Report of the announced inspection of medication safety at Bantry General Hospital, County Cork.

Date of announced inspection: 08 November 2016
Report of the announced inspection of medication safety at Bantry General 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. 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.

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 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 which is available on HIQA’s website: www.hiqa.ie

An announced medication safety inspection was carried out at Bantry General Hospital by Authorised Persons from HIQA; Sean Egan and Kathryn Hanly. The inspection was carried out on 08 November 2016 between 09:30hrs and 14:50hrs. During the inspection, inspectors used specifically developed observation, interview and record review tools.

Interviews were held in Bantry General Hospital with the following groups:

- Group one: a medical senior house officer and a medical intern
- Group two: The hospital pharmacist, the Clinical Director, the Hospital Manager and the Director of Nursing
Inspectors visited the following clinical areas and spoke with staff regarding medication safety and reviewed documentation:

- Medical Assessment Unit
- Medical Ward

In addition a survey was conducted among patients attending the Outpatients 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 Bantry General Hospital

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

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 unannounced inspection which are aligned to the lines of inquiry.

2.1 Risks identified

During the unannounced inspection on 08 November 2016, an immediate high risk finding was identified in relation to medication safety. On the day of inspection HIQA found that an intravenous medication administration guidance document specifically designed for use in Cork University Hospital was in use in Bantry General Hospital. It was explained to authorised persons that this guidance document had not been formally approved for suitability of use in Bantry General Hospital. There was therefore a risk that instructions for administration of intravenous medications could be incorrect, resulting in patient harm.

Details of this risk was communicated to hospital management. A copy of the letter issued to the hospital regarding this issue on 08 November 2016 and a copy of the response received from the hospital are included in Appendices 2 and 3 respectively.

Following this inspection the hospital reported that up to date reconstitution and administration guidelines for intravenous medication had been made available to staff in clinical areas across the hospital.

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.

Bantry General Hospital is a member of the Cork University Hospital Group. The hospital is linked in through shared senior management with Cork University Hospital Group. This management arrangement also includes Cork University Hospital and Mallow General Hospital. Whilst all hospital sites within the group fall within the same governance structure, it was identified during the inspection that there was no formalised governance structure for medication safety at Bantry General Hospital.
which linked in with the other hospitals within the Group. Despite a recommendation made by HIQA in 2013\(^5\), medication management at the hospital was still not overseen by a drugs and therapeutics committee. Drugs and therapeutics committees are responsible for the governance of medication management and ensuring safe use of medications. In the absence of a drugs and therapeutics committee, HIQA was informed that medication safety issues at Bantry General Hospital were dealt with by the hospital’s Quality and Safety Committee. HIQA noted that the operational norm in the majority of hospitals inspected is that the governance of medication management and ensuring safe use of medications issues are dealt with by a drugs and therapeutics committee to ensure that medications are appropriately managed and medication related risks are mitigated.\(^6\)

During the inspection inspectors viewed correspondence from Cork University Hospital Group, dated 24 October 2016, which indicated that the terms of reference of the Cork University Hospital Drugs and Therapeutics Committee had recently been revised to include membership of a pharmacist and a consultant physician from Bantry General Hospital. It is important that this arrangement progresses as planned to address the risks associated with the governance arrangements at the time of this inspection.

HIQA noted the low numbers of medication related incidents and near misses reported throughout 2016, relative to other hospitals. As a result key medication related risks could not be understood, recorded, escalated or mitigated effectively by the organisation. Low numbers of incidents reported does not necessarily mean a low number of incidents occurring. Studies have found a positive association between increased incident reporting rates and measures of safety culture where an increase in incident reporting was indicative of a positive reporting culture within the hospital.\(^7\) The hospital therefore needs to begin to better quantify and report medication related risks through improved reporting to more appropriate governance oversight committees.

2.3 Audit and evaluation

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

Medication safety was not systematically monitored and evaluated at the hospital. Elements of medication safety were audited at the hospital but these audits were not aligned to a formalised medication safety strategy.

Documentation reviewed showed that some medication safety-related audits had been performed at the hospital including an audit of access to the hospital pharmacy.
by nursing staff outside of the pharmacists core working hours to obtain emergency medications and an audit of the management of MDA controlled drugs*. Nursing quality care metrics in relation to medication safety were also collected. However audit activity throughout the hospital was neither strategically driven nor centrally coordinated. In addition, the results of audits conducted were not communicated and disseminated hospital wide. Current arrangements should be strengthened and formalised to provide assurance to the senior hospital management team about medication safety at 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.

