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

Date of announced inspection: 26 November 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 Rotunda Hospital by Authorised Persons from HIQA; Emma Cooke and Aoife Lenihan. The inspection was carried out on 26 November 2019 between 09:15hrs and 16:45hrs.

Inspectors met the hospital's master, Professor Fergal Malone, at the outset of this inspection. During the inspection, inspectors spoke with staff, reviewed documentation and observed systems in place for medication safety during visits to the following clinical areas:

- Postnatal ward
- Theatre department.

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

- Group one: representatives of the Adult and Neonatal Medication Safety Committee, the chief pharmacist, the risk manager.
- Group two: the general manager and the clinical director.

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

Information about the hospital

The Rotunda Hospital is a stand-alone specialist maternity hospital and is a tertiary referral centre for maternity services including maternal fetal medicine, gynaecology and neonatal services.

2. Findings at Rotunda Hospital

Section 2 of this report presents the general findings of this announced inspection.

The inspection findings are outlined under each of the eight lines of enquiry and opportunities for improvement are highlighted at the end of each section.

2.1 Leadership, governance and management

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

The Rotunda Hospital had formalised governance arrangements and organisational structures with clear lines of accountability in place to support the safe use of medications.[15]

The hospital had an established Drugs and Therapeutics Committee in place with responsibility for overseeing all processes relating to medication safety in the hospital. The Drugs and Therapeutics Committee reported to the hospital's Quality and Safety Committee. The Quality and Safety Committee was operationally accountable to the Executive Management Team, and through the Master, reported to the hospital board's subcommittees which included the Risk Committee and the General Purpose Committee. Medication safety was a standing agenda item for discussion at the Drug and Therapeutics, the Clinical Risk and the Quality and Safety Committees. Documentation reviewed by inspectors showed that medication related updates and indicators were included in the monthly Master's report.

Operational implementation of the medication safety programme was effectively led and overseen by two multidisciplinary teams, an adult medication safety team and a separate neonatal medication safety team. Both teams reported to the hospital's Drugs and Therapeutics Committee.

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 hospital had a medication safety strategy for 2016-2020 which included three overall objectives and seven long term goals. To support the implementation of the strategy, the hospital had developed an adult and neonatal medication safety operational plan for each year. Inspectors found that the majority of the goals set out for both operational plans for 2019 had been actively progressed. One of the biggest objectives achieved within this strategy since the last inspection was the implementation of the Maternal and Newborn Clinical Management System (MN-CMS), an Electronic Health Record (EHR) for all women and babies who access Maternity Services in Ireland. To support the implementation

of this, the hospital had set up an MN-CMS medication safety working group to support safe medication use processes in MN-CMS for maternal, newborn and gynaecological care with multidisciplinary collaboration to assess risk, improve quality and eliminate medication-related avoidable harm.

Overall, inspectors found that the Rotunda Hospital had formalised leadership, governance and management arrangements in place with clearly defined reporting structures for medication safety.

2.2 Risk management

The Rotunda Hospital had arrangements in place to proactively identify, report and manage risk related to medication safety throughout the hospital. Medication-related risks requiring additional control measures were documented on the hospital's corporate risk register. Hospital management reported the following key medication-related risks:

- increase in oxytocin administration errors

- intravenous infiltration in the neonatal intensive care unit

- medication errors in neonatal intensive care unit.

The risk register detailed the control measures in place to mitigate against the risk, person responsible for actions and an expected completion date. Inspectors were informed that risks that could not be managed at a local level were escalated to the Royal College of Surgeons Ireland (RCSI) Hospital Group.

Consistent with HIQA's previous inspection, inspectors found that there was an established system in place for the reporting of medication safety incidents at the hospital. High incident reporting rates are generally associated nationally and internationally with a strong patient safety culture.[18] A total of 265 medication incidents were reported in 2018 which showed an increase from 171 incidents reported in 2017 and 155 incidents reported in 2016 (see figure 1).

Inspectors were informed that despite recent success in improving incident reporting rates, medication-related near misses were still likely under reported at the hospital. The hospital had plans in place to develop a 'good catch system'[§] to increase the reporting of medication-related near misses and had recently developed a good catch template. Reporting a 'good catch' has a positive effect on patients, staff and

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§ ₊A good catch is recognition by staff of a condition or situation that had the potential to cause a medication safety incident but did not cause one due to corrective action and/or timely intervention by the staff member.

the hospital as it presents an opportunity to take corrective action and reduce the risk of future harm.

