Trust-wide Document

Great Western Hospitals NHS Foundation Trust

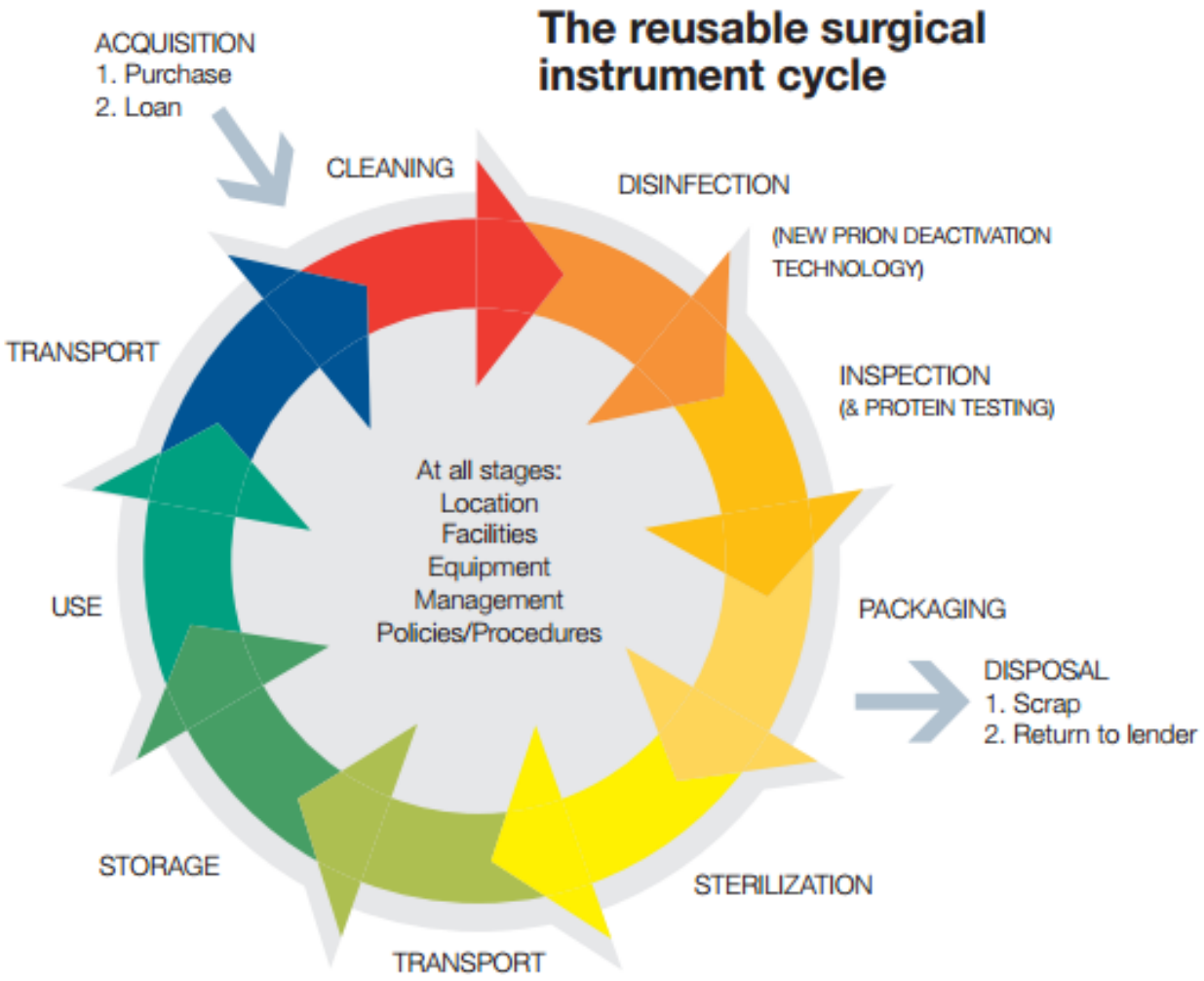
Cleaning and Decontamination of Reusable Surgical Instruments – Trust-wide Policy

Document No	IP&C - 00010	**Version No**	2.0
Approved by	Policy Governance Group	**Date Approved**	30/06/2020
Ratified by	Infection Control Committee	**Date Ratified**	24/06/2020
Date implemented (made live for use)	14/07/2020	**Next Review Date**	24/06/2023
Status	LIVE		

