

Further submission to Information Governance Review: Evidence Gathering: Genetics and Genome

GeneWatch UK
October 2012

GeneWatch UK has already submitted evidence to the review which highlights our concerns about the Wellcome Trust/Human Genomics Strategy Group (WT/HGSG) plan to store the whole genome sequences of 60 million people attached to electronic medical records in the NHS, and to make the “anonymised” medical and genome data (stored as variant files containing the individuals’ genome minus the reference genome) available as Open Data via the cloud. Our evidence is available online¹, as is the WT/HGSG plan.² This submission provides additional responses to the panel’s questions: it should be read in conjunction with our previous submission.

PROBLEMS WITH THE CONSULTATION

Failure to highlight the existence of the WT/HGSG plan during the consultation is poor practice because it leaves stakeholders in the dark about what is actually proposed. Major omissions from the paper provided for this session are:

- Failure to highlight the difference between a searchable database of biometric data linked to individual’s names and other identifying information and the existing situation, in which small amounts of genetic information (e.g. a test of a specific gene) from a much smaller number of people are stored and shared in a much more limited way;
- Failure to discuss who the researchers will be who are expected to gain access to the data, the definition of research, and the role of fully informed consent in (i) restricting the collection, storage and use of biometrics by the state and (ii) attempting to ensure that the research agenda in the NHS serves the public interest.

QUESTIONS

Principles

GeneWatch UK supports the principles set out by the Human Genetics Commission in Inside Information.

Legislation and Guidance

There are some important omissions in the section. Surprisingly, the Helsinki Declaration³ and the European Convention on Biomedicine⁴ (the Oviedo Convention) are not mentioned at all, perhaps because they highlight that informed consent is not purely a data-protection issue. Article 24 of the Helsinki Declaration covers the process of seeking informed consent. It states that 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 also be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.

The Oviedo Convention has two relevant Protocols: one on biomedical research⁵ and one on genetic testing for health purposes.⁶

Article 8 of the European Convention on Human Rights (implemented in the UK by the Human Rights Act) is mentioned, but its significance has been ignored. Article 8 states: *“Everyone has the right to respect for his private and family life, his home and his correspondence. There shall be no interference by a public authority with the exercise of this*

right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others". In a unanimous judgment by the Grand Chamber in December 2008 in the case of *S. and Marper v. the UK*, the European Court found that the indefinite retention of two innocent persons' biological samples, forensic DNA profiles and fingerprints "*constitutes a disproportionate interference with the applicants' right to respect for private life and cannot be regarded as necessary in a democratic society*". GeneWatch UK provided expert evidence on behalf of the applicants in this case.⁷ New legislation on police retention of samples, DNA profiles and fingerprints has recently been adopted in the Protection of Freedoms Act 2012: this requires the destruction of biological samples within six months of the computerised DNA profiles being obtained from them and the removal of innocent people's records from the DNA and fingerprint databases (allowing temporary retention in some circumstances). Although the *S. and Marper* case referred to whether the retention of the samples and data was "*necessary...for the prevention of disorder or crime*" similar principles are likely to apply to the protection of health.

Consent

The WT/HGSG plan involves two aspects:

- (1) Collection, storage and sharing of new data which is largely irrelevant to the individual's care (files linked to the electronic medical records containing the individual's genome, collected, in the majority of cases, without any clinical justification);
- (2) Sharing of data collected during the course of an individual's care (data stored in the electronic medical record).

For research purposes it is also possible that additional data will be collected or obtained by linking to other information (e.g. the individual's employment record).

The Guidance for clinicians obtaining clinical consent does not adequately cover the circumstances envisaged in the WT/HGSG plan, which is primarily concerned with the secondary use of biological material and data for sequencing and for data-mining/research, combined with feedback of these research results on request to individuals. This is completely different from the current process where data is collected and analysed as part of clinical care, in circumstances where clinical judgment and relevant guidelines have led to the ordering of a specific test, or where a screening programme has been approved by the National Screening Committee (NSC).

