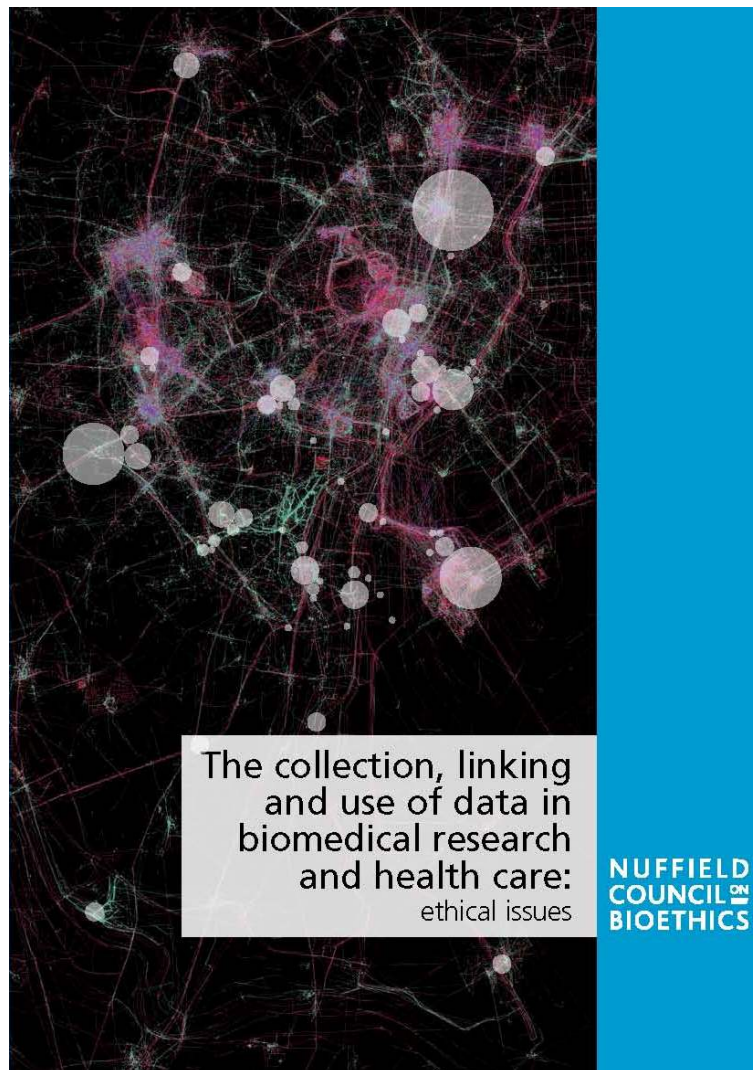


NUFFIELD COUNCIL ON BIOETHICS

The collection, linking and use of data in biomedical research and health care: ethical issues

Report developments

July 2016



The collection, linking
and use of data in
biomedical research
and health care:
ethical issues

NUFFIELD
COUNCIL ON
BIOETHICS

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Introduction

The Nuffield Council's report *The collection, linking and use of data in biomedical research and health care: ethical issues* was published on 3 February 2015.¹ This paper notes key developments since the report's publication.

Reactions

Reception among key stakeholders

Several stakeholder organisations highlighted the report in statements or news stories on their websites shortly after the launch, including the Farr Institute,² PHG Foundation,³ and the Association of Medical Research Charities.⁴

Simon Denegri, National Institute for Health Research (NIHR), National Director for Patients and the Public in Research and Chair of INVOLVE, wrote:

“...The set of expectations about how data will be used (or re-used) in a data initiative, and the appropriate measures and procedures for ensuring that those expectations are met, should be determined with the participation of people with morally relevant interests. This participation should involve giving and receiving public accounts of the reasons for establishing, conducting and participating in the initiative in a form that is accepted as reasonable by all. Where it is not feasible to engage all those with relevant interests – which will often be the case in practice – the full range of relevant values and interests should nevertheless be fairly represented. The report has laid down an important and powerful principle here which (...) should be a benchmark for how all data access and sharing is governed and managed.”⁵

General media coverage

Members of the Working Party presented the report at a press briefing held prior to the launch and on the morning of publication, Susan Wallace, member of the Working Party, was interviewed on BBC Radio 4's Today Programme. The report

¹ Nuffield Council on Bioethics (3 February 2016) *Public participation should be at the heart of big data projects*, available at <http://nuffieldbioethics.org/news/2015/public-participation-heart-big-data-projects/>.

