

Possible future work topics

The following topics have been suggested as possible project areas for further investigation by the Council. These topic summaries do not aim for comprehensiveness; rather, they are intended to signpost some of the key considerations and to provide a starting point for discussion. Each summary includes links to relevant publications on the topic.

This list is regularly updated as topics are selected and/or revised following discussions among members of the Future Work Sub-Group and the Council. This list was updated in November 2016.

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Animals and research

There is a global push to reduce the number of animals used in biomedical research. Recent scientific developments have made this increasingly possible and yet also increasingly challenging.

Are there recent scientific, legal or social developments?

The [Russell and Burch](#) principles of the 3Rs (replacement, reduction and refinement) are now widely recognised as providing a framework for minimising suffering in animal laboratory research. In 2010 the EU adopted a [directive](#) based on the 3Rs which lays down minimum standards and regulates the use of animals in research. The [NC3Rs](#) is the UK's national organisation which leads on the 3Rs. Scientists continue to make [progress](#) in reconstructing tissues and making organ models or '*organoids*' such as the [lung-on-a-chip](#) which can be used to test substances for therapeutic and toxic effects. Advances in neural-imaging and computer modelling of the brain have brought [people](#) to question whether experiments involving primates in particular, have become obsolete. The Dutch Government has passed a motion in parliament to phase out experiments on non-human primates and has set the goal to be using only human-relevant, non-animal testing methods by 2025.

And yet developments in the sphere of genetics are leading to a contradictory drive to increase animal use in research. Countries such as China and Japan are [investing heavily](#) in research in monkeys and exploiting new genetic-engineering techniques. [The EU-COST action SALAAM](#) (Sharing Advances on Large Animal Models) runs from 2014-2018 and aims to share advances in genetic engineering and phenotyping of non-rodent mammals to develop predictive animal models for translational medicine.

Are there complex ethical issues?

The Council's 2005 [report](#) highlights the difficult ethical questions related to the limits of what research on animals should be allowed, and the morally relevant characteristics of different animal species. There has been an increasing recognition of the challenges in implementing the 3Rs and [questions](#) about their continued applicability. There has also been a [call](#) to look beyond the 3Rs to consider issues such as the need for more comprehensive [reporting](#) and improved experimental design. Harm-benefit analysis in animal research can be morally complex, especially if the translational value of research is not always immediately clear.

Recent gene expression profiling [studies](#) have increased our understanding of the differences between mouse and human models and have brought into question the usefulness of many mouse models for studying human disease. Mice often display very different phenotypes or show different responses to drugs compared with humans. Thus to ensure efficient translational medicine, this may mean that larger or higher-order animals are required. Advances in genome editing are likely to lead to [an expansion](#) of the numbers of animals and the variety of species that can be used in biomedical research. In particular the use of genome-edited primates to mimic neurological and behavioural disorders such as [autism](#), raises questions as to the acceptability of manipulating non-human primates given their advanced cognitive capacity and potential for suffering. Organoids offer great potential to reduce the use of animal models and, in combination with gene-editing techniques, can make very accurate [human models](#) of disease. Yet [some](#) have cautioned against researchers rushing to use organoids until they have been properly validated, and argue that they will never fully replace animal models. Diseases that involve multiple organ systems for example could not be modelled by organoids. Another potential issue is the type of tissue being created; growing human brain models or human gonads for example may raise particular ethical concerns.

Is there a potential policy impact?

There are likely to be changes to both UK and EU policy in this area in the near future and hence the Council may be able to offer a balanced consideration of the ethical issues involved which could influence public policy and legislation. A [Universal Declaration on Animal Welfare](#) has been proposed to the United Nations and policy such as this may be needed to create global pressure to enforce animal welfare.

Is it a subject of public concern?

Many people are concerned about animal rights. A 2015 campaign from the [Stop Vivisection](#) group gathered 1.1 million signatures in a bid to persuade the European Commission to ban experiments on animals and to make it compulsory to use human-relevant data instead. [Opinion polls](#) show public support for in vivo research to be dependent on there being evidence of tangible benefit, a lack of alternatives and the use of humane techniques.

Is the consideration timely?

An EU directive is due for review in 2017 and a [symposium](#) is planned for December 2016 to discuss whether the current animal use practices can be reduced and improved. The [World Congress on Alternatives and Animal Use in the Life Sciences](#) takes place every 3 years and the next conference will be held in August 2017.

Can the Council offer a distinctive contribution?

The Council may be able to offer an update to the 2005 report [The ethics of research involving animals](#) report. An [interdisciplinary interactive workshop](#) held in 2016 highlighted how work in the humanities and social sciences can help understand the social, economic and cultural processes that enhance or impede humane ways of working with laboratory animals. The Council would similarly be in a position to bring together experts from a myriad of disciplines to examine the issue of animal research in light of recent developments.

Artificial wombs (ectogenesis)

Partial ectogenesis (PE) would involve the use of an artificial womb (or aspects of a womb, such as an artificial endometrium and placenta) for part of the reproductive process, and could also be used to further human embryo research. This may lead in the future to full ectogenesis (FE) which would involve the entire reproductive process (from fertilisation to birth) occurring outside of the female human body in an artificial womb.

Are there recent scientific, legal or social developments?

The focus of research is now twofold: firstly extending the length of time embryos can be kept alive prior to implantation in the mother, with a [recent study](#) achieving 13 days; and secondly being able to keep extremely premature babies (< 22 weeks) alive, using an artificial womb. Both of these areas would contribute to PE (and potentially FE), although the former is mainly being developed for human embryo research, and the latter is at the stage of research in animals, such as a [study](#) that kept premature lambs alive with an artificial placenta for one week.

Are there complex ethical issues?

There may be a concern that research into and the use of PE for both embryo research and assisted reproduction is an unjustifiable use of limited resources, as infertility is not a life-threatening or primary concern. There are other options for infertile individuals, such as adoption, which arguably have more social benefits. However, [some](#) claim that there is a fundamental desire for your own genetic children, which society may have a duty to help citizens fulfil. If fully developed and available, PE may be regarded as safer and better, as an artificial womb is a controlled environment. Questions concerning whether all women should use PE, or whether certain 'higher risk' women (e.g. those who would drink and take drugs during pregnancy) should be compelled to use PE will arise, as well as the idea of fetal rights, and the best interest of the child. This may also lead to 'natural' pregnancy and birth being considered as risky and stigmatised (for further discussion on concept of 'naturalness, see the Council's [recent project](#).) On the other hand, the mother's bodily autonomy is important, and PE may affect the mother-child bond that is thought to begin in the womb, although the bonds that fathers and adoptive parents build with their children downplays the strength of this point. PE may also further gender equality and reproductive autonomy, as it provides women with another option. However, using a medical solution to tackle a social issue raises its own questions. PE is also relevant to the abortion debate, as it potentially enables both a pregnant woman's right to choose abortion and the fetus' right to life to be satisfied, by providing an alternative womb for the fetus to develop in, making the fetus 'viable' earlier. Questions concerning whether this creates a duty to use PE, or whether a pregnant woman also has as a right the death of the fetus have been [raised](#). FE generates further issues. The cited benefits include: enabling people who currently cannot have children to have children without needing a surrogate; eradicating the risk of pregnancy for women and minimising the risk for the fetus; removing women as the sole bearers of the risks and burdens of pregnancy, and potentially achieving gender equality. However, FE brings new possibilities for controlling reproduction. Some may be beneficial, enabling us to ensure that the fetus is in the best possible environment for it to develop. Others may be more ethically complex, such as the ability to control which fetuses are eligible for FE, and which people can become parents. The likely high cost of FE will also raise issues of equal accessibility.

