



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the announced inspection of medication safety at St Michael's Hospital, Dun Laoghaire.

Date of announced inspection: 16 January 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 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 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-termreduction 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 St Michael's Hospital by Authorised Persons from HIQA; Nora O' Mahony and Dolores Dempsey Ryan. The inspection was carried out on 16 January 2020 between 09:00hrs and 16:15hrs.

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

- Theatre department
- Male ward
- High dependency unit.

One group interview was held in the hospital with the following staff:

- The chairperson of the Drugs and Therapeutics Committee, the chief pharmacist, the quality and risk manager (also deputising for the general manager) 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

St Michael's Hospital is a model 2 voluntary hospital within the Ireland East Hospital Group. The hospital is also part of the St Vincent's Healthcare Group which incorporates St Vincent's University Hospital and St Vincent's Private Hospital. St. Michael's Hospital provides a range of acute and specialised hospital services including an emergency department which is open 08:00 to 20:00 seven days a week.

2. Findings at St Michael's 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

St Michael's Hospital had formalised governance arrangements in place for medication management and safety. The Drugs and Therapeutics Committee was responsible for overseeing medication safety in the hospital and was accountable to the Hospital's Executive Committee. While overall corporate responsibility for the oversight of medication safety within the hospital rested with the General Manager, the hospital also demonstrated reporting lines to the St Vincent's Healthcare Group and the Ireland East Hospital Group.

Membership of the Drugs and Therapeutics Committee was multidisciplinary to reflect the fact that medicines management is the responsibility of a number of clinical professional groupings. The Drugs and Therapeutics Committee met three times a year with good attendance from members however, membership did not include a surgical or community representative. Inspectors were informed that relevant issues would be discussed with surgical consultants, and they could be invited to attend Drugs and Therapeutics Committee meetings as required. Surgical consultants are members of the Hospital's Executive Council, through which any issues could be raised and discussed.

Representatives from the hospital also attended the St Vincent's University Hospital's Drugs and Therapeutics Committee to share learning and information. The positive impact of this sharing across the sites was evident to inspectors during this inspection.

In line with recommended practice^{10,16} St Michael's Hospital had developed a five year hospital Medication Safety Strategy 2019-2024, with annual objectives outlined in a medication safety programme. Progress with the medication safety objectives outlined for 2019 was evident to inspectors during this inspection, and details of actions taken to achieve the 2018 objectives were outlined in the medication programme for 2018.

2.2 Risk management

The hospital had arrangements in place to identify report, manage and escalate risks related to medication safety. The hospital's corporate risk register had one medication safety risk related to the actual or potential risk of injury to patients from

prescribed and/or administered medication. The existing control measures in place, as well as the additional controls required to mitigate the risks were outlined. The risk register was reviewed by the hospital's Patient Safety Committee.

Medication incidents were currently reported on a hard copy incident form, but the hospital planned to move to an electronic incident reporting system as part of their five year strategy. The hospital used the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index to categorise medication incidents in terms of severity of outcome (Appendix 3). Incidents were also categorised and inputted onto the National Incident Management System (NIMS).[§]

The hospital's medication incident reporting rates, although low, had increased year on year from 25 in 2013 to 99 in 2018. However, the reporting rate had dropped to 70 in 2019 (See Figure 1). The majority of medication incidents were reported by nurses and pharmacists.

