

Workshop on genomics, health records, database linkage and privacy

Academy of Medical Sciences, 41 Portland Place, W1B 1QH, 22nd February 2012, 10:00 – 15:30

Background to the workshop

The theme of genomics, health records, database linkage and privacy was selected for a 'forward look' meeting of the Council in 2011. Following this meeting the Council agreed that the topic should be taken forward for more detailed consideration at a workshop, which was held on 22 February 2012.

The workshop was tasked with identifying what 'important and distinctive contribution' the Council might make in this area. Four broad, interlinked themes were considered:

- Consent and control of personal biodata by individuals;
- Authorisation to access, share and link personal biodata without the consent of a person to whom the data relate;
- Anonymisation, data security and privacy protection; and
- Feedback of information and the ongoing relationship between controllers and subjects of biodata.

All participants were asked to provide approximately 300 words on what original and valuable contribution the Council could make to existing knowledge and ongoing debate in this area. Participants also received supplementary materials including a background paper previously prepared for the forward look meeting, a note of the discussion at that meeting, a summary of some current initiatives relevant to the workshop, a programme, a participant list and the collated submissions sent by invitees prior to the meeting.

The day was divided into three sessions: two morning sessions (each comprising two presentations and discussion) and an afternoon 'workshop' session during which attendees were divided into four separate discussion groups in order to develop ideas around the four key themes. The results of these discussions were then fed back to all attendees.

Broadly, the purpose of the morning sessions was to identify developments that raise questions of ethical significance and the purpose of the afternoon session was to define those questions and examine why they are significant. A note of both sessions is provided below.

Presentations

Protecting privacy in a global networked world

- 1 The main issues associated with this area had been germane for several years: advances in information and computing technologies had led to improved capabilities associated with the processing, storage, movement and analysis of large quantities of data.
- 2 The meaning of 'privacy' was discussed, with an example given of a narrowly defined, legalistic definition,¹ which focused on the individual's mastery of facts regarding their own identity and their presumed ownership and control of those aspects of him/herself. It was questioned whether this was a sufficient understanding.
- 3 Scientific research was increasingly interconnected and research networks existed on all levels – regional, national and global; 'a network of networks'. This was influencing the nature of research, especially where large datasets were concerned. Given the nature of these networks, and the increasing sophistication of information technology, in the future researchers will be able to access large, seamless datasets where previously they would have had access only to more fragmentary data. Appropriate governance frameworks were not in place to manage these developments.
- 4 Participation in research had traditionally been based on respect for the individual but also altruism and an appeal to solidarity – participants would be offered confidentiality, but not control or (in some cases) preservation of anonymity. The absence of control was contrasted to the legalistic definition of privacy provided above. Established procedures had built up around this social contract, such as Research Ethics Committees in the UK and Institutional Review Boards in the USA.
- 5 'Informed consent' was understood to focus specifically on the needs of individuals rather than the concerns of groups (family, communities, populations etc.) The concept of informed consent had been described and discussed many times. It was noted that the Declaration of Helsinki required that consent must be obtained at the beginning of the research process. However, it was argued that these requirements were designed in relation to physical harm and 'one project, one jurisdiction' research. Under these requirements, and the current methods of conducting research, it was often difficult or impossible to inform research participants at the time of collection of all possible research uses and who would have access.
- 6 In the context of the topic of the workshop, 'broad consent' referred to the range of as-yet unspecified purposes to which research data might be put (i.e., asking individuals to give a one-off consent for the use of their medical information for

¹ Laws LJ *Wood v Commissioner of Police for the Metropolis* [2009] EWCA Civ 414 at §21

research purposes, which could be used for many years building up profiles.) It was used in a number of fields, particularly biobanking, but was considered to be a contentious issue as it was effectively 'consent for governance' – the individual 'drops out of the picture' and decisions about the appropriateness of future use of the research resource are made instead by access committees and/or overseen by ethics bodies.

