Government response to the 
House of Commons 
Science and Technology 
Committee 
Report of Session 2014-15: 
After the storm? 
UK blood safety and the risk of 
variant Creutzfeldt-Jakob Disease
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Presented to Parliament
by the Secretary of State for Health
by Command of Her Majesty

October 2014
Cm 8940

INTRODUCTION

On 24 July 2014, the House of Commons Science and Technology Committee (the Committee) published the report: After the storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease. The Government strongly believes that the written and oral evidence presented to the Committee during their Inquiry are of great value in strengthening Parliamentary and public understanding of science, in particular that related to transfusion, transplantation and to prion diseases, and Government's actions in relation to those issues.

The Government is committed to continuing to work with the UK blood and transplant services, scientific advisory committees and public and commercially funded researchers in developing policy affecting these areas of science.

Departmental response

We welcome this report and have carefully considered the Committee’s recommendations and the issues they raise. We fully accept the scientific uncertainties highlighted by the Committee about many aspects of prion diseases such as variant Creutzfeldt-Jakob disease (vCJD), and the resultant potential risks to public health that the Government continues to assess and manage.

Whilst it remains reassuring that the number of UK cases of vCJD peaked in 2000 and that there have been no recognised secondary transmissions of vCJD after 1999, we note the concern expressed by the Committee that the Government is taking a less precautionary approach to risks than formerly, and we can assure the Committee that this is not the case. There has been no relaxation of the range of risk reduction measures introduced by the health departments and their agencies since the late 1990s, when concern was at its height. We continue to fund CJD-related research and surveillance, for example to clarify the true level of asymptomatic infection in the UK population: indeed, the Department of Health’s only ring-fenced research budget is dedicated to prion diseases. Previous and current risk assessments have been based on precautionary assumptions, and these have been endorsed by independent experts.

The Committee’s concern appears to have been sparked by recent decisions not to recommend the adoption of additional potential risk reduction technologies for prion filtration, pathogen inactivation of platelets and decontamination of surgical instruments, following assessment by independent expert bodies. The Government firmly considers, however, that if new risk reduction technologies are properly to assure safety, they must be effective,
practicable to implement, and proportionate in cost. Innovative technologies are essential for the health services, and the Committee has highlighted the need to work with developers and support the process where possible. The UK Blood Services have a long history of collaborating with developers on clinical trials of such technologies and other work to progress development and potential adoption, and will continue to do so: equally, the Advisory Committee on the Safety of Blood, Tissues and Organs will seek to maintain good communication with developers and manufacturers when assessing their products, though the need to obtain evidence may sometimes make the process slower than all concerned would wish.

In order to clarify the level of risk, both in public health terms and for individuals, we agree it would be extremely helpful to have a reliable test for vCJD. The Government has watched with interest the work of a number of laboratory teams, and has provided funding for some. There would of course be considerable practical and ethical issues with the use of a test which is not fully reliable, and a second, confirmatory test for positive results becomes all the more important. We do not yet have tests which are sufficiently advanced to screen blood donations, as the Committee noted, or to test with any confidence individuals who have been notified they are at increased risk of developing vCJD. However we will explore the possibility of using the prototype test developed by the Medical Research Council Prion Unit to carry out a blood prevalence study, as the Committee recommended: we will take expert advice from the Transmissible Spongiform Encephalopathy Sub Group of the Advisory Committee on Dangerous Pathogens on a number of issues that will need to be resolved. There are competing research priorities for our limited funding, however, including studies related to susceptibility to prion infections (one of the key inputs to our risk assessments, about which unlike prevalence we have little current information) and, as recommended by the Committee, to exploring the possibility that some vCJD may be undiagnosed, for example in elderly people with dementia.

The Government will continue to work with its scientific expert advisory committees, the UK Blood Services, Public Health England and others to assess and manage the risk of vCJD, and to maintain the excellent safety record of the blood supply. There are, as the Committee has pointed out, many other risks to be addressed, and the Government will continue to use the output of its excellent surveillance and horizon scanning systems for early warning of issues on which action might be required.

This memorandum provides the Government’s response to the recommendations directed to the Department of Health. In preparing it, we have considered the evidence presented to the Committee, both oral and written; and have taken the views of many clinicians, scientists and policy makers who deal with the risks of CJD (including vCJD) on a daily basis.

Jane Ellison
Parliamentary Under Secretary of State for Public Health
RISKS TO THE UK BLOOD SUPPLY

1. Blood transfusions save lives and we should be proud, as a nation, of our long tradition of altruistic donation. In recent years, the UK blood supply has proved to be extremely safe and, in the vast majority of cases, the benefits of receiving a transfusion will far outweigh the risk of acquiring a transfusion-transmitted infection. However, we urge against complacency and stress the need for UK Blood Services to remain vigilant to the threat posed by blood-borne pathogens. (Paragraph 9)

We agree, and can assure the Committee that the UK Health Departments and their Blood Services take the matter of any threat to the safety of the UK blood supply very seriously. As shown by the evidence presented by Serious Hazards of Transfusion (SHOT), transfusion transmitted infections are very rare in the UK, but the Government is not complacent about the potential risks.

The UK Blood Services monitor current and emerging threats through the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) Standing Advisory Committee for Transfusion Transmitted Infections, which includes inputs from Public Health England (PHE) as well as international surveillance. The remit of this committee includes horizon scanning and suggestions for further research for agents where a risk to the blood supply might be material, for example the recent study on hepatitis E. This process already includes provision for alerting the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and the health departments to potentially significant risks, and these bodies take action in response: for example, in May 2014 SaBTO set up a hepatitis E working group which will report in early 2015.

NHS Blood and Transplant (NHSBT)’s internal auditors will review its processes during 2014-5, and JPAC will provide an annual summary to SaBTO of all infectious agents under review.

In addition, UK Blood Services have in place a thorough system of haemovigilance, which provides a feedback loop that results in the continual improvement of transfusion safety. Incidents from Blood Services and hospitals are reported and analysed, and used to inform recommendations to improve the safety of transfusion practice in hospitals, and also, where relevant, to improve the safety of products supplied by the Blood Services.

2. The evidence that we have heard suggests that we cannot be confident that prions are not present in the blood supply. There remains considerable uncertainty about the potential implications of such contamination. We consider it imperative that a precautionary approach to this risk be maintained until further evidence becomes available. (Paragraph 17)

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Despite there being no evidence of any vCJD cases having arisen through blood borne transmissions since 1999, none ever being recorded from surgical transmissions, and the number of new clinical vCJD cases being extremely small (with only one new UK case since 2010), the Government accepts that uncertainties remain. In particular, it is possible that ‘silent’ transmission of vCJD infection could occur, without so far being apparent from the numbers of clinical cases seen.

