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

Date of announced inspection: 22 February 2019

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 Office of 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.

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- **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-

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[*] 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 Standards[1] (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 situations.

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 Organization[3] 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 the Mercy University Hospital by Authorised Persons from HIQA; Nora O' Mahony and Kay Sugrue. The inspection was carried out on 22 February 2019 between 09:00hrs and 16:50hrs.

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

- Interventional radiology room
- St. Mary's ward
- St. Catherine's ward.

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

- Group one: the chairperson of the Drugs and Therapeutics Committee, the chief pharmacist and the quality and patient safety manager.
- Group two: the deputy chief executive officer, the clinical director and the nurse practice development coordinator (deputising for the director of nursing).

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

Information about the hospital

The Mercy University Hospital is a model $3^{§}$ public acute hospital in the South/South West Hospital Group providing inpatient, day and outpatient services, including a 24/7 emergency department, an urgent care centre, St. Francis Unit (Transitional Care Unit) and various medical and surgical specialities.

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§ Model 3 hospital admits undifferentiated acute medical patients; provide 24 hour/7 day week acute surgery, acute medicine and critical care.

2. Findings at Mercy University Hospital

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] The Mercy University Hospital had a Drugs and Therapeutics Committee with overall responsibility for governance of medication safety within the hospital. However, inspectors found that oversight of medication safety was not consistent in all areas visited by inspectors. This was particularly evident within the interventional radiology room, which requires focused attention following this inspection. This will be further outlined in section 2.3.

Membership of the Drugs and Therapeutics Committee was multidisciplinary, and included a pharmacist from the community and University College Cork. The hospital reported that despite efforts they were still unable to get a general practitioner to join the committee.

The Drugs and Therapeutics Committee met as per terms of reference but were not adhering to all outlined functions such as, the management of a formulary or submitting an annual report to the Executive Management Board. Evidence of discussion regarding issues and concerns were outlined in committee minutes reviewed, and inspectors were informed that the required actions were assigned to individuals at meetings. However, this was not documented to support follow-up of actions at subsequent meetings.

The hospital had developed a multidisciplinary Medication Safety Working Group, which was a subcommittee of the Drugs and Therapeutics Committee. The work of this committee, as reviewed in minutes from the previous 12 months, consisted of reviewing medication incident reports and medication safety audits, progression of the Time Sensitive Medication policy and the revision of the hospital's medication record.[**]

Medication strategy

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

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[**] The Medication Record is the medication prescription and administration record, drug kardex or drug chart.

goals.[10,17] The Mercy University Hospital did not have a medication safety strategy to clearly set out the short and long-term goals for the organisation. The absence of such a strategy was apparent and the hospital's medication safety programme required improved focus and direction.

The hospital had identified the need for a key individual to progress the management of an overall strategy or plan and had submitted a business case for a medication safety officer to fulfil this role. The lack of a medication safety lead had been identified as a risk by the hospital and was escalated to the hospital's risk register. Despite this, the hospital should look to progress the development of a strategic medication safety plan within current resources to focus the direction for medication safety within the hospital.

Opportunities for improvement

- The hospital should look to develop a medication safety strategy to clearly articulate the short and long-term operational goals for medication safety.

2.2 Risk management

Medication incidents[††] reported were inputted onto the National Incident Management System[‡‡] (NIMS).[18] The number of medication incidents reported continued to increase each year, with 340 reported in 2018 (see Figure 1).

**Medication incidents reported
2013- 2018**
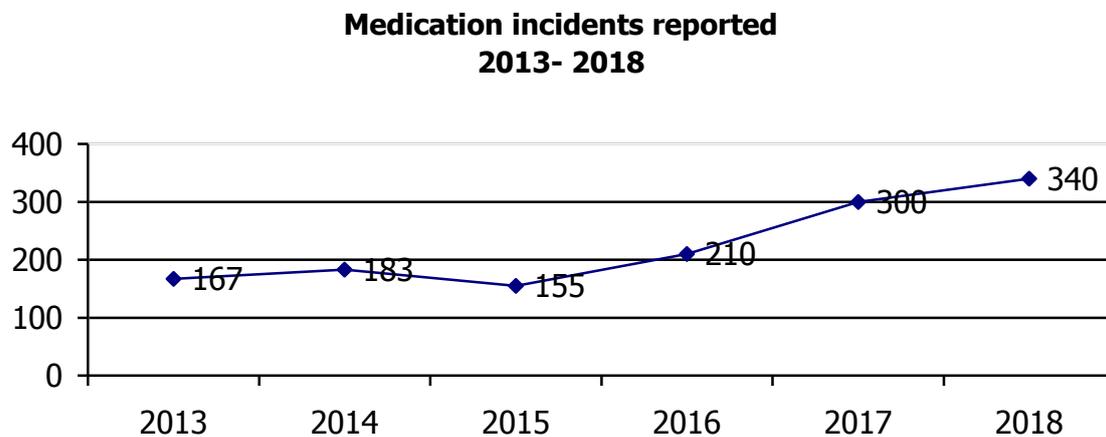
Figure 1. Medication incidents reported 2013 to 2018

[††] 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).

