources including medicines. Work done earlier in a healthcare system generally produce benefits at a lower cost than work performed later in the system. Healthcare priorities for the population with intellectual disabilities, the pharmacy profession, the research community and clinical care identified during this thesis are detailed in Table 5.3

Maximizing the expertise and scope of pharmacists and minimizing expansion barriers for an already existing and successful health care delivery model is a health system improvement that is well supported by the evidence-base (Giberson et al., 2011). However, increasing demand and limited supply of pharmacists is a recognised barrier to the ability of the pharmacy workforce to expand (Anderson and Roy, 2012).

There is currently limited evidence available in the literature suggesting that pharmacists can make positive interventions in relation to the quality of the medication use process, in collaboration with other healthcare professionals, carers and patients with intellectual disabilities (O'Dwyer et al., 2015). It is also acknowledged that

'absence of evidence is not evidence of absence'.

Even though there is no rigorous body of evidence to support provision of clinical pharmacy services to people with intellectual disabilities, extrapolation of evidence from other clinical areas suggests that benefits are likely (Richardson et al., 2014). There is a social responsibility to target services to vulnerable patient groups at high risk of adverse drug events for whom minimal evidence currently exists (Bell et al., 2015).

A review designed to assess the effects of interventions which target healthcare consumers to promote safe and effective medicines use identified some promising interventions to improve adherence and other key medicines-use outcomes (Ryan et al., 2014). These include:

- simplified dosing regimens with positive effects on adherence,
- interventions involving pharmacists in medicines management, such as medicines reviews with positive effects on adherence and use, medicines problems and clinical outcomes,

- pharmaceutical care services (consultation between pharmacist and patient to resolve medicines problems, develop a care plan and provide follow-up; with positive effects on adherence and knowledge).

There is a high prevalence of drug related problems in this population (Scheifes et al., 2015). A structured medication review, in conjunction with the Medication Review Crucial QI developed in this project, is a valuable instrument to optimize pharmacotherapy and to support psychiatrists, pharmacists and others in a quality medication use process for psychotropic and somatic medications.

Table 5.3 Healthcare Priorities

Healthcare Priorities			
Population with ID	Pharmacy	Research	Clinical
DIA, HIA and EHIA of all healthcare policies, guidelines, strategies.	Strategic plan – allocation of pharmacy resources in primary, secondary and tertiary care.	Establish evidence base for specialist pharmacy input in population with ID.	Population with ID to be considered at development stage for all policies, strategies etc. Include 'experts by experience'.
Population with ID want equal outcomes not equal care.	Evidence based care – use of QIs to monitor care of people with ID and behaviour disorders.	Barriers and facilitators of 'Specialist Pharmacist' role to be identified.	Pharmacy profession to be included in all National healthcare policy, strategy development groups.
Raise awareness determinants of health in population with ID. Provide annual health assessment in ID population.	'Specialist Pharmacist' in ID, support available in all care environments. Provide enhanced medication use services. Establish reimbursement mechanism for specialist pharmacy involvement.	New systems of provision of pharmaceutical care eg Home Medication Review, Primary Care Pharmacist, Specialist Pharmacist roles.	Appropriateness of self care by people with ID and high risk illnesses on high risk medications.
Focus on most vulnerable i.e. those with ID and behaviour disorders – introduce use of QIs.	Financial resources available for Home Medication Review in ID population as appropriate.	Pharmacists role on interdisciplinary healthcare teams supporting people with ID.	Recognition of excellence in care provision e.g. pharmacy, speech and language therapy, dietician.
Healthcare records and death certificates should include ID. Introduction of unique patient, clinician and location identifiers.	Pharmacy support rational and economic prescribing of medications e.g. examine refill dispensing process examine widespread use MDS.	Develop accessible information resources.	HIQA to include pharmacy profession input at development stage of disability and medication related standards. HIQA to use QIs in monitoring of medication use process.

Impacts of deinstitutionalisation policy on mortality, morbidity, medication use and health related quality of life to be determined.	Vulnerable population with ID to register with a named/specialist ID pharmacist of their choice.	Clinical and financial appropriateness of widespread use of MDS.	Monitor medication safety incident reports in ID sector. Include information person has ID on national incident reporting systems.
Health Passport for all people with ID.	Specialist Pharmacists to be integrated in healthcare teams for people with ID.	Develop tools for applying QIs in all care environments.	Improve training in ID for all health and social care staff.
Human rights of vulnerable people with ID recognised, including right to health and healthcare. Service providers and staff to be aware of what is acceptable practice.	Pharmacy profession to accept responsibility for outcomes of medication use in population with ID – focus care on the most vulnerable i.e. those with behaviour disorders.	NIDD to develop method of monitoring input of pharmacy profession in care of people with ID.	Improve training in medication matters for all nursing and care staff in care of people with ID.
Liaise with ID support groups.	Identify cost effective medication distribution methods - make the best use of limited resources to maximize health and medication use.	Develop technical supports for people with ID and dexterity difficulties, sensory difficulties etc.	Provide accessible information in all healthcare settings.
Examine distribution model of high risk medications to high risk patients with high risk illnesses.	Healthcare systems need to take account of pharmaceutical care as a working method for the promotion of the safety and quality of medication use.	Which pharmaceutical services are essential to guarantee the best performance of pharmaceutical care in health care system for people with intellectual disabilities.	Multifaceted professional interventions to enhance the performance of health professionals in managing vulnerable patients with diabetes.
Hospitals to fulfil their legal duty of care/ provide appropriate levels of support to patients with ID while in hospital e.g. specialist pharmacist ID. Ensure adequate workforce.	Reform the funding model for community pharmacy - move pharmacist remuneration from a fee-per-item volume model/align incentives with broader healthcare priorities.	Establish an evidence based, objective approach for allocating resources to 'specialist' pharmacists in hospitals, long term care or community services.	Ensure safety of people with ID in all general hospitals e.g. staff awareness of swallowing ability, appropriate form of medication administration, meaning of – 'Do Not Attempt Resuscitation' and 'Nil by mouth'.
Patients with ID to be 'flagged'/identified in all healthcare settings including GP surgeries, community pharmacies and general hospitals etc.		Research outcomes of differing HIQA Standards for medication review in general population and population with disabilities.	Consult population with intellectual disabilities and their support organisations to understand the 'real life' medication use process.

5.5.4 Future Research

The priority areas identified above indicate that the practice of pharmacy must evolve to provide high risk patients with intellectual disabilities with enhanced medicines-use services and processes. People with intellectual disabilities who take medicines, and their carers, know better than most what needs to change and pharmacy must include their perspectives in future research.

In particular, to improve outcomes for the most vulnerable population with intellectual disabilities and behaviour disorders pharmacy and healthcare must research how pharmacy can contribute to ensuring:

- access to a quality medication use process,
- access to 'specialist pharmacists' and pharmaceutical care.

The impact of disability on health and healthcare and the medication use process is rarely considered in healthcare policy. Multi-centre studies to evaluate the cost-effectiveness of 'Specialist Pharmacists' providing pharmaceutical care to the population with intellectual disabilities are required.

5.6 Complexity of Care

The complex healthcare and medication needs of people with intellectual disabilities should be the driving forces behind a new generation of 'specialist' pharmacy services for this vulnerable population. The outcomes for the population with intellectual disabilities must be uppermost in the minds of all pharmacists, pharmacy leadership and those in healthcare management resourcing and reimbursing the Irish pharmacy services.

Political will and investment are crucial aspects to secure pharmacy human resource capacity building in the disability sector in Ireland. If the pharmacy profession is to add value to the patient with intellectual disability and the healthcare system through a quality medicines use process, the pharmacy workforce must be present in sufficient numbers and specialities and with the competencies required to fulfil the needs of the local population with intellectual disabilities.

The changing demography of the population with intellectual disabilities with the associated changes in morbidity and the continuing health inequalities set major

challenges for pharmaceutical care in this population in the future. The proportion of over 40s, who are the highest users of medications and for whom prescribing and pharmaceutical care can be particularly complex, will increase in the next ten years. The pattern of disease in this population will see a continuing shift towards long term conditions, with growing numbers of those with multi-morbidity, co-morbidity of physical and mental disorders, behaviour disorders and resulting complex needs and multiple medication use.

In the aftermath of Winterbourne View and Aras Attracta it is particularly important that the voices of potentially very vulnerable individuals are not lost when developing policies and services to support individuals and their families and carers. Access to quality medicines and competent, skilled pharmacists are fundamental aspects of any health care system. Pharmaceutical human resources should ensure the uninterrupted supply of quality medicines to the population with intellectual disabilities, their management and responsible use, as vital components in improving the health of this vulnerable population and narrowing the health inequality and health inequity gaps.

There is an 'art' in providing pharmaceutical care to vulnerable people with intellectual disabilities. Pharmacists will need to accept responsibility for this high risk population. Individual pharmacists, Schools of Pharmacy, the IloP and the PSI must ensure that barriers to good health in the population with intellectual disabilities are dismantled. These include poor access to quality medical products, lack of access to trained health professionals and care, an inadequate health workforce and poor standards of education of health-care professionals.

The QIs developed in this project, based on two of the determinants of health in this population group, will provide a tool for 'specialist' pharmacists and others, to be used to lessen the health inequality and health inequity gap that currently exists between the population with intellectual disabilities and behaviour disorders and their peers with intellectual disabilities, and between the population with intellectual disabilities and the general population.

This project shone a spotlight on aspects of the medication use process in this population. Improving patients' experience of the entire medication use process is central to pharmaceutical care. It is a moral and human imperative to protect people with intellectual disabilities and behaviour disorders who may be weak and vulnerable, to strive towards recovery and healing and to ensure the humanity of care in all care environments. The need to do so within complex diverse systems and institutions that

are under pressure is a fundamental challenge for pharmacy and healthcare. It will always be important to find solutions to protect vulnerable people by ensuring that the care they receive is equitable and not equal.

Equal outcomes are what is important for people with intellectual disabilities and behaviour disorders. The evidence of what intervention works in the population with intellectual disabilities as mentioned before is sparse. It is likely that any successful interventions to improve medication health related outcomes will be complex and person specific, highly individualised, involve education and information transfer, involve the person with intellectual disability and their direct care giver, require skilled communicators, require an awareness of the person's sensory profile, manual dexterity ability and mobility status and be time consuming.

The original aim of this project was to improve the quality of care for the vulnerable population with intellectual disabilities. The rate of behaviour disorders in the population with intellectual disabilities is high. They burden the individual with intellectual disability, increase strain on families and caregivers, impair social interactions, increase the risk of restrictive practices being used, increase the risk of out of home placements and they are costly for the service provider. However Professor James Mansell reminds us that people with behaviour problems

'have the same needs as anyone else, in addition to special needs for help to overcome the problems their behaviour presents. They do not surrender their needs for personal relationships, for growth and development or for anything else because their behaviour presents a challenge to services. They have the same human and civil rights as anyone else' (Mansell, 2007).

The QIs developed in this project and the integration of 'Specialist Pharmacists' into healthcare teams will ensure that this vulnerable population receive a quality health service, i.e. that the entire medication use process will increase the likelihood of desired health outcomes and will be consistent with current professional knowledge.

REFERENCES

- AAPOR 2011. Standard Definitions: Final Dispositions of Case Codes and Outcome Rates for Surveys. 7th ed. Deerfield, IL: The American Association for Public Opinion Research.
- ADAMS, K. & CORRIGAN, J., EDS. 2003. Priority areas for national action. Transforming health care quality. Washington, D.C.
- ADDINGTON, D., MCKENZIE, E., ADDINGTON, J., PATTEN, S. & SMITH, H. 2005. Performance Measures for Early Psychosis Treatment Services. *Psychiatric Services*, 56.
- AGENCY FOR HEALTH CARE POLICY AND RESEARCH 1998. Measures of Quality of Care for Vulnerable Populations, Rockville, Maryland: National Institutes of Health.
- AGRICH, G. 1993. *Autonomy and Long Term Care*, Oxford University Press.
- AHMED, Z., FRASER, W., KERR, M., KIERNAN, C., EMERSON, E., ROBERSTON, J., FELCE, D., ALLEN, D., BAXTER, H. & THOMAS, J. 2000. Reducing antipsychotic medication in people with a learning disability. *The British Journal of Psychiatry*, 176, 42-46.
- AHRQ 2003. National Healthcare Disparities Report, 2003. Rockville, MD: Agency for Healthcare Research and Quality.
- AHRQ. 2005. *Guide to Healthcare Quality - How to Know it when you see it* [Online]. Rockville, MD: Agency for Healthcare Research and Quality. [Accessed Feb 14th 2012].
- AHRQ 2009. National Healthcare Quality Report 2009. *In*: US Department of Health & Human Services (ed.). Rockville, MD.
- AHRQ. 2010a. *Health Literacy Universal Precautions Toolkit* [Online]. Rockville, MD. [Accessed 14 June 2015].
- AHRQ 2010b. Health Literacy Universal Precautions Toolkit. Rockville, MD: Agency of Healthcare Research and Quality.
- AHRQ. 2010c. *Health Literacy Universal Precautions Toolkit* [Online]. Rockville, MD: U.S. Department of Health & Human Services.
- AHRQ. 2010d. *Scientific Evidence Base for Quality Measure Development. Developing Quality of Care Measures for People with Disabilities. Summary of Expert Meeting Sept 2010* [Online]. Rockville, MD.: Agency for Healthcare Research and Quality. [Accessed Feb 27th 2012].
- AHRQ. 2011. *Closing the Quality Gap Series: Measuring Outcomes of Care for Persons With Disabilities* [Online]. Rockville, MD: Agency for Healthcare Research and Quality.

- AHRQ 2014. Pharmacy Health Literacy Center. *In: Agency For Healthcare Research And Quality* (ed.). Rockville, MD: US Department of Health and Human Services.
- AKINS, R., TOLSON, H. & COLE, B. 2005. Stability of response characteristics of a Delphi panel: application of bootstrap data expansion. *BMC Medical Research Methodology*, 5, 37.
- AL-LAWATI, S. 2014. A Report on Patient Non-Adherence in Ireland. Irish Pharmacy Union, Pfizer, Irish Patients' Association.
- ALBAN-METCALFE, J. 2008. Effective Leadership and Organisational Culture for the Recruitment and Retention of People with Disabilities in the Irish Public Sector. *Disability Research Series 10*. Dublin: National Disability Authority.
- ALLEN, D. 2000. Recent research on physical aggression in persons with intellectual disability: An overview. *Journal of Intellectual and Developmental Disability*, 25, 41-57.
- ALLEN, D. & DAVIES, D. 2007. Challenging Behaviour and Psychiatric Disorder in Intellectual Disability, *Current Opinion in Psychiatry*, 20, 450-455.
- ALLEN, D., LOWE, K., BROPHY, S. & K. M. 2009. Predictors of Reactive Strategy Use in People with Challenging Behaviour. *Applied Research in Intellectual Disabilities* 22, 159-168.
- ALZHEIMER'S SOCIETY 2011. Optimising treatment and care for people with behavioural and psychological symptoms of dementia. *In: Dementia Action Alliance*, R. C. G. P., Department of Health UK, College Mental Health Pharmacists, Royal College of Psychiatrists, (ed.).
- AMERICAN ASSOCIATION OF DIABETES EDUCATORS 2011. Strategies for Insulin Injection Therapy in Diabetes Self-Management.
- AMERICAN ASSOCIATION ON INTELLECTUAL AND DEVELOPMENTAL DISABILITIES. 2010. *Defintion of Intellectual Disability* [Online]. Washington, DC. [Accessed 27 Feb. 2015].
- AMNESTY INTERNATIONAL 2003. Mental Illness – the Neglected Quarter: promoting the rights of the one in four Irish people affected by mental illness. Dublin: Amnesty International.
- ANDERSON, C., BATES, I., BROCK, T., BROWN, A. N., BRUNO, A., FUTTER, B., RENNIE, T. & ROUSE, M. J. 2012. Needs-Based Education in the Context of Globalization. *American Journal of Pharmaceutical Education*, 76, 56.
- ANDERSON, C. & ROY, T. 2012. 2012 FIP Global Pharmacy Workforce Report. Part 2. The Hague: International Pharmaceutical Federation.

- ANDERSON, S. 2007. Community pharmacy and public health in Great Britain, 1936 to 2006: how a phoenix rose from the ashes. *Journal of Epidemiology and Community Health*, 61, 844-848.
- ANTHONY, S. 2012. Consent to medical treatment in Ireland. An MPS guide for clinicians. *In: Medical Protection Society (ed.)*.
- ANTOINE, S.-L., PIEPER, D., MATHES, T. & EIKERMANN, M. 2014. Improving the adherence of type 2 diabetes mellitus patients with pharmacy care: a systematic review of randomized controlled trials. *BMC Endocrine Disorders*, 14, 53-53.
- ANTONACCI, D. J., MANUEL, C. & DAVIS, E. 2008. Diagnosis and Treatment of Aggression in Individuals with Developmental Disabilities, *Psychiatric Quarterly*, 79, 225-247.
- APA. 2014. *Principles of Practice for Pharmaceutical Care* [Online]. American Pharmacists Association.
- ARAH, O. A., WESTERT, G. P., HURST, J. & KLAZINGA, N. S. 2006. A conceptual framework for the OECD Health Care Quality Indicators Project. *International Journal for Quality in Health Care*, 18, 5-13.
- ARMESTO, S., KELLEY, E. & WEI, L. 2007. Health Care Quality Indicators. Dublin: Organisation for Economic Co-operation and Development.
- ARSCOTT, K., DAGNAN, D. & STENFERT KROESE, B. 1999. Assessing the ability of people with a learning disability to give informed consent to treatment. *Psychological Medicine*, 29, 1367-1375.
- ARSCOTT, K., STENFERT KROESE, B. & DAGNAN, D. 2000. A Study of the Knowledge that People with Intellectual Disabilities have of their Prescribed Medication. *Journal of Applied Research in Intellectual Disabilities*, 13, 90-99.
- ARSCOTT, K., STENFERT KROESE, B. & DAGNAN, D. 2010. A Study of the Knowledge that People with Intellectual Disabilities have of their Prescribed Medication. *Journal of Applied Research in Intellectual Disabilities*, 13, 90-99.
- ASKARI, M., WIERENGA, P. C., ESLAMI, S., MEDLOCK, S., DE ROOIJ, S. E. & ABU-HANNA, A. 2012. Studies pertaining to the ACOVE quality criteria: a systematic review. *International Journal for Quality in Health Care*, 24, 80-87.
- ASSISTED DECISION-MAKING (CAPACITY) BILL 2013.
- AUSTRALIAN PSYCHOLOGICAL SOCIETY 2011. Evidence-based guidelines to reduce the need for restrictive practices in the disability sector. Melbourne.
- BAILEY, S., FRIDLEY, J. & GEREENHILL, B. 2010. Challenging behaviour: a human rights-based approach. *Advances in Mental Health & Intellectual Disabilities*, 4, 20-26.

- BALFE, M., DOYLE, F., SMITH, D., SREENAN, S., BRUGHA, R., HEVEY, D. & CONROY, R. 2013. What's distressing about having type 1 diabetes? A qualitative study of young adults' perspectives. *BMC Endocrine Disorders*, 13, 25.
- BALOGH, R., BROWNELL, M., OUELLETTE-KUNTZ, H. & COLANTONIO, A. 2010. Hospitalisation rates for ambulatory care sensitive conditions for persons with and without an intellectual disability - a population perspective. *Journal of Intellectual Disability Research*, 54, 820-832.
- BALOGH, R. S., OUELLETTE-KUNTZ, H., BROWNELL, M. & COLANTONIO, A. 2011. Ambulatory Care Sensitive Conditions in Persons with an Intellectual Disability – Development of a Consensus. *Journal of Applied Research in Intellectual Disabilities*, 24, 150-158.
- BANERJEE, S. 2015. Multimorbidity - older adults need health care that can count past one. *The Lancet*, 385, 587-589.
- BARBER, N. D., ALLDRED, D. P., RAYNOR, D. K., DICKINSON, R., GARFIELD, S., JESSON, B., LIM, R., SAVAGE, I., STANDAGE, C., BUCKLE, P., CARPENTER, J., FRANKLIN, B., WOLOSHYNOWYCH, M. & ZERMANSKY, A. G. 2009. Care homes' use of medicines study: prevalence, causes and potential harm of medication errors in care homes for older people. *Quality and Safety in Health Care*, 18, 341-346.
- BARRY, P., O KEEFE, N., O CONNOR, K. & O MAHONY, D. 2006. Inappropriate prescribing in the elderly: a comparison of the Beers criteria and the improved prescribing in the elderly tool (IPET) in acutely ill elderly hospitalised patients. *Journal of Clinical Pharmacy & Therapeutics*, 31, 617-26.
- BAUMEISTER, R. F. & LEARY, M. R. 1997. Writing narrative literature reviews *Review of General Psychology* 1, 311-320.
- BEANGE, H., MCELDUFF, A. & BAKER, W. 1995. Medical disorders of adults with mental retardation: a population study. *American Journal on Mental Retardation*, 99, 6, 595-604, 99, 595-604.
- BEATTIE, E. & MACKWAY-JONES, K. 2004. A Delphi study to identify performance indicators for emergency medicine. *Emergency Medicine Journal*, 21, 47-50.
- BELL, J. S., KIRKPATRICK, C. & ALDERMAN, C. 2015. Balancing evidence and social responsibility when targeting clinical pharmacy services: the example of people with intellectual disabilities. *International Journal of Clinical Pharmacy*, 1-2.

- BENNETT, I., CHEN, J., SOROUI, J. & ET AL 2009. The contribution of health literacy to disparities in self-rated health status and preventive health behaviors in older adults. *Annals of Family Medicine* 7, 204-11.
- BENSON, B. A. & BROOKS, W. 2008. Aggressive challenging behaviour and intellectual disability. *Current Opinion in Psychiatry*, 21, 454-8.
- BERGMAN, B., NEUHAUSER, D. & PROVOST, L. 2011. Five main processes in healthcare: a citizen perspective. *BMJ Quality & Safety*, 20, i41-i42.
- BERNAL, J. 2006. *Consent and People With Intellectual Disabilities: The Basics* [Online]. St George's, University of London. [Accessed Jan 14 2015].
- BERTA, W., BARNESLEY, J., BLOOM, J., COCKERIL, R., DIVIS, D., JAAKKUMAINEN, L., MIOR, A. M., TALBOT, Y. & VAYDA, E. 2008. Enhancing continuity of information. Essential components of a referral document. *Canadian Family Physician*, 54, 1432-1433.
- BESWICK, T. & BARRETT, T. 2014. *UKMI Medicines Compliance Aid Database* [Online]. NHS, South West Medicines.
- BHAUMIK, S. & MICHAEL, D. M. 2004. Pharmacotherapy and pharmacovigilance in learning disability. *Learning Disability Psychiatry*, 6, 9-10.
- BIGBY, C. 2004. *Ageing with a lifelong disability*, London, Jessica Kingsley Publishers
- BLACKBURN, D. F., YAKIWCHUK, E. M., JORGENSON, D. J. & MANSELL, K. D. 2012. Proposing a Redefinition of Pharmaceutical Care (March). *The Annals of Pharmacotherapy*, 46, 447-9.
- BLAND, R., HUTCHINSON, N., OAKES, P. & YATES, C. 2003. Double jeopardy? Needs and services for older people who have learning disabilities. *Journal of Learning Disabilities*, 7, 327.
- BLOM, L. & KRASS, I. 2011. Introduction: The role of pharmacy in patient education and counseling. *Patient Education and Counseling*, 83, 285-287.
- BLOZIK, E., NOTHACKER, M., BUNK, T., SZECSENYI, J., OLLENSCHLAGER, G. & SCHERER, M. 2010. Simultaneous Development of Guidelines and Quality Indicators - How Do Guideline Groups Act? A Worldwide Survey. *International Journal of Health Care Quality Assurance*, 25 (8): 712-29.
- BOULKEDID, R., ABDOUL, H., LOUSTAU, M., SIBONY, O. & ALBERTI, C. 2011. Using and Reporting the Delphi Method for Selecting Healthcare Quality Indicators: A Systematic Review. *PLOS ONE*, 6, e20476.
- BOURKE, J. 2012. Languages of pain. *The Lancet*, 379, 2420-2421.
- BOWERS, B., NOLET, K., WEBBER, R., BIGBY, C. & STUMM, E. 2013. Support for Older People with Intellectual Disability: A Manual for Promoting Health. University of Wisconsin-Madison.

- BRANFORD, D. 1994. A study of the prescribing for people with learning-disabilities living in the community and in national-health-service care. *Journal of Intellectual Disability Research*, 38, 577-86.
- BRANFORD, D. 1996. Factors associated with the successful or unsuccessful withdrawal of antipsychotic drug therapy prescribed for people with learning disabilities. *Journal of Intellectual Disability Research*, 40, 322-329.
- BRANFORD, D. 2007. New Ways of Working for Mental Health Pharmacists and Other Pharmacy Staff. *New Ways of Working for Everyone*. National Institute for Mental Health in England, College of Mental Health Pharmacists, Care Services Improvement Partnership, Psychiatric Pharmacy Group
- BRITISH PHARMACOLOGICAL SOCIETY 2010. Ten Principles of Good Prescribing. London.
- BROLAN, C. E., BOYLE, F. M., DEAN, J. H., TAYLOR GOMEZ, M., WARE, R. S. & LENNOX, N. G. 2012. Health advocacy: a vital step in attaining human rights for adults with intellectual disability. *Journal of Intellectual Disability Research*, 56, 1087-1097.
- BRYLEWSKI, J. & DUGGAN, L. 2004. Antipsychotic medication for challenging behaviour in people with learning disability. *Cochrane Database of Systematic Reviews Issue 3. Art. No.: CD000377*.
- BURNAM, A. 2005. Commentary: Selecting Performance Measures by Consensus: An Appropriate Extension of the Delphi Method? *Psychiatric Services*, 56, 1583.
- BUSH, A. & BEAIL, N. 2004. Risk Factors for Dementia in People With Down Syndrome: Issues in Assessment and Diagnosis. *American Journal on Mental Retardation*, 109, 83-97.
- BUSHARDT, R., MASSEY, E., SIMPSON, T., ARIAIL, J. & SIMPSON, K. 2008. Polypharmacy: Misleading, but manageable. *Clinical Interventions in Aging*, 3, 383-389.
- CALDWELL, P. & HORWOOD, J. 2007. *From Isolation to Intimacy. Making Friends without Words*, Jessica Kingsley.
- CAMPBELL, S. M., BRASPENNING, J., HUTCHINSON, A. & MARSHALL, M. 2002. Research methods used in developing and applying quality indicators in primary care. *Quality and Safety in Health Care*, 11, 358-364.
- CAMPBELL, S. M., SHIELD, T., ROGERS, A. & GASK, L. 2004. How do stakeholder groups vary in a Delphi technique about primary mental health care and what factors influence their ratings? *Quality and Safety in Health Care*, 13, 428-434.
- CAPLIN, D. A., RAO, J. K., FILLOUX, F., BALE, J. F. & VAN ORMAN, C. 2006. Development of Performance Indicators for the Primary Care Management of

- Pediatric Epilepsy: Expert Consensus Recommendations Based on the Available Evidence. *Epilepsia*, 47, 2011-2019.
- CARDOL, M., RIJKEN, M. & VAN SCHROJENSTEIN LANTMAN-DE VALK, H. 2012. Attitudes and dilemmas of caregivers supporting people with intellectual disabilities who have diabetes. *Patient education and counseling*, 87, 383-388.
- CARTER, W. 2006. Challenging Behaviour and Disability: A Targeted Response. *Report to Hon William Pitt MP, Minister for Communities Disability Services and Seniors*. Queensland.
- CASTELINO, R. L., BAJOREK, B. V. & CHEN, T. F. 2009. Targeting Suboptimal Prescribing in the Elderly: A Review of the Impact of Pharmacy Services. *The Annals of Pharmacotherapy*, 43, 1096-1106.
- CDC & NCBDDD 2009. U.S. Surveillance of Health of People with Intellectual Disabilities. A White Paper. Kingston, Ontario, Canada: Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities Health Surveillance Work Group.
- CENTRAL STATISTICS OFFICE 2012. Profile 8. Our Bill of Health. Cork.
- CENTRAL STATISTICS OFFICE 1996. Life Tables and Vital Statistics. *In*: CSO (ed.). Dublin.
- CESCR 2000. The right to the highest attainable standard of health, General Comment 14, 11/8/2000. Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4) United Nations Committee on Economic Social & Cultural Rights.
- CHADWICK, D. & JOLLIFFE, J. 2009. A descriptive investigation of dysphagia in adults with intellectual disabilities. *Journal of Intellectual Disability Research*, 53, 29-43.
- CHEW, M. L., MULSANT, B. H., POLLOCK, B. G., LEHMAN, M. E., GREENSPAN, A., MAHMOUD, R. A., KIRSHNER, M. A., SORISIO, D. A., BIES, R. R. & GHARABAWI, G. 2008. Anticholinergic Activity of 107 Medications Commonly Used by Older Adults. *Journal of the American Geriatrics Society*, 56, 1333-1341.
- CHISHOLM-BURNS, M., LEE, J., SPIVEY, C., SLACK, M., HERRIER, R., HALL-IPSY, E., GRAFF ZIVIN, J., ABRAHAM, I., PALMER, J., MARTIN, J., KRAMER, S. & WUNZ, T. 2010. US Pharmacists' Effect as Team Members on Patient Care. Systematic Review and Meta-Analyses. *Medical Care*, 48.
- CLARKE, J. & FORDE, R. 2006. *Diabetes mellitus: Psychosocial issues in diabetes* [Online]. Dublin.

- CLEARY, M., HORSFALL, J., JACKSON, D., O'HARA-AARONS, M. & HUNT, G. E. 2012. Patients' views and experiences of pro re nata medication in acute mental health settings. *International Journal of Mental Health Nursing*, 21, 533-539.
- CLEGG, J. 2008. Holding services to account. *Journal of Intellectual Disability Research*, 52, 581-587.
- COMMITTEE ON HEALTH LITERACY 2004. Health Literacy: A Prescription to End Confusion. In: NIELSEN-BOHLMAN, L., PANZER, A. & KINDIG, D. (eds.). Washington, DC.
- COMMITTEE ON THE QUALITY OF HEALTHCARE IN AMERICA 2001. Crossing the Quality Chasm: A New Health System for the 21st Century 2001. Washington, DC: Institute of Medicine.
- COOPER, S. A., 2003. Classification and Assessment of Psychiatric Disorders in Adults with Learning [Intellectual] Disabilities. *Psychiatry*, 2, 12-17.
- COOPER, S. A., MELVILLE, C. & MORRISON, J. 2004. People with Intellectual Disabilities. Their health needs differ and need to be recognised and met. *British Medical Journal* 329, 414-415.
- COOPER, S. A., MORRISON, J., MELVILLE, C., FINLAYSON, J., ALLAN, L., MARTIN, G. & ROBINSON, N. 2006. Improving the health of people with intellectual disabilities: outcomes of a health screening programme after 1 year. *Journal of Intellectual Disability Research*, 50, 667-677.
- COORAY, S. E. & BAKALA, A. 2005. Anxiety disorders in people with learning disabilities. *Advances in Psychiatric Treatment*, 11, 355-361.
- CORBIN, J. & STRAUSS, A. 1990. Grounded theory research: Procedures, canons, and evaluative criteria. *Qualitative Sociology*, 13, 3-21.
- CORBIN, S., HOLDER, M. & HOOD, H. 2005. Changing attitudes, changing the world: The health and health care of people with intellectual disabilities. Washington, DC: Special Olympics.
- CORNISH, P. 2005. "Avoid the crush": hazards of medication administration in patients with dysphagia or a feeding tube. *Canadian Medical Association Journal*, 172, 871-872.
- COULTER, A. & COLLINS, A. 2011. Making Shared Decision-Making a Reality. No decision about me, without me. London: The King's Fund, The Foundation for Medical Decision Making.
- COULTER, A. & ELLINS, J. 2006. Patient-focused interventions. A review of the evidence. London: Picker Institute Europe.

- COULTER, A., PARSONS, S. & ASKHAM, J. 2008. Where are the patients in decision making about their own care? Policy Brief. *In: WHO Regional Office for Europe and European Observatory on Health Systems and Policies, (ed.) WHO European Ministerial Conference on Health Systems.* Tallinn, Estonia: WHO Europe.
- CQC 2012a. Community Mental Health Survey 2012. London: Care Quality Commission.
- CQC 2012b. Market Report Issue: 1 June 2012. London: Care Quality Commission.
- CRIBB, P. A. 2011. Involvement, Shared Decision-Making and Medicines. London: Royal Pharmaceutical Society.
- CROMBIE, I., INRVINE, L., ELLIOTT, L. & WALLACE, H. 2005. Closing the Health Inequalities Gap: An International Perspective. *In: WHO (ed.).*
- CRONIN, H., O REGAN, C. & RA, K. 2011. Physical and behavioural health of older Irish adults *In: BARREE A., S. G., TIMONEN, V & KENNY RA (ed.) Fifty Plus in Ireland 2011.* Dublin: Trinity College.
- CRONIN, P., RYAN, F. & COUGHLAN, M. 2008. Undertaking a literature review: a step-by-step approach. *British Journal Of Nursing* 17, 38-43.
- CROOKS, D. L. 2001. The Importance of Symbolic Interaction in Grounded Theory Research on Women's Health, *Health Care for Women International*, 22, 11-27.
- CROSSLEY, R. & WITHERS, P. 2009. Antipsychotic Medication and People with Intellectual Disabilities: Their Knowledge and Experiences. *Journal of Applied Research in Intellectual Disabilities*, 22, 77-86.
- CURTICE, M. J. & EXWORTHY, T. 2010. FREDa: a human rights-based approach to healthcare. *The Psychiatrist*, 34, 150-156.
- CUSTER, R., SCARCELLA, J. & STEWART, B. 1999. The Modified Delphi Technique - A Rotational Modification. *Journal of Vocational & Technical Education*, 15.
- D'EATH, M., SIXSMITH, J., CANNON, R. & KELLY, L. 2005. The Experience of People with Disabilities in Accessing Health Services in Ireland: Do inequalities exist? Report to the National Disability Authority. Centre for Health Promotion Studies, Department of Health Promotion, National University of Ireland, Galway.
- D&TB 2012. An introduction to patient decision aids. *Drug and Therapeutics Bulletin*, 50, 90-92.
- DAHLGREN, G. & WHITEHEAD, M. 1998. Determinants of health model. *In: ACHESON, D. (ed.) Independent Inquiry into Inequalities in Health Report* London: The Stationary Office, 1998.

