Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

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

Date of announced inspection:

02 May 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.

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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.[3] This global safety initiative, launched in March 2017, aims to address the weaknesses in health systems that lead to medication errors and the severe harm that result.

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 University Hospital Waterford by Authorised Persons from HIQA; Nora O' Mahony, Aoife Lenihan, Emma Cooke and Maureen Burns Rees on 02 May 2018 between 09:00hrs and 16:20hrs.

This inspection was prompted by consideration of a previous HIQA inspection of medication safety on 06 December 2016 which identified a number of risks with regard to medication safety including:

- The availability in clinical areas of outdated and potentially conflicting reference information for the reconstitution and administration of intravenous medication.
- The absence of strategic and operational plans detailing the development, implementation and maintenance of hospital-wide medication safety systems.
- Inadequate arrangements to identify, report and manage risks associated with medication use.
- A lack of systematic monitoring and evaluation of the effectiveness of medication management systems to ensure they are effective.
- A relative lack of policies, procedures, protocols and guidelines to support staff in the safe prescribing and administration of medications.

During this inspection interviews were held in the hospital with the following groups of managers and clinical staff:

- Group one; the Chairperson of the Medicines and Therapeutics Committee , the chief pharmacist, the medication safety pharmacist, the clinical risk manager and the quality and patient safety manager

- Group two; the general manager, the interim director of nursing, the clinical director for the Medical Services Directorate, the director of midwifery and the quality and patient safety manager.

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

- Orthopaedic 1
- Paediatric General Ward
- Medical 3.

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

2. Findings at University Hospital Waterford

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

- **Section 2.1** outlines risks identified during this announced inspection.
- **Sections 2.2 to 2.7** present the general findings of this announced inspection.

2.1 Risks identified

During this announced medication safety inspection conducted at University Hospital Waterford risks were identified in relation to medication safety. These risks relate to:

- a failure to control and monitor temperature conditions for storage of refrigerated medicinal products in a number of clinical areas
- uncontrolled access to a treatment room in a paediatric clinical area containing unsecure refrigerated medicines, clean and sterile consumables including needles, syringes, intravenous fluids, intravenous cannulae and sharps waste disposal bins.

Details of these risks were communicated to hospital management so that the hospital could act to mitigate and manage these risks as a matter of urgency.

In response, hospital management reported that the paediatric ward fridge was replaced with a pharmaceutical grade fridge, and a key pad was fitted to the paediatric ward treatment room door immediately following the inspection. The hospital also outlined that refrigerators for the storage of medicinal products in other clinical areas would be replaced with pharmaceutical grade refrigerators.

A copy of the letter issued to the hospital regarding the risks identified during the inspection on 02 May 2018 and a copy of the response received from the hospital are shown in Appendices 2 and 3 respectively.

2.2 Governance and 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.

University Hospital Waterford is a model 4 hospital in the South/South West Hospital Group. The hospital provides acute medical, surgical, orthopaedic, oncology, paediatric and maternity services.

HIQA undertook an announced inspection of medication safety in University Hospital Waterford in 2016 which highlighted issues related to leadership and governance of medication safety, with a lack of essential elements in place to drive and support medication safety.

HIQA therefore used this repeat inspection to review the current arrangements in place to support medication safety and to assess the level of progress achieved since the last inspection.

The Medicines and Therapeutics Committee

Since the last inspection the hospital Medicines and Therapeutics Committee had met as per their updated terms of reference, chaired by a consultant rheumatologist with clearer reporting structures to the Safety and Quality Executive Steering Group who in turn reported to the Executive Management Board.

Attendance at the Medicines and Therapeutics Committee was good from most disciplines, but not all representatives identified by the hospital were attending the Medicines and Therapeutics Committee meetings. For example, representatives from antimicrobial stewardship, obstetrics/gynaecology or paediatrics were not in attendance for the past year as detailed in meeting minutes reviewed by inspectors.

The terms of reference outlined that a function of the Medicines and Therapeutics Committee was to receive reports from the Antimicrobial Stewardship Team on issues related to usage of antimicrobials in the hospital. However, no antimicrobial stewardship reports were seen on minutes of the Medicines and Therapeutics Committee reviewed by inspectors. The hospital needs to review the oversight of antimicrobial stewardship, in line with the terms of reference of the Medicines and Therapeutics Committee, following this inspection.

The hospital had set up a Medication Safety Committee which was under the governance of the Executive Management Board and also presented reports as a standing agenda item to the Medicines and Therapeutics Committee. Hospital management informed inspectors that the reporting relationship to the Executive Management Board was an interim arrangement put in place by the hospital to facilitate a focus on medication safety with oversight at senior management level, and from now on the Medication Safety Committee would become a sub-committee of the Medicines and Therapeutics Committee.

