

Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the unannounced inspection at Sligo University Hospital.

Date of on-site inspection: 6 June 2019

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

Health Information and Quality Authority

About the Health Information and Quality Authority (HIQA)

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

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

- Setting standards for health and social care services Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- Regulating social care services The Office of the Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** Regulating medical exposure to ionising radiation.
- Monitoring services Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- Health technology assessment Evaluating the clinical and costeffectiveness 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 serviceuser experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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Health Information and Quality Authority

1.0 Introduction

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

HIQA's focus in 2019 will include a detailed evaluation of how hospitals organise themselves to minimise the spread of healthcare-associated infections; with a particular focus on systems to detect, prevent, and manage multidrug-resistant micro-organisms, and the approach taken to reduce the risk of reusable 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 <u>www.hiqa.ie</u>

2.0 Information about this inspection

This inspection report was completed following an unannounced inspection carried out at Sligo University Hospital by Authorised Persons, HIQA, Bairbre Moynihan, Kathryn Hanly, Noreen Flannelly-Kinsella and Lee O'Hora on 6 June 2019 between 09:00hrs and 16:30hrs.

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

Inspectors used specifically designed monitoring tools and focused on:

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

During this inspection inspectors spoke with hospital managers, staff and representatives from the Infection Prevention and Control Committee and Decontamination Group. Inspectors requested and reviewed documentation, data

^{*} 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.

and observed practice within the clinical environment in a sample of clinical areas which included:

- Medical North: 30-bedded general medical ward comprising of four sixbedded rooms and 6 isolation rooms with en-suite facilities.
- Ear Nose and Throat treatment room (located on Surgical North).
- Our Lady's Hospital Manorhamilton: Glenview Unit: two 12-bedded nightingale-style rooms[‡], three two-bedded rooms and five single rooms.

In light of the ongoing National Public Health Emergency Plan[§] to address Carbapenemase-Producing *Enterobacterales* ^{**}(CPE) in our health system which was activated by the Minister for Health on 25 October 2017, HIQA sought assurance regarding arrangements in place to ensure compliance with the national guidelines on screening for CPE.

Hospital managers told inspectors that screening for CPE³ was in line with national guidelines. This was further validated following discussions with staff in the clinical area inspected.

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

Sligo University Hospital is a model 3 acute teaching hospital which is owned and managed by the Health Service Executive and is part of the Saolta University Health Care Group.^{††} The hospital provides a range of services including acute inpatient, outpatient and day services, regional specialty services in ophthalmology, neurology,

⁺ 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.

[§] A public health emergency is described as any serious or unexpected event, due to an infectious disease, which causes, or threatens to cause, death or serious illness to large sections of the population, an individual region or a specific cohort of individuals and which will have a major impact on the normal functioning of the health system and on society in general.

^{**} Carbapenemase-Producing *Enterobacterales* (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.

⁺⁺ 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.

dermatology, rheumatology, orthodontics and ear nose and throat. The hospital had a bed capacity of 281 inpatient beds.

Our Lady's Hospital Manorhamilton, Leitrim is a model 2 hospital which operates under the governance of Sligo University Hospital. The hospital provides inpatient and outpatient rehabilitation and rheumatology services. The hospital had 35 inpatient beds.

Sligo University Hospital was providing a decontamination and reprocessing service for reusable medical devices used at the hospital. Decontamination and reprocessing of critical and semi-critical devices such as surgical instruments and gastro-intestinal (GI) endoscopes was performed in centralised decontamination facilities in the:

- Central Sterile Supplies Department (CSSD)
- Endoscopy Decontamination Unit (EDU).

A satellite decontamination facility located within the footprint of an Operating Theatre (OT) Department reprocessed endoscopes used 'out of hours'.^{‡‡}

Additionally decontamination and reprocessing of semi-critical devices using manual high level disinfectant multi-wipe systems was performed in satellite decontamination facilities located in the:

- Out-Patient Department (OPD), Emergency Department (ED) and an Ear Nose Throat (ENT) treatment room; for ENT endoscopes.
- Cardiology Department; for a transoesophageal echocardiography ultrasound probe.
- Radiology Department; for transvaginal and transrectal ultrasound probes.
- Fetal Assessment Unit, Interventional Radiology, ED, OT and Intensive Care Unit; for semi-invasive and non-invasive ultrasound probes used in semicritical procedures.

