



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Report of the unannounced inspection at Galway University Hospitals.

Date of on-site inspection: 22 August 2019

**HIQA's consolidated programme of monitoring 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 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 includes 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 medical 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 guide² to this monitoring programme which is available to view on HIQA's website www.hiqa.ie

2.0 Information about this inspection

This report sets out the findings of the unannounced inspection carried out by HIQA at Galway University Hospitals (incorporating University Hospital Galway and Merlin Park University Hospital, Galway). The inspection was carried out by Authorised Persons from HIQA, Noreen Flannelly-Kinsella, Kathryn Hanly, Bairbre Moynihan and Agnella Craig. The inspection were carried out on 22 August 2019 between 09:00hrs and 16:45hrs.

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.†

* 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.

During this inspection inspectors spoke with hospital managers, staff and representatives from the Infection Prevention and Control Committee and Decontamination Working Group Committee. Inspectors requested and reviewed documentation, data and observed practice within the clinical environment in a sample of clinical areas which included:

- St Teresa's Ward located at University Hospital Galway. This was a medical ward that specialised in renal and infectious diseases medicine. The ward comprised six single rooms one of which had en-suite facilities, one four-bedded room, one eight-bedded room and one nightingale-style[‡] room containing 13 beds and an en-suite toilet and shower.
- The Radiology Department located at University Hospital Galway.
- Unit 7 Haemodialysis Unit located at Merlin Park University Hospital. The Haemodialysis Unit comprised 19 stationed dialysis unit; 17 stations were in a nightingale-style room and the remaining two stations were isolation rooms.

In addition, the central area for reprocessing reusable cleaning textiles for example mop heads, at University Hospital Galway was re-visited to assess the level of progress which had been made after the 2018 inspection.

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

Galway University Hospitals is located on two sites: University Hospital Galway and Merlin Park University Hospital, Galway. The Galway University Hospitals has a bed capacity of 639 inpatient beds.

The hospital is a member of the Saolta University Health Care Group[§] of hospitals.

University Hospital Galway is a model 4** academic teaching hospital providing 24/7 acute surgery, acute medicine, critical care and a wide range of tertiary referral services.

[‡] A nightingale-style room consists of one long ward with a large number of beds arranged along the sides, without subdivision of the room into bays. From an infection prevention and control perspective, the higher number of patients accommodated in nightingale wards increases the risk of infection transmission, especially if beds are spaced too close together.

[§] 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 of Limerick Hospitals Group. 6. RCSI Hospitals Group. 7. Children's Health Ireland Hospital Group.

** Admits undifferentiated acute medical patients including tertiary referred patients. Level 4 Hospitals have a category 3 or 3S ICU on site, a Medical Assessment Unit which is open on a continuous basis (24 hours, every day of the year) and an ED, including a CDU on site.

Merlin Park University Hospital is a Level 2 hospital with non-complex elective medical and surgical services including out-patient services and a Dialysis Unit.

Decontamination and reprocessing service for reusable medical devices

Galway University Hospitals was providing a decontamination and reprocessing service for reusable medical devices used at each respective hospital.

Decontamination and reprocessing of critical devices (such as surgical instruments) and semi-critical devices (such as endoscopes) was performed in centralised decontamination facilities at University Hospital Galway in the:

- Hospital Sterile Supplies Department (HSSD).
- Endoscopy Decontamination Unit for:
 - gastro-intestinal endoscopes used in the Endoscopy Unit and Operating Theatres (OT)
 - ear nose and throat (ENT) endoscopes used in the Out-Patients Department (OPD)
 - ENT endoscopes used at Merlin Park University Hospital.

Decontamination and reprocessing of critical and semi-critical devices was performed at Merlin Park University Hospital in the:

- Central Sterile Supplies Department (CSSD).
- Orthodontic Unit.
- Bronchoscopy Unit for:
 - bronchoscopes used at the hospital.

Decontamination and reprocessing of semi-critical devices using high level disinfectant manual multi-wipe systems was also performed locally in satellite decontamination facilities at University Hospital Galway, located in the:

- Radiology Department (for transvaginal and transrectal ultrasound probes).
- OPD (for transvaginal and transrectal ultrasound probes).
- Cardiac Theatre (for transoesophageal echocardiography ultrasound probes).
- OT Department (for semi-invasive ultrasound probes used).

In addition, documentation reviewed showed that semi-invasive and non-invasive ultrasound probes, and doppler devices used in other clinical areas such as the Intensive Care Unit, vascular laboratories and Emergency Department were decontaminated locally after use in each respective area.

