PARLIAMENTARY QUESTION

DEPARTMENT OF HEALTH

7951	2010/2011
Lords Written	

to ask Her Majesty's Government what assessment they have made of the feasibility of introducing a test to detect the presence of infectious prions in blood.

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MP (Party):	The Baroness Masham of Ilton (Crossbench)

DRAFT REPLY TO REACH PARLIAMENTARY BRANCH BY

12:00 25/03/2011

PARLIAMENTARY RELATIONS UNIT
FINAL MINUTE

To Parliamentary Relations Unit:

I confirm that the attached suggested reply has been drafted in accordance with the Departmental guidance. Drafted by:

Name	*Mark Noterman*	Building	*WEL*
		Room	*530*
Branch	*ID&BP*	Ext	GRO-C
		Date	*25 March 2011*

I confirm that the attached suggested answer has been approved in accordance with the Departmental guidance. Approved by (a member of the SCS):

Name	*Dr Ailsa Wight*	Ext	GRO-C
Room	*524*	Building	*WEL*
		Date	*25 March 2011*

3. The following special points should be noted:

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Written Answer Han Ref: Vol

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The Baroness Masham of Ilton (NONE) to ask Her Majesty's Government what assessment they have made of the feasibility of introducing a test to detect the presence of infectious prions in blood. [7951]

SUGGESTED REPLY

The potential for future use of the prototype diagnostic blood test for variant Creutzfeldt-Jakob disease (vCJD), described in the paper published in the *Lancet* on 3 February 2011, for blood screening purposes will be considered by the United Kingdom Blood Services Prion Working Group (PWG). Professor John Collinge and colleagues from the Medical Research Council Prion Unit met with members of the PWG on 14 February 2011 and discussed the test. It was agreed that the assay would require further development to make it suitable for large throughput blood donor screening. An important next step is to establish how specific the assay is, and blood samples from non-UK sources are being organised to facilitate this assessment.

There is no fixed timetable to bring the blood test into use as it is dependent on the outcomes of further test development and evaluation by the research team.

Background

This is one of five PQs asked by Lady Masham related to prion diseases and associated matters.

There are a number of possible uses of any variant Creutzfeldt-Jakob disease (vCJD) blood test:

a. as a diagnostic tool for testing those with clinical neurological symptoms where vCJD may be one of several possible diagnosis
b. testing those who have no symptoms but who have been notified that they are at "an increased risk" of vCJD. These include:
    i. those who have a definite history of exposure to blood derived from a specific donor known to have later developed clinical vCJD;
    ii. those with an uncertain history of exposure who have been notified that they are "at increased risk" of vCJD (includes about 100 blood donors to vCJD cases and 30 other recipients of blood donors to vCJD cases);
    iii. those with an history of potential exposure via surgical instruments;
    iv. those with bleeding disorders with a history of potential exposure by receipt of UK sourced plasma products (about 4,000 people); and
    v. those with a history of potential exposure via human derived Growth Hormone and notified that they are "at increased risk" of CJD (about 1,500 people)
c. testing of blood from asymptomatic individuals such as blood donations, or as part of a study of vCJD prevalence.

Very initial results published MRC Prion Unit show that although the test has potential as a blood diagnostic test it was only able to identify correctly 15 of 21 blood samples from individuals in the clinical stages of vCJD (a test sensitivity of about 70%). Further work is therefore needed on its suitability for wider use as a diagnostic or screening test, and this is underway by Professor Collinge's team, including testing of a much larger sample of presumed CJD negative blood from the US.

The use of such a test needs very careful evaluation. This is because blood tests depends on detecting abnormal prion protein (PrP^{Sc}) in blood samples, and there is no guarantee of how well absence or presence of PrP^{Sc} correlates

with vCJD infection or infectivity. For any test we take into account both the sensitivity (the higher the sensitivity the greater the reliability of a test identifying a truly positive sample) and specificity (the higher the specificity the less chance of false positive results). No test for PrP^{Sc} is likely to be either 100% sensitive or specific, and no test result will be able with certainty to clarify the status of an asymptomatic individual.

It is difficult to give a firm timetable as much will depend on the speed of further technical development and the availability of further results which will require thorough expert evaluation.

It should be noted that there are other prototype CJD blood tests in development by commercial and academic bodies.