

## **REPLIES RECEIVED IN RESPONSE TO PHASE III OF THE POLICY CHANGE NOW CAMPAIGN**

**On behalf of Rt Hon. Andrew Lansley, Secretary of State for Health:**

*Thank you for your further recent email to Andrew Lansley about xenotropic murine leukaemia virus-related virus (XMRV) and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME). I have been asked to reply on his behalf.*

*You raise a number of scientific points regarding the Department's previous reply with which you disagree. There is always plenty of disagreement in scientific circles; this is part of the nature of healthy scientific debate. The Department of Health relies on external scientific advice provided through advisory committees and arms length bodies, such as the National Expert Panel for New and Emerging Infections (NEPNEI), the Advisory Committee on the Safety of Blood, Tissues and Organs, the Health Protection Agency (HPA) and NHS Blood and Transplant. All of these organisations are continuing to monitor scientific findings on XMRV.*

*I note that you ask about further research into developing and applying a test for an antibody to XMRV, which was being considered at the time of the Department's previous reply. The HPA Research Committee has considered the research proposal and has decided not to take it forward currently. If you have concerns about this decision, you may wish to contact the HPA directly. A contact form is available on the HPA's website at:*

<http://www.hpa.org.uk/AboutTheHPA/ContactUs/ContactForm/>.

*You also ask whether there will be a UK study that replicates the techniques used by the scientists responsible for the 'Science' study you quote in your email. The Department is not aware of plans for such a study in the UK. The Medical Research Council (MRC) supports research into CFS/ME, and welcomes high quality research applications in this area. However, the selection of projects for MRC research funding is determined through peer review. The primary considerations in funding decisions are research excellence and importance to health.*

*With regard to ring-fencing funding for CFS/ME topics, prioritisation of an individual research council's spending is not a decision for ministers.*

*I also note that you request clarification on the Government's current stance on XMRV and its potential role in human disease. NEPNEI considers that, although it appears that XMRV can infect some people, it is still not known whether there is any association between the presence of XMRV and any human disease. Studies published since NEPNEI's consideration of XMRV in May 2010 have not changed the conclusions of the meeting.*

*There is no new evidence of a risk to patient health and no adverse effect to a donor has been reported. The UK blood services decided to introduce lifelong deferral from donating blood 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 the lifelong exclusion for CFS/ME sufferers, as an additional measure to the Donor Selection Guidelines, 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.*

*All donors are asked if they are well on the day of donation and if they have ever had a serious illness in the past. Donor health screening depends on full disclosure by donors. There are not direct questions on every serious illness. Should a donor not disclose a past history of CFS/ME that is their decision. However, the questions are designed to establish whether donors have suffered from any condition that may prevent them from donating. The donor questionnaire needs to balance ensuring the continued health of the donors, not putting off people from donating by over intrusive or onerous questions, and the requirement to protect patient safety. There are no plans to add more questions to those already asked of donors.*

*If NHS Blood and Transplant 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.*

*Regarding further studies on XMRV, the MRC has just confirmed a commitment of up to £1.5million to support research into the causes of CFS/ME. The new funding call will focus on six priority areas that have been identified by leading experts in the research community. One of these research areas is immune dysregulation, such as through viral infection. The five other research areas that have been identified are:*

- autonomic dysfunction;*
- cognitive symptoms;*
- fatigue;*
- pain; and*
- sleep disorders.*

*The call will also encourage capacity building in CFS/ME research and the entry of new researchers into the field.*

*Details of the call are currently being finalised, in consultation with the MRC's CFS/ME Expert Group, and the full specification of the call will be published on the MRC website shortly at:*

<http://www.mrc.ac.uk/Ourresearch/ResearchInitiatives/CFSME/index.htm>.

*You also enquire about providing a mailing list for people to be notified of the latest information. The above web page includes information that people can access for up-to-date information on CFS/ME research.*

*You also ask if the MRC will provide guidance on universal safety precautions for people with XMRV. I should explain that it is not the MRC's responsibility to do this. The primary role of the MRC is to encourage and support research into human health, such as through promoting skilled researchers.*

*Finally, you request that a Department of Health official attends the Sixth Annual Invest in ME International Biomedical Conference in Westminster on 20 May. Policy officials have indicated that they will make a decision when they receive the invitation.*

*I hope this reply is helpful.*

*Yours sincerely,*

*Paul Larkin*

*Customer Service Centre*

*Department of Health*

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**On behalf of Sir John Savill, Chief Executive of the Medical Research Council:**

*Thank you for your recent messages to Sir John Savill, I have been asked to reply on his behalf.*

*A number of the issues raised in your message are matters for the Department of Health. In this reply I have tried to address the issues relating to MRC research funding and priorities.*

*In your message you ask about MRC plans to support research relating to CFS/ME and XMRV. The MRC recognises that CFS/ME is a debilitating condition which has a serious impact on the lives of sufferers, their families and carers. As such, research relating to all aspects of CFS/ME, including studies into the biological basis of the condition, has been a priority area for the MRC for a number of years. Details of the MRC's past and present activities in supporting CFS/ME research, including the work of the Expert Group and recommendations relating to research topics and priorities you*

mention in your message can be found on our website  
at <http://www.mrc.ac.uk/Ourresearch/ResearchInitiatives/CFSME/index.htm>

*I am pleased to say that as part of our continuing commitment to CFS/ME research, the MRC has recently announced plans to invest up to £1.5m in high-quality research proposals investigating the underlying causes of CFS/ME, focusing on the short-term research priorities identified by the Expert Group. Details of this initiative can be found at the link above. As with all MRC research funding, awards will be made on the basis of an assessment of the quality and likely impact of investigator-led proposals generated by the biomedical research community*

*In addition, we continue to welcome high-quality proposals relating to CFS/ME at any time. Researchers investigating aspects of CFS/ME other than those areas identified in the initiative may apply through the normal mechanism. Details of how to apply can be found on our website at <http://www.mrc.ac.uk/Fundingopportunities/Applicanthandbook/index.htm>, and details of specific funding opportunities can be found at <http://www.mrc.ac.uk/Fundingopportunities/index.htm>.*

*Yours sincerely,*

*Declan Mulkeen*

*Director of Research Programmes*

*Medical Research Council*

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**On behalf of Dame Sally Davies, Chief Medical Officer at the Medical Research Council:**

*Thank you for your recent email to Professor Dame Sally Davies about xenotropic murine leukaemia virus-related virus (XMRV) and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME). I have been asked to reply on her behalf.*

*I was sorry to read that you were dissatisfied with the Department's response to previous emails.*

*You raise a number of scientific points regarding the Department's previous reply with which you disagree. There is always plenty of disagreement in scientific circles; this is part of the nature of healthy scientific debate. The Department of Health relies on external scientific advice provided through advisory committees and arms length bodies, such as the National Expert Panel for New and Emerging Infections (NEPNEI), the Advisory Committee on the Safety of Blood, Tissues and Organs, the Health Protection Agency (HPA) and NHS Blood and Transplant. All of these organisations are continuing to monitor scientific findings on XMRV.*

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*and the requirement to protect patient safety. There are no plans to add more questions to those already asked of donors.*

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*Finally, you request that Professor Davies attends the Sixth Annual Invest in ME International Biomedical Conference in Westminster on 20 May. I hope you will appreciate that, due to the pressures on Professor Davies' diary, she is unable to attend the conference.*

*I hope this reply is helpful.*

*Yours sincerely,*

*Paul Larkin*

*Customer Service Centre*

*Department of Health*