Medication safety activity and performance measures were reported by the Drugs and Therapeutics Committee to the Hospital's Executive Management Team and the Board of Governors through the Hospital's Quality and Safety Committee. Inspectors were informed that regular scheduled multidisciplinary meetings were held with risk management and senior management, to discuss medication incident reports, review recurring trends and identify key areas for improvement. Medication incidents[**] that occurred in the hospital were reported to the State Claims Agency using the National Incident Management System[††](NIMS).[19]

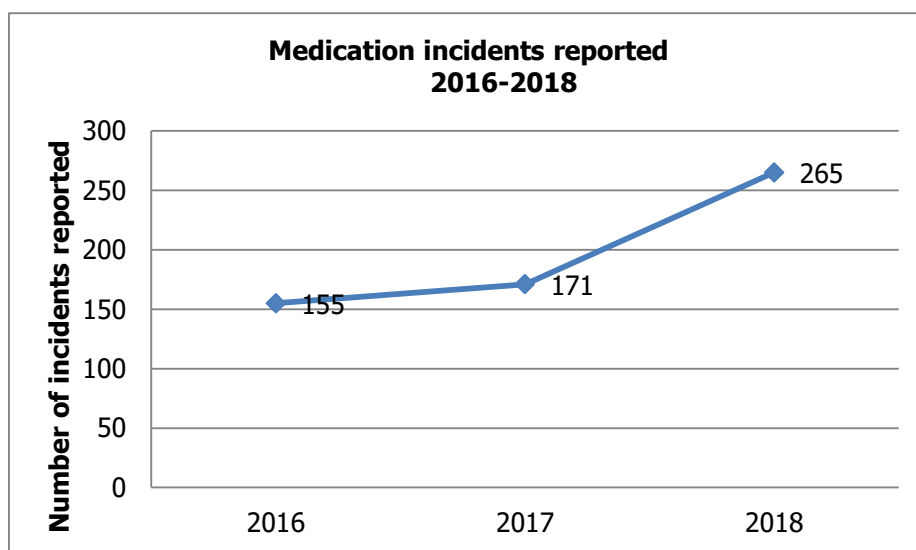**Medication incidents reported 2016-2018**

Figure 1. Medication incidents reported 2016 to 2018

Analysis of incidents

The reporting of incidents is of little value unless the data collected is analysed to identify trends or patterns in relation to risk and the resulting recommendations for improvement are shared with frontline staff.[21] Medication variance reports reviewed by inspectors showed that medication incidents were trended and analysed based on numbers, location of incident and occurrence of incident within the medication management process. Reports also outlined the top five medication safety incidents at the hospital. The hospital used this information to inform practice changes and target medication safety education sessions.

[**] 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).

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] Inspectors were informed that the chief pharmacist disseminated quarterly medication safety reports throughout the hospital. Staff in the clinical areas reported that the clinical risk and safety manager or clinical risk co-ordinator often attended morning ward huddles to provide direct feedback to staff on incidents which had occurred.

The hospital had undertaken a number of proactive risk assessments in response to near miss medication incidents. The hospital had adapted the Institute for Safe Medication Practices (ISMP) Assess-ERR Medication System Worksheets[‡‡] [22] and developed a template for collecting key information from a medication safety incident or near miss. The purpose of the template was to provide a standardised approach to assessing the incident and identify opportunities for improvement. Examples of completed forms viewed by inspectors outlined potential short, medium and long term risk reduction strategies that could be implemented to prevent a near miss from re-occurring.

The hospital's Senior Incident Review Team also reviewed medication-related risks or adverse incidents when required. Inspectors were informed that the hospital had recently convened a meeting to review and identify any learning opportunities in response to an incident which had occurred external to the hospital.

Alerts and recalls

The pharmacy department received and acted on alerts and recalls[§§] related to medication. An example of the action taken in response to a recent alert was outlined to inspectors.

Opportunities for improvement

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

[‡‡] The **Assess-ERR™** Medication System Worksheets are designed to help with error report investigations by collecting critical information in a standarised approach after a medication error or near-miss occurs and helps to reveal the underlying system deficiencies that contributed to the error.
[§§] Recalls are actions taken by a company to remove a product from the market. Recalls may be conducted on a firm's own initiative or by authorised authority.
[***] The framework of a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace.

