Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the announced inspection of medication safety at Mallow General Hospital, Cork.

Date of announced inspection:

19 July 2017

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

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]

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*[3] 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* [4] which is available on HIQA's website: www.hiqa.ie

An announced medication safety inspection was carried out at Mallow General Hospital by Authorised Persons from HIQA; Kay Sugrue and Noelle Neville. The inspection was carried out on 19 July 2017 between 09:30hrs and 16:20hrs. Interviews were held in the hospital with the following groups of managers and clinical staff:

- Group one: the General Manager and the Senior Pharmacist*.
- Group two: the Clinical Director† and the Director of Nursing.

* The Senior Pharmacist was a member of the Cork University Hospital Group Drugs and Therapeutics Committee.
† The Clinical Director was a member of the Cork University Hospital Group Drugs and Therapeutics Committee.

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

- St. Mary's Ward
- Day Ward.

In addition a survey was conducted among outpatients in the Outpatient Department.

HIQA would like to acknowledge the cooperation of staff who facilitated and contributed to this announced inspection and and the hospital outpatients who completed an anonymised questionnaire.

2. Findings at Mallow General 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.

Mallow General Hospital is a Model two[5] statutory hospital, owned and managed by the Health Service Executive (HSE), and a member of the South/South West Hospital Group.[‡] The hospital is linked through shared senior management with Cork University Hospital Group (see Appendix 2). This management arrangement also includes Cork University Hospital and Bantry General Hospital.

Mallow General Hospital had formalised governance arrangements and organisational structures in place to support the safe use of medications, which included formal representation on the Cork University Hospital Group Drugs and Therapeutics Committee.[6] However, inspectors noted some ambiguity during senior management interviews at Mallow General Hospital in relation to who was ultimately corporately responsible for oversight of medication safety within the hospital. Effective leadership and clear lines of accountability are vital components of any healthcare service. The hospital must assure itself that systems are in place to ensure that accountability arrangements for medication safety are clear.

In addition, it was identified by HIQA that the Cork University Hospital Group were intending to recruit a Medication Safety Officer to advance medication safety. It was of concern to inspectors and acknowledged by senior management at Mallow General Hospital that the remit of the new post of Medication Safety Officer was not planned to extend group wide to include Mallow General Hospital as the position was based solely at Cork University Hospital. The lack of involvement of Mallow General Hospital with this new appointment runs the risk of further lack of integration. This may represent a missed opportunity to use resources more efficiently and effectively to progress a medication safety agenda across the Cork University Hospital Group rather than a piece-meal approach to medication safety at each hospital site.

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

A formal medication safety strategy for Mallow General Hospital was not evident at the time of the inspection. Despite this weakness, hospital management had endeavoured to support and progress a medication safety agenda at Mallow General Hospital through the formation of a Medication Management Committee towards the latter end of 2016. The Committee's terms of reference were approved in March 2017 and an action plan for 2017 was developed by the Committee. Senior management outlined some progression with this action plan on the day of inspection. However, inspectors determined that the medication safety programme in place at the hospital remained significantly underdeveloped and limited by resource constraints. Fundamentally, further time, effort and resources will be needed to fully implement and embed an effective programme of medication safety at the hospital and this should be addressed as a matter of priority with the support of the Cork University Hospital Group.

The Drugs and Therapeutics Committee

Cork University Hospital Group had a Drugs and Therapeutics Committee which represented Cork University Hospital, Mallow General Hospital and most recently Bantry General Hospital. The Drugs and Therapeutics Committee has been in existence at Cork University Hospital since the early 1990's. The Committee's terms of reference had been amended in 2013 as part of new governance arrangements within the Cork University Hospital Group; the latest version was approved in January 2017. The Committee's terms of reference outlined the objectives, membership, frequency of meetings and reporting relationship. The Committee was chaired by a Consultant Physician.

