Report of the announced inspection of medication safety at Children’s Health Ireland at Crumlin.

Date of announced inspection: 14 May 2019
About the Health Information and Quality Authority (HIQA)

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

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

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

- **Regulating social care services** — The Office of the Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children’s special care units.

- **Regulating health services** — Regulating medical exposure to ionising radiation.

- **Monitoring services** — Monitoring the safety and quality of health services and children’s social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.

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

- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.
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1. Introduction

HIQA’s medication safety monitoring programme began in 2016 and monitors public, acute hospitals in Ireland against the National Standards for Safer Better Healthcare to ensure patient safety in relation to the use of medications.\(^1\) The programme aims to examine and positively influence the adoption and implementation of evidence-based practice in relation to medication safety in acute healthcare services in Ireland.

Medications are the most commonly used intervention in healthcare. They play an essential role in the treatment of illness, managing chronic conditions and maintaining health and wellbeing. As modern medicine continues to advance, increasing medication treatment options are available for patients with proven benefit for treating illness and preventing disease. This advancement has brought with it an increase in the risks, errors and adverse events associated with medication use.\(^2\)

Medication safety has been identified internationally as a key area for improvement in all healthcare settings. In March 2017, the World Health Organization (WHO) identified medication safety as the theme of the third Global Patient Safety Challenge.\(^3\) The WHO aims to reduce avoidable harm from medications by 50% over 5 years globally. To achieve this aim the WHO have identified three priority areas which are to:

- improve medication safety at transitions of care
- reduce the risk in high-risk situations
- reduce the level of inappropriate polypharmacy.*

Medication safety has also been identified by a number of organisations in Ireland as a key focus for improvement.\(^4,5,6,7,8,9\) Medication safety programmes have been introduced in many hospitals to try to minimise the likelihood of harm associated with the use of medications, and in doing so maximise the benefits for patients. These programmes aim to drive best practice in medication safety by working to encourage a culture of patient safety at a leadership level and through the introduction of systems that prevent and or mitigate the impact of medication-related risk.\(^10\)

**HIQA’s medication safety monitoring programme 2019**

HIQA published a national overview report of the medication safety monitoring programme *Medication safety monitoring programme in public acute hospitals- an overview of findings*\(^11\) in January 2018 which presented the findings from thirty-

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* Polypharmacy: the use of many medications, commonly five or more.
four public acute hospital inspections during phase one of the programme. This report identified areas of good practice in relation to medication safety and areas that required improvement, to ensure medication safety systems were effective in protecting patients. A number of recommendations were made focusing on improving medication safety at a local and national level. The recommendations are detailed in the report which is available on the HIQA website (www.hiqa.ie).

The final phase of HIQA’s medication safety monitoring programme has been updated and developed and the current approach is outlined in eight lines of enquiry†. The lines of enquiry are based on international best practice and research, and are aligned to the national standards1 (see Appendix 1). The monitoring programme will continue to assess the governance arrangements and systems in place to support medication safety. In addition, there will be an added focus on high-risk medications and high-risk situations during this monitoring programme.

High-risk medications are those that have a higher risk of causing significant injury or harm if they are misused or used in error.12 High-risk medications may vary between hospitals and healthcare settings, depending on the type of medication used and patients treated. Errors with these medications are not necessarily more common than with other medications, but the consequences can be more devastating.13

High-risk situation is a term used by the World Health Organization3 to describe situations where there is an increased risk of error with medication use. These situations could include high risks associated with the people involved within the medication management process (such as patients or staff), the environment (such as higher risk units within a hospital or community) or the medication.

International literature recommends that hospitals identify high-risk medications and high-risk situations specific to their services and employ risk-reduction strategies‡ to reduce the risks associated with these medications (Appendix 2).14

System-based risk-reduction strategies have a higher likelihood of success because they do not rely on individual attention and vigilance, and a small number of higher-level strategies will be more likely to improve patient safety than a larger number of less effective strategies.14 Therefore, risks associated with the procurement, dispensing, storage, prescribing, and administration of high-risk medications need to be considered at each step of the medication management pathway.15

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† Lines of enquiry are the key questions or prompts that inspectors use to help inform their inspection, assessment or investigation.
‡ Risk-reduction strategies: a term used to describe different ways of dealing with risks. Strategies include risk avoidance, transfer, elimination, sharing and reducing to an acceptable level.
**Information about this inspection**

An announced medication safety inspection was carried out at Children’s Health Ireland at Crumlin by Authorised Persons from HIQA; Nora O’ Mahony, Aoife Lenihan and Lee O’ Hora. The inspection was carried out on 14 May 2019 between 09:00hrs and 16:30hrs.

