Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the unannounced inspection at Croom Hospital, Croom, Co Limerick.

Date of on-site inspection: 04 April 2019

HIQA's monitoring programme against the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*

About the Health Information and Quality Authority (HIQA)

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

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

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

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

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

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

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

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

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

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1.0: Introduction

Under section 8(1)(c) of the Health Act 2007, Authorised Persons of the Health Information and Quality Authority (HIQA) monitor the implementation of the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*[1] in public acute hospitals.

HIQA's focus in 2019 will include a detailed evaluation of how hospitals organise themselves to minimise the spread of healthcare-associated infections; with a particular focus on systems to detect, prevent, and manage multidrug-resistant micro-organisms, and the approach taken to reduce the risk of reusable device-related infection. These two areas are internationally recognised as being major contributors to potentially preventable patient harm as a consequence of healthcare provision.

HIQA has published a guide[2] to this monitoring programme which is available to view on HIQA's website www.hiqa.ie

2.0 Information about this inspection

This inspection report was completed following an unannounced inspection carried out at Croom Hospital by Authorised Persons from HIQA; Kathryn Hanly and Bairbre Moynihan on 04 April 2019 between 09.30hrs and 16.30 hrs.

Specific lines of enquiry were developed to facilitate this monitoring programme and are included in this report in Appendix 1.

Inspectors used specifically designed monitoring tools and focused on:

- the prevention and control of transmission of antimicrobial-resistant bacteria and healthcare-associated infections
- decontamination facilities[*] outside of designated controlled decontamination units.[†]

During this inspection inspectors spoke with hospital managers, staff and representatives from the Infection Prevention and Control Committee, the Decontamination Committee and staff from the Theatre Department. Inspectors

[*] Decontamination facilities refers to the physical infrastructure where decontamination of reusable medical devices is provided.
[†] A controlled decontamination unit, such as a Central Decontamination Unit or Endoscope Reprocessing Unit, is a designated unit which has defined governance arrangements and is designed, constructed, maintained and controlled with structures, systems, processes and outcomes that are continuously monitored, measured and validated to provide assurances that reusable medical devices are safely and effectively reprocessed consistently in accordance with legislation, manufacturer's instructions, national decontamination standards and guidelines, National Standards and best practice guidance.

requested and reviewed documentation, data and observed practice within the clinical environment in a sample of clinical areas which included:

- Sterile Services Department (SSD): located within the footprint of the theatre department.
- St Mary's Ward: 17-bedded elective orthopaedic ward which comprised two four-bedded wards, a three-bedded ward, two two-bedded wards and two ensuite single rooms.

HIQA would like to acknowledge the cooperation of the hospital management team and staff who facilitated and contributed to this unannounced inspection.

3.0 Hospital profile

Croom Hospital is a stand-alone statutory specialist orthopaedic hospital owned and managed by the Health Service Executive (HSE), and is part of the University of Limerick Hospitals Group.[‡]

The University of Limerick Hospitals Group governance structure comprises six hospitals with four clinical directorates responsible for daily operations relating to specific specialties across the hospital group. Croom Hospital operated as part of the Peri-Operative Care Directorate governance structure of the University of Limerick Hospitals Group.

Elective orthopaedic services are provided at the hospital by consultant orthopaedic surgeons based at University Hospital Limerick. The hospital also accepts transfers of orthopaedic patients from University Hospital Limerick for post-acute care.

The hospital has a bed capacity of 54 beds; 37 in-patient beds, 13 day-case beds and four rheumatology beds and two operating theatres.

[‡] Hospital groups: The hospitals in Ireland are organised into seven hospital groups: 1. Ireland East Hospital Group. 2. Dublin Midlands Hospital Group. 3. South/South West Hospital Group. 4. Saolta University Health Care Group. 5. University Limerick Hospitals Group. 6. RCSI Hospitals Group. 7. National Children's Hospital Group.

