

Written evidence submitted by the Nuffield Council on Bioethics (DDA0020)

Background

1. The Nuffield Council on Bioethics is an independent organisation that examines and reports on ethical questions raised by recent advances in biological and medical research. For more than 30 years, the Council has achieved an international reputation for advising policy makers and stimulating debate in bioethics. We aim to inform policy through timely and thorough consideration of ethical implications, engaging a wide range of people in order to inform our deliberations, and help to ensure that the benefits of developments in medicine and the biosciences are realised in a way that is consistent with public values.

2. Our submission draws on the Council's previous work in relation to the use of data and AI in health care and biomedical research, principally (though not exclusively):

- Nuffield Council on Bioethics (2015) *The collection, linking and use of data in biomedical research and health care: ethical issues*, (<https://www.nuffieldbioethics.org/publications/biological-and-health-data>) (referred to subsequently as 'Biodata')
- Nuffield Council on Bioethics (2018) *Artificial intelligence (AI) in healthcare and research* (<https://www.nuffieldbioethics.org/publications/ai-in-healthcare-and-research>)
- Nuffield Council on Bioethics (2020) *Research in global health emergencies: ethical issues* (<https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies>)

3. We welcome the Committee's timely decision to launch the present inquiry and, in particular, its willingness to raise questions of ethics that have not always received sufficient attention in strategy documents. Below, we first offer below some general observations on the framing of the inquiry, and in particular on the need for a more nuanced approach to the interests (both private and public) that are at stake. We then respond to the specific question raised in the call for evidence regarding the ethics underpinning the use and sharing of individuals' data in health and care contexts.

General comments

4. We set out below a number of considerations about data sharing that we believe require special attention in developing an ethical approach to the sharing of data in which the public can have confidence.

- **Sharing health-related data can play an important role in protecting individual and public health**, both now (as demonstrated during the pandemic) and in securing future benefits

through advances in diagnosis, treatment and prevention. Seeking to promote responsible data sharing is therefore a legitimate policy aim. However, in order to secure those benefits in ways that are equitable, it is foundational that datasets should be **inclusive** (partial datasets not only exclude parts of the population from potential benefit but may actually lead to harmful outcomes), **accurate** and **appropriate**.

- The use of health-related data raises complex questions of public and private interests which should not be reduced to a simple contrast between ‘personal privacy’ and ‘public benefit’. Rather, **public and private interests are inseparably bound together**: Individuals have a strong personal interest in the public good of an effective healthcare system and in research that is able to improve that system. Meanwhile, there is strong public interest in developing and maintaining data sharing systems in which individuals feel able to place their confidence.
- Crucially, a person’s private interests in how their data are being used are not limited to concerns about confidentiality: preventing unauthorised access or re-identification of anonymised information. Health-related data provide information about a *person*, often provided in relationships of trust. **Individuals have a stake in how and for what purpose those data are being used** – and trustworthy governance systems will show respect for persons through the way that this stake has been recognised.
- Data obtained in a healthcare setting may be aggregated or anonymised in a way that makes the re-identification of a data subject more difficult. However, the possibility remains that **individual-level data and even some aggregated data could be linked to a subject** (re-identification), either maliciously or accidentally. The richer the information (the more linked data points), the more useful it may be for a range of purposes but the harder it is likely to be to anonymise meaningfully.
- Requirements relating to data being handled “safely, lawfully and transparently” (as in, for example, the draft strategy **Data saves lives**) are therefore necessary but not sufficient. Other measures are required which provide confidence regarding the future purposes for which data may be used. These might, for example, include such measures as diverse **public involvement** in agreeing what is, and what is not, an acceptable purpose for sharing, and **transparency** about the systems in place to determine specific access requests to datasets.
- The interest that any individual has in data about them does not necessarily mean that they are entitled to control all use of it. Certain uses, such as sharing of data for quality assurance and safety purposes, for example, could be regarded as part of an implied understanding about the responsibilities of users and providers in the provision and use of publicly funded health

systems. Further uses of data that are not implied or required for the use of a service, such as in biomedical research, may fall outside the terms of this implied understanding, and any decision to do so should not be determined without users having a say.

