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DECONTAMINATION OF MEDICAL DEVICES: A DEVELOPMENT PLAN FOR HEALTHCARE ORGANISATIONS

Date of Expiry/Review: January 2017

For action by Healthcare organisations:
Chairs
Chief Executives
Board Secretaries
Secretary to the Board Secretary Group
Board Decontamination Leads
HB Operational Decontamination Leads
Nurse Directors
Medical Directors
Directors of Public Health
Infection Control Doctors & Nurses
Hospital Chief Pharmacists
PHW HCAI & AMR Programme Leads & CCDCs
CNHS Direct Wales
NWSSP-SES

For action by Healthcare organisations (cont.)
NWSSP-Procurement Services
Surgical Materials Testing Laboratory
NWSSP for distribution to GP practices, community pharmacies & General Dental Practices
Ambulance Trust

For Welsh Government action (or information)
DG/Chief Executive NHS Wales
Deputy Chief Exec NHS Wales
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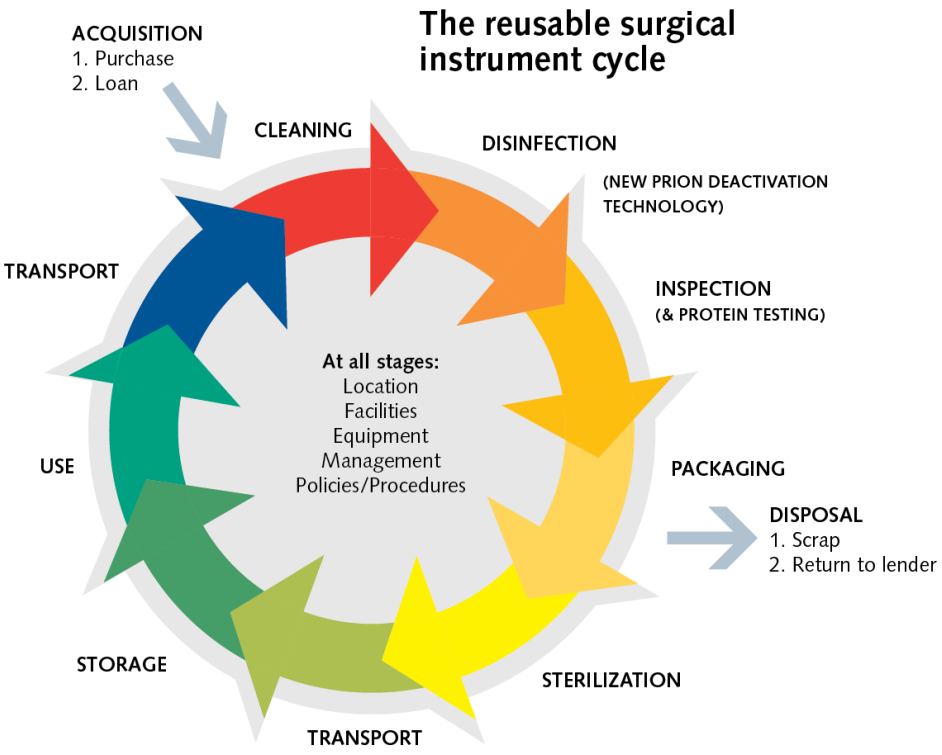
Enclosure: n/a

1. The aim of this *Decontamination Improvement Plan* is to ensure re-usable medical devices are safe for use on a patient and for staff to handle without presenting an infection risk. Decontamination is the combination of processes, including cleaning, disinfection and/or sterilisation. Standards and guidance relating to decontamination have been published over many years. The requirements of healthcare organisations have become more stringent as a result of greater knowledge, experience and technological advancements.

2. The essential requirements for good decontamination practice are:

- management controls are in place and effected;
- medical devices are used appropriately i.e:
  - fit for purpose;
  - in accordance with manufacturers' instructions;
  - properly maintained, monitored and validated;
  - used by staff who are fully trained and competent;
  - conforming to standards and requirements;
  - track and trace systems link device usage to individual patients;
  - robust records are maintained throughout the process;
- appropriate facilities are provided; and
- single use instruments are not decontaminated for subsequent use.

