Report of the announced inspection of medication safety at St James's Hospital, 12 December 2019

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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-

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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 St. James's Hospital by Authorised Persons from HIQA; Emma Cooke, Dolores Dempsey-Ryan and Nora O'Mahony. The inspection was carried out on 12 December between 09:00hrs and 16:30hrs.

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

- Abraham Colles ward
- Victor Synge ward
- Theatre department.

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

- Group one: the deputy chief executive officer, the executive medical director, the director of nursing and the director of quality and safety
- Group two: the chairperson of the Pharmacy and Therapeutics Committee, the deputy director of pharmacy, the medication safety facilitator, and the quality manager.

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

Information about the hospital

St James's Hospital is a model 4 acute hospital in the Dublin Midlands Hospital Group. The hospital provides acute, chronic and emergency care across a number of speciality areas including plastics, burns, haemophilia services, bone marrow and facial surgery.

2. Findings at St. James'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

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

St James's Hospital had formalised governance arrangements and organisational structures with clear lines of accountability in place to support the safe use of medications.[15] The hospital operated a directorate structure with overall responsibility and accountability for medication safety resting with the lead for the Quality, Safety and Improvement Directorate.

The hospital had an established Pharmacy and Therapeutics Committee which provides leadership and oversight for medication safety issues in the hospital. Monthly updates in respect of medication safety were reported by the Pharmacy and Therapeutics Committee to the Hospital Safety Committee. The Hospital Safety Committee reports to the Quality, Safety and Risk Board Sub-Committee on a quarterly basis. However, inspectors were informed the Board Sub-Committee was going through a transitional period and had not met since April 2019. It was explained that in the interim of the Board Sub-committee reconvening, medication safety updates were reported by the Quality and Safety lead directly to the Hospital Board.

Membership of the Pharmacy and Therapeutics Committee was multidisciplinary to reflect the fact that medicines management is the responsibility of a number of clinical professional groupings.[16] Since the last inspection, the committee were successful in appointing a community pharmacist and a general practitioner as a member which was a positive finding. The Pharmacy and Therapeutics Committee should update its terms of reference to reflect these changes in membership.

Operational implementation of the medication safety programme was effectively led by a multidisciplinary Medication Safety Committee and managed by a medication safety facilitator. In line with recommended practice[10,17] the hospital had a strategic plan for medication safety which outlined three overarching strategic priorities for 2019-2021.

To support the implementation of the strategy, the hospital had developed yearly work plans outlining medication activity priorities in addition to the routine undertakings of the medication safety programme. Progress and activities of the Pharmacy and Therapeutics Committee were evaluated and detailed in annual reports produced by the committee for 2017 and 2018. A review of these annual reports demonstrated that the committee had made good progress with work plans set out. One of the biggest objectives achieved since the last inspection was the implementation of the Electronic Patient Record (EPR).

Similar to findings from the previous medication safety inspection in 2017, inspectors found that St. James's Hospital had leadership, governance and management arrangements in place with clearly defined reporting structures for medication safety.

Opportunities for improvement

- The hospital should ensure that formalised reporting structures set out for medication safety at the hospital are re-established.

2.2 Risk management

St. James's Hospital had arrangements in place to proactively identify, report and manage risk related to medication safety throughout the hospital. Since the last inspection, the Pharmacy and Therapeutics Committee had developed a medication safety risk register. Risks identified by the Pharmacy and Therapeutics Committee also informed the hospital's corporate risk register. A number of medication-related risks were documented on the corporate risk register at the time of this inspection. These included:

- medication safety programme limitations due to resource constraints

- insufficient clinical pharmacy service for some inpatient wards

- insufficient medication reconciliation for all patients

- unavailability of commercially available oral syringes to accurately measure liquid medications.

The risk register detailed the control measures in place to mitigate against the risk, person responsible for actions, progress notes and review date. Inspectors were informed that risks that could not be managed at a local were escalated, if required, to the Dublin Midlands Hospital Group by the Hospital Board if required.

Consistent with HIQA's previous inspection, inspectors found that there was an established system in place for the reporting of medication safety incidents at the

hospital. Since the last inspection, the hospital had introduced a new information management system for reporting and management of medications incidents and near misses.

