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I am now two years into my time as Chair of the Nuffield Council on Bioethics and it is proving an enormously rewarding and stimulating role.

Following a transitional year in 2017, where we laid the foundations for major strategic changes that allow the Council more flexibility to respond in different ways to a wider range of current debates, in 2018 it has been wonderful to see two new streams of work – the Active Responsive Programme and the Horizon Scanning Programme - go from strength to strength and to note the fantastic impact these new programmes are already having.

A highlight of 2018 was the July publication of the eagerly awaited report on genome editing and human reproduction. This report achieved record levels of media coverage for the Council and firmly established us as a leading international authority in this widely contested and controversial area of scientific advancement.

Little did we - or in fact anyone - know at the time we published our report that the ‘potential use’ of CRISPR-Cas9 to alter for clinical purposes the genome of a human embryo, was no longer a ‘potential use’ but in fact a reality. It was used clinically for the first time by a scientist in China, to alter the DNA of two embryos, resulting in the birth of two baby girls late in 2018. When this news broke, our report once again became integral to the international discussions that ensued amongst scientists, bioethicists and the media across the world.

Whilst events in China gave our genome editing report a somewhat unexpected and immediate relevance on the global scale, we were meanwhile working hard on our other in-depth inquiry, a truly international collaboration exploring research in global health emergencies. This promises to be another report with huge potential for impacting on policies and practises across many different countries and I look forward to the publication of the findings in 2019.

The global context for work in biotechnology and medicine highlights the importance of our collaboration beyond the UK with other bioethical organisations – in Europe, the United States and China. This collaboration has developed throughout the last year. As this report demonstrates, the work of the Nuffield Council on Bioethics reaches far beyond the UK. The international recognition of our work and our wider reputation as a leading global source of bioethical reflection and authority is something that I am particularly proud of and look forward to developing further during my time as Chair.

It was certainly an eventful year. I hope you enjoy reading about all the important work and achievements of the Nuffield Council on Bioethics as much as I have enjoyed being a part of it.

David Archard
The Nuffield Council on Bioethics’ in-depth inquires (or the ‘full Nuffield’, as they are sometimes known) have been our hallmark product since we were founded in 1991. Since then we have published more than 40 reports, many of which remain influential several years or even decades after they were published.

The task of balancing our in-depth inquiries – on which our reputation for thoroughness, inclusiveness and quality is founded – with a new work programme to foster more responsive and flexible activities was always going to be a challenge, but it has been a very welcome challenge for all of us and one that I was pleased to see being addressed so positively in our work throughout the course of 2018.

The Active Responsive Programme is a new programme of responsive activities to maximise our contributions to policy and public affairs through diversifying our portfolio of work and providing timely policy advice when it is most needed. At the heart of this programme are our flagship ‘bioethics briefing notes’ which aim to provide timely, independent and balanced assessments for policy-makers and others on the ethical issues raised by a specific development in biological and medical research. In 2018 we published four Bioethics briefing notes, on the medicalisation of ageing; on whole genome sequencing of newborns; and on artificial intelligence in healthcare; and experimental medical treatments.

As you will read later in this report, these have been a helpful and valued addition to the Council’s core work, with feedback indicating that policy-makers and others have found them to be an invaluable and unrivalled source of succinct, accurate and clear information about ethical considerations and questions raised. In some cases, these briefing notes have proved influential in shaping ongoing and emerging policy discussions and some have also gained considerable media attention when launched.

Another important part of the Active Responsive Programme has been to bolster our public affairs activities to develop closer links with policy-makers and further establish ourselves as the go to organisation for independent, thorough and robust advice on ethical issues arising within biosciences and health. We have created a new role of Public Affairs Manager to lead our work in this area.

With our Horizon Scanning Programme fully up and running now, we have consolidated and strengthened our work in identifying and monitoring upcoming developments in biological and medical research that are likely to raise ethical issues and may invoke public concerns. And that is, of course, at the heart of why we exist.

I thank colleagues on the Council and the Executive for a great year’s work and I look forward to 2019 where our strategic priorities will include fostering international relationships, working in partnerships, and reinvigorating our public engagement activities.