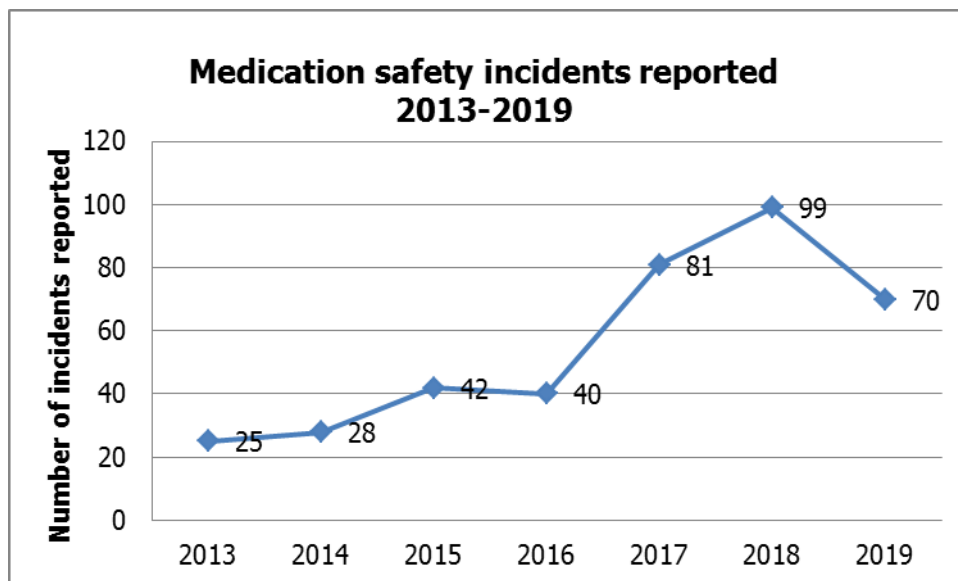


Figure 1. Medication incidents reported 2013 to 2019

[§] 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).

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.¹⁷ Within St Michael's Hospital, medication incidents were analysed by the Quality and Risk Department under the following categories:

- number per month and year
- location the incident occurred
- NIMS and NCC MERP categorisation
- medication involved
- type of incident.**

Medication incident reports were reviewed by the Drugs and Therapeutics Committee, the Patient Safety Committee and the St Vincent's Healthcare Group. Learning from incidents was circulated to staff in memos, newsletters and shared learning notices. Quality improvements were developed such as the revision of the medication record^{††} to mitigate and prevent recurrence of reported incidents.

Alerts and recalls

The process in place for the management of alerts and recalls^{††} relating to medications was outlined to inspectors.

Opportunities for improvement

- The hospital should continue to promote incident reporting among all clinical staff and across all clinical areas within a just culture,^{§§18} to strengthen reporting of medication incidents so that safety surveillance is enhanced.

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-

** Incident type for example: expired medication, drug interaction, pump driver malfunction, unprescribed medication administered, documentation contradiction or allergy, medication stopped or cancelled in error, frequency, dose or route incorrect or transcription error.

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

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

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

risk situations^{***} may include high leverage, medium leverage or low leverage risk-reduction strategies^{†††} (see Appendix 2).

High leverage risk-reduction strategies such as forcing functions, standardisation and simplification, need to be implemented alongside low leverage risk-reduction strategies such as staff education, passive information and the use of reminders.

St Michael's Hospital had implemented evidence-based safety measures for high-risk medications. The hospital had developed a high-risk medications list based on both evidence-based literature and local incidents, supported by a high-risk policy which outlined the associated risk-reduction strategies in place.

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

- anticoagulants
- insulins
- concentrated potassium chloride
- medication safety during the peri-operative period.

Anticoagulants

The hospital had a combination of risk-reduction strategies in place for anticoagulants including a number of high leverage forcing functions to mitigate identified risks as outlined below:

- only one strength of unfractionated heparin was stocked in the hospital and this was restricted to specific clinical areas
- the medication record had a specific colour-coded section for the prescribing of all anticoagulants,††† to support reducing the risk of duplicate anticoagulant prescriptions
- the hospital had selected one low molecular weight heparin (LMWH) §§§ for preferred use within the hospital, and only this LMWH was stocked on the wards

^{***} High-risk situation is a term used by the World Health Organization to describe situations where there is an increased risk of error with medication use.

^{†††} 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.

^{§§§} 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.

- clinical pharmacists reviewed all inpatient's medication records and provided education to patients newly prescribed anticoagulants using the Ireland East Hospital Group Oral Anticoagulants Therapy Record
- the pharmacists were also available to guide and support staff
- staff had access to up-to-date guidance to support safe anticoagulant therapy management, and updates were distributed to staff through the pharmacy medication safety newsletters, shared learning notices and medication safety alerts.