High incident reporting rates are generally associated nationally and internationally with a strong patient safety culture.[18] A total of 798 medication incidents were reported in 2018 which was a 2% increase from 781 incidents reported in 2017 (see figure 1). Inspectors were informed that despite increasing incident reporting rates, medication-related near misses were still likely under reported. While HIQA acknowledges that this is the case for many hospitals, the hospital outlined that it will continue its work in emphasising to staff the importance of reporting near misses as well as actual medication incidents.

HIQA noted that the majority of medication incidents were reported by nursing staff, followed by pharmacy staff with some reported by medical staff. Following on from findings in the last inspection and in an effort to improve medication-related incident reporting among medical staff, the medication safety facilitator had undertaken a survey to investigate doctor's views on reporting medication safety events and to gather data on the safety culture. Documentation reviewed by inspectors demonstrated that reporting of medication safety events by doctors in 2018 (5%) was the highest since records began in 2004**.**

The hospital used the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Medication Error Index (Appendix 3) to categorise medication incidents in terms of severity of outcome.
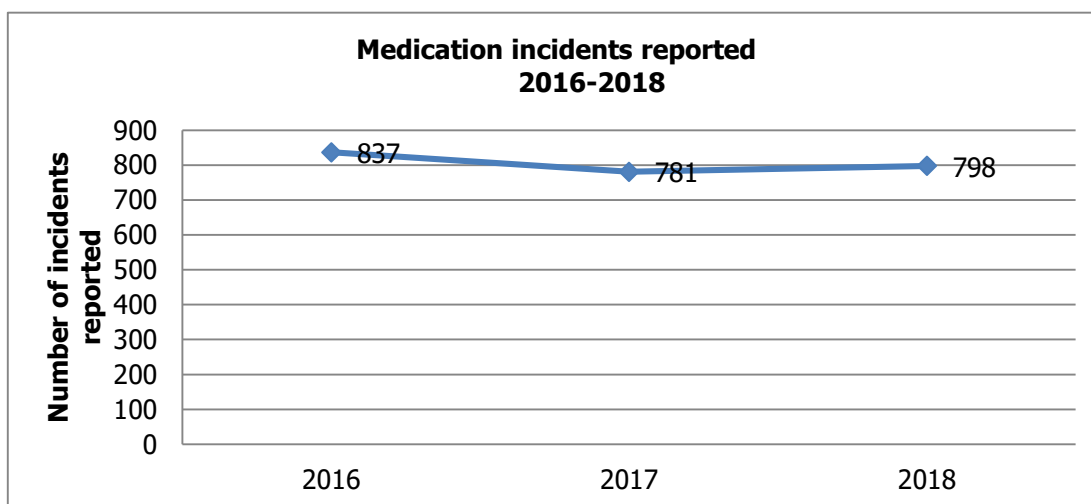

Figure 1. Medication incidents reported 2016 to 2018

Analysis of incidents

The reporting of incidents is of little value unless the data collected is analysed to identify trends or patterns in relation to risk and the resulting recommendations for improvement are shared with frontline staff.[19]

Medication safety events and near misses were tracked and trended according to numbers, location, category of staff reporting, type of medication event, severity of incident, classes of medication involved, patient outcome and types of medication error causing harm. The hospital used this information to identify emergent medication safety concerns, prioritise medication safety activities and assess progress. Annual reports reviewed by inspectors outlined the top five medication safety incidents at the hospital. The categories of 'missed dose', 'documentation error', 'frequency/time incorrect' and 'dose incorrect' had also been identified as the most frequently reported medication safety events in 2018.

One factor which increases incident reporting is the timely provision of feedback to staff on medication incidents reported and the actions required to avert future risks.[19,20] Medication safety issues or incidents were discussed at daily pharmacy huddles[§] and at clinical handovers in the clinical areas. In addition, 'Medication Safety Minutes'[**] were issued weekly to all staff around the hospital. Inspectors were informed that the medication safety facilitator reviewed all reported medication safety events and followed up as required.

Alerts and recalls

The Pharmacy Senior Management Team received and acted on alerts and recalls[††] related to medication. Documentation reviewed by inspectors outlined that a total of 70 alert notices were managed in 2018 as per the hospital's Medication Safety Alert and Recall Notices Management Protocol. All relevant alerts were uploaded onto the hospital Intranet and were accessible to staff in some of the clinical areas inspected.

Opportunities for improvement

- The hospital should continue to promote incident reporting and near misses among all clinical staff, within a just culture,[‡‡21] to strengthen reporting of medication incidents, so that safety surveillance is improved.

