



## **The history of UK Biobank, electronic medical records in the NHS, and the proposal for data-sharing without consent**

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### **1. Introduction**

UK Biobank is currently recruiting volunteers willing to allow researchers to access information about their illnesses and lifestyles, linked with samples of their blood and urine, stored in a 'biobank'. Although data is being collected for the biobank with the consent of the people involved, it is a pilot project for a much larger NHS-wide biobank for which data in electronic medical records would be linked with genetic data. The legislation that would allow this to happen was published as part of the Coroners and Justice Bill in January 2009. The Bill is the first step in a two step process which could allow this 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 an 'information-sharing order' to allow a national DNA database of everyone registered in the NHS to be built without parliamentary scrutiny.

### **2. Summary**

This case study is part of a forthcoming report by GeneWatch UK on the role of the Knowledge-Based Economy and how research funding decisions are made in biosciences, funded by the Joseph Rowntree Charitable Trust. The case study is an investigation of how the decision was made to fund UK Biobank and to make the investment needed in NHS information technology (IT), in order to begin to build a national genetic database in the NHS.

The main findings are:

- In 1999, a small group of influential people with close links to the biotechnology, venture capital and pharmaceutical industries (Sir George Poste, Sir Richard Sykes, Sir John Bell, and Sir David Cooksey) began lobbying for a national database of NHS electronic medical records linked to individuals' DNA.
- The proposal was intended to allow Britain to take the lead in commercialising the human genome and to transform the NHS into a service based on the genetic 'prediction and prevention' of disease, in which large numbers of people could be given 'pre-symptomatic' treatment, massively expanding the drug market.
- Following lobbying via the House of Lords Science and Technology Committee, this proposal strongly influenced the Government's decision to upload electronic medical records to a central database (the 'Spine'), at an additional cost of more than £11 billion compared to a localised system.
- Despite widespread scientific criticism of this strategy for health, government ministers have repeatedly claimed that genetics will transform healthcare and allow common diseases such as heart disease, cancer and diabetes to be predicted from a

person's genes. A Ministerial Medical Technology Strategy Group has been set up to drive forward this agenda, co-chaired by US company GE Healthcare.

- Risk assessment of every individual in the UK population means turning healthy people into patients and could lead to massive over-treatment and huge financial burdens on the NHS, as well as causing major privacy concerns. No Government analysis of the cost-effectiveness, impact on health, or impact on the NHS has ever been undertaken to support this plan. Industry lobbying has also led to Government opposition to any regulation of the health claims made for genetic tests, most of which are known to be misleading.
- The genetic research project UK Biobank, funded jointly by the Government and the Wellcome Trust, was developed as a pilot project for the planned national genetic database. Although it continues to recruit volunteers to give their DNA, the project shifted its emphasis away from genetics in the face of strong scientific criticism. However, as more data confirms criticisms that genes will be poor predictors of common diseases in most people, the Wellcome Trust is leading plans to link DNA databases across Europe in an attempt to make a study big enough to identify very small genetic effects.
- The current Director of the Wellcome Trust (Sir Mark Walport) and other enthusiasts for genetic 'prediction and 'prevention' of disease have lobbied for researchers – including those from industry – to be able to access information in people's electronic medical records without their consent, via the Secondary Uses Service (SUS). This would allow UK Biobank to expand without consent to include the entire NHS, for example by using DNA contained in the blood spots collected from every baby at birth, linked to their electronic medical records.
- Proposals which would allow this to happen were made in the Data-Sharing Review, led by Walport and the Information Commissioner Richard Thomas in 2008, and have been included in the Coroners and Justice Bill published in January 2009. Current legislation would not prevent the police from being given access to DNA stored by the NHS, but the data-sharing proposals in the Bill mean that this could happen as a matter of routine. DNA collected for health purposes could also be used to reveal paternity. There is widespread expert agreement that privacy cannot be protected if individuals' genome sequences are widely accessible.
- A series of public engagement exercises conducted by the Royal Society, the Medical Research Council (MRC), the Wellcome Trust and the Office of Science and Technology (OST) have highlighted public opposition to research without consent; concern about the role of commercial companies and the lack of regulation of genetic tests, and about protection of personal data; and a "*striking trust deficit*" regarding whether research is being conducted in the public interest.
- The same small group of people that backed the original plans for UK Biobank is now lobbying for further public money to include more detailed levels of medical surveillance, as well as genetic make-up, in an attempt to improve predictions of each individual's risk. GE Healthcare and other companies have also backed this plan via the Ministerial Medical Technology Strategy Group. However, individual health predictions will always be limited by the complexity of biology, the role of chance, and the multiple environmental and social factors which are involved.
- The proposals imply that GPs will be replaced with computer systems and Smart cards containing genetic and other screening data. However, most screening programmes need careful evaluation to avoid doing more harm than good, and most laboratory and genetic tests require expert interpretation. The implications of a major

shift in the role of the NHS away from treatment to 'prediction and prevention' have never been debated.

