



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the announced inspection of medication safety at Letterkenny University Hospital.

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About the Health Information and Quality Authority

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

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

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

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

Regulation — Registering and inspecting designated centres.

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

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

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

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

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1. Introduction

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

Medication related events were the third most common type of adverse event recorded in the Irish National Adverse Events Study.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 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*⁴ which is available on HIQA's website: www.hiqa.ie

An announced medication safety inspection was carried out at Letterkenny University Hospital by Authorised Persons from HIQA; Dolores Dempsey Ryan and Nora O' Mahony. The inspection was carried out on 3 August 2017 between 09:00hrs and 17:10hrs. Interviews were held in the hospital with the following groups of managers and clinical staff:

- Group one: the General Manager, the Chief Pharmacist, and the designated person deputising for the acting Risk Manager/Advisor.
- Group two: the Chairperson of the Drugs and Therapeutics Committee, the Associated Clinical Director for the Medical Directorate, the Associated Clinical Director for the Woman's and Children's Directorate, the Assistant Director of

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Nursing for Woman's and Children's Directorate and the Assistant Director of Nursing for the Peri-operative Directorate.

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

- Medical 2 Ward
- The Paediatric Ward

In addition, a survey was conducted among outpatients in the Outpatient's department.

HIQA would like to acknowledge the cooperation of staff who facilitated and contributed to this announced inspection and the hospital's outpatients who completed an anonymised questionnaire.

2. Findings at Letterkenny University Hospital

The following sections of this report outline the main findings of the inspection. The report is structured as follows:

- **Section 2.1** outlined an immediate high risk identified during this announced inspection.
- **Sections 2.2 to 2.6** present the general findings of this announced inspection which are aligned to the lines of enquiry.

2.1 Risks identified

During the announced inspection conducted at Letterkenny University Hospital on 03 August 2017, HIQA identified an immediate high risk at the hospital relating to a relative lack of leadership, governance and management of medication safety related risk. In short, while the hospital had a Drugs and Therapeutics Committee which met up to September 2016, this committee had remained suspended until a very recently reconvened Committee met, in the week preceding HIQA's inspection. Consequently, appropriate governance oversight of medication safety related risk was not present during this time period at the hospital. Consequently, HIQA wrote to the hospital to express that this apparent lack of sustained governance represented a high risk to patients which needed to be comprehensively addressed.

In response, to assure HIQA that risks identified during the inspection were appropriately addressed; the hospital reported that they had acted to address the deficiencies in leadership, governance and management of the medication safety service highlighted by HIQA through the following actions:

- The hospital planned to strengthen governance structures, and to enhance and sustain the re-formed Drugs and Therapeutics Committee. It intended to do this through reviewing its membership, to ensure representation of key staff members from each directorate, through the revision of its terms of reference, and through the agreement of a formalised regular schedule of meetings for the remainder of 2017. In addition, to further enhance existing governance arrangements, the hospital planned to establish a medication safety sub-group of the Drugs and Therapeutics Committee to advance a medication safety programme and promote patient safety relating to medicine usage in the hospital.
- The hospital reported to HIQA that they have taken corrective action to improve communication and oversight relating to medication safety at the hospital with the Quality and Patient Safety Advisory Committee and the Hospital Executive Board. It was reported that the Drugs and Therapeutics Committee's Report will be a standing item on the agenda of the Quality and

Patient Safety Advisory Committee, and additional feedback relating to medication safety concerns and quality recommendations from the Drugs and Therapeutics Committee will form part of the 'Quality and Safety Site Activity and Monitoring Report' for the Hospital Executive Board.

- To ensure the management of medication safety within the hospital is appropriately integrated with and supported by the Saolta University Healthcare Group, it is intended that the General Manager and the Chair of the Drugs and Therapeutics Committee will attend the Saolta Group's Drugs and Therapeutics Committee meetings. HIQA note that for the hospital to comply with the Saolta Group's Drugs and Therapeutics Committee terms of reference 2016, the Chief Pharmacist should also attend these meetings – this should be further reviewed following this inspection.

A copy of the letter issued to the hospital regarding the risks identified during the inspection on 03 August 2017 and a copy of the response received from the hospital are shown in Appendices 2 and 3 respectively.

2.2 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.

Letterkenny University Hospital is a Model 3 hospital⁵ within the Saolta University Health Care Group delivering acute general and maternity services to the North-Western region of Ireland.