[**] The Medication Safety Minutes are once-weekly communications comprising of a single medication safety message in a question and answer format which can be read and understood within one minute.
[††] Recalls are actions taken by a company to remove a product from the market. Recalls may be conducted on a firm's own initiative or by authorised authority.
[‡‡] The framework of a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace.

2.3 High-risk medications and situations

St James's hospital had developed a high-risk medications list, using international literature and locally identified high-risk medications. High-risk medication lists were displayed in the clinical areas inspected and staff who spoke with inspectors had an awareness of the high-risk medications available in their clinical areas and the risk-reduction strategies[§§] in place.

The hospital had implemented a combination of associated risk-reduction strategies which were observed by inspectors in practice. It was evident that the implementation of the electronic medication prescription administration record had enabled the hospital to effectively implement a number of high leverage forcing functions[***] such as automation and computerisation of the medication management process.

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

- anticoagulants[†††]
- insulin
- antimicrobials
- medication management during the perioperative period.

Anticoagulants

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

- a clinical pharmacist service was available for most inpatients, and pharmacists were available to guide and support staff

- prescribing plans for heparin and warfarin were automatically available on the electronic patient medication administration record (EPMAR)

- prescribing order sentences to guide dosing of direct oral anticoagulants (DOACs) were automatically available on the electronic medication and administration record

- rationalisation of supply of unfractionated heparin and heparin flushing to wards

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[§§] 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.
[***] Forcing functions: are design processes so errors are virtually impossible to make.
[†††] 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.

- staff had access to up-to-date guidance to support safe anticoagulant therapy management

The hospital had created a number of alerts for staff in relation to anticoagulants on the electronic medication and administration record. These included:

- an alert for duplicate prescribing of anticoagulants

- an alert for medications to avoid/caution in patients with known bleeding disorders

- an alert to complete a venous thromboembolism (VTE) risk assessment within 24 hours of admission

- an alert requiring completion of warfarin indication, target international normalized ratio (INR)[‡‡‡] and duration of therapy.

Insulin

It was explained to inspectors that the insulin inpatient prescription chart had yet to transition to the electronic medication prescription administration record due to a number of further developments required within the system. In the interim of this transfer, insulin was to be prescribed and managed outside the electronic record system.

Staff in some of the clinical areas inspected informed inspectors that there was no reminder for staff in the form of a placeholder alert in place on the electronic patient record to show that a patient was on insulin and that this information was passed over during clinical handover. Hospital management informed inspectors that placeholders were used to remind staff when a patient was prescribed insulin to reduce the risk of patients missing doses. The hospital should review the process for insulin prescribing, administration and use of alerts to ensure that all staff are aware of patients who require insulin and to prevent potential omission of insulin.

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

- the term 'units' was pre-printed on the insulin inpatient prescription chart to support safe prescribing of insulin

- the insulin prescription chart contained detailed guidance for prescribers

- insulin was double checked prior to administration

[‡‡‡] the international normalized ratio (INR) is used to monitor how well the blood-thinning medication (anticoagulant) warfarin is working to prevent blood clots.

- clinical areas had a hypoglycaemic box[§§§] which contained medications and instructions in the form of a treatment algorithm for staff to manage a hypoglycaemic[****] episode

- a diabetes clinical nurse specialist was available for patient review and education

- insulin pens in use in the hospital were for single person use only

- the hospital had a protocol for the safe management of pen devices

- perioperative insulin guidelines were available to staff.

Antimicrobials

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

- plans for prescribing of high-risk intravenous antibiotics e.g. vancomycin and amikacin on the electronic prescribing medication and administration record

- prescriber order sentences to guide dosing of antimicrobials

- 72 hour alert to notify prescribers and pharmacists that an antimicrobial agent had passed its review date

- staff had access to intravenous administration guidelines for antimicrobials and empiric antimicrobial guidelines 'App' for dosing and monitoring guidance for patients on antimicrobials.

A pharmacy work list was automatically generated from the electronic healthcare record system which enabled clinical pharmacists to identify patients receiving intravenous antibiotics so a clinical pharmacy review could be prioritised.

Inspectors were informed that monitoring of antimicrobials which required therapeutic drug monitoring was supported locally by an antimicrobial pharmacist and an antimicrobial stewardship strategy was also in place at the hospital.