The Committee's primary purpose was stated in its terms of reference as assisting the Executive Management Board, Clinical Directors and the Executive Quality and Safety Committee in developing and maintaining medication management policies, procedures and guidelines to support the evidence-based, safe, effective and economic use of medications in Cork University Hospital, Cork University Maternity Hospital, Mallow General Hospital and Bantry General Hospital.

The Drugs and Therapeutics Committee reported to the Cork University Hospital Executive Quality and Safety Committee. The Committee's terms of reference stated that the Committee was to provide reports three times a year against the achievement of objectives to the Executive Quality and Safety Committee. However, there was some inconsistency with respect to the level of awareness of the frequency of these report identified during interview with senior management at Mallow General Hospital, who stated that a report was submitted on an annual basis.

Mallow General Hospital was represented on the Drugs and Therapeutics Committee by a Consultant Physician and Senior Pharmacist. However, inspectors noted that pharmacy representation by Mallow General Hospital at Committee meetings was

limited and possibly reflective of the limited capacity of a stand-alone pharmacist to attend such meetings off-site.

An effective Drugs and Therapeutics Committee should have ongoing oversight of the medication management and safety system within a hospital.[7] Overall, inspectors were not assured on the day of inspection that an overarching strategy or plan, driven by the Drugs and Therapeutics Committee, was in place to progress medication safety across the Cork University Hospital Group.

Risk Management

Hospital staff reported medication incidents and near misses on a paper based reporting system. Inspectors were informed that medication incidents were graded using the Health Service Executive (HSE) risk matrix.[8] In addition, senior management stated that the hospital inputted all medication incidents reported within the hospital to the National Incident Management System (NIMS).[§]

HIQA noted through this inspection, a low number of medication related incidents and near misses reported throughout 2016 and 2017 to date, even when considered in the context of the hospital activity levels, services provided and the population of patients cared for in the hospital. As a result, key medication related risks were likely not being fully understood, recorded, escalated or mitigated effectively by the organisation. Low numbers of incidents reported does not necessarily mean a low number of incidents occurring. 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 reporting culture within the hospital.[8]

Important lessons can be learned from analysis of medication-related incidents and near misses. Reporting of incidents is of limited value unless the data collected are analysed and recommendations disseminated.[9]

Senior managers acknowledged that there was significant under reporting of medication related incidents and near misses. The hospital needs to begin to better quantify and understand medication related risks through improved reporting.

Hospital management reported a non-punitive incident reporting culture and ongoing efforts to eliminate a legacy culture of blame that existed in the hospital in relation to reporting incidents and near misses. However, inspectors were informed that following errors that occurred while administering medications, nurses involved in the incident or near miss were required to complete the HSELanD Medication

[§] 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 State Claims Agency (Section 11 of the National Treasury Management Agency (Amendment) Act, 2000).

Management online training programme.[10] In evaluating this approach to error mitigation, HIQA acknowledges the importance of promoting a culture of professional responsibility for practice, and the use of a standardised checking system to try to spot error. However, it is important that such an approach is complemented by an evaluation of potential system related causes for latent error, which should also form a focus for error reduction efforts allied to improved nurse vigilance.[11,12]

Open disclosure occurs when staff in the health and social care service communicate with patients in an open and honest manner when things go wrong with patient care.[13] Inspectors were informed that the hospital had a policy in place to promptly inform patients when medication-related incidents occurred. Staff who spoke with inspectors could provide examples of when this open disclosure policy was adhered to.

Staff who spoke with inspectors reported that monoclonal antibodies were prepared on site at Mallow General Hospital.[**] Inspectors were informed that intravenous infusions and monoclonal antibodies were prepared in an open, unsegregated and relatively congested area adjacent to patient bedsides. Evidence based research recommends that separate and identifiable areas for the storage of monoclonal antibodies and the preparation and delivery of treatment should be available within or adjacent to wards or units. [14,15,16]

HIQA acknowledges that while monoclonal antibodies may not all absolutely need to be made in an aseptic compounding unit on safety grounds, other safety measures do need to be applied including risk assessment by hospital management.[17] Senior management acknowledged this issue during interview and informed inspectors that measures were being put in place to address this deficit. The hospital needs to assure itself that the potential risks to patients and staff in this regard are fully understood, managed and mitigated as a matter of priority.