Reusable ophthalmic (eye care) medical devices used in the Ophthalmology OPD and ED were reprocessed locally using high level disinfectant soakage systems.

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.

 $^{^{\}rm \pm\pm}$ "Out of hours" was defined as after 18.30 hours on weekdays and 24 hours on the weekends and Bank Holidays.

4.1 Governance and management structures

4.1.1 Infection prevention and control programme

Sligo University Hospital was managed by a general manager who holds overall accountability for the prevention and control of healthcare-associated infections. Inspectors found that there were formalised governance and management arrangements in relation to the prevention and control of healthcare-associated infections at Sligo University Hospital.

The infection prevention and control team reported to the Infection Prevention and Control Committee. Hygiene services and decontamination committees were subgroups of this committee. The Infection Prevention and Control Committee also reported to the Saolta Prevention and Control of Healthcare-Associated Infections Committee on a quarterly basis via teleconference.

The Infection Prevention and Control Committee was chaired by the assistant general manager who was also a member of the Quality and Safety Executive Committee. Management informed inspectors that the minutes of the infection prevention and control committee were brought to and discussed at the Quality and Safety Executive Committee. The Quality and Safety Executive Committee reported to the executive management team.

Inspectors reviewed the quality improvement plan following HIQA's inspection in 2017. Although some progress was evident, a medication preparation room on a surgical ward had not been addressed due to the fact that minor capital funding had reduced by over 35% in 2018. In the interim of funding hospital management need to be assured that measures to control any hazards or risks in relation to healthcare environments are effectively implemented and monitored.

Governance arrangements and organisational structures were outlined in an organogram provided to HIQA showing lines of communication for infection prevention and control and decontamination at the hospital (Appendix 2).

Infection prevention and control and clinical microbiology service

The infection prevention and control team was led by one whole-time equivalent (WTE)^{§§} consultant microbiologist, with the current position holder having taken up the post in May 2018. This is a standalone position, with the microbiologist effectively on call to provide clinical microbiology advice twenty-four hours a day, seven days a week. Furthermore hospital staff told inspectors that locum cover arrangements were not formalised. A second consultant microbiologist post had

^{§§} Whole-time equivalent (WTE): allows part-time workers' working hours to be standardised against those working full-time. For example, the standardised figure is 1.0, which refers to a full-time worker. 0.5 refers to an employee that works half full-time hours.

been approved but management informed inspectors that recruitment efforts had not been successful to date.

The infection prevention and control team also had two WTE infection prevention and control nurses (one at Assistant Director of Nursing (ADoN) grade and one at Clinical Nurse Specialist (CNS) grade). Inspectors were informed that the infection prevention and control ADoN was also temporarily assigned to other duties approximately 0.2 WTE^{§§} hours.

Inspectors were informed that the infection prevention and control team's workload had increased particularly in relation to the management of patients with antimicrobial resistant organisms such as Carbapenemase-Producing *Enterobacterales* (CPE).

Our Lady's Hospital Manorhamilton

During the course of the inspection at Our Lady's Hospital Manorhamilton it became apparent that the hospital had embedded a number of effective infection prevention and control practices locally. In addition there was good access to infection prevention and control expertise and education which was provided to the hospital by a community based infection prevention and control nurse.

Nevertheless, inspectors were informed that while Our Lady's Hospital Manorhamilton was under the governance of the general manager at Sligo University Hospital, management did not have oversight of infection prevention and control at Our Lady's Hospital Manorhamilton. For example:

- Our Lady's Hospital Manorhamilton was not represented on Sligo University Hospital's infection prevention and control committee.
- Sligo University Hospital infection prevention and control programme and plan did not include Our Lady's Hospital Manorhamilton.
- Performance updates and assurances in relation to infection prevention and control and antimicrobial stewardship were not consistently reported through the established infection prevention and control governance structures in Sligo University Hospital.
- Inspectors were informed that Our Lady's Hospital Manorhamilton was represented on Sligo University Hospital's Quality and Safety Executive Committee. However a review of the minutes from 02 November 2018 to 05 April 2019 did not detail any feedback or assurances on the prevention and control of healthcare-associated infections being provided from Our Lady's Hospital Manorhamilton through these governance structures.

