



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the announced inspection of medication safety at the Midland Regional Hospital Portlaoise.

**Date of announced inspection:
28 September 2017**

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

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

Setting Standards for Health and Social Services — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.

Regulation — Registering and inspecting designated centres.

Monitoring Children's Services — Monitoring and inspecting children's social services.

Monitoring Healthcare Safety and Quality — Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.

Health Technology Assessment — Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.

Health Information — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Table of Contents

1. Introduction.....	1
2. Findings at Midland Regional Hospital Portlaoise	3
2.1 Governance and risk management.....	3
2.2 Audit and evaluation.....	8
2.3 Medication safety support structures and initiatives	10
2.4 Person-centred care	13
2.5 Policies procedures and guidelines and access to information	14
2.6 Training and education	16
3. Conclusion	18
4. References	20
5. Appendices	24
Appendix 1: Medication safety monitoring programme Phase One: Lines of Enquiry and associated National Standard for Safer Better Healthcare	24

1. Introduction

Medications are the most commonly used intervention in healthcare, and advances in medication usage continue to play a key role in improving patient treatment success. However, where medicines are used, the potential for error, such as in prescribing, administering or monitoring, also exists. While most medication errors do not result in patient harm, medication errors have, in some instances, the potential to result in catastrophic harm or death to patients.

Medication related events were the third most common type of adverse event recorded in the Irish National Adverse Events Study.¹ Medication safety has also been identified internationally as a key focus for improvement in all healthcare settings and it is estimated that on average, at least one medication error per hospital patient occurs each day.²

HIQA's medication safety monitoring programme, which commenced in 2016, aims to examine and positively influence the adoption and implementation of evidence-based practice in public acute hospitals around medication safety. HIQA monitors medication safety against the *National Standards for Safer Better Healthcare*³ to determine if hospitals have effective arrangements in place to protect patients from harm related to medication use.

An expert advisory group was formed to assist with the development of this medication safety monitoring programme. The advisory group membership included patient representation, alongside members with relevant expertise from across the Irish health service. Specific lines of enquiry were developed to facilitate medication safety monitoring. The lines of enquiry which are aligned to HIQA's *National Standards for Safer Better Healthcare* are included in Appendix 1 of this report. Further information can be found in a *Guide to the Health Information and Quality Authority's Medication Safety Monitoring Programme in Public Acute Hospitals 2016*⁴ which is available on HIQA's website: www.hiqa.ie

An announced medication safety inspection was carried out at Midland Regional Hospital Portlaoise by Authorised Persons from HIQA; Dolores Dempsey Ryan and Nora O' Mahony. The inspection was carried out on 28 September 2017 between 10:00hrs and 16:35hrs. Interviews were held in the hospital with the following groups of managers and clinical staff:

- Group one: the Chairperson of Drugs and Therapeutics Committee, the Chief Pharmacist and the Quality and Patient Safety Manager.
- Group two: the Deputy General Manager, the Director of Nursing and the Director of Midwifery.

Inspectors visited the following clinical areas and spoke with staff and reviewed documentation:

- The Medical Ward
- The Paediatric Ward

In addition, a survey was conducted among outpatients in the Outpatients Department.

HIQA would like to acknowledge the cooperation of staff who facilitated and contributed to this announced inspection and the hospital outpatients who completed an anonymised questionnaire.

2. Findings at Midland Regional Hospital Portlaoise

The following sections of this report present the general findings of this announced inspection which are aligned to the inspection lines of enquiry.

2.1 Governance and risk management

Lines of enquiry:

- Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.
- There are arrangements in place to identify report and manage risk related to medication safety throughout the hospital.

The Midland Regional Hospital Portlaoise is an acute general hospital delivering acute, maternity and paediatric services with a co-located Approved Centre providing mental health services on site. The services include elective and emergency adult and children's services on an inpatient, day and outpatient basis. The hospital is part of the Dublin Midlands Hospital Group.

The Midland Regional Hospital Portlaoise had formalised governance arrangements and organisational structures with clear lines of accountability in place to support the safe use of medications.⁵

The hospital had a functional Drugs and Therapeutics Committee that was responsible for the governance and oversight of the hospital's medication management system and for ensuring its safety. The Committee was chaired by a Consultant Physician who was also the hospital's Clinical Director, and comprised multidisciplinary membership to reflect the fact that medicines management was the responsibility of a number of clinical professional groupings.⁶ HIQA confirmed that the Committee meetings were well attended by the majority of members from both the general and obstetric services, with a structured agenda. However, the Committee did not have a representative from anaesthetics, general practice or a community pharmacist. In the absence of a general practitioner (GP) representation and a community pharmacist, inspectors were informed that relevant information was communicated with GP's and local Community Pharmacist's through the hospital's Quality and Patient Safety Manager. Documentation reviewed by inspectors confirmed this.

