

## **Symposium on building sustainable public trust in the responsible use of health and care data**

**Nuffield Council on Bioethics, The Nuffield Foundation,  
28 Bedford Square, London WC1B 3JS  
19th June 2015, 10.00 am**

### **Background to the meeting**

1. The meeting was chaired by Jonathan Montgomery, Chair of the Nuffield Council on Bioethics.
2. Dr Cavendish explained the Department of Health's interest in the use of health, care, and social data: data are a fundamental resource of the health and care system and provide a platform for a range of functions including patient care, research, innovation and the running and management of the healthcare system. The Department of Health (DH) has set up a multimillion-pound project to understand and improve the use of data, responding to the impact of 'big data' technologies and a constant increase in the availability of data, e.g. through online data, wearable technology and scientific approaches of genomics, proteomics etc. There is a perception of enormous capacity and excitement around the potential benefit from using these data, which come at a time of fundamental change at DH.
3. The recent experience of the 'care.data' programme came at a very sensitive moment. Although its implementation might have been managed better, Dr Cavendish said it was important to contextualise the public's perception: the critical attention given to the privacy policies of large-scale social media platforms such as Facebook, and accessing and sharing of data by GCHQ had intensified scrutiny and public cynicism. Initially, DH had not systematically investigated concerns arising in connection with data use at this unprecedented scale, nor issues around public engagement and trust in data use, about which, however, people have legitimate expectations.
4. Dr Cavendish suggested that we are currently at a potential turning point. Developments in the use of data could follow a path analogous to the introduction of IVF, which was handled both innovatively and pragmatically within an open, democratic approach. On the other hand they could follow a path analogous to the introduction of GMOs, which had led to paralysis. DH acknowledges that it needs to think very carefully about the challenges ahead and how to address these and is very keen to hear in more depth about opportunities, risks and possible moral frameworks as well as ideas around public engagement.

5. Professor Montgomery explained the Nuffield Council's interest in the use of health and care data in the light of its recently published report ["The collection, linking and use of data in biomedical research and health care: ethical issues"](#). He drew out some key themes developed in the report including:
  - limitations of the current 'data protection paradigm', which struggles to address new challenges in 'big data'-driven healthcare and research, and its reliance on 'consent or anonymise'
  - the unfeasibility of categorising data into distinct classes within a 'big data' context
  - a mismatch of the legal framework and the governance driving it with public social norms and expectations
6. Professor Montgomery said that the approach developed in the Nuffield Council's report is based, among other things, on the identification of a publicly statable set of morally reasonable expectations about the use of data through deliberation with affected stakeholders. In particular it involves attending to the moral norms at stake in the protection of privacy, 'sharing' and disclosure of data, and what follows from this for individual rights and choices, as well as the important duties placed on professionals operating in this area.
7. An overarching topic and focus of both academic and public discussion has been around the notion of 'trust' and, in particular, public trust in relation to government and other actors driving reuse of health and care data. Professor Montgomery said that the present meeting was intended to gather views on the reasons for supposed public mistrust in this area, and to develop a better understanding of why public trust in the use of data beyond traditional contexts is fragile, and difficult to earn and maintain.

## **The importance of public trust in data use**

### *Specific public concerns identified about the use of health and health-related data*

8. Dr Taylor said that according to the literature public concerns can be grouped into three broad categories:
  - (i) Misuse of data
    - a. Access and potentially discriminatory uses by employers, insurers or others
    - b. Marketing uses
    - c. Differential treatment in the NHS