4.0 Inspection findings

The following sections present the general findings of this unannounced inspection. The report is structured as follows:

- Sections 4.1 to 4.3 present the general findings of this unannounced inspection.

4.1 Governance and management structures

4.1.1 Infection prevention and control programme

Inspectors found that there were formalised governance and management arrangements in relation to the prevention and control of healthcare-associated infection at Croom Hospital.

The hospital was managed on a day-to-day basis by a local hospital management team who, as part of the University of Limerick Hospitals Group directorate governance structure, reported to the Peri-Operative Care Directorate of the University of Limerick Hospitals Group.

The infection prevention and control programme at the hospital was provided by the infection prevention and control team based at University Hospital Limerick who reported to the University Hospital Limerick Hospitals Group Infection Control Committee. This committee in turn reported up through to the Groups Quality and Patient Safety Executive Committee (Qualsec).

The infection prevention and control team provided ongoing support to Croom Hospital and advised on the management of infection prevention and control issues via telephone as required. An infection prevention and control clinical nurse manager 2 based in University Hospital Limerick attended Croom Hospital for a half day each fortnight.

4.1.2 Decontamination and reprocessing of reusable medical devices

It was explained that the University of Limerick Hospitals Group Decontamination Users Committee reported to the University of Limerick Hospitals Group Pan Directorate Decontamination Committee. Inspectors were informed that Croom Hospital was represented of both committees.

An organogram provided to inspectors (appendix 2) outlined that the Pan Directorate Decontamination Committee reported through the University of Limerick Hospitals Group Infection Control Committee (HICCM) to the Groups Quality and Patient Safety Executive Committee (Qualsec). However on the day of inspection inspectors noted that there was ambiguity amongst staff with respect to these governance structures for decontamination.

Responsibilities for the operational management of the SSD were spread among managers within the theatre department. This resulted in fragmented responsibility for reusable medical device decontamination with no named person as decontamination lead at the hospital.

Likewise there was no group decontamination lead position in the University of Limerick Hospital Group. A leadership role in decontamination should be advanced to drive and support the implementation of national and international best practice guidance across the group in line with HSE recommendations.[3]

4.2 Monitoring, audit and evaluation systems including risk management

4.2.1 Monitoring, audit and evaluation systems

Infection prevention and control of healthcare-associated infection

The infection surveillance programme at the hospital included surveillance of:

- 'alert' organisms and 'alert' conditions[§]
- multidrug-resistant organisms and healthcare-associated infection
- clusters or outbreaks of infection
- data reported to the European Antimicrobial Resistant Surveillance Network (EARS-Net)[**]
- enhanced colonisation and bloodstream infection surveillance including *Staphylococcus aureus* bacteraemia surveillance
- new and recurrent enhanced hospital-acquired *Clostridium difficile* infection

Quarterly breakdown of cases of antimicrobial-resistant bacteria and healthcare-associated infection were provided by the surveillance scientist based at University Hospital Limerick for Croom Hospital.

The hospital did not have a surgical site surveillance programme.[1] In the absence of a surgical site infection surveillance programme, the hospital did not have appropriate mechanisms in place to assure itself that identified infrastructural risks in the SSD did not negatively impact on patients from an infection prevention and control perspective.

[§] Alert conditions include physical symptoms such as skin rashes, vomiting, diarrhoea, respiratory illness that could be due to an infectious illness.