This potential risk is fully and precautionarily reflected in successive risk assessments that have been produced by Department of Health analysts, endorsed by independent experts through the Advisory Committee on Dangerous Pathogens (ACDP) Transmissible Spongiform Encephalopathy (TSE) Sub Group and its predecessors, and put into the public domain. These assessments rightly leave open a wide range of scenarios, but clearly demonstrate that potential secondary transmission could eventually lead to a larger number of clinical vCJD cases than has been seen so far. Modelling work published by independent academic researchers leads to similar conclusions.

Accordingly, the Government has not reduced any of the significant steps taken since the late 1990s to reduce the potential for secondary transmission, despite the ongoing cost of these measures and the rarity of new cases. Research funding also continues to support evidential development. This represents the Government’s ongoing commitment to appropriate application of the precautionary principle.

3. We echo concerns that population-level risk assessment could lead to inaccurate and potentially discriminatory judgements being made about the risk posed by individuals, particularly men who have sex with men. We recommend that the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) reconsider the feasibility of a move to more individualised risk assessment as part of its 2015 work programme, following completion of the current UK blood donor survey. (Paragraph 22)

In 2011, SaBTO published an evidence-based review of the blood donor selection criteria relating to men who have sex with men. This led to the change from permanent exclusion of men who have had sex with men from blood donation to temporary deferral for 12 months from the last such sexual contact. As part of this review, SaBTO considered the possibility of implementing deferral based on individual sexual behaviour, but rejected such a possibility on the following grounds:

- there was insufficient evidence available to be able to determine the impact on blood safety of such a system. Research also indicated that not everyone could objectively assess their own level of risk
- the collection model employed by UK Blood Services does not support conducting individual behavioural risk assessments prior to blood donation
- studies suggest that the introduction of extensive donor health check questions regarding sexual history would lead to a loss of existing donors.

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2 Donor Selection Criteria Review
In order to be successful, a system of individualised risk assessments must lead to the selective deferral of individuals who are carrying transfusion transmitted viruses, while producing low rates of deferral of donors who are not carrying such viruses. Further, there would have to be a strategy for rolling the policy out to the frontline, and the system must be cost effective.

The Government has currently seen no evidence that would lead to a change in SaBTO’s advice. Given SaBTO’s current work plan, which includes:

- hepatitis E in the blood donor population
- Donor/Organ Risk Assessment – in support of organ transplantation
- a review of the Guidance on the microbiological safety of human organs, tissues and cells used in transplantation
- continued review of the potential use of blood donations by those born after 1 January 1996, and
- if resources allow, a review of the current blood donor deferral criteria related to those who have (had sex with a partner who has) been sexually active in areas where AIDS/HIV is common (especially sub-Saharan Africa),

the Government does not intend to ask SaBTO to consider the use of individualised risk assessments for blood donation again. If significant new evidence emerges SaBTO would of course evaluate.

UK Blood Services acknowledge the value of this approach and continue to support manufacturers in the assessment of pathogen inactivation technologies which have broad application against a range of pathogens. A list of such studies is appended:

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<th>STUDY</th>
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<tr>
<td>Platelets</td>
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<tr>
<td>Pre-validation work on Intercept platelets including establishing methods to measure the amount of red cells in platelets – a requirement for units to be treated. Output published Vox Sang. 2004; 87:264-71.</td>
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<tr>
<td>Operational assessment of the impact of using the Intercept system for pooled platelets (NHSBT) – completed 2003.</td>
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<tr>
<td>Laboratory evaluation of the quality of platelets treated using the Mirasol system (NHSBT) and stored in additive solution. Performed in collaboration with the manufacturer. Data was used in conjunction with other studies to extend the CE mark for the process which previously required platelets to be stored in plasma. Output published: Transfusion 2012; 52:983-94.</td>
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<tr>
<td>Laboratory studies and assessment of recovery and survival in healthy subjects of platelets treated using the Theraflex UVC system (NHSBT). Performed in collaboration with the manufacturer. Data was used to CE mark the process and to enable the manufacturer to proceed to phase II/III clinical studies in patients.</td>
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4. Pathogens are constantly emerging and evolving; novel pathogens will therefore always pose a threat to the blood supply. In the past, it has often taken multiple cases of transfusion-transmitted infection before these threats have been recognised and mitigated. This will remain the case as long as risk mitigation measures remain pathogen-specific. We urge the Government to take steps to support the development of broader spectrum technologies with the potential to mitigate the risk of both known and unknown pathogens. (Paragraph 26)

Co-investigators for randomised control trial assessing the clinical efficacy of Intercept platelets stored for 6-7 days (Scottish National Blood Transfusion Service (SNBTS)). Outcome published: British Journal of Haematology 2011; 153: 393-401.


Evaluation of the capability of pathogen inactivation systems to kill clinically relevant strains of bacteria – ongoing.

Plasma


Methylene blue treated plasma available to hospitals in 2002 from UK plasma, and in 2004 from imported plasma.


Red cells

Laboratory study of Intercept red cells (NHSBT) – 2013.

Manufacture and provision of a trial component to support a phase III clinical study of Intercept-treated red cells in transfusion-dependent recipients - work ongoing, trial expected to commence 2015.

In addition, following a December 2013 SaBTO recommendation, pathogen inactivation systems for platelets are being assessed by NHSBT against a broader range of bacterial species and strains.

There are many existing measures in place to reduce risk, including leucodepletion of all donations, the Donor Health Check questionnaire to identify risk factors before donors give blood and the screening of blood donations, in addition to the surveillance and horizon scanning referred to in section 1 above. Also, the data analysed and published annually by SHOT highlight any transmissions of infection. Through the Blood Services haemovigilance system, measures are reviewed and if appropriate revised on the basis of evidence and cost effectiveness.