Target Audience- who does the document apply to and <u>who should be using it</u>. - The target audience has the responsibility to ensure their compliance with this document by: • Ensuring any training required is attended and kept up to date. • Ensuring any competencies required are maintained. • Co-operating with the development and implementation of policies as part of their normal duties and responsibilities.	All employees directly employed by the Trust whether permanent, part-time or temporary (including fixed-term contract). It applies equally to all others working for the Trust, including private-sector, voluntary-sector, bank, agency, locum, and secondees. For simplicity, they are referred to as 'employees' throughout this policy
Special Cases	The Policy relates solely to the microbiological decontamination of surgical instruments including flexible endoscopes. The policy does not relate to items which may be contaminated with chemicals that are corrosive, irritant, toxic, catatonic or radioactive. The latter information can be located with the Control of Substances Hazardous to Health (COSHH) (Ref 1)
Accountable Director	Medical Director
Author/originator – Any Comments on this document should be addressed to the author	Hospital Sterilisation and Decontamination Unit (HSDU) Sterile Services Manager
Division and Department	Planned Care, HSDU
Implementation Lead	Decontamination Lead Advisor/IP&C Lead Nurse
If developed in partnership with another agency ratification details of the relevant agency	None
Regulatory Position	The Health and Social Care Act 2008 (Ref 4) Care Quality Commission (CQC) (Ref 13) HTM 01-01 (Ref 5) HTM 01-05 (Ref 7) HTM 01-06 (Ref 6) ISO: 13485 (Ref 9) Medical Devices Directive 93/42 EEC (Ref 12) European and International Standard (EN ISO) 15223 (Ref 2)
Review period. This document will be fully reviewed every three years in accordance with the Trust's agreed process for reviewing Trust -wide documents. Changes in practice, to statutory requirements, revised professional or clinical standards and/or local/national directives are to be made as and when the change is identified.	

Contents

Instant Information 1 - The Reusable Medical Devices Life Cycle



NB Any device which is marked with the following symbol MUST NOT be reused as it is designated as single use.

Single use symbol as per European and International Standard (EN ISO) 15223 (Ref 2)

Instant Information 2 - The Spaulding Classification for Medical Devices and Levels of Disinfection (Ref 3)

- **Critical**
  A device that enters normally sterile tissue or the vascular system or through which blood flows should be sterile. Such devices should be sterilised, which is defined as the destruction of all microbial life.
- **Semi-critical**
  A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices should receive at least high-level disinfection, which is defined as the destruction of all vegetative microorganisms, mycobacterium, small or non-lipid viruses, medium or lipid viruses, fungal spores, and some bacterial spores.
- **Noncritical**
  Devices that do not ordinarily touch the patient or touch only intact skin. These devices should be cleaned by low-level disinfection.

1 Introduction & Purpose

1.1 Introduction & Purpose

Decontamination of reusable medical devices and equipment is a priority for the Trust and is essential to ensure the delivery of safe services to patients, staff and other service users. In order to be registered with the Care Quality Commission (CQC), the Trust is required to maintain appropriate levels of cleanliness and hygiene in relation to reusable medical devices set out in the Health and Social Care Act 2008 : The code of practice on the prevention and control of infections and related guidance (July 2015) (Ref 4).

The Code of Practice provides guidance on how providers can meet this registration requirement, including key recommendations on the provision of a safe decontamination service that generates a clean and sterile product. The Trust has a responsibility to systematically identify, assess and monitor all decontamination processes relating to reusable medical devices, ensuring that they are compliant with required standards and processes.

This policy covers the decontamination of reusable medical devices such as surgical instruments and flexible endoscopes and does not address issues of environmental cleanliness or the decontamination of other 'near-patient' reusable devices. For further advice refer to The Infection Prevention and Control Team Documents. **Infection Prevention & Control**

This policy promotes a consistent and standardised approach and focuses on embedding and sustaining a culture of best practice across the organisation. Through this the Trust will ensure that a robust programme of audit and review is in place, in order to provide assurance that the required standards are being met. When any deficiencies are identified, immediate remedial action will be taken and a robust action plan will be developed and implemented.

