Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the unannounced inspection at Mercy University Hospital, Cork.

Monitoring of decontamination and reprocessing of reusable medical devices in public acute hospitals.

Date of on-site inspection: 02 November 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 Mercy University Hospital, Cork

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.

Table of Content

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)[†] in Ireland 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 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 Carbapenemase-Producing *Enterobacteriales* (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 focussed, in the first instance, on decontamination facilities[§] outside of a designated controlled decontamination unit[**] to ensure structures, systems, processes and outcomes in these facilities were aligned to national guidelines.

Further 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 Mercy University Hospital, Cork by Authorised Persons from HIQA; Noreen Flannelly-Kinsella and Kathryn Hanly. The inspection was carried out on 02 November 2018 between 10:15hrs and 15:20hrs.

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 members of the Decontamination Committee and Infection Prevention and Control Team. Inspectors requested and reviewed documentation and data and observed practice within two satellite decontamination facilities where decontamination of reusable medical devices were carried out in the:

- Operating Theatre Department (OT)
- Radiology Department.

[‡] 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.

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

2.0   Mercy University Hospital profile

Mercy University Hospital is a voluntary acute general hospital and is part of the South/South West Hospital Group.[††] The hospital has a current treatment capacity of 321 beds, including off site units and mental health. The hospital has a 24-hour emergency service including an urgent care centre, and provides a range of diagnostic and support services.

2.1   Carbapenemase-Producing *Enterobacteriales*

While a full evaluation of CPE management at the hospital was beyond the scope of this inspection, in light of the increased incidence of CPE at the hospital, and cognisant that a declaration of a National Public Health Emergency to address CPE was issued by the Minister for Health on 25 October 2017, HIQA sought assurance regarding the current status of CPE within the Mercy University Hospital.

Inspectors were informed that the hospital experienced a CPE outbreak, with a cluster of cases in January 2018. While numbers of CPE cases had reduced after the first quarter of 2018, documentation provided demonstrated ongoing intermittent hospital attributed cases such that the outbreak was still considered ongoing.[‡‡]

A review of this documentation found evidence that the CPE issue at the hospital had been escalated and discussed at senior management level within the hospital and actively addressed since the onset of the outbreak. An Outbreak Control Committee was convened to oversee the management of the outbreak. The National Lead for Healthcare-Associated Infection / Antimicrobial Resistance (HCAI/AMR) and a representative from local Public Health Department had attended an Outbreak Control Committee meeting in January and again in June 2018. However the frequency of meetings could not be verified as minutes after June 2018 were not provided to HIQA.

Measures implemented at the hospital to reduce the spread of CPE included an extensive programme of screening[§§] for CPE and the implementation of isolation

---

[††] 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.

[‡‡] Guidelines advise that where there are three or more patients with the same CPE associated with a hospital in the past three months this should be interpreted as prima facia evidence of transmission in your hospital and an outbreak control team should be convened to assess what if any further action is required.

[§§] Performing active surveillance cultures, active screening tests or contact screening of at-risk patients to detect colonisation with Carbapenemase-Producing *Enterobacteriales.*

precautions for identified cases and contacts. The hospital had increased screening and surveillance of CPE in excess of national recommendations on screening patients for CPE.[4] A programme of universal CPE screening for all overnight admissions had been introduced. This was a positive initiative, HIQA acknowledges that the true burden of CPE colonisation may be unknown in some other Irish hospitals and in the community because of limited screening.

As outlined in the provided documentation, there were 16 new cases of CPE colonisation detected between January and October 2018, of which 12 cases were attributed as hospital-acquired. Inspectors were also informed that 110 CPE contacts had been identified since December 2017. All contacts had been informed either verbally or by letter. A dedicated CPE clinic was run to screen patient contacts.

While the hospital had not seen a reversion to zero incidents of CPE,[***] its efforts to date had succeeded in containing the number of new CPE cases and maintaining CPE related bloodstream infections at very low levels. The hospital has also identified background rates of CPE in the community which may indicate it may not be possible to fully eradicate CPE in the hospital.

However, a review of documentation indicated that a number of factors likely contributed to the transmission of CPE at the hospital and these included:

- Insufficient infection prevention and control resources had impeded the ability of the team to perform in the face of an increased workload imposed as a consequence of the CPE outbreak. This had also impacted on the delivery of the wider infection prevention and control programme.