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

- St Anne’s ward
- St Michael’s ward.

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

- Group one: the interim chair of the Drugs and Therapeutics Committee, the chief pharmacist, the chair of the Medication Safety Committee, the patient safety and clinical risk management advisor and the medication safety officer.
- Group two: the chief executive officer, a consultant anaesthetist (in their capacity as the quality and patient safety lead) and the director of nursing.

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

**Information about the hospital**

Children’s Health Ireland at Crumlin, previously known as Our Lady’s Children’s Hospital Crumlin, is an acute paediatric hospital which provides care for children in the local catchment area. The hospital is also a national referral centre for a range of specialities including children’s childhood cancers and blood disorders, cardiac diseases, major burns, cystic fibrosis, and rheumatology.

Children’s Health Ireland at Crumlin is a part of Children’s Health Ireland, a single statutory entity, established following the publication of the Children’s Health Bill 2018, to provide paediatric services and take over the services currently provided by the existing three Dublin children’s hospitals; Our Lady’s Children’s Hospital, Crumlin, Temple Street Children’s University Hospital, and the National Children’s Hospital at Tallaght University Hospital.
2. Findings at Children’s Health Ireland at Crumlin

Section 2 of this report presents the general findings of this announced inspection. The inspection findings are outlined under each of the eight lines of enquiry and opportunities for improvement are highlighted at the end of each section.

2.1 Leadership, governance and management

Children’s Health Ireland at Crumlin’s Drugs and Therapeutics Committee was responsible for oversight of medication safety within the hospital, with formalised governance arrangements and clear lines of accountability in place for medication safety. The Drugs and Therapeutics Committee was meeting in line with its terms of reference and there was good attendance from members. However, there was opportunity to broaden out membership to ensure representation at meetings from all required disciplines and specialities. The Committee’s terms of reference were due for review, and the hospital had identified this as an opportunity to review membership, to provide assurance that appropriate representation was present at meetings to support decision-making.

Medication safety was further supported by the hospital’s Medication Safety Committee. This committee was accountable to the Corporate Management Team but reported activity and key issues to the Drugs and Therapeutics Committee.

In line with recommended practice, the hospital had developed a formalised Medication Safety Strategy 2018-2020, with a supporting Medication Safety Programme 2018-2019. The strategy informed medication safety activities for the Drugs and Therapeutics Committee and the Medication Safety Committee, with oversight by the Corporate Management Team.

The vision and objectives for medication safety were outlined in the Medication Safety Strategy, with short, medium and long-term goals to achieve these objectives mapped out under the following themes:

- create, communicate and demonstrate a leadership driven culture of safety
- improve error detection, reporting and use of information to improve medication safety
- investigate where technology can help reduce the risk of medication errors
- reduce risk of error with high-risk medication at all stages of the medication use process, including but not exclusive to vulnerable periods of transfer through the healthcare system
- establish a fair and just learning environment for responding to errors
- involve the patient in medication safety initiatives and medication self-management programs
- support and expand the hospital formulary, where selected medications are based on safety and efficacy.

The hospital’s Medication Safety Programme was developed and monitored by the Medication Safety Committee, with annual objectives aligned to the hospital’s overall strategic medication safety goals. Annual medication safety reports were submitted to the Quality, Patient Safety and Risk Governance Committee using the hospital’s assurance template.

Overall the Children’s Health Ireland at Crumlin’s had the essential elements in place to support effective oversight and governance of medication safety with clear strategic objectives for the hospital's medication safety programme.

