

Bundle of documents for Oral hearings commencing from 16 September 2025 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

Bundle 52 – Volume 11 Miscellaneous Documents

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Table of Contents

1.	A54550231	Fourth Floor Plan - NSGH Haemato-Oncology Ward Drawing Sign off - 07 May 2010	Page 4
2.	A32938411	Healthcare Improvement Scotland - Healthcare Associated Infection Standards - February 2015	Page 5
3.	A42362222	NHS Greater Glasgow and Clyde - PAG - Ward 2A - Cupriavidus - 19 February 2018	Page 56
4.	A54680896	NHS Greater Glasgow and Clyde - Whistleblowing cases - 1 April 2017 - 31 March 2020	Page 58
5.	A54598175	Paper - Investigating hospital Mycobacterium chelonae infection using whole genome sequencing and hybrid assembly - Christopher H. Gu et al 09 November 2020	Page 65
6.	A34735209	RHCYP - Positive Pressure Ventilated Lobby Isolation Rooms: Information for ward staff: March 2021	Page 82
7.	A51217034	Email – J Marshall to T Ali – FW Letter from Caroline Lamb – 13 June 2022	Page 83
7.1		FW_Letter from Caroline Lamb	Page 84
7.1.1		Final - QEUH Response - DG Letter - Jane Grant - 13 June 22	Page 85
8.	A51690056	Scottish Government news - Change to health board escalation - 13 June 2022	Page 86

9.	A44943484	NHS Greater Glasgow and Clyde - RFI response - No 18 - Ventilation Systems - Physical Changes - PICU - 14 July 2023	Page 88
10.	A54471690	NHS Greater Glasgow and Clyde - RFI response dated 28 October 2025	Page 89
11.	A44943366	NHS Greater Glasgow and Clyde - RFI response - No 18 - Ventilation Systems - Isolation Rooms QEUH	Page 92
12.	A44943564	NHS Greater Glasgow and Clyde - RFI response No 18 - Ventilation Systems - Physical Changes - RHC Wards 2A & 2B	Page 94





Healthcare Associated Infection (HAI)

Standards February 2015





Healthcare Improvement Scotland is committed to equality and diversity. We have assessed these standards for likely impact on the nine equality protected characteristics as stated in the Equality Act 2010 and defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation. A copy of the impact assessment is available upon request from the Healthcare Improvement Scotland Equality and Diversity Advisor.

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First published February 2015

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Contents

Introduction	4		
Development of the HAI standards			
Standards for HAI			
Standard 1: Leadership in the prevention and control of infection	9		
Standard 2: Education to support the prevention and control of infection	13		
Standard 3: Communication between organisations and with the patient or their representative	17		
Standard 4: HAI surveillance	21		
Standard 5: Antimicrobial stewardship	24		
Standard 6: Infection prevention and control policies, procedures and guidance	29		
Standard 7: Insertion and maintenance of invasive devices	33		
Standard 8: Decontamination	36		
Standard 9: Acquisition of equipment	40		
References			
Appendix 1 Membership of the standards for HAI short-life working group			

Introduction

About Healthcare Improvement Scotland

We believe that every person in Scotland should receive the best healthcare possible every time they come into contact with their health service.

We have a key role in supporting healthcare providers to make sure that their services meet these expectations and continually improve the healthcare the people of Scotland receive.

We are a public body and have four principle functions:

- providing sound evidence for improved healthcare, through the Scottish Medicines Consortium, the Scottish Health Technologies Group, and the Scottish Intercollegiate Guidelines Network
- supporting the delivery of a safer health service and the reliable spread of best practice in quality improvement
- ensuring the effective participation of the public in the design and delivery of healthcare, principally through the Scottish Health Council, and
- scrutinising and quality assuring the provision of healthcare.

Our work programme supports the healthcare priorities of the Scottish Government, in particular those of NHSScotland's Healthcare Quality Strategy and the 2020 Vision.

For more information about our role, direction and priorities, please visit: www.healthcareimprovementscotland.org/drivingimprovement.aspx1.

Background to the revision of HAI standards

The prevention and control of infection is everybody's responsibility, with standards being one part of the drive towards a safer NHSScotland. In March 2008, NHS Quality Improvement Scotland published the *National Standards for Healthcare Associated Infection (HAI)*² emphasising the need for all NHS board staff to be involved in infection control initiatives, and since April 2009, the 2008 HAI standards have been applied in inspections of hospitals across NHSScotland. However, the standards were not developed explicitly for this inspection purpose.

The Scottish Government HAI Task Force National Policy Group tasked Healthcare Improvement Scotland with revising the 2008 standards, to ensure clarity around infection prevention and control of HAI, at the point of patient care. The 2015 standards are aligned to the *National Infection Prevention and Control Manual (2013)*³, with content supporting that of the manual, and together they are the key publications for all healthcare organisations to adhere to, to ensure robust HAI practice and policy across all healthcare and social care settings.

These 2015 standards supersede the NHSScotland Code of Practice for the Local Management of Hygiene and Healthcare Associated Infection and all previous HAI

standards produced by Healthcare Improvement Scotland's predecessor organisations.

Scope of the standards

The standards apply to all healthcare organisations and practitioners, including independent healthcare providers, and recognise the role of all patients, their representatives and the public. The standards should be reviewed pragmatically by service providers: *not every criterion will apply to all settings or all service providers*.

Whilst the standards routinely make mention of specific infection-related policies, organisations should consider the clinically-appropriate policy or policies when implementing and demonstrating compliance to the standards.

The HAI standards have been reviewed against The Vale of Leven Hospital Inquiry Report⁴ published in November 2014, with criteria amended to reflect the recommendations, where appropriate. It should be noted that while the Vale of Leven report gives specific consideration to *Clostridium difficile*, the generic nature of the Healthcare Improvement Scotland HAI standards encompass all HAI infections.

These standards have been developed in recognition of the integration of health and social care services and the principles apply to both health and social care; standards are mandatory for healthcare settings (NHS boards), and considered best practice guidelines for social care settings. For social care settings, the standards should be read in conjunction with *The National Care Standards*⁵, produced by the Scottish Government, and regulated against by the Care Inspectorate.

The Healthcare Improvement Scotland standards for HAI cover the following areas:

- leadership
- education
- communication
- HAI surveillance
- antimicrobial stewardship
- infection prevention and control policies, procedures and guidance
- insertion and maintenance of invasive devices
- decontamination, and
- acquisition of equipment.

These 2015 standards incorporate key areas in line with existing policy and service objectives to allow for:

- ease of application at the point of care
- ease of transfer across all care settings
- · the inspection of care settings in the prevention and control of infection, and
- continuous quality improvement.

Information for patients and members of the public

It should be noted that the standards document is a technical document, developed to support staff to ensure the highest standards of infection prevention and control wherever healthcare is delivered. Each standard details what patients, their representatives and the public can expect of healthcare services in Scotland following implementation.

Format of the standards

All our standards follow the same format. Each standard includes a statement of the level of performance to be achieved, a rationale providing reasons why the standard is considered important, and a list of criteria describing the required structures, processes and outcomes. Within these standards, all criteria are considered 'essential' or required in order to demonstrate the standard has been met. At the end of each standard is a list of examples of evidence of achievement (taking either **verbal** or **written** form) matched to specific criterion, which will enable service providers to demonstrate it has met the standard.

Terminology

Readers are advised that, wherever possible, Healthcare Improvement Scotland has incorporated generic terminology which can be applied across all healthcare and social care settings, those being NHS boards and independent healthcare providers. Examples include: infection control committee which should be read as infection control committee or equivalent throughout, and infection prevention and control team, which should be read as infection prevention and control team (or team fulfilling this role) throughout.

Development of the HAI standards

The development of the HAI standards builds on the current relevant evidence and two previous sets of national standards produced by Healthcare Improvement Scotland's predecessor organisations. Namely, the Clinical Standards Board for Scotland's standards for *Healthcare Associated Infection (HAI) Infection Control*⁶, and NHS Quality Improvement Scotland's standards for *Healthcare Associated Infection (HAI)*² published in 2001 and 2008, respectively.

A short-life working group, chaired by Dr Margaret McGuire (Director of Nursing, NHS Tayside) was convened in January 2014 to consider these and other documents, including the *Prevention and control of healthcare-associated infections: Quality improvement guide*⁷, a National Institute for Health and Clinical Excellence publication, to help identify key themes for standards development.

For information, membership of both the short-life working group and sub-groups is set out in Appendix 1.

To ensure each standard is underpinned with the views and expectations of both patients and the public in relation to HAI, information was gathered from a number of sources, including:

- patient complaints relating to infection control
- a focus group involving members of a public partnership forum, specific to HAI, and
- public partner feedback following inspections carried out by the Healthcare Environment Inspectorate.

This information was provided to each sub-group to inform the standards development process.

Consultation

We contacted professional bodies and independent healthcare organisations (such as The Faculty of Public Health Medicine and St. Columba's Hospice) and healthcare professionals involved in infection prevention and control, requesting feedback using a variety of media, including:

- the Healthcare Improvement Scotland website
- a feedback form provided with the distributed draft standards, and
- a public partnership forum.

Consultation feedback

Comments have been received from a variety of sources, including:

- 13 NHS boards
- the Association of Independent Healthcare Organisations
- the Care Inspectorate, and
- the Association of Antimicrobial Pharmacists Group.

A full consultation report is available from Healthcare Improvement Scotland.

Standards for HAI

Standard 1: Leadership in the prevention and control of infection

Standard statement

The organisation demonstrates leadership and commitment to infection prevention and control to ensure a culture of continuous quality improvement throughout the organisation.

Rationale

Robust leadership in infection prevention and control is essential for effective decision-making, efficient use of resources and ensuring the provision of high quality, safe, effective, person-centred care.

References: 4, 8, 9, 10, 11, 12

Criteria

- **1.1** Executive leaders and their teams have a working knowledge, appropriate to their role in the organisation, of the infection prevention and control policies and procedures as well as the national and local priorities that impact on care within their organisation.
- **1.2** There is an executive board member assigned to lead on infection prevention and control for the organisation.
- **1.3** There are local arrangements to ensure HAI issues are addressed by NHS board management.
- **1.4** There is an infection prevention and control team with the necessary expertise and leadership skills to support the organisation.
- 1.5 The organisation agrees and monitors key performance indicators for infection prevention and control, and executive leadership receives, reports and acts on these.
- 1.6 There is an infection prevention and control accountability framework, approved by executive leadership, which specifies the responsibilities, reporting structure and clinical governance of infection prevention and control risks at all levels in the organisation.
- 1.7 The organisation can demonstrate to patients, their representatives and staff:
 - (a) HAI risk assessments are undertaken to ensure continuity of safe patient care during periods of service planning and reorganisation, and
 - (b) effectiveness and improvement in maintaining a safe care environment.

- **1.8** The organisation can demonstrate effective management of outbreaks, including:
 - (a) preparedness
 - (b) assessment of patient care and safety
 - (c) reporting, and
 - (d) remedial action plans.
- **1.9** The organisation has strategic, operational and quality assurance systems, with clinical governance oversight to demonstrate compliance with infection prevention and control policies.
- 1.10 The organisation demonstrates a culture of learning from positive reporting, and adverse events, including outbreaks and incidents, and seeks confirmation of system change to reduce risk, prevent recurrence and promote resilience.
- **1.11** The organisation uses data from a variety of internal and external sources to meet its objectives and to support learning and continuous improvement in infection prevention and control practice.

What does the standard mean for people receiving treatment or visiting a healthcare or social care setting?

 Patients and visitors have confidence that the organisation has effective leadership and governance and that it promotes an organisational culture committed to continuous improvement in infection prevention and control.

What does the standard mean for the organisation?

• The organisation is able to demonstrate achievements in continuous improvement in infection prevention and control practice.

What does the standard mean for the infection prevention and control team?

- The infection prevention and control team is able to provide a proactive infection prevention and control service, supported by executive leadership, with whom they communicate risks and recommend actions.
- The infection prevention and control team supports clinical, and other staff, with data, training, environmental assessments, risk assessments, practice audits and recommendations for practice that facilitate safe, effective patient care and service improvement.

What does the standard mean for staff?

- Support is provided by senior staff and the infection prevention and control team through the provision of resources, a suitable environment, a reporting structure, guidance, training and education, and data that facilitate the delivery of effective infection prevention and control.
- Staff, where appropriate to their role, use data to assess the quality of care or service provided and to improve practice.
- All staff are aware of their role in maintaining a safe care environment.

Examples of evidence of achievement (NOTE: this list is not exhaustive.)

The **executive team** can:

i. describe organisational accountability and support for continuous quality improvement, specific to infection prevention and control.

The infection prevention and control team can:

- ii. demonstrate regular review of guidelines to optimise the provision of a proactive infection prevention and control service.
- iii. articulate their role in the strategic, operational and quality assurance systems that demonstrate compliance with infection prevention and control policies.
- iv. describe how learning from adverse events, including outbreaks and incidents, have reduced risk, prevented recurrence and promoted resilience.
- v. demonstrate how the organisation uses data to meet its objectives and support learning and continuous improvement in infection prevention and control.

Staff can:

- vi. describe organisational infection prevention and control priorities.
- vii. describe the data they use to influence practice to minimise infections and improve care processes.
- viii. explain their own role and responsibilities in the prevention and control of infection.
- ix. articulate the reporting structure and the process for reporting and escalating infection prevention and control risks or incidents, and make contact with the infection prevention and control team when necessary.
- x. demonstrate the availability of action plans to address any deficiencies.

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. A named designated HAI executive lead. (1.2)
- 2. An organisational chart that shows the management and accountability of infection prevention and control from executive level to the point of care. (1.2, 1.3)
- 3. Executive board reports or minutes. (1.1)
- 4. HAI improvement data. (1.6, 1.8, 1.9, 1.11)
- 5. Infection control committee reports (or equivalent). (1.1, 1.4, 1.5, 1.7, 1.8, 1.9, 1.11)
- 6. Infection prevention and control annual programme. (1.1, 1.5, 1.7, 1.8)
- 7. Infection prevention and control key performance indicators. (1.4, 1.7, 1.8, 1.10)
- 8. Outbreak management plans, including details of the internal investigation team, as instigated by the NHS board. (1.6, 1.7, 1.8, 1.9)
- 9. Patient involvement in learning from adverse events. (1.8, 1.9)
- 10. Patient safety / leadership walk rounds timetable and inspections. (1.1, 1.6)
- 11. Patient satisfaction survey reports. (1.9)
- 12. Quarterly reports on current and emerging threats (1.10, 1.11)
- 13. Risk registers (or equivalent). (1.5, 1.7, 1.8, 1.10, 1.11)
- 14. Staff, patient and visitor feedback (1.10, 1.11)
- 15. Ward scorecards (or equivalent). (1.6, 1.9)

Standard 2: Education to support the prevention and control of infection

Standard statement

Education on infection prevention and control is provided and accessible to all healthcare teams to enable them to minimise infection risks that exist in care settings.

Rationale

To minimise the infection risks associated with healthcare, all staff are provided with the necessary knowledge and skills in infection prevention and control to confidently and competently demonstrate behaviours integral to safe, effective and person-centred care.

References: 3, 4, 8, 12, 13, 14, 15, 16, 17, 18

Criteria

- 2.1 The organisation assesses the education and training needs of all staff relating to infection prevention and control through performance management reviews.
- **2.2** All relevant staff within the organisation are provided with clear guidance on:
 - (a) roles and responsibilities in relation to infection prevention and control
 - (b) identifying and addressing education and training needs, and
 - (c) infection-specific management, including *Clostridium difficile* and loose stools policies.
- **2.3** Education and training needs of specialist practitioners are aligned to career and development frameworks appropriate to their role.
- **2.4** The organisation provides an education programme that meets the need of staff which includes:
 - (a) mandatory induction, training and updates on HAI guidance, policies and procedures commensurate with staff roles
 - (b) tailored HAI education to meet roles and responsibilities, and
 - (c) learning and sharing of HAI best practice, internally and externally.
- 2.5 The organisation evaluates the provision, quality and uptake of infection prevention and control training and responds to any unmet infection prevention and control education needs.
- 2.6 The organisation has multiple and integrated approaches to ensure the timely delivery of infection prevention and control education across all professions and disciplines.