1.2 Glossary/Definitions

The following terms and acronyms are used within the document:

AE(D)	Authorised Engineer Decontamination
AP(D)	Authorised Person Decontamination
BE ISO	British and European International Standard
CQC	Care Quality Commission
EIA	Equality Impact Assessment
EN	European Standard
HCAI	Healthcare-associated infection
HSDU	Hospital Sterilisation and Decontamination Unit
HTM	Health Technical Memorandum
IP&C	Infection Prevention and Control
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service

2 Main Document Requirements

2.1 Key Factors for Consideration when Assessing Decontamination Risks

2.1.1 Definition of a Medical Device

The Department of Health Managing Medical Devices (guidance for Healthcare and Social Services organisations) April 2014 (Ref 10) defines a medical device as "any instrument, apparatus, appliance, material or other article whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of: control of conception, diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or physiological process'.

Decontamination of 'near patient' medical devices for example, commode chairs, drip stands, dressing trolleys, Blood Pressure cuffs, bedpans are not covered in this policy.

2.2 The Medical Device Decontamination Cycle

The decontamination of reusable medical devices is the combination of processes, which if not correctly undertaken, individually or collectively, may increase the likelihood of micro-organisms being transferred to patients, staff or visitors.

The manufacturers of medical devices give clear instructions on how the reusable product can be safely decontaminated between uses. The users must be able to demonstrate that local cleaning and decontamination procedures comply with this advice and that regular audit of user's compliance is evident.

NB Additional procedures are required for equipment which has been used on patients who have known Creutzfeldt-Jakob disease or Variant Creutzfeldt-Jakob disease Refer to Infection Prevention and Control of CJD/ vCJD and other Human Diseases policy. (Ref 11).

2.3 Level of Decontamination

The level of decontamination required directly relates to the level of risk posed i.e. the degree of contamination, the purpose for which the equipment is to be used and the vulnerability of the patient. The appropriate level and method of decontamination identified by risk assessment will always be supported by the manufacturers' recommendations for their product.

2.4 Cleaning

This may be done immediately after use with Flexible Endoscopes or within HSDU via manual wash, ultrasonic process or the washer disinfector machine.

It is a process designed to physically remove contamination but does not necessarily destroy microorganisms. The reduction of microbial contamination is not routinely measured and will depend upon many factors, including the efficiency of the cleaning process and the initial bio-burden. Cleaning removes micro-organisms and the organic material on which they thrive.

2.5 Disinfection

A process used to reduce the number of viable microorganisms but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection may not achieve the same reduction in microbial contamination levels as sterilisation.

2.6 Sterilisation

Sterilisation - A process used to render an object free from microorganisms including viruses and bacterial spores. Normal sterilisation methods will not destroy prions.

NB If there are any queries about either the level of decontamination required or which method is most appropriate it is essential to contact the HSDU Manager.

2.7 Equipment Track and Trace

2.7.1 Surgical Instruments

There is a need to track and trace reusable surgical instruments throughout their use and reprocessing. This is to avoid instrument migration and is an essential requirement of the HTM 01-01. Records should be maintained for a nationally recognised time frame for all surgical instrument sets (and supplementaries for high-risk procedures) identifying the following

- The cleaning and sterilization method used
- A record of the decontamination equipment and cycle
- The identity of the person(s) undertaking decontamination at each stage of the cycle
- The patients on whom they have been used and details of the procedures involved.

Each area that is using reusable instruments should have a local procedure available informing staff how to

- Comply fully with monitoring condition and functionality of the instruments
- Report damaged instruments in need of replacement or repair
- Comply with track and trace of instruments
- Safely store before use and returned to HSDU for reprocessing.

2.7.2 Equipment Requiring Inspection, Service or Repair

Equipment that is sent to the manufacturer for service/repair requires a certificate to confirm whether it has been decontaminated. A decontamination certificate will be provided by HSDU equipment. If a full decontamination procedure has not been carried out, this must be clearly stated on the outer wrapper.

External contractors will have completed a permit to work and a local induction prior to carrying out any work; they will have supplied a 'method statement' which will include the decontamination responsibilities for equipment being used.

Ultimately it is the responsibility of users to present equipment to repairers that has been decontaminated, and affix appropriate labels (this applies internally and externally).

Recipients of equipment for inspection, service or repair which does not have a decontamination certificate attached MUST NOT handle the equipment until the ward/department staff have been contacted to clarify whether the equipment has been decontaminated.

2.7.3 Upgrade or Replacement of Medical Equipment

Equipment management also requires that programmes are developed to upgrade and/or replace any equipment decontamination facilities that do not meet the requirements of current standards and test methods. Any medical device that does not meet best practice decontamination standards must be highlighted on the directorate risk register and an action plan developed to move to best practice if

appropriate. Any medical device that does not meet essential decontamination quality requirements must be removed from use.

