



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

# **Report of the announced inspection of medication safety at St Luke's General Hospital, Kilkenny.**

**Date of announced inspection:  
11 October 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.



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## **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.<sup>1</sup> 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.<sup>2</sup>

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*<sup>3</sup> 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*<sup>4</sup> which is available on HIQA's website: [www.hiqa.ie](http://www.hiqa.ie)

An announced medication safety inspection was carried out at St Luke's General Hospital, Kilkenny by Authorised Persons from HIQA; Kathryn Hanly, Dolores Dempsey Ryan and Nora O'Mahony. The inspection was carried out on 11 October 2017 between 10.00hrs and 16.30hrs. 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 Clinical Risk Manager.
- Group two: the General Manager, the Clinical Director and two Assistant Directors of Nursing (deputising for the Director of Nursing).

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

- Paediatric Ward
- Medical 1

In addition, a survey was conducted among outpatients in the Outpatient's 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 St Luke's General Hospital, Kilkenny**

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.

St Luke's General Hospital, Kilkenny is a statutory hospital owned and managed by the Health Service Executive (HSE) and is part of the Ireland East Hospital Group\* governance structure.

An organogram provided to HIQA showed that the Drugs and Therapeutics Committee had a direct reporting line to the hospital's Quality and Safety Committee who in turn reported into the Executive Management Team which included the General Manager. The General Manager as the person with overall accountability and responsibility for the hospital, reported to the Ireland East Hospital Group Chief Executive Officer.

However, a review of the minutes from the Drugs and Therapeutics Committee meetings indicated that the Quality and Safety Committee did not receive regular structured feedback from the Drugs and Therapeutics Committee. Inspectors were informed that the scope and function of the Quality and Safety Committee was under review with the Drug and Therapeutics Committee meeting report to be added as a standing item on the agenda.

The Drugs and Therapeutics Committee was chaired by a Consultant Endocrinologist and was composed of physicians, pharmacists, nurses and other representative staff who were involved in the medication-use process.<sup>5</sup> A review of the minutes indicated that the Committee did not have representation in attendance from obstetrics, surgery, general practice (GP) or a community pharmacy. Minutes from the Drugs and Therapeutics Committee meetings indicated that the Committee had reviewed attendance at meetings with the aim of ensuring greater and more consistent

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\* The Ireland East Hospital Group comprises 11 hospitals operating across the counties Dublin, Westmeath, Meath, Wexford and Kilkenny . This group is led by a Group Executive Officer with delegated authority to manage statutory hospitals within the group under the Health Act 2004.

representation from required stakeholders as listed in the Committee's terms of reference.

In the absence of GP attendance, inspectors were informed that relevant information was communicated with GPs through the GP liaison committee meetings. The Chief Pharmacist attended these meetings.

Evaluation of medications, with a view to adding or removing them from the formulary, is an important function of a Drugs and Therapeutics Committee.<sup>5</sup> The Drugs and Therapeutics Committee had recently developed a process for assessing and evaluating requests for the supply of new medications. However, at the time of the inspection, there was no evidence to indicate that requests for new medicines had been discussed at Drugs and Therapeutics Committee meetings.

An up-to-date local approved medication formulary did not exist in the hospital at the time of this inspection. The purpose of maintaining a hospital formulary is to ensure that appropriate governance exists around what is approved for use and that in doing so, a proper safety evaluation occurs before medications are introduced into practice at the hospital.<sup>6</sup> While the hospital did not have a formulary, inspectors were given examples of where the hospital minimised unnecessary duplication of the same basic drug type, drug entity, or drug product. For example the hospital had optimised the number of proton pump inhibitors (PPIs)<sup>†</sup> available to prescribers in the hospital. Optimising the number of medications and products available from the pharmacy can produce both safer patient care and financial benefits.<sup>7</sup>

Generic medicines provide an opportunity for savings on expenditure on medicines due to their typically lower price. Inspectors were informed that policies promoting pharmacist led generic substitution of medications based on interchangeability at active substance level had been introduced in the hospital 20 years ago.

All medicines must undergo clinical trials before they are granted a licence in Ireland, or in Europe.<sup>8</sup> However, the Drugs and Therapeutics Committee was not formally notified of clinical trials involving medication occurring within the hospital. It is recommended that Drugs and Therapeutics Committees should have a role in assessing the risks of clinical trials to the hospital other than the ethical considerations.<sup>5</sup>

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<sup>†</sup> Proton pump inhibitors (PPIs) treat heartburn and other symptoms caused by gastroesophageal reflux disease.

## **Medication Safety Programme**

The hospital's medication safety programme was formally overseen by the recently formed Medication Safety Committee. This Committee was chaired by the Clinical Risk Manager and reported into the Drugs and Therapeutic Committee under a regular agenda item.

It was reported that the medication safety programme was in the early stages of development. A draft medication safety programme for 2018 had been developed. It is recommended that the Medication Safety Committee at the hospital is well supported as it is being established and embeds within the hospital.

St Luke's General Hospital did not have a formalised medium to long-term medication safety strategy; however it was evident that the medication safety agenda was being actively progressed at the hospital through the Pharmacy Department's quality improvement service plan for 2017. There was evidence that this quality improvement plan for medication safety was reviewed and updated on a regular basis.

To avoid duplicated effort, the Medication Safety Committee and Pharmacy Department should look to further progress their work in this area by adopting a hospital wide medication safety programme with a single, coordinated agenda. The Pharmacy Department's quality improvement service plan should be integrated into the hospital's overall medication safety programme. 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 should be used.<sup>9,10</sup>

It was reported that St Luke's General Hospital was also represented in the recently formed Ireland East Hospitals' Chief Pharmacists' group. This group had met four times to date. While this structure is a welcome development, senior managers at the hospital reported that there was potential to further improve information sharing, learning and support within the group.

