



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the unannounced inspection at Naas General Hospital

**Phase 3: Monitoring of decontamination and reprocessing of
reusable medical devices in public acute hospitals**

Date of on-site inspection: 16 August 2018

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

Report of the unannounced inspection of the prevention and control of healthcare-associated infection at Naas General Hospital

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 engaging with 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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1.0 Introduction

HIQA monitors the implementation of the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*¹ in public acute hospitals in Ireland to determine if hospitals have effective arrangements in place to protect patients from acquiring healthcare-associated infection. The *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services* will be referred to as the National Standards in this report.

In 2017, HIQA commenced a revised monitoring programme against the National Standards. The aim of this revised monitoring programme is to assess aspects of the governance, management and implementation of designated programmes to prevent and control healthcare-associated infections in hospitals. This monitoring programme comprises Phases One, Two and Three:

Phase One

All public acute hospitals were requested to complete and return a self-assessment tool to HIQA during April and May 2017.

Phase Two

Phase 2 commenced in May 2017 and involved unannounced inspections in public acute hospitals, focusing on elements of the prevention and control of healthcare-associated infection in line with National Standards.²

In light of the ongoing national public health emergency* in relation to Carbapenemase-Producing *Enterobacteriales* (CPE)[†] the focus of these inspections was on systems to detect, prevent and respond to healthcare-associated infections and multidrug-resistant organisms. It is anticipated that this phase will continue throughout 2018 and 2019 in parallel with Phase 3.

* A National Public Health Emergency Plan was activated on 25 October 2017 by the Minister for Health in response to the increase and spread of CPE in Ireland. As a result a National Public Health Emergency Team was convened and they have been meeting on a weekly basis since 02 November 2017. Please refer to the Department of Health webpage for further details: <http://health.gov.ie/national-patient-safety-office/patient-safety-surveillance/antimicrobial-resistance-amr-2/public-health-emergency-plan-to-tackle-cpe/nphet-press-releases-minutes-of-meetings/>

[†] Carbapenemase-Producing *Enterobacteriales* (CPE), are Gram-negative bacteria that have acquired resistance to nearly all of the antibiotics that would have historically worked against them. They are therefore much more difficult to treat.

Phase Three

From quarter 3 2018 onwards the programme focussed on decontamination and reprocessing of critical and semi-critical reusable medical devices.[‡] HIQA will focus, in the first instance, on decontamination facilities[§] outside of a designated controlled decontamination unit^{**} to ensure structures, systems, processes and outcomes in these facilities are aligned to national standards and guidelines.

Additional information can be found in the *Guide to HIQA's programme of monitoring of the decontamination and reprocessing of reusable medical devices in public acute hospitals*³ which was published in July 2018 and is available on HIQA's website: www.hiqa.ie

Information about this inspection

This inspection report was completed following an unannounced inspection carried out at Naas General Hospital by Authorised Persons from HIQA; Noreen Flannelly-Kinsella and Kathryn Hanly. The inspection was carried out on 16 August 2018 between 09:00hrs and 14:30hrs.

Prior to this inspection, authorised persons reviewed the hospital's completed self-assessment tool and related documentation submitted to HIQA earlier in May 2017.

During this inspection inspectors spoke with hospital managers and staff, and the hospital's decontamination lead. Inspectors requested and reviewed documentation, data and observed practice within a satellite decontamination facility where decontamination of reusable medical devices was carried out:

- The Radiology Department.

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

[‡] The Spaulding classification, dating back to the 1950s, is a widely used classification system which is used to determine the level of decontamination a reusable medical device requires. The level of decontamination required is dependent on the equipment's purpose, and ranges from cleaning, through disinfection to a requirement for sterilisation. Devices may be classified as 'critical' (presenting a high risk of infection transmission if not fully cleaned, disinfected and sterilised), 'semi-critical' or 'non-critical' (presenting a low risk).

[§] 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.

2.0 Naas General Hospital profile

Naas General Hospital is a statutory hospital owned and managed by the Health Service Executive (HSE) and is part of the Dublin Midland Hospital Group.^{††}

The hospital has a bed capacity of 243 patient beds which includes 18 day service beds. The hospital provides general medical, surgical, acute psychiatric services and a 24-hour emergency service including a range of diagnostic and support services.

