Report of the announced inspection of medication safety at Ennis Hospital.

Date of announced inspection: 5 December 2019

About the Health Information and Quality Authority (HIQA)

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

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

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.

- **Regulating social care services** — The 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 Ennis Hospital by Authorised Persons from HIQA; Dolores Dempsey Ryan and Nora O' Mahony. The inspection was carried out on 5 December 2019 between 09:00hrs and 17:00hrs.

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

- Burren ward
- Operating theatre department and the surgical day ward.

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

- Group one: the chairperson and vice chair of the Drugs and Therapeutics Committee, the chief pharmacist, the general manager of the office of the chief clinical director and the medication safety officer for the group.
- Group two: the operational director of nursing, the chair of the group medication safety committee represented the chief clinical director, the chair of the local medication safety committee and the diagnostics directorate general manager for the group.

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

Information about the hospital

Ennis Hospital is a model 2[§] public acute hospital and is part of University Limerick Hospitals Group.[**] Ennis Hospital provides a range of services including non-complex care to medical and surgical patients. In addition to 50 inpatient beds, there are also 12 day beds, seven endoscopy beds, a local injuries unit and a medical assessment unit.

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§ Model 2 hospital: admit low acuity medical patients and have a range of ambulance bypass protocols in place. They commonly have a daytime Medical Assessment Unit (MAU), day care surgery and a local injury unit.

** University Limerick Hospitals Group includes University Hospital Limerick, University Maternity Hospital Limerick, Ennis Hospital, Nenagh Hospital, Croom Hospital and St. John's Hospital Limerick.

2. Findings at Ennis 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] University Limerick Hospitals Group Drugs and Therapeutics Committee represented University Hospital Limerick, University Maternity Hospital Limerick, Ennis Hospital, Nenagh Hospital and Croom Orthopaedic Hospital with the exception of St. John's Hospital Limerick.[††] The Drugs and Therapeutics Committee reported to the Quality and Safety Executive Committee (QUALSEC) each quarter and the QUALSEC committee was operationally accountable to the Executive Management Team and subsequently to the group chief executive officer of University Limerick Hospitals Group.

The chief clinical director of University Limerick Hospitals Group had overall executive responsibility and authority for medication safety in Ennis General Hospital through the operational director of nursing in Ennis Hospital.

A number of committees including a group medication safety committee and three local medication safety committees supported the work of the Drugs and Therapeutics Committee including Ennis Hospital's local Medication Safety Committee. University Limerick Hospitals Group had appointed a medication safety officer who attended medication safety committee meetings across the group and had overall responsibility for reviewing medication safety incidents and generating reports for the Drugs and Therapeutics Committee.

Ennis Hospital's Medication Safety Committee was responsible for providing oversight and promoting best practice in medication management. This committee was chaired by a consultant physician, met monthly and reported to the Group Medication Safety Committee and to the Drugs and Therapeutics Committee. Membership of the Medication Safety Committee was multidisciplinary to include a consultant physician, a non-consultant hospital doctor representative, the operational director of nursing, the pharmacist manager and nursing managers. The committee followed a standardised agenda which included items for discussion such as reports from the medication safety officer, audits, medication alerts,

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†† St. John's Hospital Limerick has its own Drugs and Therapeutics Committee for oversight of medication safety within the hospital.

medication minutes, learning notices, policies, procedures and guidelines, quality improvement initiatives and an action log with named persons or committees identified to complete actions. The Medication Safety Committee provided reports to the Drugs and Therapeutics Committee and reported every six months to the Group Medication Safety Committee.

The chief pharmacist represented Ennis Hospital on the Drugs and Therapeutics Committee. However, inspectors found that Ennis Hospital was not always represented at the Drugs and Therapeutics Committee meetings. Documentary evidence provided to inspectors indicated that Ennis Hospital was represented at less than half of the Drugs and Therapeutics Committee meetings in 2018 and 2019. The hospital should ensure that the chief pharmacist from Ennis Hospital is in attendance at the Drugs and Therapeutics Committee meetings or alternative arrangements are made for another representative to attend these meetings.

Hospitals should have a clear corporate strategy that sets out the organisation's mission, values, role, functions and actions to be taken to meet organisational goals.[10,17] The Drugs and Therapeutics Committee had a group medication safety strategy, in draft format, aligned to the overall University Limerick Hospitals Group corporate strategy 2018-2022. The key strategic priorities planned for Ennis Hospital related to increasing the reporting of medication safety incidents and a focus on medication reconciliation.