Hugh Whittall
IN-DEPTH INQUIRIES

In-depth inquiries have been our core activity since we were founded in 1991. Our inquiries are overseen by multi-disciplinary working groups and are informed by extensive research and consultation with a wide range of stakeholders. We tackle some of the most difficult issues in bioethics and the reports we produce are influential in informing policy, practice and public debate, both nationally and internationally.

In 2018 we published the findings of our inquiry on genome editing and human reproduction, and started a new inquiry on the ethics of research in global health emergencies.

Genome editing and human reproduction: social and ethical issues

The findings of our in-depth inquiry on genome editing and human reproduction were published on 17 July 2018. The working group’s report sets out the range of ethical issues that arise in relation to the prospect of genome editing becoming available as a reproductive option for prospective parents.

The report concludes that the potential use of heritable genome editing interventions could be ethically acceptable in some circumstances. We therefore recommended immediate action to support broad and inclusive public debate, and to put in place appropriate governance arrangements developed in accordance with the principles of welfare of the future person and of social justice and solidarity.

Launch

Following a press briefing held in advance of publication, the report launch generated extensive media coverage in the UK and internationally, across print and broadcast media. The initial wave of coverage prompted several subsequent comment and analysis pieces in the days after the launch.

We held a conference one week after the report was published, providing an opportunity for participants to engage with the approach and conclusions of the report, having had sufficient time to read and digest it. The event hashtag #genomeditconf topped the Twitter trending list for London for two days after the conference and resulted in an estimated reach of 153,902 (no. of accounts reached) and 1,059,701 impressions (no. of tweets delivered to an account).

We have been working to promote awareness of our work in this area and to follow up recommendations, both through the media, and more directly e.g. through meetings with UK policy-makers and involvement with international advisory groups set up to facilitate the governance of genome editing [see more on this in ‘presentations and events, p10].

Key developments

On 26 November 2018 the world’s media reported the first ever clinical use of heritable human genome editing. Chinese scientist Dr He Jiankui reported the use of CRISPR-Cas9 genome editing to alter the CCR5 gene in the embryos of twin baby girls born in China. We issued a media statement in response to this, which was picked up in over 20 countries, and led to significant further media coverage of the Council’s report in the US, China and UK.

From the blog

• What He said (November 2018)
Research in global health emergencies

In January 2018, we announced our new working group to examine how research may be conducted ethically during global health emergencies. The working group includes international expertise in disaster and epidemic response, health systems research, drug development, medicine, ethics, political philosophy, law, data sharing, community engagement, and the history of medicine. Almost half of working group members are from outside the UK, and most have extensive experience of working in non-UK countries, particularly those with low or middle incomes.

An open call for evidence was held from June-August 2018. 58 responses were received from a very wide range of respondents from across the globe and from many different roles and perspectives within global healthcare research.

As part of the wider research and evidence gathering we were involved in leading or speaking at several international workshops and events. We partnered with the African coaLition for Epidemic Research, Response and Training (ALERTT) to co-host a joint workshop on community engagement for ethical research in outbreaks of infectious disease and other humanitarian crises in Dakar, Senegal, and presented our work at international meetings in Beirut, Singapore and Ohio, gaining invaluable input into our project. The findings of this inquiry will be published in late 2019.

From the blog

• Ebola and ‘other’ infectious diseases: read all about it? (June 2018)
2018 was the first full year of our Active Responsive Programme, a new programme of activities designed to maximise our contributions to policy and public affairs, through providing timely briefs for policy-makers and others on the ethical issues raised by developments in biological and medical research.

