

NUFFIELD COUNCIL ON BIOETHICS

Response to the Department for Digital, Culture, Media & Sport consultation

Data: a new direction

We welcome the opportunity to respond to the Department for Digital, Culture, Media & Sport (DCMS) consultation on reforms to the UK's data protection regime.

The Nuffield Council on Bioethics is an independent body that examines and advises on ethical issues arising from developments in bioscience and health. It was established by the Trustees of the Nuffield Foundation in 1991, and since 1994 it has been funded jointly by the Foundation, Wellcome and the Medical Research Council. We have an international reputation for providing independent and balanced advice to policy-makers and stimulating debate in bioethics. Our recommendations are backed up by a thorough process of consultation, engagement and deliberation with a wide range of people and organisations.

This response focuses on the collection, linking and use of data in biomedical research and health care contexts, drawing on the findings of our 2014-15 inquiry on this subject¹, our 2019-20 work on research in global health emergencies,² and our contributions to policy and public debate since then. Our focus has been on the ethics of data use by considering the relationship between private and public interests.

Innovation, privacy and the public interest

Whether in health care or biomedical research, the widest access to the richest data is implicitly desirable in order to advance research or improve the efficiency of public services. There is strong public interest in the responsible use of data to support the development of knowledge and innovation through scientific research and to improve the wellbeing of all through improved health advice, treatment and care. The opportunities offered by biomedical and health data use include:

- Making health services more efficient through better informed decisions about how to allocate resources.

¹ Nuffield Council on Bioethics (2015) The collection, linking and use of data in biomedical research and health care: ethical issues, available at: <https://www.nuffieldbioethics.org/publications/biological-and-health-data>

² Nuffield Council on Bioethics (2020), Research in global health emergencies: ethical issues, available at <https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies>

- Improving health by building a stronger evidence base to predict, prevent and treat disease, developing new treatments and using data to personalise treatment and care.
- Generating economic growth by driving innovation in the life sciences.

Data collected in biomedical research and health care are not intrinsically more or less sensitive than other data relating to individuals. However, they can be extremely sensitive depending on the context in which they are used and how they are related to other information.

Therefore, it is important to balance the opportunities of data use with the potential risks. These include cyber security threats, state surveillance, discrimination, the misuse of data leading to harm for individuals or institutions, and failure to respect people's interests in having control over their own data. Examples of harms of biomedical and health data use include:

- The receipt of suboptimal care through inefficient sharing of data between clinical teams.
- Discrimination and stigmatisation resulting from the use of information about mental health status for profiling purposes.
- Personal distress through the use of personal data in ways that are experienced as disrespectful, regardless of whether concrete harms ensue.
- Inhibiting potentially valuable research through loss of public trust in the medical profession.

Those governing and designing data initiatives therefore find themselves in a situation where they are obliged to generate, use and extend access to data, while at the same time protecting individual private interests.

Principles

The proposed principles that underpin the reforms set out in the consultation document focus on the promotion of innovation, growth and economic benefit, while delivering a high standard of data protection for citizens (p7).

We propose a complementary set of ethical principles for the use of data in biomedical research and health care:

- 1 **Respect for persons:** the terms of any data initiative must take into account both private and public interests. Enabling those with relevant interests to have a say in how their data are used and telling them how they are, in fact, used is a way in which data initiatives can demonstrate respect for persons.
- 2 **Respect for human rights:** the terms of any data initiative should respect people's basic rights, such as the right to protection of private or family life. This includes limitations on the power of states and others to interfere with the privacy of individual citizens in the public interest.

- 3 **Participation:** decision makers should not merely imagine how people ought to expect their data to be used, but should take steps to discover how people do, in fact, expect their data to be used, and engage with those expectations.
- 4 **Accounting for decisions:** data initiatives should include formal accountability, through regulatory, judicial and political procedures, as well as social accountability through periodic engagement with a broader public, as a way of re-calibrating expectations. Data initiatives must tell affected people what will be done with their data, and must report what actually has been done, including clear reports of any security breaches or other departures from the established policy.

