ANNEX M

MANAGING vCJD RISK IN GENERAL SURGERY AND LIVER TRANSPLANTATION

CONTENTS

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Introduction

M1. This guidance aims to provide practical advice for handling instruments that come into contact with medium infectivity tissues, involved in liver transplants and general surgical procedures, in order to reduce risk of vCJD transmission. It applies to all patients with or at increased risk of vCJD undergoing these procedures. The guidance has been produced by the Surgical Subgroup (membership list included as Appendix 1 of this document) of the ACDP TSE Risk Management Sub Group. It has been written in response to clinical concerns raised by both general and liver transplant surgeons.

M2. There is no evidence to suggest that vCJD is spread from person-to-person by close contact. However, it is known that transmission can occur, in specific situations, associated with medical interventions causing iatrogenic infections. Due to the possibility of iatrogenic transmission of vCJD, precautions need to be taken for certain procedures in healthcare to reduce the potential risk of transmission.

M3. The scientific rationale underlying this guidance is provided in Appendix 2.

Scope of this guidance

Type of tissue/surgery

M4. The potential risk of iatrogenic transmission of vCJD during a surgical or invasive diagnostic procedure is dependent on the level of tissue infectivity and the nature of the procedure itself. This guidance applies to medium infectivity tissue likely to be encountered in general surgical procedures and liver transplantation. These include:

- gut-associated lymphoid tissue
- lymph nodes and other organised lymphoid tissues containing follicular structures
- appendix
- spleen

- thymus
- tonsil

This guidance applies to surgical procedures where instruments come into contact with the cut surface of such tissues, for example operations involving the large and small bowel, the porta hepatis and axillary or cervical lymph nodes. It does not apply to procedures where only lymphatic channels are cut. See Annex A1 for further information on tissue infectivity.

M5. Olfactory epithelium and spinal ganglia are **not** included in this Annex as these tissues are not usually encountered in general or liver transplant surgery. Refer to Table 4d (Part 4) for guidance on the handling of instruments which may come into contact with these tissues.

Patient groups

M6. This guidance applies to:

- Patients who have been identified as being at increased risk of vCJD as defined in Table 4a (Part 4);
- Symptomatic patients with probable or definite vCJD.

It does not relate to patients with or at increased risk of, other prion diseases such as familial CJD and sporadic or iatrogenic CJD. For guidance on handling instruments used on these patient groups see Table 4c (Part 4).

M7. Annex J of the ACDP TSE Risk Management Sub Group guidance recommends that all patients about to undergo any surgery or endoscopy should be asked if they have ever been notified that they are at increased risk of vCJD. Annex J recommends that more detailed risk assessment questions should be asked of those patients who are undergoing high risk procedures. This Annex M applies to any patients presenting for general surgery and liver transplantation identified as at increased risk of vCJD through the initial question ‘have you ever been notified that you are at increased risk of CJD or vCJD for public health purposes’ only. These patients should not be asked any additional screening questions.

Surgical management

Elective surgery

M8. Any patient to whom this guidance applies should be identified at pre-surgical assessment. When any such patient has been identified, thought should be given to minimising the risks and costs involved in the planned surgical procedure. Communication with relevant individuals should be undertaken and this should include a discussion on the choice of instrumentation. For example, instruments could be streamed (see M9 for more detail) or single use (i.e. disposable) instruments could be procured.

Note: The quality of any alternative instruments should, however, be no less than those which would normally be used.

Streaming instruments

M9. Instruments may be streamed into those for incineration/quarantine or those that may be reprocessed. Instruments that have been in direct contact with the cut surface of medium infectivity tissues (see M4 above) should be regarded as potentially contaminated with the TSE agent. If possible, they should be separated from other instruments that have only come into contact with the external surface of medium or low infectivity tissues. Such instruments should either be incinerated after use or quarantined for re-use exclusively on the same patient. Instruments that have not been in direct contact with the cut surface of medium infectivity tissues may be reprocessed. Staff should liaise with the local sterile services provider to ensure that quarantined instruments are appropriately labelled and stored and also to ensure that destroyed instruments are replaced. The detail of how this is achieved will depend on local circumstances; the final decision rests with the local Infection Control Team.

Staffing levels

M10. Consideration should be given to increasing staffing, for example having two scrub nurses present to help identify and manage instruments that have not come into contact with the cut surface of lymph nodes. The role of one of the scrub nurses would be to manage the instruments which have been in contact with the cut surface of lymph nodes. A local policy should be in place to clarify these roles.

Emergency surgery

M11. In emergency surgery performed on a patient who has been notified they are at increased risk of vCJD, single use disposable instruments should be employed where possible. It is important that these instruments are of appropriate quality to deliver safe care. If the instruments used were not designed for single use, they should be incinerated following use.

General

M12. All instruments should be kept moist prior to being sent for conventional decontamination and reprocessing. There are a variety of methods, for example gels, sprays and use of wet towels, that could be applied to keep instruments moist; the choice of the exact method used rests with the local Infection Control Team following local risk assessment.

M13. Instruments quarantined may, following conventional decontamination, be made available for reuse exclusively on the same patient. The instrument set should be reprocessed through the sterile services provider in the usual manner. No special precautions are necessary because of the high dilution factor involved in the washer/disinfection process.

Equipment

M14. For high cost equipment (e.g. some complex retractors), where it is feasible, efforts should be taken to protect the retractor by using physical barriers, for

example sheaths and impervious drapes. In cases where only part of the instrument has come into contact with the cut surface of medium infectivity tissue, where possible, that specific instrument component should be discarded or quarantined for reuse exclusively on the same patient.

M15. The risk from ultrasonic dissectors or division devices used during these procedures is negligible.

Potential for the future

M16. This Annex will be regularly reviewed in the light of new developments in the areas of TSEs. In particular, developments in decontamination, single instrument labelling to enable tracking, and the possibility of developing instruments using materials (e.g. glass and plastic) to which TSEs do not adhere well will be considered.

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Appendix 1

List of members of the ACDP TSE Risk Management Sub Group's Surgical subgroup

Name	Role
Dr Adam Fraise (Chairman)	Consultant Microbiologist, University Hospital Birmingham NHS Foundation Trust
Professor James Ironside	Professor of Clinical Neuropathology, University of Edinburgh Head of the Neuropathology Laboratories, National CJD Surveillance Unit
Professor Don Jeffries	The Late Chair of the ACDP TSE Risk Management Sub Group
Mr Simon Bramhall	Consultant Hepato-pancreato-biliary & Liver Transplant Surgeon, University Hospital Birmingham NHS Foundation Trust
Mr John Forsythe	Clinical director of the Transplant Unit at the Royal Infirmary of Edinburgh Chair of the UK Advisory Committee on the Safety of Blood, Tissues & Organs
Professor John Lumley	General surgeon (retired) Member of the CJD Incidents Panel
Mr Thomas Groot-Wassink	Gastrointestinal surgeon, Ipswich Hospital NHS Trust Member of the Association of Surgeons of Great Britain and Ireland
Dr Miles Allison	Consultant Gastroenterologist, Royal Gwent Hospital, South Wales Member of the CJD Incidents Panel

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Appendix 2

Scientific rationale

A1. A number of current issues, including the epidemiology of vCJD and distribution of prion proteins in tissues, were considered whilst formulating these guidelines. These include:

- The prevalence of asymptomatic infection with vCJD in the UK population is uncertain; however, a figure of around 1 in 2,000 is estimated on the basis of current evidence. The number of clinical cases of vCJD to date is relatively small and all probable and definite cases have occurred in individuals who have a MM genotype at codon 129 in the prion protein gene. There is a possibility of further waves of cases in other genetic subgroups; it has been suggested that those patients with MV and VV *PRNP* codon 129 genotypes may have longer incubation periods than MM genotypes and that vCJD cases in these subgroups may yet be seen.
- vCJD diagnostics are difficult. No antibody response occurs following infection and no PCR-based test is available. At present it is not possible to screen for vCJD in asymptomatic individuals, but this is an area of active research.
- TSEs are resistant to conventional forms of decontamination. Procedures have been advocated in decontamination guidelines; however these are not completely suitable for use on all surgical instruments. Activity against prions has been claimed for some enzymes and detergents. These have been shown to work however they are difficult to implement in the NHS in a safe and practical way.
- vCJD has a wider distribution of tissue infectivity than other human TSEs. Infectivity in lymphoid tissue is present before the onset of neurological symptoms, but without a reliable screening method it is impossible to identify asymptomatic infected individuals. The incubation period for vCJD is unknown, but is estimated to be a period of years. Thus, there is the potential

for individuals to be infective and transmit the infection to others (via blood or surgical instruments) before being diagnosed with clinical vCJD themselves.

- It seems likely that exposure to vCJD infectivity will be greater from the cut surfaces of lymph nodes than the external surface or lymphatic channels.
- There have been no known cases of vCJD transmission via surgical instruments and no proven transmission of vCJD has occurred via instruments used on gut or lymph nodes; however, there is difficulty in identifying if transmission has occurred by this route through epidemiological studies, primarily because of the long incubation period in vCJD.

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