Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the announced inspection of medication safety at Connolly Hospital, Dublin.

Date of announced inspection:

23 November 2016

About the Health Information and Quality Authority

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

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

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

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

Regulation — Registering and inspecting designated centres.

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

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

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

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

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1. Introduction

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

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

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

An expert advisory group was formed to assist with the development of this medication safety monitoring programme. The advisory group membership includes 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 this report in Appendix 1. Further information can be found in a *Guide to the Health Information and Quality Authority's Medication Safety Monitoring Programme in Public Acute Hospitals 2016* [4] which is available on HIQA's website: www.hiqa.ie

An announced medication safety inspection was carried out at Connolly Hospital by Authorised Persons from HIQA; Kathryn Hanly, Aileen O' Brien and Judy Gannon. The inspection was carried out on 23 November 2016 between 10:30hrs and 16:45hrs. Interviews were held in the hospital with the following groups of managers and clinical staff:

- Group one: a medical senior house officer, a surgical intern and a senior pharmacist
- Group two: the Chairperson of the Drugs and Therapeutics Committee, the Chief Pharmacist, and the Head of Risk Management
- Group three: the Clinical Director, the General Manager and the Director of Nursing

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

- Maple Ward
- Laurel Ward

HIQA would like to acknowledge the cooperation of staff who facilitated and contributed to this announced inspection and the hospital outpatients who spoke with inspectors.

2. Findings at Connolly Hospital

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

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.

At the time of this inspection, Connolly Hospital did not have a formal medication safety programme in place, which was underpinned by an overarching medication safety strategy, prioritised on the basis of identified risk.

The hospital had a Drugs and Therapeutics Committee with a stated mission to promote the safe and effective use of all aspects of the medication management process in the hospital. However, inspectors were informed that the Drugs and Therapeutics Committee only met once in 2015 due to the lack of a nominated chairperson. The committee was reconvened in 2016 with a new chairperson, a senior clinician. However, administrative support for the committee was not resourced by hospital management until July 2016. Up until the date of inspection the Drugs and Therapeutics Committee had met five times during 2016.

Multi-disciplinary membership of the committee included senior clinicians from the rheumatology, microbiology and psychiatric services. Other members included the Chief Pharmacist, the Risk Manager, a nurse practice development coordinator, a non consultant hospital doctor and an emergency department clinical nurse manager. Minutes of 2016 committee meetings reviewed did not show attendance by representatives of the hospital Executive Management Team or the surgical

service. The Drugs and Therapeutics Committee membership did not have representation from general practice or community pharmacy.

The Drugs and Therapeutics Committee was one of 18 committees that reported into the hospital's Quality and Safety Executive. The chairperson of the Drugs and Therapeutics Committee was a member of the Quality and Safety Executive. The Quality and Safety Executive reported into the Hospital Executive which was chaired by the General Manager. The chairperson of the Drugs and Therapeutics Committee informed the inspection team that the Drugs and Therapeutics Committee reported annually to the Quality and Safety Executive. In addition both the Chief Pharmacist and the Risk Manager sat on the Drugs and Therapeutics Committee and the Hospital Executive Committee, identified risks were escalated directly to the Hospital Executive through this mechanism.

A number of risks in relation to medication safety identified were recorded on the hospital's executive risk register and these included:

1. The financial risk of uncontrolled use of high-cost drugs.
2. The clinical and corporate risk of not having a robust electronic document management system
3. The clinical and corporate risk of not having a medication safety infrastructure in Connolly Hospital. In this regard, the Drugs and Therapeutics Committee had endorsed the submission of a business case for a Medication Safety Pharmacist.
4. The clinical and corporate risk of not having an adequately resourced clinical pharmacy service.

There was no defined plan or timeframe in which these substantive issues would be addressed. It was reported that the Drugs and Therapeutics Committee were planning to conduct a baseline audit of medication safety at the hospital at the beginning of 2017 in order to identify areas for improvement.

Senior management told inspectors that there was likely underreporting of medication-related incidents at the hospital. A system was in place for staff to voluntarily report medication-related incidents and near misses using a printed incident report form. Staff who spoke with inspectors were able to describe the hospital process for reporting medication-related incidents. In order to improve clinical incident reporting the hospital had provided training to staff about incident reporting to coincide with the introduction of a new national incident report form which was introduced in early 2016. A staff survey regarding the use of this form was performed in June 2016. An action plan was developed to address issues identified by the survey which included provision of a training update for staff with feedback regarding reported incidents. Frontline staff who spoke with inspectors on the day of inspection reported that they had not received feedback on medication-

related incidents that they had reported. Inspectors were informed that medication-related incident forms were reviewed by the Pharmacy Department. However at the time of inspection the hospital did not have an established system to track and trend medication-related incidents. It is recommended that there is appropriate oversight of medication-related incident management at the hospital to facilitate the identification of medication-safety related risks and the implementation of evidence-based system changes to enhance medication safety across the hospital. Current structures and systems to support medication safety at the hospital need to be strengthened.

