NUFFIELD COUNCIL ON BIOETHICS

Response to Wellcome's *'Emerging science and technology: consultation on oversight'*

Introduction

1 The Nuffield Council on Bioethics is an independent organisation that examines and reports on ethical issues arising from developments in biological and medical research that concern the public interest.

2 This consultation response draws primarily on the conclusions and recommendations of our report '*Emerging biotechnologies: technology, choice and the public good'* (published in 2012).[1]

3 Other recent Council reports of relevance to our submission are:

- *Genome editing and human reproduction: social and ethical issues* (published July 2018)[2]
- *Genome editing: an ethical review*[3](published 2016)
- *The collection, linking and use of data in biomedical research and health care: ethical issues* (published in 2015)[4]
- *The findings of a series of engagement activities exploring the culture of scientific research in the UK* (published 2014)[5]

Key messages

4 **Engaging public perspectives, including with non-specialist groups, about how new biotechnologies can contribute to society, is an essential part of any ethically robust public decision making process.**

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1 Nuffield Council on Bioethics (2012) *Emerging biotechnologies: technology, choice and the public good* available at: http://nuffieldbioethics.org/project/emerging-biotechnologies

2 Nuffield Council on Bioethics (2018) *Genome editing and human reproduction: social and ethical issues* available at: http://nuffieldbioethics.org/project/genome-editing-human-reproduction

3 Nuffield Council on Bioethics (2016) *Genome editing: an ethical review* available at: http://nuffieldbioethics.org/project/genome-editing

4 Nuffield Council on Bioethics (2015) *The collection, linking and use of data in biomedical research and health care: ethical issues* available at http://nuffieldbioethics.org/project/biological-health-data

5 Nuffield Council on Bioethics (2014) *The findings of a series of engagement activities exploring the culture of scientific research in the UK* available at http://nuffieldbioethics.org/project/research-culture

5 **We propose the establishment of an independent UK body to support public engagement to promote public debate on the use of genomic and related technologies to respond to societal challenges; to help to identify and understand the public interests at stake; and to monitor social, cultural, legal, and health impacts.**

CONSULTATION QUESTIONS

Q1. Thinking of approaches in the UK and internationally, what are the key elements of good oversight that should be in the UK's approach for emerging science and technology?

6 Your consultation begins with the question: "*When a new development within science and technology emerges, how should society respond?"* This framing puts society in a reactive position, but research developments do not simply arrive out of nowhere. In our view, 'oversight' should have a broader meaning, which includes shaping the aims and directions of research towards solving problems and meeting public interests, rather than simply responding to developments. The key questions relating to how these technologies develop are those regarding ensuring public safety whilst ensuring that the benefits of potential technologies reach people quickly, and are distributed evenly.

7 How 'the public' is constituted in relation to questions of biotechnology governance and how participants in public engagement are informed (bearing in mind the role of popular or sectional media perspectives), can have a significant bearing on how opinions are formed. Unless there are trustworthy governance systems in place that can engage with and reflect reasonable expectations in continuously evolving circumstances, initiatives that could have wide public benefits may continue to be challenged, and fail to secure public confidence.

8 In '*Emerging biotechnologies: technology, choice and the public good*', we identified the following virtues to foster the application of public ethics to the governance of emerging science and technologies and their implications in practice:

- **Openness and inclusion** – members of society should have the information required and, where appropriate, access to participate in biotechnological governance.
- **Accountability** – there should be explicit acceptance and acknowledgement of where responsibility for governance lies and how it might legitimately, and democratically, be influenced.
- **Public reasoning** – reasoning should be clear, explicit and aimed at finding common ground rather than promoting sectional interests, including in the presentation of evidence.
- **Candour** – uncertainties associated with emerging biotechnologies should be represented truthfully and in good faith.

- **Enablement** – appraisal of emerging biotechnologies should highlight alternative social and technological choices and the implications of each, and encourage wider political debate.
- **Caution** – the degree of uncertainty and ambiguity associated with emerging biotechnologies should mean there is a responsibility to gather more extensive knowledge prior to making policy commitments

Public consultation

9 Participation in inclusive consultation activities is an important element in building public trust around the development of emerging science and technology. **Engaging a wide range of public perspectives - including with non-specialist groups - about how new biotechnologies can contribute to society and the potential wider consequences, is an essential part of any ethically robust public decision making process.**

