

GeneWatch UK response to the Department of Health's consultation on strengthening the NHS Constitution

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GeneWatch UK is a not-for-profit organisation which aims to ensure genetic science and technology is used in the public interest. We welcome the opportunity to input to the consultation. Our comments focus on the storage and use of patient data, including genetic and genomic data. We have provided more detailed information on these topics to the Caldicott Review.^{1,2,3}

Summary of response

The Department of Health claims in its consultation document⁴ that the new draft NHS Constitution does not, itself, create new rights or replace existing ones, but merely codifies rights contained in existing legislation, drawing them together in one place (paragraph 11). However, the intention of the document has already been stated: it removes the requirement to seek fully informed consent to medical research, in order to allow patients' data to be automatically used for research by third parties (including commercial companies) unless the patient specifically chooses to opt out.⁵ In order to achieve this aim, existing obligations have been ignored or undermined, including the Helsinki Declaration⁶, the European Convention on Biomedicine⁷, Article 8 of the European Convention on Human Rights (the right to privacy), and the Human Tissue Act.⁸ Important issues regarding the application of the Data Protection Act to biometric data (which includes genomic data) have also been omitted. In addition, no account has been taken of the fact that data that is de-identifiable cannot be regarded as anonymised.

The answer to question 8 of the current consultation (Do the proposed changes to the NHS Constitution make clear how the NHS will safeguard and use patient data?) is clearly 'no'. The proposed changes fail to clarify the NHS's responsibilities and individuals' rights in relation to the collection, storage, sharing and use of personal data. The changes appear to change the requirement for individuals to give informed consent to medical research and replace it with a weak form of 'opt-out' in which patients are not asked for their consent but instead are supposed to be informed of how their data is to be used and may be allowed to opt-out in some cases. This is not consistent with the legal and ethical obligations of the NHS and its staff and undermines the rights of patients and members of the public. The draft constitution also fails to set out the obligations of staff in relation to obtaining informed consent for research or to provide information for individuals on what to do if their rights in relation to research uses of their data are breached.

A more detailed response is provided below.

Background

The Wellcome Trust (WT) Sanger Centre and the Human Genomics Strategy Group (HGSG) have proposed building a DNA database in the NHS by including a variant file, containing the whole genome of every person minus the reference genome, as an attachment to every medical record in the NHS in England.^{9,10,11} This data would be made available to 'researchers' (including commercial companies) for data-mining in the cloud and personalised results would be returned to individuals. Those proposing the plan are well aware that only a small minority of individuals are likely to give their fully informed consent to the storage and use of their DNA and genomic information in this way. The intention is therefore to implement the proposal without informed consent.

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 e.g. by insurers or employers.

A pilot project to sequence 100,000 genomes has been announced (focused on people with genetic disorders and cancer, rather than the healthy population) and it has been implied that this project will be run on an “opt-out” basis, rather than by obtaining fully informed consent from potential participants. There are plans for genomic data and linked health data to be shared with commercial companies and others in an anonymised form for data mining, without the knowledge or consent of individuals,¹² although it is well known that whole genomes cannot be reliably anonymised and that individuals’ identities and those of their families can be deduced.^{13,14} The plan for storing genomes in the NHS also assumes that genetic data will be linkable back to individuals, in order to feedback personalised results, even if the companies using the data for research are not given names and addresses.

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*”.¹⁵ 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.¹⁶

A blanket approach to sequencing the whole population of England will mean that medical screening criteria are abandoned and everyone will be tested for everything, with significant cost implications for both genome analysis and follow-up tests and treatments. The Wellcome Trust Sanger Centre has run a consultation on how people might access their own genetic data.¹⁷ Since genes are poor predictors of most diseases and drug responses in most people and there is considerable uncertainty in genetic risk predictions, there is significant potential to impact negatively on health by providing misleading interpretations of individual genomes.¹⁸ There is considerable commercial interest in using personalised risk predictions to significantly expand the market for drugs and other health products sold to healthy people, but no evidence that this would be of benefit to health.¹⁹

Important questions about the proposal to build a DNA database of the whole population in the NHS include:

- Is this a good use of resources? Why should this database be built?
- Do claims about “anonymisation” really stand up to proper scrutiny?
- Who will the researchers be, who will they be working for, and how will this data really be used?
- What will be the impacts on the NHS and public health?
- How will plans to build a DNA database in the NHS and undertake research without informed consent impact on public trust in the NHS and in medical research?

Rather than attempting to answer or consult on these questions, the Department of Health has issued a draft Constitution for consultation which undermines requirements for informed consent, presumably with the intention of implementing the proposal for a DNA database in the NHS without proper public scrutiny and debate.

Response to Q8. Do the proposed changes to the NHS Constitution make clear how the NHS will safeguard and use patient data?

Proposal to delete statement about managing treatment in best interests: *You have the right of access to your own health records. [Delete: These will always be used to manage your treatment in your best interests].*

This deletion is objectionable: it implies that the use of medical records will indeed shift from managing treatment in a patient's best interests to using data to market products to people based on personalised risk predictions. This is not in the best interests of the public or the NHS.

Existing wording: *You have the right to privacy and confidentiality and to expect the NHS to keep your confidential information safe and secure.*

This statement is fatally undermined by the proposals that follow and by the overall objective of creating a DNA database of the whole population in the NHS. It is well known that privacy cannot be maintained in such circumstances. For example, Professor Sir John Sulston has stated that: "There will be no secrets about paternity anymore".²⁰ A Round-Table Discussion held by the ESRC-funded Cesagen in 2009 found: "It is becoming impossible for medical researchers to guarantee privacy to the research participants they recruit – especially with the pressure from funding agencies who insist upon open-access archiving of genomic sequence data, as these data inevitably contain potentially identifying information. Indeed, it would now be misleading to promise privacy of personal genome information to research participants in exchange for consent to donate samples".²¹ This problem requires a strengthening of requirements for informed consent, so that people who chose to have their whole genomes sequenced are fully aware of the implications. It does not justify the weakening of consent requirements proposed in this document.