2.7 National HAI-related intelligence and other data are utilised in the identification of education and training needs and the planned programme of education and training offered.

What does the standard mean for people receiving treatment or visiting a healthcare or social care setting?

 People using the services are assured that staff delivering care are educated and trained in infection prevention and control, and use their learning to ensure care is safe, effective and person-centred.

What does the standard mean for the organisation?

 The organisation can demonstrate a continuous quality improvement approach and a learning culture to ensure the knowledge and competency of staff involved in infection prevention and control is maintained.

What does the standard mean for the infection prevention and control team?

 The infection prevention and control team supports the organisation to identify, provide and evaluate organisation-wide infection prevention and control education needs.

What does the standard mean for staff at the point of care?

Staff are:

- able to demonstrate knowledge and competence in the delivery of care, and act as role models in the promotion of infection prevention and control.
- responsible to the organisation for identifying issues relating to infection prevention and control.
- able to effectively challenge and support colleagues to promote best infection prevention and control practices.

What does the standard mean for support services?

 Support services staff (for example, domestic, estates and procurement) have the skills to practice safely and promote infection prevention and control.

Examples of evidence of achievement (NOTE: this list is not exhaustive.)

The **executive team** can:

 describe organisational accountability in supporting and maintaining the continuing professional development of staff, specific to infection prevention and control.

The **HAI education lead** and the **infection prevention and control team**, where appropriate to role can:

ii. describe the methods used in the provision of HAI training and education to healthcare teams.

- iii. describe the evaluation process used to address HAI training needs.
- iv. articulate the review process for the organisation's HAI training programme.

Staff can:

- v. describe types of training undertaken in relation to infection prevention and control processes and procedures.
- vi. describe systems and procedures to identify individual education and training needs.
- vii. explain escalation procedures for issues specific to infection prevention and control.

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. A range of training methods to give staff the opportunity to learn from each other's experiences in relation to infection prevention and control. (2.3)
- 2. Active organisational programmes for HAI education. (2.3)
- 3. Completion data and observation of implementation of national and local training programmes (assessment data, peer review, reflection). (2.1, 2.3, 2.4, 2.6, 2.7)
- 4. Evaluation processes to ensure that HAI training is appropriate, fit for purpose, quality assured and consistent with national guidance and standards. (2.4)
- 5. Inclusion of training issues and needs in significant event analysis relevant to HAI. (2.1, 2.3)
- 6. Alignment of roles to profession-specific competencies and frameworks (for example, Career Development Framework for IPC Nurses or Post Registration Career Development Framework for Nurses, Midwives and Allied Health Professionals in Scotland). (2.2, 2.3)
- 7. Performance indicators for staff performance management in infection prevention and control, which are checked on a regular basis. (2.1, 2.4, 2.7)
- 8. Recording and reporting structures for monitoring the uptake of training. (2.3, 2.4, 2.5, 2.6)
- 9. Reports of the proportion of staff undertaking mandatory infection prevention and control induction and update training. (2.1, 2.4)
- 10. Staff education and training requirements, in relation to infection prevention and control are included in organisational policies and procedures. (2.3, 2.5)
- 11. Staff feedback on their experiences on infection prevention and control, which inform learning activities. (2.4, 2.6)
- 12. Training and achievement records. (2.1, 2.2)

- 13. Training evaluations (individual and organisational). (2.4)
- 14. Training needs analysis informed by national initiatives, organisational strategy and local HAI outcomes. (2.6)

Standard 3: Communication between organisations and with the patient or their representative

Standard statement

The organisation has effective communication systems and processes in place to enable continuity of care and infection prevention and control throughout the patient's journey.

Rationale

Patients are vulnerable to infections and some present an infection risk to other patients, visitors and staff. As a single patient journey can involve staff in multiple care settings, effective care provider communications are vital in infection prevention and control, and safe, effective and person-centred care.

Wherever possible, patients and their representatives must be assured of, and involved in, communications regarding their care.

References: 3, 4, 11, 18, 19, 20

Criteria

- 3.1 The organisation has systems that require an infection prevention and control risk assessment (to and from the patient) to be made and documented on patient admission and transfer.
- 3.2 Where infection risks to the patient are identified, appropriate actions are taken to minimise these risks. Both risks and actions are communicated with, and involve, the patient or their representatives.
- 3.3 Where infection risks from the patient are identified, appropriate actions are taken to minimise these risks. Both risks and actions are communicated with, and involve, the patient, their representatives and relevant healthcare teams.
- **3.4** Patients, or their representatives, are provided with information, in a format appropriate to their needs, on specific infection-related risks (including any longer term implications) if relevant, during their care stay, for example, leaflets on HAI, *Clostridium difficile*, norovirus.
- 3.5 Support and information about specific infection-related care issues and procedures are accessible to patients or their representatives from healthcare staff, including during visiting times.
- 3.6 All communication with patients or their representatives is recorded in their records and is used to inform the patient's care plan.
- 3.7 Staff communicate with a patient's representative, where cause of death is related to an HAI. This information is recorded in the patient's record.

- **3.8** Staff communicate with the infection prevention and control team
 - (a) for advice and information regarding specialist infection prevention and control risks for individual patients. This information is recorded in a patient's record and care plan.
 - (b) when an outbreak is suspected.
- 3.9 There is continuous quality improvement of all HAI communication systems and processes, making use of feedback such as patient survey data, complaints data, and staff survey data.
- **3.10** The organisation communicates and engages with the public on matters related to infection prevention and control, including reducing specific risks.

What does the standard mean for people receiving treatment or visiting a healthcare or social care setting?

People receiving treatment in, or visiting one or more care settings can expect effective communication:

- on infection-related risks and to be involved in care decisions taken to mitigate these risks, and
- between care providers resulting in a seamless continuity of care to mitigate any infection risks.

What does the standard mean for the organisation?

The organisation:

- has systems in place to enable effective, safe, person-centred communications throughout the patient journey
- will monitor data and take appropriate actions to learn and improve communications
- has effective communication to enable wider public health issues to be acted on,
 and
- responds to any feedback on communications issues.

What does the standard mean for the infection prevention and control team?

The infection prevention and control team supports the organisation to attain its communication standard by:

- the delivery of HAI education, to include risk assessment and communications
- working with colleagues to devise and implement communication documentation, and
- providing advice on the improvement of, wherever possible, tools used to optimise communication, which will enhance safe person-centred care.

What does the standard mean for staff?

Staff (where appropriate to their role):

- are aware of their responsibilities, in ensuring patients, or their representatives, receive effective communications to minimise infection risks.
- will effectively communicate with patients, or their representatives, regarding the mitigation of risks to themselves and other persons in the care settings.
- will be competent in communicating risks, to enable the provision of continuity of care, and to mitigate risks to other persons in the care settings.

Examples of evidence of achievement (*NOTE:* this list is not exhaustive.)

The **executive team** can:

i. describe organisational accountability and support for effective communication systems and processes.

The infection prevention and control team can:

- ii. demonstrate the provision of HAI information to healthcare teams, patients, their representatives and the public.
- iii. provide action plans to address any deficiencies.
- iv. demonstrate the regular review of guidelines to optimise communication systems and processes.

Staff can:

- v. confirm the infection prevention and control team lead (or equivalent) from whom specialist infection prevention and control advice can be sought, and how to contact them.
- vi. describe types of communications with patients, or their representatives and/or agencies to achieve continuity of care in relation to infection prevention and control.
- vii. describe systems and procedures to identify communication risks on admission, during treatment/patient stay and/or transfer.
- viii. explain how to access infection prevention and control resources, for example, leaflets.

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. Audits of internal communication, and action plans. (3.1, 3.8, 3.9, 3.10)
- 2. Availability of easy to understand standardised information on HAIs, in a format appropriate to the needs of patients, their representatives and staff. (3.4)
- 3. Completion of RIDDOR (Reporting of incidents, diseases and dangerous occurrences regulations) form, and notification to the Health and Safety Executive (3.2, 3.3)
- 4. Evidence of enquiries and responses to and from the infection prevention and control team. (3.5)
- 5. Examples of communications between different health and social care providers, detailing any infections (for example, discharge summaries to GPs, admission letters from care homes and ambulance care records). (3.1, 3.2, 3.3, 3.5)
- 6. Examples of patient records/care plans (anonymised) for communication between the patient or their representative and healthcare staff about HAIs (for example, the patient's MRSA status, cause of death) throughout an hospital episode. (3.4, 3.6, 3.7, 3.8, 3.10)
- 7. Media releases. (3.9)
- 8. Minutes, reports, patient feedback and evidence of actions updating communication issues. (3.1, 3.2, 3.3, 3.8, 3.9)
- 9. Sample patient (or representative) feedback. (3.3, 3.8, 3.9)
- 10. The organisation's communication strategy (particular to the general public). (3.8, 3.9)
- 11. Written information accessible in clinical areas for staff. (3.8)

Standard 4: HAI surveillance

Standard statement

The organisation has a surveillance system to ensure a rapid response to HAI.

Rationale

HAI surveillance is the ongoing and systematic collection, analysis and interpretation of data, relating to HAI, which is used to reduce the risk of infection and improve patient outcomes.

References: 4, 15, 21, 22, 23

Criteria

- The organisation has an annual surveillance programme that incorporates mandatory national and local surveillance of infections and alert organisms. This programme is developed by the infection prevention and control team and endorsed by the infection control committee.
- The IT systems used within the organisation are simple to use and support real-time surveillance and response.
- 4.3 Triggers have been incorporated into surveillance systems that allow prompt detection and response to any variance from the normal limits, including outbreak.
- The infection prevention and control team follow standard operating procedures that detail the response to surveillance triggers.
- 4.5 Surveillance outputs and interpreted data are communicated to the relevant healthcare teams, patients, their representatives and visitors in a format, appropriate to their needs.
- The infection prevention and control team review surveillance data and produce a report detailing both adverse incidents and areas of low incidence. The report should also recognise new, emerging or re-emerging infection-related risks.
 - There is clinical governance oversight for this report through the organisation's reporting structure, to chief executive and NHS board level (or equivalent).
- 4.7 The infection prevention and control team produces a summary annual report of the effectiveness of surveillance activity which considers modifications to further reduce infection risks.
- 4.8 Users of HAI surveillance systems undertake up-to-date training with training needs assessed, and are aligned to career and development frameworks appropriate to their role.

What does the standard mean for people receiving treatment or visiting a healthcare or social care setting?

 Patients, visitors and the public can expect to be cared for in an environment where the executive team, infection prevention and control team and clinical teams are effectively working together to monitor, minimise and manage infection risks.

What does the standard mean for the organisation?

 The organisation can demonstrate that surveillance systems are in place to detect, respond to and reduce infection-related incidents.

What does the standard mean for the infection prevention and control team?

The infection prevention and control team:

- will ensure the outputs from surveillance systems are reported in a clear and concise manner to the relevant healthcare teams.
- will use surveillance outputs to focus infection prevention and control team resources for improvement and risk reduction activity.

What does the standard mean for staff at the point of care?

- Staff are engaged in using surveillance data to drive improvement.
- Where surveillance data indicate there may be local infection-related issues, the clinical team engage with the infection prevention and control team to understand these issues and respond as necessary to reduce infection-related risks.

What does the standard mean for support services?

 Support services staff will have assurance that their working environment is controlled and safe, where the risk of them being exposed to infectious agents is minimised.

Examples of evidence of achievement (NOTE: this list is not exhaustive.)

The **executive team** can:

 describe organisational accountability and management processes for HAI surveillance.

Clinical leads can:

- ii. describe what surveillance activity takes place within their clinical area.
- iii. interpret surveillance data generated from their clinical area.
- iv. describe the procedures to be followed when a trigger has been identified.

The **infection prevention and control team** can (where appropriate to role):

v. articulate the reporting structure for risks identified.

- vi. describe the process for the development of action plans to address any deficiencies.
- vii. describe types of communications with healthcare teams, patients, their representatives and visitors in relation to surveillance data and outputs.

Staff can:

viii. confirm the infection prevention and control team lead (or equivalent) from whom specialist infection prevention and control advice can be sought, and how to contact them.

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. Action plans from trigger incidences. (4.2, 4.3, 4.4, 4.5)
- 2. Alert organisms surveillance data. (4.1, 4.6)
- 3. Alignment of roles to profession-specific competencies and frameworks (4.8)
- 4. An annual surveillance programme developed by the infection prevention and control team (based on identified risks and priorities) approved by the infection control committee, and agreed by the executive board. (4.1, 4.2, 4.4)
- 5. Availability of charts and/or graphs within staff and patient areas. (4.5)
- 6. HAI reporting template. (4.3, 4.5, 4.6)
- 7. Inclusion of training issues and needs in significant event analysis relevant to HAI surveillance. (4.8)
- 8. Minutes of meetings, for example, infection control committee, clinical governance committee. (4.1, 4.6. 4.7)
- 9. Standard operating procedures for trigger alerts. (4.3, 4.4)
- 10. Surveillance annual report. (4.7)

Standard 5: Antimicrobial stewardship

Standard statement

The organisation demonstrates effective antimicrobial stewardship.

Rationale

Antimicrobial stewardship, in the form of a co-ordinated programme, has been shown to reduce inappropriate antimicrobial use, improve patient outcomes and reduce adverse consequences of antimicrobial use including, antimicrobial resistance, toxicity and unnecessary costs.

References: 4, 12, 24, 25, 26, 27

Criteria

- 5.1 There is senior management support (chief executive, medical director, HAI executive lead) for the antimicrobial management team or equivalent.
- There is access to an antimicrobial management team, consisting of a minimum, a lead clinician, microbiologist and antimicrobial pharmacist, to support the development, communication, implementation and evaluation of antimicrobial stewardship.
- 5.3 There is continuous quality improvement of the organisation's antimicrobial stewardship through alignment with the work programmes of, for example, infection prevention and control team and antimicrobial management team, with consideration given to the work programmes of the public health, patient safety and clinical governance teams.
- The antimicrobial management team produces and updates, at least every two years, the antimicrobial policies. These include empirical prescribing, surgical prophylaxis, gentamicin / vancomycin, and controls to manage the use of restricted antimicrobials, aligned to the Scottish Antimicrobial Prescribing Group and Scottish Management of Antimicrobial resistance Action Plan (ScotMARAP2).
- 5.5 The antimicrobial management team's policies on antimicrobial stewardship are accessible to staff who prescribe, administer and supply antimicrobials.
- 5.6 The organisation readily communicates any changes in policy and guidance on antimicrobial practice to staff.

- 5.7 The antimicrobial management team monitors the quality of antimicrobial stewardship (including antimicrobial stewardship and antimicrobial resistant organisms), and unintended consequences, through an annual programme of audits and monitoring of antimicrobial consumption data. The intelligence is fed back to prescribers and lead clinicians and fed forward to the executive team, with an assessment of the risks and a summary of the actions being taken or planned.
- 5.8 The antimicrobial management team detects and responds to data which indicate poor antimicrobial stewardship with monitored action plans.
- 5.9 The antimicrobial management team has a planned programme of education on antimicrobial stewardship for all healthcare teams involved in the prescribing, supply and administering of antimicrobials.
- 5.10 The organisation provides information to the public, in a format appropriate to their needs, to raise awareness to the risks from unnecessary use of antibiotics and, to individuals receiving antimicrobials, about the need for antimicrobial course completion and instructions for use.

What does the standard mean for people receiving treatment or visiting a healthcare or social care setting?

Every patient will get the most appropriate antibiotic (type, dose, route and duration) in a timely fashion for their infection, according to local and national policy and/or guidelines:

- patients or their representatives are involved in discussions regarding the reason for antimicrobial treatment, the intended duration and any major potential adverse reactions
- for every patient receiving antimicrobial therapy: indication, duration or a review plan are documented in the patient's record according to local and national guidelines
- the need for parenteral antimicrobial treatment is reviewed daily, with a view to making decisions to continue, change or stop the administration route. This review and the rationale for the decision are documented in the patient's record
- staff demonstrate knowledge of local and national policies and guidance regarding antimicrobial prescribing that is relevant to their responsibilities and duties, and
- improvement plans are implemented if deficiencies in antimicrobial prescribing are highlighted by antimicrobial utilisation or prescribing indicator data review.

