
Data Sharing Review: Use and sharing of personal information in the public and private sectors**Response by the Wellcome Trust****February 2008****Introduction**

1. The Wellcome Trust is pleased to respond to the consultation on use and sharing of personal information in the public and private sectors. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research in the UK and internationally, spending around £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. In our answers to the consultation questions below, we have focused on the use and sharing of personal information in the context of biomedical and health research. Our response has been developed within the Wellcome Trust, based on our experience of supporting the research community to shape and apply good practice in the use personal information for research. In particular, the Trust has been actively working to ensure that the research potential of electronic patient records is realised and that researchers are able to take advantage of emerging new technologies such as the NHS National Programme for Information Technology being delivered by the Connecting for Health Programme. At the same time, the Trust supports public engagement activities to ensure that personal information in biomedical research is used in ways that are acceptable to the public and healthcare providers. The Trust also funds a number of large-scale longitudinal studies involving the collection and use of personal information, such as UK Biobank and the Avon Longitudinal Study of Parents and Children (ALSPAC).
3. The Trust's guidelines on Good Research Practice¹ and its policy on Data Management and Sharing² reflect our view that available data should be shared to advance research that can improve human and animal health, while taking the utmost care to protect the individual on whom research is based.
4. To simplify our response, we describe three case studies – UK Biobank, ALSPAC and Connecting for Health – prior to answering the consultation questions. These examples are referenced later in a number of our answers to consultation questions.
5. We would be happy to discuss any of the issues raised in this response in further detail if it would be helpful.

Summary of Wellcome Trust views on the use and sharing of personal information

6. There is tremendous value in sharing information for research and healthcare. The use and sharing of personal information provides the foundation for much medical research. Sharing information for research across the public sector, as well as between the public and private

¹ Available at: http://www.wellcome.ac.uk/doc_WTD002757.html

² Available at: http://www.wellcome.ac.uk/doc_WTX035043.html

sectors (e.g. pharmaceutical companies) can advance medicine and public health. Personal health information is one vital input to this, but data on factors related to health, such as housing, environment and education are also essential. The same systems of health data sharing that benefit research also directly improve the safety and quality of care for individuals involved.

7. New technologies will increase the potential benefits of sharing information for research. Sharing information through large-scale research collaborations has already produced benefits (see Case Study 2 on ALSPAC). However, new information technologies and systems are providing far greater quantities of useful information, which if shared for biomedical research, could deliver even greater health benefits in the future. For example, electronic patient records – currently being developed in the UK through Connecting for Health – will be able to serve as a rich source of data for biomedical research, in addition to directly improving patient care and patient safety. Technological advances are also allowing rapid sequencing of a tremendous amount of genetic information, including full genomes of individuals. The 1000 Genomes Project, which involves the Wellcome Trust Sanger Institute, will sequence the genomes of 1000 different people. In combination, these growing information resources could serve as the basis for very significant breakthroughs in our understanding of human health and disease.
8. New opportunities for sharing data require new approaches to protect individuals' privacy. Systems for protecting the privacy of individuals must be integral to efforts to take advantage of the new data becoming available for biomedical research. There are still questions about when it is necessary to seek peoples' consent to use information about them for research, and in what circumstances they must be re-approached for consent for further uses. Procedures for anonymising data used in biomedical research are well established but new issues are emerging around methods for safely storing, accessing and sharing data.
9. The Wellcome Trust and other organisations are now working to address these emerging issues. The Trust is now providing funding for both dialogue and research to develop the use of personal information in biomedical research in a way that is acceptable to the individuals involved. The Trust has supported discussions between biomedical researchers, healthcare providers, government and industry on the use of electronic patient records in research. We hosted a conference on this subject in May 2007³ and are planning a consensus workshop for GPs and biomedical researchers in May 2008. The Trust has launched a new funding initiative on Electronic Patient Records and Databases in Research⁴, in partnership with other UK funders, to stimulate and support the use of electronic patient records for health research. As part of this initiative, the Trust will support public engagement activities to explore the issues around the use of patient records in research, as well as training programmes/ workshops to develop methods and technologies.
10. The Trust has provided support and input to many studies, reports and consultations on the subject of using patient records for biomedical research. A list of recent studies and reports, some of which we cite elsewhere in our response, is provided as **Annex A**.

