

Report of the announced inspection of medication safety at Our Lady's Children's Hospital, Crumlin, Dublin.

Date of announced inspection: 25 May 2017

Report of the announced inspection of medication safety at Our Lady's Children's Hospital, Crumlin.

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 personcentred 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.

Report of the announced inspection of medication safety at Our Lady's Children's Hospital, Crumlin.

Table of Contents

1.	Introduction	1
2.	Findings at Our Lady's Children's Hospital, Crumlin	3
	2.1 Governance and risk management	3
	2.2 Audit and evaluation	8
	2.3 Medication safety support structures and initiatives	9
	2.4 Person-centred care	13
	2.5 Policies procedures and guidelines and access to information	14
	2.6 Training and education	16
3. C	onclusion	17
4. R	eferences	19
5. A	ppendices	24
	Appendix 1: Medication safety monitoring programme Phase One: Lines of Enquiry and associated National Standard for Safer Better Healthcare	
	Appendix 2. National Coordinating Council for Medication Error Reporting as Prevention. Index for Categorizing Medication Errors	

Report of the announced inspection of medication safety at Our Lady's Children's Hospital, Crumlin.

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. 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. The World Health Organisation (WHO) has identified Medication Safety as the theme of the next Global Patient Safety Challenge on Medication Safety. This global initiative, launched in March 2017, safety aims to address the weaknesses in health systems that lead to medication errors and the severe harm that results.

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*⁴ 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* 5 which is available on HIQA's website: www.higa.ie.

An announced medication safety inspection was carried out at Our Lady's Children's Hospital, Crumlin by Authorised Persons from HIQA; Kathryn Hanly, Dolores Dempsey Ryan and Nora O'Mahony. The inspection was carried out on 25 May 2017 between 10.30hrs and 16.30hrs. Interviews were held in the hospital with the following groups of managers and clinical staff:

 Group one: the Chief Executive Officer, the Clinical Director and the Director of Nursing. • Group two: the Chairperson of Drugs and Therapeutics Committee, the Chief Pharmacist, the Medication Safety Officer and the Head of Risk Management.

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

- St Peter's Ward (Infant Medical/ Surgical ENT, gastroenterology, hepatology)
- Nephro-Urology Ward
- Children's Heart Centre

In addition a survey was conducted among parents in the Outpatient's Department.

HIQA would like to acknowledge the cooperation of staff who facilitated and contributed to this announced inspection and the parents of patients completed the survey.

2. Findings at Our Lady's Children's Hospital, Crumlin

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.

Our Lady's Children's Hospital, Crumlin had formalised governance arrangements and organisational structures with clear lines of accountability in place to support the safe use of medications. The Drugs and Therapeutics Committee was re-established in late 2015. This Committee was responsible for the governance of the hospital's medication management system and for ensuring its safety. It was reported at interview that the Drugs and Therapeutics Committee reported directly to the Corporate Management Team, who in turn reported to the Chief Executive Officer and the Board of Directors.

There was evidence that the senior management actively sought assurance in relation to medication safety. For example members of the Corporate Management Team conducted regular quality and safety walk-rounds. These walk-rounds provided an opportunity for frontline staff to identify and discuss their safety concerns related to clinical risks including medication safety.⁶

There was also evidence of significant effort by the Board of Directors to provide leadership to support a safer patient culture related to medication usage. For example, a Quality, Patient Safety and Risk Governance Committee was established with the stated aim of providing "assurance to the Board of Directors that the governance systems, structures, procedures and processes for ensuring improvements in quality of care, patient safety and risk mitigation were appropriate and robust for the hospital." This committee was chaired by a member of the Hospital Board. Membership of the Quality, Patient Safety and Risk Governance Committee composed of Board members and members of the Corporate Management Team. Each hospital Committee associated with quality, patient safety and risk, including the Drugs and Therapeutics Committee, the Antimicrobial Stewardship Committee and the Medication Safety Committee were required to prepare and present an assurance report for the Quality, Patient Safety and Risk Governance Committee on an annual basis.

The Drugs and Therapeutics Committee was chaired by a Consultant Paediatric Gastroenterologist and was further composed of physicians, pharmacists, nurses and other representative staff who were involved in the medication-use process. ⁷ However the Committee did not have a representative from surgery, risk management, general practice or a community pharmacist. Furthermore, a review of the minutes indicated that committee member attendance at meetings was variable. The hospital should work to ensure more consistent attendance and broader membership of the Drugs and Therapeutics Committee.