- Dated hospital infrastructure including insufficient numbers of single rooms with en-suite facilities had been an identified challenge at the hospital for many years and had the potential to increase the risk of transmission of healthcare-associated infection to inpatients.

- Poor performance demonstrated in a recent infection prevention and control audit of patient equipment. The average hospital wide compliance for medical equipment hygiene in September 2018 was 78.6%. Whilst the audit trend result for equipment was 78.6%, hospital management confirmed that all non-conformances were actioned immediately.

[***] A period of 90 consecutive days without a newly detected CPE patient assessed as a "probable" hospital associated case should be considered as reasonable evidence that transmission has ceased.

2.2 Overview of decontamination services

Decontamination and reprocessing of flexible endoscopes such as gastro-intestinal endoscopes were undertaken centrally in a dedicated endoscope reprocessing unit (ERU) in the Endoscopy Department. Cystoscopes used in an Urology Ward and Transoesophageal Echocardiography (TOE) probes used in the Cardiology Department were transported, decontaminated and reprocessed within this facility.

Procedures for decontamination and reprocessing of surgical instruments in a satellite Sterile Service Department (SSD) located in OT were undergoing a period of transition. Apart from every once in a while when surgical instruments used after hours for emergency surgery were reprocessed in the department, a process to outsource surgical instrument and surgically-invasive choledochosope decontamination and reprocessing at the hospital to an off-site external private service provider was 99% complete. Full outsourcing of the SSD service to an external service provider was due to be completed within the coming months.

Decontamination of semi-critical ultrasound probes used in the Radiology Department and oesophageal manometers used in the Gastro-Intestinal Laboratory, were performed locally in each respective clinical area (see table 1.0 overleaf).

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
Critical items Items that enter sterile tissues/ sterile body areas or the vascular system	99% of surgical instruments / sets and surgically-invasive choledochoscopes used in OT were decontaminated and reprocessed at an outsourced external private decontamination facility. - On rare occasions surgical sets used after hours for emergency surgery were decontaminated and reprocessed in the decontamination facility in OT.
Semi-critical items Items in contact with mucous membranes or non-intact skin	- Gastro-intestinal endoscopes and duodenoscopes used in the Endoscopy Department were decontaminated and reprocessed in ERU. - Emergency GI endoscopes, and bronchoscopes used in OT were manually pre-cleaned and transported, decontaminated and reprocessed in ERU (endoscopes were pre-cleaned and stored in OT and transported to ERU the following day). - Cystoscopes used in Urology Ward were transported, decontaminated and reprocessed in ERU, and returned vacuum packed for storage on the ward. - Transvaginal and transrectal ultrasound probes used in Radiology Department were decontaminated locally by use of high level disinfectant manual chlorine dioxide multi-wipe systems. - Oesophageal manometer probes used in the Gastro-Intestinal Laboratory were decontaminated locally by use of a high level disinfectant soakage system.
Non-critical items Items in contact with intact skin but not mucous membranes or not in contact with the patient	Non-critical ultrasound probes used in ICU, OT and other clinical areas were decontaminated locally in each respective clinical area.

3.0 Findings at Mercy University Hospital

Findings during this inspection showed that hospital staff had actively endeavoured to address deficiencies identified in HIQA's previous inspections in 2016.[5]

At the time of HIQA's inspection a process commenced in 2016 to outsource surgical instrument decontamination and reprocessing to an independent private service provider was 99% complete. Hospital management anticipated that the full service would be outsourced within coming months. This was a significant positive development.

A quality improvement plan published by the hospital showed that many of the issues identified in the previous inspections were addressed.

3.1 Governance and management

Inspectors found that clinical governance issues relating to decontamination and reprocessing of reusable medical devices as identified in the previous inspection had improved.

The hospital had an established Decontamination Committee with formalised governance arrangements and lines of accountability now in place for decontamination of reusable medical devices. The committee chaired by the deputy chief executive officer met monthly. Multidisciplinary membership included senior nursing and local satellite decontamination managers, representatives from the infection prevention and control team (IPCT), quality and risk and technical services. This committee reported to the Hygiene Committee who in turn reported to the hospital's Executive Management Board (EMB). Defined local governance and management arrangements at service delivery level were also in place.