[**] EARS-Net performs surveillance of antimicrobial susceptibility of bacteria causing infections in humans including; *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Acinetobacter species, Streptococcus pneumoniae, Staphylococcus aureus, Enterococcus faecalis and Enterococcus faecium.*

Decontamination and reprocessing of reusable medical devices

Validation, maintenance, periodic testing and monitoring are required to demonstrate compliance of installed equipment with current standards.[4] Planned maintenance including ventilation and water systems was overseen by the hospital's maintenance manager. Validation maintenance was performed by contracted external service providers. The validation and periodic testing data was audited quarterly by an authorised engineer for decontamination (AED).[††]

However the hospital had not introduced sufficient quality controls to provide ongoing assurances that an effective decontamination process had occurred. For example:

- ongoing microbiological monitoring of the inspection, assembly and packaging area including air and contact surfaces was not performed in line with national guidelines and international standards.[4,5]
- automated control tests[‡‡] were not completed in the SSD in line with national guidelines.[4]
- the national track and trace system[§§] using global asset identifier[***] coding had not been introduced in the SSD. A manual track and trace system was in use. However the absence of audit made it difficult to identify and deal with potential poor practice with this manual system.
- audits to monitor adherence to decontamination and reprocessing procedures for surgical instruments were not undertaken in line with national guidelines. [4]

4.2.2 Risk management

The hospital had systems in place to identify and manage risk in relation to the prevention and control of healthcare-associated infections. Inspectors were informed that a risk register was maintained by each ward area which was reviewed quarterly with the risks being escalated to the hospital risk register.[†††] The hospital risk register was maintained by hospital management and included infection prevention and control-related risks.

[††] A suitably qualified person designated by management to provide testing, advice and review validation records and is suitable qualified to graduate level.
[‡‡] Endoscope washer disinfectors automatic control test is performed to verify that the control instrumentation on the endoscope washer disinfector is working within validated parameters, such as time and temperature, using the machines own indicated measurements on the display.
[§§] Electronic system tracking surgical instrument trays through the decontamination process, linking these devices to the patient on whom they have been used.
[***] GS1 Individual Asset Identifier, in a barcode format, it uniquely identifies each instrument set and allows the set to be linked to a patient in theatre.
[†††]A risk register is a database of assessed risks that face any organisation at any one time. Always changing to reflect the dynamic nature of risks and the organisation's management of them, its purpose is to help hospital managers prioritise available resources to minimise risk and target improvements to best effect. The risk register provides management with a high level overview of the hospital's risk status at a particular point in time and becomes an active tool for the monitoring of actions to be taken to mitigate risk.

Inspectors were informed that risk assessments were carried out following identification of issues relating to infection prevention and control as required. Risk assessments viewed by inspectors outlined the existing control measures enacted by the hospital to address current infection prevention and control risks.

Risks on the hospital risk register were reviewed every two months and escalated to the appropriate UHL directorate. Risks were discussed at the University of Limerick Hospitals Group Infection Control Committee meetings and this was confirmed when inspectors reviewed the minutes.

HIQA notes that the risks identified relating to SSD facilities and staff resources had been longstanding, and had been recorded as the highest possible risk rating on the hospital risk register. An externally-led strategic review of decontamination facilities across the University of Limerick hospital group was undertaken in October 2018. Management stated that proposals and recommendations were being explored by University of Limerick Hospitals Group to fully address the issues identified.

4.3 Implementation of evidence-based best practice

Systems to detect prevent and manage multidrug-resistant organisms

Evidence of good practice

Outbreaks of infection

- there had been no outbreak of infection identified at the hospital in the preceding 12 months.

Screening and microbiological testing

- screening for CPE was done in line with the latest national guidance.[6]

Standard and transmission infection control precautions[‡‡‡]

- All patients requiring transmission based precautions were correctly isolated in single rooms. Appropriate signage was in place and doors were closed
- Overall patient equipment hygiene in the ward inspected appeared clean
- Single patient use blood pressure cuffs were in use
- The hospital was endeavouring to improve current facilities and physical infrastructure at the hospital. For example, flooring had recently been replaced throughout the ward inspected.

[‡‡‡] Standard precautions are a set of protective measures that need to be used by all health and social care staff consistently in order to achieve a basic level of infection prevention and control. Transmission-Based Precautions are the second tier of basic infection control and are to be used in addition to Standard Precautions for patients who may be infected or colonised with certain infectious agents for which additional precautions are needed to prevent infection transmission.