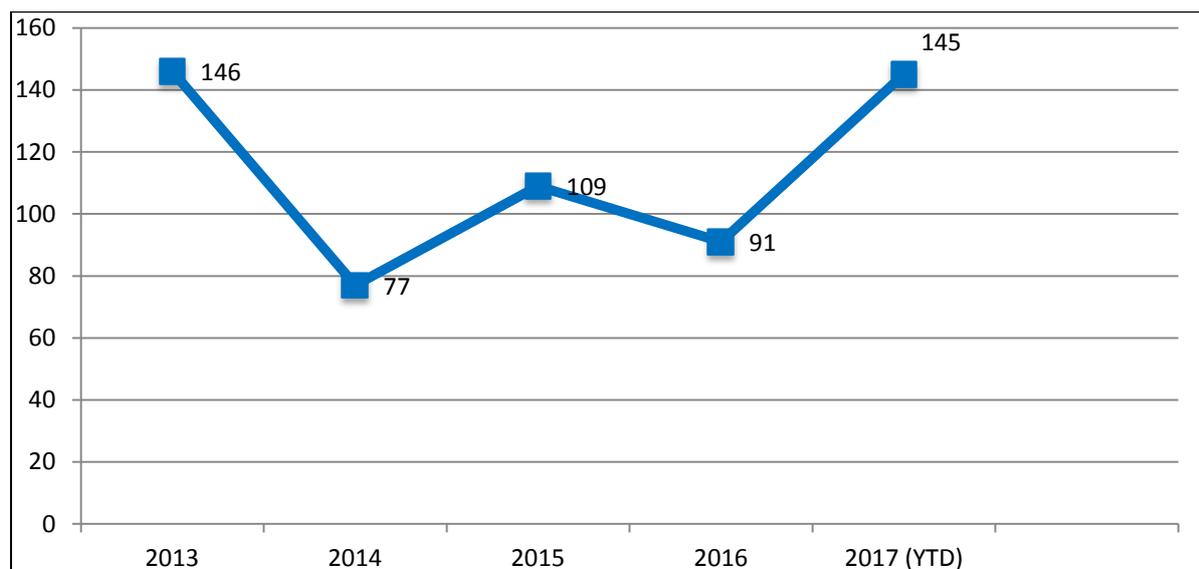
## **Risk Management**

Inspectors were informed that medication incidents were discussed at the Medication Safety Committee meetings. It was confirmed at interview, and verified in the documentation which was reviewed, that clinical risk management was a standing agenda item on the Quality and Safety Committee meeting agenda. All high risks were escalated to the hospital's Quality and Patient Safety Executive Committee while serious incidents were also escalated directly to the Executive Management Team.

Higher incident reporting rates both demonstrate and promote an improved culture of safety.<sup>11</sup> Senior management recognised that the current level of medication

incident reporting was not in line with internationally accepted norms and had committed to increasing reporting from 10 incidents per 10,000 bed days to 40 incidents per 10,000 bed days in 2017. A record of medication incident reporting from 2013 - 2017 highlighted a downward trend in reporting from 2014 to 2016 with a notable increase in 2017 (figure 1).

**Figure 1: Number of medication safety incident and near miss reports received annually in St Luke's Hospital, Kilkenny 2013 - 2017 (Year to date)**



A new dedicated, paper based medication incident reporting form had been piloted and was due to be launched in October 2017 with the view of further improving the reporting of medication incidents including near misses. The creation of positive medication error and adverse drug reaction reporting culture is an important step in enabling hospitals to tackle medication safety risks to their patients.

HIQA notes that notwithstanding the recent positive trend in reporting, the majority of reports were submitted by clinical pharmacists and nursing staff with limited evidence available to suggest that medical staff were reporting medication incidents. Therefore, the culture of reporting medication incidents needs to be broadened out to include other healthcare staff so that safety surveillance is improved, learning is shared, and safety culture is promoted and enhanced across the organisation.

The Pharmacy Department graded all medication incidents using the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) Medication Error Index to categorise incidents in terms of patient harm (appendix 2). The index considered factors such as whether the error reached the patient and, if the patient was harmed, to what degree. It was reported that the hospital

inputted all medication incidents and near misses reported within the hospital to the National Incident Management System<sup>‡</sup>.

Reporting of incidents is of little value unless the data collected is analysed and recommendations are disseminated. Medication incidents and near misses were tracked and trended to assess progress, identify emergent medication safety concerns and prioritise medication safety activities. Through this process the hospital had identified that direct oral anticoagulant medications were implicated in a significant percentage of overall medication incidents reported. In response the hospital had proactively introduced a number of measures to address this risk including:

- Direct oral anticoagulant medications were not stocked at ward level and were supplied on a "named-patient basis" to the wards. High impact risk reduction strategies<sup>12</sup> such as dispensing high-alert drugs on a named patient basis can catch and correct errors before they reach patients (Appendix 3).
- Clinical pharmacists offered counselling to all patients newly prescribed oral anticoagulant medication.
- Senior clinicians and pharmacists in the Ireland East Hospital Group had collaborated to develop a direct oral anticoagulant therapy record. This booklet contained an anticoagulant therapy record and practical guidelines for the management of direct oral anticoagulant medications for both patients and healthcare professionals. Written information has also been shown to augment patients' knowledge about prescription drugs, even when oral communication does occur.
- Alert labels were used on medication prescribing and administration record to highlight that direct oral anticoagulants had been prescribed.

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.<sup>13</sup> Other approaches used to inform the overall picture of medication safety risks included retrospective chart review, direct observation, trigger tools, risk assessments and patient surveys.

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.<sup>3,14</sup> Inspectors were informed that the hospital had a process in place to promptly inform patients when medication-related incidents occurred.

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<sup>‡</sup> 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).

A Risk register of the assessed risks with existing controls in place was maintained at both departmental and corporate level. Issues which are considered to potentially compromise the safe administration of medication were included on the pharmacy department risk register. Risks identified locally were addressed at departmental level or were escalated through the corporate risk management processes.

An unannounced HIQA inspection undertaken against the *National Standards for the Prevention and Control of Healthcare Associated Infections* in December 2015 identified that the central storage facilities for intravenous fluids were not fit for purpose. On return to the hospital as part of its current programme of monitoring in the area of medication safety, HIQA noted that this issue remained on the pharmacy risk register. There was no defined plan or timeframe in which this issue would be addressed. This should be reviewed by the hospital following this inspection.

## 2.2 Audit and evaluation

### Line of enquiry:

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

Documentation reviewed indicated that the hospital had conducted a number of audits to evaluate the safety of medication management systems. Although, the pharmacy department had identified a number of audits for completion in 2017, audit activity throughout the wider hospital was neither strategically driven nor centrally coordinated. Current arrangements regarding a strategic audit plan should be strengthened and formalised to provide assurance to the senior hospital management team about medication safety at the hospital.

