

1. Introduction

The Academy of Medical Sciences welcomes the opportunity to respond to the House of Commons Health Committee Inquiry into the Electronic Patient Record and its use. The Academy's core objectives are to promote advances in medical science and ensure that these are converted as quickly as possible into healthcare benefits for society. Our focus is therefore on the research aspects of the Committee's Inquiry and our submission will concentrate on the fourth area of the terms of reference: *'How data held on the new systems can and should be used for purposes other than the delivery of care, e.g. clinical research'*.

2. The use of patient health records in research was the subject of a recent major study by the Academy, chaired by Professor Robert Souhami CBE FMedSci and involving a working group of senior researchers and clinicians.¹ The study culminated in the publication of a report, *'Personal data for public good: using health information in medical research'*, which is enclosed with this submission.² Publication was followed in June 2006 by a symposium involving senior members of the legal profession, including barristers, solicitors, academics and members of the judiciary, the report of which is also enclosed.³
3. *'Personal data for public good'* describes in detail how information contained in patient records provides much of the evidence on which improvements in healthcare are based. This kind of 'secondary research' has identified important causes of disease, led to effective measures for control of epidemics, demonstrated the long-term effects of treatment, and shown how the health of the population can be improved by better services. The late Sir Richard Doll OBE FRS FMedSci put it thus: *'Much of the research on the effects of ionising radiation and the use of oral contraceptives, leave alone smoking, would have been impossible without the facility of obtaining unbiased access to medical records'*.

4. Opportunities and challenges

The UK already has an outstanding record in population-based research and epidemiology. The development of the National Programme for IT (NPfIT) and the Electronic Patient Record offer unparalleled opportunities for research that could have a real and significant impact on future health in the UK. In 2005, the Chancellor of the Exchequer, Gordon Brown, and the Health Secretary, Patricia Hewitt, stated a new commitment to develop the capability within NPfIT to facilitate *'the gathering of data to support groundbreaking work on the health of the population and the effectiveness of health interventions'*.⁴ This was reflected in Sir David Cooksey's Review of UK Health Research, which identified an essential need *'to ensure that research is fully embedded in and integral to the NHS IT programme, and prioritised on a par with other service uses for the system.'*⁵

¹ For further details see <http://www.acmedsci.ac.uk/p48prid5.html>

² Further copies can be downloaded from <http://www.acmedsci.ac.uk/images/project/Personal.pdf>

³ Further copies can be downloaded from <http://www.acmedsci.ac.uk/images/project/1170326729.pdf>

⁴ http://www.hm-treasury.gov.uk/newsroom_and_speeches/press/2005/press_100_05.cfm

⁵ Sir David Cooksey (2006) *A review of UK health research funding*. The Stationary Office, London
<http://www.acmedsci.ac.uk/images/project/1170326729.pdf>

5. However, the Academy is concerned that a number of factors, including confusing legislation and professional guidance, bureaucracy of process and an undue emphasis of privacy and autonomy, are having a detrimental effect on UK research activity in this area. The report '*Personal data for public good*' describes how disproportionate constraints on the use of health information can compromise the quality and validity of research results, leading to potentially misleading claims, or even costing lives. The UK must avoid mistakes made elsewhere, for instance the decision by the Hyogo prefecture in Japan to halt cancer registration on the basis of privacy concerns, which led to delays in the detection of a significant cluster of asbestos-related mesothelioma cases.
6. There is no doubt that information held in electronic health records can be extremely sensitive; inappropriate use or disclosure of such information has the potential to cause embarrassment or distress. Experience or fear of inappropriate disclosure might induce patients to withhold information from a health professional or even avoid treatment altogether. We also note that the introduction of more pervasive CCTV, aggressive use of data for commercial marketing purposes and the national debate over identify cards have all influenced the climate in which issues related to research using health information are discussed.
7. Policies that emphasise choice within healthcare focus on the value of individual autonomy. But this emphasis presents challenges for activities such as medical research, which are performed for public, rather than individual, benefit. It could be maintained that a patient has the right to say 'use my data to treat me, but not to improve care for others'.⁶ Or more starkly, 'use evidence from other people's data to treat me, but don't use my data to help them.'
8. In the following sections, we outline some of the considerations around consent, confidentiality and anonymisation that should be taken into account during the development of systems supporting the Electronic Patient Record. We also share our hopes and concerns for the Secondary Uses Service and Care Record Development Board, before discussing ways forward and the need for public engagement.
9. **Using patient records in research: consent**
Consent is quite rightly the cornerstone of all interventional research involving human subjects, including clinical trials and invasive investigations. However, the nature of records-based research can make obtaining consent unfeasible or impracticable. For instance, 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.⁷ 3000 of the patients had died and the population had dispersed, making obtaining consent impractical in most cases and impossible in some. The results of Professor Barker's research have linked low birth weight with risk of hypertension, type II diabetes and other disorders in adult life.
10. Seeking consent can also bias a dataset, leading to misleading results. For example, until 2001 there was a great deal of 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

⁶ Detmer D (2000) *Your privacy or your health – will medical privacy legislation stop quality health care?* International Journal for Quality in Healthcare **12**, 1–3.