In light of the National Public Health Emergency in relation to CPE inspectors sought assurance regarding arrangements in place to ensure compliance with the latest national guideline⁴ on screening for CPE at the hospital. Following this inspection management confirmed that the hospital had ensured the full implementation of this guideline.

Overview of decontamination services

Decontamination of reusable medical devices was undertaken centrally in the Central Sterile Supplies Department (CSSD) and in satellite decontamination facilities located in the Endoscopy Unit and Radiology Department.

The hospital was also providing a decontamination service to an external hospital within the same hospital group.

Decontamination of non-critical ultrasound probes used in clinical areas were performed locally in each respective clinical area (see table 1.0 overleaf).

^{††} 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.

Table 1.0: Decontamination facilities and reusable medical devices decontaminated and reprocessed at the hospital

Spaulding risk categorisation	Reusable medical device and location of decontamination
<p>Critical items Items that enter sterile tissues/sterile body areas or the vascular system</p>	<ul style="list-style-type: none"> ▪ Surgical instruments and surgical sets used hospital wide and from: <ul style="list-style-type: none"> ❖ an external hospital (part of the same hospital group) ❖ a HSE dental clinic (located in the hospital's OPD) were decontaminated and reprocessed in the CSSD.
<p>Semi-critical items Items in contact with mucous membranes or non-intact skin</p>	<ul style="list-style-type: none"> ▪ Gastro-intestinal endoscopes and bronchoscopes used in the Endoscopy Unit and General Theatre were decontaminated and reprocessed in the Endoscopy Unit. ▪ Semi-invasive ultrasound probes (SIUP's) used in the Radiology Department were decontaminated locally. ▪ Semi-invasive ultrasound probes used at an outreach antenatal clinic in OPD were transported, decontaminated and reprocessed in their respective hospital. ▪ A Transoesophageal Echocardiography (TOE) ultrasound probe from OPD cardiac services/CCU was decontaminated locally after use and, sometimes in the CSSD.
<p>Non-critical items Items in contact with intact skin but not mucous membranes or not in contact with the patient</p>	<ul style="list-style-type: none"> ▪ Non-invasive ultrasound probes used for vascular access and bladder scanners used in local clinical areas were decontaminated in each respective local clinical area.

3.0 Findings at Naas General Hospital

3.1 Governance and management structures

Inspectors found that there were clear lines of accountability and responsibility in relation to governance and management arrangements for decontamination and reprocessing of reusable medical devices at Naas General Hospital. Notwithstanding this, management need to formalise arrangements of services provided by another external hospital at an outreach clinic located in the hospital's Out Patient Department.

At a hospital group level and in line with the HSE's own recommendation⁵ a group decontamination lead position to lead, support and drive the effective implementation of best practice guidance in relation to decontamination service provision across the Dublin Midland Hospital's Group should be progressed.

The hospital had an assigned local decontamination lead who was responsible for decontamination service provision across the hospital and produced an annual decontamination report for hospital management. Defined management arrangements in relation to decontamination and reprocessing of reusable medical devices at service-delivery level were also in place.

A Decontamination Committee was established at the hospital in 2007. The committee, chaired by the decontamination lead, met quarterly and reported to the Quality and Safety Committee at the hospital. Multidisciplinary committee membership included managers from satellite decontamination facilities and representatives from infection prevention and control. Hospital staff told inspectors that a representative from the external hospital who had a service contract with Naas General Hospital had also been invited to join the Decontamination Committee. As part of the governance and management structures a decontamination sub-group had been recently put in place to undertake a gap analysis of decontamination service provision at the hospital.

A service-level agreement in relation to provision of decontamination services by Naas General Hospital to the external hospital in the hospital group had been prepared. However hospital management informed inspectors that there was no formal arrangement in place for another hospital conducting an outreach antenatal clinic in the hospital's OPD.

3.2 Risk management

Inspectors were informed that a risk management system was in place to identify the hazards associated with the decontamination process, to estimate, evaluate the risks, and monitor the effectiveness of the control. A risk on the hospital risk

register^{††} in relation to decontamination and reprocessing included infrastructure and decontamination facilities in the Endoscopy Unit.