2.3 High-risk medications and situations

The Rotunda Hospital had developed a comprehensive high-risk medications list, using international literature and locally identified high-risk medications. The list had also been informed by medication safety incidents which occurred at the hospital. As the high-risk list incorporated up to 19 medication groups, inspectors were informed that the hospital was implementing a combination of associated risk-reduction strategies [†††] on a phased basis and that some had already been effectively implemented which were observed by inspectors in practice. High-risk medication lists were displayed in the clinical areas inspected and staff who spoke with inspectors had an awareness of the high-risk medications available in their clinical areas and the risk-reduction strategies in place.

Women who do not usually take medications may develop certain conditions related to pregnancy which requires treatment with certain high-risk medications. The following sample of high-risk medications were reviewed in detail during this inspection to identify the risk-reduction strategies in place:

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

Insulin

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

- the term 'units' was pre populated on the electronic medication administration record to support safe prescribing of insulin

- a high-risk alert for insulin was built into the electronic medication administration record

- insulin was double checked prior to administration

- the hospital had a hypoglycaemic box[§§§] which contained instructions for staff to manage a hypoglycaemic[****] episode

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[†††] Risk reduction strategies: a term used to describe different ways of dealing with risks. Strategies include risk avoidance, transfer, elimination, sharing and reducing to an acceptable level.
[‡‡‡] 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.
[§§§] Hypoglycaemic box: 'Hypo box' provides quick access to equipment required to support effective treatment for patients in the event of hypoglycaemia.
[****] Hypoglycaemic: when a person's blood sugar falls below the normal level.

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

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

Inspectors were informed that women were encouraged to retain their own insulin pens and were provided with labels to ensure they were labelled in accordance with hospital policy.

Inspectors viewed person specific insulin care plans that had been put in place at a pre-assessment clinic. Care plans outlined insulin regimes which had been ordered to support the management of blood sugar levels before, during and after birth.

The hospital had established an insulin working group with the aim of optimising insulin medication use processes, including resolving difficulties in getting insulin charted promptly for unexpected antenatal admissions where the insulin requirement may change frequently.

Anticoagulants

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

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

- the hospital had chosen only one low molecular weight heparin[††††] for use in the hospital however another type was only available from pharmacy in the event of short supply

- the hospital had developed an electronic venous thromboembolism (VTE) risk assessment tool 'thrombocalc' [‡‡‡‡][23]to facilitate safe, weight-based prescribing of low molecular weight heparin

- the storage of unfractionated heparin was restricted to certain areas such as pharmacy, neonatal intensive care unit and theatre department

- the hospital had recently created an alert for the electronic healthcare record for inpatients receiving anticoagulants. The rule was designed to alert users if no thrombocalc assessment was recorded for a woman

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[††††] Heparin is an anticoagulant specifically used in the initial treatment and prevention of deep vein thrombosis, pulmonary embolism, and arterial thromboembolism.
[‡‡‡‡] Thrombocalc was designed as a score-based tool to facilitate rapid assessment of all women after childbirth. Calculation of a total score estimates risk of venous thromboembolism in line with consensus guidelines.

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

The hospital had established a thromboprophylaxis committee which was led by the consultant haematologist. The committee reviewed the management of thromboprophylaxis at the hospital and used audit findings to make recommendations and inform practice changes on the duration of thromboprophylaxis for women at the hospital.

Antimicrobials

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

- staff had access to dosing and monitoring guidance for locally identified adult and neonatal antimicrobials

- an electronic dose calculator was available on the electronic healthcare record

- a pharmacy worklist was automatically generated from the electronic healthcare record system which enabled clinical pharmacists to identify women and infants receiving intravenous antibiotics so a clinical pharmacy review could be prioritised.

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

Medication management during the perioperative period

A hospital's operating theatre presents a unique situation with the use of multiple high-risk medications, high patient throughput and complex procedures.[24] A diverse range of medications are used which have the potential for a serious adverse event if administered incorrectly.[25] Therefore, the perioperative period is a high-risk situation in relation to medication safety.

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

- medications were drawn up by the person who will administer them
- international colour-coded labeling of drawn up medications applied in practice
- medications were stored in a standard and organized manner to support safe selection

- colour-coded administration pumps were used to differentiate modes of administration such as oxytocin pumps, epidural pumps and patient controlled analgesia pumps
- emergency drugs were drawn up by the on-call anaesthesiologist at the start of each day, labelled and stored in a separate tray and disposed of at the end of each shift.
- the hospital used some prefilled syringes for medications

There was evidence of good communication regarding medications administered at transitions of care throughout the perioperative patient pathway. In response to a number of incidents associated with the documentation and administration of vitamin K at the transition of care from the delivery suite to post-natal, the hospital had developed an alert for the electronic healthcare record to prompt staff to check and clarify if Vitamin K had been prescribed or administered.