### 2.2 Risk management

Medication-related risks were documented on the hospital’s corporate risk register. Medication safety was identified as a risk on this register. The risk was reviewed and risk rated, the existing controls in place were outlined, along with the action plans or additional control measures required to mitigate the risks associated with medication safety.

Vinca alkaloids§ are chemotherapy drugs that should only be administered intravenously (IV) and never by any other route. Deaths have been reported worldwide when a vinca alkaloid was dispensed in a syringe but administered into the spinal fluid instead of intravenously. National and international organisations have recommended rigorous safety measures to prevent recurrence of these sentinel** events.¹⁸,¹⁹,²⁰,²¹,²²,²³,²⁴

Children’s Health Ireland at Crumlin had undertaken proactive risk assessments in this high-risk area to mitigate the risk of inadvertent administration of these medications through the intrathecal route††.

The risk assessment:

- examined the controls currently in place to prevent an error associated with the use of vinca alkaloids

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§ Vinca alkaloid: a neurotoxic chemotherapeutic agent which is always administered intravenously. The following drugs are examples in the class of drugs referred to as vinca alkaloids: vincristine, vinblastine, vindesine, vinorelbine and vinflunine.

** A sentinel event: an unexpected patient safety event involving death or serious physical or psychological injury.

†† Intrathecal route: administration of drugs via an injection into the spinal canal, or into the subarachnoid space so that it reaches the cerebrospinal fluid (CSF).
examined the hospital’s compliance against the National Cancer Control Programme (NCCP) 2016 recommendations
risk assessed where the hospital was not fully compliant with the NCCP recommendations, due to current hospital structure and resources constraints.

The hospital had a suite of control measures in place to support the safe practice of administration of vinca alkaloids. To further enhance safety, the hospital was reviewing the introduction of additional high leverage risk-reducing strategies to mitigate the risks associated with vinca alkaloids, such as the use of minibags and NRFit System‡‡.

Administration of vinca alkaloids via minibags serves as a strong forcing function to prevent inadvertent intrathecal administration, and the use of specifically designed devices that cannot connect to a standard luer lock system to avoid the accidental, but potentially fatal, connection of an intravenous infusion or injection have been recommended by international organisation.

**Medication incident reporting**

The hospital had a system in place for the management of medication incidents. Incidents were reported on the hospital’s electronic reporting systems or on hard copy paper versions, which were then inputted into the electronic system.

Reported medication incidents were categorised in terms of severity of outcome as per the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Medication Error Index (Appendix 3). All incidents rated category D§§ and above, were inputted onto the National Incident Management System.***

The number of medication incidents reported by the hospital continued to rise each year, (Figure 1), with the majority of incidents reported by pharmacy and nursing staff. Despite the increase in medication safety reporting, there was still opportunity for improvement with reporting levels of medication incidents from doctors.

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‡‡ NRFit system: different connection for intrathecal medications reducing the risk of misconnections
§§ Category D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.
*** 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).
Analysis of incidents

The medication safety officer produced quarterly medication incident reports outlining quarterly and annual analysis and trending for the:

- number of incidents reported
- disciplines reporting
- location of incidents reported
- report type†††
- stage of the medication process involved in the incidents‡‡‡
- breakdown of the top 10 categories of prescribing and administration errors (the stages of the majority of reported incidents)
- NCC MERP category
- class of medications, and report type involved.

The Medication Safety Committee reviewed the medication incidents, and these were reported quarterly to the Drugs and Therapeutics Committee. A positive trend was seen in quarter four of 2018, with higher numbers of medication safety near miss and risk issues reported rather than actual medication incidents. All medication incidents categorised D§§§ or above were described in detail in quarterly medication incident reports, to share learning and follow-up actions with staff.

Each clinical area received quarterly ward reports presented with graphical displays called dashboards which identified: the number and stage of medication incidents

††† Report type: adverse drug event, incident, near miss or risk issue.
‡‡‡ Stage of medication process: presentation or packaging, delivery, supply ordering, preparation or dispensing, storage, administration or prescribing.
§§§ Category D; An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to prevent harm.

Figure 1. Medication incidents reported 2016 to 2018
reported from the area, the most common medications involved, and whether it was an incident, a near miss or a risk issue. The dashboards also included:

- the most recent trend alert for the hospital
- any significant incidents which had occurred during the quarter
- recommendations to prevent reoccurrence.