- DANDI, R. & CASANOVA, G. 2012. Quality Assurance Indicators of Long-Term Care in European Countries. Brussels: The Centre for European Policy Studies (CEPS).
- DARZI, L. 2008. High Quality Care for All. *NHS Next Stage Review*. Whitehall, London: Department of Health England, NHS.
- DE KUIJPER, G., HOEKSTRA, P., VISSER, F., SCHOLTE, F. A., PENNING, C. & EVENHUIS, H. 2010. Use of antipsychotic drugs in individuals with intellectual disability (ID) in the Netherlands: prevalence and reasons for prescription. *Journal of Intellectual Disability Research*, 54, 659-667.
- DE MERYICK, J. 2003. "The Delphi method and health research". *Health Education* 103, 7-16.
- DEB, S. 2007. The role of medication in the management of behaviour problems in people with learning disabilities. *Advances in Mental Health and Learning Disabilities*, 1, 26-31.
- DEB, S. 2012. *The Use of Medications for the Management of Problem Behaviours in Adults who have Intellectual [Learning] Disabilities* [Online]. London: Saint George's, University of London. [Accessed Jan 5 2015].
- DEB, S., CHAPLIN, R., SOHANPAL, S., UNWIN, G., SONI, R. & LENOTRE, L. 2008. The effectiveness of mood stabilizers and antiepileptic medication for the management of behaviour problems in adults with intellectual disability: a systematic review. *Journal of Intellectual Disability Research*, 52, 107-113.
- DEB, S., CLARKE, D. & UNWIN, G. 2006. Using Medication to Manage Behaviour Problems among Adults with a Learning Disability: Quick Reference Guide. London: Royal College of Psychiatrists, Mencap 60, University of Birmingham.
- DEB, S. & FRASER, W. 1994. The use of psychotropic medication in people with learning disability: towards rational prescribing. *Human Psychopharmacology* 9, 259-272.
- DEB, S., MATTHEWS, T., HOLT, G. & BOURAS, N. 2001a. Practice guidelines for the assessment and diagnosis of mental health problems in adults who have intellectual disability. London: European Association for Mental Health in Mental Retardation (EAMHMR).
- DEB, S., SALVADOR-CARULLA, L., BARNHILL, J., TORR, J., BRADLEY, E., KWOK, H., BERTELLI, M. & BOURAS, N. 2009. Problem Behaviours in Adults with Intellectual Disabilities: International Guide for Using Medication. The World Psychiatric Association (WPA): Section Psychiatry of Intellectual Disability (SPID).

- DEB, S., SOHANPAL, S. K., SONI, R., LENTRE, L. & UNWIN, G. 2007. The effectiveness of antipsychotic medication in the management of behaviour problems in adults with intellectual disabilities. *Journal of Intellectual Disability Research*, 51, 766-777.
- DEB, S., THOMAS, M. & BRIGHT, C. 2001b. Mental disorders in adults with intellectual disability. 2: The rate of behaviour disorders among a community based population aged between 16 and 64 years. *Journal of Intellectual Disability Research*, 45, 506-514.
- DEB, S. & UNWIN, G. 2006a. Guide to using psychotropic medication for the management of behaviour problems among adults with intellectual disability. Technical Document. Birmingham: University of Birmingham. Mencap, The Royal College of Psychiatrists.
- DEB, S. & UNWIN, G. L. 2006b. Guide to Using Psychotropic Medication to Manage Behaviour Problems among Adults with Intellectual Disability. Technical Document Section 2: The Recommendations.
- DEB, S. & UNWIN, G. L. 2007. Guide to using psychotropic medication for the management of behaviour problems among adults with intellectual disability *Technical document, Section 3. Systematic Reviews*. Birmingham UK: University of Birmingham.
- DEVAPRIAM, J., ANAND, A., RAJU, L. B. & BHAUMIK, S. 2009. Monitoring for Metabolic Syndrome in Adults with Intellectual Disability on Atypical Antipsychotic Drugs. *The British Journal of Development Disabilities*, 55, 3-13.
- DEVINE, M. & TAGGART, L. 2008. Addressing the mental health needs of people with learning disabilities. *Nursing Standard*, 22, 40-48.
- DEVON LOCAL PHARMACEUTICAL COMMITTEE 2012. Diabetes Medicines Use Review (MUR) Toolkit.
- DH 1999. Facing the Facts: Services for People with Learning Disabilities: Policy Impact Study of Social Care and Health Services. London: Department of Health England.
- DH 2005. Choosing health through pharmacy. *In: Department of Health (ed.)*. London.
- DH 2012a. Department of Health Review: Winterbourne View Hospital. Interim Report. England: Department of Health.
- DH 2012b. Department of Health: Winterbourne View Review Engagement: a summary of responses. Whitehall, London: Department of Health.
- DH 2012c. Future Health – A Strategic Framework for Reform of the Health Service 2012-2015. *In: Department of Health (ed.)*. Dublin.

- DH 2012d. Transforming care: a national response to Winterbourne View hospital. Department of Health Review: Final Report. Whitehall, London: Department of Health, England.
- DH 2012e. Value for Money & Policy Review of the Disability Services. Dublin: Department of Health.
- DH 2012f. Winterbourne View Review. Concordat: Programme of Action. Whitehall, London: Department of Health.
- DH 2012g. Winterbourne View. Summary of the Government Response. London: Department of Health.
- DH 2013a. Healthy Ireland, A Framework for Improved Health and Wellbeing 2013-2025. *In: Department of Health (ed.)*. Dublin.
- DH 2013b. Pharmaceutical Needs Assessments: Information Pack for Local Authority Health and Wellbeing Boards. *In: Department of Health, England*.
- DH 2013c. Winterbourne View: Transforming Care One Year On. England: Department of Health.
- DH 2010. Making written information easier to understand for people with learning disabilities. *Guidance for people who commission or produce Easy Read information - Revised Edition 2010*.
- DHHS 2007. Medication Regimen Review. *Surveyor Guidance Pharmacy Services F428*. Baltimore, MA: Department of Health & Health Services.
- DI BLASI, A., KENDALL, S. & SPARK, M. J. 2006. Perspectives on the role of the community pharmacist in the provision of healthcare to people with intellectual disabilities: exploration of the barriers and solutions. *International Journal of Pharmacy Practice*, 14, 263-269.
- DIABETES IRELAND. 2014. *Living with diabetes*, [Online]. [Accessed Nov 24 2014].
- DIABETES SPECTRUM. 2000. *Diabetes and Quality of Life* [Online]. [Accessed Nov 24 2014].
- DISABILITY FEDERATION OF IRELAND. 2005. *Disability & Population Health Discussion Paper* [Online].
- DISABILITY RIGHTS COMMISSION 2006. Equal Treatment: closing the gap. A formal investigation into the physical health inequalities experienced by people with learning disabilities/mental health problems 2006.
- DJ&E 2012. How to Conduct a Disability Impact Assessment. Guidelines for Government Departments. Dublin: Department of Justice and Equality.
- DJ&E. 2014. *Civil Law Reform: Proposed Legislation* [Online]. Department of Justice & Equality.

- DOH 2011. Towards a Restraint Free Environment in Nursing Homes. Dublin: Department of Health.
- DOH&C 2006. A Vision for Change. Report of the Expert Group on Mental Health Policy. Dublin: Department of Health & Children.
- DOH&C 2010. Report on Public Consultation. Efficiency and Effectiveness of Disability Services in Ireland. *Review of Disability Services under the Value for Money and Policy Review Initiative 2009-2011*. Dublin.
- DONATI, R., MAINO, D., BARTELL, H. & KIEFFER, M. 2009. Polypharmacy and the lack of oculo-visual complaints from those with mental illness and dual diagnosis. *Optometry*, 80, 249-54.
- DONLEY, M., CHAN, J. & WEBBER, L. 2012. Disability support workers' knowledge and education needs about psychotropic medication. *British Journal of Learning Disabilities*, 40, 286-291.
- DOYLE, G., CAFFERKEY, K. & FULLAM, J. 2012. The European Health Literacy Survey: Results from Ireland. Executive Agency for Health & Consumers, Department of Health ROI, National Adult Literacy Agency, HLS-EU.
- DUERDEN, M., MILLSON, D., AVERY, A. & SMART, S. 2011. The quality of GP prescribing. The King's Fund.
- DYSCH, C., CHUNG, M. & FOX, J. 2012a. How do people with Intellectual Disabilities and Diabetes Experience and Perceive their Illness? *JARID*, 25, 39-49.
- DYSCH, C., CHUNG, M. C. & FOX, J. 2012b. How Do People with Intellectual Disabilities and Diabetes Experience and Perceive their Illness? *Journal of Applied Research in Intellectual Disabilities*, 25, 39-49.
- EDELSON, G., SCHUSTER, J., CASTELNOVO, K., TERHORST, L. & PARTHASARATHY, M. 2014. Psychotropic Prescribing for Persons With Intellectual Disabilities and Other Psychiatric Disorders *Psychiatric Services*, 65, 201-7.
- EGEDE, L. & DISMUKE, C. 2012. Serious psychological distress and diabetes: a review of the literature. *Current Psychiatry Report*, 14, 15 - 22.
- EINFELD, S. L. 2001. Systematic management approach to pharmacotherapy for people with learning disabilities. *Advances in Psychiatric Treatment*, 7, 43-49.
- ELLENBECKER, C., SAMIA, L., CUSHMAN, M. & ALSTER, K. 2008. Patient Safety and Quality In Home Health Care. In: HUGHES, R. (ed.) *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville, MD.
- ELLENBECKER, C. H., FRAZIER, S. C. & VERNEY, S. 2004. Nurses' observations and experiences of problems and adverse effects of medication management in home care. *Geriatric nursing (New York, N.Y.)*, 25, 164-170.

- ELLIOTT, N. & LAZENBATT, A. 2005. How to Recognise a 'Quality' Grounded Theory Research Study. *Australian Journal of Advanced Nursing*, 22, 48-52.
- EMEA 2009. Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations. London: European Medicines Agency.
- EMERSON, E. 2001. *Challenging Behaviour: Analysis and intervention in people with learning disabilities (2nd Edition)*, Cambridge, Cambridge University Press.
- EMERSON, E. & BAINES, S. 2010. Health Inequalities and People with Learning Disabilities in the UK. *In: Learning Disabilities Observatory (ed.) Improving Health & Lives*.
- EMERSON, E., BAINES, S., ALLERTON, L. & WELCH, V. 2011. Health Inequalities and People with Learning Disabilities in the UK:2011. *Improving Health & Lives*, Public Health England: The Learning Disabilities Observatory.
- EMERSON, E., BAINES, S., ALLERTON, L. & WELCH, V. 2012. Health Inequalities & People with Learning Disabilities in the UK: 2012. *Improving Health & Lives*. Learning Disabilities Observatory: Public Health England.
- EMERSON, E., KIERNAN, C., ALBORZ, A., REEVES, D., MASON, H., SWARBRICK, R., MASON, L. & HATTON, C. 2001. The prevalence of challenging behaviors: a total population study. *Research in Developmental Disabilities*, 22, 77-93.
- EMERSON, E., ROBERTSON, J., GREGORY, N., HATTON, C., KESSISSOGLU, S., HALLAM, A. & HILLERY, J. 2000. Treatment and Management of Challenging Behaviours in Residential Settings. *Journal of Applied Research in Intellectual Disabilities*, 13, 197-215.
- EPILEPSY SOCIETY. 2013. *Learning disability and epilepsy* [Online]. [Accessed 30 Nov. 2014].
- EQUALITY AUTHORITY. 2014. *Your Equal Status Rights Explained* [Online]. [Accessed 21 Sept 2014].
- EUROPEAN COMMISSION 2005. Improving the mental health of the population. Towards a strategy on mental health for the European Union. Green Paper. Brussels,: Health & Consumer Protection Directorate-General.
- EUROPEAN COURT ON HUMAN RIGHTS & COUNCIL OF EUROPE 1950. European Convention on Human Rights. Rome.
- EUSSEN, S. R., VAN DER ELST, M. E., KLUNGEL, O. H., ROMPELBERGG, C. J., GARSSEN, J., OOSTERVELD, M. H., DE BOER, A., DE GIER, J. J. & MARCEL, L. B. 2010. A Pharmaceutical Care Program to Improve Adherence to Statin Therapy: A Randomized Controlled Trial. *Annals of Pharmacotherapy*, 44, 1905-1913.

- EVENHUIS, H., HENDERSON, C. M., BEANGE, H., LENNOX, N. & CHICOINE, B. 2001. "Health Ageing – Adults with Intellectual Disabilities: Physical Health Issues". *Journal of Applied Research in Intellectual Disabilities*, 14, 175-194.
- FACULTY OF DENTAL SURGERY 2012. Clinical Guidelines and Integrated Care Pathways for the Oral Health Care of People with Learning Disabilities London,: Royal College Surgery, British Society for Disability & Oral Health, Princess Diana Memorial Fund.
- FACULTY OF LEARNING DISABILITY PSYCHIATRY 2014. A Guidance Document on Dementia in Persons with Intellectual Disability. *In: College of Psychiatrists of Ireland (ed.)*.
- FAMILY PRACTITIONER UNIT 2003. A Guide to Patient Medication Review. *In: Northern Health & Social Services Board (ed.)*. Ballymena: Family Practitioner Unit.
- FDA. 2006. *Information for Healthcare Professionals: Selective Serotonin Reuptake Inhibitors (SSRIs), Selective Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), 5-Hydroxytryptamine Receptor Agonists (Tryptans)* [Online]. Rockville, MD.
- FDA 2008a. FDA Alert 6/16/2008 Information for Healthcare Professionals: Conventional Antipsychotics. Rockville, MD.
- FDA 2008b. Statistical review and evaluation: antiepileptic drugs and suicidality. *In: Centre for Drug Evaluation and Research (ed.)*. U.S. Department of Health and Human Services.
- FDA 2009a. FDA'S Safe Use Initiative. Collaborating to Reduce Preventable Harm from Medications.
- FDA 2009b. Suicidal Behavior and Ideation and Antiepileptic Drugs. Silver Spring, MD.
- FIP & WHO 2012. Good Pharmacy Practice. Joint FIP/WHO Guidelines on GPP: Standards for quality of pharmacy services. The Hague.
- FISCHER, K. 2004. Health Disparities and Mental Retardation. *Journal of Nursing Scholarship*, 48-53.
- FISCHHOFF, B., BREWER, N. & DOWNS, S. 2011. Communicating Risks and Benefits: An Evidence Based User's Guide. FDA.
- FISHER, L., HESSLER, D., POLONSKY, W. & MULLAN, J. 2012. When is diabetes distress clinically meaningful? *Diabetes Care*, 35, 259 - 264.
- FLETCHER, R., LOSCHEN, E., STAVRAKAKI, C. & FIRST, M. 2007. *DM-ID: A Textbook of Diagnosis of Mental Disorders in Persons with Intellectual Disability*, Kingston, New York, The National Association for the Dually

Diagnosed (NADD), in association with the American Psychiatric Association (APA).

- FLOOD, B. 2013a. Bone health medication and adults with intellectual disabilities: an audit of bone health medication dispensed by a pharmacist in long-term care. *British Journal of Learning Disabilities*, 41, 239-240.
- FLOOD, B. 2013b. How to improve health outcomes for patients with learning disabilities. *Clinical Pharmacist*, 5, 231-232.
- FLOOD, B. 2013c. Tackling Health Inequalities. Improving Medicines Use for People with Intellectual Disabilities. *College of Mental Health Pharmacists Bulletin*, March, 3-4.
- FLOOD, B. 2014a. Intellectual disabilities: An introduction for pharmacists. *Irish Pharmacy News*, S1-4.
- FLOOD, B. 2014b. Safety of people with intellectual disabilities in general hospitals. How the pharmacist can help reduce inequalities. Poster. *Hospital Pharmacist's Association of Ireland Annual Educational Conference*. Santry, Dublin.
- FLOOD, B. 2015. Poster Abstract: Medication Use in Long Term Care for People Ageing with Intellectual Disabilities. 'Not a simple process'. *Irish Ageing Studies Review*, 6.
- FLOOD, B. & HENMAN, M. 2010. An Invisible Profession: Pharmacists and the Population with Intellectual Disability. *Irish Pharmacy Journal*, 88, 166-167.
- FLOOD, B. & HENMAN, M. 2011. The Intellectually Disabled. A neglected group who need pharmacist's help. *The International Pharmacy Journal*, 27, 41-43.
- FLOOD, B. & HENMAN, M. 2015a. Optimisation of Medication Use in People with Intellectual Disabilities: We Need to Listen to What They Can Tell Us. *PRIMM 2015, One for all and all for one – different perspectives in Medicines Optimisation*. Russel Square, London.
- FLOOD, B. & HENMAN, M. C. 2015b. Building quality indicators for medication use in people aging with intellectual disabilities and behaviour disorders. *International Journal of Developmental Disabilities*, 2015 (Print ISSN: 2047-3869, Online ISSN: 2047-3877). Advance article.
- FLOOD, B. & HENMAN, M. C. 2015c. Building quality indicators for medication use in people aging with intellectual disabilities and behaviour disorders. *International Journal of Developmental Disabilities*, 2015, Advance Article.
- FLOOD, B. & HENMAN, M. C. 2015d. Case study: hidden complexity of medicines use: information provided by a person with intellectual disability and diabetes to a pharmacist. *British Journal of Learning Disabilities*, 2015: Advance Article.

- FPLD 2004. Green Light Toolkit. Foundation for People with Learning Disabilities, Department of Health UK.
- FREDHEIM, T., LIEN, L., DANBOLT, L. J., KJØNSBERG, K. & HAAVET, O. R. 2011. Experiences with general practitioners described by families of children with intellectual disabilities and challenging behaviour: a qualitative study. *BMJ Open*, 1.
- FREUND, T., CAMPBELL, S., GEISSLER, S., KUNZ, C., MAHLER, C., PETERS-KLIMM, F. & SZECSENI, J. 2013. Strategies for reducing potentially avoidable hospitalizations for ambulatory care-sensitive conditions. *Annals of Family Medicine*, 11, 363-70.
- FRID, A., HIRSCH, L., GASPAR, R., ALI, E. & SCIENTIFIC ADVISORY BOARD FOR THE THIRD INJECTION TECHNIQUE WORKSHOP 2010. New injection recommendations for patients with diabetes. *Diabetes and Metabolism*, 36, S3-S18.
- FRIEDLE, L. 2009. Mental Health, Resilience, and Inequalities. World Health Organisation Europe.
- FRIGHI, V., STEPHENSON, M. T., MOROVAT, A., JOLLEY, I. E., TRIVELLA, M., DUDLEY, C. A., ANAND, E., WHITE, S. J., HAMMOND, C. V., HOCKNEY, R. A., BARROW, B., SHAKIR, R. & GOODWIN, G. M. 2011a. Safety of antipsychotics in people with intellectual disability. *The British Journal of Psychiatry*, 199, 289-295.
- FRIGHI, V., STEPHENSON, M. T., MOROVAT, A., JOLLEY, I. E., TRIVELLA, M., DUDLEY, C. A., ANAND, E., WHITE, S. J., HAMMOND, C. V., HOCKNEY, R. A., BARROW, B., SHAKIR, R. & GOODWIN, G. M. 2011b. Safety of antipsychotics in people with intellectual disability. *The British Journal of Psychiatry*.
- FYSON, R. & CROMBY, J. 2013. Human rights and intellectual disabilities in an era of 'choice'. *Journal of Intellectual Disability Research*, 57, 1164-1172.
- GAZMARARIAN, J. A., KRIPALANI, S., MILLER, M. J., ECHT, K. V., REN, J. & RASK, K. 2006. Factors Associated with Medication Refill Adherence in Cardiovascular-related Diseases: A Focus on Health Literacy. *Journal of General Internal Medicine*, 21, 1215-1221.
- GEARTY, C. 2006. *Can Human Rights Survive?*, New York and Cambridge, Cambridge University Press.
- GIBERSON, S., YODER, S. & LEE, M. 2011. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Rockville, Maryland: Office of the Chief Pharmacist U.S.

- GIFFORD, D. 2012. A Perspective on CMS'S Antipsychotic Reduction Initiative. American Healthcare Association.
- GILBERT, M. 2008. Accessibility for Customers with Disabilities in Community Pharmacies. Irish Pharmacy Union and Equality Authority.
- GILL, D., SPAIN, M. & EDLUND, B. J. 2012. Crushing or Splitting medications: Unrecognised Hazards. *Gerontological Nursing*, 38, 8-12.
- GLASER, B. 1978. *Theoretical Sensitivity*, University of California.
- GLASER, B. 1998. *Doing Grounded Theory - Issues and Discussions*, Sociology Press.
- GLASER, B. & STRAUSS, A. 1967. *The Discovery of Grounded Theory: Strategies for Qualitative Research*.
- GLASSHEIM, B. 2009. A Guide to Evidence-Based Practices for Individuals with Developmental Disabilities. Saginaw County Community Mental Health Authority.
- GLOVER, G. & EVISON, F. 2013. Hospital Admissions That Should Not Happen. Admissions for Ambulatory Care Sensitive Conditions for People with Learning Disabilities in England. IHAL.
- GOLDSMITH, L., SKIRTON, H. & WEBB, C. 2008. Informed consent to healthcare interventions in people with learning disabilities – an integrative review. *Journal of Advanced Nursing*, 64, 549-563.
- GONZALEZ, J., FISHER, L. & POLONSKY, W. 2011. Depression in diabetes: have we been missing something important. *Diabetes Care*, 34, 236 - 239.
- GOODMAN, C. M. 1987. The Delphi technique: a critique. *Journal of Advanced Nursing*, 12, 729-734.
- GOODRICH, J. & CORNWELL, J. 2008. Seeing the person in the patient: The point of care review paper. In: Rowling, E. (ed.) *The Point of Care*. Cavendish Square, London.
- GORDON, T. J. 2009. The Delphi Method. *Futures Research Methodology V3.0 ed.* <http://fpf.ueh.edu.vn/imgnews/04-Delphi.pdf>: The Millennium Project.
- GRAVESTOCK, S. 1994. Quality assurance for adults with mental retardation and mental health needs. In: Bouras, N. (ed.) *Mental Health in Mental Retardation: Recent advances and practices*.
- GRAY, R., ROFAIL, D., ALLEN, J. & NEWHEY, T. 2005. A survey of patient satisfaction with and subjective experiences of treatment with antipsychotic medication. *Journal of Advanced Nursing*, 52, 31-37.
- GRIFFITHS, C. & DOYLE, A. 2013. Review of Healthcare Interdisciplinary Research Conference, Trinity College Dublin, Themes and Speeches *Frontline*, Winter.

- GRIFFITHS, H. N. 2012. Antipsychotic prescribing in people with intellectual disabilities: a clinical audit. *Advances in Mental Health and Intellectual Disabilities*, 6, 215-222.
- HAGGER, M. & ORBELL, S. 2003. A meta-analytic review of the common-sense model of illness representations. *Psychology and Health* 18, 141-84.
- HAGGERTY, J., REID, R., FREEMAN, G., STARFIELD, B., ADAIR, C. & MCKENDRY, R. 2003. Continuity of care: a multidisciplinary review. *British Medical Journal*, 327, 1219-21.
- HALE, L. A., TRIP, H. T., WHITEHEAD, L. & CONDER, J. 2011. Self-Management Abilities of Diabetes in People With an Intellectual Disability Living in New Zealand. *Journal of Policy and Practice in Intellectual Disabilities*, 8, 223-230.
- HALL, I., HIGGINS, A., PARKES, C., HASSIOTIS, A. & SAMUELS, S. 2006. The development of a new integrated mental health service for people with learning disabilities. *British Journal of Learning Disabilities*, 34, 82-87.
- HANAFIN, S. 2004. Review of the Literature on the Delphi Technique. Dublin: National Children's Office.
- HANAFIN, S. & BROOKS, A. M. 2005. The Delphi Technique: A Methodology to Support the Development of a National Set of Child Well-being Indicators. Dublin: The National Children's Office.
- HANZEL, T. E. & KALACHNIK, J. E. 2006. Behavioural Side Effects of Benzodiazepine Medications in People with Mental Retardation. *In: DISABILITIES*, Office of the Ombudsman for Mental Health and Developmental Disabilities (ed.).
- HARKINS, V. 2008. A practical guide to integrated type 2 diabetes care. Health Services Executive, Dublin.
- HARNOIS, G. P. & SARACENO, B. 2007. Atlas. Global Resources for Persons with Intellectual Disabilities. *In: World Health Organisation* (ed.). Department of Mental Health and Substance Abuse.
- HASSIOTIS, A. & HALL, I. 2008. Behavioural and cognitive-behavioural interventions for outwardly-directed aggressive behaviour in people with learning disabilities. *Cochrane Database of Systematic Reviews 2008*, CD003406.
- HASSIOTIS, A., ROBOTHAM, D., CANAGASABEY, A., MARSTON, L., THOMAS, B. & KING, M. 2012. Brief report: impact of applied behaviour analysis (ABA) on carer burden and community participation in challenging behaviour: results from a randomised controlled trial. *Journal of Intellectual Disability Research* 56, 285-290.
- HASSON, F. & KEENEY, S. 2011. Enhancing rigour in the Delphi technique research. *Technological Forecasting and Social Change*, 78, 1695-1704.

- HASTINGS, R. P. & BROWN, T. 2000. Functional Assessment and Challenging Behaviors: Some Future Directions. *Research and Practice for Persons with Severe Disabilities*, 25, 229-240.
- HAW, C. & STUBBS, J. 2010a. Administration of medicines in food and drink: a study of older inpatients with severe mental illness. *International Psychogeriatrics*, 22, 409-16.
- HAW, C. & STUBBS, J. 2010b. Covert administration of medication to older adults: a review of the literature and published studies. *Journal of Psychiatric and Mental Health Nursing*, 17, 761-768.
- HEALTH FOUNDATION 2012. Overcoming challenges to improving quality.
- HEALTH RESEARCH BOARD. 2015. *National Intellectual Disability Database* [Online]. Available: <http://www.hrb.ie/health-information-in-house-research/disability/nidd/> [Accessed Jan 15 2015].
- HEALTHCARE COMMISSION 2007. Investigation into the Service for People with Learning Disabilities Provided by Sutton and Merton Primary Care Trust. London: Commission for Healthcare Audit and Inspection.
- HENRY, R. 2015a. Antipsychotic Dosage Ready Reckoner - Version 6. In: POMH-UK, C. (ed.) *Prescribing Observatory for Mental Health*.
- HENRY, R. 2015b. Guidelines for the use of High Dose Antipsychotics (HDAT). Southern Health NHS.
- HEPLER, C. & STRAND, L. 1990. Opportunities and responsibilities in pharmaceutical care. *American Journal of Hospital Pharmacy*, 47, 533-43.
- HERMANS, H. & EVENHUIS, H. M. 2012. Life events and their associations with depression and anxiety in older people with intellectual disabilities: Results of the HA-ID study. *Journal of Affective Disorders*, 138, 79-85.
- HESLAM, S. 2011. Health Issues for Adults with Down's Syndrome. *Learning Disability Practice*, 14, 26.
- HESLOP, P., BLAIR, P. S., FLEMING, P., HOGHTON, M., MARRIOTT, A. & RUSS, L. 2014a. The Confidential Inquiry into premature deaths of people with intellectual disabilities in the UK: a population-based study. *The Lancet*, 383, 889-895.
- HESLOP, P., FLEMING, P., HOGHTON, M., NEEDLEMAN, D., MALLETT, R. & MARRIOTT, A. 2014b. Premature deaths of people with learning disabilities – reflections on Department of Health progress report. *Working with Evidence about Learning Disabilities* [Online].

- HESLOP, P., FOLKES, L. & RODGERS, J. 2005. The Knowledge People with Learning Disabilities and their Carers have about Psychotropic Medication *Tizard Learning Disability Review*, 10.
- HESS, J., MATSON, J., NEAL, D., MAHAN, S., FODSTAD, J., BAMBURG, J. A. Y. & HOLLOWAY, J. 2010. A Comparison of Psychotropic Drug Side Effect Profiles in Adults Diagnosed With Intellectual Disabilities and Autism Spectrum Disorders. *Journal of Mental Health Research in Intellectual Disabilities*, 3, 85-96.
- HEYVAERT, M., MAES, B. & ONGHENA, P. 2010. A meta-analysis of intervention effects on challenging behaviour among persons with intellectual disabilities. *Journal of Intellectual Disability Research*, 54, 634-649.
- HIGASHI, T., SHEKELLE, P., ADAMS, J. L., KAMBERG, C., ROTH, C., SOLOMAN, D., REUBEN, D., CIANG, L., MACLEAN, C., CHANG, J., YOUNG, R., SALIBA, D. & WENGER, N. 2005. Quality of care is associated with survival in Vulnerable Older Patients. *Annals of Internal Medicine*, 143, 274-281.
- HILMER, S. N., MCLACHLAN, A. J. & LE COUTEUR, D. G. 2007. Clinical pharmacology in the geriatric patient. *Fundamental & Clinical Pharmacology*, 21, 217-230.
- HIQA 2009a. National Quality Standards for Residential Care Settings for Older People in Ireland. Cork: Health Information and Quality Authority.
- HIQA 2009b. National Quality Standards: Residential Services for People with Disabilities Cork: Health Information and Quality Authority.
- HIQA 2012. National Standards for Safer Better healthcare. Dublin: Health Information and Quality Authority.
- HIQA 2013a. Guidance for Designated Centres. Restrictive Procedures. *In: Health Information and Quality Authority (ed.)*. Cork.
- HIQA 2013b. National Standards for Residential Services for Children and Adults with Disabilities. Cork: Health Information and Quality Authority.
- HIQA 2013c. National Standards for Residential Services for Children and Adults with Disabilities, Health Information and Quality Authority.
- HIQA 2014. Guidance for health and social care providers. Principles of good practice in medication reconciliation. Cork: Health Information and Quality Authority.
- HIQA 2015. Guidance on Dementia Care for Designated Centres for Older People. Cork: Health Information and Quality Authority.
- HLS-EU CONSORTIUM 2012. The European Health Literacy Project (HLS-EU). Final Report. Executive Summary.

- HOGHTON, M. & RCLD GROUP 2013. A Step by Step Guide for GP Practices: Annual Health Checks for People with a Learning Disability. *In: Royal College of General Practitioners, (ed.)*.
- HOGHTON, M., TURNER, S. & MURPHY, K. 2011. Improving the Health and Wellbeing of People with Learning Disabilities: An Evidence Based Commissioning Guide for Emerging Clinical Commissioning Groups (draft). The Improving Health and Lives Learning Disabilities Observatory, Royal College of General Practitioners.
- HOLEY, E., FEELEY, J., DIXON, J. & WHITTAKER, V. 2007. An exploration of the use of simple statistics to measure consensus and stability in Delphi studies. *Bio Medical Central Medical Research Methodology*, 7, 52.
- HOLMAN, R. R., PAUL, S. K., BETHEL, M. A., MATTHEWS, D. R. & NEIL, H. A. W. 2008. 10-Year Follow-up of Intensive Glucose Control in Type 2 Diabetes. *New England Journal of Medicine*, 359, 1577-1589.
- HOM, C. L., TOUCHETTE, P., NGUYEN, V., FERNANDEZ, G., TOURNAY, A., PLON, L., HIMBER, P. & LOTT, I. T. 2015. The relationship between living arrangement and adherence to antiepileptic medications among individuals with developmental disabilities. *Journal of Intellectual Disability Research*, 59, 48-54.
- HOSMAN, C. & JANE-LOPIS, E. J. 2002. Political Challenges 2: Mental Health *In: International Union for Health Promotion and Education (ed.) The Evidence of Health Promotion Effectiveness: Shaping Public Health in a New Europe*. Paris: Jouve Composition & Impression.
- HOUSE OF COMMONS & HOUSE OF LORDS 2007. Joint Committee on Human Rights. Eighteenth Report. London: Parliament.
- HSCIC 2009. Measuring for Quality Improvement. Health and Social Care Information Centre, Department of Health, England.
- HSCIC 2013. A guide to confidentiality in health and social care: references. Treating confidential information with respect. Health and Social Care Information Centre, England.
- HSCIC 2014. Learning Disabilities Census Report, England - 30 September 2013, Further analysis. Leeds, West Yorkshire: Health and Social Care Information Centre.
- HSCIC 2015. Learning Disability Census Further Analysis Report England 30 September 2014 experimental statistics. Community and Mental Health Team.
- HSE 2012. National Healthcare Charter, You and Your Health Services.

- HSE 2013. Health Service National Service Plan 2014. Naas, Co Kildare, Health Service Executive.
- HSU, C. & SANDFORD, B. 2007. The Delphi Technique: Making Sense Of Consensus. *Practical Assessment, Research & Evaluation* [Online], 12.
- HUGHES, R. 2008. Nurses at the 'Sharp End' of Patient Care. *In: HUGHES, R. (ed.) An Evidence Based Handbook for Nurses*. Rockville,MD: Agency for Healthcare Research and Quality.
- HUGHES, R. G., MAREK, K. D. & ANTLE, L. 2008. Medication management of the community-dwelling older adult. *In: Patient Safety and quality: An Evidence Base Handbook for Nurses*.
- HULBERT-WILLIAMS, L., HASTINGS, R., OWEN, D. M., BURNS, L., DAY, J., MULLIGAN, J. & NOONE, S. J. 2014. Exposure to life events as a risk factor for psychological problems in adults with intellectual disabilities: a longitudinal design. *Journal of Intellectual Disability Research*, 58, 48-60.
- HUNEKE, N. T. M., GUPTA, R., HALDER, N. & CHAUDHRY, N. 2012. Difficult decisions: Are intellectually disabled patients given enough information to consent to medical treatment? *Journal of Intellectual Disabilities*, 16, 265-274.
- HUNT, P. 2005. Economic, Social and Cultural Rights. Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Commission on Human Rights.
- HUNT, P. 2006. Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
- HUNT, P. & MCNAUGHTON 2006. Impact Assessments, Poverty and Human Rights. A Case Study Using The Right to the Highest Attainable Standard of Health. Paris, France: Human Rights Impact Resource Centre.
- HURTADO, B., JONES, L. & BURNISTON, F. 2014. Is Easy Read information really easier to read? *Journal of Intellectual Disability Research*, 58, 822-829.
- HUTCHINGS, A. & RAINE, R. 2006. A Systematic Review of Factors Affecting the Judgments Produced by Formal Consensus Development Methods in Health Care. *Journal of Health Services Research & Policy*, 11, 172-179.
- IASSID. 2002. *Health Guidelines for Adults with an Intellectual Disability* [Online]. St George's, University of London.
- IDZINGA, J. C., DE JONG, A. L. & VAN DEN BEMT, P. M. L. A. 2009. The effect of an intervention aimed at reducing errors when administering medication through enteral feeding tubes in an institution for individuals with intellectual disability. *Journal of Intellectual Disability Research*, 53, 932-938.