Other high-risk medications

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

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

Alerts were created for women with complex medical histories. These were often placed by the pharmacy department in advance of women attending the hospital following discussion at multidisciplinary meetings. This enabled early identification and prioritisation for women who required a clinical pharmacy review.

The hospital did not identify a list of sound-alike look-alike drugs (SALADs)[§§§§], however inspectors were provided with SALAD posters which had been circulated to the clinical areas and included information on how to reduce the risk of error when prescribing and administering SALADs such as; writing clearly in block capitals, including the indication for the medication when prescribing and minimising close storage of similar packaging. Inspectors also viewed examples of SALAD stickers in some of the clinical areas inspected.

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

Weight based order sentences had been implemented for some medications as a forcing function for prescribers on the electronic administration record.

The electronic healthcare record incorporated a number of decision support tools. These included;

- pre-written prescriptions and groups of orders for specific indications (care plans). These were age and weight specific and provided dosage guidance for commonly prescribed medications such as intravenous paracetamol.

- prescribing of medications could not take place without documenting measured or estimated weight and allergy checking

- high alert medication classification and customised alerts.

Overall, the Rotunda Hospital had implemented evidence-based safety measures for high-risk medications. It was evident that the implementation of the electronic healthcare record had enabled the hospital to identify women at higher risk and prioritise their care and medication safety needs. Furthermore, the hospital had acted on issues identified with the administration of medications at transition of care and medication incident reports and had implemented high leverage forcing functions ***** such as automation and computerisation of the medication management process to improve practices with medication safety at the hospital. Consideration had also been given to the number of alerts in use to prevent alert fatigue†††††.

Opportunities for improvement

- The hospital should continue to progress the implementation of risk reduction strategies for all high-risk medications identified on the hospital's high-risk list.

2.4 Person centred care and support

Women attending a maternity service should be well informed about any medications they are prescribed and any possible side effects. This is particularly relevant for those women who are taking multiple medications.[26, 27]

***** Forcing functions: are design processes so errors are virtually impossible to make.
††††† Alert fatigue: describes how healthcare clinicians become desensitised to safety alerts, and as a result ignore or fail to respond appropriately to such warnings.

Patient information

Inspectors were informed that information about medications was provided by midwives, nurses, clinical pharmacists and medical staff. Information leaflets on anticoagulants were available in some of the clinical areas inspected.

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.[28, 29,30]

Formal medication reconciliation was not consistently performed for all women in all clinical areas on admission and discharge. It was explained that key elements of the process were in place and supported by the electronic healthcare record and that clinical pharmacists, midwives or prescribers would aim to complete a medication history for every woman on admission. Inspectors were informed that women with complex medical conditions were currently being prioritised for review.

A medication reconciliation audit had been completed at the hospital in 2017 which included a review of 50 healthcare records. Findings demonstrated that only 21% of women had their current medications matching their medication administration record. The audit concluded that there was significant room for improvement at the hospital in relation to medication reconciliation.

In response to audit findings a multidisciplinary working group had been established to assess issues relating to medication reconciliation in the electronic healthcare record and progress the implementation of medication reconciliation at the hospital. A number of quick reference guides had been developed by the pharmacy department to support staff with completing a medication history on admission and discharge on the electronic healthcare record system. In addition, the medication reconciliation process had been integrated into clinical scenario based training which all NCHDs received at induction.

Systems to support medication safety and optimisation

The Rotunda Hospital had multiple systems in place to support medication safety and optimisation including:

- electronic health records which facilitated identification of high risk women
- documented medication history for all women
- participation of pharmacists in Maternal Medicine Multidisciplinary Team Meetings and proactive identification of patients who require additional pharmacy input
- neonatal discharge medication service
- alert system in place for pharmacy team to notify when women with complex needs have been admitted facilitating targeted medication reconciliation

- neonatal infusion label generator to minimize the risk of transcription errors
- the use of smart pump technology with medication libraries to facilitate the safe administration of neonatal standard concentration infusions, oxytocin and magnesium sulphate.