The Pharmacy Department was responsible for administering a formulary* system under governance of the Drugs and Therapeutics Committee. The Committee, on an ongoing basis, objectively appraised, evaluated, and selected medications for addition to or removal from the formulary. Inspectors were given examples of when the Committee had taken steps to minimise unnecessary duplication of the same basic drug type, drug entity, or drug product. Optimising the number of drug entities and products available from the pharmacy can produce safer patient care and financial benefits.8 The committee ensured that mechanisms were in place to communicate with health care professionals about all aspects of the formulary system.

All medicines must undergo clinical trials before they are granted a licence in Ireland, or in Europe. Inspectors were informed that all clinical trial applications were reviewed and approved by the hospital's Research Ethics Committee and the Health Products Regulatory Authority (HPRA). However, contrary to the Drugs and Therapeutics Committees terms of reference, the 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. It was reported that the hospital Drugs and Therapeutics Committee was reviewing this anomaly and reported that consideration will be given to a process that includes medication safety for clinical trials.

Our Lady's Children's Hospital, Crumlin and Temple Street Children's hospital had recently held a joint Drugs and Therapeutics Committee meeting. The aim of this meeting was to pre-empt the move to the National Paediatric Hospital by having joint systems and processes in place where possible across the amalgamating hospitals. A review of this committee was outside the scope of this inspection. However, formation of this committee demonstrated that there was collaboration about medication management between the hospitals.

^{*} A formulary is a hospitals preferred list of medicines that staff can use as a reference document to ensure safe and cost-effective prescribing.

Risk management

The prevalence of medication errors and corresponding harm is higher in children than in adults due to greater complexity with respect to prescribing and administration in particular. Children are also at increased risk of harm from medication errors because of their relative size, immature renal and hepatic function, and an inability to communicate signs of the adverse effects of medications. The hospital had established a Medication Safety Committee which was accountable to the Corporate Management Team and provided medication safety reports on activity and key issues to the Drugs and Therapeutics Committee on a monthly basis.

A review of medication safety reports by the Medication Safety Committee highlighted issues that needed to be addressed and formed the basis for the 2016 - 2017 medication safety programme. There was evidence that this programme was reviewed and updated on a regular basis. However, the hospital should look to further progressing its work in this area by devising a formalised overarching medication safety strategy, potentially linking in with other paediatric hospitals in advance of amalgamation as part of the national paediatric hospital project. 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. 13,14

Hospital staff voluntarily reported medication incidents and near misses on a medication incident reporting form. This form was available in both electronic and paper formats. The Medication Safety Committee reviewed all medication incidents and near misses reported. Clinical incident reports were prepared by the Medication Safety Officer and presented to the Drugs and Therapeutics Committee throughout the year. The hospital inputted all medication incidents reported within the hospital to the National Incident Management System[†]. Near misses were not reported to this system. The Medication Safety Officer also 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.

Inspectors were informed that medication incident reporting rates in the hospital had increased significantly in recent years, with a year on year increase of approximately 25% since 2014, as shown in Figure 1. This reflects the emphasis placed on patient

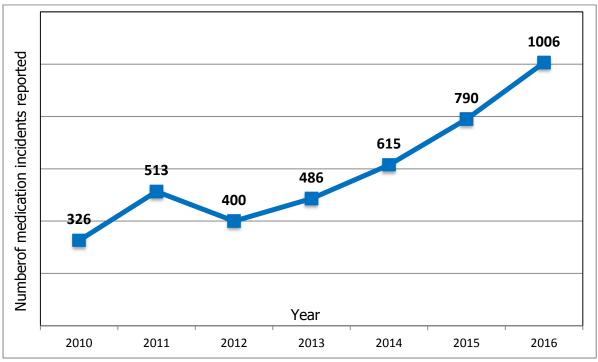
+

[†] 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).

safety by the pharmacy department and the willingness of front-line staff to provide information that is ultimately intended to reduce the risks of harm.

HIQA note that notwithstanding this 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 medications 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. In addition, a review of the documentation provided indicted that despite recent success in improving incident reporting rates, medication-related near misses were still likely under reported at the hospital.

Figure 1: Number of medication safety incident and near miss reports received annually in Our Lady's Children's Hospital, Crumlin 2010-2016.