- (ii) Privatisation/commercialisation of data or data-relevant systems such as the NHS and beyond
    - a. Secondary, un-consented and unexpected uses – concern about companies profiting from data given altruistically for research
  - (iii) A perception of loss of control
    - a. Absence of the ‘courtesy’ of consent: when people are not asked they want nonetheless to understand why they are not being asked, they want to hear reasons and these are not obvious
9. These concerns should be considered as complex and ‘layered’, a key linking theme being potential exploitation. Professor Murtagh said that, in research, additional concerns have been identified that data are not used sufficiently and/or not sufficiently in the public interest, specifically in longitudinal studies. Participants are concerned that data are not treated as a public good – they expect data to be used for the benefit of the public.
10. Lord Darzi adverted to the concern that individuals and institutions handling data and calling for more ‘data sharing’ are not seen as trustworthy, in particular government agencies, which it cannot be assumed will be accepted as always acting in the public’s best interest. Mr Booth added that there is a widespread perception that what were previously ‘environments of trust’, such as the relationships between GPs and patients, are put at risk due the ‘conditioning’ of an environment’ in the NHS in which mistrust at this important level increases. He suggested that this contributes to a ‘data trust deficit’ which threatens the limited amount of ‘trust capital’ remaining.
11. Mr Booth said that according to medConfidential’s research, people believe that data use should be consensual, transparent, and take place within safe environments with consistent rules for all and meaningful sanctions for abuse. There is a crucial distinction between data use for direct care and data used for all other purposes – what are called ‘secondary uses’ in the NHS. Clear options to ‘opt out’ were found to be preferable to unclear opt-in choices, as has been the case hitherto in healthcare where a large amount of data jargon is used. There should also be some form of oversight and accountability: Mr Booth noted that the abolition of existing structures with the Health and Social Care Act 2012 was inexplicable to many.
12. Ms English said that concerns also derive from a feeling of not being sufficiently informed about the implications of new technologies, and especially the expectations of public benefit. This has been documented in past cases, such as ART where it emerged that the experimental work being undertaken was not well-understood, leading to uncertainty and speculation about the implications of the technology.

Implications of these concerns for securing benefits and minimising harms for individuals and the general public

[Communication as an antidote to speculation]

13. It was suggested by Sir Nick Partridge that the supposed lack of trust in health services using data derives from more general failures of communicating the positive impact of 'big data' approaches. These are currently too 'top-down', so that the public cannot, as yet, relate to the benefits of data use in specific areas of application such as in health and social care. The suggestion was made that communication focussed on more geographically localised outcomes could help to address this problem.
14. A number of participants suggested that civil society expects to be better informed and involved in decision-making around what is perceived as an unbounded and risky 'data sharing agenda'. Individuals participating in research and users of healthcare services, as well the general public, expect to be given reasons for data use rather than general appeals to public benefits: although there is an expectation of data use benefitting the public, these benefits should be more explicit.
15. Lord Darzi agreed that there is a need to be more careful about appeals to the general utility of 'data' and 'data sharing', which should be more discriminating. Both users of data and providers of infrastructure in healthcare and research must make their case and demonstrate their trustworthiness in relation to both the current utility of the data and what is envisaged for the future.
16. Professor Bobrow said that an approach based on openness and 'no surprises' is important for the public. Reasons for the 'necessity' of 'data sharing' must be communicated adequately. Liz Hill suggested that the starting point, before thinking about trust, should be telling people about the uses of data and the practice of research in a transparent manner. There is a lack of knowledge about the use of data in academic research, about what kinds of research are being undertaken and how research is funded.
17. Mr Booth asserted that, from the perspective of patients, care professionals and privacy advocates dealing with both groups (e.g. medConfidential), there is an important difference between the perceived and actual threat to confidentiality that needs to be addressed. He warned that if individuals and the public more generally perceive that they cannot trust their GP to safeguard confidentiality, there is not only a direct risk to their own and the public health, but potential for real, long-term harm to the entire system.

[Uncertainty as a constraint on what can be communicated]

18. Dr Pagliari suggested that there is a need for a clearer communication of the potential for de-identification risks and other risks where data become 'richer' through linkage in data sets. In research and other data systems the communication processes involved should be two-way and form ongoing participatory processes.
19. Professor Severs pointed out that in 'care.data' it was not apparent, for example, who would have access to the data, leading to a perception of potential insecurities attached to the project as a whole. With regard to opt-out options, it emerged that offering an opt-out was not part of the initial project of the Health and Social Care Information Centre (HSCIC), although this would be demanded by the *NHS Constitution*, and arguably the Data Protection Act 1998 and Human Rights Act 2000. Explaining issues around privacy and identity management to even one person, however, is very resource intensive, and the implications might be different for different kinds of databases. As a consequence, it would first have been necessary to have very clear policies pertaining to scope as well as adequate technologies enabling a standard procedure that could be transparent to the public. HSCIC did not decide on the opt-out provisions, and the legal situation was unclear at least until the Health and Social Care Act 2012 and the HSCIC was not in a position properly to manage the complex issues involved. There are, in fact, many questions remaining around implementation of trustworthy use of data, among which are whether HSCIC has the mandate and resources to execute most of such a project by itself, and who the 'thought leaders' in this area should be.
20. Lord Darzi noted that it has not been sufficiently recognised who the most important holders and users of data relevant to health are going to be in the future, and what the implications might be. Supermarkets already access more data relevant to potential health risks than an individuals' GP; this will likely be the case for companies such as Apple through, e.g., access to exercise data. Behavioural data are of increasing importance for population health and are just beginning to be tapped. The integration of different data sets, however, will be a key issue.
21. Mr Knight suggested that one way of increasing transparency and clarity about the use of data and its benefits is clearer communication about what is *not* done with data in order to limit unfounded speculation (especially in the case of the NHS and Health and Social Care Information Centre). This also relates to a need for a better public dialogue about privatisation. The benefits of the commercial life science research and development sector in the UK, which is worth £5 billion per year compared to £2.4 billion in the public sector, should not be ignored. Following on from research conducted as part of the Research Capability