² The Farr Institute of Health Informatics Research (2015) *Public Participation Should be at the Heart of Big Data Projects, Says Nuffield Council on Bioethics Report*, available at <http://www.farrinstitute.org/news/public-participation-should-be-at-the-heart-of-big-data-projects-says-nuffield-council-on-bioethics-report>.

³ PHG Foundation (2015) *Protecting the people behind biomedical big data*, available at <http://www.phgfoundation.org/news/16565/>.

⁴ AMRC (2015) *Handling NHS patient data, where are we now?*, available at <http://www.amrc.org.uk/blog/handling-nhs-patient-data-where-are-we-now>.

⁵ Simon Denegri's Lay Review (3 February 2016) *Nuffield report underlines importance of public participation if people are to trust how their medical records are used for research*, available at <https://simondenegri.com/2015/02/03/nuffield-report-on-use-of-medical-data-underlines-importance-of-public-involvement-in-governance-to-nurturing-public-trust/>.

received significant coverage in the general press, including in the Financial Times,⁶ the Guardian,⁷ the Independent,⁸ via Press Association,⁹ and in the British Medical Journal.¹⁰

Since the launch, Council representatives have been interviewed and the report referred to in media coverage of developments such as the publication of an Icelandic study using the largest-ever set of human genomes from a single population,¹¹ developments in relation to the care.data scheme,¹² and work by UCL researchers on developing software to predict life span based on data collected by data providers.¹³

Dissemination, presentations and events

As at July 2016, the report has been downloaded over 2,160 times from the Council's website, the short guide has been downloaded 830 times, and the one-page summary over 470 times.

Copies of the report, short guide and one-page briefing were sent to key stakeholders including research funders, the Health Research Authority (HRA), the Health and Social Care Information Centre (HSCIC), NHS England, and relevant government departments, in addition to about 350 MPs and Peers. Further dissemination has been initiated at conferences, presentations, and other meetings.

Members of the Working Party and Secretariat have presented at or attended several events since publication of the report, including:

- Assistant Director Peter Mills presented at the symposium '[How companies use genetic and health data: protecting patient confidence](#)' held by the Sheffield Institute for Biotechnology Law and Ethics on 30 January 2015

⁶ Financial Times (3 February 2016) *Health advances using 'big data' at risk, ministers warned*, available at <http://www.ft.com/cms/s/0/870ca844-aaf3-11e4-81bc-00144feab7de.html#axzz3QfitcXoL>.

⁷ Guardian (3 February 2016) *Public should be consulted on NHS medical data-sharing scheme*, available at <http://www.theguardian.com/society/2015/feb/03/medical-data-sharing-scheme-nuffield>.

⁸ The Independent (3 February 2016) *Government told to make it easier to opt out of care.data database*, available at <http://www.independent.co.uk/news/uk/politics/government-told-to-make-it-easier-to-opt-out-of-caredata-database-10019135.html>.

⁹ Press association (3 February 2016) *Concerns over health data*, available at <http://home.bt.com/news/science-news/concerns-over-use-of-health-data-11363959298576>.

¹⁰ BMJ (3 February 2015) *Tougher penalties, including imprisonment, are urged for misuse of personal data*, available at <http://www.bmj.com/content/350/bmj.h619>.

¹¹ See for example: BBC News (26 March 2015) *DNA of 'an entire nation' assessed*, available at <http://www.bbc.co.uk/news/health-32024158>.

¹² See for example: Mail Online (4 May 2016) *Could Google look after our NHS data? Controversial plans could be revived after minister says technology firms are best-placed to look after information securely*, available at <http://www.dailymail.co.uk/news/article-3066758/Could-Google-look-NHS-data-Controversial-plans-revived-minister-says-technology-firms-best-placed-look-information-securely.html#ixzz45icyqVw7>.

¹³ Mail Online (1 April 2016) *A computer could soon tell you when you're going to DIE: Scientists are developing a test to accurately predict your death*, available at <http://www.mailonsunday.co.uk/sciencetech/article-3519033/A-computer-soon-tell-going-DIE-Scientists-developing-test-accurately-predict-death.html>.