Is there a potential policy impact?

As research into PE advances, policy makers need to (re)consider regulations and guidelines pertaining to research, in particular, the acceptability of testing artificial wombs on human premature babies, and the potential extension of the 14 day rule (the topic of a [current council project](#)) for human embryo research. The implications of FE will also need to be considered. If/when artificial wombs are available for clinical use, specific legislation, regulation and guidelines detailing when, who and in what circumstances they can be used (especially as growing organs for transplant in humans may be possible at that time), and who is responsible for the fetus will be required. The impact on existing policy, such as that regarding abortion, and the legal understanding of parenthood or motherhood, also need to be considered.

Is it a subject of public concern?

It appears that the public is not widely aware of either PE or FE as a real possibility, although there are some articles available from specialist media outlets such as the [Genetic Literacy Project](#), and it has been addressed in a 2015 [Guardian article](#). Reproduction, infertility and abortion are however topics of public concern, as is the possibility of keeping younger premature babies alive, and the existence of technology that has the potential to vastly change our biological and social lives.

Is consideration timely?

Scientific research in the field is advancing, and it has been [suggested](#) that some new technology (in particular artificial placentas) may be ready for clinical use within five years, highlighting the need to initiate discussions soon to enable legislation and regulation to be in place.

Can the Council offer a distinctive contribution?

The Council could offer a platform to initiate discussions with policy makers and medical professionals, regarding the unique ethical issues surrounding clinical use of PE and FE, and how this relates to current regulation, such as abortion laws.

Autism

Recent research into the genetics of autism has raised speculative questions about the prospect of prenatal testing for the condition and the development of preventative interventions and treatments in the future. This research also has wider implications for our perception of behavioural disorders in general.

Are there recent scientific, legal or social developments?

There has been a dramatic increase in the number of children diagnosed with autism in recent years which is thought to be principally as a result of heightened awareness and new diagnostic criteria. Only a small number of cases of autism can be attributed to a medical condition or single gene defect. However, there is increasing [evidence](#) that 'idiopathic autism' is in fact heritable and due to the interactions between multiple genes, with environmental and epigenetic factors accounting for the variable phenotypes seen. It is hoped that discovery of these susceptibility genes may lead to new treatment targets and potential screening tests. The [Autism Genome Project](#) was established in 2004 and is currently planning a third phase of activities. Another approach to testing for autism has been to look for [biomarker patterns](#). Other studies have identified neuroinflammation and autoimmune disorders as potential causative factors. In 2013, scientists reported a [trial](#) using deep brain stimulation (DBS) to alleviate symptoms in a boy with severe autism, which showed promising results.

Are there complex ethical issues?

Some have raised concerns that these developments represent the increasing pathologisation of behaviours and question the permissibility of neurological treatments that aim to normalise individuals with these conditions. Advocates of the neurodiversity movement argue that autism is just a particular type of cognitive style, rather than a disorder to be treated, and that part of the problem stems from society's inability to respond to the needs of people with autism. Supporters of this view are worried that increased genetic testing and intervention will further stigmatise those with the condition, and that resources will be directed towards the eradication of the disorder, rather than on improving the lives of those living with autism. [Some](#) have argued that research with the aim to 'cure' autism may be undesirable, especially to adult individuals who may consider autism to be an important part of their identity. [Concerns](#) have also been expressed that if an inherited mutation is found to be the cause of autism in a particular family this may lead to parental guilt or stigmatisation within families. Since autism is a multifactorial condition a genetic diagnosis will simply convey a susceptibility; if children who test positive never go on to develop the condition they may be [unnecessarily stigmatised](#) and thus have their 'right to an open future' compromised. Whilst there is an argument that early diagnosis can mobilise early intervention and improve outcomes for children with autism, a genetic diagnosis of autism [may actually reduce the availability](#) of services for patients in low and middle income countries. However, others stress that autism exists as a spectrum, and that for some it can have a profound effect on their quality-of-life. For these individuals and their families, genetic research could result in significant improvements in diagnosis and treatment. It may also provide important information for families who want to know how likely it is that their other children will be affected. Finally, the ethical considerations of conducting research into autism, particularly [research directly involving children](#) with the condition, should not be overlooked. In particular there is [an argument](#) that 'neurotypical' parents may not be the best placed to consent for their autistic children to participate in research.

Is there a potential policy impact?

If a genetic test for autism were to become clinically feasible, regulators would need to decide whether such a test should be made available, and if so, the criteria for eligibility. In making this decision, policy makers will need to take account of the wider implications that permitting genetic testing for autism would have on our conceptualisation of behavioural disorders.

Is it a subject of public concern?

The sharp increase in the number of children diagnosed with autism and the controversy surrounding the proposed link between the condition and the MMR vaccine has resulted in autism being a subject of significant public concern. This is perhaps reflected in the [Autism Act 2009](#), the first condition-specific legislation of its type in England, which places a duty on the Secretary of State for Health to introduce a strategy for meeting the needs of adults with autism.

Is consideration timely?

Although there are no conclusive biological tests for autism currently available, it has been [speculated](#) that they could happen within five years, thus making the argument for an early ethical debate about their implications.

Can the Council offer a distinctive contribution?

The Progress Educational Trust is currently running a [project](#) on autism supported by the Wellcome Trust, which is focussing on the interplay between genetics and psychology, and the public's understanding of spectrum disorders. An alternative approach for the Council could be to look at the wider issue of behavioural disorders and the implications of new genetic research and cure-directed therapies on a number of conditions (e.g. autism, ADHD and addiction). It will be important that there is input from individuals and families directly affected by these conditions. There is likely to be some overlap with the Council's previous work on [novel neurotechnologies](#) and the current work on [non-invasive prenatal testing](#) and [genome editing](#).

Biotechnology and globalisation

Biotechnology refers to any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products and processes for specific uses, for example in the fields of agriculture, pharmacology and bioengineering. The interplay between the phenomenon of globalisation and the biotechnology industry raises significant ethical and policy issues.

Are there recent scientific, legal or social developments?

The costs of international transportation and communication are declining, and there is a progressive dismantling of barriers to trade and capital mobility. These make possible the outsourcing and relocating of research and development, and foreign investment in national biotechnology concerns.

There are many examples of biotechnology stakeholders collaborating on a global scale. [The European Federation of Biotechnology](#) and [Global Biotech Revolution](#) for example, are two non-profit organisations aiming to connect biotech think-tanks, industrial leaders, researchers and young bio-leaders to ensure the life sciences are used in a safe, sustainable and beneficial way and to grow a 'global bio-economy' through collaborative ventures. In October 2016 the European Commission published a report recommending immediate action on the creation of a [European Open Science Cloud](#) to allow researchers and science and technology professionals to store, share and re-use their data across disciplines and borders.

