Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the announced inspection of medication safety at the Regional Hospital Mullingar.

Date of announced inspection:

20 April 2017

About the Health Information and Quality Authority

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

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

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

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

Regulation — Registering and inspecting designated centres.

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

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

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

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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 use.

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 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 Regional Hospital Mullingar by Authorised Persons from HIQA; Kay Sugrue, Dolores Dempsey-Ryan and Noelle Neville. The inspection was carried out on 20 April 2017 between 09:30hrs and 15:10hrs. Interviews were held at the Regional Hospital Mullingar with the following groups of managers and clinical staff:

- Group one: the Chairperson of the Drugs and Therapeutics Committee (who is also the Clinical Director), the Chief Pharmacist and the Clinical Quality and Safety Manager.
- Group two: the General Manager and the Director of Nursing.

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

- Paediatric Ward
- Surgical 1 Ward

In addition a survey was conducted among outpatients in the Outpatient Department.

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 the Regional Hospital Mullingar

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

- **Section 2.1** outlines risks identified during this announced inspection.
- **Sections 2.2 to 2.7** present the general findings of this announced inspection which are aligned to the lines of enquiry.

2.1 Risks identified

During this announced inspection by HIQA on 20 April 2017, a composite of medication safety related risks were identified in the Regional Hospital Mullingar in relation to medication safety. The collective nature of the risks identified may present a serious risk to the health and welfare of patients.

Specifically, the immediate risk identified related to the cumulative potential impact of:

- a relative lack of effective systems in place to ensure minimum standards of safety and quality are met relating to medication safety
- the ongoing lack of a Clinical Pharmacy service
- the lack of an up-to-date, locally adapted and approved set of hard copy A-Z intravenous product information monographs at the point of care
- the ongoing presence of potentially conflicting reference information in the ward setting relating to advice in the reconstitution and administration of intravenous medication.

In addition, in line with international best practice, essential elements of medication systems and processes required to improve the safety and quality of medicines use in a hospital setting were either in the very early stages of development or not in place at the time of this inspection. HIQA found risks concerning the following;

- The absence of strategic and operational plans detailing the development, implementation and maintenance of hospital wide medication safety systems.
- Inadequate arrangements in place to identify, report and manage risks associated with medication use.
- An ongoing absence of a drug formulary to ensure that there are robust and transparent criteria for adopting, removing or updating the hospital's drug prescribing list.
- A relative lack of current policies, protocols, and guidelines to support relevant clinical staff in safe prescribing and administration of medications at ward level.

Details of these risks were communicated to hospital management at the time of this inspection, and in writing following this inspection. In response, hospital management provided HIQA with an action plan to address the risks identified. The response from the hospital indicated that the risks identified were being escalated to the Ireland East Hospital Group and prioritised. However, the timeframes allocated to addressing these risks outlined in the action plan did not seek to mitigate the immediate risks as a matter of priority. This should be urgently addressed both by the hospital, and the Ireland East Hospital group, following the publication of this report.

HIQA acknowledges that the hospital has acted to develop governance arrangements relating to medication safety at the hospital in 2016, on a background of apparently very weak arrangements prior to this time. However, while these recent improvements in organisational oversight and multidisciplinary involvement are welcome and much needed, the hospital is also attempting to provide services with a relatively low number of Clinical Pharmacists when compared to many of its peer hospitals. Such professional resources form a key workforce component in more advanced medication safety programmes both in Ireland and internationally. Furthermore, HIQA note that a significant proportion of Pharmacy Department resources at the Regional Hospital Mullingar are dedicated towards supply of medication to off-site locations in primary and community care. Conversely, with the exception of specialist resources dedicated to the area of Antimicrobial Stewardship, no ward or team-based Clinical Pharmacy service is provided to hospitalised patients availing of acute services. This is contrary to the operational norm in hospitals inspected by HIQA as part of its medication safety programme so far.

The action plan provided to HIQA to address the risks identified during this inspection states that the hospital has commenced the recruitment process to address the deficiencies in pharmacy resources. However, it was explained to HIQA by the hospital that completion of this process is likely to take six months. This potentially means that additional pharmacists, or resources needed for a greater focus on hospitalised patient medication related risk may not be fully addressed until December 2017. In the interim, it will be difficult for the hospital to meaningfully address many of the risks identified during this inspection, without further support from the Ireland East Hospital Group to expedite this timeframe.