2.7.4 Procurement

Before any new reusable medical device is purchased the manufacturer decontamination instructions must be reviewed by the HSDU manager to ensure that it is possible to reprocess: this must be documented, signed and dated on the relevant paperwork.

The Supplies Department, in supporting procurement of instrumentation, will ensure that purchasers are aware of the requirement to check manufacturer's instructions to enable the product to be processed as required i.e. by sterilisation or disinfection and HSDU are required to approve.

2.8 Monitoring and Audit

2.8.1 Surveillance of Healthcare Associated Infection

The lead nurse practitioner for infection prevention and control will ensure that there is a robust structure in place for Surveillance of Healthcare Associated Infection and monitor compliance against agreed targets. Outcomes of this surveillance are discussed at the monthly Infection Prevention and Control (IP&C) meeting where suitable action plans are agreed and progress towards improved practice monitored.

Managers of departments and units will add any significant infection prevention and control risks to the directorate risk registers. Any significant on-going unresolved risks will be identified and discussed at the Infection Control Committee.

2.8.2 Audit of Regulatory Requirements ion HSDU

HSDU is registered with the Medical Devices Directive 93/42 EEC (Ref 12) and runs a validated quality management system to ISO EN 13485. The Quality Assurance Management System and Operational Policies detail the department's ability to provide a consistent service that meets the regulatory requirements. The department is also responsible for the repair and maintenance of all surgical instruments (excluding flexible endoscopes) via nominated third party contractors. The department has a robust internal quality management system and is also independently audited once a year by a 'Notified Body', who is appointed by the MHRA. Audit reports identifying non conformity from both internal and external audits and actions taken to improve quality are reported to the HSDU Manager monthly.

3 Monitoring Compliance and Effectiveness of Implementation

The arrangements for monitoring compliance are outlined in the table below: -

Measurable policy objectives	Monitoring or audit method	Monitoring responsibility (individual, group or committee)	Frequency of monitoring	Reporting arrangements (committee or group the monitoring result is presented to)	What action will be taken if gaps are identified
Compliance with the health and social Care Act criterion 1, 2, 6, 9, 10	This policy	• Head of Sterile Services • Infection control forum • Infection control committee • Decontamination review group (DRGM) meeting	3 years or sooner if changes are required Monthly Twice yearly Quarterly	Governance Officer Infection Control Committee Trust Board Infection Control Committee and Infection Control Forum	Policy review and update by Head of Sterile Services
HSDU Compliance with ISO13485 MDD 93/42 EEC	Systematic Internal audit against all key components	HSDU quality representative	Annual progress reports via quality report	Monthly progress reported at the internal performance board.	Corrective action plan against any non-conformance identified
HSDU Compliance with ISO13485 MDD 93/42 EEC	Systematic External audit against all key components	by Notified body.	Compliance assessments yearly. Re certification every 3 years	Quality Governance meeting	Corrective action plan against any non-conformance identified
Equipment Management compliance with ISO 9001	Systematic internal and external audit against relevant components	Trust Equipment team	Rolling programme of audits and annual surveillance	Trust Equipment Group by exception	Corrective action plan against any non-conformance identified

4 Duties and Responsibilities of Individuals and Groups

The Health Technical Memorandum 01-01 (Ref 5), 01-05 (Ref 7) and 01-06 (Ref 6), provide guidance on management and decontamination of reusable medical devices. The reporting structure within the Trust, for decontamination, is outlined in Appendix B.

The roles and responsibilities for a range of key officers with responsibility for aspects of decontamination are clearly defined and outlined below:

4.1 Chief Executive

The Chief Executive is ultimately responsible for the implementation of this document. The Chief Executive is the Executive Manager with roles and responsibilities as defined in HTM 01-01, and has

ultimate management responsibility for allocation of resources and appointment of personnel for the organisation in which the decontamination equipment is installed.

4.2 Ward Managers, Matrons and Managers for Non Clinical Services

All Ward Managers, Matrons and Managers for Non Clinical Services must ensure that employees within their area are aware of this document; able to implement the document and that any superseded documents are destroyed.

4.3 Document Author and Document Implementation Lead

The document Author and the document Implementation Lead are responsible for identifying the need for a change in this document as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and resubmitting the document for approval and republication if changes are required.

