



**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: 04 February 2020

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

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

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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1. Introduction

HIQA's medication safety monitoring programme began in 2016 and monitors public, acute hospitals in Ireland against the *National Standards for Safer Better Healthcare* to ensure patient safety in relation to the use of medications.¹ The programme aims to examine and positively influence the adoption and implementation of evidence-based practice in relation to medication safety in acute healthcare services in Ireland.

Medications are the most commonly used intervention in healthcare. They play an essential role in the treatment of illness, managing chronic conditions and maintaining health and wellbeing. As modern medicine continues to advance, increasing medication treatment options are available for patients with proven benefit for treating illness and preventing disease. This advancement has brought with it an increase in the risks, errors and adverse events associated with medication use.²

Medication safety has been identified internationally as a key area for improvement in all healthcare settings. In March 2017, the World Health Organization (WHO) identified medication safety as the theme of the third Global Patient Safety Challenge.³ The WHO aims to reduce avoidable harm from medications by 50% over 5 years globally. To achieve this aim the WHO have identified three priority areas which are to:

- improve medication safety at transitions of care
- reduce the risk in high-risk situations
- reduce the level of inappropriate polypharmacy.*

Medication safety has also been identified by a number of organisations in Ireland as a key focus for improvement.^{4,5,6,7,8,9} Medication safety programmes have been introduced in many hospitals to try to minimise the likelihood of harm associated with the use of medications, and in doing so maximise the benefits for patients. These programmes aim to drive best practice in medication safety by working to encourage a culture of patient safety at a leadership level and through the introduction of systems that prevent and or mitigate the impact of medication-related risk.¹⁰

HIQA's medication safety monitoring programme 2019

HIQA published a national overview report of the medication safety monitoring programme '*Medication safety monitoring programme in public acute hospitals- an overview of findings*'¹¹ in January 2018 which presented the findings from thirty-

* Polypharmacy: the use of many medications, commonly five or more.

four public acute hospital inspections during phase one of the programme. This report identified areas of good practice in relation to medication safety and areas that required improvement, to ensure medication safety systems were effective in protecting patients. A number of recommendations were made focusing on improving medication safety at a local and national level. The recommendations are detailed in the report which is available on the HIQA website (www.hiqa.ie).

The final phase of HIQA's medication safety monitoring programme has been updated and developed and the current approach is outlined in eight lines of enquiry[†]. The lines of enquiry are based on international best practice and research, and are aligned to the National Standards¹ (see Appendix 1). The monitoring programme will continue to assess the governance arrangements and systems in place to support medication safety. In addition, there will be an added focus on high-risk medications and high-risk situation.

High-risk medications are those that have a higher risk of causing significant injury or harm if they are misused or used in error.¹² High-risk medications may vary between hospitals and healthcare settings, depending on the type of medication used and patients treated. Errors with these medications are not necessarily more common than with other medications, but the consequences can be more devastating.¹³

High-risk situation is a term used by the World Health Organization³ to describe situations where there is an increased risk of error with medication use. These situations could include high risks associated with the people involved within the medication management process (such as patients or staff), the environment (such as higher risk units within a hospital or community) or the medication.

International literature recommends that hospitals identify high-risk medications and high-risk situations specific to their services and employ risk-reduction strategies[‡] to reduce the risks associated with these medications (Appendix 2).¹⁴

System based risk-reduction strategies have a higher likelihood of success because they do not rely on individual attention and vigilance, and a small number of higher level strategies will be more likely to improve patient safety than a larger number of less effective strategies.¹⁴ Therefore, risks associated with the procurement, dispensing, storage, prescribing, and administration of high-risk medications need to be considered at each step of the medication management pathway.¹⁵

[†] Lines of enquiry are the key questions or prompts that inspectors use to help inform their inspection, assessment or investigation.

[‡] Risk reduction strategies: a term used to describe different ways of dealing with risks. Strategies include risk avoidance, transfer, elimination, sharing and reducing to an acceptable level.

Information about this inspection

An announced medication safety inspection was carried out at University Hospital Waterford by Authorised Persons from HIQA; Emma Cooke, Nora O' Mahony and Joan Heffernan. The inspection was carried out on 04 February 2020 between 09:00hrs and 16:55hrs.

Inspectors spoke with staff, reviewed documentation and observed systems in place for medication safety during visits to the following clinical areas:

- Ardkeen ward
- Medical 6
- Theatre department.

Medical 7 Ward and Paediatric Ward were also briefly visited.

Two group interviews were held in the hospital with the following staff:

- Group one: the chief pharmacist, the assistant risk manager, the medication safety officer, the temporary medication management project officer clinical nurse manager 2.
- Group two: the general manager, the director of nursing, the director of midwifery and the clinical director.

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

Information about the hospital

University Hospital Waterford is a model four tertiary referral hospital which provides a range of services including general medical, surgical, maternity and specialist care. The hospital is part of the South/South West Hospital Group.[§]

[§] Hospital groups: The hospitals in Ireland are organised into seven hospital groups. 1. Ireland East Hospital Group. 2. Dublin Midlands Hospital Group. 3. South/South West Hospital Group. 4. Saolta University Health Care Group. 5. University of Limerick Hospitals Group. 6. RCSI Hospitals Group. 7. National Children's Hospital Group.

2. Findings at University Hospital Waterford

Section 2 of this report presents the general findings of this announced inspection.

The inspection findings are outlined under each of the eight lines of enquiry and opportunities for improvement are highlighted at the end of each section.

2.1 Leadership, governance and management

Hospitals should have governance arrangements in place to support the development, implementation and maintenance of a hospital-wide medication safety system.^{15,16}

HIQA found on a previous medication safety inspection in University Hospital Waterford in 2017, that the hospital had the required governance structures and arrangements in place for oversight of medication safety. However, at the time of this inspection, HIQA found that appropriate governance and oversight arrangements for medication safety at the hospital were not in place due to the absence of a functioning Medicines and Therapeutics Committee and formalised reporting structures for medication safety at the hospital.

Inspectors were informed that the Medicines and Therapeutics Committee which was due to meet on a quarterly basis had not met since June 2019. The reason given for this was a lack of the necessary quorum for the meetings not being met due to a lack of attendance by key members and the absence of a dedicated administrative support. A review of the minutes of the Medicines and Therapeutics Committee from 2018 and 2019 showed that attendance at meetings was variable and not in line with its terms of reference.

Inspectors were informed that governance and oversight of medication safety at the hospital had been severely impacted during 2019 due to a number of key vacant quality, risk, pharmacy and medication safety officer posts. In addition the Medication Safety Committee, which was a subcommittee of the Medicines and Therapeutics Committee, had not met since August 2019.