A copy of the letter issued to the hospital on 24 April 2017 regarding the risks identified during the inspection 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.

2.2.1 Introduction

The Regional Hospital Mullingar is a Model three[5] general hospital which provides general medical, surgical, paediatric, maternity and specialist care services, including an Emergency Department and Intensive Care Unit. In addition, the hospital provides a pharmacy service to St Loman's Psychiatric Hospital, three community and continuing care facilities in Longford/Westmeath and the National Ambulance Service locally.

Measures to promote safe use of medicines for inpatients at the Regional Hospital Mullingar were identified to be significantly underdeveloped during this inspection. Inspectors acknowledge recent efforts to better formalise and improve the governance arrangements in relation to medication safety at the hospital. However, much remains to be done to bring the hospitals approach in line with most hospitals inspected by HIQA so far as part of its medication safety monitoring programme. There was a sustained lack of leadership, governance, oversight and support for medication safety at the hospital prior to 2016. This resulted in a failure to progress a programme comparable with better performing peer hospitals as identified by HIQA. The lack of progression is of particular concern when considered in the context of a busy general hospital providing complex and specialist clinical care.

2.2.2 Background

The Ireland East Hospital Group (IEHG) was established in January 2015 and is the largest of the hospital groups comprising 11 hospitals[6] .The Regional Hospital Mullingar is a member of the Ireland East Hospital Group. In September 2015, shortly after becoming a member of the Group, an internal appraisal of the Pharmacy Department within the hospital was commissioned by the Ireland East Hospital Group, and completed by a Chief Pharmacist from a larger hospital in the Group.

The report, which has been viewed by HIQA, made 10 general recommendations relating to staffing and service provision within the Pharmacy Department. In

summary, the report found that there was significant scope for improvement relating to available staffing resources at that time, particularly the identified lack of pharmacists at the hospital. Moreover it also recommended a need for a greater degree of clinical service provision targeted towards inpatients at the hospital, as opposed to medication supply external from the hospital. Many of the recommendations made were dependent on the provision of additional resources to enable change and facilitate the implementation of systems and processes to support medication safety within the hospital. The hospital acted to only partially address these recommendations by appointing one whole time equivalent antimicrobial stewardship pharmacist in October 2015.

In June 2015, HIQA commenced a national review of antimicrobial stewardship programmes in public acute Irish hospitals including an examination of the overall national approach to managing antimicrobial stewardship in the acute hospital system. The review required each of the 49 public acute Irish hospitals to complete a self assessment questionnaire about antimicrobial stewardship in their hospitals. In addition, 14 announced inspections were undertaken at that time by HIQA in a sample of hospitals. While these inspections were conducted to inform a composite national report, each of the hospitals inspected also received an individual report of HIQA's findings. A composite national report was published on the findings of this review in July 2016.

As part of this national review, HIQA conducted an announced antimicrobial stewardship inspection at the Regional Hospital Mullingar in November 2015. Significant scope for improvement was identified during this inspection related to medication safety practices in general, which were communicated to the hospital during the inspection, in writing and through the provision of the report. In its response to HIQA, the hospital indicated that these issues would be addressed as a priority.

2.2.3 2017 Medication Safety Announced Inspection

On return to the hospital as part of its current programme of monitoring in the area of medication safety, HIQA found that the governance arrangements relating to medication safety in place in the Regional Hospital Mullingar at the time of this inspection still did not deliver sufficiently effective quality assurance or quality improvement mechanisms in line with international best practice.[7]

Since the 2015 inspection by HIQA, the Regional Hospital Mullingar has commenced a body of work in an effort to improve medication safety in the hospital. It was explained to HIQA that the wider hospital organisational structure had been reconfigured and streamlined in mid 2016. It was also reported by hospital management that medication safety governance arrangements were evolving within this new configuration.

There was evidence that progress had been made in implementing and developing a medication safety agenda in 2016. The hospital had acted to strengthen governance arrangements relating to medication safety. Measures implemented included the:

- re-establishment of the Drugs and Therapeutic Committee at the end of 2015 following a period of a year when it did not meet
- establishment of a hospital Medication Safety Committee with multidisciplinary representation
- introduction of an Antimicrobial Stewardship Programme
- engagement with staff on medication safety related issues within the hospital
- appointment of three business managers to provide support to clinical teams.