Activities in 2018 included:

- Publication of four ‘Bioethics briefing notes’
- Three ‘Bioethics in focus’ workshops, each focussing on a new or emerging topic where the Council may be able to offer a distinct contribution
- Contributions to media stories through issuing press statements on topical issues, giving broadcast interviews and publishing 20 blog posts from a range of contributors
- Informing national and international policy discussions through meetings and presentations in 14 different countries, and several advisory roles
- Responses to 21 policy and government consultations, drawing on our work on animal research, public health, human bodies for donation and research, forensic bioinformation, biological data, mitochondrial donation, dementia, cosmetic procedures, and non-invasive prenatal testing
Bioethics briefing notes

The search for a treatment for ageing
Published January 2018
(drawing on 2016 workshop)

This briefing note explores scientific developments and ethical issues in the burgeoning field of geroscience research, which is exploring interventions that delay biological ageing and reduce the risk of age-related diseases. The note highlights calls for an ethical framework for ageing research to help guide researchers, policy-makers and consumers. On the day it was published, our Deputy Chair Professor Julian Hughes was interviewed on BBC Radio 4 Today Programme.

Whole genome sequencing of babies
Published March 2018

This briefing note sets out the ethical issues raised by whole genome sequencing of babies, providing a timely and balanced review to help with questions such as whether whole genome sequencing could be used to expand NHS screening for newborns.

On the day of publication, our briefing note was featured on BBC Radio 4 Today programme and it was the focus of an article in New Scientist.

Following our work in this area, Assistant Director Catherine Joynson was invited to be a member of the Genomics England Genomics Analysis in Children Task Group. The group advised on potential research to explore the clinical outcomes and ethical issues raised by the future use of whole genome sequencing in newborn babies.

Artificial intelligence in healthcare and research
Published May 2018

This briefing note examines the current and potential applications of AI in healthcare, its limits, and the ethical issues arising from its use. It concludes that AI has the potential to help address important health challenges, but might be limited by the quality of available health data, and by the inability of AI to display some human characteristics. This briefing note was featured in the Financial Times and was widely shared and praised on social media.

Patient access to experimental treatments
Published November 2018
(drawing on 2018 roundtable meeting)

This briefing note examines the ethical issues that can arise when patients and doctors wish to use experimental treatments. The note highlights three examples of experimental treatments: advanced therapies, fertility treatment ‘add-ons’ and innovation in surgery. The note concludes that a key challenge is balancing the interests of patients in accessing experimental treatments and the need to support innovation, with ensuring there are sufficient safeguards to protect patients from potential harm(s).
Bioethics in focus workshops

**Novel medical treatments: innovation, hope and headlines**
*Held April 2018*

This workshop set out to explore the practical and ethical issues raised by the offer of and access to experimental medical treatments in the UK and abroad. A range of experts attended the workshop, from the areas of policy, regulation, healthcare, patient perspectives, research funders, industry, academia and the media. The workshop went on to inform the Council’s briefing note on *Patient access to experimental treatments* (see above), and a number of the workshop participants also contributed as reviewers of that note.

**The human-technology frontier: biohacking, cyborgs and wearables**
*Held November 2018*

This workshop looked at the current trends and possible future scenarios in wearable and implantable devices, as well as the legal, social and ethical issues that might arise from their development and uses. Participants included individuals and experts from a range of fields and backgrounds including defence, policy, engineering, law, healthcare ethics and bioethics, sociology, healthcare technology and research governance. The workshop went on to inform a bioethics briefing note on medical implants, published June 2019.

**Disagreements in the care of critically ill children**
*Held November 2018*

Drawing on our strength as an independent facilitator of discussion around sensitive topics, this workshop aimed to explore the social and medical factors that might be contributing to how disagreements about the care of critically ill children develop in the UK, and how they are being resolved. The workshop brought together parents, patient groups, healthcare professionals, government and policy officials, academic researchers, experts in law and the justice system, mediators, and others. The discussion went on to inform a bioethics briefing note on this topic, published in April 2019.
Media, presentations and events

Media overview

In July 2018, the Nuffield Council on Bioethics generated news coverage across the world when we launched our landmark report *Genome editing and human reproduction: social and ethical issues*. In the days and weeks following publication, the report was discussed in 25 different broadcast pieces many of which featured interviews with Council spokespeople. Following a live interview and package on BBC Radio 4’s Today Programme, plus further BBC and other national coverage, we reached beyond the UK with news pieces on ABC Australia news, Fox News in the US, WNYC - America’s largest public radio station, Sputnik Radio in Russia, BBC World News and EuroNews TV. The report generated around 100 mainstream news articles and 300 further articles in local, specialist and online only media.

