

Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Policy and management

**Choice Framework for local Policy and
Procedures (CFPP) 01-06
Decontamination of flexible endoscopes:
Policy and management**

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Preface

Introduction

The Choice Framework for local Policy and Procedures (CFPP) is an initiative being piloted by the Department of Health.

It forms a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.

Purpose

The purpose of CFPP is to enable local choices to be made regarding the management, use and decontamination of reusable medical devices at controlled costs using risk control.

CFPP is designed to reflect the need to continuously improve outcomes in terms of:

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

Essential Quality Requirements and Best Practice

The Health Act Code of Practice recommends that healthcare organisations comply with guidance establishing Essential Quality Requirements and demonstrate that a plan is in place for progression to Best Practice.

Essential Quality Requirements (EQR), for the purposes of this best practice guidance, is a term that encompasses all existing statutory and regulatory requirements. EQRs incorporate requirements of the current Medical Devices

Directive and Approved Codes of Practice as well as relevant applicable Standards. They will help to demonstrate that an acute provider operates safely with respect to its decontamination services.

Local policy should define how a provider achieves risk control and what plan is in place to work towards Best Practice.

Best Practice is additional to EQR. Best Practice as defined in this guidance covers non-mandatory policies and procedures that aim to further minimise risks to patients; deliver better patient outcomes; promote and encourage innovation and choice; and achieve cost efficiencies.

Best Practice should be considered when developing local policies and procedures based on the risk of surgical procedures and available evidence. Best Practice encompasses 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.

The CFPP suite is listed below.

- Choice Framework for local Policy and Procedures 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care
- Choice Framework for local Policy and Procedures 01-04: Decontamination of linen for health and social care
- Choice Framework for local Policy and Procedures 01-06: Decontamination of flexible endoscopes

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Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

ACDP-TSE RM [subgroup]: Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies Risk Management [subgroup] (formerly the TSE Working Group)

ACDST: Advisory Committee on Decontamination Science and Technology

AE(D): Authorising Engineer (Decontamination)

BS: British Standard

CFPP: Choice Framework for local Policy and Procedures

CJD: Creutzfeldt-Jakob disease

CQC: Care Quality Commission

DH: Department of Health

DIPC: Director of Infection Prevention and Control

EN: European norm

EWD: endoscope washer-disinfector

HCAI: healthcare-associated infections

HCAI Code of Practice: DH's 'Health and Social Care Act 2008: Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance'

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

Executive summary

Choice Framework for local Policy and Procedures (CFPP) 01-06 offers best practice guidance on the management and decontamination of flexible endoscopes (principally gastrointestinal scopes and bronchoscopes). It also aims to support commissioners and providers in implementing appropriate and effective decontamination measures to reduce the risks of person-to-person transmission of human prion diseases.

For an introduction to the CFPP framework, please see 'Choice Framework for local Policy and Procedures'.

Scope

This document covers flexible endoscope management and decontamination only. Clinical issues relating to endoscopy or the manufacture of EWDs are not discussed. In addition this document does not cover the processing of flexible endoscopes used to examine sterile body tissues. These endoscopes should be sterile, possibly using low temperature gas sterilization, and may be the subject of future guidance.

Structure

CFPP 01-06 is divided into five volumes:

- The 'Policy and management' volume sets the Department of Health's (DH) policy context and

discusses the Essential Quality Requirements and Best Practice recommendations for an endoscope decontamination service. Transmissible spongiform encephalopathy (TSE) infectious agents are discussed and guidance given on management and handling of an endoscope after it has been used on a patient at increased risk of vCJD.

- The 'Design and installation' volume gives guidance on the design and fitting of endoscope reprocessing units.
- The 'Operational management' volume gives guidance on operational responsibility together with advice on the procurement and operation of an endoscope washer-disinfector (EWD).
- The 'Validation and verification' volume highlights the types of tests and maintenance procedures that are needed to ensure that decontamination has been achieved.
- The 'Testing methods' volume discusses the principles and methods that are used in the tests described in this CFPP and the tests detailed in BS EN ISO 15883-4.