There was no up to date, local approved list of medications stocked in the hospital. The purpose of maintaining an approved list of medications used in the hospital is to ensure that appropriate governance exists 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. In addition, the hospital did not have a process to formally evaluate the quality and safety of new medicines before introducing them for use. Standard criteria for such decision making should be defined and consistently implemented by a Drugs and Therapeutics Committee. The absence of such a committee in the hospital meant that appropriate governance controls and medicines evaluation and risk management were therefore not in place.

The hospital maintained a list of high alert medications that present a heightened risk of causing significant patient harm if not used correctly. High risk medicines and risks associated with the use of medicines were supported by policies, procedures, protocols and guidelines. Inspectors were informed of restricted prescribing rights for hospital interns in respect to specified high risk drugs.

There was one whole time equivalent pharmacist position employed by the hospital providing cover Monday to Friday. The pharmacy service within the hospital was almost entirely restricted to dispensing. While efforts were extended by the pharmacist to support staff in safe medicines usage, the hospital was not sufficiently resourced to provide a comprehensive clinical pharmacy service. There are currently no agreed national standards outlining requirements for the provision of clinical

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* A controlled drug is any substance, product or preparation specified in the Schedule of the Misuse of Drugs Act 1977. The main objective of the Act is to ensure the availability of controlled drugs for medical and scientific purposes and to prevent the non-medical use of those drugs.
pharmacy services in Irish hospitals. However, international studies support the role of clinical pharmacists in hospital wards in preventing adverse drug events.\textsuperscript{8,9,10,11,12,13} Inspectors were informed that the hospital had advertised for an additional full time senior pharmacist position which, if filled, would provide clinical pharmacy services at the hospital. At the time of inspection this post remained unfilled. Inspectors were informed that risks in relation to coverage provided by the clinical pharmacy service had been recorded on the hospital’s risk register.

There was a formalised and clearly defined system in place in the pharmacy department to promptly identify and act in accordance with guidance, alerts, recalls and recommendations issued by regulatory bodies relevant to the hospital. Staff reported that medication safety alerts were circulated via email.

Inspectors were informed that formalised medication reconciliation was not routinely carried out in Bantry General Hospital. Medicines reconciliation is a formal, systematic process 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.\textsuperscript{14,15,16,17}

Medication safety quality improvement initiatives were not strategically driven by learning gained from analysis of medication incidents or near misses. Nevertheless, despite this weakness, a number of good practices were identified during the inspection. For example, interruptions during medication administration rounds are thought to be a prominent causative factor of medication errors.\textsuperscript{18} To reduce interruptions, red “do not disturb” tabards were worn by nursing staff while administering medications. This intervention was designed to draw attention to the fact that the medication round was in progress, and that nurses should not be interrupted while administering medications. Additionally, to facilitate timely administration of medications additional drug trolleys were in use on the medical ward, a 33-bedded ward. However it was reported to inspectors that these initiatives had not been formally evaluated since implementation.

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.\textsuperscript{3,19} Staff spoken with throughout the inspection were familiar with the hospital’s open disclosure policy.
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.

Bantry General Hospital had systems in place to support the provision of patient information and education in relation to medication usage. This included the availability of written patient information leaflets that were available at the point of care. In addition, inspectors were advised that clinical nurse specialists in diabetes and stroke care attended clinical areas to provide advice and support to patients.

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

- four said that as well as being provided with a prescription form to take to their local pharmacy or GP, they had also been given a list† that outlined what medicines they were on in a way they could understand.
- four said that a staff member had explained the purpose of new medication
- four said that a staff member told them about possible medication side effects to look out for following discharge home.
- four said that they received instruction on how to take their medications at home.

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

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

There were no locally adapted guidelines for clinical staff in relation to the reconstitution and administration of intravenous medications in Bantry General Hospital. On the day of inspection HIQA found that an intravenous medication administration guidance document specifically designed for use in Cork University Hospital was in use in Bantry General Hospital. It was explained to inspectors that the intravenous drug administration guidance document had not been double checked to ensure that all product monographs contained in this document corresponded with the Bantry General Hospital intravenous product inventory. As a result, there was a potential that the wrong information could be used regarding the reconstitution and administration of intravenous medication. This prompted HIQA to highlight concerns with the hospital and to communicate these concerns in writing to the hospital (Appendix 2). In response, the hospital communicated how this risk had been mitigated (Appendix 3).

The hospital had developed a range of nursing policies and guidelines to support medication usage. However these had not been reviewed or approved by a Drugs and Therapeutics Committee. The development of medication management policies should be overseen by a multidisciplinary group to reflect the fact that medicines management is the responsibility of a number of clinical professional groupings.

Junior medical staff at the hospital described ready access to clinical advice from consultant physicians at the hospital as required. It was reported that there was a high degree of consultant delivered care at Bantry General Hospital, and consequently a high level of supervision and support available for non consultant hospital doctors around prescribing and advice.

