NUFFIELD COUNCIL ON BIOETHICS

Future Challenges in Bioethics roundtable discussion Forward Look 2016

26 February

Introduction

1 The Nuffield Council on Bioethics Forward Look roundtable meeting was convened to provide an opportunity for bioethicists, clinicians, academics, policymakers and others working in bioethics related fields to discuss future challenges and issues arising in bioethics. Attendees are listed at **Annex 1**.

2 Participants had been asked to nominate three priority areas to discuss in the meeting and the conversation opened with discussion on genome editing as this was considered to be a key area and the subject of a current Nuffield Council on Bioethics project. Themes falling under broad categories of data science, and access and social justice were also discussed.

Genome editing

Novelty, distinctiveness and risk

3 Some argued that the ethical questions surrounding the use of genome editing techniques were not genuinely new and that instead it was the speed, ease of use and availability of the technology that set it apart from previous forms of genetic modification. It was observed nevertheless that the debate about genome editing might usefully be employed to clarify issues discussed within the context of older debates on genetic modification: for example, whether we should be concerned about societal 'slippery slopes' towards unacceptable practices. It was also said that the technology itself should not be the primary focus of ethical discussion, but instead debate should concern the ethics of particular applications to which it gives rise.

4 It was noted that the claims being made about the efficiency and difference of genome editing as a tool were becoming stronger with time and it was questioned whether these were justified. The need for safeguards in the context of genome editing was raised. It was said by one person that we should start thinking about whether there would ever be enough possible benefits to outweigh the risks, and suggested that there might be some uses to which we would never judge it appropriate to put genome editing.

Public attitudes

5 On public attitudes m It was said that there were a wide range of possible uses of genome editing technology, which might generate quite different reactions from the public. It was said that there was a wide range of possible uses of genome editing technology, which might generate quite different reactions from the public.

6 More broadly, it was suggested that the ways in which genome editing is publicly described would be likely to influence how it was received. Its potential medical applications were thought to be more likely to receive support, and specifically, its capacity to accelerate research into treatments for debilitating disease. It was observed that the field of medical applications was emerging as a key area, and one participant reported that GlaxoSmithKline had recently recruited new staff in this field to focus on research into rare disorders. It was noted that the debate on mitochondrial donation could be informative in considering how to engage the public. The long period preceding the Parliamentary vote in favour of regulations permitting mitochondrial donation in 2014-5[1] had been important and useful, it was said, and it was suggested that a similarly long period of discussion on the use of genome editing might be worthwhile. Media coverage was raised and it was pointed out that discussion of 'three-parent babies' and routine description of genome editing as 'controversial' were not helpful.

Concerns relating to specific uses of genome editing

Use in humans

7 Some noted that there was a high, possibly disproportionate, level of public attention focused on the prospect of human genome editing and it was felt that a broader view should be taken of the technology. However, it was also said this was an area of research in which funders, such as the Wellcome Trust, were taking a particular interest.

Gene drives

8 The use of gene drives and their potential for providing solutions to pandemic disease such as Zika, was another area in which Wellcome was interested, it was reported. There was a broader general interest in gene drives, a field some felt was a key area of promise for genome editing, and it was suggested by one participant that the general public may have a lower awareness about gene drives, and their risks, than they perhaps should.

Use in animals

9 The potential consequences for animals were broached. It was said that CRISPR was likely to increase the number of experiments involving the insertion of human tissue into animals, and that it was important to consider the ethics of those research practices. Another way in which genome editing might impact on animals was in connection with animal breeding. It was said that the techniques might

[1] See Parliament UK (3 February 2015) *Commons debate statutory instrument on mitochondrial donation*, available at: http://www.parliament.uk/business/news/2015/february/commons-debate-statutory-instrument-on-mitochondrial-donation/

revolutionise animal breeding practices and suggested that some of these changes were already underway.

International aspects

10 There was discussion on the nature of the UK's distinct role within developments relating to the technology. Some of this discussion concerned regulatory differences between the UK and elsewhere. It was pointed out that the HFEA had granted a licence[2] for genome editing on human embryos for research purposes and said that human genome editing was already taking place in a number of research contexts in China. Another point concerned the fact that genome editing technologies had been designed and created in rich countries, but would be applied in poor ones, and this would have implications for how use of the technologies might be governed. It was said that the UK was sometimes seen as a leader in debates about the ethics of novel technology, for example as with the case of mitochondrial donation, and suggested that whilst the UK could not legislate in other countries, it might play some role in providing guidance.