Nevertheless, the inspection team was provided with examples of hospital-specific medication safety and medication management audits undertaken in the past 12 months which included:

- antibiotic point prevalence study
- *Clostridium difficile* retrospective audit
- intravenous iron administration in pregnancy
- ward based medication information sources
- venous thromboembolism prophylaxis audit
- ward medication fridges audit
- geriatric emergency medicine referral audit.

Evidence was submitted and reviewed which verified that clinical audit activities at the hospital led to changes aimed at improving the delivery of clinical services. For example, following a 2016 audit the hospital medication prescribing and

administration record had been revised and there were now designated sections for medication reconciliation, a signature record, venous thromboprophylaxis, antimicrobials, infusions and a designated section for communication of medication issues. The section for anticoagulants (which are high-risk medications) contained a risk assessment. The new chart was introduced in January 2017 and implementation was augmented by multidisciplinary staff education.

Nursing metric<sup>§</sup> data in relation to medication safety identified good performance across a number of areas. However, there were consistently less than satisfactory findings in relation to observations around medication prescribing. Medications have both a trade name (brand name) and a generic name (active ingredient). The same drug formulation can be produced by different companies and given multiple different trade names. The use of the generic drug names is recommended when prescribing, to reduce the potential for confusion and error.

An annual audit day was held at the hospital to feedback results of audits conducted at the hospital to staff. However more work is required to ensure that there is a more systematic approach to audit selection and dissemination of audit findings throughout the hospital.

### **Key Performance Indicators**

Hospital management reported that seven key performance indicators were used to evaluate medication safety at the hospital and these included:

- number of medical incidents reported and grading
- medication reconciliation on admission
- medication reconciliation on discharge
- geriatric emergency medical assessment
- Drug and Therapeutics Committee meetings schedule
- Ireland East Hospital Group activity data
- antimicrobial consumption reports.

Further information relating to performance against a number of these key performance indicators is further referenced throughout this report.

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<sup>§</sup> 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.

Inspectors saw examples of quality improvement initiatives that had been implemented and evaluated.

The hospital maintained a list of high alert medications that present a heightened risk of causing significant patient harm if not used correctly. The acronym 'A PINCH' which grouped medications into categories was used to facilitate education and to raise awareness of high risk medications.<sup>15</sup> The hospital promoted medication safety awareness of high-alert medications through in-service education and through the use medication safety alerts prepared by the Pharmacy Department.

Concentrated electrolytes are high-risk medications and should not be stored in patient care areas. Inspectors were informed that removal of stocks of concentrated electrolyte solutions from patient care areas had reduced the risk of sentinel events associated with these agents.

St Luke's General Hospital was also participating in the Health Service Executive (HSE) Quality Improvement Division venous thromboembolism 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 minimize harm and expenditure associated with unnecessary thromboprophylaxis.

### Clinical pharmacy services

There are currently no agreed national standards outlining requirements for the provision of clinical pharmacy services in hospitals. International studies support the role of clinical pharmacists in hospital wards in preventing adverse drug events.<sup>16,17,18,19,20,21</sup> The hospital had resourced all inpatient general adult wards with a designated clinical pharmacy service<sup>\*\*</sup>. However, it was reported that due to resource deficiencies, clinical pharmacy services were not standardised practice across all clinical areas in the hospital. The pharmacy service to the paediatric ward

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<sup>\*\*</sup> Clinical pharmacy describes the activity of pharmacy teams in ward and clinic settings.

and the maternity unit which included a Special Care Baby Unit, was described as a limited/ reactive service due to the lack of a dedicated clinical pharmacist allocated to these areas.

Children are at increased risk of harm from medication errors because of their relative size, immature kidney and liver function, and an inability to communicate signs of the adverse effects of medications.<sup>11,22,23</sup> Published studies also indicate that babies in the Special Care Baby Units are more likely to experience a medication error than other hospitalised patients and to experience more harm when a medication error does occur.<sup>24,25</sup> The limited and incomplete clinical pharmacy cover in areas treating high risk patients in the paediatric ward and Special Care Baby Unit was of concern to HIQA. Inspectors were informed that the clinical pharmacy service planned to reconfigure from the current ward based service into a team-based model of clinical pharmacy with the aim of better inter-disciplinary working. As part of this reconfiguration of clinical pharmacy service, the hospital must ensure that a system is put in place to ensure consistent cover in the paediatric and maternity wards to support medication safety for patients in these areas.

The clinical pharmacy service was provided from Monday to Friday. Inspectors were informed that the Chief Pharmacist could be contacted by phone for advice at weekends if required. This informal arrangement was solely dependent on the willingness of the Chief Pharmacist to provide this level of service.

### **Medication reconciliation**

Transitions of care are known to be a point of vulnerability for medication management. Medication reconciliation was defined as the process of obtaining and maintaining an accurate and detailed list of all prescribed and non-prescribed drugs a patient is taking, including dosage and frequency, through all transitions of care. This list is then compared the physician's admission, transfer, and or discharge prescription, recognising any discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated.<sup>26,27,28,29,30</sup>

The hospital was involved in a pilot of a pharmacy-led discharge medication reconciliation initiative in collaboration with e-Health Ireland<sup>††</sup>, the School of Pharmacy at University College Cork, a pharmaceutical company sponsor and Naas General Hospital. Additional clinical pharmacist hours for the initiative were funded by the GP Liaison Committee. The initiative was supported by a medication reconciliation standard operating procedure (SOP) which specified that all patients

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<sup>††</sup> eHealth (Electronic Health) involves the integration of all information and knowledge sources involved in the delivery of healthcare via information technology-based systems. eHealth Ireland was established by the Department of Health in 2015 to focus on the promotion and implementation of an eHealth agenda across the Irish Health Service. It is managed through the Office of the Chief Information Officer.

aged over 70 admitted to adult wards should be prioritised to have medication reconciliation completed within 24 hours of admission.