CFPP 01-06 supersedes the relevant parts of Health Technical Memorandum 2030 dealing with endoscope decontamination.

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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 England.
- 1.2 Patients have a right to be investigated and treated in a safe and clean environment with consistent standards every time care is given. It is essential that the risk of person-to-person transmission of infections be minimised as far as reasonably possible.
- 1.3 This guidance follows the essential principles given in the ‘Health and Social Care Act 2008: Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance’ (the HCAI Code of Practice). This requires that effective prevention and control of healthcare-associated infection be embedded in everyday practice.

In May 2004 an incident was reported from Northern Ireland concerning failure to decontaminate adequately a flexible gastrointestinal endoscope. This incident led to a look-back exercise. Although this exercise did not yield 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” in October 2005.

On [page 2](#) are a revised and updated Top Ten Tips based on the guidance in CFPP 01-06.

ENDOSCOPE MANAGEMENT AND DECONTAMINATION

CFPP 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. **Essential Quality Requirements and Best Practice (as described in CFPP 01-06).** Endoscopes should always be decontaminated and maintained to a level specified in Essential Quality Requirements. A continuous process of evaluation and improvement should be in place to progress towards locally determined Best Practice.
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'.

2 Flexible endoscopes and decontamination

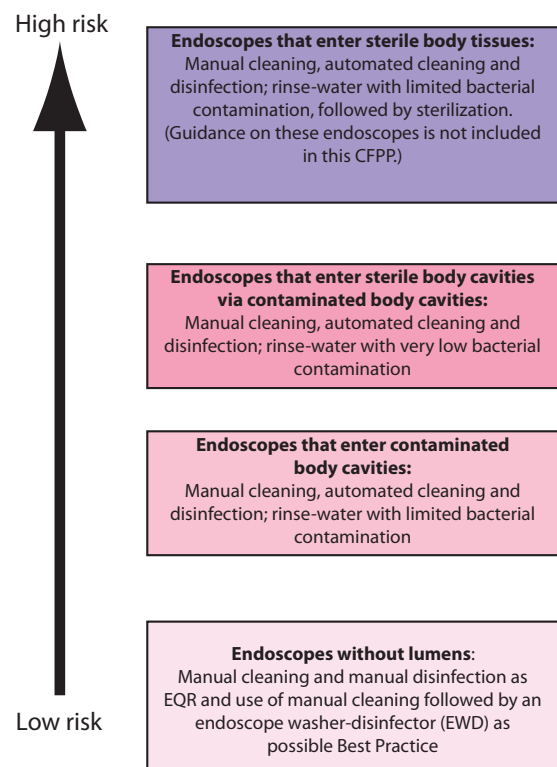
Note

The term “endoscopy unit” is used throughout in this volume 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 cannot be reached by cleaning brushes and rely on the flow of detergent fluids for cleaning.

- 2.6 The following diagram shows the principle of relative risks and endoscope variety with regard to decontamination requirements. As with all generalisations, it cannot represent all possible variations. For example, endoscopes with wire-carrying lumens will require extra steps in their decontamination; if endoscopes are intended for use on highly immunocompromised patients, they



Note:

In many endoscopies, an accessory will be passed through a lumen and will itself enter sterile tissue in taking a biopsy. It is a clinical judgement whether this presents no increased risk of infection, as seems to be the case for example in a colonoscopy, or whether it does present an increased risk of infection, as in a trans-rectal prostate biopsy. The consideration of infection risk in these cases should be a clinical risk assessment and control would be via antibiotic prophylaxis rather than increased endoscope decontamination

may require rinse water with very low levels of contamination. 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.