Medication management during the perioperative period

A hospital's operating theatre presents a unique situation with the use of multiple high-risk medications, high patient throughput and complex procedures.[22] A diverse range of medications are used which have the potential for a serious adverse event

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[§§§] Hypoglycaemic box: 'Hypo box' provides quick access to equipment required to support effective treatment for patients in the event of hypoglycaemia.
[****] Hypoglycaemic: when a person's blood sugar falls below the normal level.

if administered incorrectly.[23] Therefore, the perioperative period is a high-risk situation in relation to medication safety.

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

- medications were drawn up by the person who will administer them
- international colour-coded labeling of drawn up medications applied in practice
- medications were stored in a standard and organised manner to support safe selection
- emergency drugs were drawn up by the on-call anaesthesiologist each day, labelled and stored in a separate tray and disposed of at the end of each shift.
- the hospital used some prefilled syringes for medications.

Documentation relating to the perioperative period had yet to transition to the electronic healthcare record and a paper based anaesthetic record sheet was in use at the time of inspection.

Each anaesthetic room had a standardised medication list detailing what medications should be available and where these medications should be stored. It was explained to inspectors that only the lower concentration of heparin injection flushing solution should be stored in each anaesthetic room, however, inspectors found that some higher strength heparins were available. Standardising or reducing the availability of similar looking or sounding items can reduce the risk of mis-selection, however, the hospital must ensure that such risk-reduction strategies have been effectively and consistently implemented in practice.

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.

An alert was built into the electronic medication prescription administration record for all medications to prevent medications from being administered outside of the prescribed frequency. For example, if staff wanted to administer medication outside the recommended frequency, an alert was issued and a clinical decision would have to be recorded. This was also required for medications in which administration had been delayed.

The hospital had a list of sound-alike look-alike drugs (SALADs)[††††]. Medication Safety Minutes on the topic of SALADS had been circulated to the clinical areas and included information on how to reduce the risk of error when prescribing and administering SALADs such as; writing clearly, including the indication for the medication when prescribing and minimising close storage of similar packaging. Inspectors were informed that the implementation of the electronic medication and administration record had greatly reduced the risk of SALAD error as the issue of illegible prescriptions was no longer applicable.

The electronic healthcare record incorporated a number of decision support tools. Prescribing plans for intravenous paracetamol were available within the electronic medication administration records and an alert was also created to flag duplicate prescribing of paracetamol. However, inspectors found an example whereby a patient had received multiple doses of intravenous paracetamol without a documented weight.

It was explained to inspectors that prescribing of medications could not take place without allergy checking which was automatically visible on the electronic medication prescription administration record.

Overall, St James's Hospital had implemented evidence-based safety measures for high-risk medications. It was evident that the implementation of the electronic healthcare record had enabled the hospital to identify patients at higher risk and prioritise their care and medication safety needs. Furthermore, the hospital had acted on issues identified with medication safety events and had implemented high leverage forcing functions to improve practices with medication safety at the hospital.

To further support awareness of high-risk medications and associated risk reduction strategies, a number of medication safety minutes had been issued by the medication safety facilitator which were described as very effective by staff in some of the clinical areas inspected.

Opportunities for improvement

- The hospital should progress with work to integrate the insulin prescription chart and peri-operative process onto the electronic healthcare record.
- The hospital should ensure that risk-reduction strategies that have been developed for high-risk medications are effectively implemented in the operating theatre department.

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

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.[24, 25]

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 1,619 people discharged from St James's Hospital during the month of May 2019, 716 people completed the survey, achieving a response rate of 45%.[26]

Two questions related directly to medication in the Survey. The scores for the 2019 Hospital and the national scores for 2017[‡‡‡‡], 2018[§§§§] and 2019 are illustrated in table 1 below.

Questions	Year	St. James' 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	8.0	8.0
	2018	7.9	8.0
	2017	7.8	7.8
Q45. Did a member of staff tell you about medication side effects to watch for when you went home?	2019	5.3	5.3
	2018	5.1	5.2
	2017	5.1	5.1

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

[‡‡‡‡] Please note that the numbering of questions changed after the 2017 survey was completed. Question 44 '…..' was originally question 45 in the 2017 survey and question 45 '….' was originally question 46.
[§§§§] National Inpatient Experience Survey known as the National Patient Experience Survey in 2017 and 2018.