4.1.2 Decontamination and reprocessing of reusable medical devices

Inspectors found that the hospital had defined governance and management structures in relation to decontamination and reprocessing of critical and semi-critical reusable medical devices used at the hospital. It was evident that the decontamination coordinator (0.8 WTE^{***} position) provided oversight and coordination of the decontamination programme.

The Decontamination Group chaired by the hospital's assistant general manager, provided guidance and direction on matters relating to decontamination. Membership included representatives from satellite decontamination facilities and the risk management department. Documentation viewed by inspectors following this inspection showed that an orthodontic service based at the hospital was also represented on this group.

It was reported to HIQA that the Decontamination Group reported to the Infection Prevention and Control Committee on an as required basis and was facilitated by shared membership of senior management representatives at both meetings. A more formalised reporting structure to an oversight committee should be put in place.¹

Minutes of meetings were made available to members of decontamination, infection prevention and control and quality and safety executive committees on a central electronic repository at the hospital. This was further validated following discussions with staff in a satellite decontamination facility inspected.

Documentation viewed by inspectors showed that senior management walk-rounds of central and satellite decontamination facilities took place in August 2018.

Hospital management told inspectors that decontamination-related issues were also discussed at the Saolta University Health Care Group Infection Prevention and Control Committee meetings held quarterly.

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

In compliance with the *National Standards for Prevention and Control of Healthcare*-*Associated Infections in acute healthcare services*¹, the infection prevention and control surveillance programme included surveillance of:

^{***} Whole-time equivalent (WTE): allows part-time workers' working hours to be standardised against those working full-time. For example, the standardised figure is 1.0, which refers to a full-time worker. 0.5 refers to an employee that works half full-time hours.

- `alert' organisms and `alert' conditions^{†††}
- multidrug-resistant organisms
- data reported to the European Antimicrobial Resistant Surveillance Network (EARS-Net)^{###}
- antimicrobial usage and resistance patterns catheter-related bloodstream infection (CRBSI)^{§§§} in the Intensive Care Unit
- neonatal infections.

Clostridium difficile

The monthly *Clostridium difficile* infection surveillance report showed an increased incidence of *Clostridium difficile* at Sligo University Hospital in January 2019 with an incidence of 4.85 per 10,000 bed-days used. This figure was higher than the desirable Health Service Executive (HSE) performance indicator for *Clostridum difficile* infection which is less than 2 cases per 10,000 bed-days used.

Ribotyping of samples taken from a small number of patients who acquired *Clostridium difficile* infection in the hospital indicated that the strains detected were found to be unrelated. This would indicate that there was no evidence of cross infection between patients. In a hospital with persistently high patient activity levels and limited isolation facilities, the prevention and control of *Clostridium difficile* infection must remain a priority for all relevant hospital staff and hospital management.

Hand Hygiene

- The hospital achieved 93.8% compliance rate in the national hand hygiene audit in October/December 2018 which is above the current required compliance target of 90% set by the HSE.
- Documentation indicated that 84% of hospital staff had attended hand hygiene theory training in the previous two years.

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

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

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

Our Lady's Hospital Manorhamilton

Inspectors identified gaps in the assurance process between Sligo University Hospital and Our Lady's Hospital Manorhamilton. These included routine monitoring of risk reports and national key performance indicators (KPI), such as:

- hospital-acquired Staphylococcus aureus bloodstream infection
- hospital-acquired Clostridium difficile infection
- compliance with hand hygiene technique.

Subsequent to this inspection HIQA was informed that Our Lady's Hospital Manorhamilton has had zero hospital-acquired *Staphylococcus aureus* blood stream infections and zero hospital-acquired *Clostridium difficile* infections in 2017 or 2018 or to date in 2019. This data should be included in Sligo University Hospital's national KPI reports.

Senior managers informed inspectors that the decision to screen for multi-drug resistant organisms including CPE was based on advice from the community infection control nurse or consultant microbiologist based in Sligo University Hospital. However inspectors found that there was lack of clarity among staff in the ward inspected in relation to local screening guidelines for multi-drug resistant organisms including CPE on admission. Local microbiological screening guidelines should be clearly communicated and accessible to relevant clinical staff.