It was explained at interview that the Medicines and Therapeutics Committee reported to the Executive Steering Committee for Safety and Quality and to the Executive Management Board. However, it was reported that the Executive Steering Committee for Safety and Quality had not met for the previous six months. This was also partly attributed to vacancies of key roles including the quality manager and the risk manager.

Inspectors were informed that in the absence of operational and oversight committees responsible for medication safety, senior hospital managers assured

themselves about medication safety at the hospital through senior incident management team (SIMT) meetings and individual directorate meetings. While these arrangements enabled oversight for serious medication safety issues at the hospital in the interim, inspectors found that more sustainable formalised governance arrangements were required to provide assurance on medication safety at the hospital.

Hospital management explained that medication safety was a standing agenda item at some departmental meetings. Documentation reviewed by inspectors showed that medication management was a standing agenda item at senior nurse management meetings. However, evidence of formalised reporting on medication safety to the Executive Management Board was not available on the day of inspection.

Hospital managers who spoke with inspectors acknowledged that there was a significant gap between the last meeting of the Medicines and Therapeutics Committee and the relevant oversight committees. Inspectors were informed that the General Manager was undertaking a review of the terms of reference for both the Medicines and Therapeutics Committee and the Executive Steering Committee for Safety and Quality in light of issues identified. A draft organogram outlining revised reporting governance structures was presented to inspectors on the day of inspection.

Hospitals should have a clear corporate strategy that sets out the organisation's mission, values, role, functions and actions to be taken to meet organisational goals.^{10,17} The hospital had a medication safety operational plan for 2018 and 2019 which outlined the vision and system-wide priorities for medication safety at the hospital. Operational plans for 2019 and an annual report produced for 2018 reviewed by inspectors demonstrated good progress made against key objectives and deliverables. Notwithstanding the deficits in governance and oversight arrangements, it was clear that the hospital had managed to achieve many of the objectives set out for medication safety since the last inspection and prior to August 2019, the hospital had a functioning Medicines and Therapeutics Committee and an operational Medication Safety Committee which was driving improvement for medication safety at the hospital.

Overall, HIQA concluded that appropriate governance and oversight arrangements for medication safety were not in place at the time of this inspection. This was as a result of a number of relevant committees responsible for medication safety at the hospital not functioning for a period of time and a number of key vacant posts. HIQA found that there was no agreed timeframe in place to re-convene oversight committees and formalised reporting structures for medication safety at the hospital. Following this inspection, correspondence received by HIQA from the General Manager outlined planned dates for 2020 in which relevant oversight committees for

medication safety were to convene and meet. This correspondence also provided an update in respect of pharmacy resources at the hospital which will be outlined in Section 2.5 of this report.

The hospital now needs to ensure that communication and oversight at senior management level of medication safety at the hospital is strengthened so that medication safety is consistently supported and improved within the hospital.

Opportunities for improvement

- The hospital needs to ensure that the necessary oversight committees responsible for governance, accountability and oversight arrangements for medication management and safety are effective. This includes ensuring that these committees are functioning appropriately in line with their terms of reference.
- The hospital should revisit the membership of the Medicines and Therapeutics Committee with the aim of ensuring greater, more consistent involvement and leadership from key staff from each clinical directorate at these meetings in line with its terms of reference.
- The hospital should look to develop a medication safety strategy in line with previous years to clearly articulate the short and long-term operational goals for medication safety and build on the work completed to date.

2.2 Risk management

In the absence of a risk manager, an assistant risk management position was in place at the hospital as an interim measure to deal with day-to-day issues relating to risk management.

Medication-related risks requiring additional control measures were documented on the hospital's corporate risk register. Examples of medication-related risks recorded included:

- inadequate pharmacy facilities, staffing and equipment
- an inability to progress a hospital formulary
- a lack of pharmacy cover during out of hours and at weekends.

Risk assessments** in relation to risks on the corporate risk register outlined existing control measures enacted by the hospital to address current risks. While risks had a

** A risk assessment is an overall process of risk identification, risk analysis and risk evaluation.

risk owner and were risk rated, a due date was not evident. Senior hospital management explained that the risk register was reviewed and updated by the quality manager when in post. However, given the vacant quality manager post and the absence of a functioning Executive Steering Committee for Safety and Quality, it was not clear as to where medication-related risks on the risk register were currently discussed and updated. Hospital management told inspectors that risks pertaining to specific directorates were reviewed and managed at directorate level and risks related to staffing issues were discussed at Executive Management Board meetings. The hospital must ensure that the necessary arrangements are put in place so that medication-related risks are reviewed and updated by the relevant clinical governance structures.

Similar to HIQA's previous inspection, the lack of a comprehensive clinical pharmacy service for all patients at the hospital remained a concern to HIQA given the size, speciality and complexity of services provided at the hospital. Inspectors were informed that risks relating to the lack of clinical pharmacy services at the hospital had been escalated to the South/South West Hospital Group. Progress made against this risk will be further discussed later in this report.

Medication Incident Reporting

Consistent with HIQA's previous inspection, inspectors found that there was an established system in place for the reporting of medication safety incidents at the hospital. A total of 1,054 medication safety incidents were reported in 2019 which showed a slight decrease in the number of reported incidents since 2018 (see figure 1). Inspectors were informed that the slight decrease in numbers reported for the previous year was partly attributed to a vacant medication safety officer post as well as other key vacant positions.