Inspectors were informed that the hospital is awaiting to proceed to tender for a new Endoscopy Unit supported by the Dublin Midland Hospital's group. During the design phase inspectors were told that consideration was also given in relation to centralising decontamination service provision at the hospital.

Risk assessments were undertaken in relation to decontamination and reprocessing-related issues. Risks identified and control measures implemented included for example:

- the use of high level disinfectant (HLD) manual multi-wipe system to decontaminate ultrasound probes:
in line with national guidance⁶ a risk assessment was undertaken; existing control measures included the use of transducer covers for ultrasound probes and the rollout of education and training. A business case to support advancing to an automated validated system of decontamination had been developed
- equipment failure in CSSD:
the hospital had formalised contingency plans with another hospital in the group in the event of decontamination equipment failure
- use of medical equipment beyond recommended working life:
a specialist group at the hospital liaised with the national medical device equipment replacement programme; two endoscope washer-disinfectors were replaced and a paediatric colonoscope was procured by the hospital in 2017.

The hospital had a comprehensive inventory of reusable medical device and decontamination equipment in line with national guidelines. The global asset identifier coding and national track and trace programme to support quality assurance of decontamination practices had been rolled-out in the CSSD, General Theatre and Endoscopy Unit.

The hospital's inventory showed that some equipment including steam sterilisers, washer-disinfectors and gastro-intestinal endoscopes were 10-12 years old. The hospital needs to ensure that manufacturer's recommendations regarding the expected lifetime of equipment are followed and any device that is deemed unfit is decommissioned.^{7,8} Documentation reviewed by inspectors showed that

^{††} 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.

approximately 17% of €1.5million requested by the hospital for equipment replacement in 2018 was received to date. Staff told inspectors that due to an insufficient quantity of equipment, service capacity had to be reduced at times to facilitate testing, maintenance, validation^{§§} and downtime for repairs. Hospital management need to conduct a risk assessment of demand and equipment supply to ensure capacity meets service delivery needs.

Following a discussion with hospital staff, inspectors identified that decontamination of a transoesophageal echocardiography probe in the CSSD, despite being in accordance with a hospital policy and manufacturer's instructions, was not in line with the latest national guidance⁶ and approved high-level disinfectants/sterilants for such devices.^{9,10,11} Following this inspection hospital management informed HIQA that decontamination methods had changed and were in line with the latest national guidance in relation to this device.⁶

Inspectors were told by staff that non-conformances were managed locally and/or escalated to the hospital management team. The general manager stated that risks that could not be effectively mitigated at a local hospital level were escalated to the hospital group through risk management reporting structures. Analysis of decontamination incidents on the National Incident Management System^{***} was reported to the decontamination committee meeting by the hospital's quality, risk and patient safety manager.

The national medical devices eAlert system^{†††} had been implemented at the hospital. The clinical engineer, as the nominated "designated person" and the Device Safety Notice Committee were responsible for internal hospital distribution to the relevant personnel for implementation of the recommended actions where applicable.

The hospital had developed a risk assessment for the identification of service users at increased risk^{†††} of developing a transmissible spongiform encephalopathies (TSE).^{§§§}

^{§§} A planned programme of testing of decontamination facilities, environment and equipment in accordance with national and international standards, European legislation, manufacturer's instructions and local policies, procedures, protocols and guidelines.

^{***} The State Claims Agency National Incident Management System is a risk management system that enables hospitals to report incidents in accordance with their statutory reporting obligation.

^{†††} The national eAlert system receives notification directly from the HPRA of all medical device safety / hazard notifications or any internally generated HSE safety notifications for distribution.

^{†††} Critical and semi-critical medical devices contaminated with high-risk tissue (i.e., brain, spinal cord, and eye tissue) from high-risk patients—those with known or suspected infection with Transmissible Spongiform Encephalopathies require special treatment. Patients who are due to undergo a procedure involving high-infectivity or medium-infectivity tissues must be questioned pre-operatively and have their medical records searched to determine if they are at increased risk of developing a TSE.