The Drugs and Therapeutics Committee had a medication safety programme in place for the group which set out governance structures, incident reporting systems, management of alerts and high risk medications, education and monitoring of key performance indicators and audit results. Evidence provided to inspectors indicated the Ennis Hospital was implementing this programme to support medication safety.

Inspectors found that Ennis Hospital benefited from membership of University Limerick Hospitals Group Drugs and Therapeutics Committee through collaboration and sharing of information, for example there was a group electronic formulary system and Ennis Hospital participated in the development of a new group-wide medication prescribing and administration record.

Opportunities for improvement

- Senior hospital management should ensure that Ennis Hospital is represented at the Drugs and Therapeutic Committee meetings as per terms of reference.

- Ennis Hospital should develop a medication safety strategy to articulate its short and long-term operational goals for medication safety aligned to an overall medication safety strategy for the hospital group.

2.2 Risk management

Ennis Hospital had a pharmacy department risk register and a hospital risk register. The hospital's risk register was reviewed monthly and more often if required.

The recorded risks included:

- Lack of cover for Ennis Hospital's pharmacy department as a result of no locum or agency pharmacist available to cover leave.
- Lack of clinical pharmacy service to support medication reconciliation and medication education.
- Lack of a medication safety officer with dedicated hour's onsite to monitor and audit practice.

Risks which could not be managed locally were escalated to the group diagnostics risk register or corporate risk register as required. Risks were discussed at directorate meetings and the corporate risk register was reviewed by the Hospital Executive Team every two months. Risks recorded on the corporate risk register relating to Ennis Hospital included the lack of cover when the chief pharmacist was on leave.

Medication-related risks for Ennis Hospital were documented on the hospital's electronic quality management software system. Medication safety incidents‡‡ that occurred in the hospital were reported to the State Claims Agency using the National Incident Management System§§(NIMS).[18] The hospital had no serious reportable incidents in the last two years relating to medications. The majority of incidents were reported by nurses and more recently by doctors. Hospital management acknowledged the low reporting rates of medication incidents, but reported that there was improvement in reporting of medication safety incidents in

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‡‡ An incident is an unplanned, unexpected or uncontrolled occurrence which causes (or has the potential to cause) injury, ill-health, and or damage. An incident can be a harmful incident (adverse event), a no harm incident, a near miss, dangerous occurrence or complaint.
§§ The State Claims Agencies (SCA) National Incident Management System (NIMS) is a risk management system that enables hospitals to report incidents in accordance with their statutory reporting obligation to the SCA (Section 11 of the National Treasury Management Agency (Amendment) Act, 2000).

2019. While a total of 8 medication safety incidents were reported in 2018, 20 medication safety incidents were reported in 2019.

Higher incident reporting rates both demonstrate and promote an improved culture of safety.[19] Documentary evidence provided to inspectors indicated that the low level of medication incident reporting in Ennis Hospital was raised at the Drugs and Therapeutic Committee in May 2019. Hospital management reported that additional education sessions were provided to nurses and doctors to encourage staff to report more medication incidents and near misses.

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.[20,21] Staff were provided with feedback on medication safety incidents at clinical nurse management meetings and at Medication Safety Committee meetings. In addition, staff also had access to a medication safety shared drive where medications safety minutes and learning notices were stored to share learning on medication safety incidents from the hospital group.

Analysis of incidents

The medication safety officer reviewed all medication safety incidents reported on each hospital's electronic quality management software system within the group including Ennis Hospital. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Medication Error Index (Appendix 3) was used to categorise medication incidents in terms of severity of outcome. The medication safety officer provided a report on medication safety incidents each month to the Drugs and Therapeutics Committee and produced a medication safety annual report. The Drugs and Therapeutics Committee had oversight of all incidents including a breakdown on the types of medication safety incidents reported across the group. Learning notices were produced in response to medication safety incidents assigned a high grade according to the NCC MERP categorisation to prevent similar incidents happening across the group.

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.[21] Inspectors were informed that due to the low level of reporting of medication safety incidents in Ennis Hospital, it was difficult to trend medication safety incidents. However, documentary evidence provided to inspectors indicated that overall medication safety incidents trends observed within the hospital group were discussed at the Drugs and Therapeutics Committee meetings. For example, there was an increase in the number of medication safety incidents relating to vancomycin in 2019 and a vancomycin guide for staff was produced to address this.