An effective Drugs and Therapeutics Committee should have ongoing oversight of the medication management and safety system within a hospital.[8] The Drugs and Therapeutics Committee was one of 19 committees that reported into Clinical Governance Quality and Safety Committee. This group in turn reported in to the Hospital Executive. Both the Medication Safety Committee and the Antimicrobial Stewardship Committee reported into the Drugs and Therapeutic Committee under regular agenda items. However, this reporting structure was not clearly evident on the hospital organogram viewed by HIQA.

The Drugs and Therapeutics Committee had recently updated their terms of reference that outlined the objectives, membership, frequency of meetings and reporting relationship. There was broad representation on the Committee with representatives from across the hospital. However, there was no representation on the Drugs and Therapeutics Committee from the paediatric service, general practitioners (GPs) or community pharmacists. The hospital should revisit the membership of the Committee with the aim of ensuring greater and more consistent representation from required stakeholders.

A strategic, planned approach to managing medication safety was not in place at the hospital at the time of this inspection. However, one of the functions outlined in the terms of reference of the recently formed Medication Safety Committee is to develop a medication strategy for the hospital. Inspectors found that a medication safety agenda was in the early stages of implementation at the hospital. By way of example, one of the first actions initiated by this Committee was to engage with clinical staff relating to medication safety issues within the hospital. The feedback received in June 2016 had formed the basis for initiatives and interventions implemented in the second half of 2016 and early 2017. In all, 32 issues were identified which required action. These issues were categorised into 10 'quick wins', five immediate priorities and the remaining 17 were classified as 'subsequent priorities'. While actions were in progress relating to the immediate priorities, only

one of these issues had been fully addressed. These immediate priorities are listed as follows:

- medicines information
- medication incident and near miss reporting
- high risk medicines
- policy development
- introduction of pre-filled emergency drugs in theatre*.

There are currently no agreed national standards outlining requirements for the provision of clinical pharmacy services in hospitals. However, international studies support the role of clinical pharmacists in hospital wards for preventing adverse drug events.[9,10,11,12,13] Furthermore, HIQA has identified through its monitoring programmes that the operational norm around ensuring medication safety in the majority of Irish hospitals includes dedicated resources for clinical pharmacy services. Such resources are notably lacking at the Regional Hospital Mullingar, and the Pharmacist resources that are in place are directed towards the provision of medication supply both within and external to the hospital, as opposed to providing a clinical service for inpatients.

The hospital has identified the ongoing lack of a clinical pharmacy service as a risk which has been escalated to the hospital's executive risk register since January 2016. A business case for clinical pharmacy had been developed and submitted for approval of funding. However, HIQA was informed that to date, the hospital had not received the necessary funding to implement this service. In addition, it was explained to inspectors that a whole time equivalent pharmacist vacancy existed from its existing compliment of positions. Ongoing resource issues had been further challenged by difficulty recruiting and filling roles left vacant due to sudden or unexpected leave and maternity leave. HIQA was informed that the hospital had identified that additional resources in excess of the current allocation of pharmacists was required to ensure the provision of a high quality safe pharmacy service at the hospital. It was reported to inspectors that under resourcing of the pharmacy service had been escalated to the Ireland East Hospital Group for additional support.

The hospital had recently developed a process for assessing and evaluating requests for the supply of new medications. However, an up-to-date local approved medication formulary† did not exist in the hospital at the time of this inspection. A controlled drug formulary system should be established to manage risk and ensure efficiency in the use of medicines used in hospitals. While HIQA acknowledges that

* A usage and wastage audit of emergency drugs drawn up in theatre in advance of some procedures resulted in a quality improvement initiative to introduce licensed pre-filled syringes (prepared under required controlled conditions) of these emergency drugs.

† Local formulary is a defined as list of medicines approved for use within a healthcare organisation

the development of a formulary is a considerable undertaking, local arrangements as identified during this inspection have been slow to progress.

Higher incident reporting rates both demonstrate and promote an improved culture of safety.[14] HIQA notes the low numbers of medication related incidents reported throughout 2016, relative to other hospitals. As a result, key medication related risks may not be understood, recorded, escalated or mitigated effectively by the organisation. A system was in place for staff to voluntarily report medication-related incidents and near misses using a printed incident report form. There was evidence to support regular reporting of medication incidents, including trending and analysis to the Drugs and Therapeutic Committee and upwards to the Hospital Executive. It was reported that the Clinical Incident Management Group met fortnightly and medication incidents were discussed in this forum.