3. To undertake decontamination effectively requires all the processes illustrated in the life-cycle (below) to be implemented correctly and consistently – with all appropriate controls and monitoring in place.



4. The speed at which medical devices pass through the cycle can impact on the effectiveness of decontamination. One influencing factor is the healthcare organisation's stock size of medical devices to ensure clinical demand is met without compromising the safety of patients or staff. Healthcare organisations are required to ensure that all the requirements of good decontamination practice are complied with to render re-useable devices safe for use.

5. Healthcare organisations are asked to review and develop policies and practice on the basis of the Implementation Plan that has taken into account the common themes identified in the 2014 national review of endoscope decontamination:

- **planned preventative maintenance** (of the automated endoscope re-processors) - not carried out in accordance with manufacturers' recommendations;
- **testing and validation** - a lack of knowledge of what testing and validation should be carried out; schedules not being completed fully in accordance with requirements (Welsh Health Technical Memorandum 01/06 Part D – testing methods);
- **water quality** - failures in final rinse water testing; a lack of understanding of risks associated with using contaminated final rinse water;
- **equipment not fit for purpose in use** – deemed obsolete as end of service life exceeded;
- **inappropriate decontamination practises** - scopes decontaminated outside of the main endoscopy department; incorrect storage of decontaminated scopes; out of hours unscheduled scopes usage;
- **the built environment** - inadequate space; lack of physical separation to provide clear segregation of clean and dirty procedures, poor ventilation; and a lack of capacity to deal with growing demand; and
- **Transoesophageal Echocardiograph (TOE) probes** - a failure to appropriately decontaminate;
- **Traceability** – inadequate processes.

6. We consider that the requirements in this Implementation Plan will help healthcare organisations to build on efforts to date in tackling the problems associated with re-use and re-processing of medical devices.

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Decontamination of Medical Devices:

a development plan for healthcare organisations

January 2016

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Foreword

Eliminating preventable healthcare associated infections (HCAIs) requires the proactive involvement of every member of staff across all healthcare settings. The commitments set out in the

> *Decontamination of medical devices:* a *Development Plan for healthcare organisations* (*Development Plan*)

builds on the progress made by healthcare organisations to date, and embeds the zero tolerance approach to preventable HCAIs that every patient rightfully expects. In conforming to the principles of *Prudent Health and Care*, healthcare organisations and individuals involved in providing services are obliged to prevent cross infection when using medical devices in patient care.

In 2014, the Welsh Government commissioned a survey of the decontamination of flexible endoscopes within health boards (HBs) and Velindre NHS Trust. The survey by NHS Wales Shared Services Partnership - Specialist Estates Services in collaboration with HBs, Velindre NHS Trust and Public Health Wales (PHW) raised a number of issues about facilities and practices and feedback from the survey has informed this *Development Plan*.

The *Development Plan* sets out for healthcare organisations the standards, guidance and requirements on decontamination of medical devices.

Contents

1. Introduction

1.1 All premises, equipment and processes used to decontaminate Welsh Health Technical Memorandum 01-01[1] re-usable medical devices contain elements of risk that need to be identified, monitored, controlled and managed. Technological advancements have brought significant benefits to patient care but, with along with this, the necessity for increasingly complex requirements for decontamination.

1.2 In addition, the advent of variant *Creutzfelt-Jacob Disease* (vCJD) derived from *Bovine Spongiform Encephalopathy* (BSE) led to UK health departments developing programmes of work to address specific risks associated with decontamination of re-usable medical devices.