- Working Party member Ross Anderson spoke about the report in the Oxford Internet Institute Bellwether Lecture: '[Big conflicts: the ethics and economics of privacy in a world of Big Data](#)' on 27 February 2015
- Working Party members Susan Wallace and Paul Matthews presented the report at the [UK-Korea Future Health Forum](#) on 16 March 2015
- Working party member Jane Kaye spoke about the report at the Royal Society policy lab panel discussion '[Consumer data: what's in store for you?](#)' on 15 April 2015
- Working party member Jane Kaye and Assistant Director Peter Mills spoke about the report in a workshop on the '[Ethics of Biomedical Big Data](#)' at the Oxford Internet Institute on 27 April
- Assistant Director Peter Mills spoke about the report in a [webinar on Big Data ethics](#) held by the Pistoia Alliance on 21 May 2015
- Working party members Susan Wallace and Paul Matthews spoke about the report at the [Cheltenham Science Festival](#) on 6 June 2015
- Working Party Chair Martin Richards presented the report during the [HeLEX Conference 2015: 'Translation in Healthcare'](#) on 23-25 June 2015
- Assistant Director Peter Mills presented at a meeting of the AstraZeneca Bioethics Advisory Group on 8 July 2015
- Working Party member Ross Anderson presented at the [Information Security for the Public Sector Annual Conference](#) in Stockholm, Sweden on 1-2 September 2015
- Research Officer Bettina Schmietow presented at the [Amsterdam Privacy Conference](#), 23-26 October 2015
- Assistant Director Peter Mills presented during a [panel session](#) on precision medicine and bioethics organised by the UK Science and Innovation Network at the AAAS Annual Meeting in Washington DC, 13 February 2016¹⁴

Policy developments

Department of Health and the National Information Board

The Council hosted two meetings with attendees from the Department of Health and National Information Board in 2015, the first on 19 June¹⁵ to explore ways of building sustainable public trust in the responsible use of health data; and the second on 14 December to discuss the National Data Guardian Review on data security and consent.

The meetings were chaired by Jonathan Montgomery, and attendees included Dame Fiona Caldicott, National Data Guardian and Chair of the Independent Information Governance Oversight Panel and senior representatives from the Department of

¹⁴ A transcript of Peter Mills' talk is available at <http://nuffieldbioethics.org/blog/2016/for-whom-the-bell-tolls-precision-medicine-private/>.

¹⁵ Nuffield Council on Bioethics (2015) *Symposium on building sustainable public trust in the responsible use of health and care data*, available at http://nuffieldbioethics.org/wp-content/uploads/NCoB_Roundtable-on-trust-note_FINAL_22-Sept-15.pdf.

Health, HSCIC, Involve, Monitor, MedConfidential, Expert Advisory Group on Data Access, the Academy of Medical Research Charities, and British Medical Association.

The National Information Board has published a roadmap for their *Workstream 4: build and sustain public trust*¹⁶ which highlights the Council's report as one of recent studies which "provide valuable insight into the questions around the use of data", and sets out the roundtable meeting on 19 June 2015 as a key step in its priority to "get public dialogue right".

National Data Guardian

In September 2015, Dame Fiona Caldicott set out her priorities as National Data Guardian for Health and Social Care, recognising the Council's conclusion on the essential role of public dialogue before engaging in major projects to gather and share data. In her statement, she said:

"As the Nuffield Council for Bioethics made clear in a report published this year, 'The collection, linking and use of data in biomedical research and health care: ethical issues', there is an essential requirement to engage in such a dialogue, before embarking on major projects to gather and share data."¹⁷

The Council responded¹⁸ to a consultation on the roles and functions of the National Data Guardian for health and social care in December 2015, which highlighted the following key points:

- The Council welcomes, in the establishment in law of the role of the National Data Guardian, the recognition that an opportunity for missing or underrepresented voices in the governance of data is needed. Though the National Data Guardian (NDG) cannot be expected to represent 'the voice of the public' they should have sufficient powers and resources to broaden participation and provide the opportunity for a wider range of interests to be represented.
- The powers of the NDG should include the initiation of criminal proceedings for the deliberate misuse of data. The Government should legislate to create an offence of deliberate misuse of data whether or not it results in demonstrable harm to individuals.

¹⁶ National Information Board (2015) Work stream 4 roadmap: Build and sustain public trust, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/465068/Work_Stream_4_Final.pdf.

