

Review: Choice Framework for local Policy and Procedures 01-01 (CFPP 01-01) – Management and decontamination of surgical instruments (medical devices) used in acute care

Part A: the formulation of local policy and choices manual

Version: 1.0: England.

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The CFPP 01-01 Part A supersedes Health Technical Memorandum 01-01 Part A. The decision to introduce a Choice Framework for local Policy and Procedures (CFPP) 01-01 was to give healthcare providers guidance on the best decontamination practice relating to the whole decontamination cycle including the management and decontamination of surgical instruments used in acute care.

Part A covers the policy, management approach and choices available in the formulation of a locally developed, risk-controlled operational environment. In addition to the prevention of transmission of conventional pathogens, precautionary policies in respect of human prion diseases which include variant Creutzfeldt-Jakob disease (vCJD) are clearly stated. CFPP 01-01 Part A also includes advice on surgical instrument management related to surgical care efficiencies and contingency against perioperative non-availability of instruments.

This review of CFPP 01-01 Part A has been developed by the Institute of Decontamination Sciences (IDSc) – National Chairman: Geoff Sjogren, the Infection Prevention Society (IPS) – President (2010 – 2012): Tracey Cooper and the Association of Perioperative Practice (AfPP) President: Tracy Coates, to summarise the key points within the document. *(N.B. If you choose to use their review of the document as a means to understanding the challenges this document brings it is advised that you still read the document to ensure your view agrees with theirs – Editor).*

Many of the sentences within this document have been taken directly from CFPP 01-01 Part A. Therefore this is an acknowledgement for reference. Other areas are a personal interpretation of the document. Please be aware that all parts of the CFPP 01-01 series (legislation and standards must also be followed) must be followed when developing

a decontamination of invasive medical devices service.

Note: Parts B – E are aimed at the engineering principles of decontamination equipment and will need an engineering expert review.

Part B: Common Elements

Part C: Steam Sterilization

Part D: Washer-Disinfectors

Part E: Alternatives to steam for the sterilization of reusable medical devices

1. Part A: the formulation of local policy and choices manual. Version: 1.0: England

1.1 Introduction:

Part A covers the policy, management approach and choices available in the formulation of a locally developed, risk-controlled operational environment. The prevention of transmission of conventional pathogens, and precautionary policies in respect of human prion diseases including variant Creutzfeldt-Jakob disease are clearly stated (Page 6).

This document details the requirements for best practice guidance on the management and decontamination of surgical instruments. This guidance supports the Health and Social Care Act 2008 (2010 revision), and supports the NHS as set out in the Health and Social Care Act 2012 (Page 11).

It also supports commissioners and regulators in assessing the local policies and practices of a provider in terms of their approach to the management and decontamination of surgical instruments. Definitions of Essential Quality Requirements (EQR) and Best Practice (BP) are provided. (Page 11).

EQR (Page 19): encompasses all existing statutory and regulatory requirements. For Sterile Services this will mean that they must apply the essential requirements of the Medical Device Directive 93/42/EEC (as updated by Directive 2007/47/EC), if providing both an in-house and external service.

BP (Page 19): is additional to EQR. **BP** covers non-mandatory policies and procedures that aim to further minimise risk to patients; deliver better patient outcomes, promote innovation and choice, and achieve cost efficiencies. **An example includes improved instrument management as detailed in recommendation 8 below. It is suggested that all providers liaise with their local commissioning groups to agree a timescale for achievement to BP.**

NICE Interventional Procedure Guidance 196 CJD is referenced throughout as some aspects of decontamination practice need addressing to reduce the risk of CJD transmission (e.g. Page 12).