Dashboards were emailed to managers, available to staff on all computers and could be displayed as screen savers.

Learning opportunities were identified by the hospital from incidents reviewed. For example, a trend in medication incidents related to paracetamol was reviewed by the hospital and some initiatives were introduced to mitigate the associated risks. This information was discussed and disseminated through the hospital’s Risk Huddles, with a resulting decrease in the number of paracetamol-related incidents reported in 2018.

Risk Huddles were set up on nine clinical areas to monitor and coordinate action on risk issues which may impact on the safe and effective delivery of care and services on wards or units. These multidisciplinary groups met fortnightly or monthly as per the local terms of reference and:

- discussed reported incidents and complaints
- identified and escalated risk issues
- agreed, delegated and monitored action plans identified from discussions.

Since the development of the Risk Huddles the hospital had seen a rise in incident reporting and medication safety improvements, in areas such as paracetamol prescribing (Zero Tolerance PO or IV) **** and the circulation of medication safety alerts.

Staff also outlined how the Yorkshire Framework†††† was used to review a medication incident, and support implementation of quality improvements to mitigate the risk of a reoccurrence of the incident.

**Alerts and recalls**

The hospital had a system in place for acting on medication-related alerts and recalls‡‡‡‡ for both in hours and out of hours. The steps followed in relation to a recent recall was outlined to inspectors.

****Zero tolerance for prescribing of paracetamol by the intravenous or oral route at the same time because of the dosing difference between routes in the paediatric population.

†††† Yorkshire Contributory Factors Framework: a tool which has an evidence base for optimising learning and addressing causes of patient safety incidents by helping clinicians, risk managers and quality and safety advisors identify contributory factors of Patient Safety Incidents.
Opportunities for improvement

- The hospital should identify and support targeted promotion of incident reporting among disciplines with lower reporting rates, so that a culture of reporting incidents is enhanced across all disciplines within a just culture, to support identification of medication-related risks.

2.3 High-risk medications and situations

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

High leverage risk-reduction strategies such as forcing functions, standardisation and simplification needs to be implemented alongside low leverage risk-reduction strategies such as staff education, passive information and the use of reminders.

Children’s Health Ireland at Crumlin had developed a high-risk medications list adapted from the literature and based on local incidents, with a combination of associated high, medium and low leverage risk-reduction strategies in place. To alert staff to these medications, red high-alert stickers were applied to medication packaging prior to dispensing to clinical areas.

The following sample of high-risk medications and high-risk situations were reviewed in detail during this inspection to identify the risk-reduction strategies in place:

- anticoagulants
- insulins
- concentrated potassium chloride
- intravenous paracetamol.

### Notes

++++ Recalls are actions taken by a company to remove a product from the market. Recalls may be conducted on a firm's own initiative or by authorised authority.

§§§§ Just culture: a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace.

***** High-risk situation is a term used by the World Health Organization to describe situations where there is an increased risk of error with medication use.

††††† Risk-reduction strategies: a term used to describe different ways of dealing with risks. Strategies include risk avoidance, transfer, elimination, sharing and reducing to an acceptable level.

‡‡‡‡‡ Anticoagulants: are commonly referred to as blood thinners that prevent or treat blood clots, but these medicines also carry an increased risk of bleeding or clots, so patient education and regular for example monitoring of blood levels are essential to maintain patient safety and ensure good patient outcomes: example warfarin and heparin.
Anticoagulants

Children’s Health Ireland at Crumlin had the following risk-reduction strategies in place to support safe use of anticoagulants:

- warfarin and heparin stocks were rationalised on wards to mitigate risk
- heparin infusions were restricted to specialised areas, and administered using standard concentrations via smart pumps
- clinical pharmacy service was available for all inpatients
- pharmacists were available to guide and support staff
- high-alert sticker were placed on anticoagulants when being dispensed
- warfarin alert stickers were placed on the front of the patient’s medication records, to alert staff that patients were prescribed warfarin
- staff had access to guidance to support safe anticoagulant therapy management
- antidotes were available, and a poster displayed on clinical areas advised regarding same.