What does the standard mean for the organisation?

 The organisation is aware of the risks from poor antimicrobial stewardship and is assured that it has a programme in place to continuously improve antimicrobial stewardship and to detect and respond to data on poor prescribing and administration practices.

The organisation must ensure there are resources and processes in place to:

- provide executive leadership and governance for antimicrobial stewardship
- provide a clinical microbiology service to support antimicrobial stewardship
- provide expert advice on infection management and antimicrobial stewardship through an established antimicrobial management team
- support the antimicrobial management team to utilise national education resources on antimicrobial stewardship for the public
- provide an integrated approach to infection prevention, management and safety through team working, and
- ensure an annual work plan is implemented and its effectiveness measured.

What does the standard mean for the antimicrobial management team and the infection, prevention and control team?

- The antimicrobial management team is supported in its efforts to continuously improve antimicrobial stewardship by the executive team and clinical colleagues.
- The infection prevention and control team works in close collaboration with the antimicrobial management team and patient safety team.

What does the standard mean for staff at the point of care?

- All healthcare teams involved in the prescribing, supply and administering of antimicrobials are aware of the importance of, and their role in, optimising antimicrobial stewardship for the benefit of patients and the public, and can demonstrate this in practice.
- All healthcare teams involved in the prescribing, supply and administering of antimicrobials should be able to demonstrate knowledge of common infections, microbiology investigations required and their antimicrobial management following the local guidelines.
- Prescribing clinical staff will:
 - demonstrate basic competency in relation to prudent and safe antimicrobial prescribing for treatment and prophylaxis
 - know how to access local antibiotic policy and/or guidance
 - participate in data collection about antimicrobial prescribing and feedback data in relation to the quality of prescribing, and

- participate in education on prudent prescribing as part of their continuing professional development.

Examples of evidence of achievement (*NOTE:* this list is not exhaustive.)

The **executive team** can:

i. describe the organisational accountability and support for antimicrobial stewardship.

The **antimicrobial management team** (in partnership with the **infection prevention and control team**) can:

- ii. demonstrate that guideline reviews are completed every two years.
- iii. demonstrate regular antimicrobial stewardship audit and surveillance of antimicrobial use as per Scottish Antimicrobial Prescribing Group policy and guidance.
- iv. feedback data to all healthcare teams involved in the prescribing, supply and administering of antimicrobials and to the executive team.
- v. provide action plans to address any deficiencies.
- vi. demonstrate the provision of education to healthcare teams, patients, their representatives and public involved in the prescribing, supply and administering of antimicrobials.

Staff can:

- vii. demonstrate awareness of how to access advice from local experts on management of infection and use of antimicrobials.
- viii. demonstrate awareness of antimicrobial guidelines relevant to their roles and responsibilities and can access them.

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. Access to the *Clostridium difficile* infection decision aid developed in partnership between Scottish Antimicrobial Prescribing Group, the Care Inspectorate, Health Protection Scotland, NHS microbiology expertise in *Clostridium difficile* infection and Scottish care. (5.4, 5.5)
- 2. Access to the urinary tract infection decision aid for older people (developed in partnership between Scottish Antimicrobial Prescribing Group and the Care Inspectorate, Scottish Care and Health Protection Scotland). (5.4, 5.5)
- 3. Antimicrobial stewardship audits (including national Scottish Antimicrobial Prescribing Group required, local targeted and point prevalence), surveillance of antimicrobial use, reports and action plans. (5.7, 5.8, 5.10)
- 4. Antimicrobial stewardship policies are easily accessible and meet Scottish Antimicrobial Prescribing Group minimum requirements. (5.4, 5.5)

- 5. Evidence of communication of the above to staff at the point of care and the organisation's chief executive (or equivalent). (5.1, 5.6, 5.8, 5.10)
- 6. Information received by patients, their representatives and the public, both verbal and written on antimicrobials. This will be provided in a format appropriate to their needs. (5.10)
- 7. Membership, terms of reference, minutes, annual programme/plan of the antimicrobial management team. (5.2)
- 8. Planned programme of education and training records on antimicrobial stewardship for healthcare teams involved in the prescribing, supply and administration of antimicrobials. (5.3, 5.8, 5.10)
- 9. Review of individual treatment records to establish if the antimicrobial prescribed has indication documented, is compliant with local policy and all prescribed doses have been administered and appropriate documentation has been completed, as per local policy. (5.7, 5.8, 5.9)
- 10. Utilisation of national education resources on antimicrobial use for patients, their representatives and the public. (5.10)

Standard 6: Infection prevention and control policies, procedures and guidance

Standard statement

The organisation demonstrates implementation of evidence-based infection prevention and control measures.

Rationale

The minimum standard of infection prevention and control to be practiced by all staff, in all care settings, for all care procedures is the application of standard infection control precautions, as detailed in chapter one, of the *National Infection Prevention and Control Manual*.

Standard infection control precautions are the most effective means to prevent cross-transmission and cross-infection with micro-organisms in care settings.

References: 3, 4, 12, 19, 28, 29, 30, 31, 32

Criteria

- 6.1 The current version of the *National Infection Prevention and Control Manual* has been adopted by the organisation and is accessible by all staff.
- 6.2 Staff are supported by senior management and empowered to challenge colleagues who do not adhere to guidance set out in the *National Infection Prevention and Control Manual*.
- 6.3 There is a system in place to update staff on any changes in the content of the *National Infection Prevention and Control Manual*.
- The infection prevention and control team responds to any data which suggest that *National Infection Prevention and Control Manual* implementation may not be optimal.
- The organisation executes a systematic programme of audits, policies, procedures, including standard infection control precautions, and guidelines for all clinical areas and HAI-related infections. These will be reviewed, at least every two years, to assess compliance with the *National Infection Prevention and Control Manual* and to provide assurance for the organisation.
- 6.6 The organisation has a clinical microbiology service that provides best practice testing including laboratory processing and rapid diagnostics as available, and specialist clinical advice on individual patient treatment.

- Where there is an outbreak, incident or where patients have an infection or alert organisms have been identified
 - (a) an assessment is undertaken by staff, using a (hospital) infection incident assessment tool, and
 - (b) a care plan is actioned and reviewed following condition-specific guidance.
- Where audit data suggest actions are needed there is a procedure followed to ensure remedial action plans are implemented.
- Reports on all audits are **fed back to** clinical staff and **fed forward to** leadership teams and the executive team to provide assurance, drive improvement, and to communicate any residual risks.
- **6.10** When the agreed audit programme is not undertaken, this is communicated through the organisation's risk reporting system.
- **6.11** The healthcare team discusses and acts to improve *National Infection Prevention and Control Manual* compliance locally.

What does the standard mean for people receiving treatment or visiting a healthcare or social care setting?

 Every patient receives care in a safe place without unnecessary exposure to infection. Staff providing care demonstrate knowledge of infection prevention and control practices and provide appropriate information to patients, their representatives and visitors on how to prevent infection transmission.

What does the standard mean for the organisation?

The organisation is assured that infection risks are reduced through:

- availability of policies, procedures and guidance that support the application of safe care practices
- processes that assess adherence to the policies and procedures
- systems and resources being in place to enable a safe level of care to be practiced by staff for all patients and visitors
- effective systems to monitor, report and respond to implementation (process) and infection (outcome) data
- a culture which promotes the reporting of incidents and the improvement of care systems, and
- supporting the infection prevention and control team in its efforts to measure, identify and minimise risks through the monitoring and reporting of audit data.

What does the standard mean for the infection prevention and control team?

The infection prevention and control team:

- has a critical role in devising and reviewing systems that measure the implementation of policies, procedures and guidance based on the infection risks within individual clinical areas
- works in close collaboration with staff at the point of care and the patient safety team, and
- is able to demonstrate a process for developing or reviewing policies, procedures and guidance.

What does the standard mean for staff at the point of care?

Staff:

- are aware of relevant policies, procedures and guidance and are able to evidence the provision of a safe level of care in minimising infection risks, and
- know how to respond if they have insufficient resources or support to minimise infection risks.

What does the standard mean for support services?

 Support services staff are aware of their role and responsibilities in the prevention and control of infection, are competent to carry out this role.

Examples of evidence of achievement (NOTE: this list is not exhaustive.)

The **executive team** can:

i. describe organisational accountability and support for infection prevention and control.

The infection prevention and control team can:

- ii. demonstrate feedback of data to clinical teams at the point of care and to the organisation's executive team.
- iii. provide action plans to address any deficiencies.
- iv. demonstrate the provision of education, information and awareness raising sessions to healthcare teams, patients, their representatives and public.

Staff can:

- v. demonstrate in their daily practice the application of the *National Infection Prevention and Control Manual* for all patient contacts in the care setting.
- vi. explain how to access infection control policies, procedures and guidance.

- vii. discuss their role in the prevention and control of infection (for example, recognising unsafe activities, intervening when breaches in infection control are identified).
- viii. describe practice changes (for example, any altered standard of care).
- ix. articulate the process of reporting incidents and infection risks.

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. Audit of microbiology services. (6.6)
- 2. Completed rapid event investigations into hospital healthcare acquired infections, for example, *Staphylococcus aureus bacteraemias*. (6.2, 6.6, 6.7)
- 3. Education programme and training records on infection prevention and control. (6.2, 6.3)
- 4. Environmental and equipment cleaning schedules. (6.5, 6.9)
- 5. Infection control annual programme and annual report of infection prevention and control. (6.3, 6.5, 6.9)
- 6. Memberships, terms of reference, minutes of the infection control committee. (6.1, 6.3, 6.5)
- 7. National Infection Prevention and Control Manual implementation and compliance audits, and improvement and action plans. (6.1, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 6.10, 6.11)
- 8. Provide examples of (anonymised) condition-specific care plans following an outbreak or incident. (6.7)

Standard 7: Insertion and maintenance of invasive devices

Standard statement

Systems and processes are in place to ensure the safe and effective use of invasive devices, for example, peripheral venous catheters, central venous catheters and urinary catheters.

Rationale

Invasive devices present a significant infection risk to patients. These risks can be minimised by:

- avoidance of device use where possible
- following evidence-based procedures for insertion and maintenance, and
- removing the device as soon as there is a clinical indication to do so.

References: 3, 4, 8, 33

Criteria

- **7.1** Staff are aware of the infection risks associated with invasive device use and, where appropriate, use non-invasive alternatives.
- 7.2 Staff inform patients, or their representatives, of risks associated with invasive device use and involve patients and representatives in the decision-making process and, where relevant, the care and monitoring of device use.
- **7.3** Staff follow key practice recommendations on how and when invasive devices are to be used, maintained, monitored and removed.
- **7.4** Staff have access to an appropriate selection of invasive devices enabling them to provide the safest device options for their patients.
- **7.5** Staff document:
 - (a) the decision-making for invasive device use
 - (b) specifics of the insertion procedure
 - (c) observations and maintenance of the device, and
 - (d) planning for removal.
- **7.6** Staff are supported by senior management and empowered to challenge colleagues who do not follow best practice on the use of invasive devices.
- 7.7 Staff respond to data that indicate the presence of infection risks with a commitment to improvement through investigations, actions and peer support.

- 7.8 Local clinical teams are supported to optimise their practice by the use of improvement and surveillance data, provision of training, accessibility to guidance and investigations into any device-related bloodstream infections.
- **7.9** Governance processes ensure the executive team and management explicitly consider infection risks associated with invasive device use and of any significant issues related to local or organisation-wide use of invasive devices.
- **7.10** The organisation has a planned programme of education for all healthcare teams involved in the insertion and maintenance of invasive devices.

What does the standard mean for people receiving treatment or visiting a healthcare or social care setting?

- Every individual with an invasive device is reassured that the staff in the clinical area are competent and committed to providing the safest possible decision-making and care, and display data showing evidence of that commitment.
- If a patient has an invasive device in situ, insertion and maintenance are clearly documented in the patient's record and includes date of insertion and reason for insertion.
- The patient, or their representative, understands the need for the device and how to care for it.

What does the standard mean for the organisation?

The organisation:

- is able to demonstrate the safety of the systems that enable staff to minimise infection risks from invasive device use, and detect and respond to device-related incidents.
- evidences, through governance processes, the organisational culture of continuous improvement to optimise care, by reporting errors and incidents.

What does the standard mean for the infection prevention and control team?

Infection prevention and control teams:

- are able to demonstrate how effectively they support clinical teams, for example, through direct engagement on invasive device use, the provision of training, guidance, data and practice audits.
- are able to provide, through governance processes, the executive board with assessments of the effectiveness and safety of device use, reports on invasive device incidents and recommendations to reduce risks.

What does the standard mean for staff at the point of care?

Staff:

 will be supported to practice safely and minimise infection risks through the availably of resources, guidance, data and training and a culture committed to optimising patient care related to device use.

- will show commitment to the safe use of devices by compliance with procedures, maintenance of personal skills, provision of peer support to colleagues, response to data and reporting of any identified device-related issues.
- are aware that patients with invasive devices are vulnerable to infection and escalate to senior colleagues if they have any concerns.

Examples of evidence of achievement (NOTE: this list is not exhaustive.)

The **executive team** can:

i. describe organisational accountability and support for the procurement and management of invasive devices.

The infection prevention and control team can:

- ii. demonstrate the support provided to clinical teams for the management of invasive devices.
- iii. provide feedback data to the organisational executive on the management of invasive devices, including recommendations where risks have been identified.

Staff can:

- iv. explain how to access procedures and guidance for the insertion and maintenance of invasive devices.
- v. articulate the key elements of improvement tools, for example, care bundles relevant to their care area.
- vi. discuss their role in the prevention and control of infection related to invasive devices (for example, recognising unsafe activities, intervening when breaches in infection control are identified).

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. Compliance monitoring and improvement plans relating to invasive devices. (7.5, 7.6, 7.7, 7.8, 7.9)
- 2. Patient documentation is used for invasive device management. (7.4)
- 3. Patients know their invasive device is checked every day with patient (or their representative's) feedback sought. (7.2, 7.4, 7.5)
- 4. Quality improvement data are used to improve patient outcomes, for example, root cause analysis, care bundles. (7.5, 7.7, 7.8, 7.9)
- 5. Staff can describe and apply the principles of asepsis. (7.1, 7.3, 7.10)
- 6. Surveillance and audit data which demonstrates monitoring of practice to improve patient outcomes. (7.5, 7.7, 7.8, 7.9)

Standard 8: Decontamination

Standard statement

The environment and equipment (including reusable medical devices used) are clean, maintained and safe for use. Infection risks associated with the built environment are minimised.

Rationale

Effective decontamination is critical in the provision of a safe, clean environment and equipment. The built environment must be designed, planned, constructed, refurbished and maintained to minimise the risk of infection.

This standard covers the decontamination, management and maintenance of:

- reusable communal patient care equipment
- reusable medical devices, and
- the built environment.

References: 3, 4, 12, 17, 29, 30, 31, 34, 35, 36, 37, 38

Criteria

- **8.1** The organisation provides equipment and an environment that is safe and clean, minimising the risk of cross-infection.
- **8.2** The organisation has, and implements, decontamination policies, records and procedures in line with relevant national guidance and legislation.
- 8.3 There is continuous quality improvement and assurance in place to monitor and ensure the environment and equipment (including reusable medical devices) is clean and safe.
- 8.4 There are robust reporting and escalation procedures in place to deal with any identified issues regarding cleanliness and maintenance of equipment (including reusable medical devices) and the built environment.
- 8.5 Specialist infection prevention and control advice is sought and adhered to when additional cleaning or decontamination activity is identified as necessary, or existing activity is assessed as sub-standard.
- 8.6 Equipment (including reusable medical devices) and environmental cleanliness is assessed during and following an outbreak or incident. Findings are shared within the organisation and with external partners.
- 8.7 In an incident or outbreak involving reusable medical devices, all relevant stages of the decontamination process are assessed and reviewed. Findings are shared within the organisation and with external partners.