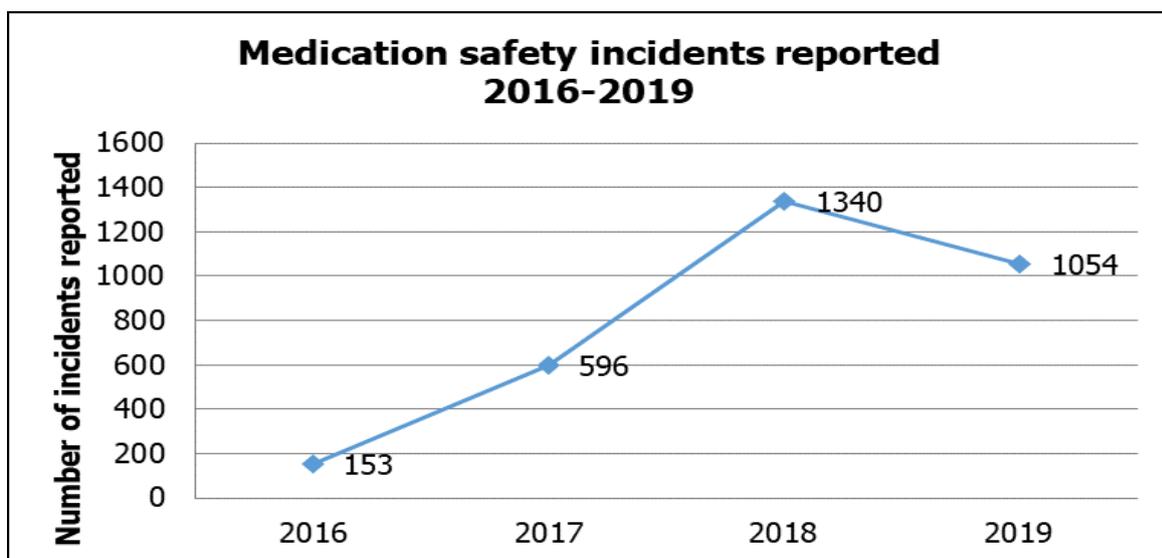


Figure 1. Medication incidents reported 2016 to 2019

Inspectors found there was scope to improve incident reporting across some disciplines, particularly for medical staff, with only 2% of incidents reported by doctors and the majority of incidents reported by pharmacists and nurses.

Medication incidents^{††} that occurred in the hospital were reported to the State Claims Agency using the National Incident Management System^{‡‡}(NIMS).¹⁸ The hospital used NIMS and the National Coordinating Council for Medication Error Reporting (NCC MERP) index to categorise medication incidents (see Appendix 3).

Analysis of incidents

The reporting of incidents is of little value unless the data collected is analysed to identify trends or patterns in relation to risk and the resulting recommendations for improvement are shared with front-line staff.¹⁹ Medication incidents were tracked and trended according to numbers, location, directorates, outcome of incident, process and type of error. Through this process, the hospital had identified their top five medication safety incidents reported and top five type of medication incident. For example, unclear or incomplete prescriptions or incorrect dose.

Medication safety reports and minutes of meetings reviewed by inspectors outlined reviews and discussion on incidents associated with harm and during this inspection, staff outlined changes that had been implemented in response to these incidents. For example, heparin 25,000 units had been removed from theatre following an incident and medication safety bulletins had been issued outlining dosing guidance on intravenous paracetamol following an incident associated with paracetamol.

One factor which increases incident reporting is the timely provision of feedback to staff on medication safety incidents reported and the actions required to avert future risks. Documentation reviewed by inspectors showed that learning from incidents was shared at the Nursing Quality, Safety and Risk Meetings and senior nurse management meetings. This was then further disseminated to frontline staff. Inspectors were also informed that medication safety bulletins were used to provide feedback to staff on medication safety incidents throughout the hospital.

It is recommended that in addition to incident analysis, a proactive approach is taken to gaining intelligence around medication safety.²⁰ Given the limited pharmacy sources, hospital management should encourage a broader proactive approach

^{††} 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).

across all disciplines for the monitoring and evaluation of medication safety at the hospital.

Alerts and recalls

Medication safety alerts and recalls were managed through the pharmacy department. An example of action taken in response to a recent alert was outlined to inspectors.

Opportunities for improvement

- The hospital must promote incident reporting among all clinical staff, within a just culture,^{§§21} to strengthen reporting of medication incidents, so that safety surveillance is improved, learning is shared, and the safety culture is enhanced across the organisation.

2.3 High-risk medications and situations

High-risk medications require special safeguards to reduce the risk of errors and minimise harm. Strategies for reducing risk with high-risk medications and in high-risk situations⁺⁺⁺ may include high leverage, medium leverage or low leverage risk-reduction strategies^{§§§} (see Appendix 2).

University Hospital Waterford had developed two high-risk medication policies and lists for use, using international literature and locally identified high-risk medications. The hospital had designed a high-risk medication list using the acronym 'PINCH'^{***} which outlined the high-risk medications for use throughout the hospital. Hospital staff had also designed a specific list of high-risk medications for use in maternity services. The 'MUMM'⁺⁺⁺ acronym had been designed by the hospital to assist clinicians working in the maternity service to focus on a group of medicines known to be associated with high potential for medication-related harm. This initiative was an example of good practice.

The hospital had implemented a combination of associated risk-reduction strategies⁺⁺⁺ which were observed by inspectors in practice. The majority of staff who spoke with inspectors had an awareness of the high-risk medications available in their clinical areas and the associated risk-reduction strategies in place. The

^{§§} The framework of a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace.

^{***} The 'PINCH' acronym and classification is widely used to assist clinicians focus on a group of medicines known to be associated with high potential for medication-related harm.

⁺⁺⁺ The 'MUMM' acronym was designed by the hospital to identify the following high-risk medications specific to the maternity service: (M)agnesium Sulphate, (U)terotonics e.g. Ergometrine, Oxytocin, (M)-Mifepristone, Misoprostol, Methotrexate and (M)ethodone.

⁺⁺⁺ Risk reduction strategies: a term used to describe different ways of dealing with risks. Strategies include risk avoidance, transfer, elimination, sharing and reducing to an acceptable level.

following sample of high-risk medications was reviewed in detail during this inspection to identify the risk-reduction strategies in place:

- anticoagulants^{§§§}
- insulin
- concentrated potassium chloride
- medication management during the perioperative period.

Anticoagulants

The hospital had a combination of risk-reduction strategies in place to mitigate against the risks associated with anticoagulants such as:

- all direct oral anticoagulant^{§§§} required double checking at administration
- storage of anticoagulants in clinical areas was rationalised and segregated
- higher strength low molecular weight heparins were segregated in a designated high-risk medication press
- rationalisation of supply of unfractionated heparin and heparin flushing to wards
- staff had access to up-to-date guidance to support safe anticoagulant therapy management.

The hospital's medication record had recently been redesigned to incorporate a designated section to prescribing anticoagulants in response to medication safety incidents associated with anticoagulants. Staff reported that this was a welcome improvement and supported safe prescribing.

It was explained to inspectors that all patients starting on anticoagulants should receive counselling on the medication. While it was identified that pharmacists were best placed to do this, it was explained that this was not always possible given the limited clinical pharmacy resources.

Concentrated potassium chloride

Inspectors viewed a number of risk-reduction strategies to mitigate against the risks associated with concentrated potassium chloride including:

^{§§§} Anticoagulants: are commonly referred to as blood thinners that prevent or treat blood clots, but these medicines also carry an increased risk of bleeding or clots, so patient education and regular monitoring of blood levels are essential to maintain patient safety and ensure good patient outcomes.