The Drugs and Therapeutics Committee had updated its terms of reference outlining the objectives, roles, functions, membership, operational issues, agenda and frequency of meetings. While the Drugs and Therapeutics Committee's terms of reference did not detail its reporting structures, inspectors were informed that the

Committee reported into the Quality and Safety Executive Committee that in turn reported to the 'Weekly Management Operations' meetings on a quarterly basis. The hospital reported to the Dublin Midlands Hospital Group at their monthly performance meetings.

For a Drugs and Therapeutics Committee to be effective, there must be a structured drug selection system that is transparent and evidence-based and explicit in its methodology.⁷ Inspectors found that while the Midland Regional Hospital Portlaoise had individualised ward stock drug lists, they did not have a locally approved hospital formulary*. Inspectors found that decisions to add or remove medications to the pharmacy ward stock lists was not guided by written criteria or a formalised application process. Notwithstanding this, the hospital reported at interview that they had an informal process in place whereby a consultant communicated with the Chief Pharmacist and the Drugs and Therapeutics Committee regarding the introduction of a new drug. Concerns around the introduction of a new drug were subsequently reviewed. Documentation viewed by inspectors indicated that discussions had taken place at the Drugs and Therapeutics Committee meetings regarding requests for the addition of new drugs to specific specialities under defined conditions. For example, the approval of a new drug for use in the Emergency Department was recently approved by the Drugs and Therapeutics Committee subjected to the development of a protocol governing its use.

The hospital should now consider as a next step, the development of written criteria supported by a formal application process to ensure that appropriate governance exists with the Drugs and Therapeutics Committee around what is approved for use and that in doing so, a formalised safety evaluation occurs before medications are introduced into practice at the hospital.⁷

The hospital had developed a policy on choosing and introducing generic substitutes to ensure that appropriate generic substitution could take place. In addition, the Antimicrobial Pharmacist provided regular feedback to the Drugs and Therapeutics Committee on antimicrobial stewardship activities.

All medicines must undergo clinical trials before they are granted a licence in Ireland, or in Europe.⁸ Inspectors were informed that currently there were no clinical trials at the hospital, but in line with the Drugs and Therapeutics Committee's terms of reference, the Committee would have oversight of submissions of proposed clinical trials should they occur.

Inspectors found that medication safety was effectively led and coordinated by the Chief Pharmacist with the support of the Drugs and Therapeutics Committee, the

*A formulary is a hospital's preferred list of medicines that staff can use as a reference document to ensure safe and cost-effective prescribing.

Senior Hospital Management Team and healthcare staff at the hospital. Medication safety was a standing agenda item for discussion at the Drug and Therapeutics Committee, the Quality and Safety Executive Committee and the Weekly Management Operations Meetings. This provided governance and oversight on medication related matters to senior hospital management.

The Drug and Therapeutics Committee's agenda was used to inform a medication safety plan for quality improvement initiatives. However, a formal medication safety strategy or medication programme plan for the hospital was not evident at the time of the inspection. Despite this, the hospital had implemented a number of quality improvement initiatives to improve medication safety. The hospital should now look to further progress its work in this area by devising a formalised overarching medication safety strategy and medication programme plan for 2017/18. Such a strategy should not only determine the content of the medication programme, but also advance the achievement of clearly defined objectives. In the absence of national guidance in this area, international guidelines which outlined best practice in relation to medication safety strategic planning and quality improvement planning should be considered.^{9,10}

Risk Management

The main source of medication error surveillance in the Midland Regional Hospital Portlaoise was a voluntary reporting system. The hospital had an established system for reporting and addressing medication errors and near misses. Medication incidents were inputted to the National Incident Management System (NIMS) system[†] and graded using the NIMS classification grading system.¹¹ Each department in the hospital had its own risk register alongside the hospital's risk register.

Documentation provided to inspectors indicated that where risks were recorded on the hospital's risk register, existing and additional controls were identified with the name of the person responsible for actioning same.

Medication incidents were the second highest category of clinical incidents reported in the hospital. The hospital reported that where serious medication incidents were identified, there were managed by a serious incident management team and reported to the Dublin Midlands Hospital Group.