HIQA found on the day of inspection that there was a relative lack of leadership, governance and management of medication safety related risk at Letterkenny University Hospital.⁶ The Hospital had no formalised governance arrangements and organisational structures with clear lines of accountability in place to support the safe use of medications due to the absence of a functioning Drugs and Therapeutics Committee.⁶ Despite this, HIQA noted that prior to September 2016, the hospital had a functioning Drugs and Therapeutics Committee in place that provided governance and oversight for medication safety.

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In August 2017, the hospital re-formed the Drugs and Therapeutics Committee with the appointment of a medical consultant as its chair.⁷ The Drugs and Therapeutics Committee had agreed terms of reference dated 2015 which outlined the purpose, roles and responsibilities, accountability reporting relationships and membership. Membership of the Committee was multidisciplinary and included medical representation from some of the clinical directorate, pharmacy representatives, nursing staff, the General Manager and the acting Clinical Risk Manager/Advisor to reflect the fact that medication management was the responsibility of a number of clinical professional groupings.⁷ A review of the minutes of the Drugs and Therapeutics Committee dated 2015 and 2016 showed that attendance at meetings was variable and not in line with its terms of reference. Inspectors were informed that the primary reason for the cessation of the Drugs and Therapeutics Committee meetings after September 2016 was due to the resignation of the chairperson, exacerbated by the lack of attendance by key members which resulted in the failure to achieve a smooth transition to a new chairperson of the Drugs and Therapeutics Committee. The hospital should revisit the membership of the committee with the aim of ensuring greater, more consistent involvement and leadership from key staff from each of the clinical directorate at these meetings in line with its terms of reference.

Hospital managers who spoke with inspectors acknowledged that there was a significant gap between the last meeting of the Drugs and Therapeutics Committee in September 2016 and the first meeting of the newly re-formed Committee August 2017. The absence of a Drugs and Therapeutics Committee had been recorded on a risk register viewed by inspectors. Inspectors were informed that in the absence of the Drugs and Therapeutics Committee meetings, senior hospital managers assured themselves of medication safety at the Quality and Patient Safety Advisory Committee by relying on; incident reports recorded in the monthly 'Quality and Safety Site Activity and Monitoring Report'; concerns raised by clinical and pharmacy staff; and from medication safety related investigations. Nonetheless, the Quality and Patient Safety Advisory Committee could not provide full oversight and governance of medication safety consistent with the responsibilities of a functioning Drugs and Therapeutics Committee. The hospital should now ensure that the re-formed Drugs and Therapeutics Committee is sustained and functions in line with its terms of reference.

The Drugs and Therapeutics Committee reported to the hospital's Quality and Patient Safety Advisory Committee and through that Committee to the hospital's Executive Board. Documentation provided to inspectors showed that there were deficits with regard to the level of communication between the Drugs and Therapeutics Committee, the Quality and Patient Safety Advisory Committee and the Hospital Management Board regarding medication safety incident reporting and a

medication quality improvement plan. The Drugs and Therapeutics Committee needs to strengthen and formalise its communication with the Quality and Patient Safety Advisory Committee, and the Hospital Management Board, to assure senior hospital managers on the governance and oversight of medication management system within the hospital following this inspection. In addition, communication and oversight at senior management level at the hospital and hospital group level needs to be strengthened to ensure that medication safety is consistently supported and improved within the hospital.

For a Drugs and Therapeutics Committee to be effective, there must be a structured drug selection system that is explicit in its methodology, transparent and evidence-based.⁷ Inspectors found that while Letterkenny University Hospital had a pharmacy stock drug list, they did not have a locally approved hospital formulary.* The purpose of maintaining a formulary is to ensure that appropriate governance exists with the Drugs and Therapeutics Committee around what is approved for use and that in doing so, a proper safety evaluation occurs before medications are introduced into practice at the hospital.⁸ The hospital had a drug request form to support the addition of a new drug to the pharmacy stock list, but overall, there was no formal criteria in place to support the application or evaluation of new medicines based on efficacy, safety, quality or cost. As Letterkenny University Hospital is part of the Saolta Group, the potential of hospitals developing and sharing a medicines formulary should be considered within the group.

Inspectors were informed that the hospital did not have a formalised written medication safety programme plan or medication strategy, but had implemented a number of quality improvement initiatives to support medication safety. The re-formed Drugs and Therapeutics Committee should now progress with devising a formalised written medication safety strategy and a quality improvement plan with clearly defined objectives. In the absence of national guidance in this area, international guidelines^{9,10} which, outline best practice in relation to medication safety strategic planning and medicine quality improvement initiatives should be considered.

