

GeneWatch UK submission to the Data Sharing Review

February 2008

GeneWatch UK is a not-for-profit policy research group concerned with the science, ethics, policy and regulation of genetic technologies. GeneWatch believes people should have a voice in how these technologies are used: our aim is to ensure that genetics is used in the public interest.

Our response to the data-sharing review focuses on DNA and genetic data. It also considers the records that are being linked to this data in DNA databases and biobanks, including electronic medical records and records on the Police National Computer.

1. Concerns about the consultation process

GeneWatch UK has major concerns about the consultation process. In particular:

(i) It covers a very wide range of data, ranging from medical data to so-called 'criminal' records (now held permanently for everyone arrested for a recordable offence), without adequate explanation of the potential rationales for data-sharing in a multitude of very different circumstances. As a result, the consultation glosses over numerous issues of great public importance, for example the sharing of sensitive data (including genetic information or information on sexual health) and data on vulnerable persons (including children, the mentally ill, or persons who have suffered abuse and require their identities to be protected).

(ii) Whilst claiming to deal with a wide range of issues, such as consent, and to inform "data sharing policy", the consultation does not mention any relevant legislation beyond the Data Protection Act. The questions in the consultation cannot be properly considered without reference to a wide range of legislation and international agreements such as the Declaration of Helsinki, the Human Tissue Act, the Council of Europe's 2001 Convention on Human Rights and Biomedicine, and so on. The document therefore provides an extremely blinkered view of the issues at stake: for example, the existing requirements for informed consent for medical research are not laid out for consultees, nor are the consequences of abandoning it considered.

(iii) For similar reasons, the list of consultees is woefully inadequate: for example, GPs and nurses appear to have been omitted from the list. In addition, the consultation does not make the principles at stake understandable to members of the public.

(iv) The consultation also fails to make explicit the consequences of data-sharing between the public sector and commercial companies, including the pharmaceutical industry's ongoing attempts to access data contained in electronic medical records, and the role of private sector laboratories in analysing DNA collected by the police. There is no discussion of how data-sharing between the NHS and the private sector (including health, biotech and pharmaceutical companies) will be managed, including critical and contentious issues, such as the payment of licensing fees and the ownership of intellectual property (including gene patenting).

(v) There is also no mention of the international nature of much data-sharing, including plans to link electronic medical records and genetic data across Europe (led by the Wellcome Trust) and to share DNA profiles, fingerprints and police records with other EU countries. As police forensic services are privatised, DNA samples may be increasingly analysed offshore: the security implications of this major shift in practice cannot be addressed by minor changes to the Data Protection Act.

(vi) The appointment of Dr Walport to jointly run the consultation is inexplicable, given his ongoing role in lobbying for access to electronic medical record data by the pharmaceutical and biotech industries, including access to sensitive personal information in the 'sealed' and 'sealed and locked' envelopes of electronic medical records for research (contrary to the recommendations of the Health Select Committee¹).^{2,3,4,5} The Wellcome Trust is a major funder of the controversial genetic research project UK Biobank and is also leading a project to integrate UK Biobank with other biobanks of DNA linked with medical records across Europe.^{6,7}

2. Substantive issues

In view of these major limitations, GeneWatch has chosen not to respond to the review's list of questions, and to outline instead three principles that should be central to the document:

(i) Before data sharing is considered, it is important to address the issue of the extent to which data collected without consent (usually in the context of the criminal justice system) may be retained and used, particularly in the absence of any judicial oversight. Personal data - including names, addresses, DNA and fingerprints - may now be collected without consent from anyone aged ten or above for "*purposes related to the prevention and detection of crime*". This personal information is retained indefinitely, used for multiple purposes (including controversial genetic research without consent), and shared internationally and with private laboratories. Although restrictions on data-sharing are important, time limits on the retention of surveillance data, such as DNA samples and profiles, fingerprints and police computer records, are also an essential safeguard against misuse.

(ii) Where personal information is properly retained, the consultation itself acknowledges that a key question is the rationale for sharing information in the first place. It is not sufficient for un-elected bodies (such as the Wellcome Trust) to determine what is in the 'public interest': potential participants in research must be allowed to make up their own minds. As the Helsinki Declaration clearly states: "*The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal*".

(iii) Public trust will be eroded if genuine concerns about the retention and sharing of data without consent are seen to be ignored – particularly if the outcomes of the consultation reflect prior commitments (made by the Government and the Wellcome Trust) to commercialising electronic medical record data and linked samples.

These issues are considered in turn below.