Insulin

The hospital had risk-reduction strategies in place to mitigate against the risks associated with insulin. Examples of these are outlined below.

One type of rapid acting insulin pens were stocked on wards with blank flag labels.^{****19} These pens were stored in a fridge with central temperate control until required. Once opened the patient's name and date of opening was recorded on the flag label.

All other insulin pens were dispensed for named patients, with the expiry date on the flag label. All insulin pens in use were stored in the individualised patient compartments of the medication trolley.

Clinical pharmacists reviewed inpatient medication records and clinical nurse specialists in diabetes reviewed diabetic patients and provided education.

The hospital had recently developed an insulin medication record which also contained information for staff on the management of hypoglycaemia and the procedure for major surgery infusion for patients on insulin. Staff education sessions were provided by the diabetes clinical nurse specialist during the implementation of the insulin medication record.

However, there was no prompt on the regular medication record to indicate to staff that an insulin medication record was in use, which may pose a risk of insulin being inadvertently omitted.^{20,21}

**** §§§§ Flag labels are used to attach label on 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.

Hospital staff had access to a hypoglycaemic box,⁺⁺⁺ and guidance on the management of diabetic conditions such as diabetes ketoacidosis and hypoglycaemia.

Concentrated potassium chloride

Concentrated electrolyte solutions for injection are especially dangerous with potentially fatal consequences when not prepared and administered properly.²² 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 stored segregated from other solutions.^{22,23,24,25}

The hospital had a combination of risk-reduction strategies in place to support safe management of potassium chloride.

Stocking of concentrated potassium ampoules was restricted to specific areas with storage and labelling controls in place.

Intravenous potassium was supplied in pre-mixed potassium chloride solutions with additional labelling, outlining that the product contains potassium. These fluids were stored segregated from other intravenous fluids and administered via an electronic pump.

The systems in place for potassium chloride were outlined in guidance documents accessible to staff, and updates on safe use were distributed to staff through a pharmacy medication safety newsletter.

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.²⁶ A diverse range of medications are used which have the potential for a serious adverse event if administered incorrectly.²⁷ 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:

- medications were stored in a standard and organised manner to support safe selection

⁺⁺⁺ Hypoglycaemic box: provided quick access to equipment required to support effective treatment for patients in the event of hypoglycaemia.

- international colour-coded labels were applied to drawn up medications
- medications drawn up on the sterile field were labelled with sterile labels
- emergency drugs were drawn up and double checked by the anaesthesiologist and the non-consultant hospital doctor, labelled and stored in a separate coloured tray and disposed of at the end of each shift. One of the two doctors who had drawn up the emergency medications was available onsite to administer them in the operating theatre
- medications administered during a case were recorded on the appropriate documentations
- medications were reconciled and disposed after each case
- there was evidence that risk reduction strategies were in place for high risk medications. For example, only one strength of midazolam was stocked
- Neuromuscular blocking agents^{****} had warning 'paralyzing agent' stickers applied to the packaging of these medications which were stored segregated from other medications.

An open container was used for a medication on the sterile field which may pose a risk of a drug error.^{28,29} However, these containers were labelled with sterile labels, checked by two nurses and also checked by a nurse and the surgeon when being administered during the surgical case.

The hospital had introduced a sealed 'anaesthetic emergency box' with medications for use by anaesthesiologists for medical emergencies outside of the theatre setting and when accompanying critically ill patients between hospitals.

The sealed anaesthetic emergency medications were stored in the high dependency unit and the emergency department. Anaesthetic medication syringe labels were included in the emergency drug box. The use of a designated box set a standardised practice within the hospital to improve medication safety as medications were clearly identifiable, in date and prefilled syringes were used where possible.

Pre-filled syringes were not used during perioperative period, but the hospital planned to introduce them where possible.

Other high-risk medications

^{****} Neuromuscular blocking agents provide skeletal muscle relaxation during surgery.