- the availability of concentrated potassium solutions for injection was limited to certain clinical areas including paediatrics, neonates, critical care areas, theatres and the delivery unit in maternity services
- outside of critical care areas, local policy indicated that concentrated potassium chloride ampoules were dispensed on a patient specific basis and in sufficient quantities for the individual patient
- there was rationalised storage of pre-mixed potassium chloride observed in the ward area separated from other intravenous solutions
- ready mixed 40mmol of potassium in 1000ml sodium chloride were required to be labelled with 'caution-potassium containing intravenous fluid'
- guidelines on the management of hypokalaemia and the use of potassium was available for staff
- local policy defined maximum rates of potassium infusions should be 10mmol/hour for general wards and outlined that greater rates required central line and cardiac monitoring
- intravenous pumps were used for the administration of concentrated electrolyte solutions.

The usage of concentrated potassium chloride in general wards was monitored as a key performance indicator and quarterly reports produced by the medication safety committee outlined a consistent reduced usage of concentrated potassium chloride in general ward areas since 2017.

Overall, high risk-reduction strategies were in place for concentrated electrolytes. However, inspectors observed two concentrated potassium chloride ampoules stored in the controlled drug cupboard in one clinical area inspected that were no longer required for use. This was highlighted to the ward manager at the time.

Insulin

Risk-reduction strategies in place to mitigate against the risks associated with insulin included:

- insulin was double checked prior to administration
- insulin products were labelled with a 'high-risk medication sticker' attached
- a diabetes clinical nurse specialist was available for patient review and education
- insulin pens in use in the hospital were for single patient use only

- unopened vials of fast acting insulin were stored in a temperature controlled fridge in line with good practice
- insulin was administered using an insulin syringe or insulin pen device.

Insulin pens stored in medication trolleys were for single patient use only with individual patient details and date of opening recorded on them. At ward level, insulin was stored in a designated red box labelled 'insulin'. While it was explained to inspectors that these boxes were used to store insulin only, inspectors observed other high-risk medications were also stored in some boxes. Inspectors found one example of an opened insulin pen that did not have the date of opening recorded on the pen.

Inspectors were informed that the hospital did not have guidelines for staff on the management of a hypoglycaemic**** episode. While access to medication used to treat low blood sugars was observed in the clinical areas inspected, inspectors were informed that the practice for the management of a hypoglycaemic episode varied throughout the hospital and that there was no standardised approach or clear guidance for staff. The hospital should look to prioritise the development of a hypoglycaemic policy to ensure that the management of low blood sugars is standardised throughout the hospital.

Medication management during the perioperative period

A hospital's operating theatre presents a unique situation with the use of multiple high-risk medications, high patient throughput and complex procedures.²² A diverse range of medications are used which have the potential for a serious adverse event if administered incorrectly.²³ Therefore, the perioperative period is a high-risk situation in relation to medication safety.

Examples of risk-reduction strategies in place to mitigate against the risks of medications used within the theatre department are outlined below:

- anaesthetic medications were prepared, labelled and administered by the same individual, and unused medications were discarded at the end of each case
- international colour-coded labels were used
- some prefilled syringes were available and their use encouraged
- emergency drugs for planned surgeries were drawn up and labelled by the anaesthetist at the start of each day, stored separately and disposed of at the end of the day

**** Hypoglycaemic: when a person's blood sugar falls below the normal level.

- medications were stored in a standardised and organised manner across theatres.

Inspectors were informed that the hospital was in the early stages of implementing a process whereby medications for on-call emergency surgery were prepared by the on-call anaesthetist, labelled, dated and stored in a labelled box in a dedicated fridge. This box was viewed by inspectors.

Inspectors were informed that the hospital was in the process of reviewing the system in place for prescribing medication to be administered 'as required' in the recovery area. This work should be progressed to ensure safe prescribing practice.

Hospital policy stated that multidose vials were used for single named patient only with some exceptions in distinct approved clinical areas, away from the patient environment. However, inspectors were informed that a multidose vial of a medication was used for multiple patients in one theatre. The hospital should ensure that the use of multidose vials is safe and in line with hospital policy and evidence-based practice.^{24,25,26}

Other high-risk medications

Examples of risk-reduction strategies in place to mitigate the risks for other high-risk medications and situations were also identified during this inspection and are outlined below.

The hospital had a number of high level risk-reduction strategies in place for oral methotrexate. Inspectors were informed that oral methotrexate was not stocked in clinical areas and the hospital only stocked one strength of methotrexate tablets, and these were dispensed with a high-alert label in single patient doses. The high-risk medication policy outlined prescribing guidelines which required the prescriber to specify the day of the week the oral methotrexate is to be administered and to block out all other days with an 'x' on the medication record to prevent inadvertent daily administration.

The medication record had a separate antimicrobial section which facilitated prescribing, monitoring and administration of antimicrobials requiring therapeutic drug monitoring. The antimicrobial section included prompts for staff to review intravenous antimicrobials after three days with a view of switching to oral antibiotics and also included a 'Day seven review'. Staff could access dosing and monitoring information for antimicrobials on the University Hospital Waterford mobile phone application.

At the time of inspection there was no oversight of procedural sedation at University Hospital Waterford. It was of concern to HIQA that the hospital had no processes or systems in place to monitor the safe administration of procedural sedation within the

hospital. Procedural sedation was administered in a number of non-theatre areas including the Emergency Department, Endoscopy, the Radiology Department and the Paediatric Unit. It was explained to inspectors that the hospital did not have a locally developed policy to support the administration of procedural sedation which had been identified as a priority area for the Medicines and Therapeutics Committee. The hospital should look to prioritise the development of a local hospital policy to support the administration of procedural sedation and ensure practices are safe and in line with evidence based practice.

The hospital had a list of sound-alike look-alike drugs (SALADs)⁺⁺⁺⁺ which were observed on display in the clinical areas inspected. The hospital had developed a critical medicines list to highlight medications which cannot be missed which inspectors also observed in the clinical areas visited.

Overall, HIQA found that University Hospital Waterford had implemented a number evidence-based safety measures for high-risk medications. The hospital demonstrated an awareness of the key areas which required further improvement and development.

Opportunities for improvement

- The hospital should ensure that the risk reduction strategies and policies in place are audited periodically to provide assurance to hospital management that risk reduction strategies have been effectively and consistently implemented in practice across all clinical areas.
- The hospital should prioritise the development of clear systems and oversight arrangements for the use of procedural sedation to provide assurance around the practice of procedural sedation at the hospital.