The WT/HGSG plan as it is envisaged creates a searchable DNA database of the entire genomes and medical data of the whole population. This would allow:

1. The tracking of every individual and their relatives, due to the role of DNA sequences as biometrics and as a means to identify relatedness (including paternity and non-paternity);
2. Feedback of calculated risks (prognosis) to individual patients in a way which undermines medical screening criteria and is likely to be used for commercial marketing of health-related products;
3. The categorisation of individuals according to these calculated risks, which may lead to "personalised marketing" and perhaps also to discrimination.

To facilitate this plan a consultation on the NHS Constitution due to start this month is set to overturn people's right to confidentiality and the requirement to seek informed consent, in order to allow patients' data to be automatically used for research unless the patient specifically chooses to opt out.⁸

In addition, a number of proposals have been made to amend the Human Tissue Act to allow biological samples to be sequenced without an individual's knowledge or consent. The Academy of Medical Sciences (then led by Professor Sir John Bell, who Chairs the HGSG, and has been a long-term proponent of universal genetic screening in the NHS) proposed in 2011 that human saliva and some blood products should be exempt from the Human Tissue Act.⁹ Professor Sir John Burn, Chair of the HGSC's Innovation Working Group, subsequently lobbied the Human Genetics Commission to allow the sequencing of samples of blood or saliva taken as part of routine care in the NHS on the basis of opt-out consent.¹⁰

These proposals follow a failed plan – dropped due to massive public opposition - to hide similar data-sharing proposals (based on the Thomas-Walport report) in Clause 152 of the Coroners and Justice Bill in 2009.^{11,12,13} Amongst many critics, the British Medical Association (BMA) warned that "*This Bill strips patients and doctors of any rights in relation to the control of sensitive health information*" and opposed the adoption of the data-sharing Clause.¹⁴

Important questions for the panel are:

- Could whole genome sequences be obtained and attached to electronic medical records using a system of “presumed” consent, without breaching legal requirements and/or losing public trust?
- Can data stored in electronic medical records (with or without additional genomic information) be widely shared as open data using a system of “presumed” consent, without breaching legal requirements and/or losing public trust?

In GeneWatch's view the answers to both these questions are quite clearly no.

Genetic information, identifiability and the clinical record

This section of the paper completely fails to acknowledge what is proposed in the WT/HGSG plan and is thus misleading to stakeholders. The Korn quote (from 1998) is selective and is relevant only to the current situation where specific tests (e.g. for cystic fibrosis or mutations in the BRCA1/2 genes associated with familial breast cancer) are likely to be included in the medical records of a relatively small number of individuals. Currently, stored samples such as babies' blood spots can be accessed by the police with approval of a court and this has occurred in only a few specific circumstances. The WT/HGSG plan would totally transform this situation, by creating a searchable database in which a person's genome sequence would be stored as an attachment to their electronic medical record and available for use as a biometric.

Biometric systems are tightly linked to a person because they can use a certain unique property of an individual for identification and/or authentication. While a person's biometric data can be deleted or altered the source from which they have been extracted can in general neither be altered nor deleted. The EU's Article 29 Data Protection Working Group has warned that biometrics allow for automated tracking, tracing or profiling of persons and as such their potential impact on the privacy and the right to data protection of individuals is high.¹⁵ The Group defines biometric data as:

“biological properties, behavioural aspects, physiological characteristics, living traits or repeatable actions where those features and/or actions are both unique to that individual and measurable, even if the patterns used in practice to technically measure them involve a certain degree of probability.”

The question of when genetic data is sufficient to become a unique identifier is largely irrelevant: the important question is when sequences or partial sequences have sufficient discriminatory power to act as biometrics, and whether the manner of their storage (in a searchable genetic database) allows them to be used as such. Forensic DNA profiles collected by the police (based on analysing “non-coding” parts of the sequence known as

Short Tandem Repeats at multiple loci) have high discriminatory power, although adventitious matches can occur by chance. Individual Single Nucleotide Polymorphisms (SNPs) have lower discriminatory power but panels containing multiple SNPs can have sufficient discriminatory power to be used as biometrics. Whole genome sequences are believed to be unique (except perhaps in the case of identical twins), however, there will continue be errors in the system (e.g. mixed up or contaminated samples, false or mistyped names) which mean that whenever DNA is used as a biometric some mistakes will inevitably occur.