All medication errors were reviewed by the Chief Pharmacist, Quality Patient Safety Manager and the lead non-consultant hospital doctor. Ward staff reported to inspectors that they manually fill in the national incident management form (NIMS) following a medication incident and report the incident to their relevant line

[†] 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).

managers and the Quality and Patient Safety Department. Since 2017, the pharmacy department was piloting an interactive NIMS incident report form for pharmacists to complete, and they planned to roll this system out hospital wide.

Ward staff confirmed that they received feedback on medication incidents relevant to their ward with recommendations and learning on how to improve practices relevant to medication safety.

Important lessons can be learned from analysis and trending of medication-related incidents and near misses. Reporting of incidents is of little value unless the data collected is analysed and recommendations are disseminated.¹² Quarterly medication incident reports were presented to the Drug and Therapeutics Committee and the Quality and Safety Executive Committee. Inspectors were provided with a copy of the medication incident report for quarter one and two for 2017. While this report categorised incidents as negligible, minor and moderate, it had not categorised incidents according to drug class or directorate/ ward in which medication incident/near miss occurred. The report did however; provide a breakdown of the percentages of incidents relating to direct oral anticoagulant medications (DOACs[‡]) and incidents relating to medication reconciliation.

Medication incidents and near misses were tracked, but not sufficiently trended to assess progress, identify emerging medication safety concerns and prioritise medication safety activities. Notwithstanding this, following an analysis of medication incidents in 2016 and 2017 the hospital had identified that a number of detected medication-related incidents related to the use of direct oral anticoagulant medications. A number of risk mitigation strategies had been introduced to address this risk which included:

- a colour sticker to be placed on DOAC packaging in the Pharmacy Department to highlight anticoagulant use
- anticoagulation prescribing tips as part of the intern induction programme
- procedure for pharmacists for reviewing and documenting review of DOAC in-patient prescriptions
- a pharmacy department dispensary queries and interventions sheet to be completed by a pharmacist on receipt of a request for a DOAC drug on a ward requisition book, to provide extra care and expert input over the dispensing of DOAC medicines

Documentation viewed by inspectors indicated that the overall number of medication incidents reported had been 417 in 2015; 232 in 2016 and 108 to date for 2017. Inspectors concluded that there was an overall downward trend in the number of medication incident being reported since 2015. Low numbers of incidents reported

[‡] Direct oral anticoagulants: medication used in the management of venous thromboembolism, which is when a blood clot forms in a vein.

does not necessarily mean a low number of incidents occurring. Studies have found a positive association between incident reporting and safety culture, where an increase in incident reporting was indicative of a positive reporting culture within the hospital.¹³ The hospital reported that medication incident reported had increased throughout 2017 from ten in January to 20 in August 2017. The majority of medication incidents were reported by nurses, midwives and clinical pharmacists. While it was reported that some incidents were also reported by consultant obstetricians and physicians, inspectors formed the opinion that the culture of reporting medication incidents needs to continued to be broadened out to ensure that all healthcare staff consistently report medications incidents so that learning is shared, and safety culture is promoted and enhanced across the organisation. The hospital reported to inspectors that they were working on supporting a culture of reporting with the piloting of an interactive incident NIMS form. In addition, they had provided staff with education sessions and distributed an incident and near miss reporting leaflet 2016 on how to report an incident.

HIQA notes that the overall number of medication incidents reported had declined since 2015. Consequently, further efforts to enhance a greater level of incident reporting should therefore be encouraged following this inspection. The Drugs and Therapeutics Committee should continue to provide leadership, governance and oversight on medication incidents and near misses, and support the implementation of medication safety initiatives.

Medication related incident reporting facilitates the identification of risk and opportunities for improvement. However, on its own it does not provide a complete picture of all potential sources of risk and patient harm. The hospital used a variety of additional information sources to identify strengths and weaknesses in the hospital's medication management system including; audit, direct observation, patient experience survey and nursing and midwifery metrics.

Open disclosure occurs when staff in the health and social care service communicate with patients in an open and honest manner when things go wrong with patient care.¹⁴ Inspectors were informed that the hospital had a process in place to promptly inform patients and their families when medication-related incidents occurred. Examples were provided to inspectors at interview of when this open disclosure policy was adhered to.

2.2 Audit and evaluation

Line of enquiry:

- The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.