2.4 Person centred care and support

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}

National Inpatient Experience Survey

⁺⁺⁺⁺ Sound-alike look-alike drugs (SALADS) or Look-alike sound-alike (LASA). The existence of similar medication names is one of the most common causes of medication error and is of concern worldwide. With tens of thousands of drugs currently on the market, the potential for error due to confusing drug names is significant.

University Hospital Waterford National Inpatient Experience Survey^{****} was completed by 445 patients discharged from the hospital in May 2019. Two questions related directly to medication in the survey. The scores for the hospital and the national scores for 2017,^{§§§§} 2018^{*****} and 2019 are illustrated in table 1 below.

Questions	Year	University Hospital Waterford score	National score
Q44. Did a member of staff explain the purpose of the medicines you were to take at home in a way you could understand?	2019	7.4	8.0
	2018	7.6	8.0
	2017	7.3	7.8
Q45. Did a member of staff tell you about medication side effects to watch for when you went home?	2019	4.7	5.3
	2018	4.6	5.2
	2017	4.5	5.1

Table 1: Comparison between University Hospital Waterford and national scores for Questions 44 and 45 of the National Inpatient Experience Survey 2017, 2018 and 2019.

The results obtained by University Hospital Waterford illustrate a slight improvement in relation to Question 45 and a slight disimprovement for Question 44 for 2019 compared to the previous year with overall scores⁺⁺⁺⁺ less than the national average.

In response to the National Patient Experience Survey the hospital had developed a discharge information pack to address the areas needing improvement. The pack

**** The National Inpatient Experience Survey is a nationwide survey which asks people for feedback about their stay in hospital. The survey is a partnership between HIQA, the Health Service spent 24 hours or more in a public acute hospital, and have a postal address in the Republic of Ireland are asked to complete the survey.

§§§§ Please note that the numbering of questions changed after the 2017 survey was completed. Question 44 '.....' was originally question 45 in the 2017 survey and question 45 '.....' was originally question 46.

***** National Inpatient Experience Survey was known as the National Patient Experience Survey in 2017 and 2018.

++++ 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.

included information on contacting general practitioners and community pharmacists following discharge as well as an information leaflet on 'Five questions to ask about your medications'.

Patient information

Inspectors were informed that patient information was provided primarily by nurses and doctors. However, it was reported that pharmacy would aim to provide information to patients if specifically requested. All clinical nurse specialists also provided patient information in areas such as diabetes, respiratory and cardiology.

Plans to develop information resources in relation to high-risk medication were outlined in operational plans for 2018 and 2019. The hospital provided staff access to patient information leaflets via the medicines information icon on the computer desktops. The hospital had implemented a direct oral anticoagulant (DOAC) booklet for patients with further plans in place to develop a 'know your medicines booklet' for 2020. The hospital should progress with plans in place for patient education and the availability of medication information leaflets for patients.

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.^{29,30,31}

Inspectors were informed that the hospital did not have a formal medication reconciliation process in place. Clinical pharmacists carried out medication reconciliation, however, a clinical pharmacy service was only available in critical care areas and the Emergency Department. Therefore, medication reconciliation could not be facilitated for all patients on admission or discharge but was prioritised by clinical pharmacy within the Emergency Department for admitted patients.

HIQA acknowledges the challenges, complexity and resource requirement to implement an effective medication reconciliation process but notes that this has been progressed in other similar sized hospitals. Within the clinical areas visited by inspectors, which did not have a clinical pharmacy service, inspectors were informed that staff would contact community pharmacists or general practitioners to clarify prescriptions as required. The hospital had also recently developed a medication reconciliation guideline which had been approved for use by the Medicines and Therapeutics Committee.

Systems to support medication safety and optimisation

Some systems were in place to support medication safety and optimisation in relation to the:

- prescribing and administration of crushed medications
- prescribing and administration of medications intended for nasogastric administration
- prevention of unintended administration of enteral medication through the intravenous route.

Patient weight measurements are important for medications that require an individual weight-based dose.³² Patient weights and allergies were documented on all medication records reviewed by inspectors during the inspection.

Opportunities for improvement

- The hospital needs to work towards establishing medication reconciliation for patients on admission, and progressing towards the development of this service to include patients on discharge.

2.5 Model of service and systems in place for medication safety

International studies support the role of clinical pharmacy service^{33****} in hospital wards in preventing adverse drug events.^{34,35,36,37,38,39} As detailed earlier in this report, University Hospital Waterford's clinical pharmacy service was limited to covering critical care areas and the Emergency Department. It was also explained to inspectors that the appointment of a new medication safety officer had resulted in a reduced clinical pharmacy service for the paediatric ward. Other clinical areas including high-risk areas such as maternity did not have a clinical pharmacy service which can pose a potential risk to patient safety.

Inspectors were informed that the antimicrobial stewardship pharmacist position at the hospital had been vacant since October 2019. This was of concern to HIQA given the consumption rates of antimicrobials at the hospital and the identification of antibiotics requiring therapeutic monitoring within the top five category of medication incidents at the hospital. Senior hospital management reported that in the interim of recruiting an antimicrobial stewardship pharmacist, a dispensary pharmacist had been appointed to review antimicrobial requests.

Similar to HIQA's previous medication safety inspection at the hospital, the lack of clinical pharmacy services* remained a significant concern to HIQA considering the

**** Clinical pharmacy service describes the activity of pharmacy teams in ward and clinic settings. The following core activities are involved in providing clinical pharmacy services: prescription monitoring, prescribing advice, optimising therapeutic use of medicines, adverse drug reaction detection and prevention, patient education and counselling, inter-professional education about medicines. It may also involve some or all of the following: medication history taking, medication reconciliation, specialist clinics e.g. HIV, clinical audit, protocol/guideline development. Source: Pharmaceutical Society of Ireland. *Future Pharmacy Practice in Ireland - Meeting Patients' Needs*. Dublin; 2016. Pharmaceutical Society of Ireland.

size and complexity of the services provided by the hospital. Of note, other comparable 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. At the time of this inspection, inspectors were informed that the hospital had approximately 14.5 whole time equivalent (WTE) vacant posts within the pharmacy department. Senior hospital managers told inspectors that authorisation to recruit approved posts for pharmacy services rested with the Health Service Executive (HSE) at a national level. It was also noted that the hospital provided an external community pharmacy service within the current limited resources available at the hospital.

During the inspection, inspectors were also informed that the hospital had recently received approval for a number of vacant posts throughout the hospital, however, this only included approval for one pharmaceutical technician post and no additional pharmacist posts.