The decontamination process

- 2.7 The process of decontaminating flexible endoscopes with lumens has three basic 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.
 - c. **Automated disinfection:** followed by rinsing with water that offers only very low pathogenic risk, and drying or air-purge of all exposed surfaces of the endoscope.
- 2.8 If a validated low temperature sterilization process is being used, steps (a) and (b) are essential, step (c) is optional. 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 The reprocessing of lumened endoscopes should include all three decontamination components listed above. 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, 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 For further information on the cleaning, disinfection and rinsing of endoscopes, see 'EWD operation, and endoscope storage and transport' in the 'Operational management' volume. This section also gives guidance on the processing of nasendoscopes and transoesophageal echocardiography, transvaginal and trans-rectal ultrasound probes.

Sealed cassette devices

- 2.12 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.
- 2.13 Endoscopes should be correctly fitted or positioned within the cassette to constrain unwanted movement.
- 2.14 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.
- 2.15 Where electronic tracking is used, the GS1 coding system is recommended as a safeguard against misidentification.
- 2.16 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 the 'Validation and verification' volume.
- 2.17 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.

3 Essential Quality Requirements and Best Practice

Summary for commissioners and quality inspectors

This chapter discusses the Essential Quality Requirements contained in this document and how to risk assess applicable Best Practice.

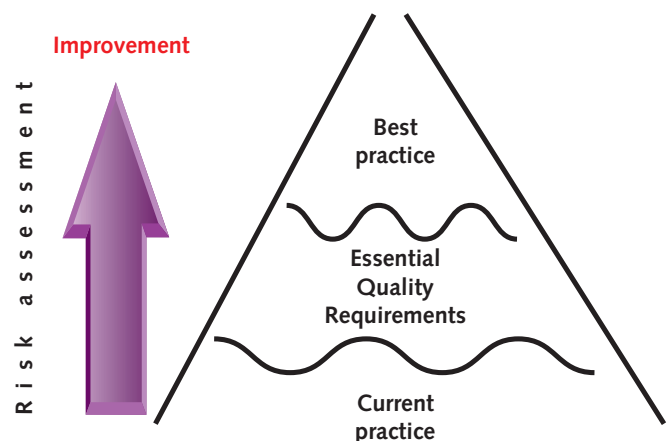
Although policy is primarily directed towards the commissioning exercise, the requirements will be of direct interest to providers of care and those working in endoscope management and decontamination.

For an introduction to the CFPP framework, see the [Preface](#).

Introduction

- 3.1 **Essential Quality Requirements** meet the existing statutory and regulatory requirements. They incorporate those of the current Medical Devices Directive and Approved Codes of Practice and relevant applicable Standards. They will help to demonstrate that an acute care service provider operates safely with respect to the management and decontamination of instruments.
- 3.2 Attainment of the Essential Quality Requirements should also include a local risk-assessment for surgical 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 and what plan is in place to work towards Best Practice.
- 3.4 Commissioners and quality regulators are encouraged to use local policies as part of their assessment of a provider. Comparison of local policy statements and Quality Systems with audit results will confirm attainment of Essential Quality Requirements and progression towards Best Practice. Such assessment could provide a mechanism for differentiating between care providers in commissioning services.

- 3.5 The aim of this guidance is to achieve a reprocessed flexible endoscope that is fully compliant with the “Essential Requirements” 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 **Best Practice** is additional to Essential Quality Requirements. Best Practice as defined in this guidance covers non-mandatory policies and procedures that aim to further minimise risks to patients; deliver better patient outcomes; and achieve cost efficiencies.
- 3.7 CFPP01-06 supports Best Practice by promoting and encouraging innovation and choice as components of local policies and procedures.
- 3.8 Best Practice should be considered when developing local policies and procedures based on the risk of surgical procedures and available evidence. Best Practice encompasses 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.