³ A report of this conference, titled "Use of electronic patient records for research and health benefit" is available at: <http://www.wellcome.ac.uk/assets/wtx039410.pdf>. A video of the conference is available at: http://www.flyonthewall.com/FlyBroadcast/wellcome.ac.uk/UKCRC_FrontiersMeeting/.

⁴ Details on the funding initiative are available here: <http://www.wellcome.ac.uk/node2168.html>.

Case Study 1: UK Biobank

UK Biobank is a research project that has developed a strong set of controls for protecting participant confidentiality while sharing data for medical research. Funded by the Wellcome Trust in collaboration with the Medical Research Council (MRC), the Department of Health and the Scottish Executive, UK Biobank is a large-scale study designed to identify genetic, environmental and behavioural factors involved in a range of common illnesses such as diabetes, heart diseases, arthritis and dementia. UK Biobank will involve 500,000 people, currently aged 40-69, from around the UK and will examine how their health is affected by their lifestyle, environment and genes. Personal information and tissue samples gathered in the course of the study will be stored anonymously, linked to each person's identity only by a code.

Biobank will track participants' health by accessing, with their informed consent, medical records and other information sources, so it is necessary to be able to connect participants with their information and samples. Only a very small number of Biobank staff will have access to the codes that link data on participants with their identities and these codes are held securely. External researchers using Biobank resources will only have access to anonymised data and samples. To further protect participants, research conducted on the Biobank data and samples will need to be approved by the Biobank Ethics and Governance Council. The Council is an independent advisory group set up to advise the project and to publish periodic reports on the conformance of Biobank with its Ethics and Governance Framework and with the interests of participants and the public.

Biobank is now enrolling participants. Before commencing recruitment, however, Biobank researchers had to work through some uncertainty to arrive at a procedure for inviting people to join the study. In order to identify eligible individuals for many biomedical studies, including Biobank, it is necessary to draw on health records held by GPs or the Department of Health. The Patient Information Advisory Group (PIAG) is currently in place to provide advice on the use of patient information for purposes such as this, but its recommendations were not workable for a project of Biobank's scale. The existing procedure would have required the GP of each potential participant to contact him or her in the first instance, to ask for consent to share his or her contact details with Biobank so that he or she could be invited into the study. If the potential participant agreed to this, Biobank would then be allowed to make direct contact to actually invite the individual to participate. Because it would not be possible to recruit 500,000 people to Biobank in this way, Biobank researchers worked with the Department of Health to obtain direct contacts for potential participants. This is working well. In the course of recruitment, only a very small number of people invited to participate have expressed any concern about having been contacted directly, and senior Biobank research staff are available to talk with those who do raise concerns. Although the Biobank recruitment arrangements have worked satisfactorily, the initial uncertainty highlighted the need to establish greater clarity for future large-scale studies.

Biobank provides a good model for balancing participants' access to information about themselves. Upon enrolment in Biobank, participants provide blood and urine samples, and undergo a physical examination. Results of the physical examination – such as blood pressure and lung function – are provided to the patients (unless they do not want to know). However, participants are informed in advance that they will not be provided with any results from genetic or biochemical analysis conducted on their blood and urine samples in the future. It is not yet known exactly what types of analyses will be performed on these materials, or when, and making it easy to identify the materials with individuals (a prerequisite for informing them about genetic results) would weaken the confidentiality of their information. Participants are also informed that their information may be used by pharmaceutical companies as well as by academic researchers.

Case Study 2: Avon Longitudinal Study of Parents and Children (ALSPAC)

The Avon Longitudinal Study of Parents and Children (ALSPAC) has been running since 1991 and, like Biobank, has well-developed methods to support the sharing of data to enable groundbreaking research while protecting participants. In 1991, about 14,000 expectant mothers living near Bristol were recruited into the study. Their children have been followed from the time of birth to examine the genetic and environmental pathways that predispose children to a range of medical conditions. Since it is known that all of the participants were born in 1991 and 1992, and lived near Bristol, special care must be taken to preserve their anonymity. Researchers using the data and tissue samples gathered from participants have access only to anonymised versions, and the ALSPAC study team reviews all research reports based on the ALSPAC sample before they are published to ensure that they do not jeopardise confidentiality.