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.

St Michael's 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. Only one strength methotrexate tablets were stocked in the hospital and dispensed as a patient specific single dose. Pharmacists would indicate the day of the week the methotrexate was to be administered and block out all other days with an 'x' to prevent inadvertent daily administration

The hospital's medication record had a colour coded section for antimicrobials requiring therapeutic monitoring. St Vincent's University Hospital antimicrobial guidance was approved for use within the hospital and easily accessible to staff. The clinical pharmacist reviewed antibiotics prescribed, and provided support and advice to staff as required. A microbiologist reviewed patients and was available to provide guidance on antimicrobial use.

The hospital had developed a policy and list of sound-alike look-alike medications (SALADs)^{§§§§} which was displayed in clinical rooms visited by inspectors. The pharmacist considered sound-alike look-alike medications during procurement of new medications and provided an example of sourcing two strengths of the same medication from different suppliers to avoid similar packaging.

A venous thromboprophylaxis risk assessment was undertaken and recorded on patient's medication records reviewed by inspectors. A laminated risk assessment card was placed in each patient's records folder, to aid prescribers when undertaking the risk assessment.

Opportunities for improvement

- The hospital should proceed with the plan to introduce pre-filled syringes where possible in the operating theatre.

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.^{30, 31}

^{§§§§} 'Sound-alike look-alike drugs' (SALADs) or Look-alike sound-alike (LASA). The existence of similar drug and 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.

National Inpatient Experience Survey****

The National Inpatient Experience Survey is a nationwide survey that offers patients the opportunity to describe their experiences of public acute healthcare in Ireland. Of the 236 people discharged from St Michael's Hospital during the month of May 2019, 121 people completed the survey, achieving a response rate of 51%.³²

Two questions related directly to medication in the National Inpatient Experience Survey. The scores for St Michael's Hospital and the national scores for 2017⁺⁺⁺⁺, 2018⁺⁺⁺⁺ and 2019 are illustrated in table 1 below.

Questions	Year	St Michael's 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?	2019	8.6	8.0
	2018	8.4	8.0
	2017	8.4	7.8
Q45. Did a member of staff tell you about medication side effects to watch for when you went home?	2019	5.4	5.3
	2018	5.6	5.2
	2017	4.7	5.1

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

**** 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 Executive (HSE) and the Department of Health. All patients over the age of 16 discharged during May who 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 2018 survey and question 45 '.....' was originally question 46.

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

St Michael's Hospital score for question 44 was higher than the national average score each year. Question 45 was above the national average for the previous two years however, there was still room for improvement in this area.

In response, the hospital had adopted the World Health Organization and Health Service Executive 'Know, Check, Ask campaign'.^{§§§§§ 33,34} The campaign supports patients to record the medications they are currently taking to keep an up-to-date list to help patients know their medicines, and also help when discussing medications with healthcare professional. Posters highlighting the initiative and blank leaflet were available for patients, although not routinely given or discussed with patients on discharge. A clinical pharmacist informed inspectors that they completed this leaflet on occasions for patients on multiple complex medications or poor understandings of their medications, to support safer medication management on discharge.

Patient information

Pharmacists provided counselling to patients commenced on anticoagulants, opioids and other medications as requested by nurses or doctors. Patient education was also provided by clinical nurse specialists in specialties such as diabetes, respiratory, palliative care and gerontology.

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.^{35, 36,37}

In St Michael's Hospital, the clinical pharmacist undertook medication reconciliation for patients on admission which was recorded in the 'pre-admission medications and medication reconciliation' section of the medication record.³⁶

Medication reconciliation was not undertaken for patients on discharge but the hospital had two initiatives to support appropriate discharge whereby:

- each regular prescription had an option to indicate if the medication was prescribed pre-admission (Y/N pre admission)
- the clinical pharmacist recorded 'changes or additions to medications during the inpatient stay' on the medication record.