- 7 Such oversight bodies were usually required to deliberate on the issues from the perspective of the participants. However, their powers were understood to be variable, especially regarding research conducted by international networks because the jurisdiction of most bodies was limited to their home nation. Furthermore, it was noted that there was little in the way of enforcement following the initiation of the research, as powers of enforcement are 'front loaded' at the beginning of the research process.
- 8 The issue of post-initiation enforcement was highlighted by problems related to the withdrawal of consent. The Declaration of Helsinki requires that research participants should be able to withdraw from research at any time. Although unproblematic for standalone projects, this could be extremely problematic when research was conducted – and data shared – across networks. Data might cross jurisdictional boundaries and datasets continually (and easily) archived and re-distributed. Under such circumstances, data – once shared – are difficult to 'claw back'.
- 9 It was argued that given developments in information technology – and concomitant shifts in the way research is conducted – it was no longer possible to guarantee anonymity: DNA is by definition a unique identifier; data can be shared, linked and replicated globally and indefinitely; genome sequence data was becoming more accessible to people outside the research community. Despite these changes, participants were still expected to act in an altruistic way and hold to their side of the social contract.
- 10 As a consequence, the limits of anonymisation should be more explicitly recognised. It was unclear whether anonymisation was a genuine concern for most research participants. A failure to address these issues was considered likely to be detrimental to science and translational medicine.
- 11 One possible response to these challenges could be the use of 'e-governance' mechanisms, a way of channelling behaviour using electronic measures. This could be thought of as 'ELSI by design', as a counterpart to 'privacy by design'. Furthermore, a shift in the way these problems are approached was considered necessary: they must be conceptualised as global, not local, issues. Research governance frameworks should be constructed so that they apply to networks and not only single projects. The relationship between the researcher and the participant should be re-framed as a partnership beyond the orthodox, paternalistic researcher/patient relationship.

Discussion of issues arising from the presentation

- 12 The Council should endeavour to link with national and international organisations involved with similar issues. The Council could usefully act as an independent 'broker' on these matters, free of the vested interests (actual or perceived) particular to the area.
- 13 The goal of engaging the 'public' with research is laudable, but there were difficulties (primarily in defining what research is and who researchers are). Commercial organisations such as 23andMe were seen as blurring the line between research and clinical applications. The Council should aim to clarify these boundaries and identify what is appropriate: what values need to be protected? What is the public interest in this area?
- 14 It would be useful for the Council to consider both research and clinical aspects, despite the difficulties in facilitating both research and clinical care. It was suggested that the Council consider carefully, through examples, where clinical care and research overlap and where they conflict. It was noted that in terms of privacy, there is a significant drive to keep the two areas separate, but from a translational research point of view this was considered untenable.
- 15 Finally, it was argued that it would be useful for the Council to consider what research participants/members of the 'public' really felt were the issues at stake (such as commercialisation, media access to data and discrimination). This was accepted to a degree, but it was noted that the rules relating to privacy and anonymisation should not be ignored or overturned en masse – new systems could be put in place that would appropriately implement those rules within the new research and clinical context created by the technological advances referred to above.

Current opportunities and threats of biobanks

- 16 A large number of competing definitions of 'biobank' were available. The main features were seen as the storage of biological samples, the retention of relevant data and an open-ended research purpose. Biobanks could be divided into three main categories: disease-orientated, population-oriented and twin-cohort studies.
- 17 The number of biobanks had increased dramatically in a relatively short space of time from (globally) around ten with more than 10,000 participants in 2006 to approximately 163 in 2012.
- 18 The individual outcomes of donating DNA to a biobank could be intended or incidental. They included:
 - 1) Identifiability: complete anonymisation of DNA is not possible;