Medication incidents and near misses were tracked and trended to assess progress, identify emergent medication safety concerns and prioritise medication safety activities. The hospital had identified that a number of detected medication-related incidents related to the use of parenteral nutrition[‡] and had introduced a number of quality improvement measures to address this risk. For example, the '*L* is for LIPID' initiative used multi-faceted risk reduction strategies aimed at reducing the number of prescribing and administration incidents by standardising the way patient specific parenteral nutrition was 'hung' and the order in which the infusion pumps rates were

-

[‡] Parenteral nutrition bypasses the normal digestion in the stomach and bowel. It is a special liquid food mixture given into the blood through an intravenous catheter (needle in the vein). The mixture contains proteins, carbohydrates (sugars), fats, vitamins and minerals (such as calcium).

set. Staff education was used to augment these error prevention strategies. The hospital used the percentage of parenteral nutrition administration incidents reported as one of their medication safety key performance indicators, with a target of zero administration errors. Inspectors were informed that the initiative had resulted in a significant reduction in the number of medication-related incidents related to the use of parenteral nutrition throughout the hospital.

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. Inspectors were informed that the hospital had a process in place to promptly inform parents of patients when medication-related incidents occurred. Staff spoken with reported that it was practice to inform patients if an error was made in relation their medication. Inspectors were informed that over 70 senior members of healthcare staff was provided with training on the national open disclosure policy.

Incident reporting in itself does not improve safety. It needs to be accompanied by strategically targeted quality improvement efforts. Risks, including medication safety incidents and patient complaints were discussed at regular ward/ department based "risk huddles" in the Theatre, Paediatric Intensive Care Unit (PICU), the Cardiology Ward, the Haematology/Oncology Department and on St Michael's Ward. "Risk huddles" took the form of brief and routine multidisciplinary meetings for sharing information about potential or existing safety problems facing patients or staff members. The aim of the risk huddles was to increase communication between the multidisciplinary team, to educate staff on specific topics relating to clinical risk, to highlight areas for improvement and to encourage discussion around patient safety. Minutes were recorded and circulated to the multidisciplinary group following each meeting.

Clinical staff on St Peter's Ward told inspectors that ward operated a 'safety pause'¹⁷ system whereby staff communicated information about patient safety issues at the ward shift handover. This included relaying information about medication risks and medication incidents.

A high medication error and adverse drug reaction reporting rate is an important step in enabling hospitals to tackle medication safety risks to their patients. Other approaches used to inform the overall picture of medication safety risks included retrospective chart review, direct observation, audit, risk assessments, patient surveys, risk meetings and pharmacy team meetings.

Clinical risks that could not be completely eliminated locally were recorded on the corporate risk register. Medication safety was included on this risk register. Inspectors were informed that the Clinical Risk Department was supporting and advising managers in relation to the development of departmental risk registers. It

was explained that departmental risk registers would capture risk information from the "bottom up" within each ward/ department in line with national guidelines. Where actions required to mitigate risks identified are not within the control of the manager at that level risks would be escalated to a more senior level of management for action.

2.2 Audit and evaluation

Line of enquiry:

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

Audit represents a key component of all effective clinical governance programmes. ¹⁹ Elements of medication safety were audited at the hospital but these audits were not aligned to a formalised medication safety audit programme. Furthermore, audit activity throughout the hospital was neither strategically driven nor centrally coordinated. The corporate risk register, dated November 2016 recommended the development of a formal medication safety audit programme for 2017. However, at the time of the announced inspection there was no defined plan or timeframe in which this issue would be addressed. Current arrangements 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 which included:

- 2017 point prevalence survey of healthcare associated infection and antimicrobial use in European acute care hospitals
- 2016 antimicrobial point prevalence survey
- audit of compliance with our lady's children's hospital, Crumlin institutional guideline for treatment of bronchiolitis
- audit of 'out of hours' supply of medicines from the pharmacy over a holiday period
- audit of parental nutrition prescriptions to determine the potassium concentration of the parental nutrition bags and rate of potassium administration
- baseline audit of the pharmacy aseptic compounding service intravenous monoclonal antibody service
- improving the preparation and documentation process for rapid induction kits in Our Lady's Children's Hospital, Crumlin.

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

clinical services. For example, nursing metrics[§] were monitored across the hospital to review practice around some aspects of medication safety and security.²⁰ Action plans were devised for elements that scored poorly and required improvement. Nursing metrics data in relation to medication safety indicated increasing compliance in the storage and security of medications. Medication safety and security audit results were displayed on a "Quality Boards" in ward areas.