SURGICAL TRANSMISSION OF PRIONS

5. The Government has acknowledged that contaminated surgical instruments are a potential source of prion transmission and states that it has taken a precautionary approach in its response to this risk. However, this response appears to rest heavily on guidance which, based on the available evidence, may not have been fully implemented. We
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recommend that the Government work with the National Institute of Health and Care Excellence (NICE) and the Advisory Committee on Dangerous Pathogens to better understand the extent to which the precautions recommended by these bodies have been implemented across the NHS. We ask the Government to provide us with an update on this work well before the dissolution of Parliament, together with an indication of the steps it will take if preliminary findings suggest that implementation has been incomplete. (Paragraph 29)

The Government accepts the intent of the recommendation, working with the ACDP - and taking account of NICE’s views - to ensure guidance is fit for purpose3. It will work with the Care Quality Commission (CQC) to seek their support to ensure healthcare providers are implementing best practice guidance.

Regarding the guidance itself, the ACDP has established a short-life working group to consider the outcomes of Department of Health funded research related to decontamination and protein identification, and any other new evidence in this field, with a view to updating and revising current practical guidance on decontamination and the use of surgical instruments to ensure it is fit for purpose and accessible to those in the field. The group is expected to report in 2015.

Regarding implementation, a wide ranging set of changes designed to improve the regulation of health and social care providers and provide assurance that services users receive safe, quality care and treatment is well underway. These arise from several inquiries, reviews and consultations; for example, The Mid Staffordshire NHS Foundation Trust Public Enquiry (the Francis Inquiry) and the Berwick Review into Patient Safety.

Consequently, the CQC has strengthened its inspection regime through, for example, the appointment of Chief Inspectors, and from April 2015 it will regulate providers against a new set of fundamental standards, being introduced by the Government (Health and Social Care Act 2008 [Regulated Activities] regulations 2014). These fundamental standards will apply to all registered providers of health and social care, and set out the standards below which care must not fall. Where providers are not meeting them CQC will take appropriate enforcement action.

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- Choice Framework for local Policy and Procedures (CFPP) 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care (published in 2012 it is a revision of Health Technical Memorandum (HTM) 01-01, published in 2007)
- HTM 01-05: Decontamination in primary care dental practices (first published in 2009 with a revised edition published in 2013)
- CFPP 01-06: Decontamination of flexible endoscopes (published in 2012).

HTMs are specifically referenced in the CQC’s ‘schedule of applicable publications’ as a means of compliance with Outcome 10 of their Essential standards of quality and safety, pertaining to the safety and suitability of premises. CQC continuously monitors compliance with essential standards through a system of assessors and inspectors.
The fundamental standards will be supported with guidance provided by CQC. The fundamental standards and associated guidance will be in place from April 2015.

Accordingly, the Department will discuss with the CQC the need for the implementation of decontamination guidance to be addressed in its regulatory activity, and provide the Committee with an update on this, and ACDP’s, work.

NHS National Services Scotland (Public Health and Information) will collaborate with PHE on any work to take forward this recommendation. NHS Scotland is actively working to ensure compliance with the NICE IPG 196 guidance, including the procurement and testing of new surgical instruments, and implementing the necessary sterilisation processes to ensure that people born after 1997 are not exposed to the risk of vCJD transmission during surgery.

Case study 1: decontamination of surgical instruments

6. Given the NHS’s resistance to change and the well-documented challenges associated with initiating a UK clinical trial, the Minister’s assessment that “no barriers” were put in the way of DuPont’s prion inactivation product does not reflect the reality of the situation. Where technologies are developed in direct response to Government need—and on the back of Government funding— the Government must be prepared to take steps to help companies overcome barriers to adoption. We ask the Government to set out how, in future, it will ensure that the directed research that it funds is better supported through the technology readiness pathway. In particular, we ask the Government to set out how it will ensure that promising clinical technologies are promptly trialled in an NHS setting, so that potential adoption challenges can be quickly identified and resolved. (Paragraph 37)

NHS England supports and delivers the Innovation, Health & Wealth strategy – first published in December 2011 – which aims to accelerate the adoption of innovation. Innovation Health & Wealth is a 10-year strategy, co-produced with industry, which is tackling the key barriers to innovation, in a collaborative manner across the NHS. Key to this, NHS England provides Innovation Exchange, a web portal for the NHS, clinicians, managers and innovators, to collaborate on getting innovations into use; and Innovation Connect, a service that provides a fast-track for emerging healthcare innovations to become widely used. This is done by signposting innovators to new forms of evaluation, research and funding for their innovations. NHS England has also developed an inclusive and collaborative relationship with industry, investigating barriers to uptake of innovation in partnership with innovators, senior clinicians, and the local NHS.

In June 2012 the Scottish Government launched Health and Wealth in Scotland: A Statement Of Intent For Innovation In Health. This vision is being overseen by the Innovation Partnership Board between Government, NHS Scotland, industry and the research community. The Board has created Health Innovation Partnerships in medical technology and digital arenas which are managing new ways into NHS Scotland for industry partners. The work is evolving, with the
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recent initiation of the Health Innovation Procurement Portal.

In relation to DuPont’s prion inactivation product, the Government gave significant support to DuPont through the Rapid Review Panel (RRP) process, to help ensure that their product was suitable for use within the NHS. This included specialist support from Dr Beryl Oppenheim (consultant microbiologist, City Hospital Birmingham), who convened an expert group to work with and advise DuPont. More examples of the support given by the Government to the implementation of new technology are the extensive range of studies listed in section 4.

Decisions on whether to market products are a matter for individual commercial companies, and not for the Government.

7. We also question the value of a scientific review panel which has no mandate or power to ensure that the products that it recommends can be tested in, and eventually adopted by, the NHS. We see this as further evidence of the Government’s passive approach to technology uptake. We propose that the Rapid Review Panel (RRP) be given stronger powers to ensure that its recommendations open the door to in-use evaluation and stimulate NHS uptake. (Paragraph 38)

It is imperative that the RRP remains impartial and objective in its recommendations. Therefore it would not be appropriate for the RRP to be given stronger powers, because by influencing such uptake and procurement practices, the RRP would risk its position of impartiality and objectivity.

The purpose of the RRP’s recommendations is to demonstrate publicly to the NHS Supply Chain, and PHE, the robustness of scientific evidence supporting the product claims relating to the improvement of infection prevention and control measures and/or reduction in healthcare associated infections. Recommendations are formulated on the scientific evidence presented by the company. The RRP does not take into consideration the commercial challenges, including cost effectiveness of a product, in its recommendations. RRP guidance has recently been updated to provide clearer information regarding the ‘process and review criteria’ to applicants. The Panel has worked to increase transparency, making details of RRP guidance and its processes publicly available via the gov.uk website.