- 2) disease risk attributed: very small, but could change as result of future research;
 - 3) attributes and abilities: e.g. cognitive function (more likely than disease risk); and
 - 4) family relationships: e.g. (non-)paternity.
- 19 Opportunities to individuals included altruistic benefit to future generations through participating in research and (perceived) access to a 'health MOT'. From a group perspective, disease interest groups could become actively involved in research into relevant illness. Numerous opportunities existed for society, including the identification of disease risk, understanding biological mechanisms of disease and the development of stratified medicine.
- 20 Participating in biobanking research could expose individuals to risks including identifiability, lack of confidentiality, unwanted feedback, unexpected and unwanted information about family relationships (such as non-paternity) or involvement in research with which the participant disagreed on moral grounds. Risks to groups included the unanticipated 'lag' time between research and implementation (in the case of disease interest groups) and discrimination based on genetic risk. The high cost, possibility of gene patenting and a failure to give full consideration to the ethical and legal implications of biobank research were highlighted as some of the risks posed to society in general.
- 21 Uncertainties existed for individuals participating in biobanking research, including the legal status of the donated samples, the capacity to withdraw from the study (and the actions taken following withdrawal) and the friction between participant autonomy and the professional's duty of care. Uncertainties relevant to groups included the precise nature of research possible and relevant after sample collection and how biomarker research could be translated to the implementation of clinically relevant research. On a societal scale, it was noted that the full legal and ethical implications remained uncertain and it was unclear whether, what and how to feed back (genetic) results. The future relevance of current research was also uncertain.
- 22 An exit questionnaire performed by Generation Scotland found that project participants had a generally positive experience. This was attributed to a (hypothetical) health-MOT test and satisfaction in contributing to future healthcare. A survey of prospective participants, which gave information on what the project would involve, found that 57% of respondents would be willing to take part. Those who responded positively tended to be better educated, middle aged and with a medical history. Given reasons including altruism, aiding scientific advance, a specific interest or a relative with a family illness. Reasons given by those who would not participate included lack of time, no interest and a fear of needles. Among those already willing to take part, the

possibility of pharmaceutical companies or police forces accessing biobank data resulted in an *increase* in the likelihood of participation.

Discussion of issues arising from the presentation

- 23 The lack of sufficient representation of types within the sample was an on-going factor in biobank research and would limit the extent of the scientific questions that can be addressed. The level of appropriate feedback provided to participants in biobank research was identified as an important issue, especially in light of how unrepresentative biobanks are of the general population; feedback might encourage interest in studies and help ensure that those who participate initially remain involved. Furthermore, it was unclear how much feedback should be given to participants where users of the participant's data had concerns and fed those concerns back to those managing the biobank. Although some exploratory work had been done, biobank researchers were unwilling to commit to a particular form of action until the issues had been resolved by their funders. It was suggested that a potential Council report might offer a useful analysis of these issues.

Medical records

- 24 It was argued that the mechanisms by which medical and research data are used must change: information governance at the English national level has, in the past, presented significant barriers to research and innovation resulting in a wealth of local knowledge and developments that cannot be joined up nationally.
- 25 The main issue was the extreme variety of medical systems used across different fields of medical care, leading to fragmentary and disaggregated information in non-standard and incompatible formats. Patients cannot manage the data themselves currently and there are questions to consider regarding who ultimately 'owns' the data.
- 26 Electronic health records were argued to provide better access to, and permanence and sharing of, data. Electronic health records systems in the UK were being developed at a more local level, following the (perceived) failure of the national level system proposed for the NHS. There were a number of associated problems: standardisation, difficulty in having clinicians use the same parts of the record, avoiding error in data mining tools, etc.
- 27 Whether or not these systems should be established on a patient 'opt-in' or 'opt-out' basis was an issue of some import. The Summary Care Record (SCR) launch resulted in the creation of approximately 11m records so far. It was predicted that more will follow. It was noted that those who established the project had had to reduce the scope – information governance concerns had reduced the amount of information transferred from the general practitioner to the record. Given the local level roll-out of different record systems, it was

uncertain whether or not the SCR had a future given that in some areas it was simply not felt to be needed.

- 28 Health record systems in other countries were discussed. The Australian model is 'opt-in' and has slow uptake but the intended usage is much more extensive than the SCR. The US Veteran's Health Administration (VHA) adopted a very similar system to the SCR (there are approximately 27 million US veterans, of which around seven to eight million use VHA services), and is of interest as information governance requirements do not seem to have been so inhibiting.
- 29 Risks and uncertainties associated with electronic health record systems included access by multiple parties (especially contractors), anonymisation, audit trail problems as systems become aggregated, misuse of data by care providers and parental access to sexual health details of minors.