Two processes were used by clinical pharmacists to generate discharge prescriptions; handwritten and computer generated. An electronic reconciliation tool was used to generate the computer generated record of medication reconciliation on admission and to generate the electronic discharge prescriptions. The use of information technology can increase the accuracy of documentation used for the medication reconciliation.<sup>31</sup> However it was reported that there was no connectivity between this computer software and existing information technology (IT) systems used within the hospital.

Following discharge medication reconciliation, the discharge prescriptions were signed by the patient's doctor and sent to the patient's GP, community pharmacy and nursing home where applicable. An evaluation of this initiative found that the key benefits included time saving, increased patient safety, clearer prescriptions and reduced prescription queries from GPs and community pharmacists.

The 'Geriatric Emergency Medicine Service (GEMS)' screened all patients over 75 years of age for frailty at point of triage. This service facilitated assessment of patients over 75 and referrals to pharmacy, physiotherapy, occupational therapy, dietetics or speech and language therapy as required. The service saw 66% of patients categorised as frail older patients referred to the pharmacy team for medication reconciliation. An analysis of this process identified 2.5 pharmacist interventions per prescription reviewed. Inspectors were informed that the hospital planned to merge the GEMS and the pharmacy-led discharge medication reconciliation initiatives in the near future.

### **Paediatric ward**

During a visit to a ward, inspectors observed paediatric patients undergoing medical assessment in ancillary rooms. This posed a risk to children of unsecure access to medications, clean and sterile consumables including needles, syringes, intravenous cannulae and sharps waste disposal bins containing contaminated sharps. Furthermore, one of the rooms accommodating paediatric patients was also used for the preparation of intravenous medications.

In addition to this, there was a risk with unsecure access to clean and sterile consumables which should be securely stored in a dedicated room to protect from unauthorised access and potential contamination and intravenous medications should be prepared in a dedicated area free from potential contamination and distractions.

HIQA highlighted the risks detailed above immediately to the hospital for mitigation. In response, hospital management reported that a number of measures had subsequently been taken to mitigate the risks identified by HIQA. Specifically, sharps waste disposal bins were relocated to an area inaccessible to children, new locks were fitted to storage presses and drawers to restrict patient and public access to medications and clean and sterile consumables. In addition, the area used for preparation of intravenous medications was no longer used to accommodate patients.

A copy of the letter issued to the hospital regarding the risks identified during the inspection on 11 October 2017 and a copy of the response received from the hospital are shown in appendices four and five of this report.

## **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.

St Luke's General Hospital had systems in place to support the provision of patient information and education in relation to medication. Patient information material was available at the point of care. Inspectors were also informed that clinical nurse specialists had an important role in patient education.

A clinical pharmacy education service was provided to all outpatients attending the Cardiac Rehabilitation service at St. Luke's.

As part of this inspection, HIQA asked a small sample of hospital outpatients attending the Outpatients Department to complete an anonymised questionnaire in relation to prescribed medications. The questionnaire was completed by 13 people who had been inpatients in St Luke's General Hospital within the past year and who were prescribed regular medications. Of the 13 people surveyed:

- eight patients said that while in hospital, a staff member had explained the purpose of new medication in a way that they could completely understand.
- seven patients said that prior to discharge from hospital, a staff member told them about all the possible medication side effects to look out for following discharge home.
- 10 patients said that they received complete instruction on how to take their medications at home.

It is acknowledged that this was a small sample of outpatients and therefore was not representative of all recently discharged patients taking prescribed medication. This

information did however, provide some information about outpatients understanding and could be expanded upon and used to identify opportunities for 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.

All medication-related policies, procedures and guidelines were reviewed by the Drugs and Therapeutics Committee prior to final approval by the Executive Management Team. The hospital did not have a document control management system. However, medication policies, procedures, protocols and guidelines were hosted on the hospital's intranet.

Generalised prescribing supports were available to clinical staff. Hard copies of the most current version of the 'British National Formulary' were available in the clinical areas visited. Clinical staff also had access to online evidence-based clinical information resources for reference. The use of mobile technology gave prescribers easy access to antimicrobial guidelines at the point of prescribing.

Intravenous medication monographs<sup>††</sup> are a valuable reference source serve to standardise and ensure best practice and should be easily accessible to all staff members at point of medication preparation. To reduce the risk of clinical staff accessing outdated information a decision was made to remove hard copies of intravenous medication monographs from wards. Intravenous medication monographs were accessible via the hospital intranet and were controlled by the Pharmacy Department. However as there was no online access in medication preparation rooms, some wards still maintained hard copies of the monographs. Hard copy versions of these documents were controlled by staff at ward level.

Healthcare requires access to complete and accurate patient information, relevant to the safe use of medications, at the point of clinical decision making to help ensure

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<sup>††</sup> An approved set of standardised and approved instructions which comprise a number of different sections detailing how the intravenous medication is presented, how it should be reconstituted and/or diluted if appropriate, how it should be administered, information on adverse effects that may occur during administration and any monitoring required. Monographs should be specifically tailored to the intravenous medicines stocked within the hospital. All monographs are checked for accuracy and for consistency by suitably experienced pharmacists.

patient safety. Clinical staff had access to patient's diagnostic results on computers in ward offices in clinical areas across the hospital.

St Luke's General Hospital had been granted permission to access to Our Lady's Children's Hospital, Crumlin drug information page. The safety benefits of this cross site standardisation of paediatric drug information facilitated a reduction in the risk of medication error given the shared care paediatric network model<sup>§§</sup> and the rotation of non-consultant hospital doctors across hospitals.

Medication safety alerts and memos were circulated to all relevant medical and nursing staff by the Pharmacy Department. There was 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 to the relevant department by the Risk Manager.

Staff also reported that they received support and information from the Pharmacy Department as requested.

## **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.<sup>32</sup> The hospital did not have a formalised education programme for clinical staff linked to an overall medication safety strategy. Medication safety awareness in the hospital was promoted through staff communication including circulation of pharmacy medication safety alerts, clinical pharmacy advice at ward level and through medication safety education and policies.