8. In our view, all Scientific Advisory Committees should adhere to both the 2010 ‘Principles of Scientific Advice to Government’ and the 2011 ‘Code of Practice for Scientific Advisory Committees’. We were disappointed to find that the Rapid Review Panel (RRP) failed to do so. We recommend that the Chief Medical Officer takes action to rectify current weaknesses. We request a progress report be sent to us well before the dissolution of Parliament. (Paragraph 40)

The RRP is not, and has never been, a Scientific Advisory Committee (SAC), primarily because it deals with voluntarily provided detailed confidential

4 https://www.gov.uk/government/groups/rapid-review-panel

(commercially sensitive) information as part of its work to review products for potential use within the NHS. It simply assesses potential products that companies bring forward, and as such is very different from a SAC. Due to the commercially sensitive nature of this information the RRP cannot publish details of a review, neither in the form of minutes of the meeting nor a full report, without presenting potential significant liability to the company (a SAC would be required to do this). The natural consequence is that the RRP cannot function as a SAC and so it has never been considered a SAC.

However, while the RRP is not a SAC, it endeavours to follow both the Code of Practice for Scientific Advisory Committees and the Principles of Scientific Advice to Government where possible, and aims to be as transparent as possible. The RRP considered this very recently (prior to publication of this report), and revised Terms of Reference are currently being approved by the PHE Antimicrobial Resistance and Stewardship and Healthcare Associated Infections (AMRS & HCAI) Programme Board, to which the RRP reports.

Case study 2: prion filtration

9. We do not wish to question the scientific decision-making of the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and we respect its decision not to recommend adoption of prion filtration at present. However, we feel that the time taken to reach this decision was excessive and that the process, particularly in its latter stages, entailed an unnecessary level of uncertainty for the commercial developer. We have some sympathy for SaBTO’s desire to wait until more evidence was available before making a decision; however, if industry is to continue to develop innovative blood safety products for the UK market, SaBTO must introduce greater speed and predictability into its evaluation process. We recommend that, in future, when assessing a new technology, SaBTO agree with stakeholders at the outset what the evaluation will consist of, together with key dates, milestones and decision points. This ‘evaluation roadmap’, and any subsequent amendments, should be made publicly available to ensure maximum transparency and accountability”.

(Paragraph 45)

Informed by advice commissioned from the Spongiform Encephalopathy Advisory Committee (SEAC), the UK Blood Services provided a road map of the decision-making process to prion filter manufacturers, indicating key milestones and decision points, and NHSBT produced a project timetable. While SaBTO and UK Blood Services endeavour to progress such studies without undue delay, and have tried hard to keep good communication links with relevant companies, the primary task of SaBTO is to ensure safety and efficacy in the areas of blood transfusion and tissue and organ transplantation. It is therefore imperative that SaBTO decisions are based upon relevant

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6 Principles of scientific advice to government https://www.gov.uk/government/publications/scientific-advice-to-government-principles

evidence which is as robust as it can be. Where possible SaBTO avoids making decisions based on partial, unverified or unanalysed data when scientific and clinical studies are ongoing.

Unfortunately, clinical studies and animal work are inherently lengthy and unpredictable. Where decisions are made to commission studies recommended by a scientific advisory committee, funding sources for those studies must first be identified, and the set-up time for any clinical trial can be up to 12 months. Furthermore, biological assessments of prions inevitably have a long read-out time. SaBTO’s decision framework is tailored appropriately to the issues of blood transfusion and tissue and organ transplantation and is publicly available, but it is not appropriate for SaBTO to make decisions to pre-set key dates if the evidence is lacking.

10. We also consider it important that the health technology appraisals conducted by SaBTO—and all other SACs—use the same methodology and meet the same high standards as those undertaken by the UK’s centre of excellence for this activity: NICE. We therefore recommend that the Government Office for Science work with NICE over the next 12 months to develop and publish a standard methodology for all SACs tasked with conducting health technology appraisal. Until this guidance is published, we recommend that a NICE representative review and, where necessary, provide input to all such appraisals undertaken by, and on behalf of, SACs. (Paragraph 46)

The Government Office for Science does not normally seek to set out the substance of what a SAC is asked to do, or how it does it, as long as both are within the Principles of Scientific Advice to Government. However, work is in progress to explore differences in appraisal methodology between NICE and other health-related bodies, including SaBTO. This work is being carried out through an Appraisal Alignment Working Group set up under the auspices of the Department of Health Chief Economist, and will report on the scope for greater consistency of methodology among the relevant bodies.

It should be noted, however, that the methodology used by NICE might not be easily adapted for use by SaBTO, as SaBTO must take a precautionary approach and be mindful of issues that could generate a response from the public that have an impact on blood supplies. Other SACs may have other unique constraints. With that in mind, it is not appropriate or proportionate for NICE representatives to review all appraisals undertaken by SACs.

11. Scientific Advisory Committees should be—and be seen to be— independent of the bodies to which they are providing advice. At present, the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) comprises members who are both contributing to, and acting on, the advice that it formulates. We consider that this could be damaging to its perceived independence and a source of potential conflicts of interest. We recommend that SaBTO’s terms of reference be amended to reflect the fact that it does, in effect, provide advice to UK Blood Services as well as the Government. We suggest that SaBTO’s current membership be reviewed and
We will review SaBTO’s terms of reference and ensure they are clarified appropriately. SaBTO provides advice on the safety of the blood supply and also tissue and organ transplantation, and its membership reflects this. The scientific advice provided by SaBTO is of a highly specialised nature, and its current membership provides the necessary range of senior input and experience in the implementation of safety measures in blood transfusion, in addition to the purely scientific and medical expertise, to ensure SaBTO’s ability to give sound, practical advice that is founded on scientific principles. All members act in accordance with the Code of Practice for Scientific Advisory Committees and the Principles of Scientific Advice to Government, and were appointed by an independent and open process.

While we do not believe there is any conflict of interest, we accept that the perception of independence is important. Therefore SaBTO is planning to amend its Code of Practice so that future working groups and sub groups will not be chaired by someone who holds a senior policy-making position in an organisation if the topic under consideration directly relates to that organisation’s interests or activities:

**Working groups / sub-groups**

16. Where SaBTO requires additional relevant expertise to consider an issue fully, appropriate experts may be co-opted to the Committee, to serve on a specialist working group or sub-group established on an ‘ad hoc’, time-limited basis to consider the issue. The Chair of such a working group or sub-group will usually be a SaBTO member.