However, acknowledging the year on year improvement there was still likely underreporting of medication incidents, with continued low reporting rates by doctors and low reporting in some clinical areas. The culture of reporting medication incidents needs to be extended to include other healthcare staff and all clinical areas, so that safety surveillance is improved, learning is shared, and safety culture is promoted and enhanced across the hospital.

Analysis of incidents

Inspectors reviewed quarterly and annual medication incident reports presented by the quality and patient safety department. The data taken from NIMS was trended and analysed based on number, process, problem, outcome, severity, location, drug classification and discipline reporting. The majority of incidents reported in 2018 were categorised as no injury, with 17 medication incidents categorised as moderate.[§§] The incidents categorised as moderate were outlined in detail to facilitate review and shared learning.

The medication safety reports were reviewed by both the Medication Safety Committee and Drugs and Therapeutic Committee. Staff reported receiving quarterly and annual medication incident reports and doctors received feedback on medication incidents during grand rounds.

Medication incidents were analysed and discussed in detail, the related improvement were for the most part incorporated into the latest draft of the medication record which was due to be implemented.

One ward visited by inspectors did outline a quality improvement implemented following an insulin related incident. A poster was developed and ward-based education provided to staff to share the learning and prevent a recurrence. Similarly, education was provided to prescribers following a cluster of incidents related to intravenous paracetamol.

Alerts and recalls

The chief pharmacist received and acted on alerts and recalls[***] related to medication. An example of the 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 and across all clinical areas within a just culture,[†††19] to strengthen reporting of medication

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[§§] Moderate: injury requiring medication treatment
[***] Recalls: 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.

incidents so that safety surveillance is improved. Clinical areas and professional groups with consistently low reporting rates should be targeted for improvement.

2.3 High-risk medications/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 for more information).

The Mercy University Hospital had developed a high-risk medications list. Many of the associated risk-reduction strategies, which were observed by inspectors in practice, were low to medium-leverage strategies. Inspectors identified missed opportunities to implement higher-leverage risk-reduction strategies such as system based forcing functions, for example removing high-risk medications from clinical areas.

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

- anticoagulants[§§§]
- insulins
- antimicrobials requiring therapeutic drug monitoring
- procedural sedation in the non-theatre environment

Anticoagulants

The hospital had some risk-reduction strategies[****] in place to mitigate against the risks associated with anticoagulants. The medication record[††††] had a separate section for the prescribing of thromboprophylaxis, antiplatelet and anticoagulants including warfarin to support awareness of medications prescribed, and avoid inappropriate duplication of antithrombotic medications.

[‡‡‡] High-risk situation is a term used by the World Health Organization[2] to describe situations where there is an increased risk of error with medication use.
[§§§] 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.
[****] 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.
[††††] The Medication Record is the medication prescription and administration record, drug kardex or drug chart.

A pharmacy request for a new direct oral anticoagulant[‡‡‡‡] triggered a review by the dispensing pharmacist, which included a review of the indications for the medication, interactions and associated blood results. When required the prescription was discussed with the prescribing doctors before dispensing. However, inspectors were informed that if the dispensed anticoagulant was then used for another patient the dispensing pharmacy review was not triggered, and the review was undertaken by the clinical pharmacist on the ward.

Unfractionated heparin and low-molecular weight heparin when used or omitted in error can cause life-threatening or fatal bleeding or thrombosis. The hospital had included a section for administration of unfractionated heparin in the updated medication record to support safer prescribing and administration. However, inspectors observed a number of different strengths of unfractionated heparin routinely stocked on the clinical areas visited, which posed a risk of misselection of medication. The hospital should review the storage and utilisation of unfractionated heparin with a view to implementing higher-leverage risk-reduction strategies such as elimination and standardisation.[20]

The hospital did not stock prefilled syringes of one brand of a higher therapeutic dose low-molecular weight heparin.[§§§§] This required staff to prepare and administer higher doses of this low-molecular weight heparin from multidose vials. These were not maintained for single patient use. The hospital should ensure that the use of multidose vials is safe and in line with evidence-based practice.[21,22,23,24]

Insulin

The hospital had designed an insulin prescribing and capillary blood glucose monitoring record. This record was seen in use by inspectors attached to the main medication record, to support safe administration of insulin.

This record also contained easily accessible information for staff on the initial management of hyperglycaemia and hypoglycaemia as well as information on insulin therapies used in the hospital. The hospital also had 'hypoglycaemic kits' which provided quick access to equipment required to support effective treatment for patients in the event of hypoglycaemia.