11 It was suggested that it might be better for developments to take place in the UK where, it was said, there is a higher standard of regulation and transparency, and appeal to the idea that 'if we don't do it, someone else will.' Some also felt that the opportunities for constructive and open debate about genome editing were better in the UK. A separate point related to competition and it was said that there was a pressure on the UK to stay ahead of the rest of the world on 'cutting edge' science.

Data science

Care robots

12 Some of the discussion around data science centred on robotics and the use of robots in care settings. Key concerns here were the implications for the nature of interactions between people and their caregivers and issues relating to the idea that robots might be able to 'care' at all.

13 Some raised worries about the replacement of nursing with robotics and machine learning applications, and suggested that important aspects of caregiving such as kindness, warmth and intimacy might be lost if robots were to be used in care settings. It was suggested that care relations based on a transactional, as opposed to interpersonal, elements might compromise standards of care. A further point concerned the sensitivity of these tools, and it was suggested that there might be certain things that machines or algorithms could not understand or capture, that might require the tacit knowledge of a healthcare professional. It was said too that some patients might not be appropriate candidates for recipients of care from robots and that children's early development, for instance, might be influenced by care of this kind. A further issue to arise concerned the appearance of care robots and how this might affect their capacity to provide care.

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[2] HFEA licence (2016) *The Francis Crick Institute at Mill Hill*, available at: http://guide.hfea.gov.uk/guide/InspectionReport.aspx?code=246

14 On the other hand, one participant said that their experience of interacting with care robots had been positive and reported that it had been surprisingly easy to engage with them anthropomorphically. Others suggested that robots might be able to learn in light of interactions with people and might potentially be able to develop and improve their abilities to care.

15 Potential benefits of care robots were also discussed. It was said that their use might be helpful in caring for people with dementia and with managing certain kinds of behaviour that human care givers might find challenging, for example being asked the same question many times over. It was proposed that they might also be able to help to support people with dementia who 'wander' and that this might be a better solution than locking doors to restrain people. It was also said that there was potential for machine learning and robotics to assist with the prescription and administering of drugs in certain kinds of context. A more general point about machine learning was that it is inevitably framed by the assumptions of the person who programmes the machine and there may be quite different ways in which machines might develop, and 'learn', depending on how this process is itself designed.

16 Some thought there was a political aspect to the topic and raised concerns about economic drivers that might play a role in moves to involve robots in care settings. There was concern that this would be motivated primarily by cost-cutting considerations. The impact on the human care workforce was also raised and it was suggested that these technologies may give rise to paid care professionals losing their jobs – and on the other hand, suggested that robots may be seen as a solution to an ageing workforce and ageing population.

17 It was suggested said there was inadequate level of discussion around regulatory considerations within the debate and said that care robots may be difficult to monitor and regulate effectively.

Health apps

18 A separate issue within data science that was discussed concerned the use of mobile health apps and other medical technologies. It was observed that the Academy of Medical Sciences (AMS) had held a meeting in 2014[3] on health apps and that there was growing interest in the area.

19 Regulation of health apps and 'fit bits', wearable technologies which track variables such as distance moved or calories burned by the user, was raised. It was noted that they are currently not considered by the Medicines and Healthcare products Regulatory Agency (MHRA) to be medical devices, and so were not regulated.

20 On the other hand, the benefits of these technologies were also discussed and it was pointed out that concerns about these technologies were not necessarily shared by all. It was said that in the US people use smartphones for a very wide range of tasks and suggested that there were fewer concerns about data

[3] The Academy of Medical Sciences (31 March 2015) '*Health apps: regulation and quality control' report published*, available at: http://www.acmedsci.ac.uk/more/news/publication-of-the-forum-meeting-report-on-health-apps-regulation-and-quality-control/

protection. People were more likely to focus on the benefits, it was claimed, and health apps were compared, by one participant, to store loyalty cards.

21 Issues surrounding accountability and this kind of technology were raised. It was suggested that there might be concerns about how people respond to or act on results or measurements read from health apps or other medical technologies, outside the context of a clinical or healthcare setting. On the other hand, it was also said that individuals were responsible for their own decisions, that apps themselves were just tools, and that individuals bore responsibility for the judgements and actions that they made on the basis of information sourced using them.

Storage and use of personal data

22 A different aspect of the discussion on data centred on issues relating to storage and use of personal data. One point concerned consent to use of personal information and how this could be assured for use of personal data in large research projects. It was said that individuals may be losing control over their personal information.