A service-level agreement outlining governance and management arrangements in relation to service provision and transport on behalf of the hospital to the external service provider was in place. Hospital management confirmed that ongoing oversight of performance of the external provider was provided by a sub-group of the Decontamination Committee. It was reported that the committee's terms of reference would be amended to reflect these arrangements.

An authorised engineer for decontamination (AED)[†††] was appointed by the hospital to oversee and audit the technical aspects of the decontamination programme. However, similar to inspections in 2016 there was still no named person as decontamination lead at the hospital. A business case to support this position had

---

[†††] A suitably qualified person designated by management to provide testing, advice and review validation records and is suitable qualified to graduate level.

been advanced by the hospital to the hospital group in 2017 and was awaiting funding.

Likewise there was no group decontamination lead position in the South/South West Hospital Group. A leadership role in decontamination to drive and support the implementation of national and international best practice guidance across the group in line with HSE recommendations should be advanced.[6]

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 and evaluate the risks, and monitor the effectiveness of the control. The Quality Risk Management Department was responsible for monitoring and managing incidents and risks and for reporting to the EMB. The quality and risk manager attended decontamination committee meetings, however risk management did not appear to be included as a standing agenda item; this should be progressed.

Risks on the hospital risk register[‡‡‡] in relation to decontamination and reprocessing included two overarching decontamination-related risks:

- Non-compliance with HSE's decontamination standards.
- HIQA's programme of monitoring of decontamination and reprocessing of reusable medical devices.

Hospital management confirmed that risks outlined in the hospital's corporate risk register were at a hospital-wide level and therefore generally broad in nature. To address identified risks, existing control measures documented included outsourcing of decontamination service provision from OT to an external certified accredited service provider which was 99% completed on day of inspection. Monthly performance reports including non-conformances and complaints were provided from the provider to the hospital as part of this contract. Inspectors were told that contingency plans between the external decontamination service provider and a local private hospital in the event of decontamination equipment failure had also been drawn up.

Further existing control measures documented in relation to these risks included decontamination-related governance structures and review of incidents and complaints and quality improvement plans in relation to decontamination.

[‡‡‡] 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.

In light of the fact that these risks were broad and non-specific making it difficult to identify the actual risk the hospital needs to ensure that local risk registers give an accurate description of the impact, cause and context of the risk to effectively identify the necessary controls required to manage the risk.[7] Furthermore actions required should be assigned to dedicated personnel to mitigate the risk and, undertaking risk assessments to identify what is in place against what should be in place to control the risk should form part of the risk management process.

Hospital management told inspectors that risk assessments in relation to the use of HLD manual systems in satellite decontamination facilities was performed by the AED and results were pending.

Risks that could not be effectively mitigated at a local hospital level were escalated to the hospital group through risk management reporting structures. Incidents were reported through the hospital incident management system and uploaded to the National Incident Management System.[§§§] Staff told inspectors that 10 decontamination-related incidents were reported in 2017; there were 6 reported incidents by the end of quarter 3 2018.

The hospital had a comprehensive inventory of reusable medical device and associated decontamination equipment in use however some items did not have a date of purchase as recommended in line with national guidance.[9,10,13] The inventory showed that one piece of equipment was greater than 15 years old. As equipment that goes beyond the minimum technical life expectancy puts additional pressure on service provision due to possible downtime for repairs, it is recommended that replacing and upgrading of this equipment is prioritised. Documentation reviewed following this inspection showed that a steriliser in OT was last validated in 2016 – hospital management must ensure that this equipment is validated annually in line with national guidelines.[13]

Staff told inspectors that technical services liaised with both the national medical device equipment replacement programme and procurement in relation to replacement of equipment. To support the transition to outsourcing a significant supply of reusable medical devices including surgical instruments had been purchased by the hospital. The risk register showed that equipment replacement capital funding was prioritised to the OT instrumentation replacement programme. The global asset identifier coding and national track and trace programme to support quality assurance of decontamination practices had been implemented in the ERU and satellite decontamination facility in OT.

[§§§] 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.