The Medication Safety Committee had developed the hospital's Medication Safety Systems Strategic Plan from which the Medication Safety Operational plans for 2017 and 2018 were devised. The strategy and operational plans were approved and overseen by the Executive Management Board and update reports were presented to the Medicines and Therapeutics Committee. The strategy set out the organisation's key strategic goals for medication safety, and the operational plans outlined the objectives and deliverables to achieve these strategic goals, with a responsible individual and proposed time frames outlined.

The Medication Safety Committee's Annual Report for 2017 outlined the progress achieved against the outlined strategic goals. For example, one of the hospital's key strategic goals was to design, resource and implement a hospital wide medication safety system. Evidence of completion of the associated deliverables for 2017 was seen through the development of:

- a high-risk medication list with accompanying risk reduction strategies
- a medicines information folder icon on each computer desk which contained material produced by the Medication Safety Committee and the pharmacy department such as information on high-risk medications, medication safety alerts and memos, ward stock lists of medicines and paediatrics/neonatal medication safety information
- a medication incident report form with an accompanying policy introduced through ward-based education
- a dedicated medication safety email address for staff to direct medication safety queries
- monthly medication safety bulletins.

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.[7] University Hospital Waterford had a list of medicines which were approved for use in 2012 and inspectors were informed that some sections had been updated in conjunction with specialist consultants. However, inspectors were informed that there were no current plans to continue this review or replicate this to other specialty areas.

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

- indication for which the medicine was required
- key references, primary randomised control trials or systematic reviews
- comparative studies, if the medicine replaced an existing option
- reason for addition, if the medicines did not replace an existing option
- cost of treatment
- number of patients requiring the treatment.

The hospital should continue to review the medicines that are approved for use within the hospital and provide information and guidance on the use of these medicines to promote rational, evidence based, clinically appropriate, safe and cost effective medication therapy.[6, 8] This work could be supported through collaboration with other hospitals within the South/South West Hospital Group.

Risk Management

The hospital had identified a number of risks related to medication management on the hospital's risk register including inadequate pharmacy staffing, facilities and equipment and these were escalated to the South/South West Hospital Group. As part of this, hospital management at University Hospital Waterford identified a need for a chief 2 pharmacist for medication safety and additional clinical pharmacist posts. A submission was made to the South/South West Hospital Group on this

*Formulary: a managed list of preferred medicines that have been approved by the hospital's Drugs and Therapeutics Committee for use at the hospital. Use of a formulary ensures governance oversight of the introduction and ongoing use of medicines in practice at the hospital, and in doing so ensures an appropriate level of management control over medicines use, in the interest of both patient safety and financial management.

basis. The hospital informed inspectors that they were awaiting the outcome of the National Pharmacy Review in order to progress to filling these posts. To date, University Hospital Waterford had no additional personnel in place to address medication safety matters.

Considering the size and complexity of the services provided by the hospital, clinical pharmacy services[†] were limited to cover in the paediatric unit, critical care areas and a surgical ward. This was of significant concern to HIQA as other comparable model 4 hospitals, inspected as part of this monitoring programme, were found to deliver ward or team based[‡] clinical pharmacy services to most if not all ward areas which was not evident in University Hospital Waterford.

While actively progressing the need for additional pharmacists, hospital management should ensure that the current pharmacy service is utilised most appropriately to mitigate risk and promote patient safety.

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.[9] All incidents[§] that occurred in the hospital were reported to the State Claims Agency using the National Incident Management System[**] (NIMS)[10]

A total of 656 medication incidents were reported in 2017, an increase from 106 and 110 in the previous two years (Figure 1).

[† †] Clinical pharmacy service describes the activity of pharmacy teams in wards and clinic setting.
[‡] clinical pharmacists are deployed to clinical teams rather than wards, and may have certain direct intervention powers agreed with medical consultants.
[§] 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.
** The State Claims Agencies (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).

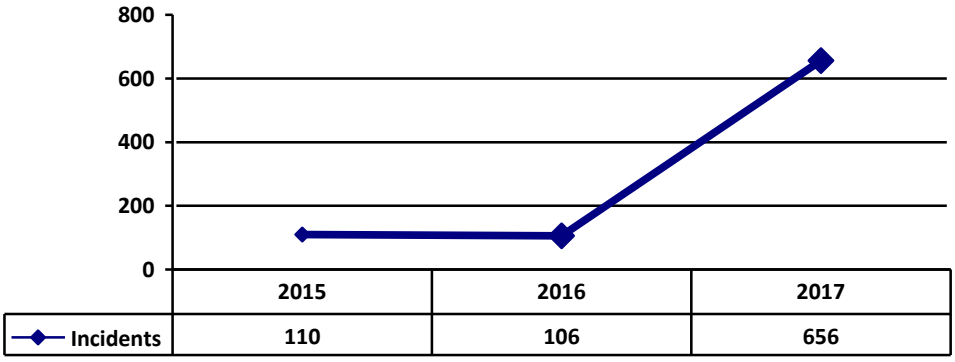

Figure 1: Comparison of medication incidents reported in 2015, 2016 and 2017.