Patient weight measurements are important for medications that require an individual weight-based dose.[31] Patient weights and allergies were documented on all electronic medication records reviewed by inspectors during the inspection. The electronic medication prescription administration record system was designed so that no medication could be prescribed unless weight and allergies were recorded.

Opportunities for improvement

- The hospital needs to work towards establishing medication reconciliation for all women on admission, and progress towards the development of this service to include patients on discharge.

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] The Rotunda Hospital had 6.5 WTE clinical pharmacists. A clinical pharmacy service was provided to almost all clinical areas apart from the delivery suite and operating theatre.

Since the last inspection, the hospital board had funded the initial development of the Irish Medicines in Pregnancy Service (IMPS) and the hospital had recruited a senior pharmacist to this role in October 2019. The service consists of a multidisciplinary team that aims to support safe and effective medication use in pregnancy and breastfeeding through clear, evidence-based risk communication. Although based at the Rotunda Hospital, inspectors were informed that the hospital's strategic plan is to provide a national service acting as an information resource for maternity services throughout the country and advocating for the safe and effective use of medicines in pregnancy.

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‡‡‡‡‡ 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 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]

The establishment of a hospital formulary in which selected medications are based on safety rather than cost had been identified as a long term goal within the medication safety strategy. The hospital had a system in place for the approval of new medications which was under the governance of the Drugs and Therapeutic Committee. Documentation reviewed by inspectors outlined discussion and decisions on new medication applications. The hospital should continue to progress the work identified for the hospital formulary as set out in the medication safety strategy.

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]

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

- intravenous medication monographs***
- RCSI antimicrobial App
- standardised treatment protocols
- British National Formulary
- British National Formulary for children.

Inspectors observed that some medication information and decision support tools were automatically available within the electronic medication prescription and administration record. For example, when prescribing, certain information and requirements for the medication automatically displayed to guide prescribers.

It is recommended, by both the Health Service Executive[40] and the National Clinical Effectiveness Committee [41] that policies, procedures and guidelines are reviewed and updated every three years. The majority of medication related policies, procedure and guidelines viewed by inspectors during the inspection were up-to-date.

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

2.7 Monitoring and evaluation

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

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

- medication reconciliation audit for babies transferred into the neonatal intensive care unit
- drug chart compliance with medication management policy
- clinical audit of intra-operative use of prophylactic anti-emetics for caesarean delivery under regional anaesthesia
- evaluation of clinical work-flow before implementation of electronic health record to identify potential risk to patient safety
- an audit of the level of compliance with hospital prescribing guidelines on the neonatal intensive care unit.

The Clinical Audit Department at the Rotunda Hospital ensured that clinical audit was centrally controlled and that audit activity was a cyclical process.[42] The hospital had an audit list for 2018 and had also identified completed audits which required re-auditing. It was explained that some audits were prioritised based on hospital need and others were selected based on individual choice. Inspectors were informed that a new process had been applied to medication safety-related audits whereby the pharmacy department is notified when medication-related audits are planned and if there are any relevant recommendations.

Minutes of the Drugs and Therapeutics Committee reviewed by inspectors outlined discussion on medication safety audits. Clinical audit activity reports were also submitted monthly to the Quality and Safety Committee and bi-annually to the Board of Governors. Updates of audit activity were shared locally via journal clubs and clinical handovers. Twice yearly audit days were held where staff were encouraged to present an overview of audits they had undertaken.

Evidence was submitted and reviewed by inspectors which verified that clinical audit activities had led to changes aimed at improving the delivery of clinical services.

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

- number of medication safety incidents reported

- clinical pharmacy review data

- midwifery and nursing quality care metrics******[43]

Midwifery metrics†††††† were monitored across the hospital to review practice around some aspects of medication storage, prescription and administration. Inspectors noted incremental improvements in prescribing and administration metrics for 2018.

Pharmacy review data provided information on the number of women who had received a pharmacy review while at the hospital. This information was recorded on every woman's electronic healthcare record with oversight and accountability of the process assigned to the Chief Pharmacist.

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

Opportunities for improvement

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

2.8 Education and training

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.[44]

Inspectors were informed that non consultant hospital doctors received a one hour medication safety session from the Pharmacy Department. NCHDs also attended weekly journal clubs which covered aspects of medication safety.

All midwifery and nursing staff in identified clinical areas were required to complete an intravenous medication workshop and the Health Service Executive medication management online training programme.[45] Training records provided to inspectors identified that there was significant improvement required in the uptake of mandatory medication training for midwives and nurses within the hospital. Hospital management must ensure that the necessary arrangements are put in place to support staff in attending mandatory medication safety training.