Local medication incidents and near misses were discussed at Ennis Medication Safety Committee monthly meetings. In addition, information was shared regarding medication safety incidents that occurred within the group including relevant learning notices and medication safety minutes. Clinical nurse mangers who spoke with inspectors reported that they attended the Medication Safety Committee meetings and were aware of the number of medication safety incidents reported each month and the type of incidents reported.

Alerts and recalls

The chief pharmacist received and acted on alerts and recalls[***] related to medication. These alerts were stored on the medication safety shared drive for staff to access.

Opportunities for improvement

- The hospital should continue to identify and support targeted promotion of medication safety incident reporting, so that a culture of reporting is enhanced across all disciplines to mitigate against key medication-related risks identified.

2.3 High-risk medications and situations

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

Ennis Hospital had developed a local list of high-risk medications, using international literature and locally identified high-risk medications. The hospital had also displayed a generic list of high-risk medications in the clinical areas visited. The hospital had implemented a combination of associated risk-reduction strategies which were observed by inspectors in practice. 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 following sample of high-risk medications was reviewed in detail during this inspection to identify the risk-reduction strategies in place:

[***] 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.
[†††] High-risk situation is a term used by the World Health Organization[2] to describe situations where there is an increased risk of error with medication use.
[‡‡‡] 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[§§§]
- insulin
- 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:

- unfractionated heparin was not stocked on general wards
- the medication prescribing and administration record was being revised to support safer management of anticoagulants with thrombophylaxis, warfarin and anticoagulants prescribed in the same section of the medication record to minimise inadvertent duplication of these medications.
- low molecular weight heparins[****] (LMWH) were stored in the ward, but segregated from other medications
- a high alert sticker was applied to direct oral anticoagulants (DOACS)
- University Limerick Hospitals Group had a guideline on the use of direct oral anticoagulants in draft format.

Insulin

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

- insulin pens in use in the hospital were for single patient use only
- opened insulin pens were stored in the medication trolley in a special insulin box with a high alert sticker applied, and individual patient details and date of opening were recorded on a flag label [22]
- unopened multidose insulin vials and insulin pens with plastic flag labels, were stored in a temperature controlled fridge
- insulin was double checked prior to administration
- the hospital had 'hypoglycaemic boxes[††††]
- University Limerick Hospitals Group had a guideline for storage and administration of insulin in draft format

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[§§§] 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.

[****] Heparin is an anticoagulant specifically used in the initial treatment and prevention of deep vein thrombosis, pulmonary embolism, and arterial thromboembolism.

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

- staff had access to up-to-date information on insulin through the electronic software formulary system.

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.[23] A diverse range of medications are used which have the potential for a serious adverse event if administered incorrectly.[24] Therefore, the perioperative period is a high-risk situation in relation to medication safety.

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

- anaesthetic medications were prepared, labelled and administered by the same anaesthesiologists
- international colour-coded labels were used
- emergency drugs were drawn up by the anaesthesiologist at the start of each day, labelled and stored in a separate red container and disposed of at the end of each day
- medications on the anaesthesiology trolley were rationalised,[‡‡‡‡] and medications were stored in an organised logical uncluttered manner
- patient identification and drug allergies were checked prior to drug administration
- the theatre manager in conjunction with the chief pharmacist had developed a list of high-risk medications and a SALADS list relevant to the theatre department and these medications had identifiable high-alert and SALAD stickers applied
- there was evidence of good communication regarding medications administered at transitions of care throughout the perioperative patient pathway.

On the day of inspection, propofol was found to be unlabelled by inspectors. All medications should be individually labelled in line with best practice regardless of identifiable traits [23, 24,25,26] Inspectors were informed that the medication safety perioperative working group in University Hospital Limerick were currently reviewing initiatives to improve patient safety within the perioperative period such as the use of prefilled syringes in anaesthesia which would be shared with the group when completed.

[‡‡‡‡] Rationalisation: reducing the number of similar groups of medications available.

Other high-risk medications

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

The hospital has a look-alike sound alike medications (LASA)[§§§§] poster 2018 displayed in clinical rooms visited by inspectors. Inspectors found that identified sound-alike look-alike drugs (SALADs) were labelled with yellow salad stickers. Medication safety minutes were also displayed in the clinical room to provide information to staff on SALADs.