1.3 Manufacturers and users make judgements on the safety of medical devices and the acceptability of associated risks. Standards for manufacturers to specify a process to identify hazards; estimate and evaluate risks; control risks; and monitor the effectiveness of those controls are set out in *BS EN ISO 14971 (Medical Devices - Application of risk management)*.[2]

1.4 Failure to recognise the requirements of adequate decontamination increases the risks of infection that can cause significant morbidity and mortality. Healthcare organisations need to consider not only the quality and safety of equipment used but also its decontamination.

1.5 All staff using medical devices need to understand the complexity of their choice, use and methods of decontamination where re-use is appropriate. Decontamination is a science in its own right and best undertaken by professionals specifically trained and competent for this task within a Quality Management System (QMS).

1.6 In secondary care decontamination departments are located within hospitals. Devices used in primary care (GP practices, dental practices and podiatry), are decontaminated in-house; through private service providers; or through NHS accredited departments. The decontamination process should be of consistently high quality irrespective of location.

1.7 Effective cleaning to remove organic material is an essential part of the decontamination process. Delays in re-processing devices/sets will make cleaning more difficulty and increase the risk of decontamination failures and patient safety. Therefore, timely commencement of decontamination is essential within both primary and secondary care.

1.8 Where a healthcare organisation is determining how and where decontamination is undertaken, all considerations and costs must be considered including the risk of moving away from on site processing;

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[1] NHS Wales Shared Services Partnership - Specialist Estates Services publications

[2] Available from BSI or MHRA web site. Copies of the document will be held by accredited central Sterile Services Departments.

transportation implications; the number of additional devices required if decontamination is to be undertaken off-site; and the challenges of meeting the demands of the service. Patient safety is paramount in the decision making process.

1.9 The Department of Health (England) Decontamination Science Group, with input from the other UK countries, is addressing some of the difficult issues associated with medical devices: washing processes, disinfection and sterilization; and prion and protein adhesion. The emerging body of evidence and guidance from the Advisory Committee on Dangerous Pathogens, such as that published guidance in May 2015 on endoscope and surgical instruments decontamination, has and will continue to inform direction, standards and policies in Wales.

1.10 It is essential that the procurement process is managed carefully. Healthcare organisations must ensure that users and procurement leads consult decontamination and infection control leads, authorized engineers and capital planning and the estates department in determining which devices to procure. Sufficient numbers of new devices must be procured to ensure compliance with manufacturers' decontamination guidelines that conform to appropriate standard UK decontamination/sterilisation techniques.

1.11 For decisions of choice between single use and re-usable devices, advice can be sought from NHS Wales Shared Services Partnership – Procurement services and the Surgical Materials Testing Laboratory (SMTL).

2. Aim of the *Development Plan*

2.1 The aim of the *Development Plan* is to set out the standards expected of healthcare organisations and actions to ensure there are suitable and sustainable arrangements in place for decontamination of medical devices. Essential elements underpinning a standardised approach include:

- explicit policies and procedures for the procurement of medical devices (and other equipment) which include reference to decontamination processes;
- provision of appropriate training including refresher requirements for those involved in using or re-processing medical devices;
- compliance with the Personal Protective Equipment at Work Regulations 1992;
- ensuring that automated equipment is used, maintained, tested and validated according to manufacturer instructions, regulatory

requirements (e.g. European standards[3], Pressure Systems Safety Regulations[4]) and other guidance;

- implementation of the QMS incorporating documented and validated procedures and processes; management review; and quality audit.

- ensuring effective segregation exists between *clean* and *dirty* areas/processes;

- appropriate storage of medical devices.

3. Roles and responsibilities

3.1 The development and/or implementation of decontamination standards and guidance are implemented through or supported by a number of bodies:

- **Health Boards and Trusts (healthcare organisations)**
  Healthcare organisation's Boards are responsible for the management of control of risks. While the ultimate responsibility rests with the Chief Executive, specific responsibilities may be delegated to decontamination leads at Board and operational levels.

- **Surgical Materials Testing Laboratory (SMTL)**
  SMTL provides medical device testing, quality assurance & technical services: http://www.smtl.co.uk/

- **All Wales Decontamination Advisory Group**
  This group provides advice on all aspects of decontamination to the Welsh Government and healthcare organisations.