23 Points were also made about the implications for **different sectors** of society of using data in these ways. It was suggested that younger people may be less interested in data and privacy than older generations, which may be a concern. One participant suggested that the concept of privacy itself may be changing as we become more accustomed to the idea that personal information is stored, linked and shared.

24 Further implications concerned trust in institutions. Questions were raised about who has access to individuals' data and what they are able to do with it. Large scale public data initiatives were said by one participant to be imposed rather than chosen, and a related point concerned the speed with which such projects were implemented. On the other hand, it was pointed out that that not everyone had concerns about the use of personal information. Some of the information being used in big data projects, it was said, was being created by individuals themselves and a privacy framework might not be the most appropriate means of addressing this area.

25 Issues relating to incidental findings in research, (undiagnosed medical conditions identified in participants taking part in research projects) and the potential for these to increase with larger amounts of health data. Another point concerned the prospects for genome sequencing in larger numbers of people and increasing amounts of, and access to, genetic information.

Access and social justice

Issues relating to disability

26 A subset of these issues concerned mental health and how the UK might meet its obligations under the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), in light of the UN monitoring committee's 2014 General Comment on Equal Recognition before the Law. The comment states that forced treatment by psychiatric and other health and medical professionals is a violation of the right to equal recognition before the law and an infringement of the rights to personal integrity. It was thought by some that this interpretation of the convention would significantly constrain what was legally permitted in terms of treatment for mentally ill people without their consent and said that it would be difficult for the UK comply with such restrictions.

27 It was said that uncertainty around the implications of the convention may also give rise to adverse outcomes for people who lacked capacity. It was suggested that insecurities about how to manage patients without capacity might mean that they would not be offered treatments that would be offered to patients who did have capacity. It was said that the convention could give rise to a fundamental change in the treatment of these kinds of patients, if it was not possible to treat them without their consent, and some felt that there was lack of discussion about how the convention would be implemented.

28 Broader observations about the notion of disability itself were also raised. One participant suggested that judgements about what counts as a disability might be quite subjective, and another said that as innovations are made and technology develops, our perception of what counts as a disability may also be altered.

Personalised medicine

29 Personalised medicine within healthcare was thought by some to be a key issue, both in the context of personal responsibility and consumer choice. There was concern that an overemphasis on personal responsibility within healthcare may result, ultimately, in enforced compliance with public health prescriptions or people being blamed for their own ill health. Some were concerned by the idea that a person's access to some treatments might be restricted according to whether they had lived a healthy life. This might concern factors over which people have little control, such as access to healthy food. [4]

30 The increasing options for consumers of medical technology and services were discussed. Concerns about genuinely supporting people to use these options to make decisions about their own health, and avoiding overloading people with information, were expressed. It was said that choice and too much information could be disempowering and suggested that we might need a better understanding of how people respond, and make decisions, in these contexts.

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[4] See Nuffield Council on Bioethics (2007) *Public health: ethical issues* and Nuffield Council on Bioethics (2010) *Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age* for a fuller discussion of these issues.

Impact of the private sector

31 The wider impact of the private sector was also discussed and questions concerning the role of industry and for-profit companies in healthcare were raised. The prominent position that large corporations play in the research and development of new medicines was mentioned and concern expressed by some that decisions about what particular drugs to develop and market are informed predominantly by economic considerations.

32 An issue overlapping discussions relating to both private sector drug development and personalised medicine concerned safety. A question was raised about how safety could be assured under more personalised approaches for which the pool of potential research participants was smaller. This would mean that medicines would be developed for, and tested on, smaller groups of people with potential implications for safety. More general anxieties were expressed about the role of private companies in health research, and the access they might be given to personal data, such as in the case of Google Deepmind's collaboration with the Royal Free NHS Foundation Trust. Issues relating to both storage and use of this information were raised.

33 It was pointed out that many reproductive technologies were available only through private sector companies, and not available on the NHS, which raised a question about consent and the quality of patient information. Patients accessing health services through these routes may be less well-informed about the risks and benefits of these treatments, it was noted. Some of these privately provided services, it was said, might also have significant societal effects. The practice of egg freezing, for example, was said to have ramifications for the notion of parenthood, potentially.

34 Accountability was seen to be an issue in this context too and there was concern expressed that in cases where something went wrong with consumer services there was not necessarily anyone to be held responsible.