Intravenous paracetamol was used for patients with moderate pain or fever where the oral route was not clinically indicated. Information to guide staff on paracetamol intravenous drug administration was available on the hospital group electronic formulary system. Staff had access to information on intravenous paracetamol administration for adults over 50kg, and for children or adults under 50kg. The hospital group had a high-risk medication policy in draft format on the prescribing, dispensing and administration of intravenous paracetamol.

Ennis Hospital had a number of high leverage risk-reduction strategies in place for oral methotrexate including a standard operating procedure relating to the supply of oral methrotrexate. Inspectors were informed that oral methotrexate was not stocked in clinical areas. Only one strength methotrexate tablets was stocked in the hospital and dispensed as a patient specific single dose.

Inspectors viewed a number of risk-reduction strategies to mitigate against the risks associated with concentrated potassium chloride. Concentrated potassium ampoules were not stocked on the wards. Intravenous potassium was supplied in pre-mixed potassium chloride solutions and the box was labelled with a high alert sticker. These fluids were stored securely, segregated from other intravenous fluids and administered via an electronic pump. Staff had access to up-to-date guidance on safe administration of intravenous potassium and the hospital group also had an up to date policy on the use of intravenous potassium.

Overall, Ennis Hospital was proactive in implementing evidence-based safety measures for high-risk medications. Staff who spoke with inspectors were aware of the risk-reduction strategies employed to protect patients from the risk of harm. In addition, the group medication safety annual report 2018 prioritised three high risk medications for special focus following medication safety incidents. Evidence

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

provided to inspectors on the day of inspection indicated that insulin, intravenous paracetamol and intravenous potassium were prioritised for focus and risk reductions strategies were in place to support safer medication safety practices and mitigate the risks associated with these medications and prevent the same medication safety incidents recurring.

Opportunities for improvement

- The hospital should conduct a risk assessment into the practice of drawing up individual syringes of medications in advance of use including labelling to ensure that practices are safe and in line with current best practice.

2.4 Person centred care and support

Patients should be well informed about any medications they are prescribed and any possible side effects. This is particularly relevant for those patients who are taking multiple medications. [27, 28]

National Inpatient Experience Survey

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 149 people discharged from Ennis Hospital in May 2019, 65 people completed the survey, achieving a response rate of 44%.

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

***** 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 2017 survey and question 45 '….' was originally question 46.
[‡‡‡‡‡] National Inpatient Experience Survey known as the National Patient Experience Survey in 2017 and 2018.

Questions	Year	Ennis 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	7.9	8.0
	2018	7.8	8.0
	2017	7.9	7.8
Q45. Did a member of staff tell you about medication side effects to watch for when you went home?	2019	6.1	5.3
	2018	4.5	5.2
	2017	4.6	5.1

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

Overall, the 2019 results show that Ennis Hospital scored slightly below the national average for question 44, which indicates that this is an area for potential improvement. Question 45 received an overall score of 6.1 in 2019 which was higher than the national average score of 5.3, and showed improvement on the 2017 and 2018 scores.

Hospital management had identified areas for improvement in relation to providing patients with information on medications on discharge. The hospital had adopted the World Health Organizations and Health Service Executive 'Know, Check, Ask campaign'. Inspectors observed on the day of inspection two posters in a patient's room. One poster related to 'Know, Check, Ask campaign and the second poster prompted patients to ask 'do you need medication education, just ask'. Patients were also given a booklet titled 'Let's Talk Medication Safety', which explained the basics about medications, included a checklist for using medicines safely and questions to ask about medicines.

Patient information

Inspectors were informed that doctors, nurses, advanced nurse practitioners and clinical nurse specialists, provided patient information on medications. Doctors provided counselling to patients on direct oral anticoagulants and on any new medications prescribed. In addition, clinical nurse specialists working in areas such as respiratory and diabetes also provided patient education. Inspectors were informed that patients were provided with patient information leaflets and observed samples of patient leaflets in the clinical areas visited. The hospital had produced a

patient information booklet, which included information on medication safety for patients.