Overall, St. James's Hospital scores have marginally improved over the three years. In response to Question 44, inspectors were informed that engaging patients and carers in medication safety had become a strategic priority for the hospital and had been identified as an area of action in their 2019 work plan. The hospital intended to collate patient information leaflets which were locally developed for specific medications into a central electronic repository in the hospital so that staff can access easily access them. However, this was not in place at the time of this inspection and inspectors were informed that this work was ongoing. The hospital should progress work plans outlined in relation to engaging patients and carers in medication safety and ensure that initiatives have been effectively implemented in practice.

Patient information

Inspectors were informed that information about medications was provided by nurses, nurse specialists, clinical pharmacists and medical staff. Inspectors were informed that patient information leaflets were given to all patients newly commenced on warfarin and direct oral anticoagulants (DOACs) with counselling provided by the pharmacist or doctor. Staff had access to patient education and information material on medications in the clinical areas.

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.[27, 28,29]

Inspectors were informed that formal medication reconciliation was provided to approximately 70-75% of patients on admission and was undertaken by the clinical pharmacist. However, only a limited medication reconciliation service was provided at discharge by pharmacists to selected patients on certain wards. It was explained that key elements of the process were supported by the electronic healthcare record such as electronic discharge summaries.

A pilot of a pharmacist medication reconciliation service in the discharge lounge occurred at the hospital in November 2019. The purpose of this was to see how the electronic healthcare record system could be further developed to support medication reconciliation at discharge.

Systems to support medication safety and optimisation

St James's Hospital had systems in place to support medication safety and optimisation including:

- electronic health records which facilitated identification of high risk patients

- alert system in place for clinical pharmacy to identify newly admitted patients and prioritise medication reconciliation

Patient weight measurements are important for medications that require an individual weight-based dose.[30] Patient weights and allergies were documented on the majority of electronic medication records reviewed by inspectors during the inspection.

Some systems were in place to support medication safety and optimisation in relation to the prescribing and administration of crushed medications. For example, the prescribing and administration of medications intended for nasogastric administration was guided and supported by clinical pharmacists. However, inspectors were informed that staff in the clinical areas often had to use intravenous syringes to measure small oral doses due to the unavailability of small volume oral syringes to accurately measure liquid medications. This had been identified as a high risk and placed on the hospital's risk register.

Best practice evidence and literature recommends that obtaining oral and parenteral syringes that look different can add an extra precautionary measure to help signal to staff that the correct or incorrect device is being used for a particular route of administration.[31,32,33] In addition, the consistent use of oral syringes for preparing and administering small-volume oral and enteral liquids is an effective risk-reduction strategy that is appropriate in all health care settings.[34] The hospital should review this practice and update the hospital's risk register in relation to actions taken and progress notes.

Opportunities for improvement

- The hospital should continue to work towards the expansion of the medication reconciliation service to all patients on transitions of care.

- The hospital should review the practice of using intravenous syringes for the preparation and administration of small volume oral and enteral liquids in line with best practice evidence.

2.5 Model of service and systems in place for medication safety

International studies support the role of clinical pharmacy service[35]***** in hospital wards in preventing adverse drug events.[36,37,38,39,40,41] A clinical pharmacy service

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

was provided in nearly all inpatient clinical areas with some exceptions including assessment and transitional clinical areas.

Inspectors were informed that clinical pharmacy services had increased since the previous inspection. However, the hospital had identified the need for an additional medication safety facilitator to support the future progression of the medication safety programme at the hospital. It was explained that a business case had been submitted for an additional pharmacist in June 2017 but this had yet to be approved at the time of this inspection.

St James's Hospital provided 24 hour, seven day a week out of hours access to on call pharmacy services which was described as a valuable resource by staff in the clinical areas inspected.

The hospital had a list of medications approved for use in the hospital, also referred to as a formulary.[†††††] The purpose of maintaining this list is to ensure appropriate governance of medications approved for use within the hospital and that a safety evaluation occurs before new medications are introduced.[42] The hospital had a system in place for formulary oversight and the approval of new medications which was under the governance of the Pharmacy and Therapeutics Committee.

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]

St James's Hospital had a number of medication information sources electronically available such as:

- intravenous administration guidelines
- empiric antimicrobial guide
- prescribers' guide
- British National Formulary
- repository of medication safety bulletins.

Medicines information was mainly accessible to staff electronically with some information available in hard copy also. Inspectors observed that some medication information and decision support tools were automatically available within the electronic medication prescription and administration record. For example, when

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Pharmaceutical Society of Ireland. *Future Pharmacy Practice in Ireland - Meeting Patients' Needs*. Dublin; 2016. Pharmaceutical Society of Ireland.

