



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the announced inspection of medication safety at Regional Hospital Mullingar

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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.

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Table of Contents

1.	Introduction.....	1
2.	Findings at Regional Hospital Mullingar.....	4
2.1.	Risks identified	4
2.2.	Governance and risk management.....	5
2.3.	Audit and evaluation	10
2.4.	Medication safety support structures and initiatives	12
2.5.	Person-centred care.....	15
2.6.	Policies procedures and guidelines and access to information	16
2.7.	Training and education	18
3.	Conclusion.....	21
4.	Appendices.....	27
	Appendix 1: Medication Safety Monitoring Programme Phase One: Lines of Enquiry and Associated National Standard for Safer Better Healthcare.....	27
	Appendix 2: Copy of letter sent from HIQA to Regional Hospital Mullingar	28
	Appendix 4: National Coordinating Council for Medication Error Reporting and Prevention. Index for Categorizing Medication Errors.....	32
	Appendix 5: Hierarchy of Effectiveness of Risk Reduction Strategies in Medication Safety.....	33

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 Regional Hospital Mullingar by Authorised Persons from HIQA; Nora O' Mahony, Aoife Lenihan, Emma Cooke and Geraldine Ryan. The inspection was carried out on 17 May 2018 between 09:30hrs and 15.55hrs.

This inspection was prompted by consideration of a previous HIQA medication safety inspection on 20 April 2017 which identified a number of risks with regard to medication safety including:

- a relative lack of effective systems in place to ensure minimum standards of safety and quality were met relating to medication safety
- an ongoing lack of a clinical pharmacy service
- a lack of an up-to-date, locally adapted and approved set of hard copy A-Z intravenous product information monographs at the point of care
- the ongoing presence of potentially conflicting reference information in the ward setting relating to advice in the reconstitution and administration of intravenous medication.

In addition, at the time of the previous inspection essential elements required to improve the safety and quality of medicines use in a hospital setting were either in the very early stages of development or not in place at all. HIQA found risks concerning the following:

- the absence of strategic and operational plans detailing the development, implementation and maintenance of hospital wide medication safety systems
- inadequate arrangements in place to identify, report and manage risks associated with medication use
- an ongoing absence of a drug formulary to ensure that there are robust and transparent criteria for adopting, removing or updating the hospital's drug prescribing list
- a relative lack of current policies, protocols, and guidelines to support relevant clinical staff in safe prescribing and administration of medications at ward level.

Interviews were held in the hospital with the following groups of managers and clinical staff:

- Group one; the chairperson of the Drugs and Therapeutics Committee/clinical director, the chief pharmacist and the risk manager.
- Group two; the general manager and the director of midwifery.

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

- ward 4
- The paediatric ward
- medical 1

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

2. Findings at Regional Hospital Mullingar

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 Regional Hospital Mullingar, Authorised Persons* identified significant concerns in relation to the overall leadership, governance and management of medication safety at the Regional Hospital Mullingar.

This was due to the fact that specific risks identified during this inspection were previously identified by HIQA in two separate inspection reports following an inspection in November 2015 during a review of antimicrobial stewardship and again during a medication safety inspection in April 2017.

These risks relate to:

- A lack of clinical pharmacy services
- A relative lack of access to locally developed or adapted information to guide clinical staff in the safe use of medicines such as a hospital formulary and comprehensive up-to-date, policies, procedures, guidelines and intravenous medicine information monographs.

HIQA wrote to the hospital to seek assurance as to how these specific risk issues would be comprehensively and speedily addressed following the inspection.

In response hospital management reported that they are working with the National Recruitment Service to urgently progress the appointment of a clinical pharmacist and a senior pharmacist focusing on medication safety for the hospital.

The hospital also acknowledged the limited on-site support for nurse education, and they continue to progress initiatives with the Regional Nursing and Midwifery Planning and Development Unit and the Regional Centre for Nursing and Midwifery Education. The hospital also outlined that they have received approval for a half-time clinical skills facilitator position for the acute services.

* 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.

A copy of the letter issued to the hospital regarding the risks identified during the inspection on 17 May 2018 and a copy of the response received from the hospital are shown in Appendices 2 and 3 respectively.

2.2. 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.

Regional Hospital Mullingar is a model 3[†] hospital within the Ireland East Hospital Group. The hospital is an acute general hospital with medical, surgical, paediatric, maternity, critical care and emergency department services. The Pharmacy Department provides pharmacy services to the Regional Hospital Mullingar and in addition, provides a dispensing pharmacy service to community services including St. Loman's Psychiatric Hospital.

A previous inspection of medication safety in the Regional Hospital Mullingar on April 2017 highlighted that measures to promote safe use of medicines for inpatients were significantly underdeveloped at that time and the structures to support medication safety were at the early stages of development. 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 Drugs and Therapeutics Committee

The Drugs and Therapeutics Committee was responsible for overall governance of medication safety within the Regional Hospital Mullingar. The Drugs and Therapeutics Committee reported to the hospital's Clinical Governance Quality and Safety Committee and the Hospital Executive.