Discussion of issues arising from the presentation

- 30 Secondary care was understood to be lagging behind primary care in terms of practitioners accepting patient control of data – secondary care practitioners often considered records to be 'theirs' and found it difficult to share information with patients.
- 31 Audit trails were extremely important and should be taken into account when designing relevant systems, especially from the point of view of regulators.
- 32 It was argued by some that patient desire for access and control over data was not clear cut: NHS HealthSpace had not been taken up widely, for example. A government strategy review was due on these issues; the possibility of an NHS online portal with links to all patient-related NHS health information aggregated in one place was a possibility, although it was recognised that many elements had already been provided at a local level.
- 33 The possibility of patients maintaining their own records and bringing them to both primary and secondary care was understood to be useful only in certain circumstances (such as those patients heavily involved with their own care due to complex, chronic illness). No approach was a panacea, but it was agreed that self-maintenance would disengage a large proportion of patients.

Genomics – current opportunities and threats

- 34 It was noted that there was a tendency in all fields to consider only *active* risks and uncertainties. It was, however, vital to consider also the risks of failing to act to promote scientifically sound research.
- 35 The main driver for ethical issues in this area, relating to genomics, was argued to be the drop in sequencing costs from approximately £1 billion to approximately £3000. Sequencing costs were already close to the cost of an

existing single test and would allow the data, once obtained, to be stored and reused for further analyses as and when needed.

- 36 Both the genotype and the phenotype were considered necessary to build up a sufficient model to describe links between genome variation and disease. The simplest way of doing this was with genome-wide association studies (GWAS). However, some of these study data had been reproduced using patient record systems (especially in the US). Although those data were 'noisier' than those derived from GWAS, disease relationships could still be discovered using such techniques.
- 37 The discussion around these issues in the UK was driven by the establishment in 2006 of the Office for Strategic Coordination of Health Research (to increase coordination of MRC and NHS research), and its E-health Board in 2007 (to enable research using health records). In 2009, the House of Lords published a report on Genomic Medicine and in 2010 the UK Government created the Human Genomic Strategy Group.
- 38 A recent funding call, led by the MRC, was designed to establish a network of e-health researchers, based on the model of those in Scotland and Wales, to work not with personal data but suitably-anonymised data.
- 39 The first report of the Human Genome Strategy Group identified three patient application areas for sequencing: personal genomes, cancer genomes and pathogen genomes.
- 40 It was argued that much of the attention on personal genome sequences was focused on disease risk identification, to the detriment of the much more useful areas of personalised drug prescription/dosage and rare genetic defects.
- 41 Cancer sequencing could allow for treatment design based on exact genetic defects. Recent publications in the US demonstrated the feasibility of this approach.
- 42 Pathogen surveillance was an area of promise as pathogens are small and easily sequenced. For example, an MRSA outbreak could be more easily understood by identifying its origin. Real-time sequencing allowed for extremely precise identification of the geographical origins of pathogens.
- 43 Personal genome sequencing was understood to have the largest transformative potential, particularly given the impending capacity to obtain and store a full genome sequence at the same cost as an existing single test. This would likely have a significant impact on health economics. For example, drugs that had hitherto been removed from the market would likely now remain as it will be possible to identify with more accuracy those on whom such drugs would work; relevant tests on the stored genome sequence could be near instant and costs restricted mostly to IT resources.

- 44 It was possible to attach electronically a 'variant file' to an individual's electronic health record – the file would contain information on some of the individual's genetic variants and be small enough that it would be technically feasible to implement with current technology and systems. This represented the 'personalised' element of genomic medicine.
- 45 However, such data could also be anonymised and aggregated from all available electronic health records into a central cluster and kept separate from the original personalised medical records. This would allow for research to identify, anonymously, new disease correlations. Applying this would require identifying the (relatively) few clinically actionable correlations and would need significant resources to achieve. However, with the cost of sequencing and storage dropping, and the identification of relevant correlations improving, at some point it was likely to become useful.
- 46 It was noted that there was an interest within the pharmaceutical industry in creating a business model based on selling drugs with 'companion diagnostics'. This would represent a modification of the current pharmaceutical business model but it would be significantly disrupted by the availability of stored genome data from individual sequencing. Although the initial cost of sequencing would be (relatively) high, drug costs would be reduced as the number of different, ineffective drugs tried on an individual should be lowered.
- 47 It was argued that local and national databases of aggregated, clinically useful variants should be linked globally. The number of clinically relevant variants in such a set of linked databases would increase over time, thus becoming more useful. This would become a dominant source of data for genomic researchers, replacing cohort studies.
- 48 The benefits derived from the sequencing of the human genome came from suitably-managed open access to the data; over-control of data could limit potential research benefits. It was argued that preventing bona fide researchers from accessing the data inhibited the development of innovative ways of looking for correlations and therefore led to poorer healthcare – effectively depriving people of interventions that might save lives.
- 49 What were the risks to individuals when researchers had access to anonymised data? The greater the amount of data available, despite attempts at anonymisation, the easier it becomes to identify particular individuals. Solutions could either be social (changing the way people viewed and valued privacy in this context, for example) or technical. Social changes would take time. One possible technical intervention was not to distribute the relevant data, but to allow researchers to compute the data in a highly constrained way where, for example, they could use their own algorithms but only within a 'box' which stopped them exporting any data – only summaries of data could be exported, which would contain useful information such as disease correlations. No raw