Decontamination and reprocessing of reusable medical devices

The focus of inspection was on decontamination facilities outside of designated controlled decontamination units.

Inspectors were informed and documentation reviewed showed that an audit of decontamination facilities at the hospital took place in 2018. Audit components included decontamination processes, infrastructural compliance, and decontamination equipment. Findings in relation to the ENT treatment room audit will be presented in section 4.3.2 in this report.

The annual decontamination audit reports reviewed by inspectors showed that recommendations and action plans were included. An updated decontamination quality improvement plan (QIP) was shared with the decontamination group on a central repository to address areas for improvement following the audit.

In addition monthly audits of manual traceability systems were undertaken in satellite decontamination facilities. When a history of 100% compliance was achieved audit schedules were reduced to six monthly. An audit report showed that audit results were tracked and trended by management. A local traceability audit reviewed in the area inspected showed 80% compliance was achieved in May 2019.

However it was unclear as to what action was taken to address this finding. The hospital needs to ensure that where areas for improvement are identified in local audits, quality improvement plans are implemented to address findings.

During the course of this inspection HIQA was provided with an updated version of the decontamination QIP. The CSSD was not reviewed on this inspection however inspectors noted following this inspection that some intended actions on the decontamination QIP were in relation to water and environment periodic testing regimes and cleaning issues. These intended actions need to be progressed as a matter of priority and hospital management need to be assured of the standard and quality of cleaning in this area.

Inspectors were informed that decontamination equipment was maintained and periodically tested, monitored and validated by specialist groups at the hospital and external service providers in line with national guidance and best practice recommendations. An Authorised Engineer for Decontamination^{****} was appointed by the hospital to oversee and audit technical aspects of the decontamination programme.

4.2.2 Risk management

The hospital had systems in place to identify and manage risk in relation to the prevention and control of healthcare-associated infections. Inspectors were informed that the hospital had one risk register which contained both the infection prevention and control and decontamination-related risks.

Inspectors reviewed the corporate risk register and noted the risk descriptions were non-specific and contained multiple risks in the risk description making it difficult to identify the actual risk. The hospital need to ensure that the corporate risk register gives an accurate description of the impact, cause and context of the risk to effectively identify the necessary controls required to manage the risk.⁴ Furthermore, infection prevention and control staff were unsure of the infection prevention and control risks on the corporate risk register. Hospital management need to ensure that there are clear processes for communication and oversight by the infection prevention and control team of infection prevention and control related risks entered on the corporate risk register.

A draft standard operating procedure on risk registers was provided to inspectors. The draft document clearly outlined the roles, responsibilities, review, addition and follow-up of risks on the corporate risk register. The hospital was in the process of

^{****} 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.

transferring the risk register onto the HSE risk register template and this was confirmed in the documentation reviewed by inspectors.

Risks identified in Our Lady's Hospital Manorhamilton were addressed at clinical area level or were documented and escalated to the local hospital risk register as required. Inspectors were informed by management that high risks were escalated in line with HSE risk management processes. Inspectors noted however that risks identified on inspection in relation to infrastructure had not been escalated to the Sligo University Hospital corporate risk register.

The risk register was a standing agenda item on the Quality and Safety Executive Committee.

Management informed inspectors that incidents were reported on the National Incident Management System.^{††††} Minutes reviewed from the infection prevention and control committee noted that infection prevention and control incidents were discussed at the meeting and were a standing agenda item. Management reported that they received a monthly report from an electronic system of infection prevention and control incidents for the month. Inspectors were informed that infection prevention and control incidents for example lack of isolation facilities were reported but that incidents of newly acquired healthcare-associated infection were not routinely reported in line with national guidance.^{1,5} Healthcare-associated infections must be reported and inputted into the National Incident Management System (NIMs) in line with national guidance.^{1,5}

Decontamination and reprocessing of reusable medical devices

Inspectors reviewed the hospital's corporate risk register which identified one highrated risk in relation to decontamination service provision. The risk was entered in February 2019 and was in relation to regular breakdown of the reverse osmosis water filtering system in CSSD. Documented existing controls included staff vigilance and engineer call out. To provide additional assurances water testing in line with national standards as an additional control measure need to be progressed as a matter of priority.

