



**NUFFIELD
COUNCIL ON
BIOETHICS**



**ETHICS IN GENOMICS
HEALTHCARE & RESEARCH:
BUILDING CONNECTIONS &
SHARING BEST PRACTICE**



Summary report

Ethics in genomics healthcare and research: building connections and sharing best practice

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Key points

- Clinicians, researchers, patients and policy makers are encountering a variety of ethical issues in genomics healthcare and research.
- The development of a UK best practice approach – or gold standard model – for ethics in genomics healthcare and research could help those working in the field to negotiate ethical issues, promote consistency of approach and, ultimately, create better, more equitable experiences for patients and research participants.
- A best practice approach would need to incorporate different components such as ethical principles, professional guidance, discussion fora, and practical tool kits. The approach should be flexible to allow for interpretation in different contexts and regional variation.
- It is important that any best practice approach is transparent and inclusive, both in how it is produced and developed, and in who has access to it. A joined-up community and high-level buy-in around ethics and genomics will be needed.
- A UK approach to genomics ethics would need to be both sensitive to the international context of genomics and specific to UK audiences. It is not appropriate for the UK to aspire to lead the world in ethics. We should approach this task with humility and be open to diverse views.
- A next step would be to create a comprehensive map of existing resources in order to understand what is already available and identify areas where further work is needed.
- Further consideration is needed on the question of whether some elements of a best practice approach should be a requirement, or whether this is a purely advisory initiative.

Background

In its 2020 [Genome UK strategy](#), the Government committed to establishing a ‘gold standard UK model’ for how to apply strong and consistent ethical standards in genomics research and healthcare. In a 2022 UK-wide [shared commitments plan](#) for the implementation of Genome UK, the four countries of the UK recognised the need for more discussion on how to achieve this in a meaningful way. From March-December 2022, the Nuffield Council on Bioethics (NCOB) helped facilitated those discussions in partnership with the [Office for Life Sciences](#) (OLS) and genomics healthcare leads in Scotland, Wales and Northern Ireland.

The aims were to:

- ✓ Gather and share best practice
- ✓ Build connections between people and organisations in the UK with an interest in the ethical issues raised by genomic healthcare and research
- ✓ Identify the potential features or steps of a ‘gold standard UK model’ for ethics in genomics, as well as the challenges and barriers to applying such a model.

A call for case studies went out in summer 2022 to gather examples of how people in the UK are considering the ethical issues raised by genomics healthcare and research. ‘Genomics’ is an encompassing term covering a wide range of genomic practices focused on the human genome, from genetic sequencing to emerging technologies. A [summary of the 30 submissions](#) received is available. Two workshops were held by Genomics Partnership Wales in October, and two UK-wide workshops were held in London and online in December. Around 40 people took part in the UK-wide workshops, bringing experience of clinical genetics, public health, ethics, public engagement, research, policy and regulation, and personal experience of genetic conditions. This report provides a summary of the case studies and workshop discussions.

What kinds of ethical issues are arising in genomics?

The case studies spanned a range of initiatives that involved genomic testing or screening, or research on the link between genes and health. They included work to design research, clinical services or screening programmes, the development of professional, organisation or national policy, public engagement exercises, professional education and training, and individual patient case studies.

Clinicians, researchers, patients and policy makers are encountering a variety of ethical issues in genomics healthcare and research. These include:

- Weighing the potential **benefits and harms** of genomics initiatives, such as biobanks and research programmes.
- What needs to happen to ensure that patients and participants are able to provide **informed consent** for genomic and genetic testing and screening, and make decisions about this testing in children and people who are not able to give consent themselves.
- Deciding what **findings** should be returned to patients and participants and their families, how to do this and whose responsibility it is.
- Resolving the tension between respecting **data privacy** and facilitating the sharing and use of data for research and diagnosis.
- Addressing **inequalities** in how people experience and benefit from genomics healthcare and research and mitigating the potential for genetic discrimination.

- Understanding and aligning genomics initiatives with **public values**, for example in response to changing societal perceptions of disability and impairment.
- Managing the expectations of participants and patients, and generally **avoiding hype** around genomics.
- Supporting patients and members of the public in the context of a growing **commercial genomic and genetic testing** market.
- Considering the implications of **genomics beyond health**, such as in the fields of education and employment.

To help them and others navigate ethical issues such as these, people involved in genomics healthcare and research in the UK are undertaking activities such as patient and public engagement exercises, multi-disciplinary discussion, empirical research, and professional education.

However, in doing so, they are facing challenges such as a lack of awareness of what ethics can offer and a reluctance on the part of others to think about ethical issues; problems with communication and engagement around ethics; practical challenges relating to funding and resources; and difficulties reaching consensus on findings and conclusions in relation to ethical issues.

The surrounding context

The context within which genomics healthcare and research is taking place has implications for the ethical issues that arise and how they are tackled.

The mainstreaming of genomics in the NHS means there will be an increasing number and range of healthcare professionals who encounter the ethical issues raised by genomics. More patients also will be aware of or be offered genomic testing. There is a need for greater awareness of the implications of this testing across society more generally. Routes to achieving this include education in genomics ethics in schools, public access to trusted sources of information, and embedding the importance of access to genetic counselling in policy.

An increasing number of people are accessing genomics services through the commercial sector, both in the UK and abroad, and there is an expectation that this will have implications for NHS staff and services. There have been calls for regulations and standards in the sector to be strengthened, and a government commitment to do so,¹ although there is currently no timeline on when this will happen.

The many difficult challenges facing the NHS more broadly must also be considered. An ethical approach to genomics will only be possible in a functioning system with an awareness of the place of genomics in patient care more generally.

Would a best practice approach to ethics in genomics be helpful?

