

UNLOCKING PATIENT DATA FOR BETTER CARE AND RESEARCH



Sir Mark Walport
Director, Wellcome Trust

On 5 December 2011, the Prime Minister launched the *Life Sciences Strategy*, a comprehensive package of actions that has the potential to transform healthcare innovation in the UK. A series of proposals address funding for translation, streamlining of regulation, and the development of skills and careers. A review of innovation in the NHS, published at the same time, makes a number of much-needed recommendations to encourage the adoption and diffusion of innovative ideas and new technologies in the NHS.

I am delighted to see the Government recognise the importance of the life sciences sector, particularly at a time of economic difficulty. But the recommendations that I am most excited about are those designed to increase access to patient data for research. Research charities have been calling for this for many years.

Using patient information integrated from general practice and hospital clinics to provide and monitor clinical care can be immensely powerful. It can provide rapid and important benefits to patients in improving the quality of care. For example, Scotland has a real-time clinical information system on its diabetes patients. From this we know that there are 246,328 patients with diabetes in Scotland. The database also ensures earlier diagnosis and more targeted treatment. Evidence from Tayside shows a 40 per cent reduction in amputations due to complications with diabetes, over six years; and a 43 per cent reduction of people needing laser treatment for eye

disease that threatens sight.

Patient records can also be an extremely valuable resource for research – research that is essential if the NHS is to deliver the best possible healthcare. Data are used for epidemiological research, to understand more about the causes of disease, to detect outbreaks of infectious diseases, to monitor the safety and efficacy of drugs, and to study the effectiveness of treatments and interventions. Patient records also offer a helpful starting point to identify potential recruits to invite to take part in a clinical trial or cohort study.

Wherever possible, researchers use anonymised, non-identifiable information. But we cannot avoid the fact that sometimes researchers working as part of clinical teams will need to access data from which it may be possible, directly or indirectly, to identify a patient. For example, a study of 33,000 children showed that those who lived close to a power line at birth had an increased risk of leukaemia.¹ This study involved information that a child of a

particular age lived at a particular postcode. Together, these two pieces of information could lead to the identification of individual children, but it would not have been feasible – or proportionate – to seek individual consent from all 33,000 families.

Until now, access to this type of information has been locked up in red tape. Researchers have faced considerable uncertainty, and a lack of consistency, about the processes that should be used when information from patient records is required for research. The issue of inviting patients to take part in research has been particularly problematic. Researchers may need to review medical records to determine whether patients meet the eligibility criteria for the study, such as diagnoses, age or gender. However, because this may involve viewing identifiable information, researchers have often been prevented from accessing the data. Once potential participants have been identified, GPs are sometimes required to contact patients in the first instance to ask whether

they are happy to be contacted at a later time with information about a study. Only after this initial contact can researchers contact patients to invite them to participate in the study. The *Data Sharing Review Report* (Thomas and Walport, 2008) described this need for 'consent to gain consent' as a 'problem that requires a solution'.

We need to ensure that unnecessary and inappropriate bureaucracy such as this does not prevent vital research. Of course, medical records are both personal and sensitive, and everyone agrees there must be safeguards for confidentiality. But mechanisms are already in place to ensure this. An ethics committee assesses the risks and benefits of every individual research study before it can proceed. In situations where it is not possible to seek informed consent to use identifiable records, researchers must apply for special permission to the Ethics and Confidentiality Committee of the National Information Governance Board.

That is why we welcome the actions announced in the Chancellor's *Autumn Statement* and the Government's *Life Sciences Strategy*. The reports commit to the provision of secure data linkage services by the Health and Social Care Information Centre. This service, which will link primary and secondary healthcare datasets, will deliver data extracts at an unidentifiable, individual level. It will be available to all users of health and care information and will operate on a user-pays basis by September 2012. In addition, the Clinical Practice Research Datalink (CPRD), a new secure data service, will be established within the Medicines and Healthcare Products Regulatory Agency (MHRA) to service the

specialised needs of the research and life sciences communities.

Perhaps more importantly, there will also be a consultation on amending the NHS Constitution to introduce a default assumption that patient data can be used for approved research, and patients approached about taking part in research studies. This would be on an 'opt-out' basis and should solve the difficulties of 'consent for consent'.

This is a huge step forward. The aim to make every NHS patient a willing research participant is absolutely the right one. As the NHS *Innovation Review* points out, 'the greater the number of patients involved in research, the wider the public benefit'. But if this aim is to be achieved, we must work together to ensure public trust is maintained. The press coverage immediately after the announcements suggests that this will not be an easy task.

Public attitudes are varied, but do generally appear supportive of research using personal information. A Wellcome Trust Monitor survey in 2009 of 1,179 UK adults found that 74 per cent were willing to allow access to their medical records for medical research.² This is backed up by results in practice. The General Practice Research Database (GPRD) has been collecting data on over 3.6 million patients from more than 450 primary care practices, using an opt-out system similar to that proposed in the NHS Constitution. The opt-out rate is less than 1 per 1000 patients.

The evidence also suggests that patients do not mind being contacted about research projects.

Of nearly 60,000 people invited to take part in the pilot phase of UK Biobank, only 0.1 per cent asked how they had been selected or how their name and address had been obtained. Very few of these people had serious concerns, and the majority of the telephone respondents went on to participate following discussion of their questions. Twenty-five per cent of the people who were invited to participate responded to the primary invitation letter. The situation was similar with the UK Collaborative Trial of Ovarian Cancer Screening. Of 1.2 million women invited to participate, only 32 complained about being contacted. An Ipsos MORI poll earlier this year found that, of 990 people over the age of 15, 80 per cent were definitely or probably happy to be approached about research that would involve allowing a researcher confidential access to their medical records for health research.³

Research charities, clinicians, academics and the Department of Health must work together over the coming months to ensure the importance of research using patient records is communicated effectively, and to reassure patients that the confidentiality of their data will be safeguarded. As a first start, the UK Clinical Research Collaboration has developed leaflets to increase understanding of the use of personal data in research.⁴ These leaflets have been distributed to GP surgeries across England, Wales and Scotland.

The other potential hurdle is a legislative one. We must ensure that the revisions to the European Data Protection Directive, and any resulting

changes to the UK Data Protection Act, do not undermine this progress. The current legislative framework is complex and confusing, and needs urgent simplification. The revisions must develop a clearer definition of 'personal data'; clarify the status of anonymised and pseudonymised data in research; and make adequate provision for research access.

We need to strike a better balance between the right to privacy and the sharing of information for the public good in health research. A cancer patient once said to me, 'giving my anonymous data is the most painless thing I can do to help others get better'. We must work together to ensure that giving data is easier than giving blood. The recent announcements are an excellent step in the right direction.

References

- 1 Draper G, Vincent T, Kroll ME & Swanson J (2005) 'Childhood cancer in relation to distance from high voltage power lines in England and Wales: a case-control study'. *BMJ* 330:1290-1294
- 2 <http://www.wellcome.ac.uk/About-us/Publications/Reports/Public-engagement/WTX058859.htm>
- 3 <http://www.ipsos-mori.com/researchpublications/researcharchive/2811/Public-support-for-research-in-the-NHS.aspx>
- 4 <http://www.ukcrc.org/patientsandpublicawareness/patientdata/>