Audit represents a key component of all effective clinical governance programmes.¹⁵ Elements of medication safety were audited at the hospital. The hospital reported that while their audit programme was not formalised to link to a medication safety strategy, they had an audit plan for the adult, maternity and paediatric services for 2017.

Inspectors viewed the clinical audit plan for the maternity service for 2017 and noted that audits were identified with a timeframe, a responsible person to complete the audit and the current status of the audit. For example, the audit of oxytocin[§] in practices during labour was ongoing and led to the revision of the policy on the use of oxytocin. Inspectors also viewed the Paediatric Department's clinical audit annual plan for 2016/17 whereby audits were outlined relating to compliance with paediatric guidelines, sepsis audit, safe prescribing, nursing metrics and audit of medication round interruption or distractions.

The hospital had a clinical audit co-ordinator in place and clinical staff had to complete a proposal form to undertake a clinical audit. Documentation viewed by inspectors highlighted that audit recommendations for the maternity service were categorised with regard to training and practices, equipment, communication and resources.

Audit reports and recommendations was an item on the Quality and Safety Executive Committee and the Drug and Therapeutics Committee meetings. This provided oversight on audit practice and recommendations made to the hospital's Senior Management team.

Documentation reviewed showed that some medication-related audits had been undertaken by clinical staff at the hospital which included the following:

- preventing venous thromboembolism** (VTE) prophylaxis in medical patients, part of the National Medication Safety Programme, "Safermeds", which is one of the priority safety programmes within the Health Service Executive (HSE) Quality Improvement Division

[§] Oxytocin used to induce labour or strengthen uterine contractions during labour and to contract uterine muscle after delivery.

^{**} Thromboembolism : when a blood clot breaks loose and travels in the blood

- concentrated potassium ampoule consumption
- audit of compliance with British Thoracic Society Pneumonia Guidelines in paediatrics
- annual antimicrobial point prevalence survey, 2017
- audit of prevalence and compliance of antimicrobial prescriptions
- management of urinary tract infections in medical patients audit
- empirical antimicrobial choice in cases of suspected lower respiratory tract infection - an audit on compliance, 2016
- medicines reconciliation audit
- audit of medication rounds distractions/interruptions, 2017

Inspectors viewed the antimicrobial consumption and prevalence audit for 2016/17. The audit results highlighted that antimicrobial consumption had decreased slightly in 2017 when compared to 2016. The audit results also included prevalence of patients prescribed antimicrobials per medical consultant.

Nursing and midwifery quality care metrics^{††} were monitored monthly across the hospital. These acute, midwifery and paediatric metrics results reflected practices around prescribing, storage and administration of medicines. Metric results viewed by inspectors, over the previous six months, identified compliance of over 80% to 100% in most areas, with the exception of the prescribing metrics. For example, prescribing metrics results varied across the adult, paediatric and midwifery services. While some of the prescribing metrics results in 2017 were greater than 80%, there was however, more improvement required with regard to medication prescription metrics and prescription legibility.

Inspectors noted that the hospital's nursing, paediatric and midwifery metric results were reviewed with action plans being developed relating to specific areas identified for improvement. For example, action plans for September 2017 included a plan to address allergy status on the patient's healthcare documentation not being completed. In addition, feedback on medication metrics had been provided to medical and nursing staff as part of the action plan in September 2017.

HIQA concluded that there was evidence that audit activity throughout the hospital was supported by Senior Hospital Managers and linked to an audit plan across the adult, paediatric and midwifery services. Current medication safety auditing arrangements should be strengthened to formalise the audit plans in the acute, paediatric and maternity services into an overall strategic annual clinical audit forward plan.¹⁵ This should be used to regularly provide assurance to the hospital's Senior Management team about medication safety at the hospital.

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

2.3 Medication safety support structures and initiatives

Line of enquiry:

- Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.

The hospital had implemented quality improvement initiatives aimed at optimising medication safety. Medication safety quality improvement initiatives were strategically driven by learning gained from analysis of medication incidents or near misses. While the hospital had no formal quality improvement plan linked to a medication strategy, there was evidence that quality improvement initiatives such as medication reconciliation, high alert medications and review of the medication administration record were implemented by learning gained from medication incidents. For example, the hospital redesigned the adult medication prescription and administration chart with a section designated to medication reconciliation, antimicrobials, insulin, oral anticoagulant and allergy status in response to medication incidents.