DNA profiles and fingerprints differ from some other biometrics (such as iris scans or facial recognition) in that they can be left wherever a person goes (i.e. in places where there are no security cameras or other monitoring equipment installed). This allows them to be used to identify whether or not a person has been at a crime scene or any other place (e.g. a political meeting where they may have left their DNA and/or fingerprints on a glass or coffee cup). DNA profiles differ from fingerprints in that partial matches between DNA profiles can indicate who is a close relative of the individual, including identifying paternity and non-paternity. Storing an individual's DNA profile linked to their name and other identifying information therefore allows a form of biological tagging or "biosurveillance" which can be used to track them or their relatives.¹⁶ There is widespread agreement that the creation of such databases raises human rights concerns.

Under the WT/HGSG plan a searchable genetic database would be created in which the individual genome of each person in the NHS is stored as an attachment to their electronic medical record. Once complete, this would allow anyone who can obtain a DNA sample from an individual to search their genetic profile against the database and use biometric matching (or partial matching with close relatives) to:

- identify that individual and their relatives, if they can obtain access to the linked identifying information.
- obtain linked personal health information made publically available (as Open Data) for research purposes, even if they cannot access identifying information. This may or may not be sufficient to identify the individual (and/or their relatives) via "deductive identification".

This proposal differs significantly from the current situation in which genetic test results focused on a specific gene or genes are stored in the health records of a relatively small number of patients. Whilst such relatively limited genetic data can lead to the deductive identification of an individual (e.g. based on knowledge that they have a rare disease, combined with other information), its collection and storage in specific cases based on clinical need does not amount to the creation of a biometric database.

The process envisaged in the WT/HGSG plan amounts to instigating biometric enrolment and storage on the basis of "presumed consent". In GeneWatch's view, it is likely that this process would endanger public trust in the storage and use of their data in the NHS. It is also likely to be subject to legal challenge, particularly as a potential breach of Article 8 of the European Convention of Human Rights. Since whole genome data will not in general be immediately relevant to a person's care, or meet screening criteria for the general population, it is highly unlikely that the collection and storage of such data would be regarded as proportionate and necessary for the protection of public health.

Under the EU Data Protection Directive (95/46/EC) biometric data are in most cases personal data. Therefore they may only be processed if there is a legal basis and the processing is adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed. The EU's Article 29 Data Protection Working Group states that a prerequisite to using biometrics is a clear definition of the purpose for which the biometric data are collected and processed, taking into account the risks for the protection of

fundamental rights and freedoms of individuals. Yet, the WT/HGSG plan envisages that biological samples collected for one purpose (i.e. babies' blood spots taken for specific screening tests or "spare" adult samples taken for tests during a person's routine medical care) can have DNA extracted, sequenced, stored, linked to personal and medical data and widely shared (as Open Data on an "anonymised" basis) without the individual's knowledge and fully informed consent. This appears to breach the principle of data minimisation, which means that only the required information and not all available information should be processed, transmitted or stored. Further, it does not address the need to set retention limits which should not be longer than is necessary for the purposes for which the data were collected or for which they are further processed. The controller must ensure that the data, or profiles derived from such data, are permanently deleted after that justified period of time.

According to the Article 29 Data Protection Working Group, the grounds on which data can be processed include that a person has given (valid) consent and: "*It must be clear that such consent cannot be obtained freely through mandatory acceptance of general terms and conditions, or through opt-out possibilities*". Valid alternatives must exist for consent to be regarded as freely given (e.g. people must not be forced to seek care outside the NHS or go without treatment if they do not want their genomes sequenced). Data can be processed without consent only if this is necessary for the purposes outlined in Article 8 of the European Convention on Human Rights.