We were also very active in responding to live media stories relating to non-invasive prenatal testing (NIPT), to organ donation, and to cosmetic procedures throughout the year. Across all projects our work was featured in around 40 broadcast pieces, mentioned in 150 mainstream articles and in around 1,300 further articles including online newswires, local and trade press. Collectively, the Council’s work received 365 citations in academic journals, averaging one per day.

Presentations and events

We organise, attend and give presentations at numerous events each year, in order to ensure we remain actively involved in a wide range of bioscience and health policy and research networks in the UK and internationally.

In 2018 we were involved in informing national and international policy discussions through events in 14 different countries. The Executive, Council members and working group members collectively gave 37 presentations about our work and we held or attended a further 48 meetings with policy-makers and stakeholders to discuss how our work could inform policy and practice across different areas of bioethics. High-level advisory roles for senior Council staff included:

• Assistant Director Pete Mills was appointed to the World Economic Forum Global Future Council on Biotechnology and to the Council of Europe DH-BIO Working Group on public debate, where he has been involved in developing a guide for Member States on public engagement relating to emerging technologies.

• Related to our work on NIPT and on whole genome sequencing, Assistant Director Catherine Joynson was appointed to the Genomics Analysis in Children Task Group set up by Genomics England, advising on the research questions that need to be addressed in relation to the use of whole genome sequencing in the care of acutely ill children and, in future, in newborn screening programmes.

• Related to our work on public health, Director Hugh Whittall was invited to join Wilton Park global advisory committee looking at reducing the harmful effects of alcohol, which includes representatives from UK, Georgia, South Africa, Switzerland and the US.
The Nuffield Council on Bioethics influences policy in a number of ways.

We engage with civil servants and directly at Ministerial level as Government departments develop policy. In 2018 we responded to consultations drawing on our work across animal research, public health, organ and tissue donation, forensic bioinformation, biological data, novel genetic therapies, dementia, cosmetic procedures, and non-invasive prenatal testing.

Where necessary we brief MPs and Peers as legislation progresses through Parliament to ensure bioethical issues are always fully considered. We do this through meetings and briefings, drafting of parliamentary questions, presentations to All-Party Parliamentary Groups, and submissions and presentations to Select Committees. In December 2018, we called for the Science and Technology Committee to scrutinise issues around commercial genomics services and they began a formal inquiry on this topic in 2019.

Below are two case studies that illustrate the considerable range of our influence. Our work on non-invasive prenatal testing shows how our work impacts not only policy drivers but industry too. The activity around a move to an opt-out system for organ donation demonstrates that when we need to make a case to parliament our views are taken seriously.

**Provision of non-invasive prenatal testing (NIPT)**

Our 2017 report on NIPT made recommendations across several areas, including:

- provision of NIPT in NHS screening programmes
- provision of information in the private sector
- the scope and regulation of NIPT
- development of prenatal screening policy
- support for and inclusion of disabled people

Throughout 2018 there were a number of developments across these areas that were directly influenced by or aligned with our recommendations. Highlights of these developments include:

- Public Health England set up an Information and Education Working Group for the Fetal Anomaly Screening Programme (FASP) to develop new patient information materials on NIPT and training for healthcare professionals involved in the offer and delivery of NIPT.
  As we recommended, the group actively engaged with organisations that support and represent people with Down’s syndrome, Edwards’ syndrome and Patau’s syndrome. The materials will be published when NIPT becomes available to women in the NHS in England (date tbc). Training has already been rolled out in preparation for this.

- Public Health Wales reviewed and revised its patient information materials on prenatal screening in response to feedback we and others provided. The materials now include more balanced information about the lives and prospects of people with Down’s syndrome.
• The Church of England General Synod held a debate on valuing people with Down’s syndrome. We wrote to the Bishop of Carlisle and provided a briefing highlighting relevant principles from our report. We also briefed speakers ahead of a fringe event to discuss the motion. The General Synod gave unanimous backing to the call for people with Down’s syndrome to be welcomed, celebrated and treated with dignity and respect.

