GeneWatch UK submission to the Caldicott Review

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Informatics for Genomic Medicine – 2012?

- **Component 1**: Human sequence data repositories
  - EBI: repositories (petabytes of genome sequence data)
  - **Sanger**: sequencing (1000 genomes, uk10K)

- **Component 2**: Genotype and Phenotype relationship capture

- **Component 5**: Electronic Health Record
  - eHR system (e.g. emis): ~10 Mb Variant file as attachment per record
  - Anonymised

- **Component 6**: Research on Clinical data
  - SHIP, GPRD, LSDBs, Research Capability Programme (RCP)

- **Individual genome sequence**: ~3 gigabytes
  - Variant file: ~10 megabytes

- **Test**

Source: Tim Hubbard’s presentation on at AMS, 22\textsuperscript{nd} February 2012
The WT/HGSG plan involves

- Complete removal of people’s right to know who is using their health and/or genomic data for what purpose (including any conflicts-of-interest) as required by the Helsinki Declaration
- Construction of a biometric database without consent: allowing tracking and categorisation of every individual and their relatives
- A massive reallocation of resources towards collecting and storing data that is mostly not relevant to a person’s care
- Abandoning of screening criteria in favour of individual feedback of personalised risk predictions
- Significant scope for misuse of data for “personalised marketing” of healthcare products to individuals or their relatives
Will “presumed consent” be valid?

• Only 7% of people approached opted in to UK Biobank: should 93% be presumed to have given their consent unless they actively refuse?

• People do not trust the system to keep their data secure or anonymised and, whilst supportive of research, want to be asked for their consent (WT/MRC 2007, CfH 2008)

• There was significant public and professional opposition to previous attempts to share data without consent (Clause 152)

• Art 8 of the ECHR requires storage of samples and genetic profiles to be necessary and proportionate

• Failure to meet these requirements led to significant loss of public trust in police use of DNA

• Data protection legislation does not appear to allow biometric databases to be built without consent: an “opt-out” process is inadequate and unworkable
Whose vision of the NHS?

• The WT/HGSG proposal has been promoted as a vision for the NHS since at least 1999
• There has never been a public consultation on the plan
• There has never been an assessment of the costs and benefits
• There is substantial commercial interest in the plan as a means to expand the market for healthcare products (using “personalised marketing” based on individual risks)
• The idea of genetic screening was originally proposed by the tobacco industry (later backed by the food, chemical and nuclear industries) as a means to undermine public health measures
Recommendations for the Panel

• It is essential to be open about the existence of the WT/HGSG plan
• Do not endorse the sequencing of people’s genomes in the NHS without their fully informed consent
• Recognise that data-sharing of medical records on the basis of “presumed consent” removes people’s right to know who has access to their data and is unlikely to be publicly acceptable
• Acknowledge that anonymisation of the entire population’s medical records is impossible (and people realise this)
• Be aware that loss of public trust could damage legitimate medical research