However, on one ward visited by inspectors, heparin sodium flushing solution and heparin sodium solution for injection were stored alongside each other in the medication storage cupboard, which could present a risk of misselection.

The standard operating procedure for Prescribing and Administration of Therapeutic Heparin on another ward advised staff that different strengths of heparin were available in the hospital and that extreme caution is required to ensure the correct strength of heparin is used. One heparin solution was 100 times more concentrated than the heparin solution used for locking lines, intravenous access devices or cannulas. To mitigate the risk of misselection, this unit’s procedure outlined that the high-strength heparin should be stored in the controlled drugs cupboard to keep separate from the weaker, more frequently used heparin locking solution.

The hospital should review the storage of different strength heparins in clinical areas, and implement risk-reduction strategies to mitigate risk of misselection across the hospital following this inspection.\(^ \text{27} \)

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\(^{5555} \) Smart pump technology: 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.
Insulin

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

- the hospital had just begun a pilot of an Insulin Therapy Prescription and Administration Record on one ward, to support safe prescribing, administration and monitoring for patient’s prescribed insulin
- the term ‘units’ was used when prescribing insulin
- insulin was double checked prior to administration
- a diabetes clinical nurse specialist was available for patient review and education
- insulin pens in use in the hospital were for single patient use only
- unopened insulin pens were dispensed from pharmacy with a blank flag label and tamper evident seal, and stored in a temperature controlled fridge. Staff reported that when first opened, the patient’s details and the date of opening were recorded on the flag label
- opened insulin pens were stored in the medication trolley within a clear zip lock bag
- the hospital had guidelines to support diabetes care.

However, one opened insulin pen observed by inspectors had the patient’s addressograph attached to the pen, but the date of opening was not recorded, nor did the pen have a flag label.28

Concentrated potassium chloride

Concentrated electrolyte solutions for injection are especially dangerous with potentially fatal consequences when not prepared and administered properly.29 National and international evidence recommends the complete removal of concentrated potassium from patient care areas as the goal, with the use of pre-mixed potassium infusions which were stored segregated from other solutions.29,30,31,32,33

The hospital did not currently stock pre-mixed potassium chloride solution on wards. Inspectors were informed that the specific requirements of the hospital’s patient cohort, and the lack of storage space, were the reasons premixed potassium chloride solutions had not been introduced to ward areas.
The availability of pre-mixed potassium chloride solutions to reduce the requirement for concentrated potassium chloride should be reviewed and risk assessed by the Children’s Health Ireland during future developments.

Concentrated potassium chloride ampoules in use in the hospital did have additional controls in place to support its safe use, for example:

- concentrated potassium chloride was:
  - only stocked in one strength
  - stored securely in the controlled drugs cupboard with its use documented
  - segregated from other medications
  - double checked during preparation and prior to administration

- potassium chloride infusions were administered via electronic infusion pumps

- higher concentrations of potassium chloride were administered via smart pumps in specialist areas

- potassium chloride guidelines were available to guide staff

- policy defined maximum rates and the use of a central line and cardiac monitoring for higher concentrations.

**Intravenous paracetamol**

Intravenous paracetamol was on the hospital’s high-risk medication list, with its use restricted for patients who could not receive this medication by other routes. The hospital had also developed a Zero Tolerance PO or IV policy for prescribing of paracetamol which was being piloted with success, on one ward.

Intravenous paracetamol:

- was administered via electronic infusion pumps or smart pumps where available

- was only available in one intravenous strength

- had guidance available to support staff.

- prescriptions were to be reviewed every 24 hours and switched to oral or rectal route when possible.

An intravenous paracetamol medication safety notice had been developed and was seen displayed on clinical areas visited. Intravenous paracetamol was to be the first topic on the Medication Safety Minute, an initiative adopted from another hospital to share learning in bite size information, which could be read in one minute. This initiative was due to be implemented in May 2019.
Paracetamol prescriptions reviewed by inspectors demonstrated full compliance with hospital policy.

