GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board	**Reference Number:** UHB 282 **Version Number:** 1 **Date of Next Review:** 23 Feb 2019 **Previous LHB Reference Number:** T40

DECONTAMINATION OF REUSABLE MEDICAL DEVICES POLICY

Policy Statement

Every patient has the right to expect that medical devices used in their care will be clean and safe.

Reliable, consistent and fit for purpose decontamination processes and procedures based on contemporary evidence for multi-use medical devices are a fundamental tenet for the provision of good health care. Decontamination of non-sterile reusable medical devices is pivotal to maintaining a high standard of infection prevention and protection for patients, staff and visitors within Cardiff and Vale UHB's diverse healthcare settings.

Therefore effective decontamination of reusable medical devices needs to be everybody's business and must be part of everyday healthcare practice and based on the best available evidence so that people are protected from preventable Healthcare Associated Infections (HCAIs). Improving, adapting and sustaining reusable medical device decontamination services forms an important part of the UHB's overarching HCAI prevention framework.

Decontamination covers all aspects of cleaning, disinfection and sterilisation of reusable medical devices. Therefore there is a critical clinical safety need to comply with decontamination procedures by all staff who are required to use, maintain or store reusable medical devices and equipment. Medical devices should be decontaminated and stored in accordance with available legislation, evidence based best practice guidance and in line with manufacturers' reprocessing instructions.

Cardiff and Vale UHB is required to provide safe decontamination systems which generate a clean, disinfected or sterile product as appropriate for its intended clinical use. This must be embedded as part of the UHB's culture in support of successful clinical outcomes and the associated safety, health and well-being of patients and staff. This Policy describes the requirements for the UHB's overarching decontamination framework to ensure that all reusable medical devices are properly decontaminated prior to use or maintenance, and that the risks associated with decontamination facilities and processes are well managed.

The UHB has historically tended to focus major decontamination improvement policies on acute (secondary and tertiary) services as this is where the perceived major risks of infection transmission by reusable medical devices and in particular surgical instruments exist. However the risk of encountering HCAI exists in primary care as well as the secondary and tertiary care sectors. The UHB owes the same duty of care to patients and staff across all sectors where it provides healthcare including primary and community services.

Therefore UHB healthcare services delivered in community settings (General Practitioner surgeries, dental practices and community clinics, pharmacies etc.) must have in place fit

for purpose processes and facilities to ensure decontamination is in accordance with current national policy including Welsh Health Technical Memoranda (WHTM), EU Directives and Welsh Government's 'Health and Care Standards'.

Policy Aims:

- To deliver a system-wide, consistent and robust decontamination infrastructure to provide appropriate advice to staff to ensure that effective decontamination is achieved at all UHB locations which complies with national standards.
- To provide advice on the approved materials and their use for effective decontamination.
- To provide advice on the approved methods for standard and effective decontamination.

Policy Commitment

- Cardiff and Vale UHB's Board acknowledge that decontamination procedures for reusable medical devices play an essential part in the prevention and control of Healthcare Associated Infections (HCAI). As such decontamination will be prioritised accordingly by the Executive team, recognising that it is critical to safety and therefore a core business for the UHB.
- Wherever reasonably practicable Cardiff and Vale UHB healthcare services will use single use medical devices to reduce the risks of avoidable HCAI. Where this is not reasonably practicable Cardiff and Vale UHB will adopt the best available evidence based decontamination practices. Patient safety must take primacy in the decision making process.
- The UHB will ensure decontamination procedures and facilities across the UHB's healthcare services are fit-for-purpose and meet the WHTM 01-01 (Parts A to E), WHTM 01-05, WHTM 01-06 (Parts A to E) and HBN 13, (2004) (for refurbished decontamination facilities and new builds). This will ensure statutory regulatory compliance, ISO standard compliance and a move to achieving fully Joint Advisory Group (JAG) on Gastro-Intestinal Endoscopy Accreditation of relevant services.
- All reusable medical devices used in acute healthcare settings requiring sterilisation will be reprocessed in a Medical Device Directive (MDD) accredited facility.
- Local reprocessing will only be carried out in community settings which meet the requirements of WHTM 01-05 where it is not reasonably practicable to send the medical devices to an MDD accredited facility.
- All reusable medical devices will be covered by suitable tracking and traceability systems to ensure full tracking and traceability records are available covering all episodes of use. This requirement extends to reusable medical devices which are loaned ('on demo' or as part of business continuity plans) or 'ex demo' purchased items.
- The choice of decontamination methodology must be proportionate to the level of risk of infection.
- All re-usable medical devices must be decontaminated in accordance with manufacturer's instructions.
- Lumened reusable medical devices must be reprocessed using a validated automated process.
- Only chemicals approved by the UHB's Infection Prevention and Control (IP&C) team will be used in UHB decontamination procedures.

