Tackling fraud in medical research and scientific communication: A report of the lecture by Dr Frank Wells at the 28th EMWA Conference

by Catherine Mary

Between 1996 and 2008, Scott Reuben, a famous American anaesthetist, published 21 fraudulent articles showing positive effects of drugs, millions of doses of which had been sold. An investigation by the Health Service of Baystate Medical Center (Massachusetts, USA) showed that none of the patients described in those 21 science articles signed by Reuben had ever existed [1]. This recent high-profile case—one of the biggest in the history of biomedical science—illustrates the extent to which fraud can compromise the integrity of biomedical research, and dash the public's hopes and their confidence in medicine.

In his lecture at the 28th EMWA Conference, held last May in Ljubljana, Dr Frank Wells (Co-Chairman, Cambridgeshire 4 Research Ethics Committee and joint editor, with Michael Farthing, of the definitive textbook, Fraud and Misconduct in Biomedical Research) stressed the urgent need to tackle fraud in biomedical research in Europe.

A blurred picture

Although most clinical research is honest, suspect data do occur and investigation may reveal a fraud. Having been involved for more than 12 years in the forensic investigation of suspected irregularities in the UK, Dr Wells pointed out gaps in the overall picture of fraud and research misconduct, especially the lack of prevalence data. Based on his own experience, Dr Wells estimates that fraud could involve 1% to 5% of results published in the scientific literature. This would suggest that, of an estimated 2000 sponsored clinical research projects taking place within the UK at any one time, at least 20 might include investigators who are generating, or attempting to publish, false data. "This is too much", he stated. "In this field, zero tolerance should be the rule".

Multiple forms of fraud

Shedding light on several high-profile cases in the UK, Dr Wells showed that fraud can occur at any stage in the research process, ranging through multiple use of material, forging patients' handwriting, bribery, animal research fraud, and fabrication of ethics committee approval, to non-existent patients. A recent case in 2007 in the UK, for example, involved a paediatric clinical trial of a new treatment for eczema, which had poor recruitment. In this case, mothers were asked by a fraudulent paediatrician to sign a second consent form for their children using their maiden names.

Of 212 issues discussed by the Committee on Publication Ethics (COPE) [2] between 1997 and 2004, 58 involved duplicate or redundant publications, 26 involved authorship issues, 25 involved a lack of ethical approval, 22 involved no or inadequate informed consent, and 19 involved falsification or fabrication.

Dr Wells also emphasised that people who have committed a fraud are likely to do so again. This is exemplified by the case of Malcolm Pearce, a UK gynaecologist who simultaneously published two fraudulent articles: one involving a patient with an ectopic pregnancy that he claimed to have successfully transplanted, when he had done no such thing and the other involving a trial of 200 patients that never took place [3, 4]. Seeing this pattern repeatedly has lead Dr Wells to advocate that people who have committed a fraud, should never again be used as research investigators.

Caravaggio, *The Cardsharps*, **c. 1594, oil on canvas. Kimbell Art Museum**

The need for national bodies

Only the Nordic countries and the USA have established national bodies able to tackle fraud and research misconduct effectively . Because the profile of those committees is high enough to inspire the confidence of stakeholders, they receive complaints of suspected research misconduct, which they can then assess and deal with accordingly. In contrast, most European countries lag behind, and research misconduct is poorly reported.

The establishment of a UK Panel for Research Integrity in Health and Biomedical Sciences (UKRIO) in 2006 has so far yielded poor results. This panel has such a low profile that few workers in the field know of its existence. To be effective, such committees should not only set standards that all interested parties should be trained in and adhere to, but should also put in place corrective procedures. It is essential, in the interests of the public, the profession and the

industry, that the investigator at fault is dealt with appropriately, stressed Dr Wells. In all of the high-profile cases in the UK described by Dr Wells, the investigators were removed from the medical register after they were shown to have exploited patients or submitted fraudulent data.

In Dr Wells's view, national bodies, similar to those of the Nordic countries, should be set up in every country conducting research. Such committees should provide guidance, set up clear definitions of fraud and research misconduct, ensure training and implement corrective procedures. This is all the more important because the situation is increasingly complex and frauds are becoming, correspondingly, increasingly difficult to detect, explained Dr Wells.

Stakeholder commitment

The commitment of all stakeholders, from the researcher to the editor is a key element in the implementation of research integrity policies. In the peer-review publishing world, two organisations stand out, COPE, which advises editors on ethical procedures and the International committee of Medical Journal Editors (ICMJE), a group of editors that lays down voluntary guidelines on manuscript format and ethics policies. However, all stakeholders from the nurse to the medical writer should be aware of their responsibilities, and should be encouraged to act as whistleblowers if suspicious events occur. Dr Wells specially underscored the responsibility of the medical writer. "Anybody who writes has the responsibility to write what he believes to be true", he stressed. If medical writers come across suspect data or text, they should therefore do whatever is appropriate. This raises the question of where to turn for advice and where to submit a concern. Guidelines are needed to fill this gap and guide stakeholders on how to proceed in such situations.

Concluding his lecture, Dr Wells again stressed that "Research integrity really does matter".

Catherine Mary
Caluire, France
contact@avicenne-sciences.com
www.avicenne.sciences.com

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A 12-point plan to tackle research integrity in the European Union

Fraud was the subject of the first European Forum for Good Clinical Practice (EFGCP) meeting held in Prague, last January. The meeting highlighted the need for statistical data, for a clear definition on fraud and research misconduct, for education of all stakeholders, for the protection of whistleblowers and for the development of means to detect and prevent fraud.

The meeting concluded with the creation of a research integrity subgroup, under the chairmanship of Dr Frank Wells. A 12-point list for action integrating all the above topics was also established, as a roadmap for this subgroup.

http://www.efgcp.be/

Definitions of the US Commission Defense Health Services Systems (DHSS)

Research misconduct:
'Significant misbehavior that improperly appropriates the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices.'

Fraud:
'The generation of false data with the intent to deceive.'

Transparency and whistleblowers

Transparency is a major theme in the 1 August 2009 issue of the *BMJ*. Articles include one by Jane Cassidy that traces the fate of 4 whistleblowers and indicates that the whistleblower often suffers more than the organisation that is exposed. Other articles highlight the relationships between governmental agencies and the large producers that lobby them. Dealings between the bodies occur mostly out of view and a call is made for them to be routinely documented to allow public scrutiny. Of particular interest to medical writers, Rosalind L. Smyth reports on making information about clinical trials publicly available.