17. To avoid any potential or perceived conflict of interest, a person who holds a position on the Board of their employing organisation, or a similarly senior policy-making position in that organisation, shall not act as the Chair of a working group if the topic under consideration directly relates to their employing organisation’s interests or activities. They may, however, serve as a member of that working group.

12. Several witnesses expressed concern about the way in which access to vCJD samples was controlled in the UK…. Dr Alex Raeber, Head of Research and Development at Prionics AG, agreed that, “as a foreign company”, Prionics was “not treated in the same way as other stakeholders” and had faced “big challenges” in obtaining access to samples. According to Dr Raeber, while the NIBSC had done “an excellent job” in setting up the test validation process, the number of samples made available through this process was “very limited”. Prionics’ test was evaluated on the basis of two samples from known vCJD patients and, on the basis of this evaluation, was deemed “not sufficiently fit for purpose”. The test was never used by UK Blood Services. (Paragraph 57)

13. Dr Raeber criticised this evaluation process, stating that it was “really not adequate” for the NIBSC to validate the efficacy of his company’s test on the basis of only two samples, particularly given that there was no guarantee that prions were present in
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these particular samples. Professor Sheila Bird, MRC Biostatistics Unit, agreed that the statistical significance of this evaluation was questionable and pointed out that “provision of fewer than five or six vCJD samples within a blind panel of 500” was an “inadequate—or very harsh” statistical assessment to which to submit a prototype test. In contrast, the test developed by the MRC Prion Unit (discussed below) has so far been validated on the basis of 21 samples from known vCJD cases, all sourced directly from its own collection of patient samples. In response to these criticisms, the NIBSC stated that its process was “open to all” and that, in fact, “most interactions” had been with non-UK developers rather than UK companies. It acknowledged that it was “not ideal that only two samples were made available” to Prionics, but stressed that this decision was made only after “substantial discussion in the Oversight Committee”. (Paragraph 58)

We note that in paragraphs 57 and 58, where the Committee discusses the evaluation of the Prionics assay, it states that the assay was evaluated and rejected on the basis of two samples from vCJD patients. We would like to clarify that this is only part of the truth. While failure to identify the two samples in a panel of negative sera was the final factor, the test’s success or otherwise in other stages of the assessment protocol (developed taking into account SEAC’s advice8) was also taken into account.

These included assessing the limits of detection of dilutions of infected brain and spleen, where the test only just met the defined acceptable levels. In examination of animal blood samples, which used clinically affected or uninfected sheep as a model for human blood samples from vCJD patients, the Prionics test failed to distinguish between blood from infected animals and blood from healthy controls (although it is possible that there were technical explanations for this). There was therefore reason to suspect that the test might fail to detect activity in samples from infected patients. In the final test using human samples there was not the slightest hint of positivity in the test results compared to the negative samples tested in the same blinded panel.

With respect to the statistical discussion on numbers of samples tested, the sensitivity of the Medical Research Council (MRC) Prion Unit’s test is approximately 70%, which has led to the assumption that only 70% of samples will be scored positive by any test. If this is indeed true, we agree that failing to detect either of two samples was not a fair test of the Prionics assay. However, in some animal models, infectivity is detectable in all (100%) blood samples at clinical stage, so the assumption that only 70% are positive could be an underestimate.

Case study 3: vCJD blood testing

14. We understand the need to carefully control access to rare vCJD samples and commend the National Institute of Biological Standards and Controls (NIBSC) for putting in place

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a standard protocol for test validation. However, we are disappointed that so few samples are currently held by the NIBSC and consider its process to be undermined by the fact that the two major centres of UK prion research—the National CJD Research and Surveillance Unit and the MRC Prion Unit—can each use and distribute samples independent of NIBSC evaluation. All test developers should be given equal opportunity to gain access to the available samples and these should be distributed on the basis of merit alone. We recommend that access to all vCJD patient samples—including those currently held elsewhere in the UK—be managed through the NIBSC, according to a consistent set of test validation protocols. (Paragraph 59)

We agree that before use in a research or service setting, all requests for access to valuable samples should be subject to independent evaluation through the National Institute for Biological Standards and Control’s (NIBSC’s) protocols. NIBSC currently operates a consistent test validation protocol, which to help test developers has been applied in a flexible manner to accommodate the specific requirements of each test submitted for validation.

There are restrictions on the use of many samples, either due to the consent provided by the donors or to their chemical treatment following collection. Tests are designed to work within a narrow range, so that, for example, they may require a blood sample to be of a particular structure (e.g., whole blood or plasma) or to have been stored in a particular anticoagulant. Thus not all samples will be suitable for the evaluation of any given prototype test.

Access to patient samples held by the MRC Prion Unit for blood test development is already managed through NIBSC, under the governance of the CJD Resource Centre Oversight Committee, which was set up precisely to oversee access by third parties to irreplaceable and limited samples—notably to manage multiple requests which could rapidly deplete the samples without necessarily providing value. The MRC Prion Unit is committed to continue to provide aliquots of suitable samples to NIBSC under the existing governance arrangements.

The National CJD Research and Surveillance Unit (NCJDRSU) holds a large number of tissue samples from a wide range of CJD (including vCJD) and non-CJD patients, which were collected at autopsy with consent from the relatives for use in research. These are held as part of the MRC Edinburgh Brain Bank. Ethics approval is in place to provide these tissue samples to researchers through an open access policy that involves scrutiny of requests by an Access Committee and a Steering Committee with an independent Chair, in accordance with MRC guidance. Numerous tissue samples have been provided to researchers across the world, and samples of brain and spleen have been provided to NIBSC for use as national reference standards and as WHO reference standards for vCJD and sporadic CJD (sCJD). In this manner, further tissue samples can also be made available to NIBSC if needed.

NCJDRSU also holds a limited number of blood samples: it has supplied such samples whenever requested by NIBSC, and will continue to do so where possible so that any putative blood test for vCJD can be properly independently evaluated through the NIBSC system.
15. We were also concerned by the apparent statistical weakness of past NIBSC evaluations. We recommend that the CJD Resource Centre Oversight Committee add to its membership an individual with expertise in biostatistics, who can provide it with expert advice on this matter during future deliberations. (Paragraph 60)

As listed in the written evidence from NIBSC, Dr Nick Andrews, a biostatistician, is a member of the CJD Resource Centre Oversight Committee, where he has had significant input into the protocol including definitions of acceptable levels of sensitivity and specificity and the number of samples required to demonstrate them. He has also been key to the assessment of results submitted by various developers.