Inspectors noted from review of the quality improvement plan that a business case which had been prepared for a surgical site infection surveillance programme and submitted to the hospital group had not been progressed since the last inspection; clinical audit provides assurance to the hospital that the service provided is in line with best practice should be progressed.

HIQA also sought assurance during this inspection regarding arrangements that were in place to ensure compliance with national guidance on minimising the risk of transmission of developing a transmissible spongiform encephalopathies (TSE).[****] The hospital must ensure that national guidance is followed and a risk assessment[††††] for the identification of service users at increased risk of developing a transmissible spongiform encephalopathies (TSE) is developed if appropriate.

The national medical devices eAlert system[‡‡‡‡] had been implemented at the hospital. The health and safety officer as the nominated 'designated person', was responsible for internal hospital distribution to the relevant personnel for implementation of the recommended actions where applicable.

3.3 Monitoring and evaluation including audit

Although the focus of inspections was on decontamination facilities outside designated controlled decontamination unit, and inspections were guided by specific lines of enquiry, inspectors sought assurances in relation to monitoring and evaluation systems implemented in decontamination facilities at the hospital.

In response hospital management stated that decontamination and reprocessing equipment in the ERU was tested, maintained, and validated to current standards. Planned maintenance including ventilation and water systems was overseen by the hospital's maintenance manager whereas validation maintenance was performed by contracted external service providers. A business case to support advancing to an on-site clinical engineer position had been completed by the hospital and was submitted to the hospital group for approval.

Documentation reviewed showed that an independent audit of decontamination facilities undertaken by the AED in October 2018 recommended advancing to

---

[****] 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.

[††††] 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

[‡‡‡‡] 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.

automated validated systems for semi-invasive ultrasound probes (SIUPs) decontamination in line with national guidance;[8] as a follow-on from risk assessments undertaken, testing in relation to automated processes for SIUP's were imminent.

It was reported that microbiological monitoring and testing of water within controlled areas had been implemented. Notably a review of decontamination committee minutes received showed that air monitoring was due to re-commence in August 2018; the hospital should ensure that on-going periodic microbiological monitoring and testing is performed in line with national guidance in decontamination facilities in ERU and SSD.[9,10,]

Inspectors were informed that accreditation status of the Endoscopy Department by the Joint Advisory Group (JAG)[§§§§] had been achieved in 2012 and as yet a follow-up accreditation assessment site visit had not taken place.

3.4 Staff training and education

In line with HSE recommendations a number of staff had either completed or were in the process of undertaking an academic qualification in decontamination practices and sterile services at the hospital. It was reported that approximately 75% of relevant staff had undertaken this training. In light of the inherent risks associated with reprocessing of duodenoscopes hospital management also reported that 100% of relevant staff had received training in this regard.

Staff had also completed the HSELand[11] online training in relation to decontamination and regular operator training was provided by the manufacturers/suppliers of endoscope and decontamination equipment and training records were maintained. Inspectors were informed that staff had also completed chemical safety training.

Inspectors were also told that individual competencies of staff in ERU were assessed by the unit manager; to concur with best practice guidance a formalised competency assessment framework validated annually needs to be rolled-out.[12]

In the Radiology Department staff had completed both online and face-to-face training in the use of the HLD manual multi-wipe systems for SIUP's. A number of staff had also commenced the HSELand online training in relation to decontamination. Overseeing decontamination training was assigned to a staff member in the department and plans to undertake regular on-going competency assessment in relation to decontamination were underway.

[§§§§] JAG accreditation is the formal recognition that an endoscopy service has demonstrated that it has the competence to deliver against the criteria set out in the JAG standards.

3.5 Policies, procedures, protocols and guidelines

The hospital had an electronic document management system to facilitate document version control and access to staff across the hospital. Policies were ratified by the Policy Approval Committee (PAC) at the hospital.

Inspectors were informed that work in relation to both standard operating procedures (SOP's) and policy development was underway at the time of this inspection. Documentation reviewed showed that policies and procedures in relation to decontamination procedures such as pre-wash, contingency policy and loan instrumentation were signed off and awaiting PAC approval.

Standard operating procedures in relation to outsourcing of contaminated instruments to the externally contracted provider were also in place. A policy for the decontamination of flexible endoscopes, accessories and related equipment in the Endoscopy Department and reviewed by inspectors showed that this policy was awaiting final approval.