Risk management

The main source of medication error data in the hospital was the voluntary reporting system. The hospital had recently implemented a new incident management system

*A formulary is a hospital's preferred list of medicines that staff can use as a reference document to ensure safe and cost-effective prescribing.

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for reporting and addressing medication errors and near misses. This new incident management system was also used within the Saolta University Health Care Group.

All incidents including medication incidents were inputted into the hospital's new incident management database and also inputted on the National Incident Management System (NIMS)[†]. Issues which were considered to potentially compromise the safe administration of medication were included on the hospital's risk register. The incidents on the corporate risk register were graded using the Health Service Executive (HSE) risk matrix¹¹. Inspectors viewed the Pharmacy Department's and the hospital's risk registers, and noted that risks relating to medication safety were recorded with existing controls identified.

Inspectors were informed that medication incidents reports were sent to each directorate, the risk department and the Chief Pharmacist for review. An email would be automatically generated to alert department managers that an incident had been reported. The Chief Pharmacist reviewed and graded all medication related alerts and escalated as appropriated, to the Quality and Patient Safety Advisory Committee for further clarification. However, inspectors were informed that there was no formal evidence based tool used in the hospital to grade medication incidents.¹² This is an area that the Drugs and Therapeutics Committee should address following this inspection.

The hospital acknowledges that a low numbers of medication -related incidents were being reported relative to other hospitals. Inspectors were informed at interview that a total of 276 medication incidents were reported from March 2016 to July 2017. Approximately 78% percent of reports were submitted by clinical pharmacists with limited evidence available to suggest that medical and nursing staff were reporting medications incidents. The hospital reported that medication incident reporting was directly related to the presence of a clinical pharmacist on medical wards where the reporting of medication incidents was higher. The absence of a clinical pharmacy service in the Women's and Children's Directorate, which included the paediatric and maternity wards, also meant there was likely underreporting in these areas. As a result key medication-related risks in these areas could not be understood, recorded, escalated or mitigated effectively. Therefore, the culture of reporting medication incidents needs to be broadened out to include other healthcare staff, rather than reliance on clinical pharmacists, so that safety surveillance is improved, learning is shared, and safety culture is promoted and enhanced across the organisation.

Important lessons can be learned from analysis and trending of medication-related incidents and near misses. Reporting of incidents is of little value unless the data

[†] 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).

collected is analysed and recommendations are disseminated.¹³ Medication incidents and near misses were tracked, but not trended to assess progress, identify emerging medication safety concerns and prioritise medication safety activities. A monthly Quality and Safety Site Activity and Monitoring Report highlighted the number of medication errors reported each month. Inspectors viewed the June 2017 Quality and Safety Site Activity and Monitoring Report. While this report identified the number of medication incidents for June was seven, medication incidents were not categorised by individualised directorate or classification by the type of medication incidents to identify trends. In addition, ward staff who spoke with inspectors reported that they did not routinely receive updates on medication errors that had occurred within the hospital. Following this inspection, the hospital should commence efforts to track and trend medication incidents and near misses to assess progress, identify emerging medication safety concerns and prioritise medication safety quality improvement initiatives to address concerns.

Inspectors were informed at interview that serious medications incidents were reviewed and recommendations made by the Serious Incident Management Team (SIMT) and the Hospital's Executive Board.¹⁴ Hospital managers provided inspectors with an example of a serious medication incident involving a high alert drug where a patient received the wrong dose. This incident was investigated by the hospital and reported to the Saolta Group's Serious Incident Management Team (SIMT). However, following interviews with senior management and ward staff, inspectors were not assured that sufficient learning was achieved by clinical staff from a quality improvement initiative implemented to address the prescribing risk associated with this high -risk drug to prevent the incident reoccurring. The re-formed Drugs and Therapeutics Committee should follow up on this incident with additional risk reduction strategies to proactively aim to prevent this incident reoccurring and support patient safety with regard to prescribing and administration of high alert medications.

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.¹⁵ Inspectors were informed that the hospital had a process in place to promptly inform patients when medication-related incidents occurred. Examples were given of when this open disclosure policy was adhered to.

2.3 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.¹⁶ Letterkenny University Hospital had a Clinical Audit Committee where audits were centrally coordinated. Inspectors were provided with examples of audits completed in 2016 and 2017 using a clinical audit report template. This report template provided a framework outlining the audit methodology used, identified audit findings with a quality improvement action plan to address these key findings.

