

The Coroners and Justice Bill: A DNA database by stealth?

Parliamentary Briefing



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The Coroners and Justice Bill proposes amendments to the Data Protection Act, which include a power to enable information sharing.¹ The proposed power would allow ministers to issue 'information-sharing orders' to enable any person to share information which consists of or includes personal data, for any purpose with which their department is concerned, without scrutiny by parliament. Ministers and departments in Scotland, Wales and Northern Ireland will also be able to issue information orders relating to devolved matters.

The second reading of the Coroners and Justice Bill, including its controversial data-sharing clause, will take place on Monday 26th January 2009. The information-sharing proposals would allow a national DNA database to be built by stealth, linked to electronic medical records in the NHS. If the proposals are adopted, the rationale for building such a database would receive no parliamentary scrutiny.

This briefing considers the implications of the data-sharing provision in the Bill for DNA and genetic information.

What is proposed?

Data-sharing orders will allow any information – including DNA and genetic information - to be disclosed, consulted or used for a purpose other than that for which it was originally collected. Once issued, an order may remove or modify any legal barrier to information-sharing. This could be by repealing or amending other primary legislation, changing any other rule of law (for example, the application of the common law of confidentiality to defined circumstances), or creating a new power to share information where that power is currently absent.

An order can confer powers on ministers to allow onward disclosure of information to third parties, including foreign governments and commercial companies.² The proposals also contain provisions to create offences for individuals or organisations that refuse to share the information required by an order.

A national genetic database by stealth?

"...The strategy, of course, is not to go to a national genetic database as a first step, the strategy is to join the MRC and the Wellcome Trust in assembling a large cohort of approximately half a million people...There is an element of this which is going to be, as it were, worked out with a large research study". Professor Sir John Pattison, Director of R&D for the NHS, December 2000.³

“The NHS provides a unique research resource – offering potential to link large-scale genomic data with information on health outcomes and responses to treatments captured in electronic patient records...The Government must plan effectively for the implementation of genomic medicine in the health service”.
Wellcome Trust, 2008⁴

The Coroners and Justice Bill provides the first step in a two step process which could allow data in electronic medical records linked with genomic data to be shared with third parties – including private companies and the police – without consent. Once the Bill is adopted ministers in the Department of Health and/or the Home Office will be able to issue a ‘data-sharing order’ to allow a national DNA database of everyone registered in the NHS to be built by stealth.

A national DNA database, linked to electronic medical records, to be established as a public-private partnership with the pharmaceutical industry, was first proposed by Sir George Poste (then at SmithKline Beecham, and subsequently Bush’s bioterrorism advisor⁵) in 1999.⁶ It was supported by the House of Lords Science and Technology Committee, which also lobbied for the adoption of the expensive centralised system of electronic medical records known as the Spine, in order to implement the planned genetic database.^{7,8}

The research study UK Biobank is a pilot project for this much larger NHS-wide biobank.^{9, 10} UK Biobank is currently recruiting half a million volunteers willing to allow researchers to access information about their illnesses and lifestyles, linked with samples of their blood and urine. The project involves linking data in electronic medical records with DNA and genetic data. The biobank is funded by the Wellcome Trust and the UK Government (via the Medical Research Council, Department of Health and Scottish Executive) and has been set up as a charity.¹¹ The data – minus some identifying information - will be accessed by researchers, including those from private companies, who will apply to use it in the future.

The proposals in the Coroners and Justice Bill come from the Data-Sharing Review led by Dr Mark Walport, Director of the Wellcome Trust, and the Information Commissioner Richard Thomas.¹²

On 21st January, the Rt Hon Dawn Primarolo MP, Minister of State for Public Health, gave oral evidence the House of Lords Science and Technology Committee’s Inquiry on Genomic Medicine.¹³ Asked about the Data-Sharing Review, the Minister told the Committee that the Department of Health had accepted the recommendations in the Thomas-Walport report and that: *“Everyone in front of you and the Government is absolutely determined to exploit this research opportunity. In fact, Lord Drayson and I were discussing how unique it is in this country that we have this cradle to grave community into specialist care data and to link that to genomics is very powerful as a way of learning how to improve public health and individuals’ care. That’s why we are making substantial investment in this research capability programme for NHS Connecting for Health...”*.