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

The Infection Prevention and Control Committee reported to the Quality, Safety and Risk Committee. Inspectors were informed that a number of subcommittees including the Hygiene Committee, Decontamination Working Group Committee and the Environmental Monitoring Committee reported to the Infection Prevention and Control Committee.

A review of documentation indicated that the Hygiene Services Committee had not met to date in 2019. This finding was significant in the overall context of the ongoing CPE outbreak.

University Hospital Galway was experiencing an ongoing hospital outbreak of Carbapenemase-Producing *Enterobacteriales* (CPE)^{††} since 2017. An outbreak control team was convened to oversee the management of the outbreak.³ This committee was chaired by the general manager. Management of the on-going CPE outbreak at the hospital will be outlined in section 4.3 of this report.

The hospital had a progressive and well established antimicrobial stewardship programme. The Antimicrobial Stewardship Committee was a subcommittee of the Drugs and Therapeutics Committee. Regular performance updates in relation to antimicrobial stewardship were reported through established hospital governance structures.

The infection prevention and control team had a remit for both University Hospital Galway and Merlin Park University Hospital. Inspectors were informed that the full complement of infection prevention and control nursing staff was in place. The infection prevention and control team advised on all aspects of infection prevention and control, performed surveillance of alert organisms and delivered education to all grades of staff. However due to the prolonged CPE outbreak, inspectors were informed that much of the team's activity was reactive in nature.

^{††} Carbapenemase-Producing *Enterobacteriales* (CPE), are a family of bacteria which can cause infections that are difficult to treat because they are resistant to most antimicrobials, including a class of antimicrobials called carbapenems which have typically been used as a reliable last line treatment option for serious infection. Bloodstream infection with CPE has resulted in patient death in 50% of cases in some published studies internationally.

Governance arrangements and organisational structures were outlined in an organogram provided to HIQA (appendix 2).

Quality Improvement Plan

Inspectors reviewed the quality improvement plan developed following the 2018 unannounced inspection. Overall, it was apparent that progress had been made in addressing the findings of the 2017 inspection. Fourteen of the 28 actions identified in the plan had been completed and work was in progress to complete 13 actions. However the quality improvement plan viewed by inspectors did not include time bound action plans to address the outstanding issues.

The central laundering facility in University Hospital Galway for reprocessing reusable cleaning textiles was re-visited. Inspectors found that issues identified during HIQA's 2018 inspection had not been fully addressed. The infrastructure of this area remained unchanged and did not support functional separation of the clean and dirty phases of the laundering process.

4.1.2 Decontamination and reprocessing of reusable medical devices

During this inspection coordination of the decontamination programme across both hospitals was clearly evident. An annual decontamination report highlighting risk issues and reciprocal quality improvement plans was produced by the decontamination coordinator for hospital management which is in line with National Standards.¹ In addition defined management arrangements in relation to decontamination service provision at service-delivery level were also in place. However inspectors found that the hospital needed to have clearly defined responsibilities for reporting and escalation on decontamination-related performance, to provide an accurate level of assurance in relation to decontamination service provision.

Hospital management told inspectors that the Decontamination Working Group Committee, which met two-monthly reported to the Infection Prevention and Control Committee. Membership of both committees included the infection prevention and control team. It was reported that this dual membership facilitated reporting on decontamination-related issues up to the Infection Prevention and Control Committee as required. However these reporting arrangements were not reflected in the decontamination committee's terms of reference and governance organogram provided (appendix 3).

Membership of the Decontamination Working Group Committee also included representatives from satellite decontamination facilities such as orthodontics and the bio-engineering department. Inspectors were told that minutes were circulated to committee members. This was further validated following discussions with staff in a satellite decontamination facility inspected.

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

Inspectors were informed that surveillance and microbiology laboratory updates were presented at the hospitals' infection control committee meetings and the Saolta University Healthcare Group Infection Control Committee on a quarterly basis. The infection prevention and control surveillance programme included surveillance of:

- 'alert' organism^{##} and 'alert' conditions
- multidrug-resistant organisms
- data reported to the European Antimicrobial Resistant Surveillance Network (EARS-Net)^{§§}
- central venous access device-related infection^{***} in the Intensive Care Unit
- surgical site infections in relation to elective orthopaedic implant surgeries.

Hospital management also monitored and regularly reviewed performance indicators in relation to the prevention and control of healthcare-associated infection in line with HSE national reporting requirements⁴ and the HSE's Business Information Unit.⁵

Clinical surveillance in relation to urinary catheter-associated urinary tract infection and ventilator-associated pneumonia (VAP) was not carried out as recommended in national guidelines.^{6,7} Surgical Site Infection Surveillance for cardiothoracic surgery had been suspended in 2018.