Programme at NHS Connecting for Health in 2008, there is a need for a clear research paradigm and new 'social contract' in this area, in which what the innovation system is delivering for individuals and the contribution of individuals in return should be recognised.

[Confused purposes and double effects.]

22. Dr Pagliari noted that the public has complex views, e.g. many individuals and groups are not universally against commercial use of data, subject to a number of other factors, although this is often not recognised. There is a misalignment of priorities of policy and their communication in the UK context that contributes to this situation. Economic benefit, public health and scientific advance are co-existing narratives, yet it is often unclear which one is the key driver. It can and should not be denied that there is an imperative to derive commercial value from the increasing use of data and to 'drive innovation'. How this relates to scientific advances and healthcare benefits and the improvement of people's lives is not obvious.

23. Lord Darzi suggested that there was a need to acknowledge the opportunities for both health and commercial gain, in particular the benefits for 'UK plc'. Professor Montgomery asked whether this commercial involvement should be treated as contradicting the altruism behind the willingness of the public to share data and whether what is involved is seen as a trade off or rather part and parcel of the system, where individuals and the public contribute but also receive something of value in return.

24. Professor Severs observed that the meaning of 'commercialisation' is often unclear when referred to in the context of data use: although selling data is not permitted under the Health and Social Care Act 2012, outsourcing and cost-recovery are often more affordable than support for public bodies, and private bodies holding data increases risks and makes the control of data flows harder. An undervalued risk is that the NHS 'brand' may be affected by people wanting to use, e.g. smart devices or 'share' with commercial companies.

[Commercial service v. social service models]

25. Mr Knight agreed that the HSCIC system and its policies are indeed complicated, with the two opt-out options and their implications very difficult to understand for many people. He suggested that from the HSCIC perspective, a balance between individual choice and 'directed choice' would best reflect the public's interests overall. This could follow the example of commercial systems such as internet banking apps, in which users are given more choices to turn data flow and

particular services on or off. As the user becomes more aware of the possibilities of the technology, more choice and more data tracking is possible. What works for a bank account might also be possible for health care. In fact, in the NHS/HSCIC such an approach is now imminent with the availability of personal health records via mobile phones. The health system will continue to have to innovate along those lines to remain competitive and to be able to sustain high quality service provision. The public expects services to be run efficiently, with competence and trustworthiness being secured.

26. Mr Booth observed, however, that different companies and brands have very different approaches to managing transactions: Apple is very distinct, for example, from Google. Mr Knight agreed that these providers have distinct communities and operate in a particular social environment, and careful thought would be required about whether and how they might offer models for data use in healthcare and research. Dr Pagliari argued that public expectations of the NHS differ from those of large corporations such as Google, and these must be considered, especially where negative associations, such as concerns about exploitation, are attached to data use in companies.
27. Baroness O'Neill observed that choice and consent function very differently in biomedicine and health care compared to the commercial world, as a matter of ethics, law, and custom. While 'ignorant' consent and 'box-ticking' as 'choice' is perfectly acceptable in the commercial world, in biomedicine ignorant consent is not considered acceptable; indeed, ethical guidance such as the Declaration of Helsinki is very demanding with regard to consent. Individuals should be able to understand the consequences of what they are consenting to, although in practice it is very difficult to uphold this requirement when applied to personal and biomedical big data.
28. Professor Bobrow proposed that members of the public have ambivalent or even contradictory attitudes with regard to 'data sharing', privacy and trust, with sharing of data in social networks or through apps being common, while in the healthcare and research system there appears to be widespread uncertainty, concern and mistrust. This should not be unexpected, however, given that the issues involved are indeed complicated. Professor Bobrow asked to what extent these social network models might be adopted for healthcare and research. Most people, he said, do not seem to want to be confronted with a complex set of choices concerning data 'donation'; instead they want to trust health professionals and researchers and believe that they can be trusted.
29. Professor Severs concurred that people contributing data have very different mindsets and often ambivalent or even contradictory attitudes towards 'sharing'. Some people, for example, object to sharing that is for their own care within the hospital but not to wider data use. If such individual, distinct and inconsistent

preferences are expressed via new data technologies this is likely to make governing data use more difficult.