16. Based on the testimony that we have heard, we consider that a vCJD blood prevalence study utilising a version of the prototype test developed by the MRC Prion Unit would be of considerable value, both for test development and research purposes. We recognise that significant public funds have already been directed towards the development of this test; we view this as even more reason to ensure that a return on this investment is realised. To cut off support now would be a false economy. We recommend that the Government ensures that a large-scale vCJD blood prevalence study be initiated in the UK within the next 12 months. (Paragraph 66)

While we appreciate that a blood prevalence study using the MRC Prion Unit’s test (or another test) could yield some useful information, there are scientific and technical issues that must be resolved before such a study could be initiated. Beginning such a study within twelve months would be ambitious, given the lead time necessary to resolve these issues.

Published information on the MRC Prion Unit test suggests it is suitable for an anonymous survey, which would provide data on abnormal prion reactivity in blood. The results could lead to a re-evaluation of current risk assessments. It is not clear, however, whether the MRC Prion Unit blood test can detect asymptomatic vCJD-infected individuals (published results relate either to use on individuals with signs and symptoms of vCJD, or in a population unlikely to contain individuals with asymptomatic vCJD). Furthermore, 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.

The Government’s current risk assessments take into account the 1:2000 figure of UK prevalence of abnormal prion infection derived from an appendix study completed in 2012. Results from a blood prevalence study that either confirmed or were less than this estimate would be unlikely to change


our blood risk assessment (RA), or the current range of precautionary blood-related risk reduction measures recently reviewed by SaBTO. If the study showed prevalence greater than 1:2000, we would need to reconsider the RA, and such a revision would need to be informed also by the results of the current Appendix III study and any new evidence on the other key inputs to the RA: infectivity and susceptibility. The Appendix III study is looking for the possible presence of abnormal prion protein in what are assumed to be negative populations: 15,000 UK appendix samples removed before 1980, i.e., before BSE was thought to be circulating, and 15,000 UK appendix samples removed from individuals born after 1996, i.e., after meat controls had been introduced. We are committed to revisiting the RA on completion of the Appendix III study in 2015.

We will seek the views of the TSE Sub Group of the ACDP on the scientific and technical issues mentioned above, as well as on other issues such as the interpretation of results from the Appendix III study, the potential value of a blood prevalence study and how the findings of such a study could be used. This will inform our views on whether a blood prevalence study would be a scientifically justified use of the Department’s limited budget for research, and its importance in comparison to other research priorities.

The Government are also aware of international work developing diagnostic and screening tests for the detection of the vCJD prion in blood and urine.\(^\text{12, 13}\)

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**CJD RISK MANAGEMENT**

17. People who are notified that they may have been exposed to CJD will inevitably be alarmed by this information and will likely have questions that cannot be answered in the leaflets currently provided by Public Health England. We consider it totally inappropriate for this news to be communicated solely in writing. We recommend that the Government put robust measures in place to ensure that all individuals assigned this designation receive the news verbally, either from a healthcare provider or from a CJD specialist with experience in patient communication. (Paragraph 70)

We welcome the opportunity of this response to redress the Committee’s understanding of the approach to notifying individuals that they may have been exposed to CJD. Whenever possible, patients are given the news verbally.

The current public health guidance\(^\text{14}\) sets out the recommended approach to managing CJD incidents developed over many years by the CJD Incidents Panel (2000 to 2013). This approach was developed with a wide range of contributors and included public consultation. It reflects the learning from previous notifications about patient preference. It specifies that:

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\(^{14}\) Public health action following a report of a new case of CJD or a person at increased risk of CJD http://webarchive.nationalarchives.gov.uk/20140714084352/http://www.hpa.org.uk/web/HPAweb &HPAwebStandard/HPAweb_C/1225960588712
“the GP is usually best placed to inform patients that they are at increased risk of CJD. In some cases a specialist doctor who provides ongoing care may inform a patient. In these cases, the specialist should also inform the GP of the patient’s increased risk status and that public health actions are required. For most CJD surgical incidents the small number of patients involved allows a personalised and tailored approach to this communication.

When discussing CJD risks with a patient, it is important to communicate two messages. First that the risk of the patient being infected with CJD is uncertain, but is likely to be low. Second, that it is important that the patient should follow advice to reduce any risk of the infection spreading to other patients. Patients may find the news that they are at increased risk of CJD both distressing and difficult to understand. They may want an absolute guarantee that they will not develop CJD. This is clearly not possible.

Many patients are likely to need more than one opportunity to discuss what this means for them in order to come to terms with what they have been told. It may be helpful to consult a trained counsellor for advice on managing this process. The healthcare professional informing a patient of their increased CJD risk status may wish to arrange follow up visits to give the patient opportunities to discuss these complex issues with appropriate staff.

Two patient leaflets – ‘Who has an increased risk of CJD?’ and ‘Information for people who have an increased risk of CJD’ should be given to patients during these consultations. These are available on the CJD section of the PHE website.”

However, large scale notification exercises like the one for plasma product recipients in 2004, which involved contacting around 6,000 individuals, necessarily require a staged approach, with initial contact being made by letter. This is needed both to respond to demands that those affected should be informed as soon as possible and to ensure that everyone affected is informed at the same time, and before finding out indirectly through the media. During the planning process there is widespread involvement of patient groups, clinical specialists and general practitioners to ensure that they are prepared in advance to support their patients. An NHS or other dedicated helpline is usually set up to handle CJD related calls. The letters specifically and directly ask whether affected individuals wish to have further information in writing or in person, and if they wish to arrange an individual consultation with their care team, who will contact them to organise it.

18. It is clear that the prototype vCJD blood test developed by the MRC Prion Unit cannot yet be relied upon for universal screening purposes. However, it could be of significant value to those people who have been notified that they are at increased risk of carrying the disease. Until the implications of a negative test result can be more firmly established, current precautions must remain in place for those considered to be ‘at risk’ of vCJD. However, the results of an imperfect test may provide comfort to some. We
therefore recommend that ‘at risk’ individuals be given the opportunity to participate in the blood prevalence study recommended in paragraph 66.  
(Paragraph 73)

Great caution should be exercised in using an imperfect test, especially where this is being used to provide reassurance. Until the test parameters (sensitivity, specificity) are well quantified, and until the prevalence of the condition being tested, as well as the proportion of asymptomatic test positives who go on to develop the disease, are known, it is impossible to properly counsel a patient who has been deemed ‘at risk’ about the meaning for that person of their positive or negative test result. Furthermore, a negative test result would be unlikely to result in the lifting of an ‘at risk’ notification for the individual concerned.

