Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the announced inspection of medication safety at Cork University Hospital.

Date of announced inspection:

15 June 2018

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

Setting Standards for Health and Social Services — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.

Regulation — Registering and inspecting designated centres.

Monitoring Children's Services — Monitoring and inspecting children's social services.

Monitoring Healthcare Safety and Quality — Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.

Health Technology Assessment — Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.

Health Information — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Table of Contents

1. Introduction 1
2. Findings at Cork University Hospital 3
   2.1 Governance and risk management 3
   2.2 Audit and evaluation 10
   2.3 Medication safety support structures and initiatives 12
   2.4 Person-centred care 15
   2.5 Policies procedures and guidelines and access to information 16
   2.6 Training and education 17
3. Conclusion 19
4. References 21
5. Appendices 25
   Appendix 1: Medication safety monitoring programme Phase One: Lines of Enquiry and associated National Standard for Safer Better Healthcare 25
   Appendix 2: Hierarchy of Effectiveness of Risk Reduction Strategies in Medication Safety 26

1. Introduction

Medications are the most commonly used intervention in healthcare, and advances in medication usage continue to play a key role in improving patient treatment success. However, where medicines are used, the potential for error, such as in prescribing, administering or monitoring, also exists. While most medication errors do not result in patient harm, medication errors have, in some instances, the potential to result in catastrophic harm or death to patients.

Medication related events were the third most common type of adverse event recorded in the Irish National Adverse Events Study.[1] Medication safety has also been identified internationally as a key focus for improvement in all healthcare settings and it is estimated that on average, at least one medication error per hospital patient occurs each day.[2] The World Health Organisation (WHO) has identified Medication Safety as the theme of the next Global Patient Safety Challenge on Medication Safety.[3] This global initiative, launched in March 2017, safety aims to address the weaknesses in health systems that lead to medication errors and the severe harm that results.

HIQA's medication safety monitoring programme, which commenced in 2016, aims to examine and positively influence the adoption and implementation of evidence-based practice in public acute hospitals around medication safety. HIQA monitors medication safety against the *National Standards for Safer Better Healthcare* [4] to determine if hospitals have effective arrangements in place to protect patients from harm related to medication use.

An expert advisory group was formed to assist with the development of this medication safety monitoring programme. The advisory group membership included patient representation, alongside members with relevant expertise from across the Irish health service. Specific lines of enquiry were developed to facilitate medication safety monitoring. The lines of enquiry which are aligned to HIQA's *National Standards for Safer Better Healthcare* are included in Appendix 1 of this report. Further information can be found in a *Guide to the Health Information and Quality Authority's Medication Safety Monitoring Programme in Public Acute Hospitals 2016* [5] which is available on HIQA's website: www.hiqa.ie

A national overview report of the of medication safety monitoring programme *'Medication safety monitoring programme in public acute hospitals- an overview of findings'* [6] was published in January 2018 which presented the findings from thirty-four public acute hospitals inspected from November 2016 to October 2017 (the report is available on HIQA's website, www.hiqa.ie). In this report HIQA identified areas of good practice in relation to medication safety and areas that require

improvement to ensure medication safety systems were effective in protecting patients.

An announced medication safety inspection was carried out at Cork University Hospital by Authorised Persons from HIQA; Emma Cooke, Nora O'Mahony and Noelle Neville. The inspection was carried out on 15 June 2018 between 09:00hrs and 16:10 hrs. Interviews were held in the hospital with the following groups of managers and clinical staff:

- Group One: the chairperson of the Drugs and Therapeutics Committee, the chairperson of the Medication Safety Committee, the chief pharmacist, the risk manager and medication safety pharmacist.
- Group Two: the chief executive officer, the clinical director of medicine, the director of nursing.

Inspectors visited the following clinical areas and spoke with staff and reviewed documentation on:

- Medical Ward 3A
- Acute Medical Ward 3B

HIQA would like to acknowledge the cooperation of staff who facilitated and contributed to this announced inspection.

2. Findings at Cork University Hospital

The following sections of this report present the general findings of this announced inspection which are aligned to the inspection lines of enquiry.

2.1 Governance and risk management

Lines of enquiry:

- Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.
- There are arrangements in place to identify report and manage risk related to medication safety throughout the hospital.

Cork University Hospital is a model four[7] statutory hospital, owned and managed by the Health Service Executive (HSE), and a member of the South/South West Hospital Group.[*]

Cork University Hospital had formalised governance arrangements and organisational structures in place to support the safe use of medications. The hospital had a Drugs and Therapeutics Committee which represented Cork University Hospital, Mallow General Hospital and Bantry General Hospital.

The Drugs and Therapeutics Committee reported directly to the Executive Quality and Safety Committee and membership of this commitee included the chair of The Drugs and Therapeutics and the chief pharmacist. The Executive Quality and Safety Committee in turn reported to the hospital's Executive Management Board.

The chief executive officer as the person with overall responsibility and accountability for medication safety at the hospital reported to and attended monthly performance management meetings for the South/South West Hospital Group.

The Drugs and Therapeutics Committee

The Drugs and Therapeutics Committee was chaired by a consultant physician and meetings were held every two months. Terms of reference, approved in November 2017, outlined the committee's primary purpose which is to assist the Executive Management Board, clinical directors and the Executive Quality and Safety Committee in developing and maintaining medication management policies,

[*] The South/Southwest Hospital Group comprises of nine hospitals operating across the counties Cork, Kerry, Waterford, Tipperary and Kilkenny. This group is led by a Group Chief Executive Officer with delegated authority to manage statutory hospitals within the group under the Health Act 2004.

procedures and guidelines to support the evidence-based, safe, effective and economic use of medications in Cork University Hospital, Mallow General Hospital and Bantry General Hospital. Terms of reference also detailed the committee's objectives, membership, frequency of meetings and reporting relationship. Correspondence received following this inspection outlined that the Drugs and Therapeutics Committee also represented Cork University Maternity Hospital. However, terms of reference did not outline this.