Examples of Essential Quality Requirements

3.9 Every endoscopy decontamination management and quality system should be capable of meeting the Essential Quality Requirements contained in this document, that is:

- The decontamination policy should demonstrate that:
 - (i) it complies with guidance establishing essential quality requirements and a plan is in place for progression to best practice;
 - (ii) decontamination of reusable medical devices takes place in appropriate facilities designed to minimise the risks that are present (see Figures 2–5 in the ‘Example layouts’ of the ‘Design and installation’ volume);
 - (iii) appropriate procedures are followed for the acquisition, maintenance and validation of decontamination equipment;
 - (iv) staff are trained in cleaning and decontamination processes and hold appropriate competences for their role; and
 - (v) a record-keeping 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.
- The quality of water used is of importance to risk control. Characteristics are listed in Table 3 of the ‘Design and installation’ volume (see also Table 2 in that volume).
- Lumened instruments should be reprocessed using a validated automated process (where applicable) following the manual cleaning stage. At the end of the reprocessing cycle they should be fit for their intended purpose. Using the ‘Validation and verification’ and ‘Testing methods’ volumes of this CFPP 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 an extent such that it compromises patient safety. For example, 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 and in respect of the facilities used. There should be input from the control of infection team with regard to local policies.
- The production, maintenance and use of written procedures for each stage in the management, use and decontamination of endoscopes is 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 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 prior-related incidents or other events that may render the endoscope unfit for purpose (such as damage or failing a leak test).

This guidance framework is based on European harmonised standards and other technical specifications (BS EN ISO 15883-4 and ISO/TS 15883-5). The standards organisations specifically referenced are CEN, ISO and BSI. In every case, compliance with these standards is regarded as Essential Quality Requirements.

Examples of Best Practice

3.10 To progress to Best Practice, further improvements will be required in the following main areas:

- In Essential Quality Requirements, the environment where decontamination is carried out should be such as to minimise the risks of recontamination of instruments or the inadvertent use of incompletely decontaminated endoscopes and of cross-contamination between clean and dirty areas. Best Practice may require

Note

This CFPP’s ‘Validation and verification’ and ‘Testing methods’ volumes are designed against the appropriate harmonised standards including BS EN ISO 15883-4.

the use of separate rooms for the accommodation of clean (output) and dirty (input) work. In these facilities, the rooms should be used for this purpose only and access should be restricted to those staff performing decontamination duties (see Figures 2 to 5 in the 'Example layouts' section of the 'Design and installation' volume).

- 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.

3.11 See 'Tracking, traceability and audit trail' in the 'Operational management' volume and DH's 'Coding for success'.

- 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 and the infection control team should be sought in the initial assessments of risk related to water quality and infection. For example, endoscopes used in the gastrointestinal tract may possibly be processed using less costly process water, or indeed that available from the organisation's cold water system (see Table 3 in the 'Design and installation' volume and Table 2 in the 'Testing methods' volume for guidance on quality of water).
- Endoscopes should be kept moist from the end of patient procedure to the start of decontamination. 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.

- Endoscopes should be stored securely to prevent unauthorised access and to permit their easy identification.
- Use of a local self-audit tool should be used and completed ((such as that being developed by the Infection Prevention Society).
- The move from Essential Quality Requirements to Best Practice may involve obtaining Essential Quality Requirements performance in a more economical or rapid way. If similar results can be obtained using alternative methods that can be demonstrated to have an advantage, they should be carefully considered and adopted if appropriate.
- The quality and fitness-for-purpose of all endoscopes should be periodically reviewed in accordance with manufacturers' instructions.

3.12 **Best Practice will involve keeping up to date with developments and new equipment in the endoscope reprocessing field. This guidance may be amended when such new developments are apparent.**

Progression towards Best Practice via risk assessment

3.13 To assess what Best Practice should be set as a target, a local risk assessment group (see next section) 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 aspects of Best Practice consequently apply.

The risk assessment group

3.14 The Director of Infection Prevention and Control (DIPC) or equivalent will have ultimate responsibility for the risk assessments. Others included in the group could be:

- The DIPC or their designated appointee.
- Surgical Instrument 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.