Membership of the Drugs and Therapeutics Committee was multidisciplinary to reflect the fact that medicines management is the responsibility of a number of clinical professional groupings.⁷ Membership as outlined in the terms of reference included clinicians, pharmacists, nurses, midwives, hospital management, the risk manager, the quality and patient safety manager and a representative from

[†] Model-3 hospitals admit undifferentiated acute medical patients; provide 24-seven acute surgery, acute medicine, and critical care.

community healthcare.[‡] Attendance at the Drugs and Therapeutics Committee was good with most representatives identified by the hospital attending the Drugs and Therapeutics Committee meetings.

However, in 2017 HIQA highlighted a lack of representation from paediatrics, general practitioner and community pharmacists on the Drugs and Therapeutics Committee, an issue also identified on this inspection. Inspectors were informed that regular attendance by a paediatric representative was difficult due to current work constraints, but that a paediatric representative attended to address issues pertaining to paediatrics. The hospital also informed inspectors that they had recently sent invitations to a general practitioner and a community pharmacist to join the committee.

The functions of the Drugs and Therapeutics Committee included:

- promotion of evidence-based cost-effective prescribing and medicines use
- oversight of new medicines
- monitoring and evaluation of medication incidents
- review and approval of all medicines related documentation
- review of policies procedures and guidelines prior to submission to the Policies Procedure and Guidelines Committee for final approval
- proposing and leading on medicines related quality improvement interventions,
- oversight of medicines devices and pharmaceutical items[§]
- governance of nurse prescribing
- establishing and maintaining a preferred prescribing guide where possible.

The Drugs and Therapeutics Committee also aimed to address issues related to medication use at transitions of care, and establishing and maintaining pathways of communication with general practitioners. Inspectors were informed that antimicrobial stewardship had been incorporated into the Drugs and Therapeutics Committee. The terms of reference of the Drugs and Therapeutics Committee and the hospital's organogram need to be updated to reflect this.

The chairperson of a hospital's Drugs and Therapeutics Committee should have the necessary leadership, expertise, interest and time to devote to the position.⁷ The chairperson of the Drugs and Therapeutics Committee was the clinical director as outlined in the Committee's Terms of Reference. The committee's terms of reference also required the presence of the clinical director to make up a quorum for decision making and in the event of a tied vote the chairperson had the casting vote.

[‡] Community pharmacist and general practitioner

[§] Pharmaceutical items included nutritional supplements, disinfectants medicated dressings etc.

Inspectors found that the assigned chairperson had chaired the last meeting but during 2017 the hospital's general manager had chaired four committee meetings in the absence of the chairperson. This role should be re-assigned to a clinician with the necessary expertise if the chairperson is unavailable for any period of time.

The hospital's Medication Safety Committee, established since 2016, was chaired by the chief pharmacist with membership from pharmacy, nursing, midwifery, medical, quality and risk, and management. Minutes reviewed by inspectors demonstrated good attendance from all disciplines including the clinical director and the clinical audit nurse. The committee reported to the Drugs and Therapeutics Committee as a standing agenda item.

The hospital had developed a medication safety strategy for 2017 to 2022 and a medication safety operational plan for 2017 to 2018 which were overseen by the Drugs and Therapeutics Committee. The medication safety strategy outlined long term goals, and the medication safety operational plan outlined the short term objectives and deliverables with identified resources required, individuals responsible and proposed timeframes. However, the resources required to action a number of the identified deliverables outlined in the operational plan included a medication safety pharmacist, a position currently not filled in the hospital. In the absence of the medication safety pharmacist post, inspectors were informed that these deliverables were being actioned by other pharmacy staff. Some evidence of this was seen by inspectors, for example, the grading of medication safety incidents allocated to the medication safety pharmacist was currently undertaken by other pharmacy staff.

Overall, the hospital had the appropriate accountability and governance structures and had set objectives and a plan for the hospital's medication safety programme. However, inspectors found that on the day of the inspection the hospital did not consistently adhere to the terms of reference of the Drugs and Therapeutics Committee and still lacked a number of essential elements required for an effective medication safety programme. The hospital should ensure that the leadership, governance and management responsible for medication safety address these gaps including recommendations made in this and previous inspection reports.

Formulary

The hospital had a list of medicines stocked in the hospital but did not have an evidence-based formulary.^{**} The purpose of maintaining a formulary is to ensure

^{**} 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 and 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.

that appropriate governance exists within the Drugs and Therapeutics Committee around what medicines are approved for use within the hospital and that in doing so, a proper safety evaluation occurs before medications are introduced into practice at the hospital.⁸

The hospital had a form for requesting new medicines, that was completed by the requesting consultants and reviewed by the Drugs and Therapeutics Committee before a new medicine was added to the hospital medication list. This process was guided by a recently approved policy on the evaluation and selection of medications for use within the hospital. The decision to approve a new medicine was based on the product profile, indication for use, reason for request, comparison of cost of drug treatments, issues regarding safe use and details of applicant including completed conflict of interest questions. Supporting documentation was required to be submitted along with prescribing criteria protocols or guidelines as required. The hospital also identified the need for, and put in place, a process to approve medicines for individual patients.

To build on this work, the hospital should move towards the development of a defined formulary system, to outline medicines that are approved for use in the hospital and provide information and guidance on the use of these medicines.⁶ This work could be supported through collaboration with other hospitals within the Ireland East Hospital Group who are more advanced in formulary development.