- Local environmental and equipment hygiene audits were done monthly with results ranging from 89%-95%.
- The University of Limerick Hospitals Group peri-operative directorate of which Croom reports into achieved hand hygiene compliance of 91.4% in October 2018 exceeding the required compliance target of 90% set by the HSE.

Required areas for improvement

Infrastructure

- As highlighted in previous HIQA inspection reports ceiling fans remained in place and continued to be in use. Inspectors observed dust on the fans. Inspectors were informed that they were on a cleaning schedule weekly but this was not being consistently done.[7] Inspectors were informed that infection prevention and control had advised removal of the fans and hospital management have requested maintenance to remove them. As recommended in previous inspection reports the hospital should consider decommissioning the fans immediately.
- Minimal spatial separation[§§§] between beds in multi-occupancy rooms did not comply with best practice guidelines.[8]
- General ward maintenance for example, inspectors observed damage to doors and skirting boards.
- The design of clinical hand wash sinks in the area inspected did not comply with HBN 00-10 Part C: Sanitary assemblies[9] and outlets were observed to be rusty
- Sanitary facilities in the ward required upgrading.
- Shower outlets were visibly unclean.
- Exposed piping was noted throughout the ward which didn't facilitate effective cleaning.

Environment hygiene

- Dust was observed under bed frames, bed tables and air vents.
- Disposable curtains in patient rooms had not been changed within the previous six months in line with hospital guidelines.
- Inspectors were informed that bi-annual peer auditing programme had been discontinued. National guidance and best practice recommend that managerial audits, should be carried out to validate the local audit process, provide an independent objective view of cleanliness and should form part of the ongoing management and supervision of ward/ department hygiene.[10]

[§§§] Patients should be separated by at least 2.4 metres between bed centres in multi-bed areas.

Equipment hygiene

- A green tagging system which alerted staff to when patient equipment was last cleaned was in use on the ward inspected, however the inspector found evidence that this system was not consistent.

Decontamination and reprocessing of reusable medical devices

The SSD was configured such that it was located within the footprint of the theatre department. This facility provided a decontamination service to the theatre department five days a week.

Evidence of good practice

Environmental hygiene

Environmental hygiene audits were carried out in the SSD in line with national guidance.[10]

Staff training and education

- A dedicated operative assigned in the satellite decontamination facility in the theatre department was undertaking an academically recognised decontamination training course.
- Technical and user training was provided by the manufacturers of decontamination equipment.
- All staff working within the ssd had completed the hseland online training programme in relation to decontamination.
- Inspectors were informed that staff completed chemical safety training annually. Material safety data sheets were available to staff who used potentially hazardous chemicals.

Required areas for improvement

Infrastructure of the decontamination facilities

- As highlighted in section 4.2 of this report the infrastructure of facilities used for surgical instrument decontamination did not comply with the Health Service Executive Standards and Recommended Practices for Central Decontamination Units.[4]
- The configuration of this unit did not facilitate a unidirectional flow for medical device reprocessing in line with national guidelines. The current layout did not include dedicated gowning areas between dirty and clean areas. Furthermore there were no hand washing facilities within the unit.

Equipment

- The hospital had an inventory of reusable medical device and decontamination equipment used hospital-wide. The inventory of decontamination equipment showed that decontamination equipment was greater than 15 years old. Inspectors were informed that there was no equipment replacement programme in place. The hospital needs to ensure that manufacturer's recommendations regarding the expected lifetime of equipment are followed and any equipment that is deemed unfit is decommissioned.[11]
- Comprehensive formalised off-site contingency plans to cover decontamination service disruptions were not in place for the SSD.