Quality improvement forum meetings were held every two months to review audit findings. Audit findings were presented at a lunch time forum to encourage hospital staff to attend.

In addition, the hospital had an annual multidisciplinary research symposium where staff were encouraged to present an overview of their research and audits findings.

The inspection team was provided with examples of hospital-specific medication safety audits which included:

- re-audit on prescribing on medical inpatients - March 2017 and July 2017
- audit of supply and storage of intravenous concentrated Potassium solutions - May 2017
- the assessment and documentation of constipation and use of laxatives - Nov 2016
- audit of patient's own drug use - June 2017
- monthly nursing metrics.

Prescribing audits were completed in 2011, 2014 and 2017. In the audit of July 2017, 894 individual drug prescriptions for 50 patients were reviewed. Data was collected on a number of factors which included auditing of the quality of writing when prescribing individualised drugs. The data findings showed that in July 2017 there was a disimprovement with regard to the quality of writing and legibility of prescriptions when prescribing individualised drugs. The hospital sought to address prescribing issues with the introduction of prescribing stations for doctors. The prescribing stations had access to computers with copies of the British National Formulary and the hospital's Adult Antimicrobial Guidelines available in hard and electronic versions. Prescribers at the prescribing station were not to be interrupted by other staff.

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Completed audit reports viewed by inspectors included a quality improvement action plan proposed by the clinical team based on the audit findings. For example, following an audit on the use of patient's own drugs, the quality improvement plan highlighted the requirement for a summary of the results to be provided to all staff, a signed consent and assessment form to be completed when using the patient's own drugs, and an update of the policy accompanied with the provision of training to relevant individual staff.

Nursing quality care-metrics[‡] were monitored across the hospital to review practice around some aspects of medication. Nursing quality care-metrics results for a 12 month period were reviewed by inspectors. While the results relating to medication storage, custody and administration varied from 82% to 100% from October 2016 to June 2017, improvement was required with regard to medication prescribing which showed results of 67% for June 2017. These findings concurred with the multidisciplinary team audit findings of the quality of writing when prescribing individualised drugs for July 2017 which showed results of 69.8%. Hospital managers and ward staff who spoke with inspectors confirmed that regular written feedback was provided on nursing quality care-metrics to ward staff with an action plan if required.

A Director of Nursing and Midwifery Performance Report was produced monthly for the Saolta Group. Inspectors viewed the Director of Nursing and Midwifery Performance Reports for January and May 2017 which highlighted quality and patient's safety issues, including reports of monthly nursing metric results.

HIQA concluded that there was evidence that audit activity throughout the hospital was supported by Senior Hospital Managers and centrally coordinated.

2.4 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.

Medication safety quality improvement initiatives were not strategically driven by learning gained from analysis of medication incidents or near misses. Nevertheless,

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

despite this weakness, a number of good practices were identified during the inspection.

In 2016 the pharmacy department led on a review of the hospital's medication prescription and administration record overseen by the Drugs and Therapeutics Committee. The record was redesigned and piloted following consultation among nursing, medical and pharmacy staff. The pilot phase was completed and analysed in January 2017. The revised record included additional sections for signature recording, venous thrombophylaxis[§], warfarin and direct oral anticoagulants^{**} (DOAC), oxygen therapy, therapeutic drug monitoring, antimicrobial prescribing and documentation of non-administration of medications.

Managers told inspectors, that to reduce interruptions while administering medications, red "do not disturb" tabards were worn by nursing staff. This intervention was designed to draw attention to the fact that medication administration was in progress, and that nurses should not be interrupted, as interruptions during medication administration rounds are thought to be a prominent causative factor of medication errors.¹⁷ In the paediatric ward, inspectors were informed that while nurses had not implemented the red "do not disturb" tabards, two nurses double check medications prior to administration.

Risk reduction strategies¹⁸ were implemented in relation to intravenous potassium chloride to support the safe administration of this high alert medication. Intravenous concentrate potassium solutions were only supplied to specially designated areas within the hospital. They were stored in a separate locked cupboard with additional ordering, supply and administration safety measures in place. This was supported by policy. An audit of the supply and storage of intravenous concentrated potassium solutions undertaken in 2016 identified 100% compliance with all required criteria.

The hospital had automated medication management and dispensing systems in operation in a number of areas within the hospital. This initiative was supported by staff education and a policy. The automated storage system electronically dispensed medication in a controlled manner and could be used to track medication use. Biometric identification using finger print or username and password was required to access the system.