Systems to support medication safety

^{§§§§§} The campaign encourages people who take regular medicines, and those assisting them to: *know* their medicines and keep a list, to bringing the list to appointments and if admitted to hospital. To *check* that they are using the right medicine in the right way and to *ask* their healthcare professional if they are unsure

Systems were in place to support medication safety and optimisation in relation to the prescribing and administration of crushed medications, and the prescribing and administration of medications intended for nasogastric administration, supported by clinical pharmacists.

Patient weight measurements are important for medications that require an individual weight-based dose,³⁸ and patient known allergies should be available throughout the episode of care.¹⁵ Patient allergies were recorded on all medication records reviewed by inspectors on the day, and patient's weights were recorded on the nutritional assessment form which was stored in a folder which also contained the medication record, and was accessible to staff when prescribing.

The patient's weight was not recorded on the medication record in line with the Health Service Executive guidance.²¹ It was hospital practice to use the most up-to-date patient weight, which was recorded on the nutritional assessment form, for calculating weight-based medication doses.

As highlighted in the previous medication safety inspection, this process was not outlined in the medication management policy nor was there a prompt on the medication record to guide staff to the most up-to-date weight. However, staff who spoke to inspectors during the inspection were familiar with the process.

Opportunities for improvement

- The hospital should work towards the expansion of the medication reconciliation service to patients on discharge.
- The hospital should ensure that the process in place for documenting and accessing patient's weight for weight-based medication doses is clearly outlined in hospital guidance and audited to ensure compliance.

2.5 Model of service and systems in place for medication safety

Clinical pharmacy service

International studies support the role of clinical pharmacists in hospital wards in preventing adverse drug events.^{39,40,41,42,43,44}

In line with best practice, St Michael's Hospital had a clinical pharmacy service^{*****} in all inpatient clinical areas. Inspectors found systems in place to support the safe

***** 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 counselling, inter-professional education about medicines. It may

prescribing and administration of medications, as clinical pharmacists reviewed patient's medication records daily and identified opportunities to optimise the impact of medications while minimising medication-related problems.

List of approved medications (Formulary⁺⁺⁺⁺⁺)

Since the previous inspection the hospital had formalised the system in place for the approval of new medications to ensure appropriate oversight of medications approved for use within the hospital.⁴⁵ This process was under the governance of the Drugs and Therapeutic Committee.⁴⁶

Consultants requesting new medications for addition to the formulary completed the St Michael's Hospital formulary application form and were invited to attend the Drugs and Therapeutics Committee meeting to discuss their application. The process was guided by the St Michael's Hospital - Procedure for Formulary. The hospital's formulary was not routinely reviewed, but removal of other similar agents was considered on the addition of a new medication.

2.6 Use of information

Access to relevant up-to-date and accurate medication reference information is essential at all stages of the medication management pathway.^{11, 15}

St Michael's Hospital had access to the St Vincent's University Hospital's medications information which was approved for use within the hospital, and accessible to staff via the desktop of the hospital's computers, and on a mobile phone application. This information also included access to an antimicrobials guide and the A to Z of injectable medications.

Ward based clinical pharmacy staff provided key information about medications to medical and nursing staff, and clinical nurse specialists provided specific medication education relevant to their area of expertise such as diabetes, respiratory, gerontology and palliative care.

The Health Service Executive⁴⁷ and the National Clinical Effectiveness Committee⁴⁸ recommend that policies, procedures and guidelines are reviewed and updated every three years. St Michael's Hospital had a wide range of up-to-date medication related policies, procedures and guidelines which were reviewed and approved by the Drugs and Therapeutics Committee. These documents were easily accessible to staff on the hospital's computers.

also involve some or all of the following: medication history taking, medication reconciliation, specialist clinics clinical audit, protocol/guideline development.

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

However, not all clinical areas visited had access to medication guidance in areas where medications were prepared. Facilitating quick access to up-to-date medications information in the hospital was an objective outlined in the hospital's 2019 annual plan. Implementation of this objective was still a work in progress but progress to date was outlined to inspectors.