These principles were adopted by the Department for Health and Social Care in the recent update of its guide to good practice for digital and data-driven health technologies.³

The principle of participation

Although a stated aim of the reforms is to ensure UK laws more accurately reflect people's views about how they expect their data should be used and when they should actively give consent (p12), the overarching principles and reforms themselves could pay more attention to the principle of *participation*.

Involving people in the design and governance of a data initiative allows their interests and values to be expressed, transformed and reconciled. It can also help to secure their commitment to the outcome and build trust.

There should be appropriate mechanisms in place so that governance arrangements can evolve during the life of any data initiative through deliberation with participants, the public, funders and the research community in order to ensure that the interests of participants are respected over the life of the project.

The recent General Practice Data for Planning and Research (GPDPR) initiative highlights the pitfalls of attempting to implement a data initiative without involving and consulting those with morally relevant interests in the scheme, or ensuring that the public are well placed to have confidence in the proposed governance arrangements.⁴

Changes to the lawful grounds for data processing in research

The consultation proposes exploring the creation of a more explicit and reflective foundation for extending data access in 'the public interest' and a new, separate lawful ground for research.

³ Department for Health and Social Care (updated 2021) A guide to good practice for digital and data-driven health technologies, available at: <https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology>

⁴ See Zulueta P (2021) Blog: Health data, medical confidentiality, and the right to privacy – is GPDPR the new care.data? Available at: <https://www.nuffieldbioethics.org/blog/health-data-medical-confidentiality-and-the-right-to-privacy-is-gpdpr-the-new-care-data>

Any change to the lawful grounds for data processing in research should be accompanied by robust and comprehensive rules, guidelines and measures that protect private interests. Among other things these should aim at:

- Providing greater clarity for members of the public about the governance arrangements that are in place, and the ways that their biomedical data are used, and may be used in the future, along with a realistic acknowledgement that no system can guarantee privacy and confidentiality in all circumstances.
- Securing commitments from data controllers to a responsible approach to the extension of data access as part of their core mission statement; they must publish information about their approach to data access, transparency and accountability, and whether, and on what terms, they will consider extending access to data.
- Demonstrable and continual improvement of collection, storage and data access procedures against explicit standards for accuracy, reliability and security.

In addition, any statutory definition of scientific research should include the condition that such research is in the public interest (Q1.2.3). A discussion of the meaning of public interests in the context of biological and health research can be found in paragraphs 3.18-3.28 in our report on the ethics of biological and health data.⁵

Consent and anonymisation

In considering any changes to the law on anonymisation of data in research (p44), it is important to note that the de-identification of individual-level data cannot, on its own, protect privacy as it is simply too difficult to prevent re-identification.

It is also important to note that consent at the time of data collection cannot, on its own, protect all of a person's interests, where they cannot foresee or comprehend the possible consequences of how their data will be available for linkage or re-use (p16).

The limitations of 'consent or anonymise' mean that those who manage data initiatives have a continuing duty to promote and protect the legitimate rights and interests of those who have provided data about themselves irrespective of the terms of any consent given. Additional governance arrangements are usually required, including oversight committees authorising access to data; limiting data access through 'safe havens';⁶ or formal agreements on the limitations of data use.

AI and machine learning

AI technologies have the potential to help address important health challenges and reduce human bias and error, but they can also reflect and reinforce biases in the data used to train them. Concerns have been raised about the potential of AI to lead

⁵ Nuffield Council on Bioethics (2015) The collection, linking and use of data in biomedical research and health care: ethical issues, available at: <https://www.nuffieldbioethics.org/publications/biological-and-health-data>

⁶ Safe havens started as medical record libraries in hospitals or health authorities, but more recently have been used for data centres providing a pseudonymisation and linkage service, so that medical records whose names have been removed can be linked up with other records from other providers that refer to the same individual patients.

to discrimination in ways that may be hidden or which may not align with legally protected characteristics, such as gender, ethnicity, disability, and age.