Regulation

10 We note that regulation is often led by concepts of risk and harm (including safety and security) and the likelihood of benefits. However, as emerging science and technologies are characterised by uncertainty and ambiguity, the risks and benefits associated with them are hard to determine or agree. **We therefore argue that risk-benefit models of regulation are not always appropriate for emerging sciences and technologies. Regulatory design doesn't hold the solution to every challenge. Adaptive governance, requiring a continuous and reflective engagement with broader societal interests, is important.**

Research policy

11 Owing to the novelty and complexity of innovation systems for emerging biotechnologies, research policy lacks a relevant, reliable basis in evidence. This deficit tends to be made up by assumptions, which are rarely examined in detail, for example, public investment in emerging biotechnologies is increasingly justified by poorly supported claims about their expected economic impact, which tend to marginalise other important values. **Research policy for emerging biotechnologies should take account of wider social values and diverse bodies of evidence, not just market value or economic benefit.**

12 There is no single source of policy for publicly funded research and the principles upon which it is based are not clearly defined. Without clear principles, there is a danger that research policy is determined through closed engagement between scientific, political and industry elites, with no assurance that there is adequate consideration of important social value.

13 We recommended that there should be a clearly defined, written and published Governmental research policy against which public research policies (e.g. those of Government departments and funding bodies) can be assessed. **We also proposed that the Government considers bringing Government research**

policy and funding bodies under a senior minister free from departmental responsibilities.

Research culture

14 Our report '*The findings of a series of engagement activities exploring the culture of scientific research in the UK* concludes that there is a collective obligation for all actors in the scientific research system to do everything they can to ensure the culture of research supports good research practice and the production of high quality science. We provide a number of suggestions for action for funding bodies, research institutions, publishers and editors, professional bodies and individual researchers. Key examples are:

- **Funders:** ensure funding strategies, policies and opportunities, and information about past funding decisions, are communicated clearly to institutions and researchers; and provide training for peer reviewers to ensure they are aware of and follow assessment policies.
- **Research institutions:** cultivate an environment in which ethics is seen as a positive and integral part of research; ensure that the track record of researchers is assessed broadly; and provide mentoring and career advice to researchers throughout their careers.
- **Publishers and editors:** consider ways of ensuring that the findings of a wider range of research meeting standards of rigour can be published; consider ways of improving the peer review system; and consider further the role of publishers in tackling ethical issues in publishing and in promoting openness among scientists.
- **Researchers:** actively contribute to the adoption of relevant codes of ethical conduct and standards for high quality research; use a broad range of criteria when assessing the track record of fellow researchers; and engage with funders, publishers and learned societies to maintain a two-way dialogue and contribute to policy-making.
- **Learned societies and professional bodies:** promote widely the importance of ensuring the culture of research supports good research practice and the production of high quality science; and take account of the findings of this report in relation to guidelines for members on ethical conduct and professionalism.

Q2. From your perspective, what current areas of emerging science and technology offer opportunities for the Government to improve how oversight is provided?

Health data

15 One area where public engagement is crucial, and where public trust has been compromised in recent years, has been the subject of health data. The streamlining and optimisation of patient data is a clear policy goal for the Government and NHS, with promised benefits including improved individual care and accelerated research. A key issue for data initiatives and health systems as a whole is what uses of data should be 'expected' as part of delivering national health care with quality, safety, and cost-effectiveness with ongoing improvement in the standards of care. The National Data Guardian is doing some of the important work here, but there needs to be a more systematic approach, including developing the new 'social contract' and arrangements to support and deliver it.

16 It is becoming increasingly evident that there are commercial drivers behind many high-profile initiatives that have been proposed in recent years and, as empirical studies show, this is of significant concern for the public. The issues go beyond individual privacy, especially as datasets start to be linked together, and there is a need to have governance structures in which all interests are enabled to participate and that involve continuing review and reflection on the societal implications of such initiatives. Two concerns that bear consideration are whether the case for use of large-scale secondary use of data has been adequately made, and that the benefits of data-driven health care and precision medicine will be equitably distributed.

17 In '*The collection, linking and use of data in biomedical research and health care: ethical issues'* we set out four ethical principles for the use of data in biomedical research and health care:

- **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.
- **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.

- **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.

- **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.