The Drugs and Therapeutics Committee were required to formally report to the hospital's Executive Quality and Safety Committee three times a year as set out in the committee's terms of reference. However, due to the reorganisation of the Executive Quality and Safety Committee , the Drugs and Therapeutics Committee were unable to report to the Executive Quality and Safety Committee in line with their terms of reference. Inspectors were informed that reporting arrangements were in place outside of the formal process that would allow for issues or concerns to be escalated in a timely manner. The Drugs and Therapeutics Committee needs to ensure its reporting arrangements with the Executive Quality and Safety Committee are in line with their terms of reference to provide senior management with the necessary assurance and oversight of medication management within the hospital.

Membership of the Drugs and Therapeutics Committee was multi-disciplinary to reflect the fact that medicines management is the responsibility of a number of clinical professional groupings.[8] Membership included physicians, pharmacists, nursing management, risk management, representation from peri-operative and a non consultant hospital doctor[†] representative.

Membership should reflect the size of the hospital and services provided with representatives from all the major specialities and other relevant stakeholders including community partners.[9] Inspectors found that not all specialities in the hospital were represented such as representation from the diagnostics directorate. Hospital management outlined that consultation with the relevant expertise would often occur outside the formal process.

It was explained to inspectors that meeting agendas were circulated two weeks in advance of committee meetings and some members would not attend as agenda items were not applicable to their speciality. Attendance at the Drugs and Therapeutics Committee was good for the majority of members, however, following a review of minutes of meetings, inspectors observed gaps in attendance from some key members.

[†] Non-consultant hospital doctor (NCHD) is a term used to describe qualified medical practitioners who work under the (direct or nominal) supervision of a consultant in a particular speciality.

The hospital needs to ensure that membership and expertise of the Committee reflects the decisions the Committee are being asked to make. Strong commitment and regular attendance are essential requirements from all members of a drugs and therapeutics committee. The committee did not have representatives from a general practice (GP) or community pharmacy.

The hospital's Antimicrobial Stewardship Committee and Medication Safety Committee were sub-committees of the Drugs and Therapeutics Committee. The Medication Safety Committee was established in October 2017 and from an operational perspective was responsible for promoting and managing the safe use of medication and supporting standardisation of medication practices at the hospital. The committee met monthly and reported to the Drugs and Therapeutics Committee via the medication safety pharmacist under the standing item agenda of medication safety. The committee was chaired by a consultant and membership was also multidisciplinary. Terms of reference detailed the committee's scope which included some of the following activities:

- leading on medication safety initiatives
- promoting, disseminating and communicating medication safety initiatives to clinical staff
- support the training and education of staff in aspects of medication safety initiatives
- reviewing medication safety incident reports and ensure learning points and recommendations are shared amongst staff.

The hospital had a medication safety programme in place for 2017-2018 and identified five key areas to focus on which included: safety culture, communication, data, infrastructure, training and education. Operational implementation of the medication programme was effectively facilitated by the medication safety pharmacist in conjunction with the Medication Safety Committee. Following a review of an interim medication safety committee report, it was evident that the medication safety programme was being actively progressed at the hospital. Inspectors found evidence of good progress with implementation of elements of the plan. For example, increasing incident reporting was identified as an area of focus within the medication plan and hospital management outlined that there was a noticeable increase in the number of reported medication-related incidents. Furthermore, the report detailed progress to date and outlined ongoing and future work identified to improve medication safety at the hospital.

An effective Drugs and Therapeutics Committee should have ongoing oversight of the medication management and safety system within a hospital. Overall, inspectors found that the medication safety agenda at the hospital was being actively

progressed by the Medication Safety Committee and the Drugs and Therapeutics Committee.

Formulary

The purpose of maintaining a medicines formulary is to ensure that appropriate governance exists within a hospital of what medicines are approved for use by a hospital's Drugs and Therapeutics Committee and that in doing so, a proper safety evaluation occurs before medications are introduced into practice at the hospital.[10] Cork University Hospital had a preferred list of medicines which were approved for use in the hospital. Inspectors were informed that some sections of the preferred medicines list were updated on a yearly basis in conjunction with specialist consultants.

The hospital had a new medicine applications form which was completed by requesting consultants and reviewed by the Drugs and Therapeutics Committee before new medicines were approved for use in the hospital. The decision to approve a new medicine was based on certain information, for example:

- indication for which the medicine was required
- relevant literature to support the proposed medicine
- therapeutic benefits and advantages of the medicine
- cost of treatment
- number of patients requiring the treatment
- medicines to be replaced in the preferred list of medicines.

A review of the Drugs and Therapeutics Committee meetings minutes outlined that applications for new medicines were regularly discussed along with decisions around appropriate prescribing recommendations.

In order to promote rational, evidence based, clinically appropriate, safe and cost effective medication therapy and provide information and guidance on the use of medicines the hospital should continue to review medicines in all specialities that are approved for use in the hospital.[6] This work could be supported through collaboration with other hospitals within the South/South West Hospital Group.

Risk Management

Risks in relation to medication safety at the hospital were included on the hospital's risk register. These risks included included:

- a lack of out-of-hours pharmacy service
- infrastructural issues within the pharmacy department.

The risk register detailed the existing control measures in place to mitigate against current medication safety risks. For example, in response to a lack of out-of-hours pharmacy service, the hospital had convened a review group to look at all practices within pharmacy including out-of-hours dispensing and supply of medications. Pending the outcome of this review the hospital had implemented local control measures such as a database of ward stock that is accessible to all clinical areas and a 'Friday's initiative' to prompt clinical areas to check ward stock levels prior to the weekend to ensure adequate supply.

Medication safety incidents

Studies have found a positive association between increased incident reporting rates and measures of safety culture, where an increase in incident reporting was indicative of a positive safety culture within the hospital.[11] A review of hospital incident summary reports demonstrated that medication-related reporting rates had improved for 2018. By way of example, a total of 250 medication-related incidents had been reported for the first six months of 2018 compared with a total of 255 incidents reported for all of 2017.