- **NHS Wales Shared Services Partnership – Specialist Estates Services (NWSSP-SES) Authorised Engineers (Decontamination)**
  AEs (D) provide independent advice on decontamination.

- **HIW – Health Inspectorate Wales**
  HIW assess all healthcare organisations in Wales against standards for health, to include decontamination considerations: http://www.hiw.org.uk/

- **Sterile Services Decontamination Working Group** chaired by NWSSP - Specialist Estates Services (NWSSP-SES);
- **Endoscopy Decontamination Working Group** chaired by NWSSP-SES.

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3 HSE PPE guide
4 Pressure Systems Safety Regulations

4. The Decontamination Development Plan

Changing the culture

4.1 All healthcare organisations and individuals should recognise the risks associated with medical devices and have systems in place to ensure those risks are identified, managed and eliminated or minimised.

4.2 Decontamination and sterilisation must be recognised as requiring specialist expertise and competence, which can be undertaken by different staff groups. Each individual involved in decontamination must be fully trained and assessed competent.

4.3 All Hospital Sterilisation and Decontamination Units (HSDU) are accredited to the EU Medical Device Directive standard[5]. The 2014 national endoscope decontamination review put decontamination high on the agenda for healthcare organisations. Standards and good practice must be maintained and strengthened in accordance with new techniques; evidence based research and technologies.

4.4 Part of the change process is to instil in device users an awareness of the risks all medical devices can pose. Staff should satisfy themselves they are content the device is safe and this includes being assured that the device is appropriately decontaminated before and after use. Any deviation from the manufacturer's decontamination and sterilisation instructions necessitates a local risk assessment with documented agreement from the organisation's risk management leads. Effective procurement should negate the need to deviate from manufacturer instructions.

4.5 In secondary care where users have access to accredited services, local decontamination should cease within wards and departments and devices should be reprocessed within a central dedicated facility utilising validated processes.

4.6 All staff using medical devices should understand the limitations of the device and the management of decontamination as appropriate. Responsibilities for decontamination best lie with trained and competent staff. However, it is the end users' responsibility to ensure that the device is safe to use, be it a single use device or a decontaminated/sterilised re-usable item. If the end user deems the device unsafe for use at the time of the procedure, it should be rejected, a replacement found, and a non-conformance/no surprise/serious incident form raised dependant on the severity and impact of the failure. All staff should be made aware of the process to follow in such a case.

[5] EU harmonised standards for medical devices

4.7 Devices have traditionally been decontaminated in primary care by staff working within the facility. In making decisions that ensure effective decontamination, staff can consider a range of options including use of a centralised accredited service provided by HBs; investment in validated processes and training of staff locally; or a combination of both. Additionally, the availability and benefit of single use devices for certain procedures can be taken into account. Changing the way that devices are decontaminated (that may have been re-processed in the same way for many years) is not without challenges but there are opportunities to improve the quality and safety of services.

4.8 All device failures irrespective of location must be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) [6] and healthcare organisations must ensure they have systems in place that make timely reports. The MHRA collects national trending information and timely reporting allows for wider health service alerting within appropriate timescales.

Changing the culture – Actions	
1.	Healthcare organisations with the support of local decontamination committees/groups should establish; monitor; and maintain the status of compliance with decontamination standards and guidance.
2.	For aspects of non-compliance, healthcare organisations need to identify improvement options and agree an implementation programme as soon as possible.
3.	Healthcare organisations should work with primary care service providers in assessing their compliance status and in the introduction of necessary improvements.
4.	Healthcare organisations must ensure that all staff involved in using or processing medical devices are appropriately trained, assessed as competent, and re-trained as required.
5.	Healthcare organisations must ensure that staff understand and comply with the MHRA statutory reporting arrangements for device failures and Wales-specific procedures.