Risk Management

There was a lack of clinical pharmacy services⁺⁺ in the hospital which the hospital had identified as a high risk. The lack of clinical pharmacy services had been included in the hospital's risk register and had been escalated to the Ireland East Hospital Group. Following the submission of business cases for three posts, the hospital had received approval for two additional pharmacists' posts, and was awaiting commencement of these pharmacists.

Considering the services provided by the hospital, the lack of clinical pharmacy services constituted a risk to patient safety. This was of significant concern to HIQA especially as this specific risk was identified in two previous inspection reports of Antimicrobial Stewardship in November 2015 and again during a medication safety inspection in April 2017.⁹

⁺⁺Clinical pharmacy service describes the activity of pharmacy teams in wards and clinic setting.

Medication incidents

Incidents⁺⁺ that occurred in the hospital were reported to the State Claims Agency using the National Incident Management System^{§§} (NIMS).¹⁰ A total of 132 medication safety incidents were reported in 2017 with only 48 medication safety incidents reported to date in 2018. A low number of medication safety incidents does not necessarily mean a low number of incidents occurring, and studies have found a positive association between increased incident reporting rates and measures of safety culture, where an increase in incident reporting was indicative of a positive safety culture within the hospital.¹¹ Hospital management acknowledged the low reporting rates and informed inspectors that nurses reported the majority of incidents.

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 improvement⁶ with recommendations implemented and monitored.¹²

The hospital's risk manager was tracking medication incidents based on numbers reported, timeframe, location and category of the medication process^{***} involved. Grading in terms of severity rating was undertaken within the NIMS system. Incidents were also tracked in relation to high-risk medications by the pharmacy department and graded 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).

Medication incident summary reports were discussed at the Medication Safety Committee and the Drugs and Therapeutics Committee. Inspectors were informed that summary reports of medication safety incidents were communicated to clinical and divisional nurse managers and to the general manager who included the information in reports for the hospital's Group monthly performance meeting, the Clinical Governance Quality and Safety Committee and the Hospital Executive meetings. Inspectors were also informed that the chief pharmacist and the risk manager met monthly to review and discuss medication-related incidents. The

⁺⁺ 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).

^{***} Medication management process: including; selection, procuring storing, ordering, prescribing, transcribing, distribution, preparing, dispensing, administration documentation, reconciliation, monitoring and disposal of medications

clinical director, the director of nursing, the director of midwifery and the general manager met fortnightly to review and discuss incidents.

The hospital had identified some safety concerns related to medication incidents and had put measures in place to address these risks. For example, in response to increasing trends of incidents related to co-administration of oral and parenteral anticoagulants, the hospital had added an anti-coagulation section to the adult medication prescription and administration record.

The hospital circulated 'Medication Learning Notices' following incidents, recognising the opportunity to learn from incidents and near misses and examples of these 'Medication Learning Notices' were viewed by inspectors.

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.¹² The hospital used additional information sources to identify strengths and weaknesses in the medication management system including; risk registers, nursing metrics, audits and key performance indicators.

Overall inspectors found that there was still underreporting of medication incidents and the hospital needs to continue to promote incident reporting among all clinical staff within a just culture⁺⁺⁺¹³ to strengthen reporting of medication incidents so that safety surveillance is improved, learning is shared, and a safety culture is promoted and enhanced across the organisation.

2.3. Audit and evaluation

Line of enquiry:

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

Hospitals should have arrangements in place to ensure the effectiveness of healthcare is systematically monitored and continuously improved. The information gathered should be used to improve services, and the learning gained should be shared throughout the hospital.⁴

Examples of audit undertaken by the pharmacy department in the past year were reviewed by inspectors which included:

+++ The framework of a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace. Engineering principles and human factors analysis influence the design of these systems so they are safe and reliable.

- antibiotic prescribing in obstetric patients
- delays and omitted doses attributed to lack of availability of medicines on wards
- audit of intravenous potassium storage and record keeping
- audit of appropriate use of new features of the amended medication prescription and administration record
- point prevalence audit of venous prophylaxis in surgical and medical inpatients.

Inspectors were informed that audit was encouraged for non-consultant hospital doctors⁺⁺⁺ guided and supported by the clinical director. Audits undertaken by non-consultant hospital doctors were assigned a consultant lead, which facilitated re-audit using the same methodology when doctors moved to other hospitals.

Dissemination of audit results is essential so that the clinical workforce is informed of the areas that need improvement, and also to motivate them to change practice and participate in improvement activities.^{14, 15} Inspectors were told that audit reports were disseminated to the Drugs and Therapeutics Committee and presented at relevant governance groups and that a clinical audit nurse was recently appointed to support future planning and coordination of medication-related audits.

Nursing and midwifery quality care metrics^{§§§¹⁶} monitored on a monthly basis included a number of elements focused on medication management. Results reviewed by inspectors for the past year outlined good compliance with medication storage and custody, schedule controlled drugs and medication administration. However, medication prescription results varied between 61% and 90% compliance. Inspectors were informed that in response to poor compliance to nursing metrics, prescribers were provided with a 'stamp' with prescriber's details to use with their signature when prescribing.