Correspondence received by HIQA following this inspection outlined that out of the 14.5 WTE current vacancies, eight WTE posts were in the process of recruitment. While the filling of these posts would address some of the clinical pharmacy deficiencies within the hospital, HIQA notes that the hospital would still be operating at a significant deficit in clinical pharmacy resources when compared to hospitals of similar size and complexity of services. This deficit was also outlined in the hospital's correspondence to HIQA following a benchmarking exercise of pharmacy resources of similar sized hospitals completed by the hospital. The hospital needs to be supported by the South/South West Hospital Group and at national HSE level to ensure that clinical pharmacy services provided at the hospital is reflective of the model, size and complexity of services provided by the hospital.

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

University Hospital Waterford had a list of medicines which were approved for use in 2012. Some sections of this list had been updated over the years, however, inspectors were informed that progress towards the development of a hospital formulary was challenging given the current level of pharmacy resources. The inability to progress with a hospital formulary^{§§§§§} was documented on the hospital's risk register. The hospital outlined that it was actively looking at formularies that had been designed and developed by other similar sized hospitals and identified opportunities for these to be adapted locally for use within the hospital.

^{§§§§§} Formulary: a managed list of preferred medications that have been approved by the hospital's Drugs and Therapeutics Committee for use at the hospital.

The hospital had a system in place for the approval of new medications which was under the governance of the Medicines and Therapeutic Committee.

Opportunities for improvement

- The hospital should continue to progress with the recruitment of pharmacy staff and in the interim examine how best to allocate the resources to ensure that high-risk patient areas are prioritised.
- The hospital should look to progress the development of a hospital formulary to improve patient care through improved selection and rational use of medications and ensure appropriate governance of prescribed medications. This work could be progressed by collaboration with other hospitals within the group.

2.6 Use of information

Hospitals should support clinical staff in achieving safe and effective medication use through the availability of up-to-date evidence-based information and decision support tools for medications.¹⁵

The hospital had identified the need to ensure patient information resources were available to aid staff on the safe and effective use of medications as a strategic goal for 2018 and 2019.

University Hospital Waterford had a number of medication related policies, guidelines and information sources which were accessible to staff through hard copy or electronic version such as:

- intravenous guidelines
- clinical guidelines
- NEWT guidelines*****
- antimicrobial guide
- direct oral anticoagulant prescribing guide
- prescribing policy
- high risk medication policy
- medication reconciliation guideline
- management of hypokalaemia
- medication safety alerts and memos
- patient information leaflets.

***** 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.

It is recommended, by both the Health Service Executive⁴⁰ and the National Clinical Effectiveness Committee⁴¹ that policies, procedures and guidelines are reviewed and updated every three years. The majority of policies, procedure and guidelines viewed by inspectors during the inspection were up-to-date. Medication safety operational plans reviewed for 2019 detailed medication policies, procedures and guidelines which had been newly developed, revised or awaiting approval by the Medicines and Therapeutics Committee.

Inspectors observed that access to medication information at the point of prescribing or administrating was a challenge within some clinical areas inspected given the limited numbers of computers available and issues identified with internet connection. Hospital management demonstrated an awareness of the existing challenges for staff accessing information and outlined that this had been placed on a project list to be addressed.

2.7 Monitoring and evaluation

Inspectors were informed that audit activity was centrally controlled by the quality office and that staff were requested to register audits with this office.

The hospital did not have an audit plan aligned to the medication safety strategy. The development of an audit programme with a particular focus on high-risk medicines and high-risk situations was documented in the hospital's operational plan for 2019 but this had yet to be progressed at the time of inspection.

Inspectors found that medication audits were not strategically driven and were selected on the basis of trends in incident reports or personal preference. Evidence of monitoring and evaluation of medication safety provided to inspectors for the past two years consisted of:

- audit of the use of concentrated potassium chloride ampoules at ward level
- audit of medication refrigerators
- a review of medication related information in clinical areas
- medication safety audit of missed doses 'To bleed or not to bleed: A failure at the heart of NOACs'.⁺⁺⁺⁺⁺

Medication quality care metrics,⁺⁺⁺⁺⁺ monitored on a monthly basis included a number of elements that focused on medication management. Results reviewed by inspectors for 2019 outlined good compliance with medication storage and custody,

⁺⁺⁺⁺⁺ Medication used in the management of venous thromboembolism, which is when a blood clot forms in a vein.

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

scheduled controlled medication and administration and opportunities for improvement across other medication safety parameters.

Documentation reviewed by inspectors outlined that the Medicines and Therapeutics Committee had approved five key performance indicators for medication safety at the hospital. These included:

- number of medication incident report forms completed
- number of medication incidents resulting in harm
- usage of concentrated potassium chloride in general wards
- number of incidents of chemotherapy extravasation
- number of incidents of patients receiving a medication they are known to be allergic to.

Quarterly medication safety committee reports produced for the Medicines and Therapeutics Committee outlined data and performances against the identified key performance indicators. The hospital should continue to build on the work achieved to date with key performance indicators and re-establish oversight committees to support monitoring and evaluation of medication safety at the hospital.

Monitoring of medication safety should be formally planned, regularly reviewed and centrally coordinated with resulting recommendations actioned and the required improvements implemented.¹⁵ Inspectors reviewed medication safety audits undertaken by the hospital. Some audits had clear actions and recommendations arising from audit findings, however, other audits reviewed, did not have recommendations or associated time-bound actions. Inspectors also noted that there was further potential to expand and enhance medication safety auditing capacity from a multidisciplinary perspective.

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.^{42,43} Inspectors were informed that audit results were disseminated through directorate structures and departmental meetings as well as medication safety bulletins and clinical update programmes.

Hospital management acknowledged that there was scope to further develop medication safety audits at the hospital. The hospital needs to put a system in place to ensure that audits are planned based on local priorities and that recommendations are implemented and the required improvements achieved, driven by and with oversight from hospital management.⁴³

Overall, inspectors found that a more structured, coordinated approach to planning medication safety audits aligned to a formal medication safety strategy could

potentially enhance the hospital's current approach to evaluation and monitoring of medication safety.

Opportunities for improvement

- Evaluation and monitoring of the use and safety of medication should be planned in line with the hospital's overall priorities and aligned to a medication safety strategy and conducted in a multidisciplinary manner.
- The hospital should ensure that audits are centrally controlled and strategically driven with appropriate oversight around the implementation of recommendations.

2.8 Education and training

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.⁴⁴

Multidisciplinary staff education was identified as a strategic goal within the medication safety operational plan for 2018 and 2019. The hospital had a structured induction programme for doctors, nurses and midwives which included medication safety education.

