Public dialogue on genome editing

Why? When? Who?
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Report of a workshop on public dialogue for genome editing
May 2016
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Research on genome editing techniques is advancing rapidly and leading to applications in a wide variety of fields.

- A need for public dialogue has been recognised by researchers but there has been no reflection on the rationale for this or what forms it should take.
- There is a need to distinguish between the needs of policy makers for public dialogue to inform immediate policy decisions and the value of public dialogue in shaping responsible research and innovation, and to identify prospectively the need for policy change.
- In prospective applications for human health and reproduction, existing legal and policy measures cover genome editing. There is no current evidence of public pressure to amend these; however, the pace of scientific advance suggests a need to think prospectively.
- In animal, plant and microbial applications there is a need to examine the applicability and suitability of GMO regulation, and the consequences for human health and the environment (especially in the case of gene drives in wild animal populations).
- There is concern that engaging the public too soon may pander to hype and entrench negative attitudes; equally there is a concern that failing to engage early will leave the field open to misinformed speculation. On balance, the public should be trusted to appraise technologies reasonably.
- Researchers, research funders and others with an interest in developing genome editing have a responsibility to engage the public about their work and to take account of public responses.
- Professionals with an interest in research need institutional support to communicate candidly the possibilities and uncertainties associated with genome editing research, and to engage with the concerns of NGOs.
- Those with policy responsibilities need to be responsive and flexible in the light of emerging applications of genome editing, and this would be enabled by a background of informed public discussion.
- Distributed ‘micro-dialogues’ would provide a valuable opportunity for citizens to engage with scientists and other interested parties in a context that allows information to be exchanged and assumptions examined.
- A networked ‘observatory’ across public institutions and interested organisations would be desirable to identify developments in genomic science with potential impact on public policy, particularly those that cut across organisational distinctions and divisions of formal responsibility.
Introduction

The purpose of the workshop

Over the past few months there have been a number of calls for a public conversation about the new biological techniques of genome editing and their potential applications.

The techniques, which allow precisely targeted changes to be made to the sequence of DNA in living cells, are powerful, effective and economical, and have enabled rapid advances in biological sciences. However, some of their potential uses are controversial. The speed with which they have been adopted has caused many to ask whether the UK is adequately prepared for the possibilities they create. In particular, as the techniques come to public attention, we wanted to ask how public voices might contribute to understanding the implications of these technologies.

In order to consider this we convened a meeting of people with three distinctive kinds of interest in discussing genome editing: scientists and research funders who are involved in the developing the techniques and applying them to understand and manipulate living systems; policy makers who will have to set the conditions in which this takes place to protect and promote the public interest; and dialogue specialists who can offer advice on the different modes, benefits and limitations of public engagement. The purpose of the workshop was to address three main questions:

1. What are the policy issues involving genome editing that are likely to have the greatest public salience?
2. What are the likely benefits and limitations of public dialogue in relation to the issues identified?
3. What are the possible timings and contexts for any public dialogue on the issues identified?

What is genome editing and how can it be used?

Genome editing describes a range of techniques that make it possible to alter a selected part of the genome in a living cell by removing or changing existing elements or adding new ones. It differs from previous techniques of genetic engineering in that the alterations can be precisely targeted and controlled at the molecular level and are extremely efficient. The CRISPR-Cas9 system, in particular, has revolutionised genome editing because it is
comparatively low in cost, quick to prepare and easy to use. These features have led to its widespread adoption in biological science, even though it is only three or four years old.

Genome editing techniques are already having a huge impact on research but they also have many different potential practical applications in fields as diverse as plant and animal breeding, industrial biotechnology, clinical medicine and human reproduction.