Clinical staff had access to patient's laboratory results on computers in clinical areas across the hospital. Healthcare requires 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.

Healthcare professionals demonstrated ready access to patient information, relevant to the safe use of medications, at the point of clinical decision making. Decision
support tools including an antimicrobial prescribing application were available to staff in the clinical area. Clinical staff also had access to the British National Formulary in clinical areas.

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.

Inspectors were informed however that new nursing staff were required to complete the HSELanD online Medication Management training programme. Records reviewed showed that the majority of nursing staff had also completed anaphylaxis training to facilitate the administration of first doses antimicrobial medications by nurses.
3. Conclusion

Medications represent the primary measure for treatment intervention in hospitalised patients. Error associated with medication usage constitutes one of the major causes of patient harm in hospital. Medication-related events were the third most common type of adverse event recorded in the recently published Irish National Adverse Events Study. Medication safety should therefore be a priority area for all acute hospitals as they seek to ensure a high quality and safe service for patients.

At the time of this inspection, formalised governance arrangements and organisational structures for medication safety were not in place at Bantry General Hospital.

Bantry General Hospital did not have a drugs and therapeutics committee. In the absence of membership of a drugs and therapeutics committee, the governance and oversight of medication safety was both poorly defined and weak. An effective drugs and therapeutics committee should have ongoing oversight of the medication management and safety system within a hospital.

Despite being part of the Cork University Hospital Group, at the time of inspection this integration did not extend to formal representation of Bantry General Hospital at Cork University Hospital’s Drugs and Therapeutics Committee. As a result arrangements and organisational structures for medication safety had evolved in isolation at Bantry General Hospital and were not planned as part of an integrated hospital group system. Greater integration and collaboration between Bantry General Hospital and Cork University Hospital Group, from a medication safety governance perspective would provide a valuable opportunity to share learning, experience and resources. Furthermore, it should be recognised that given the level of patient bidirectional flow between Bantry General Hospital and other hospital in Cork University Hospital Group, the absence of formalised governance arrangements for medication safety in Bantry General Hospital presents risks across all sites if left unchecked. Governance arrangements for medication safety need to be further developed and fully formalised following this inspection.

At the time of this inspection the hospital did not have adequate arrangements in place to identify, report and manage risk related to medication safety at the hospital. Inspectors identified that medication related incidents were likely significantly under reported at the hospital. This could lead to a lack of understanding as to the exact nature and contributory factors leading to medication errors and, as a result, an inability to effectively engage in prevention, multi-disciplinary learning or systems improvement. Arrangements for improving reporting and learning from medication incidents should be part of clinical governance structures in Bantry General Hospital.
These structures should ensure that medication error reporting systems are operating effectively and that the quality of incident reports supports learning.

In strengthening the medication safety governance arrangements at the hospital, the establishment of a more formal programme of audit and assurance should be embedded as an early first step. Audit facilitates decision making regarding medication safety quality improvement initiatives and ensures that the accountable person can be confident that medication safety is being managed effectively and thus be able to make a judgment on the level of risk to patients.

Inspectors were informed that staff did not take a systematic approach to medication reconciliation. Medications reconciliation should be carried out in a structured manner by trained and competent health professionals with the necessary knowledge, skills and expertise.\textsuperscript{14,15,16,17,21,22}

Patient education is an essential component of the safe, effective and cost-effective use of medicines. Patient medication education should be initiated upon admission and continue throughout the hospital stay.\textsuperscript{22,23} The majority of patients surveyed reported that education was provided in relation to the use of medications.

While there were some systems in place clinically to support medication safety, inherent issues were identified around governance of medications within the hospital. The hospital needs to embrace a wider approach to medication safety rather than focusing on specific, circumscribed safety initiatives. The aim of clinical governance is to accomplish continuous quality improvement and is designed to consolidate fragmented approaches to quality improvement.

Many of the identified opportunities for improvement require the wider involvement of the Cork University Hospital Group’s Drugs and Therapeutics Committee to fully evaluate and address identified deficiencies in medicines governance in Bantry General Hospital. It will then be the responsibility of Bantry General Hospital to ensure effective mechanisms are in place to implement decisions, policy or guidance. There is also potential for greater tie in for the hospital with other hospitals in the South/ South West Hospitals Group around medication safety which will allow the hospital to make better use of the limited resources available.
4. References†


† All online references were accessed at the time of preparing this report. Web addresses may change over time.
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18 Relihan E, Brien V, Hara S, Silke, B. The impact of a set of interventions to reduce interruptions and distractions to nurses during medication administration. Quality and Safety in Health Care. 2010 Oct; 19(5):pp 1-6. Available online from: http://qualitysafety.bmj.com/content/19/5/e52.long


20 Health Service Executive. HSELaND. Health Services e-Learning and Development. Available online from: https://www.hsland.ie/dash/Account/Login.