Hygiene audits

Monthly environmental hygiene audits were co-ordinated by the services department and included participation from infection control nursing staff. A risk based approach was taken to audit scheduling where all wards & departments were categorised into a risk category as per the National Hospital Office guidelines.

Opportunities for improvement in relation to the management and oversight of hygiene and associated storage systems were observed in the Radiology Department inspected. Unacceptable levels of dust and inappropriate storage of sterile supplies was observed in a room used as access and egress to changing and toilet facilities

^{##} Alert organisms are micro-organisms that pose a significant risk of transmission to non-infected patients or staff, resulting in colonisation or healthcare-associated infection, or that pose a significant risk of transmission to non-infected people in the wider population or community.

^{§§} 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*.

^{***} Catheter-related bloodstream infection (CRBSI) is defined as the presence of bacteraemia originating from an intravenous catheter.

for patients; this also meant that patients had unattended access to sterile supplies. In addition surfaces and finishes including wall paintwork and flooring were poorly maintained. These deficiencies were brought to the attention of the hospital management team so that they could be addressed at the time of inspection. The high compliance scores achieved in hygiene audits from 2018-2019 in this department were not evident in this room on the day of this inspection.

The findings identified on the day of inspection indicated that similar findings identified in a hygiene audit undertaken by the infection prevention and control team in June 2019 had not been addressed. A review of all aspects of hygiene service delivery including management and oversight arrangements, management of supplies and storage facilities and associated resources is recommended as a matter of priority.⁸

In Merlin Park University Hospital environmental and equipment audits were carried out monthly in the Haemodialysis Unit by a hygiene auditor with one to two members of staff from the unit. Following the audit a quality improvement plan was devised. Results were uploaded onto an information technology system and the clinical nurse manager addressed the actions from the quality improvement plan; this is good practice.

Decontamination and reprocessing of reusable medical devices

The focus of this inspection was on satellite decontamination facilities outside of designated controlled decontamination units. HIQA acknowledges the progress made at University Hospital Galway in developing a centralised endoscopy decontamination model which is in line with national and international best practice guidance.^{9,14}

A decontamination audit was undertaken in central and satellite decontamination facilities by the decontamination coordinator across both hospitals on a yearly basis. Following each audit a quality improvement plan identifying areas for improvement was created in collaboration with the local manager. An overall trended audit report was included in the annual report for 2018. Local decontamination audits appeared as an agenda item on the Decontamination Working Group Committee minutes.¹

Hospital management told inspectors that an audit of the effectiveness of 'out of hours' decontamination and reprocessing for emergency procedures had not taken place to date. However subsequent to this inspection documentation received by HIQA showed that an audit of endoscope decontamination documentation was carried out annually. This included confirmation that a pre-clean and manual clean had been completed 'out of hours'.

Inspectors identified that surgical instruments used overnight⁺⁺⁺ were not moistened prior to transportation to the Hospital Sterile Supplies Department (HSSD) for decontamination and reprocessing the following morning which is not in line with best practice guidance.^{10,11} Inspectors highlighted this issue to hospital management during this inspection.

Hospital management confirmed that periodic maintenance, testing and validation was performed on all decontamination-related equipment in line with national standards and recommended practices.^{12,13,14,15} An authorised engineer for decontamination (AED)⁺⁺⁺ was appointed by the hospital to oversee and audit technical aspects of the decontamination programme. Inspectors were told that an equipment priority list for replacement was in place and that formal contingency plans in the event of decontamination equipment failure were available. A register of intracavity semi-invasive ultrasound probes used at the hospital which included the date of purchase of each item was reviewed by inspectors. Hospital management stated that periodic testing schedules for water and environment (air and surfaces) were undertaken in centralised decontamination facilities at both hospitals.

Other findings in relation to the satellite decontamination facility inspected will be presented in section 4.3.2 in this report.

4.2.2 Risk management

The hospital had an infection prevention and control risk register^{§§§} in place. A small number of infection prevention and control risks had been escalated to the corporate risk register for example risk of acquisition of CPE of patients attending Galway University Hospitals. The risks were risk rated and the risk registers identified the existing controls and the additional controls required to mitigate the risks. The risk registers did not identify when the risk registers were last reviewed, a person responsible for the actions or a due date for the actions. Risk registers should be managed in line with national guidance.¹⁶

Risk registers were a standing agenda item at the Quality and Patient Safety Committee meetings. Minutes of meetings reviewed showed that the quality and

⁺⁺⁺ The Hospital Sterile Supplies Department (HSSD) is open from: 06.00hrs to 20.30hrs Monday to Thursday, 06.00hrs to 19.30hrs on Friday and 07.00hrs to 16.30hrs on Saturdays and Sundays.