Staff who spoke with inspectors were able to describe the hospital's process for reporting medication-related incidents. However, feedback relating to updates on medication errors that had occurred in other areas of the hospital was not evident in the two clinical areas visited by inspectors. The hospital had provided staff with training in relation to clinical incident reporting to improve reporting rates.

Inspectors were informed that following errors that occurred while administering medications, nurses and midwives involved in the incident or near miss were required to complete the HSELanD Medication Management online training programme.[15]

In evaluating this approach to error mitigation, HIQA acknowledges the importance of promoting a culture of professional responsibility for practice. However, it is important that such an approach is complemented by an evaluation of potential system and process related causes for latent error, which should also form a focus for error reduction efforts allied to improved multidisciplinary vigilance.[16,17]

The hospital needs to continue to work towards improving reporting of medication-related incidents to enable understanding of the exact nature and contributory factors leading to medication errors. Such information is key to the implementation of prevention strategies developed from learning gained through trending and analysis of reported data.

Hospital management had endeavoured to progress a medication safety agenda at the Regional Hospital Mullingar. Much progress had been made in strengthening governance arrangements in 2016, albeit evidence would suggest that they were very weak prior to this time period. However, the hospital continues to struggle to implement the core elements of an effective medication programme.

HIQA acknowledges that it will be challenging for the hospital to perform well in relation to the risks identified in this report until these issues are resolved. Regional Hospital Mullingar, as a member of the Ireland East Hospital Group, needs to be supported by the group and national structures to effectively address these issues as a priority.

2.3 Audit and evaluation

Line of enquiry:

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

Inspectors were informed that there was a formal process in place to undertake clinical audit. However, medication safety was not systematically monitored and evaluated at the hospital. Elements of medication safety were audited but these audits were not aligned to a formalised medication safety strategy. HIQA noted that significant progress had been made relating to antimicrobial stewardship audits since the 2015 announced HIQA inspection. However, many of the initiatives relating to medication safety implemented in 2016 had yet to be evaluated at the time of this inspection.

HIQA was informed that there was limited clinical auditing capacity at the hospital. However, approval had recently been received for the appointment of a clinical audit nursing post to be shared between the Intensive Care Services and the main hospital. It was reported that medication safety will form part of this role.

An audit of 'Prescriptions from a Medics Point of View' conducted in 2016 looked at prescription standards on one ward. The aim of this audit was to improve compliance with prescribing standards through the implementation of a continual quality improvement cycle (plan, do, study, act cycle of improvement).[18] Measures implemented were reaudited and the overall prescription compliance improved significantly over a four month period. The audit concluded that support for prescribers at the point of care is key to improving prescription related interventions and sustaining compliance with prescribing standards.

Nursing quality care-metrics[‡] were monitored across the hospital to review practice around some aspects of medication storage and administration. Inspectors viewed the nursing quality care-metrics findings for one ward over a 14 month period and

[‡] Metrics are parameters or measures of quantitative assessment used for measurement and comparison or to track performance.
¥ A prophylactic is a medication or a treatment designed and used to prevent a disease from occurring.

noted that the results relating to medication storage, custody and administration were generally good. However, more improvement was required with regard to medication prescribing metrics; an issue also highlighted through the staff survey on medication safety conducted by the hospital.

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.

Inspectors saw examples of quality improvement initiatives that had been implemented in 2016. Completed initiatives included:

- introduction of a larger and revised medication prescription and administration record (which was intended to reduce risk associated with use of multiple prescription and administration records and includes box for all oral anticoagulants)
- hospital wide learning notices on administration errors and administration of partial doses
- distribution of medication safety bulletins
- introduction of look a-like sound a-like list of drugs and labelling of these medicines dispensed from pharmacy
- improved medicine information reference sources at ward level
- implementation of new policies on potassium and controlled drugs.

It was reported that formal medicines reconciliation[§] was not provided at the hospital. However, it was explained to inspectors that limited medication reconciliation occurred at the time of patient admission to hospital. A double check or follow up of this process did not take place and there was no hospital policy relating to this process. The aim of medication reconciliation is to provide assurance on the accuracy of a patient's medication information at transitions of care to ensure continuity of medication management.[7] A significant proportion of medication errors occurring in hospitals are estimated to occur either on patient admission, patient discharge or transfer between units or facilities. Senior managers informed HIQA

§ Medicines reconciliation is a formal, systematic process, conducted by an appropriate trained individual, for obtaining a current and accurate list of medicines a patient was taking when admitted to hospital, known as a best possible medication history, and reconciling this history against the patient's medicines prescribed at admission, transfer and discharge on the medication chart.

that failure to implement a formalised medication reconciliation process was due primarily to resource deficiencies in the Pharmacy Department. HIQA acknowledges the challenges, complexity and resource requirement to implement an effective medication reconciliation process but recommends that the hospital prioritises this multidisciplinary process as a fundamental building block of its medication safety programme in the future.