This marked increase in medication incident reports was attributed to the introduction of a specific medication incident report form which was supported through ward-based education and hospital wide promotion. This reflected the emphasis placed on medication safety by the hospital and the willingness of front-line staff to report medication incidents. Higher incident reporting rates both demonstrate and promote an improved culture of safety.[11] HIQA noted that notwithstanding this positive trend in reporting, the majority of reports were submitted by nursing and pharmacy staff. The hospital should continue to promote reporting among all clinical staff so that safety surveillance is improved, learning is shared, and the safety culture is enhanced across the organisation.

In response to a reported medication incident the hospital undertook an audit of medicine refrigerators in all ward and outpatient areas in April 2018. The audit found that medicines were stored in refrigerators with no method for monitoring temperature in 10 of the areas audited and four additional clinical areas had catering fridges with temperature monitoring facilities. Inspectors were informed that this risk was entered on the corporate risk register and escalated at a corporate level. A risk assessment completed for wards and clinical areas in March 2018 identified the storage of refrigerated items outside pharmacy as a source of risk, and that failure to manage and monitor medicine refrigerator temperatures could result in a clinical risk to patients from ineffective or degraded medicines.

Inspectors observed medicines requiring storage between two and eight degrees Celsius in refrigerators without temperature monitoring facilities in clinical areas visited. Medicines requiring storage between two and eight degrees must be stored in a pharmaceutical grade refrigerator with maximum/minimum temperature monitoring and recording.[12] The failure to control and monitor temperature conditions for storage of refrigerated medicinal products was identified by HIQA as an immediate high risk to patients. As outlined in section 2.1 this was brought to the attention of hospital management during the inspection and subsequently inspectors

wrote to the Hospital's general manager to seek assurances, in writing, how this risk was being mitigated as a matter of urgency.

The quality and risk department tracked medication incidents based on numbers, time frame, location, process, cause and outcome and incidents were graded within the NIMS system. Inspectors were informed that the medication safety pharmacist graded incidents using the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) Medication Error Index to categorise incidents in terms of patient harm (Appendix 4). Summary incident reports were presented at the Medicines and Therapeutics Committee and at the Directorate Team meetings[††] and discussed at group Monthly Performance Meetings. Medication incident reports were also included in the Quality and Patient Performance Report for 2017.

Important lessons can be learned from analysis and trending of medication-related incidents and near misses. Data from medication incidents should be routinely analysed to identify trends or patterns in relation to risk and identify areas that need targeted improvement [6] with recommendations implemented and monitored.[13]

The hospital had identified safety concerns related to incidents and had put measures in place to address these risks, for example, high strength unfractionated heparin was removed from all but critical care areas, and guidelines were updated to reflect the change.

Medication related incident reporting facilitates the identification of risk and opportunities for improvement. However, on its own it does not provide a complete picture of all potential sources of risk and patient harm.[13] The hospital used additional information sources to identify strengths and weaknesses in the hospital medication management system including, audit, quality improvement projects using the plan-do-study-act[‡‡] format, risk assessments, risk registers and nursing metrics. Issues which were considered to potentially compromise medication safety were included in the hospital's risk register.

2.3 Audit and evaluation

Line of enquiry:

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

[††] The hospital had Directorates for; peri-operative, medical services, maternity/neonatal services, diagnostics services and the hospital had children's services.
[‡‡] Plan-do-study-act: Conducting a small scale test of change by planning a change, trying it, observing the results and acting on what is learned.

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.[4]

Medication safety monitoring was included in the hospital's Medication Safety Operational Plans for 2017 and 2018. Evidence of compliance with the 2017 monitoring plans was seen through audits completed such as:

- audit of the use of concentrated potassium chloride ampoules at ward level
- audit of medication refrigerators
- audit of oral anticancer medication prescribing
- audit of year one post implementation of national intrathecal chemotherapy (ITC) policy
- antiemetic prophylaxis.

The quality and risk department maintained a database of audits. The database outlined the audit lead, title and department, the start and completion dates, and any action or quality improvements required.