4.4 Director of Infection & Prevention & Control (DIPC) (Designated Person)

The DIPC is nominated as Decontamination Lead, with roles and responsibilities as defined in HTM 01-01, and has responsibility for decontamination at Board level and reports directly to the Chief Executive. This person is responsible for the effective and technically compliant provision of decontamination services, implementing and monitoring operational policy for decontamination and is responsible for clearly defining the roles and responsibilities of all personnel involved in the use, installation and maintenance of decontamination equipment. The DIPC also has responsibility for chairing the Trust's Infection Prevention & Control Committee, which oversees the work of the Decontamination Risk Group.

4.5 Hospital Sterilisation and Decontamination Unit / Sterile Services Manager

The Hospital Sterilisation and Decontamination Unit/ Sterile Services Manager is the lead for the safe decontamination and management of reusable surgical instruments and is termed the 'user' as defined in HTM 01-01.

Associated Decontamination Specialist Policies and Standard Operating Procedures' are as follows:

- Decontamination of Flexible Endoscopes Policy (Ref 8)
- Quality Management System ISO: 13485 (Ref 9) and associated standard operating procedure/flow charts to demonstrate compliance.

4.6 Trust Equipment Manager

The Trust Equipment Manager is the Specialist Lead for Trust-wide procurement and management of medical devices.

4.7 Lead Nurse Practitioner for Infection Prevention & Control (Including Community Services)

The Lead Nurse Practitioner for Infection Prevention and Control is the Trust wide lead for the monitoring and control of transmissible infections

4.8 Divisional Directors of Nursing / Midwifery / Matrons

Divisional Directors of Nursing/Midwifery and Matrons are the Specialist Leads for monitoring cleanliness of environment and medical equipment used at point of care.

4.9 Authorised Person (Decontamination) (AP(D))

The AP(D) will be an individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the Designated Person (in conjunction with the advice provided by the AE(D)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of decontamination equipment and other duties as set down in HTM01-01.

4.10 Trust Decontamination Equipment Specialists

Trust Decontamination Equipment Specialists have adequate technical knowledge and relevant training and work under the (AP(D)), these specialists would be classified as Competent Persons within HTM01-01.

4.11 External Independent Authorising Engineer (Decontamination (AE(D))

The AE(D) is designated by management to provide independent auditing, validating and professional advice on all decontamination procedures, washer disinfectors, sterilisers and sterilisation and to review and witness documentation on validation. The AE(D) will assist in the appointment of AP(D)s and their consequent annual assessments.

4.12 Operators

Employees who operate decontamination equipment are nominated as Operators, with roles and responsibilities as defined in HTM 01-01. They must be adequately trained and competent to carry out the task, under the management and supervision of the 'User'.

4.13 Employees

Employees using Clinical facilities and medical equipment including surgical instruments are responsible for complying with all Trust policy and procedures relating to the management of decontamination and reporting to their line managers any shortfalls that they have identified.

5 Further Reading, Consultation and Glossary

5.1 References, Further Reading and Links to Other Policies

The following is a list of other policies, procedural documents or guidance documents (internal or external) which employees should refer to for further details:

Ref. No.	Document Title	Document Location
1	HSE (2002) Control of Substances Hazardous to Health Regulations:	www.hse.gov.uk/coshh
2	European and International Standard (EN ISO) 15223	Available in HSDU
3	Spaulding scale of classification	Available in HSDU
4	Health and Social care (2008) The code of practice on the prevention and control of infections and related guidance (July 2015)	www.health and social care act 2008

Ref. No.	Document Title	Document Location
5	Department of Health HTM 01 01 management and decontamination of surgical instruments (medical devices) used in acute care.	www.gov.uk/dh
6	HTM 01-06 Decontamination of Flexible Endoscopes	www.gov.uk/dh
7	HTM 01-05 Decontamination in primary care dental practices	www.gov.uk/dh
8	Decontamination of Flexible Endoscopes Policy	T:\Trust-wide Documents
9	Quality Management System ISO: 13485	Available in HSDU
10	Managing Medical Devices (guidance for Healthcare and Social Services organisations) April 2014	www.mhra.gov.uk
11	Infection Prevention and Control of CJD/ vCJD and other Human Diseases policy.	T:\Trust-wide Documents
12	Medical Devices Directive 93/42 EEC	Available in HSDU
13	CQC	https://cqc.org.uk/

5.2 Consultation Process

The following is a list of consultees in formulating this document and the date that they approved the document:

Job Title / Department	Date Consultee Agreed Document Contents
Clinical Lead - Theatres	18/06/2020
End User	19/06/2020
HSDU Production Manager	19/06/2020
Authorised Person in Decontamination	19/06/2020

6 Equality Impact Assessment

An Equality Impact Assessment (EIA) has been completed for this document and can be found at Appendix A.