A list of high-risk medications or a related policy was not available at the hospital at the time of this inspection. However, the Medication Safety Action Agenda targeted anticoagulant and concentrated potassium as a focus for quality improvement initiatives in 2017. Progress relating to these issues was evident at the time of this inspection.

Documentation viewed by inspectors showed that three medication safety bulletins and two medication learning notices were distributed to heads of departments and various staff members by the Pharmacy Department in 2016. However, inspectors found that awareness amongst staff varied relating to these communications during ward visits.

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.[3,19] Staff spoken with reported that it was practice to inform patients if an error was made in relation their medication, in line with best practice. Training relating to open disclosure had been provided.

Scope for improvement was identified by HIQA relating to collaboration between Regional Hospital Mullingar and other hospitals within the Ireland East Hospital Group of which the hospital was a part. Inspectors were informed that a Chief Pharmacists Group within Ireland East Hospital Group was formed in 2016. This group had met several times in 2016 with varied attendance reported. Similarly, a Group Quality and Patient Safety Committee was in place at which medication safety issues were discussed. While these structures are a welcome development, senior managers at the hospital reported that there was potential to further improve information sharing, learning and support within the Group.

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.[20,21] This is particularly relevant for those patients who are taking multiple medications.

Regional Hospital Mullingar had some systems in place to support the provision of patient information and education in relation to medication usage. Patient information leaflets were provided to some patients taking certain medications and consultants provided education to patients about the use of anticoagulants. Clinical nurse specialists provided education and support to patients, for example, around the management of diabetes mellitus, respiratory disease or oral anticoagulants.

As part of this inspection, HIQA asked a small sample of hospital outpatients attending the Outpatient Department to complete an anonymised questionnaire in relation to prescribed medications. The questionnaire was completed by 14 people who had been inpatients in Regional Hospital Mullingar within the past year and who were prescribed regular medications. Of the 14 patients surveyed, six patients had not been prescribed any new medicines and eight patients had been prescribed new medicines. Of these eight patients:

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

It is acknowledged that this was a small sample of patients who completed the anonymised questionnaire in relation to prescribed medications at the hospital's Outpatient Department, and therefore was not representative of all recently discharged patients taking prescribed medication. The information did however, provide some information about outpatient's understanding of medications and could be expanded upon and used to identify opportunities for 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 of the safe use of medicines is readily available in a user friendly format and is adhered to when prescribing, dispensing and administering medications.

A relative lack of up-to-date policies, procedures, protocols and guidelines to support staff in the safe prescribing and administration of medications were identified during this inspection. Policies, procedures and guidelines available in hardcopy on wards visited by inspectors were developed in 2010 with no evidence of review or update. On the Paediatric Ward, inspectors were informed that hardcopy reference material relating to paediatric supportive care guidelines from another large paediatric hospital was frequently referred to. These guidelines were issued in November 2013. Assurances were not provided at the time of inspection that these guidelines were the most current version. In addition, the hospital's controlled document management system was not accessible to staff at the time of the inspection in one of the areas visited.

HIQA noted that the hospital was in the process of updating several policies relating to medication safety. A multidisciplinary 'Policy for the Administration of Intravenous Medication to Adult Service Users' had been approved in January 2017. A limited 'Intravenous Administration of Non-Antimicrobial Medicine Guidelines for Adults' was included as an appendix in this policy. However, general awareness of this policy by staff who spoke with inspectors was not evident.

Clinical staff reported that they had electronic access to patient's laboratory and radiological imaging results at clinical level. Generalised prescribing supports were available to clinical staff. Hard copies of the most current version of the British National Formulary were available in the clinical areas visited by inspectors.

While hospital intravenous antimicrobial guidelines were available at the point of care, standardised locally adapted hospital guidelines on the reconstitution and administration of other intravenous medications were not readily accessible. The hospital had recently purchased online intravenous guidelines which were introduced in February 2017 and available on computers at nurse's stations. It is recommended that local prescribing guidelines should be consulted for prescribing information

alongside these online intravenous guidelines. The lack of locally adapted prescribing guidelines was a deficiency in the provision of medicines information and progress had been slow in addressing this issue.