Nursing and midwifery staff attended intravenous drug administration training and medication management sessions during induction. Nurses and midwives also attended the clinical safety update day which included a medication safety presentation delivered by the pharmacist and staff from the nursing practice development unit. Documentation reviewed outlined that 469 nursing and midwifery staff attended this training in 2018 and 2019. Dates for monthly clinical safety update programmes were planned for all staff to attend in 2020.

Medication safety training had been prioritised as a key topic for non-consultant hospital doctor (NCHD) induction training and the hospital had introduced a safer prescribing eLearning module in July 2018 as part of each NCHD's training. It was explained that this training was relatively new and currently not mandatory for doctors but it was anticipated that it would be made mandatory going forward. Documentation reviewed by inspectors outlined that uptake of this training amongst doctors was poor and required improvement.

Other medication focused sessions were provided for staff on an ongoing basis such as:

- patient safety updates
- clinical pharmacists weekly meeting
- medical grand rounds

- medication safety month which was rolled out in 2019
- medication management project.

Opportunity for improvement

- The hospital should ensure that professionals have the necessary competencies to deliver high-quality medication safety through induction and ongoing training. This could be supported by developing a structured targeted ongoing programme of education for medication safety aligned to the hospital's medications safety programme.¹¹
- The hospital should implement the necessary measures to ensure all staff attend the required medication safety training within the hospital.

3. Summary and conclusion

Medications play a crucial role in maintaining health, preventing illness, managing chronic conditions and curing disease. However, errors associated with medication usage constitutes one of the major causes of patient harm in hospitals and the impact of medication errors can be greater in certain high-risk situations. Understanding the situations where the evidence shows there is higher risk of harm from particular medications and putting effective risk-reduction strategies in place is key for patient safety.

Since the last HIQA inspection in May 2018, HIQA found that there had been a disimprovement in relation to governance and oversight arrangements for medication safety at University Hospital Waterford as evidenced by the absence of a functioning Medication Safety Committee, Medicines and Therapeutics Committee and Executive Steering Quality and Safety Committee. However, it was clear that prior to the cessation of these committee meetings, the medication safety agenda was actively being progressed by these key committees as set out in the hospital's medication safety operational plans.

Similar to previous inspection findings, there remained a lack of clinical pharmacy services in the hospital, and considering the size and complexity of the services provided by the hospital, the lack of a comprehensive clinical pharmacy service constituted a risk to patient safety. Notwithstanding the efforts made to recruit additional pharmacy resources, and the escalation of this risk to the hospital group level, the hospital should work to assure itself that the current pharmacy service is utilised most appropriately and prioritises high-risk areas in order to mitigate risk and promote patient safety.

Correspondence received by HIQA from the hospital's General Manager and copied to the South South/West Hospital Group Chief Executive Officer following this inspection outlined dates for which the relevant oversight committees for medication safety were to re-convene and provided an update in respect of clinical pharmacy resources. Senior hospital management must ensure that dates to re-convene oversight committees are actively progressed as per timelines outlined. In regards to clinical pharmacy resources, the hospital should be supported by the South/South West Hospital Group and at national HSE level to ensure that clinical pharmacy resources provided reflect the size, needs and complexities of services provided by the hospital.

University Hospital Waterford had established systems in place for high-risk medications that had been developed over the previous two years as a result of sustained effort and focus in relation to medication safety. The hospital had identified high-risk medications in use for the general hospital and also the maternity

service. Inspectors found that the hospital had implemented evidence-based safety measures to protect patients from the risk of harm associated with these high-risk medications and that staff had a good awareness of the risk-reduction strategies in place.

HIQA acknowledges the positive progress made in the area of high-risk medications given the clinical pharmacy resources available and the absence of oversight committees for medication safety at the hospital for part of 2019. The hospital should ensure that the risk reduction strategies and policies in place are audited periodically to provide assurance to hospital management that risk reduction strategies have been effectively and consistently implemented in practice across all clinical areas.

Some systems were in place to monitor the effectiveness of medication management systems at the hospital, however, it was evident that formal updates in respect of medication safety with senior hospital management had ceased in recent months due to key oversight committees not convening. Inspectors determined that there was scope to improve the culture and ownership on incident reporting of medication safety across all disciplines. Hospital management acknowledged the opportunity to further strengthen the monitoring of medication safety through audit activity which is centrally controlled and strategically driven.

Hospital management should progress plans outlined to HIQA in correspondence received following this inspection and work towards re-establishing the services required for medication safety. In addition, the hospital needs to restore its medication safety programme to ensure that the essential elements required for medication safety are implemented and improvements are sustained. Furthermore, the hospital should look to expand responsibility for medication safety to include other disciplines and departments so that all opportunity to sustain current progress and identify opportunities for further improvement in relation to medication safety can be utilised.

This report should be shared with relevant staff at University Hospital Waterford and the South/South West Hospital Group to highlight the findings from this inspection including what has been achieved to date and to foster collaboration in relation to opportunities for improvement.

The opportunities for improvement highlighted in this report requires renewed focus for leadership and management at the hospital to ensure that medication safety is seen as a priority and that patients are protected from known and avoidable harm.