3.6 Decontamination of reusable medical devices in a satellite decontamination facility

Inspectors visited two decontamination facilities outside of designated controlled decontamination units to ensure that structures, systems, processes and outcomes were aligned to national guidance.

The Operating Theatre Department (OT)

Outsourcing of surgical instrument decontamination and reprocessing to an independent private service provider was 99% complete at the time of this inspection. Notwithstanding this the configuration and location of the remaining decontamination facilities was not fit-for-purpose and did not facilitate the implementation of effective infection prevention and control measures.

Reprocessing of surgical instruments should be undertaken away from the clinical environment where possible, and preferably in a centrally controlled decontamination unit.

Evidence of good practice

- procedures for the recall of nonconforming surgical instruments and sets in line with national guidelines were present[13]
- surgical instruments sets were checked for content in the wash room prior to transport of uncleaned reusable invasive medical devices (RIMD) by road
- a dedicated trained operative whose sole responsibility was management of the decontamination facility during normal working hours was undertaking an academic qualification in decontamination; nursing staff from the theatre

department were responsible for the decontamination process out of hours and at weekends

- Manufacturer's Instructions for Use (MIU's) were available for surgical instruments and sets
- sterilised surgical instruments were stored in a purpose built storage area
- the hospital had invested in some improvements and upgrade works which included the construction of an access corridor to the wash room so that transport of soiled instruments through the operating theatre was avoided
- a recent environmental and patient equipment hygiene audit showed 93-95% compliance was achieved with desirable standards in November 2018.

Opportunities for improvement

- Management of unclean surgical instruments:

Inspectors were informed that on the advice of the independent private decontamination service provider an enzyme spray was not used to coat the unclean surgical instruments during transportation. It was explained that the chemical used to coat the unclean surgical instruments was corrosive to the instruments.

To increase cleaning efficiency, instruments should be prepared in such a way to prevent drying of blood, soil and debris on the surface and within lumens. In line with best practice guidance,[14] if instruments cannot be returned in a timely manner, they should be kept moist using appropriate approved methods prior to being sent for reprocessing to enable efficient prion removal. There are a variety of methods, for example gels, sprays and use of wet towels, that could be applied to keep instruments moist; the choice of the exact method used rests with the decontamination manager, decontamination lead or IPCT following a local risk assessment.

- Reprocessing endoscopes out of hours:

The reprocessing of endoscopes used within the OT had been centralised in the Endoscopy Unit in 2016. To avoid encrustation and clogging, soiled endoscopes used in OT were flushed and pre-cleaned manually in advance of transport to the ERU. Where endoscopes were used 'out of hours'***** at the hospital leading to a delay in disinfecting the endoscope in the AER, enzyme spray and sterile endoscope storage bags were used after pre-cleaning to maintain the integrity of endoscopes and keep them moist.

***** "Out of hours" was defined as after 18.30 hours on weekdays and 24 hours on the weekends and Bank Holidays.

Prompt cleaning of endoscopes reduces or eliminates the population of biofilm-forming microorganisms and thus prevents the formation of biofilm. More intensive pre-cleaning is recommended where there is a delay in transferring to an AER.

Inspectors were informed that endoscopes were stored in the above described manner for a maximum of 24 hours. As an additional control measure hospital guidelines advised that protein tests were carried out on all endoscopes used 'out of hours' as appropriate.

Ideally soiled endoscopes should be transported immediately to the decontamination area for reprocessing to prevent blood, body fluids and other contaminants from drying on the surface. Where there is a delay measures such as protein testing along with ongoing audit and monitoring of processes to provide assurances in relation to the quality and safety of these processes is required.

- Track and trace systems:

Inspectors were informed that the hospital had implemented the national electronic track and trace system for surgical instruments however in light of the external contract with a private provider the hospital had to manually record the patient details separately in a log book to facilitate tracing to the patient.

The hospital must ensure that externally contracted decontamination services are fully integrated and compatible with Health Service Executive (HSE) surgical instrument traceability systems to ensure the traceability chain is maintained throughout the decontamination process and to the patient.