30. Dr Cavendish and Sir Nick Partridge drew attention to a 'technological deficit' across health and social care in comparison to commercial and online operations in other sectors. At the same time, there has been a public perception of an overwhelming pace of change – from virtually no computerised interaction to a perception of a free flow of data. Professor Murtagh noted these developments in healthcare might be considered in relation to what has been described as the 'translucence' of technologies in the 'internet of things' – smart technology which becomes part of an individual and his or her environment. There is, nonetheless, a large number of issues in 'big' health data looming, such as how to use observational data from self-tracking, e.g. in diabetes patients.
31. Sir Nick Partridge and Dr Cavendish both agreed that the healthcare system must strive to demonstrate greater adaptability to the pace of innovation; professionals in the field and in related policy areas are still creating a framework for innovations that have been technically feasible for some time. The NHS does not, however, have the capacities and infrastructure of Google Life Sciences or Apple to use, e.g., real-time health data. It has even proved challenging to involve people in clinical trials and research in the existing healthcare systems which are not 'participatory' in this way.

#### *Determination of the appropriate level of individual choice and participation*

32. Professor Montgomery suggested that the central concern from the research and policy side is what degree of individual choice is both practically feasible and non-detrimental for research. Consent and continuing participant involvement might be too costly for research, both because of resource pressures and because of issues such as selection bias. He asked whether there should be 'one big offer' of consent rather than what might be an overly complex set of choices, and whether consent should be all 'front-loaded' (confronted at the beginning of a project) or be offered as a more continuing, dynamic process to help foster trustworthiness.
33. Dr Pagliari stated that research participants want to be able to change their minds over time and are surprised to learn that more flexible governance models do not already exist, although there are positive exceptions in some contexts. Any system should allow people to 'own' their decisions concerning data sharing and enable them to turn data collection off so that, for example, their GP would not be able to monitor all of the individuals' nutrition choices. These choices are not narrowly about 'privacy', but about identity control. More generally, when participants are informed and involved, they tend to become more positive about data sharing.

34. Baroness O'Neill argued that it is not merely the inconvenience of consent for large projects and secondary data use that can be problematic; consent, in itself, is very much a signifier of respect for people, which, however becomes 'bogus' if attached to issues that are too complex for the consenting parties to understand. It is a matter of respect that the public should be involved in all aspects of wider policy around data use, and such matters should not be expressed in incomprehensible language that deny the opportunities for ethical choice.

[The need for clear, comprehensible and meaningful language]

35. Mr Shah noted that the broader discourse around 'big data' and data 'sharing' in health and care is still being shaped, which will have an impact on the outcome to be expected. One aspect appears to be an emerging public view of 'personal data ownership' which diverges from the idea of health data as a co-created good.

36. Baroness O'Neill and Professor Montgomery argued that simplicity and clarity of language are crucial. The meaning of expressions in the current discourse, such as, e.g. 'my data', is unclear. To speak of 'my data' is ambiguous if we consider that useful data exist only as the consequence of a system of relationships that brings such data into being. There is a relevant difference between 'data pertaining to me' and 'data I own' that becomes blurred when speaking of ownership of data. 'Data sharing' is also used in a vague and too broad manner – ways of describing data use such as 'sharing' refer to contexts in which particular norms and rules or restrictions apply.

37. Dr Caldwell observed that at all stages of the research process, there is an enormous amount of confusion around terms such as 'research', 'register', 'health record', 'anonymisation', 'pseudonymised', etc. This includes professionals, even those professionals seeking consent from research participants. Participants often do not understand the consequences of signing up for research projects and hold contradictory views concerning their privacy and data confidentiality, e.g. they wish to be completely 'anonymous' while simultaneously preferring to be re-contacted. There is often a mismatch between people's motivations for choices as observed in the research context and the concepts that currently structure research governance. The confusion is compounded by the imprecise language currently used in the wider public discourse, which contributes to a conflation of purposes for which data may be used.