⁷ Barker D (2003) *The midwife, the coincidence and the hypothesis.* British Medical Journal **327**, 1428–9.

disclose information about termination than women without cancer. It was only when a data linkage study was done on records accessed without consent that the absence of risk was demonstrated conclusively.⁸

11. Using patient records in research: confidentiality and anonymisation

All patient records must be handled in a manner that reflects obligations and expectations of confidentiality, namely that:

- Effective procedures are in place to prevent the unintentional disclosure of sensitive data.
- Data are only used for authorised purposes.
- Those handling data understand and respect patients' interests.

12. Many guidance documents now emphasise anonymisation of data (i.e. stripping the data of any identifiers) as the preferred approach for records-based research. However, we emphasise that anonymising data is only one component in protecting confidentiality and can sometimes compromise the integrity of the research.

13. There may be several reasons why constructing a research dataset would require access to identifiable information:

- **To assess/avoid double counting.** For example, congenital anomaly registers were set up in response to the thalidomide tragedy and are essential in identifying teratogenic exposure in pregnancy. Many of the anomalies only come to light later in life so data must be collected from paediatricians, midwives, genetic counselling services and many other sources. In many instances, notification of the same individual will be received from several sources and matching reliable personal information is the only way to identify duplicates and avoid double counting.⁹
- **For longitudinal research.** Without long-term research based on large, complete datasets the risks of occupational, environmental or social factors would not be known with certainty. This is exemplified by studies on the health of coal miners¹⁰, fluoridation of water¹¹ and social distribution of cancer.¹² Understanding how exposure to a risk factor influences later health requires that information on an individual be updated over time. This is impossible if data are irreversibly anonymised.
- **For validation.** The quality of the data contained in health records can vary significantly, and the ability to test the validity of a sample of records is essential. This is generally done by taking a random sample and retrieving the original records to confirm that data subject x really is data subject x. This can only be achieved using identifiers to match the records.
- **Identifiers contain useful information.** Many of the identifiers that might be stripped from data during anonymisation are useful to research.¹³ For instance, postcode, date of birth, date of death and occupation are all routinely used as important factors in analysing

⁸ Goldacre M J, Kurina L M, Seagroatt V & Yeates D (2001) *Abortion and breast cancer: a case-control records linkage study*. *Journal of Epidemiology and Community Health* **55**, 336–7.

⁹ Richards I D, Bentley H B & Glenny A M (1999) *A local congenital anomalies register: monitoring preventive interventions*. *Journal of Public Health Medicine* **21**, 37–40.

¹⁰ Fox A J, Goldblatt P & Kinlen I J (1981) *A study of mortality of Cornish tin miners*. *British Journal of Industrial Medicine* **38**, 378–80.

¹¹ Kinlen L & Doll R (1981) *Fluoridation of water supplies and cancer mortality.III: A re-examination of mortality in cities in the USA*. *Journal of Epidemiology and Community Health* **35**, 239–44.

¹² Kinlen L J (1988) *The longitudinal study and the social distribution of cancer*. *British Medical Journal* **297**, 1070.

¹³ Ohno-Machado L, Silveira P S & Vinterbo S (2004) *Protecting patient privacy by quantifiable control of disclosures in disseminated databases*. *International Journal of Medical Information* **73**, 599–606.

population health data, but are stripped out when data are anonymised.

14. This final point illustrates that 'anonymised' and 'identifiable' are not distinct categories of data. There is no consensus guidance on the identifiers that should be stripped from a dataset to render it anonymised, and, as illustrated above, removing potential identifiers can leave the data unusable for research purposes.

15. Secondary Uses Service and Care Record Development Board

The Secondary Uses Service (SUS), which is being delivered as part of NPfIT through NHS Connecting for Health, is 'a system designed to provide timely, pseudonymised, patient-based data and information for management and clinical purposes other than direct patient care'. The plan is for information from SUS to be available in pseudonymised form to researchers.¹⁴ It will also provide results of standard and bespoke analyses, as well as extract anonymised data sets on behalf of researchers and other users.

16. One aim of SUS is to reduce the overall burden on local NHS services of data collection, abstraction and submission by centralising and automating these processes. However, the Academy seriously doubts whether SUS will be able to provide the flexible access needed to allow existing research methods to be applied to the new datasets. The plan relies on SUS undertaking much of the work currently done by research groups, such as linkage, validation and additional data collection from patients. Although this is theoretically possible, we doubt that it will be a high priority among the other calls on the resources of SUS, not least the implementation of 'Payment by Results'. Researchers have also expressed concern that the different IT systems being developed in England and the devolved nations will not be sufficiently compatible and integrated to allow UK-wide research.
17. Given these concerns, the Academy welcomes the formation of the UK Clinical Research Collaboration (UKCRC) R&D Advisory Group to Connecting for Health, which followed an explicit recommendation in our 2006 report.¹⁵ The Advisory Group, which is chaired by Professor Ian Diamond, is tasked with 'obtaining and presenting evidence to help prioritise the research agenda in future development commissioning of the NHS Care Records Service'. The Group is now completing a series of simulations designed to interrogate the NHS Care Records Service (including the Secondary Uses Service) for its suitability to support research. These simulations cover research applications in observational epidemiology, clinical trials, surveillance and prospective tracking of a cohort (longitudinal research). We look forward with interest to the publication of the results of these simulations in March, which we hope will address concerns around data quality (completeness, validity and reliability), removal of identifiers and data linkage, as well as issues of information governance. We urge careful examination of the Research Simulation Report by the Health Committee and on the part of all those involved.
18. We are also aware of a forthcoming report from the Care Record Development Board Working Group on the Secondary Uses of Patient Information. The date of publication is to be confirmed, but might be in April 2007. This is likely to make a number of recommendations on governance issues around