Outdated and potentially conflicting reference information in relation to the reconstitution and administration of intravenous medication was observed in one clinical area. This was a similar issue identified by HIQA during the 2015 announced inspection.

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.

Training for nursing and medical staff can be a key success factor in contributing to good, multidisciplinary engagement in medicines management. The hospital did not have a formalised education programme for clinical staff linked to an overall medication safety strategy. Medication safety awareness at the hospital was promoted through staff communication including circulation of medication safety bulletins and medication safety notices.

Inspectors were informed that clinical staff received induction training which included medication safety from the Pharmacy Department. In addition, a schedule of 10 pharmacy in house education sessions were planned for 2017; topics were yet to be decided.

Training on medication safety issues and prescribing was also provided by pharmacists to clinicians during 'Grand Rounds'[**].

Staff interviewed described a recent initiative called 'Lunch and Learn' occurring on a weekly basis. Topics discussed during these sessions include medication related issues.

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

3. Conclusion

Medications represent the primary measure for treatment intervention in hospitalised patients. Error associated with medication usage constitutes one of the major causes of patient harm in hospital. Medication 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 composite risks relating to medication safety at the Regional Hospital Mullingar during this inspection. Cumulative risks related to the lack of basic systems and processes that should underpin an effective medication programme were identified. Such core elements included a lack of up-to-date policies, procedures, guidelines and protocols in relation to medication safety related issues, the lack of a local formulary and locally approved medicines information that reflects the complexity of services provided at the hospital. In addition, assurance mechanisms relating to medication safety were underdeveloped. While medication safety governance structures had recently been strengthened, these arrangements could not sufficiently support the implementation of an effective medication safety strategy and plan due to a relative lack of pharmacists.

Notwithstanding more recent efforts made by the hospital to improve medication safety at the hospital, it was evident during this inspection that more support was required from the Ireland East Hospital Group to assist Regional Hospital Mullingar in addressing deficits relative to many of its peer hospitals, including other hospitals in their group that have much more advanced programmes. Many of the issues identified were symptomatic of a lack of pharmacists relative to other hospitals of similar size providing the same level of complex care. However it is possible that in the very short term, existing resources might be better targeted towards the provision of an inpatient clinical pharmacy service to high risk areas from a medication safety perspective such as critical care and paediatric services. Such a shift in prioritisation may require reconfiguration of medication supply arrangements for community services to free up necessary resources, and may require support from other hospitals in the group in order to build staff capability in fulfilling a more clinical role.

HIQA found that clinical pharmacy staffing varied widely across public acute hospitals during its review of antimicrobial stewardship in Irish acute hospitals carried out in 2015. This national review concluded that in the absence of national planning with respect to what constituted a minimum acceptable level of clinical pharmacy staffing, many hospitals had over a period of time acted to locally develop and resource such programmes, in keeping with international norms. However others had not, and significant variance had emerged as a result.

Such a situation has continued at the Regional Hospital Mullingar. It is concern to HIQA that there has been a relative lack of progress achieved in enhancing medication safety, despite risks associated with current arrangements having being previously flagged at hospital and group level through a number of sources prior to this inspection. Moreover, while relative resource deficits are significant in accounting for much of the reasoning behind the hospitals poor performance in this inspection, more rapid improvement would be achievable at the hospital through greater sharing of knowledge and expertise across the hospital group – other hospitals in the group have much more advanced medication safety programmes, and could do more to support Regional Hospital Mullingar. In particular, it is likely that greater mentorship support at a clinical leadership level from peer hospitals would be of significant benefit in Mullingar. This should be readily attainable through hospital group coordination and oversight, within existing resources.

It is HIQA's opinion that a high level strategic plan, to be devised, resourced, implemented and managed at Hospital Group level is required to effectively address the issues identified at the Regional Hospital Mullingar both internally and by HIQA. Such a plan should also involve representation from the local Community Healthcare Organisation, given the impact that a requirement for ongoing medication supply functions to community services has on the ability of the hospital to focus on inpatient safety needs. Given the risks identified during this inspection, both short term and longer term measures need to be rapidly progressed.

Following this report, the hospital and hospital group must focus their collective 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.