2.1 Indefinite retention and use of DNA samples, profiles and records without consent

GeneWatch's views and evidence on these issues are contained in our recent submissions to the Home Affairs Committee⁸ and the Constitution Committee⁹. In summary:

1. England and Wales are the only countries in the world which keep DNA profiles and samples from innocent people and people convicted of minor offences for life. The practice of taking DNA on arrest for a very wide range of offences, and retaining both DNA samples and the computerised DNA profiles permanently is disproportionate to the need to tackle crime.
2. The rapid expansion of the National DNA Database has enormous implications for the balance between the power of the state to implement "biosurveillance" on an individual and the individual's right to privacy. Issues of cost and cost-effectiveness are also raised by the practice of keeping DNA profiles and samples permanently from so many people. There is also significant potential for others – including organised criminals – to infiltrate the system and abuse it, for example by using it to reveal changed identities and breach witness protection schemes.
3. There has been little public or democratic oversight of this shift in approach and current safeguards are inadequate to prevent errors or abuses. Proposals to further expand police powers and to share DNA data with other countries will exacerbate this situation.
4. GeneWatch UK believes that there are important changes that could be made that would improve safeguards for human rights and privacy without compromising the role of the DNA Database in tackling crime. A better balance would be struck by:
 - reintroducing a system of time limits on how long people are kept on the Database – so that only DNA profiles from people convicted of serious violent or sexual offences are kept permanently;
 - destroying all individuals' DNA samples once an investigation is complete, after the DNA profiles used for identification have been obtained;
 - ending the practice of allowing genetic research using the Database or samples, so that research is limited to performance management and database improvements;
 - better governance, including an independent regulator;
 - public and parliamentary debate before new uses of the Database are introduced;
 - a return to taking DNA on charge rather than arrest, except where it is needed to investigate a specific offence.

2.2 Controversy over when data-sharing is in the 'public interest'

The Government has already made a strong commitment to making electronic medical records, linked with DNA, available to private industry for research.

On 8th December 1999, the Department of Trade and Industry (DTI) published its report "*Genome Valley: the economic potential and strategic importance of biotechnology in the UK*"¹⁰, following a series of discussion groups involving representatives of the biotech, food and pharmaceutical industries.

Paragraph 2.9 states: "*The collection of DNA samples, with associated health records, would facilitate studies to detect susceptibility to genetic disease, and to*

understand the impact of genes on diseases...The National Health Service (NHS) in the UK is the largest source of clinical data and would be invaluable for comparative studies...". Paragraph 2.27 describes how "Biotechnology, and in particular applied genomics, is expected to revolutionise health care", including (unsubstantiated) claims that "it [will be] possible to tailor treatments for each individual on the basis of knowledge from each person's genetic code (i.e. his/her predispositions for diseases, allergies and an understanding of which drugs will work most effectively for that individual)". In the section "What does industry want from government?"(para 5.1), the list includes: "Availability of NHS information for research purposes within an appropriate ethical framework".

In this context, the UK Biobank proposal (funded jointly by the Medical Research Council and the Wellcome Trust) was developed as a pilot project for a national database of DNA linked to electronic medical records - in a public-private partnership originally proposed by the pharmaceutical industry.^{11,12}

In December 2006, Sir David Cooksey's Review of UK Health Research¹³ identified a need (paragraph 8.23) *"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."* In his foreword, Cooksey states that *"first and foremost"* amongst the new opportunities for pharmaceutical, devices, diagnostics and biotech companies in the UK *"is the potential offered by the new 'connecting for Health' IT database which will contain the medical records of the 48+ million inhabitants of England and should be accessible for important research..."*. He recommended the establishment of a new Office for Strategic Coordination of Health Research (OSCHR), of which Dr Walport is now a member.¹⁴

This ideological commitment to a 'genetic revolution' in healthcare - moving from treatment to 'prediction and prevention' of disease, combined with commercial access to NHS electronic medical records - is strongly supported and advocated by the Wellcome Trust and has been a major area of investment in research by the pharmaceutical, biotechnology, food, nuclear, chemical and tobacco industries since the 1950s. However, this approach to health is extremely controversial amongst geneticists and medical professionals, many of whom have questioned the reliability and usefulness of genetic predictions of common diseases, and the role of commercial influences in advocating this approach^{15,16,17}. Other scientists have warned that undertaking ever larger studies in an attempt to identify cancer susceptibility genes is a waste of money.¹⁸ Although recent large studies undertaken by the Wellcome Trust Case Control Consortium (WTCC) have identified some new genes linked with common diseases, the researchers have also highlighted the *"limited potential of the [genetic] variants thus far identified (singly or in combination) to provide clinically useful prediction of disease"*.¹⁹ Despite many misleading claims, no 'susceptibility' genes that meet medical screening criteria have yet been identified²⁰, and claims that they will do so in the future rest largely on the misinterpretation of data from twin studies²¹.