Medication reconciliation

Medication reconciliation is a systematic process conducted by an appropriately trained individual, to obtain an accurate and complete list of all medications that a patient is taking on admission, discharge and other transitions in care.[29, 30,31]

Medication reconciliation checklist was piloted in September 2018 for all inpatient admissions. An audit of compliance with the medication reconciliation checklist was carried out in September and October 2018 and showed that 72% of the checklists were completed by non-consultant hospital doctors. Recommendations were included in the audit findings. Inspectors were informed that the medication reconciliation checklist pilot project ceased due to a lack of resources to support the implementation of medication reconciliation. This risk was escalated to the Drugs and Therapeutics Committee and to the group diagnostic directorate risk register.

Inspectors were informed that some patients transferred from a model four hospital within the group to Ennis Hospital had medication reconciliation completed in this hospital.

Systems to support medication safety and optimisation

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

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

Inspectors were informed that patients' medication prescribing and administration records were reviewed daily during consultant-led ward rounds to support medication optimisation. All patients taking more than six medications had their medication prescribing and administration records reviewed.

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

2.5 Model of service and systems in place for medication safety

International studies support the role of clinical pharmacy services[32][§§§§§] in hospital wards in preventing adverse drug events.[33,34,35,36,37,38] Inspectors found on the day of inspection that the pharmacy service within the hospital was almost entirely restricted to dispensing due to a lack of resources.

There was one whole time equivalent (WTE) chief pharmacist position employed by the hospital providing cover Monday to Friday. The hospital had an antimicrobial pharmacist (0.2 WTE) one day a week from a hospital within the group to review patient records with regard to antimicrobial stewardship. In addition, the hospital employed one WTE pharmaceutical technician and a 0.5 WTE pharmaceutical technician.

Staff informed inspectors that the chief pharmacist was easily accessible for medication information and visited the wards daily to respond to queries.

Inspectors were informed on the day of inspection that there were challenges for the hospital to provide cover when the chief pharmacist was on leave. It was practice to arrange for an agency clinical pharmacist to provide cover for leave for the chief pharmacist. While the agency may provide cover for annual leave when notified in advanced, it was not always possible to provide cover for leave for the chief pharmacist. Senior hospital managers who spoke with inspectors reported that in these circumstances when the pharmacy department was closed, the nursing site manager provided cover whereby they could access medications for the wards as required from the pharmacy department. As discussed above in section 2.2, senior hospital managers had escalated this risk to the hospital group where it was recorded on the diagnostic directorate and corporate risk registers. Senior hospital managers and the hospital group needs to progress with its plan to address deficiencies in clinical pharmacy resources in Ennis Hospital and while addressing this continue to put in place contingency arrangements to ensure that pharmacy service are safe and effective.

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

The hospital group 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.[39] In addition, the group had a system in place for the approval of new medications which was under the governance of the Drugs and Therapeutic Committee.[40]

Opportunities for improvement

- Senior hospital managers and the hospital group needs to progress with its plan to address deficiencies in clinical pharmacy resources in Ennis Hospital and while addressing this continue to put in place contingency arrangements to ensure that pharmacy service are safe and effective.

2.6 Use of information

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

Inspectors found that clinical staff had access to up-to-date information on hospital computer desk tops, but not available to staff at the point of medicines preparation in all clinical areas visited by inspectors. Senior managers reported that due to wireless networking technology connectivity issues, there were delays with implementing computers devices in clinical medicines preparation areas.

Ennis Hospital had a number of medication information sources available such as:

- electronic formulary system
- electronic 'up-to-date' system
- antimicrobial guide
- medicines complete
- British National Formulary and British National Formulary for Children in electronic format
- prescribing algorithms available on the medication safety shared drive
- guide to dosing and monitoring of gentamicin and vancomycin in adult patients.

The Health Service Executive[41] and the National Clinical Effectiveness Committee[42] recommend that policies, procedures and guidelines are reviewed and updated every three years. The hospital group had a medication safety policies, procedures and guidelines working group. Medication-related policies, procedures and

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

guidelines were reviewed and approved by the Drugs and Therapeutics Committee. Inspectors viewed a number of group policies, procedure and guidelines and noted that some were in draft format.

Ennis Hospital Medication Safety Committee reviewed and adapted the group policies, procedures and guidelines for local use. These documents were easily accessible to staff on the hospital's electronic quality management software[††††††] available on each computer desk top. This is an example of good collaboration and sharing of policies, procedures and guidelines across the group.

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 Drugs and Therapeutics Committee had a medication safety audit working group. Medication safety audits were selected based on group medication safety incidents, medication safety minutes, and national and group key performance indicators for completion across the group.