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

To support the implementation of the Maternal and Newborn Clinical Management System, the hospital had delivered a comprehensive staff training programme for implementation of the new system. Clinical pharmacists were allocated the role of 'super users' and had received two full days training to support them in their role. NCHD's also received weekly bulletins from the MN CMS office in relation to any issues or trends identified in relation to prescribing.

A regular pharmacy staff journal club[++++++] included patient case studies, medication safety initiatives, new developments and clinical audit at the hospital.

Opportunity for improvement

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

[++++++] A journal club has been defined as an educational meeting in which a group of individuals discuss current articles, providing a forum for a collective effort to keep up with the literature.

2. Summary and conclusion

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

The Rotunda Hospital had a well established medication safety programme in place. The hospital had set clear objectives for medication safety outlined in a medication safety strategy with short, medium and long term operational plans in place to support the implementation of the strategy. Progress with medication safety plans was evident to inspectors during this inspection and it was clear that medication safety was prioritised at executive level in the hospital with strong leadership from the Chief Pharmacist.

The hospital had identified high-risk medications with a combination of risk-reduction strategies in place appropriate to the services provided by the hospital. It was evident that implementation of the electronic healthcare record had enabled the hospital to apply many high leverage forcing functions for high-risk medications. Furthermore, it enabled the identification of high risk women so that their care and medication safety needs could be prioritised. The hospital should continue to progress the implementation of risk-reduction strategies for all high-risk medications identified on the hospital's high-risk list.

Rotunda Hospital used a variety of information sources to identify strengths and weaknesses in the hospital medication management system including medication-related incident reporting, proactive risk assessments, pharmacy intervention review, clinical audit and electronic healthcare record data. The hospital had acted on issues identified with the administration of medications at transition of care and medication incident reports and had implemented high leverage forcing functions to improve practices associated with medication safety at the hospital. The hospital needs to work towards establishing medication reconciliation for all women on admission, and progress towards the development of this service to include patients on discharge.

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

Overall, it was apparent that the implementation of the electronic healthcare record had greatly facilitated better medication safety intelligence and improved medication

safety at the hospital. However, it was reported that the system had potential for greater impact on medication safety by linking the hospital electronic patient record with existing smart pump technology purchased but this could not be advanced due to funding issues.

This report should be shared with relevant staff at the Rotunda Hospital and the Royal College of Surgeons in Ireland Hospital Group to highlight the findings from this inspection including what has been achieved to date and to foster collaboration in relation to opportunities for improvement.