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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	1. 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	2. 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	3. 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	4. 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	5. 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	6. 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	7. 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 Regional Hospital Mullingar

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Shona Schneemann
General Manager
Midland Regional Hospital Mullingar
Longford Road
Mullingar
Co. Westmeath
shona.schneemann@hse.ie

24 April 2017

Ref: MS/067

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

Dear Shona

During the course of the announced Medication Safety inspection conducted at Mullingar Regional Hospital on 20 April 2017, Authorized Persons[1] identified a composite of medication safety related risks at the hospital that may collectively present a serious risk to the health or welfare of patients, and immediate measures needs to be put in place to mitigate these risks.

The immediate risk related to;

- An identified relative lack of effective systems in place to ensure minimum standards of safety and quality are met relating to medication safety. In addition, the hospital has failed to act to fully address risks previously identified and communicated by HIQA to the hospital following an inspection related to antimicrobial stewardship in November 2015 relating to:

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

☑ **Head Office:**
Unit 1301, City Gate, Mahon, Cork, Ireland.
Tel: +353 (0) 21 240 9300
Fax: +353 (0) 21 240 9600

☐ Dublin Regional Office:
George's Court, George's Lane,
Dublin 7, Ireland
Tel: +353 (0) 1 814 7400
Fax: +353 (0) 1 814 7499

e-mail: info@hiqa.ie **www.hiqa.ie**

- the ongoing lack of a Clinical Pharmacy service
- the lack of up-to-date approved set of intravenous product information monographs
- the ongoing presence of potentially conflicting reference information in the ward setting relating to advice in the reconstitution and adminsitration of intravenous medication.

In addition, in reviewing the totality of findings from the inspection, the inspection team has determined that the current approach at the hospital to the leadership, governance and management of medication safety related risk is not sufficiently effective and represents a potential risk to patients. The risks concerned include;

- The absence of strategic medication safety and operational plans detailing the development, implementation and maintenance of hospital wide medication safety systems.
- Inadequate arrangements in place to identify, report and manage risks associated with medication use.
- An ongoing absence of a drug formulary to ensure that there are robust and transparent criteria for adopting, removing or updating the hospital's drug prescribing list.
- A relative lack of current policies, protocols,and guidelines to support relevant clinical staff in safe prescribing and administration of medications at ward level.

In light of these findings, I am writing to you to seek both further clarification and seek assurance in relation to the risks identified. Please formally report back to HIQA by 26 April 2017 to qualityandsafety@hiqa.ie, providing:

- An outline as to how you have mitigated the immediate risk outlined above and
- A time bound plan with identified accountability for resolution of the additional risks identified.

☑ **Head Office:**
Unit 1301, City Gate, Mahon,
Cork, Ireland.
Tel: +353 (0) 21 240 9300
Fax: +353 (0) 21 240 9600

☐ Dublin Regional Office:
George's Court, George's Lane,
Dublin 7, Ireland
Tel: +353 (0) 1 814 7400
Fax: +353 (0) 1 814 7499

e-mail: info@hiqa.ie **www.hiqa.ie**

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

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

KAY SUGRUE
Authorized Person

CC: May Day, CEO, Ireland East Hospital Group
Mary Dunnion, Chief Inspector and Director of Regulation, Health Information and Quality Authority

☑ **Head Office:**
Unit 1301, City Gate, Mahon,
Cork, Ireland.
Tel: +353 (0) 21 240 9300
Fax: +353 (0) 21 240 9600

☐ Dublin Regional Office:
George's Court, George's Lane,
Dublin 7, Ireland
Tel: +353 (0) 1 814 7400
Fax: +353 (0) 1 814 7499

e-mail: info@hiqa.ie **www.hiqa.ie**

Appendix 3: Copy of the response received by HIQA from Regional Hospital Mullingar

Ireland East
HOSPITAL GROUP

Regional Hospital Mullingar
Longford Road
Co. Westmeath
☎ (044) 93 94140
(044) 93 43155

26th April 2017

Ms. Kay Sugrue
Authorised Person
Health Information & Quality Authority
Dublin Regional Office
George's Court
George's Lane
Dublin 7

Ref: MS/067

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

Dear Kay,
With reference to your letter of the 25th April 2017 and your request for further clarification and assurance in relation to the risks identified. Please find below an outline of how we plan to manage the risks outlined. An action plan with accountability for the resolution for the risks is attached as requested. I have also attached correspondence which was verbally requested by you from the Chief Pharmacist.

With reference to the Antimicrobial Stewardship Review (November 2015), response is outlined below.