Additional practices to enhance medication safety in the hospital were identified during this inspection. These included the introduction of:

- adult antimicrobial guideline-pocket guide and application⁺⁺
- antimicrobials intravenous administration poster March 2017
- adult intravenous administration monographs for the general wards
- anaphylaxis kits
- standardisation of emergency trays
- sealed bags for the transfer of medications within the hospital
- pre-mixed potassium infusion bags to wards

Interruptions during medication administration rounds are thought to be a prominent causative factor of medication errors.¹⁶ To reduce interruptions, red “do not disturb” tabards were worn by nursing staff while administering medications in a medical ward. This intervention was designed to draw attention to the fact that the medication round was in progress and that nurses should not be interrupted while administering medications. The red apron initiative was underpinned by a ‘procedure for the administration of medication to the adult patient on a medication round using the red apron do not interrupt system’. The effectiveness of this system was evaluated by an audit in May 2017 which highlighted that the overall compliance

⁺⁺ Application is a computer program with an interface, enabling people to use the computer as a tool to accomplish a specific task.

with the procedure was greater than 66% in the adult ward with minimal interruptions. While the red apron had yet to be introduced into the paediatric ward visited, the audit result showed that there was 100% compliance with checking the patient's identification bracelet, allergy status and documenting the patient's weight in the medication administration and administration record.

The hospital was also participating in the Health Service Executive (HSE) Quality Improvement Division venous thromboembolism (VTE) quality improvement collaborative. This is a collaborative among multidisciplinary teams in Irish adult acute public and voluntary hospitals who are working together to achieve appropriate thromboprophylaxis^{§§} for their hospital's inpatients, to reduce the risk of venous thromboembolism and to minimise harm and expenditure associated with unnecessary thromboprophylaxis. The hospital used the plan, do, study, act (PDSA) methodology to drive incremental improvement through this initiative. The initiative led to the introduction of the 'Padua risk score'^{***} system to support thromboprophylaxis prescribing practices.

Evidence-based risk reduction strategies¹⁷ were implemented to reduce unwarranted clinical variation in medication prescribing and administration of high alert drugs. For example, the hospital introduced pre-prepared potassium bags to reduce the risk of error when administering medicines underpinned by a policy on the safe use of intravenous potassium. The hospital had introduced coloured labels for the administration of potassium and intravenous potassium rules governing its administration in line with the potassium intravenous monograph. In addition, the hospital had completed an audit on concentrated potassium ampoule consumption to determine key users of this high alert drug with a focus on reducing consumption. The Drugs and Therapeutics Committee provided oversight through monitoring the usage data of concentrated potassium ampoules. In addition, feedback on the audit findings had been provided to relevant healthcare staff by the pharmacy department.

High-risk medicines can cause significant harm when system errors occur.⁶ The hospital had identified a list of high-alert medicines⁺⁺⁺ used within the organisation, and was taking appropriate actions to ensure that they were stored, prescribed, dispensed and administered safely. For example, drugs such as DOAC and methotrexate were not stored in the wards, as individual patient orders had to be

^{§§} Thromboprophylaxis : any measure taken to prevent thrombosis

^{***} Padua risk score is a risk assessment model for the identification of patients at risk of venous thromboembolism.

⁺⁺⁺ High-Alert Medications are medicines that bear a heightened risk of causing significant patient harm when they are not used correctly. Errors with these medicines may not be more common than those from other groups but their consequences can be more devastating as they have smaller margins of safety than other medications and therefore warrant particular caution in their handling.

checked before the pharmacist released this drug. Additional risk reduction strategies were implemented where a warning label was applied to DOAC boxes when dispensing to ensure it was not administered with another anticoagulant. A flag label with insulin stickers was applied to prefilled pens and vials of insulin. This was underpinned by a procedure for labelling insulin products in the pharmacy department.

In the maternity services, the hospital sought to reduce risk by implementing evidence based risk reduction strategies¹⁷ for oxytocin by stocking one concentration of oxytocin (used to induce and augment labour) and also introduced pre-mixed infusion bags of magnesium (used to treat pre-eclampsia) on the maternity floor.

Inspectors viewed the coloured high alert medications poster 2017 in the clinical area visited which outlined the storage and processes governing the administration of high risk drugs.

Clinical pharmacy services

There are currently no agreed national standards outlining requirements for the provision of clinical pharmacy services in Irish hospitals. However, international studies support the role of clinical pharmacists in hospital wards in preventing adverse drug events.^{18,19,20,21,22,23} The hospital had a clinical pharmacy^{***} service in adult wards allied to an antimicrobial pharmacist service which covered all adult wards. The antimicrobial pharmacist also provided cover to the paediatric ward in the absence of a paediatric clinical pharmacist. The maternity service was covered by a clinical pharmacist on request. All wards including the maternity service had a pharmacy technician service.