- IHAL & NDTI 2013. The Health Equalities Framework (HEF). An outcomes framework based on the determinants of health inequalities. Improving Health and Lives, National Development Team for Inclusion.
- IHAL, RCGP & RCPSYCH 2012. Improving the Health and Wellbeing of People with Learning Disabilities: An Evidence-Based Commissioning Guide for Clinical Commissioning Groups (CCGs) The Improving Health and Lives Learning Disabilities Observatory.
- IHRC. 2014. *IHRC publishes observations on the Assisted Decision-Making (Capacity) Bill 2013* [Online]. Irish Human Rights Commission. [Accessed Oct 26 2014].
- IMSN 2014. Best Practice Guidelines and Template for a National Medication Incident Report Form. Irish Medication Safety Network, Patient Safety First.
- IRAZABAL, M., MARSA, F., GARCIA, P., GUTIERREZ-RECACHA, A., MARTORELL, L. & SALVADOR-CARULLA, L. 2012. Family burden related to clinical and functional variables of people with intellectual disability with or without a mental disorder. *Research in Developmental Disabilities*, 33, 796-803.
- IRISH HUMAN RIGHTS COMMISSION 2010. Enquiry Report on the Human Rights Issues Arising from the Operation of a Residential and Day Care Centre for Persons with a Severe or Profound Intellectual Disability. Dublin.
- JACOBS, J. 1996. *Essential Assessment Criteria for Physical Education Teacher Education Programs: A Delphi Study*. Unpublished doctoral dissertation, W Virginia University, Morgantown.
- JACQUES, R. 2003. Family Values. *Psychiatry*, 2, 39-42.
- JANICKI, M. 2000. IASSID/WHO Healthy Ageing reports: an update from the IASSID Ageing Special Interest Research Group, *Journal of Intellectual Disability Research*, 44, 185-188.
- JOHNSON, T. J. & WISLAR, J. S. 2012. Response Rates and Nonresponse Errors in Surveys. *The Journal of the American Medical Association*, 307, 1805-6.
- JOINT COMMISSION 2008. Behaviours that undermine a culture of safety. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_40. Washington, DC.
- JOINT COMMISSION 2009. Hospital National Patient Safety Goals 2009. In: Joint Commission (ed.). Washington, DC.
- JONES, J. & HUNTER, D. 1995a. Consensus methods for medical and health services research. *British Medical Journal*, 311, 376 - 380.
- JONES, J. & HUNTER, D. 1995b. Qualitative Research: Consensus methods for medical and health services research. *British Medical Journal*, 311, 376-380.

- JONES, K. 2004. Mission Drift in Qualitative Research, or Moving Toward a Systematic Review of Qualitative Studies, Moving Back to a More Systematic Narrative Review *The Qualitative Report*, 9, 95-112.
- JOPP, D. A. & KEYS, C. B. 2001. Diagnostic Overshadowing Reviewed and Reconsidered. *American Journal on Mental Retardation*, 106, 416-433.
- JORGENSEN, D., PARSONS, M., REID, M. G., WEIDENBOHM, K., PARSONS, J. & JACOBS, S. 2009. The providers' profile of the disability support workforce in New Zealand. *Health & Social Care in the Community*, 17, 396-405.
- JOYCE, T., DITCHFIELD, H. & HARRIS, P. 2001. Challenging behaviour in community services. *Journal of Intellectual Disability Research*, 45, 130-138.
- KALACHNIK, J. E., HANZEL, T. E., SEVENICH, R. & HARDER, S. R. 2002. Benzodiazepine Behavioral Side Effects: Review and Implications for Individuals With Mental Retardation. *American Journal on Mental Retardation*, 107, 376-410.
- KEENEY, S., HASSON, F. & MCKENNA, H. 2011. *The Delphi Technique in Nursing and Health Research*, Blackwell Publishing Ltd.
- KEENEY, S., HASSON, F. & MCKENNA, H. P. 2001. A critical review of the Delphi technique as a research methodology for nursing. *International Journal of Nursing Studies*, 38, 195-200.
- KELLEY, E. T., ARISPE, I. & HOLMES, J. 2006. Beyond the initial indicators: lessons from the OECD Health Care Quality Indicators Project and the US National Healthcare Quality Report. *International Journal for Quality in Health Care*, 18, 45-51.
- KELLY, C. 2012. Annual Report of the National Intellectual Disability Database Committee 2011. Dublin.
- KELLY, C., KELLY, F. & CRAIG, S. 2009. Trends in demand for services among those aged 50 years and over with an intellectual disability, 2003-2007. *HRB Trends Series*. Dublin: Health Research Board.
- KELLY, C. & O'DONOHUE, A. 2014. Annual Report of the National Intellectual Disability Database Committee 2013. In: HEALTH RESEARCH BOARD (ed.) *HRB Statistics Series*,. Dublin.
- KELLY, F., KELLY, C. & ODONOGHUE, A. 2013. Annual Report of the National Intellectual Disability Database Committee 2012. Dublin: Health Research Board.
- KELLY, J. 2011. Diabetes and Me: Learning disabilities and diabetes. *Journal of Diabetes Nursing*, 15, 308-312.

- KELLY, J., D'CRUZ, G. & WRIGHT, D. 2010. Patients with dysphagia: experiences of taking medication. *Journal of Advanced Nursing*, 66, 82-91.
- KELLY, J., WRIGHT, D. & WOOD, J. 2011. Medicine administration errors in patients with dysphagia in secondary care: a multi-centre observational study. *Journal of Advanced Nursing*, 67, 2615-2627.
- KELLY, P. 2014. Call for policy makers to 'understand pharmacy'. *Irish Pharmacist*, May.
- KENNEDY, A. & BIDDLE, M. 2014. Practical Strategies for Pharmacist Integration with Primary Care. A workbook of things we wish we knew before we started. Burlington, Vermont: The University of Vermont.
- KERINS, G., PETROVIC, K., BRUDER, M. & GRUMAN, C. 2008. Medical conditions and medication use in adults with Down syndrome: A descriptive analysis. *Down Syndrome Research and Practice* 12, 141-147.
- KERR, M. 2004. Improving the general health of people with learning disabilities. *Advances in Psychiatric Treatment*, 10, 200-206.
- KERR, M., FELCE, D. & FELCE, J. 2005. Equal treatment: Closing the Gap. *Equal Treatment investigation publications*. Stratford upon Avon: Disability Rights Commission.
- KEYS, M. 2007. 'Capacity - whose decision is it anyway?' *Law & Mental Health Conference*. Law Faculty, NUI Galway.
- KEYS, M. 2008. *New Pharmacy Legislation Must Protect the Vulnerable* [Online]. [Accessed Oct 2 2011].
- KILROY, D. & DRISCOLL, P. 2006. Determination of required anatomical knowledge for clinical practice in emergency medicine: national curriculum planning using a modified Delphi technique. *Emergency Medicine Journal* 23, 693-696.
- KIND, A., ANDERSON, P., HIND, J., ROBBINS, J. & SMITH, M. 2011. Omission of Dysphagia Therapies in Hospital Discharge Communications. *Dysphagia*, 26, 49-61.
- KING, J. & ANDERSON, S. 2004. Therapeutic implications of pharmacotherapy: Current trends and ethical issues. *Journal of Counseling & Development*, 82, 329-336.
- KIRKEVOLD, O. & ENGEDAL, K. 2005. Concealment of drugs in food and beverages in nursing homes: cross sectional study. *British Medical Journal*, 330, 20.
- KISSANE, S. & GUERIN, S. 2009. Meeting the Challenge of Challenging Behaviour *In: National Disability Authority* (ed.).

- KNAPP, K., PAY, M., LAW, A., AKAMOTO, M. & CHANG, P. 2005a. *The Role of Community Pharmacies in Diabetes Care: Eight Case Studies* [Online]. California Healthcare Foundation.
- KNAPP, M., COMAS-HERRERA, A., ASTIN, J., BEECHAM, J. & PENDARIES, C. 2005b. Intellectual disability, challenging behaviour and cost in care accommodation: what are the links? *LSE Research Articles Online*.
- KNAPP, M., COMAS-HERRERA, A., ASTIN, J., BEECHAM, J. & PENDARIES, C. 2005c. Intellectual disability, challenging behaviour and cost in care accommodation: what are the links? *Health & Social Care in the Community*, 13, 297-306.
- KNIGHT, E. & AVORN, J. 2001a. Quality Indicators for Appropriate Medication Use in Vulnerable Elders. Santa Monica, CA: RAND Corporation.
- KNIGHT, E. & AVORN, J. 2001b. Quality Indicators for Appropriate Medication Use in Vulnerable Elders. *Annals of Internal Medicine*, 135, 703-710., 135, 703-710.
- KOTTER, T., BLOZIK, E. & SCHERER, M. 2012. Methods for the guideline-based development of quality indicators - a systematic review. *Implementation Science*, 7, 21.
- KOVACH, C. R., WEISSMAN, D. E., GRIFFIE, J., MATSON, S. & MUCHKA 1999. Assessment and Treatment of Discomfort for People with Late-Stage Dementia. *Journal of pain and symptom management*, 18, 412-419.
- KRAHN, G. (ed.) 2003. *Changing concepts in health, wellness and disability*. Portland, Or.: Oregon Health & Sciences University.
- KREUGER, J. & HERMANSEN-KOBULNICKY, C. 2011. Patient perspective of medication information desired and barriers to asking pharmacists questions. *Journal of the American Pharmacists Association*, 51, 510-519.
- KROGER, E., TOURIGNY, A., MORIN, D., COTE, L., KERGOAT, M.-J., LEBEL, P., ROBICHAUD, L., IMBEAULT, S., PROULX, S. & BENOUNISSA, Z. 2007. Selecting process quality indicators for the integrated care of vulnerable older adults affected by cognitive impairment or dementia. *Bio Med Central Health Services Research*, 7, 195.
- LAMBERT, M., CONUS, P., EIDE, P., MASS, R., KAROW, A., MORITZ, S., GOLKS, D. & NABER, D. 2004. Impact of present and past antipsychotic side effects on attitude toward typical antipsychotic treatment and adherence. *European Psychiatry*, 19, 415-422.
- LAMBRECHTS, G., PETRY, K. & MAES, B. 2008. Staff Variables that Influence Responses to Challenging Behaviour of Clients with an Intellectual Disability: A Review. *Education and Training in Developmental Disabilities*, 43, 454-473.

- LANCET, T. 2008. The right to health: from rhetoric to reality. *The Lancet*, 372, 2001.
- LAVIN, K. E., MCGUIRE, B. E. & HOGAN, M. J. 2006. Age at death of people with an intellectual disability in Ireland. *Journal of Intellectual Disabilities*, 10, 155-164.
- LAWRENCE, M. & OLESEN, F. 1997. Indicators of quality in health care. *European Journal of General Practice*, 1, 103-108.
- LEADING EDGE GROUP 2012. Adding Value to Irish Community Pharmacy. Preliminary Report. Cobh, Co Cork.
- LENNOX, N., BAIN, C., REY-CONDE, T., PURDIE, D., BUSH, R. & PANDEYA, N. 2007. Effects of a comprehensive health assessment programme for Australian adults with intellectual disability: a cluster randomized trial. *International Journal of Epidemiology*, 36, 136-146.
- LENNOX, N., DIGGENS, J. & UGONI, A. 1997. The general practice care of people with intellectual disability: barriers and solutions. *Journal of Intellectual Disability Research*, 41, 380 - 390.
- LENNOX, N. & EDWARDS, N. 2001. Lessons from the Labryinth. *Views of Residential Care Officers on Barriers to Comprehensive Health Care for Adults with an Intellectual Disability*. Queensland, Australia: Developmental Disability Unit, School of Population Health, The University of Queensland.
- LEVY, H. B., MARCUS, E.-L. & CHRISTEN, C. 2010. Beyond the Beers Criteria: A Comparative Overview of Explicit Criteria. *The Annals of Pharmacotherapy*, 44, 1968-1975.
- LEWIS-FERNÁNDEZ, R., DAS, A. K., ALFONSO, C., WEISSMAN, M. M. & OLFSON, M. 2005. Depression in US Hispanics: Diagnostic and Management Considerations in Family Practice. *The Journal of the American Board of Family Practice*, 18, 282-296.
- LEWIS, C. 2009. Interventions to reduce emergency hospital admissions for diabetes. Liverpool Public Health Observatory.
- LINDSEY, M. 2002. Comprehensive health care services for people with learning disabilities. *Advances in Psychiatric Treatment*, 8, 138-147.
- LINEHAN, C., O'DOHERTY, S., TALLOW-GOLDEN, M., CRAIG, S., KERR, M., LYNCH, C., MCCONKEY, R. & STAINES, A. 2014. Moving Ahead. Mapping the National Disability Policy Landscape. Dublin: School of Social Work & Social Policy, Trinity College Dublin.
- LINSTONE, H. & TUROFF, M. 1975. *The Delphi Method Techniques and Applications*, Massachusetts, Addison-Wesley.
- LINSTONE, H. A. 1978. The Delphi technique. In: Fowles, J. (ed.) *Handbook of futures research* Westport, CT: Greenwood Press.

- LOHR, K. 1990. *Medicare: A Strategy for Quality Assurance, Volume I*, Washington, DC, The National Academies Press.
- LTCPLC 2008. The Medication Use Process. *In: Long Term Care Professional Leadership Council* (ed.). Maryland.
- MABEN, J. 2008. The art of caring: Invisible and subordinated?: A response to Juliet Corbin: 'Is caring a lost art in nursing?' *International Journal of Nursing Studies*, 45, 335-338.
- MACCANN, G. 2008. The Effects of Advocacy on the Lives of Persons with Intellectual Disabilities. *International Association for the Scientific Study Of Intellectual Disability (IASSID) World Congress*. Cape Town, South Africa.
- MACKENBACH, J., STIRBU, I. & ROSKAM, A. 2008. European Union Working Group on Socioeconomic Inequalities in Health. Socioeconomic inequalities in health in 22 European countries *New England Journal of Medicine*, 358, 2468-2481.
- MADDEN, D. 2008. Building a Culture of Patient Safety Dublin: Department of Health & Children.
- MAIDMENT, I., BROWN, P. & CALNAN, M. 2011. An exploratory study of the role of trust in medication management within mental health services. *International Journal of Clinical Pharmacy*, 33, 614-620.
- MAINZ, J. 2003. Defining and classifying clinical indicators for quality improvement. *International Journal for Quality in Health Care*, 15, 523-530.
- MANSELL, J. 2007. Services for people with learning disability and challenging behaviour or mental health needs. Mansell Report - revised edition 2007. London: Department of Health.
- MANSELL, J. & BEADLE-BROWN, J. 2004. Grouping People with Learning Disabilities and Challenging Behaviour in Residential Care. *Tizard Learning Disability Review*, 9, 4-10.
- MANSOOR, L. & DOWSE, R. 2003. 'Effect of pictograms on readability of patient information materials'. *Ann Pharmacother*, 37, 1003-1009.
- MAREK, K. D. & ANTLE, L. 2008. Chapter 18 Medication Management of the Community Dwelling Older Adult. *In: HUGHES, R. G. (ed.) Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville.
- MARSHALL, T. 2004. Audit of the use of psychotropic medication for challenging behaviour in a community learning disability service. *Psychiatric Bulletin*, 28, 447-450.
- MARTORELL, A. & TSAKANIKOS, E. 2008. Traumatic experiences and life events in people with intellectual disability. *Current Opinion in Psychiatry*, 21, 445-448.

- MATSON, J. & WILKINS, J. 2008. Antipsychotic drugs for aggression in intellectual disability. *The Lancet*, 371, 9-10.
- MATSON, J. L., BIELECKI, J., MAYVILLE, S. B. & MATSON, M. L. 2003. Psychopharmacology research for individuals with mental retardation: methodological issues and suggestions. *Research in Developmental Disabilities*, 24, 149-157.
- MATSON, J. L. & BOISJOLI, J. A. 2009. Restraint procedures and challenging behaviours in Intellectual Disability: An Analysis of Causative Factors. *Journal of Applied Research in Intellectual Disabilities* 22, 111-117.
- MATSON, J. L. & NEAL, D. 2009. Psychotropic medication use for challenging behaviors in persons with intellectual disabilities: An overview. *Research in Developmental Disabilities*, 30, 572-586.
- MATSON, J. L., SMIROLDO, B. B., HAMILTON, M. & AL., E. 1997. Do anxiety disorders exist in persons with severe and profound retardation? *Research in Developmental Disabilities*, 18, 39-44.
- MATTHEWS, T. & WESTON, S. N. 2003. Experience of thioridazine use before and after the Committee on Safety of Medicines warning. *Psychiatric Bulletin*, 27, 87-89.
- MATTKE, S., EPSTEIN, A. M. & LEATHERMAN, S. 2006. The OECD Health Care Quality Indicators Project: history and background. *International Journal for Quality in Health Care*, 18, 1-4.
- MCCALLION, P. & MCCARRON, M. 2004. Aging and Intellectual Disabilities: A Review of Recent Literature, *Current Opinion in Psychiatry*, 17, 349-352.
- MCCARRON, M. 2014. *New Longitudinal Report Shows the Challenging Reality of Ageing with an Intellectual Disability in Ireland. Report showed increasing levels of dementia, a lack of social connections, and serious communication and mobility challenges.* [Online]. TCD.
- MCCARRON, M., MCCALLION, P., CARROLL, R., BURKE, E., CLEARY, E., MCCAUSLAND, D., MCGLINCHY, E., O'DONOVAN, M., MULRYAN, N. & SHIVERS, C. 2014a. Advancing Years, Different Challenges: Wave 2 IDS-TILDA. School of Nursing & Midwifery, TCD.
- MCCARRON, M., O'DWYER, M., BURKE, E., MCGLINCHEY, E. & MCCALLION, P. 2014b. Epidemiology of Epilepsy in Older Adults With an Intellectual Disability in Ireland: Associations and Service Implications. *American Journal on Intellectual and Developmental Disabilities*, 119, 253-260.
- MCCARRON, M., SWINBURN, J. & ANDREWS, V. 2009. An Intellectual Disability Supplement to the Irish Longitudinal Study on Ageing.

- MCCARRON, M., SWINBURNE, J., BURKE, E., MCGLINCHEY, E., MULRYAN, N., ANDREWS, V., FORAN, S. & MCCALLION, P. 2011a. Growing Older with an Intellectual Disability in Ireland 2011: First Results from The Intellectual Disability Supplement of The Irish Longitudinal Study on Ageing. Dublin: School of Nursing & Midwifery, Trinity College Dublin.
- MCCARRON, M., SWINBURNE, J., BURKE, E., MCGLINCHEY, E., MULRYAN, N., ANDREWS, V., FORAN, S. & MCCALLION, P. 2011b. Growing Older with an Intellectual Disability in Ireland 2011: First Results from The Intellectual Disability Supplement of The Irish Longitudinal Study on Ageing. Dublin: School of Nursing & Midwifery, Trinity College Dublin.
- MCCONKEY, R., KELLY, F., MANNAN, H. & CRAIG, S. 2011. Moving from Family Care to Residential and Supported Accommodation: National, Longitudinal Study of People with Intellectual Disabilities. *AJIDD*, 116, 305-314.
- MCDONALD, K. E., KIDNEY, C. A. & PATKA, M. 2013. 'You need to let your voice be heard': research participants' views on research. *Journal of Intellectual Disability Research*, 57, 216-225.
- MCGILLIVRAY, J. & MCCABE, M. 2005. The Relationship Between Residence and the Pharmacological Management of Challenging Behavior in Individuals with Intellectual Disability. *Journal of Developmental and Physical Disabilities*, 17, 311-325.
- MCGILLIVRAY, J. A. & MCCABE, M. P. 2006. Emerging Trends in the Use of Drugs to Manage the Challenging Behaviour of People with Intellectual Disability. *Journal of Applied Research in Intellectual Disabilities*, 19, 163-172.
- MCGIVNEY, M., MEYER, S., DUNCAN-HEWITT, W., HALL, D., GOODE, J. & SMITH, R. 2007. Medication Therapy Management: Its Relationship to Patient Counseling, Disease Management, and Pharmaceutical Care. *Journal of the American Pharmacists Association*, 47, 620-8.
- MCGLYNN, E. & ASCH, S. 1998. Developing a clinical performance measure. *American Journal of Preventive Medicine*, 14, 14 - 21.
- MCGUIRE, B. E., DALY, P. & SMYTH, F. 2010. Chronic pain in people with an intellectual disability: under-recognised and under-treated? *Journal of Intellectual Disability Research*, 54, 240-245.
- MCKELVEY, V., MORGAIN, K. & THOMSON, W. 2014. Adults with intellectual disability: a mixed-methods investigation of their experiences of dental treatment under general anaesthetic. *The New Zealand Dental Journal*, 110, 58-64.

- MCKENNA, H., BRADLEY, M. & KEENEY, S. 2000. Primary Care Nursing: A Study Exploring Key Issues For Future Developments. Ulster: University of Ulster.
- MCLOUGHLIN, V., MILLAR, J., MATTKE, S., FRANCA, M., JONSSON, P. M., SOMEKH, D. & BATES, D. 2006. Selecting indicators for patient safety at the health system level in OECD countries. *International Journal for Quality in Health Care*, 18, 14-20.
- MCPHEETERS, M., KRIPALANI, S., PETERSON, N., IDOWU, R., JEROME, R., POTTER, S. & ANDREWS, J. 2012. Quality Improvement Interventions to Address Health Disparities. Executive Summary. *In: Agency for Healthcare Research and Quality*.
- MENCAP 2004. Treat me right - better healthcare for people with a learning disability. London: Royal Mencap Society.
- MENCAP 2007. Death by Indifference. London: Royal Mencap Society.
- MENCAP. 2010. *Doctors say patients with a learning disability receive poorer care* [Online]. [Accessed July 12 2014].
- MENOLASCINO, F. J. 1977. *Challenges in Mental Retardation. Progressive ideology and services.*, New York, Human Services Press.
- MENTAL HEALTH COMMISSION 2009. Code of Practice Guidance for Persons working in Mental Health Services with People with Intellectual Disabilities. Waterloo Road, Dublin 4: Mental Health Commission.
- MENTAL HEALTH SPECIAL INTEREST GROUP 2001. Mental Health & Intellectual Disabilities. *In: IASSID (ed.) Addressing the Mental Health Needs of People with Intellectual Disabilities*. WHO.
- MENTAL WELFARE COMMISSION FOR SCOTLAND 2006. Covert Medication. Legal and Practical Guidance. Edinburgh.
- MENTAL WELFARE COMMISSION FOR SCOTLAND 2014. Visit Report, Dignity and Respect: dementia continuing care visits.
- MICHAEL, J. & RICHARDSON, A. 2008. Healthcare for All. The Independent Inquiry into Access to Healthcare for People with Learning Disabilities. *Tizard Learning Disability Review*, 13, 28-34.
- MILLAR, G. 2001. 'The development of indicators for sustainable tourism: results of a Delphi survey of tourism researchers'. *Tourism Management*, 22, 351-362.
- MILLER, L. 2006. Determining what could/should be. The Delphi technique and its application. *Mid-Western Educational Research Association*. Columbus, Ohio.
- MINISTRY OF HEALTH NZ 2011. Health Indicators for New Zealanders with Intellectual Disability.

- MITCHELL, A. J. & SELMES, T. 2007. Why don't patients take their medicine? Reasons and solutions in psychiatry. *Advances in Psychiatric Treatment*, 13, 336-346.
- MITCHELL, B., ARMOUR, C., LEE, M., SONG, Y. J., STEWART, K., PETERSON, G., HUGHES, J., SMITH, L. & KRASS, I. 2011. Diabetes Medication Assistance Service: The pharmacist's role in supporting patient self-management of type 2 diabetes (T2DM) in Australia. *Patient education and counseling*, 83, 288-294.
- MIZEN, L. A., MACFIE, M., FINDLAY, L., COOPER, S.-A. & MELVILLE, C. 2012. Clinical guidelines contribute to the health inequities experienced by individuals with intellectual disabilities. *Implementation Science*, 7, 42.
- MONTORI, V. & GUYATT, G. 1992. Progress in Evidence-Based Medicine. *The Journal of the American Medical Association*, 268, 2420-2425.
- MORAN, J., RAFII, M., KELLER, S., SUNGH, B. & JANICKI, M. 2013. The National Task Group on Intellectual Disabilities and Dementia Practices Consensus Recommendations for the Evaluation and Management of Dementia in Adults With Intellectual Disabilities. Mayo Clinic.
- MOTT, D., PEDERSON, C., DOUCETTE, W., GAITHER, C. & SCHOMMER, J. 2001. A National Survey of U.S. Pharmacists in 2000: Assessing Nonresponse Bias of a Survey Methodology. *The American Association of Pharmaceutical Scientists Journal*, 3.
- MOTT, S. & POOLE, J. 2005. Physical and chemical restraints in acute care: their potential impact on the rehabilitation of older people. *International Journal of Nursing Practice*, 11, 95-101.
- MURPHY, M., BLACK, N., LAMPING, D., MCKEE, C., SANDERSON, C., ASKHAM, J. & MARTEAU, T. 1998a. Consensus development methods, and their use in clinical guideline development. *Health Technology Assessment*, 2, i - 88.
- MURPHY, M., BLACK, N., LAMPING, D., MCKEE, C., SANDERSON, C., ASKHAM, J. & MARTEAU, T. 1998b. Consensus development methods, and their use in clinical guideline development. *Health Technology Assessment*, 2, i - iv, 1-88.
- MURRAY, C. J. L. 2007. Towards good practice for health statistics: lessons from the Millennium Development Goal Health Indicators. *The Lancet*, 369, 862-873.
- NAIR, K., DOLOVICH, L., CASSELS, A., MCCORMACK, J., LEVINE, M., GRAY, J., MANN, K. & BURNS, S. 2002. What patients want to know about their medications. Focus group study of patient and clinician perspectives. *Canadian Family Physician*, 48.
- NATIONAL ACADEMY ON AN AGING SOCIETY. *Fact Sheet: Low Health Literacy Skills Increase Annual Health Care Expenditures by \$73 Billion* [Online].

- NATIONAL GATEWAY TO SELF DETERMINATION. 2012. *What is Self-Determination?* [Online]. Kansas City,.
- NATIONAL NETWORK OF LIBRARIES OF MEDICINE. 2014. *Health Literacy* [Online]. Available: <http://nnlm.gov/outreach/consumer/hlthlit.html> [Accessed Jan 15 2015].
- NATIONAL PRESCRIBING CENTER 2008. Dispensing with Repeats. A practical guide to repeat dispensing. 2nd edition.
- NDA. 2003. *Review of Access to Mental Health Services for People with Intellectual Disabilities* [Online]. Dublin: National Disability Authority. [Accessed 18.4 2015].
- NDA 2011a. Guidelines on Person Centred Planning in the Provision of Services for People with Disabilities in Ireland. National Disability Authority.
- NDA 2011b. The Introduction of Individual Budgets as a Resource Allocation System for Disability Services in Ireland. A Contemporary Developments in Disability Services Paper Dublin: National Disability Authority.
- NDTI, DH & NETWORK, M. H. 2013. Green Light Toolkit 2013. A guide to auditing and improving your mental health services so that it is effective in supporting people with autism and people with learning disabilities. *In*: National Development Team for Inclusion, Department of Health, Mental Health Network, NHS CONFEDERATION, (ed.).
- NELSON, C. 2012. The Leeds Health and Social Care Transformation Programme: Clinical Values in Prescribing – Cross Sector Project.
- NFVB 2005. Guidelines for Researchers when Interviewing People with an Intellectual Disability. National Federation of Voluntary Bodies.
- NFVB. 2008. *Basic Ethical Principles in Conducting Research* [Online]. National Federation of Voluntary Bodies [Accessed March 22 2013].
- NFVB 2014. National Federation Newsletter Winter 2014. *In*: National Federation of Voluntary Bodies (ed.). Galway, Ireland.
- NHS. 2013. *Transforming Patient Experience* [Online]. [Accessed March 17 2013].
- NHS FIFE. 2015. *Clinical Pharmacy* [Online]. Dunfermline. [Accessed May 10 2015].
- NHS WALES. 2015. *Pharmacy staff become dementia 'champions' to support vulnerable patients* [Online].
- NICE 2014. Draft Medicines Optimisation Guidelines. Medicines and Prescribing Centre.
- NICE 2015a. *Anticipated guidelines learning disabilities* [Online]. qualitystandards@nice.org.uk: National Institute for Health and Care Excellence. [Accessed April 24 2015].

- NICE 2015b. Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges. London: National Institute for Health and Care Excellence.
- NIGAM, R., MACKINNON, N., U, D., HARTNELL, N., LEVY, A., GURNHAM, M. & NGUYEN, T. 2008. Development of Canadian Safety Indicators for Medication Use. *Healthcare Quarterly*, 11, 47-53.
- NISHTALA, P. S., MCLACHLAN, A. J., BELL, J. S. & CHEN, T. F. 2008. Psychotropic prescribing in long-term care facilities: Impact of medication reviews and educational interventions. *American Journal of Geriatric Psychiatry*, 16, 621-632.
- NOONAN WALSH, P. 2011. ETHICS: a Public Private Partnership, *Frontline*, 82, 28.
- NOONAN WALSH, P. & MCCONKEY, R. 2009. Inclusive Health and People with Intellectual Disabilities. In: HODAPP, R. (ed.) *International Review of Research in Mental Retardation*.
- NORTHWAY, R. 2011. *Equality and Equity of Access to Healthcare for People with Intellectual Disabilities* [Online]. St George's University of London. Available: <http://www.intellectualdisability.info/>.
- NØTTESTAD, J. A. & LINAKER, O. M. 2003. Psychotropic drug use among people with intellectual disability before and after deinstitutionalization. *Journal of Intellectual Disability Research*, 47, 464-471.
- NPSA 2004a. Listening to people with learning difficulties and family carers talk about patient safety. www.npsa.nhs.uk: National Patient Safety Agency England.
- NPSA 2004b. Safeguarding people with learning disabilities within the NHS: an agenda for the National Patient Safety Agency. National Patient Safety Agency.
- NPSA 2004c. Understanding the patient safety issues for people with learning disabilities. www.npsa.nhs.uk: National Patient Safety Agency England.
- NPSA 2007. Guide to levels of negative health consequences from dysphagia.
- NPSA 2009. Safety in Doses. Improving the use of medicines in the NHS. National Patient Safety.
- NUFFIELD TRUST 2014. Now more than ever. Why pharmacy needs to act. Cavendish St. London.
- NUTBEAM, D. 2000. Health literacy as a public health goal: A challenge for contemporary health education and communication strategies into the 21st century. *Health Promotion International*, 15, 259–267. *Health Promotion International*, 15, 259-276.

- O'BRIEN, G. 2003. The classification of problem behaviour in Diagnostic Criteria for Psychiatric Disorders for Use with Adults with Learning Disabilities/Mental Retardation (DC-LD). *Journal of Intellectual Disability Research*, 47, 32-37.
- O'DWYER, M., PEKLAR, J., MAIDMENT, I., MCCALLION, P., MCCARRON, M. & HENMAN, M. 2014. Prevalence and factors associated with high anticholinergic burden among an Ageing Population with Intellectual Disability in Ireland. *Journal of Applied Research in Intellectual Disabilities*, 27, 325.
- O'MAHONY, D. & GALLAGHER, P. F. 2008. Inappropriate prescribing in the older population: need for new criteria. *Age and Ageing*, 37, 138-141.
- O BRIEN, G. 2003. Behavioural Phenotypes in Adulthood. *Psychiatry*, 2.
- O HARA, D. 2012. Self Determination and Health. *National Gateway to Self Determination*. Kansas City.
- O HARA, J., MCCARTHY, J. & BOURAS, N. 2010. *Intellectual disability and ill health*, Cambridge University Press.
- O REILLY, E. 2007. Human Rights and the Ombudsman. *Biennial Conference of the British and Irish Ombudsman Association*. University of Warwick, England
- O REILLY, E. 2009a. Be the Change You Want to See: - A role for Advocacy. *National Conference - A Place for Independent Advocacy*. Mayo.
- O REILLY, E. 2009b. 'Hiding in plain sight - The social justice demands of today' (30.06.2009). *Sisters of Charity Conference*. Dublin Castle.
- O REILLY, E. 2009c. The Role of the Ombudsman in an Economic Downturn (25.11.2009). *40th Anniversary of the Northern Ireland Ombudsman's Office*.
- O REILLY, E. 2010. Launch of Irish Human Rights Law Review (20.05.2010). Address by Ms. Emily O'Reilly *Irish Human Rights Law Review Launch*. Morrison Hotel, Ormond Quay, Dublin 1
- O'DWYER, M., MEŠTROVIĆ, A. & HENMAN, M. 2015. Pharmacists' medicines-related interventions for people with intellectual disabilities: a narrative review. *International Journal of Clinical Pharmacy*, 1-13.
- OECD. 2015. *Health Care Quality Indicators-Mental Health Care* [Online]. Directorate for Employment, Labour and Social Affairs. Available: <http://www.oecd.org/health/hcqi> [Accessed May 20 2015].
- OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION 2010. National action plan to improve health literacy. Washington, DC: Department of Health and Human Services.
- OFFICE OF THE HIGH COMMISSIONER FOR HUMAN RIGHTS. 2012. *Training Package on the Convention on the Rights of Persons with Disabilities. What is disability?* [Online]. [Accessed Jan 14 2015].