Inspectors were also informed that some staff had completing audits using the plan-do-study-act[§§] format to complete the quality improvement cycle and examples of these were reviewed by inspectors such as:

- audit of antiemetic prophylaxis anticancer treatment patients
- implementing programmed intermittent bolusing for labour analgesic.

However the hospital did acknowledge that audits were not strategically driven. The hospital needs to put a system in place to ensure that audits are planned based on local priorities. This should be coordinated to ensure recommendations are implemented and the required improvements achieved, driven by and with oversight from hospital management.[15]

Dissemination of audit results is also 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.[14, 15]

Nursing and midwifery quality care metrics[***16] were monitored every month in inpatient areas to review practice around prescribing, storage and administration of medicines. Quality care metrics results specifically standards on medication practices viewed by inspectors showed full compliance in the majority of areas measured

[§§] Plan-do-study-act: Conducting a small scale test of change by planning a change, trying it, observing the results and acting on what is learned.
*** Metrics are parameters or measures of quantitative assessment used for measurement and comparison or to track performance.

except for prescribing metrics such as; capital letters, [†††] generic prescribing, legible signatures and discontinued drugs. Nursing metric results were reported to the Safety and Quality Executive Steering Group and some action plans with associated recommendations were viewed by inspectors in the paediatric unit.

The hospital also undertook quarterly medication management audits within day services such as the dialysis unit, outpatients' department and the operating theatre department. The average compliance seen against these standards for 2017 was 96% and an overview report was developed for all areas highlighting non-conformance issues. Medication fridges were included in this audit process and non-conformances related to safe storage of medication were highlighted. For example, refrigerators were found to be unsecure and not solely used for storage of medical products. However, the monitoring of refrigerator temperatures was not addressed during this audit.

The hospital had also defined medication safety key performance indicators. The current key performance indicators were:

- incidents reports analysed by number, drug type, location and grade of staff reporting
- nursing metrics for inpatient areas
- antimicrobial consumption data.

2.4 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.

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.[17,18,19,20,21,22] As detailed earlier in this report University Hospital Waterford's clinical pharmacy service was limited to cover in the paediatric unit, critical care areas and a surgical ward. The hospital also had a temporary antimicrobial pharmacist who worked to ensure safe and effective use of antimicrobial agents at the hospital.

[†††] The prescription is written in capital letter. The generic name is used for each drug prescribed. The prescription has a legible prescriber's signature (in ink). Discontinued drugs are crossed off, dated and signed by prescriber

[‡‡‡] Clinical pharmacy describes the activity of pharmacy teams in ward and clinic settings.

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. [15,23,24,25] Clinical pharmacists undertook medication reconciliation for patients on admission in the areas they were assigned, and this was guided by a standard operating procedure. However, due to the limited clinical pharmacist service, formal medication reconciliation was uncommon practice across the hospital. On one ward visited by inspectors, which did not have a clinical pharmacy service, an inspector was informed that doctors and nurses would contact community pharmacists to clarify prescriptions as required.

High-risk medicines

High-risk medicines are those that have a high risk of causing injury or harm if they are misused or used in error. The hospital had recently developed a high-risk medicines list represented by the acronym PINCH[§§§] which grouped medications into categories to facilitate education and to raise awareness of high-risk medicines.[26] The hospital had some risk reduction strategies in place for high-risk medication (Appendix 5) for example:

- the use of premixed potassium chloride solutions and restricted access to potassium chloride ampoules (only available in critical care areas)
- restricted and segregated access to high strength unfractionated heparin
- high strength insulin dispensed with yellow labels to alert staff.

Medication safety alerts and recalls were managed though the pharmacy department and clinical staff had ready access to patients' diagnostic results on computers in clinical areas visited by inspectors.

The hospital had recently initiated a combined meeting for hospitals in the South/ South West Hospital group to share best practice in medication safety and possibly identify key areas requiring collaborative development. Members from the hospital's Medicines and Therapeutics or Drugs and Therapeutics Committees and Medication Safety Committees were invited to attend the meeting. This type of collaboration could support the sharing of expertise and learning, and avoid duplication of effort to support medication safety.

[§§§] **P**otassium, **I**nsulin's, **N**arcotics and Opioid, **C**hemotherapy and cytotoxic agents, **H**eparin and anticoagulants.

2.5 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.[27, 28]

The University Hospital Waterford National Patient Experience Survey[****] was completed by 50% of the 960 people discharged from the hospital in May 2017.[29] Two questions related directly to medications and these were answered by 46% of respondents:

- **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
- **Question 46:** Did a member of staff tell you about medication side effects to watch for when you went home?