1.2 The main recommendations

1. A decontamination policy must be developed and led by the Decontamination Lead. This includes the need to ensure a plan is in place for progression from EQR to BP (Page 16). The guidance also introduces a number of defined roles with descriptive responsibilities, this includes:
 - New (Page 23): Director of Infection Prevention and Control (DIPC): **Ultimate** responsibility for risk assessment – decontamination option requirements and consideration of what aspects of BP should be implemented.
 - New (Page 65): Surgical Instrument Manager/coordinator: The manager of surgical instruments (medical devices) is designated as the person assuming responsibility for coordinating activity between the theatre, decontamination and supply/purchase team. Note: This role could be co-managed between the sterile services and theatre management teams.
2. For the key elements of a decontamination policy, see section on ‘Health and Social Care Act 2008: Code of Practice’ (Page 21).
3. Improve instrument set integrity (Page 14)
4. Ensure a separate pool of instruments (and neuroendoscopes) are available for high risk procedures on patients born since 1 January 1997 (Page 14).
5. Ensure contingency for dropped or unavailable instruments (Page 14).
6. Ensure (high-risk) instruments are kept within a moist environment between use and decontamination (Page 14) – see section 1.3 below.
7. Ensure maximum efficiency in protein removal during cleaning and disinfection of instruments (Page 14).
8. Have an audit system in place for surgical instrument management and to cover the quality, condition and suitability of reusable surgical instruments (Page 14).
9. Undertake a full assessment of the volume and types of surgical service provided, the turn around time required for decontamination of instruments, the prion risk associated with the tissues encountered, and the instrument stock required for decontamination to be undertaken safely and effectively (Page 18).
 - To ensure attainment of EQR: a full assessment must be undertaken to assess (Page 19):
 - the provision of instruments (and instrument sets) that are safe to use
 - adequate numbers of instruments (instruments sets) are available
 - all sets with missing instruments to be withdrawn, and instrument sets completed before they are used again
 - An assurance must be made that instruments are matched to the available resources.
10. Theatre practices may need to be amended to improve the audit trail of instruments, and provide instrument sets that do not require the use of supplementary instruments (Page 19).
11. Other management principles within the guidance include (Page 57):
 - Use of loan sets (especially if used on high-risk cases)
 - Instrument repairs – risks include operative failure due to the absence of key instruments or poor adherence to scheduled instrument maintenance
 - Tracking policy to include single use instrument tracking and records.

Attainment of EQR will provide a mechanism for differentiating between standards delivered by care providers when commissioning services (Page 19).

12. To assess BP:

- A local risk assessment group may be set up. This group could assess decontamination option requirements and consider what aspects of BP should be implemented, based on improving patients outcomes, decontamination benefits, efficiencies and risks, including those prion risks as defined by the Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies Risk Management Subgroup (ACDP-TSE RM) (Page 23).
- Identify the surgical instrument coordinator/manager as defined within the guidance to coordinate activity between the theatre, decontamination and purchasing teams (Page 65).
- The Director of Infection Prevention and Control (DIPC) will have **ultimate responsibility** for the risk assessments and options driven forward (Page 23).
- Local risk assessment group membership could include (Page 23):
 1. DIPC (or designated appointee);
 2. the decontamination lead (see Page 64);
 3. the surgical instrument manager/coordinator (see Page 65) – this could be co-managed between the clinical device user and the sterile services manager;
 4. representative(s) from the Infection control Team;
 5. representative(s) from the clinical device users;
 6. the user (see Page 66-67)
 7. Authorised Engineer (Decontamination) (see Page 67)
 8. Estates and facilities
 9. Other as co-opted at the discretion of the DIPC.

1.3 High risk surgery (vCJD)

'DH policy is that measures defined in NICE IPG 196 be incorporated into practice and supplemented by guidance derived from the ACDP-TSE RM subgroup' (Page 44). This policy has been adopted due to the National Decontamination Survey results detailing that a number of high-risk centres had not followed the guidance within NICE IPG 196 (2006) (Page 55-56).

For high risk surgery, steps must be in place to reduce the risk of transmission.