Clinical audit findings were presented at the hospital's multidisciplinary annual research and audit conference. Inspectors were informed that over 100 posters were submitted for inclusion in the recent research and audit conference, representing all disciplines showcasing the variety of research and audit activity within the hospital. A pharmacy presentation outlining the impact of electronic prescribing and standard concentration infusions facilitated by smart-pump technology on medication errors in a paediatric intensive care unit won the prize of best overall presentation at the conference.

Key performance indicators

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

- the percentage of prescribers who receive training in paediatric prescribing and medication safety on induction
- the percentage of prescription orders without unapproved abbreviation of medicine name, units or frequency
- the percentage of TPN Administration incidents reported
- the percentage of Level 3 harm errors** and over.

2.3 Medication safety support structures and initiatives

Line of enquiry:

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

The following section of this report provides examples of interventions implemented by Our Lady's Hospital for Sick Children, Crumlin to reduce medication errors and improve patient safety.

* Medication incidents resulting in moderate harm/ significant injury requiring medical treatment.

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

The medication safety week, held in February 2017, aimed to raise awareness of medication safety issues and solutions. A different topic was addressed each day including:

- Tips for safe prescribing
- Safe administration of medicines
- High risk medications and sound alike look alike medicines
- Parenteral nutrition, medicines via feeding tubes
- Formal launch of the medication management policy at Grand Rounds.

Prior to the announced inspection, the hospital was required to submit examples of quality improvement initiatives that had been implemented in the last two years. Several examples were submitted. Strategies employed to improve medication safety included ward based clinical pharmacists, computer technology, standardised concentration medication infusions and educational programmes. Initiatives were designed to ensure that patients received the standardised process of care, often within multifaceted interventions. In reviewing these medication safety initiatives onsite, inspectors found evidence to demonstrate that a number of the medication safety initiatives had been disseminated across the hospital.

Local quality improvement projects were also displayed on the 'quality boards' in clinical areas. These 'quality boards' were observed in areas of high visibility and high footfall to maximise impact. Inspectors were informed that data displayed on the 'quality boards' was discussed at ward handover, ward meetings and during the Corporate Management Team Quality and Safety Walk Around. Frontline staff reported that their experience in displaying quality metrics and quality improvement initiatives on the boards had been positive.

The hospital had identified a list of high risk medications that present a heightened risk of causing significant patient harm if not used correctly. The list was based on the acronym 'A PINCH' to group medications into categories and to facilitate education and to raise awareness of high risk medications.²¹ The medications on the list included:

- Anticoagulants and Anti-thrombotic
- Potassium and Intravenous Paracetamol
- Insulins and Intrathecal/ epidural administration
- Narcotics and Neuromuscular blocking agents
- Cytotoxics
- Hypertonic and Hypotonic intravenous fluids.

This list of high risk medications was identified from international evidence and following the analysis of medication incidents and near misses reported.²² The Medication Safety Committee, in communication with the Drugs and Therapeutics

Committee, reviewed the hospital's high risk medications list every two years or as deemed necessary by either committee. The hospital had also identified a list of sound-alike and look-alike drugs (SALADs). Risk reduction strategies were implemented to ensure that high risk medications and SALADs were prescribed, dispensed and administered safely.²³ Measures included limiting high risk prescribing and availability to specified prescribers and wards and the generation of automatic alerts on the formulary smart phone application. These strategies were augmented by staff education and through the use medication safety alerts displayed in clinical areas. Inspectors also observed policies, procedures and guidelines to support the use of high alert medicines and SALADs.

The hospital is a tertiary referral centre and by actively engaging with other hospitals in the Children's Hospitals Group, was committed to standardising practice and sharing expertise across hospitals. Collaboration within the hospital group in relation to medication safety provided a valuable opportunity to share learning, experience and resources. For example the hospital had collaborated with Temple Street Children's University Hospital to develop a new medication prescription and administration chart. The chart was redesigned to facilitate safe medication prescribing and included the introduction of features to reduce medication errors. The new chart was introduced in May 2016 and its implementation was supported by multidisciplinary staff training.