18 Our recommendations include that:

- **Public and private research funders and the Department of Health should ensure there is continued research into the potential harms arising from abuses of data, and should remain vigilant to any new harms that may emerge.**

- **The UK Government should ensure that privacy breaches involving individual data are reported in a timely and appropriate fashion to the individual(s) affected.**

- **The UK Government should introduce robust penalties, including imprisonment, for the deliberate misuse of data, whether or not it results in demonstrable harm to individuals.**

- **In relation to the data collected by the NHS (at the time the Health and Social Care Information Centre (HSCIC), now NHS digital):**

- **An independent, broadly representative group of participants should be convened to develop a public statement about how data held should be used.**

- **There should be complete audit trails of everyone who has been given access to NHS data, and the purposes to which they have been put. These should be made available to all individuals to whom the data relate or relevant authorities in a timely fashion on request.**

19 We welcome the work of Wellcome and MRC in supporting the UK Biobank Ethics and Governance Council, which we discuss and review in Chapter 7 (starting paragraph 7.4) of '*The collection, linking and use of data in biomedical research and health care: ethical issues'.*

Q3a. Thinking in the longer term about what may present challenges to existing regulation, which areas of science and technology still in their early stages of development should the Government be aware of?

Heritable genome editing interventions

20 The Nuffield Council's report *Genome editing and human reproduction: social and ethical issues'* sets out the ethical considerations raised by these potential uses of heritable genome editing interventions, relating to the people immediately involved; others in society and society as a whole; and future generations.

21 Informed by these ethical considerations, we set out a number of conditions that would need to be met if the law were to change to permit heritable genome editing interventions and how these ethical considerations might inform the development and application of governance measures.

22 We concluded that the potential use of heritable genome editing interventions to influence the characteristics of future generations could be ethically acceptable in some circumstances, so long as:

- it is intended to secure, and is consistent with, the welfare of a person who may be born as a consequence of interventions using genome edited cells; *and*
- it is consistent with social justice and solidarity, i.e. it should not be expected to increase disadvantage, discrimination, or division in society.

23 Our key recommendations are:

- **Research should be carried out on the safety and feasibility of heritable genome editing interventions to establish standards for clinical use.**
- **Social research should be carried out to develop greater understanding of the implications of genome editing for the welfare of the future person.**
- **Before any move is made to amend UK legislation to permit heritable genome editing interventions, there should be sufficient opportunity for broad and inclusive societal debate.**
- **We propose the establishment of an independent UK body to support public engagement institutionally – to promote public debate on the use of genomic and related technologies to respond to societal challenges; to help to identify and understand the public interests at stake; and to monitor social, cultural, legal, and health impacts.**
- **Governments in the UK and elsewhere should work with international human rights institutions, such as the Council of Europe and**

UNESCO, to promote international dialogue and to develop a framework for international governance of heritable genome editing interventions.

- **Heritable genome editing interventions should only be licensed on a case-by case basis subject to:**
  - assessment of the risks of adverse clinical outcomes for the future person by a national competent authority (in the UK, the HFEA); *and*
  - strict regulation and oversight, including long-term monitoring of the effects on individuals and social impacts.

The '14 day rule' in human embryo research

24 Relating to human genome editing interventions is the current statutory limit in the UK for the culture of human embryos used in research. In 2016 the Council brought together a range of experts to discuss whether there may be persuasive reasons to review the legal time limit. We published a document in 2017 that collated a number of individual reflections on this issue.[6]

Stem-cell derived gametes

25 Stem-cell derived gametes are in the process of development and there is ongoing research, yielding incremental advances, into the development and use in human reproduction. In our report '*Genome editing and human reproduction: social and ethical issues*' the possibility of modifying gametes prior to fertilisation is discussed as one of a number of possible strategies that might make use of genome editing to influence or secure inherited characteristics in offspring.

26 Our report notes that the autologous transplantation of modified gametes from stem cells or gamete precursor cells, or the autologous engraftment of gamete-producing tissues or organoids may fall outside the scope of the current HFEA licensing regime and may be desirable to bring within the regime. **We suggest that if necessary, this could be remedied by extending the scope of legislative provision through regulations under section 1(6) of the Human Fertilisation and Embryology Act.**

Q3b. In the future, how do you think the Government should ensure that it is aware of emerging areas of science and technology in good time?

27 We would like to emphasise the importance of identifying conditions (including foresighting of ethical issues) that could affect pathways to innovation, and

[6] Nuffield Council on Bioethics (2017) Human embryo culture: Discussions concerning the statutory time limit for maintaining human embryos in culture in the light of some recent scientific developments available at http://nuffieldbioethics.org/project/workshop-time-limits-maintaining-human-embryos-research

putting anticipatory governance in place in time to respond appropriately to these conditions.

28 Part of the wider picture is to ensure that researchers are encouraged and supported to carry out their research ethically – i.e. they have appropriate targets to aim at and secure and predictable conditions in which to work such as funding, regulation, infrastructure, investment, public approval.