Staffing

- Staff involved in the reprocessing of reusable medical devices also rotated within the Theatre Department. The area should be staffed by dedicated personnel whose sole or primary responsibility is the decontamination of reusable medical devices.[4]
- Individual competencies of staff in the SSD were not assessed by the unit manager. Management need to be assured that current staffing arrangements between the theatre and the SSD do not dilute the effectiveness of both roles.[7]

Policies, procedures, protocols and guidelines

- The hospital had developed a number of multidisciplinary policies, procedures and guidelines to support the decontamination and reprocessing of reusable medical devices. However, staff in the ssd had identified that a number of policies, procedures and guidelines relating to decontamination work processes were not in place and planned to develop same.

5.0 Conclusion

5.1 Infection prevention and control of healthcare-associated infection

A National Public Health Emergency Plan was activated by the Minister for Health on 25 October 2017 as response to the increase and spread of Carbapenemase Producing *Enterobacteriales* (CPE) in Ireland. The National Public Health Emergency Team developed guidelines for screening of patients' for CPE in the Acute Hospital Sector. Croom Hospital was screening for CPE in line with national guidance.[12]

Inspectors found that overall leadership, governance and management arrangements were in place for the infection prevention and control programme within the University of Limerick Hospitals Group governance structure. A risk management system to identify, evaluate, and monitor hazards and risks associated with the infection prevention and control programme was in place.

HIQA acknowledges the hospital's progress and compliance levels in relation to:

- compliance with national CPE screening guidelines
- appropriate application of appropriate transmission based precautions.

HIQA notes the infrastructural challenges of the original older footprint of the hospital. However a number of deficiencies which had the potential to impact on effective infection prevention and control measures were again identified during this inspection. Inspectors identified the following areas for improvement:

- immediate decommissioning of the ceiling fans
- spatial separation between beds
- general ward maintenance
- review the green tagging system so that it is consistent throughout the ward
- cleaning schedules need to be reviewed
- review and recommence the peer auditing programme.

5.2 Decontamination and reprocessing of reusable medical devices

National standards[1] recommend that governance and communication arrangements need to be clearly defined and communicated to relevant staff to ensure that there is clarity on individual roles and responsibilities in addition to reporting lines and accountability. In line with national guidance, the hospital needs to ensure that a designated person with responsibility for reusable medical device reprocessing within Croom Hospital is in place.

It is acknowledged that the hospital had identified inherent infection prevention and control risks relating to the decontamination facility and had escalated such risks within the hospital and hospital group risk management structures.

During the course of this inspection HIQA identified opportunities for improvement which included:

- decontamination facility design and infrastructure
- microbiological testing and monitoring of the environment
- audits to monitor adherence to decontamination and reprocessing procedures
- dedicated staffing in the SSD
- policies, procedures and guidelines relating to decontamination work processes .

Croom Hospital, as a member of the University Limerick Hospitals Group needs to be supported within group and national structures to effectively address issues in relation to decontamination and reprocessing of reusable medical devices in order to comply with the National Standards[1] and other national decontamination standards.

6.0 References

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7.0 Appendices

Appendix 1: Lines of enquiry

1. Governance and management structures

The hospital has formalised governance arrangements with clear lines of accountability and responsibility around the prevention and control of healthcare-associated infections and the decontamination and reprocessing of reusable medical devices.

2. Monitoring and evaluation systems including risk management

The hospital has effective arrangements in place to respond to the ongoing monitoring, evaluation, audit and outcome measurement in relation to the prevention and control of healthcare-associated infection programme and the decontamination and reprocessing of reusable medical devices.

The hospital has a risk management system in place to identify, manage and report all hazards, adverse events, near misses and risks in relation the prevention and control of healthcare-associated infections and thedecontamination and reprocessing of reusable medical devices.