- Transparency is not the same as giving control (although these concepts at times seem to be conflated in ***Data saves lives***). Indeed, where people do not have control over data about them because those data can be shared regardless of their wishes, it is particularly important that they are aware of this.

Ethical underpinning of the use and sharing of individuals' data in health and care contexts

5. Our submission draws on the general approach to the use of data in healthcare and biomedical research that was initially set out in our 2015 *Biodata* report. It is a foundational observation of that report that, the mutual implication of public and private interests in the use of data (referred to above) shapes the relation between moral norms, individual agency and practical governance. Thus, the presumptive 'right to privacy' (the general rubric of the Inquiry) should be seen to imply a right to consideration of interest in the benefits of data sharing in relation to others' rights to privacy. Furthermore, it may do so differently depending on the possibilities afforded by a given state of knowledge or technology (such as technologies for collecting and processing data, or for extracting value from it which could lead to population benefits). In the Council's view, it is necessary, therefore, to identify what constitutes a set of morally reasonable expectations about the use of data for a given data initiative.

6. In our 2015 report we identified a policy and governance vacuum between the overarching legal provisions, intended to safeguard the privacy of individuals, and the administration of data use aimed at securing public benefits. We argue that filling this vacuum requires a dynamic, reflective process that acknowledges the importance of general principles (like the right to consent) but gives effect to these against a background of social norms and values that apply in particular circumstances. These relate to how people understand the relation between public and private interests and, therefore, the costs or risks that they are willing to bear on behalf of others and the expectations they have of others in return. This understanding may be different in different circumstances and may change over time.

7. We suggest that three sorts of considerations are relevant to defining a set of morally reasonable expectations about how data should be used in any given initiative, giving proper attention to the morally relevant interests at stake:

- the norms of privacy and disclosure applicable among those who participate in a data initiative (as set out, for example, in an initial consent process where a data initiative operates on an 'opt-in' model)

- the ways in which individual freedoms are respected, for example, the freedom to modify these norms by consent, and
- the form of governance that will give acceptable assurance that people's reasonable expectations will be met.

8. Some scholars have used the language of a 'social contract' to express a notional acknowledgement of how this problem of collective action is resolved in the interests of public good. What we regard as important about this, however, is not the form in which it is expressed but that the process through which it is defined should take account of the interests involved and render an account of how they are accommodated.

9. While we welcome the Government's explicit recognition that the desired transformation of data infrastructure will only be possible and sustainable if developed within a robust ethical framework, we are concerned that elements elaborated in the *National Data Strategy* (transparency, safeguards and assurance) do not suggest learning from failures of recent healthcare data initiatives to secure public trust. The confident language of 'building' public trust suggests that trust can be secured by simply *demonstrating* trustworthiness to people (through law, frameworks and compliance) rather than *involving* them in processes that may establish trusting relations. Repeated attempts to cajole members of the public into accepting arrangements about which they have legitimately held reservations have highlighted the risks of implementing a data initiative without assurance that there is well-founded public confidence in the proposed governance arrangements. The risks are serious, widespread and lasting erosions of trust in public institutions, without which those institutions must either compromise the attainment of their aims or the legitimacy of the mandate on which they do so.

10. The **participation** of people with morally relevant interests in the design and governance of data initiatives allows the identification of relevant privacy norms and the development of governance measures (such as design of consent and authorisation procedures) in relation to these norms; it allows preferences and interests to be expressed and transformed through practical reasoning, and account to be given of how these interests are respected in decision making, helping to foster trust and cooperation. **Accounting for decisions** is another key principle: data initiatives should include formal accountability, through regulatory, judicial and political procedures, as well as social accountability through periodic engagement with a broader public. This ensures that expectations, as well as failures of governance and control, are communicated to people affected and to others more widely. It also ensures that data initiatives remain in touch with changing social norms.

We are happy to elaborate on any points made in this submission or others addressed in our previous work.