⁺⁺⁺ A suitably qualified person to graduate level designated by management to provide independent auditing and technical advice in relation to decontamination facilities, and equipment testing and validation records.

^{§§§} 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.

safety department was co-ordinating training for the revised format of recording risks on risk registers.

Inspectors were informed that the quality and safety department was advised if a patient acquired a new healthcare-associated infection or if there was lack of isolation facilities for patients so that these could be entered onto the National Incident Management System (NIMs).****

Decontamination and reprocessing of reusable medical devices

Decontamination-related risks were entered on the services departments' risk register with some risks also featuring on the infection prevention and control risk register. It was reported that plans to amalgamate and introduce a dedicated hospital decontamination risk register were underway.

Documented risks on both risk registers reviewed were risk rated with existing controls and additional controls required to mitigate risks documented. However a risk owner, action owner or a date by which these actions were to be completed was not evident which is not in line with national guidance. The terms of reference of the Decontamination Working Group Committee meetings showed that risk management was a standing agenda item and quality and risk management representatives attended when required.

From a review of the risk register it was evident that a risk in relation to tracking and traceability⁺⁺⁺ of some single-packed ENT surgical instruments in ENT OPD had been identified and discussed at decontamination committee meetings over the previous year. Hospital management need to be assured that tracking and traceability systems are in place for all critical and semi-critical reusable medical devices^{****} used in line with national guidance and relevant medical device legislation.^{10,15}

A risk assessment and a chemical risk assessment in relation to the use of manual multi-wipe high level disinfection systems for semi-invasive ultrasound probes had been completed which is in line with national guidance; an action owner and due date was documented. In the interim a trial of an automated validated decontamination system had taken place; this needs to be progressed as manual

***** 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.

+++ Track and trace systems record the decontamination process used on critical and semi-critical reusable medical devices and link them to the patient on which they have been used.

**** 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).

multi-wipe high level disinfection systems are the least preferred option for decontamination of semi-invasive ultrasound probes.¹²

Hospital management told inspectors that the national medical devices eAlert^{§§§§} system had been implemented at the hospital. Patient safety notices featured as a standing agenda item on decontamination committee meetings. The global asset identifier coding and national track and trace programme to support quality assurance of decontamination practices had been rolled-out in central decontamination facilities at the hospital.

Decontamination-related incidents were also reported electronically to the Quality and Patient Safety Department and entered on NIMs. Minutes of a decontamination committee meeting in April 2019 showed that plans to undertake quarterly reviews of reusable medical device-related incidents at this forum were underway.¹⁷ In the satellite decontamination facility inspected staff told inspectors that no recent decontamination-related incidents or risks had been reported.

4.3 Implementation of evidence-based best practice

4.3.1 Systems to detect, prevent and manage multidrug-resistant organisms

During this inspection the inspection team focused on measures to prevent the spread of antimicrobial-resistant organisms including CPE.

The hospital had seen an increase in the number of patients colonised with CPE year on year despite the implementation of multimodal infection prevention and control strategies to prevent and control CPE.^{18,19} However the hospital had succeeded in maintaining CPE related bloodstream infections at very low levels during this time.

Evidence of good practice included:

Screening

- The hospital had implemented the national CPE screening guidelines.²⁰
- Additional CPE screening was offered to patients accommodated in high risk wards and during outbreaks on the advice of the infection prevention and control team.
- To trace the possible environmental reservoirs, environmental screening was performed on the outbreak wards as recommended by the infection prevention and control team in line with national guidelines.³

^{§§§§} 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.

Antimicrobial stewardship

- Overall antibiotic use in the hospital had steadily decreased since 2008, and has been below the national median since 2014.
- The hospital had introduced restricted antimicrobial prescribing rights for the broad-spectrum carbapenem antibiotic meropenem^{*****} in July 2017, which is a last line antibiotic used to treat serious gram-negative infection. Inspectors were informed that there was approximately 98% compliance with this policy.²¹

Environment and infrastructure

- St Teresa's Ward and the Haemodialysis Unit were generally clean with a few exceptions.
- Shower facilities in St Teresa's Ward had recently been refurbished.
- Inspectors were informed that during the current CPE outbreak on St Teresa's Ward additional cleaning hours had been allocated to carry out additional toilet checks and cleans.

