

## **ANNEX I**

### **Outline Protocol for Management of Instruments and Tissues from Brain Biopsy Procedures on Patients with Progressive Neurological Disorders**

The Department of Health has taken expert advice on the need for additional guidance on the quarantine of surgical instruments following brain biopsies.

The Chief Medical Officer issued a protocol for management of surgical instruments and tissues from brain biopsy procedures on patients with progressive neurological disorders on 17 May 2004.

This protocol is attached as the next 4 pages of this document.

17<sup>th</sup> May 2004

Dear Colleague



## **REDUCING THE RISK OF EXPOSURE OF PATIENTS TO THE AGENT OF CJD THROUGH BRAIN BIOPSY PROCEDURES**

A brain biopsy can reveal a diagnosis of CJD that was not suspected prior to the biopsy because CJD can present in atypical ways with a differential diagnosis that includes conditions such as cerebral vasculitis. The biopsy could result in inadvertent exposure of subsequent patients to CJD agent via the instruments used. The Department of Health has taken expert advice on the need for additional guidance for the quarantine of surgical instruments following brain biopsies in such circumstances.

The attached protocol has been prepared in conjunction with neurosurgeons, neurologists, neuropathologists and the National CJD Surveillance Unit.

I strongly urge that this protocol be implemented within your NHS Trust with immediate effect.

National guidance "Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection"<sup>1</sup> on the prevention of infection arising from the agents that cause Creutzfeldt-Jakob Disease (CJD) and other spongiform encephalopathies was last revised and issued in December 2003.

I would be grateful if Medical Directors would also review present policies, procedures and practices within your NHS Trusts to ensure that this guidance is being fully complied with and that all staff in key roles are aware of it and fully understand how to apply it. The protocol for brain biopsy developed by the Department of Health has been added as an Annex to this Guidance.

A handwritten signature in blue ink that reads 'Liam Donaldson'.

**Sir Liam Donaldson  
Chief Medical Officer**

## **From the Chief Medical Officer**

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Sir Liam Donaldson  
MSc,MD,FRCS(Ed),FRCP,FFPHM

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Richmond House  
79 Whitehall  
London SW1A 2NS

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Gateway Reference: 3105

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### **For Action**

- Medical Directors of NHS Trusts
  - Neurologists
  - Neurosurgeons
  - Pathologists
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### **For further information:**

please contact:  
Naima Khondkar  
Tel: 020 7972 5057  
Naima.Khondkar@doh.gsi.gov.uk

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**Requests for further copies** should be addressed to:

Fax: 01623 724 524  
Write to Department of Health  
PO Box 777, London SE1 6XH

Email: [doh@prolog.uk.com](mailto:doh@prolog.uk.com)

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**For correction of any discrepancies in changes of address, practice or name,** please contact:

The Medical Mailing Company  
PO Box 60, Loughborough  
Leicestershire LE11 0WP  
Tel: Freephone 0800 626387

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This letter is also available on the Internet at:  
<http://www.dh.gov.uk/cmo>

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<sup>1</sup> [www.dh.gov.uk](http://www.dh.gov.uk) > Policy and Guidance>Health and Social Care Topics >CJD >CJD publications > Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection.

# Outline Protocol for Management of Instruments and Tissues from Brain Biopsy Procedures on Patients with Progressive Neurological Disorders

Department of Health 2004

CJD can present in atypical ways with a differential diagnosis that includes conditions such as cerebral vasculitis. A brain biopsy therefore could reveal a diagnosis of CJD that was not suspected prior to the biopsy. The protocol below minimises the risk that this could result in inadvertent exposure of subsequent patients to CJD agent via surgical instruments. A single person involved in the clinical care of the patient should take responsibility for co-ordination of the procedures and communications, including alerting the neuropathology laboratory in advance of sending samples and monitoring all aspects of the protocol.

## A. Clinical assessment and biopsy procedure

1. This protocol should apply to all patients who have unexplained progressive dementia (or ataxia or neuropsychiatric syndromes) in whom diagnostic brain biopsy is considered appropriate in order to establish or exclude a diagnosis.
2. The neuro-radiology in such patients usually shows no evidence of a space-occupying lesion.
3. The patient does not fulfil the WHO criteria<sup>2</sup> for probable or possible CJD<sup>3</sup>. Indeed CJD may not have been considered on clinical grounds.
4. Brain biopsy, preferably an open block biopsy, is performed for diagnosis.

## B. Handling the neurosurgical instruments and the biopsy tissues

5. Single use instruments should be used wherever possible without compromising patient safety.
6. Any instruments that may have come into contact with brain or meninges of patients identified (A) should be washed at the point of use and quarantined immediately after use<sup>4</sup>
7. Send the tissue samples from the biopsy procedure unfixed directly to the neuropathology laboratory, ideally within 10 minutes of collection.
8. In the neuropathology laboratory, using containment conditions appropriate for fresh human brain, remove a small portion of unfixed cortical grey matter (at least 0.1g) from the biopsy. Store the sample frozen, clearly labelled, and preferably at -70°C (-20°C is sufficient for storage for several weeks) in a designated freezer.
9. Fix the remainder of the tissue samples in formalin and process into paraffin wax.

<sup>2</sup> The WHO criteria can be found at [www.cjd.ed.ac.uk](http://www.cjd.ed.ac.uk)

<sup>3</sup> Precautions to be taken for procedures on symptomatic patients with possible or probable CJD, or when CJD is under active consideration are set out in the ACDP/SEAC TSE Joint Working Group Guidance, which can be found at [www.dh.gov.uk](http://www.dh.gov.uk) > Policy and Guidance > Health and Social care Topics > CJD > CJD Publications > Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection.

<sup>4</sup> Annex E of the above guidance for guidance on quarantine of instruments

## **C. Neuropathological diagnosis and the fate of the neurosurgical instruments**

**10. If a definite diagnosis of a disorder other than CJD is made** (and there is no other evidence to suggest any form of CJD).

- The neurosurgical instruments can be reprocessed and reused.

**11. If a definite diagnosis of CJD is made**

- Destroy the neurosurgical instruments<sup>5</sup> and refer the case to NCJDSU by the clinician responsible for the patient (a request to review the biopsy will be made as part of NCJDSU's routine activities). Precautions to minimise the risk of transmission as a result of procedures carried out in the pathology laboratory and the clinic should be taken in accordance with the ACDP/SEAC TSE Guidance.

**12. If the diagnosis is uncertain**

- If the local neuropathologist cannot exclude CJD as a possible diagnosis, contact NCJDSU to refer the case for further investigation. NCJDSU will arrange uplift and transport of the fixed and frozen tissues.
- If an alternative diagnosis is made by the NCJDSU, the neurosurgical instruments can be reprocessed and reused.
- The neurosurgical instruments should be destroyed<sup>4</sup>, if a definite diagnosis of CJD is made by NCJDSU.
- If the diagnosis remains uncertain, the neurosurgical instruments should remain in quarantine until a definite diagnosis is made, or the patient dies. Precautions to minimise the risk of transmission as a result of procedures in the pathology laboratory and the clinic should be taken in accordance with the ACDP/SEAC TSE Guidance<sup>2</sup>.

**13. If the patient dies without a diagnosis**

- Seek consent for postmortem examination of the brain and, if it is given, follow the procedures set out in box 12 above.
- The instruments used for the biopsy should be destroyed<sup>4</sup>, if consent for postmortem examination is not given.
- If the diagnosis is still uncertain after post-mortem examination of the brain, the instruments used for biopsy should be destroyed<sup>4</sup>.

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<sup>5</sup> Certain instruments can be used as a resource for research. Please contact the Department of Health (John.Stephenson@doh.gsi.gov.uk / 0207 972 5607) to arrange for collection of any surgical instruments that would otherwise be destroyed.

## D Flow diagram of essential communications

A single person, usually the consultant neurologist responsible for the patient's care, should ensure that the relevant information is communicated to the appropriate people.

<b>STEP</b>	<b>INFORM</b>	<b>ACTION</b>
<b>Brain biopsy planned on a patient identified in Box A</b>	IC Team /SSD	quarantine instruments
	Neuropathology Lab	process and store biopsy sample
<b>Neuropathologist excludes CJD as a diagnosis</b>	IC Team/SSD	release quarantined instruments
<b>Neuropathologist diagnoses CJD</b>	IC Team/SSD	destroy instruments <sup>1</sup>
	NCJDSU	CJD surveillance
	National Prion Clinic	Consideration for clinical trial
<b>Neuropathologist neither diagnoses nor excludes CJD</b>	NCJDSU	diagnosis
<b>NCJDSU gives non-CJD diagnosis</b>	IC Team/SSD	release quarantined instruments
<b>NCJDSU diagnoses CJD</b>	IC Team/SSD	destroy instruments <sup>1</sup>
	CCDC	report to CJDIP
<b>NCJDSU neither diagnoses or excludes CJD</b>	IC Team/SSD	continue quarantine of instruments
	CCDC	report to CJDIP
<b>Patient dies without diagnosis and post mortem is not permitted</b>	IC Team/SSD	destroy instruments <sup>1</sup>
	CCDC	report to CJDIP

<sup>1</sup> Certain instruments can be used as a resource for research. Please contact the Department of Health (John.Stephenson@doh.gsi.gov.uk / 0207 972 5607) to arrange for collection of any surgical instruments that would otherwise be destroyed.

### Abbreviations used

IC	Infection control
SSD	Sterile Services Department
NCJDSU	National CJD Surveillance Unit
CCDC	Consultant in Communicable Disease Control
CJDIP	CJD Incidents Panel