HIQA acknowledges that it will be challenging for the hospital to assure the quality and safety of patient care in relation to the issues identified in this report until resource constraints are addressed. Mallow General Hospital, as a member of the Cork University Hospital Group and South/South West Hospital Group, needs to be supported by the group and national structures to effectively address these issues as a priority.

[**] Monoclonal antibodies are a type of biological medicine, often used to treat a number of conditions including cancer, or inflammatory conditions.

2.2 Audit and evaluation

Line of enquiry:

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

Audit represents a key component of all effective clinical governance programmes.[18] Elements of medication safety were audited at the hospital, but these audits were not aligned to a formalised medication safety strategy. In addition, audit activity throughout the hospital was neither strategically driven by an audit programme nor centrally coordinated. However, inspectors were informed that one of the goals of the 2017 action plan for medication management was to establish a central repository for all audits undertaken at the hospital to include medication safety audits.

There was little evidence to show that findings and learning gained from medication safety audits undertaken at other hospitals within the Cork University Hospital Group were either constructively shared or informed quality improvement inititiatives at Mallow General Hospital.

Documentation reviewed showed that some medication safety-related audits had been undertaken by clinical staff at the hospital which included the following:

- a red apron[††] audit
- drug chart audits
- resuscitation trolley audit.

Nursing Quality Care-Metrics[‡‡] were monitored across the hospital to review practice around some aspects of medication storage and administration. Inspectors viewed the nursing quality care-metrics. Inspectors were also informed that an audit was undertaken in December 2016 to assess the level of prescriber compliance with the recently introduced revised hospital prescription sheet. Poor compliance shown in this audit resulted in a follow up audit undertaken in May 2017. Inspectors were informed that compliance had improved between the first and second audit. Findings

[††] Red aprons are worn by nursing staff while preparing or administering medications to highlight to other staff, patients and visistors that they are in the process of conducting a high risk operation, so as to minimise or eliminate nurse distraction during the medication administration process.
[‡‡] Metrics are parameters or measures of quantitative assessment used for measurement, and comparison or to track performance.

from the initial audit were presented at grand rounds[§§] and it was planned to present the findings of the follow up audit in the same forum in the near future.

HIQA found that in the absence of an audit programme and structures to centrally coordinate audits, opportunities were lost to share learning and implement medication safety initiatives to support an effective medication safety programme. Current arrangements with regard to medication safety audit should be strengthened to ensure that there is a more systematic approach to audit selection and dissemination of audit findings throughout the hospital to provide assurance to the hospital's Senior Management Team about medication safety at 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 found during the inspection that medication safety quality improvement initiatives were not strategically driven by learning gained from analysis of medication incidents or near misses. Nevertheless, despite this weakness, inspectors did identify some examples of implemented quality improvement initiatives. For example, quality improvements included the introduction of:

- red aprons to reduce interruptions to nursing staff during a medication round
- revised drug prescription chart
- a national sepsis form (used for the timely administration of appropriate antibiotics)
- new medication storage cupboards
- posters with information about high risk medications
- insulin prescribing kardex.

Mallow General Hospital was also participating in the Health Service Executive (HSE) Quality Improvement Division venous thromboembolism[***] quality improvement collaborative.[19] This is a collaborative among multidisciplinary teams in Irish acute public and voluntary hospitals who are working together to achieve appropriate thromboprophylaxis for their hospital's inpatients, to reduce the risk of venous

[§§] 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.

[***] Thromboembolism is the obstruction of a blood vessel by a blood clot that has become dislodged from another site in the circulation.

thromboembolism and to minimise harm and expenditure associated with unnecessary thromboprophylaxis.