[‡‡‡‡] Direct oral anticoagulants: Options for anticoagulation have been expanded recently with the introduction of new anticoagulants called direct oral anticoagulants.
[§§§§] Heparin is an anticoagulant specifically used in the initial treatment and prevention of deep vein thrombosis, pulmonary embolism, and arterial thromboembolism.

Insulins not in use were observed stored securely in a temperate controlled fridge with a tamper proof seal and blank flag label.*****[25] Insulins in use for patients were stored in the medication trolley with individual patient details recorded on the flag label. An audit undertaken by the hospital in July 2018 identified that 90% of unopened insulin were stored in the fridge however, only 67% of insulin pens or vials in current use were stored at room temperature in the medication trolley during that audit.

Multidose insulin vials were maintained for single patient use and dated when opened, for use within 28 days. Insulin, which should have been discarded, was observed by an inspector in one clinical area fridge, and the daily temperature fridge monitoring was not consistently recorded across areas inspected. In addition, a 2018 hospital audit identified that only 22% of opened insulin pens/vials were labelled with patient name, identification number and date of opening.

Antimicrobials requiring therapeutic drug monitoring

The hospital used a number of antimicrobials, which required therapeutic drug monitoring. The medication record was developed with a separate antimicrobial section, which facilitated prescribing, monitoring and administration of gentamicin and vancomycin. The hospital had also developed an Adult Antimicrobial Prescribing Guideline in conjunction with the South Infirmary Victoria University Hospital, which staff could also access on a locally approved electronic application.

Inspectors were informed that therapeutic drug monitoring was supported by both the clinical and antimicrobial pharmacists. The antimicrobial pharmacist was onsite in the hospital three days a week, but available by telephone for advice Monday to Friday. The consultant microbiologist was also available for advice and review of patients on antimicrobials.

Procedural sedation in the non-theatre environment

When sedation is provided in the non-theatre environment including radiology departments, the same standards of care is required for each patient throughout the procedure.[26,27,28] Sedation should be administered by a well-trained sedation team with oversight provided by a governing committee.[26]

In the Mercy University Hospital, procedural sedation was provided in the interventional radiology room within the radiology department. HIQA found that procedural sedation was not overseen by a governing committee, and formal training was not provided for staff involved in procedural sedation. The systems in

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***** Flag labels : a method of attaching labels to small syringes and containers where part of the label is applied to the syringe, leaving an exposed 'flag' portion to ensure that details on the labels can be read, and the markings and contents of the pen remains visible.

place for procedural sedation were not standardised across the hospital or supported by a hospital wide policy. For example, a recent quality improvement introducing a benzodiazepine 5mg/5mL to facilitate optimisation of patient focused sedation in one area of the hospital, with reported overall reduction in the use of this medication, was not shared or extended to all areas providing procedural sedation.

Inspectors were informed that process mapping of procedural sedation within the interventional radiology room had been undertaken recently with a view to standardising processes across departments. The hospital should continue and prioritise this plan following the inspection.

Inspectors were informed that patients were assessed prior to receiving procedural sedation, and doses of sedatives were titrated to individual patients' needs. Patient monitoring was undertaken throughout the procedure by a nurse and the doctor performing the procedure. However, the interventional radiology room did not have a separate recovery area or formal discharge criteria [26] and patients were monitored in the procedure room until responsive to verbal stimuli. This lack of standardisation in the recovery of sedated patients could present a risk of patients not fully recovered being transferred back to the ward areas.

Reversal agents were accessible to staff and administered if required. Although rarely used, their use was not a trigger for review [29] and there was no monitoring of how often this occurred.

Another issue highlighted through this inspection was the inappropriate area allocated for the preparation of intravenous medications in the interventional radiology room. This should be addressed immediately following the inspection.

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-leverage risk-reduction strategies in place for oral methotrexate. Inspectors were informed that oral methotrexate was not stocked in clinical areas and a pharmacy request for methotrexate triggered a pharmacist review. The hospital only stocked one strength methotrexate tablets which were dispensed as patient specific single doses.

Concentrated electrolyte solutions for injection are especially dangerous with potentially fatal consequences when not prepared and administered properly.[30] National and international evidence recommends the complete removal of concentrated potassium from patient care areas as the goal, with the use of pre-

mixed potassium infusions, which must be stored segregated from other solutions.[30,31,32,33,34]

However, in the Mercy University Hospital concentrated electrolytes were routinely stocked in general clinical areas. Inspectors observed two boxes of potassium chloride and a box of potassium phosphate stocked in a general ward area. The hospital had introduced some risk-reduction strategies such as; individual 'must be diluted' labels on each concentrated ampoules of potassium and phosphate, and the secure storage of these ampoules in the controlled drugs cupboard separated from other medications. However, this practice was not consistent across all areas visited by inspectors and some potassium ampoules were seen stored in the stock medication cupboard.