- Environmental hygiene audits:

A review of a hospital environmental audit tracker showed that hygiene audits were not performed in line with recommended national guidance in relation to periodic hygiene audit schedules for very high risk areas. [15]

Radiology Department

While both transvaginal and transrectal ultrasound probes were used in the department, a review of transvaginal ultrasound probe decontamination processes was possible at the time of inspection.

Evidence of good practice

- HLD manual multi-wipe system was used for disinfecting SIUP's; a risk assessment was performed in line with national guidance as this is the least preferred method of high level disinfection
- a manual track and trace system had been introduced

- sterile single use protective sheaths were used
- a recent audit of adherence to decontamination procedures was undertaken to assess compliance; a repeat audit was due in early 2019
- plans to undertake a risk-assessment of decontamination facilities by the health and safety officer were underway
- Manufacturer's Instructions for Use (MIU's) were available for SIUP's.

Opportunities for improvement

- the infrastructure of the decontamination facility was not in line with national standards and relevant guidelines; there were insufficient work surfaces and hand hygiene sinks were not HTM compliant; an infection prevention and control risk assessment of the facility was recommended
- storage of disinfected SIUP's was inappropriate; the hospital must ensure that dedicated probe storage systems are provided in line with recommended best-practice guidance and manufacturers' instructions
- a defined system which clearly indicates when SIUP's have been decontaminated is required
- validated automated systems for decontaminating reusable medical devices should be progressed
- to support speedy retrospective recall in the event of exposure to potential risk traceability labels should also be placed in patient's medical records
- SOPs in relation to decontamination processes and procedures should be readily accessible to staff at point-of-use as guidance for users
- eye wash facilities and material safety data sheets should be available for hazardous chemicals used in the department
- as some dust was observed of floor surfaces in the procedure room visited and latest environmental hygiene audit reports for quarter 3 2018 showed 88% compliance, a review of hygiene specifications is recommended in particular with regard to procedure rooms in the department.

4.0 Conclusion

Overall HIQA found that Mercy University Hospital was committed to improving decontamination and reprocessing practices at the hospital and was endeavouring to fully implement the National Standards and HSE best practice guidance in this regard. The hospital had actively worked to mitigate risks in relation to non-compliant facilities for surgical instrument decontamination and reprocessing identified in previous HIQA inspections. Outsourcing to an independent private service provider was 99% complete at the time of this inspection.

Other notable areas of good practice observed by HIQA during this inspection included some of the following:

- clear lines of accountability and responsibility and management arrangements in relation to decontamination and reprocessing of reusable medical devices at the hospital
- a risk management system was in place and risks previously identified in relation to decontamination facilities were being actively addressed
- good reporting of decontamination-related incidents
- training and education for staff working in decontamination was well established.

Notwithstanding this hospital management must also ensure that:

- a suitable dedicated non-clinical space for decontamination and storage of semi-critical ultrasound probes in the Radiology Department is identified
- ventilation systems in decontamination facilities at the hospital as identified by an independent decontamination audit are addressed
- validated automated systems for decontamination of semi-critical reusable medical devices are progressed
- a culture of continuous audit, feedback and quality improvement is embedded to provide assurances of the efficacy of cleaning and decontamination practices
- policies, procedures, SOP's and guidelines are reviewed promptly to ensure that staff have access to the most up-to-date documents to support practice
- frequency of hygiene audits need to be appropriate to the risk associated with the functional area
- ongoing validation of processes based on outcome measurements and microbiological testing on surgical instruments or endoscopes kept overnight and transported for decontamination the following day takes place.

At a corporate level and in line with the HSE's own recommendation the hospital needs to be supported in their endeavours to establish a decontamination lead position either at a local hospital or hospital group level.

In light of the National Public Health Emergency in relation to CPE HIQA sought assurances in relation to screening and the current status in relation to CPE at the hospital. The hospital had increased screening and surveillance of CPE in excess of national recommendations on screening patients for CPE which is commendable. However factors which likely contributed to the transmission of CPE at the hospital and identified in this report need to be addressed.