Monitoring of medication safety in Ennis Hospital was through key performance indicators, audit and Nursing and Midwifery Quality Care Metrics.[‡‡‡‡‡‡] [43] Ennis Medication Safety Committee agreed a medication safety audits list. Audits were undertaken by the chief pharmacist, clinical nurse specialists, assistant directors of nursing, non-consultant hospital doctors, and by the antimicrobial stewardship team with some examples outlined below:

- audit of documentation of allergy status on the patient's medication prescribing and administration record
- evaluation of antimicrobial prescribing for medical inpatients 2018
- antimicrobial care bundle audit
- vancomycin dosing and monitoring audit
- audit of polypharmacy in hospitalised elderly patients
- paracetamol prescribing audit 2019
- audit of storage and labelling of dispensed insulin pens
- nebulizer audit
- prevention of adverse drug events in hospital 2018

[††††††] The electronic quality management software which includes modules such as document control

[‡‡‡‡‡‡] Quality Care-Metrics (QC-M) are a measure of the nursing and midwifery clinical care processes, in healthcare settings in Ireland, aligned to evidenced-based standards and agreed through national consensus. The QC-M is a monthly cyclical process where a random sample of 25% of the patient complement in the ward or unit are selected for evaluation. Data from these patients and patient records are entered on the electronic system.

- oxygen prescribing audit.

In Ennis Hospital, medication audits were carried out following a structured format and clear recommendations were made with an action plan. However, the action plan was not always a time bound action plan with a responsible person identified to ensure that recommendations made were implemented to achieve the required improvement. The Medication Safety Committee provided oversight of medication audits and audit reports were sent to the committee.

Four key performance indicators were identified by the hospital to monitor medication safety. Two national key performance indicators related to the rate of hospital acquired venous thromboembolism and the rate of medication incidents reported to NIMS. Inspectors were informed that the hospital group plan to set up a venous thromboembolism§§§§§§ (VTE) prophylaxis sub-committee.

Ennis Hospital had identified two local key performance indicators to monitor medication safety. One key performance related to the percentage of all medication records with the section for allergies and adverse drug reactions completed and the second performance indicator related to the percentage of compliance with antimicrobial guidelines. Documentary evidence provided to inspectors indicated that the hospital was monitoring these local key performance indicators through audit.

Nursing and midwifery quality care metrics were monitored on a monthly basis and included a number of elements that focused on medication management. Results reviewed by inspectors for May 2019 outlined good compliance with medication storage and custody, schedule controlled drugs and medication administration.

Dissemination of audit results is essential so that the clinical workforce is informed of the areas that need improvement, and also to motivate them to change practice and participate in improvement activities.[15] Medication safety audit results were discussed at medication safety committee meetings, grand rounds******* and at the Drugs and Therapeutic Committee meetings.

Opportunities for improvement

- Medication safety audits should have a time-bound action plan for recommendations with a responsible person identified to ensure that recommendations made were implemented.

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§§§§§§ Venous thromboembolism (VTE) refers to a blood clot or thrombus occurring in the deep veins.

******* Grand rounds consist of presenting the medical problems and treatment of a particular patient to an audience consisting of doctors, residents, and medical students

2.8 Education and training

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.[44] Ennis Hospital had a structured induction programme for doctors and nurses which included medication safety education. The medication safety officer provided induction training to non-consultant hospital doctors on medication safety. Doctors were provided with an in-patient prescribing medication administration standards booklet and were provided with training on correct prescribing.

Nurses completed an intravenous drug administration study day with associated competency assessment as part of their induction programme and also completed a refresher course every three years on intravenous drug administration. In addition, nurses completed the HSELanD[†††††††] medication management module. Records of staff that had attended education session and completed eLearning programmes were recorded on the hospital's electronic record system. The hospital group provided a two-week induction programme for new nurses.

During the inspection, inspectors found that there was awareness among staff of the educational and learning opportunities within the hospital. Staff could attend 'Lunch and Learn' talk monthly where for example, clinical nurse specialists provided a talk on a topic related to their speciality.

Medical staff attended grand rounds on a Friday where sub-committees of the Drugs and Therapeutics Committee including the medication safety officer presented at grand rounds on medication safety which was available to all nursing, pharmacy and medical staff at Ennis Hospital.