Opportunities for improvement

- Staff should have access to the hospital medication information at all stages of the medication management pathway. The hospital should progress its plan to facilitate quick access for staff.

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

The hospital had a Clinical Audit Committee who had oversight of all clinical audits. Audits were centrally coordinated on a spread sheet for the St Vincent's Healthcare group. Staff from St Michael's Hospital were members of both the St Vincent's Healthcare Group Audit Committee and the St Vincent's Healthcare Group Clinical Audit Review Committee, where all audits were reviewed. Clinical audit was included in the hospital's 2019 medication safety programme.

Monitoring and evaluation of medication safety was undertaken in St Michael's Hospital through audit, routine Nursing and Midwifery Quality Care-Metrics,^{*****} key performance indicators and through participation in the 2019 point prevalence study.

Medication audits conducted in 2019 were limited to antimicrobial usage and prescribing undertaken by pharmacists, and ongoing metrics undertaken by nurse practice development.

Audits undertaken in 2017 and 2018 were demonstrated to inspectors such as:

- venous thromboprophylaxis prescribing
- opioid prescribing
- use of patients' own drugs
- review of methoxyflurane in the emergency department.

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

The audits reports reviewed by inspectors had recommendations outlined, but did not include a time-bound action plan or evidence of re-audit to ensure recommendations had been implemented in practice to support patient safety.

The hospital did inform inspectors that new non-consultant doctors were advised of audits previously undertaken in the hospital to support re-audit. The hospital should continue to progress this initiative to ensure audit recommendations are implemented to support patient safety.

Feedback on some audits undertaken was provided to doctors and pharmacists at education sessions.

Key performance indicators and metrics monitored by the hospital in 2019 included:

- antimicrobial stewardship key performance indicators
- antimicrobial consumptions
- nursing and midwifery quality care metrics.

Opportunities for improvement

- The hospital should look to expand systematic monitoring arrangements in place for medication safety.
- Medication safety audits recommendations should have time-bound action plans, with re-audit to ensure the required improvements are achieved.

2.8 Education and training

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.⁴⁹

In St Michael's Hospital medication management was included in the induction programme for doctors and nurses.

The hospital did not have a structured, ongoing medication safety education programme but inspectors were informed that medication safety was a regular feature in weekly medical teaching which non-consultant hospital doctors attended. Updates for nurses were presented by the pharmacist on the intravenous study day organised by the clinical nurse facilitator.

Examples of medication safety education topics included:

- Sound alike look alike medication and other issue with administration
- analgesia for acute pain
- insulin safety talks

- medication management for nurses
- medicine information for doctors.

Information to support medication safety was also circulated to staff through emailed memos, monthly pharmacy medication safety newsletters and shared learning notices. These updates were seen displayed on clinical areas and in a hard copy folder on each ward visited. Also, staff who spoke with inspectors were familiar with the information and could access the information circulated.

Opportunities for improvement

- The hospital should ensure that professionals have the necessary competencies to deliver high-quality medication safety. This could be further supported by the hospital through the developing a structured targeted ongoing programme of education for medication safety aligned with the hospital's medications safety plan.¹¹
- Training records should be maintained for all staff who have attended medication safety training, so that the hospital can identify staff who have or have not attended required medication safety training.

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.

St Michael's Hospital had formalised governance and accountability arrangements in place for medication management and safety. The Drugs and Therapeutics Committee was responsible for overseeing medication safety and was accountable to the Hospital's Executive Committee. Overall corporate responsibility for the oversight of medication safety within the hospital rested with the General Manager.

The hospital had developed a five year strategy which set the strategic aims for medication safety from 2019-2024. Medication safety objectives were outlined in the annual medication safety programme. Progress against the hospital's medication safety objectives and plans was evident to inspectors.

The hospital had identified high-risk medications with a combination of risk-reduction strategies in place appropriate to the services provided by the hospital, including some high leverage forcing functions.

The hospital provided a full clinical pharmacy service for all inpatients, and completed medication reconciliation for all patients on admission. The positive impact of this service was evident to inspectors.