2.2 Audit and evaluation

Line of enquiry:

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

Hospital management reported that three performance indicators were used to evaluate medication safety at the hospital and these included compliance with nursing metrics, compliance with antimicrobial guidelines and medication-related incident reporting rates. Feedback in relation to these performance parameters was fed back to prescribers, the Drugs and Therapeutics Committee and senior hospital management.

Inspectors were told that the hospital reported patient safety metrics[*] to the management of the Royal College of Surgeons in Ireland Hospital Group on a monthly basis and these included any clinical risks related to medication safety, audits and quality improvements related to medication management. Serious medication-related incidents would be reported through this forum if they were identified.

Elements of medication safety were evaluated through audit at the hospital but these audits were not formally aligned to a medication safety strategy.

It was reported that the hospital had formalised arrangements to implement an annual programme of clinical audit across clinical directorates with oversight of audit proposals by the Quality and Patient Safety Committee. The hospital had developed an audit proposal form to facilitate this process.

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

2.3 Medication safety support structures and initiatives

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

The hospital did not have a medication formulary[†] or an up to date, locally approved list of medications stocked in the hospital or readily available from outside sources. The purpose of maintaining an approved list of medications used in the hospital is to ensure the appropriate and safe use of medicines. Development of a medication formulary was included in the role of the Drugs and Therapeutics Committee as outlined in the committee's terms of reference.

A formal process for evaluating requests for the supply and evaluation of new medications in the hospital had been recently developed and approved by the Drugs and Therapeutics Committee.

High-alert medications are medications that bear a heightened risk of causing significant patient harm when used in error. The hospital did not have an identified list of high-alert medications that bear a heightened risk of causing significant patient harm when they are not used correctly.

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 hospitals in preventing adverse drug events.[5,6,7,8,9,10] Clinical pharmacy service provision was limited at Connolly Hospital and was not standardised across the hospital. The hospital had implemented an innovative multidisciplinary team care pathway to meet the care needs of frail elderly patients at time of their admission to hospital. It was reported that a senior clinical pharmacist, with support from a senior pharmacy technician, performed medication reconciliation[‡] and medication review for elderly patients in the Emergency Department. A clinical pharmacist was allocated to the Intensive Care Unit for two hours a day from Monday to Friday.

The Drugs and Therapeutics Committee had approved the introduction of a new medication prescription and administration chart for hospital-wide use. The chart was redesigned to facilitate safe medication prescribing and included sections for

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[†] Formulary: a hospital's approved list of medicines that staff can use as a reference document to ensure safe and cost-effective prescribing.

[‡] Medication reconciliation at admission involves using a systematic process to obtain an accurate and complete list of all medications taken prior to admission

recording therapeutic dose monitoring, warfarin[§], venous thromboembolism (blood clot) prophylaxis and treatment, antimicrobials including surgical prophylaxis, infusions and additives, continuous medication infusions and oxygen therapy. The chart also included specific instructions for clinical staff around safe prescribing and administration of medication. There was designated space to record medication reconciliation. However the utilisation of this section of the prescription chart was not standardised across the hospital. It is recommended that medication reconciliation is carried out in a formalised manner by trained and competent health professionals with the necessary knowledge, skills and expertise.[11,12,13,14]

The new chart was introduced in August 2016 and its implementation was supported by multidisciplinary staff training. The hospital had audited the use of this chart and surveyed staff to ascertain their satisfaction with it. They found that staff were generally satisfied with the new medication prescription chart and that there was generally good compliance with completion of revised sections of the chart. This is an example of good practice and allows the hospital to customise this document for the benefit of staff and patients. There were plans to repeat this audit in 2017.

The hospital has recently introduced a form to formally evaluate the quality and safety of new medicines before use. However, there was no documented procedure in place for urgent requests for the use of non-listed medicines in an emergency situation. Standard criteria for decision making should be defined and consistently implemented by the Drugs and Therapeutics Committee across all decisions for new medicines.

Inspectors were informed that the hospital has a process in place to promptly inform patients when medication-related incidents occurred. Staff who spoke with inspectors were familiar with this policy and could provide examples of when they had utilised this policy in practice. 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.

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.

Connolly Hospital had some systems in place to support the provision of patient information and education in relation to medications. Inspectors were informed that clinical pharmacists endeavoured to provide education to patients upon initiation of

[§] a medicine used to treat or prevent blood clots

oral anticoagulant medication. However, due to insufficient pharmacy resources such practice was not standardised across the hospital.

Patient information leaflets in relation to medication use from the Health Products Regulatory Agency and the Pharmaceutical Society of Ireland were observed in clinical areas. Other examples of patient information leaflets available included a warfarin information booklet, a methotrexate leaflet and a patient information document for patients who had suffered a heart attack.

Clinical nurse specialists in Connolly Hospital attached to respiratory and endocrinology specialities provided direct patient education for example on inhaler and injection technique and monitoring of blood sugars.