¹⁷ National Data Guardian and Dame Fiona Caldicott (2015) *Building trust in the use of data across health and social care*, available at <https://www.gov.uk/government/speeches/national-data-building-trust-across-health-and-social-care>.

¹⁸ Nuffield Council on Bioethics (2015) *Response from the Nuffield Council on Bioethics to the Department of Health Consultation on the roles and functions of the National Data Guardian for Health and Care*, available at <http://nuffieldbioethics.org/wp-content/uploads/Response-to-Consultation-on-the-Role-of-the-National-Data-Guardian.pdf>.

- The NDG should help to ensure that the frameworks and procedures of data governance are in accordance with a publicly statable set of morally reasonable expectations, which take account of the underlying norms of privacy and disclosure at stake, the appropriate level of freedom for individuals to make choices about data use that concerns them and the duties of professionals to safeguard privacy while promoting the public interest.

In July 2016 Dame Fiona published a Review of Data Security, Consent and Opt-Outs.¹⁹ The review makes a number of recommendations to the Department of Health, and to Government bodies, including proposals for new data security standards for the NHS and social care, a method for testing compliance against the standards, and a new opt-out consent model.

In line with the Council's own recommendation, the review recommends that the Government should consider introducing stronger sanctions to protect anonymised data, including criminal penalties for deliberate and negligent re-identification of individuals.

House of Commons Science and Technology Committee inquiry

The Council submitted written evidence²⁰ to the House of Commons Science and Technology Select Committee inquiry on big data, and was invited to give oral evidence to the Committee on 17 November 2015. Jonathan Montgomery gave evidence on behalf of Council, which is cited several times in the final report of the Committee which was published on 12 February 2016. The report echoes the Council's recommendation to criminalise serious misuse of data, and suggests that the Government should establish an independent 'Council of Data Science Ethics' as a means of addressing the growing legal and ethical challenges associated with balancing privacy, anonymisation, security and public benefit.²¹ This is consistent with the Council's recommendation that there is a need for independent deliberation resulting in published advice about how data should be used in major data initiatives.

Statement on EU Data Protection Regulation

The Council issued a statement on 24 June 2015 on the issue of broad consent for the use of data in scientific research in the EU's Data Protection Regulation, highlighting that "In well-governed research, with low risks to individual privacy, 'broad' consent, which envisages data being used for a defined range of possible

¹⁹ National Data Guardian for Health and Care (2016) Review of Data Security, Consent and Opt-Outs https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF

²⁰ Nuffield Council on Bioethics (2015) *Response to the Science and Technology Select Committee (Commons) inquiry: The big data dilemma*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Big-Data-dilemma-Nuffield-Council-on-Bioethics-September-2015.pdf>.

²¹ In the government response to 'The big data dilemma' Report published on 26 April (available at: <http://www.publications.parliament.uk/pa/cm201516/cmselect/cmsctech/992/992.pdf>), the Government agrees to set up a 'Council of Data Science Ethics'. The government is developing an ethical framework for government data science, details of which will be published in the next few months.

research purposes, can be perfectly adequate and, in such cases, should not be regarded as an inferior form of consent compared to more narrowly specified forms.” However, as outlined in the report, no particular type of consent is either necessary or sufficient to protect the privacy interests of those involved; consent therefore can only ever be part of appropriate ethics and governance of any data initiative.

International organisations

The Council has contributed to calls for input on guidelines such as the World Medical Association draft Declaration on Ethical Considerations regarding Databases and Biobanks,²² the Global Alliance consent policy,²³ and the CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects.²⁴

Responses to and progress on recommendations of the report

- The secretariat has been in conversations with the BMA to follow up its recommendation for the introduction of criminal penalties for the deliberate misuse of data whether or not it results in demonstrable harm to individuals.
- Assistant Director Peter Mills advised on ethics and governance for the establishment of a Cabinet Office data ethics framework.
- Assistant Director Peter Mills advised on two [citizens' juries](#) on data access and control held at the University of Manchester.

Literature

The report has been the subject of or highlighted in a number of publications since its launch. This section of the report summarises the contents of some of those citations.

Publications by the Council

Policy briefing: Ethical challenges for the new Parliament

In July 2015, the Council published the policy briefing *Ethical challenges in bioscience and health policy for the new UK Parliament*²⁵ which set out 5 key challenges, including ‘Use data responsibly to advance science and wellbeing’,

²² Nuffield Council on Bioethics (2015) *Comments on WMA Declaration on Ethical Considerations regarding Health Databases and Biobanks*, available at http://nuffieldbioethics.org/wp-content/uploads/WMA-health-databases-declaration_Nuffield-Council-on-Bioethics-June-2015.pdf.

²³ Nuffield Council on Bioethics (2015) *Global Alliance for Genomics and Health: Consent Policy*, available at http://nuffieldbioethics.org/wp-content/uploads/Global-Alliance-consent-policy_Nuffield-Council-on-Bioethics_-22-May-2015.pdf.

²⁴ Nuffield Council on Bioethics (2016) *Consultation response: Revision of CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects*, available at <http://nuffieldbioethics.org/wp-content/uploads/Nuffield-Council-on-Bioethics-response-to-revision-of-CIOMS-guidelines-March-2016.pdf>.

²⁵ Nuffield Council on Bioethics (2015) *Ethical challenges in bioscience and health policy for the new UK Parliament* <http://nuffieldbioethics.org/wp-content/uploads/ParliamentaryBriefingNCOB2015.pdf>

drawing on the report. The briefing was distributed to all MPs and Peers, relevant government bodies, parliamentary staff and science policy organisations.

Policy briefing: Zika: ethical considerations

In February 2016 the Council published a briefing note on the ethical considerations relevant to the Zika epidemic.²⁶ The note sets out ethical considerations relating to the development of public health policies including interventions to manage outbreaks of infectious disease, including surveillance and data sharing. It draws on previously published work by the Council, including the ethical principles for data sharing set out in the report.

Publications by secretariat staff and Working Party members

Assistant Director Peter Mills has written a chapter for the forthcoming book *Ethics of Biomedical Big Data*, edited by Floridi and Mittelstadt, Springer (forthcoming).

Two blog posts have also been published on the Council's website:

- [For whom the bell tolls: precision medicine, private virtue and the public good](#) by Peter Mills
- [Biological and health data: 8 months on](#) by Bettina Schmietow

Articles that cite the Council's report

The report has been cited in 28 scholarly articles and books, including the following highlights:

Laurie G & Dove, Es (2015) '[Consent and anonymisation: Beware binary constructions](#)' *BMJ*

Brack M, Castillo T (2015) '[Data Sharing for Public Health: Key Lessons from Other Sectors](#)', *Chatham House research paper*

Taylor MJ, (2015) '[Legal bases for disclosing confidential patient information for public health: distinguishing between health protection and health improvement](#)', *Medical Law Review*

Burton PR et al (2015) '[Data Safe Havens in health research and healthcare](#)', *Bioinformatics*

Deetjen U, Meyer ET, Schroeder R (2015) '[Big Data for Advancing Dementia Research: An Evaluation of Data Sharing Practices in Research on Age-related Neurodegenerative Diseases](#)', *OECD Digital Economy Papers*

²⁶ Nuffield Council on Bioethics (2016) *Zika: ethical considerations*, available at <http://nuffieldbioethics.org/wp-content/uploads/NCOB-briefing-note-zika-ethical-considerations.pdf>

Whiteman IA, (2015) ['The decline of medical confidentiality medical information management: The illusion of patient choice'](#), *Clinical Ethics*

Laurie G et al (2015) ['On moving targets and magic bullets: Can the UK lead the way with responsible data linkage for health research?'](#), *International Journal of Medical Informatics*

Gkoulalas-Divanis A, Loukides G (eds) (2015) ['Medical Data Privacy Handbook'](#) Springer

Mittelstadt BD, Floridi L (2016) ['The Ethics of Big Data: Current and Foreseeable Issues in Biomedical Contexts'](#), *Science and Engineering Ethics*

Other media

Imperial College published a podcast with Working Party member Paul Matthews discussing the report's main findings and recommendations to mark the launch of the report.²⁷

Conclusion

The Council will continue to promote the values and approach developed in the report, in particular the introduction of criminal penalties for deliberate misuse of data, when the opportunity arises.

²⁷ Imperial College London (3 February 2015) *Interview with Professor Matthews on a new report on ethics and big data*, available at http://www3.imperial.ac.uk/newsandeventspggrp/imperialcollege/newssummary/news_3-2-2015-11-8-45.