- OGLESBY, A. 2013. Clinical Adverse Events Notified to the State Claims Agency under the terms of the Clinical Indemnity Scheme. Incidents occurring between 01/01/2012 and 31/12/2012 – Final Report. State Claims Agency, Clinical Indemnity Scheme, NTMA.
- OLIVER, D. 2013. *Let's hear it for allied health professionals* [Online]. The King's Fund.
- OSBORN, C., PAASCHE-ORLOW, M., COOPER BAILEY, S. & WOLF, M. 2011. The Mechanisms Linking Health Literacy to Behavior and Health Status. *American Journal of Health Behavior*, 35.
- PAASCHE-ORLOW, M. K. & WOLF, M. S. 2007. The causal pathways linking health literacy to health outcomes. *American Journal of Health Behavior*, 31, 19-26.
- PARKES, C., SAMUELS, S., HASSIOTIS, A., LYNGGAARD, H. & HALL, I. 2007. Incorporating the views of service users in the development of an integrated psychiatric service for people with learning disabilities. *British Journal of Learning Disabilities*, 35, 23-29.
- PATON, C., FLYNN, A., SHINGLETON-SMITH, A., MCINTYRE, S., BHAUMIK, S., RASMUSSEN, J., HARDY, S. & BARNES, T. 2011. Nature and quality of antipsychotic prescribing practice in UK psychiatry of intellectual disability services. *Journal of Intellectual Disability Research*, 55, 665-674.
- PCPCC MEDICATION MANAGEMENT TASK FORCE 2010. Integrating Comprehensive Medication Management to Optimize Patient Outcomes. Washington, D.C.: Patient-Centered Primary Care Collaborative.
- PEREZ, W. 2002. *Top Ten Tips For Effective Consultation* [Online].
- PETERSON, A., TAKIYA, L. & FINLEY, R. 2003. Meta-analysis of trials of interventions to improve medication adherence. *American Journal of Health System Pharmacy*, 60, 657-65.
- PEYROT, M., RUBIN, R. R., KRUGER, D. F. & TRAVIS, L. B. 2010. Correlates of Insulin Injection Omission. *Diabetes Care*, 33, 240-245.
- PHARMACEUTICAL JOURNAL 2009. Important role for pharmacists supporting vulnerable groups during pandemic. *Pharmaceutical Journal*, Aug 6.
- PHARMACEUTICAL JOURNAL 2014. Branford re-elected as English Pharmacy Board chairman as Gidley takes over as vice-chairman. *The Pharmaceutical Journal*, June 23.
- POLIT, D. & HUNGLER, B. 1997. *Essentials of Nursing Research*, New York, Lippincott.
- PORTER, M. E. 2010. What Is Value in Health Care? *New England Journal of Medicine*, 363, 2477-2481.

- POWELL, C. 2003. The Delphi technique: myths and realities. *Journal of Advanced Nursing*, 41, 376-382.
- PRASHER, V. P. & JANICKI, M. 2002. *Physical Health of Adults with Intellectual Disabilities*, Oxford, Blackwell Publishing.
- PSI 2010. Submission: Towards a Restraint Free Environment in Nursing Home, DoHC public consultation. The Pharmaceutical Society of Ireland.
- PSYCHIATRIC PATIENT ADVOCATE OFFICE 2009. Covert Medication (Medication Hidden in Food or Drink). Ontario, Canada.
- PUBLIC HEALTH ALLIANCE 2007. Public Health Advocacy Toolkit. *In: Public Health Alliance Ireland for the Island of Ireland (PHA) (ed.)*. Belfast & Dublin: PHA.
- QUEENSLAND GOVERNMENT 2014. Amendments to restrictive practices in Queensland. *In: Department of Communities, Child Safety and Disability Services (ed.)*.
- QUINN, P. 2015. Speaking notes, Phelim Quinn, CEO of HIQA. *National Disability Summit 9 April 2015*.
- RAND 2004a. Developing Quality of Care Indicators for the Vulnerable Elderly. The Assessing Care of Vulnerable Elders (ACOVE) Project. *In: Rand Corporation. (ed.) ww.rand.org*. Santa Monica, California.
- RAND. 2004b. *The Quality of Health Care Received by Older Adults* [Online]. Santa Monica, California: RAND Corporation.
- RAND. 2008. *Improving the Quality of Health Care for Older Adults* [Online]. Santa Monica, California: RAND Corporation.
- RASARATNAM, R., CROUCH, K. & REGAN, A. 2004. Attitude to medication of parents/primary carers of people with intellectual disability. *Journal of Intellectual Disability Research*, 48, 754-763.
- RC PSYCH, RCGP & HQIP 2014. Executive Summary and Recommendations: National Audit of Learning Disabilities Feasibility Study.
- RCGP 2010. Care of Adult Patients with Intellectual Disability. *In: Royal College of General Practitioners (ed.) Curriculum 14*. London.
- RCGP, RCP & NHS Guidance and Competencies for the Provision of Services using Practitioners with Special Interests [PwSIs]. Learning Disabilities.
- RCGP, RPS & NHS 2009. Guidance and Competencies for the Provision of Services using Practitioners with Special Interests [PwSIs]. Learning Disabilities. London: Royal College of General Practitioners, Royal Pharmaceutical Society, Department of Health, NHS.
- RCN 2013a. Dignity in health care for people with learning disabilities. *RCN Guidance*. 2nd ed. London: Royal College of Nursing.

- RCN 2013b. Guidance on the minimisation of and alternatives to restrictive practices in health and adult social care, and special schools. London: Royal College of Nursing.
- RCPSYCH 2014a. Consensus statement on high-dose antipsychotic medication. London: Royal College of Psychiatry.
- RCPSYCH. 2014b. *Coping with physical illness* [Online]. [Accessed Dec 24 2014].
- RCPSYCH, RCGP & HQIP 2014. Report on the National Audit of Learning Disabilities Feasibility Study (NALD-FS).
- REGNARD, C., REYNOLDS, J., WATSON, B., MATTHEWS, D., GIBSON, L. & CLARKE, C. 2007. Understanding distress in people with severe communication difficulties: developing and assessing the Disability Distress Assessment Tool (DisDAT). *Journal of Intellectual Disability Research*, 51, 277-292.
- REICHARD, A. & STOLZE, H. 2011. Diabetes among adults with cognitive limitations compared to individuals with no cognitive disabilities. *J of Intell & Develop Disabilities*, 49, 141-154.
- REICHARD, A. & STOLZLE, H. 2011. Diabetes Among Adults With Cognitive Limitations Compared to Individuals With No Cognitive Disabilities. *Intellectual and Developmental Disabilities*, 49, 141-154.
- REISS, S. & AMAM, M. G. 1997. The international consensus process on psychopharmacology and intellectual disability. *Journal of Intellectual Disability Research*, 41, 448-455.
- REISS, S. & AMAN, M. G. 1997. The international consensus process on psychopharmacology and intellectual disability. *Journal of Intellectual Disability Research*, 41, 448-455.
- REY-CONDE, T. & LENNOX, N. 2007. Delivering diabetes care to people with intellectual disability. *Diabetes Voice*, 52.
- RICHARDSON, T., O'REILLY, C. & CHEN, T. 2014. A comprehensive review of the impact of clinical pharmacy services on patient outcomes in mental health. *International Journal of Clinical Pharmacy*, 36, 222-232.
- ROBERTSON, J., ROBERTS, E., EMERSON, E., TURNER, S. & GREIG, R. 2011. Invited review: The impact of health checks for people with intellectual disabilities: a systematic review of the evidence. *Journal of Intellectual Disability Research*, 55, 1009-1019.
- ROBINSON, S. & CHENOWETH, L. 2011. Preventing abuse in accommodation Services: From procedural response to protective cultures. *Journal of Intellectual Disabilities*, 15, 63-74.

- ROOSE, S. P. 2003. Compliance: the impact of adverse events and tolerability on the physician's treatment decisions. *European neuropsychopharmacology: the Journal of the European College of Neuropsychopharmacology*, 13, 85-92.
- ROYAL COLLEGE OF PSYCHIATRISTS 2001. DC-LD [Diagnostic criteria for psychiatric disorders for use with adults with learning disabilities/mental retardation]. Occasional Paper OP 48. London: Gaskell.
- ROYAL COLLEGE OF PSYCHIATRISTS. 2013. *Coping with physical illness* [Online].
- ROYAL COLLEGE OF PSYCHIATRISTS, BRITISH PSYCHOLOGICAL SOCIETY & THE ROYAL COLLEGE OF SPEECH AND LANGUAGE THERAPISTS 2007. *Challenging Behaviour: a Unified Approach*. London: Royal College of Psychiatrists, Faculty of Psychiatry of Intellectual Disability.
- RPS 2013. Improving patient outcomes. The better use of multi-compartment compliance aids. Royal Pharmaceutical Society.
- RPS 2014. Handbook for Homecare Services in England. *In: Royal Pharmaceutical Society* (ed.). London.
- Inside Bungalow 3*, 2014. Directed by RTE.
- RUDD, R. E. 2010. Improving Americans' Health Literacy. *The New England Journal of Medicine*, 363, 2283-5.
- RUEDRICH, S., SWALES, T., ROSSVANES, C., DIANA, L., ARKADIEV, V. & LIM, K. 2008. Atypical antipsychotic medication improves aggression, but not self-injurious behavior, in adults with intellectual disabilities. *Journal of Intellectual Disability Research*, 52, 132-140.
- RUSH, R. & KELLY, M. 1999. Guidelines for the inclusion of adults with learning disabilities into literacy schemes. *In: National Adult Literacy Agency* (ed.).
- RUTZ, W. 2003. Rethinking mental health: a European WHO perspective. *World Psychiatry*, 2, 125-127.
- RYAN, R., SANTESSO, N., LOWE, D., HILL, S., GRIMSHAW, J., PRICTOR, M., KAUFMAN, C., COWIE, G. & TAYLOR, M. 2014. Interventions to improve safe and effective medicines use by consumers: an overview of systematic reviews. *Cochrane Database of Systematic Reviews 2014*.
- SACKETT, D., STRAUSS, S., RICHARDSON, W. & AL, E. 2000. *Evidence-based medicine: how to practice and teach EBM.*, London, Churchill-Livingstone.
- SAFREN, S. A., GONZALEZ, J. S., WEXLER, D. J., PSAROS, C., DELAHANTY, L. M., BLASHILL, A. J., MARGOLINA, A. I. & CAGLIERO, E. 2013. A randomized controlled trial of cognitive behavioral therapy for adherence and depression (CBT-AD) in patients with uncontrolled type 2 diabetes. *Diabetes Care*.

- SALMAN, S. 2013. *Service users join watchdog's inspection team as 'experts by experience'* [Online]. London: The Guardian.
- SCHALICK, W., WESTBROOK, C. & YOUNG, B. 2012. *Communication with Individuals with Intellectual Disabilities and Psychiatric Disabilities: A Summary of the Literature*. University of Michigan.
- SCHEEPERS, M., KERR, M., O'HARA, D., BAINBRIDGE, D., COOPER, S.-A., DAVIS, R., FUJIURA, G., HELLER, T., HOLLAND, A., KRAHN, G., LENNOX, N., MEANEY, J. & WELMEYER, M. 2005. *Reducing health disparity in people with learning disabilities: A report from the health issues special interest research group of the International Association for the Scientific Study of Intellectual Disabilities*. *JPPID*, 2, 249-255.
- SCHEIFES, A., EGBERTS, T. C. G., STOLKER, J. J., NIJMAN, H. L. I. & HEERDINK, E. R. 2015. *Structured Medication Review to Improve Pharmacotherapy in People with Intellectual Disability and Behavioural Problems*. *Journal of Applied Research in Intellectual Disabilities*, n/a-n/a.
- SCHEIFES, A., STOLKER, J. J., EGBERTS, A. C. G., NIJMAN, H. L. I. & HEERDINK, E. R. 2011. *Representation of people with intellectual disabilities in randomised controlled trials on antipsychotic treatment for behavioural problems*. *Journal of Intellectual Disability Research*, 55, 650-664.
- SCHELLY, D. 2008. *Problems associated with choice and quality of life for an individual with intellectual disability: a personal assistant's reflexive ethnography*. *Disability & Society*, 23, 719-732.
- SCHILLINGER, D., GRUMBACH, K., PIETTE, J. & ET AL. 2002. *Association of health literacy with diabetes outcomes*. *Journal of the American Medical Association*, 288, 475-482.
- SCHMIDT, E., BYARS, J., FLAMUTH, D., SCHOTT, J. & SEVER, C. 2004. *Prevalence of Low Bone-Mineral Density Among Mentally Retarded and Developmentally Disabled Residents in Intermediate Care*. *The Consultant Pharmacist*, 19, 45-51.
- SCHOLTE, F. A. 2008. *European manifesto: Basic standards of Healthcare for people with intellectual disabilities*. *Salud Pública de México*, 50, s273-276.
- SCHREUREN, F. 2004. *What is a survey?* In: 2nd ed.: The American Statistical Association.
- SCOTTISH GOVERNMENT 2013. *Prescription for Excellence. A Vision and Action Plan for the right pharmaceutical care through integrated partnerships and innovation*. Edinburgh.

- SERGI, G., DE RUI, M., SARTI, S. & MANZATO, E. 2011. Polypharmacy in the Elderly: Can Comprehensive Geriatric Assessment Reduce Inappropriate Medication Use? *Drugs & Aging*, 28, 509-519
- SHAW, K., CARTWRIGHT, C. & CRAIG, J. 2011. The housing and support needs of people with an intellectual disability into older age. *Journal of Intellectual Disability Research*, 55, 895-903.
- SHEKELLE, P., MACLEAN, C., MORTON, S. & WENGER, N. 2001a. Assessing Care of Vulnerable Elders: Methods for Developing Quality Indicators. *Annals of Internal Medicine*, 135, 647-652.
- SHEKELLE, P. G., MACLEAN, C. H., MORTON, S. C. & WENGER, N. S. 2001b. Assessing Care of Vulnerable Elders: Methods for Developing Quality Indicators. *Annals of Internal Medicine*, 135, 647-652.
- SHERIDAN, A., HOWELL, F. & BEDFORD, D. 2012. Hospitalisations and costs relating to ambulatory care sensitive conditions in Ireland. *Irish Journal of Medical Science*, 181.
- SHIELD, T., CAMPBELL, S., ROGERS, A., WORRALL, A., CHEW-GRAHAM, C. & GASK, L. 2003. Quality indicators for primary care mental health services. *Quality and Safety in Health Care*, 12, 100-106.
- SHOGREN, K., WEHMEYER, M., REESE, R. & O'HARA, D. 2006. Promoting self-determination in health and medical care: A critical component of addressing health disparities in people with intellectual disabilities. *Journal of Policy and Practice in Intellectual Disabilities*, 32, 105-113.
- SHOGREN, K. A., FAGGELLA-LUBY, M. N., SUNG JIK BAE & WEHMEYER, M. L. 2004. The Effect of Choice-Making as an Intervention for Problem Behavior. *Journal of Positive Behavior Interventions*, 6, 228-237.
- SINHA, I. P., SMYTH, R. L. & WILLIAMSON, P. R. 2011. Using the Delphi Technique to Determine Which Outcomes to Measure in Clinical Trials: Recommendations for the Future Based on a Systematic Review of Existing Studies. *PLoS Med*, 8, e1000393.
- SLEATH, B., RUBIN, R. H. & HUSTON, S. A. 2003. Hispanic ethnicity, physician-patient communication, and antidepressant adherence. *Comprehensive Psychiatry*, 44, 198-204.
- SLEVIN, E., TAGGART, L., MCCONKEY, R., COUSINS, W., TRUESDALE-KENNEDY, M. & DOWLING, L. 2011. A rapid review of literature relating to support for people with intellectual disabilities and their family carers when the person has: behaviours that challenge and/or mental health problems; or they are advancing in age. Belfast: University of Ulster.

- SLOWIE, D. 2014. *RE: Learning Disability Feasibility Study*.
- SMITH, S., O'KEANE, V. & MURRAY, R. 2002. Sexual dysfunction in patients taking conventional antipsychotic medication. *The British Journal of Psychiatry*, 181, 49-55.
- SNYDER-HALPERM, R., THOMPSON, C.B. & SCHAFFER, J. Comparison of mailed vs. Internet applications of the Delphi technique in clinical informatics research. Proceedings of the AMIA Symposium 2000, 2000 Washington, DC. American Medical Informatics Association, 809-13.
- SOCIAL CARE POLICY 2011. Safeguarding Adults: The role of Health Service Practitioners. *Care and Compassion; Report of the health Service Ombudsman on ten investigations into NHS care of older people; Parliamentary and Health Service Ombudsman 2011; Mid Staffordshire NHS Foundation Trust Public Inquiry 2010; Death By Indifference; No Secrets Consultation Report, Dept Health 2009*. London.
- SOHANPAL, S., DEB, S., THOMAS, C., SONI, R., LENOTRE, L. & UNWIN, G. 2007. The effectiveness of antidepressant medication in the management of behaviour problems in adults with intellectual disabilities: A systematic review. *Journal of Intellectual Disability Research*, 51, 750-765.
- SOMERAI, S. B., MCLAUGHLIN, T. J., ROSS-DEGNA, D., CASTERIS, C. & BOLLINI, P. 1994. Effects of limiting Medicaid drug re-imburement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. *New England Journal of Medicine*, 331, 650-655.
- STOLKER, J. J., KOEDOOT, P., HEERDINK, E., LEUFKENS, H. & NOLEN, W. 2002. Psychotropic drug use in intellectually disabled group-home residents with behavioural problems. *Pharmacopsychiatry* 35, 19-23.
- STRAETMANS, J. M. J. A. A., SCHROJENSTEIN LANTMAN-DE VALK, H. M. J. V., SCHELLEVIS, F. G. & DINANT, G. J. 2007. Health problems of people with intellectual disabilities: the impact for general practice *British Journal of General Practice*, 57, 64-66.
- STRATH, A. 2001. Repeat Prescribing and Dispensing Systems: An Option Appraisal. A Report for the Primary Care Unit, Scottish Executive.
- STRAUSS, A. & CORBIN, J. 1998. *Basics of qualitative research.*, CA, Sage Publications.
- STRUCKMANN, V., SNOEIJIS, S., MELCHIORRE, M., HUJALA, A., RIJKEN, M., QUENTIN, W. & VAN GINNEKEN, E. 2014. Caring for people with multiple chronic conditions in Europe. *Eurohealth International: ICARE4EU*.

- STRYDOM, A., FORSTER, M., WILKIE, B. M., EDWARDS, C. & HALL, I. S. 2001. Patient information leaflets for people with learning disabilities who take psychiatric medication. *British Journal of Learning Disabilities*, 29, 72-76.
- STRYDOM, A., LEE, L., JOKINEN, N., SHOOSHTARI, S., RAYKAR, V., TORR, J., TSIOURIS JA, COURTENAY, K., BASS, N., SINNEMA, M. & MAASKANT, M. 2009. Report on the State of Science on Dementia in People with Intellectual Disabilities. *In: IASSID Special Interest Group on Aging and Intellectual Disabilities*. (ed.).
- SULLIVAN, W., BERG, J., BRADLEY, E., CHEETHAM, T., DENTON, R., HENG, J., HENNEN, B., JOYCE, D., KELLY, M., KOROSSY, M., LUNSKY, Y. & MCMILLAN, S. 2011. Primary care of adults with developmental disabilities. Canadian consensus guidelines. *Canadian Family Physician*, 57, 541-53.
- SUSSEX MULTI AGENCY 2011. Sussex Multi-Agency Policy and Procedures for Safeguarding Adults at Risk. *Part 2: Empowerment and Prevention*. Brighton & Howe City Council, West Sussex County Council, East Sussex County Council.
- SWENSON, S. L., BUELL, S., ZETTLER, P., WHITE, M., RUSTON, D. C. & LO, B. 2004. Patient-centered Communication: Do Patients Really Prefer It? *Journal of General Internal Medicine*, 19, 1069-1079.
- SYED, A., HJARNOE, L. & ARO, A. 2009. The Delphi Technique In Developing International Health Policies: Experience From The SARS Control Project. *The Internet Journal of Health*, 8.
- TAGGART, L., COATES, V. & TRUESDALE-KENNEDY, M. 2013. Management and quality indicators of diabetes mellitus in people with intellectual disabilities. *Journal of Intellectual Disability Research*, 57, 1152-1163.
- TAGGART, L. & COUSINS, W. 2014. *Health Promotion For People With Intellectual And Developmental Disabilities*, UK, McGraw-Hill Education.
- TALBOT, L. & VERRINDER, G. 2014. *Promoting health: the primary health care approach*, NSW, Australia, Elsevier.
- TASK FORCE ON MEDICINES PARTNERSHIP & PROGRAMME, The National Collaborative Medicines Management Services Programme 2002. Room for review. A guide to medication review: the agenda for patients, practitioners and managers.
- TAYLOR, D. & SUTTON, J. 2006. Report on the Mental Health and Learning Disabilities Secondary Care Pharmacy Workforce Survey. *In: College of Mental Health Pharmacists, National Institute for Mental Health in England, Psychiatric Pharmacy Group United Kingdom, Care Services Improvement Partnership* (ed.).

- TAYLOR, D. & SUTTON, J. 2009. Clinical Governance Issues arising from the Mental Health and Learning Disabilities Pharmacy Workforce Survey England 2006. *International Journal of Pharmacy Practice*, 17, 171-9.
- TERAMURA-GRÖNBLAD, M., MUURINEN, S., SOINI, H., SUOMINEN, M. & PITKÄLÄ, K. H. 2011. Use of Anticholinergic Drugs and Cholinesterase Inhibitors and Their Association with Psychological Well-Being Among Frail Older Adults in Residential Care Facilities. *Annals of Pharmacotherapy*, 45, 596-602.
- THE JOINT COMMISSION 2007. 'What did the doctor say?' Improving Health Literacy to Protect Patient Safety.
- THE PHARMACEUTICAL JOURNAL 2014. How pharmacists can improve the care of vulnerable patients. *Pharmaceutical Journal*, 293.
- THERAPEUTIC RESEARCH CENTER 2011. Drugs with Anticholinergic Activity. *Pharmacist's Letter/Prescriber's Letter*. Stockton, CA.
- THOMAS, S., CORKERY-LAVENDER, K., DAFFERN, M., SULLIVAN, D. & LAU, P. 2010. Senior Practitioner Disability, mental health and medication: Implications for practice and policy. State Government Victoria.
- THOMPSON COON, J., ABBOTT, R., ROGERS, M., WHEAR, R., PEARSON, S., LANG, I., CARTMELL, N. & STEIN, K. 2014. Interventions to Reduce Inappropriate Prescribing of Antipsychotic Medications in People With Dementia Resident in Care Homes: A Systematic Review. *Journal of the American Medical Directors Association*, 15, 706-718.
- THOMSON, J., WANG, W., BROWNING, C. & KENDIG, H. 2010. Self-reported medication side effects in an older cohort living independently in the community - the Melbourne Longitudinal Study on Healthy Ageing (MELSHA): cross-sectional analysis of prevalence and risk factors. *BMC Geriatrics*, 10, 37.
- THOMSON, R., LEWALLE, P., SHERMAN, H., HIBBERT, P., RUNCIMAN, W. & CASTRO, G. 2009. Towards an International Classification for Patient Safety: a Delphi survey. *International Journal for Quality in Health Care*, 21, 9-17.
- TJIA, J., GURWITZ, J. H. & BRIESACHER, B. A. 2012. Challenge of Changing Nursing Home Prescribing Culture. *The American Journal of Geriatric Pharmacotherapy*, 10, 37-46.
- TOTSIKA, V., TOOGOOD, S., HASTINGS, R. P. & LEWIS, S. 2008. Persistence of challenging behaviours in adults with intellectual disability over a period of 11 years. *Journal of Intellectual Disability Research*, 52, 446-457.

- TSIOURIS, J. A. 2010. Pharmacotherapy for aggressive behaviours in persons with intellectual disabilities: treatment or mistreatment. *Journal of Intellectual Disability Research*, 54, 1-16.
- TULLY, J., SCHIRLIU, D. & MORAN, M. 2012. Application of DC-LD to an intellectual disability population. *Advances in Mental Health and Intellectual Disabilities*, 6, 259-264.
- TUNE, L. 2001. Anticholinergic effects of medication in elderly patients. *The Journal of Clinical Psychiatry*, 62, 11-4.
- TURNER, S. 2011. Health Inequalities and People with Learning Disabilities in the UK: 2011. Implications and actions for commissioners and providers of social care. *Evidence into practice report No. 4. Improving Health and Lives*, Learning Disabilities Observatory.
- TURNER, S. & EMERSON, E. 2013. Making Reasonable Adjustments to Diabetes services for People with Learning Disabilities. IHAL.
- TURNER, S. & ROBINSON, C. 2011. Reasonable Adjustments for People with Learning Disabilities – Implications and Actions for Commissioners and Providers of Healthcare. *Evidence in Practice Report* IHAL.
- TYRER, P., OLIVER-AFRICANO, P. C., AHMED, Z., BOURAS, N., COORAY, S., DEB, S., MURPHY, D., HARE, M., MEADE, M., REECE, B., KRAMO, K., BHAUMIK, S., HARLEY, D., REGAN, A., THOMAS, D., RAO, B., NORTH, B., ELIAHOO, J., KARATELA, S., SONI, A. & CRAWFORD, M. 2008. Risperidone, haloperidol and placebo in the treatment of aggressive challenging behaviour in patients with intellectual disability: A randomized controlled trial. *The Lancet*, 371, 57-63.
- UKMI 2013. What are the therapeutic options for patients unable to take solid oral dosage forms. UK Medicines Information Pharmacists, NHS.
- UN 1948. Universal Declaration of Human Rights. *G.A. res. 217A (III), U.N. Doc A/810 at 71 (1948)*. Paris: United Nations.
- UN 1991. The principles for the protection of persons with mental illness and for the improvement of mental health care. [MI Principles]. New York: United Nations.
- UN 2006. Convention on the Rights of Persons with Disabilities New York: United Nations.
- UNWIN, G. L. & DEB, S. 2011. Efficacy of atypical antipsychotic medication in the management of behaviour problems in children with intellectual disabilities and borderline intelligence: A systematic review. *Research in Developmental Disabilities*, 32, 2121-2133.
- US PHARMACOPEIA 2004.

- VAN DEN BRENT, P. M., EGBERTS, A. C., LENDERINK, W. A., VERZIJJ, J. M., SIMONS, K. A., VAN DER POL, W. S. & LEUFKENS, H. G. 2000. Risk factors for the development of adverse drug reactions in hospitalised patients. *Pharmacy World and Science*, 22, 62-66.
- VAN SCHROJENSTEIN LANTMAN-DE VALK, H., LINEHAN, C., KERR, M. & NOONAN-WALSH, P. 2007. Developing health indicators for people with intellectual disabilities. The method of the Pomona project. *Journal of Intellectual Disability Research*, 51, 427-434.
- VANCE, J. 2013. AMDA—Choosing Wisely. *Journal of the American Medical Directors Association*, 14, 639-641.
- VITALE, M. 2012. My Health, My Choice, My Responsibility: A Curriculum to Promote Health Self-Advocacy *National Gateway to Self Determination*, Sept.
- VON DER GRACHT, H. A. 2012. Consensus measurement in Delphi studies: Review and implications for future quality assurance. *Technological Forecasting and Social Change*, 79, 1525-1536.
- WALKER, B. & SPENGLER, P. 1995. Clinical judgement of major depression in AIDS patients: The effects of clinical complexity and stereotyping [Electronic version]. *Professional Psychology Research & Practice*, 26, 269-273.
- WALTER, L. C., DAVIDOWITZ, N. P., HEINEKEN, P. A. & COVINSKY, K. E. 2004. Pitfalls of Converting Practice Guidelines Into Quality Measures: Lessons Learned From a VA Performance Measure. *The Journal of the American Medical Association*, 291, 2466-2470.
- WARD, R. L., NICHOLS, A. D. & FREEDMAN, R. 2010. Uncovering health care inequalities among adults with intellectual and developmental disabilities. *Health and Social Work*, 35, 280-90.
- WEAFER, J. 2003. Jigsaw of Advocacy. A Research Report. Comhairle.
- WEHMEYER, M. & METZLER, C. 1995. How self-determined are people with mental retardation? The National Consumer Survey. *Mental Retardation*, 33, 111-119.
- WELSH, S. & DEAHL, M. 2002. Covert medication - ever ethically justifiable? *Psychiatric Bulletin*, 26, 123-126.
- WENSING, M., GROL, R. & SMITS, A. 1994. Quality judgements by patients on general practice care: a literature analysis. *Social Science and Medicine*, 38, 45-53.
- WERNER, S. 2012. Individuals with Intellectual Disabilities: A Review of the Literature on Decision-Making since the Convention on the Rights of People with Disabilities (CRPD). *Public Health Reviews*, 34.

- WHITE, P., EDWARDS, N. & TOWNSEND-WHITE, C. 2006. Stress and burnout amongst professional carers of people with intellectual disability: another health inequity. *Current Opinion in Psychiatry*, 19.
- WHITEHEAD, M. 1991. Whitehead, M. (1991) The concepts and principles of equity and health, *Health Promotion International*, 6 (3) 217 – 22. *Health Promotion International*, 6, 217 – 22.
- WHITTY, P. & DEVITT, P. 2005. Surreptitious Prescribing in Psychiatric Practice. *Psychiatric Services*, 56, 481-483.
- WHO 1978. Declaration of Alma-Ata *In: World Health Organization*, (ed.). International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978
- WHO 2003. Adherence to long term therapies - Evidence for action.
- WHO 2004. A Glossary of Terms for Community Health Care and Services for Older People. *In: WHO CENTRE FOR HEALTH DEVELOPMENT* (ed.) *Ageing & Health Technical Report*. Geneva.
- WHO 2011a. International Statistical Classification of Diseases and Related Health Problems. Geneva, Switzerland: World Health Organisation.
- WHO 2011b. Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. *WHO Technical Report Series, No. 961, 2011*.
- WHO 2013. WHO methods and data sources for global burden of disease estimates 2000-2011. Department of Health Statistics and Information Systems.
- WILKINSON, J., POWELL, A. & DAVIES, H. 2011. Are clinicians engaged in quality improvement? A review of the literature on healthcare professionals' views on quality improvement initiatives. The Health Foundation.
- WILLIAMS, A. 26/1/2010 2010a. *RE: Letter to Directors of Adult Services in Local Authorities: Parliamentary Ombudsman's Report on Learning Disability-Recommendations for Local Authorities*.
- WILLIAMS, D. E. 2010b. Reducing and eliminating restraint of people with developmental disabilities and severe behavior disorders: An overview of recent research. *Research in Developmental Disabilities*, 31, 1142-1148.
- WILLIAMSON, M. & HARVEY, T. 2007. Ageing successfully in place. *Initial Literature Review/Scoping Paper*. National Disability Services, Western Australia.
- WILLNER, P., JAHODA, A., ROSE, J., STENFERT-KROESE, B., HOOD, K., TOWNSON, J., NUTTALL, J., GILLESPIE, D. & FELCE, D. 2011. Anger management for people with mild to moderate learning disabilities: Study protocol for a multi-centre cluster randomized controlled trial of a manualized intervention delivered by day-service staff. *Trials*, 12, 36.

- WILSON, H. & BARBER, N. 2013. Review of NHS Pharmaceutical Care of Patients in the Community in Scotland.
- WILSON, N., CLEGG, J. & HARDY, G. 2008. What informs and shapes ethical practice in Intellectual Disability services? *Journal of Intellectual Disability Research*, 52, 608-617.
- WINDLEY, D. & CHAPMAN, M. 2010. Support workers within learning/intellectual disability services perception of their role, training and support needs. *British Journal of Learning Disabilities*, 38, 310-318.
- WIZOWSKI, L., HARPER, T. & HUTCHINGS, T. 2014. *Writing health information for patients and families*, Canada, Hamilton Health Series.
- WORKING GROUP ON CONGREGATED SETTINGS 2011. Time to move on from congregated settings - A Strategy for Community Inclusion. Dublin: Health Service Executive.
- WORLD FEDERATION FOR MENTAL HEALTH 2004. The relationship between physical and mental health: co-occurring disorders. *In: World Federation For Mental Health (ed.)*. Alexandria, VA, USA.
- WORLD PSYCHIATRIC ASSOCIATION 2008. Problem Behaviour in Adults with Intellectual Disabilities: International Guide for Using Medication. Switzerland: World Psychiatric Association - Special Interest Group Intellectual Disability.
- WPA 2008. Problem Behaviours in Adults with Intellectual Disabilities: International Guide for Using Medication. Switzerland: The World Psychiatric Association Section Psychiatry of Intellectual Disability (SPID).
- WUBBEN, D. P. & VIVIAN, E. M. 2008. Effects of Pharmacist Outpatient Interventions on Adults with Diabetes Mellitus: A Systematic Review. *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*, 28, 421-436.
- WWW.SURVEYMONKEY.COM. [Accessed April 17 2012].
- YAMADA, K., KOICHIRO, W., NAOYUKI, N., HIDECHIKA, F., CHIKAYO, C., KEITA, Y., GOHEI, Y., MASAHIRO, A. & SHIGENOBU, K. 2006. Prediction of medication noncompliance in outpatients with schizophrenia: a 2-year follow up study. *Psychiatry Research*, 141, 61-69.
- YOUNG, H., BELL, R., EPSTEIN, R., FELDMAN, M. & KRAVITZ, R.L. 2006. Types of information physicians provide when prescribing antidepressants. *Journal of General Internal Medicine* 21, 1172-1177.
- ZERMANSKY, A. G., ALLDRED, D. P., PETTY, D. R., RAYNOR, D. K., FREEMANTLE, N., EASTAUGH, J. & BOWIE, P. 2006. Clinical medication review by a pharmacist of elderly people living in care homes - randomised controlled trial. *Age and Ageing*, 35, 586-591.