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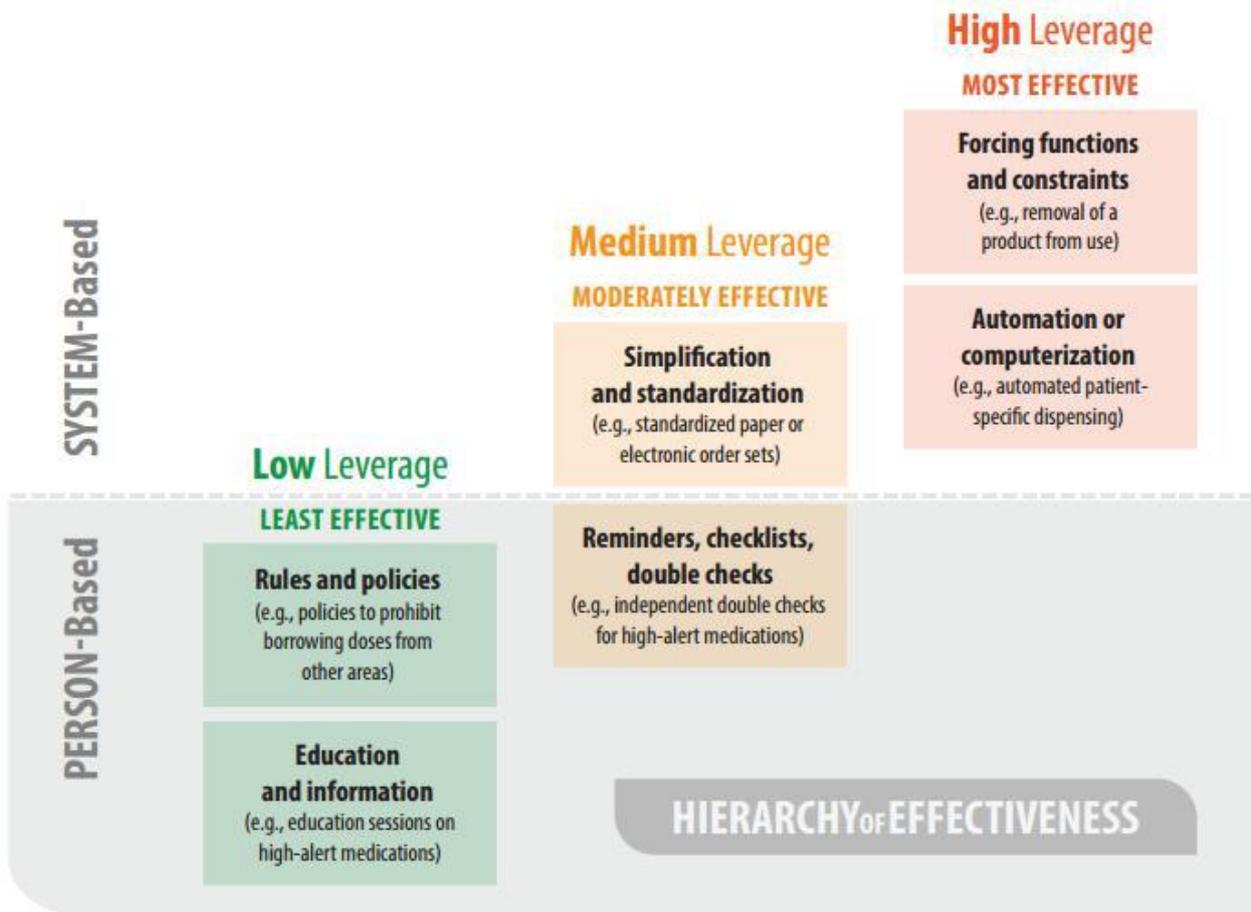
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5. Appendices

Appendix 1: Lines of enquiry and associated National Standards for Safer Better Healthcare.

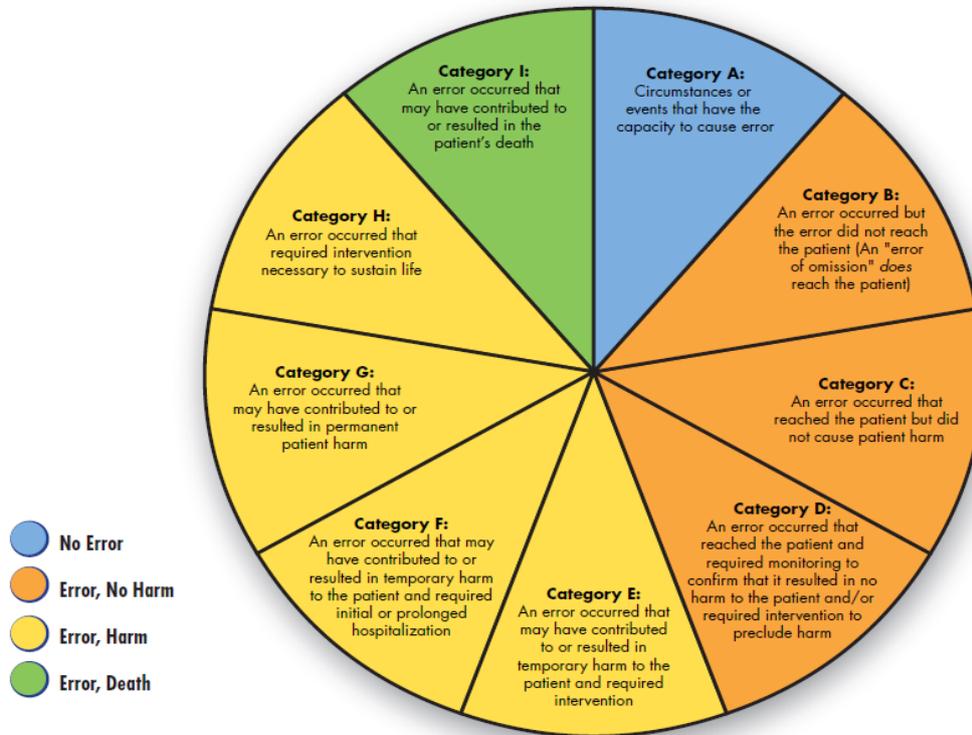
Area to be explored	Lines of enquiry	Dimensions/ Key Areas	National Standards
Leadership, governance and management	1. Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.	Capacity and capability	3.7, 5.1, 5.2, 5.5, 5.4, 5.6, 5.11
Risk management	2. There are arrangements in place to proactively identify report and manage risk related to medication safety throughout the hospital.	Quality and Safety	3.1,3.2,3.3,3.6, 5.8, 5.11, 8.1
High-risk medications	3. Hospitals implement appropriate safety measures for high-risk medications that reflect national and international evidence to protect patients from the risk of harm.	Quality and Safety	2.1, 3.1
Person centred care and support	4. There is a person centred approach to safe and effective medication use to ensure patients obtain the best possible outcomes from their medications.	Quality and Safety	1.1, 1.5, 3.1, 2.2, 2.3
Model of service and systems for medication management	5. The model of service and systems in place for medication management are designed to maximise safety and ensure patients' healthcare needs are met.	Quality and Safety	2.1, 2.2 ,2.3, 2.6, 2.7, 3.1,3.3, 5.11, 8.1
Use of Information	6. Essential information on the safe use of medications is readily available in a user-friendly format and is adhered to when prescribing, dispensing and administering medications.	Quality and Safety	2.1, 2.5, 8.1
Monitoring and evaluation	7. Hospitals systematically monitor the arrangements in place for medication safety to identify and act on opportunities to continually improve medication.	Quality and Safety	2.8, 5.8
Education and training	8. Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.	Capacity and capability	6.2, 6.3

Appendix 2: Hierarchy of effectiveness of risk-reduction strategies in medication safety.



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Appendix 3: National Coordinating Council for Medication Error Reporting and Prevention. Index for categorising 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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