3.3 Monitoring and evaluation including audit

Although the focus of these inspections was on decontamination facilities outside of designated controlled decontamination units, and inspections were guided by specific lines of enquiry, inspectors sought assurances in relation to monitoring and evaluation in central and satellite decontamination facilities apart from the facility visited by inspectors at the hospital.^{12,13,14}

In response hospital management stated that decontamination and reprocessing equipment in CSSD and the decontamination facility in the Endoscopy Unit was tested, maintained, and validated to current standards. An authorised engineer for decontamination (AED)^{****} was appointed by the hospital to oversee and audit technical aspects of the programme. In addition, microbiological monitoring and testing of the environment within controlled areas including air, contact surfaces and water had been implemented.

The frequencies of environmental hygiene audits in decontamination facilities was not carried out in line with national guidance¹⁵ for higher risk functional area i.e. monthly; inspectors were informed that environmental hygiene audits were undertaken on a quarterly basis and if compliance with recommended hygiene standards was not achieved, a re-audit was performed and an improvement plan put in place within a 2-3 week timeframe.

3.4 Staff training and education

In line with HSE recommendations⁵ a number of staff had either completed or were in the process of undertaking an academic qualification in decontamination practices and sterile services in both the CSSD and Endoscopy Unit at Naas General Hospital. It was reported that approximately 50% of staff had undertaken a third level qualification in decontamination and or sterile services in the CSSD. In addition a staff member in the radiology department was currently undertaking an ultrasound probe decontamination academic award.

Staff had also completed the HSELand online training in relation to Decontamination and Managing Health and Safety in Healthcare Chemical Agent Hazards training programme.¹⁶ A database of chemicals and Material Safety Data Sheets were available to staff who use potentially hazardous chemicals.

^{§§§} Transmissible spongiform encephalopathies (TSEs) are a group of progressive, invariably fatal, conditions that affect the brain (encephalopathies) and nervous system of many animals, including humans, cattle, and sheep.

^{****} A suitably qualified person designated by management to provide testing, advice and review validation records and is suitable qualified to graduate level.

Additionally, regular operator training was provided by the manufacturers/suppliers of endoscope and decontamination equipment and training records were maintained.

Inspectors were told that individual competencies of staff in the endoscopy decontamination unit were assessed on an ongoing basis by the unit manager; to concur with best practice guidance¹⁷ a formalised competency assessment framework validated annually needs to be rolled-out across all decontamination facilities at the hospital.

Members of the decontamination committee provided training to hospital management and nurse managers on decontamination and reprocessing of reusable medical devices. Inspectors were told that plans to roll-out similar information sessions across the hospital were imminent.

3.5 Policies, procedures and guidelines

Staff were supported to implement best practice in relation to decontamination and reprocessing of reusable medical devices. Policies, procedures and guidelines were available to staff through an electronic document management system. Hospital policies relevant to decontamination were developed by the decontamination lead and local decontamination managers and approved by the Decontamination Committee. At the time of inspection, a clinical water system management manual was being updated.

Staff told inspectors that some policies were due to be reviewed but the lack of dedicated administration support did not always facilitate this process in a timely manner; a hospital risk assessment in relation to this issue showed that a time bound action was in place.

3.6 Decontamination of reusable medical devices in a satellite decontamination facility

Inspectors visited a decontamination facility outside of designated controlled decontamination units to ensure that structures, systems, processes and outcomes were aligned to national guidelines.

Radiology Department

Evidence of good practice

- high level disinfection using the manual multi-wipe system was used for disinfecting semi-invasive ultrasound probes (SIUP's); a local risk assessment was performed in line with national guidance as this is the least preferred method of high level disinfection
- preparation, pre-cleaning, cleaning, disinfection, storage and transport of SIUP's as demonstrated to inspectors, was aligned to recommended best-practice guidance
- the department had a defined system which clearly indicated when SIUP's had been decontaminated; this included a storage system
- a manual track and trace system had been introduced and advanced locally by scanning traceability labels to the electronic radiology patient record
- a quality improvement initiative had been recently introduced by staff; proactive testing of the environment and SIUP's was commenced to provide assurances of the efficacy of cleaning and decontamination practices.