• The UK National Screening Committee (UKNSC) took a number of steps to take proper account of the psychological, ethical and social consequences of prenatal screening where termination of pregnancy is an option. For example, it has set up an ethics task group to provide a framework for in-depth consideration of the ethical issues related to screening, to which we provided input.

• Having previously considered NIPT to be out of its remit, the Care Quality Commission (CQC) announced that it would regulate NIPT, and started to inspect clinics in 2018. We are continuing to advise regulators and companies on the ethical issues regarding the provision of NIPT, and we expect further developments in the private NIPT industry as a result of our recommendations and sustained follow-up.

From the blog

• **NHS Wales offers non-invasive prenatal testing one year on from our ethics report** (April 2018)

• **Our concerns about non-invasive prenatal testing in the private sector** (February 2019)
Moving to an opt-out system for organ donation in England

Using the conclusions of our 2011 report, *Human bodies: donation for medicine and research*, we made a valuable and constructive contribution to the debate in the media and amongst professionals, regulators, and parliamentarians throughout 2018 regarding a planned move to an opt-out system of consent for organ donation.

In our report, we concluded that opt-out systems could be ethical if people are well-informed, families are appropriately involved and supported by specialist nurses, and trust in the system is not compromised. We did not recommend a change to opt-out because of the lack of evidence that this would in itself lead to an increase in the number of organs donated. At the time of our report, Wales had expressed an interest in moving to an opt-out approach and we recommended robust research into the effect of any legislative change, if introduced.

In responding to the Department of Health and Social Care consultation, we expressed our concern that a move to opt-out was premature, given that evidence to date from Wales has proved inconclusive. We expressed this concern in media interviews, and through participation in various panels and events throughout the UK.

The Organ Donation (Deemed Consent) Bill was introduced to Parliament in February 2018. From the earliest stages of the Bill we worked to brief Geoffrey Robinson MP - sponsor of the Bill - and other key members of Parliament. We focussed firstly on making our concerns about the lack of evidence known, and later to encourage clear commitments from Health Ministers to investing in infrastructure and systems that we consider essential to ensuring that opt-out is introduced in an ethical way.

In the second reading in the Commons, our concerns were acknowledged by Geoffrey Robinson MP when he said:

“I think it behoves us to note the caution expressed by the Nuffield Council on Bioethics. We want to proceed carefully and with all the necessary infrastructure in place. One of the great aspects of our present system is that it is trusted by the public, and we cannot and will not put that trust at risk. We must ensure that the new system is introduced properly.”

During the Lords stages of the Bill, we worked with several supportive Peers to encourage Government to offer further reassurances. Crossbencher Baroness Deech argued our case particularly eloquently by saying:

“... the very expert Nuffield Council on Bioethics did not originally recommend a change to an opt-out system, because, as it said, there was a, “lack of evidence that such a change alone would increase organ donation rates”, and because of ethical concerns about the operation of the scheme. Now, the Nuffield Council, accepting the situation as it is in this Bill, emphasises how it can be made to work ethically. It says, “it is vital to have measures in place that encourage people to express and document their wishes about organ donation during their lifetime.””
The Nuffield Council further says that, “information about the donation process must be easily accessible”. It is not enough to have a publicity campaign when this Bill is passed. It needs to be maintained on an ongoing basis so that those who might donate, but are not thinking about it now, are as aware in the future as those who benefit from the publicity that will no doubt accompany this Bill’s success.”

The Nuffield Council suggests that a solution is to invest further in the network of specialist nurses for organ donation, who can support bereaved families. So the Nuffield Council is opening up the debate to the wider context and emphasising the need to maintain trust in the system.”

We also wrote to Health Minister, Jackie Doyle-Price and met with Lord Hunt of Kings Heath, who sponsored the bill in the House of Lords. The Minister confirmed to us in December 2018 that Government will ensure “continuous engagement with the public” and that, “no family will be forced to agree to donation.”

We also met with NHS Blood and Transplant to discuss the practical aspects of implementation and will continue to monitor as opt-out is introduced in England in 2020.