There are currently no agreed national standards outlining requirements for the provision of clinical pharmacy services in Irish hospitals. However, international studies support the role of clinical pharmacists in hospital wards in preventing adverse drug events.[20,21,22,23,24,25] While efforts were made by the hospital's stand-alone pharmacist to support staff in safe medicines usage, the hospital was not sufficiently resourced to provide a clinical pharmacy service at ward level to prevent, identify and intercept medication prescribing-related incidents. Inspectors found on the day of inspection that the pharmacy service within the hospital was almost entirely restricted to dispensing with approximately 10 percent of the pharmacist's time dedicated to ward visits. In addition, the hospital did not have an antimicrobial pharmacist or pharmacy technician to support the pharmacy service at Mallow General Hospital. This sustained lack of resources was acknowledged by senior management and the deficits were recorded on the hospital's corporate risk register.

High-risk medicines can cause significant harm when system errors occur.[6] A list of high-alert medicines[†††] was in place at Mallow General Hospital and communication of this list to clinical staff was evident in the areas visited at the time of inspection. The list was based on the acronym 'A PINCH' which grouped medications into categories and to facilitate education and to raise awareness of high risk medications. The medications on the list included:

- Anticoagulants and anti-thrombotics
- Potassium and intravenous paracetamol
- Insulins and intrathecal/epidural administration
- Narcotics and neuromuscular blocking agents
- Cytotoxics
- Hypertonic and hypotonic intravenous fluids.

Medication reconciliation is a formal, systematic process for obtaining a current and accurate list of medicines that the patient was taking when admitted to the hospital, and reconciling this medicines list against the patient's medicines prescribed at admission, transfer and discharge.[26,27,28,29] Inspectors were informed that medication reconciliation was carried out by nursing and medical staff on admission of patients to the hospital. In addition, a new medication reconciliation section was introduced to the drug kardex following audit of this process. However, inspectors were told that a further audit of this process revealed that this section of the drug kardex was

[†††] High-Alert Medications are medicines that bear a heightened risk of causing significant patient harm when they are not used correctly. Errors with these medicines may not be more common than those from other groups but their consequences can be more devastating as they have smaller margins of safety than other medications and therefore warrant particular caution in their handling.

not being used for each patient admission. As a result, it was difficult to determine whether medication reconciliation was carried out for every patient admitted to Mallow General Hospital.

A process for assessing and evaluating requests for the supply of new medications was in place. There was evidence to support that new medications were discussed at the Cork University Hospital Group Drugs and Therapeutics Committee. However, it was explained to inspectors that an up to date local approved medication formulary[‡‡‡] did not exist in any of the Cork University Hospital Group hospitals at the time of the inspection. The purpose of maintaining an approved list of medication used in the hospital is to ensure that appropriate governance exists around what is approved for use and that in doing so, a proper safety evaluation occurs before medications are introduced into practice at the hospital.

Inspectors were informed during the inspection that a medication formulary was under development at Cork University Hospital. Mallow General Hospital planned on adapting this formulary for local application and had commenced work in this regard with a timeline for completion of 2018. While HIQA acknowledges that the development of a local formulary is a considerable undertaking, efforts should be extended to formalise the agreed list of all medicines used at the hospital, with the provision of supporting policies, procedures and guidelines, following this inspection.

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.

Establishing and maintaining a strong patient centred approach is key for reducing medication errors. A well-informed patient and/or family can help prevent medication errors by hospital staff and is less likely to make medication errors at home. Adherence to the medication regimen is another goal achieved through patient education.

Mallow General Hospital had systems in place to support the provision of information and education to patients in relation to medication. Patient information leaflets were available to patients. Senior managers told inspectors that there was a multidisciplinary approach to patient information and education. Inspectors were informed that clinical nurse specialists provided education and support to patients, for example, around the management of respiratory disease and diabetes mellitus.

[‡‡‡] Local formulary is defined as a list of medicines approved for use within a healthcare organisation.