Are there complex ethical issues?

There is a recognised positive moral value in developing biotechnologies to avoid or alleviate harms, and to increase human welfare and well-being. Biotechnologies offer the possibility of providing solutions to some of the key dilemmas that have emerged out of globalisation such as how to address food security (e.g. with genetically engineered food crops) and energy security (e.g. with biofuels). As highlighted by the Council's report on [emerging biotechnologies](#), decisions that shape or constrain the development of biotechnologies have to take into account key values in public ethics such as those of equity, solidarity and sustainability. Concerns have been raised that the benefits and opportunities of globalisation have been largely limited to a relatively small number of wealthier countries, whilst the costs have largely been borne by developing and poorer countries. Market incentives are also such that biotechnology developments tend to address disorders of most concern among rich populations and [neglect conditions](#) that affect the poor in developing countries. Using populations in less economically developed countries as sources of inexpensive labour and as clinically naive patient populations raises important questions surrounding both consent and exploitation. The sustainability of biotechnologies will require avoiding significant or irreversible depletion of non-renewable natural resources or damage to ecosystems or the environment. This may be even harder to guarantee in a globalised marketplace. Not all advances in biotechnology are fed from the developed to the developing world however and there are easily accessible, rapidly advancing biotechnologies in the developing world with international customers (e.g. reproductive tourism).

Is there a potential policy impact?

At the [UN Millennium Summit](#) in 2002, ensuring that globalisation becomes a positive force for all was declared a central challenge. A potential focus for policy impact in this area is in respect to the global responsibilities of corporations developing new biotechnologies, such as encouraging private companies to incorporate an ethical approach to their activities. For example, the [UN Global Compact](#) is a voluntary initiative that seeks to promote responsible corporate citizenship so that businesses help to respond to the challenges of globalisation. Some question how effective these voluntary ethical codes can be, and whether more regulatory control is needed.

Is it a subject of public concern?

There have been important political developments which could be seen as a [backlash against globalisation](#) and the increased flows of goods and workers across borders. It was a factor in the British vote to leave the EU, the rise of anti-establishment political parties across Europe (Podemos in Spain, the Five Star movement in Italy and more) and in Donald Trump's criticism of American trade agreements in the US election campaign. Some members of the public also have [concerns](#) that the fruits of global economic growth are not fairly shared with less developed countries.

Is consideration timely?

The 2016 US presidential election has been at the centre of a [rising tide of disquiet](#) against free trade and globalisation. The [2016 European and Global Biotech week](#) took place in September and included a record number of countries working across 4 continents.

Can the Council offer a distinctive contribution?

This is a huge topic involving an array of issues related to globalisation and economics, and so any contribution by the Council would need to be carefully focussed. One possible avenue of work could be a follow-up activity linked to the [emerging biotechnologies](#) report, with a focus on the global responsibilities of biotechnology corporations.

Building genomes from scratch

Small viral and bacterial genomes synthesised from scratch have demonstrated the feasibility of creating synthetic genomes and it may soon be possible to synthesise an entire human genome de novo. This differs from the recoded genomes that have been made possible by genome editing tools such as CRISPR/Cas9 and could allow more widespread manipulation of genetic material.

Are there recent scientific, legal or social developments?

In 2002 scientists [described](#) the de novo synthesis of infectious poliovirus using a synthetic genome built from scratch. This was followed in 2010 by the successful [construction](#) of the first self-replicating, synthetic bacterial cell. The cell was produced using a bacterial genome constructed from smaller DNA subunits which was then transplanted into the empty cytoplasm of a related bacterium.

In May 2016 an invitation-only meeting of over 100 scientists, entrepreneurs, lawyers and ethicists took place at Harvard University to discuss [Human Genome project - Write](#) (HGP-write), which was formally unveiled on 2 June 2016. The project describes its primary goal as being to reduce the costs of engineering, or writing, human and other large genomes in cell lines more than 1,000-fold within ten years.

Are there complex ethical issues?

The development of this technology offers the potential for wide-reaching benefits to human health. Potential applications include engineering 'ultrasafe' human cell lines which could be used to secrete proteins used in medical treatments but which would be resistant to viruses. Other possibilities include engineering therapeutic cell lines which have been manipulated to ensure cancer resistance, or eventually growing transplantable human organs. The theoretical end-point of such technology, however, would be the possibility of engineering cells to create so-called 'designer' humans with no genetic parents, and this inevitably raises considerable ethical dilemmas. Concerns have been raised about the unknown environmental and health impacts of genetically altered organisms. A further concern is related to unwanted commercialisation of the products that emerge from the research as well as the direct financial interests of some of the founding members of the HGP-write project. The technology could lead to the creation or release of organisms that could be used as biological weapons with fears that the research may ultimately pose threats to public health and safety that might outweigh the benefits.

From a philosophical standpoint there may be deeper implications of the reductionist approach to the origin and meaning of life which is implicit in the science of building human genomes from scratch. [Some have warned](#) of the danger that the identification and synthesis of minimal genomes will be presented by scientists, depicted in the press, or perceived by the public as proving that life is reducible to, or nothing more, than DNA. If we extend the reductionism implicit in minimal genome research to a definition of human life, this has repercussions for the ethical debates about stem cells/early embryos and abortion. Creating new living organisms from scratch could ultimately change how we frame our ideas of what life is.

Is there a potential policy impact?

The broad scope and potential applications of this technology will call for the development of appropriate regulatory policies. The HGP-write project itself has called for scientific communities to set standards within the context of national and international laws and to develop regulations in the model of existing stem cell research guidelines. As the technology of building genomes advances there will be a need for a new regulatory framework to govern the intellectual property associated with these genes and the resultant new organisms in order to ensure that public and commercial interests are protected.

Is it a subject of public concern?

Whilst the public may not currently be widely aware about recent progress in synthesising genomes, the birth of Dolly the sheep in 1997 and the ensuing tsunami of media attention and public concern highlights society's deeply rooted fears about the consequences of humanity's ability to manipulate biology. [Press attention](#) for the HGP-write project has highlighted concerns that it might be possible, such as through cloning, to use a synthetic genome to create human beings without biological parents. In particular, the secretive nature of the initial scientific meetings has sparked some [public criticism](#).

Is the consideration timely?

In June the HGP-write project expressed their goal to launch in 2016. [Some critics have warned](#) that the HGP-write team has not properly justified its aims, and that the project should be abandoned until there is an adequate public debate with participation from a broad range of people.

Can the Council offer a distinctive contribution?

This topic follows on from many of the issues raised by the [genome editing](#) project. The Council may be able to act as an independent body that is able to bring together the views of scientists, policymakers and the public in order to make a critical appraisal of the HGP-write project and to put down a marker about the need for a responsible and ethical approach to building human genomes from scratch.

Chimeras

A chimera is a single organism with a genetic composition from genetically different zygotes but in which the DNA is never mixed on a chromosomal or intracellular level.* Research using animal models containing human cells is not a new phenomenon; for example chimeric animal models with human cells in the brain have been used to study neurological diseases such as Alzheimer's and Parkinson's, and human tumour cells are routinely grown in mice to study cancer processes. However, newer forms of stem-cell-based chimera research, which may involve the use of embryos, has raised special concern about the possibility of a human cell contribution to multiple organs and tissues in animals and hence increased human/non-human mixing.