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

prescribing, certain information and requirements for the medication automatically displayed to guide prescribers.

It is recommended, by both the Health Service Executive[43] and the National Clinical Effectiveness Committee[44] that policies, procedures and guidelines are reviewed and updated every three years. The majority of policies, procedures and guidelines viewed by inspectors during the inspection were up-to-date.

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 registered clinical audits. Since the last inspection, the hospital had implemented a process whereby all audits were required to be registered to improve coordination and responsibility for recommendations.

The hospital had a medication safety audit plan for 2017-2019. Evidence of monitoring and evaluation of medication safety provided to inspectors for the past two years consisted of the following audits:

- Clinical pharmacists interventions for inpatients 2019
- Hypoglycaemia management audit 2019
- Patient education on medications delivered by clinical pharmacists 2018
- Quality of prescribing and administration of medications to patients with enteral feeding tubes or swallowing difficulties 2017
- Quality of medication administration documentation.

Inspectors reviewed medication safety audits undertaken by the hospital, which had clear actions and recommendations arising from audit findings. However, some audits reviewed, did not have recommendations or associated time-bound actions. Similar to the previous inspection, inspectors noted that there was further potential to expand and enhance medication safety auditing capacity from a multidisciplinary perspective.

Minutes of Pharmacy and Therapeutics Committee reviewed by inspectors outlined discussion on medication safety audits. Clinical audit activity reports and medication safety metrics were also submitted to the Director of Quality and Safety Improvement. Updates of audit activity were shared locally via journal clubs, clinical handovers, medication safety minutes and medication safety bulletins. Annual quality and audit days were held where staff were encouraged to present an overview of audits they had undertaken.

The hospital had also identified two medication safety key performance indicators which were as follows;

- Analysis of medication safety events

- nursing quality care metrics[‡‡‡‡‡45]

Nursing quality care metrics[§§§§] were monitored across the hospital to review practice around some aspects of medication storage, prescription and administration. Inspectors reviewed examples of action plans in response to nursing metric findings in some of the clinical areas inspected.

Considering the stage of development of the medication safety programme at St. James's Hospital there is scope for further improvement in relation to use of metrics and indicators to monitor the effectiveness of the medication safety programme.

Opportunities for improvement

- The hospital should look to expand systematic monitoring arrangements through the use of metrics and indicators to monitor the effectiveness of the medication safety programme and further support continually improve safety with medication use.

- Medication safety audits should have time-bound action plans for recommendations with plans for 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.[46]

In St James's Hospital medication management was included in a structured induction programme for doctors and nurses and pharmacists. Nurse's induction included classroom, on line and practical assessment of medication learning. All nursing staff were required to complete:

- St James's Hospital medication management competency programme electronic assessment

- St James's Hospital intravenous therapy management programme and competence assessment

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

Ongoing medication management training for nurses involved yearly medication administration competency assessments which were completed by ward managers.

Non consultant hospital doctors received a one hour education session from the medication safety facilitator on induction. Doctors also received electronic prescribing record training on induction. Inspectors were informed that medication education was also provided as part of weekly teaching sessions to medical interns and at departmental meetings and hospital grand rounds.

Pharmacists also attended weekly medication teaching sessions which was organised by the clinical services manager.

Medication safety awareness was continuously promoted at the hospital through staff communication using medication safety minutes, bulletins and alerts.

To support the implementation of the new Electronic Healthcare Record system, the hospital had delivered a comprehensive staff training programme for implementation of the new system.

Opportunity for improvement

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

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 James's Hospital had governance arrangements and organisational structures with clear lines of accountability in place to support the safe use of medications. The hospital should ensure that reporting structures set out for medication safety at the hospital are re-established to provide the necessary oversight at an executive level. The hospital had a well established medication safety programme in place with clear objectives as outlined in a medication safety strategy. Progress with medication safety plans was evident to inspectors during this inspection and it was clear that medication safety was prioritised at senior level in the hospital with strong leadership from the Medication Safety Facilitator.

The hospital had identified high-risk medications with a combination of risk-reduction strategies in place appropriate to the services provided by the hospital. It was evident that implementation of the electronic healthcare record had enabled the hospital to apply many high leverage forcing functions for high-risk medications.

