Written evidence submitted by Dr Peter Wilmshurst (RES0025)

Oral Evidence to Science & Technology Committee inquiry into Research Integrity on 24th October 2017

I want to correct a repeated typographical error in the transcripts of my oral evidence. In my response to Q49 the transcripts show me saying the word “mistrial” three times. That should be “MIST Trial” where the acronym “MIST” stands for “Migraine Intervention with STARFlex Technology”. That trial was mentioned in my written evidence and is mentioned below in this letter. I am sorry that my pronunciation was not clear.

In response to Q88 I stated that I would provide a copy of the letter that a whistleblower at the Royal Brompton National Heart and Lung Hospitals received from the Chair of the Board of Governors. I am attaching a scanned copy with this letter. (I can supply supporting documents if you require them.)

This leads me on to a couple of additional comments that I want to make about the oral evidence session.

The Committee heard the opinions of senior academics that research misconduct is a relatively small problem, which universities are dealing with successfully. They have not provided any evidence to support their opinions. I have the opposite opinion, at least as far as medical research is concerned – I believe that the problem is large. Support for my view comes from the fact that about half of published reports of medical research cannot be reproduced or confirmed by others.

You and Mrs Ford MP objected to me extrapolating from the many cases that I know about to my belief that misconduct in medical research is common. As far as I recall, every UK case that I have dealt with over the last 35 years was characterised by hospitals and academic institutions concealing the misconduct and silencing whistleblowers. There is clear evidence in those cases that the deans of UK medical schools and senior professors concealed misconduct. In some cases, the concealment succeeded for many years. It follows that other examples of misconduct are likely to have been concealed successfully. I know of many allegations of cover up of misconduct where there is insufficient evidence to prove the case with certainty, but there are so many cases that it is likely that some are true. It appears that the types of organisations that have for years concealed research misconduct are the ones who now say that the problem is small and manageable.

It would be remarkable if the culture in medical institutions for concealment of research misconduct differed from the culture in the same institutions of concealing scandalous patient care as highlighted by many inquiries (e.g. Inquiry into children’s cardiac surgery in Bristol and in Oxford, Mid-Stafford Inquiry, Alder Hey Inquiry, etc). I believe that there are also analogies with the Catholic Church’s cover up of sexual abuse of children by priests and the recent examples of sexual misconduct by politicians and powerful celebrities. It appears that in those cases powerful people concealed the extent of the crimes and misconduct for decades by threats to whistleblowers and victims. Because of that concealment the true extent of the misconduct is underestimated.
I note that in response to Q86 Professor Walmsley and Professor Sir Ian Diamond each said that whistleblowers are protected. There is no institution that protects whistleblowers, not even the NHS or the GMC. (See: House of Commons Health Committee Report “Complaints and raising concerns”, January 2015; “Speaking up review” by Sir Robert Francis QC for the Secretary of State for Health, February 2015; and Report by Sir Anthony Hooper QC on “The handling by the GMC of cases involving whistleblower”, March 2015.) Recent news reports suggest that even people working in Parliament are bullied into silence.

Mrs Ford (Q73) also objected to my description of (medical) research ethics committees as “amateurish” in my response to Q72. You should know that members of medical research ethics committees are not paid. So they are unquestionably amateur. (They have professional administrative staff that organise meetings and take minutes, but have no role in making decisions.)

The committees consist of medical and lay members, who receive training in matters related to approving research applications. The committees receive no training in dealing with research misconduct and when I have raised concerns about research misconduct with the committees that approved research projects they said that it is not their role to consider or investigate allegations of research misconduct and that they are not trained or funded to deal with it.

I would like to expand on what I said about ethics committees. In medicine there are Local Research Ethics Committees (LRECs) which deal with the research in that institutions or locality. It follows that the medical members of those committees often work with doctors making applications. The lay members will also know doctors who make frequent applications. As a result personal relationships can influence the members of a LREC.

When it is planned that a trial will take place in a number of hospitals or GP practices (i.e. multicentre trials) the NHS has a number of Multicentre Research Ethics Committees (MRECs) that can approve an application. A Principal Investigator can apply to a MREC distant from his/her place of work because the application is for national approval. The MRECs are co-ordinated by the National Research Ethics Service. Each site involved in a multicentre trial must also get confirmation from their local LREC that the site has the facilities and local support in order to participating. A doctor involved in a number of multicentre research studies may have approval via a number of MRECs, which will be notified to the National Research Ethics Service and his LREC.

From this it might be assumed that if one MREC expresses concerns about a researcher or makes a decision to terminate the participation of a doctor in a multicentre study that information will be transmitted via the National Research Ethics Service to other MRECs that have approved research in which he is participating or via his LREC, which should be aware of all the research studies in which the doctor is participating. One might anticipate that the communication of concerns will be more urgent if a doctor is the Principal (or Chief) Investigator in research projects. The 2015 findings of a Fitness to Practise Panel of the Medical Practitioner Tribunal Service that Dr Andrew Dowson was guilty of misconduct including two counts of dishonesty and the subsequent rejection of his appeal by
Mr Justice Edis shows that this basic communication between research ethics committee does not happen. (Fitness to Practise Panel - Determination on the Facts 3 February 2015: Dr Andrew John Dowson (2953399); and, Neutral Citation Number: [2015] EWHC 3379 (Admin) – Case number: CO/1265/2015- Andrew John Dowson v the General Medical Council.)

The Fitness to Practise Panel told Dr Dowson “It was your duty to inform the WMMREC (West Midlands MREC) of the concerns raised by NYMREC (Northern and Yorkshire MREC) about your suitability to act as a Chief Investigator. The panel found that you were in breach of that obligation……. The panel has no doubt that you recognised the relevance and potential impact of the concerns expressed by NYMREC. You must have known that, had these been communicated to WMMREC at the time of your application for approval of the MIST trial, there was a risk that your appointment as Chief Investigator would have been questioned. The panel considers it unlikely that you simply assumed the information would reach WMMREC by another route. It has concluded that, in all probability, you recognised that you should have disclosed it yourself, but chose not to do so, in order to maximise the chances of gaining approval for the MIST trial and your role as its Chief Investigator.”

If a research ethics service cannot communicate between different ethics committees bureaucratic information, such as the fact that an investigator’s conduct has resulted in him being removed from one clinical trial, it is unlikely to be able to deal with the more complex issue of investigating allegations of research fraud.

Finally, I wondered why Mrs Ford MP appeared so hostile to the suggestions that research fraud is common and that research ethics committees are amateurish. I note that she disclosed that her husband is a doctor. His own interests are documented elsewhere as lead investigator of a number of multicentre research trials and a member of the National Cancer Research Network Upper Gastrointestinal Study Group. So he is not purely a clinician, but he is actively involved in medical research. In addition, he was until recently director and a member of the Dr Foster Ethics Committee. I believe that Mrs Ford’s conflicts of interest should be disclosed more explicitly.

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