The need for public engagement and dialogue

It is evident from discussions that have already taken place within the academic and policy communities that genome editing raises a range of scientific, ethical and social issues in which there is a presumed public interest. The nature of this interest ranges from the protection of individuals or populations from possible health risks, to moral and political interests regarding the acceptable limits to intervening in natural processes and the states of affairs that it might be desirable to bring about in this way.¹

This public interest has been recognised by many of those at the forefront of research. In papers in major scientific journals and statements from high-level meetings and conferences, the voices of researchers, funders and others have joined together in calling for early and open engagement about genome editing with policy makers and the wider public.²

These published statements do not, however, discuss what form this ‘engagement’ should take. Few of them examine the rationale for engaging public constituencies – publics – or the ‘wider public’ in general (for example, to inform, educate or involve). Little consideration has been given, so far, to the expected sites of this engagement (for example, in the media, other public fora, organised consultation activities, public events, or invited discussion groups), the terms on which engagement should take place (for example, whether to address specific normative questions or open up the assumptions about the desirability of different research objectives), or its aims (for example, to build consensus around policy positions or to seek a ‘social licence’ for the conduct of research).
It is likely that, as genome editing research advances and its possible applications become clearer and closer, many different forms of engagement will be desirable. Initially, this might involve simply publicising and explaining what scientists have achieved. But as innovations become imminent there may be a greater need for consideration of the societal implications and how they affect the interests and values of wider groups of people, especially where progress in any direction requires questions of public policy to be resolved.

The workshop was intended to focus specifically on exploring the potential role of public dialogue for policy, which brings together members of the public, policy makers, scientists and other expert stakeholders to deliberate, reflect and come to conclusions on national public policy issues. The discussion, however, ranged more broadly than this, across a spectrum of interactions between different societal groups, and reflecting on the current state and directions of genome editing science and technology, and the public policy and regulatory measures in place. Some conclusions therefore address the broader need for public dialogue (and other forms of engagement) to support responsible research and translation of research into practice within the limits of existing policy, and to envisage possible futures that might be attained if policy conditions were different.

Structure of the discussions

Twenty-eight people participated in the workshop. (A full list of participants is included in the appendix.) In small group discussions, which mixed participants from the different groups (researchers and funders, policy makers, and dialogue specialists), each of the questions set out at the start of this report was addressed in turn. After each discussion the main points considered were reported to all participants and examined by the whole group. The workshop concluded with a plenary session that allowed time to identify areas of consensus and continuing uncertainty.

Rather than reporting the range of views on each question in turn we have structured this report around the feedback from the discussions as a way of extracting the most salient points. We have drawn on the plenary session, in particular, where we make suggestions about the future role of public engagement and dialogue on genome editing.
Too soon for dialogue?

Are there specific applications requiring urgent dialogue?

Given the recent attention that genome editing has received, including in the popular media, it was perhaps surprising how little urgency there was to review relevant policy in some areas. This did not, however, imply that genome editing could be ignored from a public engagement perspective. There was a perception that the speed of the development of the technology and its potential applications were alarming for some people, raising concerns about whether regulation can keep up with the speed of technological innovation, whether society or scientists themselves have fully appreciated the implications of what science can deliver, and whether it would be possible to reverse undesirable outcomes. These concerns had not, for the most part, been linked with specific questions of policy.

Three areas that were identified as significant, near-term issues, however, were mosquitoes genetically altered to control the spread of infectious diseases such as the Zika virus (especially combined with ‘gene drives’ that can spread the alteration rapidly through the natural insect population), the regulation of food crops and livestock that had been altered using genome editing techniques (especially whether they should be subject to existing GMO regulation), and the application of genome edited products (e.g. stem cells) in humans.4

In the plenary discussion it became clear that there was a marked difference between the perspectives of researchers and policy makers in relation to the need for dialogue on human applications in the near term. Policy makers recalled that in many areas, including health technologies and assisted conception, established policy and regulatory mechanisms were already in place that adequately provided for current or anticipated uses of the genome editing techniques. In the absence of a clear indication from the public that policy or legal change was
necessary or desirable in the near future, the UK was said to be well prepared to manage developments in genome editing.