The hospital identified the need to develop a clinical audit plan aligned to the medication safety strategy in its operational plan. This should be progressed to ensure that audit activity is planned and coordinated based on local priorities, driven by and with oversight from hospital management to ensure recommendations are implemented and required improvements achieved.¹⁵

⁺⁺⁺ Non-consultant hospital doctor: doctors that have not yet reached hospital consultant grade. Non-consultant hospital doctors include specialist registrars, registrars, senior house officers and interns.

^{§§§} Metrics are parameters or measures of quantitative assessment used for measurement and comparison or to track performance.

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} Inspectors found that an antimicrobial pharmacist was the only pharmacist involved in direct clinical work. Inspectors observed a number of improvements related to antimicrobial stewardship that was clearly visible in ward areas and support and advice given by this service were articulated by clinical staff.

However, the hospital had no other clinical pharmacy services available for the in-patient population. In addition, the available pharmacy resources were also deployed providing a dispensing function to healthcare providers external to the hospital.

As outlined earlier two additional pharmacists had been recruited and were due to commence employment in the hospital in the near future. On the day of inspection the hospital informed inspectors that the planned new clinical pharmacy service would focus on paediatric/neonates and maternity areas. The hospital had developed a plan for the introduction of clinical pharmacy services at the hospital, which outlined that further recruitment and appointment of additional pharmacy staff would be required to implement a clinical pharmacy service to all areas of the hospital

As the hospital is providing complex medical and surgical care including critical care and emergency services the hospital should immediately review arrangements for pharmacy services. This should include management arrangements, pharmacy services provided, allocation of staffing resources and priority areas requiring a clinical pharmacy service to ensure that current and future resources are used to maximum effect and the needs of patients prioritised.

Medication reconciliation

Medication reconciliation is a systematic process conducted by an appropriately trained individual, to obtain an accurate and complete list of all medications that a patient is taking on admission, discharge and other transitions in care.^{15,23,24,25}

**** Clinical pharmacy describes the activity of pharmacy teams in ward and clinic settings.

Inspectors were informed that doctors would ring the general practitioner or community pharmacists to clarify prescriptions if necessary. In the previous report of the announced inspection of medication safety in 2017, HIQA acknowledged the challenges, complexity and resource requirement to implement an effective medication reconciliation process but recommended that the hospital prioritises this multidisciplinary process as a fundamental building block of its medication safety programme in the future. However, inspectors found that the hospital had no formal process for medication reconciliation and limited progress had been made in relation to this.

High-risk medicines

High-risk medicines are those that have a high risk of causing significant injury or harm if they are misused or used in error.²⁶ The hospital had recently developed a High-Alert Medicines poster with an associated policy which grouped medications into categories⁺⁺⁺⁺ and outlined the associated risk reduction strategies in place (Appendix 5). For example:

- neuromuscular agents⁺⁺⁺⁺ were all labelled with 'Paralysing Agent' stickers by pharmacy, they were stored in a designated section of the pharmacy and theatre fridges and flag labelled^{§§§§} in theatre once drawn up
- oral anticoagulants^{*****} were labelled with 'Oral Anti-coagulation' stickers by pharmacy and prescribed on the separate section in the medication prescription and administration record.

To further support staff, information was distributed and education provided at grand rounds in relation to direct oral anticoagulants⁺⁺⁺⁺⁺ (DOACS). This information included a colour poster of available DOACs placed on ward medicine trolleys, and prescribing and administration guidance on anticoagulants.

Concentrated potassium has the potential to cause serious harm or death if not prepared or administered carefully. Therefore ideally concentrated potassium should be completely removed from patient care areas.²⁷

⁺⁺⁺⁺ Anticoagulants and anti-thrombotic medicines, Potassium and paracetamol, Insulin and Intrathecal or epidural administration, Narcotics and neuromuscular agents, Cytotoxic and hypertonic and hypotonic intravenous fluids.

⁺⁺⁺⁺ Neuromuscular blocking agents are used clinically to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery.

^{§§§§} Label applied as a flag to highlight and alert staff.

^{*****} Medication used in the management of venous thromboembolism, which is when a blood clot forms in a vein.

⁺⁺⁺⁺⁺ Medications used to treat or prevent blood clots. Options for anticoagulation have been expanded recently with the introduction of new anticoagulants called direct oral anticoagulants

The hospital had developed a guiding policy on the management of intravenous potassium which included the introduction of pre-mixed potassium chloride intravenous fluids but potassium ampoules were still available on 13 of the 16 ward areas audited by the hospital in line with the hospital's policy with controls in place such as; segregated storage in the locked controlled drug cupboard, 'must be diluted' stickers on the ampoules, and the usage of concentrated potassium ampoules was recorded by ward staff. The hospital should consider the restriction of concentrated potassium to a limited number of identified areas.

Other medication safety quality improvement initiatives identified during the course of the inspection included:

- the introduction of pre-prepared emergency drugs in theatre and intensive care
- the development and circulation of look-alike-sound-alike posters and stickers
- the introduction of updated inpatient and outpatient discharge prescriptions with additional security measures such as secure storage of prescription pads.

As part of the Health Service Executive's (HSE) Quality Improvement Division initiative to improve venous thromboembolism⁺⁺⁺⁺⁺ (VTE) prevention ²⁸ the Regional Hospital Mullingar aimed to achieve appropriate thromboprophylaxis^{§§§§§} for medical and surgical inpatients in the hospital within 24 hours of admission.