However, given the above, we recognise that fully informed participation of ‘at risk’ individuals in a clinical trial of the test application in this circumstance could be valuable. This would be a research exercise to aid test development, and as such would be subject to appropriate ethical review and wider evaluation against other priorities for research funding (see section 16).

CJD SURVEILLANCE

19. The Government claims to be undertaking close surveillance of those it considers to be ‘at risk’ of CJD. Yet it cannot provide reliable data either on the total number of people designated ‘at risk’ or the number who have been notified of this fact. This is unacceptable. We recommend that the Government conduct an immediate audit of the entire ‘at risk’ cohort to establish whether any notifications remain outstanding and to ensure that appropriate support and follow-up is in place for all those affected. We also propose that the Government commission an independent review of the transfusion data pathway to ensure that, in the event of any future blood contamination incident, it can promptly trace, notify and provide support to affected recipients.  
(Paragraph 77)

We welcome further opportunity to confirm that all processes for these notifications are already in place.

The number of identifiable people designated as ‘at risk’ of all forms of CJD is known. They are recorded and appropriately followed up by the organisations that have the systems in place, information governance approval and expert oversight to do so. These include PHE, the MRC’s National Prion Monitoring Cohort, the UK Haemophilia Doctors’ Organisation (UKHCDO – for bleeding disorder patients) and the Institute of Child Health/University College London (for human growth hormone patients). Because of this spread of responsibility, an update covering all patients is produced every six months by PHE, which collates the information and produces a summary table. This is published in the Health Protection Report, the latest on 8 August 2014.  

Better information about who among the group has been notified is required and PHE works with the other organisations to continually improve this. It is important to note that attempts have been made to

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notify all the identified individuals, but not all may have been contactable.

It is a legal requirement under Blood Safety and Quality Regulations for Blood Services and hospitals to be able to trace the ultimate fate of each blood component to a named user and to keep such records for 30 years in case lookbacks are required. A system for identifying all recipients of blood donations from individuals who later develop vCJD, the Transfusion Medicine Epidemiology Review, has been in place since 1997, funded by the Department of Health and the National Blood Services. This collaborative study between the NCJDRSU, NHSBT and the National Blood Services allows the prompt identification of any vCJD case who has been a blood donor, and all recipients of these donations are identified and informed of their risk via PHE and Health Protection Scotland.

In the reverse process, any case of vCJD who has received a blood transfusion is investigated and the donors identified. This study has led to a number of publications that describe in detail the methodology and outcome of this research\(^\text{16, 17, 18, 19, 20, 21, 22}\), which has been of critical importance for public health as it allows a prompt and detailed investigation of all transfusion incidents linked to vCJD.

**20.** We were disappointed by the evident lack of support provided to those designated ‘at risk’ of CJD. We consider it inappropriate for the Government to have effectively delegated responsibility for the care and surveillance of a large proportion of these individuals to external bodies such as the UK Haemophilia Centre Doctors’ Organisation—a charitable organisation with no formal relationship with the Executive. We recommend that the Government, through its public health agencies, assume direct responsibility for the surveillance and support of all those considered to be ‘at risk’ of CJD, with input from other specialist organisations as required. (Paragraph 78)

As noted in section 17 above, support for those designated ‘at risk’ of CJD is best provided on a face-to-face basis by

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\(^{22}\) Davidson LRR, Llewelyn CA, Mackenzie JM, Hewitt, PE, Will RG. Variant CJD and blood transfusion: are there additional cases? Vox Sanguinis 2014 DOI: 10.1111/Vox 12161.
healthcare professionals who have an established relationship with these individuals, and the individual’s GP is often best placed both to notify them of their status in the first place, and to be responsible for the needs of the patient. However, in some cases it is more appropriate for a specialist clinician to be responsible for the needs of the patient: for example, haematologists who have treated patients with haemophilia over a period of years. These professionals in turn will need support on how to answer questions on this complex disorder, and in the communication of increased risk and its potential consequences.

The UKHCDO is not a charitable organisation but the professional body for clinicians who manage patients with bleeding disorders. The Organisation was established in 1968 to improve haemophilia care, research into bleeding disorders, their treatment, epidemiology and complications, and to facilitate healthcare planning. The UKHCDO has an established reporting relationship with the 24 comprehensive care centres and 49 haemophilia treatment centres covering the whole of the UK. The Organisation’s national haemophilia database was set up in 1978 to collect information for planning, audit and research. It has been modernised over time and now operates through individually networked haemophilia centre management systems for real-time data downloading. The ongoing established relationship with the clinicians who manage and care for haemophilia patients clearly identifies the UKHCDO as the most appropriate custodians of the data and providers of follow-up for haemophilia patients at risk of CJD.

As noted earlier, PHE works closely with the UKHCDO and others to compile a regular summary of individuals at risk of CJD, followed up through the different surveillance strands.

The vCJD Clinical Governance Advisory Group, who considered follow-up care and support for individuals identified as ‘at risk’ from developing vCJD, said in their report23:

“Centres other than those concerned primarily with CJD will have, on occasion, an important role to play. For example, the United Kingdom Haemophilia Centre Doctors’ Organisation (UKHCDO) has been the route of advice and support about CJD for haemophiliacs. There are good reasons why this should continue and we recommend that for these patients close contact with the GP and the UKHCDO should also be maintained.”

21. In our view, the decision to participate in research should always rest with the individual or, in exceptional circumstances, their loved ones. Nevertheless, samples contributed by those potentially exposed to CJD are of immense scientific value and we are disappointed that more has not been done to obtain consent from those willing to participate in research. We recommend that the Government consider ways to increase the number of ‘at risk’ individuals giving consent for research participation, particularly post-mortem. We ask that the

Government summarise its plans for achieving this in its response to this Report. (Paragraph 81)

We agree with the Committee’s view that the decision to participate in research should rest with the individual or, in exceptional circumstances, their loved ones.

Greater opportunity for the examination of tissues post mortem from all ‘at risk’ individuals would provide valuable information about the presence (or lack) of subclinical vCJD infection. We do not propose, nor think it would be justified, to contact ‘at risk’ people solely to ask for their consent for post mortem. The majority of these individuals are relatively young and relatively well. Government propose to provide better patient information about research, including post mortem, which will be placed on PHE’s website and disseminated through appropriate channels. Patient groups will be involved in developing these materials, and their opinions sought on how best to inform people, and seek views about research participation.