At the hospital, clinical pharmacists participated in medication reconciliation, clinical audit activities, developed protocols and engaged with the multidisciplinary team in managing medication use within the hospital. This service was provided from Monday to Friday.

Medication reconciliation

Medicines reconciliation is a formal, systematic process for obtaining a current and accurate list of medicines that the patient was taking when admitted to the hospital, and reconciling this medicines list against the patient's medicines prescribed at admission, transfer and discharge.^{24,25,26,27} Medication reconciliation was formalised, pharmacy-led and supported by a medication reconciliation policy. The hospital had implemented medication reconciliation on admission in the adult inpatient wards.

^{***} Clinical pharmacy describes the activity of pharmacy teams in ward and clinic settings.

The revised medication administration and administration record had a section for medication reconciliation where the patient's medication list was recorded on admission and checked against the medication history source from the family, GP or the community pharmacist. This medication reconciliation service was not provided at patient discharge and this was noted on the hospital risk register.

In the paediatric ward, inspectors were informed that the acute paediatric link nurse would check the medication list on admission for children with long term chronic illness or special needs with the family, GP or community pharmacist as required.

2.4 Person-centred care

Line of enquiry:

- Patients and/or carers are informed about the benefits and associated risks of prescribed medications in a way that is accessible and understandable.

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.^{28, 29}

Inspectors were informed that doctors, nurses and clinical nurse specialists^{§§§} provided education to patients on newly prescribed medication. Patient information leaflets were available at the point of care. A clinical pharmacist would provide education to patients on newly prescribed medication such as DOAC's on request.

As part of the HIQA inspection, HIQA requested that a small sample of patients attending the Outpatient Department complete an anonymised questionnaire in relation to prescribed medications. Twenty patients who had been inpatients in the Midland Regional Hospital Portlaoise within the past year, and who were prescribed regular medications, completed the questionnaire. Of the 20 patients surveyed, 18 patients had been prescribed new medicines, one patient received no information and one patient had not been prescribed any new medicines. Of these 18 patients:

- Fifteen patients said that while in hospital, a staff member had explained the purpose of new medication in a way that they could completely understand.
- Six patients said that prior to discharge from hospital, a staff member told them about the possible medication side effects to look out for following discharge home.

^{§§§} A clinical nurse specialist has specially focused knowledge and skills, required to improve the quality of patient care with a clinical focus on assessment, planning, delivery and evaluation of care given to patients and their families

- Sixteen patients said that they received complete instruction on how to take their medications at home.

It is acknowledged that the sample size of patients who completed the anonymised questionnaire was small, and therefore was not representative of all recently discharged patients taking prescribed medication. However, patient education is an integral component of the safe, effective and cost-effective use of medications. This patient questionnaire did provide some baseline information about outpatients' understanding of their medications and may be used as a focus for further improvement.

2.5 Policies procedures and guidelines and access to information

Lines of enquiry:

- Hospitals develop effective processes for medication management that are implemented and supported by clear and up to date policies, procedures and/or protocols.
- Essential information supporting the safe use of medicines is readily available in a user friendly format and is adhered to when prescribing, dispensing and administering medications.

Medication policies, procedures, protocols and guidelines were readily available to staff through the hospital's intranet system. The hospital reported that they did not have a formal document control management system to manage policies and provide alerts when policies required updating. Despite this, the hospital had a number of policies in place to support safe medication practices relating to administering and dispensing of medications.

Inspectors were informed that these policies, procedures, guidelines and protocols were reviewed and approved by the relevant specialist group^{****} prior to submission to the Drugs and Therapeutics Committee for final approval. While the hospital had a multidisciplinary policy for the administration of intravenous medication to adult service users, the hospital had yet to update their registered nurses and midwives policy 2010 which included a number of policies for the administration of medication.

The hospital acknowledged that some of the hospital medication management policies, procedures, guidelines and protocols were due for review, and had recently appointed a Nurse Practice Development Co-ordinator and clinical skills staff to support policy development and dissemination.

^{****} The hospital had nine specialist groups: surgery, medicine, emergency department, paediatrics, anaesthetic and critical care, pathology, radiology, and maternity.

HIQA concluded that the hospital should continue to strengthen its processes on updating policies and protocols to support medication safety in all areas of the hospital including paediatric and maternity services.