The current consultation is based on a mistaken assumption that people who allow their personal data (including genetic information) to be used in research, care only about potential harm to their own interests (for example, invasion of their privacy) and have no right to consider whether the research itself is conducted in the public interest, before agreeing to take part.

The Declaration of Helsinki states (paragraph 22):²²

“In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed”.

There is considerable and growing evidence that members of the public, whilst generally supportive of medical research, have major concerns about vested interests and whether research is being conducted in the public interest. The former Chairman of GlaxoSmithKline, Sir Richard Sykes, has predicted that within 20 years most people in developed countries will receive ‘pre-symptomatic treatment’ while they are still healthy²³. Whilst expanding the drug market in this way is clearly in the interest of the pharmaceutical industry, it is not clear it serves the interests of the public or the NHS.

A hidden political commitment to transforming the NHS to a ‘prediction and prevention’ service, based on genetic and other screening tests (provided by the commercial sector²⁴) and combined with new technologies for permanent monitoring and surveillance²⁵, continues to drive the move towards ‘data sharing’ outlined in the consultation. However, failure to acknowledge the contentious nature of this strategy for health, and the serious limitations of screening in general and genetic screening in particular, risks a major loss of public trust in medical research.²⁶

2.3 Public concerns about consent, surveillance and genetic data

In June 2007, the Medical Research Council (MRC) published the findings of its Public Consultation on the Use of Personal Health Information in Research.²⁷ The majority of members of the public felt that consent should always be sought to use their personal information. People taking part in the Wellcome Trust study indicated they were not unwilling to provide personal data for research if they understood why it was wanted and had confidence in the integrity of the research process, but this confidence could be undermined by a variety of factors. Public acceptance depended greatly upon expectations of how information is used and how well its use is regulated. Other concerns were over who can view the data, with particular resistance to the police and security services having access.²⁸

In September 2007, the UK Government published the reports of the three strands of its Science Horizons project (a deliberative panel, facilitated public events and small group discussions).²⁹ The future scenarios for its ‘Mind and Body’ theme included: an Alzheimer’s Disease patient whose clothes had been electronically tagged and whose jogging cap was tracked by satellite, and a computerised health check-up for a busy professional using miniaturised sensors and chips.³⁰ The major areas of policy relating to biosciences which were raised by the discussions were:

- Regulation of personal genetic information
- Protection of personal data on computer and DNA databases
- Insurance issues relating to increasing genetic understanding and medical profiling
- Public confusion and apprehension about genetics and biotechnologies

- Support for advanced vaccine technology being made affordable and available to people in need in developing countries.
- Overarching issues raised by the Deliberative Panel³¹ included:
- trust in expertise - who can be trusted?;
- concerns about the security, privacy and integrity of personal information (IT- or genetically-based);
- concerns about safeguards against abuse of technologies by authorities or by criminals;
- and fears about loss of the 'human touch' in everyday interactions, for example in relation to health, and in work.

There was a "*striking trust deficit*" and some people saw expert priorities for research investments as inevitably not the same as those of the average citizen.

In the light of these concerns it seems perverse – as well as of questionable legality - to be considering abandoning the principles in the Declaration of Helsinki by allowing data-sharing for 'research' without informed consent.

A thorough public assessment is also needed of the extent to which the data from electronic medical records, even when supplied on an 'anonymised' basis, could be used to identify individuals. Recent research seeking to build up a 'genetic photo-fit' from DNA samples left at crime scenes – including predicting surname or red hair colour - renders the idea of truly anonymous genetic information rather meaningless³². Both postcodes and employment information are likely to be used by some third parties - but they may also help reveal an individual's identity. Certain health events – including adverse drug reactions (a topic likely to be of interest to pharmaceutical companies), or employment-related conditions - are also often rare enough that access to specific information may be sufficient to identify an individual.

3. Conclusions and recommendations

1. Operation and control of the National DNA Database should be put on a legislative basis. Time limits on the retention of DNA profiles, fingerprints and linked police records should be re-introduced, based on the seriousness of the offence committed. If proceedings are dropped or an individual is acquitted, their data and samples should be destroyed (except in specific carefully justified circumstances, for limited time periods and with judicial oversight). The Database and/or samples should not be used for genetic research without consent and biological samples should be destroyed once a successful DNA profile has been obtained.