Researchers, on the other hand, generally argued for prospective discussion of the need to make policy changes in the future, particularly given the current pace of scientific advance, and as the anticipation of future conditions might shape directions taken in research in the present. It was noted that this was also a concern for national science and innovation policy more generally, in relation to putting in place conditions to maximise social and economic benefits (while avoiding outcomes that might be detrimental or undesirable).

One area in which there was more ambivalence about the need for a change in regulatory policy was the use of genome editing in plant science, such as commercial crop development. It is currently unclear whether (or which) crops produced using genome editing techniques would be categorised as genetically modified organisms (GMOs) under current regulatory regimes. This uncertainty was acknowledged to have potentially significant commercial implications for breeders and to be strongly linked to public attitudes towards GM products. Exploring whether genome edited products would be considered analogous to GMOs may be strongly relevant to discussions around regulatory policy in this area, which is markedly different between the US and Europe. Similar uncertainties and concerns extend to the use of genome editing in livestock. The techniques of genome editing have wide application in biology and it was noted that they will surface, in unpredictable ways, in many more applications, than those discussed, with associated ethical and societal issues. A view emerged during the plenary discussion that what might be required at this stage is a thorough, and regularly reviewed, surveillance exercise. This would have the aim of identifying which genome editing research activities are most likely to lead to applications that raise issues of interest or concern to the public. (We return to this suggestion below.)
Workshop participants noted that it would be important, when deciding where public engagement might be needed, to keep an eye on what engagement exercises have already happened so as to take account of existing findings and avoid unnecessary duplication. They noted that there are recurring themes in related discussions that could be expected to arise in relation to genome editing. For example, questions of fairness and equity in distribution of outcomes, of who benefits and how this can be known in advance, of what we already know about the challenges for regulation in keeping up with the speed of change of technology, and of institutional governance and democratic accountability, were frequently returning themes of relevance to genome editing across different areas of application.

** Might dialogue be unnecessary, premature or counterproductive? **

On one view, there might not be anything new of significance to examine with regard to genome editing. This view emphasises that genome editing is simply a new technique, providing a new set of tools, for doing what previous generations of genetic engineering technologies have been striving to achieve over longer periods. Though new techniques may be more effective, faster, simpler and cheaper, once reasoned and principled positions on genome modification have been established, these contingent facts about the specific technique used are unlikely to change them. Such a view is consonant with the view that there are no pressing policy questions to address and, from this perspective, is supported by pointing to the existence of legal and regulatory provisions of demonstrated effectiveness.6

Workshop participants identified the view that the lack of any immediate pressure to review policy in the light of concrete genome editing innovations could support a conclusion that there is no reason actively to initiate public dialogue – or any other form of public engagement – at present: that there is simply nothing new to talk about. On this view, even if reasons emerged to support a review of policy in the longer term, starting public dialogue now would be premature, at least. They also noted the further view that it could even be counterproductive: unbalanced debate might be harmful to genome editing across many of its potential applications if a widespread prejudice towards all uses of the technique were established early on, for example, by responses to its most controversial applications.
Accordingly (on this view), it might be desirable to hold back preemptive forms of engagement until a variety of applications were sufficiently well advanced that the issues they raise could be addressed on their own terms.

Concerns about the consequences of unbalanced debate are not merely speculative: they are linked to experience of the public debates relating to GMOs in food in the 1990s and nanotechnology in the 2000s, and the legacy that those debates have had for biotechnology innovation and regulation. These heightened sensitivities, understandably, encourage circumspection, even reticence, about public discussion. But it is important to distinguish between debate in the popular media, which is often rhetorical and deliberately divisive, and the kind of conscientious and respectful invited dialogues that Sciencewise, for example, has supported.

Furthermore, it is possible that the earlier debates took the shape they did in a vacuum, from which clear and reliable scientific engagement was absent until after the debate had been framed.

While there are likely to be recurring themes in the use of genome editing (as noted above), which may be relevant to other technological innovations as well, workshop participants agreed that striving to ensure that distinct applications are examined on their own terms is important so as to allow the relevant considerations to be discussed in a fair and balanced way. Nevertheless, it seems mistrustful of the public, to withhold opportunities for discussion of controversial applications, even if they are more speculative, and probably futile to do so.