When former health minister Lord Warner stated that: *“the great prize for researchers in this area is being able to access the current data that is in the medical record plus the new genomic data as it emerges for individuals”*, the Minister replied *“I agree. If they are linked for clinical purposes then the only issue is about access and as long as we develop safe havens effectively to pseudo-anonymise...then we’ll be all right”*.

However, the minister refused to be drawn on whether Government would revisit legislation to make access easier, stating “*At the moment it’s two steps*”.

Genetic ‘prediction and prevention’: a Government commitment

The government has long been a strong advocate of the genetic ‘prediction and prevention’ of disease.

In 2002, in his major speech on science to the Royal Society, Prime Minister Tony Blair claimed: ¹⁴ “...we can now see a future where the doctor will swab a few cells from inside your cheek, put them into a DNA-sequencing machine and a computer will spit out a complete reading of your unique genetic makeup - all 30,000 or so genes that make you who you are. From that, doctors could pinpoint flawed genes and gene products and predict what diseases you are likely to develop years in advance of any symptoms - and how to help you avoid them”. He added: “We have a unique resource in this regard in the national health service. There are crucial issues of privacy of genetic information that we need to deal with. But our national, public system will enable us to gather the comprehensive data necessary to predict the likelihood of various diseases - and then make choices to help prevent them”.

This vision was endorsed by the 2003 White Paper on Genetics, which also proposed genome screening every baby in the NHS at birth.¹⁵ The proposal was rejected by the Human Genetics Commission, but is due to be revisited in 2010.¹⁶

The Ministerial Medical Technology Strategy Group (MMTSG) was set up in 2007 to promote a paradigm shift to the genetic ‘prediction and prevention’ of disease, along with ongoing medical surveillance of individuals.^{17,18}

In January 2008, Prime Minister Gordon Brown claimed:¹⁹ “...we are at the dawn of a whole new era:

- *with growing understanding of individual risk factors;*
- *the possibility of anticipating the development of future illness;*
- *and perhaps even that of pre-empting such illness with specific advance interventions.”*

Later in the year, Lord Darzi’s report on the NHS stated²⁰: “*With the advances currently underway in genomic testing, we may be able to predict future disease rather than simply understand present illness*”.

Genetic prediction and prevention: a science fantasy?

“The humility that in the end long-term disease prediction (except in small sub-groups) will ultimately remain as fundamentally impossible as long-term weather prediction, might be a pervasive attitude in this project. It might also help not to oversell the expectations, neither to the public, nor to the scientists involved”.
Anonymous peer reviewer of UK Biobank, 2002.²¹

“Predicting disease occurrence many years in the future for persons who appear outwardly healthy is fraught with difficulty...We may have better technologies for extracting information out of raw materials, but we fall far short of our forebears in our ability to question the validity and relevance of the scientific enterprise”. Dr Robert Millikan, Director of the North Carolina Center for Genomics and Public Health, 2005.²²

“There is absolutely no question that for the whole hope of personalized medicine, the news has been just about as bleak as it could be...It’s an astounding thing that we have cracked open the human genome and can look at the entire complement of common genetic variants, and what do we find? Almost nothing. That is absolutely beyond belief.” Geneticist Dr David Goldstein, Duke University, 2008.²³ *Combining multiple tests within a single panel will not help, because the likelihood of possessing the exact combination of risk alleles* which confers a substantial increased risk will become vanishingly small extremely quickly”.* Editorial in the journal *Addiction*, 2009.^{24*} An allele is one member of a pair of genes.

The identification of rare genetic mutations can provide useful information to individuals, including people at risk of (relatively rare) familial forms of cancer: for example, mutations in the BRCA1 and BRCA2 genes are thought to occur in about 5% of cases of breast cancer. However, the evidence that screening common genetic variants will prove useful to predict and prevent common diseases in most people is extremely weak.