The hospital did stock and use pre-mixed potassium chloride solutions. The pre-mixed potassium chloride solution bags were designed with red writing to alert staff to their contents. However the boxes of solutions containing potassium were neither stored separately to other solutions nor labelled with an identifiable alert.

The hospital did not identify a list of sound-alike look-alike medications (SALADs)[†††††] but inspectors were informed that when procuring new medications pharmacy staff endeavoured to ensure the packaging or labelling was not similar to current stock. An example was provided of where the hospital had procured different strength midazolam from different suppliers to avoid similarities in packaging.

Overall, the Mercy University Hospital had implemented some low to medium-leverage risk-reduction strategies for high-risk medications. However, significant opportunities to implement better higher-leverage strategies to protect patients against the harm associated with high-risk medications were missed by the hospital in line with national and international evidence and in comparison to other Irish hospitals.

Opportunities for improvement

- The hospital should review the current systems in place for high-risk medications, in particular in relation to concentrated electrolytes and anticoagulants, to ensure evidence-based risk-reduction strategies are in place to protect patients from potential harm associated with high-risk medications.

- The hospital should conduct a review of systems and practices with the use of procedural sedation in the non-theatre environment against international best

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[†††††] SALADS are 'Sound-alike look-alike drugs'. The existence of similar drug/medications 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.

practice and guidance. This should consider oversight arrangements, standardisation of practice across the hospital and the requirements for training and supporting policies.

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.[35, 36]

National patient experience survey

The Mercy University Hospital National Patient Experience Survey [†††††] was completed by 352 (50%) of patients discharged from the hospital in May 2018. Two questions related directly to medication in the Survey. The scores for the Mercy University Hospital and the national scores for both 2017 and 2018 are illustrated in table 1 below.

Questions	Year	Mercy University Hospital 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?	2018	8.0	8.0
	2017	8.1	7.8
Questions	Year	Mercy University Hospital score	National score
Q45. Did a member of staff tell you about medication side effects to watch for when you went home?	2018	5.6	5.2
	2017	5.7	5.1

Table 1: Comparison between Mercy University Hospital and national scores for Questions 44 and 45 of the National Patient Experience Survey 2017 and 2018.

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

In 2018 the response for Question 44 received an overall score[§§§§§] of 8.0 which was the same as the national average score.[37] Question 45 received an overall score of 5.6, which was higher than the national score of 5.2. In 2018 there was a fractional disimprovement in the hospital results compared to the 2017 scores, and the opportunity for improvement continues.

Patient information

Inspectors were informed that patient information on medications was provided by nurses, doctors, and pharmacists when requested. Clinical nurse specialists also provided patient information in areas such as diabetes and respiratory.

Inspectors observed no patient information leaflets during the inspection. However, the inspector was informed that pharmacists provided written information and alert cards to patients commenced on anticoagulants. In addition, some information leaflets were provided by clinical nurse specialists for some patients, for example patients requiring insulin.

One ward visited by inspectors was currently piloting a Healthcare Folder for patients, which contained the relevant discharge information from all healthcare staff. This ward also had a discharge medication reconciliation form, which outlined the name, dose, frequency and simple explanation of the patient's medications, which was explained and given to the patient on discharge.

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.[38, 39,40]

Medication reconciliation was undertaken on admission by a pharmacy technician and was prioritised for patients under the care of a geriatrician.[******] Inspectors were informed that medication reconciliation was also undertaken by nurses, doctors and all pharmacy staff. The medication reconciliation details were included in a separate section of the medication record. The process was monitored, and results demonstrated that 31% of patients had received medication reconciliation on admission.

[§§§§§] 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.
[******] Medical speciality involved with the health and care of old people.

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 though the intravenous route.

Patient weight measurements are important for medications that require an individual weight-based dose.[41] Patient weights and allergies were documented on medication records reviewed by inspectors. However, the weight and creatinine clearance level for admitted patients was often documented by the pharmacist in the medication record beside a particular medication prescription. This was in the absence of an appropriate recording area on the front of the medication record and is an opportunity for improvement to ensure that key information is easily available for all staff. This should be reviewed following this inspection.

Opportunities for improvement

- The hospital should look to have formal structured systems in place for patient education on medication, and also review the availability of medication information leaflets for patients.

- The hospital needs to work towards expanding the medication reconciliation service for patients on admission and the further development of this service for patients on discharge.

2.5 Model of service and systems in place for medication safety

International studies support the role of clinical pharmacists[††††††] in hospital wards in preventing adverse drug events.[42,43,44,45,46,47] Clinical pharmacy services were available to all inpatient units with the expectation of the paediatric and intensive care units, which were recently depleted of this service due to staff resignations. The absence of a clinical pharmacy service in high-risk areas such as the intensive care and paediatric units may pose a risk to patient safety.