Leadership

4.9 Healthcare organisations are responsible for clearly identifying two key leadership roles in decontamination: the **Executive Board Decontamination Lead** (representing the Chief Executive) and the **Operational Decontamination Lead**. Also to ensure there are clear management and governance structures in place to support these roles and the wider decontamination agenda.

[6] Details of MHRA adverse incident reporting arrangements are available at: Reporting Adverse Incidents

Leadership – Actions	
1.	Healthcare organisations' decontamination and device management processes should be clearly laid out in a Strategy and Action Plan which incorporates management and governance arrangements.
2.	Healthcare organisations should fully recognise and support the role of the Decontamination Leads at Board and operational levels. These leads should be capable of assessing risks associated with ineffective decontamination processes; determining appropriate remedial action and recognise areas for development. Risks must be recorded on the Board's Risk Register.
3.	Healthcare organisations should satisfy themselves that contractual arrangements with primary care ensure compliance with national standards and guidance on decontamination of re-usable medical devices – and should provide operational support where needed.
4.	Healthcare organisations should provide NWSSP-SES with details of their decontamination leads at Board and operational levels and update changes promptly.

Improving quality and safety

4.10 Decontamination is a science and requires staff who are suitably trained; can demonstrate their competence and are supported in this key role in relation to patient safety by their healthcare organisation.

4.11 There must be clear reporting lines in the management of all medical device procedures, including decontamination. Decontamination services must be appropriately linked to quality and safety, infection prevention and control, and procurement structures and processes.

4.12 Manufacturers of any re-usable medical devices are required to provide appropriate decontamination and sterilisation instructions. No medical devices should be purchased, or procured through loan or trial arrangements, without such instructions that must then be reviewed by appropriate decontamination experts. Healthcare organisations must ensure manufacturers are indemnified and appear on the Master Indemnity Agreement Register: http://www.procurement.wales.nhs.uk/supply/masterindemnity

4.13 Healthcare organisations must also consider manufacturers' re-processing instructions when selecting decontamination chemistries.

4.14 It is important to be able to track surgical instruments through the decontamination process to which they have been subjected to ensure that processes have been carried out correctly. In the event of a sterilisation cycle failure products can then be recalled. Records should be maintained for all sets identifying:

- the decontamination method used;
- the name of the person undertaking decontamination; and

- details of the item/set processed.

4.15 Records should be kept by the organisation for a minimum of 15 years; a computerised system is used for this purpose with the HSDU. The same system allows full traceability to each patient. Single instruments and sets of instruments are issued with a bar code label scanned into the patient's electronic theatre record.

Improving Quality and Safety – Actions	
1.	The All Wales Decontamination Advisory Group who currently advise healthcare organisations and the Welsh Government on the adoption of new standards/guidelines will review its Terms of Reference and membership.
2.	Healthcare organisations should revisit their planned preventative maintenance programme for all decontamination equipment/machinery and report highlighting gaps or areas for improvement should be submitted to the Board.
3.	Healthcare organisations should ensure that all re-usable medical devices currently in use are being processed appropriately.
4.	Healthcare organisations need to ensure that procurement policies and procedures for the purchase of new medical devices meet appropriate standards[7], infection prevention and control, and decontamination requirements.
5.	Healthcare organisations should ensure that equipment loan agreements – including trials - set out clearly terms and responsibilities in respect of the liabilities for the: • decontamination of equipment; • safety of patients, users and others in contact with the device; • replacement of devices following loss or damage.
6.	Healthcare organisations should ensure that decontamination processes and records are monitored by internal audit.

Measuring success

4.16 Success is achieved through robust arrangements for the appropriate selection, procurement, use, decontamination, disposal or repair and management of medical devices.

4.17 Water testing, environmental monitoring & instrument sampling can demonstrate control of systems and compliance with guidance and best practice.

4.18 Wales has a successful track record with regards to the national accreditation of all Hospital/Central Sterilising and Disinfection Units to

[7] Procurement advice can be sought from NWSSP – Procurement's Safety of Surgical Instrument Sub-group.

the Medical Device Directive standard following the completion of a Welsh Assembly Government project in 2005.

4.19 All Endoscopy Departments are required to achieve JAG Standards[8]. Accreditation will require compliance with WHTM 01-06.

4.20 In Hywel Dda University Health Board, one department has now included endoscopy decontamination in its scope of accreditation in compliance with the medical devices directive/ISO standards. This represents best practice and healthcare organisations are encouraged to review the opportunity to do the same.

Measuring success – Actions	
1.	All HSDUs in Wales will maintain accreditation to the Medical Device Directive standard. This is needed to achieve National Accreditation which in turn enables registration with MHRA.
2.	Healthcare organisations that provide endoscopy services should demonstrate compliance with standards detailed in WHTMs.
3.	Where accreditation schemes are not currently in use, healthcare organisations should implement a QMS for major areas of activity e.g. endoscopy and consider seeking accreditation.
4.	Healthcare organisations should ensure that policies and procedures are audited regularly to ensure compliance with regulatory requirements and guidance.

Sharing information and transparency

4.21 Information sharing and transparency are essential in building and maintaining the confidence and understanding of citizens and service users. In accordance with the commitment to zero tolerance of preventable HCAIs, incidents relating to medical devices are unacceptable. Patients rightly expect that medical devices have been decontaminated.

4.23 High profile infection incidents relating to medical devices often attract media coverage and can lead to anxiety among patients who may be aware that a device was or could have been used on them. Responding to either national or local issues relating to medical device incidents should always ensure appropriate engagement with communications departments and consideration of appropriate public messaging.

Sharing information and transparency – Actions

[8] Wales JAG accreditation

1.	Healthcare organisations should proactively consider communication requirements in responding to a medical device incident occurring in or involving their facilities. Decisions about the appropriateness of pro-active or reactive communications actions should be recorded.
2.	In considering a national device related incident, healthcare organisations should have systems in place following receipt of a Medical Device Alert from the MHRA or a neighbouring organisation to determine an appropriate local communication response.
3.	Device related incidents must be recorded in the DATIX system and reported under review processes at board level. Device failures and incidents should also be reported to SMTL for investigation into the failure on behalf of NHS Wales as per MDA/2004/054 (Wales)[9]. SMTL share all device incident reports with the MHRA and NWSSP (Procurement).

[9] MDA/2004/054 (Wales): Guidance on reporting adverse incidents

Annex A

GLOSSARY	
Automated Endoscope Reprocessor (AER)	An AER standardises and automates the preparation of a manually cleaned endoscope so that it is safe for immediate use. It removes the risk that a crucial step in reprocessing will be skipped.
Decontamination	Decontamination involves pre-cleaning, leak testing, cleaning, disinfection, sterilisation rinsing, inspection, transport and storage – a combination of manual and automated processes. For these to be effective, all the process stages need to be conducted correctly, with controls and monitoring in place.
Healthcare	Services provided for or in connection with the prevention, diagnosis or treatment of illness, and the promotion and protection of public health.
Healthcare associated infections (HCAIs)	Infections that arise as a result of the direct or indirect contact of people with healthcare services. HCAIs may be caused by infectious agents from endogenous or exogenous sources: • endogenous sources are body sites - such as the skin, nose, mouth, gastrointestinal (GI) trace or vagina - that are normally inhabited by micro-organisms; • exogenous sources are those external to the patient – such as staff, visitors, patient care equipment, medical devices or the healthcare environment.
Healthcare organisations	Welsh NHS bodies, independent contractors and other organisations including the independent and voluntary sectors, which provide or commission healthcare for individual patients, service users and the public.
Medical devices	All products except medicines, used in healthcare for diagnosis, prevention, monitoring or treatment.
Single use	A device that is used once on a single patient and then disposed of.
Standards	Standards are a means of describing the level of quality healthcare organisations are expected to meet now or have timed plans in place to meet them. The performance of organisations can be assessed against this level of quality.