Critically ill, paediatric patients are at high risk of medication error.²⁴ The hospital had enhanced medication safety in this vulnerable cohort of patients through the introduction of smart-pump technology^{††} and the development of a drug library containing an agreed list of standardised concentration infusions.²⁵ A post implementation audit of this initiative found that the introduction of standardised concentration infusions and smart-pump technology had significantly reduced errors associated with the prescribing of infusions in the PICU. Inspectors were informed that work was on-going to extend the use of smart-pump technology outside of the critical care setting in the hospital.

A cross-site collaborative multi-disciplinary working group was convened and the hospital's drug library was further developed to enable its use across the Irish Paediatric Acute Transport Service^{‡‡} and in the paediatric intensive care unit at Temple Street Children's University Hospital. Standardisation was achieved for paediatric patients requiring intensive care management with continuous intravenous

The Smart-pumps are computerised infusion devices with multiple safety features that include customised drug libraries, dose calculations based on programmed patient weights and the setting of dose limits.

^{‡‡} A 24 hour national service that facilitates the transfer of critically ill infants and children patients, aged from 6 weeks corrected gestational age to the eve of their 16th birthday, from the referring hospital to the PICU in the Children's University Hospital, Temple St or Our Lady's Children's Hospital Crumlin.

infusions. The safety benefits of this cross site standardisation of the smart pump infusion drug library containing a list of standardised drug concentrations facilitated a reduction in the risk of medication error when critically-ill patients were transferred from one facility to another.

Additional practices implemented and evaluated to enhance medication safety in the hospital were identified during this inspection. For example, interruptions during medication administration rounds are thought to be a prominent causative factor of medication errors. To minimize or eliminate nurse distraction during medication administration process, red aprons were worn by nursing staff while preparing or administering medications. This intervention was designed to draw attention to the fact that the medication round was in progress, and that nurses should not be interrupted while administering medications. The '*red apron initiative*' was supported by the provision parent information leaflets and staff education. An audit which was carried out to evaluate the effectiveness of this initiative found that the number of recorded interruptions and associated medication incidents had reduced significantly.

Clinical pharmacy services

The hospital had resourced the majority of clinical areas with a designated clinical pharmacist^{§§}. 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.^{27,28,29,30,31,32} Clinical pharmacists reviewed inpatient medication prescription charts to prevent, identify, and intercept medication prescribing-related incidents. Clinical Pharmacists also played a key role in communicating with the multidisciplinary team with regard to drug therapy and inpatient/ parent counselling and education. The role of clinical pharmacists was documented in a standard operating procedure for clinical pharmacy activities.

However, it was reported that due to resource deficiencies, clinical pharmacy provision was not standardised practice across all clinical areas in the hospital. At the time of the inspection the nephro-urology ward did not have a clinical pharmacy service. In assessing this provision, HIQA is conscious that the nature of the patient population served by the hospital represents a higher degree of complexity and risk from a medication safety perspective than the majority of Irish acute hospitals. It is recommended that an evaluation occurs with respect to the clinical pharmacy service provision at the hospital in light of the added challenges presented by paediatrics.

-

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

Medication reconciliation

Medication reconciliation is a systematic process conducted by an appropriately trained individual of establishing and documenting a consistent, definitive list of medicines across transitions of care and then rectifying any discrepancies. ^{19,33,34,35} The electronic-prescribing system in the PICU can facilitate the recording of medication reconciliation at admission and discharge. The computerised physician order entry (CPOE) system*** used in the PICU generated a list of medications at discharge/ transfer. This medication list with instructions was printed and used for education and review with parents and children.

Inspectors were informed that, in all other areas medication reconciliation was initiated by clinical pharmacists, doctors and nurses within the hospital. However, the effectiveness of this process had not been audited and no training program was in place to support staff in performing formalised medication reconciliation. The medication reconciliation process needs to be further developed and fully formalised throughout the hospital.

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.

Parents of patients should be well informed about any medications their children are prescribed and any possible side-effects. This is particularly relevant for those patients who are taking multiple medications.

Our Lady's Children's Hospital, Crumlin had systems in place to support the provision of information and education to parents and children in relation to medication. Inspectors were informed that clinical pharmacists ensured a seamless transition of care on discharge by liaising directly with the community and offering counselling to parents prior to the child's discharge. Clinical Nurse Specialist also played a prominent role in parent and child medication education. A suite of patient information leaflets had been developed.