APPENDICES

APPENDIX 1

List of Round 1 Candidate Quality Indicators

QI No 1 - Informational Transfer

IF a person ageing with intellectual disability exhibits a behaviour disorder **THEN** they should be accompanied at assessment by a caregiver/health facilitator, who is familiar with them and who can transfer health information **BECAUSE** consideration and evaluation of the patient's mental, physical, psychosocial and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of patients complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors and other important features) may require communication by someone familiar with the person with intellectual disability to ensure vital continuity of care and a complete record of all healthcare interventions.

QI No 2 - Communication

IF a person with intellectual disability exhibits a behaviour disorder **THEN** all clinicians/carers should try to optimize communication with the person with intellectual disability before medication is prescribed, dispensed or administered **BECAUSE** people with intellectual disabilities need to be encouraged and empowered to communicate/speak for themselves and the way medication is prescribed and the need for accessible information have been identified by people with intellectual disability as an area of concern.

QI No 3 - General Health Review

IF psychotropic medication use is considered for a person ageing with intellectual disability and a behaviour disorder **THEN** prior to medication use, consideration should be taken of possible underlying medical (UTIs, dental problems, congestive heart failure, idiosyncratic reaction to medication or other medication side effects), environmental or psychosocial stressors and any available laboratory results **BECAUSE** the use of any psychotropic medication should occur after multidimensional interdisciplinary communication and the development of a coordinated plan for treatment and follow up.

QI No 4 - Geriatric Syndromes

IF a person ageing with intellectual disability and a behaviour disorder is prescribed medication **THEN** any adverse reactions to medications that may be associated with

specific geriatric syndromes should be assessed **BECAUSE** consensus has been reached in one study in relation to assessment protocols for falls, delirium and dehydration/fluid maintenance, being used to detect potential adverse medication reactions for individuals taking certain medications and diagnosis and treatment for geriatric syndromes may be more likely to improve quality of life and enhance patient safety.

QI No 5 - Non-Pharmacological Interventions

IF a person ageing with intellectual disability presents with behaviour disorders (that may include aggression or self injurious behaviour) **THEN** medication use should be considered only after non-medication use interventions **BECAUSE** behavioural, psychological, social and environmental interventions should be considered before medication is used for aggression or self injury and medication use has been found to be the least effective treatment for problem behaviours.

QI No 6 - External Environment and Behaviour Disorders

IF a person ageing with intellectual disability presents with a behaviour disorder **THEN** external environmental factors, including staff/family/carers, should be looked at before medication use **BECAUSE** external environmental factors may be responsible for or impact on behaviour disorders and both psychiatric and applied behavioural analytical models of behaviour allow for the importance of environmental events.

QI No 7 - Pharmacist and Specialist Team

IF a person ageing with intellectual disability is prescribed psychotropic medication for a behaviour disorder **THEN** they should receive specialist attention from a mental health team (that includes a specialist pharmacist) **BECAUSE** (a) without the collaboration of a specialist team this vulnerable population may be put at risk of inappropriate medication management, (b) health related quality of life can be compromised by medication related problems, despite the benefits of pharmacotherapy, and (c) there has not been sufficient clinical trial research on the efficacy or safety of medications with individuals ageing with intellectual disability.

QI No 8 - Acute Behaviour

IF medication is used to treat an acute behaviour problem in a person ageing with intellectual disability **THEN** the underlying causes of the problem behaviour or presenting symptoms must be identified and addressed before medication is used **BECAUSE** when the acute phase has stabilized the prescriber must consider if

medication could be discontinued or reduced and low levels of intervention accountability and supervision may place many people with behaviour problems at increased risk for ineffective and unnecessary interventions.

QI NO 9 - Residential Care

IF a person ageing with intellectual disability living in residential care exhibits a behaviour disorder **THEN** care must be exercised before medication is used **BECAUSE** the use of medication in a residential setting involves a complex blending of diverse elements of clinical practice and regular medication review is advised.

QI No 10 - Medication Reconciliation

IF a person with intellectual disability and a behaviour disorder is being transferred between healthcare settings **THEN** medication reconciliation (by a pharmacist) should take place at all transition points **BECAUSE** admission, transfer and discharge are the situations when medication errors are most likely to occur and medication reconciliation (of all medications, complimentary therapies and supplements) has been demonstrated to be a powerful method of ensuring patient safety, reducing medication errors and adverse drug events across the continuum of care.

QI No 11 - Advocacy

IF medication is used to manage behaviour disorders in a person ageing with intellectual disability **THEN** advocacy services should be available to the person with intellectual disability and/or their carers to explore intervention options **BECAUSE** an advocate from outside the clinical team, should help determine the person's interests to minimize restrictions to freedom and to take past and present wishes into account and there are no clear prohibitions about a non-medical mental health professional talking with clients about psychotropic medication (although this is still a grey area).

QI No 12 - Medication Regimen Review

IF a person ageing with intellectual disability is prescribed medication(s) **THEN** the medication regimen of the patient should be reviewed, preferably on site (if living in a residential setting) at least 3 monthly and preferably by a pharmacist **BECAUSE** medication regimen review will ensure thorough evaluation of the medication regimen of a vulnerable patient, with the goal of promoting positive outcomes and minimising adverse consequences associated with medications some of which may include changes in behaviour.

QI No 13 - Restrictive Practices

IF psychotropic medication is used as a restrictive practice for a person ageing with intellectual disability and behaviour disorders **THEN** this should only be done in the best interest of the person, protecting their human rights and in the context of a comprehensive policy on the management of behaviour disorders **BECAUSE** restrictive practices (including psychotropic medication use) should only be used when the person with intellectual disability poses an immediate threat of physical harm to self or others and they should only be used as a last resort.

QI No 14 - Covert Medication Use

IF difficulties exist during the administration of medication to a person ageing with intellectual disability and a behaviour disorder **THEN** before covert administration of the medication is authorized, all other alternatives must have been explored by multidisciplinary discussion with all health care staff (directly or indirectly) involved in covert medication administration and never without the expert guidance of a pharmacist and found to be impracticable **BECAUSE** staff/carers must not give medication in a disguised form unless the intellectually disabled adult has refused to take medication and their health is at risk because of this, and covert medication administration may involve the administration of a medication outside the terms of its license, which may put the patient at risk.

QI No 15 - Adverse Drug Reactions

IF a person ageing with intellectual disability who is prescribed medication presents with a new or changed condition or a change in functioning and/or behaviour **THEN** a medication review should be undertaken (by a pharmacist) **BECAUSE** people with intellectual disability are more likely to have certain medication side effects overlooked or ignored, and unrecognised adverse drug reactions in a person with limited communication ability may be misdiagnosed as an exacerbation of an existing medical problem, as a new medical problem or behaviour related.

QI No 16 – Multiple Medication Use/Poly-Pharmacy

IF a person with intellectual disability and a behaviour disorder is prescribed more than one medication **THEN** their medication regimen should be reviewed for medication-medication interactions (by a pharmacist) **BECAUSE** people with intellectual disability are predisposed to co-existing medical conditions, such as seizure disorders, gastrointestinal and cardiovascular problems and may be prescribed a variety of medications and so subject to poly-pharmacy, which is an acknowledged problem in this population,

that increases the risk of adverse reactions to medications including behavioural changes.

QI No 17 - Inter-Class/Intra-Class Poly-Pharmacy

IF a person ageing with intellectual disability and a behaviour disorder is prescribed psychotropic medication **THEN** inter-class poly-pharmacy (prescribing more than two medications in the same class at the same time) and intra class poly-pharmacy (prescribing more than 3 medications from different classes at the same time) should be avoided (where possible) **BECAUSE** limiting poly-pharmacy is a critical clinical issue as inter-class/intra-class poly-pharmacy may result in adverse medication effects and non-compliance and many individuals ageing with intellectual disability receive medication over long periods with no clear diagnostic guidelines for the concurrent use of anti-psychotic medications from different classes.

QI No 18 - Psychotropic Medication Side Effects

IF an ageing person with intellectual disability and a behaviour disorder is prescribed psychotropic medication **THEN** the patient/carer/care-giver should be made aware of possible side effects by the prescriber and/or pharmacist **BECAUSE** antipsychotic medications may produce serious side effects that can range in intensity from mild to severe, the management of any side effects should be part of the treatment plan, studies have shown that staff awareness of side effects is low and physicians and pharmacists have been reported to be the preferred source of medication information.

QI No 19 - Psychotropic Medication - Physical Side Effects

IF psychotropic medication use is a component of the care of a person ageing with intellectual disability and a behaviour disorder **THEN** the person (and/or carer) should be aware of any possible impact of the medication on the person's physical health **BECAUSE** physical and metabolic side effects associated with psychotropic medication are not unavoidable and may be minimised by careful monitoring, dietary control and exercise regimens in people with intellectual disability and initiatives should be taken to enhance the healthcare of those ageing with intellectual disability.

QI No 20 - Anti-Cholinergic Medication

IF a person ageing with intellectual disability and a behaviour disorder is prescribed medication **THEN** the anti-cholinergic effects of all prescribed medication should be reviewed and monitored **BECAUSE** (1) many medications used to treat the intellectually disabled population have significant anti-cholinergic properties, (2) the

use of multiple medications with anti-cholinergic actions may cause problems due to cumulative effects and (3) anti-cholinergic side effects are common, especially in the older patient.

QI No 21 - Neuroleptic Side Effects

IF a person ageing with intellectual disability and a behaviour disorder is prescribed antipsychotic medication **THEN** the development of signs and symptoms of extra-pyramidal side effects must be recognized and responded to **BECAUSE** failure to do so may jeopardise the patients health and safety, as antipsychotics may produce serious side effects that can range in intensity from mild to severe and the severity of side effects may play a role in the effectiveness and tolerability of the particular antipsychotic.

QI No 22 - Anti-Epileptic Medication

IF a person ageing with intellectual disability and behaviour disorder is prescribed antiepileptic medication **THEN** the evaluation of symptoms should be used to monitor the medication regimen for effectiveness and side effects **BECAUSE** awareness of side effects is essential for safe use of AEDs and people with intellectual disability may have special conditions with regard to metabolism, sensitivity to medication effects including reduced capabilities to cope with side effects, and 'serum concentrations alone should not be used to adjust doses' (primarily because clear relationships between concentration and pharmacologic response - either efficacy or toxicity - have not been demonstrated) and individualizing dosage is as essential as choosing the correct AED.

QI No 23 - Anti-Depressant Medication and the Serotonin Syndrome

IF a person ageing with intellectual disability and a behaviour disorder is prescribed SSRIs (selective serotonin reuptake inhibitors) or MAOIs (mono amine oxidase inhibitors) medication in combination or at higher doses **THEN** 'serotonin syndrome' should be considered if the patient develops confusion, motor restlessness and tremor **BECAUSE** the addition of medications with additive serotonin effect or medication to suppress the symptoms, may be considered to jeopardise the patients health or safety and the higher the dosage the greater the chance of side effects emerging.

QI No 24 - Off Label Prescribing of Anti-Psychotic Medication

IF a person ageing with intellectual disability is prescribed psychotropic medication 'off label' (off license) **THEN** good case note documentation of the process is important

and supports the prescriber, pharmacist and administrator of the medication

BECAUSE 'off label' prescribing is common in patients with intellectual disability and mental illness and clinicians must consider the evidence that the medication is likely to be effective for the unlicensed indication and any risks involved.

QI No 25 - Excessive Dose of Anti-Psychotic Medication

IF a person ageing with intellectual disability and a behaviour disorder is prescribed an 'excessive dose' – [giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence based studies from medical/ pharmacy journals, or standards of practice for the patient's age and condition] - of an antipsychotic medication **THEN** the prescriber must document a clinically pertinent rationale for the prescription that should only be used in exceptional circumstances after full discussion with all the relevant stakeholders under appropriate safeguards and regular reviews **BECAUSE** an excessive dose may be (1) inappropriate and 'unlicensed', (2) may have the potential to cause harm to the patient and (3) may not be supported by medical-legal frameworks.

QI No 26 - Gradual Dose Reduction

IF a person ageing with intellectual disability is prescribed regular anti-psychotic medication for a behaviour disorder **THEN** gradual dose reduction must be attempted (unless contraindicated) with implementation of behavioural interventions to enable reduction or discontinuation **BECAUSE** prolonged antipsychotic medication therapy may result in functional decline, somnolence, lethargy, tremors, increased falling or impaired ambulation.

QI No 27 - PRN Prescribing of Psychotropic Medication

IF a person ageing with intellectual disability is prescribed 'prn' (as required) medication for a behaviour disorder **THEN** the use of 'prn' medication should be reserved for behaviours that occur infrequently, without provocation and that do not diminish in intensity **BECAUSE** the regular use of a 'prn' for more than a few weeks is indicative of a need to further explore environmental etiology or take a systematic review of treatment regime and 'prn' use may be associated with poly-pharmacy.

QI No 28 - Dysphagia

IF a person ageing with intellectual disability and a behaviour disorder is assessed by a Speech and Language Therapist to have dysphagia **THEN** this should be

communicated in a formal manner to relevant professionals including GP, psychiatrist, pharmacist, dietician, nurse/carer/family using standardised language **BECAUSE** multidisciplinary and carer/family awareness of dysphagia and awareness of risks posed by medication use in relation to dysphagia (which can include aspiration, upper airway obstruction, malnutrition, dehydration and increased mortality) is needed to ensure patient safety.

QI No 29 - Gastro-Intestinal Disorders

IF a patient ageing with intellectual disability presents with a behaviour disorder (including hand-mouthing) **THEN** possible gastrointestinal disorders should be considered before psychotropic medication is used **BECAUSE** gastrointestinal disorders are prevalent in patients with intellectual disability and if not treated may contribute to behaviour disorders and gastro-oesophageal reflux disease has been shown to be present in greater frequency among individuals with hand mouthing than among matched peers who did not engage in hand mouthing.

QI No 30 - Dementia and Cholinesterase Inhibitors

IF a person ageing with intellectual disability is diagnosed with dementia **THEN** quality of life should be considered before cholinesterase inhibitors are prescribed **BECAUSE** the adverse effects of the cholinesterase inhibitors and memantine should be taken into account and potential harm should be balanced against modest benefit (and in some cases no benefit).

QI No 31 - Dementia and Anti-Psychotic Medication

IF a person ageing with intellectual disability and dementia presents with a behaviour disorder **THEN** any prescribed anti-psychotic medication should be monitored and reviewed regularly **BECAUSE** an increased long-term risk of mortality in patients with Alzheimer's disease who are prescribed anti-psychotic medication has been identified and the risk should be considered within the context of medical need for the drugs, efficacy evidence, medical co-morbidity and the efficacy and safety of alternatives.

QI No 32 - Dementia and Cholinesterase Inhibitors and Anti-Cholinergic Medications

IF a person ageing with intellectual disability, behaviour disorders and dementia is prescribed a cholinesterase inhibitor **THEN** a medication review should be undertaken **BECAUSE** the concurrent use of cholinesterase inhibitors and anti-cholinergic medications such as tricyclic anti-depressants, anti-spasmodics, anti-histamines, is

common and is likely to negate the already small effect of the cognition enhancing Alzheimer treatment and is rarely appropriate.

QI No 33 - Sleep and Behaviour Disorders

IF a person ageing with intellectual disability develops behaviour disorders connected to sleep **THEN** a medication review and sleep history should be undertaken before medication is prescribed **BECAUSE** a diagnosis of short or long term insomnia should be made to rule out sleep apnoea, depressive symptoms, side effects of current medications and caffeine consumption.

QI No 34 - Insomnia Treatment

IF a person ageing with intellectual disability and a behaviour disorder requires pharmacological treatment (when appropriate) for insomnia **THEN** short term use only should be considered **BECAUSE** underlying causes of the insomnia should be identified and treated to minimise possible adverse effects of hypnotics and multiple medication use/poly-pharmacy.

QI No 35 - Pain

IF a person ageing with intellectual disability presents with a behaviour disorder and/or physical discomfort **THEN** a strong index of suspicion with regard to pain should be maintained before psychotropic medication is prescribed **BECAUSE** pain is a complex process people with intellectual disability are at increased risk for chronic pain and under treatment of physical pain may occur if psychotropic medications are prescribed as they may mask the signs of physical pain and any physical problems that causes pain or distress can also cause difficulty in focusing attention, sleeping and eating, as well as psycho-motor agitation and may be treated as a behaviour disorder.

QI No 36 - Infection

IF a person ageing with intellectual disability prescribed psychotropic medication requires treatment with an antibiotic **THEN** the effect on Cytochrome P (CYP) enzymes of all prescribed medications should be reviewed **BECAUSE** several psychotropic medications are metabolized by CYP enzymes, and physicians and pharmacists and others involved in the medication use process should be aware co-administered drugs including antibiotics may inhibit or induce these CYP enzymes.

QI No 37 - Autistic Spectrum Disorder

IF a person ageing with intellectual disability and an autistic spectrum disorder (ASD) is

prescribed medication **THEN** there should be continual review of their reactions to medications prescribed **BECAUSE** people with ASD may show intolerance to medications and/or allergic reactions to food ingredients of medications, such as yeast or gluten and also casein, their reactions to stimuli can range across a wide spectrum and the touch (feel), appearance and smell of medication may appear to be abnormal to people with ASD and may be associated with the presentation of behaviour disorders.

QI No 38 – Dental/Oral Health

IF a person ageing with intellectual disability presents with behaviour disorder **THEN** before medication is prescribed the person's dental/oral health should be considered **BECAUSE** the prevalence of untreated dental caries is higher among people with intellectual disability and may be linked to frequent vomiting or gastro-esophageal reflux, less than normal amounts of saliva, medications containing sugar, or special diets that require prolonged bottle feeding or snacking and may result in behaviour disorders.

APPENDIX 2

Research Ethics Committee Approval for Quality Indicators Project



THE UNIVERSITY OF DUBLIN

TRINITY COLLEGE

SCHOOL OF MEDICINE

FACULTY OF HEALTH SCIENCES

Professor Dermot Kelleher, MD, FRCPI, FRCP, F Med Sci
Head of School of Medicine
Vice Provost for Medical Affairs

Ms Fedelma McNamara
School Administrator

Trinity College, Dublin 2, Ireland

Tel: +353 1 896 1476

Fax: +353 1 671 3956

email: medicine@tcd.ie

email: medschadmin@tcd.ie

Ms Bernadette Flood,
St Clares,
Fernslock,
Kilcock,
Co Kildare

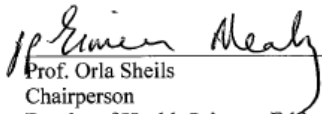
Monday, 17 May 2010

Study: Quality Indicators for medication use in people ageing with Intellectual Disability and Behaviour Disorders.

Dear Applicant (s),

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in February 2010, we are pleased to inform you that the above project has been approved without further audit.

Yours sincerely


Prof. Orla Sheils
Chairperson
Faculty of Health Sciences Ethics Committee

Cc
Dr Martin Henman,
School of Pharmacy,
Trinity College
Dublin 2

APPENDIX 3

Quality Indicator Project – Information for Delphi Panel Participants

QUALITY INDICATORS FOR MEDICATION USE IN PEOPLE AGEING WITH INTELLECTUAL DISABILITY AND BEHAVIOUR DISORDERS

INFORMATION FORM 1

My name is Bernadette Flood. I am a pharmacist working full time in a residential centre for people with intellectual disability. I am in my second year as a Ph D student in the School of Pharmacy in Trinity College Dublin. My research supervisor is Dr Martin Henman, Senior Lecturer in Pharmacy Practice, School of Pharmacy.

I am conducting a research study to identify by consensus, Quality Indicators for medication use for people ageing with intellectual disability and behaviour disorders

The study will involve the use of a Modified Delphi Technique with a panel of 'experts'.

This modified Delphi Technique, is being used to determine the extent of agreement on the Quality Indicators, obtaining expert input from individuals who are dispersed geographically. The panel will be composed of members recognized as knowledgeable of or practicing in, the areas of medication management, intellectual disability healthcare, intellectual disability clinical practice, research or education.

This modified Delphi Technique, is being used to determine the extent of agreement on the Quality Indicators, obtaining expert input from individuals who are dispersed geographically. The panel of experts are being invited to take part in a series of 2 rounds to identify, clarify, and finally gain consensus on the Quality Indicators. This modified Delphi Technique will use email as the medium for conducting the study. The process begins with a set of carefully selected items drawn from various sources including reviews of the literature, peer discussion and expert opinion.

It is hoped that the research will benefit

- i) those ageing with intellectual disability and behaviour disorders in Ireland
and
- ii) those involved in medication management in the care of people ageing with intellectual disability and behaviour disorders in Ireland.

A second part of the project will involve members of the population with intellectual disability , to ensure that people with intellectual disability, who are ‘ the experts’ in relation to medication use in their population, are also involved in this research project

You can get more information or answers to your questions about the study from Bernadette Flood who may be contacted at email beflood@tcd.ie and telephone number 01-8248640 and Dr Martin Henman at email mhenman@tcd.ie

TITLE:

QUALITY INDICATORS (QIs) for Medication Use in People Ageing with Intellectual Disability and Behaviour Disorders. Nov 2010

The following survey is part of a PhD research project.

You have kindly agreed and consented to be a member of the 'expert' panel undertaking this survey.

Quality Indicators are explicitly defined and measurable items referring to the structures, processes or outcomes of care. They infer a judgement about the quality of care provided

The QIs have been identified following literature and guideline review and discussion by researcher and supervisor.

You are asked to rate each QI under the following 3 headings-

1. Important: Quality assurance is conducted by defining key areas of importance associated with expected benefit. A QI is a key concept in the context of quality assurance and is defined as follows: a specially selected measure or attribute that may indicate and point to good or poor quality.
2. Scientifically sound: The standards of good clinical practice in this investigation are based on best scientific evidence when present; otherwise, they were based on consensus of a panel of experts where available and / or relevant guidelines.
3. Feasible: Feasibility of measurement can relate to chart review or interview. The level of documentation is, in itself, an indicator of performance; poor documentation may represent poor quality patient care.

(Feasibility here does not relate to feasibility of implementation eg due to staff shortages).

Limited Background Information is supplied for each QI.

Please return the completed survey before Dec 8th 2010.

Survey compiled by - Bernadette Flood MPSI

PhD student, School of Pharmacy & Pharmaceutical Sciences, TCD.

Project Supervisor - Dr Martin Henman MPSI

APPENDIX 4

APPENDIX 4A

Demographic Options for Round 1 Panel Members

Demographic Options for Round 1 Panel of Expertise.		
Demographic Question Number	Subject	Options for Panel in 'Drop Down' Boxes In Survey Monkey
Question 1 (Q1)	Gender	Male, Female, No answer
Question 2 (Q2)	Age	<40 years, 40-49 years, 50-59 years, 60-69 years, No answer
Question 3 (Q3)	Principal Work Setting	Pharmacy, Psychiatry, General Medicine, Geriatric Medicine, Psychology, Speech and Language Therapy, Nursing, Academia, Administration, Regulation, Other, No answer
Question 4 (Q4)	Current Position	Practitioner ID, Consultant, Lecturer, Researcher, Administrator, Other, No answer
Question 5 (Q5)	Academic Qualification	Diploma, Bachelor's Degree, Master's Degree, PhD, Higher Diploma, Other, No answer
Question 6 (Q6)	Work with Intellectual Disability	Full time, Part time, Occasionally, Not at all, Never, Other, No answer
Question 7 (Q7)	Experience Since Qualifying	<10 years, 10-19 years, 20-29 years, 30-39 years, 40 years plus, No answer

APPENDIX 4B

Demographic Information Supplied by Round 1 Panel of Expertise

Demographic Information Supplied by Round 1 Panel of Expertise n = 28							
No	Q1	Q2	Q3	Q4	Q5	Q6	Q7
1	F	<40 years	Pharmacy	Practitioner ID	Master's	Not at all	10-19
2	F	40-49 years	Nursing	Other	Master's	Full	20-29
3	M	60-69 years	Other	Researcher	PhD	Full	40 plus
4	M	40-49 years	Nursing	Consultant	PhD	Full	30-39
5	F	40-49 years	Psychiatry	Consultant	Master's	Part	20-29
6	F	<40 years	Pharmacy	Researcher	PhD	Not at all	10-19
7	F	<40 years	Psychology	Consultant	Master's	Full	<10
8	M	<40 years	Lecturer	Practitioner ID	Bachelors	Part	<10
9	M	50-59 years	Psychiatry	Consultant	Other	Full	20-29
10	M	60-69 years	Psychology	Practitioner ID	PhD	Full	30-39
11	M	60-69 years	Pharmacy	Practitioner ID	PhD	Occasion	20-29
12	F	40-49 years	Regulation	Other	Master's	Other	10-19
13	F	50-59 years	Pharmacy	Practitioner ID	Master's	Not at all	20-29
14	F	40-49 years	Administration	Administrator	Bachelors	Not at all	30-39
15	F	<40 years	S+LT	Other	Master's	Not at all	<10
16	M	No information provided					
17	M	40-49 years	Psychiatry	Consultant	No answer	Occasion	20-29
18	M	No information provided					
19	M	50-59 years	Academia	Lecturer	Other	Other	30-39
20	F	No information provided					
21	F	40-49 years	Academia	Lecturer	Master's	Occasion	10-19
22	M	40-49 years	Geriatric Med	Consultant	PhD	Occasion	40 plus
23	F	40-49 years	Pharmacy	Other	Bachelors	Full	20-29
24	F	50-59 years	S+LT	Other	PhD	Part	30-39
25	M	50-59 years	Academia	Researcher	PhD	Occasion	30-39
26	F	<40 years	Psychology	Practitioner ID	PhD	Full	<10
27	M	<40 years	Academia	Lecturer	Master's	Occasion	10-19
28	M	50-59 years	Nursing	Lecturer	Master's	Full	20-29

APPENDIX 4C

Demographic Characteristics Provided by Round 1 Panel Members

Demographic Characteristics Provided by Round 1 Panel Members (25 of 28)		
Characteristic	Number of Panel Members who Provided Information n = 25	% of Panel n = 25
Gender		
Male	12	48%
Female	13	52%
Age		
<40 years	7	28%
40-49 years	9	36%
50-59 years	6	24%
60-69 years	3	12%
Principal Work		
Pharmacy	5	20%
Psychiatry	4	16%
Geriatric Medicine	1	4%
Psychology	3	12%
Speech and Language Therapy	2	8%
Nursing	3	12%
Academia	4	16%
Regulation	1	4%
Administration	1	4%
Current Position		
Practitioner ID	6	24%
Consultant	6	24%
Lecturer	4	16%
Researcher	3	12%
Administrator	1	4%
Other	5	20%
Academic Qualification		
Bachelor's Degree	3	12%
Master's Degree	10	40%
PhD	9	36%
Other	2	8%
No answer	1	4%
Work with People with Intellectual Disability		
Full time	9	36%
Part time	3	12%
Occasionally	6	24%
Not at all	5	20%
Other	2	8%
Experience Since Qualifying		
<10 years	4	16%
10-19 years	5	20%
20-29 years	8	32%
30-39 years	6	24%
40 years plus	2	8%

APPENDIX 5

APPENDIX 5A

Pharmacists' Rating of Round 1 Candidate Quality Indicators

Quality Indicators (Number and Abbreviated Title)	Number of Pharmacists Who Rated this Quality Indicator (n = 5)		
	Important	Scientifically Sound	Feasible
1 Informational Transfer	5	4	5
2 Communication	5	4	2
3 General Health Review	5	4	3
4 Geriatric Syndromes	4	3	2
5 Nonpharmacological Interventions	4	3	2
6 External Environment	5	4	4
7 Pharmacist/Specialist Team	4	2	2
8 Acute Behaviour	1	1	1
9 Residential Care	3	2	2
10 Medication Reconciliation	5	4	4
11 Advocate	2	5	1
12 Medication Regimen Review	5	5	2
13 Restrictive Practice	5	4	2
14 Covert Medication	5	5	3
15 Adverse Drug Reactions	3	3	3
16 Poly-Pharmacy	4	3	3
17 Inter-Intra Class Poly-Pharmacy	2	2	1
18 Psychotropic Medication	5	4	4
19 Psychotropic Medication Physical Side Effects	5	4	4
20 Anticholinergic Medication	4	3	4
21 Neuroleptic Side Effects	3	3	2
22 Anti-Epileptic Medications	4	2	2
23 Anti-Depressant Medications Serotonin Syndrome	4	3	3
24 Off Label Anti-Psychotic Medications	4	2	3
25 Excessive Dose Anti-Psychotic Medications	5	4	5
26 Gradual Dose Reduction	5	4	3
27 As Required 'PRN' Psychotropic Medications	5	2	4
28 Dysphagia	4	3	3
29 Gastro-Intestinal Tract	2	2	3
30 Dementia Cholinesterase Inhibitors	1	1	1
31 Dementia Ant-Psychotic Medications	5	5	4
32 Dementia Cholinesterase Inhibitors Anti-Cholinergic Medications	4	4	4
33 Sleep Behaviour Disorder	4	3	2
34 Insomnia Treatment	5	5	4
35 Pain	4	2	2
36 Infections	4	4	3
37 Autistic Spectrum Disorder	1	5	5
38 Dental Oral Health	1	0	1

APPENDIX 5B

Psychiatrists' Rating of Round 1 Candidate Quality Indicators

Quality Indicators (Number and Abbreviated Title)	Number of Psychiatrists who Rated this Quality Indicator (n = 4)		
	Important	Scientifically Sound	Feasible
1 Informational Transfer	4	3	4
2 Communication	4	3	3
3 General Health Review	4	4	3
4 Geriatric Syndromes	4	4	4
5 Nonpharmacological Interventions	4	4	3
6 External Environment	4	3	3
7 Pharmacist/Specialist Team	3	2	2
8 Acute Behaviour	3	3	2
9 Residential Care	4	4	3
10 Medication Reconciliation	3	3	2
11 Advocate	3	1	1
12 Medication Regimen Review	2	2	2
13 Restrictive Practice	4	4	3
14 Covert Medication	4	3	1
15 Adverse Drug Reactions	3	3	3
16 Poly-Pharmacy	4	4	2
17 Inter-Intra Class Poly-Pharmacy	4	4	2
18 Psychotropic Medication	5	4	4
19 Psychotropic Medication Physical Side Effects	4	4	3
20 Anticholinergic Medication	4	4	3
21 Neuroleptic Side Effects	4	4	4
22 Anti-Epileptic Medications	4	3	3
23 Anti-Depressant Medications Serotonin Syndrome	4	4	3
24 Off Label Anti-Psychotic Medications	3	3	4
25 Excessive Dose Anti-Psychotic Medications	4	4	3
26 Gradual Dose Reduction	4	4	3
27 As Required 'PRN' Psychotropic Medications	4	3	2
28 Dysphagia	4	4	4
29 Gastro-Intestinal Tract	4	4	4
30 Dementia Cholinesterase Inhibitors	2	2	2
31 Dementia Ant-Psychotic Medications	4	4	3
32 Dementia Cholinesterase Inhibitors Anti-Cholinergic Medications	3	2	2
33 Sleep Behaviour Disorder	4	4	3
34 Insomnia Treatment	4	4	3
35 Pain	4	4	3
36 Infections	4	4	4
37 Autistic Spectrum Disorder	2	3	1
38 Dental Oral Health	4	4	3

APPENDIX 6

APPENDIX 6A

Round 1 Candidate Quality Indicators: First Analysis

Round 1 Candidate Quality Indicators First Analysis QIs Rated 7-8-9 by % of Panel						
<i>Quality Indicator (Number and abbreviated title)</i>	<i>This QI is Important</i>	<i>(n)</i>	<i>This QI is Scientifically Sound</i>	<i>(n)</i>	<i>This QI is Feasible</i>	<i>(n)</i>
1. Informational Transfer	96.4%	28	75.0%	28	83.0%	28
2. Communication	96.4%	28	78.6%	28	71.4%	28
3. General Health Review	92.9%	28	82.1%	28	75.0%	28
4. Geriatric Syndromes	85.7%	28	67.9%	28	67.9%	28
5. Nonpharmacological Interventions	89.3%	28	78.6%	28	78.6%	28
6. External Environment	89.3%	28	75.0%	28	82.1%	28
7. Pharmacist/Specialist Team	75.0%	28	60.7%	28	46.4%	28
8. Acute Behaviour	75.0%	28	71.4%	28	67.9%	28
9. Residential Care	78.6%	28	75.0%	28	71.4%	28
10. Medication Reconciliation	85.7%	28	78.6%	28	75.0%	28
11. Advocate	75.0%	28	42.9%	28	39.3%	28
12. Medication Regimen Review	82.1%	28	71.4%	28	60.7%	28
13. Restrictive Practice	92.9%	28	85.7%	28	75.0%	28
14. Covert Medication	89.3%	28	71.4%	28	60.7%	28
15. Adverse Drug Reactions	77.0%	27	77.8%	27	63.0%	27
16. Poly-Pharmacy	88.9%	27	85.2%	27	70.4%	27
17. Inter-Intra Class Poly-Pharmacy	74.1%	27	70.4%	27	59.3%	27
18. Psychotropic Medication	88.0%	27	85.2%	27	77.8%	27
19. Psychotropic Medication Physical Side Effects	88.9%	27	77.8%	27	74.1%	27
20. Anticholinergic Medication	88.9%	27	81.5%	27	77.8%	27
21. Neuroleptic Side Effects	85.2%	27	81.5%	27	81.5%	27
22. Anti-Epileptic Medications	88.9%	27	74.1%	27	74.1%	27
23. Anti-Depressant Medications Serotonin Syndrome	88.9%	27	81.5%	27	74.1%	27
24. Off Label Anti-Psychotic Medications	88.9%	27	74.1%	27	70.4%	27
25. Excessive Dose Anti-Psychotic Medications	92.6%	27	85.2%	27	74.1%	27
26. Gradual Dose Reduction	92.6%	27	85.2%	27	74.1%	27
27. As Required 'PRN' Psychotropic Medications	96.2%	27	76.9%	27	80.8%	27
28. Dysphagia	85.2%	27	81.5%	27	80.8%	27
29. Gastro-Intestinal Tract	78.8%	27	74.1%	27	77.8%	27
30. Dementia Cholinesterase Inhibitors	70.4%	27	55.6%	27	55.6%	27
31. Dementia Anti-Psychotic Medications	92.6%	27	88.9%	27	77.9%	27
32. Dementia Cholinesterase Inhibitors Anti-Cholinergic Medications	74.1%	27	74.1%	27	70.4%	27
33. Sleep Behaviour Disorder	85.2%	27	81.5%	27	74.1%	27
34. Insomnia Treatment	88.9%	27	88.9%	27	76.0%	25
35. Pain	92.3%	26	76.9%	26	69.2%	26
36. Infections	77.8%	27	70.4%	27	65.4%	26
37. Autistic Spectrum Disorder	59.3%	27	40.7%	27	48.1%	27
38. Dental Oral Health	77.8%	27	61.5%	27	66.8%	27