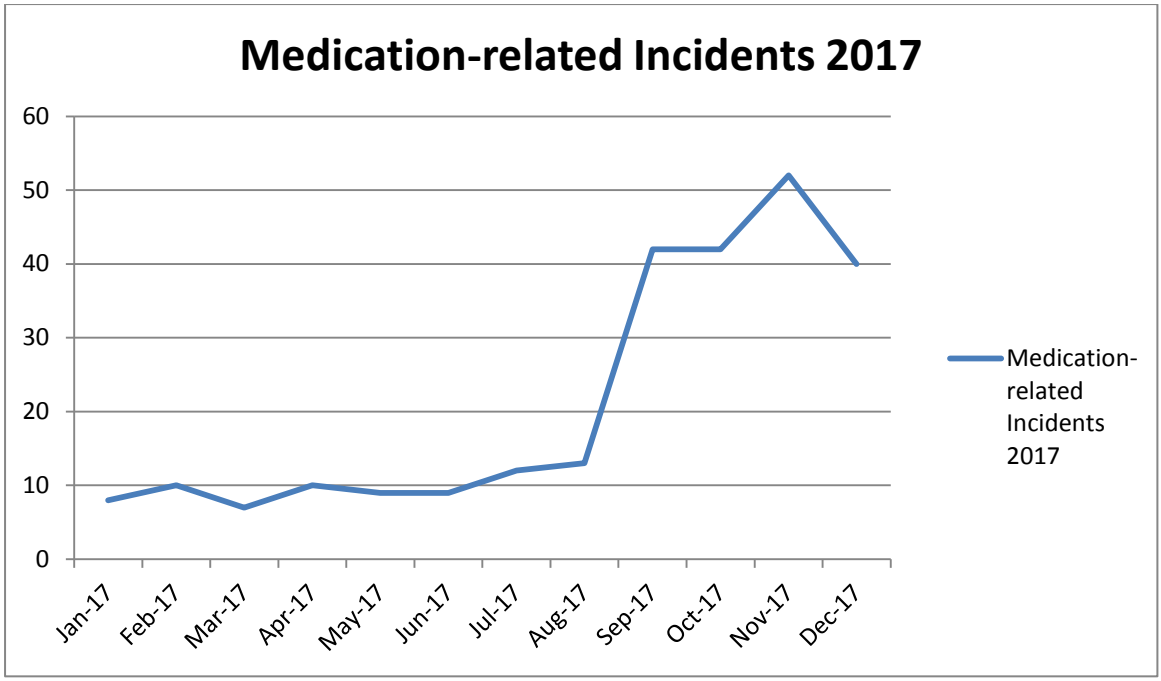


Figure 1: Number of Medication Related Incidents Reported per Month in 2017

Hospital management accredited this increased reporting to an improved culture of incident reporting driven by the medication safety committee and through good working relationships with the nurse practice development unit which supported the implementation of education in relation to incident reporting and quality improvement initiatives such as 'lunch and learn', Medication Safety Bulletins and a Safety Attitudes Questionnaire.

Notwithstanding the progress made with increased reporting rates for medication incidents, inspectors found that reporting rates remained lower than other comparable model four hospitals of similar size and level of service provision. Hospital management acknowledged that there was still under reporting of medication-related incidents at the hospital and were aware of the need for further improvement with reporting.

The hospital facilitated voluntary reporting of medication-related incidents and near misses through the use of an incident report form accessible on the hospital's Intranet. Staff who spoke with inspectors in clinical areas described the process for reporting medication-related incidents and how completed forms were sent to the risk manager for review and grading using the National Incident Management System for grading[‡](NIMS).[12] It was reported that the medication safety pharmacist received monthly reports of medication-related incidents from the risk department. Summary reports of medication safety incidents were also discussed at the Drugs and Therapeutics Committee. In addition, serious medication-related risks were discussed with the medication safety pharmacist as required and notified to the operations manager in order to convene a senior incident management team meeting in line with national standards.[13] All incidents[§] that occurred in the hospital were reported to the State Claims Agency using the National Incident Management System.

Hospital management reported that it was mainly nurses reporting medication incidents, however, reporting rates amongst pharmacists had increased by 70% this year. The culture of reporting medication incidents needs to be broadened out to include other healthcare staff so that safety surveillance is improved, learning is shared, and safety culture is promoted and enhanced across the organisation.

Important lessons can be learned from analysis of medication-related incidents and near misses. Inspectors were informed that medication-related incidents and near misses were analysed and actions were taken to address them with further recommendations made to prevent reoccurrences. Minutes of medication safety committee meetings reviewed demonstrated that corrective and preventative actions were discussed and agreed in response to incidents. For example, following a trend in incidents associated with certain medicines that require particular monitoring of

[‡] ‡ The State Claims Agency (SCA) National Incident Management System (NIMS) is a risk management system that enables hospitals to report incidents in accordance with their statutory reporting obligation to the SCA (Section 11 of the National Treasury Management Agency (Amendment) Act, 2000).

[§] An incident is an unplanned, unexpected or uncontrolled occurrence which causes (or has the potential to cause) injury, ill-health, and /or damage. An incident can be a harmful incident (adverse event), a no harm incident, a near miss, dangerous occurrence or complaint.

medicine therapeutic levels, the hospital had changed their medication prescription administration record to include a prompt to monitor these additional requirements.

Medication incidents and near misses were collated by the risk manager and tracked according to the severity of the incident, cause of incident, contributory factors, stage of the medication process and patient outcome in order to identify emergent medication safety concerns. Through this process the hospital had identified that a number of incidents in 2017 had been associated with a particular type of high-risk medicine. As a result, the hospital established a working group to review medication safety incidents associated with this particular medicine and improve practices. A report from the working group was presented to the Medication Safety Committee and the information contained within the report was disseminated to frontline staff via a medication safety bulletin.

Staff informed inspectors that they received information on incidents that had occurred throughout the hospital through daily ward huddles[**], ward meetings, medication safety bulletins, nurse management meetings and grand rounds.[††]

Overall, inspectors found that the hospital had recently improved the systems in place for identifying, evaluating and responding to risk. This was evidenced by enhanced risk management processes between the risk department and medication safety pharmacist and improved oversight and reporting arrangements for medication-related incidents. The hospital should continue to work towards improving reporting of medication-related incidents to enable understanding of the exact nature and contributory factors leading to medication errors. Such implementation is key to the implementation of prevention strategies developed from learning gained through trending and analysis.