As part of this inspection, HIQA asked the hospital to administer an anonymised questionnaire in relation to prescribed medications to a small sample of hospital parents attending the Outpatients Department with their children. The questionnaire was completed by 19 parents whose child had been inpatients in the hospital within

^{***} Computerized physician order entry (CPOE) is the process of a medical professional entering medication orders or other physician instructions electronically instead of on paper charts.

the past year and who were prescribed regular medications. Of the 19 people surveyed:

- All said that a staff member had explained the purpose of new medication in a way that they could understand
- All said that a staff member told them about possible medication side effects to look out for following their child's discharge home
- All said they received instruction on how to administer the medications to their child at home.

It is acknowledged that this was a small sample of parents and therefore may not be representative of all recently discharged children taking prescribed medication. However the results found are very positive, and may indicate that current systems to ensure parent education around medication are working effectively. Moreover these results compare favourably with what HIQA has found so far through this thematic monitoring programme in other hospitals.

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.

The hospital's Medication Management Policy was launched at the hospitals Medication Safety Awareness week in February 2017. This was a multidisciplinary policy to reflect the fact that medicines management is the responsibility of a number of clinical professional groupings. Implementation of this policy and other medicines related information was supported by communication and education provided by clinical pharmacists, the Medication Safety Officer and Clinical Nurse Facilitators.

All medication-related policies, procedures and guidelines were approved by the Corporate Management Team prior to implementation. Inspectors observed that up to date versions of medication policies, procedures, protocols and guidelines were readily available to staff in clinical areas in hard copy and on the hospital's controlled document management system.

The hospital formulary was available via a smart phone application, and on the hospital intranet.. The use of mobile technology gave prescribers easy access to up

to date prescribing guidance at the point of prescribing. This formulary application was also available to other prescribers in external organisations.

In addition, each clinical area visited by inspectors had an electronic tablet device in the clinical room which contained an electronic version of intravenous monographs, the hospital formulary and medication safety alerts. This information was standardised across the hospital, controlled by the Pharmacy Department and updated once amendments were approved though the appropriate processes. The use of electronic tablet devices was supported by an up-to-date standard operating procedure. A survey of frontline staff carried out after implementation found that their experience in using the electronic tablets had been positive with 100% staff using the tablet as the main means of checking medication information.

Clinical pharmacists provided key information about medication to medical, nursing and other staff, as well as to parents and children as appropriate.

The paediatric medicines information service was provided by the Pharmacy Department to staff within the hospital and to external health care professionals from primary, secondary and tertiary care centres. This service provided ready access to expert advice in the management of medication-related queries. It was also involved in assessing new medicines information and formulary applications to optimise safe and effective medication use while enhancing patient care.

Additional decision support tools such as prescribing standards and a quick reference guide for antimicrobial prescribing had also been developed to support prescribing practice. Online access was also available to the British National Formulary for Children.

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

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.³⁶

Medication safety training was mandatory for all new clinical staff. All registered nursing staff were required to successfully complete the:

- medication safety programme and competence assessment
- intravenous therapy management programme and competence assessment.

It was also recommended that nursing staff complete the Health Service Executive medication management online training programme, however uptake of this programme was not monitored.³⁷

Medication safety awareness in the hospital was promoted through staff communication including circulation of medication safety alerts and through medication safety education and policies. However, the hospital did not have a formalised education programme for clinical staff linked to an overall medication safety strategy. It was reported that Clinical Nurse Specialists and Clinical Pharmacists had an important role in the education of nursing and medical staff. Documentation reviewed indicated 164 nurses attend a total of 17 medication safety workshops to date in 2017. It was also reported that ongoing training on medication safety was provided to medical staff at hospital grand rounds. Hospital doctors reported that there was a high level of support available from senior medical staff around prescribing and advice.

Grand rounds are formal meetings where physicians and other clinical support and administrative staff discuss the clinical case of one or more patients. Grand rounds originated as part of medical training.

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. 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.

Medication use in children presents some additional safety challenges when compared to other patient populations. Research shows that the potential for adverse drug events within the paediatric inpatient population is about three times as high as among hospitalised adults.³⁸ Paediatric prescribing also requires weight-related dose adjustment and other complex dosing calculations, which are less commonly encountered in adult prescribing.³⁹ A small error in dose of medication given to children has a greater risk of harm compared to the adult population. For this reason, hospitals must pay special attention to the specific challenges relating to the paediatric population.