These include (Page 25):

- Maintain instruments in a moist environment following use
- Retain all instruments within their sets by the use of individual and set level tracking
- Revision of set contents in neurosurgery – instrument set leakage can be reduced when combined with e.g. utilisation of set colour codes
- Set strategies for high risk patients born since 1st January 1997. For example: instrument set revision and design to avoid instrument leakage from the high use of supplementary instruments
- Improved protein detection and quantification techniques to be utilised following the cleaning and disinfection stages – in development
- Maximise protein removal by suitably optimised washer-disinfectors and detergent systems.

Note: Department of Health surveys suggest that thousands of people might be symptom free but infected with vCJD (Page 47). Therefore risks assessments may need to be applied to all surgical patients following the above points.

It must be remembered that current standards of decontaminating surgical instruments cannot reliably fully deactivate or destroy the infectious agent that causes prion disease, this raises the possibility that vCJD could be transmitted via certain healthcare interventions (Page 47).

Extra vigilance is required to ensure that appropriate decontamination measures are in place when a patient who has been diagnosed as having a prion disease or who is considered to be 'at risk' undergoes surgery on high-risk tissues. Special measures are essential for ophthalmic surgery and intradural operations on the brain. In vCJD, lower but significant risk levels occur in lymphoid tissues; these tissues are referred to as 'medium risk tissues' (Page 53).

Patients, who have, probably have, or are at risk of infection from prion diseases (for example sCJD and vCJD) need to be identified before any surgical procedures are undertaken. For such patients, precautions will need to be considered (Page 50).

Guidance should be followed from the (ACDP-TSE RM), and the CJD Incidents Panel (Page 50).

1.4 Guidance for commissioners, regulators and providers.

In commissioning services (e.g. commissioning surgery) that are linked to the decontamination services for surgical instruments in acute care, commissioning organisations will aim to deliver (Page 29):

- High standards of patient safety;
- Improving clinical outcomes arising from a carefully considered local instrument management strategy;
- Enhanced patient experience through minimising delay and procedure cancellations associated with instrument providers and theatre teams;
- Cost efficiencies from instrument provision to the demands of the care given;
- Local choice in the means of risk control both through instrument management and in choices with regard to decontamination;
- Appropriate quality systems and engineering standards;
- Professional work by trained managers and staff throughout decontamination. Managers and senior decontamination staff at minimum should be a full member of and/or be trained and educated following the Institute of Decontamination Sciences (IDSc) University led education and qualification framework – which will lead to IDSc full membership (see Page 69). Engineers should be educated and trained to the standards set by the Institute of Healthcare Engineering and Estates Management (IHEEM/AED) (see Page 69). This is especially important as the National Decontamination Survey into instrument decontamination found that there is scope for broader training and professional development to ensure patient safety (Page 56). The IDSc and IHEEM/AED are noted as having responsibilities for staffing roles, education and training within CFPP 01 01 (Part A) (Page 69);
- When commissioning surgery, commissioning organisations should require that the healthcare provider is receiving devices, or it has a decontamination service, that meets the essential requirements of the Medical Device Regulations and is able to demonstrate evidence of an appropriate quality management system and audit system (Page 29);
- Commissioners should expect the healthcare provider to have a plan in place to achieve Best Practice (Page 30). This plan should have been developed, having taken account of the risk of surgical procedures (evidence of a Decontamination Policy, the evidence base and the risk from prion disease based on the findings of the National Decontamination Survey) (Page 30);
- Commissioners may use this plan to improve the services commissioned from providers for the benefits of patients, and to differentiate between providers (Page 30);
- BP could also be used as attainment levels against which improvements can be measured and rewarded, enabling commissioners to encourage evidence-based practice and innovation (Page 30);
- In the event of poor performance, commissioners may discuss the level of performance with their providers and address any issues and concerns before introducing more formal contractual remedies (Page 30);
- If services are provided from an external provider (external providers must comply with the Medical Devices Directive and demonstrate adherence to the essential requirements within the Directive), advice will need to be sought to implement all the changes and systems discussed above. All parties will need to work together to develop local policies and procedures in line with CFPP 01 01. The development of local policies and procedures may require a variation to the contract and changes to quality systems to accommodate (Page 31);
- Reusable medical devices transferred between legal entities are subject to the Medical Devices Regulations, and if invasive sterile devices are produced, the intervention of a third-party audit programme must be undertaken by a recognised notified body, as certified by the MHRA (the organisation must also register with the MHRA (Page 37);
- Reusable medical devices remaining within one legal entity. Although there is no requirement to register with the MHRA, or make use of the services from a Notified Body, they must still ensure instruments are safe, fit for purpose, and of suitable quality. The Care Quality Commission will assess the performance of these organisations (Page 38).