Public debate about genome editing is very likely to take off without any further provocation. It is clear that in a number of areas (as various as assisted reproduction, clinical treatments for childhood cancers, and genetically modified insects) that genome editing has emerged from the pages of learned journals and from academic conferences into the mainstream media, social networks and political debating chambers, and is already
stirring concerns and expectations among some publics. Furthermore, the techniques are diffused globally, including to countries where, unlike the UK, there may be little existing governance. While the UK, with its advanced biological, biomedical and biotechnological research infrastructure, and its tradition of robust but enabling regulation, has a vested interest and can show global leadership in genome editing at present, controversial applications may find a proving ground in countries that are less circumspect or scrupulous. Observing and engaging in emerging debates, and conducting early public dialogue in the UK, should not be under-estimated as a way of checking assumptions about the public response.

Framing the questions

The way in which issues raised by genome editing are presented and understood can have a significant influence on conclusions that are drawn about them. Often assumptions or value judgements are embedded in the way questions are presented (‘loaded questions’), which create affinities with certain kinds of response. An important first step is therefore to ask whether we are asking the ‘right’ questions and what assumptions we might be making when we ask them.\(^7\) Experience from previous dialogues, public engagement initiatives and public discussion of biotechnologies suggests that there is an important discussion to be had about the broader frame, one that involves values and visions relating to different approaches, outcomes and ways of life, rather than narrowing discussion around an assessment of the potential benefits and costs. Focussing on a technology and its implications is less constructive than talking about the ways in which it can help to address concrete challenges.\(^8\)

Participants noted that dialogue has to find an appropriate framing that is neither so broad that the discussion meanders aimlessly with no clear parameters, nor so narrow that participants feel their options are constrained, proscribed or unable to be expressed. This may make the difference between a dialogue that is orientated towards addressing a particular normative question and one that turns to critique of the assumptions that underlie it.
Sciencewise provides support for public dialogues where there are contentious issues of emerging science and technology. Two of the main reasons for initiating these dialogues are: (1) to add to the evidence base to help make better policy; and (2) to provide decision makers with the confidence to move forward with policies where widespread public opposition may block the development and application of a new technology. In the case of genome editing there might be instances where Sciencewise’s deliberative public engagement approaches are extremely valuable but it is likely that public engagement will also need to be broader than this. A cardinal principle of public engagement is that method should match purpose and, in relation to the different applications of genome editing, there are likely to different purposes.

While, at our workshop, those responsible for some policy areas were not persuaded of any urgent need to review policy and, accordingly, did not feel a need for dialogue in support of this, there was a sense from most of those present that it was important to open up the public conversation about genome editing technologies, their purposes and direction of development. The responsibility for this was thought to lie, at present, more with researchers and research organisations than policy makers. Participants agreed that there was a need to consider how researchers could be supported to communicate the possibilities and uncertainties associated with the science candidly and to engage with societal perceptions (for example, those based on previous techniques of genetic engineering).

Scientists may be unwilling to engage in oppositional public debates if they feel that they will not get a fair hearing or are put up against NGOs with political agendas (although many do so nevertheless). As workshop participants noted, NGOs do not necessarily represent the views of ‘the public’ in general but often a segment that is not opposed to science but to commercial biotechnology and globalisation, or to particular applications on principle. Whereas, in the case of innovations, public views may often be distributed across a spectrum rather than clustered around extreme positions, the interest in creating oppositions (e.g. in the media) and adopting decisive opinions (e.g. in politics) can distort
more nuanced positions and create a false impression of polarisation. Where this is the case dialogues on the model supported by Sciencewise can offer opportunities for citizens to engage with scientists and other interested parties in a context that allows prejudice and assumptions to be challenged, and more subtle questions, for example, about the right level and mode of regulation, to be addressed.