The hospital still did not have an approved list of medications[‡‡‡‡‡‡] for use in the hospital, despite HIQA's 2017 recommendation to establish this.[48] The purpose of maintaining this list is to ensure appropriate governance of medications approved for

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[††††††] Clinical pharmacy describes the activity of pharmacy teams in ward and clinic settings.
[‡‡‡‡‡‡] Approved list of medications also referred to as a formulary.

use within the hospital, and that a safety evaluation occurs before new medications are introduced.[49]

The hospital had a system in place for the approval of new medicines, which was under the governance of the Drugs and Therapeutic Committee such as; for a new class of medication, new services, costly or off-licence medications. The nationally preferred medications[§§§§§§] were encouraged but not enforced or monitored, and inspectors were informed that medications ordered were generally dispensed.

Opportunities for improvement

- The hospital should continue to progress the recruitment of pharmacy staff to re-establish the clinical pharmacy service to all clinical areas of the hospital.

- The hospital should look to develop a list of all medications approved for use in the hospital to improve patient care through improved selection and rational use of medications, and to ensure appropriate governance of prescribed medications.

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]

Inspectors found that clinical staff had easy access to up-to-date information at the point of care such as an intravenous medication administration guide, an antimicrobial guide and the British National Formulary. Medicines information was also available to staff on the pharmacy information folder on computers. The findings concurred with a hospital audit which demonstrated that the majority of staff could access required polices procedures and guidelines.

Hospital staff had access to an electronic application, which provided some generic and some hospital specific information. This application was easy to navigate, with information developed and updated locally, and approved by the Drugs and Therapeutics Committee.

It is recommended, by both the Health Service Executive[50] and the National Clinical Effectiveness Committee[51] that policies, procedures and guidelines are reviewed and updated every three years. Most policies, procedure and guidelines viewed by inspectors during the inspection were up-to-date. However, some guidance

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[§§§§§§] The Health Service Executive developed a preferred drugs list. Prescribers are encouraged to make the preferred drug their drug of first choice when prescribing a drug from that therapeutic class.

documents for procedural sedation medications in the interventional radiology room were overdue for review.

2.7 Monitoring and evaluation

Monitoring of medication safety should be formally planned, regularly reviewed and centrally coordinated with resulting recommendations actioned and the required improvements implemented.[15]

Evidence of monitoring and evaluation of medication safety provided to inspectors for the past two years included:

- medication management audit*******
- interruptions during medication rounds
- audit of the medication and insulin record
- surgical antimicrobial prophylaxis
- medication reconciliation.

However, similar to the findings from the 2017 HIQA inspection,[48] time-bound recommendations and actions were not documented for audit results reviewed. The results were discussed at the Medication Safety Working Group and some targeted areas for improvement were identified. Inspectors were also told that audit results had informed the updated version of the medication record which was viewed by inspectors and due to be implemented shortly.

Inspectors reviewed monthly audits of the medication and insulin records from February to December 2018. Many sections audited had almost full compliance such as prescribing on the thrombophylaxis, anticoagulation and regular sections of the medication record. However, there still remained room for improvement in other areas such as, the recording of weights and risk assessments for venous thrombophylaxis embolism (VTE), despite being identified by the Medication Safety Working Group and targeted for improvement.

Opportunities for improvement

- Evaluation and monitoring of the use and safety of medications should be planned in line with the hospital's overall priorities and aligned to a medication safety strategy.

- Time bound recommendations and action plans should be identified and implemented from audit findings, with oversight from hospital management to ensure required improvements are achieved.

******* Audit of medication administration compliance, medication storage including insulin pens and vials and staff access to medication policies, procedure and guidelines.

2.8 Education and training

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.[2,52]

Mercy University Hospital had developed a medication management education session, which included topics on the hospitals high-risk medication, sound-alike look-alike medications, adverse drug reactions and reporting of medication incidents. This session was well attended by both nurses and doctors throughout 2017 and 2018.

In addition:

- nurses attended a medication education session and intravenous drug administration training on induction and completed associated work books and competencies.
- nurses completed the HSELanD[†††††††] medication management module[53] .
- ward-based education sessions were provided by both pharmacist and the nurse practice development unit.
- non-consultant hospital doctors attended medication safety education sessions on induction, at weekly meetings and grand rounds.
- pharmacists attended education sessions within the pharmacy department such as diabetes education provided by the clinical nurse specialist and also attended grand rounds.

Opportunity for improvement

- The hospital should continue to ensure that professionals have the necessary competencies to deliver high-quality medication safety through continued induction and ongoing training.

[†††††††] The health service e-learning and development service

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.