Findings derived from ALSPAC demonstrate some of the societal benefits of sharing personal information from a very small population for medical research. Some of the findings from the study have included:

- Parents who smoke, even passively, are likely to take longer to conceive a child.
- A vegetarian diet during pregnancy may not be good for the developing fetus.
- Eating oily fish and breast-feeding improves a child's eyesight.
- Putting babies to sleep on their backs reduces the risk of cot death.
- Weaning babies onto lumpy foods while less than nine months old leads to fewer eating problems later in life.
- Children brought up in very hygienic homes are more likely to develop asthma.
- Nut and peanut allergies are much more common than previously thought, and in 90 percent of cases are preceded by eczema, suggesting that peanut oil-containing skin creams may be responsible.

Case Study 3: Use of electronic patient records for research and health benefit

With over 50 million people represented, medical information held by the NHS is an extremely valuable resource for biomedical research if it can be shared appropriately. Secure systems to facilitate access to electronic NHS patient data for research will be highly beneficial – both for improving patient care and public health directly, and for advancing medical knowledge. Connecting for Health, which has been set up to deliver the NHS National Programme for IT (NPfIT), includes a Research Capability Programme that offers great promise. This would establish a 'safe haven' to hold data that are being used for research. Limited amounts of data could be transferred to this secure computing system from the main Connecting for Health resource as and when they are requested for legitimate research purposes. Researchers would only be able to use data on that secure computing system and an 'honest broker' – who has dual responsibilities to protect patients and deliver accurate data for research – would transfer data from the main Connecting for Health repository to the secure computing system.

A recent report by the UK Clinical Research Collaboration (UKCRC) Advisory Group to NHS Connecting for Health has highlighted the potential uses of NHS records data for research, including:

- Surveillance of patients responses to medical interventions;
- Improved clinical trials;
- Prospective cohort studies; and
- Observational epidemiological studies.

Section 1: Background

Question 1. Please explain what your interest in information sharing is. If you have an active involvement in personal information sharing, we would be grateful for the following information:

- What kinds of personal information do you collect, hold and share?
- How do you collect, hold and share such personal information?
- For what purposes do you collect, hold and share such personal information?

Wellcome Trust-funded research

11. Our interest in information sharing relates mostly to the biomedical and health research that we fund through grants. Researchers often require personal information to investigate factors that influence health and disease. To use medical data in research, a data collector – for example a clinician – often needs to share them with a researcher, or one researcher needs to share data with another. Depending on the aims of the study, a range of different types of personal information about participants might be involved, including for example, age, address, clinical diagnoses, physical measurements, chemical or genetic analysis of blood/tissue samples, participants’ subjective opinions and information about participants’ lifestyles or exposure to different environmental conditions. After data are collected, they are usually anonymised before being shared, in order to protect participants’ confidentiality. Anonymisation consists of dissociating the participant’s name, as well as any other information that would allow the person to be identified (e.g., address, employer, etc.), from the rest of the record. Coarsening or aggregating the data can reduce the likelihood of individual participants being associated with their records. Once anonymised, the data gathered for medical research no longer constitute ‘personal information.’
12. Sometimes special circumstances require personal information to be ‘reversibly’ anonymised; that is, identifying information is separated from a participant’s record but some type of identifying code remains with both, to allow re-linking of the records in the future. For example, in longitudinal studies, which follow up with patients multiple times throughout their lives, observations of the same person at different times must be able to be connected. Re-linking is also necessary for studies that provide participants with feedback about their personal results. Only very unusual circumstances would make it necessary to share the identifying details or linkage code (for example, if the institution holding the data could no longer maintain it and had to transfer responsibility to another organisation). In rare cases where personally identifying information is integral to the research underway and not even reversible anonymisation is possible, other safeguards are used to protect the confidentiality of personal information.⁵ These commonly include encrypting data, maintaining physical security, recording computer log-ins and holding sensitive data in non-networked computers.⁶
13. Personal information is also used to contact people to invite them to participate in some of the research that the Wellcome Trust supports (as discussed in Case Study 1 on Biobank).

Wellcome Trust direct activities

14. The Wellcome Trust itself rarely holds personal information obtained for or used in research – usually we provide funding for researchers employed by other organisations to do this. We collect and store personal information in the course of our normal business activities,

⁵ For example, an epidemiological study examining the health impacts of physical proximity to a source of toxin might require individuals’ addresses and health information, which could serve as indirect identifiers.