The plan also has serious implications for medical professionals who might in future be put under pressure to build a biometric database for a dictatorial regime, by undertaking similar analysis of "spare" biological samples without seeking fully informed consent. The Helsinki Declaration was intended to prevent similar abuses and it is extremely important that its provisions are not undermined.

Family information

Identification of non-paternity can already occur in some NHS screening programmes for recessive genetic disorders¹⁷, such as the Sickle Cell and Thalassaemia screening programme. Current guidance states that the risk of non-paternity needs to be handled carefully if relationships and family units are not to be disrupted. The Guidance states it is not in the interests of anyone (professional or parent) to cause a division in the relationship by revealing this information, that the situation must be discussed with the mother alone (but only when necessary) and the possibility of errors fully considered, and that results must be carefully documented and communicated only to those professionals who need the information to support the family.¹⁸ It is difficult for physicians to know the consequences of their actions (which may go way beyond issues related to a diagnosis) if they reveal such information. Apart from family breakdown (which may not be in the best interests of the child or other members of the family) there is a risk that routine exposure of such information might drive some women away from seeking appropriate care for themselves or their children, or, in some cases, could put the woman and/or child at risk of domestic violence or even so-called "honour killings". Whilst such situations are always difficult, they will not be made any easier by breaching confidentiality.

The possibility for revelations about non-paternity to disrupt family relationships, or for health related information to have implications for other members of the family, cannot be discussed prior to testing (as recommended in the citation from the ASHG) if such testing is conducted on the basis of "presumed consent". As Professor Sir John Sulston has noted, if everyone has their whole genome sequenced and stored in the NHS "*There will be no secrets about paternity anymore*".¹⁹ Even if an individual's name is removed from data made available for research in the cloud, it is likely that relationships will be identifiable using a process of "deductive identification" based on information that is accessible.²⁰ Anyone who has access to linked data (i.e. genomes associated with names and personal identifying information) will be able to identify paternity and non-paternity with a simple search. This

adds significantly to the concerns outlined above that collecting, storing and sharing such data when it is not necessary for a person's care may not be in the best interests of them or their families. If the WT/HGSG plan is implemented, large numbers of people (including vulnerable women and children) may be forced to seek care outside the NHS to avoid their personal genetic relationships being identifiable.

Genetic profiling of children

Whole genome sequencing of babies at birth may be justified in some rare specific circumstances, when it is of direct relevance to their care (for example to identify mutations associated with an unexplained genetic disorder). However, a key conclusion of the 2005 HGC report Profiling the Newborn, which was written jointly with the National Screening Committee (NSC), was that genetic profiling could not be applied as a screening programme in the near future due to the large number of false negatives and false positives expected in the healthy population and the lack of evidence that it would be of benefit to health. There is no justification for whole genome sequencing as part of a screening programme in order to predict "genetic susceptibilities" at birth or to diagnose genetic disorders, because such tests do not meet screening criteria for the general population. This has not changed since the HGC/NSC published their report: if anything the evidence that genetic variants (alone or in combination) are poor predictors of most diseases or adverse drug reactions in most people has increased. Claims made by a few vested interests that this will change if more research is done do not stand up to detailed scrutiny: the predictive value of genetic tests is limited by the complexity of biology and the role of other factors, not by lack of data. Similarly, the NSC regularly reviews proposed screening programmes for rare genetic disorders and has approved the implementation of screening programmes for only a small number of conditions.

Since babies are unable to give fully informed consent it is hard to justify the creation of what is essentially a biometric database (see above) without their knowledge or consent, especially in the absence of any benefit to health. There are major privacy risks associated with the creation of a genetic database of every baby as this would allow them and their relatives to be identified and tracked, creating a national system of "biosurveillance" (see above).