Our Lady's Children's Hospital, Crumlin had put governance arrangements in place with systems, processes and practices to support medication safety in the hospital. It was evident that this was driven by effective local leadership and executive management support and resource allocation. There appeared to be a very good working dynamic within the multidisciplinary team working collaboratively to maximise the quality of the medication safety programme. Moreover, there was evidence that the Hospital Board actively sought assurance in relation to medication safety.

Evaluation of medicines, with a view to adding or deleting them from the formulary, is one of the most important functions of a Drugs and Therapeutics Committee.⁷ The Drugs and Therapeutics Committee provided the leadership and structure to select appropriate medications for the formulary and promoted rational drug use.

Prevention of medication errors is dependent on the presence of a well-organised reporting system, supported by a culture of openness around reporting, and greater awareness amongst staff of the systemic nature of many of these errors. 40 Healthcare staff were aware that their hospital had a medication incident reporting system. Medication-related incidents and near misses were analysed and actions were taken to address them with further recommendations made to prevent reoccurrences of such incidents. However further scope for improvement in the degree of near miss error reporting and the degree of error reporting by medical staff was identified.

Numerous interventions were used to improve medication safety, including ward-based clinical pharmacists and the increased use of technology including computerised physician order entry, smart pump infusion technology and the use of smart phone applications. The introduction of medication-use technology provided high-level error-prevention strategies, including constraints, forcing functions, automation, and standardisation.²³ None of these strategies is meant to replace vigilance, but each can greatly augment the safety of practice within the hospital.

The inspection team was provided with numerous examples of hospital-specific medication safety audit activity. However current medication safety auditing arrangements should be strengthened and formalised to regularly provide assurance to the hospital corporate management team about medication safety at the hospital.

Our Lady's Children's Hospital, Crumlin was actively collaborating with other hospitals within the Children's Hospital Group and with regional paediatric centres nationally in order to progress a shared working approach to improving medication safety. Standardising practices across sites is important ground work prior to the opening of the new National Paediatric Hospital.

Hospital management and other staff should continue to build on their work conducted to date to develop a medicines safety strategy that sets out a clear vision for medication safety across the organisation. It is recommended that this report is shared with senior managers, clinicians and other relevant staff at Our Lady's Children's Hospital, Crumlin 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

- 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. World Health Organisation. *Medication Without Harm: WHO's Third Global Patient Safety Challenge*. 2017 (online) Available online from: http://www.who.int/patientsafety/medication-safety/en/
- 4. 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
- 5. 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-medication-safety-monitoring-acute-hospitals
- Health Service Executive. *Quality and Safety Walk-rounds. A Co-designed Approach Toolkit and Case Study Report.* 2016. http://www.hse.ie/eng/about/Who/QID/governancequality/qswalkrounds/
- 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-CATAGAChieving-Effective-Medicines-Governance-final1.pdf
- 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
- 9 Irish Pharmaceutical Healthcare Association (IPHA) Available online from: http://www.ipha.ie/alist/clinical-trials-in-ireland.aspx

- 10 European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI No 190 of 2004. Available online from: http://www.irishstatutebook.ie/2004/en/si/0190.html
- 11 Fernandez, C. V. & Gillis-Ring, J. Strategies for the prevention of medical error in paediatrics. *The Journal of Paediatrics*. 2003 August; 143(2):pp 155-62. Available online from: http://www.sciencedirect.com/science/article/pii/S0022347603002440
- Institute for Safe Medication Practices. Pediatric Pharmacy Medication Safety Guidelines. 2002. Available online from: https://www.ismp.org/pressroom/PR20020606.pdf
- 13 American Hospital Association, Health Research and Educational Trust, and Institute for Safe Medication Practices. Pathways for Medication Safety: Leading a Strategic Planning Effort. 2002.
- 14 Relihan, E. Pathways for Medication Safety: Leading a Strategic Planning Effort. in National Medication Safety Intensive Course and Summit: Towards a National Approach. 2015.
- 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
- Safety briefings (IHI tool). Boston (MA): Institute for Healthcare Improvement; [2003]. Available at: http://www.ihi.org/IHI/.
- 17 Health Service Executive. The Safety pause: Information Sheet. Helping teams provide safe quality care. May 2013 [Online]. Available from http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Clinical_Governance /CG_docs/safetypause.html
- 18 Health Service Executive. Developing and Populating a Risk Register Best Practice Guidance. Dublin: Health Service Executive; 2009. Available online from:

 http://hse.ie/eng/About/Who/OQR010 20090422 v 11Developing and popula ting a Risk Register BPG.pdf
- Australian Commission on Safety and Quality in Health Care. *Safety and Quality Improvement Guide Standard 4: Medication Safety*. 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

