



House of Commons
Science and Technology
Committee

Genomics and genome-editing: future lines of inquiry

Sixteenth Report of Session 2016–17

*Report, together with formal minutes relating
to the report*

*Ordered by the House of Commons
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Science and Technology Committee

The Science and Technology Committee is appointed by the House of Commons to examine the expenditure, administration and policy of the Government Office for Science and associated public bodies.

Current membership

[Stephen Metcalfe MP](#) (Conservative, South Basildon and East Thurrock) (Chair)

[Victoria Borwick MP](#) (Conservative, Kensington)

[Stella Creasy MP](#) (Labour (Co-op), Walthamstow)

[Jim Dowd MP](#) (Labour, Lewisham West and Penge)

[Chris Green MP](#) (Conservative, Bolton West)

[Dr Tania Mathias MP](#) (Conservative, Twickenham)

[Carol Monaghan MP](#) (Scottish National Party, Glasgow North West)

[Gareth Snell MP](#) (Labour (Co-op), Stoke-on-Trent Central)

[Graham Stringer MP](#) (Labour, Blackley and Broughton)

[Derek Thomas MP](#) (Conservative, St Ives)

[Matt Warman MP](#) (Conservative, Boston and Skegness)

Powers

The Committee is one of the departmental select committees, the powers of which are set out in House of Commons Standing Orders, principally in SO No 152. These are available on the internet via www.parliament.uk.

Publication

Committee reports are published on the Committee's website at www.parliament.uk/science and in print by Order of the House.

Evidence relating to this report is published on the relevant [inquiry page](#) of the Committee's website.

Committee staff

The current staff of the Committee are: Simon Fiander (Clerk); Marsha David (Second Clerk); Sean Kinsey (Second Clerk); Dr Elizabeth Rough (Committee Specialist); Martin Smith (Committee Specialist); Sonia Draper (Senior Committee Assistant); Julie Storey (Committee Assistant); and Shagufta Hailes (Media Officer).

Contacts

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Contents

Genomics and genome editing: future lines of inquiry	3
Genomics	3
Genomics England	3
Implications for healthcare	4
Social and ethical concerns	5
Genome editing	5
Social and ethical concerns	5
Regulatory concerns	6
Implications for the NHS	7
Commercialisation and the Industrial Strategy	7
Conclusion	7
Formal Minutes	8
Witnesses	9
Published written evidence	10
List of Reports from the Committee during the current Parliament	12

Genomics and genome editing: future lines of inquiry

1. We launched our inquiry into Genomics and genome editing in November 2016, calling for evidence on the impact of these emerging scientific fields on human health, plants, animals and ecosystems. In February 2017 we announced that the inquiry would be split into two parts, with the first looking at genomics and genome editing as it relates to human health, and the second examining the impact of the technologies on plants, animals and ecosystems. So far we have received 60 written submissions and held three evidence sessions on the first of these two inquiries, and have taken evidence from 19 witnesses.¹ We also appointed Professor Sir John Burn² as a specialist adviser and we are grateful for his advice on the issues associated with both genomics and genome editing.

2. We had planned to hold two further sessions on genomics and genome editing as it relates to human health, but due to the forthcoming General Election in June 2017, we have been unable to conclude this strand of our inquiry. We have also not yet begun taking evidence on plants, animals and ecosystems. We have produced this short report to serve as a stock-take for the next Science and Technology Committee. Should it wish to pursue the matter further, the new Committee will be able to draw on the evidence we have gathered so far—both written and oral—and our interpretation of the pertinent issues for examination.

Genomics

Genomics England

3. We began by looking at the formation of Genomics England and its role in delivering the 100,000 Genomes Project. Issues for further consideration include:

- The rationale for Genomics England's status as a limited company rather than a more typical arm's length body.
- Whether lessons from the Human Genome Project and other similar initiatives have been learned (particularly in relation to stimulating commercial activity).
- Genomics England's funding history, projected funding requirements, and how its ongoing performance is being evaluated.
- Why the 100,000 Genomes Project is behind schedule. Potential reasons include delays in setting up the Project's physical and digital infrastructure, scientific barriers, low patient recruitment and issues around consent.