Are there recent scientific, legal or social developments?

There have been multiple recent examples of advances in chimera research including [sheep](#) growing partially human livers and [mice](#) with human brain cells that have advanced their learning. In 2013 scientists published [work](#) attempting to grow an entirely human pancreas through creation of chimeric pigs.

In May 2008, the House of Commons debated a proposal to ban the creation of human-animal chimera or hybrid embryos for research and came to the decision that they would be permitted, given that they would be destroyed within 14 days. In August 2016 the National Institutes of Health (NIH) in the US [proposed](#) changes to their policies on chimeric embryos to expand some of the prohibitions, whilst relaxing others. It also set up a [steering committee](#) to look at early embryo research and research where human cells could give rise to a substantial contribution or functional modification to the animal brain.

Are there complex ethical issues?

There are substantial arguments for pursuing research into chimeras given potential benefits which might include curing chronic diseases such as Type 1 diabetes or addressing the shortfall in availability of organs for transplantation. There are currently uncertainties about the effects of human cells on off-target organs and tissues in the chimeric animals, particularly in the nervous system. If the effects of this technology are to include changes in cognition, behaviour or physical appearance of the animal this could raise concern that our manipulation of animals has gone too far. Some worry that in the process of biologically humanising a research animal, scientists may also end up 'morally humanising' the resulting chimera, particularly if there is chimerism of the central nervous system. [Others](#) have argued that these concerns are overstated; that the appearance of a human-like self-consciousness is highly unlikely and that the presence of human neural matter in a non-human brain is in fact much more likely to create animal suffering and acute biological dysfunction. Questions about how basic animal rights and animal welfare are protected during such research will be important. Animal rights groups have been opposed to chimera research [stating](#) that it contributes to the 'debasement of animals' whilst others have expressed [concern](#) that creating animal-human chimera diminishes the very dignity of being human. Complex ethical issues arise when considering the use of early embryo research involving chimeras, particularly human chimera embryos in which human embryos have animal cells added to them during early development. Many people feel that human embryos have a special status which requires that we give them specific legal protection, over and above that given to animal embryos. A fusion of the two, whichever form that may take, will require fresh consideration.

Is there a potential policy impact?

Regulation of human embryo research is governed by the HFEA in the UK and that of animal embryos by the Home Office. As these technologies advance it is likely that both bodies will be required to update and clarify existing regulation. The [current regulation in the UK](#) is not particularly prescriptive but rather sets up authorities to regulate activities.

Is it a subject of public concern?

The media has expressed [outcry](#) at the prospect of a 'humanzee' and the resulting ethical minefield we would be faced with. Comments posted on the NIH website reveal the extent of public concern with many parties accusing scientists of 'playing God' or conducting 'Frankenstein science'. The HFEA designed a public [consultation](#) in 2007 to explore public opinion on hybrid and chimera research and found that the public was finely divided with people generally opposed to such research unless it was tightly regulated and was likely to lead to scientific or medical advancements.

Is the consideration timely?

Given the recent significant progress internationally in chimera research the timing seems appropriate.

Can the Council offer a distinctive contribution?

The Council's current [genome editing](#) project proposes to include consideration of xenotransplantation, but there may be larger ethical issues raised by chimeras which may warrant separate consideration. The modification of the nervous system of animals would be a particularly interesting topic to explore, where the Council may be able to provide a unique insight which could influence public policy and regulation.

*This is in contrast to a hybrid, which involves crossing two gametes to create a zygote and in which each cell from the hybrid animal contains genetic material from both parent species.

Citizen science

Citizen science is the term given to research that involves amateurs or non-professionals. These projects vary from contributory and collaborative ventures that typically involve the public collecting and processing data for researchers to projects entirely devised by individuals or communities and directed towards personal or local priorities.

Are there recent scientific, legal or social developments?

Citizen science remains prominent in environmental science, and is increasingly being used in medical and biological research. Patient-led data sharing platforms continue to be popular, for example the data sharing platform [patientslikeme](#) has a network of over 400,000 people. Technology is being developed to aid citizen science in this area: Apple's [ResearchKit](#) app, launched in 2015, is a platform for researchers to design and administer app-based studies; Google is reportedly designing a [contact lens](#) that measures glucose levels in tears; and the [#BritainBreathing](#) app which aims to track allergy sufferers in the UK was launched in March 2016.

Are there complex ethical issues?

Some view citizen science as a way to promote public engagement with science, and to empower individuals and communities to steer priority setting in research. These projects can also potentially increase productivity and diversity as well as being cost-effective. However, citizen science also raises a number of challenges, particularly in the context of medical or health research. One potential issue concerns how the risk-benefit analysis of a proposed study should be conducted and who should be responsible for this, especially when [homemade technology](#) is being used. Participant-researchers could be allowed to assess the risk themselves, emphasising respect for individual autonomy. However, there may be limits to how much risk individuals should be allowed to expose themselves to, especially if there is a possibility that their risk assessments are distorted because of their involvement, or if they could be subjected to coercion and peer pressure by keen fellow participant-researchers. Relatedly, there is the question of how to ensure that participants have given their informed consent, or whether the doctrine of consent is even appropriate in the context of participant-led research. Additionally, there is a potential conflict between the aims of researchers, and of the patients/public taking part, which may lead to issues surrounding transparency and to questions about the appropriate way to recruit participants and acknowledge or remunerate their contribution. There are also a number of issues surrounding the ownership, sharing, security and privacy of the data collected and stored online, particularly when it is personal health data.

Is there a potential policy impact?

Policymakers need to determine whether current research ethics regulation is applicable, and what unique measures citizen science (in its various forms) requires. Key questions include how to manage and ensure the security of the data collected, how to ensure regulatory oversight, and who should be responsible for this. Any research governance framework would need to strike a balance between protecting potential participant-researchers and empowering individuals who wish to pursue this research.

Is it a subject of public concern?

The citizen science web portal, [Zooniverse](#), operated by the [Citizen Science Alliance](#) (CSA) has reportedly over 1 million registered volunteers. In the UK awareness of citizen science projects as a way to influence change has increased, e.g. [Network for Clean Air](#). Researchers are encouraged to recruit the public as citizen scientists, and organisations such as the British Science Association (BSA) [encourage participation](#), which means that the public need to be aware of the ethical issues involved, their rights and responsibilities.

Is consideration timely?

In 2016 the first [European Citizen Science Association Conference](#) was held. Funding via Horizon 2020 has been announced for projects such as '[Doing it Together Science](#)' which is led by the Extreme Citizen Science ([ExCiteS](#)) project at UCL. The European [SPARKS](#) awareness raising project (2015-2018) is promoting citizens active involvement via exhibitions such as '[Beyond the Lab](#)' at the London Science Museum in summer 2016. The proposed UK [care.data](#) programme which aimed to collect patient data from across healthcare settings was halted in July 2016 after public concern and [recommendations](#) regarding health data security and consent models, but a related [project](#) by the National Information Board is going ahead.

Can the Council offer a distinctive contribution?