¹⁴ In this context pseudonymised data cannot be used by the holder of the data to identify an individual. However, the original provider of the data (in this case SUS) retains a means of identifying individuals. This will often be achieved by attached codes or other unique references to information so that the data should only be identifiable to those with access to the code or key.

¹⁵ See <http://www.ukcrc.org/activities/infrastructureinthenhs/nhsitprogrammes/advisorygroup.aspx>

researchers' access to information in the Secondary Uses System, which we hope will take into consideration issues of consent and anonymisation raised in the Academy's 2006 report and summarised above.

19. **The Care Record Guarantee**

The Academy has previously expressed significant concerns about the Care Record Guarantee, which has been drawn up and published by the Care Record Development Board (CRDB).¹⁶ The Guarantee sets out for the public the rules that will govern information held in the NHS Care Records Service (CRS) and will be the basis for an information campaign intended to reassure the public about the confidentiality of the system.

20. We are concerned that the current version of the Guarantee seems to be based on the assumption that all work with identifiable data will be accomplished within SUS and that research and public health users will be only supplied with anonymised output from SUS. It includes statements that seem to preclude any use of CRS data outside the NHS for research purposes. We welcome the mention in the document that data might be used to '*help with research*'. However, we are concerned about the explicit pledge that the new IT system will '*allow only those involved in your care to have access to records about you from which you can be identified*'. A public statement of this kind invalidates the legal basis on which public health professionals and clinical researchers currently access identifiable data for research and is therefore of grave concern.

21. We have previously recommended that the current wording of the Guarantee should be revised to make a clear distinction between *bone fide* researchers acting in the public interest and 'third parties' who should not be permitted access to records (e.g. employers, insurers, the press and other members of the public). We strongly urge the promotion of the benefits of research during the Care Record Guarantee public engagement campaign.

22. **The way forward: engaging the public**

The public, patients and researchers have a common interest in ensuring that research involving patient records is conducted efficiently and to the highest standards. NPfIT and the Electronic Patient Record offer an exceptional opportunity to allow research to inform all aspects of healthcare. However, the Academy is concerned that research needs are not being integrated into the development of these programmes.

23. The basis for accessing and using the Electronic Patient Record for research depends upon public expectations of what is involved. The public is largely unaware of the regulation that underpins research of this kind, including the role of ethics committees, NHS data controllers and Caldicott Guardians, as well as the Patient Information Advisory Group. Evidence of public attitudes towards the use of health information in research is largely absent, forcing regulatory bodies to make assumptions about what the public might find acceptable. There are two large studies - by Shickle *et al*¹⁷ and Barrett *et al*¹⁸ - which are noteworthy because of the rigorousness of the methodology and the focus of the questions. We also warmly welcome recent studies undertaken by the Wellcome Trust and Medical Research Research Council to

¹⁶ See <http://www.connectingforhealth.nhs.uk/crdb/docs/nhscrgenglish.pdf>

¹⁷ School of Health and Related Research (2002) *Patient Electronic Record: Information and Consent (PERIC) Public attitudes to protection and use of personal health information*. School of Health and Related Research, University of Sheffield.

¹⁸ Barrett G *et al* (2006) *National survey of British Public's views on use of identifiable medical data by the National Cancer Registry*. *BMJ*, **332**: 1068-72

investigate public perspectives in this area. We look forward to the publication of the outcomes of this work in April.

24. Urgent work is needed to increase public engagement about the value of research using healthcare records and the arrangements under which records are held and accessed. The introduction of NPfIT, the Electronic Patient Record and the Care Record Guarantee will provide valuable opportunities for such engagement. 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. In the development of the Electronic Patient Record, the Department of Health 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 recommends that a long-term programme of public engagement concerning research uses should be established. We consider that the benefit for health will strengthen the perceived value of the Electronic Patient Record in the opinion of the public.

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The Executive Director of the Academy is Mrs Mary Manning.

The Academy of Medical Sciences
10 Carlton House Terrace
London, SW1Y 5AH
Tel: +44 (0) 20 7969 5288
Fax: +44 (0) 20 7969 5298
e-mail: info@acmedsci.ac.uk
Web: www.acmedsci.ac.uk

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