As part of this inspection, HIQA asked a small sample of hospital outpatients attending the Outpatients Department to complete a questionnaire in relation to prescribed medications. The questionnaire was completed by 11 people who had been inpatients in Connolly Hospital within the past year and who were prescribed regular medications. Of the 11 people surveyed:

- none said that as well as being provided with a prescription form to take to their local pharmacy or GP, they had also been given a list[**] that outlined what medicines they were on in a way they could understand.
- ten said that a staff member had explained the purpose of new medication in a way that they could understand
- eight said that a staff member told them about possible medication side effects to look out for following discharge home
- nine said they received instruction on how to take their medications at home.

It is acknowledged that this was a small sample of outpatients and therefore was not representative of all recently discharged patients taking prescribed medication. This information did however, provide some information about outpatients understanding and could be expanded upon and used to identify opportunities for improvement.

[**] Patient-held medication lists are completed by a healthcare professional to accurately list all medications the patient is taking at time of discharge.

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 has developed a number of multi-disciplinary policies procedures and guidelines to support safer medication usage. These included a medication management policy and an intravenous medication administration policy. A number of intravenous medication administration guidelines reviewed by inspectors were still in draft format and had not been formally approved for use at Connolly Hospital. Delays in finalising drug monographs were acknowledged by hospital management.

The hospital did not have a controlled document control system to ensure that staff had access to the most up to date versions of hospital policies, procedures and guidelines. Inspectors found a lack of standardisation of policies, procedures and intravenous medication administration guidelines on the two wards visited during this inspection.

Healthcare professionals reported they had ready access to patient information, relevant to the safe use of medications, at the point of clinical decision making. Inspectors observed that decision support tools were available to staff in clinical areas which included:

- the British National Formulary in print and electronic formats,
- the Royal College of Surgeons in Ireland Hospital Group antimicrobial prescribing guidelines available in print format and in electronic format on computers in clinical areas and on a smart phone application.
- online evidence-based clinical decision support resources.

Both nurses and doctors reported they could contact the pharmacy during office hours from Monday to Friday for information regarding appropriate medication use.

Medication safety awareness was promoted through notices, safety alerts and newsletters, for example, the Pharmacy Department circulated internal notices regarding new medications, safety alerts, medication supply, recalls, brand switches and storage of medications. The Risk Management and Patient Services Department produced a Quality and Safety newsletter which included topics on medication safety.

The Drugs and Therapeutics Committee had also developed a policy around engagement of pharmaceutical company representatives with 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.

Nursing staff were required to attend an intravenous medication administration competency training. The provision of formal staff education and training about medication safety to medical staff was limited and was not aligned to an overarching medication safety strategy. The Pharmacy Department gave a short educational presentation to new medical staff at induction. It was reported some ongoing training on medication safety was provided to medical staff, for example at hospital grand rounds[††] and morbidity and mortality meetings. New nursing staff were required to complete the HSELanD Medication Management online training programme.[15] The hospital had held an antimicrobial awareness day in 2016 and the Consultant Microbiologist and the Antimicrobial Stewardship Pharmacist had provided training around antimicrobial use to staff.

It was reported that senior nurse managers had received training in relation to systems analysis[‡‡]. In addition, the hospital had developed a tool for nursing staff to facilitate reflective learning following a medication-related incident in order to promote professional development and prevent reoccurrence. It was also reported that 390 staff members at the hospital had been trained in relation to the hospital's open disclosure policy.

[††] 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.

[‡‡] System analysis is a retrospective review of a patient safety incident undertaken in order to identify what, how and why it happened. This process is to identify potentially preventable and predisposing factors and prevent further recurrence of such events.

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 safety should therefore be a priority area for all acute hospitals as they seek to ensure a high quality and safe service for patients.

Connolly Hospital did not have a defined, multidisciplinary medication safety programme in place at the time of this inspection. The hospitals governance structures for medication safety were being developed. HIQA notes the relative deficiencies in the hospital in relation to the overall complement of clinical pharmacy resources.

Drugs and therapeutics committee meetings should be attended by a hospital executive manager in accordance with committee terms of reference. Hospital management should build on their work to date to develop a written medium to long-term medication safety strategy that sets out a clear vision for medication safety across the hospital. In the absence of recent specific local guidance in this area, international guidelines which outline best practice in relation to medication safety governance and improvement are available, and should be considered by staff responsible for patient safety in the hospital setting.[16]

Medication-related incidents were likely significantly under reported at the hospital. However, at the time of the inspection the hospital did not have established arrangements in place to track and trend medication-relation incidents and to implement evidence-based system changes to prevent reoccurances.

The hospital had developed and implemented a new medication prescription and administration chart across the hospital. This was aimed at enhancing medication safety and was well received by staff. Nursing staff had been provided with training around open disclosure and investigation of incidents.

Patient education is an essential component of the safe, effective and cost-effective use of medicines. Patient medication education should be initiated upon admission and continue throughout the hospital stay.[17,18] The patient survey conducted by HIQA provides some information about information provided to patients and this could be used to further improve communication with patients about their medications.

The hospital should focus its efforts to address current risks in relation to medication safety, and work to ensure that the necessary governance

arrangements and resources are in place to protect patients from the risk of medication-related harm.

The hospital could also further explore the potential to collaborate within its hospital group structure, to share and develop good practice pertaining to medication safety.

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5. Appendices

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

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

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.hiqa.ie

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