The hospital was also participating in the Health Service Executive (HSE) Quality Improvement Division venous thromboembolism (VTE) quality improvement collaborative. This is a collaborative among multidisciplinary teams in Irish adult acute public and voluntary hospitals who are working together to achieve appropriate thromboprophylaxis for their hospital's inpatients, to reduce the risk of

[§] Any measure taken to prevent thrombosis

^{**} Oral anticoagulants are medications used to treat or prevent blood clots.

venous thromboembolism and to minimise harm and expenditure associated with unnecessary thromboprophylaxis.

High-risk medicines can cause significant harm when system errors occur.⁶ The hospital had a list of high-alert medicines^{††} used within the pharmacy department, but this high alert list was not circulated hospital wide or supported by a policy. Inspectors were also informed that the hospital was in the process of developing a sound-alike and look-alike drugs (SALADs) list following a recent incident where a patient was administered the wrong drug.

Clinical pharmacy services

There are currently no agreed national standards outlining requirements for the provision of clinical pharmacy services in Irish hospitals. However, international studies support the role of clinical pharmacists in hospital wards in preventing adverse drug events.^{19,20,21,22,23,24} Hospital managers told inspectors that the hospital was not sufficiently resourced to provide a clinical pharmacy service in all ward areas to prevent, identify, and intercept medication prescribing-related incidents.

Inspectors found on the day of inspection that the pharmacy service within the hospital was restricted to medical wards, allied to an antimicrobial pharmacist service which covered all adult wards. Inspectors found that there was no clinical pharmacist or pharmacy technician assigned to the paediatric ward visited, the special care baby unit or maternity services, despite the fact that these were areas where high- risk drugs were dispensed. The lack of a clinical pharmacist for the paediatric and midwifery service was highlighted by hospital managers and ward staff who spoke with inspectors as a significant deficiency in support of medication safety practices in these ward areas. This risk was also recorded on the hospital's risk register. The hospital should review its approach to governance, resource allocation, systems and associated documents to ensure consistency across adult, paediatric and maternity services with respect to Clinical Pharmacy Service input.

^{††}High-alert medications are medicines that bear a heightened risk of causing significant patient harm when they are not used correctly. Errors with these medicines may not be more common than those from other groups but their consequences can be more devastating as they have smaller margins of safety than other medications and therefore warrant particular caution in their handling.

Medication reconciliation

Medicines reconciliation is a formal, systematic process for obtaining a current and accurate list of medicines that the patient was taking when admitted to the hospital, and reconciling this medicines list against the patient's medicines prescribed at admission, transfer and discharge.^{25,26,27,28} The hospital had an informal process in place for medication reconciliation on admission in designated adult inpatient wards. A medication reconciliation service was not provided at patient discharge.

On wards where a clinical pharmacist was assigned, they reviewed all patients' medication administration record to prevent, identify, and intercept medication prescribing-related incidents. Inspectors were informed that a clinical pharmacist would undertake medication reconciliation as required where inconsistencies were noted between prescribed medications and patient's medical history.

The clinical pharmacist would contact the patient's community pharmacist, their general practitioner (GP) and check with the patient's family if they had a query relating to a patient's medication. Ward staff who spoke with inspectors on the paediatric ward visited said that they checked the medication list for children with complex needs with their parents, the GP and or the community pharmacist as required.

2.5 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.

Patients should be well informed about any medications they are prescribed and any possible side effects. This is particularly relevant for those patients who are taking multiple medications.^{29, 30}

Inspectors were informed that doctors, nurses and clinical nurse specialists⁺⁺ provided education to patients on newly prescribed medication. Patient information leaflets were available at the point of care. The nursing staff outlined that they would also review the medication list with patients and families on discharge.

⁺⁺ A clinical nurse specialist has specially focused knowledge and skills, required to improve the quality of patient care with a clinical focus on assessment, planning, delivery and evaluation of care given to patients and their families

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As part of the HIQA inspection, HIQA requested that a small sample of patients attending the Outpatient Department complete an anonymised questionnaire in relation to prescribed medications. Eighteen patients who had been inpatients in Letterkenny University Hospital within the past year, and who were prescribed regular medications, completed the questionnaire. Of the 18 patients surveyed, 12 patients had been prescribed new medicines and six patients had not been prescribed any new medicines. Of these 12 patients:

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

It is acknowledged that the sample size of patients who completed the anonymised questionnaire was small, and therefore was not representative of all recently discharged patients taking prescribed medication. However, patient education is an integral component of the safe, effective and cost-effective use of medications. This patient questionnaire did provide some baseline information about outpatients' understanding of their medications and may be used as a focus for further improvement.