Important note: This is a reference review; please ensure you follow the full guidance when developing a decontamination policy and service.

No:	Main Recommendations Above (Section 1.2: Pages 2-4)	Date/Year	Risk Rating	Necessary Actions	Division/Lead
1&2	A decontamination policy must be developed and led by the Decontamination Lead to ensure a plan is in place for progression to BP, and that all key codes recommendations within the Health and Social Care Act are compliant				
3.	Improve set integrity				
4.	Ensure a separate pool of instruments (and neuroendoscopes) are available for high risk procedures on patients born since 1 January 1997				
5.	Ensure contingency for dropped or unavailable instruments. (the IDSc do not advocate the use of small sterilizers within the theatre environment)				
6.	Ensure (high-risk) instruments are kept within a moist environment between use and decontamination – check with your infection control team and confirm within the CFPP 01-01 series				
7.	Ensure maximum efficiency in protein removal during cleaning and disinfection of instruments				
8.	Have an audit system in place for surgical instruments management and to cover the quality, condition and suitability of reusable surgical instruments				
9.	To undertake a full assessment of the volume and types of surgical service provided, the turn around time required for decontamination, the prion risk associated with the tissues encountered, and the instrument stock required for decontamination to be undertaken safely and effectively				
10.	Theatre practices may need to be amended to improve the audit trail of instruments, and provide instrument sets that do not require the use of supplementary instruments				
11.	Other management principles within the guidance include: <ul style="list-style-type: none"> • Loan sets (especially if used on high-risk cases) • Instrument repairs – risks include operative failure due to the absence of key instruments or poor adherence to scheduled instrument maintenance • Instrument tracking policy including single use instrument tracking and records 				
12.	A local risk assessment group is to be set up to assess decontamination option requirements and consider what aspects of the points above (BP) should be implemented. This group should also assess any prion risks as defined by the Advisory Committee on Dangerous Pathogens.				
	Identify the surgical instrument coordinator as defined within the guidance to coordinate activity between the theatre, decontamination and purchasing teams.				
	The Director of Infection Prevention and Control (DIPC) will have ultimate responsibility for the risk assessments and options driven forward.				
	Local risk assessment group membership includes: <ol style="list-style-type: none"> 1. DIPC (or designated appointee) 2. The decontamination lead 3. Infection control lead 4. Clinical device user (e.g. incorporating the surgical instrument coordinator within their role) 5. Sterile services manager (e.g. incorporating/sharing the objectives of surgical instrument coordinator role with Clinical Device User) 6. Authorised Engineer (Decontamination) 7. Estates and facilities 8. Others as co-opted at the discretion of the DIPC 				
No:	High Risk Surgery (vCJD) (Section 1.3: Page 4)	Date/Year	Risk Rating	Necessary Actions	Division/Lead
	DH policy is that measures defined in NICE IPG 196 be incorporated into practice and supplemented by guidance derived from the ACDP-TSE RM subgroup'. This policy has been adopted due to the National Decontamination Survey results detailing that a number of high-risk centres had not followed the guidance within NICE IPG 196 (2006).				

Note: This is a reference review; please ensure you follow the full guidance when developing a decontamination policy and service.