To achieve this, the hospital was in the process of developing a Regional Hospital Mullingar VTE risk assessment tool and prophylaxis protocol for medical and surgical patients. The risk assessment tool had been piloted and audited, and was awaiting printing of the final version at the time of inspection, and reference to the tool was included in the medication prescription and administration record. A number of opportunities for improvement were identified and recommendations outlined, and the findings had been presented at grand rounds and at the Clinical Governance Quality and Safety Committee meeting.

To support this quality improvement initiative, the hospital should identify a person responsible and timeframes to action the identified recommendation and re-audit to ensure that changes made result in improvement for patient safety.

+++++ Venous thromboembolism (VTE): a blood clot consisting of deep veins thrombus (DVT) and pulmonary embolism (PE). Blood clots (thrombus) can form within deep veins (DVT) and these clots can fragment and travel to lungs leading to Pulmonary Embolism (PE).

§§§§§ Thromboprophylaxis is the prevention of clots forming in the veins.

Alerts and recalls

Inspectors were informed that an identified person received safety alerts and circulated same. In order to prevent 'information overload' hospitals should ensure that there are systems in place to disseminate relevant information to appropriate staff.²⁹ The Chief Pharmacist received alerts related to medication and recalls^{*****} and acted on same. Inspectors were informed that the General Manager also reviewed alerts received and disseminated these as appropriate.

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.^{30, 31}

Inspectors were informed that clinical nurse specialists working in areas such as diabetes, respiratory and stroke provided education to patients on their medications. Clinical staff reported that doctors and nurses also provided advice to patients on prescribed medications.

The Regional Hospital Mullingar National Patient Experience Survey⁺⁺⁺⁺⁺ was completed by 47% of the 638 people discharged from the hospital in May 2017.³² Two questions related directly to medications and were only answered by patient prescribed medicines to take after discharge:

- 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?

^{*****} Recalls are actions taken by a company to remove a product from the market. Recalls may be conducted on a firm's own initiative or by authorised authority.

⁺⁺⁺⁺⁺ 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.

The response for Question 45 received an overall score^{*****} of 7.9 marginally above the national average score of 7.8. Question 46 received an overall score of 4.7 lower than the national average score of 5.1.³² (Figure 2).

	Regional Hospital Mullingar 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?	7.9	7.8
Question 46: Did a member of staff tell you about medication side effects to watch for when you went home?	4.7	5.1

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

The hospital had implemented the Ireland East Hospital Group Direct Oral Anticoagulants Therapy Record which contained information for the patient and also practical guidance for the prescriber. Other patient information leaflets were also observed by inspectors such as the information for parents/carer on pain management after paediatric day surgery.

Following on from the results of the National Patient Experience Survey related to medicines information the hospital should review arrangements to ensure patients receive the appropriate information on their medicines when discharged from hospital.

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

^{*****} 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.

administering medications.

In a hospital, such as the Regional Hospital Mullingar, providing complex care to undifferentiated patients the following information and policies procedures and guidelines should be in place to support medication safety including:

- a hospital formulary
- comprehensive up-to-date policies, procedures, guidelines to support medication management and safety
- locally developed or adapted intravenous medicine information monographs available to staff at point of medicines preparation.

Since the last inspection the hospital had made some efforts towards the development and updating of new and out-of-date policies, procedure and guidelines and examples of these were reviewed by inspectors. It is recommended, by both the Health Service Executive³³ and the National Clinical Effectiveness Committee³⁴ that policies, procedures and guidelines are reviewed and updated every three years. Therefore, it was of concern to HIQA that some nursing policies, procedure and guidelines previously identified by HIQA during prior inspections to be out-of-date were still not reviewed and updated by the hospital.

Although inspectors did see some locally developed hospital intravenous medicine information for antibiotics and other medicines, these were only available for a small number of commonly used medicines with limited information provided. Other sources of information for staff in relation to medicines were available on computer desktops at the nurses' station. These included generic, commercially available guides for the use and administration of intravenous medicines. Although approved for use within the hospital and printable, they were neither locally adapted nor available to staff at the point of medicines preparation in some areas inspected. Inspectors identified this as a risk, as instructions for administration of intravenous medications could be inappropriate for use in that particular clinical area or hospital with potential for patient harm. For example, medications that required additional patient monitoring in a critical care area could be administered on a general ward. The hospital needs to ensure that clinical staff have access to comprehensive locally developed or adapted information to guide them in the safe use of intravenous medicines at the point of preparation.

Medicines information resources

The pharmacy department developed a medicines information folder on computer desktops in clinical areas. This was distinguishable by a yellow icon with introductory education sessions provided, and a comprehensive step by step guide developed to

assist staff in accessing the information. The folder contained a direct link to the following:

- medicines information resources; which led to resources such as the British national formulary and the Stockley's drug interaction
- adult antimicrobial guide
- generic, commercially available guides for the use and administration of intravenous medicines
- handbook of perioperative medicines.

