

“Ethical practice poses an interesting concept as ethics change over time with increased knowledge and shifting cultural values.”

Research governance

Clinical governance is well understood and embedded in daily practice through processes such as clinical audit, root cause analysis of adverse incidents, health and safety policies, and statutory and mandatory training. Research governance is generally less well understood, other than by those directly involved in it. Yet, there are many parallels between clinical and research governance, for example: ethics, integrity, informed consent, confidentiality and good record keeping. Whereas not so many years ago it was considered blasphemy to utter the words audit and research in the same breath, the edges are now more blurred. Possibly as a result of this, it is considered that ‘research involving human participants’ should be taken in its broadest sense to include questionnaires, interviews, medical/clinical research, student practicals and the use of bodily materials.¹ Consequently, many establishments recommend that all proposed research of this type should be submitted to an appropriate Research Ethics Committee.¹

Ethical practice poses an interesting concept as ethics change over time with increased knowledge and shifting cultural values. For example, not so many years ago, it was considered normal practice in some establishments for the Head of Department to expect their name on all research papers emanating from that Department, whether they had any direct involvement in the research or not. Today, however, the *British Medical Journal (BMJ)* makes it clear that this is no longer considered ethical practice.² It sets out plainly that: ‘authorship credit should be based only on – substantial contribution to conception and design, or analysis and interpretation of data; or, drafting the article or revising it critically for important intellectual content and final approval of the version to be published’. The *BMJ* goes on to state that ‘participation solely in the acquisition of funding or the collection of data does not justify authorship’. Providing staff with research opportunity and/or the infrastructure for undertaking research is insufficient to gain authorship rights if none of the former criteria are met.

Within the world of dental research, the classic example of changing ethics, cultural values and acceptability is the Vipeholm Dental Caries Study. This study arose from the concerns over poor oral health in Scandinavian children in the 1930s, which it was thought could be linked to poor diet. By 1945, the Swedish Government had agreed to an investigation of the measures that should be taken to decrease the frequency of the most common dental diseases in Sweden. Subsequently, a longitudinal, clinical study on diet and dental caries took place

at the Vipeholm Hospital, an establishment for ‘individuals with mental handicaps’. The results of the Vipeholm study led to an information campaign about the risk of caries from frequent sugar consumption, an oral health message that survives to this day.

In his ‘Recollections and Reflections’,³ Bo Krasse, a ‘plaque collector’ in the 1945-1954 study states that, at the time, it was considered ethical to carry out the study in a ‘hospital for individuals with mental handicaps’ as it provided an opportunity for long-term nutritional studies to be performed in well-controlled conditions. One has to admit there is certain logic to this, provided one thinks no further! Although there was regular monitoring of the ‘research station’ by members of the Medical Board who had ‘a strong social commitment’, when the results were published a Bill put forward by Swedish parliamentary members and a public debate about the ethics of the study resulted in the Swedish Government’s decision that patients at the Vipeholm Hospital should no longer be used as research subjects. Nearly 50 years on, Krasse summarises his reflections on the study with two sayings: ‘The end sometimes justifies the means’ and ‘It is easy to be wise after the event’.

Today’s research governance might change these sayings to: ‘the end only justifies the means, provided individuals’ well-being is not put at risk’ and ‘It’s easy to be wise after the event, but we will ensure that every effort is taken to be wise before the event’. The Mental Capacity Act 2005, which came into place in April 2007, helps to do exactly this and provides guidance on the legality of enrolling incapacitated adults in research.⁴

Dr Janice Fiske MBE
Senior Lecturer
Sedation and Special Care Dentistry
janice.fiske@kcl.ac.uk

1. King’s College London. Guidelines on good practice in academic research. pp 2. London: King’s College London, 2004. http://www.kcl.ac.uk/college/policyzone/attachments/good_practice04.pdf. Accessed 20/05/2007
2. BMJ authorship and contributorship webpage. <http://resources.bmj.com/bmj/authors/article-submission/authorship-contributorship>. Accessed 20/05/2007
3. Krasse B. The Vipeholm dental caries study: recollections and reflections 50 years later. *J Dent Res* 2001; **80**: 1785–1788.
4. British Medical Association. The Mental Capacity Act 2005 – guidance for health professionals. London: BMA, 2007. <http://www.bma.org.uk/ap/nsf/Content/mencapact05>

DOI: 10.1038/bdj.2007.689