REPLIES RECEIVED IN RESPONSE TO PHASE II OF THE POLICY CHANGE NOW CAMPAIGN

Response on behalf of Rt Hon. Andrew Lansley:

Thank you for your recent emails to Andrew Lansley about xenotropic leukaemia virus-related virus (XMRV) and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME). I have been asked to reply on Mr Lansley's behalf.

The detection of XMRV infection in humans is a rapidly moving field in medicine. The stark differences in prevalence of apparent infection seen globally in what amount to similar studies do present issues that will need further investigation, but are unlikely to be solely the result of different methodologies. Officials are assured that detection of the XMRV genome based on amplification of the number of copies present (PCR) is widely regarded as the best and most sensitive method available for this purpose.

The methods used to seek evidence of XMRV infection in English blood donors, which employed PCR and included appropriate controls, are able to detect the XMRV genome with high sensitivity and specificity. No evidence of the XMRV genome was found in any donor in the study conducted by NHS Blood and Transplant (NHSBT) and the Health Protection Agency (HPA). The completed study of 540 donors is a prelude to further extensive studies, which NHSBT is funding. Further research to develop and apply a test for an antibody to XMRV is being considered currently by the HPA and NHSBT.

Whilst XMRV is under continuing review by the UK Blood Services Joint Professional Advisory Committee, the international published evidence does not currently support concerns about a risk to the safety of the blood supply. There is at present no accepted causal role for XMRV in human disease.

As the Department set out in its first response, the National Expert Panel for New and Emerging Infections has considered all available evidence about XMRV and reported that no public health action is required at this time. The Advisory Committee on the Safety of Blood, Tissues and Organs, on the basis of current evidence, does not recommend further measures at present. Both groups will continue to monitor the situation.

With regard to research into CFS/ME, the Department of Heath funds research for health policy development, clinical and applied health research in the NHS, and covers the NHS costs incurred in supporting research funded by other bodies such as the Research Councils. As far as current UK research into CFS/ME is concerned, the bulk of the publicly funded work is being undertaken with funding from the Medical Research Council (MRC).

Neither the Department's National Institute for Health Research nor the MRC usually ring fence funds for expenditure on particular topics: research proposals in all areas compete for the funding available. Both organisations welcome applications for support for research into any aspect of human

health and these are subject to peer review and judged in open competition, with awards being made on the basis of the scientific quality of the proposals made.

The MRC is now preparing to take forward the recommendations resulting from the work of the MRC Expert Group on CFS/ME and issues and priorities discussed at a CFS/ME Research Prioritisation Meeting in June 2010. A note of this meeting along with further information on the work of the Expert Group can be found on the MRC website at:

http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC007174.

Further information will be published on the MRC website at www.mrc.ac.uk when available.

Officials have contacted NHSBT to request further information about its decision to exclude people with CFS/ME from donating blood.

NHSBT acknowledges that it was incorrect in the response it gave to the email enquiry that deferral was also for the protection of the recipient and it apologises for this error and any distress that it may have caused. The decision that CFS/ME sufferers would be permanently excluded from donating blood from 1 November was taken solely to protect the health of the donor.

This measure was introduced to the Donor Selection Guidelines (DSGs) following a review by the expert Blood Transfusion Services/HPA Joint Professional Advisory Committee (JPAC) into the possible link between a XMRV and CFS/ME. The JPAC found no evidence that XMRV could be a risk to transfusion recipients. However, the JPAC did decide to introduce, as an additional measure to the DSGs, the lifelong exclusion for CFS/ME sufferers so that even if symptoms had been resolved, a donation must not be taken. This brings guidance for people with this condition in line with other conditions where individuals are permanently excluded from blood donation to protect their own health.

Blood donation, by its nature, can put a donor's body under significant physical stress and, in line with the UK blood services' duty to protect the health of all donors, it was decided by the JPAC that this further measure should be introduced.

The JPAC will continue to monitor the situation and will advise on any changes should new evidence come to light.

The statement that the exclusion was for those with CFS/ME and fibromyalgia was also incorrect. At present, a donor with fibromyalgia would be accepted as long as they were well at the time and did not present any additional features of CFS/ME.