The response for Question 45 received an overall score[††††] of 7.3 which was lower than the national average score of 7.8. Question 46 received an overall score of 4.5 again lower than the national average score of 5.1[29] (Figure 2).

[****] 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.

[††††] Score out of 10 was given for each question belonging to a stage of care or a stage as whole. A score of 0 indicates a very negative experience and a score of 10 indicates a very positive experience.

	University Hospital Waterford 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?	7.3	7.8
Question 46: Did a member of staff tell you about medication side effects to watch for when you went home?	4.5	5.1

Figure 2: University Hospital Waterford results for Question 45 and 46 of the National Patient Experience Survey.

In response to the National Patient Experience Survey the hospital had developed quality improvement plans to address the areas needing improvement.[29] The hospital had updated its discharge prescription to include duplicate copies and a section for medications changed or discontinued to support safer transfer of information on discharge. The hospital also provided easy staff access to patient information leaflets via the medicines information icon on the computer desktops. Inspectors were informed that staff printed off the patient information leaflet for patients as required.

2.6 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.

The hospital's medication policies, procedures and guidelines were reviewed by the Medicines and Therapeutics Committee before final approval by the Executive Management Board. Hospital policies were accessible to staff on computers via the hospital electronic document control system. The hospital was in the process of

developing and updating some medication related policies, procedures and guidelines. However, it was of concern to HIQA that some medication related policies, procedures and guidelines were found to be overdue for review since 2013. This was also found on the previous medication safety inspection in 2016.

The hospital had updated its *'Prescribing of Medication Policy'* and had an implementation plan in place to educate and promote adherence with the new policy. The hospital also had guidelines and informational aids to support staff in the safe use of high-risk medicines such as:

- the management of hypokalaemia
- heparin infusion guidelines
- DOAC[‡‡‡‡] prescribing guide
- opioid conversion chart
- table of insulin products available.

Access to relevant up-to-date and accurate medicines reference information and decision support tools[§§§§] is essential at all stages of the medication management pathway.[15] A range of medicines information and decision support tools were available to guide staff involved in providing safe and effective medication management, viewed by inspectors in the clinical areas inspected. For example, the hospital had developed a medicines information icon which was easily accessible to staff on the computer desk tops. This medicines information folder provided access to a multitude of medicines information such as:

- intravenous guidelines
- clinical guidelines
- NEWT guidelines[*****]
- antimicrobial guide
- high-risk medication
- medication safety alerts and memos
- ward stock of medicines
- paediatrics and neonatal information
- patient information leaflets, Health Products Regulatory Authority and medicines.ie.

[‡‡‡‡] Direct oral anticoagulants: medications used to treat or prevent blood clots. However, there is a potential for bleeding with their use or clotting leading to stroke with missed doses.
[§§§§] Decision support tools: are resources that provide guidance or incorporate knowledge to help clinicians make the most appropriate clinical decision for patient care.
[*****] The NEWT Guidelines aims to provide prescribers and other healthcare professionals with a single point of reference which draws together the available information relating to medicines management in patients with enteral feeding tubes or swallowing difficulties, and presents it in a practical fashion.

The development of the University Hospital Waterford intravenous medication guide was undertaken as a quality improvement plan using the plan-do-study act cycle and the project was presented at the hospital's 5th Quality Improvement Conference. The approved intravenous medication guide was available on the desktop of ward computers through the medication safety icon. However, HIQA note that this information was not easily accessible and available to staff at the point of medicines preparation, for example in clinical rooms where staff require this information to hand to ensure intravenous medicines are prepared in accordance with the hospital's guide.

In order to keep staff informed of medication safety updates the hospital developed and circulated monthly *Medication Safety Bulletins* with key messages for staff involved in the medication management process. The bulletins were also available for staff to access via the medicines information icon on computer desktops or in hard copy in folders on wards visited by inspectors. Examples of topics included: best practice in prescribing and safe administration of insulin.

The hospital also circulated monthly *Need2Know ebulletins* with short easy to read updates, which included many topics relevant to the medication safety process such as: open disclosure, medication incident reporting, registration of audits and access to policies, procedures and guidelines.

The hospital must ensure that clinical staff are provided with up-to-date information including policies, procedures, guidelines and or protocols in an easily accessible way to guide the safe use of medicines at the point of prescribing, preparation and administration.[6]

2.7 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.

Nursing staff attended intravenous drug administration training and medication management sessions during induction. Nurses also attended the clinical safety update day which included medication management which was delivered on nine occasions throughout 2017. The hospital had piloted the completion of the Health Service Executive's medication management module by nurses in four clinical areas with a view to implementation across all areas.[30]

The pharmacy department provided a medication safety education session at non-consultant hospital doctor's induction programmes as well as providing an education session at grand rounds, at governance meetings, in the operating theatre department and at a nursing management meeting.