1 [Science and Technology Committee, Genomics and genome editing inquiry](#)

2 Professor Sir John Burn declared his interests on 1 March 2017: Non-executive director of NHS England; Professor of clinical genetics, Newcastle University; Honorary consultant clinical geneticist, Newcastle Hospitals NHS Foundation Trust; Chairman and shareholder of QuantuMDx Group Ltd; member of Science Advisory Committee, Genomics England; member of Genomics Advisory Board, Health Education England; Director of Global Variome Ltd (previously Human Variome Project); member of Advisory Board to Astra Zeneca on the use of Lynparza in hereditary breast/ovarian cancer; patron of Veterans at Ease (Charity); and member of Liberal Democratic party (not active in party politics). Sir John Burn agreed from the outset of his engagement as specialist adviser that in view of his interests he would not provide advice or insights on NHS policy or funding in regard to genomics and genome-editing.

- How the devolved administrations have been involved in the 100,000 Genomes Project and further opportunities for UK-wide expansion.
- How decisions were reached about the types of cancer and rare diseases that are included in the Project, why the infectious disease arm of the Project was transferred to Public Health England, and the progress in this area since its transfer.

Implications for healthcare

4. We also investigated the NHS's involvement in the 100,000 Genomes Project, in particular how it is coping with the demands of the initiative, and how its mainstream health service will be integrated with the Project's infrastructure when it concludes. Issues for further exploration, we believe, include:

- Whether the Department of Health and the NHS were prepared for the demands of the Project when it was announced, and what the main drivers were for initiating the Project.
- Whether the development of the NHS's genomic medicine capacity will reduce or increase NHS costs, and how that might change in the short, medium and long term.
- How the NHS and Genomics England have reacted to the initiative's physical infrastructure requirements, including the creation of 13 Genomic Medicine Centres (GMCs). This includes how services and personnel delivered via the GMCs will be integrated into the NHS at the end of the 100,000 Genomes Project, and the feasibility of maintaining this infrastructure when funding for the central project ceases.
- How the NHS and Genomics England have responded to the Project's digital infrastructure requirements, particularly in relation to the creation of a centralised, aggregated and integrated genomic database.
- Whether the NHS is prepared for the mainstreaming of genomic medicine. This relates particularly to staff training requirements and emerging skills gaps (such as genetic counsellors and informatics specialists), and the level of genomic knowledge held by non-specialist clinicians and frontline health workers.

5. A further set of issues centres on the 100,000 Genomes Project's intention to deliver tangible health benefits to patients. Issues for possible further consideration include:

- Whether patients could receive faster diagnoses through mainstream NHS genomic services (due to the comparatively longer consent process and sequencing times in the 100,000 Genomes Project), and whether patients are being invited into the 100,000 Genomes Project due to perceived long-term research and commercial benefits, at the expense of more immediate benefits to their health.

- How NICE and NHS commissioning structures are affecting the availability of suitable genomic diagnostics, and whether the health service is capable of treating patients once diagnosed—particularly those with rare diseases.

Social and ethical concerns

6. We also discussed the ethical, consent and data-sharing issues associated with the 100,000 Genomes Project and genomics more generally. We believe that issues for further consideration include:

- How ethical and social concerns relating to genomics are handled by the Government and UK health bodies, and whether a new body—akin to the Human Genetics Commission (which existed until 2012)—is required.
- The suitability of the ‘broad consent’ model being employed by the 100,000 Genomes Project, and whether the consent materials and patient recruitment techniques fully inform participants of the potential commercial uses of their data. This is tied to the debate around the nature of genetic data and whether it deserves a privileged status over other forms of personal health data.
- Whether the Project’s consent model will be adopted by the NHS, and whether this would mean that patients must consent to the commercial use of their data in order to receive genomic diagnoses.
- Whether the security systems and protocols employed by Genomics England, NHS England, and NHS trusts are sufficient for the volume and nature of the data created by the 100,000 Genomes Project.
- The situations in which genetic screening is acceptable pre-birth, post-birth, and pre-conception. Furthermore, how to approach the eradication of diseases while considering the views of, and implications for, communities of individuals who already suffer from the diseases in question.
- The secondary actions that should be taken by the NHS when genetic conditions are diagnosed. For example, whether the relatives of those with genetic diseases have a right to be informed.

Genome editing

Social and ethical concerns

7. Genome editing processes, technologies and outcomes raise a variety of social and ethical considerations. Issues for further consideration, we believe, include:

- Whether there are limits to the conditions that genome editing should be used to treat.
- Whether human embryo research beyond 14 days (the current legal limit) is beneficial to the study of genetic defects, diseases or conditions in either the mother or child, and whether advancing the field of genome editing increases the number of human embryos required for research.