2.6 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.

Medication policies, procedures, protocols and guidelines were readily available to staff through the hospital's document control management system. These included a policy on the administration of medications for nurses and midwives. While the hospital had a paediatric policy for the administration of oral or enteral medication by correct route, this policy together with other policies viewed required updating.

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Medication policies and protocols were approved by the Drugs and Therapeutics Committee and final approval was completed by the Multidisciplinary or the Nursing Policy, Procedure, Protocols and Guidelines Committee.

Healthcare staff required 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 patient's diagnostic results on computers in clinical areas across the hospital.

Additional sources of medication information were readily available to staff involved in medication use including the;

- British National Formulary in print and electronic formats
- British National Formulary for Children in print 2015-2016
- Adult Antimicrobial Guidelines 2016/2017
- The paediatric service used nationally approved protocols and applications obtained through the National Network for Paediatric Services.

HIQA identified that the hospital did not have a suite of locally adapted intravenous drug administration guidelines or monographs used to assist staff in the safe administration of intravenous medicines. In addition, a number of the sources of information available in the clinical areas were out of date. For example, the protocol for displacement values of antimicrobials was dated 2009-2010 in the paediatric ward.

Inspectors noted during interviews that there was a lack of clarity regarding the number and type of mobile phone applications used by non -consultant hospital doctors to guide prescribing practices. The re-formed Drugs and Therapeutics Committee needs to strengthen its governance and oversight of the decision-making resources including applications available to healthcare staff at point of care as a priority.³¹

2.7 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.³² Medication safety was included in induction programmes for all new clinical staff.

Hospital managers told inspectors that medication safety education was included in non-consultant hospital doctors' induction training facilitated by the Pharmacy Department staff. Educational sessions included pharmacy protocols and prescribing guidelines. Additional informal education sessions were provided to doctors at ward rounds, hospital grand rounds^{§§} and journal club^{***} presentations as part of the postgraduate clinical educational programme at the hospital.

Inspectors were informed that, all nursing staff completed a competency assessment booklet during induction, on commencement of employment in the hospital. Nurses received training on the administration of intravenous medications, on the use of the automated dispensing cabinet system and incident reporting. Nursing staff also completed the Health Service Executive (HSE) medication management online training programme.³³ Training records reviewed by inspectors on one of the wards visited demonstrated that nurses had re-validated their online training, while training records on the second ward visited identified that only a small number of nursing staff had completed the online training.

^{§§} 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.

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

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.¹ 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.

HIQA identified an immediate high risk at Letterkenny University Hospital during this announced inspection relating to a relative lack of leadership, governance and management of medication safety related risk. Suspension of the Drugs and Therapeutics Committee over a sustained period substantially weakened governance and oversight of medication safety arrangements within the hospital. The hospital reported to inspectors that the suspension of the Drugs and Therapeutics Committee meetings since September 2016 was due to the resignation of the Chairperson, exacerbated by the lack of attendance of key members of the Committee which resulted in the failure to achieve a smooth transition to a new Chairperson. As a consequence, this resulted in a lack of governance and oversight regarding medication safety practices at hospital senior management level and at Saolta Group level.

Inspectors also found that in the absence of a Drugs and Therapeutics Committee, the hospital had no formulary, no strategic medication safety plan, no clinical pharmacist assigned to the paediatric and midwifery services, lack of an up-to-date, locally adapted and approved intravenous monographs at the point of care on both the paediatric and adult wards visited, and a lack of governance with regard to medicines information resources at point of care. Risks identified were such that HIQA wrote to the hospital to raise concerns, and seek assurances that these identified deficits would be addressed immediately in a sustainable way following this inspection.

HIQA found that the hospital did not have a defined, multidisciplinary medication safety programme in place at the time of this inspection. There were no clear objectives, goals or plans for medication safety in place. It was not apparent that medication safety was sufficiently supported by senior management and clinicians at the hospital. Ultimately, to drive sustainable improvements in patient safety, senior leaders must take ownership of the organisation's safety agenda. 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.

Report of the announced inspection of medication safety at Letterkenny University Hospital.

Letterkenny University Hospital management team reported that a number of measures had subsequently been taken to mitigate the risks identified by HIQA during the inspection. These included strengthening governance structures to sustain the re-formed Drugs and Therapeutics Committee through reviewing its membership to ensure representation of key staff members from each directorate, revision of terms of reference, and a formalised regular schedule for meetings for 2017. In addition, to further enhance existing governance arrangements, the hospital planned to establish a medication safety sub-group of the Drugs and Therapeutics Committee to advance a medication safety programme and promote patient safety relating to medicine usage in the hospital. The hospital also planned to introduce systems to improve communication on the governance of medication safety at committee meetings with Senior Hospital Managers and the Saolta Group.