While the technology advancements had and will have great potential to improve medication safety, the hospital should progress with plans to integrate the insulin prescription chart and peri-operative process onto the electronic healthcare record. Furthermore, medication systems at the hospital could be further improved with the consistent use of oral syringes for preparation and administration of all small volume oral and enteral liquids in line with best practice guidelines.

The hospital provided a clinical pharmacy service for most inpatients, and also provided an out of hours pharmacy service for staff which was to be commended. The hospital needs to work towards establishing medication reconciliation for all patients on admission and discharge.

St James's Hospital used a variety of information sources to identify strengths and weaknesses in the hospital medication management system including medication-related incident reporting, self-assessment tools, pharmacy intervention review, clinical audit and electronic healthcare record data. Inspectors found that the hospital had the potential to expand and enhance medication safety auditing capacity from a multidisciplinary perspective and improve systems in place to ensure

that actions and recommendations arising from audit activity are effectively monitored and implemented.

The hospital had comprehensive electronic medication information sources and decision making tools to guide staff. Clinical pharmacists were also on hand to guide and support staff.

At this stage of development the medication safety programme could be further enhanced by the development of targeted education for medication safety and by enhanced monitoring and audit arrangements, aligned to the hospital's medications safety programme, to ensure the required improvements were achieved.

Overall, similar to findings from the previous medication safety inspection in 2017, St James's hospital continued to promote and implement effective strategies for medication safety. The implementation of the electronic healthcare record had enabled the hospital to strengthen medication safety while continuing to identify opportunities for learning and improvement. The learning and knowledge gained from this process and transition could be of benefit to other hospitals in the context of improving medication safety.

This report should be shared with relevant staff at St James's Hospital and the Dublin Midland's Hospital Group to highlight the findings from this inspection including what has been achieved to date and to foster collaboration in relation to opportunities for improvement.