data would be leaked. This could be described as ‘total freedom within strict limits’ – making it easy to do the right thing and hard to do the wrong thing.

Discussion of issues arising from the presentation

- 50 There was debate as to whether wide-scale sequencing of populations would be useful from a healthcare perspective, centring on the clinical utility of SNPs and common disease variants and whether or not the prediction of pharmaceutical response was sufficiently accurate to allow for useful, personalised dosage modification.
- 51 It was agreed that one of the key issues was the establishment – and maintenance – of uniform or harmonised information governance standards when dealing with access to, and distribution of, very large scale datasets.
- 52 It was important that the problem of systemic bias be taken into account when considering the ‘noisy’, but useful, phenotypic data derived from data mining exercises involving large numbers of health records – the data therein was collected for the purposes of the healthcare provider, not researchers.

Plenary discussion

- 53 The Chair opened the discussion by inviting the group to consider to what extent the presentations and discussions had sufficiently identified the ‘right’ problems. Participants noted a number of issues they thought should receive further attention:
 - How private sector providers will respond and what effect it will have on public healthcare services (e.g. patients trying to ‘queue jump’ after privately undergoing a test which demonstrating the efficacy of a particular treatment);
 - Whether privacy and confidentiality need new moral and legal models, given modern understanding of the extent of the similarities between genomes from individual to individual;
 - How data are monetised;
 - Whether and to what extent a model based around an honest broker for research data is necessary, and how it might work;
 - What legal challenges – especially under human rights law – would occur should some of the suggestions put forward during the presentations be enacted;
 - The global nature of genomic research (and data sharing generally) should be considered in depth, especially the varying approaches taken across jurisdictions;

- An examination of the (differing) nature of the values underpinning both personal data and privacy – anonymisation was not a complete solution to privacy concerns and technical solutions were limited in scope and efficacy; and
 - That the clinical aspects of the issues raised during the presentations should be considered in as much detail as – and at the same time as – those applicable to research.
- 54 The purpose of public healthcare systems, in particular the NHS, was seen by some as a key issue; it was argued that most members of the public view the NHS as an organisation designed to provide care – the extent to which the public would be happy to see it as a ‘vehicle for research’ was uncertain. Some believed that the public was concerned by the hybridisation of the NHS while others noted that research suggested the public found it surprising that internal NHS research data was *not* used to improve clinical effectiveness, health and general well-being
- 55 It was argued that, from a regulator’s perspective, data use for research received few complaints. Rather, complaints went up where such data leaked to insurance companies and the media. The main problem from a regulator’s perspective was how to deal with ‘fair processing’ and informing people what is happening to their data: how is information being used, collected and processed? It was suggested that this was an area to which the Council could usefully contribute.
- 56 It was agreed that there was time pressure facing the information governance questions that were at stake; data were being shared globally at an unprecedented rate and this was unlikely to stop. Failure to act nationally (preferably internationally) at the earliest opportunity would lead to a free-for-all. Although it was accepted the process could not be reversed, establishing a good framework early on might help to mould development. It was suggested that the Council could usefully help to construct ethically-robust and practically-effective frameworks.
- 57 The Chair summarised the main issues raised during day:
- 1) Understanding and appreciating the values that underpin what is being attempted and also the objectives of organisations such as the NHS and the attitudes of relevant publics and researchers to the trade-offs in play;
 - 2) (In various contexts) the concept of ‘interconnectedness’ and its attendant challenges: researchers, datasets, clinical and research processes and agendas;
 - 3) Understanding relevant underlying concepts such as privacy, autonomy, control; a conceptualisation of what is actually at stake;