- 8.8 When audits or data (including patient, visitor and staff feedback) identify deficiencies in cleanliness or adherence to cleaning specifications, infection prevention and control teams liaise directly and promptly with relevant services, remedial action is taken, and unaddressed issues are escalated within the organisation.
- 8.9 The organisation actively seeks feedback from patients, staff and visitors for their view on the cleanliness of the care environment and equipment (including reusable medical devices).
- **8.10** The decontamination of reusable medical devices complies with relevant technical requirements.
- **8.11** The organisation carries out regular risk assessment and takes action if any part of the decontamination procedure cannot, or has not, been followed, or a near miss, failure or non conformance has been detected.
- **8.12** Where there is a decontamination-related incident or outbreak, an assessment is undertaken using a (hospital) infection incident assessment tool.

What does the standard mean for people receiving treatment or visiting a healthcare or social care setting?

 People using the services have confidence that they are being cared for in a clean, safe care environment and that all equipment (including reusable medical devices) used will be clean and free from contamination.

What does the standard mean for the organisation?

 The organisation has a quality assurance system in place which demonstrates the provision of a safe and clean environment and equipment (including reusable medical devices).

What does the standard mean for the infection prevention and control team?

The infection prevention and control team:

- support quality improvement to provide assurance of environment and equipment (including reusable medical devices) decontamination.
- is involved in all incident outbreaks relating to decontamination failure and proactively responds to reduce the risk of recurrence.

What does the standard mean for staff?

Staff (where appropriate to their role):

- are assured that there are effective systems in place to provide them with a safe environment and equipment (including reusable medical devices).
- have an understanding of their individual roles and responsibilities in the provision of a safe, clean environment and equipment (including reusable medical devices).

Examples of evidence of achievement (*NOTE*: this list is not exhaustive.)

The executive team can:

 i. describe organisational accountability for the decontamination, management and maintenance of the environment and equipment (including reusable medical devices).

The infection prevention and control team can:

- ii. articulate the expertise and support provided to staff at the point of care for the delivery of effective environment and equipment (including reusable medical devices) decontamination, and
- iii. provide feedback data to the organisational executive on decontamination, including recommendations where deficiencies have been identified.

Staff can:

iv. articulate their own roles and responsibilities relating to decontamination, equipment (including reusable medical devices) and environmental cleanliness.

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. A-Z of communal reusable patient equipment. (8.1, 8.3)
- 2. Bed space checklists. (8.1)
- 3. Completed and signed cleaning schedules and exception reports. (8.1, 8.2, 8.3, 8.4)
- 4. Discharge checklists. (8.1)
- 5. Education and training records. (All standard 8 criteria)
- 6. Environment and equipment is clean. (8.1, 8.2, 8.3, 8.4, 8.5, 8.6, 8.8, 8.9, 8.10, 8.11)
- 7. Evidence of compliance with National Cleaning Services Specification (or its revisions). (8.1, 8.2, 8.3, 8.4)
- 8. Evidence of the management of estates issues. (8.4)
- 9. Evidence that HAI system for controlling risk in the built environment is in place and used as an active document, with involvement of all relevant staff as appropriate. (8.2, 8.4, 8.6)
- 10. Evidence that estates staff and contractors are aware of, and use, the HAI system for controlling risk in the built environment process when planning repairs, refurbishments and new builds. (8.11, 8.12)
- 11. Individual written responses to complaints. (8.8, 8.9)
- 12. Local audits undertaken by staff (including: clinical, estates, domestic, infection prevention and control). (8.1, 8.2, 8.3, 8.4, 8.8)

- 13. Patient feedback reports. (8.8, 8.9)
- 14. Senior charge nurse weekly assurance checklists. (8.1, 8.2, 8.3)
- 15. The following audits for reusable medical devices (8.1, 8.2, 8.3, 8.4, 8.7, 8.8, 8.10):
 - surgical instruments compliant decontamination unit notified body audits
 - endoscopes endoscope decontamination unit Joint Advisory Group / Endoscopy Raising Standards and Effectiveness Programmme audits
 - dental instruments local decontamination unit board practice inspections, and
 - podiatry instruments local decontamination unit audit reports.

Standard 9: Acquisition of equipment

Standard statement

All equipment acquired (this being equipment that is procured, loaned, donated, inhouse manufactured, or for use within a trial or research) for the care environment is safe for use.

Rationale

The infection risk to patients is minimised by having an acquisition process in place that ensures all equipment (including reusable medical devices) is safe for its intended use. Safety refers to minimising the risk of transmission of infection.

References: 38, 39, 40, 41, 42

Criteria

- 9.1 The organisation has, and implements, policies and procedures for the acquisition of equipment (including reusable medical devices), in line with current national guidance and legislation, whilst recognising existing and emerging technologies.
- **9.2** All acquired reusable equipment (including reusable medical devices) is decontaminated in line with manufacturer's instructions and current national guidance.
- 9.3 All incidents and near misses associated with equipment (including reusable medical devices) are reported to the incident reporting investigation centre (or equivalent).
- 9.4 The infection prevention and control team and other key individuals are involved in all procurement decisions for new equipment (including reusable medical devices) prior to purchase.

What does the standard mean for people receiving treatment or visiting a healthcare and social care setting?

 Individuals will be confident that all medical devices and communal patient equipment (including reusable medical devices) being used by staff and/or in the healthcare and social care setting, meet the required level of safety, quality and performance.

What does the standard mean for the organisation?

The organisation has a quality assurance system in place which demonstrates
effective and efficient procurement of medical devices and communal patient
equipment (including reusable medical devices) that are safe for use.

What does the standard mean for the infection prevention and control team?

 The infection prevention and control team will be involved in all matters of procurement which impact on infection prevention and control.

What does the standard mean for staff at the point of care?

 Staff have confidence in the safety, performance and quality of medical devices and communal patient equipment (including reusable medical devices).

What does the standard mean for support services?

 Support services staff can demonstrate competency in the application of policies and procedures, within their role and responsibility, in relation to the procurement of equipment and medical devices.

Examples of evidence of achievement (NOTE: this list is not exhaustive.)

The **executive team** can:

 describe organisational accountability and management for the procurement process for equipment (including reusable medical devices) impacting on infection prevention and control.

The infection prevention and control team can:

- ii. describe their involvement in the procurement process for equipment (including reusable medical devices), and
- iii. articulate the reporting procedure to the organisational executive on the management of equipment (including reusable medical devices), including recommendations where risks have been identified.

Staff are:

- iv. aware of the procurement process for equipment impacting on infection prevention and control, and
- v. able to describe the procedure for reporting non-compatible equipment (including reusable medical devices).

Practical examples (The numbers shown in brackets correspond to relevant criterion/a)

- 1. Evidence of assessment of compatibility of all equipment which impacts on infection prevention and control with existing decontamination processes. (9.2)
- 2. Evidence of implementation of procurement policy. (9.1)
- 3. Evidence of incidence reporting. (9.1, 9.2)
- 4. Evidence of involvement of relevant staff in the procurement process. (9.1, 9.4)
- 5. Evidence of the implementation of a 'loan' policy. (9.1)
- 6. Procurement policy, procedures and records related to the acquisition of equipment which impacts on infection prevention and control. (9.1, 9.2, 9.3, 9.4)

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Appendix 1 Membership of the standards for HAI short-life working group

Name	Position	Organisation	Sub-group
Hazel Borland	Executive Nurse Director	NHS Dumfries & Galloway	Leadership, governance and accountability
Susan Brimelow	Chief Inspector	Healthcare Improvement Scotland / Healthcare Environment Inspectorate	
Alison Cockburn	Lead Antimicrobial Pharmacist	NHS Lothian	Infection prevention and control
Abigail Cork	Facilities Support Manager	Health Facilities Scotland	Decontamination / Acquisition of equipment
Evonne Curran	Nurse Consultant Infection Control	Health Protection Scotland	Communication
Lesley Davis	Regional Manager	Truvox International	Decontamination / Acquisition of equipment
Liz Dillon	Director of Nursing	Ross Hall Hospital / Scottish Independent Healthcare Advisory Service (until June 2014)	
Rose Gallagher	Nurse Advisor Infection Prevention Control	Royal College of Nursing	Leadership, governance and accountability
Pamela Harrison	Infection Control Manager	NHS Grampian	Leadership, governance and accountability
Sulisti Holmes	Head of Decontamination Services	Health Facilities Scotland	Decontamination / Acquisition of equipment
Jonathan Horwood	Infection Control Manager	NHS Forth Valley (until June 2014)	Communication
Ellen Hudson	Associate	Royal College of Nursing	

Name	Position	Organisation	Sub-group
	Director	Scotland	
Laura Imrie	Nurse Consultant Infection Control	Health Protection Scotland / Scottish Surveillance of HAI Programme	Surveillance
Pamela Joannidis	Nurse Consultant Infection Prevention and Control	NHS Greater Glasgow and Clyde	Decontamination / Acquisition of equipment
Paul Kelly	Clinical Governance Manager	Scottish Ambulance Service	Communication
Pia Kirkpatrick	Infection Control Nurse	Ross Hall Hospital / Scottish Independent Healthcare Advisory Service	
Al Leanord	Medical Advisor	Scottish Government	Surveillance
Penny Leggat	Public Partner	Healthcare Improvement Scotland	
Helen Macguire	Patient Representative	Healthcare Improvement Scotland	Communication
Annette McCafferty	Domestic Manager	NHS Greater Glasgow and Clyde	Decontamination / Acquisition of equipment
Alastair McGown	Senior Inspector	Healthcare Improvement Scotland / Healthcare Environment Inspectorate	Decontamination / Acquisition of equipment
Willie McGregor	Senior Charge Nurse	NHS Lothian	Education
Margaret McGuire (Chair)	Nurse Director	NHS Tayside	
lain McInally	Head of Estates	NHS Ayrshire & Arran	Decontamination / Acquisition of equipment

Name	Position	Organisation	Sub-group
Daniel McQueen	Public Partner	Healthcare Improvement Scotland (until July 2014)	Surveillance
Wilma Morgan	Inspector Manager	Care Inspectorate	Communication
Keith Morris	Consultant Microbiologist and Infection Control Doctor	NHS Fife	Infection prevention and control
Abigail Mullings	HAI Professional Advisor	Scottish Government	Surveillance
Geraldine O'Brien	Research Manager	Health Facilities Scotland	Decontamination / Acquisition of equipment
Ann Paterson	Infection Control Manager	Scottish National Blood Transfusion Service	Infection prevention and control
Kathryn Paterson	Associate Improvement Advisor	Healthcare Improvement Scotland / Scottish Patient Safety Programme (until December 2014)	Infection prevention and control
Christine Peters	Consultant Microbiologist	NHS Ayrshire & Arran	Surveillance
Annette Rankin	Nurse Consultant Infection Control	Health Protection Scotland	Decontamination / Acquisition of equipment
Lisa Ritchie	Nurse Consultant Infection Control	Health Protection Scotland	Infection prevention and control
Susan Roberts	Project Lead	Healthcare Improvement Scotland / Scottish Antimicrobial Prescribing Group	Infection prevention and control
Evelyn Rodger	Director of Nursing and Midwifery	NHS Borders	

Name	Position	Organisation	Sub-group
Janice Rollo	Clinical Governance Co- ordinator	NHS Grampian	Decontamination / Acquisition of equipment
Jacqueline Sneddon	Project Lead	Healthcare Improvement Scotland / Scottish Antimicrobial Prescribing Group	
Margaret Tannahill	Consultant Nurse Infection Control	Care Inspectorate	Education
Gill Walker	Programme Director	NHS Education for Scotland	Education
Tom Walsh	Infection Control Manager	NHS Greater Glasgow and Clyde	Leadership, governance and accountability
Sam Whiting	Infection Control Manager	NHS Borders	
Susan Wilson	Infection Control Manager	Scottish Ambulance Service	Infection prevention and control
Adam Wood	Senior Infection Control Nurse	NHS Borders	Education
Christine Young	Infection Control Nurse Advisor	NHS Education for Scotland	Education
Liz Young	Surveillance Nurse	NHS Lanarkshire	Surveillance



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The Healthcare Environment Inspectorate, the Scottish Health Council, the Scottish Health Technologies Group, the Scottish Intercollegiate Guidelines Network (SIGN) and the Scottish Medicines Consortium are part of our organisation.









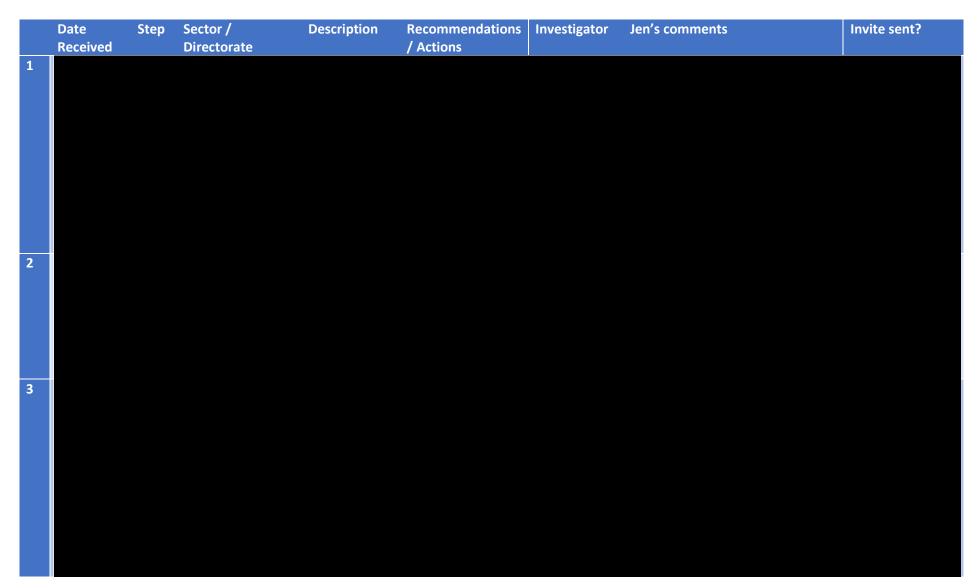


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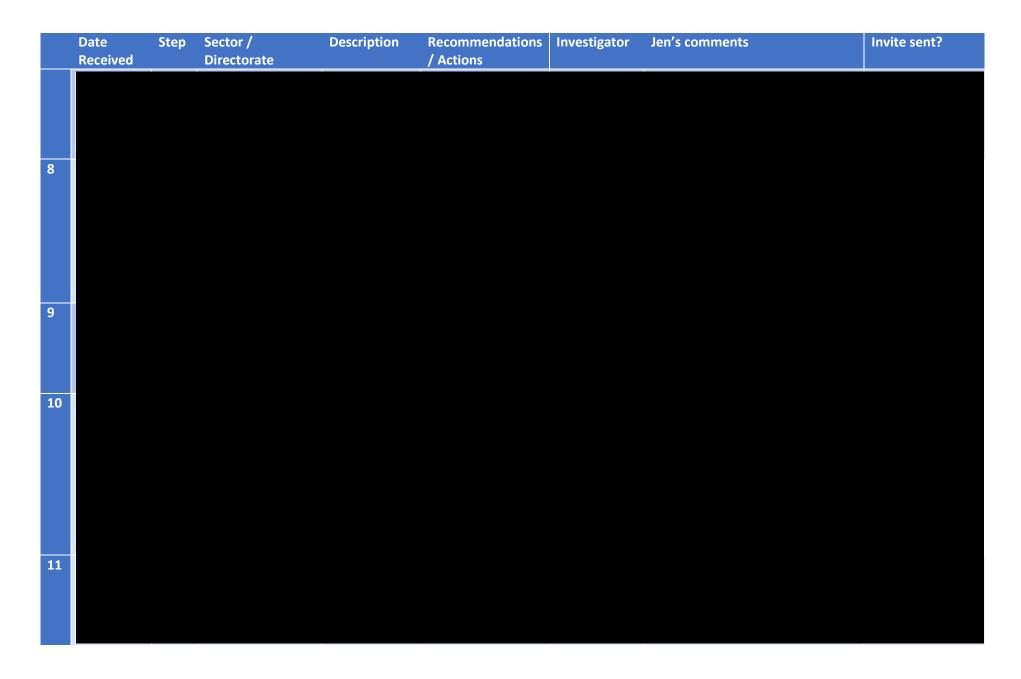
Greater Glasgow and Clyde	NHS Greater Glasgow & Clyde Infection Prevention and Control Team
Purpose:	Problem Assessment Group (PAG)
From:	Infection Prevention and Control Team
То:	Clinical SMT and IPC SMT
Date:	19/02/18
Subject / Situation:	Cupriavadis isolated from blood culture of 2 inpatients on ward 2A.
Background:	Back in Feb 2016, a patient tested positive for Cupriavadis in a blood culture and subsequent investigations found that had had TPN administered which was reconstituted in the Aseptic pharmacy. Samples taken from water outlets in the aseptic pharmacy also isolated Cupriavadis and typing of both isolates were found to be the same ().
	A 2 nd patient case was identified in September 2017 and at that time, no links were made to the previous case or the aseptic pharmacy. More recent investigations found that this patient did in fact have chemotherapy which came from the aseptic pharmacy () and was nursed on ward 2A.
	In January this year, a 3 rd case was identified who also has had IV chemotherapy reconstituted in the aseptic pharmacy () and was an inpatient on ward 2A.
	Initial investigations focused on the Aseptic pharmacy. To date, practice in the aseptic pharmacy has been found to be satisfactory and water testing has been negative. A walk round of the unit was carried out by Susie Dodd and Dr Inkster accompanied by Joanne Gallagher, Aseptic Accountable pharmacist – no concerns identified.
	As a result, water outlets in ward 2A were sampled to establish if there was any contamination of the water/outlets. Cupriavadis has been isolated from the treatment room and the prep room (clean utility) on ward 2A.
Discussed with / Communications:	Dr Teresa Inkster – Lead Infection Prevention and Control Doctor Susie Dodd (SD) – Lead Infection Prevention and Control Nurse Emma Somerville – Senior Charge Nurse, ward 2A.
Recommendation / Options:	The contaminated sinks are being dosed by DMA and will be re-sampled later today. Sinks out of use until dosing and re-sampling complete. Staff to use hand wash basin in pharmacy room meantime.