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

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5. Appendices

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

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

Appendix 2: Hierarchy of effectiveness of risk-reduction strategies in medication safety.
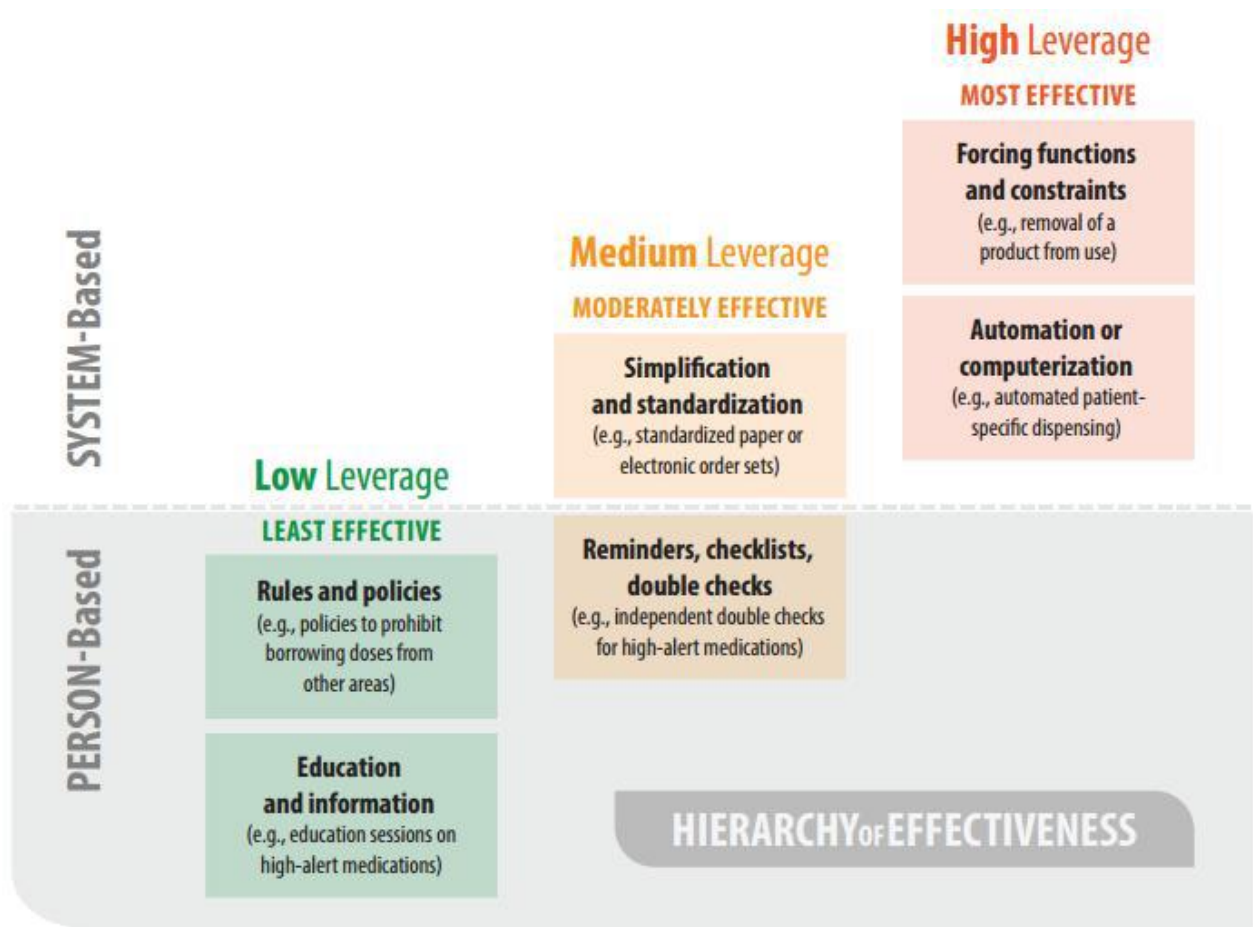
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Appendix 3: National Coordinating Council for Medication Error Reporting and Prevention. Index for categorising medication errors.
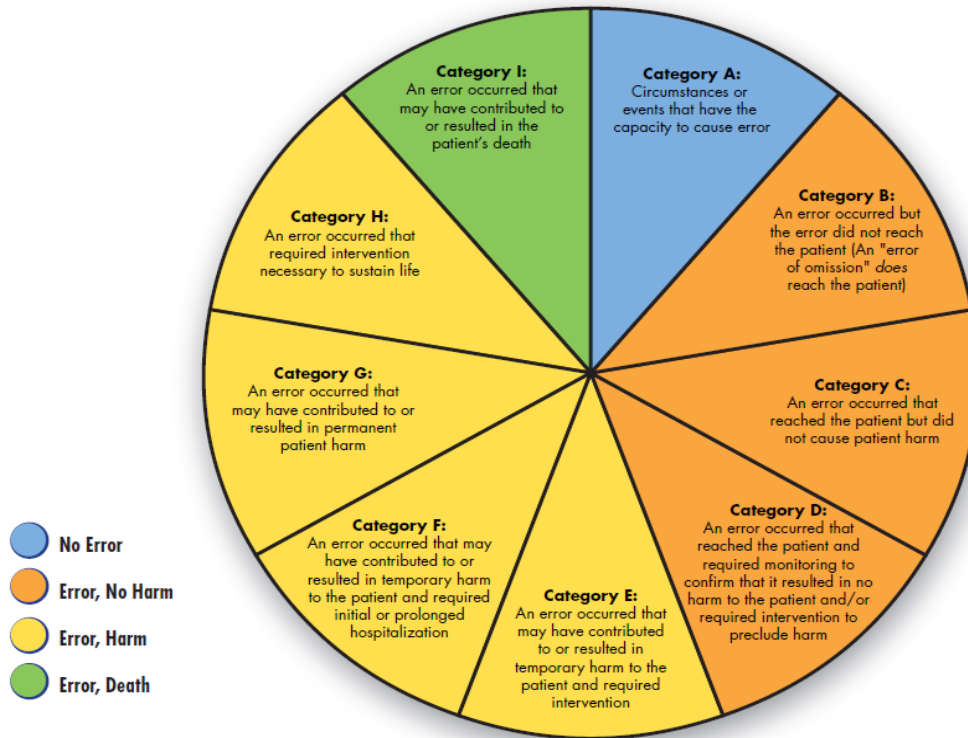
Definitions

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

Monitoring
To observe or record relevant physiological or psychological signs.

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

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

Category I: An error occurred that may have contributed to or resulted in the patient's death

Category A: Circumstances or events that have the capacity to cause error

Category H: An error occurred that required intervention necessary to sustain life

Category B: An error occurred but the error did not reach the patient (An "error of omission" *does* reach the patient)

Category G: An error occurred that may have contributed to or resulted in permanent patient harm

Category C: An error occurred that reached the patient but did not cause patient harm

Category F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization

Category E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention

Category D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

- No Error
- Error, No Harm
- Error, Harm
- Error, Death