HFS GUID-5019

Addendum to SHTM 01-01 in relation to the change of NICE IPG 196

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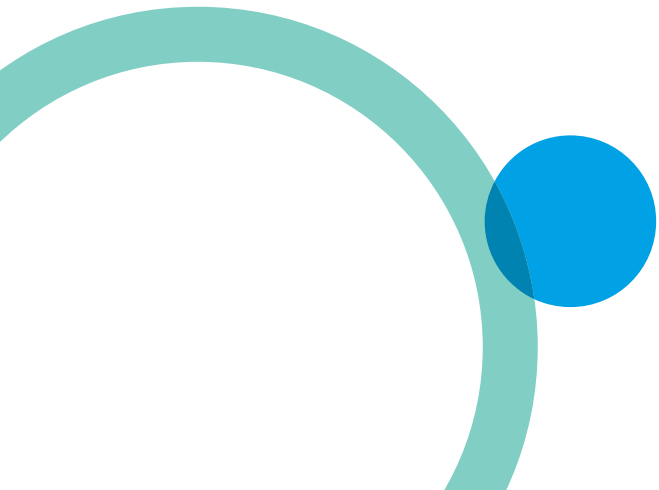

Contents

1. Introduction

1.1 Variant Creutzfeldt–Jakob Disease (vCJD) is a novel form of human prion disease, first recognised in the UK in 1996. It is believed to result from consumption of food derived from cattle infected with Bovine Spongiform Encephalopathy (BSE), a fatal neurodegenerative disease. In 2006, The National Institute for Health and Care Excellence (NICE) published IPG 196 guidance to reduce the risk of transmission of vCJD from surgical instruments used for interventional procedures on high-risk tissues. These IPG 196 recommendations are included in Part A of the Scottish Health Technical Memorandum (SHTM) 01-01 'Decontamination of medical devices in a Central Decontamination Unit' (2018) and GUID 5017: 2018 'Decontamination of medical devices (surgical instruments) Guidance for service users'.

1.2 This addendum to Part A Management (SHTM) 01-01 and GUID 5017 is developed to reflect recent changes to the recommendations in the NICE guidance for instruments used on high-risk CJD/vCJD tissues NICE guidance IPG 666: 2020 which supersedes NICE guidance IPG 196: 2006.

1.3 Therefore, any reference to NICE IPG 196 in SHTM 01-01: 2018 and GUID 5017: 2018 'Decontamination of medical devices (surgical instruments) Guidance for service users' is now replaced by IPG666: 2020.

Scope

NICE IPG 666: 2020 includes recommendations for:

- the use of reusable and single-use instruments in surgical procedures;
- arrangements for cleaning, sterilising and tracking of reusable surgical. instruments.

Out of scope

- transfusion of blood or blood products;
- extracorporeal life-support machinery, including cardiopulmonary bypass, haemodialysis and ventilator equipment;
- the safety of transplant grafts.

1.4 As NICE IPG 666: 2020 states:

"The recommendations **do not apply** to any interventional procedures done on patients already known to have or thought to be at increased risk of CJD as previously defined by the Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathies subgroup."

Therefore, the Advisory Committee on Dangerous Pathogen's guidance on 'transmissible spongiform encephalopathy agents: safe working and the prevention of infection' (2015) **must still be followed**.

2. Summary of the changes

2.1 NICE published IPG 196 (2006) risk-reduction strategy required that separate pools of medical devices be used for surgical procedures involving high-risk tissue. This guidance differentiated between patients born before or from 1 January 1997. Evidence suggested that maintaining a separate stream of instruments for people who were not exposed to vCJD via the food chain would reduce the risk of iatrogenic transmission via surgical instruments.

2.2 NICE IPG 666: 2020 **does not advise** the introduction of systems to maintain separate sets of neuroendoscopes and reusable surgical instruments for use on high-risk tissues for people born after 31st December 1996.

2.3 The NICE IPG 666: 2020 **does not support** the use of single use instruments for some medium and high CJD risk tissues during surgical procedures (i.e. tonsillectomy, back of eye surgery and neurosurgery) from a cost-effectiveness perspective.

2.4 The NICE IPG 666: 2020 guidance **supports** previous recommendations in IPG 196: 2006 to:

- keep instruments moist;
- prevent migration of instrument between sets;
- ensure supplementary instruments introduced into sets, remain with the set they were introduced to;
- use a system that enables tracking and tracing of instruments and instrument sets to the patient.

Required action

2.5 SHTM01-01 Part A: 2018 section 12.31 guidance on maintaining separate streams of surgical instruments for patients born after 31st of December 1996 is no longer a requirement, as evidenced in the NICE IPG 666: 2020. Therefore, instrument sets currently identified only for use for the post 1996 cohort can be reassessed for use on the pre-1996 patient group by carrying out a risk assessment.

2.6 All other recommendations in section 12 of SHTM01-01: 2018 Part A, and GUID 5017: 2018 ‘Decontamination of medical devices (surgical instruments) Guidance for service users’ should still be followed to ensure the risk of transmission of vCJD/CJD via clinical procedures contacting high–risk tissue, is minimised.

2.7 Table 1.1 summarizes the differences between IPG 196: 2006 and IPG 666: 2020 relevant recommendations, and the location of relevant text in SHTM01-01 where a change in practice is indicated.