[The emergence of trust 'from the bottom up'; 'communities of trust' reinforcing norms]

38. Mr Burall suggested that it was important to balance the different values held by different stakeholders. A 'deficit model' according to which public scepticism derives from insufficient information and understanding of developments in science and technology, is not the only option, as the experience in the assisted conception field has shown: it may be necessary to understand in more depth how people make moral and social choices around the use of data, and according to what values. It is well established that people are prepared to participate more if they are involved in the conversation.
39. Mr Denegri suggested that 'care.data' had damaged a significant amount of work around public attitudes and public engagement in government over a decade. The development of a community, as in the example of UK Biobank, seems crucial but requires a dedicated investment of resources over a participant's lifetime of involvement, and for a system that spans both health and research. The differences between communities, such as, e.g., the mental health community, and the requirements of data users must also be taken into consideration.
40. Ms English concurred that different projects have differing requirements and should be designed with a view to what is appropriate and desirable in a specific context. 'Care.data', for example, cannot work on the same model as smaller-scale initiatives and projects. Mr Burall said that the boundaries of the conversation around 'data sharing' and future data use must be clear. It is a long and continuing process from initiating data sharing in government and putting adequate legislation in place to developing data sharing 'pilots' that can test whether there are any problems. For any major initiative development of such a kind, senior political engagement is of paramount importance.
41. Professor Murtagh and Dr Callard adverted to examples of successful, trustworthy data or research initiatives that have developed dynamic and continuing processes of communication and engagement in which a range of people have been involved in building up a sense of community. Although information about data use provided to participants does not necessarily have to be comprehensive, and there is a practical limit to the possibilities of patient participation, this would nonetheless help to counteract a perception of the 'unboundedness' of the data flows.

[Trustworthiness; and systems supporting relationships rather than systems replacing relationships]

42. Baroness O'Neill argued that trust is only worth having if it is aligned with trustworthiness. Trustworthiness is fundamental, and more focus on it would allow for a wider view of the complex issues involved. To understand what contributes to well placed or misplaced trust, such a wider view should consider the underlying norms of competence, honesty and reliability. Professions and institutions need to demonstrate these in conjunction to achieve trustworthiness, which can be difficult when the relationships involved are only indirect.
43. Professor Bobrow said that solid, 'gut trust' is build on longstanding relationships and cannot be created ad hoc through new governance structures. Governance around new data projects can therefore fail to be constructive if it is rushed. Governance structures need to consider the wider context of social 'embeddedness' and be less inward-focused. Past technological developments, e.g. in embryology and IVF research were organised in a more gradual manner leading to dedicated organisations such as the HFEA.
44. Dame Marilyn Strathern observed that it is not possible to 'build' trust through institutional policies. Trust must instead be the result of good practice and communication. The 'audit mania' of the 1990s resulted in what were meant to be measures of success becoming targets (the REF is a current example, although this is a general phenomenon across all sectors). 'Audit culture' has not been able to 'build' trust in governance processes that function in a 'tick-box' like, automated manner, notwithstanding that all proposed targets are met.
45. Professor Severs argued that, nevertheless, to be able to understand who has access to data and for what purposes they have been used, easily accessible data usage reports are necessary. Although it is recognised that it must be possible to know where, by whom and for what purpose data are used in research and health care, there has been a lack of understanding in this area hitherto, even from a purely technical point of view, which is only now beginning to be addressed, e.g. through the publication of 'data flow' diagrams.
46. Mr Booth suggested that increased transparency might have additional positive effects in that this will help people to 'identify with' the uses of data, e.g. in research, if they were able to observe how data are part of particular projects and beneficial research.

