High Standards at the MRC?

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In his reply of 15th April 2005 to Neil Brown, Simon Burden of the MRC stated several points of importance that require public attention.

Firstly, Simon Burden wrote: "**When researchers put together a proposal they are required to define the population they are studying**". Indeed so: why, therefore, does this basic requirement not apply to the PACE trials? And why is the MRC content with the confusing lack of definition for entry criteria into these trials for patients with what the MRC itself refers to as "CFS/ME"?

If those involved with the PACE trials adhere (as required) to the Trial Identifier and select their participants by using the Oxford criteria, then, by definition as set out in the Oxford criteria themselves, those with ME will be excluded from the start, and this is unequivocal. If there is no such strict adherence to the entry criteria, then the results will be flawed from the outset and therefore meaningless (and yet more millions of pounds will have been wasted). Either the criteria are adhered to, or the results will be flawed: there is no other scientifically credible interpretation.

How does this accord with the MRC's apparent requirement for **"the high scientific standard required for funding**" (quote from the same letter from Simon Burden)?

Simon Burden then states that researchers applying to the MRC for funding are (quote) **"required to define how they will find participants in the study**". The MRC might prefer this particular aspect not to be subject to public scrutiny because in the case of "CFS/ME" and fibromyalgia (FM), the tactics to be employed are financial inducements (which in other areas of public life may be best described as "bribery", a "bribe" being defined in the Penguin English Dictionary as "a reward offered to a person to induce him to act contrary to what is just and right"). If clinicians have to be tempted by financial rewards to refer their patients into these trials, then something is very wrong, but such financial inducements are indeed to be offered to GPs to identify and refer patients to these trials and to the new Centres.

Even more disturbingly, in the case of the MRC FINE trials (Fatigue Interventions by Nurse Evaluation), whilst in the Patient Information Sheet patients are to be assured that "Your GP is not being paid for his or her participation in this trial", there is a different message for the GP because in the GP invitation letter it states: "Practices will be recompensed by the Department of Health for time spent in identifying and recruiting patients (£26.27 per referral)". Does such a discrepancy accord with the MRC's own definition of "high standards"?

On the subject of high standards, what can be the explanation for the MRC-funded FINE trial literature using the term "myalgic encephalitis" (which is not the same as "myalgic encephalomyelitis")? Is accuracy no longer considered a component of "high standards"?

The third notable point in Simon Burden's letter is that he states: "**Research proposals in all areas must demonstrate** *(sic)* **that the research will contribute to maintaining and**

improving health". If this is so, why are exceptions being made in the case of "CFS/ME" patients? Given the published evidence of serious cardiac peturbations in some patients with ME/ICD-CFS (see "Profits before Patients? PACE Trials vs. Medical Evidence": Co-Cure, 16th April 2005), how can deliberately putting participants at risk of deterioration by virtue of compulsory aerobic exercise – however it is administered – be guaranteed not to be harmful and how does such known risk constitute the (quote) "maintaining and improving health"?

Will Simon Burden confirm that, as part of the MRC's requirement for "high standards", all entrants into the PACE trials and attendees at the new Centres will first be screened by means of impedance cardiography to eliminate this very real risk?

Without such individual screening, how else will such risks be eliminated, because the Patient Invitation letter makes it clear that "The groups are selected by a computer programme which has no information about each individual patient. Your GP has carefully considered the symptoms that you have at the moment, and concluded that they fit the current guidelines for a diagnosis of CFS/ME".

Therein lies the problem.