⁶ Discussion of anonymisation and safeguards can be found in a report by William W Lowrance titled “Access to collections of data and materials for health research”, available at <http://www.wellcome.ac.uk/assets/wtx030842.pdf>.

including data on staff (for recruitment, tax, national insurance purposes, etc.) and details about applicants and grant-holders. We have a contacts management system for communicating the Wellcome Trust's funding opportunities and a marketing database for communicating information about our public venue, the Wellcome Collection. Personal information is shared according to the terms specified in our data protection statement. Within the Wellcome Trust there is executive responsibility at Board level for these activities.

15. As the Trust monitors and evaluates funded activities, there may be situations in which we would wish to share some details of grantees with other UK funders, or vice versa. This is particularly relevant for our career development schemes where we want to track what individuals have achieved and how their career progresses over time. This will help us to assess the success of our funding and inform future funding decisions. Career tracking over time may also require us to contact grantees' sponsors, programme directors, or alumni offices to seek their help in tracing grantee destinations.

Section 2: Scope of personal information sharing, including benefits, barriers and risks of data sharing and data protection

Question 2. What in your view are the key benefits of sharing personal information to (a) individuals and (b) society?

16. (a) In the area of health, we see benefits to sharing personal information for both individuals and society. For individuals, having information about their health recorded, stored and shared with health professionals as necessary offers the potential to deliver better health care. Complete and accurate medical records can help healthcare providers better diagnose and treat an individual. Records are particularly important if a person comes into contact with the health care system in an emergency and cannot provide details of his or her medical history (e.g., prior problems, allergies, etc). We welcome the NHS effort to improve the linkage of electronic health records through Connecting for Health.
17. (b) There are clear benefits to society from sharing personal information for medical research. Analysis of information gathered from individuals and populations can elucidate interactions between health, the environment, lifestyle and genes, leading to new methods of prevention and treatment, and identifying adverse reactions to health products already on the market.
18. Members of the public appear to recognise the societal value of using personal information to advance biomedical research. In a recent survey,⁷ 60% of people in the UK reported feeling that they have a responsibility to allow their personal health information to be used in medical research, and 69% reported that they would be 'likely' or 'certain' to allow their personal health information to be used for research purposes.
19. The biomedical research community has a duty to draw upon existing data sources in order to avoid the need for volunteers to enroll in unnecessary studies and to identify interventions that may be causing patients problems (i.e., enable better pharmacovigilance).

Question 3. What in your view are the key risks of sharing personal information to (a) individuals and (b) society?

⁷ Ipsos MORI, The Use of Personal Health Information in Medical Research: General Public Consultation. June 2006.

20. (a) In terms of personal information shared for biomedical research, the key risk to individuals is that sensitive health information might be released to unauthorised users and result in the research participant being stigmatised, emotionally harmed or financially disadvantaged (for example, being refused life insurance or being charged higher premiums). In medical research involving genetic analysis, there is a risk that research will provide information about familial disease susceptibility to other family members who do not want to know about it. It is very important that strong systems are in place to ensure the confidentiality of any personal information.
21. (b) The key risk to society is that if some personal information collected for biomedical research were inappropriately accessed, it might result in widespread reluctance to participate in research. Alternatively, it might lead to disproportionately prescriptive prohibitions that would block the conduct of valuable biomedical research involving human participants. This could cause medical research with the potential for enormous public benefit to be hampered or discontinued. This may be particularly true where confidentiality inhibits the collection and use of information that would be likely to benefit the very individuals who are the intended subjects of protection.
22. When making decisions about data sharing, an analysis of its risks and benefits should be one of the issues included in the assessment, and decisions should not be disproportionately cautious. There is a need for a regulatory framework that takes into account risks and inspires public confidence, but that is still coherent and proportionate.

Question 4. As mentioned in the introduction, there are wide variations in the scope and methods of personal information sharing. What scope and methods, in your view, pose the greatest opportunities or risks? Please explain the reasoning behind your response.

23. As the UK Clinical Research Collaborative (UKCRC) recommended in its report on the potential for electronic patient records to benefit research,⁸ data that is shared must be accurate and based on a set of standards for recording and processing. It is also essential that data be stored anonymously whenever possible.

Question 5.

No comments.

Question 6.

No comments.

Question 7. Please provide examples of cases where you believe the sharing of personal information between two or more bodies would be beneficial, but where it is not currently taking place.