The paediatric ward had implemented a weekly Drug-gle[†††††] which was a medications focused safety huddle [‡‡‡‡‡31] where staff met with the pharmacist to discuss a medication error of the week and a current medication topic. A poster highlighting the contents of the Drug-gle was also displayed on the ward for the week.

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 ongoing training. This should be a structured, targeted programme of education for medication safety aligned with the hospitals medications safety programme.[6]

[†††††] The drug-gle (druggle) is medication-focused session adapted from the concept of the safety 'huddle'

[‡‡‡‡‡] Safety pause/safety briefing /safety huddle is a quality initiative which put structure around actual or potential patient safety risks using 4P's: patients, professionals, processes and patterns.

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 hospitals. Medication safety should therefore be a priority area for all hospitals as they seek to ensure a high quality and safe service for patients.

This report details the findings of the second medication safety inspection at University Hospital Waterford. Inspectors concluded that many of the risks identified in the previous inspection in December 2016 were being addressed by hospital management and the Medicines and Therapeutics Committee and these efforts should continue. Inspectors found examples of improvements with medication safety, many of which had been implemented by the hospital's Medication Safety Committee.

Inspectors found that University Hospital Waterford had formalised governance arrangements with a Medicines and Therapeutics Committee that reported to the hospital's Quality and Safety Executive Committee who in turn reported to the Executive Board of Management. The hospital had a medication safety strategy and operational plans for 2017 and 2018 which were approved and overseen by the Hospital's Executive Management Board.

The Medicines and Therapeutics Committees terms of reference outlined the committee's scope and functions which included oversight of antimicrobial stewardship. However, inspectors were informed that there was no operational antimicrobial stewardship team to report to the Medicines and Therapeutics Committee and this needs to be reviewed following this inspection to ensure oversight of antimicrobial stewardship by the Medicines and Therapeutics Committee in line with its terms of reference.

The hospital had a list of medicines and a process in place for review and approval of new medicines for use in the hospital. Inspectors were informed that some sections of the hospital medicines list had been updated but there were no current plans to continue this review. The hospital should continue to review the medicines that are approved for use within the hospital; this work could be supported through greater collaboration with other hospitals within the South/South West Hospital Group.

Examples of medication related audit undertaken by the hospital were reviewed by inspectors. The hospital needs to ensure that audits are planned based on local priorities with oversight from hospital management and coordinated to ensure recommendations are implemented with required improvements achieved.

Good evidence of improvements in medicines information available to staff was seen during the inspections. However, the hospital should continue to provide clinical staff with up-to-date information and policies, procedures, guidelines and or protocols to guide the safe use of medicines at the point of prescribing, preparation and administration.

While acknowledging the improvements achieved by the hospital in the eighteen month period following HIQA's last inspection, inspectors found a number of ongoing deficits which require continued internal leadership and support, and in some instances support from group level around resource allocation and sharing of expertise. As a result essential elements to support medication safety remain relatively lacking in University Hospital Waterford in comparison to other model 4 hospitals providing similar services to patients.

In addition, inspectors identified a lack of urgency to respond to a specific risk related to control and monitoring of the temperature conditions for storage of refrigerated medicinal products in a number of clinical areas. HIQA wrote to hospital management to highlight the immediate nature of this identified risk and in response, the hospital outlined actions to mitigate the risk. The hospital now needs to ensure that measures are put in place to ensure the integrity of refrigerated medicines as a matter of urgency.

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

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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: Copy of letter sent from HIQA to University Hospital Waterford

Richard Dooley
General Manager
University Hospital Waterford
Dunmore Road
Waterford
Richard.Dooley@hse.ie

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

03 May 2018

Ref: MS/186

Medication Safety Monitoring Programme in Public Acute Hospitals

Dear Richard,

During the course of the announced medication safety inspection conducted at University Hospital Waterford hospital on 02 May 2018 Authorised Persons[20] identified specific issues that may present serious risks to the health or welfare of patients, and immediate measures need to be put in place to mitigate these risks. The risks identified were related to:

- **failure to control and monitor the temperature conditions for storage of refrigerated medicinal products in a number of clinical areas**
- **uncontrolled access to a treatment room in a paediatric clinical area containing unsecure refrigerated medicines, clean and sterile consumables including needles, syringes, intravenous fluids, intravenous cannulae and sharps waste disposal bins.**

[20] Authorised persons of the Health Information and Quality Authority (HIQA) under Section 70 of the Health Act 2007 (the Act) are authorised for the purpose of monitoring against the *National Standards for Safer Better Healthcare* pursuant to Section 8(1)(c) of the Act.