- An Authorising Engineer (Decontamination) (AE(D)).
- 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 DIPC.

3.15 The risk assessment group should report to the board; usually this would be via the DIPC or their equivalent. When an approach to openness in risk control is agreed, then a lay summary should be made available to the recognised local patient group (for example HealthWatch).

Commissioning implications of Essential Quality Requirements and Best Practice

- 3.16 This policy and guidance is designed to help healthcare professionals in commissioning and in the delivery of the standard of decontamination that our patients have a right to expect, by building on existing sound practice.
- 3.17 In accordance with the HCAI Code of Practice, commissioning organisations should assure themselves that the services that they commission are meeting expected requirements; that is, that providers are attaining the Essential Quality Requirements outlined in this document or applying an appropriate risk control strategy.
- 3.18 Commissioning organisations can use Essential Quality Requirements and Best Practice to improve the services commissioned from providers:

- by including them within the service specification element of the standard contract;
- by establishing key performance indicators as part of a tendering process; and
- as an incentive to improve provider performance.

3.19 Essential Quality Requirements and Best Practice could also be used as attainment levels against which improvements can be measured and rewarded, enabling commissioners to address gaps in service provision and encourage evidence-based practices.

3.20 Commissioning organisations should examine local policy offered by providers for evidence of a viable strategy leading to further progress towards appropriate Best Practice assessed by the risk assessment group (see [paragraph 3.13, 'Progression towards Best Practice via risk assessment'](#)). In the performance of this duty, the provider's clinical team and DIPC should be consulted. Important technical and engineering issues may require the advice of appropriate learned professionals including an AE(D).

3.21 Providers may refer to the Essential Quality Requirements and Best Practice to assess the quality of their healthcare services and demonstrate quality improvement within their organisation.

3.22 In the event of poor performance, commissioners can discuss the level of performance with their providers and address any issues and concerns before introducing more formal contractual remedies.

4 Registration with the Care Quality Commission

- 4.1 The Care Quality Commission (CQC) regulates all providers of regulated health and adult social care activities in England.
- 4.2 The CQC's role is to provide assurance that the care people receive meets essential requirements of quality and safety.
- 4.3 The registration requirements are set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and include a requirement relating to safety and suitability of premises.
- 4.4 The CQC is responsible for developing and consulting on its methodology for assessing whether providers are meeting the registration requirements (see the CQC's 'Guidance about compliance').
- 4.5 Failure to comply with the requirements is an offence, and under the 2008 Act, CQC has a wide range of enforcement powers that it can use if the provider is not compliant. These include the issue of a warning notice that requires improvement within a specified time, prosecution, and the power to cancel a provider's registration, removing its ability to provide regulated activities.
- 4.6 The registration scheme places strong emphasis on quality management and self-audit (BS EN ISO 13485, BS EN ISO 14971) . These measures

should be seen as part of clinical governance policy, which should make clear reference to this CFPP.

Quality inspection

In the assessment of performance in the management and reprocessing of endoscopes, the attainment of Essential Quality Requirements 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 CQC and those conducting audits for the quality inspectorates give particular attention to:

- The quality of local risk assessments and policies.
- Training and professional qualifications.
- Appropriate equipment and validation to the list of standards (EN).
- The suitability of the use and reprocessing 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 the DH's 'Coding for success'.

5 Human prion diseases (including CJD and vCJD)

Background

The human prion diseases include CJD, which in its sporadic form is the commonest of these rare conditions with an annual incidence worldwide of around one case per million population. In the UK, there are between 50 and 80 cases per year. Sporadic CJD (sCJD) has no known cause and is thought to arise spontaneously. About 10% of human prion disease cases are due to inherited familial prion diseases including Gerstmann-Sträussler-Scheinker disease. About 1% of human prion disease cases are iatrogenic, the vast majority caused by use of pituitary-derived growth hormone or dura mater grafts derived from sCJD cases.

vCJD emerged in the mid-1990s apparently from infection by the Bovine Spongiform Encephalopathy (BSE) agent via the oral route. Patients suffering from sCJD and vCJD have differences in the distribution of prion infectivity around the body. There is currently no effective treatment, nor a blood test, for human prion diseases, although research is ongoing.