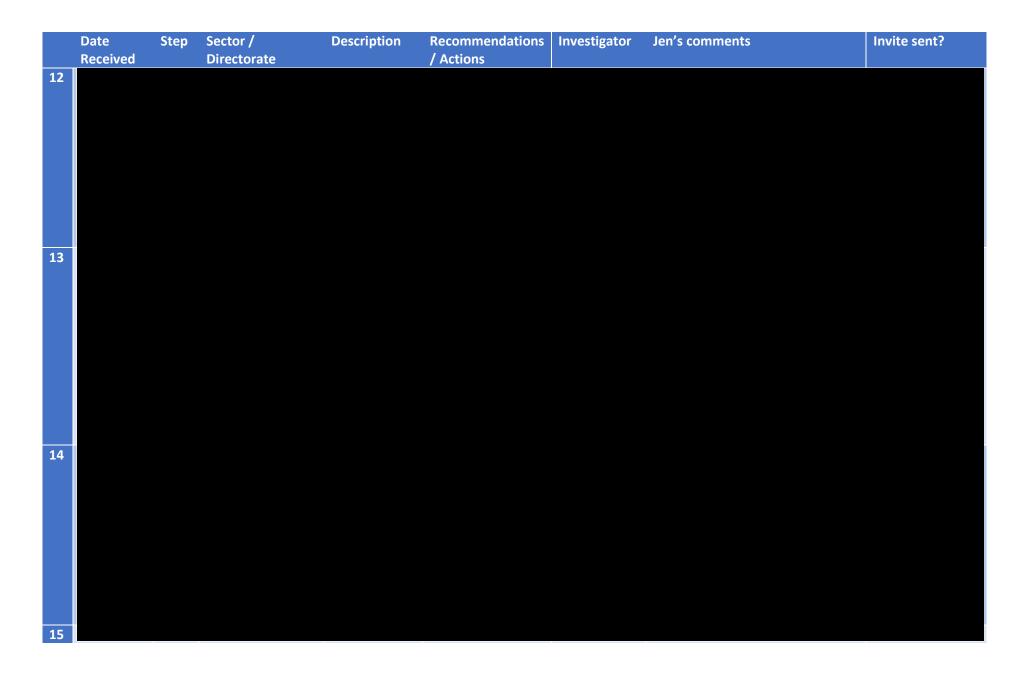
	More extensive sampling of the water outlets to be carried out. SD has provided estates with the room numbers occupied by the 2 affected patients. The sinks and the showers will be sampled in the following rooms;
	Room 2 Room 6 Room 14 Room 26
	ES will highlight hand hygiene at safety brief for all staff. Staff to ensure that trays/trolleys used for ANTT are not within splashing distance of the sink. Estates have sampled the RHC water tanks to investigate for more widespread contamination of water outlets – results awaited.
HIIAT	Severity of Illness – Moderate (case 2 and 3 required antimicrobials but are now well in respect to Cupriavadis) Impact on services – Minor
	Risk of Transmission - Minor Public anxiety – Minor Over all HIIAT – GREEN
IPCT Members:	Dr Teresa Inkster – Lead Infection Prevention and Control Doctor Susie Dodd (SD) – Lead Infection Prevention and Control Nurse

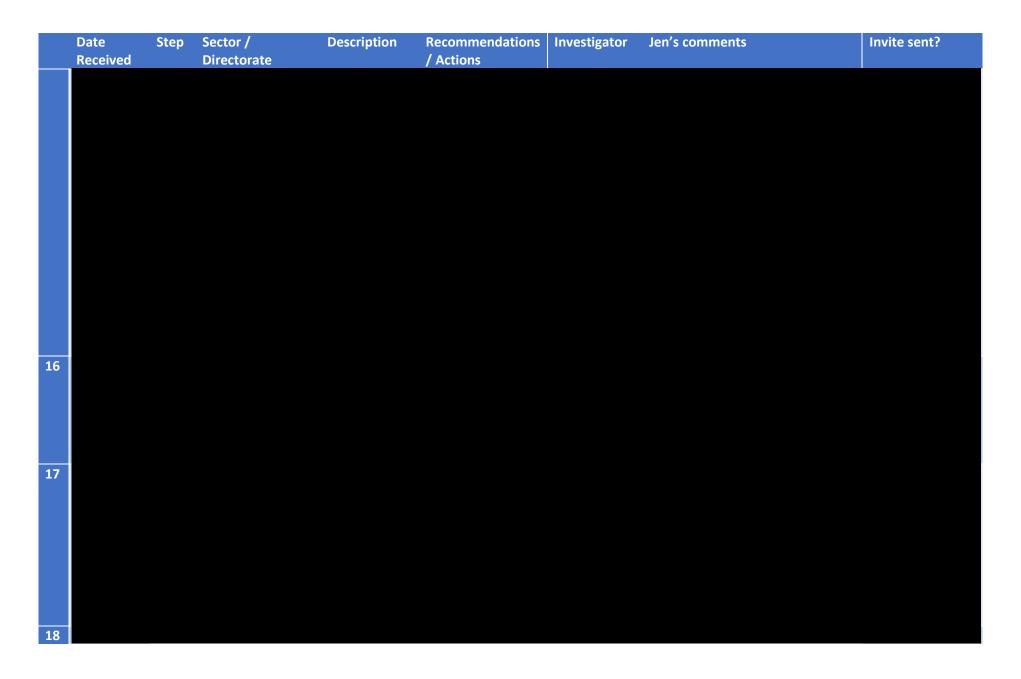
Whistleblowing Cases in NHS Greater Glasgow and Clyde 1 April 2017 – 31 March 2020



	Date Received	Step	Sector / Directorate	Description	Recommendations / Actions	Investigator	Jen's comments	Invite sent?
4								
5	15 December 2017	Step 3	Neurovascular – Diagnostics	Concerns about governance, culture and a conflict of interest	Yes	Rona Sweeney (Non Exec Director)	Named whistleblower This came in pre me working in whistleblowing, but was concluded when I had started working there. The whistleblower was quite anxious about it, which is why they requested it be handled as a Stage 3, which it	
6							was.	
7								







19	Date Received	Step	Sector / Directorate	Description	Recommendations / Actions	Investigator	Jen's comments	Invite sent?
20	21 August 2019	Step 2	Infection control	Processes and patient safety	Yes	Linda de Caestecker, supported by Barbara Anne Nelson (Director of Workforce in NHS Fife)	Declared interest	
21								
23	21 November 2019	Step 3	Infection control	Patient safety	Yes	Ian Ritchie (Non Exec Director) supported by William	Declared interest	

Date	Step	Sector /	Description	Recommendations	Investigator	Jen's comments	Invite sent?
Received		Directorate		/ Actions			
					Edwards		

Investigating hospital *Mycobacterium chelonae* infection using whole genome sequencing and hybrid assembly

Christopher H. Gu , Chunyu Zhao , Casey Hofstaedter, Pablo Tebas, Laurel Glaser, Robert Baldassano, Kyle Bittinger , Lisa M. Mattei , Frederic D. Bushman

Published: November 9, 2020 • https://doi.org/10.1371/journal.pone.0236533

See the preprint

Abstract

Mycobacterium chelonae is a rapidly growing nontuberculous mycobacterium that is a common cause of nosocomial infections. Here we describe investigation of a possible nosocomial transmission of *M. chelonae* at the Hospital of the University of Pennsylvania (HUP). *M. chelonae* strains with similar high-level antibiotic resistance patterns were isolated from two patients who developed post-operative infections at HUP in 2017, suggesting a possible point source infection. The isolates, along with other clinical isolates from other patients, were sequenced using the Illumina and Oxford Nanopore technologies. The resulting short and long reads were hybrid assembled into draft genomes. The genomes were compared by quantifying single nucleotide variants in the core genome and assessed using a control dataset to quantify error rates in comparisons of identical genomes. We show that all *M. chelonae* isolates tested were highly dissimilar, as indicated by high pairwise SNV values, consistent with environmental acquisition and not a nosocomial point source. Our control dataset determined a threshold for evaluating identity between strains while controlling for sequencing error. Finally, antibiotic resistance genes were predicted for our isolates, and several single nucleotide variants were identified that have the potential to modulated drug resistance.

Citation: Gu CH, Zhao C, Hofstaedter C, Tebas P, Glaser L, Baldassano R, et al. (2020) Investigating hospital *Mycobacterium chelonae* infection using whole genome sequencing and hybrid assembly. PLoS ONE 15(11): e0236533. https://doi.org/10.1371/journal.pone.0236533

Editor: Herman Tse, Hong Kong Children's Hospital, HONG KONG

Received: July 3, 2020; Accepted: October 20, 2020; Published: November 9, 2020

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Data Availability: Nanoflow is available at www.github.com/zhaoc1/nanoflow while all other computer code used in this study is available at www.github.com/chrgu. M. chelonae and V. campbellii assembled genomes available at GenBank under project PRJNA594977.

Funding: This work was supported by the Penn Center for AIDS Research P30 AI 045008 (https://www.med.upenn.edu/cfar) under FDB; and the PennCHOP Microbiome Program (https://pennchopmicrobiome.chop.edu). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: The authors have declared that no competing interests exist.

Introduction

Mycobacterium chelonae, a rapidly growing nontuberculous mycobacterium (NTM), is ubiquitous in the environment and is a common source of opportunistic infection in humans. *M. chelonae* has caused several outbreaks from single point sources, but no human-to-human transmission has been observed to date [1–6]. *M. chelonae* is most commonly associated with nosocomial soft tissue infections of the skin and eye, but can also cause catheter-associated infections, disseminated and invasive infections, and pulmonary infections [1]. *Mycobacterium* can be highly resistant to many antibiotics because of their naturally impermeable cell walls as well as mutation of bacterial genes that encode antibiotic targets [7–9].

Among the *M. chelonae* isolates collected in 2017 from the Hospital of the University of Pennsylvania (HUP) clinical microbiology laboratory were two isolates from female patients who underwent surgery within the same year and developed post-operative surgical site infections in breast tissue. Culture of the inflammatory lesions yielded *M. chelonae* isolates with similar drug resistance patterns, raising suspicion of a nosocomial point source infection. To investigate this possibility, we performed whole genome sequencing on every *M. chelonae* isolate collected by the HUP clinical microbiology laboratory over a one-year period (n = 7) and examined differences in the single nucleotide variants (SNVs) of each isolate's core genome. As a control, we created a dataset

from a single *Vibrio campbellii* strain that was sequenced 39 times independently, allowing us to determine a threshold of SNVs that would distinguish different strains while controlling for sequencing error. Finally, we investigated genes and SNVs related to drug resistance in each isolate.

Methods

Samples were collected as part of routine clinical practice. Penn IRB approved collection of human samples by the clinical Microbiology Laboratory at the Hospital of the University of Pennsylvania under the IRB protocol #829497. Patients had written consent from their providers. The IRB protocol also included a waiver of consent. Respiratory samples were decontaminated with NaOH and N-acetylcysteine. Tissue specimens were pulverized in a tissue grinder. Prepared specimens were inoculated on 7H11 selective and non-selective solid media and a Mycobacterial Growth Indicator Tube (MGIT) broth. All cultures were incubated at 35–37°C for 6 weeks. Positive cultures for *Mycobacterium* were identified at the species level using hsp65 gene sequencing with primers TB11 (ACCAACGATGGTGTGTCCAT) and TB12 (CTTGTCGAACCGCATACCCT) [10]. Susceptibility testing and MIC determination were performed using the RAPMYCO microbroth dilution plate (ThermoFisher, catalog number RAPMYCO) and susceptibility was determined using the CLSI M24-A2 [11]. Tigecycline susceptibility breakpoints for the MIC have not been established for *Mycobacterium* [12]. For our analysis, we based our tigecycline thresholds for resistance of ≤0.25 on the methods in Wallace et al. [13]. For antibiotic resistance gene investigation, we categorized susceptibility into susceptible, intermediate, and resistant.

All *Mycobacterium* samples had been previously frozen for routine clinical purposes. Isolates were re-isolated on chocolate agar and propagated by growth in Middlebrook 7H9 media for 5 days. Multiple DNA purification methods were compared to identify one producing high molecular weight DNA in good yield. Ultimately, DNA was purified from each sample using a phenol-chloroform DNA extraction designed for high molecular weight DNA [14]. Long-read libraries were prepared using the Rapid Barcoding Kit, version SQK-RBK004 (Oxford Nanopore, Oxford, UK) and sequenced on the MinION using a R9.4.1 flow cell. Short-read libraries were prepared using the TruSeq DNA Nano Library Prep Kit (Illumina, San Diego, CA), and sequenced on the HiSeq 2500 using 2x125 bp chemistry.

V. campbellii was grown in Difco Marine broth 2216 culture media (BD) overnight and DNA was extracted using DNeasy Blood & Tissue Kits (Qiagen). Short read libraries were prepared using the Nextera XT Library Prep Kit (Illumina, San Diego, CA) and sequenced on the HiSeq 2500 using 2x125bp chemistry.

We used the Sunbeam v1.3 [15] pipeline to process the short reads and a custom snakemake v.5.6.0 pipeline, Nanoflow (https://github.com/zhoac1/nanoflow), to process the long reads and perform the hybrid assembly. Short read processing included trimming adapters off reads using Trimmomatic (parameters: leading: 3; slidingwindow: [4, 15]; minlen:36), filtering out low quality reads using fastqc and removing low complexity reads using Komplexity (parameters: kz_threshold: 0.55) [15]. Long read processing included base calling using Albacore v2.3.4 (https://community.nanoporetech.com), trimming adaptors using Porechop v0.2.3_seqan2.1.1 (https://github.com/rrwick/Porechop), and filtering using Filtlong v0.2.0 (parameters:—min_length

1000—keep_percent 90—target_bases 1000000000) (https://github.com/rrwick/Filtlong). Hybrid assembly was performed by two methods: 1) using Canu v1.9, polishing the genome using Nanopolish v0.11.1 and correction with short reads using Pilon or 2) using Unicycler v0.4.7, a program that uses the short read assembler Spades v3.12 guided by long reads as scaffolds, which is further polished using Pilon [16, 17]. CheckM v1.1.2 and alignment to reference genome (*M. chelonae* strain CCUG 47445) were used to check the quality of the draft genomes to select the best one [18].