- The risk of ‘off-target events’ (where changes are made to genes other than those targeted) and the timeframe in which the UK will have confidence in the safety of genome editing techniques, particularly if they are to be used widely in the NHS.
- Whether the need for research subjects with genetic similarity to humans has implications for the scale of animal testing and, in particular, whether there is an increased need for testing on primates.
- The extent to which the therapeutic use of genome editing could lead to future non-therapeutic use, noting public concern about ‘eugenics’, ‘designer babies’, and the potential military applications of genome editing.
- How to stimulate an open and informed debate about genome editing between scientists, policy makers, patients and the public.

Regulatory concerns

8. When looking at the regulatory frameworks surrounding genome editing, we found the following issues to be most in need of investigation:

- Whether the UK’s approach to the regulation of genome editing should be ‘product’ driven (focused on the results of a particular genetic technique) or ‘process’ driven (focused on the technique itself).
- How to distinguish between regulation for basic research, germline (causing inheritable genetic changes) and somatic (causing non-inheritable genetic changes) editing, and whether the UK’s current regulation accurately reflects these distinctions.
- How the UK compares to international competitors in terms of its research environment for genome editing, and the degree to which the UK should align its regulatory standards with international bodies and conventions.
- The regulatory impact of the UK’s decision to leave the EU, and how the UK can continue to collaborate with European institutions after Brexit given the potential for their respective regulatory environments to diverge. In connection with this, the potential opportunities for regulatory refinement post-Brexit.
- The increased propensity for ‘health tourism’ that could result from a more liberal regulatory regime, and whether (and how) this should be countered.
- The extent to which the licensing processes for conducting research are fit for purpose, particularly in relation to working with human embryos.

Implications for the NHS

9. We also looked at the challenges of embedding genome editing techniques into the NHS, which include:

- Whether genome editing treatments are more effective (both in health and cost terms) than alternative methods currently available on the NHS. If they are not, how to determine the point at which they may become so in the future.
- How best to embed somatic (non-inheritable) genome editing into the UK's healthcare system, and how to bridge the gap between basic research and clinical delivery.
- How the UK health agencies can best coordinate to deliver the necessary medical infrastructure to deliver widespread genome editing services in the UK. In addition to this, how to ensure there is a stream of skilled clinicians who are capable of doing so.
- Whether 'gene drive' techniques are an effective, safe and ethical way of tackling infectious diseases in the UK and overseas.

Commercialisation and the Industrial Strategy

10. In the sessions we have been able to hold, we also looked at the commercial opportunities for genomics and genome editing in the UK. Areas that warrant further investigation include:

- How genomics and genome editing will fit into the 'life sciences' arm of the current Government's Industrial Strategy.
- How Genomics England is drawing experience, technology and funding from the private sector.
- How the Government can encourage UK genomics and genome editing specialists to start-up, roll-out and grow technology and health businesses in the UK, and why UK companies in this sector find it difficult—or choose not—to scale up.
- Whether patenting and intellectual property issues are limiting the development of commercial genome editing companies, and whether they are hampering scientific discovery more broadly.

Conclusion

11. Our inquiry has been timely because advances in genomics and genome editing mean that both fields are now being used in our health service, because the 100,000 Genomes Project is approaching its original completion date, and because Brexit will significantly alter the opportunities and challenges in these emerging areas. We believe that the subjects warrant further scrutiny given the opportunities and challenges they both present. We hope that the next Science and Technology Committee will consider taking our incomplete inquiry forward when it considers its work programme after the election.

Formal Minutes

Wednesday 26 April 2017

Members present:

Stephen Metcalfe, in the Chair

Victoria Borwick	Graham Stringer
Jim Dowd	Derek Thomas
Chris Green	Matt Warman
Carol Monaghan	

Draft Report (*Genomics and genome-editing: future lines of inquiry*), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 11 read and agreed to.

Resolved, That the Report be the Sixteenth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

[The Committee adjourned

Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the [inquiry publications page](#) of the Committee's website.

Wednesday 8 February 2017

Question number

Professor Sue Hill, Chief Scientific Officer, NHS England, **Professor Mark Caulfield**, Chief Scientist, Genomics England, and **Dr Julia Wilson**, Associate Director, Wellcome Trust Sanger Institute

[Q1–57](#)

Professor Sir John Burn, Non-executive Director, NHS England, **Professor Dame Kay Davies**, Non-executive Director, Genomics England, and **Dr Helen Firth**, Clinical Lead, Deciphering Developmental Disorders Project, Wellcome Trust Sanger Institute

[Q58–105](#)

Wednesday 8 March 2017

Dr Edward Hockings, Founder, Ethics and Genetics, **Professor Michael Parker**, Director, Ethox Centre, University of Oxford, and Non-executive Director and Chair, Ethics Advisory Committee, Genomics England, **Peter Counter**, Chief Information Officer and Project Manager, Genomics England, and **Alison Hall**, Head of Humanities, PHG Foundation

[Q106–155](#)

Professor Sir Mike Stratton, Director, Wellcome Trust Sanger Institute, and Chief Executive Officer, Wellcome Genome Campus, and **Dr Jean Abraham**, Academic Honorary Consultant in Medical Oncology, University of Cambridge

[Q156–187](#)

Wednesday 29 March 2017

Professor Waseem Qasim, Professor in Cell and Gene Therapy, Institute of Child Health, **Alastair Kent**, Director, Genetic Alliance UK, and **Dr Kathy Niakan**, Group Leader, The Francis Crick Institute

[Q188–222](#)

Dr Andy Greenfield, Programme Leader, Medical Research Council's Harwell Institute, **Professor Robin Lovell-Badge**, Senior Group Leader, The Francis Crick Institute, **James Lawford Davies**, Partner, Hempsons, and **Philippa Taylor**, Head of Public Policy, Christian Medical Fellowship

[Q223–250](#)

Published written evidence

The following written evidence was received and can be viewed on the [inquiry publications page](#) of the Committee's website.

GEN numbers are generated by the evidence processing system and so may not be complete.

- 1 23andMe ([GEN0028](#))
- 2 Association of Cancer Physicians ([GEN0064](#))
- 3 Advisory Committee on Releases to the Environment (ACRE) ([GEN0039](#))
- 4 Agricultural Biotechnology Council ([GEN0053](#))
- 5 Association of Genetic Nurses and Counsellors ([GEN0037](#))
- 6 AstraZeneca ([GEN0056](#))
- 7 Biosecure Ltd ([GEN0033](#))
- 8 BIVDA ([GEN0008](#))
- 9 Bob Goodall ([GEN0035](#))
- 10 British Medical Association ([GEN0012](#))
- 11 British Society for Genetic Medicine ([GEN0062](#))
- 12 BSPB ([GEN0009](#))
- 13 Christian Action Research & Education (CARE) ([GEN0034](#))
- 14 Christian Medical Fellowship ([GEN0003](#))
- 15 Compassion in World Farming ([GEN0005](#))
- 16 Cystic Fibrosis Trust ([GEN0045](#))
- 17 Department for Environment, Food and Rural Affairs ([GEN0052](#))
- 18 Department of Health ([GEN0059](#))
- 19 Desktop Genetics ([GEN0049](#))
- 20 Dr Felicity Boardman ([GEN0006](#))
- 21 Earlham Institute ([GEN0055](#))
- 22 Edinethics Ltd ([GEN0047](#))
- 23 Edward Perello ([GEN0048](#))
- 24 Ethics and Genetics ([GEN0010](#))
- 25 Extension Professor Paul Vincelli ([GEN0001](#))
- 26 GARNet ([GEN0018](#))
- 27 Genetic Alliance UK ([GEN0050](#))
- 28 Genetic Counsellor Registration Board (GCRB) ([GEN0027](#))
- 29 Genomics England ([GEN0015](#)) and ([GEN0060](#))
- 30 Health Research Authority ([GEN0041](#))
- 31 Human Fertilisation and Embryology Authority (HFEA) ([GEN0021](#))
- 32 Innogen Institute, University of Edinburgh ([GEN0031](#))
- 33 Leicester Precision Medicine Institute ([GEN0017](#))

- 34 NHS England ([GEN0007](#))
- 35 Nuffield Council on Bioethics ([GEN0051](#))
- 36 Office of the National Data Guardian for Health and Care ([GEN0026](#))
- 37 Pfizer ([GEN0044](#))
- 38 PHG Foundation ([GEN0025](#))
- 39 Premaitha Health ([GEN0019](#))
- 40 Professor David Jones ([GEN0054](#))
- 41 Professor Huw Jones ([GEN0002](#))
- 42 Professor Michael Bonsall, Dr Nina Alphey and Ms Charlotte Elves ([GEN0032](#))
- 43 Radoslav Bozov ([GEN0029](#))
- 44 Research Councils UK ([GEN0046](#))
- 45 Royal Society of Biology ([GEN0042](#))
- 46 RSPCA ([GEN0043](#))
- 47 Scottish Council on Human Bioethics ([GEN0011](#))
- 48 Society for Applied Microbiology and Microbiology Society ([GEN0057](#))
- 49 Target Malaria ([GEN0020](#))
- 50 The Academy of Medical Sciences ([GEN0013](#))
- 51 The Association of the British Pharmaceutical Industry ([GEN0040](#))
- 52 The James Hutton Institute ([GEN0061](#))
- 53 The Roslin Institute ([GEN0022](#))
- 54 The Royal Society ([GEN0058](#))
- 55 UK BioIndustry Association ([GEN0016](#))
- 56 UK Synthetic Biology Leadership Council ([GEN0023](#))
- 57 University of Cambridge and Cancer Research UK Cambridge Centre ([GEN0063](#))
- 58 University Hospitals of Leicester ([GEN0014](#))
- 59 Wellcome Trust Sanger Institute ([GEN0024](#))
- 60 Wellcome Trust, Association of Medical Research Charities, and Cancer Research UK ([GEN0038](#))

List of Reports from the Committee during the current Parliament

All publications from the Committee are available on the [publications page](#) of the Committee's website.

The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2016–2017

First Report	EU regulation of the life sciences	HC 158
Second Report	Digital skills crisis	HC 270 (HC 936)
Third Report	Satellites and space	HC 160 (HC 830)
Fourth Report	Forensic Science Strategy	HC 501 (HC 845)
Fifth Report	Robotics and artificial intelligence	HC 145 (HC 896)
Sixth Report	Evidence Check: Smart metering of electricity and gas	HC 161 (HC 846)
Seventh Report	Leaving the EU: implications and opportunities for science and research	HC 502 (HC 1015)
Eighth Report	Setting up UK Research & Innovation	HC 671 (HC 1063)
Ninth Report	Future programme: 'My Science Inquiry'	HC 859
Tenth Report	Managing intellectual property and technology transfer	HC 755
Eleventh Report	Science communication and engagement	HC 162
Twelfth Report	Science in emergencies: chemical, biological, radiological or nuclear incidents	HC 163
Thirteenth Report	Industrial Strategy: science and STEM skills	HC 991
Fourteenth Report	The Draft Spaceflight Bill	HC 1070
Fifteenth Report	Regenerative medicine	HC 275
First Special Report	Satellites and space: Government Response to the Committee's Third Report of Session 2016–17	HC 830
Second Special Report	Forensic Science Strategy: Government Response to the Committee's Fourth Report of Session 2016–17	HC 845
Third Special Report	Evidence Check: Smart metering of electricity and gas: Government Response to the Committee's Sixth Report of Session 2016–17	HC 846
Fourth Special Report	Digital skills crisis: Government Response to the Committee's Second Report of Session 2016–17	HC 936
Fifth Special Report	Robotics and artificial intelligence: Government Response to the Committee's Fifth Report of Session 2016–17	HC 896

Sixth Special Report	Leaving the EU: implications and opportunities for science and research: Government Response to the Committee's Seventh Report	HC 1015
Seventh Special Report	Setting up UK Research & Innovation: Government Response to the Committee's Eighth Report	HC 1063

Session 2015–2016

First Report	The science budget	HC 340 (HC 729)
Second Report	Science in emergencies: UK lessons from Ebola	HC 469 (Cm 9236)
Third Report	Investigatory Powers Bill: technology issues	HC 573 (Cm 9219)
Fourth Report	The big data dilemma	HC 468 (HC 992)
First Special Report	Royal Botanic Gardens, Kew: Government Response to the Committee's Seventh Report of Session 2014–15	HC 454
Second Special Report	Current and future uses of biometric data and technologies: Government Response to the Committee's Sixth Report of Session 2014–15	HC 455
Third Special Report	Advanced genetic techniques for crop improvement: regulation, risk and precaution: Government Response to the Committee's Fifth Report of Session 2014–15	HC 519
Fourth Special Report	The science budget: Government Response to the Committee's First Report of Session 2015–16	HC 729
Fifth Special Report	The big data dilemma: Government Response to the Committee's Fourth Report of Session 2015–16	HC 992