The pharmacy department developed an *Antibiotic of the Month poster* and *Medication Safety Bulletins* which were circulated to consultants and nurse managers. Examples of these posters were viewed by inspectors on wards visited during the inspection. Memorandums were also circulated from pharmacy to provide information on new medicine initiatives for example:

- the updated adult medication prescription and administration record
- new direct oral anticoagulant therapy record booklet
- neuromuscular blocking agents additional safety measures
- use of prepared pre-mixed potassium chloride fluids
- policy on the storage, supply and use of prescriptions pads

Overall, inspectors found evidence of many new information sources available to staff on ward computers including; new policies, procedures and guidelines, medication safety bulletins, some locally developed medication monographs and access to commercially available generic medication information.

However, inspectors concluded that a cohesive multidisciplinary, approach was lacking. This was evident when many new policies, procedures and guidelines were created by the pharmacy department but existing out-of-date nursing policies related to medication use highlighted on previous inspections, had not been reviewed. Also when inspectors visited ward areas some staff were not familiar with the information available.

Following this inspection the hospital should use a multidisciplinary approach to review all information sources to ensure that clinical staff have easy access to, and knowledge of, up-to-date information and/or policies, procedures and guidelines to guide the safe use of medicines at the point of prescribing, preparation and administration.

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.

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.³⁵

Nursing staff attended intravenous drug administration training, medication management and anaphylaxis training sessions provided by the Regional Centre for Nurse and Midwifery education. Inspectors were informed that nursing staff were also encouraged to complete the HSE LanD^{§§§§§} medication management module.³⁶ Inspectors were informed that nurses who commenced employment in the hospital over the previous 12 months had completed medication management training on induction.

Regular in service training was provided for midwives by the clinical skill facilitator assigned to maternity services. However, a corresponding service was lacking on the general wards.

Inspectors were informed that non consultant hospital doctors received on-going education at forums such as grand rounds and journal clubs, and pharmacy staff had attended and presented on medication related topics. Ninety percent of doctors in training attended the pharmacy department presentation during induction in the past year.

The pharmacy department held monthly lunchtime education sessions, with good attendance by pharmacy staff on records reviewed by inspectors. The hospital also held monthly 'lunch and learn' sessions which all disciplines were invited to attend.

Inspectors were informed that information on medication safety was also shared during the:

- Medical and Nursing Forum attended by the Clinical Director, nurse managers and non-consultant hospital doctors
- Non Consultant Hospital Doctors Committee, also attended by the clinical director.

Overall inspectors found on-going education in relation to medication management and safety was relatively limited when compared to many other similar hospitals inspected thus far by HIQA under this programme of monitoring, especially for nurses. The hospital should ensure that professionals have the necessary competencies to deliver high-quality medication safety through induction and

^{§§§§§} The health service elearning and development service

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

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.

Since the last medication safety inspection the Regional Hospital Mullingar had initiated a number of improvements in relation to medication safety. However, on the day of the inspection, inspectors were not assured that sufficient progress had been made in the implementation of the essential elements required to ensure and promote medication safety.

The ongoing lack of a clinical pharmacy service continued to constitute a risk to patient safety. The hospital was in the process of recruiting new pharmacy staff and had developed a plan for the introduction of a clinical pharmacy service. However, the hospital should review the management and delivery of pharmacy services, staff allocation and the prioritisation of clinical pharmacy services to ensure that resources are used to maximum effect for the needs of patients.

The hospital had made some progress in the development and updating of policies, procedure and guidelines as well as providing other medicine information resources to support medication safety within the hospital. However, inspectors found a cohesive, multidisciplinary approach to providing medication information resources was lacking and the hospital needs to ensure that all medicines information is locally developed or adapted for use within the hospital, reviewed and up-to-date, and available to staff at the point of prescribing, preparation or administration.

Hospitals should have arrangements in place to ensure the effectiveness of healthcare is systematically monitored and continuously improved. The hospital identified the need to develop a clinical audit plan aligned to the medication safety strategy in its operational plan. This should be progressed to ensure that audit activity is planned and coordinated based on local priorities, driven by and with oversight from hospital management to ensure recommendations are implemented and required improvements achieved.¹⁵

During HIQA's last medication safety inspection at this hospital in 2017, inspectors found there was under-reporting of medication incidents, and this was also identified during this inspection. The hospital needs to continue to promote incident reporting among all clinical staff to strengthen reporting of medication incidents so that safety surveillance is improved, learning is shared, and a safety culture is promoted and enhanced across the organisation.

The lack of local nursing supports to provide educational assistance to front-line staff was notable to HIQA in comparison to other similar sized hospitals. The hospital needs to ensure that systems are in place to provide education and support for learning for front-line staff to enhance medication safety.

In conclusion, acknowledging the effort made by the hospital to improve medication safety, it was previously highlighted by HIQA, and still evident that the Regional Hospital Mullingar requires more improvement to bring medication safety in the hospital up to the level expected and observed in other similar sized hospitals. This could be supported and expedited by using a collaborative approach with other hospitals within the Ireland East Hospital Group.

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

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4. 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 Regional Hospital Mullingar

Shona Schneemann
General Manager
Regional Hospital Mullingar
Longford Road
Mullingar
Co. Westmeath
shona.schneemann@hse.ie



23 May 2018

Ref: MS/192

Medication Safety Monitoring Programme in Public Acute Hospitals

Dear Shona,

During the course of the announced medication safety inspection conducted at Regional Hospital Mullingar on 17 May 2018, Authorised Persons²⁵ identified significant concerns in relation to the overall leadership, governance and management of medication safety at the Regional Hospital Mullingar.