From the blog

• Opting out of the evidence? (March 2018)
• Busting the myths around opt-out organ donation (November 2018)
HORIZON SCANNING AND TOPIC SELECTION

Through the course of 2018 we established a more sustained and coordinated programme for horizon scanning.

To ensure the broadest possible reach to identify developments relevant to biological and medical research, we developed a shared horizon scanning approach. We engage systematically with other organisations and individuals from across a wide range of areas of interest (e.g. science, engineering, ethics, policy and regulation), sectors (e.g. academic and commercial research), and geographical reach (e.g. UK, Europe, worldwide). We also set up a new advisory group of Council members for horizon scanning, initiated a programme of themed ‘bioethics futures’ workshops, and initiated monthly horizon scanning staff briefing sessions.

To document and communicate our horizon scanning activities in a new and interesting way, we developed an infographic to illustrate the range of topics that we have an interest in and may instigate work on, in the future.

Bioethics futures workshop: food sustainability

The first in a new series of annual ‘bioethics futures’ workshops took place in July 2018, which explored the role that science and technology could play in meeting food sustainability challenges. The aim of the workshop was to bring together a range of people to help us identify scientific and social developments relevant to debates about farming and food, and the ethical issues they raise, which the Council might respond to in future. Around 50 guest participants attended, including scientists, farmers, industry representatives, NGOs, government officials, journalists, philosophers, and social, political, environmental, and public health experts.

Following the workshop, the production and consumption of meat emerged as an issue that might be suitable for further Council work. We are planning to explore this topic further in 2019, with a focus on the role that scientific research and development might play in the context of significant social and political change in this area.

The next bioethics futures workshop will take place in summer 2019 and will focus on the role of biological science and technology in the future of crime and security.

From the blog

- Unpacking the ethics of food sustainability: health, harmony and beyond (October 2018)
Infographic

We published an infographic that shows the bioethics topics we identified and tracked in 2018 under seven broad themes. We developed an interactive version, which includes pop-up boxes to explain each of the topics, plus a mobile friendly version.

The infographic was shared widely on social media and resulted in suggestions for additional topics that people would like to see included in future editions of the infographic.

From the blog
• Scanning the horizon, one song at a time (January 2019)
Council Members

David Archard (Chair)
Julian Hughes (Deputy Chair)
Simon Caney
Tara Clancy
Ann Gallagher
Andy Greenfield
Erica Haimes
Roland Jackson
David Lawrence
Shaun Pattinson
Tom Shakespeare
Mona Siddiqui
Christine Watson
Robin A Weiss
Heather Widdows
Adam Wishart
Paquita de Zulueta

Executive

Hugh Whittall, Director
Sophia Griffiths, Comms Officer
Kate Harvey, Senior Research Officer
Catherine Joynson, Assistant Director
Richella Logan, Public Affairs Manager
Pete Mills, Assistant Director
Carol Perkins, Executive Administrator
Jade Rawling, Office Administrator
Ranveig Svenning Berg, Research Officer
Sarah Walker-Robson, Comms Manager
Anna Wilkinson, Research Officer
Katharine Wright, Assistant Director

Governing Board

The Chair of the Governing Board and its other members are independent and are appointed and remunerated by the funders.

Sally Macintyre (Chair)
Stephen Holgate
Vivienne Parry
Brian Scott

For more information, please see www.nuffieldbioethics.org/about
# Financial Report for the year to 31 December 2018

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Funded by:

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<th>Funding Source</th>
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<td>Other</td>
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<td><strong>Total funding 2018</strong></td>
<td><strong>834,408</strong></td>
<td><strong>793,927</strong></td>
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</table>

Less contribution to overheads shared equally among funders: -261,000

Total: 891,179

Amount drawn: 834,408

Outstanding funding 2018: 56,771
CONTACT

Nuffield Council on Bioethics
28 Bedford Square
London
WC1B 3JS

Email: bioethics@nuffieldbioethics.org
Telephone: +44 (0) 20 7681 9619

Website: www.nuffieldbioethics.org
Blog: nuffieldbioethics.org/blog
Twitter: twitter.com/nuffbioethics
Facebook: facebook.com/nuffieldbioethics
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