We used another custom snakemake pipeline, CoreSNPs (https://github.com/chrgu/coreSNPs) to investigate how related the clinical isolates were to each other and to other whole genome sequenced references collected from GenBank. CoreSNPs uses Prokka v1.14.5 for genome annotation, and Roary v3.12.0 for investigating the pangenome and a hierarchical cluster based on the presence and absence of accessory genes [19, 20]. Custom R and shell scripts were used to extract the core genes from the isolates to compare SNVs by hamming distance. SNVs per Mbp core genome were calculated dividing the hamming distances by length of core genome between the sequence sets for identical DNAs. The SNV analysis used SamTools v1.9 and SNP-sites v2.4.1 [21, 22]. Approximately maximum-likelihood phylogenetic trees for the core genes were generated by Fasttree 2 v2.1.10 [23]. Accession numbers for all *M. chelonae* isolates and references can be found in S1 Table.

The threshold for calling strain identity between genomes was determined using a dataset of a single isolate of *V. campbellii* sequenced 39 times (Illumina only) and examining the number of SNVs between sequencing runs. The dataset was analyzed using the same in-house pipelines as above. Roary defined core genes as genes present in 100% of the samples.

We used Resistance Gene Identifier (RGI) on the output of Prokka to examine resistance genes within the genome [24]. We searched for both high identity and low identity homologous hits to identify previously known genes, such as *gyrA*, and potentially novel resistance genes, respectively. We also manually aligned known genes that can harbor resistance mutations with Muscle to identify and compare mutations within the gene that corresponded with drug susceptibility [25].

Nanoflow is available at www.github.com/zhaoc1/nanflow while all other computer code used in this study is available at www.github.com/chrgu. *M. chelonae* and *V. campbellii* assembled genomes are available in GenBank under project PRJNA594977.

Results

M. chelonae was isolated from seven patients at the Hospital of the University of Pennsylvania in 2017 (<u>Table 1</u>), including the two breast tissue cases. Ages ranged from 45 to 64. Sites of infection included skin (n = 2), breast tissue (n = 2), and respiratory tract (sampled as bronchial alveolar lavage; n = 1) and sputum (n = 2).

10	SUSPECTED NOSOCOMIAL INTECTION PAIR*	AGE	SEX	SITE OF COLLECTION
MYCOL	X	46	Female	broot
MYCOG	X	47	French	Incut
MYCOO		41	Temale	dis
MYCOH		66	Male	bronchieler broge
MYCOS		63.	Male	spotum
MYC06		65	Male	spotum
MYCOT		35	Male	log skin

 $\label{thm:continuous} \textbf{Table 1. Patient demographics and the suspected transmission pair.}$

https://doi.org/10.1371/journal.pone.0236533.t001

Drug susceptibility testing was performed on each isolate using 11 different antibiotics to determine the minimum inhibitory concentration (MIC) (<u>Table 2</u>). As expected, most of the isolates of *M. chelonae* were highly resistant to antibiotics. All strains (n = 7) were either resistant or intermediately resistant to TMP-SMX, ciprofloxacin, imipenem, moxifloxacin, cefoxitin, and minocycline. Only a few drugs such as clarithromycin, tigecycline, and tobramycin, were effective against all the strains. Some variation in susceptibility and resistance was sporadic (e. g. Myco6 alone was sensitive to doxycycline).

10	TMP	UNE"	CEPRO*	EMI [®]	980002	CHFOX-	DOXY"	MINO	THOSPY	TOBBA"	CLAR"
MYCOS	>815200	10.00	4 (8)	14-00	# (30)	3428 (0)	>44400	4.00	0.3 (5)	4 (0)	6.5 (%)
MYCOGAW	>815200	30 (8)	>4(8)	>44 (X)	8 (9)	>128 (8)	>14(8)	>8 (90)	0.5150	2(9)	0.5 (%
MYCGGAB	>610200	32 (9)	>4(0)	14 (0)	8 (31)	129 (80	>1600	>4.00	0.5 (5)	200	63.00
MYCON	4/79 (R)	8 (5)	4 (9)	14-(0)	6 (90)	>129 (9)	>14 (8)	>8.00	9.5 (5)	<100	0.25 (5
MYCOS	61/12 (8)	16 (1)	4.00	30 (80)	8 (80)	>128 (8)	>04000	>4.00	8.25 (5)	209	0.5 (5)
MYCOS	>815200	16 (1)	300	30.00	4 (30)	64 (0)	1 (5)	2 (0)	1.00	4 (T)	93.00
MYCOT	>#15200	>30 (8)	100	30 (93)	4(0)	>128 (8)	>0400	>8(9)	0.5 (50	2(6)	2 (6)
TMP-SMX Linesold Oprofessoin	entokanti, I = Snia	rmediate, S	- Sexceptible								
TMP-SMX 'Linesold' 'Openfouncin 'Imipenem 'Montfouncin	tesiolanii, I = Tota	rmediate, S	- Sescrytöle								
TMP-SMX *Linesold.* *Coprofessacio *Imipenen *Sdoutkoucio **Celoutio **Douycyclase	esistanti, II – Tota	vesedate, S	· Sourptble								
TMP-SMX *Linesold *Coprofessoin *Imiposem *Sdoutkeacts **Coloutin **Desptycless **Misocycless **Misocycless	testokann, I — Tosk	veiedate, S	- Susceptible								
TMP-SMX Linewidd Oprofenacin Imipenem Steatheacin "Celestin "Despopline Minocycline "Tipopyline	eriotaesi, I = Sote	veiedate, S	· Susceptible								
TMP-SMX *Linesold *Coprofessoin *Imiposem *Sdoutkeacts **Coloutin **Desptycless **Misocycless **Misocycless		veieslate, S	· Susaptible								

Table 2. Antibiotic resistance profile of M. chelonae isolates against 11 antibiotics.

https://doi.org/10.1371/journal.pone.0236533.t002

The *M. chelonae* strains were isolated from seven patients at HUP during routine clinical treatment. Frozen stocks of the *M. chelonae* isolates were cultured and DNA was extracted. Extensive optimization was required to allow lysis of the tough *Mycobacterium* cell wall while preserving long DNA chains (see <u>methods</u>). We purified high molecular weight DNA for most strains but we were unable to do so for Myco5. DNA sequencing data was acquired using the Illumina HiSeq 2500 to generate short reads

and the Oxford Nanopore MinION to generate long reads. Two assembly methods were compared for each isolate and the best draft genome was chosen based on completeness (by checkM), number and length of contigs, and alignment to a reference genome (described in detail in the methods). For Myco5 only short read assembly was carried out.

In one case, two isolates were cultured from the same patient at different time points and analyzed separately (Myco3a/3b). In another case, a single genomic DNA preparation was sequenced and assembled twice (Myco2a/b). Both pairs provide further empirical data on the sources of error in library preparation and DNA sequencing.

The whole genome sequencing resulted in a range of contig numbers (n = 1 to 76) comprising the main chromosome. For those that were hybrid assembled, the range of contigs was one to four. Three of the nine assemblies yielded complete circular contigs for the main chromosome. The genomes ranged in size from 4.95 to 5.20 Mbp. No clearly defined episomes were found, as judged by detection of extrachromosomal circles (S1 Table).

We assessed the phylogenetic relationships by comparing the number of single nucleotide variants (SNVs) between cores genes (genes found in every isolate), which allowed us to interrogate potential transmission chains. We used all 43 whole genome sequences of *M. chelonae* present in GenBank (retrieved June 2018) as reference to construct a maximum-likelihood phylogenetic tree. The genomes were annotated by Prokka. CheckM analysis were performed to ensure completion and quality of the reference genomes prior to analysis. Analysis of our set of *M. chelonae* genomes returned a total of 17,582 genes in the pan-genome, of which only 3,368 were considered core genes. The length of the total concatenated core genes per genome was 3,296,947 bases. Of the 3,368 core genes, 25 genes did not contain any SNVs. A list of core genes along with the number of SNVs and SNVs per Mbp can be found in S2 Table. There were no obvious genes related with resistance among the top genes with SNVs. Within the core genes, the number of SNVs between unique isolates ranged from 3,383 to 62,854.

Our two samples from the same individual (Myco3a and Myco3b) differed by 3 SNVs while our technical replicates (Myco2a and Myco2b) differed by 2 SNVs. The potential transmission pair, Myco1 and Myco2a/b differed by 16544/16542 SNVs in the core genes (SNVs are indicated for Myco2 replicates a and b, respectively). A maximum likelihood phylogenetic tree based on the SNVs data is shown in Fig 1A. There was no obvious clustering of our clinical isolates compared with database samples. There was some clustering between human samples, and some of our samples fell into those clusters (e. g. Myco3a/3b and Myco5). Other strains clustered with environmental isolates (e. g. Myco2a/2b and Myco4). Likewise, the tree based on presence or absence of accessory genes (Fig 1B) also showed a lack of obvious clustering of the Phildelphia strains.

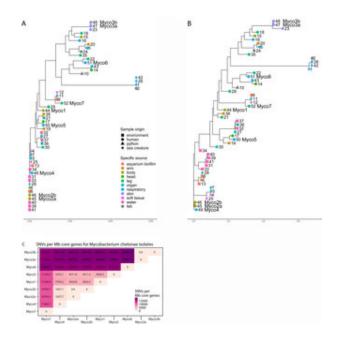


Fig 1. Relationship of *M. chelonae* genome sequences.

A. A maximum-likelihood phylogenetic tree showing relationships among *M. chelonae* isolates based on SNVs in the core genes. Numbers next to branch tips correspond with genomes found in <u>S1 Table</u>. Isolates from our study are indicated with "Myco" and the isolate number. The sampling site and host of the isolate is coded by color and shape, respectively, at branch tips. The scale at the bottom represents the number of substitutions per sequence site based on length of the tree. B: Amaximum-likelihood tree showing the relationship among *M. chelonae* isolates based on presence or absence of accessory genes. C: SNVs per Mbp core genome between *M. chelonae* isolates. SNVs, calculated as hamming distance between the core genes of all isolates divided by the total length of core genes. Myco2a/2b and Myco3a/3b are technical and biological replicates, respectively.

https://doi.org/10.1371/journal.pone.0236533.g001

To assess the likelihood of infection from a common point source, we next empirically assessed the numbers of SNVs expected due to sequencing error in a larger set of genomes. As a positive control in shotgun metagenomic studies, we repeatedly sequenced a single bacterium, *Vibrio campbellii*, a luciferase-encoding marine bacterium, that was divergent from strains likely present in our samples. We recovered an average of 9,072,182 reads over 39 replicates, allowing generation of 39 full genome

sequences from the same isolate. Analysis of the *V. campbellii* genomes using Roary disclosed 4495 core genes in our samples; 643 genes, or ~12.5%, were not 100% conserved in the *V. campbellii* genome, likely due to errors in genome sequence determination. Within the core genes, we found a range of SNVs from 0 to 74, with mean of 15 SNVs (<u>Fig 2A</u>). The total length for the concatenated core genes was 4,209,934 bases. The two most divergent *V. campbellii* assemblies also had low sequence coverage (<u>S3 Table</u>). These data provide a rough upper bound on the number of SNV errors associated with suboptimal sequence acquisition.

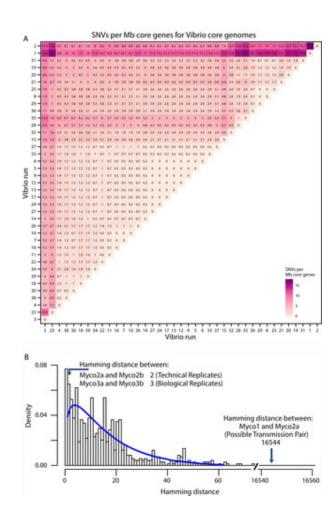


Fig 2. Comparison of Vibrio campbellii genomes by SNVs per Mbp core genome to develop statistics for calling isolate identity.

A. The set of SNVs per Mbp core genome, calculated by hamming distances divided by length of core genome between the sequence sets for identical DNAs. B. Graph showing the Hamming distances (x-axis) and the frequencies of distances between pairs (y-axis). The distances between the technical and biological replicates are marked (Myco2a and 2b, and Myco 3a and 3b), as is the distance between the candidate transmission pair (Myco1 and 2a). https://doi.org/10.1371/journal.pone.0236533.g002

This comparison takes advantage of Illumina sequence reads only, whereas our *M. chelonae* isolates were sequenced using hybrid assembly of short and long reads. We thus generated short read only assemblies for the *M. chelonae* isolates for a more direct comparison to the *V. campbellii* dataset. Our short-read-only genomes contained slightly fewer core genes (3,143 vs 3,368) compared to our hybrid assemblies. The short-read genomes also had more SNVs per Mbp core genes. Both of our technical replicates showed slightly higher SNV counts (3 and 64), but were lower than the maximum number of SNVs for identical strains in our control *V. campbellii* dataset (the maximum number of SNVs for any pair of isolates was 74). Phylogeny of the short-read-only core genomes maintained similar placement as with the hybrid assembled core genome tree.

The possible transmission pair, isolates Myco1 and Myco2a/b (Fig 3), differed by 16,542/16,544 SNVs (Fig 2B), having 99.5% nucleotide identity in the core genes. There were 1107 genes that were not shared between them. Together, this provides strong evidence that they are different strains and not related by direct person-to-person transmission, or acquisition from a common nosocomial point source. This corresponds to a difference of 5,237.58 SNVs per Mbp core genes. The smallest difference between our isolated *M. chelonae* strains was 3,426 SNVs in the core genes or 1,038.18 SNVs per Mbp core genes. Our technical replicates Myco3a and Myco3b differed by 3 SNVs (0.91 SNVs per Mbp core genes), and Myco2a and Myco2b differed by 2 SNVs (0.61 SNVs per Mbp core genes) (Fig 1C). For comparison, the mean number of SNVs in pairwise comparisons of *V. campbellii* control assemblies was 5.71 SNVs per Mbp core genes; the maximum number was 17.62 SNVs per Mbp core genes (Fig 2B). The number of SNVs in the candidate transmission pair thus far exceeds the number of SNVs that could be generated by sequencing error per Mbp as seen from the *V. campbellii* controls and exceeds the SNVs generated in our *M. chelonae* replicates (p-value < 0.001 by binomial test).

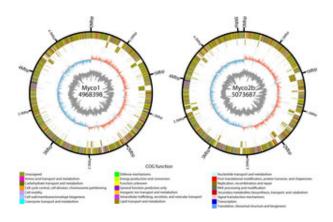


Fig 3. Comparison of genomes from the candidate transmission pair.

Circos plots are shown of assemblies of Myco1 (left) and Myco2b (right). Each ring represents, from inner to outer ring GC content; GC skew; RNA genes; genes unique to the isolate, colored by COG function; and genes shared between the two isolates, colored by COG function. Each genome's start positionwas rotated to the origin of replication and genomes with multiple contigs were merged to form a single contig for visualization. https://doi.org/10.1371/journal.pone.0236533.g003

The molecular determinants of antibiotic resistance in *M. chelonae* are not well studied, so we sought to assess possible antimicrobial resistance mechanisms disclosed in our sequence data. Analysis using Resistance Gene Identifier (RGI) searching for high identity hits to previously known genes related to resistance [24], yielded two partial hits to all the isolates, and a third in three of seven isolates. The two partial hits in all isolates were *LRA-3* (100% identity) and *erm(38)* (80% identity); the third gene was *mtrA* (95.17% identity). *LRA-3* is a gene coding for a beta-lactamase originally identified in soil samples and could possibly contribute to imipenem resistance [26]. The gene, *erm(38)*, encodes for a 23S dimethyltransferase found in *Mycobacterium smegmatis* and can provide resistance to macrolides and lincosomides [27]. It has been shown to increase resistance to Clarithromycin [28]. mtrA is a gene from *Mycobacterium tuberculosis* whose expression has been shown to influence cell morphology and drug resistance in *Mycobacterium smegmatis* [29, 30].