**Other high-risk medications**

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

Children’s Health Ireland at Crumlin had a number of high leverage risk-reduction strategies in place for oral methotrexate. Inspectors were informed that oral methotrexate was not stocked in clinical areas. Only one strength of methotrexate tablets were stocked in the hospital and dispensed as a patient specific single dose. The day of the week methotrexate was to be administered was indicated on the medication record, with all other days blocked out with an ‘x’, to prevent inadvertent daily administration. Parents or guardians and children (as appropriate) were provided with education prior to discharge.

Safe and appropriate prescribing, administration and monitoring of antimicrobials requiring therapeutic drug monitoring was supported by the antimicrobial pharmacist, the infectious disease team and a microbiologist. The hospital had a separate antimicrobial prescribing section on the medication record, with a section to record therapeutic drug monitoring levels to support safe monitoring and administration.

The hospital’s antimicrobial guidelines and intravenous administration guidelines provided guidance for staff. The hospital’s antimicrobial intravenous guidance had been incorporated onto the hospital’s electronic formulary which was accessible to staff on hospital computers and on electronic tablet devices.

The hospital had developed a list of sound-alike look-alike medications (SALADS) which was seen displayed in clinical rooms visited by inspectors. Pharmacy based procurement controls were in place, supported by a policy, to try to avoid the purchasing of new medications with packaging or labelling similar to current stock. Identified SALADS were labelled with yellow sound-alike look-alike stickers to alert staff.

**Opportunities for improvement**

- The hospital should continue to review the risk-reduction strategies in place for high-risk medications. Specifically in relation to: 

****** SALADS are 'sound-alike look-alike drugs'. The existence of similar drugs or medication names is one of the most common causes of medication error and is of concern worldwide. With tens of thousands of drugs currently on the market, the potential for error due to confusing drug names is significant.
the storage of heparin solutions
the use of concentrated potassium chloride.

2.4 Person-centred care and support

Patients should be well informed about any medications they are prescribed and any possible side effects. This is particularly relevant for patients who are taking multiple medications.\textsuperscript{35, 36}

Patient information

Inspectors were informed that medication information was provided to parents or guardians and patients from the multidisciplinary team, predominantly from clinical nurse specialists and pharmacists, as well as from doctors and nurses.

Children discharged on a number of medications received an Oral Medicines Charts which was completed by the pharmacist to support and guide parents or guardians to help children take their medications safely and appropriately post discharge.

Medication reconciliation

Medication reconciliation is a systematic process conducted by an appropriately trained individual, to obtain an accurate and complete list of all medications that a patient is taking on admission, discharge and other transitions in care.\textsuperscript{37, 38, 39}

In Children’s Health Ireland at Crumlin medication reconciliation was not formally undertaken for all patients. However, some pharmacists were reviewing the prescribed medication list using two sources of information and contacting community pharmacists to seek clarification when necessary.\textsuperscript{38}

In the absence of formal medication reconciliation, this service was prioritised by the hospital for cystic fibrosis patients and for children in the paediatric intensive care unit and children’s heart centre. The hospital was doing a baseline audit to identify the level of medication reconciliation currently being undertaken within the hospital with a review to formalising and standardising the process, depending on resources required and available.

Systems to support medication safety and optimisation

The hospital reported that medication optimisation was supported by:

- multidisciplinary team approach to medication prescribing and monitoring

\textsuperscript{****\textsuperscript{****} A Best Possible Medication History (BPMH) is a medication history obtained by a clinician which includes a thorough history of all regular medication use (prescribed and non-prescribed), using a number of different sources of information.}
• structured weekly review of patient’s medications undertaken by some teams, such as haematology and oncology

• clinical pharmacists providing services such as:
  o dose optimisation and adjustment for growing children
  o patient counselling
  o liaising with community pharmacy services to ensure continuity of medication supply post discharge

• clinical nurse specialists who were available for the majority of speciality areas treated and managed within the hospital. These clinical nurse specialists provided patient education and support

• smart pump technology and standardised concentration drug library.

Patient weight measurements are important for medications that require an individual weight-based dose\textsuperscript{40} and patient known medication allergies should be available throughout the episode of care.\textsuperscript{15} Patient’s weights and allergies were recorded on all medication records reviewed by inspectors.