Documentation reviewed by inspectors following this inspection indicated that risks were recorded on local risk registers and escalated to the Quality and Safety Executive Committee. Decontamination-related risks in relation to an ENT satellite decontamination facility inspected were documented in the annual decontamination quality and safety committee update report in 2018 which is in line with National Standards.¹ These included lack of automated systems and appropriate facilities for

⁺⁺⁺⁺ 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

decontamination of ENT endoscopes and the number of ENT endoscopes in a satellite decontamination facility. A risk assessment in relation to ENT service provision viewed showed that a number of risks, existing control measures and actions required had been identified. However what action was taken and by whom to mitigate these risks was not evident. Hospital management need to plan and manage resources to ensure it meets the quality and safety needs of providing a regional service.¹

During the inspection in the ENT treatment room an inspector was informed that occasionally the treatment room was used to accommodate inpatients during escalation periods. This practice needs to be reviewed to ensure the safety and quality of service provision.

Hospital management told inspectors that risk assessments had been undertaken in relation to the use of multi-wipe high level disinfection systems for decontamination of ENT endoscopes and ultrasound probes.⁶ The hospital had recently trialled automated validated systems for decontamination in the Fetal Assessment Unit and the Radiology Department. Inspectors were told that plans to move to automated validated systems for reprocessing ultrasound probes were underway in the Radiology Department; this needs to be progressed across the hospital. Automated disinfection in an endoscope washer disinfector for ENT endoscopes is best practice and also needs to be progressed.⁷

Decontamination-related incidents were reported on the hospital's electronic incident reporting system and discussed monthly with the risk adviser, and relevant departments such as decontamination, OT or endoscopy users group. It was hospital policy to report decontamination-related incidents on NIMs.^{####}

The national medical devices eAlert^{§§§§} system had been implemented at the hospital. The quality and safety facilitator, as the nominated "designated person" was responsible for internal hospital distribution to the relevant personnel for implementation of the recommended actions where applicable. It was evident that safety notices were discussed in minutes of decontamination group meetings reviewed.

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. Inspectors were told by management that

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

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

the hospital was in the early stages of discussion in relation to contingency plans in the event of decontamination equipment failure. The hospital had an inventory of reusable medical devices and decontamination equipment used and was working towards including the date of purchase for each item. It is important to identify equipment that is going beyond the minimum technical life expectancy in a timely manner so that it can be replaced or upgraded.⁸

Documentation reviewed showed that the hospital was working on a hospital guideline for transmissible spongiform encephalopathies^{*****} in CSSD and OT; the hospital need to be assured that the finalised guideline is in line with national guidance in this regard. A nursing assessment for patients undergoing gastrointestinal endoscopy and transoesophageal echocardiography showed that patients were asked if they had ever been informed that they were at increased risk of developing CJD or vCJD.^{†††††}

4.3 Implementation of evidence-based best practice

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

CPE management

The hospital had experienced an ongoing outbreak of CPE since July 2017. An outbreak control committee had been convened and the local Public Health Department was informed of the outbreak. During this inspection inspectors spoke with members of senior management, members of the infection prevention and control team and visited Medical North to assess measures put in place to prevent the spread of antimicrobial-resistant organisms including CPE.

There were no patients with CPE in the hospital on the day of the inspection. However as a period of 90 consecutive days without a newly detected CPE patient assessed as a "probable" hospital associated case had not been achieved the outbreak on Medical North had not yet been declared over. Inspectors were informed that there had been no newly-detected CPE patients on this ward in the previous month which indicated better control of the ongoing CPE outbreak.^{#####}

^{*****} 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.

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

^{*****} 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.