APPENDIX 6B

Quality Indicators with High Level Round 1 Consensus

Quality Indicators with High Level of Round 1 Consensus						
<i>Quality Indicator (Number and title)</i>	<i>This QI is Important</i>	<i>Number</i>	<i>This QI is Scientifically Sound</i>	<i>Number</i>	<i>This QI is Feasible</i>	<i>Number</i>
1. Informational Transfer	96.4%	28	75.0%	28	83.0%	28
3. General Health Review	92.9%	28	82.1%	28	75.0%	28
5. Non-Pharmacological Interventions	89.3%	28	78.6%	28	78.6%	28
6. External Environment	89.3%	28	75%	28	82.1%	28
10. Medication Reconciliation	85.7%	28	78.6%	28	75.0%	28
13. Restrictive Practice	92.9%	28	85.7%	28	75.0%	28
18. Psychotropic Medication	88.0%	27	85.2%	27	77.8%	27
20. Anticholinergic Medication	88.9%	27	81.5%	27	77.8%	27
21. Neuroleptic Side Effects	85.2%	27	81.5%	27	81.5%	27
27. As Required Psychotropic Medications	96.2%	27	76.9%	27	80.8%	27
28. Dysphagia	85.2%	27	81.5%	27	80.8%	27
31. Dementia Anti-Psychotic Medications	92.6%	27	88.9%	27	77.9%	27
34. Insomnia Treatment	88.9%	27	88.9%	27	76.0%	25

APPENDIX 7

Ranked Mean for Importance Round 1 Quality Indicators

Ranked Mean Importance Round 1 QIs			
<i>R1 Quality Indicator Abbreviated title</i>	<i>Important</i>		
	<i>R1 Mean</i>	<i>% R1 Panel Rated QI 7-8-9</i>	<i>R1 Consensus Achieved</i>
Communication	8.57	96.4	Yes
Informational Transfer	8.54	96.4	Yes
Health Review	8.54	92.9	Yes
Restrictive Practice	8.50	92.9	Yes
As Required Psychotropic	8.46	96.2	Yes
XS Dose Antipsychotics	8.44	92.6	Yes
Gradual Dose Reduction	8.37	92.6	Yes
Psychotropic Meds	8.33	88.0	Yes
Pain	8.31	92.3	Yes
Dementia Antipsychotics	8.30	92.6	Yes
Non Pharmacological Interventions	8.21	89.3	Yes
Poly Pharmacy	8.19	88.9	Yes
Psychotropic Meds-Physical Side Effects	8.19	88.9	Yes
Insomnia Treatment	8.19	88.9	Yes
Medication Reconciliation	8.18	85.7	Yes
Dysphagia	8.15	85.2	Yes
External Environment	8.14	89.3	Yes
Neuroleptic Side Effects	8.07	85.2	Yes
Sleep Behaviour Disorders	8.07	85.2	Yes
Anti-Cholinergic Meds	8.04	88.9	Yes
AEDS	8.00	88.9	
Anti Depressant Serotonin Syndrome	7.96	88.9	Yes
Geriatric Syndromes	7.93	85.7	
Pharmacist/Specialist Team	7.89	75.0	
Off Label Anti-Psychotic	7.89	88.9	
Covert Medication	7.82	89.3	
Inter-Intra Class Poly-Pharmacy	7.81	74.1	
Adverse Drug Reactions	7.78	77.0	Yes
GIT	7.74	78.8	
Medication Regimen Review	7.71	82.1	
Dental Health	7.70	77.8	
Acute Behaviour	7.57	75.0	
Advocate	7.54	75.0	
Residential Care	7.46	78.6	Yes
Dementia Cholinesterase Inhibitors/Anti-Cholinergics	7.41	74.1	
Dementia – Cholinesterase Inhibitors	7.30	70.4	
Infections	7.19	77.8	
Autism Spectrum Disorder	6.70	59.3	

APPENDIX 8

Round 1 Quality Indicators Mean, Median, Mode and Standard Deviation

Round 1 QIs Mean, Median, Mode and Standard Deviation												
Quality Indicator Abbreviated Title	Important				Scientifically Sound				Feasible			
	Mn	Md	Mo	SD	Mn	Md	Mo	SD	Mn	Md	Mo	SD
Informational Transfer	8.54	9	9	0.99	7.14	7	9	1.83	7.68	9	9	1.83
Communication	8.57	9	9	0.96	7.64	8	9	1.57	7.36	8	9	1.64
Health Review	8.54	9	9	1.14	7.86	9	9	1.65	7.93	9	9	1.46
Geriatric Syndromes	7.93	9	9	1.46	7.18	8	9	2.06	7.11	7	9	1.93
Non Pharmacol Interventions	8.21	9	9	1.26	7.79	9	9	1.60	7.57	8	9	1.69
External Environment	8.14	9	9	1.27	7.61	8	9	1.60	7.79	9	9	1.45
Pharmacist/Specialist team	7.89	9	9	1.45	7.14	7.5	9	1.86	6.36	6	9	1.86
Acute Behaviour	7.57	9	9	2.24	7.21	8	9	2.20	6.75	7	7	2.21
Residential Care	7.46	9	9	2.60	7.29	9	9	2.71	7.14	8.5	9	2.69
Medication Reconciliation	8.18	9	9	1.66	7.71	9	9	1.74	7.21	7.5	9	1.77
Advocate	7.54	8	9	1.50	6.39	6	5	1.99	6.25	6	5	2.03
Med Regimen Review	7.71	9	9	1.63	7.5	8.5	9	1.84	7.00	7	9	1.68
Restrictive Practice	8.50	9	9	1.17	7.79	8	9	1.42	7.57	9	9	1.99
Covert Medication	7.82	9	9	1.95	7.00	7	9	2.11	6.54	7	7	2.13
ADRs	7.78	9	9	1.74	7.59	8	9	1.76	6.74	7	7	1.99
Poly-Pharmacy (PP)	8.19	9	9	1.33	7.93	9	9	1.62	7.26	7	9	1.93
Inter-Inter Class PP	7.81	9	9	1.71	7.52	9	9	1.85	6.96	7	9	1.93
Psychotropic Meds	8.33	9	9	1.27	7.89	8	9	1.30	7.63	8	9	1.42
Psychotropic - Phys Side	8.19	9	9	1.30	7.81	9	9	1.50	7.52	8	9	1.65
Anti-Cholinergic Meds	8.04	9	9	1.29	7.59	8	9	1.45	7.56	8	9	1.48
Neuroleptic Side Effects	8.07	9	9	1.36	7.81	9	9	1.44	7.81	9	9	1.76
AEDs	8.00	9	9	1.21	7.48	8	9	1.89	7.37	8	9	1.94
AntiDep Serotonin Synd	7.96	9	9	1.29	7.52	7	9	1.42	7.37	8	9	1.82
Off Label Anti-Psychotic	7.89	9	9	1.85	7.48	8	9	1.89	7.37	8	9	2.10
XS Dose Anti-Psychotics	8.44	9	9	1.19	8.19	9	9	1.39	7.70	9	9	1.64
Gradual Dose Reduction	8.37	9	9	1.15	7.96	9	9	1.32	7.48	8	9	1.81
As Required Psychotropic	8.46	9	9	1.03	7.77	9	9	1.53	7.81	9	9	1.51
Dysphagia	8.15	9	9	1.51	7.96	9	9	1.65	7.88	9	9	1.45
GIT	7.74	8	9	1.40	7.33	7	9	1.57	7.44	7	9	1.42
Dementia Cholines Inhibs	7.30	7	9	1.90	6.81	7	5	1.90	6.74	7	5	1.93
Dementia Anti Psychotics	8.30	9	9	1.24	8.15	9	9	1.46	7.89	9	9	1.60
Dem Cholin Anticholin	7.41	8	9	1.99	7.26	7	9	1.91	7.19	7	9	2.02
Sleep Behaviour Disorder	8.07	9	9	1.41	7.81	9	9	1.57	7.56	8	9	1.72
Insomnia Treatment	8.19	9	9	1.27	7.96	9	9	1.45	7.52	8	9	1.85
Pain	8.31	9	9	1.16	7.81	9	9	1.67	7.46	8.5	9	1.84
Infections	7.19	8	9	2.29	7.04	8	9	2.36	6.81	7	9	2.33
Autistic Spectrum Disorder	6.70	7	9	2.00	6.19	6	5	2.22	6.56	6	5	1.97
Dental – Oral Health	7.70	9	9	1.66	6.92	7	9	1.81	7.11	7	9	1.74
Mn = Mean: Mo = Mode: Md = Median: SD = Standard deviation												

APPENDIX 9

List of Round 2 Candidate Quality Indicators

QI No 1 R2 - Geriatric Syndrome

IF a person ageing with intellectual disability and a behaviour disorder develops any geriatric syndrome **THEN** adverse reactions to medications and multiple medication use/poly-pharmacy that may be associated with specific geriatric syndromes should be assessed **BECAUSE** the process of ageing influences both pharmacodynamics and pharmacokinetics of medications and the adverse effects of medications such as sedation, increased confusion, constipation, postural instability, falls, incontinence, weight gain etc. and movement disorders must be minimized.

QI No 2 R2 - Pharmaceutical Care

IF a person ageing with intellectual disability is prescribed psychotropic medication for a behaviour disorder **THEN** pharmaceutical care should be available **BECAUSE** increasing numbers of people with intellectual disabilities are living into older age, creating important medication use challenges for healthcare clinicians and services and multiple medication use should be carefully monitored in the older population.

QI No 3 R2 - Acute Behaviour

IF medication is prescribed to manage an acute behaviour disorder in a person ageing with intellectual disability **THEN** the underlying causes of the behaviour or presenting symptoms must be identified and addressed (where possible) before medication is administered **BECAUSE** when the acute phase has stabilized the prescriber must consider if medication could be discontinued or reduced and low levels of intervention, accountability and supervision may place many people with behaviour problems at increased risk for ineffective and unnecessary interventions.

QI No 4 R2 - Advocate

IF medication is prescribed to manage a behaviour disorder in a person ageing with intellectual disability **THEN** advocacy services should be available to the person with intellectual disability and/or their carers to explore intervention options **BECAUSE** an advocate from outside the clinical team, should help determine the person's interests to minimize restrictions to freedom and to take past and present wishes into account and there are no clear prohibitions about a non-medical mental health professional talking with clients about psychotropic medication (although this is still a grey area).

QI No 5 R2 - Medication Regimen Review

IF a person ageing with intellectual disability and a behaviour disorder is prescribed medication(s) **THEN** the medication regimen of the patient should be reviewed by qualified multidisciplinary personnel, preferably on site (if living in a residential setting) at least 3 monthly **BECAUSE** medication review will ensure thorough evaluation of the medication used by a vulnerable patient and medication review is increasingly seen as a cornerstone of medicines management.

QI No 6 R2 - Covert Medication

IF medication is administered in a covert manner to a person ageing with intellectual disability and a behaviour disorder **THEN** the healthcare personnel/family member/carer involved in the practice of administering medication covertly should be fully aware of the aims, intent and implications of such treatment and the safety profile of the medication **BECAUSE** the best interests of the patient are paramount covert administration of medication may involve the administration of a medication outside the terms of its licence and put the patient at risk and ethical as well as legal issues are inherent in the practice of covert medication with a potential scope for misuse and abuse.

QI No 7 R2 - Inter and Intra Class Psychotropic Poly-Pharmacy

IF a person ageing with intellectual disability and a behaviour disorder is prescribed psychotropic medication **THEN** psychotropic poly-pharmacy should be avoided (where possible) **BECAUSE** limiting poly-pharmacy is a critical clinical issue, as interclass/intraclass poly-pharmacy may result in adverse medication effects and/or non-compliance and many people ageing with intellectual disability receive medication over long periods with no clear diagnostic guidelines for the concurrent use of antipsychotic medications from different classes.

QI No 8 R2 – Anti-Epileptic Medication

IF a person ageing with intellectual disability and a behaviour disorder is prescribed antiepileptic medication **THEN** there should be heightened awareness of potential side effects **BECAUSE** people with intellectual disability may have special conditions with regard to metabolism, sensitivity to medication effects, including reduced capabilities to cope with and report side effects and all patients should be monitored for notable changes in behaviour that could indicate the emergence or worsening of suicidal thoughts or behaviour or depression.

QI No 9 R2 - 'Off Label' Psychotropic Medication

IF a person ageing with intellectual disability and a behaviour disorder is prescribed 'off label' psychotropic medication **THEN** good case note documentation of the process is important and supports the prescriber, pharmacist and administrator of the medication **BECAUSE** 'off label' prescribing is common in patients with intellectual disability and mental illness and clinicians must consider the evidence that the medication is likely to be effective for the unlicensed indication and any risks involved.

QI No 10 R2 - Gastrointestinal Disorders

IF a person ageing with intellectual disability presents with a behaviour disorder, (including hand-mouthing) **THEN** possible gastrointestinal disorders should be considered **BECAUSE** gastrointestinal disorders are prevalent in patients with intellectual disability and if not treated may contribute to behaviour disorders and gastro-oesophageal reflux disease has been shown to be present in greater frequency among individuals with hand mouthing than among matched peers who did not engage in hand mouthing.

QI No 11 R2 - Dementia Cholinesterase Inhibitors

IF a person ageing with intellectual disability is diagnosed with dementia **THEN** quality of life and possible side effects should be considered before cholinesterase inhibitors are prescribed **BECAUSE** prescribers should be aware of the potential risks when treating patients with cholinesterase inhibitors and the limited benefits of the cholinesterase inhibitors should be balanced against the potential risk of serious adverse events.

QI No 12 R2 - Dementia Cholinesterase Inhibitors and Anti-Cholinergic Medications

IF a person ageing with intellectual disability and dementia is prescribed an anti-cholinergic medication **THEN** a medication review should be undertaken of all prescribed medications **BECAUSE** between 20% to 50% of people with dementia take at least one medication with anti-cholinergic activity and optimising the management of all medication in dementia offers significant potential to improve dementia care.

QI No 13 R2 - Infections

IF behaviour change in a person ageing with intellectual disability causes concern **THEN** psychotropic medication should only be prescribed following a proper assessment and where a clear rationale for medication use has been identified

BECAUSE it must be recognised that medical conditions such as infections can be a contributory factor in behaviours disorders and high rates of hospitalisation for infections have been identified.

QI No 14 R2 - Autistic Spectrum Conditions

IF a person ageing with intellectual disability and an autistic spectrum condition is prescribed medication **THEN** there should be continual review of their reactions to medications prescribed **BECAUSE** people with autistic spectrum conditions may have altered sensory sensitivity and sensory processing difficulties and any change in any behaviour after medication administration has begun must be viewed, as an indicator of a possible side effect.

QI No 15 R2 - Dental and Oral Health

IF behaviour change is observed in a person ageing with intellectual disability **THEN** an oral health assessment should be included as part of a general health assessment **BECAUSE** people with intellectual disability have poor oral health/oral hygiene and reductions in salivary flow due to medication use are associated with increased incidence of dental caries (decay), gingivitis, oral candida and difficulties in eating and speaking.

APPENDIX 10

APPENDIX 10A

Round 2 Quality Indicators Survey Results

Round 2 Quality Indicators Survey Results			
Round 2 Quality Indicator Abbreviated Title	Importance 7-8-9	Scientific Soundness 7-8-9	Feasibility 7-8-9
Geriatric Syndrome	91.7%	83.3%	58.3%
Pharmaceutical Care	95.8%	75.0%	58.3%
Acute Behaviour	83.83%	58.3%	62.5%
Advocate	66.7%	41.7%	33.3%
Medication Review	100.0%	91.7%	83.3%
Covert Medication	95.8%	58.3%	70.8%
Inter-Intra Class Psychotropic Poly-Pharmacy	79.2%	66.7%	62.5%
Anti-Epileptic Medications	87.5%	58.3%	75.0%
Off Label Psychotropic Medication	79.2%	54.2%	66.7%
Gastro Intestinal Disorders	57.0%	70.8%	62.5%
Dementia - Cholinesterase Inhibitors	95.8%	75.0%	75.0%
Dementia Cholinesterase Inhibitors and Anti-Cholinergic Medications	83.3%	83.3%	75.0%
Infections	91.7%	79.2%	79.2%
Autism Spectrum Disorder	83.3%	50.0%	62.5%
Dental Oral Health	95.8%	79.2%	79.2%

APPENDIX 10B

Round 2 Quality Indicators Importance Ranking

Round 2 Quality Indicators Importance Ranking		
<i>Round 2 Quality Indicator</i>	<i>Rank R2 Importance (1-15)</i>	<i>This QI is Important 7-8-9</i>
Medication Review	1	100.00%
Pharmaceutical Care	2	95.80%
Covert Medication	3	
Dementia Cholinesterase Inhibitors	4	
Dental Oral Health	5	
Infections	6	
Geriatric Syndromes	7	91.70%
Anti-Epileptic Medication	8	87.50%
Acute Behaviour	9	83.83%
Dementia Cholinesterase Inhibitors and Anti-Cholinergic Medications	10	83.30%
Autism Spectrum Disorders	11	
Inter-Intra Class Psychotropic Poly- Pharmacy	12	79.20%
Off Label Psychotropic Medication	13	
Advocate	14	66.70%
Gastrointestinal Disorders	15	57.00%

APPENDIX 10C

Round 2 Quality Indicators Scientific Soundness Ranking

Round 2 Quality Indicators Scientific Soundness Ranking		
<i>Round 2 Quality Indicator</i>	<i>Rank on Scientific Soundness Scale (1-15)</i>	<i>Rated Scientifically Sound 7-8-9 by % Panel</i>
Medication Review	1	91.7%
Geriatric Syndrome	2	83.3%
Dementia Cholinesterase Inhibitors – Anti-Cholinergic Medications	3	
Infections	4	79.2%
Dental Oral Health	5	
Pharmaceutical Care	6	75.0%
Dementia Cholinesterase Inhibitors	7	
Gastro-Intestinal Disorders	8	70.8%
Inter-Intra Class Psychotropic Poly- Pharmacy	9	66.7%
Acute Behaviour	10	58.3%
Covert Medication	11	
Anti-Epileptic Medication	12	
Off Label Psychotropic Medication	13	54.2%
Autism Spectrum Disorder	14	50.0%
Advocate	15	41.7%

APPENDIX 10D

Round 2 Quality Indicators Feasibility Ranking

Round 2 Quality Indicators Feasibility Ranking		
<i>Round 2 Quality Indicator</i>	<i>Rank on Feasibility Scale (1-15)</i>	<i>Rated by % Panel as Feasible 7-8-9</i>
Medication Review	1	83.3%
Infections	2	79.2%
Dental Oral Health	3	
Anti-Epileptic Medication	4	75.0%
Dementia Cholinesterase Inhibitors	5	
Dementia Cholinesterase Inhibitors Anti-Cholinergic Medications	6	
Covert Medication	7	70.8%
Off Label Psychotropic Medications	8	66.7%
Acute Behaviour	9	62.5%
Inter Intra Class Poly-Pharmacy	10	
Gastrointestinal Disorders	11	
Autism Spectrum	12	
Geriatric Syndrome	13	58.3%
Pharmaceutical Care	14	
Advocate	15	33.3%

APPENDIX 11

Round 2 Quality Indicators: Mean, Median, Mode and Standard Deviation

Round 2 Quality Indicators: Mean, Median, Mode and Standard Deviation						
<i>Quality Indicator</i>	<i>Criteria</i>	<i>Valid</i>	<i>Mean</i>	<i>Median</i>	<i>Mode</i>	<i>SD</i>
Geriatric Syndromes R1 QI 4	I	24	8.08	9	9	1.18
	SS	24	7.13	8	7a	2.27
	F	24	6.46	7	7	2.06
Pharmaceutical Care R1 QI 7	I	24	8.04	9	9	1.27
	SS	24	7.08	7	7a	2.08
	F	24	6.63	7	9	2.22
Acute Behaviour R1 QI 8	I	24	7.83	9	9	1.69
	SS	24	6.96	8	9	2.39
	F	24	6.83	7	9	2.01
Advocate RI QI 11	I	24	6.54	7	7	2.25
	SS	24	5.75	5	5	2.67
	F	24	5.21	5	5	2.64
Medication Review R1 QI 12	I	24	8.75	9	9	0.61
	SS	24	7.88	9	9	1.94
	F	24	7.46	8	9	2.13
Covert Medication R1 QI 14	I	24	8.21	9	9	1.10
	SS	24	6.75	7	9	2.21
	F	24	7.13	7	9	2.05
Inter-Intra Class Poly-Pharmacy R1 QI 17	I	24	7.75	9	9	1.80
	SS	24	6.63	7.5	9	2.73
	F	24	6.79	7	9	2.36
Anti-Epileptic Medication R1 QI 22	I	24	8.04	9	9	1.20
	SS	24	7.08	7.5	9	2.00
	F	24	7.25	7	9	1.80
Off Label Psychotropic Medication R1 QI 24	I	24	7.67	7.5	9	1.40
	SS	24	6.92	7	5a	1.72
	F	24	7.21	7	9	1.77
Gastro Intestinal Disorders R1 QI 29	I	24	7.38	7.5	9	1.69
	SS	24	6.83	7	7a	2.28
	F	24	6.96	7	9	2.14
Dementia Cholinesterase Inhibitors R1 QI 30	I	24	7.75	7.5	7	1.39
	SS	24	7.21	7	9	2.09
	F	24	7.17	7	9	2.18
Dementia Chol Inhibitors and Anti-Cholinergic Medication R1 QI 32	I	24	7.71	9	9	2.12
	SS	24	7.54	8	9	2.06
	F	24	7.29	7.5	9	2.05
Infections R1 QI 36	I	24	8.00	9	9	1.53
	SS	24	7.63	8.5	9	1.69
	F	24	7.67	8.5	9	1.69
Autism Spectrum Disorder R1 QI 37	I	24	7.42	7.5	9	2.13
	SS	24	6.63	6.5	9	2.30
	F	24	6.79	7	9	2.34
Dental Oral Health R1 QI 38	I	24	8.21	9	9	1.02
	SS	24	7.88	8.5	9	1.33
	F	24	7.46	7.5	9	1.72

a = multiple modes exist. The smallest value is shown. I = important, SS = scientifically sound, F = feasible, SD = standard deviation.

APPENDIX 12

Survey Participation: Round 1 'Partials'

Survey Participation – Round 1 'Partials'						
Quality Indicators (Number)	<i>This QI is Important</i>	<i>Valid (n)</i>	<i>This QI is Scientifically Sound</i>	<i>Valid (n)</i>	<i>This QI is Feasible</i>	<i>Valid (n)</i>
15 Adverse Drug Reactions	1	27	1	27	1	27
16 Poly-Pharmacy	1	27	1	27	1	27
17 Inter Intra Class Poly-Pharmacy	1	27	1	27	1	27
18 Psychotropic Medication	1	27	1	27	1	27
19 Psychotropic Medication Physical Side Effects	1	27	1	27	1	27
20 Anti-Cholinergic Medication	1	27	1	27	1	27
21 Neuroleptic Side Effects	1	27	1	27	1	27
22 AntiEpileptic Medications	1	27	1	27	1	27
23 AntiDepressant Medications Serotonin Syndrome	1	27	1	27	1	27
24 'Off Label' Anti-Psychotic Medications	1	27	1	27	1	27
25 Excessive Dose Anti-Psychotic Medications	1	27	1	27	1	27
26 Gradual Dose Reduction	1	27	1	27	1	27
27 As Required 'PRN' Psychotropic Medications	2	26	2	26	2	26
28 Dysphagia	1	27	1	27	1	27
29 Gastro-Intestinal Tract	1	27	1	27	1	27
30 Dementia Cholinesterase Inhibitors	1	27	1	27	1	27
31 Dementia Ant-Psychotic Medications	1	27	1	27	1	27
32 Dementia Cholinesterase Inhibitors Anti-Cholinergic Medications	1	27	1	27	1	27
33 Sleep Behaviour Disorder	1	27	1	27	1	27
34 Insomnia Treatment	1	27	1	27	3	25
35 Pain	2	26	2	26	2	26
36 Infections	1	27	1	27	2	26
37 Autistic Spectrum Disorder	1	27	1	27	1	27
38 Dental Oral Health	1	27	2	26	1	27

APPENDIX 13

Panel Members who Consented to be Identified

NAME	QUALIFICATIONS AND OCCUPATION
Allison Dunne	B.Sc. (Pharm.), MSc (Psychiatric Pharmacy Practice), MPSI. Senior Pharmacist, Mental Health, Galway University Hospital, Galway, Ireland
Tamasine Grimes	B.Sc. (Pharm.), M.Sc. (Hosp. Pharm.), Ph.D., MPSI. Associate Professor (half-time) in Practice of Pharmacy, School of Pharmacy and Pharmaceutical Sciences , Panoz Institute, Trinity College, Dublin 2, Ireland
David Branford	PhD FRPharmS, FCMHP, Chief Pharmacist, Kingsway Site, Derbyshire Healthcare NHS Foundation NHS Trust, Derby DE22 3LZ, England
Frances Bruce Foley	B.Sc (Pharm), M.Sc, M.P.S.I. Community Pharmacist. Unit 8, Palmerstown Centre, Palmerstown, Dublin 20, Ireland
Joy Lee	B.Sc (Pharm), MPSI. Senior Pharmacist, Daughters of Charity Disability Support Services, Dublin 15, Ireland
Seamus Cowman	PhD, MSc, FAAN, FFNMRCISI, PG Cert Ed (Adults), Dip N (London), RNT, RGN, RPN. First Professor of Nursing at the Royal College of Surgeons in Ireland (RCSI), Dublin. Head of Department. Ireland
Sheila O Neill	RNID, Director of Nursing/Regional Director - South Kildare Region, Muiriosa Foundation, Moore Abbey, Monasterevin, Co. Kildare, Ireland
Michael Brown	PhD, MSc, PGCE, BSc (Hons), RGN,

	RNLD, FHEA, Reader in Health & Social Care and Nurse Consultant, Edinburgh Napier University, 16 Sighthill Campus, Sighthill Court, Edinburgh, Scotland
Avril Quinn	RNID, Cert. Multi-Element Behaviour Support, MSc Analysis and Intervention in Intellectual and Developmental Disabilities. Behaviour Support Specialist, Daughters of Charity Disability Support Services, Dublin, Ireland
Caroline Dalton-O Connor	RNID, MSc, BA Nursing Studies, RNID, PGDipTLHE, Branch Leader (Intellectual Disability Nursing) and Lecturer University College Cork, Ireland
Owen Doody	PhD, MSc, BSc, RNID, Lecturer, University of Limerick, Ireland
Richard Jackson	M Sc Nursing, RNID, Reg Nurse Tutor. Lecturer in Intellectual Disability Nursing, School of Nursing and Human Sciences, Dublin City University, Ireland
Roy McConkey	Emeritus Professor Of Developmental Disabilities, University of Ulster. Vice Chancellor's Private Office, Room H204, Campus: Jordanstown, Belfast, Northern Ireland
Andre van Rensburg	BA (Psych). BEd Ortho; BEd.Hon , MEd. (Psych), PhD (Psych), D.Phil FAAH (USA). Spec.Dip.Clin Rem.Ed.(US), PTC. HPA. IST. Reg Psych PSI; HPCSA. Previously: Principal Clinical Psychologist; Psychology Department Manager Daughters of Charity Services, Dublin, Ireland. Self-employed Developmental Cognitive Consultant, South Africa
Anne Kehoe	BA (Hons) Psychology, PhD Science, D. Clin. Psych. Linn Dara CAMHS, Cherry

	Orchard, Dublin 10, HSE, Ireland
Mike Kerr	FRCPSYCH, Professor Learning Disability Psychiatry, Welsh Centre for Learning Disabilities, 2nd Floor Neuadd Meirionnydd, Heath Park, Cardiff CF14 4YS, Wales
Noel P Hannan	MB.MCH.BAO, BMedSc (Member College of Psychiatrists of Ireland (Locum Consultant Psychiatrist, St. John of God Carmona/Kildare Services), Ireland
John Hillery	Consultant Psychiatrist at Stewarts Hospital Services Ltd, Dublin. MB, LRCPI and SI, FRCPsych, Ireland
Phillip Dodd	MB., MSc., MRCPsych., MA., MD.Consultant Psychiatrist/Director of Psychiatry. St. Michael's House, Dublin, Ireland
Denis O Mahoney	MD, FRCPI, FRCP, Consultant Physician and Senior Lecturer, UCC Medical School, Cork University Hospital, Wilton, Cork, Ireland
Anthony Cummins	MB, BCh, BAO, MRCP. Department of Family Medicine, Perdana University, 43400 Serdang, Selangor, Malaysia. Previously - Clinical lecturer/Academic Research Staff, Department of General Practice and HRB Centre for Primary Care Research, RCSI Medical School, Dublin 2, Ireland
Shaun O Keefe	MB BCh NUI, MRCPI, Geriatrician, Clinical Lecturer, Dept. of Medicine, Merlin Park Regional Hospital, Galway, Ireland
Louise Gallagher	MSc BSc MIASLT, Speech and Language Therapy Department, Level 2, Primary Care Centre, Letterkenny, Co. Donegal. Previously: Speech and Language

	Therapy Department, HSE-Beechpark Services, Bryan S. Ryan Building, Main Street, Tallaght, Dublin 24, Ireland
Clothra Ni Cholmain	PhD., Senior Speech and Language Therapists/Practice Education Coordinator, Department of Clinical Speech and Language Studies, School of Linguistic, Speech and Communication Sciences, Trinity College, Dublin 2, Ireland

APPENDIX 14

APPENDIX 14A

Participant Information Sheet

PRACTICE OF PHARMACY, SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES, TCD

Participant Information Sheet

This project has approval from Faculty of Health Sciences Research Ethics Committee, TCD

TITLE: People with Intellectual Disability:

Their views and knowledge of medication use.

Who is doing the research?

The person doing the research is called Bernadette. She is a pharmacist/chemist doing a project with people with intellectual disability.

For part of her project she needs to meet and speak with people with intellectual disability who take medicines /tablets.

What is the research about?

Bernadette is interested in trying to find out what it is like to take medicines / tablets .

She is looking for people who might be able to answer some questions for her.

Other people should hear what it is like for you to take medicines / tablets.

Page 1 of 4

Why me?

You take medicines / tablets.

Page 1 of 4

Bernadette needs about 3 – 4 - 5 people to help her out with the project.

She asked staff in XXXX to ask people who take medicines / tablets if they would like to be involved.

What will I have to do?

Bernadette wants to interview you about what it is like to take medicines / tablets.

There will an interview which will probably take about an hour , although if you want to have a break during the interview that is ok.

The interviews will take place in the XXXX building.

Will my interview be recorded?

Bernadette will bring a pen and paper to the interview.

This is so that Bernadette can make notes during the interview.

The notes will be locked away in a safe place when Bernadette's project is over. They will be destroyed after 5 years.

Who will be at the interview?

Bernadette will be there. You will be there.

ZZZZ ZZZZ will also be there - if you agree – so that Bernadette will understand all that you say.

Will anybody else get to know what I've told Bernadette?

No. What you tell Bernadette is private and confidential.

Bernadette (and ZZZZ, if she is there) are the only people who will know what you have said. During and after the meeting Bernadette will write down everything that you talked about during the meeting.

Bernadette will not write down your name, where you live or any other information that could let other people know what you said.

Bernadette's supervisor might want to read some of the information, but because your name will not be written down, he will not know that it was you who talked to Bernadette.

Bernadette will need to talk to your doctor if you tell her you are at risk or in danger.

What do I do if I want to take part?

If you want to be involved in this project the XXXX staff will tell Bernadette.

She will then phone up to arrange a time to meet with you and explain more about the research.

You will get the chance to ask any questions you want to.

You will need to sign a consent sheet for Bernadette to say that you have agreed to take part in the study.

You will get a copy of these sheets to keep.

Page 3 of 4

Can I change my mind later?

Yes.

You can change your mind at any time – either before you meet with Bernadette, or even when the interview has started.

Will I get a copy of what we talked about?

Yes.

Bernadette will give you a copy of the interview if you wish to get one

How can I contact Bernadette?

If you need to contact Bernadette before or during the project you should ring 01-8248640 or email her at beflood@tcd.ie.

If she isn't able to talk with you straight away, she will call you back as soon as possible.

You will be given a copy of the consent form when you have signed it

(Century Gothic Headings 16. Font 14 Ref; Haringey Council, NHS. Communication Plan. Adults with Learning Disabilities. Barnet,Enfield & Haringey2005.)

APPENDIX 14B

Participant Consent Form

PRACTICE OF PHARMACY, SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES, TCD

Participant Consent Form

People with Intellectual Disability:

Their views and knowledge of medication use.

This project has approval from Faculty of Health Sciences Research Ethics Committee, TCD

Consent Form

I..... agree to be part of Bernadette Flood's research study.

The purpose and nature of this study has been explained to me in writing or has been read to me .

I will take part in interviews with the researcher. My views and what I know about medicines / tablets will be discussed.

I have decided to take part.

I give permission for what I say during my interview with Bernadette to be written down.

I understand that if I tell Bernadette that I am at risk or in danger she will talk to my doctor.

I understand that I can leave the study, without any effect on me, at any time, whether before it starts or while I am taking part.

I understand that no one will know any information in this study belongs to me when the study is written up.

Bernadette will not use my name in her write up of this study.