Clinical trials

All medicines must undergo clinical trials before they are granted a licence in Ireland, or in Europe.[14] Clinical trials were currently not discussed at the Drugs and Therapeutics Committee. It is recommended that Drugs and Therapeutics Committees should have involvement in monitoring and evaluating the risks of clinical trials.[8]

[**] Huddles are brief and routine meetings for sharing information about potential or existing safety problems facing patients or workers. They aim to increase safety awareness among front-line staff, allow for teams to develop action plans to address identified safety issues, and foster a culture of safety.

[††] Grand rounds: are formal meetings where physicians and other clinical support and administrative staff discuss the clinical case of one or more patients. Grand rounds originated as part of medical training.

2.2 Audit and evaluation

Line of enquiry:

- The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.

Hospitals should have arrangements in place to ensure the effectiveness of healthcare is systematically monitored and continuously improved. The information gathered should be used to improve services, and the learning gained should be shared throughout the hospital.

Elements of medication safety were audited at the hospital but not all audits were aligned to a formalised medication safety strategy. Inspectors found that some audit activity was neither strategically driven nor centrally coordinated.

Documentation provided to inspectors outlined that a total of 37 medication-related audits had been completed by a number of staff disciplines in the previous 12 months. Inspectors requested to review a number of audits from the list of completed audits, however some of these audits could not be accessed or retrieved on the day of inspection.

Inspectors were provided with other examples of medication-related audits which included:

- insulin medication prescription and admistration record audit
- anti-coagulant prescribing and administration audit
- an audit of surgical prophylaxis in patients
- medication storage and self-administration audit.

A key feature in clinical audit is the completion of the clinical audit cycle. Some of the audits reviewed by inspectors did not detail the findings and recommendations from the audit and therefore had not completed the audit cycle[‡‡].

Inspectors were informed some audit results were communicated throughout the organisation through various forums including senior nurse management meetings,

[‡‡] Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level, and further monitoring is used to confirm improvement in healthcare delivery.

grand rounds[§§], medication safety bulletins and through hospital staff emails. However, hospital management reported that audit findings and recommendations were not always communicated and disseminated between disciplines. Dissemination of audit results is essential so that the clinical workforce is informed of the areas that need improvement, and also to motivate them to change practice and participate in improvement activities.[15, 16]

Hospital management demonstrated an awareness of the inherent gaps within the hospital's clinical audit system and outlined that the audit department were in the process of reviewing current audit processes to ensure audits are more centrally controlled and shared learning occurs.

The pharmacy department had devised a medication safety audit programme for 2018 and there was evidence that feedback reports for some of these completed audits were discussed at medication safety committee meetings and drugs and therapeutics meetings.

The pharmacy department completed a pharmacy intervention audit in February 2018. Clinical pharmacists reviewed 141 patients (24% of inpatients) on the day of the audit and identified 212 interventions with the most common intervention identified by clinical pharmacy being wrong dose/frequency and omission of a medication.

The hospital used other sources of information to identify strengths and weaknesses in the hospital medication system including medication-related key performance indicators, nursing metrics, pharmacy intervention audits, retrospective patient healthcare record reviews, direct observation and voluntary reporting of adverse events.

Measurement of medication safety metrics and audit were identified as key areas of focus in the hospital's medication safety programme for 2017/2018. Key performance indicators identified by the hospital included:

- medication reconciliation and drug chart reviews
- national nursing quality care metrics.

Progress against these key performance indicators to date was detailed in a medication safety interim report for 2017/2018 and discussed at the Medication Safety Committee and Drugs and Therapeutics Committee.

[§§] Grand rounds are formal meetings where physicians and other clinical support and administrative staff discuss the clinical case of one or more patients. Grand rounds originated as part of medical training.

Nursing metrics[***] were monitored across the hospital to review practice around some aspects of medication storage and administration. Results provided for some of the clinical areas for the previous year relating to medication storage, custody and administration were generally good. However, there were consistently less than satisfactory findings in relation to observations around medication prescribing. To promote awareness across all disciplines about the nursing metric results and in particular to raise awareness about the less than desirable metric results associated with prescribing metric results, the hospital included nursing metric results in the medication safety bulletin, presented nursing metric results at doctor's teaching sessions and circulated results to doctor's emails.

Clinical audit represents a key component of all effective clinical governance programmes.[17] Cork University Hospital demonstrated evidence of some clinical audit and monitoring in relation to medication safety. Current arrangements should be strengthened and formalised to ensure a more systematic approach to audit selection. Dissemination of audit and key performance indicator results at executive level and clinical level is essential to provide assurance to senior hospital management and frontline staff about medication safety at the hospital and to motivate staff to participate in improvement activities and improve practice.[18]

The hospital should continue to progress the plans outlined to inspectors to enhance monitoring and evaluation arrangements at the hospital and to ensure dissemination of audit findings throughout the hospital.

2.3 Medication safety support structures and initiatives

Line of enquiry:

- Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.

Inspectors were informed of and reviewed some examples of quality improvement initiatives that had been implemented at the hospital which included:

- 'Friday's initiative' by pharmacy staff
- lunch and learn
- medication safety bulletin
- speciality based medication safety working groups.

[***] Metrics are parameters or measures of quantitative assessment used for measurement and comparison or to track performance.

Inspectors found examples of where medication safety quality improvement initiatives were strategically driven by learning gained from risks identified and medication incidents. For example, the 'Friday's initiative' had been implemented to predict and decrease the out-of-hours requirement to access the pharmacy at weekend. A number of actions had been implemented in clinical areas and the pharmacy department to support this initiative. This initiative was found to have a positive impact as the average number of medicines taken per weekend had significantly decreased in 2018.

