SCOTTISH EXECUTIVE

Health Department

Dear Colleague

ADDITIONAL ANNEX TO THE ADVISORY COMMITTEE ON DANGEROUS PATHOGENS (ACDP) GUIDANCE ON "TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY AGENTS: SAFE WORKING AND THE PREVENTION OF INFECTION"

Purpose

I am writing to inform you that an additional annex advising on the assessment to be carried out on patients before surgery and endoscopy to identify patients with or at risk of CJD. These guidelines are continuously reviewed to ensure that the guidance reflects most recent developments in scientific knowledge. The need for additional advice on pre-procedure assessment was identified by the CJD Incidents Panel and the ACDP TSE Working Group following a number of CJD incidents in 2005 in which patients underwent surgery without prior knowledge of the need for infection control precautions relating to their special CJD status.

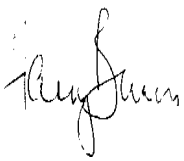
An electronic version of the complete ACDP guidance document is available at http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm.

Action

The new Annex J (attached) advises that local policy and procedures should be put in place to ensure that patients with, or at risk of, CJD are identified before a surgical or endoscopic procedure likely to involve contact with tissues of potentially high or medium level infectivity. A list of recommended questions is set out in table format within the Annex. This guidance should be taken into account in the formulation of local policies, procedures and documentation relating to patient assessment and consent prior to surgery or endoscopy.

I would also ask Chief Executives to ensure that this Letter is forwarded to the NHS Board Infection Control Manager, and to the local Infection Control, Clinical Governance and Risk Management committees.

Yours sincerely



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From the Chief Medical Officer

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ANNEX J

ASSESSMENT TO BE CARRIED OUT BEFORE SURGERY AND ENDOSCOPY TO IDENTIFY PATIENTS WITH, OR AT RISK OF, CJD

Categorisation of patients by CJD risk and infection control guidance

J1. There are special infection control precautions that should be taken in healthcare for patients with or at risk of CJD and **Part 4** of this Guidance provides advice on this. This includes the risk categorisation of patients, given in paragraphs 4.16 – 4.17 and Table 4A of Part 4.

J2. In brief, when considering measures to prevent transmission to patients or staff in the healthcare setting, it is useful to make a distinction between *symptomatic* patients and *asymptomatic* patients as below:

Symptomatic *i.e.*

- Patients who fill the diagnostic criteria of definite, probable or possible CJD and other human TSE (including sporadic CJD, sporadic fatal insomnia, variant CJD, iatrogenic CJD and familial disorders such as familial CJD, Gerstmann-Straussler-Scheinker Disease and fatal familial insomnia); and,
- Patients with neurological disease of unknown aetiology where the diagnosis of CJD is being actively considered.

Asymptomatic patients *i.e.* those with no clinical symptoms, but who are identified as potentially at risk of CJD because of either:

- Their family history, or;
- Iatrogenic exposures.

The need to ask CJD risk questions as part of pre-surgery assessment

J3. It is essential that clinicians ask CJD risk questions to all patients about to undergo a surgical or endoscopic procedure that may involve contact with tissues with high or medium level infectivity, such as brain, spinal cord, eye, olfactory epithelium, spleen, tonsil, gastrointestinal lymphoid tissue and other fixed lymphoid tissue, as part of the pre-surgery assessment. Please refer to Part 4 and Annex A1 for further advice on surgical procedures and CJD tissue infectivity and Annex F for advice on endoscopic procedures. If effective pre-surgery assessment is not carried out, there is a danger that the CJD status of a patient will not be determined and this may result in failure to take the appropriate infection control precautions. If this is the case, there is the potential for a CJD incident to occur and this may result in exposing subsequent patients to CJD infectivity.

Recommended CJD risk questions

J4. A local level policy should be put in place to ensure that patients with or at risk of CJD are identified before surgery and therefore to allow the appropriate infection controls to be followed. To facilitate this, a list of recommended questions based on the information given in Table 4A is given in Table J1 below. It is recommended that patients are asked these questions prior to elective or emergency surgical procedures likely to involve contact with tissues of potentially high or medium level infectivity.

Table J1 – CJD Risk Questions for patients about to undergo elective or emergency surgical procedures likely to involve contact with tissues of potentially high or medium level infectivity (please refer to Part 4 and Annex A1 for further advice on surgical procedures and CJD tissue infectivity):

	Question to Patient	Notes to clinician
1	Have you any history of CJD or other prion disease in your family? If yes, please specify.	Patient should be considered to be at risk from familial forms of CJD linked to genetic mutations if they have or have had: i) Genetic testing, which has indicated that they are at significant risk of developing CJD or other prion disease; ii) A blood relative known to have a genetic mutation indicative of familial CJD; iii) 2 or more blood relatives affected by CJD or other prion disease.
2	Have you ever received growth hormone or gonadotrophin treatment? If yes, please specify whether the hormone was derived from human pituitary glands?	Recipients of hormone derived from human pituitary glands, e.g. growth hormone or gonadotrophin, have been identified as potentially at risk of CJD. In the UK, the use of human-derived growth hormone was discontinued in 1985 but human-derived products may have continued to be used in other countries.
3	Have you had surgery on your brain or spinal cord before August 1992?	People who underwent neurosurgical procedures or operations for a tumour or cyst of the spine before August 1992 may have received a graft of *dura mater*, and should be treated as at risk, unless evidence can be provided that *dura mater* was not used.
4	Have you ever been contacted as potentially at-risk of CJD for public health purposes? If yes, please specify.	The CJD Incidents Panel has identified a number of individuals who are potentially at risk of CJD or vCJD for public health purposes (see paragraphs J8- J12 for further details).

The need for comprehensive pre-surgery assessment

J5. In addition to asking the patient CJD risk questions, the following actions should also be carried out before any surgical procedure involving tissues with high or medium level infectivity to ensure that a comprehensive pre-surgery assessment is carried out. The clinician undertaking the pre-surgery assessment should:

- Check the patient's medical notes and/ or referral letter for any mention of CJD status.
- Consider whether there is a risk that the patient may be showing the early signs of CJD. i.e. consider whether the patient may have an undiagnosed neurological disease involving cognitive impairment or ataxia.

These actions, in conjunction with the CJD risk questions, will minimise the chance of a CJD incident occurring and therefore greatly reduce the risk of transmission of CJD to subsequent patients.

Emergency Surgery

J6. In the event that a patient about to undergo emergency surgery is physically unable to answer questions, the next of kin should be asked the CJD risk questions before surgery takes place. If this is also not a viable option, the questions must be answered as soon as possible after the operation by either the patient or next of kin.

Training

J7. Trusts should ensure that the healthcare workers conducting the pre-surgery assessment receive the instruction and/or training necessary to understand the underlying reasons for asking these questions. It is crucial that the questions are asked in a manner that does not cause undue anxiety and therefore the questioner should be prepared to reassure the patient and provide further information, if needed.

Patients at risk of CJD for public health purposes

J8. As outlined in Table 4A in Part 4, a number of patients have been identified as potentially at risk for public health purposes on the recommendations of the CJD Incidents Panel. Paragraphs J9 to J12 provide some further information on these individuals and the steps taken to ensure that medical staff is informed of their risk status.

J9. This group of patients includes individuals identified to be at risk of:

a) CJD/vCJD due to exposure to certain instruments used on a patient who went on to develop CJD/vCJD, or was at risk of vCJD;
b) CJD/vCJD due to receipt of tissues/ organs
c) vCJD due to receipt of blood components or plasma derivatives;
d) vCJD due to the probability they could have been the source of infection for a patient transfused with their blood who was later found to have vCJD.

J10. When someone is notified that they are at risk of CJD, they are asked to take certain precautions to reduce the risk of spreading the infection to others. These include:

- Not donating blood, tissue or organs;
- Informing medical carers if they need to undergo an invasive medical procedure;
- Informing their next of kin, in case they need emergency surgery in the future.

J11. The individual's GP is asked to record the patient's CJD at-risk status in their primary records. The GP should also include this information in any referral letter should the patient require invasive medical procedures.

J12. Further information on the work of the CJD Incidents Panel is available on the HPA website, http://www.hpa.org.uk/infections/topics_az/cjd/menu.htm