## [The importance of interfaces, media and intermediaries]

47. Lord Darzi observed that the roles of ‘messengers’ and holders of ‘social capital’ calling for data sharing have been undervalued. Furthermore, it appears that government is lacking social capital in comparison to academic researchers and GPs. Liz Philpots suggested that a lack of understanding concerning the consequences of failed trustworthiness may arise where those using data are not affected by the consequences of failed trustworthiness. Trusted intermediaries, on the other hand, act with regard to disincentives, such as failures of trustworthiness leading to negative reputation.
48. Mr Shah agreed that intermediaries are of crucial importance as it is too much to ask of individuals to be ‘armchair auditors’ of the system. These include the media, as well as civil society bodies, such as the Royal Statistical Society for the statistics community. He suggested that a similar ecology was needed in the health system. Sufficient resources would need to be dedicated to help professionals in intermediary roles to on the one hand scrutinise the holders and users of data, and on the other hand communicate with the public about the trustworthiness of these bodies.
49. Dame Fiona Caldicott observed that the trustworthiness of the professions such as GPs is of crucial importance. Professionals must be enabled to demonstrate such trustworthiness. Sir Nick Partridge noted that relationships with and in the health system are mostly only occasional, minimal, and not ‘dense’; indeed most people will try to minimise interactions with the system insofar as that they try to maximise their good health. This is a real and continuous challenge. Recognising this also implies that facebook-like models, smart devices like ‘fitbits’ etc. can only be of limited help in creating a more trustworthy ‘data sharing’ environment. Such an approach cannot substitute ongoing and more direct relationships in healthcare and research with ‘big’ biomedical data.

### **Lessons from experience in existing data initiatives**

50. Dr Sprosen advised that, in the case of UK Biobank, it took a long time – about 10 years – to build up a constructive dialogue between researchers, governance and ethics experts and the public to learn to understand each other. The project also needed to find a narrative that was understandable by the public. The first thing that emerged was that participants need to learn about the researchers involved and what kind of research they conduct, e.g. how biobank research is different from other research and why it is needed. He observed that participants trusted the NHS and (local) universities holding data much more than government.

51. A further observation is that what their GP thinks about participating in research is crucial to people's own decisions. UK Biobank took steps to inform and involve GPs although this was not straightforward, given that GPs were found to represent a wide spectrum of opinions about UK Biobank and its research potential.
52. It was noted that participants may change their minds and want to be involved over longer periods of time. One in 1,000 people approached to participate in UK Biobank objected to participation; however, when approached again, and after receiving more information, more than half of them changed their mind. Nine million people were invited over a period of three years to achieve the final number of ~500,000 participants. All steps of the involvement process were monitored and reported.
53. There is a further concern that if such projects are not organised and executed within established public research institutions, other actors, in particular in commercial companies and organisations, might take the initiative and set the agenda, leaving little room for deliberation of a wider range of attitudes and expertises.
54. Professors Richards noted a general but important concern about the negative effects of time pressure. Genomics England is now, for example, working to a much more condensed schedule in comparison with UK Biobank, for which the ethics and governance framework evolved with public engagement over a decade. It was suggested that the first requirement is to build a community around any long-term research resource such as UK Biobank; only then can research and closer involvement between researchers and participants gradually build.
55. Professor Laurie explained how, in the 2009-13 Scottish Health Informatics Project (SHIP), which is now part of the UK-wide Farr Institutes, a 'good governance framework' with four key elements was co-produced with stakeholders. It comprised:
- a. proportionate assessment of risks v. benefits;
  - b. best practices from around the country to set benchmarks for good practice;
  - c. accountability and responsibility of data controllers;
  - d. accreditation; use of data in a safe environment, i.e. 'unzipping' mechanism for data use – data are not shared.
56. In SHIP, the quality of data was seen as crucial and this was built on existing structures. On the basis of an already well-developed system of data management, people were invited to take part in SHIP but their involvement was

promoted as voluntary rather than achieved through nudging or advising them to share data.

57. Research on public engagement, conducted as part of the project, showed that participants have an interest in continuous involvement and consent is very important to them. Nevertheless, it was not concluded that consent is always necessary, but that, if consent is not sought for data use or if it is not feasible to obtain it, there must be publicly understandable information available on why this is the case.
58. There is a particular role for intermediaries such as research coordinators and Caldicott guardians who hold and share information with other professionals about what kind of data, in what quantity, etc. are necessary. These fulfil roles relating to all the governance elements set out above and in particular with regard to supporting trust relationships.
59. The entire project embodies an 'accountability for reasonableness' approach and focuses on shared responsibility for the dialogue on which the project is built. A note of caution was sounded, however, in that the recent NHS register consultation in Scotland showed that there remains a lot of public concern about increasing data use and linkage, which should be taken into consideration moving forward in this and other UK projects. It was also noted that the smaller population in Scotland makes it easier to construct projects such as SHIP.
60. Dr Pagliari asserted that the public should also be consulted on policy uses of data beyond health, such as for social research. Although demanding to undertake, this means that the public often comes to accept that minor risks exist and to understand the limits of consent. Sometimes, however, only 'assent' is possible, which may be sufficient so long as appropriate, proportionate governance is in place, and ongoing relationships with researchers and other professionals involved are established and maintained.
61. Professor Murtagh advised that since 1991 the Avon Longitudinal Study of Parents and Children (ALSPAC) had made use of various forms of engagement. These were found to be a useful way of maintaining the cohort through information provision via a newsletter, website and dedicated events, but also went beyond that through involving participants, in particular younger people, in the governance of the study. This latter form of engagement is directly concerned with demonstrating trustworthiness and includes involvement in decision-making, not only reporting.
62. Other important aspects of ethics and governance in ALSPAC are the proportionate assessment of benefits and risks, openness concerning the limits of data security, understanding of participants' expectations and responsiveness to their concerns and views, and the social acceptability of the research (which must