5.0   References

1. Health Information and Quality Authority. National Standards for the prevention and control of healthcare-associated infections in acute healthcare services. Dublin: Health Information and Quality Authority; 2017. [Online]. Available online from: https://www.hiqa.ie/sites/default/files/2017-05/2017-HIQA-National-Standards-Healthcare-Association-Infections.pdf

2. Health Information and Quality Authority. Guide to the monitoring programme undertaken against the National Standards for the prevention and control of healthcare-associated infections. Dublin: Health Information and Quality Authority; 2015. [Online]. Available online from: https://www.hiqa.ie/sites/default/files/2017-05/Guide-monitor-National-Standards-healthcare-associated-infections.pdf

3. Health Information and Quality Authority. Guide to HIQA's programme of monitoring of the decontamination and reprocessing of reusable medical devices in public acute hospitals. Dublin: Health Information and Quality Authority; 2018. [Online]. Available online from: https://www.hiqa.ie/sites/default/files/2018-07/HIQA-reusable-medical-devices-guide.pdf

4. Health Service Executive. Requirements for screening of Patients for Carbapenemase Producing *Enterobacteriaceae* (CPE) in the Acute Hospital Sector. Dublin: Health Service Executive; 2018. Available online from: http://www.hpsc.ie/a-z/microbiologyantimicrobialresistance/strategyforthecontrolofantimicrobialresistanceinirelandsari/carbapenemresistantenterobacteriaceaecre/guidanceandpublications/

5. Health Information and Quality Authority. Report of the unannounced inspection at Mercy University Hospital, Cork. 2016. [Online]. Available online from: https://www.hiqa.ie/system/files?file=inspectionreports/Report_Unannounced_Mercy%20University%20Hospital.pdf

6. Health Service Executive. Quality Improvement Division. Review of Endoscope Decontamination in Acute Hospitals. Dublin: Health Service Executive; 2015.

7. Health Service Executive. Integrated Risk Management Policy. Part 2 Risk Assessment and Treatment. Guidance for Managers. Dublin: 2017. Health Service Executive. [Online]. Available online from: https://www.hse.ie/eng/about/qavd/riskmanagement/risk-management-documentation/hse-integrated-risk-management-policy-part-2-risk-assessment-and-treatment.pdf

8. Health Service Executive Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes. November 2016. [Online]. Available online from:

https://www.hse.ie/eng/about/Who/qualityandpatientsafety/Medical-Devices/decontamination/Ultrasound-Probe-Decontamination-Guidance-Feb-17.pdf

9. Health Service Executive Standards and Recommended Practices for Commissioning, Validation and Testing in Endoscope Decontamination Facilities. Dublin: Health Service Executive; 2018. [Online]. Available online from: https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/standard-and-recommended-practices-for-commissioning-validation-and-testing-in-endoscope-decontamination-facilities.pdf

10. Health Service Executive Standards and Recommended Practices for Facility Design and Equipping of Endoscope Decontamination Units. Dublin: Health Service Executive; 2017. [Online]. Available online from: http://www.hse.ie/eng/about/Who/QID/nationalsafetyprogrammes/decontamination/HSE-Standards-and-Recommended-Practices-for-Facility-Design-and-Equipping-of-EDUs-QPSDD022.pdf

11. Health Service Executive. HSELanD. [Online]. Available online from: http://www.hseland.ie/dash/Account/Login

12. British Society of Gastroenterology (BSG). The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee; 2016. [Online]. Available online from: https://www.bsg.org.uk/resource/guidance-on-decontamination-of-equipment-for-gastrointestinal-endoscopy-2017-edition.html

13. Health Service Executive National Decontamination of Reusable Invasive Medical Devices Advisory Group. *Health Service Executive Standards and Recommended Practices for Central Decontamination Units*. Dublin: Health Service Executive; 2011. Available online from: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/Decontamination/HSE_Standards_Recommended_Practices_CDUs.html

14. Health Technical Memorandum. Management and decontamination of surgical instruments used in acute care. (HTM 01-01, Part A-E) Department of Health UK. 2016. [Online]. Available online from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/536144/HTM0101PartA.pdf

15. National Hospitals Office, Quality, Risk and Customer Care. HSE Cleaning Manual Acute Hospitals. Dublin: Health Service Executive; 2006. [Online]. Available online from: http://hse.ie/eng/services/publications/Hospitals/HSE_National_Cleaning_Standards_Manual.pdf

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**	The hospital has effective arrangements in place to respond to the ongoing monitoring and evaluation of decontamination and reprocessing processes to drive quality improvement. 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.	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