On 6th November 2008, the journal *Nature* published an article called *“The case of the missing heritability”*, which stated: *“When scientists opened up the human genome, they expected to find the genetic components of common traits and diseases. But they were nowhere to be seen”*.²⁵ It reports that *“...even when dozens of genes have been linked to a trait, both the individual and cumulative effects are disappointingly small and nowhere near enough to explain earlier estimates of heritability”*. Although some scientists are optimistic that they will find the ‘missing heritability’ in more detailed tests of the human genome, others have long argued that estimates of heritability are based on out-of-date and oversimplified assumptions and are *“long-past their sell-by date”*.^{26, 27}

Despite much hype, the vast majority of associations found between genes and common diseases later turn out to be false, and estimates of the importance of genetic effects have been decreasing over time.²⁸ 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”*.²⁹ This type of study can still be useful because it helps scientists to understand the mechanisms of these diseases: but the results do not support the idea that widespread genetic screening will be useful or that it will allow the genetic ‘prediction and prevention’ of common diseases in most people.

Recent research suggests that using multiple genes to screen whole populations for genetic susceptibility to complex diseases will not be useful to predict disease.³⁰ For example, testing all 18 genes that have been linked to type 2 diabetes does not appear to improve prediction compared to measuring existing risk factors.³¹ The much-hyped ‘fat gene’ (the FTO gene), combined with other known genetic factors explains less than 1% of the differences in Body Mass Index (BMI) observed between individuals. Only 6% of differences in cholesterol levels and none of the observed differences in blood pressure have been explained by genetic factors.^{32,33,34}

Similar problems have plagued pharmacogenetic tests (genetic tests for drug response), which in general have also shown low clinical utility, with only a few exceptions.^{35,36,37,38}

Costs

“When we have been feeding the public exuberant promises of enormous return on investment, from personalized medicine to near-immortality, it is wrong to evade accountability for how their money is spent. And, arguably the stakes are higher now than they have ever been – many of the proposed [genetic] fixes for complex diseases require greater resources, for potentially smaller return than ever before... At least [the alchemists] were doing it with their own venture capital”. Buchanan, Weiss and Fullerton (Penn State University and University of Washington Medical School), 2006.³⁹

According to the National Audit Office, the Treasury approved all expenditure on the £12 billion-plus Connecting for Health programme although *“it was not demonstrated that the financial value of these benefits exceeds the cost of the Programme”*.⁴⁰ The cost is about £11 billion more than the original system of decentralised records⁴¹ that was proposed before the House of Lords Science and Technology Committee lobbied for the creation of a centralised system in their genetic databases report.⁹

The genetic ‘prediction and prevention’ of disease implies a massive expansion of the drug market to healthy people, because the sheer number of people that will be tested means the whole population will be classified as at genetic risk of one or more diseases.^{42,43,44} Because the predictive value of most tests, and particularly of genetic susceptibility tests, is poor, most people will be given wrong predictions.⁴⁵ This is why most scientists and doctors do not agree that widespread screening of healthy people for multiple diseases is a good idea.^{46,47}

The cost implications of ‘genetic susceptibility’ testing have been described as *“staggering”*⁴⁸. In February 2007, a paper published in the journal Health Policy concluded: *“Based on current evidence, an era of healthcare consisting of gene technology built on widespread predictive testing is not desirable from a health economic viewpoint”*.⁴⁹

Consent and withdrawal

“In medical research involving competent human subjects, 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, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal...” The Helsinki Declaration.⁵⁰

In 2007, the Medical Research Council (MRC) and Wellcome Trust published the results of their public consultations on the use of personal health information in research.^{51,52,53} The majority of members of the public felt that consent should always be sought to use their personal information. 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.