35 Another point linked with personalised services concerned the role of research involving large datasets in developing individualised health interventions. It was noted that if society wanted these kinds of treatments to be available, people would collectively need to engage with big data research projects.

Care of older people

36 A number of issues relating to the care of older people were raised and some general questions posed concerning how we should address and manage demographic change and the increasing number of older people in the UK.[5] The social and political implications of this trend were alluded to, and it was noted that there would be public finance implications of a larger patient population and smaller workforce.

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[5] These issues were also addressed in the discussion of longevity that took place at the Council's 2016 Forward Look future work meeting. A note of that discussion is available at: http://nuffieldbioethics.org/wp-content/uploads/NCOB-Forward-Look-2016-Longevity.pdf

37 One participant posed the question of whether we should see ageing as a disease. Longevity and ageing, it was said, are different things and it was suggested that the aim of medical developments in this field should not be to extend life at all costs, but rather to ensure that people are healthy and happy for as long as possible.

38 Whether patients in the early stages of dementia may be able to provide 'pre-consent' to treatment in the future was discussed. It was suggested by one participant, though, that those who arranged for someone close to them to have power of attorney over the healthcare decisions may anyway be less likely to have ongoing poor health.[6] It was pointed out that particular groups may be more vulnerable than others in cases where there were issues relating to capacity. For instance, one participant said that older gay people might be disproportionately affected since they may be less likely to have children involved in decisions about their care as they age.

39 A key strand of this debate concerned the absence of older people in research. It was said that we don't know enough about otherwise well people who have dementia and that there was a need for research in people with 'pre-dementia' (people at risk of or in very early stages of dementia). It was also said, though, that the notion of people with 'pre-dementia' might be problematic and involve stigmatisation. It was suggested that older people may not be fully represented in research relying on participants' use of novel technologies and devices, such as fit bits or smartphones.

(Under-) representation in research

40 Representation in research was a broader theme, and was raised in the context of children and younger people, and pregnant women.[7] The problems associated with these groups having been traditionally been excluded from research were now widely recognised, it was said, but there were no easy solutions to this issue. It was noted that there were increasing levels of recognition that it was not appropriate to give a child half an adult's dose of a drug.

41 Some expressed the view that there was an overemphasis on protection of the individual in discussions about the ethics of research. A different way of looking at the issue, it was said, was to see the benefits and costs of taking part in research as accruing to an individual over the course of their entire life, not just at the time in which they participate in a trial.

42 It was observed that the issue did not just apply to drugs and clinical trials. One participant pointed out that the use of predictive analytics in medicine was problematic in that not all demographic groups were represented in available data.

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6 See Nuffield Council on Bioethics (2009) *Dementia: ethical issues* for an earlier discussion of power of attorney and other kinds of proxy decision making, and the role that these arrangements can play in the care of people with dementia.

7 See Nuffield Council on Bioethics (2015) *Children and clinical research: ethical issues* for an earlier discussion of these issues.

Other suggested priorities

The role and function of research ethics committees (RECs).

43 The limitations of the REC system were discussed and it was suggested that the current approach to ethical review may need to be reconsidered. Some, for instance, said that the RECs had become outdated. It was claimed that RECs were finding it difficult to deal with new questions concerning the use of personal information and that the system may not be adequate to handle the complexities presented by developments in this area. It was said too that the challenges RECs face in effectively assessing data-related harms might mean that they were more likely to adopt a restrictive approach. A further question in this area concerned whether local RECs or specialised RECs were helpful and it was said that there might be a danger of proliferation.

44 The idea that the REC model was fundamentally outdated was, however, also challenged. It was suggested that RECs might simply now require a different balance of expertise, and that a problem with the current system might relate to focus. For instance, RECs might be addressing the wrong kinds of questions and in the case of observational research, for example, a REC might appraise the skills of desk researchers working with gathered data, whereas it might be more useful for the REC to assess the skills of those carrying out the observations.

Research in emergency situations

45 The way that research and treatment should proceed in **emergency situations**, such as in an infectious disease outbreak, was discussed. It was observed that often in emergencies, different rules and frameworks might be applied, and it was questioned whether this was the correct approach, or how different these should be from standard practice.

46 Points about how to identify and classify medical emergencies were made and a question about what should count as an emergency situation posed. The ebola outbreak of 2014-5, for instance, appeared to be widely accepted as a serious medical emergency, but it was noted that issues such as antibiotic resistance, with potentially widespread adverse effects on human health, were not standardly viewed in this way. A related issue was whether some health emergencies could have been predicted by Government bodies and whether they might, in that respect, not really be emergencies. It was noted that there was a political aspect to this issue and that there might be competing interests in construing a given situation either as a medical emergency, or not.