- Disinfectants must be used at the correct concentrations as recommended by relevant IP&C Standard Operating Procedures (SOPs) following manufacturer's guidelines.
- There must be sufficient stock of medical devices including surgical instrument sets and endoscopes to allow for effective decontamination cycle times. The efficacy of decontamination processes, and therefore patient safety, must never be compromised to achieve desired levels of operational performance.
- All sterile goods must be stored in clean dry conditions.
- Items returned to sterile services units must not expose staff to an avoidable infection risk / sharps injury.
- All staff that are required to decontaminate reusable medical devices must be trained and competent to do so. They must have supporting evidence of an 'up to date' competence assessment.
- Personal protective equipment must be worn to undertake decontamination practices where indicated by risk assessment.
- All novel and emergent decontamination technologies (equipment, processes, chemistries etc.) must comply with the essential requirements of the MDD, must be CE marked. They must be authorised by the Director of Infection, Prevention and Control, NHS Wales Shared Services Partnership /Facilities Services (NWSSP-FS) Authorising Engineer (Decontamination) (AE(D)) and be formally signed off by the UHB's IP&C committee and Decontamination Group. This may also be done in conjunction with the UHB's Medical Equipment Group for decontamination equipment.
- All decontamination facilities and processes used in clinical practice will be routinely audited with findings reported to the UHB's Decontamination group.
- Local self-audit tools will be available to clinical areas where decontamination of reusable medical devices is required.
- All decontamination processes must be subject to continuous quality improvement programmes to ensure that they meet or exceed evolving standards for decontamination and provide the greatest level of protection to patients, visitors and staff.
- All equipment used in decontamination processes must be validated for its intended use, and regularly checked and inspected locally to ensure its continued fitness-for-purpose and be on an approved planned preventative maintenance contract.
- A permit to work must be completed every time decontamination equipment is taken out of service for routine testing, repair and maintenance.
- An accurate declaration of contamination status form must be completed prior to inspection, service, repair or transport of medical, dental or laboratory equipment, either on hospital premises or elsewhere.
- Decontamination services must develop robust local business continuity plans to cover scheduled and unplanned disruption to service.
- The UHB is committed to deploy and utilise all available decontamination resources to maximum effect to optimise outcomes for patients and to protect staff and visitors regardless of which Department, Directorate or Clinical Board they are held within. It will manage the life cycle risks of all decontamination equipment in accordance with the Cardiff and Vale UHB's 'Management of Medical Equipment Policy'. It will ensure that all Health and Safety risks associated with the use of equipment and chemicals are managed in accordance with Cardiff and Vale UHB's 'Health and Safety Policy'.
- The UHB is committed to the overarching principles of standardisation and centralisation where patient focused benefits are evident. This will ensure that prudent healthcare principles of reducing waste, variation and harm are adhered to through the adoption of evidenced based decision making, rather than user preference. This will be done in

partnership with NHS Wales Shared Services Partnership - Facilities Services (NWSSP-FS).