Medication reconciliation was not undertaken for patients on discharge and the hospital should work towards the expansion of the medication reconciliation service to patients on discharge.

Medication incidents were mostly reported by nurses and pharmacists. Reporting rates, although low, had increased year on year from 2012 to 2018 but had dropped again in 2019. The hospital should continue to promote incident reporting among all clinical staff to strengthen reporting of medication incidents. However, the reported medication incidents were effectively analysed and trended under the governance of the Drugs and Therapeutics Committee with actions identified and implemented to mitigate the risk of reoccurrence.

Monitoring of medication safety was undertaken by the hospital with oversight from St Michael's Clinical Audit Committee and the Drugs and Therapeutics Committee, with effective links with the St Vincent's Clinical Audit Committee. However, there

was an opportunity to expand the monitoring and evaluation of medication safety, with re-audit of completed audits to provide assurance that recommendations made are implemented resulting in required improvements in practice.

The hospital had medication information sources available to guide staff and this was supported and enhanced through sharing within the St Vincent's Healthcare group. The hospital should progress the plan to facilitate quick staff access to medication information during all stages of the medication management pathway.

Clinical pharmacists provided counselling to patients on some high-risk medications as required, and clinical nurse specialists provided education to patients in a variety of specialist areas.

Overall, St Michael's Hospital continued to promote and implement effective strategies for medication safety to protect patients supported by strong links with the St Vincent's Healthcare Group.

The hospital should continue to work towards improving medication safety practices by addressing the findings of this report, and progressing the implementation of initiatives identified through its own monitoring of practices in place.

This report should be shared with relevant staff at St Michael's Hospital, the St Vincent Healthcare Group and the Ireland East Hospital Group to highlight the findings from the inspection, including what has been achieved to date and to foster collaboration in relation to opportunities for improvement.

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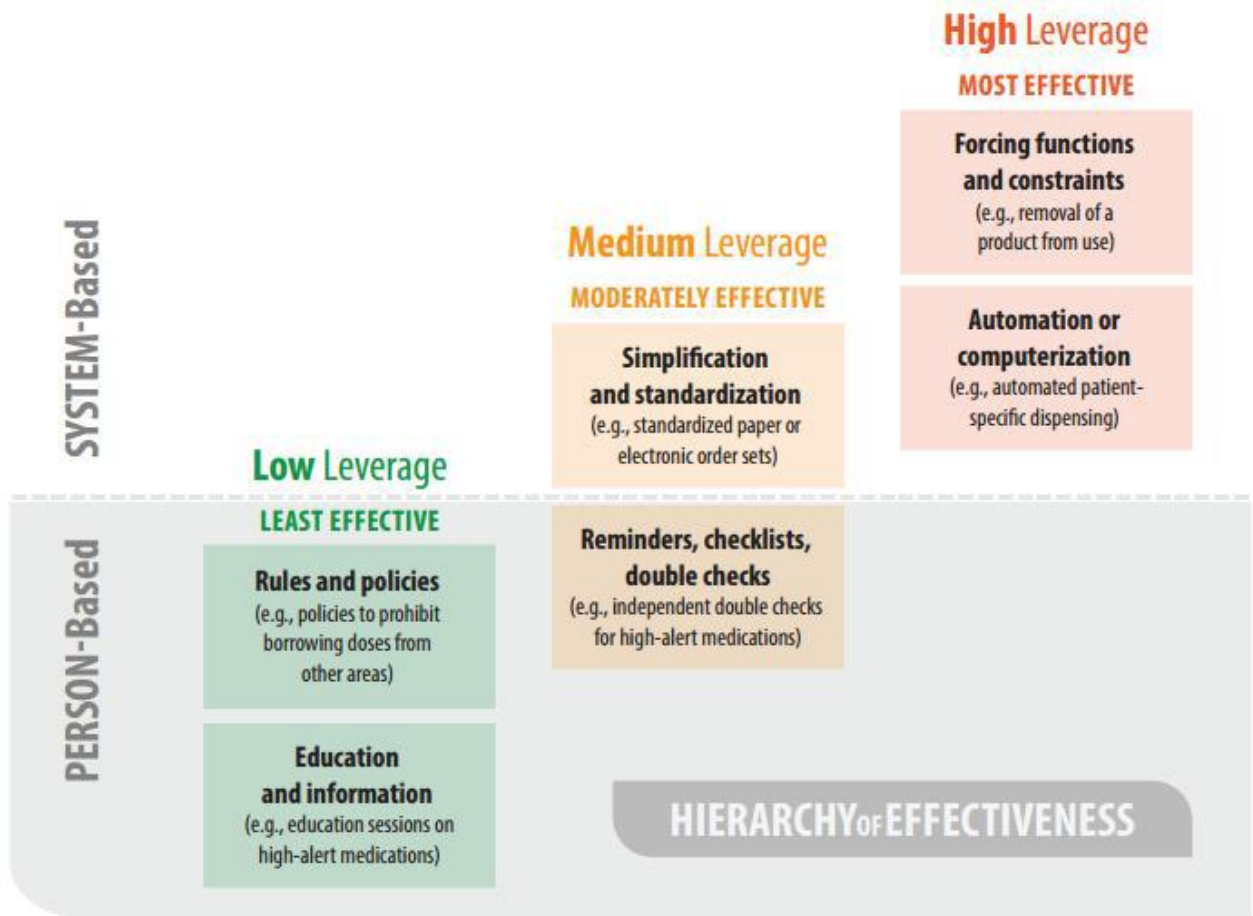
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Appendices