The scope of ethical issues relating to citizen science is recognised by organisations such as the European Citizen Science Association ([ECSA](#)) and the [CSA](#) in the US. The UK Environmental Observation Framework (UKEOF) continues to commission and produce [reports and guides](#) relating to environmental citizen science. The Council could contribute by reporting and advising on the unique ethical issues relating to the forms of citizen science being utilised in medical research - such as the contributing of personal health data, and the use of new, or homemade technology - potentially leading to a code of ethics or best-practice guide.

The human/technology frontier in health and social care

The frontier between humans and technology has become increasingly blurred; in some instances, we are seeing a merger of human biology and technology into one, in others technology has come to replace traditionally human roles. The transhumanist belief is that the human race itself can evolve beyond its current physical and mental limitations with the help of science and technology.

Are there recent scientific, legal or social developments?

There has been a recent influx of medical technologies capable of detecting, managing and preventing health problems. These vary in complexity from mobile phone apps to complex networks of sensors capable of monitoring physiological parameters and behaviours. Medication adherence has been tackled by technology which reminds people to take their medicine and telemedicine allows patients the chance to meet with a doctor remotely and relay information back to them from home diagnostic devices (for example: [MedWand](#), [Tyto](#)). Robotic technology has been used to deliver targeted radiation treatments and to assist surgeons with minimally invasive procedures such as prostatic surgery. The future generation of robots may be capable of [performing surgical procedures independently](#) or [performing antenatal screening scans](#) on pregnant women. In February 2015, an EU-funded project, [MARIO](#), was launched to address the challenges of dementia with the use of service robots. Nanotechnologies offer many potential uses in medicine including use of nanoparticles for personalised medicine delivery, nano-devices to monitor health from inside a patient or nano-robots to perform intra-cellular surgery. A significant amount of research is also being conducted on machine learning with potential applications in medical diagnostics and treatment decision-making.

Are there complex ethical issues?

A central question in this area concerns trust, and whether healthcare professionals and patients would accept the use of some of these technologies. Basic safety questions need to be answered to alleviate fears around toxicity, carcinogenicity or the unpredictable or uncontrollable behaviour of devices. Some of these technologies may threaten patient autonomy if devices are programmed to prompt users to make healthier life choices, to control their adherence to medications or to monitor their behaviours in a 'big-brother' fashion. This could result in a loss of self-determination or a sense of reduced responsibility for one's own health. Although potentially allowing more people to remain independent in their own homes, concerns have also been raised that these technologies might lead to the social isolation of vulnerable members of society, and the loss of collective responsibility to care for others. Nano-technologies offer the possibility of human 'enhancement' which might raise pertinent ethical questions. The prohibitive cost of some of these advanced technologies risks creating social and economic divide and exacerbating existing health-care disparities if care is not taken to ensure that they are implemented in a way which allows all patients to benefit. There are arguably some fundamentally human qualities which are important in medical counselling and the precious subtleties of the 'human' doctor/patient relationship may be unduly threatened by technological advancements which encroach into human roles. As highlighted in a [report](#) by the Council, the use of novel technologies which intervene in the function of the brain raise distinctive ethical and social concerns given the unique role of the brain in providing our autonomous agency, and in shaping our conceptions of ourselves and our relationships with others.

Is there a potential policy impact?

There are a number of questions for policy makers to address in this area, including the issue of liability if something goes wrong, and the impact on the current workforce. A significant issue pertains to the privacy of the information collected and how it could be used, meaning that data protection policies will be vital. For example, some companies have initiated corporate wellness programmes where employees are rewarded for making healthier lifestyle choices. Lastly, there is the need for guidance regarding responsible research and innovation.

Is it a subject of public concern?

[Studies](#) from public engagement workshops in the US and the UK looking at emerging nanotechnologies found that energy applications were seen in a substantially more positive light than applications in health and human enhancement. The very personal and human experience of health and social care is close to the hearts of many individuals and the public has shown emotive responses to technologies which impact on their personal autonomy.

Is consideration timely?

In 2015 the European Commission published its report of a [public consultation](#) on Mobile Health outlining the concerns and suggestions of key stakeholders. We are likely to see a dramatic rise in the use of robots and nanotechnologies in medicine in the immediate future.

Can the Council offer a distinctive contribution?

The Science and Technology Committee undertook an [inquiry into robotics and artificial intelligence](#) published in October 2016. The Council's report on [Medical profiling and online medicine](#) has already addressed telemedicine but the Council may be able to focus on new issues and offer a distinctive contribution by drawing in public opinion and acting as a platform for public education. A project looking specifically at nanomedicine would be one possibility or the Council could consider a broader project on robotics as a whole which could include a focus on robotics within health and social care.

The human/technology frontier in the wider context

The blurring of the boundary between humans and technology has far reaching consequences throughout different areas of society.

Are there recent scientific, legal or social developments?

There have been recent [claims](#) that the rise of robots could lead to unemployment rates greater than 50 per cent within 30 years. Virtual reality and augmented reality technology has become increasingly affordable and accessible to the general population and the recent popularity of Pokemon Go attests to the public interest. Major car manufacturers have predicted the appearance of fully autonomous cars on the road by 2021. Technological advance within the military world such as combat drones have revolutionised how war is conducted. The United Nations has held a [meeting](#) of experts on lethal autonomous weapons systems (LAWS) every year for the last 3 years to address the potential challenges and threats arising from the development of such technology.

Are there complex ethical issues?

If as a society we are conditioned to see online reality as less 'real' then there is a concern that the moral code for use of virtual reality and augmented reality may be similarly relaxed. If technology allows human acts to be detached from humanity then there is danger that people will not feel the weight of their actions. The use of drone warfare, for example, enables troops to deploy deadly weapons while safely remaining thousands of miles away from the battle frontline. If [LAWS](#) were allowed to be developed they could select and engage targets without any human intervention. Autonomous systems require guidance as to how to behave in ethically challenging situations. If an autonomous car, for example, swerves to avoid a child but risks hitting someone else. More than a simple set of rules for how to behave, autonomous systems also require rules allowing them to anticipate the possible effects of their own [actions](#). There may be further concerns about creating path dependency in automated systems such that 'normal' ways of thinking become embedded which may be exclusionary to large minorities or which miss new solutions.

Advances in artificial intelligence (AI) in the future could raise a number of fundamental questions about our notions of intelligence and consciousness, and even the very question of what it means to be human. 'Technological singularity' is the hypothesis that the invention of artificial superintelligence will ultimately trigger runaway technological growth resulting in a moment when some computers are smarter than humans. Some have questioned whether this could mean the end of the human race. The Machine Intelligence Research Institute has suggested the need to build '[friendly AI](#)' whereby the advances occurring with AI should include an effort to make AI intrinsically friendly and humane.

Is there a potential policy impact?

The best-known set of guidelines for robo-ethics are the "[three laws of robotics](#)" coined by Isaac Asimov, a science-fiction writer, in 1942. In 2010 experts at the joint EPSRC and AHRC developed the five ethical [rules](#) for robotics. In June 2016 Satya Nadella, CEO of Microsoft, roughly sketched a set of [rules](#) for artificial intelligence to be observed by designers. There is a need, however, for further guidance regarding responsible research and innovation within AI, robotics and autonomous systems. The impact of non-human technologies on the human workforce will be a matter for consideration in wider social policy.