The hospital acknowledged that medication related incidents were likely to be significantly under reported at the hospital. Medication incidents and near misses were tracked, but not trended to assess progress, identify emergent medication safety concerns and priorities medication safety activities. While there was a clinical pharmacy service available on some of the adult wards, the absence of a clinical pharmacy service in the Women's and Children's Directorate, which included the paediatric and maternity wards, also meant there was likely underreporting in these areas. As a result key medication-related risks in these areas could not be understood, recorded, escalated or mitigated effectively. Therefore, the culture of reporting medication incidents needs to be broadened out to include other healthcare staff, rather than reliance on clinical pharmacists, so that safety surveillance is improved, learning is shared, and safety culture is promoted and enhanced across the organisation.

Clinical audit at the Letterkenny University Hospital was centrally coordinated. Medication safety audit results and relevant data were used as the basis for decision-making, action and to support quality improvement medication initiatives which the hospital had implemented.

Following this report, the hospital must focus its efforts to address the risks and findings identified in this report, and work to ensure that the necessary arrangements are in place to protect patients from the risk of medication-related harm. It is recommended that this report is shared with senior managers, clinicians and other relevant staff at Letterkenny University Hospital 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.

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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

Appendix 2: Copy of the letter sent from HIQA to Letterkenny University Hospital.



Sean Murphy
General Manager
Letterkenny University Hospital
Letterkenny
Donegal
sean1.murphy@hse.ie

04 August 2017

Ref: MS/117

Monitoring Programme for Medication Inspections in Public Acute Hospitals in the Republic of Ireland

Dear Sean

During the course of the announced Medication Safety inspection conducted at Letterkenny University Hospital on 03 August 2017, HIQA identified an immediate high risk at the hospital related to a relative lack of leadership, governance and management of medication safety related risk at the hospital.

In light of same, I am writing to you to seek assurance that these identified deficits will be immediately addressed in a sustainable way following this inspection. Please formally report back to HIQA in writing by **14 August 2017** to qualityandsafety@hiqa.ie, outlining measures enacted to address these concerns.

Please note that a copy of this letter, and your subsequent written response, will be included in the published report which will be generated following this inspection.

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

Yours sincerely



DOLORES DEMPSEY-RYAN
Authorised Person

CC: Maurice Power, CEO, West/North West Hospitals Group
Mary Dunning, Director of Regulation, Health Information and Quality Authority

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Appendix 3: Copy of the response received by HIQA from Letterkenny University Hospital.



*General Manager's Office, Letterkenny Hospitals, Letterkenny Co.
Donegal*

Telephone: (074) 9123501 or (074) 9125888 Ext 4206 Fax: (074) 9104651

Ms Dolores Dempsey-Ryan
Authorised Person
Head Office
HIQA
Unit 1301, City Gate,
Mahon
Co Cork Ireland

11.08.2017

Your ref:MS/117

Monitoring Programme for Medication Inspections in Public Acute Hospitals in the Republic of Ireland

Dear Dolores,

Thank you for your letter of the 4th of August 2017 following from the announced Medication Safety Inspection conducted at Letterkenny University Hospital.

I acknowledge that HIQA identified an immediate high risk at the hospital related to a relative lack of leadership, governance and management of medication safety related risk at the hospital.

In the course of the HIQA inspection the hospital identified measures that had already been taken to address these risk areas, in particular the re-formation of the Drugs and Therapeutic Committee under a new Chairman. However, we accepted that this new committee had only recently been re-formed and as yet lacked the track records to assure the inspection team that the risks were addressed in a sustainable manner. Following the inspection we have also taken additional measures within the hospital to strengthen the governance and management of medication safety related risk at the hospital.