### 3. Conclusions

The history of the decision to fund UK Biobank and a centralised system of electronic medical records in the NHS provides a striking example of how science funding decisions are driven by a small group of unaccountable advisors. The idea of a national DNA database linked to electronic medical records was first proposed by Sir George Poste, then at SmithKline Beecham, and subsequently Bush's bioterrorism advisor and a board member or CEO of several US biotechnology companies. It was supported and promoted by Sir Richard Sykes of Imperial College, formerly Chairman of GlaxoSmithKline; Sir David Cooksey, founder of Advent Venture Partners; Professor Mark Walport of the Wellcome Trust; Professor John Bell of Oxford University; and members of the House of Lords Science and Technology Committee. They advocated a 'genetic revolution' in healthcare, which would transform the NHS into a service based on 'prediction and prevention' of common diseases, such as heart disease and cancer. They have been members of virtually every advisory committee established to consider innovation in the NHS and the role of the biosciences in health, and have repeatedly sat on committees or given evidence to inquiries established by each other.

UK Biobank was developed as a pilot project for the much larger national DNA database proposed by Poste, and the Wellcome Trust is now leading plans to share genetic data and health data internationally, including across the EU. The data-sharing proposals in the Coroners and Justice Bill, and proposals contained in the consultation on the Secondary Uses Service (SUS) held by Connecting for Health, would allow this to take place without the consent or knowledge of individuals in the NHS. Over time, the database could be expanded to use the blood spot cards which are already taken routinely from every baby at birth in the NHS and linked to their electronic medical records. Current legislation would not prevent police access to this data, which could also be used to check paternity. Research has shown that privacy cannot be protected if individuals' genome sequences are widely accessible.

Sir George Poste's proposal was intended to allow Britain to take the lead in commercialising the human genome and to massively increase the drug market by shifting the boundary between the individual and the patient, leading to an emphasis on the 'pre-symptomatic' treatment of healthy people. Access by private companies to electronic medical records in the NHS, linked to biological samples, was seen as Britain's 'unique selling point' to encourage commercial investment in research and create a 'knowledge-based economy' to compete with India and China. However, no common genetic variants that meet medical screening criteria for the general population have been identified and very little of the differences in disease risk observed between individuals has been explained by genetic factors.

The potential contribution of genetic 'prediction and prevention' to reducing the incidence of common diseases is therefore extremely questionable and the problem is compounded because genetic tests are largely unregulated, so 'genetic information' – combined with medicines, supplements, foods, skin creams, lifestyle advice and additional tests - can be marketed even when it is not valid or useful. This has the potential to harm health by:

- targeting the wrong advice at the wrong people;

- confusing healthy-eating messages or advice to quit smoking;
- leading to the costly over-treatment of healthy people;
- undermining public health approaches and diverting resources from the social, environmental and economic changes that are needed to prevent ill-health.

Numerous consultations and public engagement exercises have identified public opposition to research without consent; concern about the lack of regulation of genetic tests and about protection of personal data; and a “*striking trust deficit*” regarding whether research is being conducted in the public interest. Concerns about the role of commercial companies have been repeatedly dismissed, because a commitment to sharing NHS patient data with industry has always been central to the plan.

Policy decisions reflected the New Labour government’s strong commitment to the knowledge-based economy, as described in the main report. This included:

- adoption of a strong intellectual property regime, so that ‘knowledge’ can be patented and traded – in this case by supporting the patenting of genes;
- ‘light touch’ regulation, which focused on the needs of a claimed future business, accepted claims made by vested interests that regulation would ‘stifle innovation’, and ignored repeated calls to regulate the misleading health claims made about genetic susceptibility tests;
- closer links between industry and the public sector aimed at facilitating access by commercial companies to people’s personal health information contained electronic medical records, linked to their DNA;
- a narrow definition of wealth-creation and innovation as the main focus of public research spending, combined with an assumption that broader benefits will also be delivered (in this case, benefits to health);
- total dependence on ‘expert’ advice supplied by vested interests;
- sidelining and dismissal of concerns, leading to the loss of public trust.

The Government has provided an enormous public subsidy to a science fantasy: involving a total transformation of the NHS to facilitate the ‘prediction and prevention’ of disease. Its failure to attempt to evaluate the costs and claimed benefits to health of centralising electronic medical records – ignoring its own rules in the Treasury Green Book – has led to the entire risk of the ‘public-private partnership’ being borne by the taxpayer. The decision to create a centralised system (the ‘Spine’) is estimated to cost at least £11 billion more than the localised system which was originally planned. In addition, risk assessment of every individual in the UK population means turning healthy people into patients and could lead to massive over-treatment and huge financial burdens on the NHS, as well as causing major privacy concerns. No Government analysis of the cost-effectiveness, impact on health, or impact on the NHS has ever been undertaken to support this plan.

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