47 Other issues concerned how to make decisions about the testing or use of drugs in emergencies once it is agreed that a different approach is required. Was it acceptable, it was asked, to give those who chose it access to untested drugs? A further question related to standard practice in randomised clinical trials within the context of an outbreak of a potentially fatal infectious disease. This, it was said, raised difficult ethical issues given that research participants who received a placebo may be very likely to die. The question of what status a drug tested in this way would have in the aftermath of a medical emergency was posed too. It was suggested that a drug developed and tested in these conditions may not be useful

in less acute situations and, further, that some drugs developed this way, which might have been taken to be safe and effective, had been later shown in clinical trials to be unsafe.

Health, wellness and societal goods

48 Broader issues relating to **health**, **wellness and societal goods** were discussed. It was said that there was a need to develop an idea of what we collectively wanted the future to look like and ensure that this vision was fed into policy making.

49 Some general points were made about the value in articulating shared values and making concrete our commitments to them, and it was suggested that we might benefit from intermittently consciously scrutinising, and maybe updating, our societal visions of wellbeing.

50 It was pointed out that objectives to improve societal wellbeing should extend beyond the development of technology and that there was a need for society to consider and balance the different available options in terms of health and wellbeing. In the context of healthcare, it was said that this would require a discussion about what we really want the state to provide. This might involve a frank debate about resource allocation in public health and recognition of the cost of technological advances

51 It was said that increased patient expectations may be a developing concern and that, for instance, in the case of end of life care, a 'choice agenda' was currently being promoted in spite of the fact that, in reality, choices may be limited.

Current practice, new developments and emerging technologies

52 It was noted that the ongoing interest in new developments and novel technologies in medicine could sometimes veil the fact that there is a lot of existing medical practice that may be due for reconsideration. There was a need, it was thought, to avoid becoming overly distracted by the new, and to revisit what are thought to be well-understood areas of healthcare to ensure current practice is up to date. This, for example, might involve re-evaluating everyday care pathways and healthcare conventions.

53 Some general observations were also made about **emerging technologies**, including issues concerning regulation.[8] The global aspect of the regulation of new biotechnologies was mentioned, and a question posed about the value or purpose of regulating in the UK, when other countries may adopt very permissive approaches. One participant said that we needed new systems and a new term for how this area of science is scrutinised, and that 'governance' might be a more appropriate term for how these areas of science are managed. It was also suggested that we should endeavour to understand better public views around emerging technologies.

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[8] For an earlier discussion of these issues see Nuffield Council on Bioethics (2012) *Emerging biotechnologies: technology, choice and the public good*.

Other issues

54 Other issues discussed in this part of the meeting included:

- Increasing access to prenatal testing and the impact of this both on reproductive choice for parents and on children.[9]
- The use of fetal tissue in research, including availability of and ethical access to sources of tissue

[9] The ethical issues raised by non-invasive prenatal testing are the subject of a current Council project which is due to report around the end of 2016.

Annex 1 - Attendees

Joanne Anton, Policy Manager, Human Fertilisation and Embryology Authority

Harry Armstrong, Senior Researcher, Nesta

Mark Bale, Head of Science Partnerships, Office of the Chief Scientist, Department of Health

Pete Border, Scientific Advisor, Parliamentary Office of Science and Technology

Simon Burall, Director, Involve

Paul Colville-Nash, Programme Manager, Medical Research Council

Veronica English, Head of Medical Ethics, British Medical Association

Bobbie Farsides, Professor in Clinical & Biomedical Ethics (Clinical Medicine), University of Sussex

Robert Frost, Policy Director (Medical Policy) GlaxoSmithKline

Nick Green, Head of Projects, Royal Society

Katherine Littler, Senior Policy Advisor, Wellcome Trust

Sarah Norcross, Director, Progress Educational Trust

Mark Robertson, Director, Science Policy in the Global Policy & Corporate Responsibility team, AstraZeneca

Philippa Taylor, Head of Public Policy, Christian Medical Fellowship

Tom Wells, lead on Health, Government Office for Science

Christopher Whitty, Chief Scientific Advisor, Department of Health

Naho Yamazaki, Head of Policy, The Academy of Medical Sciences