24. As discussed in Case Study 3 on electronic patient records, the development of electronic patient records within the NHS offers great promise for advancing biomedical knowledge and public benefit. If federated with other data repositories held by the Government or other organisations, for example, environmental data, cancer registries and public health observatory data, NHS records could provide an even more powerful resource for illuminating factors that influence health.
25. Aside from sharing personal information from different sources in order to conduct research, there is also a need to provide better mechanisms to recruit participants for research. There is currently some confusion around when the Department of Health or GPs are allowed to provide patients' contact details to researchers so that the researchers can invite patients to

⁸ <http://www.ukcrc.org/publications/news/electronicpatientrecords.aspx>

participate in studies – so-called ‘consent for consent’. In the past, GPs have sometimes been required to contact patients in the first instance to ask if they are happy to be contacted at a later time by researchers. Only after this initial contact are researchers allowed to re-contact the patients to invite them to participate in the study. The presence of this initial step can be a substantial barrier to conducting research because GPs often do not have the time to do this and it can add considerable expense. Furthermore, experience from the UK Biobank recruitment has shown that patients are happy for their contact details to be passed to researchers so that they can be contacted directly (see Case Study 1 on Biobank). It would be very helpful if the Government could provide clarity about the recruitment of participants, given the public benefits likely to arise from the research and the lack of detriment to individuals involved.

Question 8.

No comments.

Section 3: The legal framework

Question 9. In your view, how well does the DPA work? Please outline the DPA’s main strengths and weaknesses and any proposals for changes you would like to see made, including suggestions for their implementation.

26. The DPA has raised awareness of good practice in managing personal information, which has been beneficial. However, it is important that the DPA is applied in the spirit in which it was intended – and not used to block potentially useful activities that would benefit individuals and society. The management of data must be proportional to risks involved. The DPA appears to work particularly well in the context of commercial organisations but works less well in the context of organisations using personal information for the public benefit.
27. There are a few areas in which the DPA remains unclear and can lead to confusion, such as the definition of ‘marketing’ and how genetic data should be treated.

Question 10.

No comments.

Question 11.

No comments.

Question 12.

No comments.

Question 13.

No comments.

Question 14. Are there any statutory powers unavailable that would enable better and more secure sharing of personal information – for example for identity authentication purposes – between (a) public authorities and (b) public authorities and private organisations? If so, what are they?

28. The second principle is key to the DPA and remains valuable. However, it is important that it is made clear when it is acceptable to share personal data in the context of recruiting participants for medical research so that activities that benefit the public are not unnecessarily blocked.

29. In health care and research, mandatory use of NHS patient numbers would be very beneficial, as recognised in the first recommendation of the report by the UKCRC Research and Advisory Group to Connecting for Health.⁹ Consistent use of NHS patient numbers would ensure that healthcare providers have a full medical history available when caring for patients. This would also substantially improve the usefulness of health data for medical research, as it would enhance the quality of data, by avoiding accidental fragmentation of records and allowing connections between data about the same patient when he or she is registered at different practices.

Question 15.

No comments.

Section 4: Consent and transparency

Question 16. Is it clear whether and when you need individuals' consent to share information about them? Are you clear about the form that consent should take? Please provide examples.

30. The requirements for obtaining consent from individuals to invite them to participate in medical research are not entirely clear. As the Academy of Medical Sciences stated in its report *Personal data for public good: using health information for medical research*,¹⁰ "The legal framework around the use of personal data in research is a complicated patchwork involving UK legislation, case decisions and European directives, augmented by various guidance documents. There are many areas of imprecision, and the courts have not tested the legislation as it applies to medical research." As a result, regulatory and professional bodies have tended to promote a very cautious approach to using medical data for research, applying a policy of 'consent or anonymisation,' even though this is not strictly a legal requirement.
31. All participants in Wellcome Trust funded research must give prior informed consent. For some subsequent uses of information gathered in the course of studies, it is not entirely clear whether "re-consent" is required to use the data for purposes not covered in the original process of consent. Where personal information is collected and then used for further public benefit, it would be useful to have guidance on whether further consent is needed.
32. Through our Biomedical Ethics Programme, the Trust funds work exploring issues involved in informed consent. Recent projects in this area include: a study of informed consent and genetic data by Baroness Onora O'Neill; a study of didactic vs. informed choice invitations to screening by Professor Theresa Marteau of King's College; and a study of public attitudes to research governance by researchers from the University of Surrey.¹¹

Question 17. What, if any barriers would a requirement for getting consent create to the sharing of personal information? Please explain your reasoning.