Evidence of good practice

- Examples of interventions to detect, prevent, and respond to multidrugresistant organisms included but were not limited to:
- In line with the HSE CPE Contact Communications Programme,⁹ the hospital had written to identified CPE patient contacts^{§§§§§} that had been discharged advising them of their CPE contact status. Inspectors were informed that 20% of patients had contacted the hospital requesting screening and that none of these patients acquired CPE.
- In line with national guidelines¹⁰ audits were completed on compliance with CPE screening policy. Documentation reviewed by inspectors showed varying results. Inspectors were informed that education and re-auditing was done if results required improvement. A recent audit of compliance with CPE screening showed an improvement from 60% in February to 100% in April on Medical North.
- Environmental screening had been performed on the outbreak ward as recommended in national guidelines. Results identified the presence of the outbreak strain affecting a number of wash-hand-basins, shower outlets, toilets and drains in Medical North. Some wash-hand basin traps were replaced as part of the remedial actions to address this finding.
- On the day of inspection all patients colonised and or infected with a transmissible infection were isolated in single rooms on the ward inspected as appropriate. An infection prevention and control risk-assessment in relation to multidrug-resistant organisms was incorporated in nursing admission documentation.
- In compliance with national guidelines,¹¹ the hospital operated a policy of restricted access to the broad-spectrum antibiotic meropenem; a last line antibiotic used to treat serious Gram-negative infection, which should not be prescribed without prior consultation with an infection specialist.

Required areas for improvement

 Inspectors were informed that regular overcrowding and insufficient bed capacity at the hospital frequently resulted in accommodating additional patients in treatment rooms on the ward which contained sterile supplies and consumables; contrary to advice from the infection prevention and control

^{SSSSS} 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 (AMAUs). 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.

team. On the day of inspection an additional patient was accommodated in the treatment room with unattended access to clean and sterile consumables including intravenous fluids. This was brought to the attention of management and staff on the day.

- Inspectors observed ward-wide issues in relation to maintenance for example damaged walls, ceiling tiles were loose, stained or damaged, ceiling lights were not working or the cover was missing.
- Oversight of general environmental hygiene: dust was noted throughout the ward for example under beds, on top of personal protective equipment storage, in patient rooms above the bed space and air vents. Staining was noted for example on commodes, in a fridge, the front of the medication dispenser and on a patient observation folder.
- There was no clearly defined system on the ward for identifying if equipment had been decontaminated between patient uses. A green tagging system which alerted staff to when the equipment was last cleaned was inconsistently applied on Medical North.
- The most recent local and managerial hygiene and equipment results were reviewed by inspectors on Medical North. The results showed a disparity between the audit scores and observations on the day of the inspection. HIQA recommends that the hospital reviews the systems and processes relating to the monitoring, management and maintenance of the physical environment and all equipment to assure its compliance with National Standards
- The design of clinical hand wash sinks in the ward did not comply with HBN 00-10 Part C: Sanitary assemblies.¹²

Our Lady's Hospital Manorhamilton: Glenview Unit

The inspection team visited Our Lady's Hospital Manorhamilton to assess measures to prevent the spread of antimicrobial-resistant organisms including CPE.

Evidence of good practice

- There was good local ownership in relation to infection prevention and control in the unit despite the challenging infrastructure.
- Overall, the physical environment and patient equipment was clean with some exceptions.
- Cleaning staff spoken with by inspectors were knowledgeable regarding infection prevention and control protocols in relation to their role.
- 90% of staff from the Glenview Unit had attended hand hygiene theory training in the previous 18 months.

Required areas for improvement

- The infrastructure and maintenance of the Glenview Unit was not optimal from an infection prevention and control perspective. For example:
 - Minimal spatial separation between beds in the nightingale-style rooms was insufficient to enable the carrying out of clinical activities without compromising infection prevention and control practices.
 - The number of toilet and shower facilities, ancillary rooms and storage facilities were insufficient on the ward. For example there was one shower available for use by patients in the 12 bedded nightingale wards.
 - The design and finish of shared patient toilets/showers did not facilitate effective cleaning. For example the underside of the shower basin grids in one patient shower was heavily stained and unclean.
 - Sinks in patient rooms were dual purpose (used by both staff and patients). There was one sink adjacent to the sluice hopper in the 'dirty' utility room. A separate sink for hand hygiene was not available so it was difficult to determine if the hand wash sink had a dual function.
 - Paintwork, finishes and flooring were damaged and poorly maintained and did not facilitate effective cleaning.
- Disposable curtains were used in the nightingale wards. However dates on the curtains indicated that they had not been changed for over six months. Curtains should be considered high on the list of possible vectors for crosscontamination.
- The last audit of hand hygiene compliance was carried out three years ago in August 2016. The hospital achieved HSE compliance with a rate of 80% which fell short of the HSE's desirable target of 90% hand hygiene compliance.

