

Response from the National Patient Safety Agency to Complaint about the PACE Trial

Margaret Williams 14th April 2010

On 1st March 2010 Professor Malcolm Hooper lodged a complaint with the Head of the National Research Ethics Service (NRES) – formerly the Central Office for Research Ethics Committees (COREC) which on 1st April 2007 became NRES – about the apparent failure of the West Midlands Multicentre Research Ethics Committee (West Midlands MREC) to fulfil its obligations before granting ethical approval for the MRC PACE Trial on the grounds that it failed to adhere to Section 9.7 of the Governance arrangements for NHS Research Ethics Committees (2001) which were in place at the time it granted ethical approval for the MRC PACE Trial.

The complaint set out numerous heads of concern and concluded:

“It seems indisputable that, either through dereliction of duty or through being inadequately informed by the Chief Investigator, the West Midlands MREC failed to adhere to section 9.7 of the Governance arrangements for NHS Research Ethics Committees (2001) which were in place at the time it granted ethical approval for the MRC Trial.

Given the nature of these ethical concerns, there should be serious consideration given to the continuation of the Trial and the publication of any data”.

The full complaint can be accessed at <http://www.meactionuk.org.uk/MREC-complaint.htm>

On 22nd March 2010 a response was sent by Dr Janet Wisely, Director of the National Research Ethics Services, which is part of the National Patient Safety Agency, 4-8 Maple Street, London W1T 5HD.

Extracts from the response include the following:

"In the case of the PACE Trial I have concluded that there is no likely benefit of a more extensive review of the original decision made by the REC because it was a decision made a long time ago".

"The REC does have a role after the original approval, however it has no power to investigate".

"Where the REC has concerns that there may be issues of misconduct then again it has no powers to investigate".

"In the case of PACE the study is closed for new recruitment and I do not think it appropriate to ask the REC to reconsider the opinion that was made several years ago. What NRES is able to do is to pass on the concerns that have been raised to those with responsibility for the conduct of the trial (*sic*) for their consideration. However, it seems there has been extensive dialogue with these relevant parties and I do not feel there is anything that NRES can usefully add to these exchanges".

Given the expressed concerns about patient safety, particularly in the graded exercise arm of the PACE Trial, the response is considered unsatisfactory.