With respect to the collection of tissue and blood from living patients, this was detailed in the PHE-sponsored “Enhanced surveillance and research study” which began in 2008. The study includes collection of tissues and blood for research, primarily from the recipients of blood from a donor who later developed vCJD. The relatively small number approached for consent to participate included all those who remained alive from the original cohort of 67. An eligible subset of the donor ‘at risk’ group declined to participate.

Additionally the UKHCDO have an ongoing study which encourages notified “at increased risk” bleeding disorder patients to consent to their tissues, taken at biopsy or autopsy, being tested for the presence of abnormal prion protein. It was as part of this study that the NCJDRSU, which performs the testing, was able to identify a single specimen taken at autopsy from the spleen of an elderly male patient with no history of neurological disease, which gave a strong positive result on repeated testing. As of 30th June 2014, 17 post mortems had been performed as part of this study, and tissue samples had been collected from an additional 11 patients. At present there are no plans to expand the collection of tissues and blood samples to further groups of ‘at risk’ individuals.

22. Evidence of potential under-reporting is also provided by the so-called “calibration problem”—that is, the discrepancy between the number of transfusion-transmitted cases of vCJD predicted by the available scientific evidence and the actual number of cases recorded in official statistics. In 2011, an analysis conducted by the Department of Health presented a model which attempted to solve the calibration problem. Under this model, assumptions about the likely infectivity of blood and susceptibility to infection of transfusion recipients were varied in order to match the actual number of transfusion transmitted cases reported by the surveillance unit. The amended assumptions generated by this model were used in the cost-effectiveness

analysis performed on ProMetic's prion filtration device. However, according to ProMetic, “making the model fit the observed number of cases could result in a serious underestimate of the possible future extent” of transfusion-transmitted vCJD. ProMetic added that if the assumed prevalence of prions across the UK population were adjusted to 1 in 2000, as per the recent appendix study findings, then “the number of cases predicted by the model would significantly exceed the actual number of cases reported to date”. According to ProMetic, “this raises the question of whether a significant number of vCJD cases are currently being missed”. (Paragraph 86)

In paragraph 86, the Committee discusses the so-called ‘calibration problem’. We would like to provide some clarification about this issue. The aim of having a “calibrated” model is to take account of the totality of evidence, including experimental studies of infection transmission, surveys of subclinical infections, and reported numbers of cases attributable to blood borne transmission. As argued in the published Department of Health papers, it would be unreasonable to ignore any part of this evidence – including the use of scenarios under which an unfeasibly large number of blood borne clinical cases would already have appeared. Importantly, the risk assessment models do not simply fit outputs to observed case numbers as implied by ProMetic, but allow for possible under-reporting, potentially by over 300%. Given the scientific uncertainties involved, the models allow a wide range of scenarios as regards numbers of clinical cases due to future transmission. The fact that predicted future case numbers are far greater than the number seen to date demonstrates the precautionary nature of the inputs and assumptions used, all of which were either suggested by, or critically examined and endorsed by, the ACDP TSE Sub Group.

23. We are confident in the integrity of the National CJD Research and Surveillance Unit and have not seen any evidence to corroborate claims of deliberate underreporting or misclassification. However, we share our witnesses’ concerns that cases could be missed due to misdiagnosis, particularly in the elderly. We recommend that the Government lend its support to research intended to give greater clarity over the causes of atypical dementia in the elderly and, through this, the potential rate of undiagnosed CJD. (Paragraph 87)

The NCJDRSU has submitted an outline proposal to the Department of Health aimed at determining whether there is any unrecognised vCJD or atypical prion disease in the older population. The Department is supportive of the research in principle, subject to the availability of funding.

CONCLUSION

24. SaBTO’s decision not to recommend the adoption of prion filtration, taken alongside the other evidence that we have gathered during this inquiry, in our view signals a change from what was a genuinely precautionary approach to vCJD risk reduction in the late 1990s to a far more relaxed approach today. Much of the uncertainty surrounding prions, their potential modes of transmission and the possible rate of
undetected infection and disease remains: recent evidence that subclinical prevalence could be as high as one in 2,000 people would suggest that a precautionary approach is now more warranted than ever. (Paragraph 94)

The Government can assure the Committee that it continues to take a precautionary approach to blood safety and that it will continue to apply evidence based and cost effective measures to ensure that potential risks are reduced. There is not a relaxed approach as the Committee suggests and the Government commends the comprehensive and thorough assessments of risks undertaken by ACDP and SaBTO amongst others. The Government has not rejected any healthcare-related risk reduction measure recommended by these independent expert scientific committees.

25. Our fear is that the Government’s current attitude is driven less by the available scientific evidence than it is by optimism: a hope that the storm has now passed and that vCJD is no longer the threat to public health that it once was. In the current economic environment, this attitude is not surprising. However, it is not justified. For all we know, the storm may well be ongoing. We conclude this report by recommending that the Government take a more precautionary approach to both vCJD risk mitigation and blood safety more generally, in order to safeguard against future infections. We suggest that it begin by assessing the key risks, known and unknown, that the UK blood supply currently faces and might face in the future, so that it can identify and fill relevant knowledge gaps and support the development of appropriate risk reduction measures and technologies. The Government should initiate this work immediately and we ask that it provide us with an update on its progress well before the dissolution of Parliament. (Paragraph 95)

We fully recognise the paramount importance of a safe blood supply, and that is why the Government’s approach continues to be based on the best evidence and driven by independent scientific advice. We actively keep the evidence base and potential need for new measures under close review (an example being the current SaBTO hepatitis E working group). To support this work the Department continues to allocate its only ring-fenced research budget to that related to prion disease, and has not reduced any of the measures taken since the late 1990s to reduce the risk of transmission.

The Government is confident that the independent scientific advisory committee structures as currently established, alongside the work of bodies such as PHE and the UK Blood Services, provide an internationally outstanding system for advice and prevention of disease transmissions via blood, tissues and organs. The success of current risk reduction measures is evidenced by the information provided by SHOT.

Government has not reduced any of the significant steps taken since the late 1990s to reduce the potential for secondary vCJD transmissions, despite there being no evidence of any blood borne transmissions since 1999, no surgical transmissions of vCJD ever
being identified and the number of new UK vCJD cases being very, very small.

The Government will provide the Committee with an update on the current work in early 2015.