4.3.2 Decontamination and reprocessing of reusable medical devices

An inspector visited a satellite decontamination facility located in an ENT treatment room (located on Surgical North) to ensure that structures, systems, processes and outcomes were in compliance with national standards and recommended practices for decontamination and reprocessing of non-channelled ENT endoscopes.^{13,14}

A hospital audit of the ENT treatment room showed 21% compliance was achieved in relation to recommended standards for the facility, cleaning, and storage in 2018. An action plan indicated that hospital management were reviewing options in relation to either upgrading the facility or centralising decontamination activity at the hospital. However there was no agreed timeframe for completion of this review. HIQA acknowledge that some findings in relation to storage issues identified in the hospital's audit in 2018 had been addressed. However it was of concern that audit findings in relation to environmental hygiene and cleaning specifications, also identified by HIQA on this inspection had not been addressed. Hospital management told inspectors that issues in relation to the environmental and patient equipment hygiene highlighted would be addressed at the time of inspection.

Evidence of good practice

- Dedicated staff operatives were assigned to the facility.
- Staff maintained unidirectional flows and segregated clean and dirty activities as much as possible within infrastructural constraints.
- A defined system which clearly indicated when ENT endoscopes had been contaminated and decontaminated was in place.
- Decontamination-related instructions for manual multi-wipe high level disinfectant systems were visible at point of use to support staff.
- Manual track and trace systems were in place and audit of practices had commenced.
- A guideline for decontamination of ENT endoscopes was in place.

Required areas for improvement

Findings of non-compliance with the national standards and recommended practices for endoscopy decontamination facilities in the ENT treatment room included some of the following:

- ENT endoscopes were not reprocessed in automated validated endoscope washer disinfectors; high level disinfection manual multi-wipe systems were used.
- Facility design and infrastructure did not ensure the complete physical separation of dirty and clean activities; decontamination procedures were performed at point of patient care in a treatment room.
- Disinfected endoscopes were not stored in line with national guidance and in line with manufacturer's instructions. Endoscopes were stored inappropriately in endoscope trays.
- The room was not secured and ventilation systems were not compliant; a window was open.
- Microbiological testing and monitoring of endoscopes and environment was not performed.
- Deficiencies in relation to the oversight of patient equipment and environmental hygiene standards were identified; daily cleaning checklists to provide assurances to management in relation to patient equipment hygiene

were not in place. There needs to be assigned and appropriate managerial oversight of environmental and equipment cleaning in this facility.

 Sterile supplies and documentation were inappropriately stored in open shelving.

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

Staff operatives including relevant medical staff working in the ENT treatment room had received training in relation to manual systems for high level disinfection of ENT endoscopes. Regular updates including face-to-face sessions were also provided by suppliers of disinfection systems. A train-the-trainer initiative in relation to manual decontamination processes was also in place.

A comprehensive nasendoscope decontamination training document reviewed by inspectors included an annual competency assessment component. However an inspector was informed that this process was not formalised in the satellite facility inspected. Hospital management must ensure that all staff operatives including medical staff and staff who reprocess endoscopes used for out-of-hours emergency procedures, once trained are assessed as competent to work independently. Additionally annual review of competency assessments for staff working in endoscopy decontamination should be undertaken to concur with best practice guidance.^{7,15}

Inspectors were informed that, in line with HSE recommendations, nine staff members from central and endoscope decontamination facilities had completed an academic qualification in decontamination practices and sterile services. In addition four staff personnel were due to commence the same course in the next academic year. Regular operator training was also provided by the manufacturers/suppliers of endoscopes and decontamination-related equipment. Going forward academic training for staff operatives working in satellite endoscopy decontamination facilities should also be progressed as per HSE recommendations.

A staff member had completed the online decontamination training programme in the satellite decontamination facility inspected; this needs to be progressed for all relevant staff.⁷ In addition chemical safety training needs to be progressed for all personnel who work in the decontamination environment.⁷

The hospital had an electronic document management control system and a comprehensive list of decontamination-related policies, procedures and guidelines (PPGs). Documentation reviewed showed that a number of additional PPGs were being finalised; the guideline for decontamination of ENT endoscopes was due for review.