Table 1.1 A summary of the differences between relevant recommendations in IPG 196: 2006 and IPG 666: 2020, and the location of relevant text in SHTM01-01where a change in practice is indicated

Subject	NICE IPG196:2006	NICE IPG 666:2020	Reference SHTM01-01 2018 Part A	Comments
Systems for people born after 1996	1.3 A separate pool of new neuroendoscopes and reusable surgical instruments for high-risk procedures should be used for children born since 1 January 1997 (who are unlikely to have been exposed to BSE in the food chain or CJD through a blood transfusion) and who have not previously undergone high-risk procedures. These instruments and neuroendoscopes should not be used for patients born before 1 January 1997 or those who underwent high-risk procedures before the implementation of this guidance. 4.1.6 Neurosurgical units should purchase or allocate new instruments and neuroendoscopes for exclusive use on children born after 1 January 1997, as described in section 3.2.9. Ophthalmic surgery units should similarly set aside new instruments for children born after 1 January 1997 who have posterior eye operations.	1.6 The evidence on cost effectiveness does not support introducing systems to maintain separate sets of neuroendoscopes and reusable surgical instruments for use on high-risk tissues for people born after 1996. 1.7 Removing the requirement to use different instruments on high-risk tissues for people born after 1996 would not markedly increase the risk of surgical transmission of CJD.	12.31 and Figure 8	Change

Subject	NICE IPG196:2006	NICE IPG 666:2020	Reference SHTM01-01 2018 Part A	Comments
Keeping instruments moist	5.3 Research is needed into the practice of keeping instruments wet during and after use, as a potential means of enhancing the efficacy of the decontamination process. Further research is also required into the effectiveness of the full decontamination cycle (washing and autoclaving) in reducing prion infectivity.	1.1 All surgical instruments that come into contact with high-risk tissues during an interventional procedure must be kept moist and separated from other instruments until they are cleaned, and then disinfected and sterilised (decontaminated). 4.2 The committee noted that the economic modelling suggests that keeping surgical instruments moist is the most cost-effective strategy, because it saves money and potentially increases societal health. Additional strategies aimed at reducing the future risk of surgically transmitted CJD (stCJD) do not appear to be cost effective.	GUID 5017 3.3	No Change
Supplementary instruments	1.1 Supplementary instruments that come into contact with high-risk tissues should either be single use or should remain with the set to which they have been introduced. Hospitals should ensure without delay that an adequate supply of instruments is available to meet both regular and unexpected needs. 4.1.3 Enough instruments should be purchased to ensure that the practice of using supplementary instruments is abolished and that all instruments stay within their sets.	1.3 Supplementary instruments that come into contact with high-risk tissues must remain within the individual set to which they have been introduced. Supplementary instruments are those that are not part of a specific instrument set. If supplementary instruments are used with different sets, this would compromise set traceability and increases the risks associated with instrument migration.	SHTM 01-01 Part A 12.45	No change

3. Additional information for keeping instruments moist

3.1 The Infection Prevention and Control team should be consulted prior to implementation of any new method for keeping instruments moist.

3.2 The method to keep instruments moist after patient use must be assessed and verified locally, to ensure the method is effective in facilitating the cleaning process and preventing unwanted effects such as foaming of washer disinfectors, corrosion of surgical instruments, leakage, etc.

3.3 Maintaining the environment around soiled medical devices in a moist atmosphere significantly assists the cleaning process (Secker et al. 2011; Secker et al 2015 & Smith et.al. 2018).

3.4 Medical device sets can be kept ‘moist’ during transportation by, for example:

- use of absorbent pads and several millilitres of purified water (usually sterile water is readily available in theatre settings). Note: saline should not be used as a substitute for the purified water as it may lead to corrosion of instruments. The amount of water to be added is subject to local risk assessment to ensure effectiveness and prevent leakage, etc.
- sprays/gels sold for the purpose of keeping the surgical instruments moist; Their effectiveness should be considered, including:
  - any possible unwanted effects on the instruments;
  - compatibility with the decontamination equipment or process;
  - biocompatibility;
  - any additional infection risk.
- trays should be covered and sealed to maintain a moist environment;
- where used tray lists, can be protected from moisture by enclosing it in a suitable bag. The tray list should be face upward so it can be read.

Note: Prior to adopting or changing the method, a trial may need to be conducted to assess the effectiveness and usability of the method and determine any possible adverse effects.

The creation of ‘moist’ conditions inside a pack should neither increase the weight of the pack significantly nor produce “free” liquid in the pack that could move about and potentially cause a spill.

List of References

National Institute for Health and Care Excellence (NICE) interventional procedure guidance 196-Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures Feb 2006 http://www.nice.org.uk/

National Institute for Health and Care Excellence (NICE) guidance IPG 666 'Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues' was published 22nd June 2020.

Advisory Committee on Dangerous Pathogens guidance on transmissible spongiform encephalopathy agents: Annex C General Principals of Decontamination and Waste ASTE Disposal (2015)

BS EN ISO 13485: Medical Devices. Quality management systems. Requirements for regulatory purposes. CEN.

BS EN ISO 15883-1: Washer-disinfectors Part 1: General requirements, terms and definitions and tests. CEN.

BS EN ISO 15883-2: Washer-disinfectors. CEN.

Secker T.J.; Herve, R., and Keevil,C.W.(2011). Adsorption of prion and tissue proteins to surgical stainless steel surfaces and the efficacy of decontamination following dry and wet storage conditions. The journal of Hospital infection. Volume 78, Issue 4 2011

Secker, T.J.; Pinchin, H.E., Herve R., and Keevil,C.W:2015. Efficacy of humidity retention bags for the reduced adsorption and improved cleaning of tissue proteins including prion-associated amyloid to surgical stainless steel surfaces. The Journal of Bioadhesion and Biofilm Research. Volume 31, 2015 - Issue 6: 2015

Smith et.al. 2018. Reducing the risk of iatrogenic Creutzfeldt–Jakob disease by improving the cleaning of neurosurgical instruments. The journal of Hospital Infection Volume 100:3-2018.