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

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4. Appendices

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

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

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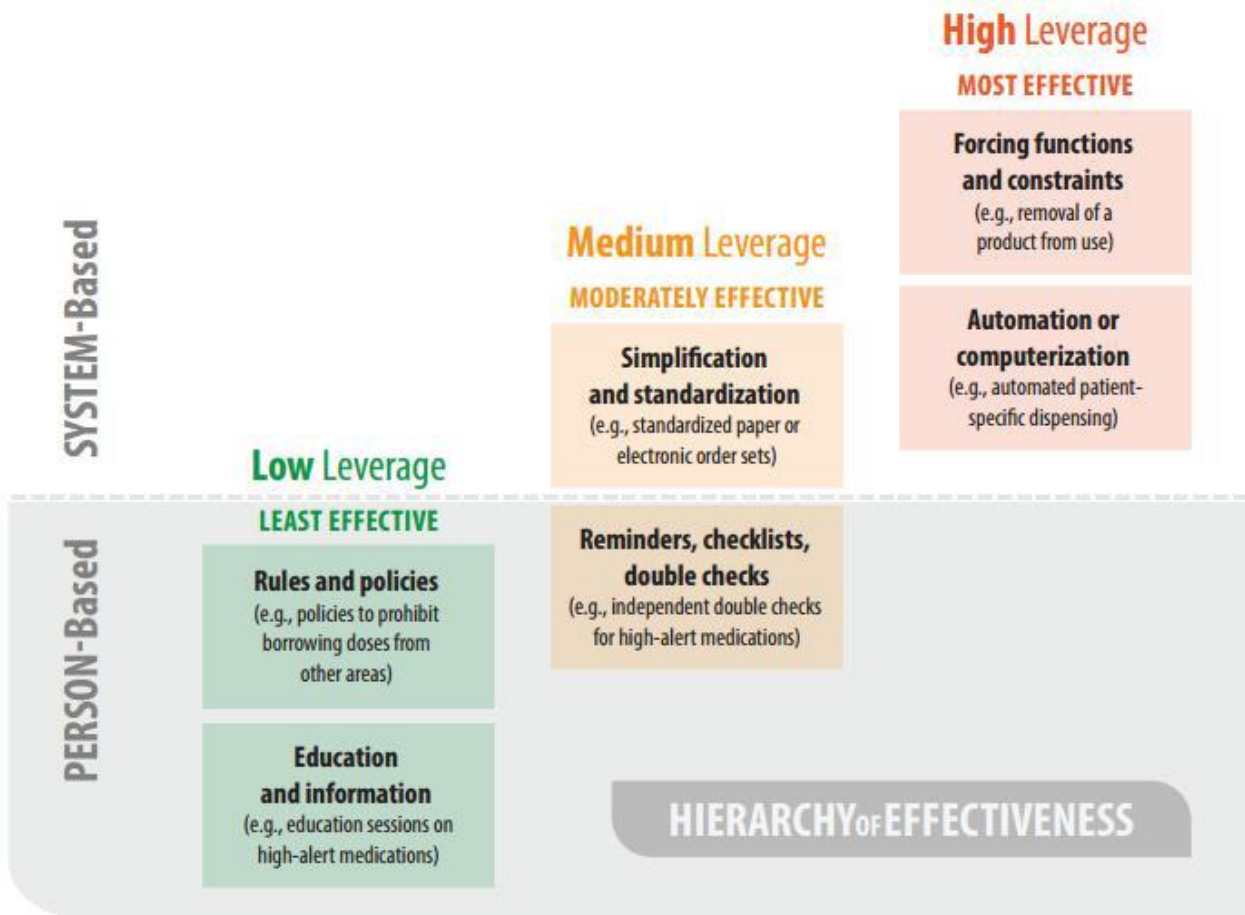
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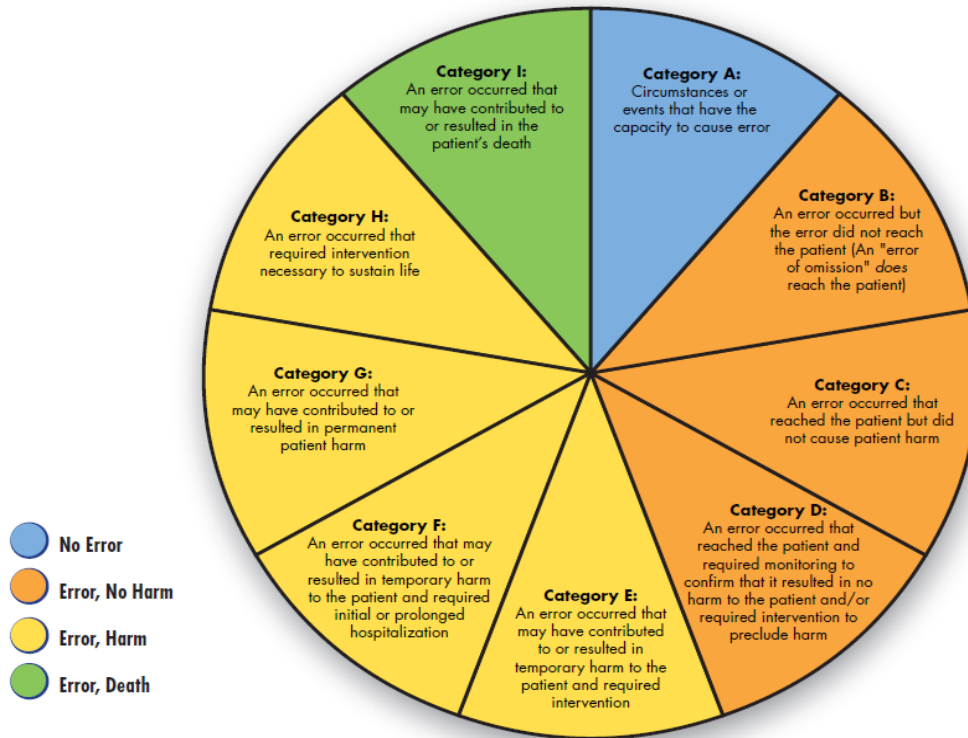
Definitions

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.)