Patient Placement

- All patients colonised with CPE in the hospital were appropriately accommodated in single rooms on the day of inspection.
- St Teresa's Ward was closed to admissions. CPE contacts⁺⁺⁺⁺ were cohorted in the nightingale ward and in an eight-bedded room.
- A member of the infection prevention and control team attended the daily bed flow meetings where advice on prioritisation for patient isolation was provided when suitable rooms are not readily available.

***** Meropenem is an ultra-broad-spectrum antimicrobial belonging to a class of antimicrobial known as carbapenems. It may be used to treat a wide range of infection types however treatment options are very limited for Gram-negative organisms resistant to meropenem. Greater use of meropenem has begun to see limited instances of the emergence of resistance to this drug — some strains of Gram-negative bacteria have evolved to produce chemicals which disable meropenem and other carbapenem antimicrobials from working. These chemicals are known as carbapenemases. Treatment options for carbapenemase producing bacteria (CPE) are limited to a handful of antimicrobial choices which are often less effective than meropenem, and sometimes more toxic.

++++ A CPE patient contact is defined as a person that has shared a multi-bed area and/or shared toilet facilities with a person identified as colonised or infected with CPE. This includes time spent in the Emergency Department (ED) and Acute Medical Assessment Units (AMAU). A person that has been cared for in an inpatient area (including ED and AMAU) by nursing staff who were simultaneously caring for one or more patients colonised with CPE in the absence of Contact Precautions. This might arise in relation to a patient who was not known to be colonised with CPE at the time in question.

- In the Haemodialysis Unit, CPE positive patients were dialysed in isolation rooms with a dedicated staff nurse and health-care assistant allocated to the two isolation rooms for each shift.

Required areas for improvement:

A number of factors which likely contributed to the ongoing CPE outbreak were identified on the day of inspection.

Screening

- There appeared to be ambiguity among staff in the Haemodialysis Unit as to the frequency of CPE screening for dialysis patients.
- Extended-spectrum b-lactamase (ESBL) screening had been suspended at the hospital due to the additional workload generated by CPE screening.²²

Equipment

- Opportunities for improvement in the management of patient equipment was seen on St Teresa's Ward. For example:
 - Extensive red staining was visible on the surface of several integrated sharps trays in the clinical room. Additionally, red staining was observed on two intravenous pumps.^{****}This was brought to the attention of the ward manager and was addressed immediately.
 - Integrated sharps trays were not included on the equipment audit tool viewed.
 - A green tagging system which alerted staff to when equipment was last cleaned was inconsistently applied.
 - Bedpans were not processed in line with best practice (contents of bedpans emptied into the sluice hopper prior to being placed in the bedpan washer disinfector).
 - Boxes of intravenous fluids were observed on the floor adjacent to the hand hygiene sink in the clinical room. This posed a risk of inadvertent contamination.

Environment and infrastructure

- University Hospital Galway did not have adequate single room facilities to effectively isolate or segregate all patients being cared for with transmission-based precautions.

^{****} An infusion pump infuses fluids, medication or nutrients into a patient's circulatory system. It is generally used intravenously.

- A number of infrastructural issues which had the potential to impact on infection prevention and control measures were identified in St Teresa's Ward during the course of the inspection. For example:
 - There were insufficient numbers of showers and toilet facilities for patients. CPE contact patients were cohorted in a room without en-suite facilities.
 - There was a lack of storage space which resulted in inappropriate storage of equipment in the area outside the nightingale-style room.
 - Bed spacing in multi-bedded wards was not in compliance with best practice guidelines. Inspectors were also informed that the hospital's escalation policy to deal with Emergency Department overcrowding included the accommodation of additional patients on a trolley located in the 13 bedded nightingale-style room on St Teresa's Ward. It was reported that the practice was a regular occurrence albeit not during the current CPE outbreak on the ward.
 - Staff changing facilities in the ward were inadequate.²³ Staff changed in a staff toilet, which was also used as a storage area for staff personal belongings. It was reported that staff compliance with the hospitals dress code policy was an ongoing issue.
 - There was no designated cleaner's room equipped with a janitorial sink, hand washing facilities and space for cleaning equipment. The ward cleaning trolley and supplies used on the ward (outbreak ward) were stored in a central location in the hospital.
 - Poster and dilution charts in relation to chlorine-based solution were available on all wards. However, inspectors identified a lack of clarity from cleaning staff regarding the correct dilution^{§§§§§} of the chlorine-based solution used for environmental disinfection on the ward.