The Mercy University Hospital's Drugs and Therapeutics Committee had overall responsibility for governance of medication safety within the hospital. However, inspectors found that there were opportunities for improvement in relation to the governance of procedural sedation in the non-theatre environment in line with international best practice.

Similar to findings during the last medication safety inspection the hospital did not have a medication safety strategy. Gaps identified in the last medication safety report, such as the introduction of an approved list of medications (formulary), had not been progressed and this demonstrated the need to set out a clear plan for medication safety. The hospital identified the need for a key individual to progress the medication safety strategy but in the absence of such a post, the hospital must look to progress this within current resources to focus the direction for medication safety within the hospital.

The Mercy University Hospital had implemented some risk-reduction strategies for high-risk medications. However, opportunities to implement better, higher-leverage strategies to protect patients against the harm associated with high-risk medications were missed by the hospital in line with national and international evidence and in comparison to other Irish hospitals. This was particularly evident in relation to availability and storage of concentrated electrolytes and anticoagulants.

Analysis and trending of medication incidents was undertaken well by the hospital and there was a consistent improvement in the overall rates of medication incident reporting since the last inspection. The hospital should build on this and improve medication incident reporting within professional groups and areas with lower levels of reporting, and use data analysis to identify areas for targeted improvement.

Currently medication reconciliation was prioritised for patients under the care of a geriatrician. The hospital should look to progress this service to other high-risk patient groups and expand the service for all patients on admission and then to the further development of the service for patients on discharge.

This report should be shared with relevant staff at the Mercy University Hospital 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.

4. References

1.   Health Information and Quality Authority. National Standards for Safer, Better Healthcare. Dublin: Health Information and Quality Authority; 2012. [Online] Available from: https://www.hiqa.ie/reports-and-publications/standard/national-standards-safer-better-healthcare

2   World Health Organization. Patient Safety Curriculum Guide: Multi-professional Edition. 2011. [Online] Available from: https://apps.who.int/iris/bitstream/handle/10665/44641/9789241501958_eng.pdf;jsessionid=D5A16C6845504A60457784D2EBD50B3A?sequence=1

3.   The World Health Organization. Medication Without Harm. The World Health Organization; 2017. [Online] Available from:http://www.who.int/patientsafety/medication-safety/medication-without-harm-brochure/en/

4.   Department of Health and Children. Building a Culture of Patient Safety: Report of the Commission of Patient Safety and Quality Assurance. Dublin: Department of Health and Children; 2008. [Online] Available from: https://health.gov.ie/wp-content/uploads/2014/03/en_patientsafety.pdf

5.   The Irish Medication Safety Network. [Online] Available from: http://www.imsn.ie/

6.   The Department of Health. [Online] Available from :https://health.gov.ie/national-patient-safety-office/

7.   Health Service Executive. The National Medication Safety Programme [Online] Available from: https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/medicationsafety/

8.   The Health Products Regulatory Authority. [Online] Available from: http://www.hpra.ie/homepage/about-us

9.   The Pharmaceutical Society of Ireland. [Online] Available from: http://www.thepsi.ie/gns/home.aspx

10.   American Hospital Association, Health Research and Educational Trust, and the Institute for Safe Medication Practices. Pathways for Medication Safety. American Hospital Association, Health Research and Educational Trust, and the Institute for Safe Medication Practices; 2002. [Online] Available from: http://www.ismp.org/tools/pathwaysection3.pdf

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

12 The Clinical Excellence Commission. Medication Safety and Quality. High Risk Medications. [Online] Available from: http://www.cec.health.nsw.gov.au/patient-safety-programs/medication-safety/high-risk-medicines/A-PINCH

13 Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. Second ed; 2017. [Online] Available from: https://www.safetyandquality.gov.au/wp-content/uploads/2017/12/National-Safety-and-Quality-Health-Service-Standards-second-edition.pdf

14   Institute of Safe Medication Practices (ISMP) Canada. Ontario Critical Incident Learning. Improving quality in patient safety. [Online] Available from: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-4_EffectiveRecommendations.pdf

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

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

17 Government of Western Australia Department of Health and Office for Safety and Quality in Healthcare ., Medication Safety Strategic and Operational Plan for WA Health 2015-2020. [Online] Available from: https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/safety/PDF/WA_Medication_Safety_Strategic_Plan_2015-20.pdf

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

19   Boysen PG. Just Culture: A Foundation for Balanced Accountability and Patient
      Safety ; 2013. [Online] Available from:
      https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3776518/

20   Institute for safer medicine Practice Canada. Enhancing Safety with
      Unfractionated Heparin: A National and International Area of Focus. 2008
      https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2008-
      05UnfractionatedHeparin.pdf

21   Joint Commission Sentinel Event Alert (2014) Preventing infection from the
      misuse of vials https://www.jointcommission.org/assets/1/6/SEA_52.pdf