At all blood donation sessions there are a number of questions that every donor must be asked at health screening or that are on the Donor Health

Check form. The answers to these questions would be expected to reveal any previous CFS/ME diagnosis. The questions include:

Have you ever had a serious illness or seen a doctor about your heart?; and

Have you ever had any hospital investigations or tests or operations?

In answering these questions, potential donors would be expected to disclose a previous CFS/ME diagnosis and blood donation staff would then review the specific DSGs entry for CFS/ME.

Additionally, all blood donation staff should be aware that anyone who has suffered from CFS/ME is now permanently excluded from blood donation and NHSBT are issuing a further notice to all staff to reiterate this and will draw this issue to the attention of the other three UK blood services.

NHSBT is sorry that its response was unclear and inaccurate and that a member of staff seemed unaware of the new exclusion. NHSBT is reviewing its internal communications processes so that in future all clinicians and public facing staff fully understand, and can properly explain, the rationale for any changes that are introduced to the donor selection criteria.

If NHSBT is informed that a donor with a past history of CFS/ME who has recovered has subsequently donated blood, they will be permanently excluded from making further donations.

I hope this reply is helpful.

Yours sincerely,

Christopher Bird

Department of Health

Response on behalf of Sir John Savill:

Thank you for your further email to Sir John Savill, I have been asked to reply.

As outlined in our response to your previous message, the MRC is now preparing to take forward the recommendations resulting from the work of the MRC Expert Group on CFS/ME and issues and priorities discussed at a CFS/ME Research Prioritisation Meeting in June 2010. A note of this meeting along with further information on the work of the Expert Group can be found on our website athttp://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC007174.

Further information will be published on our website when available.

Dr Declan Mulkeen

Director of Research Programmes

Response received on behalf of Dame Sally Davies:

Thank you for your recent emails about xenotropic murine leukaemia virus-related virus (XMRV) and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME). I have been asked to reply.

Whilst the Department of Health agrees with the World Health Organization's classification of CFS/ME as a neurological condition of unknown cause, it has many different potential causal factors, including those of a neurological, endocrinal, immunological, genetic, psychiatric and infectious nature, which have been investigated, but the diverse nature of the symptoms cannot yet be fully explained. More research into the causative factors of CFS/ME is needed.

The Medical Research Council (MRC) has recently identified and prioritised research topics where high-quality proposals should be encouraged. This exercise involved both experts in the field of CFS/ME and research leaders in aligned areas. Further information on this work can be found on the MRC website atwww.mrc.ac.uk/Ourresearch/ResearchInitiatives/CFSME/index.htm.

Regarding the recent interest around the role of XMRV, its precise role in the causation of CFS/ME remains a source of debate within the scientific community. A recent study in the USA reported that XMRV has been detected in a number of CFS/ME sufferers. The results of this study have not been replicated in Europe. An ongoing research programme characterising XMRV at the MRC's National Institute for Medical Research recently investigated the basis for this finding. The study, which was funded jointly by the MRC, the Wellcome Trust and the CFS Research Foundation, failed to replicate the findings of other studies in this area and found no association between XMRV and CFS/ME.

In addition, an expert subgroup of the National Expert Panel for New and Emerging Infections (NEPNEI) met in May 2010 to consider all available evidence about XMRV and conduct a risk assessment. The subgroup concluded that XMRV can infect humans but there is currently no evidence that it causes human disease and that, on the evidence before the group, no public health action is required at this time. Since the subgroup meeting in May there has been no new scientific evidence that would change these conclusions. In July, the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), similarly decided not to recommend further measures at present. Both groups will continue to monitor the situation.

Both NHS Blood and Transplant (NHSBT) and Health Protection Agency (HPA) experts concur with the views expressed by NEPNEI and SaBTO and

also recognise the need for further research on the prevalence of XMRV in the UK. In a recent unpublished pilot study conducted by NHSBT/HPA, a series of 540 randomly selected English blood donors were screened for XMRV and none were found to be infected.

The UK Blood Service's decision to exclude people with CFS/ME from donating blood is to protect the patient, not because of any potential infection risk. CFS/ME is a relapsing condition and blood donation may be detrimental to the affected person. This decision is in line with practice for other conditions where individuals are permanently excluded from blood donation to protect their health.

I hope this reply is helpful.

Yours sincerely, Jonathan Tringham

Customer Service Centre

Department of Health