

Striking the right balance between privacy and public good

On Jan 17, the UK's Academy of Medical Sciences issued a report, *Personal data for public good: using health information in medical research*, on the use of individual medical information for research purposes. The report highlights the tension between the vital need to respect the privacy of patients and the important task of medical research using large population datasets.

Growing concerns about privacy have spawned a great many laws and regulations governing the use of personal data, as spelled out, for example, in the UK's Data Protection Act and the EU Clinical Trials Directive. These regulations are complex in themselves, but the various ways in which they are interpreted increase complications for researchers, with the result that important and worthy projects can be long delayed or blocked entirely.

Similar concerns have been raised in the USA since the implementation in 2003 of the Health Insurance Portability and Accountability Act (HIPAA), which established standards for the confidentiality of identifiable health information. HIPAA's "common rule" governs research and specifically requires written informed consent from patients, even for so-called de-identified data for projects that combine quality improvement (QI) with research (these had not generally required consent in the past). Some US researchers have argued that HIPAA regulations can inhibit research and increase its cost, or skew data collection and therefore bias the results.

Likewise, the Academy's report argues that overregulation and overly cautious interpretation of regulation is stifling important research. It points to landmark epidemiological work—such as Sir Richard Doll's 1947 finding of the link between smoking and lung cancer—that would not have been possible without a large database of patients' records.

The UK is particularly well placed to undertake database research because large numbers of people use the National Health Service (NHS) and electronic medical records are starting to be widely used. The obstacles in the way of potentially important medical advances are therefore all the more frustrating.

To remedy these problems, the Academy's report makes recommendations, which *The Lancet* strongly endorses, in five areas. First, it claims that identifiable data can be used if the research to be undertaken is

necessary and balances privacy concerns with public benefit. The report also recommends simplifying the process of assessing proposals so that researchers can get clear and timely decisions about their projects, all of which should be done under a code of practice, to be developed. It suggests that immunity from liability for data controllers should be considered, and recommends that the needs of researchers, not just those of practitioners, should be incorporated into ongoing development of the information technology programme of the NHS. Finally, patients, in formal groups and among the general public, must be engaged in discussion and debate. A group that has been established as a temporary statutory body, the Patient Information Advisory Group, should be thoroughly reconfigured, with one of its key roles being active facilitation of research.

More generally, the public needs to be engaged about how medical records are used and how research is done. The Academy's report points to a paucity of evidence about patients' preferences for and attitudes towards participating in research, and calls for more involvement with the public to get a fuller and more accurate picture of their views. One bioethicist, John Harris (University of Manchester, UK), has even argued that patients are morally obliged to participate in research projects, as a "mandatory contribution to public goods", at least for research that is aimed at preventing serious harms and providing important benefits. Harris also claims that in the absence of knowledge about an individual's actual preferences, it is justifiable to assume that a person would want to participate in research. Such "opt-out" schemes have been proposed as default options for database study recruitment.

Better public education about how research works and about the benefits that can accrue from investigation of population data is urgently needed, as is the need to convey the message that advances in diagnostics and therapeutics are being held up by bureaucratic regulation. When patients are convinced that their personal information is being used under rigorously controlled conditions and in accordance with best research practices, they are likely to agree to give up a small amount of individual privacy for the greater societal good that can come from population research. The future of our health depends on it. ■ *The Lancet*



For the AMS report see <http://www.acmedsci.ac.uk/p47.html>