It was also recommended that nursing staff complete the Health Service Executive medication management online training programme, however uptake of this programme was not mandatory.<sup>33</sup> In-service education was provided to nursing staff during quarterly medication management study days on medication management and during intravenous study days which were held twice yearly. Nursing staff also completed anaphylaxis training to facilitate the administration of first dose

<sup>§§</sup> Our Lady's Children's Hospital, Crumlin is the centralised tertiary unit providing a national childhood and young adolescent cancer programme for the country. After initial assessment and treatment, children return home (where possible) and care is provided locally, according to agreed protocols, under the supervision of the local registered medical specialist with credentials in paediatrics, with input from a specialist at the comprehensive children's cancer centre.

antimicrobial medications. Documentation reviewed indicated that 60 nurses had attended one of the quarterly medication management study days in 2017. Inspectors were informed that representation from the pharmacy department at nurse manager meetings provided a forum for education and medication safety briefings at ward level.

Medical staff received induction training which included medication safety from the Pharmacy Department. It was reported some ongoing training on medication safety was provided to medical staff, for example at hospital grand rounds<sup>††</sup>. In addition pharmacy attended the weekly intern teaching sessions once a month at which particular aspects of medication safety were presented and discussed.

### **3. Conclusion**

Medications represent the primary measure for treatment intervention in hospitalised patients. Error associated with medication usage constitutes one of the major causes of patient harm in hospital. Medication-related events were the third most common type of adverse event recorded in the recently published Irish National Adverse Events Study.<sup>1</sup> 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.

Systems, processes and practices were in place to support medication safety, some of which were under development. St Luke's General Hospital had an established Drugs and Therapeutics Committee in place at the time of this inspection. In building sustainability with respect to governance oversight, it is important that the Quality and Safety Committee receive regular structured reports and updates from the Drugs and Therapeutics Committee.

The Drugs and Therapeutics Committee provided the leadership in the implementation of new process for assessing and evaluating requests for the supply of new medications. It is important this process further developed and enhanced into the future, and not merely a short term reaction in response to regulatory monitoring.

A local medication formulary did not exist in the hospital at the time of this inspection. There is significant potential to learn from the experience of those hospitals within the Ireland East Hospital Group that have more advanced hospital formularies. It is important that the hospital avails of links with other hospitals in the Ireland East Hospital Group to share information, expertise and resources where possible, rather than working in isolation.

It is noted that while there was a clinical pharmacy service in place, it was not fully comprehensive. At the time of the inspection, the paediatric and maternity services did not have an allocated clinical pharmacy service. It is recommended that an evaluation occurs with respect to the clinical pharmacy service provision at the hospital in light of the added challenges and risks experienced in medication use in these settings.

The aim of clinical governance is to accomplish continuous quality improvement and is designed to consolidate fragmented approaches to quality improvement. Hospital management had endeavoured to support and progress a medication safety agenda at the hospital through the formation of a Medication Safety Committee in 2016. The Pharmacy Department and the Medication Safety Committee should now create a centralised and coordinated medication safety programme to strengthen and focus existing approaches to quality improvement.

The hospital had implemented a number of proactive medication safety measures including the implementation of medication reconciliation in a systematic way. Medication reconciliation is time consuming and labour intensive. However the hospital had prioritised limited resources to a cohort of high risk patients where there was evidence of its value to care.<sup>34</sup> The focus on patients at higher risk enhanced the quality and safety of care by ensuring smoother transitions between and within services leading to improvements in medication safety at the hospital and community interface.

Overall, inspectors concluded that the hospital had conducted a number of audits relating to medication management. In order to enhance the current approach taken, the hospital would benefit from taking more structured approach to the planning of audit in the area of medication safety aligned to a formal medication safety strategy.

It is recommended that this report is shared with senior managers, clinicians and other relevant staff at St Luke's General Hospital, Kilkenny 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.

## 4. References

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1. Rafter N et al. The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals—a retrospective record review study. *British Medical Journal of Quality and Safety*. 2016; 26: pp111-119. Available online from: <http://qualitysafety.bmj.com/content/26/2/111.full.pdf+html>
2. Kohn, Linda T, Janet M, Corrigan, Molla S, Donaldson. *To Err is Human: Building a Safer Health System*. Washington: Institute of Medicine; 1999. Available online from: <https://www.nap.edu/download/9728#>
3. Health Information and Quality Authority. *National Standards for Safer Better Healthcare*. Dublin: Health Information and Quality Authority; 2012. Available online from: <https://www.hiqa.ie/reports-and-publications/standards/national-standards-safer-better-healthcare>
4. Health Information and Quality Authority. *Guide to the Health Information and Quality Authority's Medication Safety Monitoring Programme in Public Acute Hospitals*. Dublin: Health Information and Quality Authority; 2016. Available online from: <https://www.hiqa.ie/reports-and-publications/guide/guide-medications-safety-monitoring-acute-hospitals>
5. Council of Australian Therapeutic Advisory Groups. *Achieving effective medicines governance. Guiding Principles for the roles and responsibilities of Drugs and Therapeutics Committees in Australian public hospitals*. Darlinghurst: NSW Therapeutic Advisory Group. 2013. Available online from: <http://www.catag.org.au/wp-content/uploads/2012/08/OKA9964-CATAG-Achieving-Effective-Medicines-Governance-final1.pdf>
6. World Health Organisation. *Drugs and therapeutics Committees. A Practical Guide*. Virginia, USA: Virginia, USA; 2003. Available online from: <http://apps.who.int/medicinedocs/pdf/s4882e/s4882e.pdf>
7. American Society of Health-System Pharmacists (ASHP) *Statement on the Pharmacy and Therapeutics Committee and the Formulary System*. American Society of Health-System Pharmacists; 2012. Available online from: <https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements-pharmacy-and-therapeutics-committee-and-formulary-system.ashx?la=en>
8. Irish Pharmaceutical Healthcare Association (IPHA) Available online from: <http://www.ipha.ie/alist/clinical-trials-in-ireland.aspx>