3. Implementation of evidence-based best practice

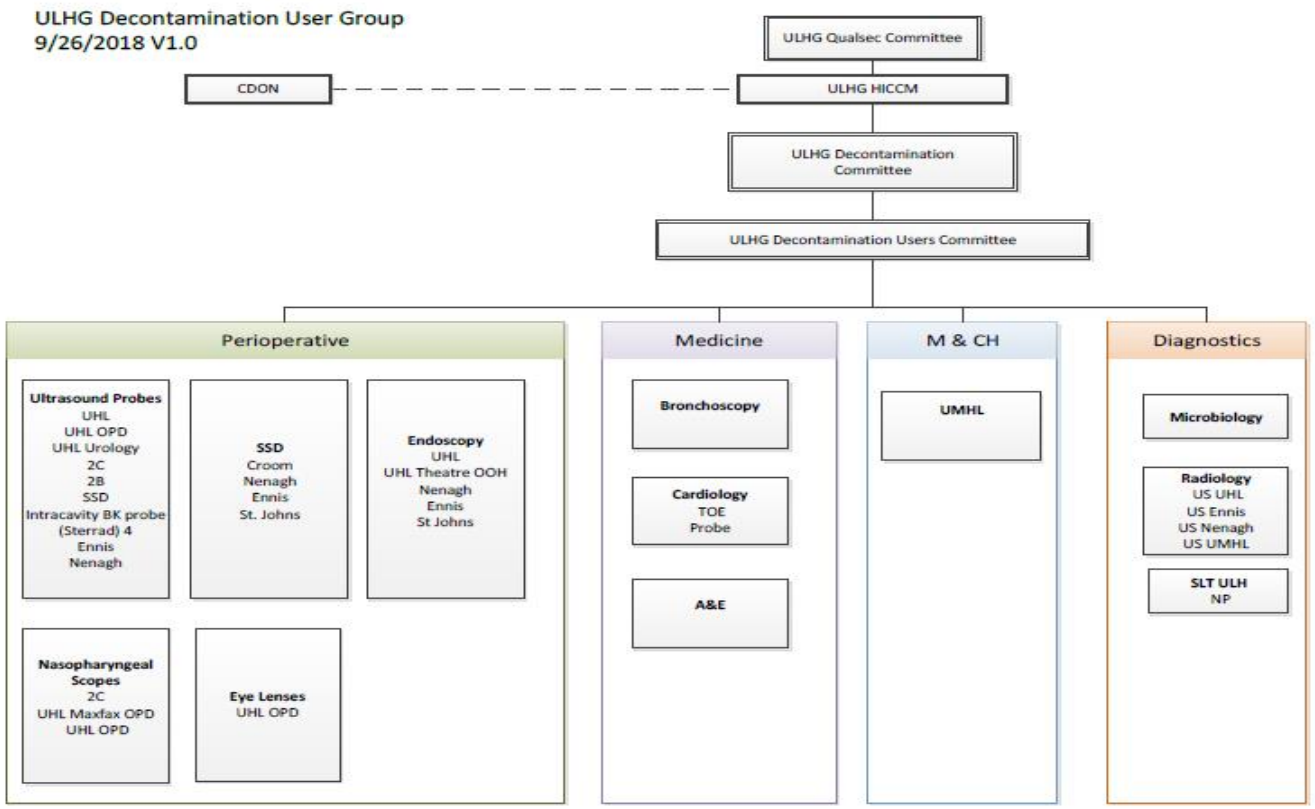
The hospital has the structures, systems and processes to detect, prevent, and manage multidrug-resistant organisms.

The hospital has the structures, systems and processes in relation to decontamination and reprocessing of reusable medical devices in satellite decontamination facilities.

The hospital ensures that key personnel have been appropriately trained to the necessary standard of competence and are supported with ongoing education and training reflecting national and international evidence.

The hospital ensures that key personnel are implementing evidenced-based best practice with up to date policies, procedures, protocols and guidelines in line with relevant legislation and national guidelines.

Appendix 2 Decontamination Governance Organogram



Mr John Doyle Perioperative GM

Majella Corkery Perioperative ADON

Ursula Morby A/CNM3 CSSD

Ospidéil OL
UL Hospitals

Governance Office ULHG

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