22   Irish Medication Safety Network. Risk of Cross-Contamination with Insulin
      Preparations;2016. [Online] Available:
      http://www.imsn.ie/images/alerts/InsulinA2016.pdf

23   Centre for Disease Control . Safe Injection Practices to Prevent Transmission of
      Infections to Patients;2007[Online] Available from:
      https://www.cdc.gov/injectionsafety/ip07_standardprecaution.html

24   Centers for Disease Control and Prevention (CDC) and the Safe Injection
      Practices Coalition (SIPC), One & Only Campaign http://test-cdcf-
      sipc.pantheonsite.io/single-dose-multi-dose-vial-infographic/

25   Australian Commission on Safety and Quality in Health Care. National Standard
      for User-applied Labelling of Injectable Medicines, Fluids and Lines. [Online]
      Available from: https://www.safetyandquality.gov.au/wp-
      content/uploads/2015/09/National-Standard-for-User-Applied-Labelling-Aug-
      2015.pdf

26   The Royal College of Radiologist. Sedation, analgesia and anaesthesia in the
      radiology department. 2nd Ed. 2018. [Online] Available
      from:https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr1
      82_safe_sedation.pdf

27   American College of Radiology and Society of interventional radiology
      ACR–SIR Practice parameters for sedation/analgesia. Revised 2015. [Online]
      Available from: https://www.acr.org/-/media/acr/files/practice-parameters/sed-
      analgesia.pdf

28   Royal College of Anaesthetists. Guidelines for the Provision of Anaesthesia
      Services in the Non-theatre Environment. 2019. [Online] Available from:
      https://www.rcoa.ac.uk/system/files/GPAS-2019-07-ANTE.pdf

29   Institute for Healthcare Improvement. Trigger Tool for Measuring Adverse Drug
      Events; 2003. [Online] Available from:
      http://www.ihi.org/resources/Pages/Tools/TriggerToolforMeasuringAdverseDru
      gEvents.aspx

30   Joint Commission, Joint Commission International, World health Organisation.
      Control of concentrated electrolyte solutions. Patient safety solutions; volume
      1, solution;007. [Online] Available from:
      http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution5.pdf

31   New South Wales Government Health. High-Risk Medicines Management Policy;
      2015. [Online] Available from:
      https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2015_029.pdf

32   Recommendations from National Patient Safety Agency alerts that remain
      relevant to the Never Events list 2018. NHS Improvement; 2018. [Online]
      Available from:
      https://improvement.nhs.uk/documents/2267/Recommendations_from_NPSA_a
      lerts_that_remain_relevant_to_NEs_FINAL.pdf

33   Irish Medication Safety Network. Best Practice Guidelines for the Safe Use of
      Intravenous Potassium in Irish Hospitals; 2013. [Online] Available from:
      http://www.imsn.ie/images/guidelines/imns-july-2013-best-practice-guidance-
      for-iv-potassium-use.pdf

34   Institute for Safer Medication Practice Canada. Potassium Chloride Safety
      Recommendations Summary; 2005. [Online] Available from: https://www.ismp-
      canada.org/download/PotassiumChlorideSafetyRecommendations2005.pdf

35   Health Service Executive, Quality and Patient Safety Division. Integrated Care
      Guidance: A practical guide to discharge and transfer from hospital. Health
      Service Executive; 2014. [Online] Available from:
      http://www.hse.ie/eng/about/Who/qualityandpatientsafety/safepatientcare/inte
      gratedcareguidance/IntegratedCareGuidancetodischargefulldoc.pdf

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

37   National Patient Experience Survey. Mercy University Hospital; 2018. [Online]
      Available from: https://www.patientexperience.ie/survey-results/results-by-
      hospital/mercy-university-hospital-cork/

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

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

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

41   Institute for Safe Medication Practices Canada. Weight-Based Medication Dose Errors. 2016. [Online] Available from: https://www.ismp-canada.org/download/safetyBulletins/2016/ISMPCSB2016-09-WeightBasedDoseErrors.pdf