9. American Hospital Association, Health Research and Educational Trust, and Institute for Safe Medication Practices. Pathways for Medication Safety: Leading a Strategic Planning Effort. 2002.
10. Relihan, E. Pathways for Medication Safety: Leading a Strategic Planning Effort. in National Medication Safety Intensive Course and Summit: Towards a National Approach. 2015.
11. Abstoss KM, Shaw BE, Owens TA, Juno JL, Commiskey EL, Niedner MF. Increasing medication error reporting rates while reducing harm through simultaneous cultural and system-level interventions in an intensive care unit. *BMJ Quality and Safety* 2011;20:pp914-922. Available online from: <https://www.ncbi.nlm.nih.gov/pubmed/21690249>
12. Institute of Safe Medication Practices (ISMP) Canada. Ontario Critical Incident Learning. Improving quality in patient safety. Available online from URL:[https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-4\\_EffectiveRecommendations.pdf](https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-4_EffectiveRecommendations.pdf)
13. World Health Organisation. Reporting and learning systems for medication errors: the role of Pharmacovigilance centres. Washington: World Health Organisation; 2014. Available online from: <http://apps.who.int/medicinedocs/documents/s21625en/s21625en.pdf>
14. Health Service Executive. *Open Disclosure. National Guidelines. Communicating with service users and their families following adverse events in healthcare.* Dublin: Health Service Executive; 2013. Available online from: [http://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open\\_Disclosure/opendiscFiles/opdiscnationalguidelines2013.pdf](http://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/opdiscnationalguidelines2013.pdf)
15. The Clinical excellence Commission. *Medication Safety and Quality. High Risk Medications.* Available online from: <http://www.cec.health.nsw.gov.au/patient-safety-programs/medication-safety/high-risk-medicines/A-PINCH>
16. Kaushal R, Bates DW, Abramson EL, Soukup JR, Goldmann DA. Unit-based clinical pharmacists' prevention of serious medication errors in pediatric inpatients. *American Journal of Health-System Pharmacy.* 2008 July 1; 65(13): pp1254-60.
17. De Rijdt T, Willems L, Simoens S. Economic effects of clinical pharmacy interventions: a literature review. *American Journal of Health System Pharmacy.* 2008 Jun 15;65(12): pp1161-72
18. Rivkin A, Yin H. Evaluation of the role of the critical care pharmacist in identifying and avoiding or minimizing significant drug-drug interactions in

- medical intensive care patients. *Journal of Critical Care*. 2011 Feb;26(1): pp104  
Available online from:  
<http://www.sciencedirect.com/science/article/pii/S0883944110001188>
19. Agency for Healthcare Research and Quality. *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Evidence Report/Technology Assessment No. 211* Chapter 4. *Clinical Pharmacist's Role in Preventing Adverse Drug Events: Brief Update Review*. . Maryland: Agency for Healthcare Research and Quality; 2013. pp31- 40. Available online from:  
<https://archive.ahrq.gov/research/findings/evidence-based-reports/ptsafetyII-full.pdf>
  20. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA*. 1999 July 21;282(3): pp267–70. Available online from:  
<http://jamanetwork.com/journals/jama/fullarticle/190687>
  21. Bond CA, Rael CL. Clinical pharmacy services, pharmacy staffing, and hospital mortality rates. *Pharmacotherapy*. April 2007; 27 (4): pp481-93
  22. Institute for Safe Medication Practices. Pediatric Pharmacy Medication Safety Guidelines. 2002. Available online from:  
<https://www.ismp.org/pressroom/PR20020606.pdf>
  23. World Health Organisation (WHO) Medication Errors. Technical Series on Safer Primary Care. 2016; 1-18. Available online from:  
<http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf>
  24. Sharek P J, Horbar JD, Mason W, Bisarya H, Thurm CW, Suresh G, Classen D. (2006) Adverse events in the neonatal intensive care unit: Development, testing, and findings of a NICU-focused trigger tool to identify harm in North American NICUs. *Pediatrics*. 2006; 118 (4):pp 1332–1340.
  25. Dabliz R and Levine, S. Medication safety in neonates. *American Journal of Perinatology*. 2012; 29 (1):pp 49–56.
  26. Institute for Healthcare Improvement. Accuracy at every step: the challenge of medication reconciliation. Patient safety/ medication systems, 2006.
  27. Health Information and Quality Authority. *Guidance for health and social care providers. Principles of good practice in medication reconciliation*. Dublin: Health Information and Quality Authority; 2014. Available online from:  
<https://www.hiqa.ie/publications/guidance-health-and-social-care-providers-principles-good-practice-medication-reconcili>

- 28 World Health Organisation. *The High 5s Project. Standard Operating Protocol. Assuring Medication Accuracy at Transitions in Care*. Washington: World Health Organisation; 2014. Available online from <http://www.who.int/patientsafety/implementation/solutions/high5s/h5s-sop.pdf>
- 29 Galvin M, Jago-Byrne MC, Fitzsimons M, Grimes, T. Clinical pharmacist's contribution to medication reconciliation on admission to hospital in Ireland. *International Journal of Clinical Pharmacists*. February 2013; 35 (1): pp14–21
- 30 .Australian Commission on Safety and Quality in Health Care. *Safety and Quality Improvement Guide Standard 4: Medication Safety (October 2012)*. Sydney: Australian Commission on Safety and Quality in Health Care; 2012. Available online from: [https://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard4\\_Oct\\_2012\\_WEB.pdf](https://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard4_Oct_2012_WEB.pdf)
- 31 Mekonnen A, Abebe TB, McLachlan AJ, Brien JE. Impact of electronic medication reconciliation interventions on medication discrepancies at hospital transitions: a systematic review and meta-analysis *BMC Medical Informatics and Decision Making*. 2016; 16 (112) <https://bmcmidinformatdecismak.biomedcentral.com/articles/10.1186/s12911-016-0353-9>
- 32 Institute of Safe Medication Practices (ISMP) *Staff competency, education*. Institute of Safe Medication Practices; 2009. Available online from: [http://pharmacytoday.org/article/S1042-0991\(15\)31825-9/pdf](http://pharmacytoday.org/article/S1042-0991(15)31825-9/pdf)
- 33 Health Service Executive. HSELand. Available online from: <http://www.hseland.ie/tohm/default.asp?message=logout>
- 34 Grimes T, Deasy E, Allen A, O'Byrne J, Delaney T, Barragry J et al. Collaborative pharmaceutical care in an Irish hospital: uncontrolled before-after study. *BMJ Quality and Safety*. 2014 February 04; 0:1–10. Available online from <http://qualitysafety.bmj.com/content/early/2014/02/06/bmjqs-2013-002188>

