Aligning CFPP 01-06 and Annex F – Endoscopy guidance
Meeting on 20th September 2012

Present:

Roland Salmon (Chair)
Geoff Ridgway
Adam Fraise (Part)
Miles Allison
John Saunders (co-opted)
Mike Painter
Katy Sinka
Emma Hollis
Ginny Belson

Background and purpose
The meeting involved members of the CJD Incidents Panel who had been involved in the development of CFPP 01-06 and who had been part of the expert advisory group on decontamination that had informed that guidance. The purpose of the meeting was

1. to discuss elements of the new guidance which do not accord with current guidance, Annex F, specifically relating to the differential management of certain patients. and
2. To reach a view that could be taken to the ACDP Risk Management Subgroup for approval and to allow the guidance to be revised in a consistent manner.

At the preceding CJD Incidents panel (CJDIP), held earlier on the 20th September 2012, the main areas where the two sets of guidance are discrepant were discussed briefly and a consensus Panel view obtained. These areas are discussed in detail beneath.

In addition, at the panel meeting it had also been confirmed that Annex F would stand as the definitive guidance on decontamination of flexible endoscopes and infection control for TSE risk management and it would not be necessary to seek amendments to the CFPP 01-06 to bring matters of detail into alignment.

Updates to the endoscopy guidance for individuals "at increased risk" of vCJD

It was agreed that:

- as set out in CFPP 01-06, a single cycle of verifiable decontamination to the approved standard was a practical and desirable approach that should be adopted in most circumstances. Special precautions, including the removal of an endoscope from general use, should continue for:
    - Symptomatic patients with confirmed, probable or possible vCJD, and possible sporadic cases, where vCJD has yet to be ruled out.
    - The sub-group of asymptomatic patients at increased risk who are considered to be most at risk ("presumed infected")

- For other asymptomatic "at increased risk" for vCJD patient groups a single cycle to the approved standard would suffice.

- it was therefore necessary to split the currently defined Asymptomatic "at increased risk" group into two sub-groups when applying the endoscopy infection control guidance. This would require amendment to Part 4 of the TSE infection control guidance.

- It should be emphasised that all endoscopes for quarantining must be decontaminated first and then quarantined; if they dry out they cannot be reused and will have be destroyed.

- endoscopes currently in quarantine can be returned to general use if
    - used for an individual in the main asymptomatic "at increased risk" but not if in the "presumed infected" sub-group.
    - Providing they have been decontaminated to the appropriate standard before being quarantined.
- The general principles – agreed above would also apply to nasendoscopy and these changes should also be reflected in the updated guidance (see end note)

Terminology

A small group of individuals who received labile blood components from a donor who subsequently developed vCJD, and who remain alive, have been identified as being at greater risk than the other groups of "at increased risk" individuals[1], such as those who have only received plasma products. The CJDIP has advised that these individuals be managed as if infected and for retrospective incident management purposes this has been put into practice. To date there has been no selective management of this group for infection

[1] Department of Health 2007. Report of the vCJD Clinical Governance Advisory Group http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073486

control purposes. This group, are identified within both sets of endoscopy guidance using different terminology (see box). The recommendations from the discussion recorded here, if accepted by the TSE RM SG, will lead to a change in policy with respect to the differential management of this small group of patients. It is therefore important to agree a clear and consistent definition.

Box: Different terminology used to define patients "at increased risk" through the receipt of labile blood components donated by vCJD cases[2]

CFPP 01-06: Presumed infected, known to have received blood or plasma products[3] for the purposes of this CFPP, this includes whole blood, red cells, plasma (FFP), cryoprecipitate, cryodepleted plasma and platelets) from a donor who had developed vCJD.

Annex F (refers to Part 4 of the TSE guidance): Individuals who have received blood from someone who went on to develop vCJD[4]

Rationale for subdividing the asymptomatic "at risk" group for the decontamination of endoscopes

It was agreed that there is a demonstrably greater risk for the patients within the small group (17 surviving) of labile blood component recipients. As transmission of clinical vCJD has been demonstrated through transfusion the risk is not just theoretical as could be argued for other groups whose risks were defined to a greater or lesser extent using mathematical modelling to take into account the available evidence.

This means that, while relaxing the procedures for infection control when carrying out endoscopic procedures for most at risk groups, the "presumed infected" group should continue to be managed in the same way as symptomatic individuals.

Potential increase in size of the "at increased risk" presumed infected group

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[2] This terminology is that used by the Transfusion Medicine Epidemiological Review which has identified these individuals and investigated their exposure history. http://www.cjd.ed.ac.uk/TMER/TMER.htm

[3] the CFPP definition includes the term "plasma products" – this could be misleading since it is not intended that recipients of fractionated plasma products (eg for the treatment of bleeding disorders) are part of the "presumed infected" group. Plasma products in the CFPP definition refers to fresh frozen plasma, cryoprecipitate and cryodepleted plasma.

[4] As one of nine groups of patients considered under the blanket term "Patients identified as "at increased risk" of CJD/vCJD through iatrogenic exposures, and under the further blanket term "Asymptomatic patients at risk of vCJD"

It was agreed that further individuals could enter the "at increased risk - presumed infected" sub-group if further blood donors developed vCJD. Living recipients of blood components from these donors would be identified and notified. The group could also include recipients of organs, bone marrow or circulating stem cells from a donor who was known to have developed vCJD. Although no individuals have yet been identified who have been exposed in this way.

Another way the "at increased risk" presumed infected sub-group could increase would be if a reliable blood test was developed. This would have a significant impact on risk assessment and management of all current "at increased risk" groups if generally applied. It would have wider impacts.

The "at increased risk" - presumed infected" sub group does not include highly transfused patients, as although the route of exposure is the same, the link to a known clinical case of vCJD is not present.

What steps would be necessary to ensure that the people within the "at increased risk" presumed infected sub-group could be identified if they presented for an endoscopic procedure?

It was agreed that

Endoscopy units would continue to ask the general pre-operative screening question for all patients to identify those who have been notified that they are at increased risk of vCJD. For those patient who say yes, an additional question would ascertain the reason for the notification. This could be confirmed with the patient's GP if necessary.

The GPs for the patient group "at increased risk – presumed infected" should be informed that public health precautions for these individuals are still required for endoscopic procedures.

GPs for this group of patients are contacted each year and asked to complete a clinical monitoring form for their patients. The cover letter also acts as a reminder of the public health precautions that should be taken and this re-enforcing message can be conveyed at the next communication. A sensitive choice of language should be used, previous correspondence has not used the term "presumed infected".

Next steps:

A revised, version of Annex F should be ready to present to the ACDP risk management sub-group on 8th November 2012.

Miles Allison would communicate the updates to the guidance to the (gastro)endoscopic community after discussion and approval at the ACDP TSE RM SG

End Note: Nasendoscopy

It is proposed to extend the one cycle of decontamination recommendation to other endoscopic procedures where there is involvement of medium risk tissues in asymptomatic at increased risk patients. This applies to nasoendoscopy where there is potential contamination with medium risk tissues if there is disruption of the olfactory epithelium

However, the removal of nasendoscopes from general use would still be advised for all symptomatic patients, and for **two** asymptomatic patient groups

1. recipients of blood transfusions from donors who later developed vCJD
2. Individuals at increased risk of genetic CJD

The inclusion of those at genetic risk reflects

1. The higher risk of developing clinical disease in these patients, especially those who have been tested and shown to carry a disease associated mutation (for whom the chances of developing disease are high and may be 100%).
2. The infectivity of olfactory epithelium in individuals who have been diagnosed with (non variant forms of) CJD.