- 20 Health Service Executive. Standard Operating Procedure for Nursing and Midwifery Quality Care-Metrics Data Collection In Acute Services. Dublin: Health Service Executive; 2015. Available online from: http://www.hse.ie/eng/about/Who/ONMSD/news/Acute%20Services%20Standard%20Operating%20Procedure%20SOP%20QCM.pdf
- 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
- Institute of Safe Medication Practices. List of High-Alert Medications in Acute Care Settings. Pennsylvania: Institute of Safe Medication Practices;2017. Available online from: http://www.ismp.org/Tools/institutionalhighAlert.asp
- 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
- Franke HA, Woods DM and Holl JL. High-alert medications in the pediatric intensive care unit. *Pediatric Critical Care Medicine*. 2009 January; 10(1): pp 85-90. Available online from: https://www.researchgate.net/publication/23572384_High-alert_medications_in_the_pediatric_intensive_care_unit
- Institute For Safe Medication Practices. Proceedings From the ISMP Summit On The Use Of Smart Infusion Pumps: Guidelines For Safe Implementation And Use. 2009. Available online from: http://www.ismp.org/tools/guidelines/smartpumps/comments/
- Relihan E, Brien V, Hara S, Silke, B. The impact of a set of interventions to reduce interruptions and distractions to nurses during medication administration. Quality and Safety in Health Care. 2010 Oct; 19(5):pp 1-6. Available online from: http://qualitysafety.bmj.com/content/19/5/e52.long
- 27. 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.
- 28. 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
- 29. 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

- 30. 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. 211Chapter 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
- 31. 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
- 32 . Bond CA, Rael CL. Clinical pharmacy services, pharmacy staffing, and hospital mortality rates. *Pharmacotherapy*. April 2007; 27 (4): pp481-93
- 33 . 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/reports-and-publications/guides/guidance-principles-good-practice-medication-reconciliation
- 34. 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
- 35 . 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
- 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
- Health Service Executive. HSELanD. Available online from: http://www.hseland.ie/tohm/default.asp?message=logout
- 38 Kaushal R, et al: Medication errors and adverse drug events in pediatric inpatients. *Journal of the American Medical Association*, 2001, 285:2114-2120
- World Health Organisation. *Medication Errors. Technical Series on Safer Primary Care.* 2016 (online) Available online from:

 $\frac{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1&ua=1}{\text{http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf}}$

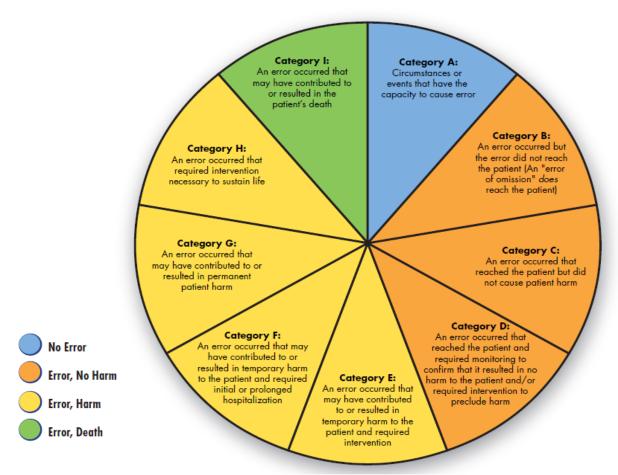
World Health Organisation. *Reporting and learning systems for medication errors: the role of Pharmacovigilance centres.* Washington: World Health Organisation; 2014. Available online from: http://apps.who.int/medicinedocs/documents/s21625en/s21625en.pdf

5.Appendices

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

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

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



2001 National Coordinating Council for Medication Error Reporting and Prevention. All Rights Reserved. Permission is hereby granted to reproduce information contained herein provided that such reproduction shall not modify the text and shall include the copyright notice appearing on the pages from which it was copied.

(C)

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.)

For further information please contact:

Health Information and Quality Authority Dublin Regional Office George's Court George's Lane Smithfield Dublin 7

Phone: +353 (0) 1 814 7400 Email: qualityandsafety@hiqa.ie

URL: www.higa.ie

© Health Information and Quality Authority 2017