- 4) Robust and proportionate governance strategies and the need for multi-level approaches – technical, legal, social and ethical; and
- 5) Overarching all of the above, the issue of commercialisation and the separation of public and private.

Workshop feedback session

58 During the afternoon session, four tables were asked to discuss the different aspects in order to respond to the general question: “What questions might the Nuffield Council on Bioethics examine in order to make a distinctive and important contribution in this area?”

Blue table: Consent and control of personal biodata by individuals

59 The group felt that the current regulatory landscape – which was presented as a continuum of measures going from informed consent, through consent to governance/ authorisation of data use by others, to use of data without consent – was not ideal, but was difficult to escape. They observed that the consent approach created areas of confusion: for example, there were cases in which it was not clear whether consent (re-consent/further consent) should be requested.

60 They were critical of the elision of the concepts of consent and control, pointing out that consent was only one mechanism through which individuals might exercise control over ‘their’ biodata. They identified a number of different ways in which control could be exercised over data, including withdrawal of consent, participation in research design, actively sharing information and open sourcing.

61 They also challenged the focus on individuals, suggesting that the focus should be on people in contexts (for example, as members of families, social groups, etc.). They identified a changing relationship between public and private in healthcare and saw this as a significant development in terms of data governance.

62 The group agreed that there was a good reason for the Council to initiate a project in this area, since existing work does not foreground the issues raised by genomics sufficiently and tends simply to map the existing terrain without imagining how this may change in the future. The Council might therefore consider developing an analytical framework that identifies the roles and responsibilities of actors in different contexts. This would assist researchers, for example, to identify their position in a set framework of relationships. The Council might also more clearly, perhaps more strongly, help to define the public interest in data use and address these questions taking account of the global context of information sharing.

Orange table: Authorisation to access, share and link personal biodata without the consent of a person to whom the data relate

- 63 The group identified the grounds of their discussion with the remit of the National Information Governance Board and its Ethics and Confidentiality Committee to advise the Secretary of State for Health on the use of regulations made under S.251 NHS Act 2006 (which establish the power to effectively set aside the common law duty of confidence if confidential patient information is to be processed for a medical purpose and there is no practicable alternative, such as consent). It was stated that this power was exercised very much in terms of decision making protocol that determined who should make the decision, the process by which the decision should be made and the criteria that should be applied. An alternative 'solidarity' model might be considered whereby, in return for the benefits offered by public institutions such as the NHS, citizens' data might be expected to be made available for approved research. Thus, the data could be used automatically or individuals could be approached to be identifiable participants. Alternatively, 'opt in' or 'opt out' systems might be used, although difficulties were noted in instituting such a system (reaching people through information campaigns, high levels of opting out, risk of poor buy-in). However, this should be seen in the context of increasing transparency in the use of data and the public becoming used to more empowering interfaces with institutions (e.g. through iPhone apps).
- 64 The group felt that the Council's independence (unlike, for example, the vested interests of government or research bodies) meant that it was well placed to consider the ethical issues associated with opt in/opt out systems or the practical implications of the positive value of solidarity in this context.
- 65 In contrast to the approach of the blue table, this group suggested that the Council might approach the question of authorisation on a blank slate, beginning with an analysis of the characteristics of an 'ideal situation' for biodata governance and then considering what measures would need to be taken to move to that situation from the present situation.