**Opportunities for improvement**

- The hospital should endeavour to develop a formal medication reconciliation service for all patients on transitions of care.

### 2.5 Model of service and systems in place for medication safety

**Clinical pharmacy service**

International studies support the role of clinical pharmacy service\textsuperscript{‡‡‡‡‡‡} in hospital wards in preventing adverse drug events.\textsuperscript{41,42,43,44,45,46} Children Health Ireland at Crumlin had a full clinical pharmacy service in place for all patient care areas apart from the emergency department. Clinical pharmacy services are important for children given that the risk of medication errors and corresponding harm is higher in children than in adults due to the greater complexity with respect to prescribing and administration.\textsuperscript{47,48,49}

**List of approved medications (Formulary)**

\textsuperscript{‡‡‡‡‡‡} Clinical pharmacy service describes the activity of pharmacy teams in ward and clinic settings; ‘core’ activities may include:- prescription monitoring, prescribing advice, optimising therapeutic use of medicines, adverse drug reaction detection and prevention, patient education and counselling.
The hospital had an electronic hospital formulary.\textsuperscript{55} The hospital reported that the intravenous administration guideline and other medication management guidance were in the process of being incorporated into the hospital formulary to streamline access to guidance. This project was being progressed using a phased approach, and had commenced with the addition of local guidance for antimicrobials being incorporated into the hospital formulary.

The system in place for the approval of new medications was under the governance of the Drugs and Therapeutic Committee.\textsuperscript{50} This process ensured appropriate oversight of medications approved for use within the hospital and that a safety evaluation occurred before new medications were introduced.\textsuperscript{51}

### 2.6 Use of information

Access to relevant up-to-date and accurate medicines reference information is essential at all stages of the medication management pathway.\textsuperscript{11, 15}

Children’s Health Ireland at Crumlin had a number of medication information sources available for staff such as:

- intravenous medication administration guidelines
- British National Formulary for Children available in hard copy and via Medicines Complete
- medication protocols and guidelines
- hospital formulary
- antimicrobial guidelines.

Medication information was easily available to staff on ward computers and on electronic tablet devices. These were located in the medication preparation room and attached to mobile medication trolleys. Medication safety information, alerts and safety notices were displayed on information boards and seen as computer screen savers in a ward area accessible to staff.

It is recommended, by both the Health Service Executive\textsuperscript{52} and the National Clinical Effectiveness Committee\textsuperscript{53} that policies, procedures and guidelines are reviewed and updated every three years. The hospital had an extensive suite of medication-related policies, procedure and guidelines. Some guidance documents reviewed by inspectors were overdue for review.
2.7 Monitoring and evaluation

Monitoring of medication safety should be formally planned, regularly reviewed and centrally coordinated with resulting recommendations actioned, and the required improvements implemented.\(^\text{15}\)

The development and implementation of a medication safety audit programme was included in the hospital’s Medication Safety Programme 2018-2019. The hospital’s Medication Safety Audit Plan for 2017-2018 outlined monthly and annual audits to be undertaken. A number of the completed audits were reviewed by inspector such as:

- audit of review of therapeutic drug monitoring on the medication record
- pharmacist review of patient’s allergy documentation on the medication record
- audit of the impact of Zero Tolerance policy on the safety of paracetamol prescribing on Our Lady’s ward
- monthly prescribing and administration audits
- medication safety and security audits
- direct observational study of infusion errors associated with smart pump technology in the paediatric intensive care.

Inspectors were informed that the results of the monthly medication safety and security audits were compared, and actions taken based on findings.

Medication safety audits undertaken identified areas for improvement, however some audits reviewed did not outline: the required action or quality improvement plans, time frames, persons responsible or re-audit plans, to ensure the desired improvements have been achieved.

The hospital had developed a medication practice nurse role in 2018 to promote, and where necessary to establish structures and processes to support safe medication practices. The medication practice nurse undertook 3-4 week placements on different clinical areas and:

- undertook a baseline review of the medication processes in the areas
- developed quality improvement plans based on issues identified
- evaluated the impact of interventions implemented in each area.