There was broad agreement among workshop participants that it would be helpful to have a UK-specific best practice approach – or gold standard model – to ethics in genomics.

¹ Medicines and Healthcare products Regulatory Agency (26 June 2022) *Government response to consultation on the future regulation of medical devices in the United Kingdom. Section 54 – Genetic Testing*. Available at: <https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom/outcome/chapter-9-in-vitro-diagnostic-medical-devices#section-54--genetic-testing>

The purposes of a best practice approach could include:

- Fostering ethical preparedness – a readiness to negotiate the ethical issues that arise.
- Providing guidance and advice on what questions need to be asked and what processes and mechanisms can be used to explore those questions.
- Helping people identify and interpret existing ethical standards and frameworks.
- Building critical ethics skills among clinicians, researchers and others.
- Providing clarity on the purpose of ethical reflection in this area
- Promoting consistency and avoiding duplication of work.
- Setting out expectations for behaviour and what bad practice looks like.
- Building public confidence that ethical standards are being applied.
- Ultimately, creating better, more equitable experiences for patients and participants.

Why genomics?

Many of the ethical principles that are invoked in genomics – such as consent, respect for privacy and equity – are shared across all health care. However, genomics healthcare and research stands out as an area requiring ethical attention due to its scale and position at the centre of UK medical science policy, and the intense ethical issues it raises – although they are not necessarily novel or special. Further work is needed to define the boundaries of genomics healthcare and research, given likely overlaps with issues raised by other technologies, such as neuroscience, data science and AI, and the application of genomics in non-health arenas.

What would a best practice approach look like?

A best practice approach would need to incorporate different components such as:

- An overarching set of ethical principles or charter that can be adapted and flexibly applied in different contexts.
- Fora or networks for discussing issues and sharing experiences.
- Professional guidance on specific topics.
- Practical ethical tools, e.g. questions that should be asked along with possible courses of action, and how-to guides on processes and activities.

However, being ethically prepared requires more than accessing a set of principles or participating in discussion. A behavioural science lens suggests ethical preparedness needs a combination of a) capabilities such as tool kits and guidance, b) opportunities to apply ethical thinking, and c) willingness to work in an ethically prepared way.² To help achieve this, a joined-up community and high-level buy-in around ethics and genomics will be needed.

A best practice approach should not be an onerous imposition on an organisation or create undue barriers. Rather, access to a best practice approach should be helpful, particularly for individuals and teams who do not have large resources.

A best practice approach should promote consideration of ethical issues in context and have practical, real-life application. It should be relevant to both present day and future developments in genomics.

² Samuel G, Ballard LM, Carley H and Lucassen AM (2022) [Ethical preparedness in health research and care: the role of behavioural approaches](#). *BMC Medical Ethics* 23:115.

There can be no prescriptive, one-size-fits-all approach to ethics in genomics. Attitudes and approaches will change over time and there is likely to be regional and international variation in how people approach ethics. It will need to be informed by continued dialogue between those involved to maintain relevance and evolve in the context of wider change.

There are differing views on whether it should be a requirement to adopt some elements of a best practice approach, with sanctions for not doing so, or whether the initiative should be purely advisory. Making it a requirement would give it 'teeth' but would also create a regulatory burden. An advisory approach might result in low uptake. The answer could be a combination of the two, combined with strong leadership and a concerted communications strategy. Further consideration is needed on this question.

How should we go about developing a best practice approach?

It would be helpful to create a comprehensive map of existing guidelines, legal frameworks, resources, committees, networks and discussion fora, in order to understand what is already available to people in the UK and identify areas where further work or co-ordination is needed. We should also consider past initiatives and those that offer a model or learning for this one.

It is important that any best practice approach is transparent and inclusive, both in how it is produced and developed, and in who has access to it. Perspectives from the wide range of communities and cultures we have across the UK should be included.

When developing a best practice approach, we need to be in conversation with other countries and be aware and learn from what they are doing.

The approach will need to be future proofed and regularly checked, updated and reviewed.

The work could be undertaken using a co-production approach, or by establishing a coalition of organisations. However, there will be a need for an organisation to take ongoing responsibility for the development and maintenance of the best practice approach, and to convene the relevant organisations and people. The lead or co-ordinating organisation should be independent of government and industry, have credibility and be able to take on a long-term commitment.

Who would use a best practice approach?

A best practice approach would be available to everyone involved with genomics healthcare and research, including clinicians, researchers, research and clinical ethics committees, professional bodies, industry, regulators, policy makers, charities, and individual patients, families and research participants.

The mainstreaming of genomics in the NHS means the range and number of healthcare professionals who encounter ethical issues will only increase in future. The existence of a best practice approach could build greater connections between stakeholders, create a sense of community, and highlight the relevance of ethics to all those involved.

A UK-wide approach to ethics could help foster discussions about equitable access to genomic and genetic testing across the UK, taking account of differences between the four nations.

It is not appropriate for the UK to aspire to lead the world in ethics. We should share our work with other countries, but we should approach this with humility and be open to diverse views.

What are the challenges?

Ensuring proper representation of different people and communities and giving different views due consideration in the discussions is likely to be challenging, as is gaining consensus on best practice and standards across the genomics ecosystem.

There is a need to bring in international perspectives given the relevance to UK initiatives of cross-border research collaboration, rules on data sharing, and the availability of commercial genetics services in other countries. A UK approach to genomics ethics will need to be both sensitive to the international context and specific to UK audiences.

Setting up and co-ordinating a best practice approach to genomics ethics will need to be properly resourced.

Next steps

Suggested next steps include:

1. Create a comprehensive map of existing resources in order to understand what is already available and identify areas where further work is needed.
2. Building on this, identify or create an organisation to bring together and disseminate the components of a UK-wide best practice approach to ethics in genomics, with the recommendations of the workshop participants in mind.

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