We have highlighted that the scope and content of the current data protection framework remain uncertain and contested. Related questions include who is accountable for decisions made by AI and how anyone harmed by the use of AI can seek redress.⁷

We therefore welcome the DCMS's exploration of views on the concept of fairness in relation to AI systems; permitting organisations to use personal data more freely for the purpose of training and testing AI responsibly; data processing for the purpose of bias monitoring, detection and correction; and clarifying what constitutes a decision based solely on automated processing.

In these explorations, the assumption that more access to data means more public benefit should be interrogated. Inconsistencies in the availability and quality of data restrict the potential of AI. While many are enthusiastic about the possible uses of AI in the NHS, others point to the practical challenges, such as the fact that medical records are not consistently digitised across the NHS, and the lack of interoperability and standardisation in NHS IT systems, digital record keeping, and data labelling.⁸

The government is also seeking views on whether a legislative reform of Article 22 in the UK GDPR is needed. When considering possible changes to the legislation, it is important to reflect on the many risks that could arise from the use of automated decision-making to make inference about individuals' health. Taking one example, alongside its use in research and clinical decision-making, information about mental health status could be utilised for profiling purposes and lead to discrimination and stigmatisation, or it could even be used to justify unnecessary or erroneous coercive interventions. As such, inaccurate categorisations in the mental health can have devastating consequences. This raises questions as to whether the use of solely automated decision-making would be appropriate in this context, and about the level of accuracy needed by automated decision-making tools to be used without the involvement of humans.

Use of personal data in an emergency

Personal health data has been collected, processed, shared in unprecedented ways in efforts to combat the COVID-19 pandemic. The consultation document seeks to facilitate the lawful processing of personal data in public health emergencies (p104).

We would emphasise the need for *ethical preparedness* in any data protection regime. Ethical preparedness is the state of being ready as a society to identify, understand and evaluate the ethical issues that arise from any relevant law or policy, being then ready to do what is ethically justified as well as necessary. In this context,

⁷ Nuffield Council on Bioethics (2018) Bioethics briefing note: Artificial intelligence (AI) in healthcare and research, available at: <https://www.nuffieldbioethics.org/publications/ai-in-healthcare-and-research>

⁸ House of Lords Select Committee on Artificial Intelligence (2018) AI in the UK: ready, willing and able? Available at: <https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/100.pdf>

ethical preparedness would allow personal data to be readily accessed and used in a public health emergency in ways that are ethically sound and engender public trust.

The potential for private companies, organisations or individuals to be involved in this endeavour reinforces the moral imperative to take long-term action across the research sector to ensure that best practices can be securely embedded in future emergencies. There is no excuse for taking an 'ethical minimum' approach when planning for future emergencies.

Preparatory measures can increase what is possible during an emergency and thereby contribute to the realisation of fairness and the alleviation of suffering. A failure to do so, by contrast, increases the prospects and severity of hard choices and difficult trade-offs. Achieving this kind of preparedness requires funding and political commitment.⁹

Reform of the Information Commissioner's Office (ICO)

The proposed reforms aim to create a clearer mandate for the ICO to take a risk-based and proactive approach to its regulatory activities. Part of this involves refocusing its statutory commitments away from handling a high volume of low-level complaints and towards addressing the most serious threats to public trust and inappropriate barriers to responsible data use.

We suggest a further role for the ICO could be to ensure there is continued research into the potential harms associated with misuse or abuse of biological and health data, as well as its benefits. This research should be sustained as available data and data technologies evolve, maintaining vigilance for new harms that may emerge. Appropriate research that challenges current policy orientations should be particularly encouraged in order to identify and test the robustness of institutional assumptions.

⁹ See Nuffield Council on Bioethics (2020), Research in global health emergencies: ethical issues, paras 4.62-63, 9.10, available at <https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies>