

“Endoscopy and individuals at risk of v CJD for public health purposes”

A consensus statement from the British Society of Gastroenterology Decontamination Working Group and the ACDP TSE Working Group Endoscopy and vCJD Sub-Group

Introduction

The incidence of new cases of variant Creutzfeldt Jacob (vCJD) disease appears to be in decline with a total of 150 deaths to date [1]. Those affected are predominantly young adults and the long incubation period [2] leaves ample time for disease transmission through routes such as incompletely decontaminated surgical instruments, endoscopy and blood transfusion. At the time of writing, 18 patients who have developed vCJD were known to have donated blood before diagnosis of vCJD and at least two patients have apparently been infected as a consequence of receiving red cell transfusions from this source. One of these recipients developed clinical disease, while the other was found at post mortem to have abnormal prion protein in the spleen and one lymph node, but had no evidence of clinical vCJD. Of potentially wider impact is the risk of transmission of vCJD via plasma products, predominantly (but not exclusively) received by haemophiliacs and patients with immunodeficiency syndromes. Those who have received sufficient “implicated” plasma-product (i.e. made from plasma from a donor who later developed vCJD) to put them at an additional 1% or greater risk of vCJD are deemed to be “at risk of vCJD for public health purposes.” In addition, others who belong to certain patient groups with relatively high exposure to UK-sourced pooled factor concentrates, or antithrombin, are also alerted to a potential public health risk, as identification of further donors who later developed vCJD may put them in the defined at risk category. The number of individuals deemed to be at risk is in the order of 6500 and the vast majority have now been told of their risk and asked to take certain public health precautions to reduce the risk of spread to others, i.e. not to give blood,

tissues or organs, and to inform healthcare staff who should follow guidelines for management of instruments potentially contaminated with tissues of medium- or high-infectivity for vCJD. The groups of individuals currently identified as at risk of vCJD are shown below in Table 1:

Table 1: Groups of individuals currently identified as potentially at increased risk of vCJD due to iatrogenic exposures or other indicators of increased risk (as at end July 2005).

Patient/exposure types	Individual identified as at risk of vCJD
1. Patients exposed to potentially contaminated healthcare instruments	Approx 60
2. Recipients of vCJD-implicated blood components	Approx 30
3. Individuals linked to vCJD cases by transfusion 3.1 Donors to vCJD cases* 3.2 Recipients of other blood donations from donors to vCJD cases*	Approx 110 Risk level TBD by CJD Incidents Panel, September 2005 – may be approx 3000
4. Recipients of plasma-product 4.1 Patients with bleeding disorders 4.2 Patients with primary immunodeficiencies 4.3 Patients with other conditions	4,000-6,500 None to date Approx 20
5. HGH recipients	Approx 1,908

* These are identified blood donors from whom blood has been transfused to individuals who have subsequently developed vCJD.

Unfortunately many of these patients have contracted serious health problems as a consequence of receiving blood or plasma products in the past and may be suffering from hepatitis B or C infection, and resultant chronic liver disease. As lymphoid tissue of the gastrointestinal tract sub-mucosal is considered a medium-infectivity tissue in terms of abnormal prion protein per gram of tissue [3], the investigation of these patients by gastroenterologists and gastrointestinal surgeons has implications for all patients requiring endoscopy.

Key issues

Flexible endoscopes are expensive and fragile pieces of medical equipment. They cannot be completely decontaminated via current methods [4] although best practice is expected to reduce the risk of patient-to-patient transmission to below 1% after several cycles of use and decontamination. However, this means the next few patients are considered potentially exposed to significant prion infectivity [5]. The basis for this risk estimate is the assumption that the suction biopsy channel of the endoscope becomes contaminated by sub mucosal lymphoid tissue containing prions, as the consequence of taking a biopsy or performing another invasive procedure. With over 6000 patients, predominantly haemophiliacs, some of whom will have cirrhosis and other medical conditions requiring endoscopy, it is now very important that clear guidance is issued to clinicians in order to prevent the unnecessary loss of endoscopes through the quarantine procedures [3]. The risks of transmission are not confined to the endoscope itself as accessories such as biopsy forceps have an equal or even greater risk attached to them as they are less easily cleaned due to their construction. As a consequence, disposable equipment is now advised wherever possible, which in itself will eliminate this source of risk. However, endoscopes are not disposable and “at risk” individuals are concentrated in large centres with significant numbers of patients (particularly haemophiliacs) requiring endoscopy. Based on a survey of hospitals serving haemophilia centres caring for an estimated 65-79% of ‘at-risk’ haemophiliac patients, the number of invasive gastrointestinal endoscope procedures in a 12 month period would result in the loss of around 3% of available endoscopes [6]. The variation in experience was notable: 70% of centres, serving an estimated 26-33% of ‘at-risk’ haemophiliac patients reported 0% usage of scopes for invasive procedures on these patients, while four centres serving an estimated 21-26% of ‘at-risk’ haemophiliac patients reported over 15% of their scopes were used for

invasive GI endoscope procedures on these patients during the past 12 months [6]. The cost and disruption to the service is likely to be enormous for those centres dealing with large numbers of “at risk” patients. It is now important that the risks of contaminating the endoscope are minimised.

How is the risk of endoscope contamination minimised?

There is currently no evidence that vCJD has been transmitted from one patient to another via an endoscopic procedure. However, there is no room for complacency and guidelines continue to emphasise that, although not a validated process, thorough manual cleaning, as a pre-requisite to an automated endoscopic decontamination procedure, is still the cornerstone of good practice. The risk is further minimised by only biopsying tissue when necessary, using disposable biopsy forceps and disposing of the biopsy port rubber cap after use on all patients. However, as a precautionary measure taking a biopsy must be considered a sufficient risk to warrant quarantining the endoscope. It is unlikely that such an endoscope will ever return to use (except on the same patient) and so the most important advice at present is **not to take a biopsy unless absolutely necessary. Random biopsies are unacceptable clinical practice and would be difficult to defend where there is no indication to do so.**

The safety of individual procedures has recently been the subject of intense scrutiny following the realisation that a large number of recipients of plasma products (mainly haemophiliacs and patients with immune deficiency syndromes) who are “at risk” will require essential endoscopy for a variety of conditions. Endoscopic investigation and therapeutic endoscopy must not be denied to these patients where clinical ‘best practice’ would dictate that a

procedure should be carried out (e.g. ERCP and sphincterotomy in a patient with stones in the common bile duct or injecting oesophageal varices). Gastroenterologists and gastrointestinal surgeons who might be presented with such a problem should consult the recently revised guidelines (Annex F) that lists each procedure likely to contaminate the endoscope and hence necessitate quarantining the instrument [3]. At present there is very little scientific evidence to back up this guidance but what the guidance does advise is that instruments used for procedures that are not expected to result in potential contamination with lymphoid tissue can be safely decontaminated in the normal way and returned to use immediately. This is on the basis that contamination of the suction biopsy channel with lymphoid tissue is not expected. Blood and bodily secretions do not pose a threat as only very small volumes are encountered and blood itself is considered a low-infectivity tissue. In contrast, the two cases of prion infection probably associated with blood transfusion involved red cell transfusions, where the volume of red cells transfused is in the order of 200-300 mls i.e. large volumes of low-infectivity tissue does put the recipient at risk in the same way as low volumes of high- (such as CNS) or medium-infectivity tissue (such as sub-mucosal lymphoid tissue). In the absence of direct evidence, the British Society of Gastroenterology Decontamination Working Party and the Advisory Committee on Dangerous Pathogens TSE Working Group, Endoscopy and vCJD Sub-Group met on August 5th 2005 to agree on a consensus view of the risks associated with individual endoscopic procedures previously considered “invasive” and therefore requiring the quarantining of the endoscope used. The agreed new guidance is now available on the DH website at <http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm> (Annex F) and a synopsis is shown below:

Endoscope procedures deemed to be invasive (i.e. expected to potentially contaminate instruments with lymphoid tissue).

Endoscopy and biopsy

Endoscopy and any use of diathermy (e.g. snare polypectomy, sphincterotomy).

Endoscopy and dilatation – only when a balloon used for dilatation is withdrawn back up through the endoscope

Endoscopy and argon plasma coagulation

Endoscopic ultrasound and biopsy

Endoscope procedures deemed non-invasive (i.e. no potential for contamination of the instruments with lymphoid tissue and therefore not requiring quarantining of the endoscope)

Endoscopy without biopsy (includes appropriate use of cytology)

Endoscopy and brush cytology (providing the brush is sheathed)

Endoscopy followed by bougie dilatation of stricture

Endoscopy and balloon dilatation (providing the balloon is not retracted into the suction/ biopsy channel)

Gastroscopy and insertion of a PEG feeding tube (providing it is performed with a ‘pull through’ technique where the wire or thread is not withdrawn into the gastroscopie but withdrawn in full view)

Endoscopic ultrasound without biopsy

Endoscopy and injection of varices or ulcer (without diathermy)

Endoscopy and mucosal clipping

Endoscopy and banding of varices

The fundamental principal that patient care must remain unaffected is paramount. With careful thought invasive endoscopy can be minimised while maintaining patient safety and the loss of endoscopes each year can be limited to approximately 1% per annum. Endoscopy units

treating large numbers of patients “at risk of vCJD for public health purposes” require funding to replace endoscopes that can effectively only be used again on the same patient following quarantine. Endoscopy units could consider retaining endoscopes that are close to decommissioning for potential use on individuals at risk of vCJD, providing that the endoscopes are fully functional. Further research is required to look into the risks associated with the use of sheathed accessories in conjunction with the use of diathermy (snare polypectomy and sphincterotomy).

References

1. **The National Creutzfeldt-Jacob Disease Surveillance Unit.** www.cjd.ed.ac.uk (data to 1st July 2005).
2. **Glatzel M, Ott PM, Lindner T et al. Human prion disease. Epidemiology and integrated risk assessment. Lancet Neurol 2003;2:757-63**
3. **Transmissible spongiform encephalopathy agents: safe working and the prevention of infection - Guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee. Department of Health, 2003.**
<http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/index.htm>
4. **Medical device agency bulletin. Decontamination of endoscopes July 2002 MDA DB 2002 (05)**
5. **CJD Incidents Panel Framework Document 2004**
http://www.hpa.org.uk/infections/topics_az/cjd/incidents_panel.htm#eight
6. **Personal communication - Professor Frank Hill, UKHCDO**