Is it a subject of public concern?

There has been substantial media coverage of the idea of robots replacing the human workforce and impacting on unemployment as well as considerable media interest in autonomous vehicles.

Is the consideration timely?

Technologies have reached a point such that the deployment of LAWS may be practically feasible within the next few years. The EPSRC UK Robotics and Autonomous Systems Network (UK-RAS Network) was established in March 2015 and the first UK Robotics Week was held in 2016 with a similar programme planned for 2017. The EPSRC has also been working this year on human-like computing and the challenges faced by researchers. At the 2012 [Singularity Summit](#) a study of AI predictions found a wide range of predicted dates for singularity to occur, with a median date of 2040.

Can the Council offer a distinctive contribution?

The UN has taken on the issue of international development of LAWS. The House of Lords Science and Technology Committee is to conduct an [inquiry](#) into future uses of autonomous vehicles in the UK and the House of Commons Science and Technology Committee [recently recommended](#) establishing a standing Commission on AI. The Council may be able to offer a particular contribution looking at the ethical rules online and specifically within the spheres of virtual reality or augmented reality. Of particular interest, might be how the younger generation come to engage morally with the ever-expanding virtual world. Another possible contribution might involve a specific focus on robotics, looking at the ethical hurdles to ensuring robots and humans come to co-exist safely and productively. A consultation with the public would be valuable in exploring acceptable decision-making principles that could be included in autonomous systems.

***In-vitro* derived gametes and embryos**

New reproductive technologies allowing the creation of rudimentary embryos and the possibility of generating gametes *in-vitro* have the potential to overhaul how we conceptualise reproduction and parenthood.

Are there recent scientific, legal or social developments?

Creating *in-vitro* or 'artificial gametes' refers to the idea of making germ cells from embryonic stem cells or induced pluripotent stem cells. [Researchers](#) have been able to derive haploid mouse spermatid-like cells by stepwise differentiation of embryonic stem cells and these male gametes have gone on to produce viable and fertile offspring. In a recent breakthrough [published](#) in October 2016 scientists in Japan were able to create *in-vitro* mouse oocytes and have been able to use these eggs to produce fertile pups. The technique has been partway successful with human cells and in 2015 [scientists](#) from the UK and Israel reported creating artificial primordial germ cells (which are precursors to gametes) from embryonic stem cells and induced pluripotent stem cells. Recent studies have shown that under the right conditions [mouse](#) and [human](#) pluripotent stem cells can form structures that have some resemblance to embryos during gastrulation, which is a critical point in development shortly after implantation during which the primary germ layers are formed. These structures have been called 'gastruloids' and although they do not currently resemble the human post-implantation embryo, they may one day, thus creating 'embryos in a dish', without the need for distinct gametes.

Are there complex ethical issues?

Such technology could potentially allow for a vast widening of reproductive choices and a redefinition of concepts of infertility. In principle the process could be used to derive egg cells from a man's body and maybe even sperm cells from a woman's body making reproduction for same-sex couples possible. In this way new genetic connections which were not previously possible may become a reality, providing same-sex couples with reproductive options that do not rely on donor material. On the other hand, there is the possibility of a de-geneticisation of human reproduction in which the genetic link between father, mother and offspring may no longer exist: for example, if a child is created with genetic material from just one person. Although donor conception and surrogacy already separate out the genetic link to a parent from the idea of parental responsibility, they both still fundamentally involve two distinct genetic origins. With this new technology the level of interference with so-called 'natural' reproduction is likely to invoke strong intuitive reactions perhaps because we attach some particular importance to a new human identity being derived from a traditionally human process. The impact on any children born as a result of this technology is also a subject of concern.

One broader ethical question might be whether there is a meaningful distinction between treating infertility as opposed to enhancing fertility. Some uses of these technologies would be to treat fertility pathologies, whereas others would extend fertility to those who would not ordinarily have it. Many existing reproductive treatments do not necessarily treat disease-related problems however. Even if these technologies would not be funded by public health systems there may be the potential for use in the private sector which would still require a regulatory response. Whilst still in the research stage, there may be concerns around appropriate informed consent for donors of biological material for research.

Many of the ethical questions surrounding artificial gametes are brought out in the Council's commissioned [background paper](#) by Dr Anna Smajdor.

Is there a potential policy impact?

If these technologies continue to advance, there will be a need for regulatory decision as to whether to permit their use for human reproduction. There may be a question as to whether the HFEA has the moral authority to license the use of *in-vitro* derived gametes for treatment, given that when the HFEA was created this technology was not envisioned. Another issue will be how parenthood is defined and ascribed. The regulatory status of gastruloids, including whether they should be subject to the 14-day rule, is currently unclear due to varying definitions of what constitutes a human embryo, and will need further attention.

Is it a subject of public concern?

Previous public [consultations](#) have shown that the overall attitudes towards fertility treatments are largely positive but with many people concerned about unknown consequences. In a similar vein to the public outcry surrounding cloning, creating new life using such techniques is bound to attract significant public interest, and likely opposition.

Is consideration timely?

Members of the [HFEA's](#) Scientific and Clinical Advances Advisory Committee thought in 2008 that the timescale for deriving artificial gametes for treatment was between 5-10 years.

Can the Council offer a distinctive contribution?

Artificial gametes were already addressed in the [February 2016 Forward Look](#) meeting and some of this topic is likely to overlap with the upcoming [workshop looking at the 14-day rule](#). The Council may be able to offer a project alongside work on the 14-day rule which could investigate a number of ethical issues that would need to be addressed in a more consistent regulatory framework that could accommodate *in-vitro* derived gametes and gastruloids.

Innovative therapies

An innovative therapy (IT) is a newly introduced or modified therapy with unproven effects. Unlike research, which follows a predetermined course of action set out in a protocol, experimental or innovative therapy involves a more speculative approach to the patient's care and may be adapted to the individual's response. However, such innovations may blur the distinction between treatment and research. Innovative medicines (unlicensed or 'off-label' use) are used quite commonly, but there are issues to be explored and addressed concerning other innovative treatments and the recording and sharing of IT results (both positive and negative).

Are there recent scientific, legal or social developments?

The use of ITs has emerged as an important and difficult issue in recent Council reports, such as on [children and clinical research](#) and [novel neurotechnologies](#). The recent Ebola outbreak also led to discussion surrounding the acceptability of giving experimental drugs or vaccines to sufferers of the disease outside the confines of a traditional research trial. In March 2016 the UK government passed the [Access to Medical Treatments \(Innovation\) Act 2016](#) (ATMTI Act 2016) which 'aims to promote access to innovative medical treatments' by establishing a database of ITs used in the UK, and the results of those treatments.

Are there complex ethical issues?