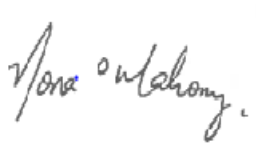
The above issues were brought to the attention of the Senior Management Team at the hospital during the inspection. This was done so that your hospital could act to mitigate and manage these identified risks as a matter of urgency.

Details of these risks will be included in the report of the announced medication safety inspection. This will include copies of HIQA's notification of this risk and service provider's response.

Given the level of potential risk associated with these findings, please formally report back to HIQA by **2pm, 11 May 2018** to qualityandsafety@hiqa.ie outlining the measures that have been inacted to mitigate the identified risks.

Should you have any queries, please do not hesitate to contact me at qualityandsafety@hiqa.ie. Please confirm receipt of this letter by email to qualityandsafety@hiqa.ie.

Yours sincerely



_____

Nora O Mahony
Authorised Person
CC: CEO Gerry O' Dwyer South/ South West Hospital Group
CC: Mary Dunnion, Director of Regulation, Health Information and Quality Authority

Appendix 3: Copy of the response received by HIQA from University Hospital Waterford

Ospidéal Ollscoile Phort Láirge
University Hospital Waterford
Regional Cancer Centre South East

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

8th May 2018

Ms Nora O'Mahony
Authorised Person
HIQA
Dublin Regional Office
George's Court
George's Lane
Dublin 7

Ref: MS/ 186 Medication Safety Monitoring Program in Public Acute Hospitals

Dear Nora,

Further to your letter of 3 May 2018 identifying specific issues which may present serious risk to patients in University Hospital Waterford, and setting out the immediate measures to be put in place, I can confirm that the following actions have been taken in relation to each of the following:

Failure to control and monitor the temperature conditions for storage of refrigerated medicinal products in a number of clinical areas

The Paediatric Ward fridge was replaced with a pharmaceutical grade refrigerator immediately following the inspection on 2nd May 2018. This will control and monitor the temperature conditions for storage of medicinal products in the Paediatric Ward.
In response to a recently completed audit of the fridges for medicinal products throughout the hospital, nine will be replaced with pharmaceutical grade refrigerators on the guidance of the Medication Safety Pharmacist.

Uncontrolled access to a treatment room in a paediatric clinical area containing unsecure refrigerated medicines, clean and sterile consumables including needles, syringes, intravenous fluids, intravenous cannulae and sharps waste disposal bins

A key pad lock was fitted to the door of the treatment room on the paediatric ward immediately following on your inspection of 02 May last.
I am informed by the Director of Nursing that the relevant Nurse Manager (CNM3) will develop an Standard Operating Procedure (SOP) which sets out clearly the fridge

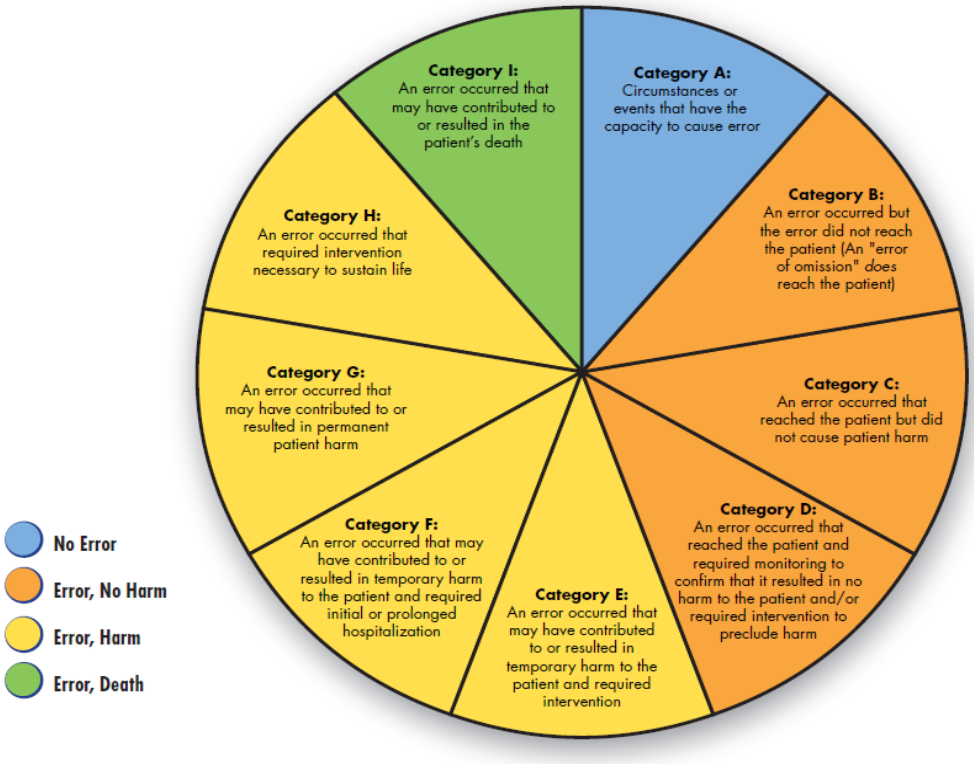
temperature monitoring and recording, and the security procedure for both the treatment room and the medication fridge. The approved SOP will be read and signed as read by all members of staff. It will be followed by a compliance audit, the results of which will be tabled at the ADON Quality Safety Risk meetings.