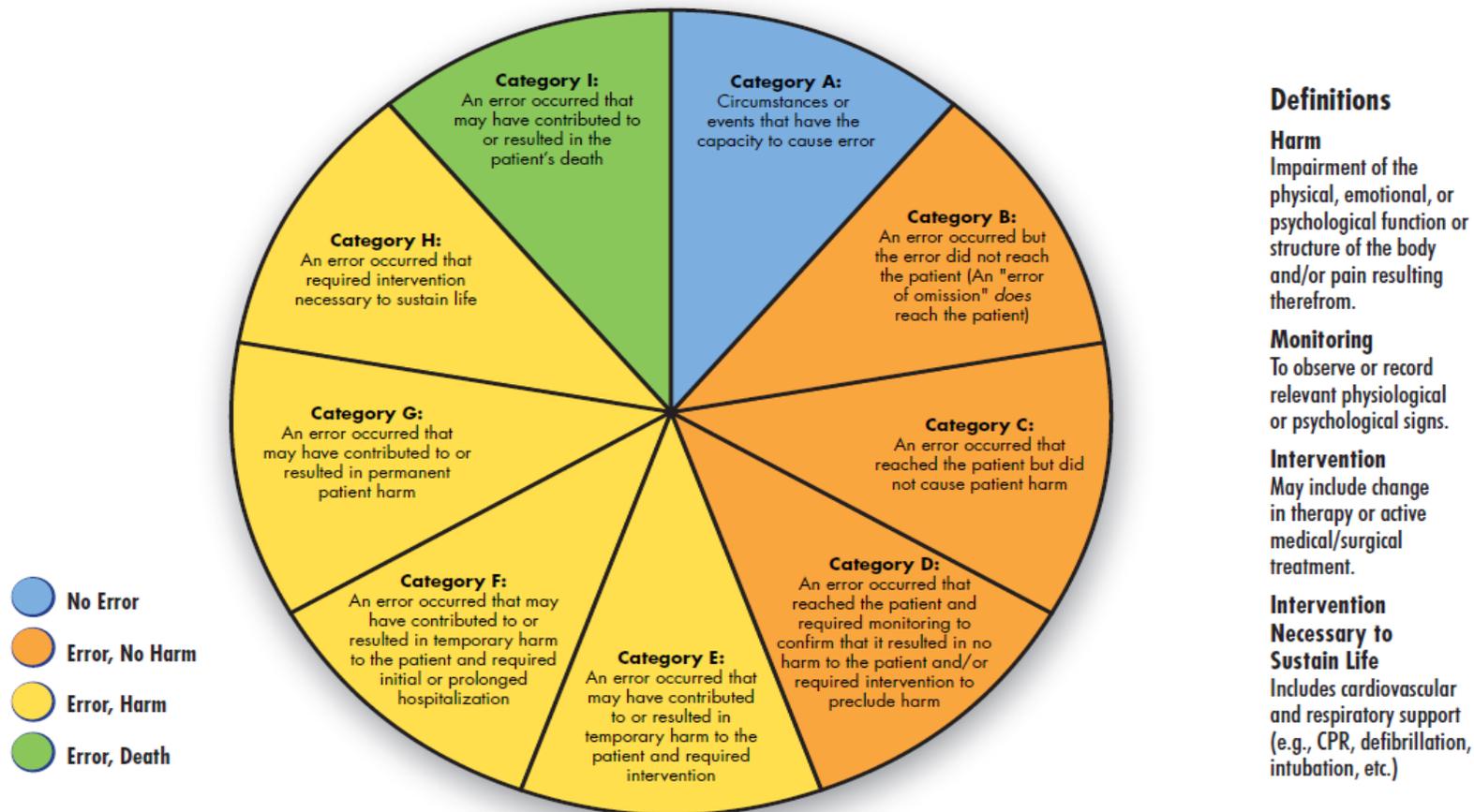
## 5. Appendices

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

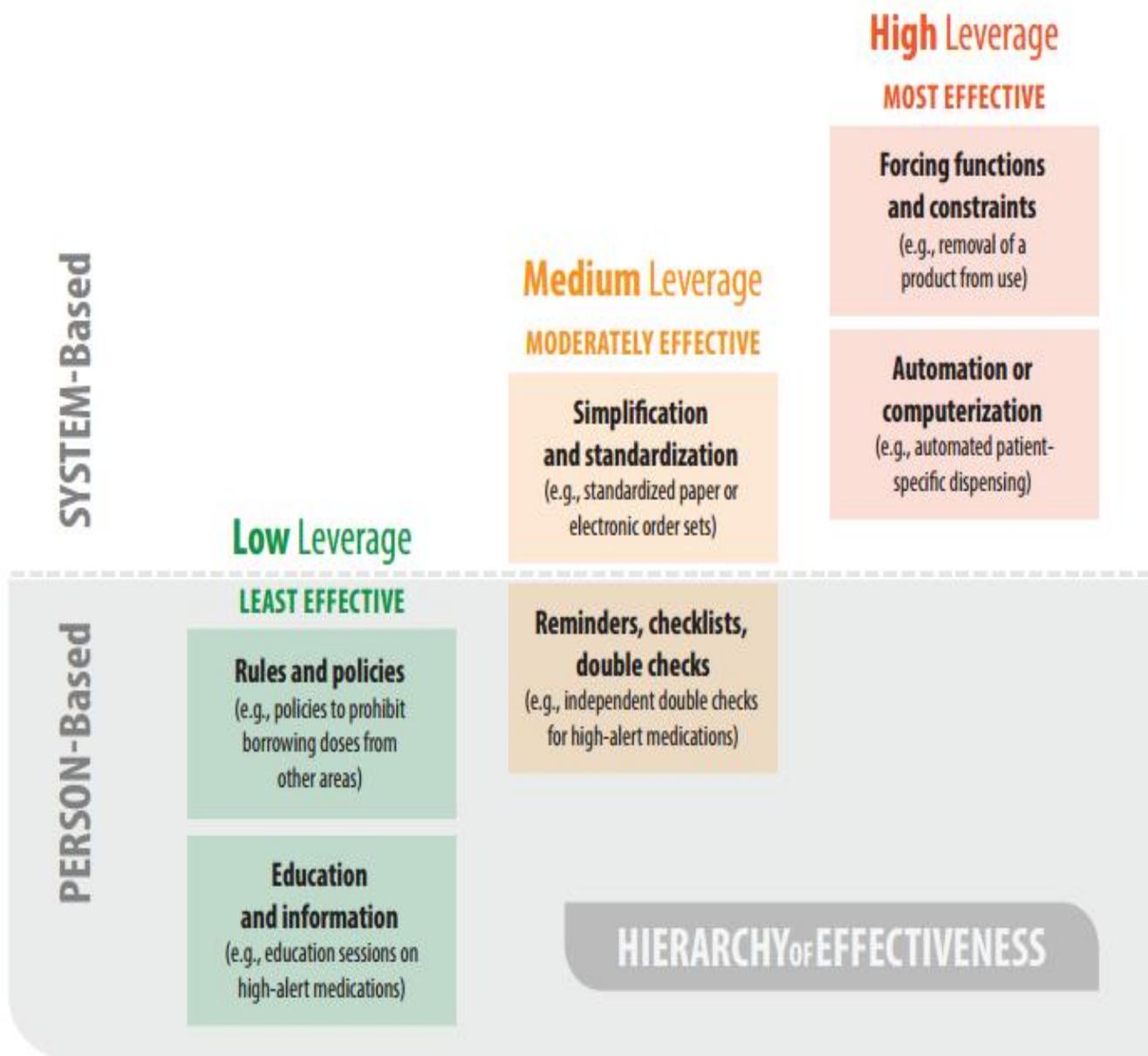
Area to be explored	Line of enquiry <sup>1</sup>	National Standards for Safer Better Healthcare
Clear lines of accountability and responsibility for medication safety	Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear 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

