

The concise argument

Soren Holm, *Editor*

Research ethics

Research ethics is one of the oldest and most discussed areas of modern medical ethics but as three papers in this issue illustrate it is still possible to advance the field.

Davies and co-authors describe a European workshop on research ethics held in Warsaw in April 2008 (*page 382*). Although all European Union and European Economic Area member states have adopted the same EC Directives on clinical trials and on good clinical practice (GCP) there are still very significant differences in their research ethics committee (REC) systems. Many RECs operate without common standards and audit and many are not sufficiently funded. The article argues that standard setting is necessary in order to foster trust between researchers, patients and the public and outlines a number of different ways in which standards can be set and performance monitored.

The paper by Dixon-Woods and Angell describe a research project which can be seen as part of such standard setting and performance monitoring (*page 377*). In England and Wales research involving adults who lack capacity to consent is governed by the Mental Capacity Act 2005 and the UK implementation of the EC GCP Directive and Dixon-Woods and Angell analyse to what degree RECs' decisions reflect these two regulatory instruments. Based on a close content analysis of 45 decision letters they show that in the period immediately after the implementation of the Mental Capacity Act "... RECs were not always giving advice to applicants that was consistent with the provisions of the Act." This seems to call for a later follow-up study!

The third paper on research ethics discusses the use of placebo controls in clinical trials of treatment for major depression and anxiety disorders (*page 384*). Placebo controls are controversial in this context because they (1) seem to be

incompatible with the Helsinki Declaration's articles on the standard of care owed to trial participants and (2) may involve depriving patients in the control group of their usual, and presumably somewhat effective, treatment. The authors argue that despite these arguments placebo controls are ethically acceptable and perhaps even required in the context of these specific disorders given that (1) detection of adverse events is important, (2) that estimation of real benefit is important and (3) the disorders in question are heterogeneous and symptoms vary over time. They show how the heterogeneity of the disorders may confound equivalence trials where both groups are given active treatment (see fig 1 in the paper). And they further discuss trials recruiting patients with severe major depressive disorder and suggests a trial design, the "double-blind discontinuation trial" that may be suitable in this group, although they do realise the potential problems in getting patient consent.

The Nazis are still causing trouble

More than 60 years after the end of the Nazi regime in Germany and Austria the Nazis are still causing trouble. Yad Vashem, the Holocaust Martyrs' and Heroes' Remembrance Authority in Israel collects information about Holocaust victims in order to preserve their memory and the memory of the Holocaust. One set of victims are the victims of the so-called "euthanasia" programme where mentally ill and mentally retarded patients in German hospitals and asylums were killed. Yad Vashem holds the names of more than 1200 Jewish victims of this programme, but should it publish them?

The paper by Strous outlines the many complex considerations that this question raises and argues that it may not have a clear and compelling answer (*page 361*). It is not clear what is in the interest of the deceased, what is in the interest of their

living descendants, or what is in the interest of society as a whole; and the rules and practices concerning confidentiality of medical information after death are also equivocal. In the concrete case a decision was made to allow full access to family members and serious researchers, but only publish data in a less identifiable form.

Despite the problem having its origin in the Nazi atrocities the discussion is of relevance to many other databases and biobanks holding health information about people who are deceased.

Medical students and abortion

The future of the ethics of the medical profession relies on the inculcation of ethical reasoning abilities, values and habits in medical students and young doctors. The *JME* believes that it has an obligation to promote the interest in ethics among medical students and we are therefore happy to publish a paper on medical students' attitudes to abortion, which not only studies medical students but is also written by a medical student based on her own research (*page 390*). The paper compares the attitude to elective abortion in a range of scenarios between medical students at Queen's University Belfast and medical students at the University of Oslo. Not surprisingly the study found that attitudes differ and that students in Northern Ireland are much less liberal in their attitudes towards abortion than students in Norway. Perhaps more surprisingly it also found that there were students at both universities who were unwilling to watch an abortion.

A note on provenance notes

The observant reader of the *JME* will notice that all our papers now carry a note stating the provenance and peer review process for the paper. We have adopted this system from the *BMJ* and hope that it will add to the transparency concerning the editorial processes.