Medication safety awareness was promoted at the hospital through staff communication using medication safety minutes, learning notices and alerts. Doctors, nurses and the pharmacist had access to learning notices issued following a medication safety incident. For example, a learning notice was issued across the hospital group following an incident related to intravenous paracetamol. [11]

Staff had access to medication safety minutes that provided bite size learning in response to an incident and medication safety messages for example on prescribing. The hospital group also produced a medication safety newsletter.

Opportunity for improvement

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

[†††††††] The health service eLearning and development service

3. Summary and conclusion

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

Ennis Hospital is a member of the University Limerick Hospitals Group. The governance and oversight for medication safety at Ennis Hospital rested with University Limerick Hospitals Group Drugs and Therapeutics Committee. HIQA found that there was evidence of effective governance arrangements, good collaboration and sharing of information between Ennis Hospital and University Limerick Hospitals Group Drugs and Therapeutics Committee. The Drugs and Therapeutics Committee had a medication safety programme and a medication safety strategy in draft format.

Ennis General Hospital had a local Medication Safety Committee which was responsible for providing oversight and promoting best practice in medication management within the hospital. Ennis Hospital was represented on the Drugs and Therapeutics Committee by the chief pharmacist. However, inspectors found that Ennis Hospital was not always represented at the Drugs and Therapeutics Committee meetings. The hospital should ensure that a representative from Ennis Hospital is in attendance at Drugs and Therapeutics Committee meetings.

Inspectors were informed on the day of inspection that pharmacy resources were limited and there were challenges for the hospital to provide alternative arrangements to cover required leave. Senior hospital managers and the hospital group needs to progress with its plan to address deficiencies in clinical pharmacy resources in Ennis Hospital and while addressing this continue to put in place contingency arrangements to ensure that pharmacy service are safe and effective.

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 had systems in place to identify and manage risk. Hospital management acknowledged the low reporting rates of medication incidents. The hospital should continue to identify and support targeted promotion of medication safety incident reporting, so that a culture of reporting is enhanced across all disciplines to mitigate against key medication-related risks identified.

Monitoring of medication safety in Ennis Hospital was through key performance indicators, audit and metrics with oversight from the local Medication Safety Committee and the Drugs and Therapeutics Committee.

The hospital through the hospital group had access to a number of medication information sources to guide staff. In addition, the hospital had access to group medication policies, procedures and guidelines which were adapted for local use. This is an example of good collaboration and sharing of information across the group.

Ennis Hospital had a structured induction programme for doctors and nurses, which included medication safety education.

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

This report should be shared with relevant staff at the Ennis Hospital and the University Limerick Hospitals 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.