Healthcare staff required access to complete and accurate patient information, relevant to the safe use of medications, at the point of clinical decision making to help ensure patient safety. Clinical staff had access to patient's diagnostic results on computers in clinical areas across the hospital.

Additional sources of medication information were readily available to staff involved in medication use including the:

- British National Formulary
- British National Formulary for Children in print 2016-2017
- adult antimicrobial guideline - pocket guide 2015 and smart phone application
- antimicrobials intravenous administration poster March 2017
- adult intravenous administration monographs for the general wards
- use of the paediatric service nationally approved protocols and applications obtained through the National Network for Paediatric Services³⁰.

The hospital reported to inspectors at interview that they had adopted with permission from Tallaght Hospital the 'Adult Medicines Guide' as an additional resource for prescribers. The hospital's intravenous monographs had also been adapted from Tallaght Hospital. This is a good example of where hospitals who are members of the same hospital group collaborate and share best practices to support medication safety, and also save time by avoiding avoidable replication of work. The maternity services had also adapted the Coombe Women and Infants University Hospital's antimicrobial guidelines. All medicines information had been approved by the Drugs and Therapeutics Committee to support governance and oversight of medicines information available at point of clinical decision making.⁶

Hospital staff were provided with information leaflets on clinical audit and incident and near miss reporting. In addition, a medication management leaflet also provided information to staff on high risk drugs, on how to report a medication incident, open disclosure relevant to a medication incident, medication resources, medication reconciliation and the role of the Drugs and Therapeutics Committee.

The hospital has an established system in place to respond to guidance, alerts, recalls and recommendations issued by regulatory bodies in relation to medication safety. Such information was communicated by the General Manager's office to the Pharmacy Department for circulation to heads of departments. Inspectors viewed a safety alert on risks associated with high-strength insulin from the Irish Medication Safety Network (IMSN) January 2017 circulated by the Pharmacy Department to staff.

Inspectors viewed a poster on a quality improvement initiative to improve 'the communication impact of pharmacy memos'. Nursing staffs' opinions were sought on the efficacy of pharmacy memos. Subsequently, a new coloured memo configuration was implemented in landscape orientation and affixed in all ward clinical areas. This coloured internal memo provided information for example, where the brand of a drug stocked had been changed to a new brand.

2.6 Training and education

Line of enquiry:

- Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.³¹ The hospital reported to inspectors that the hospital did not have a formalised education programme for clinical staff linked to an overall medication safety strategy.

Inspectors were informed that all nursing staff completed the online HSELand Medication Management programme as part of their induction and were required to undertake anaphylaxis training to facilitate the administration of first dose of antimicrobial medications.³² New midwives completed induction training and were also provided with an intensive medication management training programme which included completion a competency assessment tool.

Inspector viewed a timetable for the paediatric nurses' induction programme, which highlighted that they were provided with training on medication safety, the paediatric medication and administration record and drug calculations. In addition, paediatric nursing staff were also provided with additional training on medication by the national children's hospitals as required.

Inspectors were informed that non-consultant hospital doctors⁺⁺⁺ received induction training and were provided with an induction pack which contained information related to medication safety. This training was provided by the hospital's Pharmacy Department. In addition, further education was provided for medical staff at the hospital's Grand Rounds,⁺⁺⁺⁺ monthly master classes and at weekly multidisciplinary

⁺⁺⁺ Non-consultant hospital doctor (NCHD) is a term used in Ireland to describe qualified medical practitioners who work under the (direct or nominal) supervision of a consultant in a particular speciality.

⁺⁺⁺⁺ Grand Rounds describes a formalised meeting system to facilitate the presentation and discussion of clinical cases to hospital consultants and their teams. These meetings focus on patient outcomes, promote collaboration between different medical specialities and act as a training tool and means to educate junior doctors.

team meetings where particular aspects concerning medication safety were presented and discussed. The hospital reported that at the weekly medical multidisciplinary team meetings, information sessions were frequently provided to medical staff by a clinical pharmacist on medications topics, for example DOACs.

New pharmacy staff were provided with induction training underpinned by a procedure for departmental induction for new staff at the Pharmacy Department.

3. Conclusion

Medications represent the primary measure for treatment intervention in hospitalised patients. Errors associated with medication usage constitute one of the major causes of patient harm in hospitals. Medication-related events were the third most common type of adverse event recorded in the recently published Irish National Adverse Events Study.¹ Medication safety should therefore be a priority area for all acute hospitals as they seek to ensure a high quality and safe service for patients.

