From Andrew Miller MP, Chair

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3 November 2014

On behalf of the Committee, I would like to thank you for your Department’s recent response to our report, After the storm? UK blood safety and the risk of variant Creutzfeldt-Jacob Disease. We note your assurance that the Government’s approach to this issue remains precautionary and are pleased that you have chosen to act on so many of our recommendations.

Nevertheless, I would be grateful if you would provide additional information with regard to the following areas.

vCJD blood testing

You acknowledge that it would be “extremely helpful to have a reliable test for vCJD” and have promised to “explore the possibility of using the prototype test developed by the MRC Prion Unit to carry out a blood prevalence study”, as recommended. However, you state that your decision will be influenced by the Department’s “limited budget for research” and this study’s “importance in comparison to [sic] other research priorities”.

1. What methodology do you use to evaluate and select between competing demands on the Department’s research budget?

2. If no standard methodology is in place, how do you plan to establish this study’s value compared with other current research proposals?

You state that the final decision on this matter will depend on the resolution of certain “scientific and technical issues” and will be informed by the views of the ACDP’s TSE sub-group. We understand that the TSE sub-group previously considered the MRC Prion Unit’s prototype test earlier this year and reached a favourable conclusion regarding its potential value.

3. What was the context and nature of this previous review and what did it find? Please provide any relevant ACDP documentation.

4. What has happened in the interim that would warrant a further scientific review of this test?

5. What are the scientific and technical issues that you refer to and what is the Department doing to help resolve these?
You also note that it is not clear whether or not the MRC Prion Unit’s test can detect asymptomatic vCJD-infected individuals.

6. How do you propose this question be answered, if not by conducting a large-scale comparison of BSE-exposed and unexposed populations?

We were unable to confirm the nature of the TSE sub-group’s previous work on this test because up-to-date meeting minutes did not appear to be available of the committee’s webpage. This is despite the Code of Practice for Scientific Advisory Committees (CoPSAC) stating that “all committees are expected to publish, as a minimum, programmes of work, meeting agendas, minutes, final advice (where appropriate) and an annual report”.

7. Do you consider the ACDP to be a scientific advisory committee? If so, why is it not currently meeting these basic transparency requirements?

You agreed with our recommendation that all requests for access to vCJD patient samples be managed and evaluated through NIBSC. You state that this is already the case for samples held by the MRC Prion Unit; however, this contradicts the testimony of Professor John Collinge, the Unit’s Director, who stated in oral evidence (Q 107) that it had been “agreed upfront” that his group would not need to observe the NIBSC process when utilising its own samples for research purposes.

8. Please provide clarification and, if Professor Collinge’s testimony is accurate, a corrected response to our original recommendation.

You further state that “any test used in such a blood prevalence study would need to be reviewed and possibly further evaluated by the NIBSC CJD Resource Centre Oversight Committee”.

9. Please indicate when you intend to initiate this process for the MRC prototype test.

Decontamination of surgical instruments

You acknowledge that recommendations aimed at making current decontamination guidance fit for purpose are well founded and state that the ACDP has established a “short-life working group” to update and revise current practical guidance.

10. How will this process inform the existing guidance prepared by NICE? Will IPG 196 be updated as a result? If not, will it be rescinded?

11. What is the membership of this group and how were members recruited?

12. Why are the details of this working group not detailed on the ACDP webpage, in accordance with CoPSAC?

You state that this group will “consider the outcomes of Department of Health funded research related to decontamination and protein identification”.

13. How much has the Department invested in prion decontamination research in total during this parliament and, to date, how many operational decontamination products have resulted from this research?

In future, you indicate that implementation of decontamination guidance may be addressed in England via the CQC and that relevant discussions are
currently underway. You also note that NHS Scotland is “actively working to ensure compliance with the NICE IPG 196 guidance”.

14. If it is decided that compliance with decontamination guidance should fall under the remit of the CQC, what might inspections consist of?

15. Who will be responsible for ensuring that decontamination guidance has been implemented in Wales and Northern Ireland?

**Other outstanding issues**

You state that you have allocated a ring-fenced budget to prion disease.

16. How big is this budget and how is it spent? Please provide a breakdown.

We recommended that SaBTO “reconsider the feasibility of a move to more individualised risk assessment […] following completion of the current UK blood donor survey”. You responded that you had seen no evidence that would lead to a change in SaBTO’s advice but made no mention of the survey referred to in our recommendation.

17. What is the status of UK blood donor survey launched in October 2013?

18. Do you intend to incorporate its findings into current donor policy? If so, how and when?

You state that work is in progress to explore differences in appraisal methodology between NICE and other health-related bodies and that this is being carried out through a working group “set up under the auspices of the Department of Health Chief Economist”.

19. What involvement do the Government Office for Science and the Department’s Chief Scientific Adviser have in this working group?

20. When and where will the results of this work be published?

Your response suggests that you are still in the process of considering an outline proposal submitted by the NCJDRSU aimed at determining whether there is any unrecognised vCJD or atypical prion disease in the older population. Evidence taken from Professor James Ironside, a member of that unit, suggests that this was submitted prior to November 2013.

21. What is the current status of this proposal and why has it taken the Department so long to reach a funding decision?

I look forward to speaking to you on 3 December as part of our legacy inquiry, in which we will be looking back on this and several other reports published during this parliament. In order to make best use of the available time in that session, I would ask that you provide answers to the above queries by **Friday 21 November**.

Yours sincerely,

Andrew Miller
Chair