

**RESERVED BUSINESS  
SEAC 81/14**



**Department of Health - Update on tonsil studies.**

### **Prospective Study - Professor Collinge (MRC Prion Unit).**

1. Professor Collinge has completed the analysis (including immunohistochemistry and high sensitivity Western Blot analysis) of the original 2000 tonsil samples. A manuscript had been submitted to the Lancet in August.
2. MREC approval had been obtained for the collection and testing of a further 3000 samples (making the total 5000) and these additional samples had now been collected but not tested. The Steering Group agreed that these were important and should be transferred to the National Archive for testing as soon as possible.

### **Retrospective Studies - Dr Hilton (Derriford Hospital, Plymouth) and Professor Ironside (NCJDSU)**

3. Dr Hilton reported that his analysis was complete. A total of 16,703 samples had been tested, including samples from Edinburgh. Around 60% were in the 20-29 age group. 14,964 were appendices and 1,739 came from tonsil. 4,029 samples had been excluded from the analysis because they contained insufficient lymphoid follicles. Dr Hilton and Professor Ironside are preparing these studies for publication as soon as possible.

### **National Archive of Tonsils - Dr Gill (HPA)**

4. The Protocol agreed by the MRC/DH Steering Group has received MREC approval following a modification to include a paragraph offering the opportunity to object in the consent form. Laboratory facilities had been identified at Colindale and a lead researcher has been appointed. A tender had been put out for transporting tonsils to Colindale, with the hope that the contract would be in place by 1<sup>st</sup> March 2004. A limited collection in southern England was commenced on December 1<sup>st</sup> 2003. The National Archive would currently only cover England and Wales, but the Scottish Office was looking at this issue.
5. The original plan for testing within the National Archive was to accumulate substantial batch samples before initiating testing. However upon the recommendation of the Steering Group HPA has agreed to alter their plans and test in batches of 5000 starting as soon as practicable with the 3000 tonsils from Professor Collinge, as these can be examined immediately due to extant ethical approval

## **Analysis of samples in the National Archive of Tonsils**

6. The suggested changes to on-going testing of samples would require modifications to the protocol and would be discussed at the next Steering Group meeting.
7. As Professors Collinge and Ironside already have protocols for testing, the Steering Group agreed that the HPA would need support in translating these protocols to apply them to the National Archive. Professor Collinge noted that the Prion Unit had recently developed microtitre plate technology that might be used in place of Western Blots. The Steering Group agreed that Dr Mortimer from the HPA should consult with Professor Ironside and Professor Collinge on the most appropriate technology to employ and develop a suitable protocol by the end of January 2004.