- The overall infrastructure of the Haemodialysis Unit was outdated and was not in line with desirable modern standards for such units.²⁴ For example:
 - General wear and tear was noted throughout the unit.
 - The design of clinical hand wash sinks did not conform to Health Building Note 00-10 Part C: Sanitary assemblies.²⁵
 - There were insufficient numbers of hand hygiene sinks.^{24,26}
 - The unit did not have a clean utility room. In the absence of this room staff were preparing sterile packs and supplies for the next dialysis shift and locating them beside the nurses' station.

§§§§§ One of the most important aspects regarding the effectiveness of a disinfectant is to ensure that the concentration of the cleaning solution is correct and in accordance with the manufacturer's specifications. Using a solution that is too weak will not reliably kill micro-organisms on the surface. Using a solution that is more concentrated than specified is not cost effective, may be detrimental to the life of fixtures and fittings and may be a work health and safety risk.

- A number of water-supply outlet ports were noted to have residue around the edges. Management need to ensure that these are regularly cleaned and maintained.

Hand hygiene

Records from June 2019 showed that only 67% of staff were up-to-date with hand hygiene training.²⁶ However, inspectors were informed that this may be an underestimation of overall compliance as records may not have been updated to include recent training sessions.

Policies Procedures and Guidelines

Inspectors identified that staff had difficulty accessing the most up-to-date version of infection prevention and control screening guidelines in the Haemodialysis Unit.

Outbreak Management

- Influenza vaccine uptake

It was reported that 2018/2019 influenza vaccination uptake among staff was approximately 35%. This is significantly below the national uptake target of 60%.^{27,28}

- Legionnaires' Disease

The hospital convened an Incident Management Committee in response to a hospital-acquired case of Legionnaires' Disease diagnosed on the Merlin Park site in 2018. A number of legionella control measures were implemented in line with national and international guidance.^{29,30}

Senior management reported at interview that there were no outstanding patient safety concerns and the immediate remedial actions had been implemented and a timeframe for the remaining actions to be completed was in place. Ongoing sampling of water and monitoring of the situation continued and it was reported that the samples have shown a positive reduction in legionella counts which indicated that the remedial actions were working effectively.

The hospital had planned to replace the Building Management Systems (BMS) in Merlin Park University Hospital to provide automated temperature monitoring and alerts in early 2019. Inspectors reviewed the Environmental Monitoring Group minutes, these indicated that this had not commenced at the time of this inspection; this needs to be progressed.

4.3.2 Decontamination and reprocessing of reusable medical devices in a satellite decontamination facility

Inspectors visited a satellite decontamination facility in the Radiology Department to ensure that structures, systems, processes and outcomes were aligned to national guidelines.¹²

Whilst both transvaginal (TV) and transrectal (TR) semi-invasive ultrasound probes were used in the department, a review of the facility for transrectal probe decontamination was undertaken on this inspection.

Evidence of good practice included:

- decontamination was performed external to the clinical procedure room
- staff maintained an unidirectional flow and segregated clean and dirty activities as much as possible within infrastructural constraints
- trays for transportation of probes to the decontamination facility were available
- a manual track and trace system was in place
- single-use pre-gelled ultrasound covers, disposable biopsy needles and needle guides were used
- decontaminated probes were stored in single-use sealed bags to protect the integrity and microbial state of decontaminated probes
- an annual audit of decontamination practices had been undertaken; however all stages of decontamination including disinfection activation and contact times were not included; this is important to provide assurance that variables are controlled, and manual practices are in line with manufacturer's instructions in the absence of automated validated systems
- an up-to-date policy and procedure for decontamination of probes in the department was in place however it was not evident that a review of this policy by the infection prevention and control team had taken place; this should be considered.¹²

Required areas for improvement:

- the hospital needs to be assured that the procedure for storing decontaminated probes in single-use sealed bags are in line with manufactures' instructions, and national guidance; should any contradiction exist, this must be addressed by staff with clinical specialist expertise who can evaluate and advise

- tracking and traceability records did not include the identification details of the probe used (as two transrectal probes available) which is not in line with national guidance; it was confirmed that this would be addressed following this inspection; audit of manual traceability systems should also be progressed
- assurance was not provided that patient equipment was cleaned in line with national cleaning guidelines for high risk areas such as where invasive procedures are carried; daily equipment cleaning check lists were not available
- staff were unable to provide copies of recent environmental and patient equipment hygiene reports to inspectors
- inappropriate storage of sterile supplies was observed in the decontamination facility; this posed a risk of inadvertent contamination of sterile items and inhibited effective cleaning.