33. As mentioned in our response to question 7, the requirement for getting consent to share personal information for recruitment can be a serious barrier to conducting medical research studies. Since studies typically need to enrol people with certain characteristics (age, health

⁹ The UKCRC report is available at:

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

¹⁰ Report available at: <http://www.acmedsci.ac.uk/p48prid5.html>

¹¹ "Public Attitudes to Research Governance: A qualitative study in a deliberative context," which is available at: <http://www.wellcome.ac.uk/assets/wtx038443.pdf>.

condition, etc.), it is often necessary to approach GPs to identify eligible patients. If GPs are unable to provide these contact details to researchers directly, and instead must introduce the additional step of approaching them for consent, this makes it much more difficult to complete the recruitment. (see Case Study 1 on Biobank).

Question 18. Do you have any suggestions on how to make the sharing of information more transparent? For example, should individuals be given strengthened access rights? And if so, how? Should organisations be expected to do more to explain their use and sharing of personal information to the public? And if so, how?

34. In the context of biomedical research, we agree that people should be fully informed about how information about them will be used, including whether or not they will have access to it and what systems are in place to keep their personal information confidential.
35. However, in many cases (including Biobank) it is not appropriate or even possible for research participants to have access to all information collected and/ or discovered about them. For this reason, we do not consider strengthened access rights to be the proper approach for biomedical research. Facilitating access to identifiable information for research participants would weaken the systems keeping their personal data anonymous, could result in people receiving medical information without appropriate counselling and misinterpreting it, and in some studies, could serve as an undue inducement for participating in the research.

Question 19. How can we best ensure that information sharing policy is developed in a way that ensures proper transparency, scrutiny and accountability? For example, in your view, how valuable is the Information Commissioner's recently published Framework code of practice for sharing personal information? In your view, how valuable are privacy impact assessments along the lines announced by the Information Commissioner on 11 December?

36. In the area of biomedical research, we believe that it is important to engage healthcare providers in developing appropriate guidelines for sharing information and discussing the issue with patients. Two recent studies commissioned by the Wellcome Trust¹² and the MRC¹³ found that public awareness of the use of patient records for research is low. GPs can play an important role in this area by explaining to patients the ways in which their records might be used for research. In order to help facilitate this the Trust is working with the Royal College of GPs and the British Medical Association to hold a consensus workshop to develop guidelines for best practice in the use of patient records for research in general practice.

Section 5: Technology

Question 20. What impact in your view have technological advances had on the sharing and protection of personal information? Please provide examples.

37. With enhanced computing power, there is greater potential for taking advantage of large data sets for research. As discussed elsewhere in our response (see Case Study 3 on e-health), new information technology infrastructure for capturing high quality patient records has great potential to enhance sharing of information for biomedical research and improving patient care.

¹² Public Attitude Towards Research Governance: A Qualitative Survey in a Deliberative Context: http://www.wellcome.ac.uk/doc_WTX038446.html

¹³ The Use of Personal Health Information in Medical Research: General Public Consultation: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003810>

38. In the area of genetics, research data are now posted publicly online, often immediately after they are generated, and we strongly support this. However, as technology advances, it may become possible to identify individuals from the results of genetic analysis, particularly if full genome scanning becomes more common. This is a theoretical issue at present, as the genetic data currently available could not be identified with the person from whom they were obtained.

Question 21. Should the law mandate specific technical safeguards for protecting personal information? For example, should there be an explicit requirement that all personal information held on portable devices be encrypted to a particular standard?

39. Best practice guidance would be more appropriate than legal mandates for recommending specific technological standards. Technology in this area has advanced rapidly and is likely to continue to do so, which would make it difficult to mandate a particular standard.

Question 22. How, in your view, could 'privacy enhancing technologies', such as the anonymisation or pseudoanonymisation of personal information, help safeguard personal privacy, whilst facilitating activities such as performing medical research? Is sufficient advice about the deployment of such techniques available? Are you confident about using them? What are the barriers to using them?