The hospital maintained a list of high-risk medications that present a heightened risk of causing significant patient harm if not used correctly. The acronym 'A PINCH'[†††] which grouped medications into categories was used to facilitate education and to raise awareness of high-risk medications. Inspectors observed accessible and user friendly posters displayed in clinical areas outlining high-risk medicines. The hospital promoted medication safety awareness of high-risk medications through some risk reduction strategies as outlined in their APINCH poster, for example;

- insulin pens sealed with stickers to indicate single patient use only
- segregation of potassium containing infusion bags from non potassium containing infusion bags
- use of pre-mixed potassium solutions whenever possible
- restricted access to high strength heparin for the majority of clinical areas.

An up-to-date policy on the management of high-risk medications at the hospital was available for staff to access in the clinical areas and detailed the risk reduction strategies in place for high-risk medicines and also included live links to other associated internal policies and useful information. However, compliance with risk-reduction strategies in place for high-risk medicines was not routinely monitored. Inspectors were informed that the hospital would rely on direct observation from staff, incident reports and nursing metrics to identify concerns.

Inspectors found examples where medication safety measures designed at promoting awareness of medicines with similar names had not been effectively implemented in practice. For example, the hospital had devised a sound-alike-look-alike (SALADS) list to make staff aware of medicines that have similar names. This was supported by a locally developed policy also. However, inspectors found that some staff were not familiar with this term and lists were not displayed or used within the clinical areas inspected.

Cork University Hospital was participating in the Health Service Executive (HSE) Quality Improvement Division venous thromboembolism quality improvement

[†††] **A**nti-infectives, **P**otassium, **I**nsulin's, **N**arcotics, **C**hemotherapy, **H**eparin and other anticoagulants

collaborative. This is a collaborative among multidisciplinary teams in Irish adult acute public and voluntary hospitals who are working together to achieve appropriate thromboprophylaxis for their hospital's inpatients, to reduce the risk of venous thromboembolism and to minimise harm and expenditure associated with unnecessary thromboprophylaxis.

Clinical pharmacy service

There are currently no agreed national standards outlining requirements for the provision of clinical pharmacy services in hospitals. International studies support the role of clinical pharmacists in hospital wards in preventing adverse drug events.[19,20,21,22,23,24] A clinical pharmacy service was provided for the following high risk areas: coronary care unit, intensive care unit and the neonatal unit. It was reported that the majority of remaining clinical areas had a clinical pharmacy on a daily basis. However, the hospital had identified clinical areas which did not receive a clinical pharmacy service or required increased clinical pharmacy cover. Inspectors were informed that a business case for an additional two clinical pharmacists for oncology services had been submitted three years ago but these positions had not been approved at the time of this inspection. Correspondence received after this inspection outlined that business cases have been submitted for identified clinical areas including that of clinical pharmacy service manager. While this is being progressed, the hospital should continue to review the clinical pharmacy service available in order to ensure that clinical areas are receiving the appropriate level of clinical pharmacy cover as required and identified by the hospital.

Medication reconciliation

Medication reconciliation is a systematic process conducted by an appropriately trained individual to obtain an accurate and complete list of all medications that a patient is taking on admission, discharge and other transitions in care.[25,26,27]

It was reported that clinical pharmacists undertook medication reconciliation for patients on admission in the areas they were assigned. Inspectors were informed that newly admitted patients were prioritised for medication reconciliation. Activities relating to medication reconciliation were detailed in a recently approved guideline on pharmacy medication reconciliation. The hospital's new medication prescription administration record had a designated section for medication reconciliation. Inspectors were informed that all clinical pharmacists record the number of medication reconciliation completed and the number of medication administration records reviewed on an on-going basis. These metrics were reported to the Medication Safety Committee. Minutes of meetings reviewed showed that pharmacists completed a total of 1,616 medication reconciliations in quarter one of 2018.

2.4 Person-centred care

Line of enquiry:

- Patients and/ or carers are informed about the benefits and associated risks of prescribed medications in a way that is accessible and understandable.

Patients should be well informed about any medications they are prescribed and any possible side effects. This is particularly relevant for those patients who are taking multiple medications.[28,29]

Cork University Hospital National Patient Experience Survey [‡‡‡] was completed by 55% of the 1641 people discharged from the hospital in May 2017.

Two questions related directly to medication in the National Patient Experience Survey;

- **Question 45**: Did a member of staff explain the purpose of the medications you were to take at home in a way you could understand?
- **Question 46:** Did a member of staff tell you about medication side effects to watch for when you went home?

	Cork University Hospital score	National score
Question 45: Did a member of staff explain the purpose of the medicines you were to take at home in a way you could understand?	7.8	7.8
Question 46: Did a member of staff tell you about medication side effects to watch for when you went home?	5.0	5.1

Figure 2: Comparison between Cork University Hospital and national scores for the National Patient Experience Survey questions 45 and 46.

[‡‡‡] The National Patient Experience Survey was a nationwide survey which asked people for feedback about their stay in hospital. The survey was a partnership between the Health Service Executive (HSE), HIQA and the Department of Health. All adult patients discharged during May 2017 who spent 24 hours or more in a public acute hospital, and have a postal address in the Republic of Ireland were asked to complete the survey.

In response to the National Patient Experience Survey inspectors were informed that the hospital plans to review patient information for high-risk medicines to ensure they are written in plain english[§§§] and provide information on the side effects of medication.

2.5 Policies procedures and guidelines and access to information

Lines of enquiry:

- Hospitals develop effective processes for medication management that are implemented and supported by clear and up to date policies, procedures and/or protocols.
- Essential information supporting the safe use of medicines is readily available in a user friendly format and is adhered to when prescribing, dispensing and administering medications.

Medication policies, procedures, protocols and guidelines were readily available to staff through the hospital's controlled document management system. All medication-related policies, procedures and guidelines were approved by the Drugs and Therapeutics Committee before final approval by the Executive Quality and Safety Committee. Minutes of the Drugs and Therapeutic Committee meetings demonstrated discussion and decision making about new polices for approval.

It is recommended, by both the Health Service Executive[30] and the National Clinical Effectiveness Committee [31] that policies, procedures and guidelines are reviewed and updated every three years. However, inspectors found a number of examples where medication-related policies were overdue for review.