Appendix A - STAGE 1: Initial Screening For Equality Impact Assessment

At this stage, the following questions need to be considered:			
1	What is the name of the policy, strategy or project? Cleaning and Decontamination of Reusable Surgical Instruments Trust-wide Policy		
2.	Briefly describe the aim of the policy, strategy, and project. What needs or duty is it designed to meet? This policy promotes a consistent and standardised approach and focuses on embedding and sustaining a culture of best practice across the organisation		
3.	Is there any evidence or reason to believe that the policy, strategy or project could have an adverse or negative impact on any of the nine protected characteristics (as per Appendix A)?		**No**
4.	Is there evidence or other reason to believe that anyone with one or more of the nine protected characteristics have different needs and experiences that this policy is likely to assist i.e. there might be a *relative* adverse effect on other groups?		**No**
5.	Has prior consultation taken place with organisations or groups of persons with one or more of the nine protected characteristics of which has indicated a pre-existing problem which this policy, strategy, service redesign or project is likely to address?		**No**

Signed by the manager undertaking the assessment	Traci Parfect
Date completed	Head of Sterile Services
Job Title	22/06/2020

On completion of Stage 1 required if you have answered YES to one or more of questions 3, 4 and 5 above you need to complete a STAGE 2 - Full Equality Impact Assessment

Equality Impact Assessment

Are we Treating Everyone Equally?

Define the document. What is the document about? What outcomes are expected?

Consider if your document/proposal affects any persons (Patients, Employees, Carers, Visitors, Volunteers and Members) with protected characteristics? Back up your considerations by local or national data, service information, audits, complaints and compliments, Friends & Family Test results, Staff Survey, etc.

If an adverse impact is identified what can be done to change this? Are there any barriers? Focus on outcomes and improvements. Plan and create actions that will mitigate against any identified inequalities.

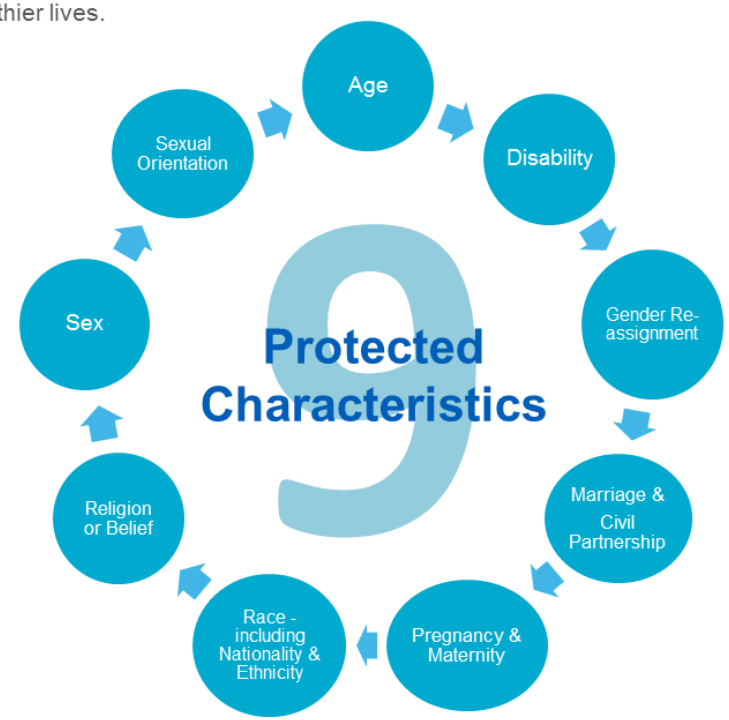
If the document upon assessment is identified as having a positive impact, how can this be shared to maximise the benefits universally?

Trust Equality and Diversity Objectives

Better health outcomes for all	Improved patient access & experience	Empowered engaged & included staff	Inclusive leadership at all levels

Our Vision

Working together with our partners in health and social care, we will deliver accessible, personalised and integrated services for local people whether at home, in the community or in hospital empowering people to lead independent and healthier lives.



Appendix B – Decontamination Responsibilities Structure