This is due to the fact that specific risks identified during this inspection were previously identified by HIQA in two separate inspection reports following an inspection in November 2015 during a review of antimicrobial Stewardship and again during a medication safety inspection in April 2017.

These risks relate to:

- A lack of clinical pharmacy services
- A relative lack of access to locally developed or adapted information to guide clinical staff in the safe use of medicines such as a hospital formulary and comprehensive up-to-date, policies, procedures, guidelines and intravenous medicine information monographs.

Despite these risks being highlighted previously, during the inspection on 17 May 2018, the Regional Hospital Mullingar was only able to demonstrate limited progress in relation to addressing these risks. In addition, inspectors noted a lack of onsite support for nurse education and efforts to benefit from the experience of hospitals in

²⁵ 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 Ireland East Hospital Group to advance medication safety had not been meaningfully progressed since the previous inspection.

Consequently, I am writing to you to seek assurance as to how the specific risk issues will be comprehensively and speedily addressed and how the overarching approach to leadership, governance and management of medication safety will be enhanced following this most recent inspection.

Please note that details of this correspondence will be included in the report of the announced medication safety inspection. This will include copies of HIQA's correspondence and the service provider's response.

Please confirm receipt of this letter by email and formally report back to HIQA by **30 May 2018** to qualityandsafety@higa.ie outlining measures to address the identified risks.

Should you have any queries, please do not hesitate to contact me.

Yours sincerely



Nora O Mahony
Authorised Person

CC: Mary Day CEO Ireland East Hospital Group

CC: Mary Dunnion Director of Regulation

Appendix 3: Copy of the response received by HIQA from Regional Hospital Mullingar

Grupa Ospideal
Oirthear na hEireann



Regional Hospital Mullingar
Longford Road
Co. Westmeath
(044) 93 94140
(044) 93 43155

30th May 2018

Ms. Nora O' Mahony
Authorised Person
Health Information & Quality Authority
Dublin Regional Office
George's Court
George's Lane
Dublin 7

Re: Medication Safety Monitoring Programme in Public Acute Hospitals Ref; MS/192

Dear Nora,

I acknowledge receipt of your letter of 23rd May 2018 following the Medication Safety Inspection on the 17th May.

On behalf of the Management Team I can assure you that progress has been made in terms of Leadership, Governance and Management of Medication Safety. Examples of Governance & Management by the Drugs & Therapeutics & Medication Safety Committee were provided during the inspection.

I can also assure you we were actively working with the NRS to urgently progress the appointment of a Clinical Pharmacist and a Medication Safety Pharmacist for the Regional Hospital Mullingar.

The new Pharmacists are scheduled to commence on the 8th June and the 16th July 2018. I can also advise the Antimicrobial Pharmacist has been in post since December 2015 and together with the Medication Safety Committee has progressed medication safety across the Hospital. I have attached the recent pharmacy led initiatives, which include Medication Safety Initiatives, Medication related Audits & Policy Procedures & Protocols recently developed. I have also attached the guidance document compiled by the Chief Pharmacist in preparation for the progression of ward based Clinical Pharmacy in the Regional Hospital Mullingar.

We acknowledge we have limited on site support for nurse education and we will continue to progress education initiatives with Regional NMPDU and the RCNME and I have enclosed a training schedule for nursing & midwives for your information. I can also advise we have recently received approval for a 0.5 Clinical Skills Facilitator for the Acute Service in addition to the Midwifery Clinical Skills Facilitator.



Report of the announced inspection of medication safety at Regional Hospital Mullingar

Grupa Ospideal
Oirthear na hEireann



Regional Hospital Mullingar
Longford Road
Co. Westmeath
(044) 93 94140
(044) 93 43155

I have also received assurance of additional support for Medication Safety from Professor Mary Day, CEO, Ireland East Hospital Group. I would like to reaffirm our commitment to Medication Safety education and continuous quality improvement.