Green table: Anonymisation, data security and privacy protection

- 66 The group approached their task through the question: "is the current [biodata information governance] framework fit for purpose and, if not, what needs to be done to make it so?"
- 67 They considered that important issues to consider go beyond simple questions of governance mechanisms (understood as the responsibilities of the custodians of data). They suggested that there was a need to consider how the sharing and use of data is contextualised by attitudes and dispositions, particularly with respect to the way in which people increasingly distribute personal information themselves through social networking websites, through online questionnaires, etc. It is clear that large amounts of personal data are

increasingly going to be available in loosely controlled environments through a variety of means, and the key question is what can be done to make such data safe. Such a question goes well beyond the responsibility of custodians of individual data-sets, such as the NHS or other public institutions. On the other hand, the increasing emphasis on personal access to and control of data should not obscure the continuing significance of the traditional governance model in which citizens/patients trust professionals to manage their data safely on their behalf and in the public interest.

- 68 Exploring these underlying attitudes and dispositions would lead to an enhanced understanding of the actual harms that people are afraid of (which are often unhelpfully obscured by the legal ‘catch-all’ of respect for privacy) and what, in preference to current measures, might be done to avert or mitigate these. In this context, anonymisation is not a single effective response but can still be useful in managing/ reducing risks.
- 69 The group also raised the question of reciprocity and what constitutes a ‘fair deal’ for those using and benefitting from public services that depend on biodata (such as the NHS) and what expectations might attach to such benefits.
- 70 They raised the question of whether the concept of ‘ownership’ of biodata was relevant or useful as a way of approaching the issues.
- 71 The group felt that the Council’s independence would allow it to act as a neutral party in an area in which there were a range of vested and competing interests. It had also discussed the extent to which the Council might play a role (perhaps in partnership with other bodies, such as the Information Commissioner’s Office or the Sanger Institute) in investigating public views and understanding both of how data is currently shared, and how it ought to be shared – and in comparing how wider public views compared with those of campaigning groups.

Yellow table: Feedback of information and the ongoing relationship between controllers and subjects of biodata

- 72 This group examined the question of research participants’ attitudes towards feedback and their continuing relationship with those who hold or use ‘their’ data. Three cases were considered:
- Where participants were expecting feedback (even though they had been told not to expect it).
 - Where participants were not expecting feedback (either because had been told there would be none or because they were not aware that the data had been used in research)
 - Where participants did not want feedback (where they had explicitly refused it or would be upset to receive it “out of the blue”)

- 73 The third of these cases was seen as especially problematic as it brought the researchers' duty of care into conflict with the expressed wishes of the participant (and raised questions of professional negligence). The difficult balance was discussed in relation to the interpretive uncertainty and context-sensitivity of biodata. For example, how should factors such as the risk, seriousness, treatability, and heritability of a condition identified incidentally in research affect the reasonableness of a decision to disclose or not disclose?
- 74 The notion of context sensitivity (particularly with genomic data over the long term) was seen as an important complicating factor: it was important to consider that researchers may be interpreting data fed back to participants, and that these interpretations would change over time, and may determine whether and when information should be fed back. This led to a discussion of the issue of the scope of advance decisions about feedback and the extent to which such decisions could be made in advance. On one view, the fact that it may be difficult for people to understand the consequences of information in the abstract might be thought to license overriding an advance refusal of feedback on the basis of a duty of care when clinically relevant information was actually discovered.
- 75 The case of research using body imaging techniques was discussed, in which agreement to receive clinically relevant feedback was a condition of participation (because the researchers felt that they could not discharge their duty of care otherwise). The 'rule of rescue' (codified in law in some continental European countries), and 'reasonableness' defences, was discussed as a principle possibly worth examining.
- 76 It was noted that the concept of a 'researcher' was not always easily applied and there areas of ambiguity are likely to increase: the example given was consumer genetic testing companies who might use customers' data to develop their service. There are also complex issues related to clinicians who also assume a researcher role, not least with respect to the nature and scope of the duties they owe to patients who become research participants.
- 77 These examples (uncertain duties, uncertain roles) were seen to mark a complication of the nature and scope of the trust relationship between participants and those (clinicians, researchers, public authorities) whom they entrust with their personal data.
- 78 It was noted that while feedback may be thought to reinforce the trust relationship the motive for offering it might not lie with the participants themselves, for example, offering feedback in order to increase participation.
- 79 The group agreed that the increase in research participants' expectations of reciprocity – the broader development of information systems (e.g. supermarket loyalty cards) creating expectations of personalised relationships between

individuals and institutions – was a model that the Council might wish to consider.