In 1990 the UK's National CJD Research and Surveillance Unit was established in Edinburgh, and in 1996 the Unit identified vCJD, which is distinguishable from sCJD 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, followed by coordination problems, dementia and muscle-twitching occurring later. The illness usually lasts about 14 months (range 6–84 months) before death. The definitive diagnosis of vCJD can only be confirmed by examining brain tissue, usually at post-mortem, and requires the exclusion of sCJD and familial CJD.

In the UK, there have been 176 deaths from definite or probable cases of vCJD. The peak year of deaths was 2000, since when numbers of cases have fallen.

Although there are no known cases of vCJD being transmitted by surgical instruments or endoscopes, it may be possible as:

- sCJD has been transmitted by instruments used in brain surgery;
- abnormal prion protein is 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 clinical vCJD.

Guidance from the ACDP-TSE Risk Management subgroup (formerly TSE Working Group) (abbreviated to ACDP-TSE RM) is in place to ensure that precautions are taken when dealing with known or suspected cases of human prion disease and with people who are at increased risk of human prion diseases.

Why human prion diseases are important

While there is still a good deal of scientific uncertainty about human prion diseases, such as the various types of CJD, the DH continues to take a precautionary approach and adapt policy as new evidence emerges. There is evidence of iatrogenic transmission (that is, contamination with tissue from an infected person, usually as the result of a medical procedure) of sCJD due to neurosurgical instrument contamination, and there have been a small number of secondary cases of vCJD transmitted by blood transfusion. 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.

A full account of the importance of human prion disease in the context of transmission risks and decontamination of equipment is given in ‘The evidence base: the risk from prion diseases and findings from the National Decontamination Survey’ from CFPP 01-01 Part A.

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). It is likely that the normal human prion protein (PrP^C) becomes misshapen and this change in molecular conformation gives rise to the disease. This misshapen abnormal PrP protein (PrP^{Sc}) may accumulate in the central nervous system and lymphoid tissues (including lymph nodes, submucosal lymphoid tissues and tonsils) of infected individuals.
- 5.2 Abnormal prion protein is heat-stable, exceptionally resistant to enzymatic digestion and, once dried onto surfaces including the internal working channels of endoscopes, is very difficult to remove or inactivate by conventional decontamination processes.
- 5.3 These tissues have lower levels of infectivity than the brain and are therefore referred to as medium infectivity tissues. They include lymphoid tissues (for example tonsils, spleen and Peyer’s patches in the gastrointestinal system).
- 5.4 This CFPP aims to support commissioners and providers in implementing appropriate and effective decontamination measures to reduce the risks of person-to-person transmission of human prion diseases. Owing to the difficulty of inactivating or removing human prion proteins from instruments, special measures are required to prevent the potential transmission of human prion disease between patients.
- 5.5 This CFPP applies principally to gastrointestinal and bronchoscope endoscopy; **it does not cover neuroendoscopy.**
- 5.6 The advice below applies to 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:
- not using alcohol or aldehyde-based disinfectants on endoscopes, as they bind proteins, including prion proteins, to surfaces;
 - 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);
 - ensuring that the appropriate precautions are put in place when performing endoscopy on patients who are suspected as having or diagnosed with a human prion disease, or have been notified as being at increased risk of human prion disease.
- 5.7 When an invasive endoscopy is required, 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 products¹ from a donor who later developed clinical vCJD.
- 5.8 A recent report by the Advisory Committee on Decontamination Science and Technology (ACDST) Endoscopy Sub-Group on the decontamination of flexible endoscopes has recommended the following approach for dealing with potential transmission risks during following flexible endoscopy.