We also used RGI to identify genes with lower homology to known resistance genes, providing possible starting points for follow up studies. We found a list of candidate genes that may contribute to resistance and further narrowed down the list using the susceptibility testing data by filtering out genes that were present in susceptible populations and genes that were not present in

intermediate or fully resistant populations. Only 6 of the 11 drugs had low identity matches associated with their resistance pattern: TMP-SMX (sulfonamide), ciprofloxacin (fluoroquinolone), moxifloxacin (fluoroquinolone), imipenem (carbapenem), cefoxitin (cephalosporin), and Minocycline (tetracycline). Genes are listed in <u>S4 Table</u>.

We further examined genes reported to be targets of mutations that may cause resistance, such as mutations in 23S rRNA for linezolid resistance and gyrA for fluoroquinolone resistance. There were no known or novel mutations present in the 23S rRNA genes in our isolates that correlated with drug susceptibility or resistance. For gyrA, we compared the two intermediate resistant isolates (Myco6 and Myco7) to five resistant isolates. We found that there were no consistent mutations that resulted in resistance, but Myco6 had two mutations (S710R and E773D) not present in the other isolates and Myco7 had one mutation not present in the other isolates (T832A).

Discussion

Here we investigated the possibility of a nosocomial *M. chelonae* transmission at the HUP in 2017 and found that there is no evidence to support a point source outbreak. Our analysis found each isolate of *M. chelonae* was no more similar to each other than to the strains collected from the NCBI database. This supports that these infections were instead likely acquired from the environment and not from a single point source. Our analysis supports the use of next generation sequencing to assess possible nosocomial transmissions within the hospital environment.

Our data provide perspective on the amount of genetic variation in the population of *M. chelonae* in Philadelphia. The number of SNVs found in our isolates of *M. chelonae* was up to 62,854 SNVs (19,082.6 SNVs per Mpb). This is similar to *Mycobacterium marinum*, a species that targets fish, and *Mycobacterium avium*, a species that can cause respiratory illness in humans, which showed up to 89,000 SNVs (24,054.1 SNVs per Mbp) and 26,871 SNVs (6249.1 SNVs per Mbp), respectively. Both show more variation than *Mycobacterium tuberculosis*, which showed a maximum 1800 SNVs between strains [31–33].

To provide a control for sequencing error, we developed a dataset to establish an empirical threshold for calling identity between two isolates that takes account of error in DNA sequence determination. We sequenced a strain of *V. campbellii* using the Illumina method 39 times independently. The number of SNVs ranged from 0 to 74 SNVs depending on which pair of sequencing runs was compared, despite the same input DNA. There were several runs that, though following the same protocol, had higher numbers of SNVs on average in pairwise comparisons, and these correlated with low sequence coverage (<u>S3 Table</u>). Upon considering the length of the core genome, the average SNVs per Mbp was 3.6 which could be used for a general threshold for comparing microbial genomes considering sequencing error. Going forward, the data presented here provides useful background for comparing microbial genomes.

Our analysis also included two samples collected from the same individual and a single isolate sequenced twice, again to help evaluate thresholds for calling identity despite sequencing error. We found that our two samples from the same patient only differed by 0.91 SNVs per Mbp core genes after our hybrid assembly; our single isolate sequenced twice differed by 0.61 SNVs per Mbp

core genes. These control *M. chelonae* genomes show SNV numbers well within the range expected for identical sequences based on our *V. campbellii* dataset. This indicates that the sequencing and hybrid assembly pipeline works as expected to generate high quality genomes and allows identification of identical organisms sequenced twice independently.

Our analysis also shed light on the host preferences of sequenced *M. chelonae* strains. Some of our isolates were closely related to environmental samples annotated as from water and sea creatures, while others clustered with human isolates. Our data did not provide evidence for a strongly human-associated clade.

Examination of SNVs in particular genes and RGI provided a list of possible mechanisms of resistance. For the SNVs that were identified in *gyrA*, the resulting amino acid changes might potentially modulate the resistance phenotype, though functional confirmation is needed. As for the genes from the RGI, while there were a few high identity resistance gene hits in our isolates, the presence of these genes did not correspond with the drug susceptibility phenotypes. For example, every isolate had an 80% identity hit to *erm(38)*, a gene found in *M. smegmatis* to mediate resistance to macrolides, such as clarithromycin, but all of the isolates were susceptible to clarithromycin. Thus, it is possible that the *erm(38)* homolog in *M. chelonae* performs a different role. For *LRA-3*, a metallo-beta-lactamase gene, all isolates were intermediately or fully resistant to the carbapenem tested. Since there are two phenotypes in the presence of the gene, this suggests that it may play a role in resistance, but other mechanisms may be involved as well. We also assessed low homology hits to resistance genes and mutations in genes that are known to influence drug susceptibility. For both, we have a list of possible genes or mutations, but given our low sample size, it is likely that many are false positives, and all require further validation to confirm. Resistance in *M. chelonae* may in part be due to blocking entry of antibiotics by the tough cell wall documented previously [34]. Data presented here may help guide future studies of mechanisms of resistance in *M. chelonae*.

In conclusion, we investigated a possible nosocomial outbreak of *M. chelonae* at HUP. Our analysis concluded that no point source transmission occurred and that each case of *M. chelonae* involved clearly distinct strains, likely acquired from the environment. Our analysis also includes a dataset to help determine thresholds for evaluating identity between different strains while controlling for sequencing error. Finally, we queried potential antibiotic resistance mechanisms by genomic analysis, providing candidate genes and mutations for potential follow up.

Supporting information

<u>S1 Table.</u> Genome sequences analyzed in this study. <u>https://doi.org/10.1371/journal.pone.0236533.s001</u> (XLSX)

S3 Table. Vibrio campbellii assembly information.

https://doi.org/10.1371/journal.pone.0236533.s003 (XLSX)

<u>S4 Table.</u> List of potential *Mycobacterium chelonae* resistance genes by drug type.

https://doi.org/10.1371/journal.pone.0236533.s004

(XLSX)

Acknowledgments

We are grateful to members of the Bushman laboratory for help and suggestions; and Laurie Zimmerman for help with figures.

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Positive Pressure Ventilated Lobby (PPVL) Isolation Rooms: Information for ward staff: March 2021

Many wards in the new RHCYP have at least one PPVL Isolation Room. These are different to the standard single ensuite bedrooms. This information is intended to briefly how these rooms work and how they should be used appropriately for patient placement.

Which patients should be placed in these isolation rooms?

These rooms can be used, without any alteration of settings, for either:

- Source isolation patients with a suspected or known infection, OR
- Protective isolation patients who are vulnerable to infection from others.

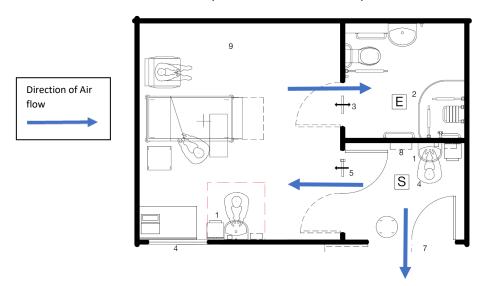
What are they & how do they work?

Positive pressure ventilated lobby rooms comprise of:

- **Lobby:** This is where staff should decontaminate their hands & don PPE. The air is pushed out from the lobby into to the corridor. Air supplied directly into here from the lobby ceiling grill comes through a HEPA filter so is 'ultra-clean'
- **Bedroom**: the ultra-clean air is supplied from the lobby **into** the bedroom. Air does not pass from the corridor directly into the room. This is why the room can be used to protect patients who are vulnerable to infection. The design of the room ensures that if the door from the bedroom to the corridor (i.e. to move a bed or equipment in or out of the room) that air does not move in or out (it is balanced).
- **Bathroom:** this has extract ventilation which pulls air **from the bedroom** and bathroom to the outside. This means any 'contaminated' air from the bedroom will not pass **to** the corridor and expose other patients/staff/visitors. This is why the room can be used to isolate patients with a known infection.

Good practice points

- Ideally only one door of the lobby should be opened at a time.
- Doors to isolation rooms should always remain closed to ensure the ventilation system can work as designed
- Outside each room there is a dial (Magnahelic gauge) which shows the air pressure in the room. This should be at 10 or above. The needle (and pressure) will fall when the door to the lobby is opened. This is because air is pushed from the lobby to the corridor. This is normal & shows the system is working.
- If the air supply, pressure or any other component of the ventilation stops working, there will be an audible and visible alarm at ward level. The facilities management team are notified immediately through the electronic building management system.
- If there is a temporary problem with ventilation not working (e.g. an alarm sounds) staff should contact the facilities management team via the help desk and continue to ensure the doors to the room are kept closed when not entering/leaving the room.
- Windows in these rooms will not open in order to maintain pressures and ultraclean air quality.



From: Marshall J (Jennie)
To: Ali T (Taiba)

Cc:Macdonald J (Jake) (Health)Subject:FW: Letter from Caroline LambDate:14 June 2022 13:22:25

Attachments: FW Letter from Caroline Lamb.msg

Taiba,

Would you be able to put this email into the Glasgow sponsorship folder? It's the letter that went out yesterday advising Glasgow of their de-escalation.

Thanks,

Jennie

From: Marr J (Jacqueline) on behalf of Burns J (John)

To: House D (Dan); "Paula Speirs"; Marshall J (Jennie)

Subject: FW: Letter from Caroline Lamb **Date:** 14 June 2022 09:38:34

Attachments: Final - QEUH Response - DG Letter - Jane Grant - 13 June 22.pdf

For information

Jackie Marr
PA/JOHN BURNS
Room 1E.05
St Andrew's House
EDINBURGH
EH1 3DG

Tel:

From: Mccoll K (Kirsteen) < > On Behalf Of DG Health & Social Care

Sent: 13 June 2022 12:29

To: jane.grant

Cc: OCENHS Mailbox < >; Burns J (John) < >; Chief Nursing

Officer <

Subject: Letter from Caroline Lamb

Dear Jane,

Please find attached a letter from the DG Health and Social Care for your attention.

Thanks

Kirsteen

Director-General Health & Social Care and Chief Executive NHSScotland Caroline Lamb



E: dghsc@gov.scot

Jane Grant
Chief Executive, NHS Greater Glasgow and Clyde
JB Russell House
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

13 June 2022

Dear Jane

NHS GREATER GLASGOW AND CLYDE: ESCALATION STATUS

I am writing to you on the above matter to inform you of the decision taken in relation to the proposed de-escalation of NHS Greater Glasgow and Clyde from Stage 4 of the NHS Scotland Performance Escalation Framework.

The Health and Social Care Management Board (HSCMB), and more recently the National Planning and Performance Oversight Group (NPPOG) on 24 May 2022 have approved the proposal to deescalate NHS Glasgow and Greater Clyde on the basis of the evidence and assurances provided.

I am now confirming that the Board will be de-escalated to Stage 2. As part of the de-escalation, we will continue to support the Board over the coming months as you continue to provide services with the implemented actions and improvements. This support shall include exception monthly reporting provided to Chief Nursing Officer Directorate and quarterly assurance meetings between the Chief Nursing Officer and Chief Operating Officer for NHS Scotland and yourself.

Yours Sincerely,



Caroline Lamb

Director-General Health & Social Care and Chief Executive NHS Scotland









Menu **≡**

Search

Home > News

News

Change to health board escalation

Published: **13 June 2022 14:31**Topic: <u>Health and social care</u>

NHS Greater Glasgow and Clyde moved to escalation Stage 2.

NHS Greater Glasgow and Clyde (NHS GGC) Health Board will move to Stage 2 of NHS Scotland's national performance framework following improvements in performance, and the completion of all 108 recommendations outlined in the Independent Review, Oversight Board and Case Note Review reports.

As part of Stage 2 escalation, robust measures will remain in place to ensure Scottish Government officials continue to provide direct support to NHS GGC.

NHS GGC was moved to escalation Stage 4 in November 2019 in response to concerns raised in relation to patient safety and healthcare associated infections at the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC).

Health Secretary Humza Yousaf said:

"The de-escalation of NHS GGC to Stage 2 is a positive step forward and highlights the significant progress the board has made in meeting all recommendations, set out by the reviews, to improve performance.

"I would like to thank all staff at NHS Greater Glasgow and Clyde who have continued to support the improvement work while delivering high quality patient care. I also want to acknowledge and thank the patients and families for their patience and understanding during what I know has been a challenging time.

"We will work closely with and support the Board over the coming months as it continues to provide high quality services."

Background

Page 87
The decision on a Boards Stage 4 Escalated position sits with the Director General for Health and Social Care, as detailed in the NHS Scotland Board Performance Escalation Framework. Any further decisions regarding NHS Greater Glasgow and Clyde's position would be undertaken through the appropriate governance channels.

Contact

Media enquiries

Was this helpful?

Yes

No

Yes, but















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Request for Information - Section 21 Notice - No 18 (Ventilation Systems)

- 1. <u>Physical changes to the ventilation system operation:</u> From handover on 26 January 2015 to date, please provide: -
- a) A list of all physical changes made by the Board to the operation of ventilation system which were made as a result of concerns about its safety or as a result of a hypothesis/risk but not a known safety concern. For the avoidance of doubt, this request includes permanent and interim steps taken to rectify, remediate, or upgrade the ventilation system.
- b) A succinct explanation of the reason why each of the steps identified was taken.
- c) A description of any steps that the Board took to install HEPA filtration. The Inquiry would like to understand the position at handover and the current position in the Hospital. For the avoidance of doubt, this request includes permanent and interim steps taken to rectify, remediate or upgrade the HEPA filtration. This should include any steps that were taken to use mobile HEPA filtration units.

PICU

This response seeks to address the information requested about physical changes to the ventilation system operation specifically to the Paediatric Intensive Care Unit (PICU) within the RHC. The isolation rooms located within the PICU are addressed within a separate response. This response should be read in conjunction with RFI 1 and RFI S21 10. Information previously provided may not have been duplicated in the response below.

PICU is identified as a Critical Care area and should meet the same criteria as Adult ICU i.e. provide a positively pressured space with 10 + air changes per hour. PICU is located on RHC level 1 and consists of single bed spaces, 4 bedded spaces, isolation rooms, office and support rooms. The area is served by two Air Handling Units (AHUs) in plant room 41, these being AHU14 and AHU46. The secondary filter within AHU 14 and AHU 46 has been upgraded from F7 to F9. There have been no changes to these AHU's since handover.

The first verification of PICU was July 2019 when the report findings recorded that the Air Change Rate (ACR) and pressure cascades failed to meet the required standard for an ICU area. The findings recorded low Air Change Rate (ACR) and poor pressure cascades from clean to less clean areas.

An option report in August 2019 outlined several proposals to resolve the findings identified in the verification reports. Estates and Infection Control agreed the option to sequentially rebalance the whole unit. No physical changes were made to the ventilation system. Work included rebalancing of dampers on both supply and extract grilles as well as the removal of ceiling ventilation grilles and replacement with solid ceiling tiles. Derogations for reduced pressure cascades were agreed and subsequent verifications have demonstrated the works done were successful in achieving a compliant, although derogated, system.

There have been no HEPA filters fitted to the system and no portable HEPA systems used in PICU.

Scottish Hospitals Inquiry Request for Information dated 24 September 2025 – revised 15 October 2025 NHSGGC Response 28 October 2025

(a) Written confirmation that the corporate Board were not aware of matters and issues as referred to in paragraphs 1-11 of the request for Information dated 24 September 2025 until such time as these matters/ issues appeared in the Corporate Risk Register which is contained in Bundle 45.