Opportunities for improvement

- the infrastructure of the decontamination facility was not in line with national standards and relevant guidelines; decontamination was performed at point of patient care; an infection prevention and control risk assessment of the facility was recommended
- to augment compliance with the hospital's own guideline in relation to the 3 hour rule⁺⁺⁺ decontamination times need to be clearly visible to users at point-of-use
- regular audit of adherence to reprocessing procedures was not carried out
- standard operating procedures in relation to decontamination processes and procedures were not readily accessible to staff at point-of-use as guidance for users

⁺⁺⁺ The 3 hour rule states that unless decontaminated endoscopes are stored in a way validated to extend usable storage life or is in sterile packaging following sterilization, they should be used within three hours of decontamination otherwise the decontamination process needs to be repeated prior to use.

- as recent environmental test results showed positive results in some areas of the environment, a review of hygiene specifications is recommended.

Hospital staff told inspectors that proposals in relation to transferring the decontamination of SIUPs to the CSSD or building a purpose build decontamination facility on site had taken place.

4.0 Conclusion

Overall HIQA found that Naas General Hospital was committed to improving decontamination and reprocessing practices at the hospital and were endeavouring to fully implement the National Standards and HSE best practice guidance. Notable areas of good practice observed by HIQA during this inspection included some of the following:

- clear lines of accountability and responsibility in relation to governance and management arrangements for decontamination and reprocessing of reusable medical devices were in place
- a risk management system to identify, evaluate, control and monitor hazards and risks associated with the decontamination process was in operation
- training and education for staff working in decontamination was well established
- practices and procedures in relation to decontamination and reprocessing of SIUP's as demonstrated to inspectors were aligned to recommended best-practice guidance
- quality improvement initiatives has been introduced in the department inspected for example; to provide assurances of the efficacy of cleaning and decontamination practices, proactive testing of SIUP's and the environment had been introduced by staff
- hospital management was in the process of addressing deficiencies in relation to decontamination facilities in the Endoscopy Unit; consideration was also given to centralising decontamination activity across the hospital.

Notwithstanding the many good practices that HIQA identified during this inspection, opportunities for improvement included:

- a need to embed a culture of continuous audit, feedback and quality improvement cycles in relation to decontamination and reprocessing procedures
- a requirement to progress to automated validated processes for decontamination of all reusable medical devices
- a need for hospital management to continue to address challenges faced by equipment that goes beyond expected lifecycles
- a need to ensure timely review of policies and procedures.

At a corporate level and in line with the HSE's own recommendation a dedicated hospital group decontamination lead position with overall executive accountability and responsibility for decontamination service provision to support all decontamination services in the hospital group should be progressed.

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6.0 Appendices

Appendix 1: Lines of enquiry for the monitoring of decontamination and reprocessing of reusable medical devices in public acute hospitals

Lines of Enquiry			Relevant national standards
1	Governance and management structures	The hospital has effective leadership, governance and management structures in place in relation to decontamination and reprocessing of reusable medical devices and has formalized and clear lines of accountability and responsibility at all levels of the service.	2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 5.2, 5.3, 5.4, 6.1, 7.1
2	Monitoring and evaluation systems including audit and risk management	<p>The hospital has effective arrangements in place to respond to the ongoing monitoring and evaluation of decontamination and reprocessing processes to drive quality improvement.</p> <p>The hospital has a risk management system in place to identify, manage and report all hazards, adverse events, near misses and risks in relation to decontamination and reprocessing of reusable medical devices.</p>	2.1, 2.3, 2.5, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.8
3	Education and training of key personnel	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 in relation to decontamination and reprocessing of reusable medical devices.	2.1, 2.8, 3.1, 3.2, 3.3, 3.6, 6.1, 6.2
4	Relevant policies, procedures, protocols and guidelines	The hospital ensures that key personnel are implementing evidenced-based best practice in relation to decontamination and reprocessing of reusable medical devices with up to date policies, procedures, protocols and guidelines in line with relevant legislation and national guidelines.	2.1, 2.5, 3.1, 3.6, 3.8, 5.4, 7.2

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