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

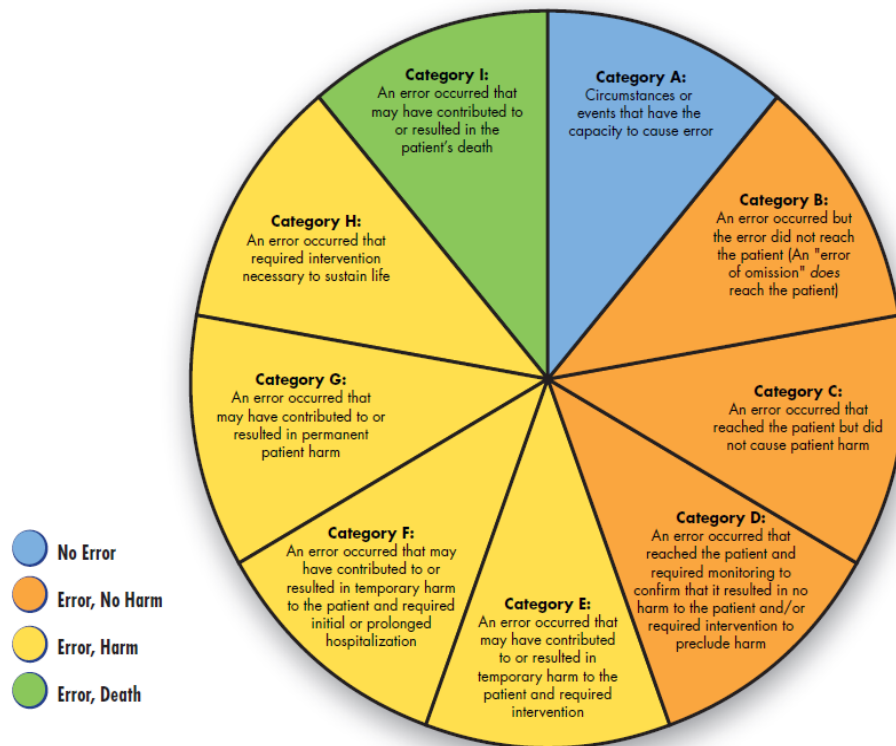
Area to be explored	Lines of enquiry	Dimensions/ Key areas	National Standards
Leadership, governance and management	1. Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.	Capacity and capability	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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