The use of ITs raises a number of ethical issues because the border between research and treatment is less clearly defined. Physicians involved in IT will need to be aware of the potential conflict that might arise between the goal of furthering medical knowledge and ensuring the welfare of the individual patient, and the potential for this conflict to undermine trust in the doctor-patient relationship. Patients may feel objectified if doctors view their condition as a subject for experimentation or for professional development via publication. Other patients may view the ability to participate in experimental therapies in a positive light if they see the treatment as their only chance of getting better. However, the ability to give informed consent in this context may be compromised by the emotional pressures of suffering from an incurable and potentially life-threatening condition. Furthermore, implicit trust in the medical profession and in the efficacy of modern medicine may cause both patients and doctors to overlook or downplay the risks inherent in a procedure. There is the question of whether clinicians involved in IT should have a duty to record and share any insight gained regarding the benefits or negative outcomes of the intervention, and if so, how this could best be achieved. This information might be of use to enable other patients to benefit from the same treatments or to avoid suffering the same adverse effects, as well as to guide potential future research strategies. However, this may further blur the distinction between what is considered treatment and what is considered research. There may also be concerns regarding equal access to IT. Patients that are well-informed and confident may request ITs which may also put pressure on health care professionals to offer them.

Is there a potential policy impact?

Unlike research, IT is aimed primarily at treating particular individuals, and so any proposed regulation would ideally need to maintain sufficient flexibility to allow for variations in individual circumstances. The biggest challenge for policy makers may be in defining exactly what constitutes treatment and what constitutes research, and how to regulate the spectrum of interventions that may fall under the umbrella term of IT. There are clear policies in law, and [government](#) and NHS guidelines concerning the use of unlicensed and 'off-label' medicines for either 'compassionate use' or on a 'named-patient' basis. There is however a lack of clear policy or governance on other ITs (such as innovative surgery). The ATMTI Act 2016 does begin to address the issues of recording the results of ITs. It has yet to be implemented, so there is still scope to influence the way that the database is set up and used, and to question whether existing models used for research governance, such as research ethics committees, are appropriate in this context and whether an international database is also needed.

Is it a subject of public concern?

ITs are often used in the context of a life-threatening condition when all other treatments have failed, and so is likely to be of significant concern for the public. The ATMTI Act 2016 (and the prior version of the Bill) have received numerous criticisms from the public and medical professionals (including the [Medical Research Council](#)), and so the implementation and any amendments of it will be of public concern.

Is consideration timely?

As well as the ATMTI Act 2016, there is also an ongoing government [Accelerated Access Review](#) (AAR) which aims to "speed up access to innovative drugs, devices and diagnostics for NHS patients" which includes the [Early Access to Medicine Scheme](#) (EAMS) which was independently [reviewed](#) this year.

Can the Council offer a distinctive contribution?

There is an opportunity for the Council to contribute in this area by conducting an in-depth analysis of the complex ethical issues involved and providing much needed guidance for both policy-makers and physicians.

Nagoya protocol

The [Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity](#) (Nagoya Protocol), which was adopted in 2010 and entered into force on 12 October 2014, is a supplementary agreement to the Convention on Biological Diversity (CBD). It provides a legal framework that governs access to non-human genetic resources and traditional knowledge.

Are there recent scientific, legal or social developments?

The Nagoya Protocol was brought into EU law by the adoption of [Regulation EU No 511/2014](#) on 16 April 2014, although some of the key provisions only became applicable on 12 October 2015. In the UK, this EU regulation has been implemented by the [Nagoya Protocol \(Compliance\) Regulations 2015](#). In particular, the Nagoya Protocol details information that must be included in the prior informed consent given by the provider country, and a general obligation to establish a benefit sharing agreement between the provider and user.

Are there complex ethical issues?

One of the fundamental elements underpinning the Protocol is the equitable sharing of benefits. In practice, the majority of the agreements are expected to be signed between biodiversity-rich, and often developing, countries, and users from more advanced countries. Access and benefit sharing for the utilisation of genetic resources has been a controversial issue in the past, and it was felt that the CBD did not offer sufficient legal clarity to protect the rights of states and indigenous communities over their local resources. Companies and scientists sometimes developed and patented commercial products based on genetic resources, resulting in accusations of biopiracy. The Nagoya Protocol aims to combat this by ensuring that developing states benefit from the use of their genetic resources by foreign institutions. A question that could be explored is whether the protocol succeeds in these aims, and whether there are further issues concerning respect for autonomy, the recognition of human rights, and justice for indigenous peoples and citizens of developing countries that cannot be addressed through legislation, and might be better addressed by education and codes of ethics and best practice. Additionally some institutions, including the [Wellcome Trust](#), have raised concerns about the potential negative impact on international research efforts (e.g. monitoring of drug resistance and responding to disease outbreaks), which rely on open and comprehensive databases that source information from many countries. The concern is that the requirements contained within the protocol will restrict the efficient sharing of information, or that research institutions might migrate to countries that have not ratified the Protocol, such as the USA or China.

Is there a potential policy impact?

DEFRA's [Consultation on implementing the Nagoya Protocol](#) (CINP) highlighted the need for clarification on a number of aspects of the EU Regulation and UK implementation. These included, what constitutes due diligence (which users must exercise when ascertaining whether a genetic resource has been accessed in accordance with regulatory requirements), whether the Protocol applies to derived materials (e.g. DNA sequences), and how to collaborate with organisations from countries that are not signatories. The government response detailed in the CINP does clarify some issues and there is minimal guidance on the [ABS: compliance and guidance](#) webpage with links to the CBD's [Access and Benefit-Sharing Clearing-House](#), and the EU's [Commission Implementing Regulation](#) for Article 5 on the register of collections, Article 7 on making declarations of due diligence, and Article 8 on best practices. DEFRA and the National Measurement and Regulation Office (NMRO) have responsibility for producing guidance relating to the UK implementation and raising awareness of the protocol and its implementation.

Is it a subject of public concern?

It would appear that the existence of the Nagoya Protocol has remained largely outside of the public's awareness thus far. However, the ability of the international community to prevent and respond to potential epidemics or pandemics is likely to be a subject of significant public concern.

Is consideration timely?

The UK government will conduct a review within five years to address any concerns that arise from the implementation of the EU Regulation. In addition, the EU Regulation requires Member States to provide a report on its application by 11 June 2017, and so a review of some type is likely to be carried out before this date.

Can the Council offer a distinctive contribution?

The Nagoya Protocol is essentially a legal development, albeit one with important implications for future biological and medical research. However, it may be that the Council can offer a neutral perspective on some of the raised concerns, or provide a platform for involved parties to debate the potential impact of this Protocol on research. In addition, this topic might provide the opportunity to explore some of the ethical challenges that were highlighted in the previous background paper on [pandemics](#) and the global response to disease outbreaks.

Predicting phenotype from genotype

It is increasingly possible to predict an organism's [phenotype](#) (observable physical properties including behaviour), or aspects of an organism's phenotype, by studying their [genotype](#) (complete set of genes). The focus here is on using this technique in humans.

Are there recent scientific, legal or social developments?