The Midland Regional Hospital Portlaoise had established governance arrangements in place with systems and processes to support medication safety practices in the hospital. It was evident that this had been progressed over a period of time, driven by effective local leadership and supported by Hospital Management and the Dublin Midlands Hospital Group. HIQA recommends that the hospital continues to collaborate with the Dublin Midlands Hospital Group structure to share good practice pertaining to medication safety and to share learning, experience and resources.

The hospital had an established Drugs and Therapeutics Committee that provided governance and oversight of the medication management safety systems within the hospital. However, inspectors found that while the hospital had ward stock lists of drugs, it did not have a hospital wide drug formulary or written criteria to support the addition or removal of medications from the pharmacy ward stock lists. The hospital should now consider as a next step developing written criteria supported by a formal application process to ensure that appropriate governance exists with the Drugs and Therapeutics Committee around what is approved for use and that in doing so, a formalised safety evaluation occurs before medications are introduced into practice at the hospital.

The Midland Regional Hospital Portlaoise collaborated well with other hospitals within the Dublin Midlands Hospital Group. The hospital provided HIQA with many examples of where they had adapted medicines information protocols and prescribing guidelines from other hospitals within and outside the group to avail of medication protocols to support shared care. These were reviewed and approved by the hospital's Drugs and Therapeutics Committee to support governance and oversight of medicines information available at point of clinical decision making.

The hospital had a system for reporting and addressing medication errors and near misses. However, inspectors found that there was an overall downward trend in the number of medication incident being reported since 2015. The hospital reported that medication incident reporting had increased throughout 2017. Low numbers of incidents reported does not necessarily mean a low number of incidents occurring. The majority of incident reporting was made by nurses, midwives and clinical pharmacists. Therefore, the culture of reporting medication incidents needs to be broadened out to include other healthcare staff particularly medical staff, so that

safety surveillance is improved, learning is shared, and safety culture is promoted and enhanced across the organisation.

HIQA found that the hospital did not have a formal medication safety strategy or medication safety plan in place. Nevertheless, the Drug and Therapeutics Committee's agenda was used to inform a medication safety plan. Inspectors were provided with examples of quality improvement initiatives implemented to improve medication safety practices as a result medication incidents. None of these initiatives are meant to replace vigilance, but each can greatly augment the safety of practice. The hospital should now look to further progress its work in this area by devising a formalised medication safety strategy and plan with clearly defined objectives, prioritised on the basis of identified risk. In the absence of national guidance in this area, international guidelines which outline best practice in relation to medication safety strategic planning and quality improvement should be considered.

The hospital had implemented a number of medication policies, but further work was required with updating policies. In addition, the inspection team was provided with examples of hospital-specific medication safety audits completed in adult, paediatric and maternity services. However, current medication safety auditing arrangements should be strengthened to formalise the audit plans across all services to an overall strategic annual clinical audit forward plan. This should be used to regularly provide assurance to the hospital's Senior Management team about medication safety.

Following this report, the hospital must focus its efforts to address the risks and findings identified in this report, and work to ensure that the necessary arrangements are in place to protect patients from the risk of medication-related harm. It is recommended that this report is shared with senior managers, clinicians and other relevant staff at the Midland Regional Hospital Portlaoise to highlight both what has been achieved by the hospital in implementing medication safety activities to date, and to foster further collective progression from this time point.

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5. Appendices

Appendix 1: Medication safety monitoring programme Phase One: Lines of Enquiry and associated National Standard for Safer Better Healthcare

Area to be explored	Line of enquiry ¹	National Standards for Safer Better Healthcare
Clear lines of accountability and responsibility for medication safety	Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.	3.1, 5.1, 5.2, 5.4, 5.5, 5.6, 5.8, 5.9, 5.10, 7.1
Patient involvement in service delivery	Patients and or carers are informed about the benefits and associated risks of prescribed medicines in a way that is accessible and understandable.	1.4, 1.5, 1.7, 3.1, 4.1
Policies procedures and guidelines	Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.	2.1, 3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.11, 8.1
Risk management	There are arrangements in place to identify, report and manage risk related to medication safety throughout the hospital.	3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.10, 5.11, 8.1
Audit and evaluation	The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.	2.8, 3.1, 5.8, 8.1
Education and training	Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.	6.2, 6.3
Access to information	Essential information of the safe use of medications is readily available in a user-friendly format and is adhered to when prescribing, dispensing and administering medications.	2.5, 8.1

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