Participant signature..... Date.....

Researcher signature..... Date

APPENDIX 14C

Information Leaflet for Support Organisation Personnel

PRACTICE OF PHARMACY, SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES, TCD

Information leaflet for XXXX personnel.

This project has approval from Faculty of Health Sciences Research Ethics Committee, TCD

TITLE: People with Intellectual Disability:

Their views and knowledge of medication use.

I am a pharmacist undertaking a Ph D research project in the School of Pharmacy & Pharmaceutical Sciences in TCD. There are two parts to my research project.

Part 1, involves assessing the degree of consensus among an 'expert' panel of health care professionals about the medicines use process in people with intellectual disability and behavioural disorders.

Part 2, of my project (Title above) involves people with intellectual disability themselves as the real 'experts' on medication use in their population.

The aims of Part 2 are to -

- discover how informed the participants with intellectual disability are about their medications
- identify key factors relating to their experiences and understanding of the medication use process.

People with intellectual difficulties (PWID) have over the past ten years or so, become increasingly seen as '*reliable informants who hold valid opinions and have a right to express them*'.

It is hoped that this research project will benefit –

- those ageing with intellectual disability who take medication
- those involved in medication management in the care of people ageing with intellectual disability'.

To ensure that people with intellectual disability, who are ' the experts' in relation to medication use in their population, are also involved in this research project, I wish to make contact with 3/4/5 people with intellectual disability to give them the opportunity to voice in their own way their expert' opinion/knowledge and / or experiences of medication use. I wish to give people with intellectual disability an opportunity to 'speak for themselves'.

[Page 1 of 3]

Any contact I would make with XXXX clients or staff will respect the Key Research Principles of the National Federation of Voluntary Bodies and ensure adherence to ethical research standards.

The consent of the PWID will be voluntary. No undue pressure will be placed on individuals in this project in order to ensure their participation. There will be no negative consequences for those that refuse.

Confidentiality is assured for each participant with intellectual disability in this project. Pseudonyms will be allocated to participants.

If participants in this study disclose risk or danger then the researcher will contact their medical practitioner.

Participants will be allowed to speak freely. Written records only of the interview will be made.

You can get more information or answers to your questions about the study from Bernadette Flood who may be contacted at email beflood@tcd.ie and telephone number 01-8248640 and Dr Martin Henman at email mhenman@tcd.ie

This project has approval from Faculty of Health Sciences Research Ethics Committee, TCD

What can you do to help me?

1. Identify 3/ 4/5 people with intellectual disability who may be interested in and able to participate in this project as 'experts'.
2. The inclusion criteria are as follows – People with intellectual disability(PWID)
 - known to XXXX
 - aged 40 years and over - preferably
 - taking medication/tablets
 - who have agreed to participate in this project
 - ability to communicate verbally
 - with capacity to consent for themselves to participating in this project
3. Supply and /or read the Participant Information Sheet to potential participants.
4. Ensure they understand what is involved in the project particularly the voluntary nature of their participation , that they may leave the project at any time and that their identity will not be revealed to anyone.
5. Allow them time to think about their proposed involvement in this project for more than 7 days.
6. Re-supply/ re-read the Participant information Form to the proposed 'expert' participants.
7. Supply /Read the Participant Consent Form to the proposed 'expert' participants.
8. Ask each participant to sign the Consent Form for this project.
9. If participants supply verbal consent and are unable to supply written consent please indicate this on their behalf and supply your own name.
10. Please sign and date the Consent Form.
11. Please forward the signed and dated Consent Form to the researcher at. - Bernadette Flood MPSI, MMMM. (Stamped, addressed envelope supplied)

[Page 3 of 3]

APPENDIX 14D

Information Leaflet for Family Members

PRACTICE OF PHARMACY, SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES, TCD

Information leaflet for Family Member(s) of XXXX Participants .

This will be distributed if the participant wishes for it to be sent to their family

This project has approval from Faculty of Health Sciences Research Ethics Committee, TCD

TITLE: People with Intellectual Disability:

Their views and knowledge of medication use.

I am a pharmacist undertaking a Ph D research project in the School of Pharmacy & Pharmaceutical Sciences in TCD. There are two parts to my research project.

Part 1 of this project involves assessing the degree of consensus among an 'expert' panel of health care professionals about the medicines use process in people with intellectual disability and behavioural disorders.

Part 2 of my project (Title above) involves people with intellectual disability themselves as the real 'experts' on medication use in their population.

The aims of Part 2 are to -

- discover how informed the participants with intellectual disability are about their medications
- identify key factors relating to their experiences and understanding of the medication use process.

People with intellectual difficulties (PWID) have over the past ten years or so, become increasingly seen as '*reliable informants who hold valid opinions and have a right to express them*'.

It is hoped that this research project will benefit –

- those ageing with intellectual disability who take medication
- those involved in medication management in the care of people ageing with intellectual disability '.

To ensure that people with intellectual disability, who are 'the experts' in relation to medication use in their population, are also involved in this research project, I wish to make contact with some people with an intellectual disability to give them the opportunity to voice in their own way their expert' opinion / knowledge and / or experiences of medication use. I wish to give people with intellectual disability an opportunity to 'speak for themselves'.

DSI staff will identify people with intellectual disability who may be interested and able to participate in this project. Any contact I would make with DSI clients or staff will respect the Key Research Principles of the National Federation of Voluntary Bodies and ensure adherence to ethical research standards.

The consent of the participants with intellectual disability in this research project will be voluntary. No undue pressure will be placed on individuals in this project in order to ensure their participation. There will be no negative consequences for those that refuse.

People with intellectual disability who are in a position to consent for themselves will be asked if they would like to be involved. Confidentiality is assured for each participant with intellectual disability who consents to be part of this project. Pseudonyms will be allocated to participants.

Participants will be allowed to speak freely. Written records only of the interview will be made.

A transcript of the interview will be given to the participant if they wish for it.

You can get more information or answers to your questions about the study from Bernadette Flood who may be contacted at email beflood@tcd.ie and telephone number 01-8248640 and Dr Martin Henman at email mhenman@tcd.ie

[The researcher as a practising pharmacist, will follow the National Federation of Voluntary Bodies guidelines for conducting ethical research]

APPENDIX 15

APPENDIX 15A

Letter from CEO National Support Organisation for People with Intellectual Disabilities

Ms Bernadette Flood, MPSI
Practice of Pharmacy,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College Dublin,
Dublin 2.
20 December 2011.

Re: Project; People with Intellectual Disability; their views and knowledge of medication use.

Dear Bernadette,

I refer to earlier correspondence and I wish to confirm that Will facilitate this project and will make staff available to

1. Distribute information/ literature on the project etc.
2. That *named staff member* or other nominated person will be present during the interviews
3. The organisation will make its premises or other accommodation available to conduct the interviews.

Yours sincerely,

Signature

Chief Executive

Mobile

email

APPENDIX 15B

Letter from Medical Director National Support Organisation for People with Intellectual Disabilities



COLÁISTE NA TRÍONÓIDE, BAILE ÁTHA CLIATH | TRINITY COLLEGE DUBLIN
Ollscoil Átha Cliath | The University of Dublin

16 September 2011

Ms Bernadette Flood
School of Pharmacy & Pharmaceutical Sciences
Trinity College Dublin

Re: Research Project "People With Intellectual Disability: Their views and knowledge of medication use."

Dear Ms Flood

Many thanks for sending me a copy of the semi semi structured questionnaire that you proposed to use in your research. In your previous correspondence you outlined that you planned to administer this questionnaire with the support of I note you plan to obtain ethical approval from the Trinity College Dublin research Ethics Committee prior to commencing that project, which would be vital.

A small note, on your questionnaire perhaps you could look at the layout of your questions and include tick boxes for ease of administration and for the open ended questions perhaps you would like to leave yourself some room to record the response. While I recognise that you will be administering the questionnaire I feel these amendments would make it easier for you to record that questions but also would reduce the duration of the interview.

Regarding your previous questions relating to facilities for the conduct of your research, as I stated in my previous letter I feel you should address this directly with

I note that you have sent a copy of this questionnaire also to
and

I wish you the very best of luck with your research.

With very best wishes.

Yours sincerely

Dr Edna Roche, MA, MB, DCH, MD, MBA, FRCOI, FRCPCH
Associated professor and Head of the Department of Paediatrics, University of Dublin, Trinity College
Consultant Paediatrician/paediatric endocrinologist
National Children's Hospital, AMNCH

cc:
cc:

2
n 12

Roinn na Péidiatraice
Ionad Choláiste na Tríonóide do na
hEolaíochtaí Sláinte,
Ospidéal Náisiúnta na Leanaí, AMNCH,
Tamhlacht, Baile Átha Cliath 24

Department of Paediatrics
Trinity Centre for Health Sciences
National Children's Hospital, AMNCH,
Tallaght, Dublin 24

T +353 (0)1 8963763
F +353 (0)1 4626393
www.medicine.tcd.ie/paediatrics

APPENDIX 16

Research Ethics Approval for Interviews with People with Intellectual Disabilities



COLÁISTE NA TRÍONÓIDE, BAILE ÁTHA CLIATH TRINITY COLLEGE DUBLIN

Dámh na nEolaíochtaí Sláinte,
An Chéad Uirlar, Foirgneamh na Ceimice (an sineadh)
Colaiste na Tríonóide,
Baile Átha Cliath 2, Éire.

Faculty of Health Sciences,
1st Floor, Chemistry Building
Extension,
Trinity College,
Dublin 2, Ireland.
T:- +353 (0)1 8964255

Ms. Bernadette Flood
St Joseph's Centre
Clonsilla
Dublin 15

22 November 2012

Study: People with Intellectual Disability: Their views and knowledge of medication use.

Dear Applicant(s),

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in February 2012, we are pleased to inform you that the above project has been approved without further audit.

Yours sincerely,

Dr. Ruth Pilkington
Chairperson
Faculty Research Ethics Committee

Supervisor:
Dr. Martin Henman

APPENDIX 17

Semi Structured Interview Tool

People with Intellectual Disability:

Their views and knowledge of medication use.

This project has approval from Faculty of Health Sciences Research Ethics Committee, TCD

SEMI STRUCTURED INTERVIEW

Format & QUESTIONS

People with Intellectual Disability:

Their views and knowledge of medication use.

FORMAT

When meeting the interviewee, the researcher-interviewer will clearly identify herself.

The researcher-interviewer will establish a good rapport with the interviewee, using incidental conversation to break the ice (e.g. weather), before embarking on the interview proper, thereby encouraging the interviewee to trust and share accurate information on the topic to be discussed.

The researcher-interviewer will explain the purpose of the interview, address terms of consent, confidentiality and anonymity, and indicate that there are no right or wrong answers

The researcher -interviewer will make it clear to the interviewee that they can withdraw from the interview at any time without consequence.

The researcher-interviewer will also inform the interviewee that they are free to ask or clarify any questions being asked of them.

The researcher-interviewer will look at and speak directly to the person being interviewed and if the interviewee has communication difficulties, the interviewer will avoid correcting or completing sentences for the interviewee.

Where necessary, the researcher-interviewer will restate what they have understood and ask the interviewee if the information is correct

In order to verify the interviewees understanding, the researcher-interviewer will observe the person's body movements, gestures and facial expressions.

The researcher-interviewer will use her usual tone, rate and volume of voice, unless asked to slow down or speak up. Every effort will be made to keep the language simple and clear (e.g. plain and concrete).

In the event that a participant becomes distressed at any stage, the interview will be terminated and support sought from the XXXX Counsellor.

SEMI STRUCTURED INTERVIEW
QUESTIONS

Hello.....

Thank you for taking the time to meet me and to answer a few questions.

I am a pharmacist / chemist and I would like to get some information from you about your tablets / medicines.

1.What is your name?

2.What age are you?

3.Who do you live with?

4.Where do you live?

5.Do you take tablets / capsules / medicines ? Yes / No

6.Do you know their names? Yes / No

7.What are the tablets/ capsules / medicine supposed to do for you?

17. Does the doctor give you information about tablets / medicine? Yes / No

18. Do you know your chemist / pharmacist ? Yes / No

19. Do you go to the Chemist Shop/ Pharmacy with the prescription?
Yes / No

--

20. Does someone go to the Chemist shop / Pharmacy with you? Yes / No

--

21. Tell me what happens when you go to the Chemist Shop / Pharmacy?

--

22. Does the chemist / pharmacist give you information about your tablets /
medicines? Yes / No / Sometimes / Never

--

23. Can you open the tablet / medicine container? Yes / No

--

24. Is the label easy to read? Yes / No

--

25. Do you ever buy tablets / medicines in the Chemist Shop / Pharmacy with no prescription? Yes / No

26. Tell me what happens when you wake up in the morning and have to take tablets / medicines?

27. Do you like taking tablets / medicine? Yes / No

28. Do you feel better after taking tablets / medicine? Yes / No / No change

29. Do you ever feel worse after taking tablets / medicines? Yes / No

30. Do people / staff / family / friends explain to you about the tablets / medicines?

Yes / No

31.If you do not want to take medicine who do you tell?

32.If the tablets / medicine makes you feel bad / worse what do you do?

33.Who have you told about this?

34.Do you know what side effects on medicines are?

35.Did you ever have any side effects when you take medicines ?

36.Have you ever spit out /hidden tablets / medicine? Yes / No

37.Did tablets / medicine ever make you feel sick? Yes / No

38.What happens if you do not want to take medicines / tablets?

39.Are the tablets / medicines easy to swallow? Yes / No

40. Do you ever visit a psychiatrist? Yes / No / Can't remember

41. What does a psychiatrist do ?

42. Do you know what problem behaviour is?

[*Problem behaviour includes hitting other people, hurting yourself, being angry, screaming, breaking things [7]]*

43. Do you take tablets / medicines for problem behaviour? Yes/ No/ Don't know

44. What does that feel like?

45. Was anything else tried to help you with this problem behaviour? Yes / No

46. Can you tell me good / bad things about taking tablets /medicines?

47.Can you remember what happened if you ever did not want to take tablets/
medicines?

48.Do you ever have blood tests? Yes / No

49.Who do you think knows most about your tablets / medicines?

- Doctor
- Pharmacist
- Staff in XXX Organisation
- Nurse
- Friend
- You do
- Other

50.Who decides most about your tablets / medicines ?

[The document to be used in practice will allow for answers to be recorded in writing at the time of
the interviews.

Question Number will be ticked when asked and answered during the interview process]

APPENDIX 18

Feedback to Counsellor

People with Intellectual Disability :

Their Views and Knowledge of Medication Use

Pseudonyms

Pat

Alex

Keelan

Gabrielle

Jamie

Frances

NB: Pseudonyms used to preserve anonymity

PARTICIPANT PAT

Age	33																																								
Lives with	Family																																								
Diagnosis	<p>Diabetic</p> <p>'Hates' being a diabetic.</p> <p>'Hates the whole thing' about being a diabetic. Mentioned this 8-10 times sometimes with great emphasis. Uses insulin only because does not want to die as is 'not ready to die yet'.</p> <p>Blood taken recently by practice nurse – has been referred to Mater Diabetic Clinic.</p> <p>Stomach 'not great' – has been referred to 'Tallaght'.</p> <p>Has attended cardiac clinic.</p>																																								
<p>All tablets in morning – presented in Monitored Dosage System – bubbles</p> <table border="1" data-bbox="315 1115 922 1367"> <thead> <tr> <th>Mon</th> <th>Tue</th> <th>Wed</th> <th>Thur</th> <th>Fri</th> <th>Sat</th> <th>Sun</th> <th></th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>Wk1</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>Wk2</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>Wk3</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>Wk4</td> </tr> </tbody> </table> <p>Participant reported no difficulty pushing tablets out of bubbles. Reported labels easy to read though not LARGE font</p>	Mon	Tue	Wed	Thur	Fri	Sat	Sun									Wk1								Wk2								Wk3								Wk4	<p>Esomeprazole 40mg, Eltroxin and Coversyl 5mg quartered</p> <p>Observation: Bubbles empty in random fashion. No bubbles week 1 empty.</p> <p>Most bubbles in week 4 empty.</p> <p>Some empty bubbles weeks 2 and 3</p>
Mon	Tue	Wed	Thur	Fri	Sat	Sun																																			
							Wk1																																		
							Wk2																																		
							Wk3																																		
							Wk4																																		
As required tablets – in bag in original packs.	<p>Motilium, Imodium – 2 boxes.</p> <p>Arret, Esomeprazole generic.</p> <p>Solpadeine. Savlon cream</p>																																								
Insulin Lantus Solostar 3ml Dose: 16iu 3 times daily Novorapid FlexPen – Dose 8 unit - Four brought in to interview	<p>One Touch Ultra-Easy</p> <p>One Touch Lancets/Teststrips</p> <p>Novofine needles</p>																																								
Issues with insulin	Participant reported stores insulins																																								

	<p>in drawer in bedroom. Lantus Insulins had 3 different batch numbers/expiry dates. All insulins removed from original packaging and held together in plastic box.</p> <p>Two Glucose Diaries. One with no entries. One with 3 entries – appeared to be from 2010. No date on any insulin to indicate when removed from fridge.</p>
As required Glucagen Hypokit	<p>3 brought in to interview. One out of date March 2012 [interview March 2013]. One going out of date May 2013 and one longer dated.</p> <p>No date on any Glucagen to indicate when removed from fridge.</p>
Hypoglycaemia	<p>Had a 'HYPO' last Saturday.</p> <p>Had to get 'needle into backside'.</p> <p>Receptionist in Doctor's surgery knows all about 'blood sugars'.</p>
Know names of tablets?	<p>Big tablet is for stomach and chest. Quarter for BP.</p> <p>And Eltroxin</p>
Taking medication	<p>Told to take medicine by named family GP.</p> <p>Doctor and mother explain about medicines.</p> <p>If did not want to take tablets would tell doctor and receptionist.</p> <p>Never spat out or hid any tablets.</p> <p>Takes big drink of water – one tablet very big. If does not want to take tablets just 'does not take them'.</p>

	Knows how to 'do it' i.e. take tablets. 'Might die' if does not take them.
Rules for taking tablets	Take tablets all at one time. Drink plenty of water. Takes big tablet – Nexium - with water. Takes tablets with Actimel. If don't take tablets will die.
Any 'side effects' of tablets	No answer to side effects question. 'Bad thing about medicines - 'Feel tired' but continues to take them. Mother explained about medicines. Don't like tablets.
Information on medicines	Doctor talks to participant and participant understands what to do.
Psychiatrist	No knowledge of this type of doctor – does not know what they do. Understood 'problem behaviour' to be 'swears the odd time'. Described personality clash during interaction with peer during activity session. Never took medicines for 'problem behaviour'.
Good – Bad things about medicines	Participant did not know any good things about medicines. Bad – 'if die don't come back'

Pharmacy

One down town and one nearer home. Mother accompanies participant sometimes. Does go alone on occasion. Gives prescription to girls in pharmacy. No information from pharmacist directly to participant. 'Mam has all information'. Does not buy vitamins etc. in pharmacy. Has bought vitamins in chain store. One pharmacy supplied most items brought into interview with researcher. Generic Esomeprazole supplied by second pharmacy in original packaging – participant appeared to be aware this was the same as one tablet in MDS bubble.

Blood Test – has had blood tests. Going 'to Mater' following blood test taken by surgery nurse.

Doctor and mother and receptionist in surgery know most about tablets. Named GP receptionist 'knows all about sugars'.

Has 'book' i.e. Long Term Illness book.

Communication/Follow Up:

I discussed some concerns I had with Pat and the counselor. I pointed out safety risks with his storage of insulin etc. With Pat's permission I wrote a letter to his family supplying my name and mobile telephone number advising:

1. Return insulin to pharmacy to get new supply which should be kept in fridge.
2. Return out of date Glucagen hypokit

With Pat's permission I requested his family make contact with me to discuss my meeting with Pat. The counsellor informed me that Pat had an appointment in the Mater Diabetic Clinic the following week. I advised Pat to bring all of his diabetic items eg MDS, insulin, medicines, blood testing equipment with him to the appointment.

PARTICIPANT ALEX

Age	29
Lives with	Parents
Tablets – list supplied by parents Mother a nurse	Allopurinol one daily Lexapro 20mg daily Stelazine 2mg at 9pm Zimovane 7.5mg - as required when working next day.
Knowledge of tablets	'See list'. Appeared to have very very little knowledge. 'Tiny' tablet in morning – appears to 'take in bed'. Take in morning and evening. Has never spat out tablets.
Told to take tablets by	Father. Easy to swallow.
Rules for tablets	Always with water. Does not mind tablets – 'no pain now'. Had pain when Allopurinol new! When started taking Stelazine 'strength went down' and it was 'hard to do things'. Sister tells about tablets as she had once worked in a pharmacy.
Side effects of medication	Not familiar with 'side effects'. No answer to 'good or bad things' about medicines question. Has 'felt sick' after tablets.
Knowledge of doctor Knows surgery receptionist name	Does know doctor – male. Confused about how many times per year – once and 5 times per year mentioned. Understood about BP check. Weight not measured by GP – High BMI? Weight is measured at home. Doctor gives prescription to participant. Goes into doctor himself. Doctor knows family for along time. Doctor gives advice about tablets to mother.
Pharmacy	Goes to same pharmacy.

	<p>Chats with staff. Mother and brother go with participant.</p> <p>Does not know pharmacist. No advice from pharmacist.</p> <p>Get bag back with no directions.</p> <p>Containers are easy to open. Hard to read labels. No memory of ever getting easy read material.</p> <p>Mother might buy vitamins while in pharmacy.</p>
Background	<p>Emotional difficulty – felt had a relationship with member of opposite sex who did not reciprocate.</p>
Problem Behaviour	<p>Sometimes gets angry. Understood ‘screaming’ as problem behaviour.</p> <p>Understood Stelazine for ‘behaviour’ – ‘parents know’.</p> <p>Named psychiatrist.</p>
Family	<p>Mother/nurse requested to meet with me.</p> <p>Concerned about level of medication use.</p> <p>Advised to bring up issue of high BMI with prescriber.</p> <p>Mother felt increasing dose of Stelazine would not be appropriate.</p>

PARTICIPANT KEELAN

Age	32
Lives with	Parents who are 'wrecking my head'.
Medicines Takes 5 individual tablets per day	Perinol for gout. Aspirin for blood. Vitamins 'to keep going' – Vit C and Zinc & Vit B Complex – advised to take by parents.
Advised to take medicines by	Parents who know most about tablets. Asks mother if needs advice. Told by 2 doctors -? GP to take medicine for gout.
Time of day	Takes aspirin before breakfast. Takes Purinol between meals. Takes vitamins in morning.
Any rules for taking tablets	Participant makes rules. No upset tummy with aspirin.
Blood Tests	Has had 'lots' – feels like 'pin cushion'. Is 'star patient', 'best patient in whole hospital'. Got box of chocolates – bone marrow test.
Doctor	Knows doctor – 2 male GPs. Has had 3 chest infections – recent visits.
Visit to doctor	Make appointment. Introduces self to receptionist. Goes to see doctor alone. Prescription given to participant who gives to parent. 'They [i.e. parents] have to know' – 'drive me mental'
Advice about medicines	Doctor tells how many times per day. Take no red meat as has too much iron.
Blood pressure Weight	Only checked in hospital. Doctor checked weight.
Pharmacist	Knows name of pharmacist. Accompanied into pharmacy by family member. No advice. Gets box of tablets in bag. No difficulty opening bottles, boxes, strips,

	etc.
Other medicines	Buy vitamins in Tesco.
Taking tablets	Get up out of bed - Get dressed - Takes vitamins - Eats breakfast - Drink orange juice. ‘Don’t mind taking tablets’. Has never forgotten tablets. Easy to swallow.
Side effects	Ever feel worse after taking tablets? Lips may bleed. I advised Keelan to talk to doctor – dose of aspirin may be too high. Participant does not mind bleeding lips - Never heard of side effects.
It don’t want to take tablets	Tell parents – ‘sometimes listen’. Always take.
Psychiatrist	Never heard of psychiatrist. Does not understand ‘problem behaviour’.

PARTICIPANT GABRIELLE

Lives with	Family – parents and 3 siblings.
Medicines Eltroxin 100 Mon-Thurs Eltroxin 50 Fri, Sat & Sun	Eltroxin – for underactive thyroid. To ‘speed self up’. Take one tablet each day in the morning with breakfast – ‘just swallow’.
Told to take medicines by	Parents and Doctor.
Other	Gets red eyes. Get ‘boils’ – take salt baths.
Doctor	Knows doctor all life. Driven to doctor by family/visits often – 2/3 times per month. BP taken if has cold/flu. Weight checked but not regularly. Doctor decides most about tablets.
Prescription	Doctor gives participant prescription. Participant never brings to pharmacy herself as cannot drive. Never gets information from doctor – leaflets in box.
Pharmacist	Knows pharmacist. Goes to pharmacy with family and gives prescription to counterhand who gives to pharmacist. Will be delay – come back after do ‘own thing’. Takes 15-20 mins. Pharmacist will explain if ‘many things’. Never given leaflets – though is ‘good reader’. Can always open containers. Labels clear.
Buy in pharmacy	Moisturisers – dry/sensitive skin Aveeno. La Passay Borocca – Vit B 12
Taking tablets	Get up at 7.30am – Breakfast – Tablet – Drink - if tablets go ‘down wrong way’ ‘Don’t mind taking tablets’

How feel after taking tablets	<p>Feel better 'now and again'. 'depends how feeling'.</p> <p>Have felt worse after taking antibiotics.</p> <p>Good thing about tablets = feel better.</p> <p>Bad thing = thought of having to take medicines and routine.</p>
Explain about medicines	'Own responsibility'.
If don't want to take medicine	<p>Pretend to take. Cod Liver oil – Don't want to take = has spat out.</p> <p>If tablets make feel bad take a drink and lie down. Get 'treat afterwards'.</p>
Who have you told	No-one. Participant 'deal with a lot' by self.
Side effects	Never had any? Did not understand term.
Psychiatrist	<p>Never visited. Work out problems by self.</p> <p>Knows is 'mental doctor'. No 'problem behaviour'.</p>
Blood tests	Every few months. Feel nervous. Results given to parent.
Know most about tablets	<ol style="list-style-type: none"> 1. Doctor 2. Pharmacist 3. Self

PARTICIPANT JAMIE

Age	32
Live with	At home with mother. Siblings abroad. Mother decides most about medicines.
Diagnosis	Diabetes – since age 7. Coeliac
Insulin	Insulin – Novorapid three times daily and Lantus. Sliding scale. Glucophage 500 – twice daily. Cozaar – one daily. Vitamin B – one daily. Lucozade
Blood glucose tests	4/5 times daily.
Taking tablets	Told by doctor. Has never had to go to hospital.
Daily medicines	3 insulin injections. Four tablets – different times of day – breakfast, dinner and evening. Always takes tablets with water – drinks 3 - 4 pints per day.
Doctor	Knows Dr since 7 years of age. Blood pressure/weight/height are measured. Always accompanied by mother to GP. Prescription given to mother. Supplies easy to read leaflets. Doctor knows most about medicines.
Blood tests	Has had blood tests in GP surgery.
Pharmacist	Known by participant. Ring pharmacy to let them know need prescription. Participant and mother go to pharmacy and give Rx to 'girls' who give to pharmacist. Quick – no delay – because ring before hand.

	<p>Use Long Term Illness Scheme.</p> <p>Get bag with medicines.</p> <p>Get information leaflets in pharmacy.</p>
Medicines - prescription	<p>Containers easy to open.</p> <p>Labels clear.</p>
Other medicines	<p>No need to buy medicines not on prescription.</p> <p>Uses 'tummy pack' for 'time of month'.</p>
Taking medication	<p>Gets up at 8.30am.</p> <p>Checks bloods – insulin – breakfast - tablets with breakfast - cup of tea - juice.</p> <p>Does not mind taking tablets or giving injections – 'used to it'.</p> <p>'Know all about' meds self.</p> <p>Would tell mother if did not want to take tablets/injections.</p> <p>Never spat out tablets. Tablets easy to swallow.</p>
Effect of medication	<p>Feel a lot better/Never felt worse after tablets.</p> <p>Reads leaflets to learn about side effects.</p> <p>Not able to identify good or bad things about tablets.</p> <p>No side effects.</p>
Occupation	<p>Works in local third level college part time in coffee shop.</p>
Psychiatrist	<p>Knows one would go to psychiatrist for 'breakdown'.</p> <p>No problem behaviour reported.</p>
History	<p>Used to get recurrent chest infections in childhood – had to mind self. Used nebuliser twice daily – stopped in early teens.</p> <p>Had diarrhoea before coeliac diagnosis.</p>

PARTICIPANT FRANCES

Age	31
Lives with	Parents and cat. Family decide most about medicines.
Involved in	Special Olympics. Ti Chi. Self Advocacy Groups. Personal development.
Medicines	Abilify 10mg in morning and 20mg at night. Takes feminax for periods.
Why takes medicines	Advised by Mum and Dad To 'stop worrying' about computers. Does not want to get hurt. Named doctor prescribed tablets to 'help with worries'.
Rules for taking medicines	Take with water. Do not drink alcohol. No memory of Dr giving information about tablets.
Doctor	Visiting Dr [psychiatrist] next Thursday. Dr 'keeps eye on me'. Weight measured. Goes to Dr with parents or sister/brother when parents away.
Prescription	Given to participant who gives it to mother.
Pharmacy	Knows pharmacist – named. Uses one pharmacy. Participant sometimes goes to pharmacy with prescription. Pharmacist gives separate sheet with information. Medicines label 'letters big enough'.
Non prescription medicines	None needed. Participant has 'a rest' if needed.
Taking medicines	Wake up – get up slowly – one tablet in morning with water. White tablet in morning and blue tablet at night. Tablets makes 'feel better' as participant

	<p>is 'very sensitive'.</p> <p>Never felt worse taking tablets.</p> <p>Tablets explained by family/staff in Voluntary sector/'circle of friends'.</p> <p>Never did not want to take tablets/never spat out.</p>
Side effects	<p>Has experienced dizziness 'sometimes'.</p> <p>Tablets never made feel sick.</p>
Swallow	<p>Tablets easy to swallow with water.</p> <p>Difficulty swallowing meat – cut into small pieces.</p> <p>Drinks mint tea.</p>
Psychiatrist	<p>Never visited.</p> <p>Has seen named 'Physios' in Voluntary sector.</p> <p>Doctor in Voluntary sector knows most about tablets.</p>
Problem behaviour	<p>Recipient of others 'problem behaviour' where participant bullied on internet. This was first experience. Hurt a lot.</p>
Effect of taking medicines	<p>Good – 'do feel more relaxed' and 'helps to be positive'.</p> <p>Don't like camera.</p>
Blood Tests	<p>No tablets for BP. Does not smoke.</p>

APPENDIX 19

Information for Participants Post Interviews

PEOPLE WITH INTELLECTUAL DISABILITY: THEIR VIEWS AND KNOWLEDGE OF MEDICATION USE

In 2013, Bernadette Flood who is a pharmacist interviewed six people with intellectual disabilities to find out what they felt and knew about medicines.

Bernadette met three women and three men who consented to take part in the research. The counsellor of the organisation was present at all interviews.

All people lived with family members. Two people lived in the Dublin area and four people lived outside the Dublin area. All six people were taking medicines. Two people had diabetes and were taking insulin.

What did Bernadette learn ?

People with intellectual disabilities.....

- Are able to provide information about medicines/tablets
- May know why they are taking medicines
- May know the name of their medicine/tablet
- May not understand 'side effects' of medicines/tablets
- May understand 'good' and 'bad' things about medicines
- Are able to say how medicines/tablets made them feel
- Depend on others to bring them to the doctor and the pharmacist
- May like more 'privacy' about using medicines
- May feel others make decisions about medicines/tablets for them
- Do not often get information about illness and medicines/tablets in a form that they can understand
- May have problems understanding how to use a Monitored Dosage System

Families of people with intellectual disabilities.....

- Support the person taking medicines
- Are very involved in their care
- Give advice about medicines
- May make decisions about medicines for the person
- May give care of their medicines/tablets to the person

People with intellectual disabilities and diabetes.....

- May know about their illness
- May understand the need for blood tests
- May self care
- May be responsible for storage of their medicines
- May find it difficult to keep a record of their blood glucose levels
- May have little problems with managing their diabetes
- May find 'diabetes' distressing
- May have had a need for glucagon injection in a public area
- May need person centred diabetic support

APPENDIX 20

The Health Equalities Framework

An outcomes framework based on the determinants of health inequalities

Indicators of the Determinants of Health Inequality, The Health Equalities Framework (HEF). An outcomes framework based on the determinants of health inequalities, page 26.

The indicator statements associated with each impact level for the determinant are presented on the following pages.