Decision support tools[****] and policies, procedures, protocols and guidelines must be readily available at the point of use[††††] to ensure the information is followed in practice. The hospital had medicines information resources available to assist staff when prescribing or administering medicines in the hospital, for example:

- antimicrobial prescribers' guide
- intravenous drug monographs
- therapeutic drug monitoring guidelines
- the British National Formulary (BNF).

[§§§] Plain English: clear and unambiguous language, without the use of technical or difficult terms
[****] Decision support tools: are resources that provide guidance or incorporate knowledge to help clinicians make the most appropriate clinical decision for patient care.
[††††] Point of use: includes when prescribing, preparing or administering.

Healthcare requires access to complete and accurate patient information, relevant to the safe use of medications, at the point of clinical decision making to help ensure patient safety. Clinical staff had access to patients' diagnostic results on computers in clinical areas across the hospital.

Inspectors were informed that medicines information and alerts were disseminated to staff via emails, ward huddles, grand rounds and medication safety bulletins. Inspectors observed recent examples of these within the clinical areas which included topics on medicines associated with high risk due to known interactions with other medicines.

Hospital management outlined a system in place for managing safety alerts and product recall. Medicines alerts and communications in relation to medication safety from other authorities was also a standing item agenda at the Drugs and Therapeutics Committee meetings.

Overall, the hospital had developed a range of medicines information and decision support tools to guide staff involved in providing safe and effective medication. The hospital needs to ensure that the development of medication support structures and processes to promote medication safety are locally adapted to the hospital, kept up-to-date and fully and effectively implemented in clinical practice.

2.6 Training and education

Line of enquiry:

- Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.[32] The hospital should ensure that professionals have the necessary competencies to deliver high-quality medication safety through induction and on-going training. This should be a structured, targeted programme of education for medication safety aligned with the hospitals medications safety programme.

HIQA found that training conducted in relation to medication use and safety was usually limited to induction training for nurses and non-consultant hospital doctors. However, there were some additional medication safety sessions provided for some staff on a variety of topics.

The hospital did not have a formalised education programme for clinical staff linked to an overall medication safety strategy. Medication safety training was included in induction programmes for all new nurses, doctors and pharmacists.

It was reported that all new nursing staff attended medication management training at induction which included intravenous medication management. As part of this training nurses were required to complete the HSELanD Medication Management online training programme.[33] It was explained to inspectors by hospital management that nurses were required to update this training every two years, however, nursing staff in the clinical areas visited were not aware of this requirement.

Non consultant hospital doctors were provided with an education session on medication safety at the hospital from pharmacy at induction. Ongoing education was delivered on an informal basis and achieved through ward rounds and journal clubs.

Healthcare providers should plan and devise training and education programmes for their workforce based on strategic objectives and the needs of their patient population.

3. Conclusion

Medications represent the primary measure for treatment intervention in hospitalised patients. Error associated with medication usage constitutes one of the major causes of patient harm in hospital. Medication-related events were the third most common type of adverse event recorded in the recently published Irish National Adverse Events Study. Medication safety should therefore be a priority area for all acute hospitals as they seek to ensure a high quality and safe service for patients.

Cork University Hospital had formalised governance arrangements and organisational structures in place to support the safe use of medications.

Overall the inspection team found that systems, processes and practices were in place at Cork University Hospital to support medication safety, some of which were in the process of implementation. There was multidisciplinary involvement with engagement and support from senior hospital clinicians working to improve medication safety across the hospital.

The hospital had a medication safety programme plan in place for 2017/2018 which was overseen by the Drugs and Therapeutics Committee. The hospital had demonstrated progress across a number of identified areas such as improved medication incident reporting rates and quality improvement initiatives. The hospital should continue to work towards improving reporting of medication-related incidents to enable understanding of the exact nature and contributory factors leading to medication errors.

The need to increase clinical pharmacy services in some clinical areas was identified by hospital management. While the hospital continues to progress additional posts required, clinical pharmacy services must be kept under review in order to provide inpatients with the desired level of clinical pharmacy service as identified by the hospital.

The hospital should progress and expand on the work completed to date with the hospital's preferred list of medicines and move towards the development of a defined formulary process to outline medicines that are approved for use in the hospital. This work could be supported through collaboration with other hospitals within the South/South West Hospital Group.

Some systems were in place to monitor the effectiveness of medication management systems at the hospital. Current arrangements for auditing and evaluating medication safety systems at the hospital should be strengthened and formalised to provide assurance to senior hospital management about medication safety at the hospital.

A range of medicines information and decision support tools had been developed to guide staff involved in providing safe and effective medication. The hospital needs to ensure that the development of quality improvement initiatives and processes to promote medication safety are fully and effectively implemented in clinical practice. Inspectors found examples of where medication safety quality improvement initiatives were strategically driven by learning gained from risks identified and medication incidents.

HIQA found that training conducted in relation to medication use and safety was usually limited to induction training for staff. Investment in ongoing education for healthcare professionals involved in medication management should be prioritised and supported at a senior and executive level in order for staff to develop and maintain their competency, skill and knowledge.

Following this report, the hospital must focus its efforts to address the risks and findings identified in this report, and work to ensure that the necessary arrangements are in place to protect patients from the risk of medication-related harm.

It is recommended that this report is shared with senior managers, clinicians and other relevant staff at Cork University Hospital to highlight both what has been achieved by the hospital in implementing medication safety activities to date, and to foster further collective progression from this time point.