As part of this inspection, HIQA asked the hospital to administer an anonymised questionnaire in relation to prescribed medications to a small sample of hospital patients attending the Outpatient Department. The questionnaire was completed by 19 patients who had been inpatients in Mallow General Hospital within the last year and who were prescribed regular medications. Of the 19 patients surveyed, 16 patients had been prescribed regular medications. Of these 16 patients:

- 11 said that a staff member had explained the purpose of new medications in a way that they could completely understand
- 12 said that a staff member had told them about all possible medication side effects to look out for following discharge home
- 12 of the patients said that they received complete instruction on how to take their medications at home.

It is acknowledged that this was a small sample of patients who completed the anonymised questionnaire in relation to prescribed medications at the hospital's Outpatient Department, and therefore was not representative of all recently discharged patients taking prescribed medication. The information did however, provide some information about outpatient's understanding of medications and could be expanded upon and used to identify opportunities for improvement.

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.

Mallow General Hospital's Senior Management Team approved some medication-related policies, procedures and guidelines with others approved through the Cork University Hospital Group's Drugs and Therapeutics Committee. Inspectors were informed that there was a variety of sources for medication-related policies, procedures and guidelines including Mallow General Hospital, Cork University Hospital and Cork University Hospital Group.

Some up to date versions of medication management policies, procedures and guidelines were available to staff in clinical areas in folders and through a controlled electronic document management system. However, many of the medication safety related policies viewed by inspectors at the time of inspection were out of date. Inspectors determined that there was the potential for confusion and use of obsolete

information arising from the multiple sources of policies, procedures and guidelines at Mallow General Hospital. In addition, there was potential to maximise the use of resources more efficiently through collective centralisation of policies, procedures and guidelines from a Cork University Hospital Group perspective.

Inspectors found that the clinical areas visited had access to printed copies of reconstitution and administration guidelines for intravenous medication. However, on the day of inspection, it was highlighted to inspectors by staff that not all regularly administered medicines, such as Infliximab, were included. This should be reviewed as part of the hospital and wider group's approach to medicines management governance.

Other decision support tools available to clinical staff included:

- the British National Formulary
- antimicrobial guidelines.

Healthcare staff require 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 patient's diagnostic results on computers in clinical areas across the hospital.

There was an established system in place to respond to guidance, alerts, recalls and recommendations issued by regulatory bodies in relation to medication safety. Such information was communicated to wards at Mallow General Hospital by the pharmacist via nursing management. In addition, staff outlined that medicines information was readily accessible through the hospital's pharmacist as required.

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.[30] The hospital did not have a formalised education programme for clinical staff linked to an overall medication safety strategy. However, inspectors were informed that non consultant hospital doctors[§§§] received induction training which included medication safety. This training was provided on a three monthly basis by the hospital's pharmacist.

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

It was evident that nursing staff achieved a high level of compliance with attendance at medication safety related training and oversight of this training was well managed at a local level. All nursing staff were required to complete the online HSELanD Medication Management programme[10] on induction. Inspectors were informed that nurses will be required to complete this training every two years. Nursing staff also completed intravenous therapy management training.

Inspectors were informed that nursing staff on the Medical Assessment Unit are due to commence administering first dose antimicrobial medications in the unit by the end of August 2017. Nursing staff in this unit have been provided with anaphylaxis training to facilitate the administration of these medications. Senior management informed inspectors that there is a plan to extend training to all nursing staff prior to implementing this practice hospital wide in the future.

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.[1] 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.

Mallow General Hospital had formalised governance arrangements and organisational structures in place to support the safe use of medications.[6] The hospital was a member of the Cork University Hospital Group Drugs and Therapeutics Committe. An effective Drugs and Therapeutics Committee should have ongoing oversight of the medication management and safety system within a hospital.[31] However, inspectors were not fully assured on the day of inspection that an overarching strategy or plan, driven by the Drugs and Therapeutics Committee, was in place to progress medication safety across the Cork University Hospital Group.