2. Access to electronic medical records and/or linked biological samples and genetic data should not be allowed without consent. The principles enshrined in the Declaration of Helsinki should be applied to all genetic research.

¹ House of Commons Health Committee (2007) The Electronic Patient Record: Report, together with formal minutes. Sixth Report of Session 2006-07. 13th September 2007. HC-422. <http://www.publications.parliament.uk/pa/cm200607/cmselect/cmhealth/422/422.pdf>

² House of Commons Health Committee (2007) The Electronic Patient Record: Written evidence. 25th April 2007. HC-422-II. <http://www.publications.parliament.uk/pa/cm200607/cmselect/cmhealth/422/422ii.pdf>

³ Wellcome Trust (2007) Frontiers Meeting: Use of electronic patient records for research and health benefit. 24-25 May 2007. http://www.wellcome.ac.uk/doc_WTX039411.html

⁴ <http://www.wellcome.ac.uk/assets/wtx039410.pdf>

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- ⁵ CRDB (2007) Report of the Care Record Development Working Group on the Secondary Uses of Patient Information. August 2007.
<http://www.connectingforhealth.nhs.uk/crdb/workstreams/secusesreport.pdf>
- ⁶ EUHEALTHGEN: Harnessing the potential of human population genetics research to improve the quality of the EU citizen. <http://www.ist-world.org/ProjectDetails.aspx?ProjectId=d4b557b278fd43b49c1f9ce5163b9f86&SourceDatabaseId=8a6f60ff9d0d4439b415324812479c31>
- ⁷ Wellcome Trust (2006) From biobanks to biomarkers. Wellcome Trust/European Commission. June 2006. <http://www.wellcome.ac.uk/assets/wtx032086.pdf>
- ⁸ GeneWatch UK (2007) GeneWatch UK submission: Home Affairs Committee Inquiry 'A surveillance society'. April 2007.
http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GeneWatchsub0407_v2.doc
- ⁹ GeneWatch UK (2007) GeneWatch UK submission to the House of Lords Constitution Committee's Inquiry: The impact of surveillance and data upon the privacy of citizens and their relationship with the state.
<http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GeneWatch0607.doc>
- ¹⁰ Genome Valley: the economic potential and strategic importance of biotechnology in the UK. <http://www.berr.gov.uk/files/file28709.pdf>
- ¹¹ Fears R & Poste G (1999) Building Population Genetics Resources Using the U.K. NHS, *Science*, **284**, 267-268.
- ¹² House of Lords Science and Technology Committee, Human Genetic Databases: Challenges and Opportunities, 4th Report, Session 2000-0. Minutes of Evidence. Para 39, p8.
- ¹³ Cooksey D (2006) A review of UK health research funding. December 2006.
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- ¹⁴ http://www.nihr.ac.uk/about_oschr.aspx
- ¹⁵ Holtzman, NA, Marteau, TM (2000), Will Genetics Revolutionize Medicine?, *New England Journal of Medicine*, **343**, 141-144.
- ¹⁶ Baird, P (2001), The Human Genome Project, Genetics and Health, *Community Genetics*, **4**, 77-80.
- ¹⁷ Vineis P, Schulte P, McMichael AJ (2001) Misconceptions about the use of genetic tests in populations. *The Lancet*, **357**, 709-712
- ¹⁸ Baker SG, Kaprio J (2006) Common susceptibility genes for cancer: search for the end of the rainbow. *British Medical Journal*, **332**, 1150-1152.
- ¹⁹ The Wellcome Trust Case Control Consortium (2007) Genome-wide association study of 14,000 cases of seven common diseases and 3,000 shared controls. *Nature*, **447**, 661-678.
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http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/MHRA07_1.doc
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<http://www.wma.net/e/policy/b3.htm>
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- ²⁵ <http://www.berr.gov.uk/files/file34991.pdf>
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- ²⁷ <http://www.mrc.ac.uk/NewsViewsAndEvents/InvolvingThePublic/Consultations/UseOfPersonalHealthInformationInResearch/index.htm>

²⁸ MRC(2007) The use of personal health information in medical research. Final Report. June 2007.

²⁹ <http://www.sciencehorizons.org.uk>

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http://www.sciencehorizons.org.uk/resources/1652_SH_Scenes_Mind%20&%20Body_AW.pdf

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³¹ Dialogue by Design (2007) Science Horizons: Deliberative Panel Report. September 2007.

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³² Human Genetic Commission (2002), Inside Information, May 2002. Section 9 (Forensic Uses). http://www.hgc.gov.uk/business_publications.htm#insideinformation .