Personal data for Public Good

A new report from the Academy of Medical Sciences on the use of personal health information in medical research

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Research using information from personal health records provides much of the evidence on which improvements in health care are based. Population-based research of this kind has shown the long-term effects of treatment, identified causes of disease, indicated how epidemics might be controlled and how delivery of health care can be improved. The UK has long been a leader in this field. With the proposed introduction of electronic health care records, and the unifying health care system provided by the NHS, the opportunities for research to improve health are now unique in size and scope.

But just at the time when the UK could forge ahead we have inhibited the development of this research through a combination of confused legal and regulatory guidance, an insistence on personal privacy and autonomy that is out of all proportion to any risk, and a stifling bureaucracy of process.

The Academy of Medical Sciences identified this problem in its 2003 report *Strengthening Clinical Research* and subsequently set up a Working Group to examine the present and future position in the UK with respect to the use of personal data in medical research. Our report *Personal data for public good: using health information in medical research* has just been published.

Such research requires access to large and representative populations. Two examples from cancer registration show how lack of access, or bias in the nature of the population studied, can lead to misleading claims or cost lives:

It is often stated that outcomes of cancer treatment are better in France than in the UK. This has no firm basis in fact because there is no systematic registration of cancer in France so the number of new cases, and the populations affected, are uncertain. Comparisons of national cure rates are therefore extremely unreliable.

A decision by the Hyogo prefecture in Japan to stop cancer registration, because of concerns about privacy, delayed the detection of increasing deaths from mesothelioma (cancer of the lining of the lung caused by asbestos). Registration has been belatedly reintroduced.

The research in question uses data from the routine records of patients. (We did not consider interventional research such as therapeutic trials or invasive investigation.) The great advantages of routine health records are that the information is based on current routine clinical practice, large numbers of patients can be included covering all social groups, and there can be rapid incorporation of the findings into routine clinical care.

The use of health data is legal if the persons concerned have given informed consent or if all the identifiable data have been removed (fully anonymised data). But informed consent or anonymisation are frequently not possible, or would undermine the validity of the results. The following examples show why this is so.

Double counting is a real risk: *Congenital anomaly registers were set up in response to the thalidomide tragedy and are essential in identifying teratogenic exposure in pregnancy. Many of the defects come to light later in life so data must be collected from databases held by paediatricians, midwives, genetic counselling services and many other sources. The individuals must be identifiable because otherwise they are very likely to be counted two or more times.*

Long term studies need to accrue additional data: *If a population is to be studied over many years (essential for determining outcomes of exposures or treatments) new data concerning events in individuals cannot be added if the data are irretrievably anonymised.*

It may be completely impractical to obtain informed consent: *The hypothesis that adverse conditions in pregnancy might increase the likelihood of cardiovascular disease in later life was developed and tested by Professor Barker using over 15,000 birth records collected in Hertfordshire from 1911 onwards. 3000 patients had died and the population had dispersed. The results linked low birth weight with risk of hypertension, type II diabetes and other disorders in adult life.*

Seeking consent may sometimes bias the data: *Until 2001 there was controversy over whether termination of pregnancy increased the risk of breast cancer. A potential bias was that women who had developed breast cancer might be more likely to disclose*

information about termination than women without cancer. When a data linkage study was done without consent the absence of risk was demonstrated conclusively.

Research therefore often needs to use identifiable data without consent. But this is where the problem lies. The law in this area is now notoriously complicated. It includes the Data Protection Act (DPA) 1998, the Human Rights Act 1998, the Health and Social Care Act 2001 and the common law of confidentiality. Most of the legislation is concerned with wide-ranging issues of confidentiality and privacy in public life of which medical research is just one aspect. Nevertheless, exceptions and schedules have been included within these laws specifically to allow the use of data without consent in the public interest. The key point is that the use must be proportionate with regard to the benefit and the possible risk. To date there has been no common law judgement with respect to medial research. The Working Group considered that, however desirable a change in legislation with respect to medical research might be, this was impractical for the immediate future and risked making matters worse.

The view of the Academy therefore is that present laws do not prohibit this type of research and we recommend that this interpretation should underpin the regulatory guidance.

The mass of legislation is interpreted by each of the numerous regulatory authorities that lie in wait for the researcher. These include the Office of the Information Commissioner (OIC), the Patient Information Advisory Group (PIAG), regional and local ethics committees, the General Medical Council, the Department of Health research governance framework and the R&D offices of NHS Trusts. Many researchers gave us instances where it had been difficult or impossible to penetrate the regulatory maze, to respond to the conflicting advice and interpretation of the law, and to surmount the slow, frustrating, bureaucracy that envelops a research proposal.

In general these bodies adopt a rather conservative, non-permissive, approach to research with little recognition that lack of information may cause suffering or cost lives. In the case of the OIC and GMC, medical research is not a major area of expertise. PIAG was set up under the Health and Social Care Act 2001 specifically to advise on research using identifiable data. We received evidence that PIAG has helped in some ways – for instance in giving class support to cancer registration whose very existence was undermined by an astonishing directive by the GMC in 2000. However, PIAG's processes are cumbersome. A simplified, efficient scheme of research assessment is now urgently needed.

Researchers must understand that public concerns about confidentiality and the use of personal data are increasing for many reasons. They cannot rest their case on the truth that, until now, there has been much benefit and no harm, and that all that is required is continued public trust in the confidentiality of research dedicated to the public good – essential though this is. Trust must nowadays be engendered and maintained by demonstrably excellent standards of data security, ethical review, staff training and requirements for consent and anonymisation. The Academy therefore recommends the development of good practice guidance in these areas and looks to the UK Clinical Research Collaboration to take this forward.

Early in its enquiry the Working Party realised that interpretation of, and concern for, public opinion and expectations lay behind the legal, regulatory and administrative difficulties. We were struck by the poor quality of most research into public attitudes. There are only a handful of studies where informed questions are asked of a large, representative population. We therefore recommended that medical research funders should support research in this area – an initiative already started by the Wellcome Trust and Cancer Research UK.

We not only need to know more but there must be better dialogue between researchers, research funders, the DH and the public on this topic. The research mission of the NHS is seldom mentioned in literature given to patients – in striking contrast to its role in teaching nurses, medical students and other staff. Consent for research within the NHS cannot be assumed if it is not mentioned as a legitimate aim. In the development of the electronic care records the DH understandably does not want the primacy of confidentiality to be undermined in gaining public acceptance. However, in our discussions with patient representatives there was strong support for research using health data. There was great concern that a vocal minority, loudly proclaiming the right of privacy, might override the unexpressed desire of many people to contribute to the public good. The Academy therefore recommends that a long-term programme of public engagement concerning research uses be established. The benefit for health will strengthen the perceived value of the electronic care record in the opinion of the public.

These recommendations will, if pursued energetically, start to reverse the damage that has been done in recent years and give the UK the chance to be, once again, the front runner in the field of research in population health.

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