In 2010, GeneWatch UK undertook a series of Freedom of Information requests which established that millions of babies blood spots were being stored within the NHS, in some cases indefinitely.²¹ None of the hospitals reported any research projects that had used the blood spots: but the long-term storage of the blood spots means they could be accessed in the future for genetic sequencing without consent. Such practices in other countries have been subject to successful legal challenge: in GeneWatch's view there should be a time limit on storage of the blood spots (for quality assurance purposes) and sequencing should not be allowed without fully informed consent.

Current ethical norms, which allow testing only when it is needed for the baby's care, should be adhered to, and are probably essential to meet the requirements of Article 8 of the European Convention on Human Rights.

GeneWatch UK is aware of many instances where children and their parents have objected to the inclusion of their records on the police National DNA Database and the storage of their biological samples by the laboratories that analyse them for the police. We have received many phone calls and emails on this issue. Many of the same concerns are likely to apply to the WT/HGSG plan to build a DNA database of the whole population within the NHS.

Genetic information and insurance

The moratorium adopts a reasonable framework, but it lacks certainty for people who have genetic tests because they do not know if it will be extended in the future. If it is not, past

tests could still be used against them (to deny insurance or increase premiums). Patient groups have long argued that most people do not agree with the use of genetic tests by insurers and that the potential for adverse selection is small.²² Concern about insurance can create added anxiety for people making the difficult decision whether or not to take a genetic test (e.g. women in high-risk families deciding whether or not to take a test for mutations in the BRCA1/2 genes) and may mean some decisions are influenced by financial considerations rather than by medical or personal priorities. GeneWatch UK believes the moratorium should be put on a legislative basis to address these concerns. There is considerable academic evidence that adverse selection based on genetic tests will not harm the insurance industry, because most highly predictive mutations are extremely rare, whereas common variants (either alone or in combination) have poor predictive value. This evidence is supported in practice by the fact that the insurance industry is quite happy to continue with the moratorium.

If the WT/HGSG plan is put into practice many millions of people will have their whole genomes sequenced without their fully informed consent. The potential for this data to be used to set premiums or deny access to insurance is an additional reason why this plan should not be implemented.

Research

The use of the term “research” can be misleading. Important questions are:

- What is this “research” and who are the “researchers” going to be?
- What is meant by “Open Data” and by the term “anonymised”?

In December 2008, Connecting for Health held a consultation about the sharing of medical data for research without consent.²³ The consultation did not mention that this would include sharing of genetic information, however the HGC’s response included a large number of concerns raised by the HGC’s Consultative Panel, including concerns about sharing of data in “sealed envelopes” and the fact that “anonymisation” of data in a way that made individuals unidentifiable was likely to be impossible for rare disorders.²⁴ In its response to the consultation the Wellcome Trust Sanger Centre “*encouraged the NHS Care Records Service to prepare for the integration of significant amounts of genetic and genomic information into patient records*” and argued that: “*If robust systems are in place.....the benefits of research will outweigh the risks associated with the use of identifiable information*” (including information that patients have requested to be kept confidential in ‘sealed’ and ‘locked’ envelopes).²⁵ However, a quarter (25%) of the members of the public stated that they did not believe that it was possible to effectively anonymise data and some people were adamant that “their data” should not be shared for any purposes. There was wide concern amongst participants in the general public about the ability of the NHS to protect personal data. Concerns included risks of data loss by NHS staff, hacking and selling of data to third parties for commercial purposes, especially insurance companies and employers. The consultation revealed widely divergent views between the general public and researchers.

The 2008 consultation did not say who the ‘researchers’ seeking access to this data were – although the group overseeing the programme included GE Healthcare, as well as five other industry representatives.

According to the EU’s Article 29 Data Protection Working Group, Biometric categorisation/segregation is the process of establishing whether the biometric data of an individual belongs to a group with some predefined characteristic in order to take a specific action. Increasingly, this process is used for “personalised marketing” of goods and services. In the WT/HGSG plan it is envisaged that individuals will be encouraged to seek feedback of their personal health risks, calculated using algorithms which will be developed to analyse their data in the cloud.

There is clear evidence that numerous commercial companies wish to use such calculated health risks for personalised marketing, as detailed in our earlier submission. Researchers are likely to include a wide range of commercial interests, including web-based companies such as Google²⁶, private healthcare companies, and the pharmaceutical and food industries, who wish to expand the market for medicines and functional foods sold to healthy people. In future, algorithms might be based on data-mining genomic data, or other health data, or a combination of the two. Since there is no clear theoretical framework to combine multiple variables there are likely to be many possible conflicting interpretations sold by different companies, as has already been the case with commercial genetic tests.²⁷

The WT/HGSG plan requires enormous resources to be sunk in collecting and storing data which is likely to be of limited value to most people's health. This is the opposite of the Future Forum's recommendation that the NHS should be: "*Moving from a focus on collecting data (often too much data) to a focus on using data to generate intelligence to inform action*".²⁸ Clinically useful data is likely to be swamped with clinically useless data which requires significant financial and energy resources to collect and store. Lack of any prior hypothesis undermines the scientific value of such an approach.²⁹

The proposal to abandon the requirements for fully informed consent outlined in the Declaration of Helsinki (cited above) removes a person's right to know the sources of funding, any possible conflicts of interest and institutional affiliations of the researcher before agreeing to take part in such research. Thus an important role of informed consent – helping to ensure that the research agenda serves the public interest – will be abandoned. The results of the 2008 Connecting for Health consultation suggest that it is unlikely that this will prove publicly acceptable.

Discrimination in relation to employment

The idea that genetic variants would be used in workplace screening was promoted by the same tobacco-funded researchers who promoted the idea of screening for genetic susceptibility to lung cancer.³⁰ Tobacco-funded researcher Jeffrey Idle was a co-author, with US National Cancer Institute researchers, of an early (1989) study of susceptibility to lung cancer in workers exposed to occupational carcinogens, which advocates screening and targeting of susceptible workers.³¹ This idea is questionable on both ethical and scientific grounds³² and is opposed by a large number of organisations and individuals.³³

The Equality Act 2010 restricts what employers can ask about in pre-employment medical checks. It means that employers can only ask for information that is directly relevant to the applicant's ability to carry out the work, or needed to make 'reasonable adjustments' to the workplace to enable a particular person to work there (as required by law). The EU's Lisbon Treaty also states (in Article 21) that any discrimination based on genetic features shall be prohibited in the European Union.

In GeneWatch's view, the Equality Act largely allays fears about genetic discrimination in the workplace because it tightly restricts the circumstances in which employers could access job applicants' or employees' genetic information. However, this protection could be undermined by the WT/HGSG plan because employers can become researchers. For example, an employer could conduct a study on their own employees by data-mining the genomes and associated medical data stored in the cloud. Because of the high potential for "deductive identification" individual workers' data is likely to be identified and could be misused e.g. to dispute a compensation claim³⁴.

Whilst strictly not an employment issue, similar concerns apply to the pharmaceutical industry conducting research without consent on individuals who may have had adverse drug reactions to their products.

This issue is best addressed by continuing to require fully informed consent from individuals who take part in research on workplace illnesses or adverse drug reactions (including information about conflicts-of-interest, as required by the Helsinki Declaration).

Direct to consumer testing

No pre-market assessment is currently made of the clinical validity or utility of genetic tests. This means that 'genetic information' – combined with medicines, supplements, foods, skin creams, lifestyle advice and additional tests – can be marketed when it is not valid (for example, even when the gene plays no role in the claimed disease) or when it serves no useful purpose (for example, when the proposed intervention is no more effective or necessary in people with one genetic variant than with another). GeneWatch UK has long argued that health-related genetic tests should be regulated so that people are not misled about their health, and has exposed many companies selling misleading genetic "information" (via the internet, high street stores, alternative healthcare providers and private medical clinics).³⁵ Recently, the market leader in selling gene tests online, the Google-funded company 23andMe, backtracked on its opposition to any form of regulation and made its first submissions to the FDA. The EU has also recently published proposed new Medical Devices Regulations which include some increased oversight for genetic tests.³⁶

Whilst regulation is important to prevent people from being misled about their health and burdening the NHS with requests for unnecessary tests and treatments, it should be noted that the private market for such tests is very small, especially outside the USA, and commercial gene test companies have struggled to devise viable business models.

People should always be fully informed about privacy policies and what will happen to their samples and data before they take a commercial genetic test. However, the relationship between an individual and a private provider is different from the NHS. Provided the individual has submitted their own sample (not another person's) they have a free choice whether or not to use a private service. In contrast, many people are dependent on the NHS for their healthcare and as a public authority the NHS has important extra obligations (such as being compliant with Article 8 of the European Convention on Human Rights).

A number of European countries (including Germany and France) have banned access to online genetic testing services and require oversight by medical professionals. Whilst the primary purpose of this is to ensure patients receive pre- and post-test genetic counselling, this is also an important means by which individuals can be prevented from submitting other people's samples (including those of children or vulnerable persons). At minimum, services accessed from the UK should contain a warning that non-consensual testing is illegal under the Human Tissue Act.

In the US Government Accountability Office (GAO) investigation of gene tests in 2010, two companies told GAO's fictitious consumer that she could secretly test her fiancé's DNA to "surprise" him with test results.³⁷

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- ⁵ Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research. <http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm>
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- ²³ CfH (2008) Consultation on the wider use of patient information.
- ²⁴ HGC (2008) NHS Connecting for Health – Consultation on Public, Patients, and other interested parties views on Additional Uses of Patient Data: Response by the Human Genetics Commission. 15 December 2008. <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/HGC%20response%20to%20CfH%20consultation%20on%20additional%20uses%20of%20patient%20data%2015-12-08.doc>
- ²⁵ NHS Connecting for Health (2009) Summary of responses to the consultation on additional uses of patient data. 27th November 2009.

http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_109310

²⁶ Professor Sir John Bell stated in 2008: “I have not directly approached people but I know Google has been involved in discussions at the Department of Health. That, it seemed to me, was a very welcome interaction. You are absolutely right. Google does have capabilities for dealing with that kind of data in a way that many of the public sector participants probably do not. There is expertise out there but I suspect that, taking some of the technical aspects of churn through very large amounts of little bitsy sequence data, getting it all to align and getting the information you want out of it, I still think we are going to be overwhelmed by a wave of data. I think that remains a big problem”. House of Lords Science and Technology Committee (2008) Memorandum submitted by Academy of Medical Sciences. Examination of Witnesses. 16th July 2008.

<http://www.publications.parliament.uk/pa/ld200708/ldselect/ldscitech/999/stii080716ev8.pdf>

²⁷ Rival genetic tests leave buyers confused. *The Sunday Times*. 7th September 2008.

http://www.thesundaytimes.co.uk/sto/news/uk_news/article234529.ece

²⁸ Information: A report from the NHS Future Forum. 10th January 2012.

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132086.pdf

²⁹ Wallace HM (2005) The development of UK Biobank: Excluding scientific controversy from ethical debate. *Critical Public Health* **15**(4): 323–333.

³⁰ Wallace HM (2009) Big Tobacco and the human genome: driving the scientific bandwagon? *Genomics, Society and Policy*, **5**(1), 1-54. <http://www.gspjournal.com/>

³¹ Caporaso, N, Hayes, RB, Dosemeci, M, Hoover, R, Ayesh, R, Hetzel, M, Idle, J (1989), Lung Cancer Risk, Occupational Exposure, and the Debrisoquine Metabolic Phenotype, *Cancer Research*, **49**, 3675-3679.

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³³ See the Joint Statement of Concern on: <http://www.genewatch.org/sub-555114>

³⁴ Railroad Agrees to Stop Gene-Testing Workers. *Washington Post*. 19th April 2001.

<http://www.washingtonpost.com/ac2/wp-dyn/A34877-2001Apr18?language=printer>

³⁵ More information is available on: <http://www.genewatch.org/sub-396520>

³⁶ http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

³⁷ Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices

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