A formal medication safety strategy for Mallow General Hospital was not evident at the time of the inspection. Despite this weakness, hospital management had endeavoured to support and progress a medication safety agenda at Mallow General Hospital through the formation of a Medication Management Committee towards the latter end of 2016. However, inspectors determined that the medication safety programme in place at the hospital remained significantly underdeveloped and limited by resource constraints.

Inspectors noted and senior management acknowledged that the hospital would benefit from greater links between the stand-alone pharmacist at Mallow General Hospital and the Pharmacy Department at Cork University Hospital. It was determined that a formalised link between the pharmacy sites had the potential to serve as a reciprocal source of peer support, information sharing and progression of a medication safety agenda between the hospital sites.

In addition, it was of concern to inspectors and acknowledged by senior management that the remit of the new post of Medication Safety Officer was not planned to extend group wide to include Mallow General Hospital as the position was based solely at Cork University Hospital. The lack of involvement of Mallow General Hospital with this new appointment runs the risk of further lack of integration. This may represent a missed opportunity to use resources more efficiently and effectively to progress a medication safety agenda across the Cork University Hospital Group rather than a piece-meal approach to medication safety at each hospital site.

On the day of inspection, some up to date versions of medication management policies, procedures and guidelines were available to staff in clinical areas in folders and through a controlled electronic document management system. However, many of the medication safety related policies viewed by inspectors at the time of inspection were out of date. Inspectors determined that there was the potential for confusion and use of obsolete information arising from the multiple sources of policies, procedures and guidelines at Mallow General Hospital. In addition, there was potential to maximise the use of resources more efficiently through collective centralisation of policies, procedures and guidelines from a Cork University Hospital Group perspective.

The level of reporting of medication related incidents and near misses at Mallow General Hospital was low in the context of the hospital activity levels, services provided and the population of patients cared for in the hospital. Significant scope for improvement was needed to further develop and promote a more effective culture of medication incident and near miss reporting as part of a wider approach to the development of a more comprehensive medication safety programme at the hospital.

Fundamentally, inspectors found on the day of inspection that senior management at Mallow General Hospital endorsed and supported the promotion and strengthening of a culture of quality and safety in relation to medication safety. However, many of the identified opportunities for improvement require strategic, combined and targeted action by Mallow General Hospital, the Cork University Hospital Group and the South/South West Hospital Group to address the issues arising and implement an effective medication safety agenda at Mallow General Hospital.

Following this report, the hospital and hospital group must focus its efforts to address the issues 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.

4. References

1. Rafter N 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. 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

4. 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

5. 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

6. 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

7. 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

8. Health Service Executive. Risk Assessment Tool and Guidance (including guidance on application). 2012;pp1-12. Available online from: http://www.hse.ie/eng/About/Who/OQR012_20081210_v4_Risk_Assessment_Tool_and_Guidance_incl_guidance_on.pdf

9. World Health Organisation. Reporting and learning systems for medication errors: the role of Pharmacovigilance centres. Washington: World Health Organisation; 2014. Available online from: http://apps.who.int/medicinedocs/documents/s21625en/s21625en.pdf

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

11. Institute for Safe Medication Practices. Just Culture and its critical link to patient safety. Institute for Safe Medication Practices; 2013. Available online from: http://www.ismp.org/newsletters/nursing/issues/NurseAdviseERR201301.pdf

12. Grissinger M. The five rights: A destination without a map. 2007. Pharmacy and Therapeutics. 2010; 35(10): 542. Available online from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957754/

13. Health Service Executive. Open Disclosure. National Guidelines. Communicating with service users and their families following adverse events in healthcare. Dublin: Health Service Executive; 2013. Available online from: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/opdiscnationalguidelines2013.pdf

14. Department of Health, UK (2013) Health Building Note 02-01: Cancer treatment facilities, Department of Health, UK. [Online] Available at: http://www.dhsspsni.gov.uk/hbn_02-01_cancer_treatment_facilities_final.pdf.