4.3.3 Staff training, education and competency in relation to decontamination practices

In the Radiology Department staff operatives had received on-line manufacturer's training in relation to manual systems for high level disinfection of semi-invasive ultrasound probes. Management planned to update this training on an annual basis. Hospital management need to be assured that staff operatives are competent to work independently following this training in line with national guidance.¹²

Inspectors were informed that in line with HSE recommendations, 10 staff members from central decontamination facilities had completed an academic qualification in decontamination practices and sterile services. In addition three staff were due to commence either this course or to degree level in the next academic year. All staff operatives working in central decontamination facilities had also completed the HSE LanD online training programme in relation to decontamination at induction and mandatory chemical safety training on an annual basis. Regular operator training was also provided by the manufacturers/suppliers of endoscopes and decontamination-related equipment.

In the satellite decontamination facility inspected a staff member had completed the HSE LanD online training programme in relation to decontamination. However chemical safety training had yet to be completed; this needs to be progressed for all staff operatives as per HSE recommendations.

Inspectors were told that individual competencies of staff working in central decontamination facilities were assessed at induction and intermittently thereafter. In addition staff competencies were assessed prior to working 'out of hours'. To

concur with best practice guidance an annual review of competency assessments for all staff working in endoscopy decontamination facilities including staff working 'out of hours' should be undertaken. Hospital management need to be assured that responsible operators at each operation stage are deemed competent at all times to undertake assigned responsibilities.

Policies, procedures and guidelines

The hospital had an up-to-date policy for the management of endoscopes used 'out of hours'.¹⁰

However following this inspection it was noted that a policy for the management of surgical instruments used 'out of hours' needs review; it had not been approved by an appropriate governance structure and was not in line with evidence-based best practice recommendations.^{11,31} Management need to ensure that staff have access to up-to-date evidenced-based guidance to support, guide and inform practices.

It was reported to inspectors that plans to review and update a guideline for the management of transmissible spongiform encephalopathies^{*****} in light of the publication of the latest 2019 HSE national guidance³² were underway.

***** Creutzfeldt-Jakob disease (CJD) and vCJD (variant CJD) are human forms of TSE (Transmissible spongiform encephalopathies). TSE is 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.

5.0 Conclusion

Galway University Hospitals has formalised governance arrangements with clear lines of accountability and responsibility around the prevention and control of healthcare-associated infections.

HIQA found that Galway University Hospitals was committed to improving infection prevention and control practices in the hospital and were endeavouring to fully implement the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*.¹

The hospital had experienced an ongoing outbreak of CPE since June 2017 and continued to screen in excess of the national HSE CPE screening guidelines. Although a number of mitigating measures³³ had been implemented at the hospital, new cases of CPE continued to be identified.

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

- outbreak management
- environmental hygiene on St Teresa's Ward and the Haemodialysis Unit, despite infrastructural challenges
- the antimicrobial stewardship programme
- the on-going microbiological surveillance programmes.

However management must ensure measures are in place to address the deficiencies identified in this report with particular emphasis on the following:

- clarity among staff as to the application of CPE screening guidelines
- influenza vaccine uptake among healthcare workers
- compliance with mandatory hand hygiene training
- frequency of hygiene committee meetings
- improvements in patient equipment hygiene and oversight of same
- storage of cleaning equipment
- the design and layout of St Teresa's Ward
- the design and layout of the central laundering facility.

Decontamination and reprocessing of reusable medical devices

While the hospital had defined management arrangements in place in relation to decontamination service provision, and coordination of decontamination services

across both sites was clearly evident, responsibilities for reporting and escalation on decontamination-related performance needed to be clearly defined.

HIQA acknowledge that significant progress was made recently at University Hospital Galway in centralising endoscopy decontamination service provision which is in line with national recommendations.

The decontamination service had systems in place to identify decontamination-related risks and incidents. However risks on risk registers must be subject to ongoing monitoring by the relevant management team to ensure actions identified to manage or mitigate the risk are assigned and completed.

The management of surgical instruments used 'out of hours' was not in line with evidenced-based best practice guidance and was highlighted to hospital management on the day of inspection.

It was evident that Galway University Hospitals was:

- embedding auditing into decontamination and reprocessing practices
- using audit findings to inform quality improvement plans
- progressing with academic training in centralised decontamination facilities.