4. References

1. Rafter N, Hickey A, Conroy R, Condell S, O'Connor P, Vaughan D, et al. The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals—a retrospective record review study. *British Medical Journal of Quality and Safety.* 2016; 26: pp111-119. Available online from: http://qualitysafety.bmj.com/content/26/2/111.full.pdf+html

2. Kohn, Linda T, Janet M, Corrigan, Molla S, Donaldson. To Err is Human: Building a Safer Health System. Washington: Institute of Medicine; 1999. Available online from:https://www.nap.edu/download/9728#

3. World Health Organisation. *Medication Without Harm: WHO's Third Global Patient Safety Challenge*. 2017 (online) Available online from: http://www.who.int/patientsafety/medication-safety/en/

4. Health Information and Quality Authority. *National Standards for Safer Better Healthcare.* Dublin: Health Information and Quality Authority; 2012. Available online from: https://www.hiqa.ie/reports-and-publications/standards/national-standards-safer-better-healthcare

5. Health Information and Quality Authority. *Guide to the Health Information and Quality Authority's Medication Safety Monitoring Programme in Public Acute Hospitals.* Dublin: Health Information and Quality Authority; 2016. Available online from: https://www.hiqa.ie/reports-and-publications/guide/guide-medication-safety-monitoring-acute-hospitals

6. Health Information and Quality Authority. *Medication safety monitoring programme in public acute hospitals-An overview of findings.* Dublin: Health Information and Quality Authority; 2018. Available online from: https://www.hiqa.ie/reports-and-publications/key-reports-and-investigations/medication-safety-monitoring-programme

7. Health Service Executive. Report of the National Acute Medicine Programme 2010. Health Service Executive 2010. Available online from: http://www.hse.ie/eng/about/Who/clinical/natclinprog/acutemedicineprogramme/report.pdf

8. Council of Australian Therapeutic Advisory Groups. Achieving effective medicines governance. Guiding Principles for the roles and responsibilities of Drugs and Therapeutics Committees in Australian public hospitals. November 2013. Available online from: http://www.catag.org.au/wp-content/uploads/2012/08/OKA9964-CATAG-Achieving-Effective-Medicines-Governance-final1.pdf

9. Australian Commission on Safety and Quality in Health Care. Safety and Quality Improvement Guide Standard 4: Medication Safety (October 2012). Sydney: Australian Commission on Safety and Quality in Health Care; 2012. Available online from: https://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard4_Oct_2012_WEB.pdf

10. National Clinical Institute for Health and Care excellence. *Developing and updating local formularied.2014.* Available online from: https://www.nice.org.uk/guidance/mpg1

11. Abstoss KM, Shaw BE, Owens TA, Juno JL, Commiskey EL, Niedner MF. Increasing medication error reporting rates while reducing harm through simultaneous cultural and system-level interventions in an intensive care unit. BMJ Quality and Safety 2011;20:pp914-922. [Online] Available from: https://www.ncbi.nlm.nih.gov/pubmed/21690249

12. State Claims Agency. National Clinical Incidents, Claims and Costs Report 2010-2014. [Online] Available from: http://stateclaims.ie/2017/05/national-clinical-incidents-claims-and-costs-report-lessons-learned-a-five-year-review-2010-2014/

13. Mental Health Commission and Health Information and Quality Authority. *National Standards for the Conduct of Reviews of Patient Safety Incidents* . Available online from: https://www.hiqa.ie/sites/default/files/2017-10/National-Standards-Patient-Safety-Incidents.pdf

14. Pharmaceutical Healthcare Association (IPHA) Available online from: http://www.ipha.ie/alist/clinical-trials-in-ireland.aspx

15. Heath Service Executive (2013) A practical Guide to clinical audit available from http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Clinical_Audit/claudit filespdfs/practicalguideclaudit2013.pdf

16. Australian Commission on Safety and Quality in Health Care. *Safety and Improvement Guide Standard 4: Medication Safety (October 2012)*. Sydney: Australian Commission on Safety and Quality in Health Care; 2012. Available online from: https://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard4_Oct_2012_WEB.pdf

17. Australian Commission on Safety and Quality in Health Care. *Safety and Quality Improvement Guide Standard 4: Medication Safety*. Sydney: Australian Commission on Safety and Quality in Health Care; 2012. Available online from: https://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard4_Oct_2012_WEB.pdf

18. Heath Service Executive. A practical guide to clinical audit; 2013. Available online from: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Clinical_Audit/claudit filespdfs/practicalguideclaudit2013.pdf

19. Kaushal R, Bates DW, Abramson EL, Soukup JR, Goldmann DA. Unit-based clinical pharmacists' prevention of serious medication errors in pediatric inpatients. *American Journal of Health-System Pharmacy*. 2008 July 1; 65(13): pp1254-60.

20. De Rijdt T, Willems L, Simoens S. Economic effects of clinical pharmacy interventions: a literature review. *American Journal of Health System Pharmacy*. 2008 Jun 15;65(12): pp1161–72.

21. Rivkin A, Yin H. Evaluation of the role of the critical care pharmacist in identifying and avoiding or minimizing significant drug-drug interactions in medical intensive care patients. *Journal of Critical Care*. 2011 Feb;26(1): pp104 Available online from: http://www.sciencedirect.com/science/article/pii/S0883944110001188

22. Agency for Healthcare Research and Quality. *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Evidence Report/Technology Assessment No. 211Chapter 4. Clinical Pharmacist's Role in Preventing Adverse Drug Events: Brief Update Review.* . Maryland: Agency for Healthcare Research and Quality; 2013. pp31- 40. Available online from: https://archive.ahrq.gov/research/findings/evidence-based-reports/ptsafetyII-full.pdf

23. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA.* 1999 July 21;282(3): pp267–70. Available online from: http://jamanetwork.com/journals/jama/fullarticle/190687

24. Bond CA, Rael CL. Clinical pharmacy services, pharmacy staffing, and hospital mortality rates. *Pharmacotherapy.* April 2007; 27 (4): pp481-93

25. Health Information and Quality Authority. *Guidance for health and social care providers. Principles of good practice in medication reconciliation.* Dublin: Health Information and Quality Authority; 2014. Available online from: https://www.hiqa.ie/reports-and-publications/guides/guidance-principles-good-practice-medication-reconciliation

26. World Health Organization. *The High 5s Project. Standard Operating Protocol. Assuring Medication Accuracy at Transitions in Care.* Washington: World Health Organisation; 2014. Available online from http://www.who.int/patientsafety/implementation/solutions/high5s/h5s-sop.pdf

27. Galvin M, Jago-Byrne MC, Fitzsimons M, Grimes, T. Clinical pharmacist's contribution to medication reconciliation on admission to hospital in Ireland. *International Journal of Clinical Pharmacists*. February 2013; 35 (1): pp14–21