The Government has already rejected the House of Commons Health Committee recommendation that:⁵⁴ *“Information in ‘sealed envelopes’ should not be made available to the [Connecting for Health] Secondary Uses Service under any circumstances”* and watered down the NHS Care Record Guarantee, which was

modified in 2006 to state that the service will: “*allow only those involved in your care to have access to records about you from which you can be identified, unless you give your permission or the law allows*” [emphasis added].⁵⁵

In February 2008, UK Biobank issued a statement that “*although data from participants can be made unusable, it is not possible to destroy it completely*”, contrary to claims in its information materials (which have since been amended).⁵⁶

Privacy and government surveillance

“*All of that will come out, absolutely. This is what I mean about getting real and getting used to it. There will be no secrets about paternity anymore*”. Professor Sir John Sulston, in response to a question about the implications of genome sequencing in the NHS for family relationships, 2008 (uncorrected transcript).⁵⁷

On 4th December 2008, the European Court of Human Rights ruled that the blanket and indiscriminate nature of the powers of retention of DNA samples and profiles in Britain’s police National DNA Database breached the right to privacy.⁵⁸ However, in August 2008, the Government reported that an interdepartmental working group had concluded that: “*Subject to an overriding public interest test and judicial oversight, the police should be able to obtain access during a criminal investigation to material held by third parties that is currently barred to them by the Police and Criminal Evidence Act 1984, such as medical, social services or educational records*”.^{59,60}

The police can already gain access to medical records and DNA stored on newborn bloodspot cards in the NHS but the power is currently used rarely and requires approval by a court.^{61,62,63} A data-sharing order could make police access to medical records, linked to DNA stored in the blood spots cards taken from all babies at birth, a matter of routine.

Last year a study showed that individuals or their relatives could be identified from the limited statistics based on individual genotypes that are often shared between researchers.⁶⁴ Another study showed that parts of a full genome withheld to protect privacy can be deduced from other information.⁶⁵

In December 2007, the Times reported a poll showing that only a fifth of doctors believe that a national electronic system for storing patients’ records will be secure,⁶⁶ following the loss of a reported 168,000 patient records by nine NHS Trusts.⁶⁷

Linkage across Europe

“*From a personal viewpoint, I think this should be the start of visualising the 21st century mode of health care where new elements such as susceptibility to disease, response to treatment, tolerance of medication, and a host of other attributes could be linked to the patient’s medical record Europe wide*”. Dr Bill Baig, Health Research Directorate, European Commission DG Research.⁶⁸

The European Commission is currently funding R&D to prepare for the construction of a pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI).⁶⁹ The initiative was instigated by the Wellcome Trust.⁶⁸ Any associated partner, such as a research institute which provides biological samples and data, may be compensated for its contribution by being granted free access to resources and technologies of the BBMRI. Users may be from academia or industry and

associated partners may also be ministries, governments, research councils, and funding agencies from interested countries.

Under the proposals in the Bill, a data-sharing order could compel sharing of genetic data across Europe or elsewhere, without people's knowledge or consent.

Loss of public trust

"Once the pursuit of science becomes heavily geared to profit, which the public feels it is not sharing in any major way, scientists may be compromised. They may be perceived as ... not working merely for the public good." Lord Winston, 2005.⁷⁰

In 2007, the Government published the reports of the three strands of its Science Horizons project (a deliberative panel, facilitated public events and small group discussions).⁷¹ The project was part-funded by GE Healthcare, the US company which co-chairs the Ministerial Medical Technology Strategy Group (MMTSG). GE Healthcare's website states: "*Our vision for the future is to enable a new "early health" model of care focused on earlier diagnosis, pre-symptomatic disease detection and disease prevention*".⁷²

The future scenarios for the Science Horizons '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.⁷³ Major areas of policy raised by the discussions included regulation of personal genetic information and protection of personal data on computer and DNA databases. Overarching issues raised by the Deliberative Panel⁷⁴ 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.

Conclusions

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 sector and combined with new technologies for permanent monitoring and surveillance, is one of the key drivers behind the move towards 'data sharing' proposed in the Coroners and Justice Bill.

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 massive waste of public money and a major loss of public trust in medical research.

If electronic medical records are linked with DNA and the scanned genome of every individual, a back-door DNA database will be built by stealth as a public-private partnership. The use of information-sharing orders would mean that access by government officials and the police could become routine.

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