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

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

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

45   Agency for Healthcare Research and Quality. *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Evidence Report/Technology Assessment No. 211Chapter 4. Clinical Pharmacist's Role in Preventing Adverse Drug Events: Brief Update Review.* . Maryland: Agency for Healthcare Research and Quality; 2013. pp31- 40. [Online] Available from: https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/evidence-based-reports/services/quality/patientsftyupdate/ptsafetyII-full.pdf
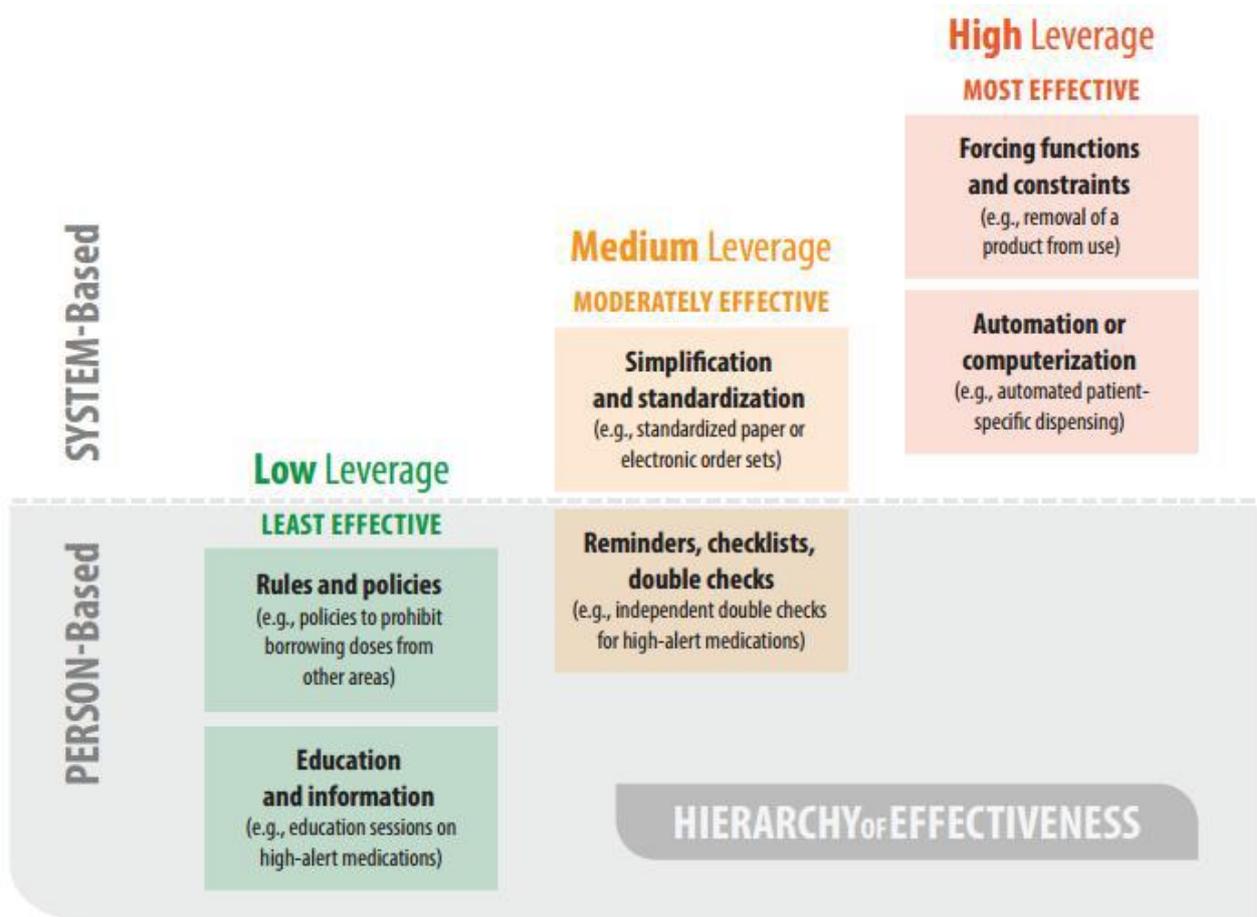
46   Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA;* 1999 July. 21;282(3): pp267–70. [Online] Available from: http://jamanetwork.com/journals/jama/fullarticle/190687

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

48   Health Information and Quality Authority. Report of the announced inspection of medication safety at the Mercy University Hospital. [Online] Available from:https://www.hiqa.ie/system/files?file=inspectionreports/mercy-university-hopsital-05-september-2017.pdf

49   National Clinical Institute for Health and Care excellence. Developing and updating local formularies ;2014. [Online] Available from: https://www.nice.org.uk/guidance/mpg1

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

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

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

53   Health Service Executive. HSELanD. [Online] Available from: https://www.hseland.ie/dash/Account/Login

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.

High Leverage
MOST EFFECTIVE

Forcing functions and constraints
(e.g., removal of a product from use)

Automation or computerization
(e.g., automated patient-specific dispensing)

Medium Leverage
MODERATELY EFFECTIVE

Simplification and standardization
(e.g., standardized paper or electronic order sets)

Reminders, checklists, double checks
(e.g., independent double checks for high-alert medications)

Low Leverage
LEAST EFFECTIVE

Rules and policies
(e.g., policies to prohibit borrowing doses from other areas)

Education and information
(e.g., education sessions on high-alert medications)

SYSTEM-Based

PERSON-Based

HIERARCHY OF EFFECTIVENESS

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