Determinant 2:	Physical and mental health problems associated with specific genetic and biological conditions in learning disabilities	
Health Inequality Indicators		
A. Assessment of Physical and Mental Health Needs and Health Checks	Impact Rating	Level
Physical and/or mental health needs not assessed and/or no current annual health check	Major	4
Physical and/or mental health needs under assessment and/or health check planned	Significant	3
Physical and/or mental health needs assessed/health check done but actions not in place	Limited	2
Physical and/or mental health needs assessed, health check carried out and being acted upon	Minimal	1
Physical and/or mental health needs assessed and fully met	No	0
B. Long Term Condition (LTC) Pathways and Planned Reviews of Need	Impact Rating	Level
No LTC pathway allocation or planned review	Major	4
Awaiting review and/or LTC pathway allocation	Significant	3
Review of needs completed but not acted on such as allocation onto LTC pathway	Limited	2
Review of needs completed and acted on such as allocation onto LTC pathway	Minimal	1
Review of needs not required	None	0

C. Care Planning/Health Action Planning	Impact Rating	Level
No Care plans/Health action plans in place	Major	4
Non condition specific care plans/Health Action plans in place (not condition specific or NICE compliant)	Significant	3
Condition specific, NICE compliant care plans/Health Action Plans in place but not reviewed or person centred	Limited	2
Condition specific, NICE compliant care plans/Health Action Plans in place, person centred and regularly reviewed	Minimal	1
No care plans or Health Action Plans required	None	0
D. Crisis/Emergency Planning and Hospital Passports	Impact Rating	Level
No crisis, emergency or relapse plans (where appropriate) or hospital passport in place	Major	4
Crisis/emergency/relapse plans and hospital passport in place, not person centred or reviewed	Significant	3
Crisis/emergency/relapse plans and hospital passport in place, not reviewed	Limited	2
Crisis/emergency/relapse plans and hospital passport in place, are person centred and reviewed	Minimal	1
No crisis/emergency plans required, hospital passport in place	None	0
E. Medication	Impact Rating	Level
Inappropriate medication or unlawful covertly administered medication	Major	4
Medication not reviewed and/or not regularly monitored	Significant	3
Medication reviewed but not regularly monitored	Limited	2
Medication reviewed and monitored	Minimal	1
No medication	None	0
F. Specialist Learning Disability Service Provision	Impact Rating	Level
No Specialist learning disability service available	Major	4
Restricted Specialist learning disability service available; not able to meet all identified needs	Significant	3
Limited Specialist learning disability service available	Limited	2
Full Specialist learning disability service available	Minimal	1
Full Specialist learning disability service available but not currently required	None	0

APPENDIX 21

Grounded Theory: Inductive Theories

Specialist Intellectual Disability Pharmacist Main Inductive Theory
<ul style="list-style-type: none">• Patient centred pharmaceutical care – Equality legislation• Integrate pharmacist into care process• Reasonable accommodations• Accessible information provision – emphasis instructions• Pharmacist must take responsibility• Need to improve outcomes in population• Awareness of healthcare issues – need to discuss with population• Awareness of vulnerabilities and risk factors• Risk stratification of patients• Medicines optimisation• Quality of medication use process• Medication reconciliation• Physical and mental health promotion• Communication skills• Language use – ‘bad things’ about medicine rather than ‘side effects’• Familiarity – people at ease and comfortable – facilitate communication• Guidelines/policies for general population may increase health inequalities• Potential inappropriate prescribing medication tools may be inappropriate• Monitored dosage systems may not be appropriate• Government policy and international movement – deinstitutionalization – will this improve outcomes• Financial and other costs – time and space• Standards of care – HIQA and PSI• CPD – IloP• Ask population what they want/need from pharmacy• Monitor effectiveness and be adaptable

Self Determination by the Person with Intellectual Disabilities

Sub-Theory

- Vulnerable in healthcare and society
- Right to Health and equal health outcomes
- Expert patient – peer learning
- Expert carer recognised
- Use one 'registered' pharmacy
- Quality of life – often does not include health aspect
- Self determination and risk
- Health literacy and language use – accessible information
- Communication skills
- Reasonable accommodations
- Language use – no understanding of 'mental health' problems

APPENDIX 22

The Leeds Health and Social Care Transformation Programme:

Clinical Values in Prescribing – Cross Sector Project

The Leeds Health and Social Care Transformation Programme: Clinical Values in Prescribing – Cross Sector Project
<p>1.0 Whole Time Equivalent clinical pharmacist (two people working part time) supported by specialist pharmacist in Elderly Care (from local acute Trust) and specialist pharmacists in learning disability and mental health (from local mental health Trust)</p> <ul style="list-style-type: none">• 678 patients reviewed – people with intellectual disabilities, dementia or a mental health problem prioritised for review• 2,309 recommendations made to GPs (average of 3.4 per patient) to improve the quality or cost-effectiveness of prescribing• Average number of medicines prescribed reduced from 6.0 to 5.3• £107,000 of annual savings to primary care prescribing budget implemented• Commissioners currently considering long term commissioning of Care Home Clinical Medication Review Service

APPENDIX 23

Self Management of Medication - Person with Intellectual Disabilities

Adapted from: Handbook for Homecare Services in England, Royal Pharmaceutical Society, London, 2014.

A risk assessment should be undertaken by a competent professional aware of the safety issues in relation to medication use in the population with intellectual disabilities. The results of any assessment should be recorded and any risk identified with suggested control measures being communicated to all other relevant healthcare professionals.

When risks in relation to medication use are identified, if suitable agreed control measures are put in place, the person with intellectual disability may be supported to manage their medication at home. Any control measures should be reviewed regularly to ensure they are successfully meeting the needs of the person with intellectual disability and/or their family/carer. Patient suitability or needs will change with time and medical condition.

**Self Management of Medication - Person with Intellectual Disabilities:
Risk Assessment**

Patient needs

- the patient's clinical condition
- the patient's willingness and ability to consent to self administer medication at home
- availability of suitable contact details in case of issue or medicine recall e.g. mobile phone
- the patient's competence to self-administer the medicine e.g. insulin, medication from a MDS, in accordance with the prescriber's instructions
- in the case of vulnerable adults or children, whether an appropriate additional care/support package is robust and in place
- the patient's (or carer's) ability to understand their responsibilities with regard to the treatment e.g.
 - attending appointments e.g. at diabetic clinic
 - taking required tests e.g. blood glucose testing
 - adhering to the treatment e.g. self administering insulin
 - reporting any adverse reactions or side effects e.g. diarrhoea
 - storing the medicines appropriately e.g. storing insulin as per manufacturer's directions
 - being available to collect medications from pharmacy
 - ensuring contact details are given to the clinical team/support organisation and are kept up-to-date.

Suitability of Living Environment/Home Situation

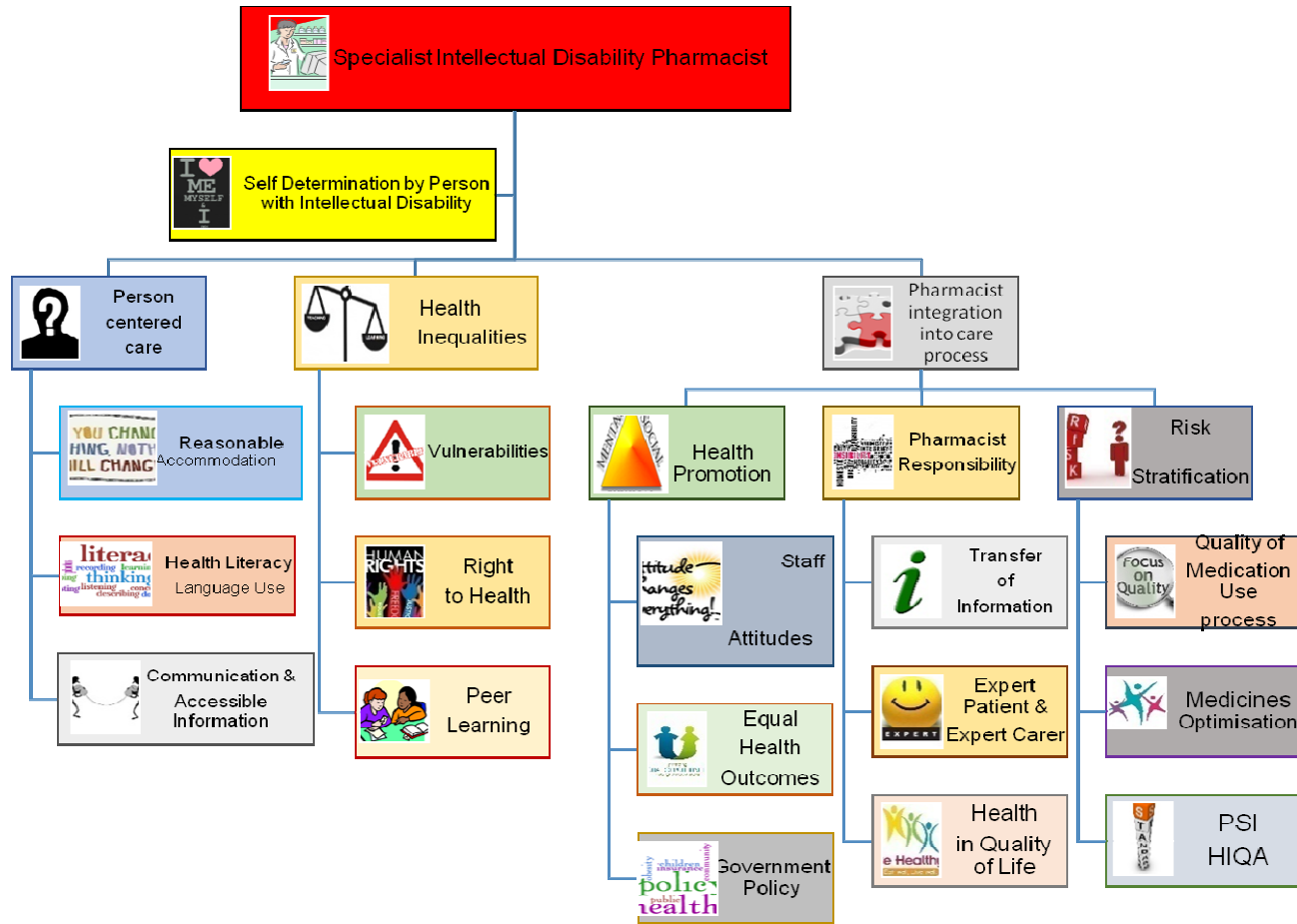
Risk factors that may be considered include/not limited to

- medicines: e.g. safe storage, storage temperature e.g. of insulin, cross contamination
- clinical: e.g. infection prevention – safe disposal of used blood testing kits
- competent use of equipment e.g. blood testing kits, insulin pens, MDS system
- risks to patients and family members/carers introduced by medication/insulin/glucagon
- safeguarding: disability, other occupants of home
- patient confidentiality: privacy, clinical records

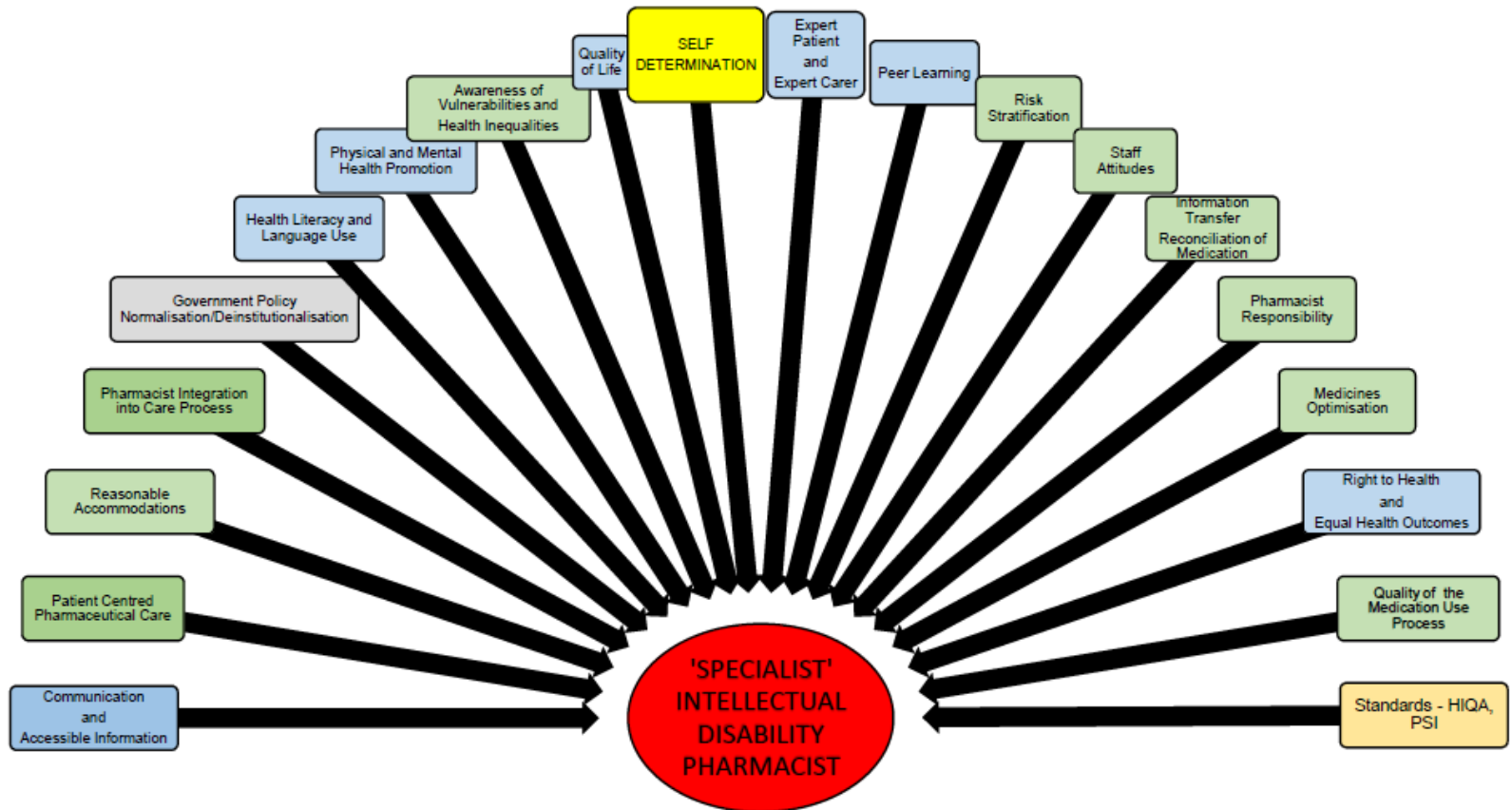
APPENDIX 24

Theories: Grounded Theory Approach to Interviews with People with Intellectual Disabilities

Theory 1 Specialist Intellectual Disability Pharmacist



Theory 2 Self Determination



APPENDIX 25

Quality Indicators – Graded

1. Crucial Quality Indicators

Medication Regimen Review Crucial QI

IF a person ageing with intellectual disability and a behaviour disorder is prescribed medication(s) **THEN** the medication regimen of the patient should be reviewed by qualified multidisciplinary personnel, preferably on site (if living in a residential setting) at least 3 monthly **BECAUSE** medication review will ensure thorough evaluation of the medication used by a vulnerable patient and medication review is increasingly seen as a cornerstone of medicines management.

General Health Review Crucial QI

IF psychotropic medication use is considered for a person ageing with intellectual disability and a behaviour disorder **THEN** prior to medication use, consideration should be taken of possible underlying medical (UTIs, dental problems, congestive heart failure, idiosyncratic reaction to medication or other medication side effects), environmental or psychosocial stressors and any available laboratory results **BECAUSE** the use of any psychotropic medication should occur after multidimensional interdisciplinary communication and the development of a coordinated plan for treatment and follow up.

Restrictive Practice Crucial QI

IF psychotropic medication is used as a restrictive practice for a person ageing with intellectual disability and behaviour disorders **THEN** this should only be done in the best interest of the person, protecting their human rights and in the context of a comprehensive policy on the management of behaviour disorders **BECAUSE** restrictive practices (including psychotropic medication use) should only be used when the person with intellectual disability poses an immediate threat of physical harm to self or others and they should only be used as a last resort.

Excessive Dose of Anti-Psychotic Medication Crucial QI

IF a person ageing with intellectual disability and a behaviour disorder is prescribed an 'excessive dose' – (giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer'

recommendations, clinical practice guidelines, evidence based studies from medical/ pharmacy journals, or standards of practice for the patient's age and condition) - of an antipsychotic medication **THEN** the prescriber must document a clinically pertinent rationale for the prescription that should only be used in exceptional circumstances after full discussion with all the relevant stakeholders under appropriate safeguards and regular reviews **BECAUSE** an excessive dose may be (1) inappropriate and 'unlicensed', (2) may have the potential to cause harm to the patient, and (3) may not be supported by medical-legal frameworks.

Gradual Dose Reduction Crucial QI

IF a person ageing with intellectual disability is prescribed regular antipsychotic medication for a behaviour disorder **THEN** gradual dose reduction must be attempted (unless contraindicated) with implementation of behavioural interventions to enable reduction or discontinuation **BECAUSE** prolonged antipsychotic medication therapy may result in functional decline, somnolence, lethargy, tremors, increased falling or impaired ambulation.

Dementia and Anti-Psychotic Medication Crucial QI

IF a person ageing with intellectual disability and dementia presents with a behaviour disorder **THEN** any prescribed antipsychotic medication should be monitored and reviewed regularly **BECAUSE** an increased long-term risk of mortality in patients with Alzheimer's disease who are prescribed antipsychotic medication has been identified and the risk should be considered within the context of medical need for the drugs, efficacy evidence, medical co-morbidity, and the efficacy and safety of alternatives.

2. Grade 1 Quality Indicators

Multiple Medication Use Grade 1 QI

IF a person with intellectual disability and a behaviour disorder is prescribed more than one medication **THEN** their medication regimen should be reviewed for medication-medication interactions (by a pharmacist) **BECAUSE** people with intellectual disability are predisposed to co-existing medical conditions, such as seizure disorders, gastro-intestinal and cardiovascular problems and may be prescribed a variety of medications and so subjected to poly-pharmacy, which is an acknowledged problem in this population, that increases the risk of adverse reactions to medications including behavioural changes.

Anti-Cholinergic Medication Grade 1 QI

IF a person ageing with intellectual disability and a behaviour disorder is prescribed medication **THEN** the anti-cholinergic effects of all prescribed medication should be reviewed and monitored **BECAUSE** (1) many medications used to treat the intellectually disabled population have significant anti-cholinergic properties, (2) the use of multiple medications with anti-cholinergic actions may cause problems due to cumulative effects, and (3) anti-cholinergic side effects are common, especially in the older patient .

Anti-Depressant Medication and The Serotonin Syndrome Grade 1 QI

IF a person ageing with intellectual disability and a behaviour disorder is prescribed SSRI (selective serotonin reuptake inhibitors) or MAOI (mono amine oxidase inhibitors) medication in combination or at higher doses **THEN** 'serotonin syndrome' should be considered if the patient develops confusion, motor restlessness and tremor **BECAUSE** the addition of medications with additive serotonin effect or medication to suppress the symptoms may be considered to jeopardise the patients health or safety and the higher the dosage the greater the chance of side effects emerging.

Psychotropic Medication Side Effects Grade 1 QI

IF an ageing person with intellectual disability and a behaviour disorder is prescribed psychotropic medication **THEN** the patient/carer/care-giver should be made aware of possible side effects by the prescriber and/or pharmacist **BECAUSE** antipsychotic medications may produce serious side effects that can range in intensity from mild to severe with the management of any side effects should be part of the treatment plan and studies have shown that staff awareness of side effects is low and physicians and pharmacists have been reported to be the preferred source of medication information.

Psychotropic Medication - Neuroleptic Side Effects Grade 1 QI

IF a person ageing with intellectual disability and a behaviour disorder is prescribed antipsychotic medication **THEN** the development of signs and symptoms of extra-pyramidal side effects must be recognized and responded to **BECAUSE** failure to do so may jeopardise the patients health and safety as antipsychotics may produce serious side effects that can range in intensity from mild to severe and the severity of side effects may play a role in the effectiveness and tolerability of the particular antipsychotic.

Dysphagia Grade 1 QI

IF a person ageing with intellectual disability and a behaviour disorder is assessed by a Speech and Language Therapist to have dysphagia **THEN** this should be communicated in a formal manner to relevant professionals including GP, psychiatrist, pharmacist, dietician, nurse/carer/family using standardised language **BECAUSE** multidisciplinary and carer/family awareness of dysphagia and awareness of risks posed by medication use in relation to dysphagia (which can include aspiration, upper airway obstruction, malnutrition, dehydration and increased mortality) is needed to ensure patient safety.

Sleep and Behaviour Disorders and Insomnia Treatment Grade 1 QI

a. IF a person ageing with intellectual disability develops behaviour disorders connected to sleep **THEN** a medication review and sleep history should be undertaken before medication is prescribed **BECAUSE** a diagnosis of short or long term insomnia should be made to rule out sleep apnoea, depressive symptoms, side effects of current medications and caffeine consumption.

b. IF a person ageing with intellectual disability and a behaviour disorder requires pharmacological treatment (when appropriate) for insomnia **THEN** short term use only should be considered **BECAUSE** underlying causes of the insomnia should be identified and treated to minimise possible adverse effects of hypnotics and poly-pharmacy.

Dementia Cholinesterase Inhibitors and Anti-Cholinergic Medications Grade 1 QI

IF a person ageing with intellectual disability and dementia is prescribed an anti-cholinergic medication **THEN** a medication review should be undertaken of all prescribed medications **BECAUSE** between 20% to 50% of people with dementia take at least one medication with anti-cholinergic activity and optimising the management of all medication in dementia offers significant potential to improve dementia care.

3. Grade 2 Quality Indicator

Geriatric Syndromes Grade 2 QI

IF a person ageing with intellectual disability and a behaviour disorder develops any geriatric syndrome **THEN** adverse reactions to medications and poly pharmacy that may be associated with specific geriatric syndromes should be assessed **BECAUSE** the process of ageing influences both pharmacodynamics and pharmacokinetics of medications and the adverse effects of medications such as sedation, increased confusion, constipation, postural instability, falls, incontinence, weight gain etc. and

movement disorders must be minimised.

4. Grade 3 Quality Indicators

Informational Transfer Grade 3 QI

IF a person ageing with intellectual disability exhibits a behaviour disorder **THEN** they should be accompanied at assessment by a caregiver/health facilitator who is familiar with them and who can transfer health information **BECAUSE** consideration and evaluation of the patient's mental, physical, psychosocial and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of patients complaints, symptoms and signs (including the onset, scope, frequency, intensity, precipitating factors and other important features) may require communication by someone familiar with the person with intellectual disability to ensure vital continuity of care and a complete record of all healthcare interventions.

Communication Grade 3 QI

IF a person with intellectual disability exhibits a behaviour disorder **THEN** all clinicians/carers should try to optimize communication with the person with intellectual disability before medication is prescribed, dispensed or administered **BECAUSE** people with intellectual disabilities need to be encouraged and empowered to communicate/speak for themselves and the way medication is prescribed and the need for accessible information has been identified by people with intellectual disability as an area of concern.

Medication Reconciliation Grade 3 QI

IF a person with intellectual disability and a behaviour disorder is being transferred between healthcare settings **THEN** medication reconciliation (by a pharmacist) should take place at all transition points **BECAUSE** admission, transfer and discharge are the situations when medication errors are most likely to occur and medication reconciliation (of all medications, complimentary therapies and supplements) has been demonstrated to be a powerful method of ensuring patient safety, reducing medication errors and adverse drug events across the continuum of care.

Residential Care Grade 3 QI

IF a person ageing with intellectual disability living in residential care exhibits a behaviour disorder **THEN** care must be exercised before medication is used **BECAUSE** the use of medication in a residential setting involves a complex blending of diverse elements of clinical practice and regular medication review is advised.

Pharmaceutical Care* Grade 3 QI

IF a person ageing with intellectual disability is prescribed psychotropic medication for a behaviour disorder **THEN** pharmaceutical care should be available **BECAUSE** increasing numbers of people with intellectual disabilities are living into older age, creating important medication use challenges for healthcare clinicians and services and multiple medication use should be carefully monitored in the older population.

*Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are

- cure of a disease,
- elimination or reduction of a patient's symptomatology,
- arresting or slowing of a disease process, or
- preventing a disease or symptomatology.

Pharmaceutical care involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This in turn involves three major functions:

- identifying potential and actual drug-related problems,
- resolving actual drug-related problems, and
- preventing drug-related problems.

Pharmaceutical care is a necessary element of health care and should be integrated with other elements. Pharmaceutical care is, however, provided for the direct benefit of the patient and the pharmacist is responsible directly to the patient for the quality of that care. The fundamental relationship in pharmaceutical care is a mutually beneficial exchange in which the patient grants authority to the provider and the provider gives competence and commitment (accept responsibility) to the patient. The fundamental goals, processes and relationships of pharmaceutical care exist regardless of practice

setting. Reference: Hepler and Strand, 1989, Opportunities and responsibilities in pharmaceutical care, American Journal of Pharmaceutical Education, Vol 53, 7S-15S

Non-Pharmacological Interventions Grade 3 QI

IF a person ageing with intellectual disability presents with behaviour disorders (that may include aggression or self injurious behaviour) **THEN** medication use should be considered only after non-medication use interventions **BECAUSE** behavioural, psychological, social and environmental interventions should be considered before medication is used for aggression or self injury and medication use has been found to be the least effective treatment for problem behaviours.

External Environment and Behaviour Disorders Grade 3 QI

IF a person ageing with intellectual disability presents with a behaviour disorder **THEN** external environmental factors, including staff/family/carers should be looked at before medication use **BECAUSE** external environmental factors may be responsible for or impact on behaviour disorders and both psychiatric and applied behavioural analytical models of behaviour allow for the importance of environmental events.

Dementia Cholinesterase Inhibitors Grade 3 QI

IF a person ageing with intellectual disability is diagnosed with dementia **THEN** quality of life and possible side effects should be considered before cholinesterase inhibitors are prescribed **BECAUSE** prescribers should be aware of the potential risks when treating patients with cholinesterase inhibitors and the limited benefits of the cholinesterase inhibitors should be balanced against the potential risk of serious adverse events.

Dental and Oral Health Grade 3 QI

IF behaviour change is observed in a person ageing with intellectual disability **THEN** an oral health assessment should be included as part of a general health assessment **BECAUSE** people with intellectual disability have poor oral health/oral hygiene and reductions in salivary flow due to medication use are associated with increased incidence of dental caries (decay), gingivitis, oral candida and difficulties in eating and speaking.

Pain Grade 3 QI

IF a person ageing with intellectual disability presents with a behaviour disorder and/or physical discomfort **THEN** a strong index of suspicion with regard to pain should be

maintained before psychotropic medication is prescribed **BECAUSE** pain is a complex process people with intellectual disability are at increased risk for chronic pain and under treatment of physical pain may occur if psychotropic medications are prescribed as they may mask the signs of physical pain and any physical problems that causes pain or distress can also cause difficulty in focusing attention, sleeping and eating, as well as psychomotor agitation and may be treated as a behaviour disorder.

Infections Grade 3 QI

IF behaviour change in a person ageing with intellectual disability causes concern **THEN** psychotropic medication should only be prescribed following a proper assessment and where a clear rationale for medication use has been identified **BECAUSE** it must be recognised that medical conditions such as infections can be a contributory factor in behaviours disorders and high rates of hospitalisation for infections have been identified.

As Required/PRN Prescribing of Psychotropic Medication Grade 3 QI

IF a person ageing with intellectual disability is prescribed 'prn' (as required) medication for a behaviour disorder **THEN** the use of 'prn' medication should be reserved for behaviours that occur infrequently, without provocation and that do not diminish in intensity **BECAUSE** the regular use of a 'prn' for more than a few weeks is indicative of a need to further explore environmental etiology or take a systematic review of treatment regime and 'prn' use may be associated with poly-pharmacy.

Psychotropic Medication - Physical Side Effects Grade 3 QI

IF psychotropic medication use is a component of the care of a person ageing with intellectual disability and a behaviour disorder **THEN** the person (and/or carer) should be aware of any possible impact of the medication on the person's physical health **BECAUSE** physical and metabolic side effects associated with psychotropic medication are not unavoidable and may be minimised by careful monitoring, dietary control and exercise regimens in people with intellectual disability and initiatives should be taken to enhance the healthcare of those ageing with intellectual disability.

Adverse Drug Reactions Grade 3 QI

IF a person ageing with intellectual disability who is prescribed medication presents with a new or changed condition or a change in functioning and/or behaviour **THEN** a medication review should be undertaken (by a pharmacist) **BECAUSE** people with intellectual disability are more likely to have certain medication side effects overlooked

or ignored and unrecognised adverse drug reactions in a person with limited communication ability may be misdiagnosed as an exacerbation of an existing medical problem, as a new medical problem or behaviour related.

5. Grade 4 Quality Indicators

Acute Behaviour Grade 4 QI

IF medication is used to treat an acute behaviour problem in a person ageing with intellectual disability **THEN** the underlying causes of the problem behaviour or presenting symptoms must be identified and addressed before medication is used **BECAUSE** when the acute phase has stabilized, the prescriber must consider if medication could be discontinued or reduced and low levels of intervention accountability and supervision may place many people with behaviour problems at increased risk for ineffective and unnecessary interventions.

Advocate Grade 4 QI

IF medication is prescribed to manage a behaviour disorder in a person ageing with intellectual disability **THEN** advocacy services should be available to the person with intellectual disability and/or their carers to explore intervention options **BECAUSE** an advocate from outside the clinical team should help determine the person's interests to minimize restrictions to freedom and to take past and present wishes into account and there are no clear prohibitions about a nonmedical mental health professional talking with clients about psychotropic medication (although this is still a grey area).

Covert Medication Grade 4 QI

IF medication is administered in a covert manner to a person ageing with intellectual disability and a behaviour disorder **THEN** the healthcare personnel/family member/carer involved in the practice of administering medication covertly should be fully aware of the aims, intent and implications of such treatment and the safety profile of the medication **BECAUSE** the best interests of the patient are paramount as covert administration of medication may involve the administration of a medication outside the terms of its licence and put the patient at risk and ethical, as well as legal, issues are inherent in the practice of covert medication with a potential scope for misuse and abuse.

Inter and Intra Class Psychotropic Poly-Pharmacy Grade 4 QI

IF a person ageing with intellectual disability and a behaviour disorder is prescribed psychotropic medication **THEN** psychotropic poly-pharmacy should be avoided (where

possible) **BECAUSE** limiting poly-pharmacy is a critical clinical issue, as inter-class/intra-class poly-pharmacy may result in adverse medication effects and/or non-compliance and many people ageing with intellectual disability receive medication over long periods with no clear diagnostic guidelines for the concurrent use of antipsychotic medications from different classes.

Anti-Epileptic Medication Grade 4 QI

IF a person ageing with intellectual disability and a behaviour disorder is prescribed anti-epileptic medication **THEN** there should be heightened awareness of potential side effects **BECAUSE** people with intellectual disability may have special conditions with regard to metabolism, sensitivity to medication effects, including reduced capabilities to cope with and report side effects and all patients should be monitored for notable changes in behaviour that could indicate the emergence or worsening of suicidal thoughts or behaviour or depression.

'Off Label' Psychotropic Medication Grade 4 QI

IF a person ageing with intellectual disability and a behaviour disorder is prescribed 'off label' psychotropic medication **THEN** good case note documentation of the process is important and supports the prescriber, pharmacist and administrator of the medication **BECAUSE** 'off label' prescribing is common in patients with intellectual disability and mental illness and clinicians must consider the evidence that the medication is likely to be effective for the unlicensed indication and any risks involved.

Gastrointestinal Disorders Grade 4 QI

IF a person ageing with intellectual disability presents with a behaviour disorder, (including hand-mouthing) **THEN** possible gastrointestinal disorders should be considered **BECAUSE** gastrointestinal disorders are prevalent in patients with intellectual disability and if not treated may contribute to behaviour disorders and gastro-oesophageal reflux disease has been shown to be present in greater frequency among individuals with hand mouthing than among matched peers who did not engage in hand mouthing.

Autistic Spectrum Conditions Grade 4 QI

IF a person ageing with intellectual disability and an autistic spectrum condition is prescribed medication **THEN** there should be continual review of their reactions to medications prescribed **BECAUSE** people with autistic spectrum conditions may have altered sensory sensitivity and sensory processing difficulties and any change in any

behaviour after medication administration has begun must be viewed as an indicator of a possible side effect.

APPENDIX 26

Principles of Good De-prescribing during Medication Review in the Population with Intellectual Disabilities and Behaviour Disorders

Principles of Good De-prescribing during Medication Review in the Population with Intellectual Disabilities and Behaviour Disorders.	
Based on the British Pharmacological Society's Principles for Good Prescribing 2010	
1	Be clear about the reasons for de-prescribing.
2	Take into account the patient with intellectual disabilities and behaviour disorders medication history before de-prescribing.
3	Take into account other factors that might alter the benefits and risks of de-prescribing treatment in the patient with intellectual disability and behaviour disorders.
4	Take into account the patient's/carer's/families/advocates ideas, concerns and expectations.
5	Ensure all medicines are effective, safe, cost-effective in appropriate form, individualised for the patient with intellectual disability, behaviour disorders and other conditions such as dysphagia, autism.
6	Adhere to national guidelines and local formularies where appropriate. Use caution where the population with intellectual disability have not been considered in the guideline development process.
7	Write unambiguous correct documentation detailing reason for de-prescribing.
8	Monitor the beneficial and adverse effects of de-prescribing medicines and any effects on behaviour.
9	Communicate and document all de-prescribing decisions and the reasons for them such as transferred to appropriate personnel such as GP, pharmacist, psychiatrist, epileptologist, carer and patient.
10	De-prescribe within the limitations of your knowledge, skills and experience of the population with intellectual disabilities and behaviour disorders.

APPENDIX 27

Statutory Instrument (S.I.) No. 367/2013 Reference to Medicines and Pharmaceutical Service

Statutory Instrument (S.I.) No. 367/2013 - Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013, makes the following reference to medicines and pharmaceutical service.

29.

(1) The registered provider shall ensure that a pharmacist of the resident's choice, in so far as is practicable, or a pharmacist acceptable to the resident, is made available to each resident.

(2) The person in charge shall facilitate a pharmacist made available under paragraph (1) in meeting his or her obligations to the resident under any relevant legislation or guidance issued by the Pharmaceutical Society of Ireland. The person in charge shall provide appropriate support for the resident if required, in his/her dealings with the pharmacist.

(3) The person in charge shall ensure that, where a pharmacist provides a record of a medication-related intervention in respect of a resident, such record is kept in a safe and accessible place in the designated centre.

(4) The person in charge shall ensure that the designated centre has appropriate and suitable practices relating to the ordering, receipt, prescribing, storing, disposal and administration of medicines to ensure that -

(a) any medicine that is kept in the designated centre is stored securely;

(b) medicine which is prescribed is administered as prescribed to the resident for whom it is prescribed and to no other resident;

(c) out of date or returned medicines are stored in a secure manner that is segregated from other medicinal products, and are disposed of and not further used as medicinal products in accordance with any relevant national legislation or guidance; and

(d) storage and disposal of out of date, or unused, controlled drugs shall be in accordance with the relevant provisions in the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988), as amended.

(5) The person in charge shall ensure that following a risk assessment and assessment of capacity, each resident is encouraged to take responsibility for his or her own medication, in accordance with his or her wishes and preferences and in line with his or her age and the nature of his or her disability.