**Appendix 2. National Coordinating Council for Medication Error Reporting and Prevention. Index for Categorising Medication Errors.**

**NCC MERP Index for Categorizing Medication Errors**



### Appendix 3: Hierarchy of Effectiveness of Risk Reduction Strategies in Medication Safety<sup>12</sup>



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## **Appendix 4: Copy of the letter sent from HIQA to St Luke's General Hospital Kilkenny**



Anne Slattery  
General Manager  
St Luke's Hospital Kilkenny  
Freshford Road  
Kilkenny  
[anned.slattery@hse.ie](mailto:anned.slattery@hse.ie)

13 October 2017

Ref: MS/140

Dear Anne

### **Medication Safety Monitoring Programme in Public Acute Hospitals**

During the course of the announced medication safety inspection conducted at St. Luke's General Hospital on 11 October 2017, Authorized Persons<sup>1</sup> identified specific issues that may present serious risks to the health or welfare of patients, and immediate measures need to be put in place to mitigate these risks. The risks identified related to;

- **the accommodation of paediatric patients undergoing medical assessment in an ancillary room with unsecure access to medications , clean and sterile consumables including needles, syringes, intravenous cannulae and sharps waste disposal bins**
- **preparation of intravenous medications within the patient zone.**

---

<sup>1</sup> Authorized Persons of the Health Information and Quality Authority (HIQA) under Section 70 of the Health Act 2007 (the Act) are authorized for the purpose of monitoring against the *National Standards for Safer Better Healthcare* pursuant to Section 8(1)(c) of the Act.

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*Report of the announced inspection of medication safety at St Luke's General Hospital, Kilkenny*

The above issues were brought to the attention of the Senior Management Team at the hospital during the inspection. This was done so that your hospital could act to mitigate and manage these identified risks as a matter of urgency.

Details of these risks will be included in the report of the announced medication safety inspection. This will include copies of HIQA's notification of this risk and the service provider's response.

Given the level of potential risk associated with these findings, please formally report back to HIQA by **2pm on 17 October 2017** to [qualityandsafety@hiqa.ie](mailto:qualityandsafety@hiqa.ie), outlining the measures that have been enacted to mitigate the identified risks.

Should you have any queries, please do not hesitate to contact me at [qualityandsafety@hiqa.ie](mailto:qualityandsafety@hiqa.ie). Please confirm receipt of this letter by email ([qualityandsafety@hiqa.ie](mailto:qualityandsafety@hiqa.ie)).

Yours sincerely



---

**KATHRYN HANLY**  
Authorised Person

CC: Mary Day, CEO, Ireland East Hospital Group  
Mary Dunning, Director of Regulation, Health Information and Quality Authority

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## **Appendix 5: Copy of the response received by HIQA from St Luke's General Hospital Kilkenny**



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

HSE South,  
St. Luke's General Hospital,  
Kilkenny,  
Ireland.

Telephone 056 7785000  
Fax 056 7785170

16/10/2017

**Ref MS/140**

**Medication Safety Monitoring Programme in Public Acute Hospitals**

**Dear Ms Hanly**

I refer to the announced medication safety inspection conducted at St. Luke's General Hospital on 11 October 2017, and the specific issues that may present serious risks to the health or welfare of patients that were identified requiring immediate measures to mitigate the risks as follows:

1. **The accommodation of paediatric patients undergoing medical assessment in an ancillary room with unsecure access to medications, clean and sterile consumables including needles, syringes, intravenous cannulae and sharps waste disposal bins.**

**Immediate Action**

All storage presses and drawers in this ancillary room have had new locks fitted and therefore patients /relatives can no longer access medications, clean and sterile consumables including needles, syringes and IV cannulae which are securely locked away. The sharps waste disposal bin has been relocated to an area inaccessible to children and all staff have since been advised and provided with a demonstration on how to secure the bins correctly following use.

2. **Preparation of intravenous medications within the patient zone**

**Immediate Action**

The area where intravenous medication were being made up on the day of inspection is no longer designated a patient zone for patient treatment, and therefore there is no longer access for patients/relatives to this area.

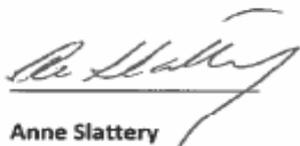
**Other Action**

It is also planned to relocate and create a new designated medication preparation room in the paediatric unit and this work will be completed by 31 December 2017.

*Report of the announced inspection of medication safety at St Luke's General Hospital, Kilkenny*

Should you have any further queries on this matter, please do not hesitate to contact me.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Anne Slattery', written over a horizontal line.

**Anne Slattery**

**General Manager**

**For further information please contact:**

**Health Information and Quality Authority  
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