When the medication practice nurse had completed placements in seven clinical areas, the re-audit data showed an improvement in the following medication metric measurements:

- medication prescribed correctly and in accordance with policy
- medication administered correctly and in accordance with policy
- metrics in relation to storage and security of medications
- metrics in relation to audit of patient allergy status.
Opportunities for improvement

- Medication safety audits should have time-bound action plans, which are implemented and re-audited to ensure the required improvements are achieved.

2.8 Education and training

Staff education can effectively augment error prevention when combined with other strategies that strengthen the medication-use system.\textsuperscript{54}

Children’s Health Ireland at Crumlin had a structured medication safety induction programme for both nurses and doctors. Nurses completed a mandatory workshop including intravenous drug administration with an associated medication management workbook to be completed.

A variety of classroom and ward-based education sessions were facilitated by; the medication safety officer, pharmacists, clinical nurse facilitators, nurse tutors, and the medication practice nurse, to keep staff up to date and informed on medication safety issues, such as:

- medication safety management
- high-risk medications and SALADS
- safe medication practice awareness
- medication safety respond near miss and incident reporting system
- antibiotic cards
- medication safety induction.

Clinical nurse facilitators allocated to clinical areas provided targeted ward-based education for nurses relevant to the cohort of patients and their conditions.

The hospital also ran annual multidisciplinary Quality Showcase Days and Research and Audit Conferences, which had medication safety themed sessions, as well as annual Medication Safety Awareness Weeks.
3. Summary and conclusion

Medications play a crucial role in maintaining health, preventing illness, managing chronic conditions and curing disease. However, errors associated with medication usage constitutes one of the major causes of patient harm in hospitals and the impact of medication errors can be greater in certain high-risk situations. Risk of medication errors in children is higher due to pharmacological factor such as age-based variability in absorption, metabolism and excretion of medications. In addition, dose calculations for children are more complex due to weight based dosing and unit conversion for the small does required.

Understanding the situations where the evidence shows there is higher risk of harm from particular medications and putting effective risk-reduction strategies in place is key for patient safety.

Overall the Children’s Health Ireland at Crumlin had the essential elements in place to support effective medication safety, with clear strategic objectives for the hospital’s medication safety programme, driven by local leadership with executive management support.

The hospital was proactive in identifying areas of risk for their paediatric population and had implemented a suite of high, medium and low leverage risk-reduction strategies to mitigate, in so far as possible, the associated risks for their high-risk population.

The hospital had systems and models in place to promote medication optimisation supported by a multidisciplinary team approach to care. A clinical pharmacy service was available on all inpatient areas and clinical nurse specialists were available to support children in a large number of specialities. The medication safety officer, the medication practice nurse and ward based clinical facilitators all further supported staff in safe medication use for the hospital’s high-risk population.

There was a system in place for the approval of new medicines which was under the governance of the Drugs and Therapeutic Committee, and medications in use in the hospital were included in the hospital’s electronic formulary.

Staff had access to medication reference information at all stages of the medication management pathway. Structured medication safety education was provided on induction, with a variety of ongoing ward and classroom based sessions provided for staff.

In the absence of formal medication reconciliation, the hospital had prioritised the service for some high-risk patients. The hospital was undertaking a review of the medication reconciliation service with a view to formalising and standardising the
process, depending on resources required and available. The hospital should endeavour to develop a formal medication reconciliation service for all patients on transitions of care.

The number of medication incidents reported continued to rise each year, but there was still opportunity to improve reporting across some disciplines. Incidents were analysed and trended, with learning opportunities identified and shared with front-line staff.

The hospital had a medication safety audit plan with evidence of audits undertaken provided to inspectors. The hospital should ensure that all audits undertaken have time-bound action plans, which are implemented and re-audited to ensure the required improvements are achieved.

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

This report should be shared with relevant staff at Children’s Health Ireland at Crumlin and at the Children’s Health Ireland Group level, to highlight the findings from the inspection including what has been achieved to date and to foster collaboration between the three paediatrics hospitals in relation to opportunities for improvement.
4. References


## 5. Appendices

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

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

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Appendix 3: National Coordinating Council for Medication Error Reporting and Prevention. Index for Categorising Medication Errors

Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting there from.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)


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