In order to assure HIQA that these risk issues are being appropriately and sustainably addressed:

- The LUH Drugs and Therapeutic Committee (DTC) has been re-formed under a new Chairmanship and the first meeting of the new Committee was held on Tuesday the 1st of August 2017 under the Chairmanship of Professor Ken Mulpeter, Consultant Geriatrician. The Hospital Management Team informed the



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HIQA Inspectors of this fact. I as General Manager will be attending all meetings and will monitor the multi-disciplinary input to the committee

- The Hospital acknowledges the limited consultant medical staff participation in the previous Drugs and Therapeutic Committee and undertook to strengthen same in the context of the development of the Clinical Directorate Structure both within the Saolta University Health Care Group and Letterkenny University Hospital in particular. This enhancement of clinical staff representation has already been implemented and details of the membership of the LUH Drugs and Therapeutic Committee is attached in Appendix A
- The Hospital acknowledged that there was a significant gap between the last meeting of the previous Drugs and Therapeutic Committee and the first meeting of the newly re-formed Committee. At the inspection visit hospital management noted that, the DTC had agreed (in light of the previous gap) to schedule the next meeting for the 26th of September 2017. The frequency of the meetings will thereafter be every 2 months as per the Terms of Reference. The HIQA Inspection Team were informed of this at their visit. I attach a schedule of meetings for the Drugs and Therapeutic for the remainder of 2017 and 2018 for your information – this is found in Appendix B
- The Chair of the Drugs and Therapeutic Committee and the Hospital Manager have agreed that the September 2017 meeting of the Committee will include a full review of its Terms of Reference to ensure that all opportunities to enhance Medication Safety Management are optimised within LUH.
- The HIQA Inspection Team were informed that the Drugs and Therapeutic Committee reports to the Hospital's Quality and Patient Safety Committee and through that Committee to the Hospital Executive Board (HEB). The inspectors were also informed that this line of communication to the Hospital Executive Board is through the formal Quality and Patient Safety Report presented each month to the HEB by the Director of Nursing. To further strengthen the governance and management of Medication Safety the Hospital General Manager has written to the Director of Nursing as Chair of the Patient Quality and Safety Committee requiring that a Drugs and Therapeutic Committee Report (to include medication safety issues) be a standing agenda item on each Quality and Patient

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Safety Committee Meeting. Furthermore the Quality and Patient Safety Report to the HEB presented by the Director of Nursing will henceforth be required to include a standing chapter on feedback from the DTC (to include medication safety issues) – a copy of this correspondence is attached in Appendix C.

- To ensure the management of Medication Safety within Letterkenny University Hospital is appropriately integrated with and supported by the Saolta University Healthcare Group, the General Manager noted during the visit that he is attending the Saolta Group Drugs and Therapeutic Committee Meeting. The new Chair person of the LUH DTC has also confirmed that he will henceforth be attending the Saolta Group DTC.
- All wards within LUH measure a suite of nursing metrics each month. Several of these metrics relate to medication management. The results of these metrics and their actions plans are then reviewed by the Director of Nursing and the Assistant Directors of Nursing. The Assistant Directors of Nursing then discuss action plan progress with ward staff. All metrics results are also presented to the Hospital Executive Board by the Director of Nursing on a monthly basis. This process was not fully outlined at the inspection visit of the 3rd of August.

Finally, the LUH Team have met to consider the immediate learning from the Inspection Visit, albeit prior to the receipt of the formal report. Reflecting on the discussions with the Inspection Team we are of the view that there is also merit in considering the introduction of a Medication Safety Group which would form a subcommittee of the LUH Drugs and Therapeutic Committee. Its primary purpose would be to reduce avoidable harm to patients and increase patient safety by consideration of data derived from medication incidents reported in LUH, and highlighting areas of risk identified from the literature. This Medication Safety Group would then recommend implementing quality improvements to reduce potential for medication misadventure in identified areas of risk. It has been agreed that the Chief Pharmacist will bring a proposal with respect to the formation of a Medication Safety Group and Draft Terms of Reference to this September LUH Drugs and Therapeutic Committee.

I trust that the above updates following the inspection and confirmation of the developments initiated prior to the inspection provide HIQA with the necessary assurances that the identified deficits in respect of leadership, governance and

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management of Medication Safety related risk at Letterkenny University Hospital are being immediately addressed and that the manner in which they are being addressed is clearly sustainable and effective.

Please do not hesitate to contact me should you require any further clarification or information.

Yours sincerely

A handwritten signature in black ink, appearing to read "Seán Murphy".

Seán Murphy
General Manager

Cc: Professor Ken Mulpeter, Chairperson of LUH Drugs and Therapeutic Committee
Mr Colm Devine, Chief Pharmacist LUH
Dr Anne Drake, Director of Nursing and Chair of Quality & Patient Safety Committee LUH
Mr Maurice Power, CEO Saolta University Healthcare Group
Ms Ann Cosgrove, COO Saolta University Healthcare Group
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