- The ongoing lack of a Clinical Pharmacy service

  Response – An Antimicrobial Pharmacist commenced in October 2015. This post was approved by Ireland East Hospital Group as an additional post. During 2016 the priority of the Hospital was to fill the vacant posts to ensure continuation of Hospital Pharmacy Services. The lack of Clinical Pharmacy was included on the Risk Register in January 2016.

- The lack of up-to-date approved set of intravenous product information monographs

  Response – Antimicrobial Administration Guidelines have been developed for Adults and Paediatrics. Administration Guidelines with a defined list of regularly used medication has also been developed in 2016. Access to Medusa Medication Monographs was implemented in February 2017.

Ireland East
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Regional Hospital Mullingar
Longford Road
Co. Westmeath
☎ (044) 93 94140
(044) 93 43155

- The ongoing presence of potentially conflicting reference information in the ward setting relating to advice in the reconstitution and administration of intravenous medication
  Response – Every effort has been made to remove all legacy reference information from clinical areas. The development of local reference guidelines is required to mitigate the risk and we will be undertaking a gap analysis at ward level and also following up with Ireland East Chief Pharmacists Forum in this regard.

I note the following comment;
"In addition, in reviewing the totality of findings from the inspection, the inspection team has determined that the current approach at the hospital to the leadership, governance and management of medication safety related risk is not sufficiently effective and represents a potential risk to patients"

Response - Leadership Governance & Management is a high priority for the Clinical, Nursing, Pharmacy and Management Teams in Regional Hospital Mullingar. This is evident through the re organisation of the Hospital Governance and Management Structure and the re - establishment of the Drugs & Therapeutics Committee and the establishment of Medication Safety Committee in 2016. Both Committees have been actively progressing the Medication Safety agenda and initiatives.

I note the risks identified in your letter and a response is outlined below;

- The absence of strategic medication safety and operational plans detailing the development, implementation and maintenance of hospital wide medication safety systems.
  Response – The Regional Hospital Mullingar have a Medication Safety Action Plan. A Strategic Plan will be drafted and will include actions from the Medication Safety Inspection, and the local Medication Safety Action Plan.

- Inadequate arrangements in place to identify, report and manage risks associated with medication use.
  Response – The Regional Hospital Mullingar is actively promoting and supporting Incident Reporting and is compliant with the HSE target for medication reporting per bed days used (Ref HSE BIU). We do recognise the importance of proactively managing risk and acknowledge the deficit in relation to auditing medication safety. In this respect we have submitted a business case to Ireland East Hospital Group for a Medication Safety Pharmacist, which will require Acute Hospital Division approval and funding. Approval has been received for a Clinical Audit Nurse for the Regional Hospital Mullingar and medication safety will be included as part of this role.

Ireland East
HOSPITAL GROUP

Regional Hospital Mullingar
Longford Road
Co. Westmeath
☎ (044) 93 94140
(044) 93 43155

- An ongoing absence of a drug formulary to ensure that there are robust and transparent criteria for adopting, removing or updating the hospital's drug prescribing list.
  Response – Preliminary work has commenced to compile a medication list which will form the basis of a drug formulary. The Hospital currently has formulary documentation for Antimicrobials, which was developed in 2016. We also have a process for the introduction of new drugs in the Hospital. The application and approval process is communicated, recorded and managed by the Drugs and Therapeutics Committee.

- Relative lack of current policies, protocols and guidelines to support relevant clinical staff in safe prescribing and administration of medications at ward level.
  Response – The Hospital PPPG Steering Committee commenced in September 2016 following the reorganisation of Regional PPPG Services in 2015 and the resulting deficit. The Committee currently coordinate the updating of all Hospital policies procedures and guidelines. To date 35 policies have been approved by the Committee, eight of which relate directly to medication safety. A review of further PPPG's relating to Medication Safety has commenced.

The risks identified and action plan will be discussed in detail with Ireland East Hospital Group and progress will be monitored by the Hospital Clinical Governance, Quality & Patient Safety Committee and the Executive Management Team.

Yours sincerely,

Ms. Shona Schneemann
General Manager

Cc: Prof Mary Day, CEO, Ireland East Hospital Group
Ms. Mary Dunnion, Chief Inspector and Director of Regulation, Health Information & Quality Authority
Ms. Ann Donovan, Acting COO, Ireland East Hospital Group
Dr. Grace Donnelly, Clinical Director, Regional Hospital Mullingar

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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