Examples of what the plan to create a DNA database in the NHS could mean for patient privacy in practice include:

- A person's employer or a pharmaceutical company could be classified as a "researcher" and thus gain access to data about individuals who suffer from a workplace-related illness or an adverse drug reaction: they are likely to be able to use "deductive identification" (based on the occurrence of a rare event with other information) to work out who these individuals are. They could try to look for data that might allow them to blame the condition on a person's genes, or for unrelated personal data (e.g. sexual health or use of drug rehabilitation services) that might be used to discredit that individual should they make a claim against the company.
- A person's DNA can be obtained easily from a beer glass, coffee cup or toothbrush. Anyone who could get that DNA sequenced could search it against stored variant files and identify the individual, either directly (if they have access to the medical record in the NHS or the de-identifying system) or indirectly by the clues stored in their public records. They could also look for partial matches to identify that person's relatives (including paternity and non-paternity). This process could be used by the police or state to track individuals who have not committed any crime (creating a "surveillance society"). It could be used by criminals to track undercover police officers, witnesses on protection schemes, and potential victims (including women and children fleeing abuse). It could also be used by individuals wanting to settle disputes about paternity and non-paternity or to expose such information in the press.
- The same process could be used to find out what personal medical information is linked to a particular genome, including e.g. use of medical services, including sexual health, or specific information about a disease or carrier status for a genetic disorder. This might be of interest to the press, private detectives, parents, neighbours, or insurance companies. Unscrupulous charities might even use the data to seek donations from the relatives of anyone with cancer.

Proposed additional wording on rights: *You have the right to be informed about how your information is used.*

You have the right to request that your confidential data is not used beyond your own care and treatment and to have your objections considered, and where your wishes cannot be followed, to be told the reasons including the legal basis.

Rather than clarifying the existing law, this proposal undermines the requirement to seek informed consent for use of personal data in research. The proposed right to make a request falls far short of the obligation on health professionals to seek fully informed consent to take part in medical research, as enshrined in the Helsinki Declaration. 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. This wording should be used here.

It is worth noting that the WT/HGSG plan 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.

Additional wording should also be added to inform people that sequencing their DNA without their consent is illegal in most circumstances, under the Human Tissue Act.

Genomic data differ from other data collected in the NHS in that they are biometric data i.e. physical attributes that can be used to identify individuals in the form of a “genetic fingerprint”. In the case of DNA, relatives can also be identified and individuals can also be tracked via the traces of DNA they leave as they go about their daily lives e.g. on a coffee cup. This means such data can be used for surveillance purposes, by the state or others.

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.²² 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 a supposedly “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".²³ 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).

Further, 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. Building any biometric database (including a DNA database) without consent within the NHS is likely to breach Article 8 of the European Convention of Human Rights. 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*". Whilst this judgement considered to what extent the retention of genetic data and DNA samples was necessary for policing purposes, similar considerations would apply to whether the collection and storage of DNA and genetic data without consent was necessary for health purposes.

Proposed additional wording on pledges:

The NHS also commits:

- *to ensure those involved in your care and treatment have access to your health data so they can care for you safely and effectively (pledge);*
- *to anonymise the data collected during the course of your treatment and use it to support research and improve care for others (pledge);*
- *where identifiable data has to be used, to give you the chance to object wherever possible (pledge);*
- *to inform you of research studies in which you may be eligible to participate (pledge); and*
- *to share with you any correspondence sent between clinicians about your care (pledge).*

The problems with these pledges are that:

- No definition of "anonymise" has been given and the problem of de-identification has been ignored (see above);
- The "chance to object" (and have your objection ignored?) is not a right to be asked to give fully informed consent (see above).

In ignoring these problems, the Department of Health is guilty of ignoring its own past consultations, as well as the ethical and legislative requirements cited above.

In December 2008, Connecting for Health held a consultation about the sharing of medical data for research without consent.²⁴ The consultation did not mention that this would include sharing of genetic information, however the Human Genetics Commission'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.²⁵ 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).²⁶ 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. It is unclear why the findings of this consultation are now being ignored.

The Wellcome Trust and Medical Research Council's own research also shows clearly that people are keen to take part in medical research, but only when they have been asked.^{27, 28} Fully informed consent is an important safeguard to protect not only individual privacy but the broader public interest.

It is worth also noting that this section of the draft Constitution goes on to provide informed choice of doctor, but the right to informed choice about sharing of an individual's data for purposes other than their care appears to have been totally removed. This contradicts the overall premise of the document which is to increase the involvement and engagement of the public in decisions which affect them.

Q9. Do you agree with the proposed changes to the wording of the staff duties and the aims surrounding the rights and responsibilities of staff? What do you think about the changes to make clear to staff around what they can expect from the NHS to ensure a positive working environment?

This section fails to lay out the responsibilities of staff with respect to personal information and the requirements for fully informed consent to take part in research. The obligations contained in the Helsinki Declaration, Human Tissue Act and Article 8 of the European Convention on Human Rights (see above) should be laid out so that staff are made aware of them.

Q16. To help shape our future consultation, do you have views on how the NHS Constitution can be given greater traction to help people know what they should do when their expectations of the NHS are not met?

Individuals should be provided for a clear and simple process they can use if their DNA, genetic and genomic information, and other health data, is stored, shared or used without their knowledge or consent.

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