- The UHB is committed to building organisational resilience, capacity and capability to effectively decontaminate reusable medical devices to ensure the safety of service users and staff and to safeguard its reputation and stakeholder confidence.
- The UHB will establish and maintain the necessary functional requirements and infrastructure to ensure that it meets its statutory obligation to, as far as reasonably practicable, ensure that all reusable medical devices are properly decontaminated prior to use. This will ensure that the risks associated with decontamination facilities and processes are adequately managed. This function is delegated by the Executive Director of Therapies and Health Science to the UHB's Decontamination Lead.
- The Decontamination Lead is organisationally responsible for the effective and technically compliant provision of decontamination services. The Decontamination Lead is responsible for the implementation of an operational policy for decontamination. The Decontamination Lead is also responsible for monitoring the implementation of the policy.
- The Decontamination Lead delegates specific responsibilities to key personnel and the UHB's Decontamination Group. The Decontamination Group's primary role is to provide assurance to Cardiff and Vale UHB that decontamination procedures and facilities across the UHB's healthcare services are fit-for-purpose and meet the requirements of WHTM 01-01 (Parts A to E), WHTM 01-05 and HBN 13, (2004) (for refurbished decontamination facilities and new builds).
- Ultimately it is the Clinician's responsibility to satisfy themselves that any medical device they are about to use is safe and this includes being satisfied that the device is appropriately decontaminated before use.

Supporting Procedures and Written Control Documents

This Policy and the Decontamination of Reusable Medical Devices Procedure describe how the UHB will discharge its duties in respect of statutory legislation and its obligations to meet external quality standards set out by health service accreditation bodies.

Other supporting documents are:

- Cardiff and Vale UHB Policies and Procedures:
  - Medical Equipment Management Policy and Procedure
  - Infection Control Standard Precaution Procedure for Cardiff and Vale University Health Board
  - Waste Disposal Policy
  - Decontamination of Ultrasound Transducers - Standard Operating Procedure
  - Health and Safety Policy
- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part A: Management and Environment
- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part B: Common Elements

- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part C: Steam Sterilisation and Steam for Sterilisation
- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part D: Washer Disinfectors
- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part E: Alternatives to Steam for the Sterilisation of Reusable Medical Devices
- WHTM 01-05 Decontamination in Primary Care Dental Practices and Community Dental Services
- WHTM 01-06 Parts A-D Decontamination of Flexible Endoscopes
- British Society of Gastroenterology (BSG) Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy: The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee (2015 Edition)
- Health Building Note (HBN) 13: Sterile Services Department, NHS Estates, Department of Health (2004).
- Medical Devices Directive (MDD) 93/42/EEC as amended 2007/47/EC.
- Medical Devices Regulations 2002
- Provision and Use of Work Equipment Regulations (PUWER), 1998
- Managing Medical Devices, Guidance for healthcare and social services organisations, MHRA, April 2014.

Scope

This policy applies to all of Cardiff and Vale UHB staff in all locations including those with honorary contracts. It applies to the decontamination of all reusable Medical Devices or Equipment used by Cardiff and Vale UHB services irrespective of whether the Medical Device or Equipment is owned, loaned, leased or used by commissioned external service providers.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) has been completed and this found there to be a positive impact.
Health Impact Assessment	A Health Impact Assessment is not required for this policy.
Policy Approved by	Quality, Safety and Experience Committee
Group with authority to approve procedures written to explain how this policy will be implemented	Decontamination Group.
Accountable Executive or Clinical Board Director	Director of Therapies and Health Science.

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date Review Approved	Date Published	Summary of Amendments
1	23/02/2016	08/03/2016	UHB Decontamination of Reusable Medical Devices Policy reviewed and updated to reflect new organisational structures and WHTM guidance on the Decontamination of Reusable Medical Devices. This is in response to the rapidly evolving scientific evidence base establishing the HCAI risks associated with the use of reusable medical devices, and to keep pace with innovative, novel and emergent decontamination technologies. The Policy and Procedure are now contained in separate documents. Updated Document
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