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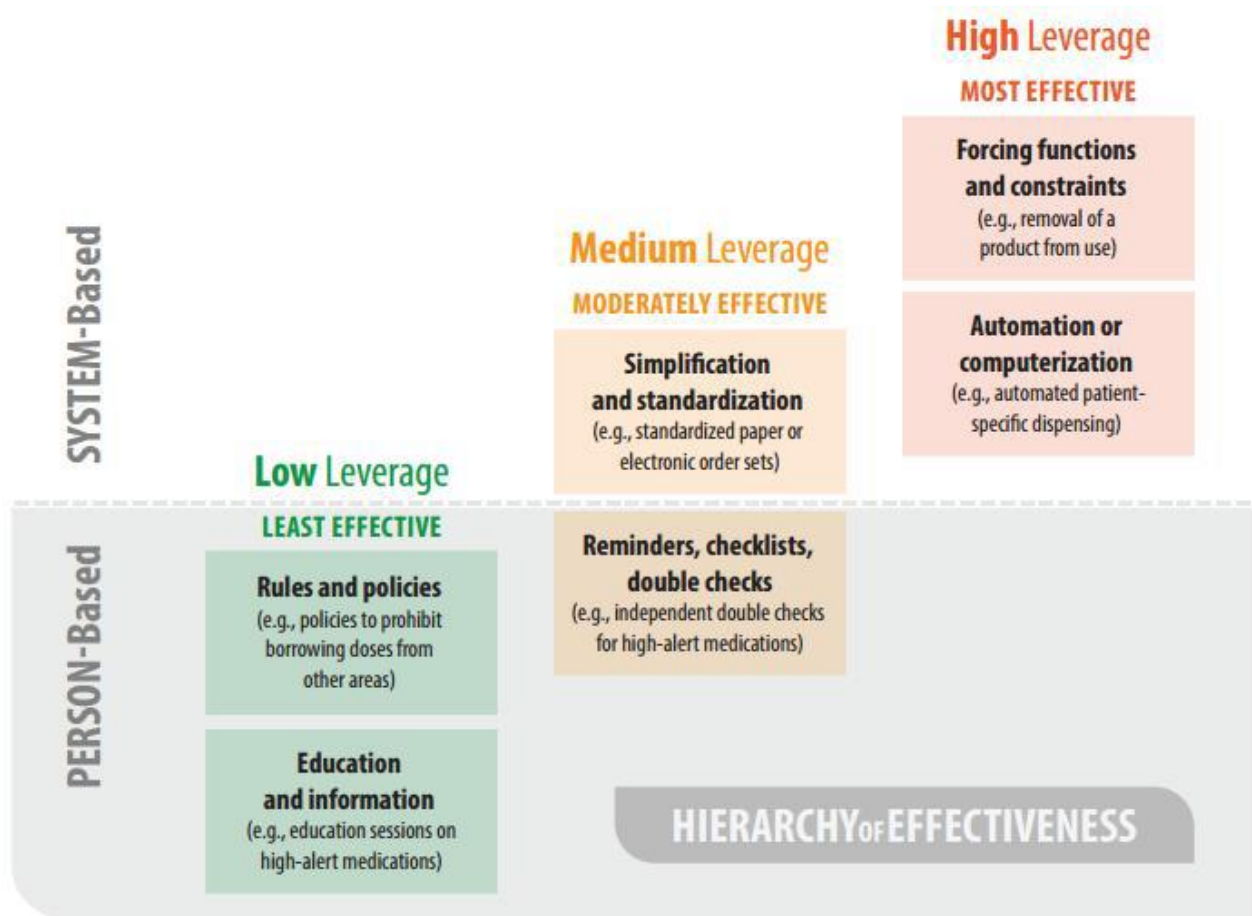
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5. Appendices

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

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

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

SYSTEM-Based

PERSON-Based

High Leverage
MOST EFFECTIVE

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

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

Medium Leverage
MODERATELY EFFECTIVE

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

Low Leverage
LEAST EFFECTIVE

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

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

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

HIERARCHY OF EFFECTIVENESS

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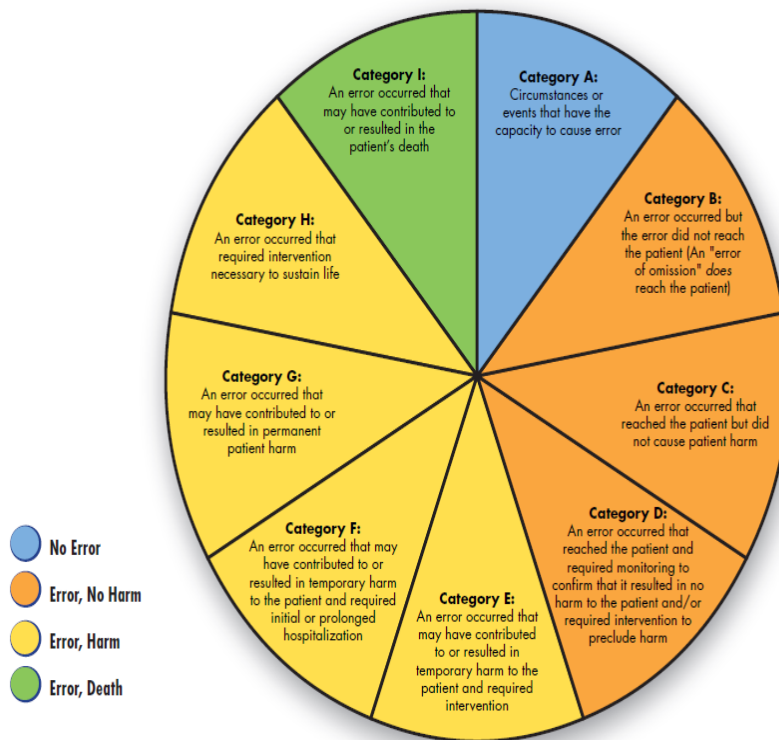
Definitions

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.)

The pie chart shows the following categories:

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

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

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

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

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

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

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

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

Legend:
- No Error
- Error, No Harm
- Error, Harm
- Error, Death