40. As discussed previously, anonymisation of personal information is widely practiced in biomedical research. This has proven to be an effective way of safeguarding personal information while facilitating research. In the case of reversible anonymisation, where there is a key to connect anonymous data with the individual from whom it was obtained, the key must be kept secure and access to it must be strictly limited.
41. Further methods are being implemented and developed to allow researchers to access data sources for research, while protecting personal information. As part of the Research Capability Programme for Connecting for Health, a 'safe haven' would be established to hold data that are being used for research. This would be a secure computing system to which limited amounts of data from the main Connecting for Health resource would be transferred, as and when they are requested for legitimate research purposes. Researchers would only be able to use the data on that secure computing system. An 'honest broker' would be responsible for transferring data from the main Connecting for Health repository to the secure computing system.

Section 6: International comparisons

Question 23.

No comments.

Question 24. Do you have any international examples of good practice in the sharing of personal information that could or should be adopted by the UK?

42. There are examples of good practice in sharing personal information for research both inside and outside of the UK. Some examples were discussed at the Wellcome Trust meeting on 'Use of electronic patient records for research and health benefit' in May 2007.¹⁴

¹⁴ Meeting report available at: <http://www.wellcome.ac.uk/assets/wtx039410.pdf>.

Scotland

43. Scotland has made significant progress in introducing and linking electronic patient records. Patients are encouraged to memorise and use their Community Health Index (CHI) numbers, which is crucial to allow records of different contacts with the health system to be linked. Researchers have already been able to use this data – for example, the pharmaceutical company Wyeth is using patient data from Scotland in the development of biomarkers.

United States

44. The US Veterans' Health Administration (VA) has also been able to use linked electronic patient records to improve health care and advance research. The VA now holds electronic records for its 5.4 million patients cared for at over 1000 sites, and is the largest US database of its kind. As part of a package of quality improvements introduced in the mid-1990s, electronic patient records have helped the VA to dramatically improve its level of service for patients. The records have also supported research.

United States

45. The US Census Bureau provides an example of how identifiable personal and business data may be made available for research under very strict safeguards. The US Census Bureau operates nine Research Data Centers in different parts of the country. Researchers may submit proposals to use detailed, identifiable data on individuals or businesses at one of the Centers. Research proposals are judged by Census Bureau and external experts on five criteria: (1) Benefit to Census Bureau programmes; (2) Scientific merit; (3) Clear need for non-public data; (4) Feasibility; and (5) Risk of disclosure. If their proposals are approved, researchers who will access confidential data must undergo a background check and assume "Special Sworn Status", which makes them liable for imprisonment of up to 5 years and fines of up to \$250,000 if they knowingly or accidentally disclose any confidential information. Researchers who need access to particularly sensitive financial data must also attend annual training in the use and protection of this data.

Question 25.

No comments.

Question 26.

No comments.

Section 7: Additional questions

Question 27.

No comments.

Question 28.

No comments.

Annex A: Recent Reports related to use of personal information in medical research

- Academy of Medical Sciences (AMS), 2006: *Personal data for public good: using health information for medical research*. This report highlights the importance of personal health information for research, and observes a need for clearer, simpler guidance to facilitate its use. Link: <http://www.acmedsci.ac.uk/p48prid5.html>
- Armstrong, V. et. al., 2007: *Public Perspectives on the Governance of Biomedical Research: A qualitative study in a deliberative context*. This study, commissioned by the Wellcome Trust, includes exploration of public attitudes toward the use of personal information in research. Link: http://www.wellcome.ac.uk/doc_wtx038446.html.
- Council for Science and Technology, 2005: *Better use of personal information: opportunities and risks*. This report finds that the use of personal data by government offers enormous benefits, with the potential to create more efficient and accessible public services and to benefit public health if potential risks are addressed appropriately. Link: <http://www2.cst.gov.uk/cst/reports/files/personal-information/report.pdf>.
- Council for Science and Technology, 2007: *Strategic decision making for technology policy*. This report identifies “E-health” as a technology area in which the UK has significant potential. Link: <http://www2.cst.gov.uk/cst/reports/files/strategic-decision-making.pdf>
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 - Mandated use of a common patient identifier to enable linkage of source of data at a patient level
 - Communication of the relevance of research to healthcare with the recognition that research is a core, not secondary, component of the development of the NHS Care Records Service, as it benefits patients directly
 - Federation of existing databases to ensure that the data made available are as comprehensive as possible
 - Improvements in data quality to ensure that data are accurate and based on a set of standards for recording and processing
 - Initiation of governance discussions to ensure appropriate access to, and use of, data for research purposes
 - Engagement with key stakeholders to communicate the joint benefits of using patient data for research and clinical care
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