Workshop participants noted that the responsibility of researchers to engage more broadly where their research raises issues of public interest is an expectation of Responsible Research and Innovation (RRI). RRI broadly encourages researchers and innovators to consider fully the implications of their research and consider how to engage with others in reflecting on the wider societal interest in science as a source of society’s response to its material conditions. It emphasises democratic determination of how science is orientated towards the achievement of desirable futures, the recognition of uncertainties in the way in which scientific knowledge plays out in the wider world, and the need for built-in responsiveness to these uncertainties on the part of infrastructures and institutions. Participants felt that many researchers are already engaged in a multitude of conversations, implicitly or explicitly putting RRI principles into practice, and would benefit from help to find the opportunities, tools, confidence and skills to develop their own discussions to contribute to the broader national picture.

Participants also noted that there was, nevertheless, a place for candid and simple presentation of information from the scientific community in response to the public appetite for information, and also for engaging in good faith with concerns expressed by NGOs.
Ground level dialogues and a high level observatory

Although the plenary discussion did not identify an appetite for general discussion about genome editing independently of specific applications it was nevertheless agreed that dialogue about specific policy questions would be enabled by a background of candid science communication and public engagement on the part of all actors in the system. The alternative was to leave a vacuum that risked being filled by assumption, rumour and suspicion. The approach envisaged was a flowering of local, micro-dialogues, which need not be strategically co-ordinated, and which individuals and small groups with an interest in research would take responsibility for initiating. Participants agreed that assistance to research professionals in developing the skills and capacity to speak publicly about their work would be highly desirable. While researchers should be encouraged and supported to engage in such initiatives it would be a mistake to rely solely on them as other actors, from the commercial and third sectors, and policy roles, are also key players.11

Although participants in the workshop did not identify a great number of policy areas under immediate public pressure from developments in genome editing, or areas that were not covered by existing policy, there was a recognition that the speed of advance in science is likely to mean that important issues emerge quickly with little lead time. For this reason policy processes will need to be responsive and policy makers will need ready capacity to initiate a wide range of communication, engagement and deliberation activities at short notice.

Participants were agreed on the need to take an active approach to anticipate the need for dialogue rather than waiting for a controversial issue to overtake and define the policy agenda. The discussion towards the end of the plenary session turned to how sensitivity and responsiveness could be brought to public policy. It was suggested that part of the answer to this might be to develop an appropriate early warning system.

The fact that genome editing applications potentially cut across established organisational distinctions and divisions of policy responsibility led participants to discuss the desirability of a
networked observatory, focussed on developments in genomic science with potential impact on public policy. This would benefit from operating across government, as well as its agencies and arm’s length bodies that have public or regulatory policy responsibilities, with input from industry and the third sector.

The observatory would work to both to horizon scan for emerging areas in need of engagement and coordinate and synthesise the micro-dialogues. The need for networked information gathering and sharing is important as it is likely that many genome editing issues will have multiple policy owners (or none).
Notes

1 The Nuffield Council on Bioethics currently has a major work programme exploring the ethical issues raised by genome editing. Initial findings from this project will be published later in 2016. For more information see: http://nuffieldbioethics.org/project/genome-editing/.


5 GMOs have been the subject of intense public debate since the appearance of GM food in the 1990s. See, for example, GM Nation? (http://webarchive.nationalarchives.gov.uk/20081023141438/http:/www.defra.gov.uk/environment/gm/crops/debate/index.htm) and more recent Sciencewise dialogue projects at http://www.sciencewise-erc.org.uk/cms/dialogue_topics/issues/5.
Conceptual questions about the framing and significance of genome editing, and the novelty of the issues raised by the technique, will be addressed in the Nuffield Council’s interim report on genome editing (see note 1, above).

The Nuffield Council on Bioethics 2012 report *Emerging Biotechnologies: technology, choice and the public good* observed that “The point of this scepticism is to draw attention to the error of committing prematurely to two sorts of potential frame: firstly, construing social ‘challenges’ as hypothecated to technological solutions (in general or particular) and therefore curtailing the exploration of other kinds of possible response; secondly, focusing the development of biotechnologies too tightly on solutions to particular challenges and therefore failing to be sensitive to the range of possible benefits they might bring, perhaps in radically different contexts.” (The report is available at: [http://nuffieldbioethics.org/project/emerging-biotechnologies/](http://nuffieldbioethics.org/project/emerging-biotechnologies/)).