General discussion

- 80 There was support from all four groups for the Council to explore this subject area further. The main reasons for this were absence of other bodies looking at the issues at the level of underlying values and principles (rather than in relation to specific kinds of data or research) and the Council's uniquely independent position, which meant that it could act as an 'honest broker' between parties with vested and competing interests.
- 81 Four areas in particular were identified as possible targets for the Council to explore:
- (i) Assessment of the current biodata governance frameworks and their fitness for purpose.
 - (ii) Unpacking different approaches to governance (e.g. harm-based, risk-based, relational, trust-based).
 - (iii) Exploring a move from approaches based on altruism to those based on solidarity or reciprocity.
 - (iv) Developing an analytical framework that identifies the duties and responsibilities that attach to those in a particular context.
- 82 Other potentially relevant issues that had not been explored in detail in the discussion were globalisation, social justice and political visions of the kind of society that different relationships between public and private interests might embody or enable.
- 83 Further consideration needs to be given to the question of how central genomics would be to any further work (there was a general feeling that this was significant). One view was that genomics was disruptive force and there was some urgency to resolve the governance of genomic information within the NHS lest there be a 'free-for-all' outside it.

Programme

09.30	Coffee	
10.00	Welcome and introduction	Chair
10.15	Presentation 1: privacy and public interest in health information	Jane Kaye
10.45	Presentation 2: biobanks – current opportunities and threats	Blair Smith
11.15	Coffee	
11.30	Presentation 3: health records – current opportunities and threats	Henry Dowlen
12.00	Presentation 4: genomics – current opportunities and threats	Tim Hubbard
12.30	Chaired discussion	
13.00	Lunch	
13.45	Welcome back and instructions for session	
13.55	Group discussions	
14.40	Feedback from tables and chaired discussion	
15.30	Close of workshop	

Attendees

Guests

Professor Paul Burton

Professor of Genetic Epidemiology, University of Leicester

Mr Phil Butcher

Head of IT, Wellcome Trust Sanger Institute

Dr Anne Cambon-Thomsen

European Sequencing and Genotyping Infrastructure

Professor Sarah Cunningham-Burley

Professor of Medical and Family Sociology, University of Edinburgh

Dr Henry Dowlen MBE

National Clinical Lead for Hospital Doctors – Information Standards and Defence Medical Services, NHS Connecting for Health

Mr David Evans

Policy Manager, Information Commissioner's Office

Ms Gemma Farmer

Policy Manager, Information Commissioner's Office

Dr Tim Hubbard

Head of Bioinformatics, Wellcome Trust Sanger Institute

Dr Jane Kaye

Director, HeLEX, University of Oxford.

Dr Alastair Kent

Director, Genetic Alliance

Dr Katherine Littler

Policy Advisor, Wellcome Trust

Professor Jonathan Montgomery

Professor of Health Care Law, University of Southampton and Chair designate, Nuffield Council on Bioethics

Ms Hilary Newiss

National Information Governance Board for Health and Social Care

Dr Siani Pearson

Senior Researcher, HP Labs Bristol

Dr Henry Potts

Senior Lecturer Centre for Health Informatics and Multiprofessional Education, University College London

Dr Chris Pounder

Amberhawk

Professor Martin Richards

Vice Chair, UK Biobank Ethics and Governance; Centre For Family Research, University of Cambridge

Ms Isabella Sankey

Director of Policy, Liberty

Professor Blair Smith

Chief Investigator, Generation Scotland; Professor of Population Science, University of Dundee

Dr Mark Taylor

Deputy Director, Sheffield Institute of Biotechnology Law and Ethics, University of Sheffield

Dr Helen Wallace

GeneWatch UK

Nuffield Council on Bioethics (Members)

Professor Graeme Laurie (Chair of the workshop)

Professor of Medical Jurisprudence, University of Edinburgh

Professor Ray Hill

Visiting Professor of Pharmacology, Imperial College London

Professor Anneke Lucassen

Professor of Clinical Genetics, University of Southampton

Nuffield Council on Bioethics (Secretariat)

Hugh Whittall, Director

Dr Peter Mills, Assistant Director

Tom Finnegan, Research Officer