28. Health Service Executive, Quality and Patient Safety Division. Integrated Care Guidance: A practical guide to discharge and transfer from hospital. Health Service Executive. January 2014. Available online from: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/safepatientcare/integratedcareguidance/IntegratedCareGuidancetodischargefulldoc.pdf

29. National Institute for Health and Care Excellence (NICE). *Clinical Guideline 76. Medicines adherence: Involving patients in decisions about prescribed medicines and supporting adherence*. National Institute for Health and Clinical Excellence; 2009. Available at http://guidance.nice.org.uk/CG76

30. Health Service Executive Framework for developing Policies, Procedure Protocols and Guidelines (PPPGs) 2016. Available online from: http://www.hse.ie/eng/about/Who/QID/Use-of-Improvement-methods/nationalframeworkdevelopingpolicies/

31. National Clinical Effective Committee. Standards for Clinical Practice Guidance (2015). Available online from: https://health.gov.ie/national-patient-safety-office/ncec/clinical-practice-guidance/

32. Institute of Safe Medication Practices (ISMP) Staff competency, education. Institute of Safe Medication Practices; 2009. Available online from: http://pharmacytoday.org/article/S1042-0991(15)31825-9/pdf

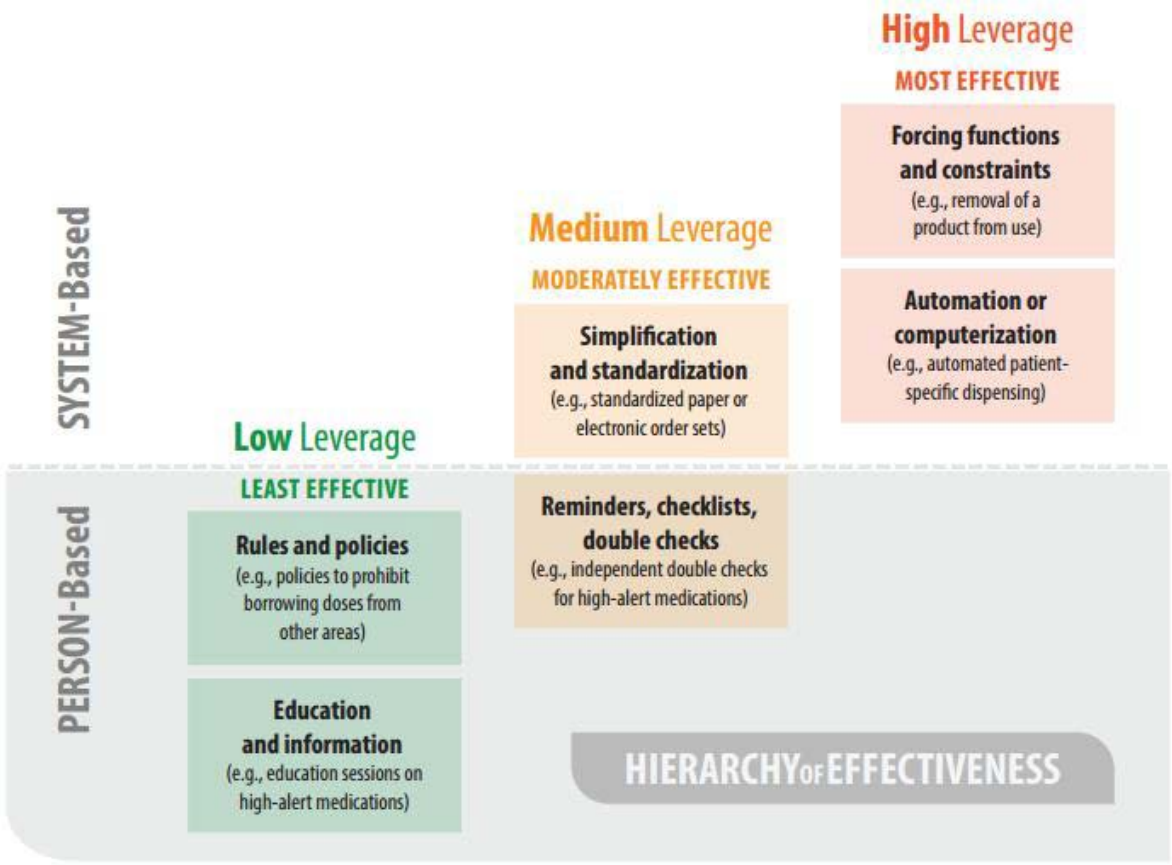
33. Health Service Executive. HSELanD. Available online from http://www.hseland.ie/tohm/default.asp?message=logout

5. Appendices

Appendix 1: Medication safety monitoring programme Phase One: Lines of Enquiry and associated National Standard for Safer Better Healthcare

Area to be explored	Line of enquiry[1]	National Standards for Safer Better Healthcare
Clear lines of accountability and responsibility for medication safety	Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.	3.1, 5.1, 5.2, 5.4, 5.5, 5.6, 5.8, 5.9, 5.10, 7.1
Patient involvement in service delivery	Patients and or carers are informed about the benefits and associated risks of prescribed medicines in a way that is accessible and understandable.	1.4, 1.5, 1.7, 3.1, 4.1
Policies procedures and guidelines	Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.	2.1, 3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.11, 8.1
Risk management	There are arrangements in place to identify, report and manage risk related to medication safety throughout the hospital.	3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.10, 5.11, 8.1
Audit and evaluation	The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.	2.8, 3.1, 5.8, 8.1
Education and training	Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.	6.2, 6.3
Access to information	Essential information of the safe use of medications is readily available in a user-friendly format and is adhered to when prescribing, dispensing and administering medications.	2.5, 8.1

Appendix 2: Hierarchy of Effectiveness of Risk Reduction Strategies in Medication Safety



Reprinted with permission from ISMP Canada.

For further information please contact:

Health Information and Quality Authority
Dublin Regional Office
George's Court
George's Lane
Smithfield
Dublin 7

Phone: +353 (0) 1 814 7400
Email: qualityandsafety@hiqa.ie
URL: www.hiqa.ie