The 'matters and issues' are:

- 1. All mentions of validation, commissioning, and verification;
- 2. All mentions of taps;
- 3. All mentions of sign off;
- 4. All mentioned of PPVL, air changes, air rate, air pressure, pressure differentials
- 5. All mentions of **Ward 4B/ 4C** including but not limited to references to ventilation, air changes, pressure differentials/ pascals:
- 6. All mentioned of **BMT/ Bone Marrow Transplant/ BMTU/ Bone Marrow Transplant Unit** in relation to transferring the service from the Beatson to QEUH;
- 7. All mentions of the **decant** of the **BMT** unit at QEUH back to the Beatson;
- 8. All mentioned of **Ward 2 A/ 2B**, including but not limited to references to HEPA filters, ventilation, validation, commissioning, sign off, decant, the water incident, taps, refit works;
- 9. All mentions of the word **derogation** in respect of ventilation;
- 10. All mentions of whistleblowing and culture within NHSGGC;
- 11. All mentions of contamination.

The NHSGGC Board was made aware of the above "matters and issues" as listed below. The level of detail provided to Board standing committees, full Board meetings and seminars varied. The Board were not made aware of these being formal documented risks until they were included in the Corporate Risk Registers (contained in Bundle 45).

The list below may not be exhaustive and covers only those elements specified above, up to the end of 2019:

02.07.2013	Quality and Performance Committee BMT move to NSGH approved brief updates on progress received at QPC at September and November meetings
15.09.2015	Acute Services Committee- Move of adult BMTU back to BWOSCC noted in minutes
21.03.2017	Acute Services Committee - Current plans for move back of adult BWOSCC noted in minutes
05.12.2017	Care and Clinical Governance Committee meeting included detailed discussion of 'Microbiologists' SBAR' meeting on 04.10.2017 with minutes and action plan from that meeting
20.03.2018	Acute Services Committee, Interim Director of Estates provides detailed update to meeting on RHC 'water incident' noting water testing being undertaken and possible tap replacement

Page 90

17.04.2018 Full Board, Consultant in Public Health presents on water incident noting 'measures put in place to prevent further contamination'. HAIRT presented at meeting also covers the incident. 15.05.2018 Acute Services Committee - Interim Director of Estates provides detailed update to meeting on RHC 'water incident' noting HPS review 12.06.2018 Care and Clinical Governance Committee- Dr Teresa Inkster provides a detailed presentation on the RHC water incident noting engagement of outside expertise and plans for long term chemical controls. 26.06.2018 Full Board - Board Medical Director presents in detail on water incident noting tap replacement plan. HAIRT covers the incident as well. 17.07.2018 Acute Services Committee - Additional water incident update 21.08.2018 Full Board - Board Medical Director presents in detail on water incident noting tap replacement plan. HAIRT covers the incident as well. Chief Executive responds to questioning on building specifications stating that work is underway to identify problems. 04.09.2018 Care and Clinical Governance Committee - Water incident update by Board Medical Director 18.9.2018 Acute Services Committee - Update from Board Medical Director on new RHC infection cases possibly associated with drains noting proposals for ward decant. 16.10.2018 Full Board - Update from Board Medical Director on new RHC infection cases possibly associated with drains noting proposals for ward decant. HAIRT covers situation as well. 20.11.2018 Acute Services Committee - Discussion of Corporate Risk Register includes noting that water safety now an element 04.12.2018 Finance and Planning Committee - Costs of water remediations at QEUH noted 11.12.2018 Care and Clinical Governance Committee - Director of Estates provides detailed update on chlorine dioxide dosing and RHC 2A/B works including review of other issues across the QEUH site in relation to the original design. 18.12.2018 Full Board- HAIRT includes detailed list of water system actions with note of costs in minutes. 15.01.2019 Acute Services Committee - Discussion of corporate risk register mentions water safety elements 05.03.2019 Care and Clinical Governance Committee - Update on water incident and detailed update on 2017 microbiologists' SBAR and progress on issues raised there 12.03.2019 Audit and Risk Committee - Discussion on estates maintenance refers to water incident.

Regular updates on the progress of the internal Estates review and on the 6A issues were also received by standing orders committees over 2019 and reflected in full Board minutes that year along with broad discussions of ventilation in the context of the cryptococcus incident. 03.12.2019 Finance, Planning and Performance Committee focussed on the Estates review and questioned the Director of Estates on the DMA water risk assessment issues.

- 20.08.2019 Full Board Progress on RHC 2A/B works discussed with Director of Estates.
- 17.09.2019 Acute Services Committee Update from Director of Estates on RHC ward 2A/B works.

- 19.11.2019 Acute Services Committee Whistleblowing policies discussed by Chief Executive in context of media attention over patient deaths
- 26.11.2019 Board seminar Coverage of 2A water incident, whistleblowing and other issues in context of current media attention
- 10.12.2019 Care and Clinical Governance Committee Board seminar presentation as above made to them prompting questioning on DMA water risk assessments, whistleblowing and ward decants.

A detailed submission on the development and discussion of whistleblowing policies, procedures and governance 2013 to 2022 was provided to the SHI under RFI 7 3 indicating the engagement of Board standing committees in this process.

(b) All and any extracts from the IPC Register in respect of QEUH/RHC (or any other name by which the QEUH/RHC is known) in the form that it was reported to the AICC/BICC from 1 January 2014 to 31 December 2019. If this is not available, please provide an explanation of why it is not available.

IPC Risk Registers from January 2014 to December 2019 have been reviewed.

The request sought extracts of the IPC Risk Registers which mention the key search terms in respect of the QEUH/RHC.

There are no specific references to the QEUH/RHC within the IPC Risk Registers. The IPC Risk Registers contain Board wide risks.

There are no specific references to the "matters and issues" listed above.

Examples are included below:

IPC Risk Register 2014

New Builds and Renovation Datix N 8	Failure to provide appropriate infection control advice and support in the assessment and reduction of risks associated with new builds and renovation projects.	NHSGGC IC Policy - assessment and reduction of infection risks associated with new builds and renovation projects. Assess the patient environment using HAI SCRIBE and prepare action plans as required.	LIVEAC	LOW	Tom Walsh / Craig Williams / Facilities / New SGH Project Team / Sector Lead ICNs/ NCIPC
Clinical management of incidents related to water sources.		Legionella Policy and control teams. Water Systems Safety policies, written scheme and risk assessment in place.	RESOLVED	LOW	Estates / Tom Walsh / Craig Williams

Note: IPC Risk Registers for 2018, 2019 and 2020 were submitted to the SHI under Request for Information 7 – 4.2 (dated 11 April 2022)

Request for Information - Section 21 Notice - No 18 (Ventilation Systems)

5. Isolation rooms:

In respect of all isolation rooms in the QEUH, please provide a schedule of all isolation rooms with the following information:

- a) Where the room is situated
- b) What patient group was intended to be accommodated in the room at handover
- c) Following handover, what changes were made to the ventilation systems in the room?
- d) A description of the patient groups who are using the rooms now.

This response will address items a) and c) for the QEUH. Responses in relation to isolation rooms in the RHC and in relation to items b) and d) are provided separately.

a) Where the room is situated

The following table indicates the room and bed references for each isolation room, where they are situated and the current isolation room type.

		Floor		Isolation Room
Room Ref	Bed Ref	Level	Ward No	Current Designation
CCW-051	Bed 11	1st	CCW HDU	PPVL
CCW-165	Bed 50	1st	CCW HDU	PPVL
CCW-157	Bed 40	1st	CCW ICU	PPVL
CCW-078	Bed 31	1st	CCW ICU	PPVL
CCW-242	Bed 3	1st	CCW HDU	PPVL
CCW-025	Bed 4	1st	CCW HDU	NPIR
CCW-245	Bed 23	1st	CCW ICU	PPVL
CCW-111	Bed 24	1st	CCW ICU	NPIR
CCW-140	Bed 44	1st	CCW ICU	NPIR
CCW-241	Bed 43	1st	CCW HDU	NPIR
RENW 041	Bed 19	4th	4A	PPVL
RENW 046	Bed 20	4th	4A	PPVL

Note:

PPVL designates a Positive Pressured Ventilated Lobby (shown in green box)
NPIR designates a Negative Pressured Isolation Room (shown in blue box)

c) Following handover, what changes were made to the ventilation systems in the room?

The supply grille in the PPVL isolation room is designed to incorporate a HEPA filter as an optional install. At handover HEPA filters were not fitted.

We consider the fitting of HEPA filtration in the supply grille of a PPVL room as a change to the system.

Handover documentation and verification reports undertaken since handover provide the data for the table below which identifies that 7 rooms have been provided with HEPA filtration and when:

		Floor		
Room Ref	Bed Ref	Level	Ward No	Filter first evidenced
CCW-051	Bed 11	1st	CCW HDU	Feb 2019
CCW-165	Bed 50	1st	CCW HDU	September 2015
CCW-157	Bed 40	1st	CCW ICU	April 2017
CCW-078	Bed 31	1st	CCW ICU	September 2015
CCW-242	Bed 3	1st	CCW HDU	June 2021
CCW-245	Bed 23	1st	CCW ICU	June 2019
RENW 046	Bed 20	4th	4A	September 2015

Of the 5 remaining isolation rooms, Room 19 on Ward 4A has had no changes made to it since handover and does not have a HEPA filter fitted.

Since June 2019, the 4 remaining rooms on level 1 have been converted to Negative Pressure Isolation Rooms (NPIR) at the request of Consultant Physicians and Infection Control Doctors (ICDs). The ventilation system changes were the installation of a supply grille in the patient room and an extract grille in the lobby. These were additional to the existing grilles. The system was then re-balanced to ensure the flow of air is always from the corridor or lobby to the patient room. Within the plant rooms, gas tight dampers were fitted to both supply and extract ductwork allowing them to be sealed for disinfection if required.

Request for Information - Section 21 Notice - No 18 (Ventilation Systems)

- Physical changes to the ventilation system operation: From handover on 26 January 2015 to date, please provide: -
- a) A list of all physical changes made by the Board to the operation of ventilation system which were made as a result of concerns about its safety or as a result of a hypothesis/risk but not a known safety concern. For the avoidance of doubt, this request includes permanent and interim steps taken to rectify, remediate, or upgrade the ventilation system.
- b) A succinct explanation of the reason each of the steps identified was taken.
- c) A description of any steps that the Board took to install HEPA (High Efficiency Particulate Air) filtration. The Inquiry would like to understand the position at handover and the current position in the Hospital. For the avoidance of doubt, this request includes permanent and interim steps taken to rectify, remediate or upgrade the HEPA filtration. This should include any steps that were taken to use mobile HEPA filtration units.

RHC Ward 2A / 2B

This response seeks to address the information requested about physical changes to the ventilation system operation specifically for Wards 2A and 2B and does not include information on the isolation rooms located within other areas as a separate response specifically covering isolation rooms will be provided.

Significant changes were made to the ventilation systems serving ward 2A and 2B after 2019, however, to describe the changes to these ventilation systems it is first necessary to describe the ventilation system that existed prior to these changes being made.

Ward 2B is on level 2 of the RHC and from handover in January 2015 was served by air handling unit (AHU) 41 AHU24. This unit also provided air to level 1. In Ward 2B the air delivered from AHU24 supplied 10 chilled beams in day units and consulting rooms and 14 grilles supplied offices, corridors, and ancillary areas. The air delivered by AHU24 was not HEPA filtered. There was no duty/standby arrangement for this AHU. The extraction ductwork on levels 1 and 2, which included toilet extract systems, were drawn through a thermal wheel within AHU24 allowing recovered heat to be transferred to the supply duct of AHU24.

Ward 2A was served by two AHUs. These were 41 AHU20A and 41 AHU20B. AHU20A delivered air to 3 floors of RHC including ward 2A providing air to the patient rooms via chilled beams while offices, corridors, and ancillary areas were supplied air by ceiling grilles. The air delivered by AHU20A was not HEPA filtered. There was no duty/standby arrangement for this AHU. The extraction ductwork from levels 1, 2 and 3 which included toilet extract systems, drew air through a thermal wheel within AHU20A allowing recovered heat to be transferred to the supply duct of AHU20A.

AHU20B provided air via ceiling mounted grilles to 3 floors of RHC including to the ward 2A offices, ancillary rooms, prep room and MIBG suite. The air provided by AHU20B was not HEPA filtered and there was no duty/standby arrangement. The extraction ductwork on levels 1, 2 and 3 which included toilet extract systems, drew air through a thermal wheel within AHU20B allowing recovered heat to be transferred to the supply duct of AHU20B.

Following extensive works undertaken between 2019 and 2022 a number of changes were made.

Wards 2A and 2B were disconnected from ductwork which had been providing ventilation to these wards as well as levels 1 and 3. The ductwork was disconnected and capped at level 2 however the AHUs continue to serve levels 1 and 3.

Plantrooms 41 and 41A were remodelled to provide new ventilation systems for wards 2A and 2B. A further plant room, 41B was created to accommodate additional units.

Listed below are descriptions of the new ventilation systems serving RHC Wards 2A and 2B.

- a) A new supply ventilation system was installed in plantroom 41 identified as BMT AHU 01/02 Supply. This operates on a duty stand by arrangement and serves BMT Ward 2A and 2B. The air delivered from the unit is HEPA filtered. The air provided to ward 2B is via ceiling mounted grilles and chilled beams. The air provided to ward 2A is via ceiling mounted supply grilles in corridors, offices and support areas. The grilles in ward 2A also incorporate HEPA filters.
- b) A new ventilation extract system was installed in plantroom 41B identified as BMT AHU 01/02 Extract. This operates on a duty stand by arrangement and serves BMT ward 2A and 2B. It provides extract ventilation from corridors, offices and support areas.
- c) A new toilet extract system was installed in plantroom 41 identified as BMT TEF 01/02 Toilet Extract. This operates on a duty stand by arrangement and serves BMT ward 2A and 2B. It provides extract ventilation from WCs, dirty utility rooms and cleaners stores etc.
- d) A new supply ventilation system was installed in plantroom 41B identified as AHU/HOTCT/01/02 Supply. This operates on a duty stand by arrangement and serves Ward 2A Haemato-oncology and Teenage Cancer Trust (HO/TCT) bedrooms. The air is delivered from the unit to Ward 2A HO/TCT bedrooms via ceiling mounted supply grilles which incorporate HEPA filters.
- e) A new ventilation extract system was installed in plantroom 41B identified as AHU/HOTCT/01/02 Extract. This operates on a duty stand by arrangement and serves Ward 2A HO/TCT. It provides extract ventilation from corridors.
- f) A new toilet extract system was installed in plantroom 41B identified as HOTCT TEF 01/02 Toilet Extract. This operates on a duty stand by arrangement and serves Ward 2A HO/TCT. It provides extract ventilation from WCs and patient en-suites.
- g) A new supply ventilation system was installed in plantroom 22 identified as AHU/MIBG/ 01/02 Supply. This operates on a duty stand by arrangement and serves BMT MIBG suite. The air supplied from the unit is provided via ceiling mounted grilles with HEPA filtration.

- h) A new ventilation extract system was installed in level 5 ventilation plant compound identified as MIBG GEF 01/02 General Extract. This operates on a duty stand by arrangement and serves BMT MIBG suite.
- i) A new ventilation extract system was installed in level 5 ventilation plant compound identified as MIBG TEF 01/02 Toilet Extract. This operates on a duty stand by arrangement and serves BMT MIBG suite.
- j) A new ventilation extract system was installed in plantroom 41B identified as Hospital Street EF 01/02. This operates on a duty stand by arrangement and serves the hospital corridors external to BMT ward 2A.
- k) A new ventilation extract system was installed in plantroom 41B identified as Hospital Street EF 03/04. This operates on a duty stand by arrangement and serves the hospital corridors external to HOTCT ward 2A.

The redesign of the ventilation systems serving RHC Wards 2A and 2B was to improve the overall performance of the ventilation systems serving the area. The installation of separate supply and extraction systems removed the risk of cross contamination from other zones and other levels. The provision of duty/standby arrangements added resilience to the systems and allowed for planned maintenance of the AHUs to be undertaken without impacting the patient group.

The new design provides HEPA filtered air to Ward 2A and 2B and that the pressure cascade from clean to less clean areas is achieved.

The MIBG suite had previously been ventilated from AHU20B and therefore the air to the Prep room was not HEPA filtered. The MIBG suite is now provided with its own dedicated ventilation system providing HEPA filtered air and the extraction systems are separate from the main ward areas.



Bundle of documents for Oral hearings commencing from 16 September 2025 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow