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Shared Services Partnership
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WHTM 01-06

Welsh Health Technical Memorandum

Decontamination of flexible endoscopes

Part A: Policy and management

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It replaces WHTM 01-06:2014 *Decontamination of flexible endoscopes. Part A: policy and management*

This publication can be accessed from the NHS Wales Shared Services Partnership – Specialist Estates Services website **www.wales.nhs.uk/ses**

Health Technical Memorandum 01-06: Decontamination of flexible endoscopes Part A: Policy and management

Overview

Scope of Welsh Health Technical Memorandum 01-06 Parts A, B, C, D and E

Welsh Health Technical Memorandum (WHTM) 01-06 is part of a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices designed to reflect the need to continuously improve outcomes in terms of:

- patient safety;
- clinical effectiveness;
- patient experience.

It is also designed to reflect the need to ensure the environment in which decontamination procedures are carried out is fit for purpose.

The revised WHTM 01-06 suite of documents supersedes the relevant parts of Welsh Health Technical Memorandum 2014 dealing with endoscope decontamination. This is to ensure that the technical content is consistent with the Department of Health HTM 01-06 series and the requirements of the ACDP TSE Subgroup's amended guidance available on the Gov.UK website (DH 2015).

The documents allow local decisions to be made in the formulation of an appropriately developed, risk controlled, operational environment within the healthcare facilities that decontaminate flexible endoscopes. They also set out how the decontamination of reusable medical devices can be carried out in a cost effective way using risk assessment controls and procedures whilst placing patient safety as its top priority.

Guidance is also offered on the management and decontamination of flexible endoscopes, principally gastrointestinal scopes and bronchoscopes. They also aim to support healthcare establishments in implementing appropriate and effective decontamination measures to reduce the risks of person-to-person transmission of human prion diseases.

WHTM 01-06 is divided into five parts:

Part A: ***Policy and management*** sets out the Welsh Government's policy for an endoscope decontamination service. The document covers flexible endoscope management and decontamination only. Clinical issues relating to endoscopy or the manufacture of endoscope washer-disinfectors (EWD) are not discussed. Furthermore, this document does not cover the processing of flexible endoscopes used to examine sterile body sites. These endoscopes should be sterile, possibly using low temperature gas sterilization, and may be the subject of future guidance.

The document discusses transmissible spongiform encephalopathy (TSE) infectious agents and sets out guidance on the management and handling of endoscopes after they have been used on patients at increased risk of vCJD.

Part B: *Design and installation* sets out guidance on the design and installation of endoscope reprocessing units.

Part C: *Operational management* sets out guidance on operational responsibilities together with advice on the procurement and operation of EWDs.

Part D *Validation and verification* highlights the types of tests and maintenance procedures that are needed to provide evidence that decontamination has been achieved.

Part E: *Testing methods* discusses the principles and methods that are used in the tests described in this WHTM and detailed in BS EN ISO 15883-4:2009.

Why has the guidance been updated?

WHTM 01-06 has been updated to take account of changes to the ACDP TSE Subgroup's general principles of decontamination (Annex C)(2015a). In relation to the decontamination of flexible endoscopes, paragraphs C5 and C20 from the Annex state:

Paragraph C5:
'For endoscopes, the bedside clean should take place immediately after the procedure has been carried out, and it is recommended that the endoscopes should be manually cleaned according to the manufacturer's recommendations and passed through an Endoscope Washer Disinfector as soon as possible after use'.

Paragraph C20:
'A routine test for washer disinfectors could be developed to measure the cleaning efficacy at validation and routine testing, such as daily or weekly tests. This method could be based on a process challenge device system that will monitor the optimised wash cycles; the results must be quantifiable and objective'.

Essentially, therefore, this update focuses on improving the washing and cleaning process, reducing the time from patient use to the decontamination process, and monitoring the cleaning efficacy of endoscope washer-disinfectors.

It is also important to point out that the ACDP TSE Subgroup's Annex C (2015a) deprecates the use of ninhydrin in the detection of protein levels because of its insensitivity. Alternative available technologies should be considered for the detection of residual proteins on the internal surfaces of flexible endoscopes following reprocessing.

Therefore reprocessing units should:

a. consider the available technologies and make a risk-based decision on the methodology to be adopted (for example BS EN ISO 14971:2012);

b. use technologies with the best available sensitivity, consistent measurement standards and quantifiable results to measure effective control of residual protein levels;

c. use trend analysis as a tool for self-improvement to demonstrate decreasing protein levels over time both on the outside of the endoscope and the lumens using available testing technologies.

List of major changes to Part A since the 2013 edition

- **Chapter 5** on prion diseases has been updated.
- New **Appendix 1** on the general principles of decontamination and pathway of a flexible endoscope has been included to reinforce the importance of the bedside clean and the reduction in time from use of the endoscope on a patient to its route through the decontamination process.
- A new **Appendix 2** has been included on the decontamination recommendations for ERCP procedures and on-table bile duct exploration (new material and not a requirement of the ACDP-TSE Subgroup's recommendations).
- All references updated.

Note
The WHTM 01-06 suite of documents is based on continued improvement of standards of delivery at the point of use and constantly striving to reduce the risk element to both users and the patient. The technology involved is constantly improving to meet the demands of the service, and evidence based results and research should always be investigated.

Who should use WHTM 01-06 Part A

Part A is intended as a guide for management, for technical personnel with appropriate training and experience and also for users responsible for the day-to-day running of decontamination equipment. It will also be of interest to microbiologists, infection control officers, architects, planners, estates managers, supplies officers, and others in both the public and private sectors.

Acknowledgements

This guidance is based on HTM 01-06:2016 *Decontamination of flexible endoscopes. Part A: Policy and management* published by the Department of Health in 2016. NHS Wales Shared Services Partnership – Specialist Estates Services is grateful to the Department of Health for its permission to adapt the original guidance for application in Wales.

The contents of the original document were reviewed by NHS Wales Shared Services Partnership – Specialist Estates Services and decontamination representatives from NHS Wales and Welsh Government.

Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

ACDP TSE [Subgroup]: Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies [Subgroup]

AE(D): Authorising Engineer (Decontamination)

AP(D): Authorised Person (Decontamination)

BS: British Standard

CJD: Creutzfeldt-Jakob disease

DH: Department of Health

EN: European norm

EWD: endoscope washer-disinfector. **This terminology supersedes that used in the previous WHTM 01-06 series, which referred to such equipment as an AER (Automated Endoscope Reprocessor).**

HCAI: healthcare associated infections

HIW: Health Inspectorate Wales

ISO: International Standards Organisation

MHRA: Medicines and Healthcare products Regulatory Agency

sCJD: sporadic Creutzfeldt-Jakob disease

TSEs: transmissible spongiform encephalopathies

vCJD: variant Creutzfeldt-Jakob disease

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Chapter 1

The need for guidance

1.1 As our knowledge of disease transmission has improved – particularly in relation to the transmission of human prion diseases (including variant Creutzfeldt-Jakob disease (vCJD)) – it has become timely to review and update decontamination guidance in endoscopy facilities. The value of guidance to assist commissioning organisations and quality inspectorates is acknowledged in this context. In addition there is a clear need for guidance that matches the developing landscape of healthcare regulation and delivery in UK.

1.2. This guidance enshrines the principles in the *Commitment to Purpose: Eliminating preventable healthcare associated infections (HCAIs). A framework of actions for healthcare organisations in Wales* (Welsh Government 2011), the WHC (2015)050 *Decontamination of medical devices: A development plan for healthcare organizations and the Decontamination Improvement Plan* published with the WHC.

1.3 This guidance assists healthcare organisations to plan and improve the environment for the decontamination of endoscopes. It requires that effective prevention and control of healthcare-associated infection be embedded in everyday practice.

In May 2004 an incident was reported in Northern Ireland concerning failure to adequately decontaminate a flexible gastrointestinal endoscope. This incident led to a look-back exercise. Although the exercise did not uncover any cases of cross-infection, a survey of other units in the Province brought several other instances of inappropriate decontamination to light. In response to the Northern Ireland incident, the Medicines and Healthcare products Regulatory Agency (MHRA) issued MDA/2004/028 *Flexible and rigid endoscopes* on 23 June 2004. The action was to carry out an immediate assessment of all endoscope decontamination processes. An Endoscope Task Force was set up in England to look into the decontamination of flexible endoscopes. The review of identified incidents classified problems into:

- incompatibilities between endoscope and the endoscope washer-disinfector (EWD);
- endoscopy staff unfamiliar with the decontamination process specific for the particular endoscope;
- poor communications between endoscope manufacturers and EWD manufacturers.

In response, the MHRA issued *Top Ten Tips. Endoscope Decontamination*, the most recent of which was published in 2013.

On **page 10** are a revised and updated Top Ten Tips based on the guidance in WHTM 01-06.

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Endoscope management and decontamination
WHTM 01-06 top ten tips

1. **Compatibility.** Ensure compatibility with the existing decontamination processes, including the endoscope washer-disinfector (EWD), when purchasing any new endoscopes.

2. **Instructions.** Ensure that all equipment is operated and controlled in accordance with the manufacturer's instructions, local endoscope decontamination policy and associated risk assessments.

3. **Track and trace.** Auto-identification and associated data capture should be used to track and trace all endoscopes, reusable accessories and EWDs to ensure appropriate maintenance, correct decontamination and traceability to associated patients.

4. **Lumen connection.** Check that all lumens in each endoscope can be connected to the EWD using the correct connectors/connection sets provided.

5. **Manual cleaning.** Ensure endoscopes and reusable accessories are manually cleaned immediately after use, including the flushing of all lumens – even if they have not been used during the procedure.

6. **Chemical compatibility.** Only use chemicals that are compatible with the endoscope and its reusable accessories, and observe the correct process parameters that have been validated and demonstrated to be effective.

7. **Decontamination guidance in the WHTM 01-06 series.** Endoscopes should always be decontaminated and maintained to a level specified in these documents. A continuous process of evaluation and improvement should be in place for all healthcare facilities.

8. **Planned preventative maintenance.** Have planned preventative maintenance and associated record-keeping in place to ensure all parts of the endoscope decontamination and management systems are optimally effective.

9. **Staff training.** Ensure all staff, including new appointees, involved in the decontamination process are specifically trained in their role and in the broad context of endoscope management, decontamination and recontamination prevention, and that this training is kept up to date.

10. **Incident reporting.** Report any potential failure in the management and decontamination of endoscopes, including equipment problems relating to endoscopes, EWDs or process chemicals, to a line manager.

These Top Ten Tips take into account the broad approach taken in MHRA's Device Bulletin MDA DB2002(05)*Decontamination of endoscopes.*

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Chapter 2

Flexible endoscopes and decontamination

Note
The term 'endoscopy unit' is used throughout in this document to specifically refer to facilities in which flexible endoscopes are used. An endoscope reprocessing unit is the facility where flexible endoscopes are reprocessed. These two units may not be in the same location.

2.1 The final use of an endoscope will dictate the details of the decontamination process used. For example, endoscopes used to examine the brain need to be sterile at the point of use; endoscopes used to examine the gut will require a different decontamination process. Manufacturers' instructions should be followed.

2.2 In addition to the site of use, consideration should be given to the tissues the endoscope passes through to gain access to the area to be examined. For instance, to gain access to the bladder, a cystoscope passes through unsterile cavities. An endoscope that has been processed through a validated EWD and carefully handled would be suitable for the purpose.

2.3 All instruments need to be thoroughly cleaned to remove residual protein and other organic matter; cleaning of flexible endoscopes should always be thorough and effective wherever they are used.

2.4 The method of decontamination may vary depending on where and how the instrument is used. Whilst in routine operation, the clinical application for which an endoscope has been used will be consistent, the possibility exists that such endoscopes will be applied to clinical examinations that carry a differing risk profile. Where this is the case, clinical teams should endeavour to ensure that those responsible for decontamination are advised of any altered risk.

2.5 Consideration should be given to the construction of a flexible endoscope and the ease of access to the inner part of the instrument. The more intricate the instrument, the harder it will be to clean reliably. The use of a validated EWD will assist in this matter, as there are some lengths of lumen in flexible endoscopes that are difficult to manually clean and the EWD's flow of detergent fluids cannot be totally relied upon for cleaning. Great efforts must be employed by the users to ensure that correct, fit for purpose, brushes are purchased and used for these difficult endoscopes.

2.6 The diagram on the next page shows the principle of relative risks and endoscope variety with regard to decontamination requirements. As with all generalisations, it cannot represent all possible variations. Local clinical advice should be sought on this point, as necessary. Where a service is provided for a range of clinical specialties, risk assessments should reflect the hazards posed to patients at highest risk.

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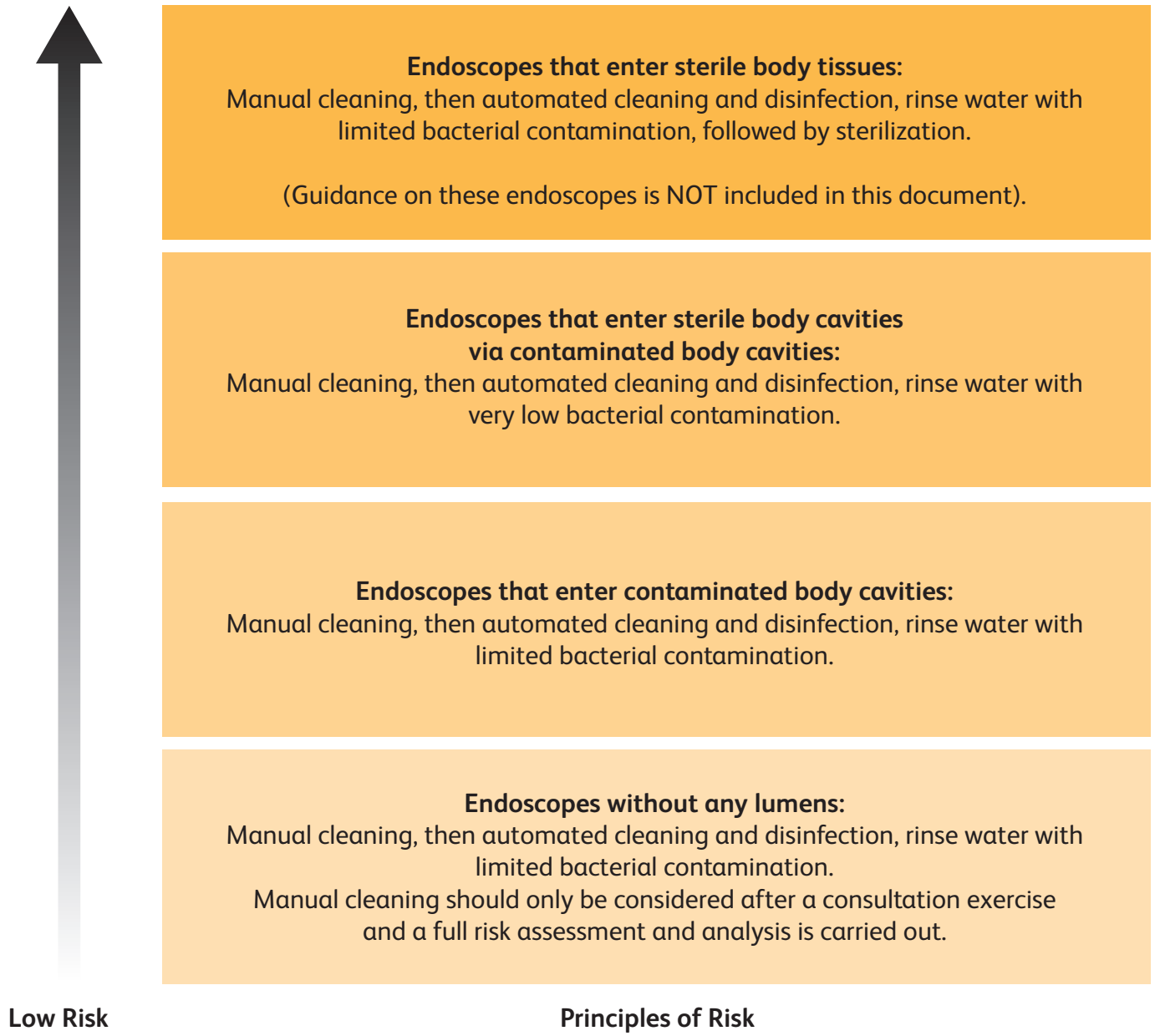
High Risk
Endoscopes that enter sterile body tissues:
Manual cleaning, then automated cleaning and disinfection, rinse water with limited bacterial contamination, followed by sterilization.
(Guidance on these endoscopes is NOT included in this document).
Endoscopes that enter sterile body cavities via contaminated body cavities:
Manual cleaning, then automated cleaning and disinfection, rinse water with very low bacterial contamination.
Endoscopes that enter contaminated body cavities:
Manual cleaning, then automated cleaning and disinfection, rinse water with limited bacterial contamination.
Endoscopes without any lumens:
Manual cleaning, then automated cleaning and disinfection, rinse water with limited bacterial contamination.
Manual cleaning should only be considered after a consultation exercise and a full risk assessment and analysis is carried out.
Low Risk
Principles of Risk

2

The decontamination process

2.7 The process of decontaminating flexible endoscopes with lumens has three components:

a. **Manual cleaning:** this includes brushing with a specific single-use cleaning device, rinsing and exposure of all external and accessible internal components to a low-foaming detergent known to be compatible with the endoscope. This procedure is uncontrolled and relies on the training of the operator for success.

b. **Automated cleaning:** this is carried out in an EWD. The stage may include the use of powerful sprays and pulsed liquid flows down lumens. This stage is reproducible and the cleaning effect can be measured and validated.

c. **Automated disinfection:** followed by rinsing with water that offers only very low pathogenic risks and drying, or air purge, of the endoscope. This process should always be verified by a validation protocol in line with the basic testing requirements identified in WHTM 01-06 Part D *Validation and verification* and BS EN ISO 15883-1:2009 and BS EN ISO 15883-4:2009.

2.8 If a validated low temperature sterilization process is being used, further preparation may be needed, such as extra drying or wrapping with sterilization-compatible materials, depending on the sterilization process to be used.

2.9 It is also essential that all endoscope lumens are included in the decontamination process after every use, even if the lumens were not accessed during the endoscope's use. Failure to follow these recommendations may not only lead to transmission of infection, but also to misdiagnosis (for example, if material from one patient is included in specimens from the subsequent patients) and to instrument malfunction.

2.10 Whether manual decontamination or an EWD is used for non-lumened endoscopes, areas other than the insertion tube that may become contaminated during use (by the operator's gloved hands, for example) should also be cleaned and disinfected.

2.11 Guidance from the British Society of Gastroenterology (2014) notes: *'Some endoscopes (particularly older models) have channels that are not accessible to automated decontamination procedures. Special consideration must be given to the cleaning of auxiliary water channels, exposed elevator wire channels and balloon inflation channels in endoscopic ultrasound probes. The channels of these models must be manually cleaned and disinfected according to manufacturers' instructions.'* Controlled environment storage cabinets (where used) should be capable of, and be validated for, passing air through these channels (see Chapter 6 in WHTM 01-06 Part D).

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2.12 For further information on the cleaning, disinfection and rinsing of endoscopes, see 'EWD operation, and endoscope storage and transport' in Part C of this WHTM 01-06 series. This section also gives guidance on the processing of nasendoscopes and transoesophageal echocardiography, transvaginal and trans-rectal ultrasound probes.

Sealed cassette devices

2.13 Some EWD systems are designed to operate with a sealed cassette device. These systems can reduce handling and may be able to simplify some aspects of both clean and dirty endoscope storage.

2.14 Endoscopes should be correctly fitted or positioned within the cassette to constrain unwanted movement.

2.15 Some designs incorporate devices to permit the tracking of both the cassette and the enclosed endoscope (this can include cassette location at last scan and the status of the enclosed endoscope in terms of clean or dirty). Various tracking systems are available. Appropriate training should be provided to operators with written procedures on how to use the chosen system.

2.16 Where electronic tracking is used, the GS1 coding system is recommended as a safeguard against misidentification.

2.17 Some cassette designs incorporate a multi-channel device to permit appropriate channel cleaning and disinfection. These cassette systems should follow the validation procedures given in WHTM 01-06 Part D *Validation and verification.*

2.18 If endoscopes are to be stored within their cassettes (as ready for use) for a period of up to seven days, an examination of microbiological contamination should be undertaken. Provided the validation results are certified by the risk assessment group, a storage time limit of seven days can be stipulated in a local policy. The storage tank must be agreed prior to validation and assessed by the users of the endoscopes and the unit manager responsible for such decontamination.

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Chapter 3

Standards of practice

Summary

This chapter provides an overview of the Welsh Government's guidance on the decontamination of flexible endoscopes. It outlines the standards required and how to carry out the risk assessment and management that influence health board/Trust practice.

For an introduction to the WHTM framework for medical devices see the current edition of WHTM 01-01 *Decontamination of medical devices within acute services Part A: Management and environment.*

Introduction

3.1 All endoscope planners and providers should seek to meet the existing statutory and regulatory requirements. They include the current Medical Devices Directive (EU Council Directive 98/42 1993) and approved codes of practice, as laid out in the WHTM suite of documents, and relevant applicable standards. They will help to demonstrate that a service provider operates safely with respect to the management and decontamination of instruments.

3.2 Attainment against these standards should also include a local risk-assessment for instrument management, encompassing the provision of instruments that are safe to use and the reliable provision of all the instruments required.

3.3 Local policy should define how a provider achieves risk control within their service.

3.4 Planners, advisers and quality regulators are encouraged to review local policies as part of their assessment of a provider. Comparison of local policy statements and quality systems with audit results will allow assessment against the standards and guidance.

3.5 The aim of this guidance is to achieve a reprocessed flexible endoscope that is fully compliant with the standards of the *Medical Devices Regulations 2002*.

This implies that the endoscope should be:

- clean and high level disinfected at the end of the decontamination process; and
- maintained in a clinically satisfactory condition up to the point of use.

3.6 Local risk assessment and management may enhance the requirement of current standards and aim to further minimise risks to patients, deliver better patient outcomes and achieve cost efficiencies.

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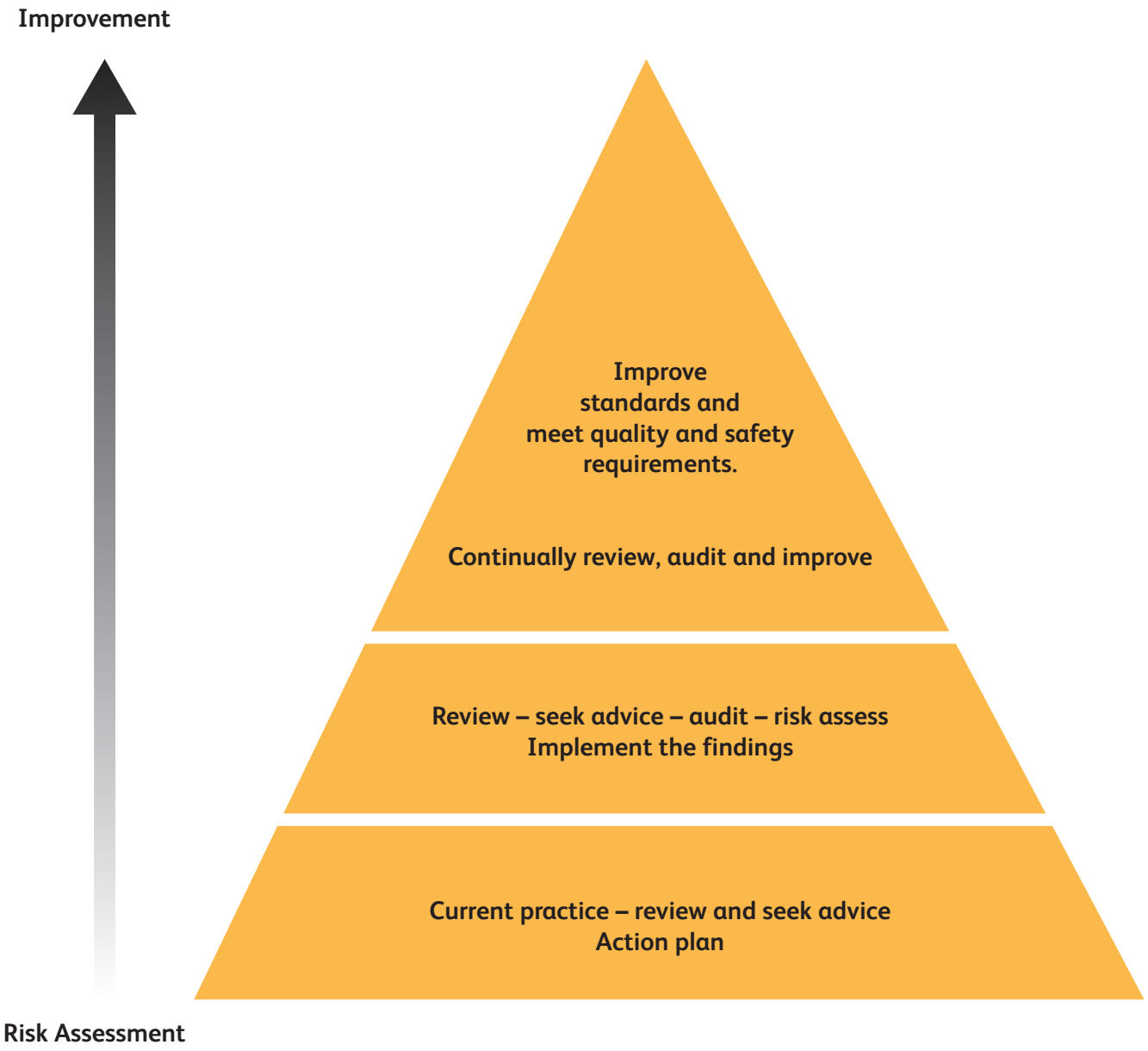
3.7 This WHTM 01-06 series supports the quality and safety ethos of the *1000 Lives Plus* (**www.1000livesplus.wales.nhs.uk**) campaign by promoting and encouraging innovation and choice as components of local policies and procedures.

3.8 Quality and safety should be considered when risk assessing and developing local policies and procedures based on the risk of procedures and available evidence. Quality and safety considerations should encompass guidance on the whole of the decontamination cycle, including, for example, improved instrument management, where there is evidence that these procedures will contribute to improved clinical outcomes.



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Meeting the standards

3.9 Every endoscopy decontamination management and quality system should be capable of meeting the standards contained in this document, as outlined below:

- The decontamination policy should demonstrate that:
  - It complies with the latest guidance and standards, establishing good practice:
  - Decontamination of reusable medical devices takes place in appropriate facilities that are designated for purpose and designed to minimise the risks that are present (see Figures 2–5 in the 'Example layouts' of WHTM 01-06 Part B *Design and installation*);
  - Appropriate procedures are followed for the acquisition, maintenance and validation of decontamination equipment;
  - All staff are trained and educated in cleaning and decontamination processes and hold appropriate competences for their role; and
  - A record-keeping and logging regime is in place to ensure that decontamination processes are fit for purpose and use the required quality systems.
- Endoscopes should be decontaminated in accordance with manufacturers' recommendations, where applicable, to ensure that the correct procedures are in place.
- The quality of water used is of importance to risk control. Characteristics are listed in Table 3 of WHTM 01-06 Part B *Design and installation* (see also Table 2 in that volume).
- All instruments with lumens should be reprocessed using a validated automated process.
- At the end of the reprocessing cycle they should be fit for their intended purpose. Using WHTM 01-06 Part D *Validation and verification* and Part E *Testing methods* is a key step to risk control and should be demonstrably in place.
- Policies and guidelines on the minimisation of recontamination or recolonisation should be in place. Following decontamination, a high standard of care is needed to ensure that neither recontamination nor recolonisation occur to such an extent that they compromises patient safety. Handwashing, gloving and the use of barrier precautions such as aprons (where appropriate), as examples of high standards of personal hygiene, are required from staff. There should be input from the control of infection team into local policies.

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- Personal protective equipment should be worn for all appropriate uses and documented in local policies.

- The production, maintenance and use of standard operating procedures for each stage in the management, use and decontamination of endoscopes are required. These procedures should take account of the local risk assessment and be so designed as to ensure that, when used with local self-audit (LSA), standards are continuously maintained.

- Reprocessed instruments should be inspected to show that they are clean and safe for reuse.

- An effective form of manual or computer-based instrument track and trace system should be in place. A procedure for the withdrawal of endoscopes from service should be in place. This should include the management of prion-related incidents or other events that may render the endoscope unfit for purpose, such as damage or failing a leak test. A log system must be employed to keep records.

Note
This guidance documentation is based on European harmonised standards and other technical specifications (eg BS EN ISO 15883-4). The standards organisations specifically referenced are CEN, ISO and BSI. In every case, compliance with these standards is regarded as 'meeting the standards'.

Examples of improvements in service delivery

3.10 The quality and safety agenda will always seek ways of improving service provision and will lead to revision of base line standards. Examples include:

- Current standards require that the environment where decontamination is carried out minimise the risks of recontamination of instruments, the inadvertent use of incompletely decontaminated endoscopes and of cross-contamination between clean and dirty areas. Continual improvement will require the use of separate rooms for the accommodation of clean (output) and dirty (input) work. In such facilities, the rooms should be used for decontamination purposes only and access should be restricted to those staff performing decontamination duties (see Figures 2 to 5 in the 'Example layouts' section of WHTM 01-06 Part B *Design and installation*).

- The centralisation of endoscope management and decontamination may offer advantages when improvements in risk control and quality systems are considered. Some commissioners and providers may find that site-level centralisation allows for the generation of enhanced and professional standards for decontamination staff.

- A reliable computerised endoscope instrument tracking and traceability system interfaced to patient records should be in place and operational, backed by reliable record-keeping. The tracking system should incorporate loan endoscopes as well as those used routinely in the unit.

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- Unless a decontaminated endoscope is being stored in a way validated to extend usable storage life or is in sterile packaging following sterilization, it should be used within three hours of decontamination.

- The views of clinical users, the AE(D) and the infection control team should be sought in the initial assessments of risk related to water quality and infection (see Table 3 in WHTM 01-06 Part B *Design and installation* and Table 2 in WHTM 01-06 Part E *Testing methods* for guidance on quality of water).

- Endoscopes should be kept moist from the end of patient procedure to the start of decontamination, cleaning may be easier. No rigorous definition of moist is provided; however, guidance users should interpret this definition as a high level of humidity but not necessarily liquid water. Where instances occur where this requirement has not been followed, the endoscope should be decontaminated as normal (see **Appendix 1**).

- Endoscopes should be stored securely to prevent unauthorised access and to permit their easy identification.

- A local self-audit tool should be used and completed (such as that published by the Infection Prevention Society (IPS 2017) or NWSSP-SES).

- The quality and fitness-for-purpose of all endoscopes should be periodically reviewed in accordance with manufacturers' instructions.

3.11 Service quality improvements will involve keeping up to date with developments and new equipment in the endoscope reprocessing field. This guidance may be amended when new developments are apparent.

Quality enhancements via risk assessment

3.12 To assess what quality enhancements should be set as a target, a local risk assessment group (see **paragraph 3.13**) will need to be set up. This group will assess the range of endoscopes that are to be processed, the various circumstances under which they will be used and then consider what improvements or enhancements are appropriate.

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The Risk Assessment Group

3.13 The Director of Nursing as health board executive lead for healthcare associated infections, or equivalent will have ultimate responsibility for the risk assessments. Others included in the group could be:

- the decontamination lead (or the management lead who has direct responsibility for decontamination);
- the sterile services manager;
- representative(s) from the infection control team;
- representative(s) from the clinical device users;
- the person(s) who have responsibility for the decontamination of the endoscopes on a day-to-day basis;
- the authorising engineer (decontamination) (AE(D));
- the appointed AP(D) for the health board;
- representative of estates management.

Others, such as representatives of decontamination services and estates and facilities, may be members of the group or co-opted at the discretion of the chair.

3.14 The risk assessment group should report to the board; usually this would be via the drector of nursing, or their equivalent.

Planning implications

3.15 This policy and guidance is designed to help healthcare professionals in the planning and delivery of the standard of decontamination that patients have a right to expect, by building on existing sound practice.

3.16 In accordance with the HCAI framework (Welsh Government 2011), health boards/Trusts and healthcare establishments should assure themselves that the services they deliver are meeting expected standards and guidance as outlined in this document, or are applying an appropriate risk control strategy.

3.17 Health boards/Trusts and healthcare establishments, in meeting their quality and safety obligations, should seek to improve the services they offer; where they have several providers of endoscopy services or are planning new providers they may wish to:

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- include enhanced elements within the service specification that go beyond the standards;
- establish key performance indicators as part of the review process; and
- develop incentives to improve performance.

3.18 In assessing their services, health boards/Trusts and healthcare establishments should address gaps in service provision and encourage evidence-based practices.

3.19 They should examine local policy offered by providers for evidence of a viable strategy leading to further quality and safety improvements assessed by the risk assessment group (see **paragraphs 3.13-3.15**). In the performance of this duty, the clinical team and the infection control team should be consulted. Important technical and engineering issues may require the advice of appropriate professionals including an AE(D) and NWSSP-SES engineers.

3.21 Providers may seek to demonstrate how their healthcare services exceed the standards and demonstrate quality improvement.

4

Chapter 4

Health Inspectorate Wales

4.1 Health Inspectorate Wales (HIW) inspects all providers of regulated health and adult social care activities in Wales.

4.2 HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to provide independent assurance for patients, the public, the Welsh Government and healthcare providers, that services are safe and good quality. Services are reviewed against a range of published standards, policies, guidance and regulations, such as the *Health and Care Standards 2015* (Welsh Government 2015) and supporting guidance.

HIW's main functions and responsibilities are drawn from the following legislation:

- *Health and Social Care (Community Health and Standards) Act 2003* and associated regulations;
- *Care Standards Act 2000* and associated regulations;
- *Mental Health Act 1983*, *Mental Capacity Act 2005* and the *Mental Health Act 2007*, and the *Mental Health (Wales) Measure 2010*;
- *Ionising Radiation (Medical Exposure) Regulations 2000* and subsequent amendments;
- *Criminal Justice and Court Services Act 2000*;
- Section 83 of the *Government of Wales Act* (clinical review of deaths in prison).

4

Quality inspection

In the assessment of performance in the management and reprocessing of endoscopes, the attainment of the standards and meeting the Welsh Government's guidance in the absence of contrary risk assessment is an important quality indicator. From this, it may be implied that appropriate quality systems and supporting measures are in place to achieve sound decontamination and consequent risk control. However, it is recommended that HIW and those recognised organisations in Wales conducting audits for the quality inspectorates give particular attention to:

- The quality of local risk assessments and policies.
- An agreed audit tool by the health board/Trust or healthcare organisation
- Training and professional qualifications.
- Appropriate equipment and validation to the list of standards (EN standards and reports as detailed in the WHTM 01-06).
- The suitability of the use and reprocessing environment.
- Appropriately designed decontamination environment
- Maintenance of instrument management and decontamination records and validation certificates.
- Application of track and trace systems, with particular attention to the coding technologies recommended in Welsh Government policies.

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Chapter 5

Human prion diseases (including variant CJD and other forms of CJD)

Background

The human prion diseases are a group of rare fatal neurological disorders that occur in sporadic, genetic and acquired forms, the latter occurring by transmission from one individual (or species) to another. These conditions are all associated with the conversion of a normal protein in the body, the prion protein, to an abnormal disease-associated form that accumulates in the brain and results in neuronal degeneration and death. The abnormal prion protein is thought to be the major component of transmissible prion agents.

The most common human prion disease is the sporadic form of Creutzfeldt-Jakob disease (sCJD), with an annual incidence worldwide of one-to-two cases per million of the population. In the UK, there are between 50 and 90 cases annually, with a peak incidence in the 60–70-year age group. This disease presents with rapidly progressive dementia and a range of other neurological signs and symptoms, with death occurring in around three-to-six months of disease onset. The genetic forms of human prion disease account for around 10 % of total cases, while acquired cases account for around 1 %, including iatrogenic CJD (iCJD) in human growth hormone and dura mater graft recipients, and variant CJD (vCJD). Incubation periods in acquired human prion diseases can vary from two to over 40 years, depending on the route of exposure. vCJD was first reported as a novel human prion disease in 1996, acquired from infection by the bovine spongiform encephalopathy (BSE) agent, most likely via the oral route.

Patients with sCJD and vCJD have differences in the distribution of prion infectivity around the body. In sCJD (and also in some cases of genetic prion diseases and iCJD), abnormal prion protein appears to be restricted to the central nervous system (CNS), whereas in vCJD it has also been detected in lymphoid tissues, including tonsils, spleen and gastrointestinal lymphoid tissue. Abnormal prion protein has been detected in the lymphoid tissues of a few individuals infected with vCJD before the onset of clinical signs and symptoms of the illness, indicating asymptomatic vCJD infection.

vCJD is distinguishable from non-vCJD in a number of ways:

- It tends to affect younger people with an average (median) age of onset of around 26 years (median age at death 28 years).
- The predominant initial clinical symptom is of psychiatric or sensory problems, with coordination problems, dementia and muscle-twitching occurring later.
- The illness usually lasts about 14 months (range 6–84 months) before death.

A definitive diagnosis of vCJD can only be confirmed by examining brain tissue, usually at post-mortem, and requires the exclusion of other forms of human prion disease, particularly sCJD. In the UK, as of 2016, there have been 177 deaths from definite or probable cases of vCJD, three of which appear to have been acquired by packed red blood cell transfusion from infected donors. The peak year of deaths was 2000, since when numbers of cases have fallen progressively with no new cases reported since 2012. However, given the long incubation periods previously seen for acquired CJD, and with evidence from tissue-based prevalence studies in the general

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population, the potential for further cases to emerge or for potential asymptomatic abnormal prion carriage within the general population has yet to be ruled out.

While three vCJD cases may have been transmitted by blood transfusion, there are no known cases of vCJD being transmitted by surgical instruments or endoscopes. However, it may be possible because:

- sCJD has been transmitted by neurosurgical instruments used on the brain;
- abnormal prion protein binds avidly to steel surfaces and can be very difficult to remove from surgical instruments; and
- prion infectivity has been found in a range of tissues (brain, spleen, tonsils etc) of patients who have developed symptomatic vCJD.

Guidance from the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup, formerly the TSE Working Group, details precautions to be taken when dealing with known or suspected cases and those at increased risk of human prion disease (DH 2015).

What is the relevance of decontamination to human prion diseases?

While there is still a good deal of scientific uncertainty about human prion diseases, the UK Government continues to take a precautionary approach and adapt policy as new evidence emerges. To maintain effective risk management, it is important to combine improved recognition of potentially infected individuals who are at increased risk of human prion disease with the most effective methods for surgical instrument decontamination.

Introduction

5.1 vCJD is one of the human prion diseases, a group of invariably fatal neurological disorders also known as transmissible spongiform encephalopathies (TSEs). The normal human prion protein (PrPC) undergoes a change in conformation to become an abnormally folded form of the protein known as PrP^{Sc} during the course of disease.

5.2 PrP^{Sc} is heat-stable, exceptionally resistant to enzymatic digestion and, once dried onto surfaces of endoscopes and surgical instruments, is very difficult to remove or inactivate by conventional decontamination processes.

5.3 PrP^{Sc} accumulates to high levels in the central nervous system of infected individuals by the clinical stage of disease.

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5.4 In vCJD there is also accumulation in lymphoid tissues during the pre-symptomatic and symptomatic stages of disease including tonsils, spleen and Peyer's patches in the gastrointestinal system.

5.5 This WHTM supports health boards/Trusts and healthcare establishments in implementing appropriate and effective decontamination measures to reduce the risks of transmission of human prion diseases. Owing to the difficulty of inactivating or removing human prion proteins from surgical instruments and endoscopes, special measures are required to prevent their potential transmission between patients.

5.6 This WHTM applies to all flexible endoscopes other than flexible neuroendoscopes and rigid endoscopes.

5.7 The advice below applies to invasive procedures in which the integrity of fixed lymphoid tissue may be breached (when taking a biopsy or causing tissue vaporisation, for example by diathermy). In summary, these precautions include:

a. not using alcohol or aldehyde-based disinfectants which will bind ('fix') proteins, including prion proteins, to surfaces on endoscopes;

b. ensuring policies and protocols are in place to address the precautions required where an endoscope comes into contact with gastrointestinal lymphoid tissue (for example, if a biopsy is taken in any patient);

c. ensuring that the appropriate precautions are put in place when performing endoscopy on patients who have been diagnosed with or are suspected as having a human prion disease, or have been notified as being at increased risk of CJD.

5.8 When an endoscopy is likely to involve an invasive procedure, it is important to determine whether a patient has definite or probable vCJD, or is presumed infected – that is, known to have received blood or blood components (for the purposes of this WHTM, this includes whole blood, red cells, white cells or platelets) from a donor who later developed symptomatic vCJD.

Patients with definite or probable vCJD or presumed infected cases

5.9 After the performance of an invasive procedure, flexible endoscopes used on patients infected or presumed infected with vCJD should be retained for use on that same patient after conventional decontamination (as defined in this WHTM) or destroyed by incineration.

5.10 The number of patients in these groups is very low. Advice should be sought before any irreversible actions, such as disposal of reusable instruments, are taken.

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Patients 'at risk' of infection with a human prion disease

5.11 There are around 5000 people in the UK who have an increased risk of CJD because of an operation or medical treatment in the past. The descriptions and definitions of these risk groups can be found in the ACDP-TSE Subgroup's *Infection control of CJD, vCJD and other human prion diseases in healthcare and community settings.*

5.12 Following an examination (including a biopsy) or treatment on patients classified as 'at increased risk' of infection with a human prion disease, decontamination of the flexible endoscope should be carried out in accordance with this guidance.

5.13 It is possible to reprocess an endoscope that may be prion-contaminated with other endoscopes in the same EWD chamber, before the contaminated endoscopes are quarantined. Endoscopes should not be in contact with each other during reprocessing.

5.14 All single-use accessories should be discarded as infectious waste and reusable accessories decontaminated to maximise protein (including prion protein) removal. Advice from the Microbiologist (Decontamination) should be sought, since some reusable items may need to be discarded as they cannot be cleaned to the required standard.

5.15 A traceability system for equipment especially where used on patients with, or at increased risk of, human prion disease is very important. Also subsequent storage (including quarantine if indicated) (see the ACDP-TSE Subgroup's Annex F *Endoscopy* (2015b)) or use of instruments must be recorded and where appropriate specialist advice obtained from the local Public Health and Protection Team.

5.16 More detailed advice on instrument management following the use of an endoscope or endoscopic accessories on a patient at increased risk of CJD can be obtained from the ACDP-TSE Subgroup's Annex F *Endoscopy* (2015b).

5.17 The guidance below is based on that from the ACDP-TSE Subgroup's Annex F (last revised in October 2015). Users should check for updates on the ACDP-TSE Subgroup's web pages (DH 2015).

a. Channel cleaning brushes and, if biopsy forceps or other accessories have been passed, the valve on the endoscope biopsy/instrument channel port should be disposed of as healthcare waste after each use. Single use biopsy forceps should be used in all patients. Endoscope accessories should be single use wherever possible. It is essential to have systems in place that enable endoscopes, together with all their detachable components and any re-used accessories, to be traced to the patients on whom they have been used.

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b. As defined below, endoscopes used for certain procedures in the CNS and nasal cavity in individuals with possible sCJD, or in whom the diagnosis is unclear, should be removed from use or quarantined pending diagnosis or exclusion of CJD (see **Table 1** for clarification). The principles and procedures recommended for quarantining of surgical instruments in Annex E of the ACDP-TSE Subgroup's guidance (2015c) should be followed.

c. Endoscopes, other than those used in the CNS and nasal cavity, which have been used for invasive procedures in most individuals designated as 'at increased risk' of vCJD (see **Table 1**) can be returned to use after decontamination. The endoscope should be put through all the normal stages of cleaning, and be disinfected separately from other equipment within an EWD.

d. Aldehyde disinfectants with fixative qualities (such as glutaraldehyde and OPA) tend to stabilise rather than inactivate prions, and are no longer recommended for use in the UK. Non-fixative disinfectants are used instead.

e. When decontaminating endoscope cleaning equipment, the EWD should be put through an 'empty' self-disinfection cycle as per recommended routine. Provided that the cleaning equipment is decontaminated as indicated, there is no known risk of transmission of TSE agents via this route.

f. Following use in patients at risk of vCJD endoscopic accessories (including normally reusable devices such as heater probes) and cleaning aids such as brushes should be disposed of as healthcare waste.

5.18 For details about action required following invasive procedures on a patient with definite or probable vCJD or presumed infected cases, see also *Public health action following report of new case or person at increased risk of CJD* (Public Health England 2015)

Protein removal and detection

5.19 Prion proteins are extremely hydrophobic, making them far more difficult to remove from instrument surfaces once they have dried on to a surface. Full endoscope decontamination should therefore commence within three hours of use. If there is a delay of more than three hours, it should be assured that the mechanism for keeping the endoscope moist until full decontamination will continue to be effective during this period.

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Table 1. Summary of precautions advised for the use of flexible endoscopes in patients with CJD, presumed infected or at increased risk. The following applies where an invasive procedure has been carried out. For non-invasive procedures, endoscopes should be decontaminated according to these guidelines.

Status of patient					
	Symptomatic – diagnosed with or suspected of having a human prion disease			Asymptomatic: presumed infected	Asymptomatic: at increased risk
Tissue Infectivity	Definite or probable: • Sporadic CJD • iatrogenic CJD • inherited prion disease	Definite or probable variant CJD	Possible CJD or diagnosis unclear[1]	At risk (blood*** recipient from a donor who later developed vCJD)	At increased risk of: • variant CJD • inherited prion disease • other iatrogenic CJD
High: • Brain • Spinal cord	Not covered by this guidance				
Medium: Olfactory epithelium*	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	Single use OR destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	Single use OR Quarantine pending diagnosis	Single use OR destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	No special precautions unless contaminated with olfactory epithelium* If contaminated: Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same index patient

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Table 1. Summary of precautions advised for the use of flexible endoscopes in patients with CJD, presumed infected or at increased risk. The following applies where an invasive procedure has been carried out. For non-invasive procedures, endoscopes should be decontaminated according to these guidelines.

Status of patient					
Symptomatic – diagnosed with or suspected of having a human prion disease				Asymptomatic: presumed infected	Asymptomatic: at increased risk
Medium: Lymphoid tissue**	No special precautions	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	Single use OR Quarantine pending diagnosis	Single use OR Destroy after use OR Quarantine[2] for re-use exclusively on the same index patient	No special precautions (see paragraphs **5.11 to 5.15**)
Low or none detectable: All other tissues	No special precautions	No special precautions	No special precautions	No special precautions	No special precautions

Notes

* The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissues.

** For the purposes of this guidance (WHTM 01-06), lymphoid tissue refers to the spleen, thymus, tonsils and adenoids, lymph nodes, the appendix and the gastrointestinal tract sub-mucosa.

*** A small number of individuals are known to have received blood or blood components from a donor who later developed vCJD.

1. This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where a diagnosis of CJD is being actively considered (see also Annex B of the ACDP-TSE guidance).
2. Quarantined endoscopes may be re-used exclusively on the same individual patient if required. The principles behind the procedures recommended for quarantining of surgical instruments in Annex E of the ACDP-TSE guidance should be followed before being quarantined. The endoscope should be decontaminated alone using an automated EWD. The EWD should be decontaminated as per paragraph 5.17(e).

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5.20 Most of the protein should be removed immediately after use with a single-use moist wipe/sponge and by the standard procedure of flushing water down each channel and wiping the insertion tube before manual cleaning. If the endoscope reprocessing unit is not close to the patient examination area, the endoscope should be transported in a rigid container lined with a plastic sheet (usually of a specific colour to indicate a contaminated device) to prevent drying and to contain infectious materials.

5.21 Manual pre-cleaning is essential to remove deposits from the lumen and around the controls of an endoscope (see 'Handling of endoscopes after use and before decontamination' in 'Cycle of use and decontamination of endoscopes' in WHTM 01-06 Part C *Operational management*).

5.22 The detection of residual proteins on cleaned endoscopes presents two main challenges:

a. the use of a sensitive protein detection system compatible with sampling methods applicable to endoscopes; and

b. the ability to effectively sample areas poorly accessible to cleaning, essentially surfaces inside lumens. Technologies chosen for protein detection on endoscopes should take both these parameters into account.

5.23 Test methods previously recommended for detection of residual proteins have limited ability to remove protein from surfaces and assays have been shown to be insensitive. Alternative available technologies should be considered for the detection of residual proteins on the internal surfaces of flexible endoscopes following reprocessing. The reprocessing unit should:

a. consider the available technologies and make a risk-based decision on the methodology to be adopted (for example BS EN ISO 14971);

b. use technologies with the best available sensitivity, consistent measurement standards and quantifiable results to measure effective control of residual protein levels;

c. use trend analysis as a tool for self-improvement to demonstrate decreasing protein levels over time both on the outside of the endoscope and the lumens using available testing technologies.

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Prion-specific decontamination technologies

5.24 There are technologies that may offer future potential to enhance the existing decontamination process to reduce protein, including prion protein contamination of instruments.

5.25 In addition to activity against abnormal prions, prion decontamination technologies must also:

a. be compatible with the existing decontamination processes;

b. remove protein and other infectious microbes;

c. have good stability;

d. have acceptable environmental and operator safety;

e. be compatible with instruments and EWDs;

f. remove and prevent biofilm formation.

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Appendix 1

General principles of decontamination and pathway of a flexible endoscope

The difficulties of cleaning these complex instruments have been well documented in DH-funded research projects. The main problems include the formation of biofilms and the inability to clean and inspect the cleanliness inside the endoscope lumens. The decontamination process is further limited by the materials used in the construction of the endoscope which may be thermolabile.

The ACDP-TSE Subgroup's guidance was updated in 2015. Sections on infection control and Annexes C and F (2015a, 2015b) have been updated to reflect the latest scientific research that affects the decontamination cycle for reusable medical devices.

It was recommended that the latest NHS guidance (that is, WHTM 01-01 and WHTM 01-06), which incorporates the most recent guidance from the ACDP-TSE Subgroup, is reviewed and any updated recommendations included in the decontamination procedures undertaken by the healthcare organisation involved in patient treatment and the implementation of any decontamination procedures.

Annex C and Annex F clearly state the need to reprocess flexible endoscopes immediately after a patient procedure has been carried out. The flowchart on the next page illustrating the timelines and basic procedures should be followed to ensure the risks to the patients are reduced to a minimum and that best practice is carried out. This will cover the majority of flexible endoscopes in use. There will always be exceptions for out-of-hours use and emergency use. In these cases a full risk analysis must be drawn up and agreed procedures put in place.

Note
Guidance from the ACDP-TSE Subgroup is continually being updated. It is recommended that the latest guidance from ACDP is accessed.

The bedside clean should be carried out immediately after the endoscope has been used.

Full endoscope decontamination should commence within three hours of use. If there is a delay of more than three hours, it should be assured that the mechanism for keeping the endoscope moist until full decontamination will continue to be effective during this period.

The pathway from patient use through the decontamination process and finally storage must be planned, controlled, monitored and recorded. Any delays in this process will impair decontamination.

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Flexible endoscope decontamination timeline

Stage 1
Immediately after a patient procedure has completed, carry out the bedside clean of the flexible endoscope to the manufacturer's instructions

Place the flexible endoscope into the lined tray (or cassette) and cover or seal as per the locally agreed system

Stage 2
Transport the endoscope to the decontamination facility without significant delay

Stage 3
Carry out a leak test and manual clean procedure, including auxiliary channels, to local policies and procedures

Process the endoscope in an EWD no more than 3 hours after the endoscope was used

Stage 4
Use the endoscope within 3 hours after removal from the EWD or store in a validated storage system and if not used, return to stage 2. If required to be sterile, dry, pack and sterilize

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Appendix 2

Decontamination recommendations for ERCP procedures and on-table bile duct exploration

Although flexible endoscopes are used in these two procedures, their decontamination requirements are different.

ERCP procedures

Endoscopic retrograde cholangio-pancreatography (ERCP) is a procedure to diagnose and treat problems in the bile duct or pancreatic duct using a flexible endoscope, appropriate single-use accessories and an x-ray detectable dye.

Decontamination requirements
Because the endoscope is passed down through the mouth, it does not need to be provided as sterile.
The endoscope should go through a bedside clean followed by a manual decontamination process, paying particular attention to the elevator mechanism and the recess surrounding the elevator mechanism. During this process, the distal cover should be removed and the elevator should be raised and lowered throughout the manual cleaning process to allow brushing of surfaces that may be obscured by the raiser bridge (see the British Society of Gastroenterology's 2014 guidelines).

Following the manual process, the duodenoscope should be reprocessed through an EWD using appropriate chemistries and adhering to the endoscope manufacturer's instructions. Ensure the EWD is capable of decontaminating endoscopes with wire-carrying channels.

On-table bile duct exploration

On-table biliary explorations are done in a theatre environment that involves intra-abdominal surgical intervention by a surgeon. It is either performed under aseptic conditions using a flexible choledochoscope passed via the cystic duct or performed as a choledochotomy either laparoscopically or at open surgery.

Decontamination requirements
Since the choledochoscope has to enter sterile tissue, the scope needs to be provided as sterile.
This is achieved with:

a. a manual cleaning process;

b. then reprocessing through an EWD; and

c. sterilization using low temperature sterilization procedures (for example, ethylene oxide or hydrogen peroxide technology).

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http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML

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Ionising Radiation (Medical Exposure) Regulations 2000
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http://www.legislation.gov.uk/ukpga/2005/9/contents

Mental Health Act 1983
http://www.legislation.gov.uk/ukpga/1983/20/contents

Mental Health Act 2007
http://www.legislation.gov.uk/ukpga/2007/12/contents

Mental Health (Wales) Measure 2010
http://www.legislation.gov.uk/mwa/2010/7/contents

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British Standards Institution

The latest version of any standard should be used, provided that it continues to address the relevant requirements of these recommendations **http://shop.bsigroup.com/en/**

BS EN ISO 14971:2012 *Medical devices. Application of risk management to medical devices.*

BS EN ISO 15883-1:2009+A1:2014 *Washer-disinfectors. General requirements, terms and definitions and tests.*

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*At the time of publication this was labeled 'work in hand'

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