5. Appendices

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

<table>
<thead>
<tr>
<th>Area to be explored</th>
<th>Line of enquiry¹</th>
<th>National Standards for Safer Better Healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear lines of accountability and responsibility for medication safety</td>
<td>Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.</td>
<td>3.1, 5.1, 5.2, 5.4, 5.5, 5.6, 5.8, 5.9, 5.10, 7.1</td>
</tr>
<tr>
<td>Patient involvement in service delivery</td>
<td>Patients and or carers are informed about the benefits and associated risks of prescribed medicines in a way that is accessible and understandable.</td>
<td>1.4, 1.5, 1.7, 3.1, 4.1</td>
</tr>
<tr>
<td>Policies procedures and guidelines</td>
<td>Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.</td>
<td>2.1, 3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.11, 8.1</td>
</tr>
<tr>
<td>Risk management</td>
<td>There are arrangements in place to identify, report and manage risk related to medication safety throughout the hospital.</td>
<td>3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.10, 5.11, 8.1</td>
</tr>
<tr>
<td>Audit and evaluation</td>
<td>The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.</td>
<td>2.8, 3.1, 5.8, 8.1</td>
</tr>
<tr>
<td>Education and training</td>
<td>Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.</td>
<td>6.2, 6.3</td>
</tr>
<tr>
<td>Access to information</td>
<td>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.</td>
<td>2.5, 8.1</td>
</tr>
</tbody>
</table>
Appendix 2: Copy of the letter sent from HIQA to Bantry General Hospital

Jackie Daly
Hospital Manager
Bantry
Cork
jackie.daly@hse.ie

10 November 2016

Ref: MS/031

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

Dear Jackie

During the course of the announced Medication Safety inspection conducted at Bantry General Hospital on 08 November 2016, Authorised Persons¹ identified a specific issue that may present a serious risk to the health or welfare of patients, and immediate measures need to be put in place to mitigate this risk. The risk identified related to:

- Compatibility checking prior to the sharing of intravenous drug administration guidance documentation with another hospital

¹ Authorised Persons of the Health Information and Quality Authority (the Authority) under Section 70 of the Health Act 2007 (the Act) are authorised for the purpose of monitoring against the National Standards for the Prevention and Control of Healthcare Associated Infections (NSPCHCAI) pursuant to Section 8(1)(c) of the Act.
Bantry General Hospital currently use an intravenous medication administration guidance document (IV monographs) that has been designed for use in Cork University Hospital. It was explained to Authorised Persons that the intravenous drug administration guidance document had not been double checked to ensure that all product monographs contained within correspond with the Bantry General Hospital intravenous product inventory.

This issue was brought to the attention of the Senior Management Team at the hospital during the inspection. This was done so that your hospital could act to mitigate and manage this risk as a matter of urgency.

Given the level of potential risk associated with this finding, please formally report back to the Authority by 2pm on 17 November 2016 to qualityandsafety@hiqa.ie, outlining the measures that have been enacted to mitigate the identified risk. 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

Kathryn Hanly
Authorized Person

CC: Tony McNamara, Chief Executive Officer, Cork University Hospital Group
    Mary Dunnion, Chief Inspector and Director of Regulation, Health Information and Quality Authority
Appendix 3: Copy of the response received by HIQA from Bantry General Hospital

16th November 2016

Ms. Kathryn Hanly,
Authorised Person,
Health Information and Quality Authority,
Unit 1301,
City Gate,
Mahon,
Cork

RE: Monitoring Programme for Medication Safety in Public Acute Hospitals in the Republic of Ireland

Dear Kathryn,

I wish to refer to the announced HIQA Medication Safety inspection conducted in Bantry General Hospital on the 8th November and your letter dated 10th November. Your letter refers to the "compatibility checking prior to sharing of intravenous drug administration guidelines documentation with another hospital" i.e. the use of the IV guideline designed by Cork University Hospital.

I wish to confirm that a review of the IV guideline has been undertaken against the Bantry General Hospital Intravenous product inventory. The products listed on the IV guidelines are predominately available in Bantry General Hospital with the exception of six items. These six items has been notified to all department and we are revising and adapting the IV guideline for local use. Once this document has been finalised I will circulate a copy to you.

If you have any queries regarding same, please do not hesitate to contact me.

Yours sincerely,

Jackie Daly
Hospital Manager

CC: Mr. Tony McNamara, CEO Cork University Hospital Group
    Ms. Maureen Minihane, Director of Nursing
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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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