¹ For the purposes of this CFPP, this includes whole blood, red cells, plasma (FFP), cryoprecipitate, cryodepleted plasma and platelets.

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 CFPP) or destroyed by incineration.
- 5.10 Details of the criteria are given in ACDP-TSE RM's Annex F – 'Endoscopy'.

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

- 5.11 Note that, following an examination (including a biopsy) or treatment on patients classified as "at increased risk" of infection with a human prion disease, there is no requirement for flexible endoscopes to undergo a minimum of ten cycles of decontamination before being allowed to return to use.
- 5.12 Decontamination of a flexible endoscope should consist of processing of the flexible endoscope through a conventional endoscope decontamination procedure involving both a manual preclean and a subsequent validated automated machine disinfectant and rinse cycle. National guidance on decontamination, drying and storage must be adhered to as recommended in this CFPP.
- 5.13 Although it is extremely unlikely that contamination of a second endoscope would occur in an EWD designed to decontaminate two scopes in a single chamber, it is recommended that, following invasive procedures in any patients with or at increased risk of human prion disease, flexible endoscopes should be reprocessed singly using a single-use, non-aldehyde-based disinfectant.
- 5.14 All single-use accessories should be discarded as infectious waste and reusable accessories cleaned to a high level 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 or use of instruments must be

recorded and where appropriate specialist advice obtained, such as that of the CJD Incidents Panel.

- 5.16 See ACDP-TSE RM's Annex F – 'Endoscopy'.

Protein material

- 5.17 Owing to the type of tissue an endoscope is likely to come into contact with, deposits of protein are normal on used uncleaned endoscopes.
- 5.18 Prion proteins are extremely hydrophobic, making them far more difficult to remove from instrument surfaces – particularly after drying. Endoscopes should therefore be kept moist before cleaning.
- 5.19 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
- 5.20 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 the 'Operational management' volume).
- 5.21 As new protein test systems are developed, the level of residual protein that can be detected after washing and disinfection will be significantly lower than that achieved with the use of the ninhydrin protein detection test. The ninhydrin test should be used with caution owing to its lack of sensitivity. Data are required from the manufacturers to determine the level of sensitivity that they have declared for their product. Alternatively this may be informed by peer-review published findings. The precise technique used will vary with sampling method used but, as a guiding principle, when detecting protein on processed endoscopes, samples from those areas that are the most difficult to clean will give the best indication of the overall efficacy of protein and biological residue removal. Where possible, lumens should be sampled, for example by passing a clean brush through the lumen and quantifying the protein it acquires.

Prion-specific decontamination technologies

5.22 DH is aware of a range of technological developments that may offer future potential to enhance the existing decontamination process to reduce protein, including prion protein contamination of instruments. CFPP 01-01 provides for the future inclusion of new technologies subject to successful evaluation of safety and efficacy.

5.23 Such technologies must embrace the following key requirements in addition to activity against abnormal prions:

- a. be compatible with the existing decontamination processes;
- b. be active against conventional infectious microbes;

- c. remove and prevent build-up of new biofilm;
- d. have good storage and reuse (if appropriate) properties;
- e. have acceptable environmental and operator safety;
- f. be compatible with endoscopes and EWDs.

Trans-rectal ultrasound (TRUS) guided prostatic biopsy

5.24 The requirements for TRUS-guided prostatic biopsy equipment are as described in 'Decontamination of transoesophageal echocardiography, transvaginal and trans-rectal ultrasound probes' in the 'Operational management' volume.

References

HCAI Code of Practice.

MDA/2004/028.

MDA DB2002(05).

Medical Devices Regulations.

BS EN ISO 15883-4.

ISO/TS 15883-5:2005.

Coding for success.

IPS audit tool.

Health and Social Care Act 2008 (Regulated Activities)
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CQC's 'Guidance about compliance'.

BS EN ISO 13485.

BS EN ISO 14971.

ACDP-TSE RM guidance.

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