Inspectors recommend that the procedure for 'out of hours'^{******} endoscope loan from the Endoscopy Unit to the Operating Theatre (OT) is reviewed so that step-bystep instructions also clearly define storage of endoscopes following high level disinfection in OT, and adherence to 3 hour rule^{†††††††} (if not stored in an automated validated system). HIQA recommends that the hospital continues to work towards full implementation of the latest national standards and recommended practices in this regard.⁷

^{****** &}quot;Out of hours" was defined as after 18.30 hours on weekdays and 24 hours on the weekends and Bank Holidays.

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

5.0 Conclusion

A National Public Health Emergency Plan was activated by the Minister for Health on 25 October 2017 as response to the increase and spread of Carbapenemase-Producing *Enterobacterales* (CPE) in Ireland.

Hospital managers told inspectors that screening for CPE³ was in line with national guidelines. This was further validated following discussions with staff in the clinical area inspected.

Sligo University Hospital had experienced an ongoing outbreak of CPE since June 2017. Although a number of mitigating measures had been implemented, recurring challenges faced by the hospital to effectively prevent and control the CPE outbreak included a lack of isolation facilities and high occupancy rates.

Inspectors found that overall leadership, governance and management arrangements were in place for the infection prevention and control programme in Sligo University Hospital. However inspectors found that governance arrangements in relation to infection prevention and control in Our Lady's Hospital Manorhamilton need to be formalised to ensure that information from local monitoring is used to identify potential risks and opportunities for improvement in relation to the prevention and control of healthcare-associated infection.

5.1 Systems to detect, prevent and manage multi-drug organisms

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

- implementation of national CPE screening guidelines
- restriction of the broad spectrum antibiotic meropenem
- environmental and equipment hygiene in the Glenview Unit, Our Lady's Hospital Manorhamilton.

Management need to put measures in place to address the following matters:

- admission of additional patients to a ward experiencing a CPE outbreak
- admission of patients to treatment rooms with unattended access to clean and sterile consumables
- oversight of environmental and equipment hygiene in Sligo University Hospital
- maintenance and infrastructure of inpatient units in Our Lady's Hospital, Manorhamilton.

5.2 Decontamination and reprocessing of reusable medical devices

Inspectors found that there was defined governance and management arrangements for decontamination and reprocessing of critical and semi-critical reusable medical devices at the hospital. In addition coordination and oversight of decontamination service provision was clearly evident.

The decontamination service had systems in place to identify and manage decontamination-related risks and incidents. However a number of intended actions on a decontamination quality improvement plan had yet to be addressed. A risk-based approach in order to identify specific risks relative to the actions required must be implemented by hospital management.

It was evident that decontamination services across the hospital was:

- embedding regular auditing into routine practice
- using audit findings to inform quality improving plans
- progressing with academic training, education and competency assessment for staff working in central decontamination services
- exploring options in relation to centralising decontamination service provision at the hospital in line with national recommendations.

Overall HIQA found that the hospital was endeavouring to implement national standards and recommended best practice guidance in relation to decontamination service provision in a satellite decontamination facility inspected. However the design of the facility and lack of automated validated systems for decontamination of ENT endoscopes impacted on the overall compliance with best practice guidance and need to be addressed.

Management also need to address the following:

- academic training and formalised competency assessments for staff working in satellite endoscope reprocessing facilities
- cleaning frequencies and auditing of environmental and patient equipment hygiene
- oversight of environmental and patient equipment hygiene.

In addition 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's own recommendations¹⁶ should be advanced.

Sligo University Hospital including Manorhamilton Hospital as member of the Saolta University Health Care Group, needs to be supported within group and national structures to effectively address issues in relation to capacity and resources in order

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to facilitate compliance with the *National Standards for the Prevention and Control of Healthcare-Associated Infections* and other existing national healthcare standards.

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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 evidencedbased best practice with up to date policies, procedures, protocols and guidelines in line with relevant legislation and national guidelines.

Appendix 2: Infection Prevention and Control and Decontamination Governance Organogram



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