Ward staff will be provided with medication safety education update session by their CNM3s. Attendance records will be maintained by the CNM3.
I will seek further assurance on this matter at the next Safety and Quality Executive Steering Committee meeting which is planned for Monday 28th May 2018.
Sincerely Yours,

_____

Mr. Richard Dooley
General Manager
University Hospital Waterford
Kilcreene Regional Orthopaedic Hospital

Appendix 4: National Coordinating Council for Medication Error Reporting and Prevention. Index for Categorizing Medication Errors.



Definitions

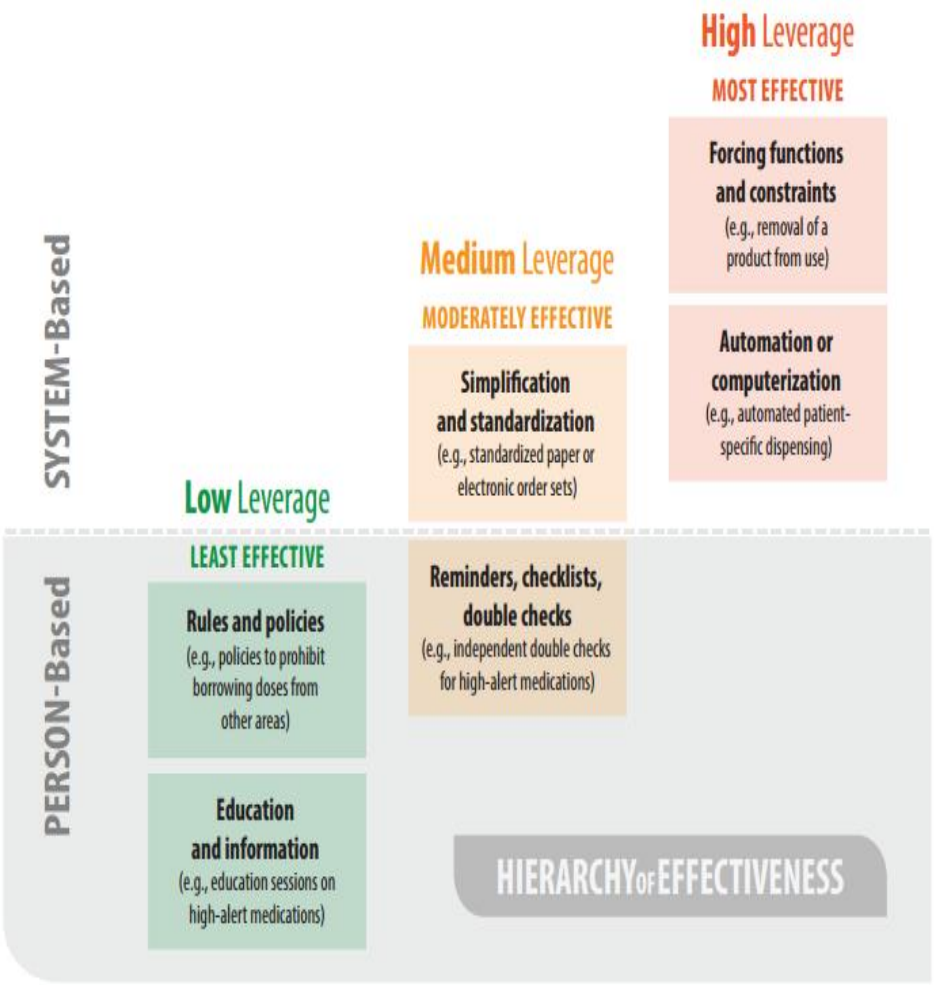
Harm
Impairment of the physical, emotional, or psychological function or
structure of the body and/or pain resulting there from.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

Appendix 5: Hierarchy of Effectiveness of Risk Reduction Strategies in Medication Safety



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