15. Clinical Oncology Society of Australia. Position Statement: Safe handling of monoclonal antibodies in healthcare settings.2013;pp1-5 – Available online from: https://www.cosa.org.au/media/173517/cosa-cpg-handling-mAbs-position-statement_-november-2013_final.pdf

16. Langford S, Fradgley S, Evans M, Blanks C. Assessing the risk of handling monoclonal antibodies. Hospital Pharmacist. Feb 2008 ; 15: pp60-64**.** http://www.pharmaceutical-journal.com/libres/pdf/hp/200802/hp_200802_monoclonal.pdf

17. National Health Service. Guidance on the Safe Handling of Monoclonal Antibody Products. 5th Edition. November 2015;pp1-8. Available online from: http://ukons.org/downloads/Proposed_national_requirements_for_overlabelling_of_foreign_%28non-English_language%29_imported_medicines.pdf

18. Health Service Executive. A Practical Guide To Clinical Audit. Dublin: Health Service Executive; 2013. Available online from: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Clinical_Audit/claudit filespdfs/practicalguideclaudit2013.pdf

19. Health Services Executive Quality Improvement Division. Medication Safety Programme. Preventing VTE in Hospitals Improvement Collaborative. Available online from: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/qpsfocuson/Medication-Safety-Programme.html

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

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

26. Health Information and Quality Authority. Guidance for health and social care providers. Principles of good practice in medication reconciliation. Health

Information and Quality Authority; 2014. Available online from: https://www.hiqa.ie/sites/default/files/2017-01/Guidance-Medication-Reconciliation.pdf

27. World Health Organisation. 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

28. 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 Pharmacy. February 2013; 35 (1): pp14–21.

29. Grimes T, Deasy E, Allen A, O'Byrne J, Delaney T, Barragry J, Breslin N, Moloney E, Wall C, Collaborative pharmaceutical care in an Irish hospital: uncontrolled before-after study, BMJ Quality & Safety.2014; 23(7); p1-10, doi:10.1136/bmjqs-2013-002188.

30. 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

31. 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

5.Appendices

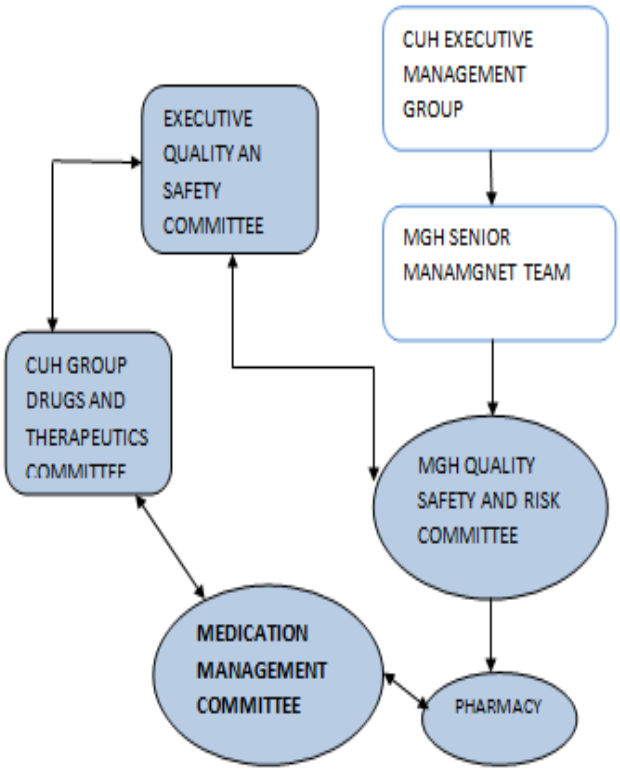
Appendix 1 : Medication safety monitoring programme Phase One: Lines of Enquiry and associated National Standard for Safer Better Healthcare

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: Mallow General Hospital Organisational Organogram

Organisational Organogram

Lines of Communication between Drugs & Therapeutic Committee CUH, Quality Safety Risk MGH and Medication Management Group MGH:



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