The Nuffield Council on Bioethics has recommended that “Commitments to particular technological pathways should be evaluated not only in terms of their expected future impacts but also by comparison to possible alternative pathways; this can help to illuminate obscured assumptions, constraints and mechanisms of the innovation system, and help to identify sites and opportunities for more constructive governance, prioritisation and control.” (Nuffield Council on Bioethics, op.cit. , recommendation 1).


An RRI Toolkit for researchers is available from [www.rri-tools.eu](http://www.rri-tools.eu).

At the time of publication the Wellcome Trust, at the request of the National Forum for Public Engagement with STEM, is working to understand better how the public engagement community might respond to a perceived need for engagement with Genomics.
Appendix

Workshop on public dialogue for genome editing, held at the Nuffield Council on Bioethics, 28 Bedford Square, London, WC1B 3JS on Thursday 17 March 2016

Participants

Diane Beddoes - Director, Deliberate Thinking
Laura Bellingan - Director of Science Policy, Royal Society of Biology
Elizabeth Bohm - Senior Policy Advisor, The Royal Society
Graham Bukowski - Associate Director, Ipsos MORI Centre for Dialogue
Simon Burall - Director, Involve
Aisling Burnand - Chief Executive, Association of Medical Research Charities (AMRC)
Jason Chilvers - Senior Lecturer, School of Environmental Sciences, University of East Anglia (UEA)
Robin Clarke - Dialogue and Engagement Specialist, Sciencewise
Mike Edbury - Head of Health and Environment, Government Office for Science
Sam Hinton - Consultant, Sciencewise
John Holmes - Head of Public Engagement with Science, Department for Business, Innovation & Skills (BIS)
Roland Jackson - Executive Chair, Sciencewise
Robin Lovell-Badge - Group Leader and Head of the Division of Stem Cell Biology and Developmental Genetics, The Francis Crick Institute
Patrick Middleton - Head of Engagement, Biotechnology and Biological Sciences Research Council (BBSRC)
Peter Mills - Assistant Director, Nuffield Council on Bioethics
Martin O’Kane - Acting Head of the Clinical Trials Unit, Medicines & Healthcare Products Regulatory Agency (MHRA)
Colin Pavelin - Head of Regenerative Medicine and Rare Diseases Policy, Department of Health
Tony Perry - Reader, Laboratory of Mammalian Molecular Embryology, Department of Biology and Biochemistry, University of Bath
Sarah Rappaport - Policy Team, Strategy Division, Wellcome Trust
Amy Sanders - National Programmes Manager, Engaging Science, Wellcome Trust
Helen Sang - Personal Chair in Vertebrate Molecular Development, Roslin
Bettina Schmietow - Research Officer, Nuffield Council on Bioethics
Jack Stilgoe - Lecturer in Social Studies of Science, University College London
Hilary Sutcliffe - Director, MATTER
Ranveig Svenning Berg - Communications Officer, Nuffield Council on Bioethics
Juliet Tizard - Director of Strategy and Corporate Affairs, Human Fertilisation and Embryology Authority (HFEA)
Anthony Whitney- Senior policy advisor; Public Engagement with Science at the Department for Business, Innovation and Skills (BIS)

Agenda

1. Welcome and introductions
   Roland Jackson (Sciencewise)
2. Discussion in groups, followed by plenary feedback
   What are likely to be the most salient policy issues, for the public, involving genome editing?
3. Discussion in groups, followed by plenary feedback
   What are the likely benefits and limitations of public dialogue in relation to the policy issues identified?
4. Discussion in groups, followed by plenary feedback
   What are the possible timings and contexts for any public dialogues on the suggested policy issues?
5. Plenary discussion