Furthermore in the satellite decontamination facility inspected HIQA found that the hospital was endeavouring to fully implement national guidance in relation to decontamination of semi-invasive ultrasound probes. A trial of automated validated systems for reprocessing semi-invasive ultrasound probes had been undertaken at the hospital; this needs to be progressed. However the facility used for decontamination inspected needs to be risk assessed as it impacted on the overall compliance with best practice guidance.

Hospital management need to undertake a review of all aspects of environmental and patient equipment hygiene service delivery including management and oversight arrangements in the satellite decontamination facility.

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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

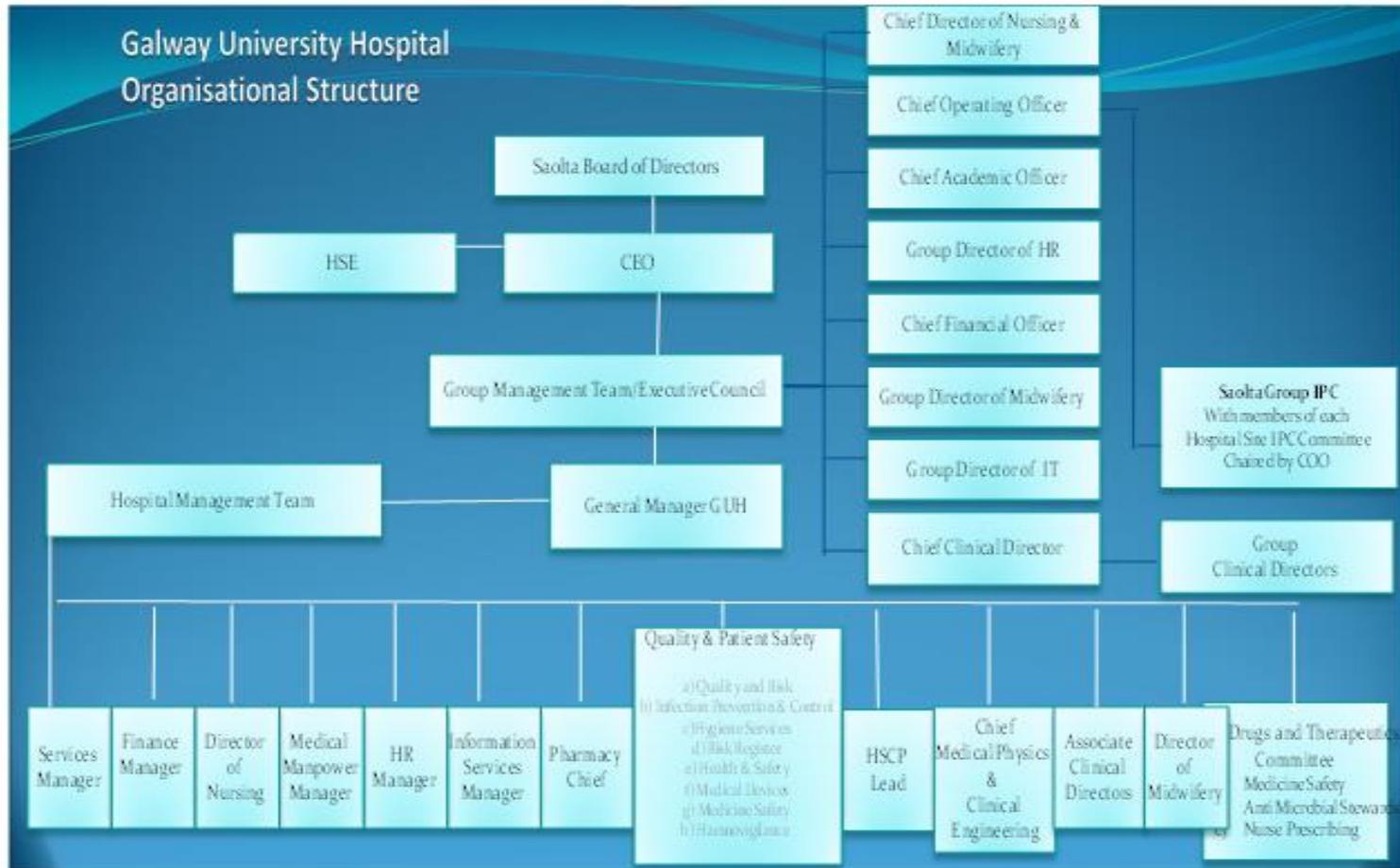
The hospital has the structures, systems and processes to detect, prevent, and manage multidrug-resistant organisms.

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: Hospital governance organogram



Appendix 3: Reusable Medical Devices Decontamination Governance Structure



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