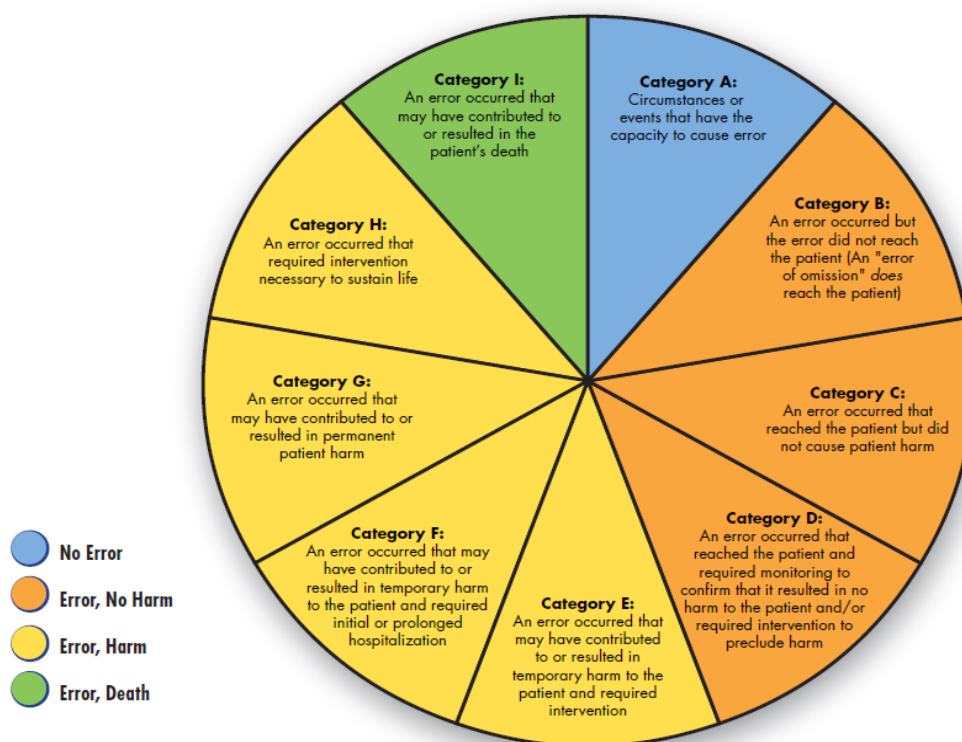
Yours sincerely,

A handwritten signature in black ink that reads "Shona Schneemann".

Ms. Shona Schneemann
General Manager

Cc: Professor Mary Day, CEO, IEHG
Mr. Paul Gallagher, Group Director of Nursing, IEHG
Ms. Anne Kelly, Director of Nursing, RHM
Ms. Marie Corbett, Director of Midwifery, RHM
Ms. Joanne Moran, Chief Pharmacist, RHM
Dr. Hilary Cronin, Clinical Director, RHM

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.

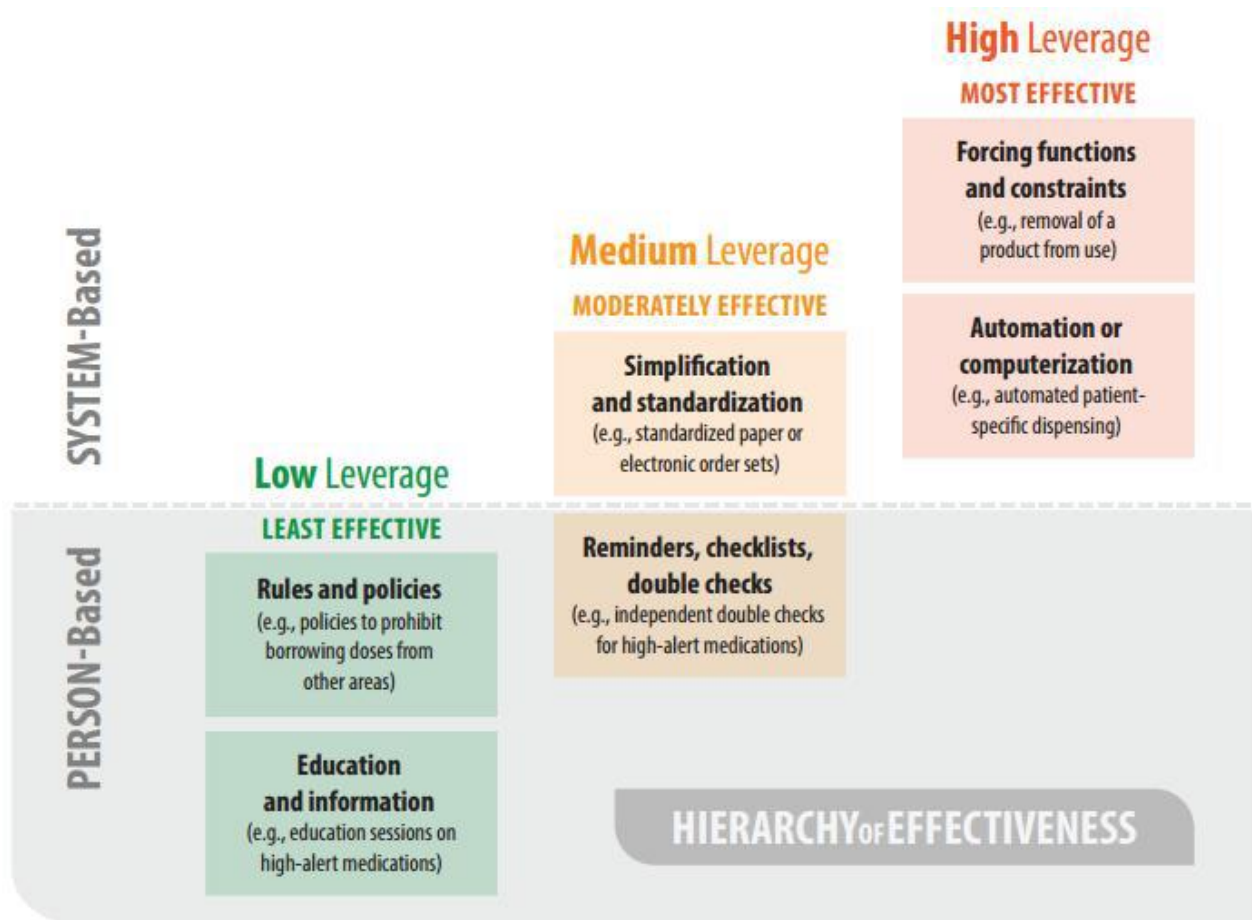
Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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



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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**

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