be in the 'public interest'). Some of these aspects remain challenging since tailoring data use to individual preferences is not yet matched by the level of 'granularity' afforded by information technology and the sensitivity of governance mechanisms.

63. Professor Bobrow said that new research and governance models, based on genomics, are only beginning to be developed by organisations such as the Global Alliance for Genomics and Health to enable responsible biomedical and health research data sharing. The basic science and aetiology of complex diseases is very difficult to study, and this remains the case with advances in whole genome sequencing. The only possible approach involves much larger quantities of genome and clinical data in a system of continuing, integrated healthcare and research. This is very different from ethics and governance models of clinical trials which are viable with fewer participants and better understood. The problem is that this emerging system is a large-scale, multi-dimensional system which requires ethics and governance measures adapted to scale, while trustworthiness is something that often evolves in a traditional manner in smaller-scale contexts and direct relationships.

### **Priorities for action**

64. Professor Montgomery invited participants to suggest steps that might be taken to take forward the matters discussed.

#### [The need to foster confidence in reasonable expectations]

65. Dr Mills recalled that the recently published Nuffield Council report emphasises that the basis of any ethics and governance framework on data initiatives should begin by establishing a publicly statable set of expectations about data use through exposing and resolving inconsistencies. Deliberative processes can help to identify the optimum relationship between social norms, respect for individual choice and proportionate governance of professional practice.

66. Dr Taylor observed that fostering better conditions for the expression of people's preferences should not be taken to undermine consistent and realistic policies, as people may come to accept conditions for data sharing other than those that they would initially prefer on the basis of what they would accept as being good reasons to do so. This might mean that publics may accept less than explicit consent, although this can be not assumed – it must be established.

67. Mr Denegri endorsed the need for more time and dedicated resources for a multi-layered conversation that would be more sensitive to expressions of concern from patients and the public. Successful examples so far have been smaller scale, such as in Scotland or the Nordic countries, where some form of social

contract underlies and advances data initiatives. To establish even local communities supporting improved data access, there must be a more consistent, multi-level government policy.

68. Dr Cavendish concluded that the trustworthiness of institutions is not only the responsibility of politicians. It requires a much broader social process and in particular a deeper understanding of different public concerns, expectations and underlying guiding values. A major task will be the transformation of the public discourse as well as the development of dynamic governance with a strong emphasis on the role of trusted intermediaries. Developing a complex set of relationships and communication processes over a long period of time should be established through, in the first place, valuing and using different kinds of existing expertise effectively and bringing these together in a democratic dialogue.

## Participants

Jessica Adkins	Head of Data Sharing Policy, Cabinet Office
Professor Martin Bobrow	Chair, expert Advisory Group on Data Access (EAGDA)
Phil Booth	Coordinator, medConfidential
Simon Burrall	Head of Dialogue, Sciencewise; Director, Involve
Dame Fiona Caldicott	National Data Guardian for health and social care and Chair, Independent Information Governance Oversight Panel
Dr Felicity Callard	Director, Hubbub at the Wellcome Collection
Dr Will Cavendish	Director General, Innovation, Growth, and Technology, Department of Health
Seil Collins (observer)	Communications Manager, Nuffield Council on Bioethics
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Simon Gray (observer)	Office of the National Data Guardian
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David Knight (observer)	Information Strategy, Department of Health
Peter Knight	Deputy Director, Research Contracting, Information Intelligence and Stakeholder Engagement, Department of Health

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Professor Jane Maher	Chief Medical Officer, Macmillan Cancer Support
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Professor Madeleine Murtagh	Chair, ALSPAC Ethics and Law Committee, School of Social and Community Medicine, University of Bristol
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