[Genetic ancestry](#) testing has been around for a number of years and involves looking at either the Y chromosome, mitochondrial DNA or single nucleotide polymorphisms (SNPs) genome to estimate a person's ethnic background in a way that can be broken down into percentages e.g. 50% African, 50% European. A newer [technology](#), DNA phenotyping uses a DNA sample to predict physical traits of the individual and build up a physical likeness of them. Researchers are building databases using information from volunteers to look for connections between facial shape and patterns of SNPs to enable them to then 'reverse engineer' a face from a DNA sample. Genome-wide association studies (GWAS) look for associations between SNPs and certain phenotypic traits across the whole genome. As well as looking at [physical traits](#) such as freckles or hair morphology these studies can look at [particular diseases](#) and offer a promising way to study complex, common diseases (such as diabetes or Parkinson's) in which many genetic variations contribute to a person's risk. Furthermore, forensic DNA phenotyping may eventually be able to make probabilistic predications about mental or behavioural traits.

There have been many [recent developments](#) in genetics, genomics and molecular biology which are likely to make human forensic case work more reliable in the near future. The UK Border Agency (UKBA) ran the [Human Provenance Pilot \(HPP\) Project](#) between Feb 2009 and March 2010 which aimed to investigate whether ethnicity testing might be applicable to the work of the UKBA, in particular in cases where it was suspected that asylum seekers were lying about their country of origin. The project was discontinued following a review.

Are there complex ethical issues?

Such technologies offer huge potential to help solve crimes and protect individuals, to better understand health and disease or to help identify missing persons or disaster victims. However there are concerns that we might come to falsely rely upon their conclusions. Much of the accuracy of this technology depends on the quantity and quality of the databases being used for comparison. This raises the question of whether and how more samples should be attained, and how to ensure representative data across populations. Ensuring that people who volunteer their genetic and phenotypic information to such databases are able to give truly informed consent may be difficult, especially as the research possibilities continue to expand exponentially. The need for large datasets also needs to be balanced with concerns about the security of the data being stored, and questions of privacy. There are risks associated with having an unbalanced number of samples from one sub-group of the population. The council's report on [bioinformation](#) cautions that inferring ethnic identity from biological samples risks reinforcing racist views. Data generated by DNA phenotyping tests are merely predictions and indicators of probability for phenotypic traits. This raises the concern that the results will be misconstrued, or taken/presented as more definite than they are, with the specific worry of them being used to justify the targeting of specific racial groups.

There is a key ethical distinction between testing known and unknown samples. If law enforcement agencies perform intrusive tests on unknown samples, and these ultimately become known individuals, then there are issues of consent, privacy and autonomy to consider. These individuals are unable to consent to the use of their DNA and previously unknown or concealed traits may be discovered, such as whether a person has had plastic surgery or has changed genders, or they may reveal unexpected information relevant to the individual's health.

Is there a potential policy impact?

Further regulation will be required to determine how these new technologies should be applied within human forensics or immigration services.

Is it a subject of public concern?

There was widespread criticism of the HPP project from the [Human Genetics Commission](#) and the [wider public](#). This included concern about the accuracy and validity of the scientific techniques involved (which fail to determine which political borders a person has come from) as well as issues of consent and the use of a vulnerable test group. Issues concerning the control of immigration are particularly prominent within the public psyche at this time, especially in the wake of Brexit.

Is the consideration timely?

In April 2010 The Crime and Security Act introduced several changes to the law, namely that DNA profiles of non-convicted individuals can only be kept for a maximum of six years (three years for under 18s) and DNA profiles of volunteers should no longer be added to the database.

Can the Council offer a distinctive contribution?

There is likely to be a fair amount of overlap with the [bioinformation](#) report as well as other Council reports such as [genome editing](#), [emerging biotechnologies](#), [genetics and human behaviour](#), [medical profiling and online medicine](#), and [genetic screening](#). The Council may, however, be able to offer a freshly updated contribution on the issues in forensics, in the light of the more recent technological developments.

Social egg freezing

Egg freezing is a relatively new medical procedure that involves extracting and subsequently freezing and storing eggs for (potential) later use in assisted reproduction. The American Society for Reproductive Medicine removed its [experimental](#) label in 2013 and recommended it for use in response to medical premature infertility. It is now also increasingly available to healthy women who wish to bear children later and 'insure' against natural fertility loss with age – dubbed 'social egg freezing' (SEF).

Are there recent scientific, legal or social developments?

New vitrification techniques for freezing eggs are [reported](#) to reduce the risks and increase rates of survival, fertilisation and pregnancy. The Office for National Statistics (ONS) [reports](#) that the average age for first time mothers is increasing. Apple and Facebook announced in 2014 that they would offer SEF [as a 'benefit'](#) for female employees in the US. The ethical debate has re-ignited, gaining a significant amount of media attention.

Are there complex ethical issues?

An overarching debate concerns whether and how society should address natural fertility decline and involuntary childlessness. Should the solution be medical, or focus on social change, [education](#) and promotion of earlier child-bearing? The apparent consensus in the academic debate is in favour of SEF. The debate mainly focuses on whether SEF promotes or hinders reproductive autonomy and gender equality in light of current social pressures on women to e.g. both have careers and bear children, and on the potential risks to both the (potential) mother and future child (which are difficult to assess due to a lack of relevant data). Further ethical issues arise due to the availability of SEF. It is expensive, leading to concerns over equality of access. Some clinics offer '[freeze and share](#)' programmes that reduce costs if patients donate some of their eggs for treatment or research purposes. However, the emotional and psychological impact of oocyte donation may be downplayed in such programmes, and the desire for SEF capitalised on inappropriately. SEF might be a candidate for public funding like IVF. Arguably, they both address infertility; however, one notable difference is that SEF is used in anticipation rather than in response to infertility.. There is a perceived negative attitude towards women who pursue SEF for career-related reasons, whereas there is more sympathy towards those who simply have not found a partner yet. The relevance of the reasons for pursuing SEF could be considered, and the impact of these attitudes on women and their choices explored. There is a concern that [marketing](#) and SEF employment 'benefits' will lead SEF to be viewed as an 'insurance policy', inappropriately encouraging or even pressuring women to pursue it and delay pregnancy, and potentially affecting their ability to make an informed decision and give informed consent as well as raising questions about providers and employers' responsibilities. A further issue relates to the lack of data on SEF and the health of future children. Do clinics have a duty to record data on SEF? Who has the responsibility to record data on the long-term health of children born from frozen eggs? Should women pursuing SEF (and their future children) be able to opt-out of studies?

Is there a potential policy impact?

The [Human Fertilisation and Embryology Act 2008](#) regulates egg freezing, and there are HFEA [guidelines](#) for all clinical processes. However, there are no specific regulations or guidelines for SEF. There are mixed messages concerning the acceptability and safety of SEF from other organisations which leads to a lack of clarity for the public. The HFEA have been [criticised](#) for not regulating the information provided (relating to the effect of age on success rates), or the costs charged by private clinics. Policy makers need to consider whether specific legislation or guidelines are required for SEF concerning age limits (max and min), marketing practices, informed consent procedures, storage time-limits (currently 10 years without medical reasons) and subsidisation.

Is it a subject of public concern?

There is a continuing trend of women getting pregnant later in life, as highlighted by the ONS report. This fact combined with a natural decline in fertility with age leads to a significant number of people suffering from infertility problems, which makes the issues of infertility, and its possible prevention, a matter of public concern.

Is the consideration timely?

The recent [HFEA report](#) includes 2014 data on egg freezing (medical and social) for the first time. It reports a 25% increase in the number of women seeking the treatment between 2013 and 2014. The 2016 [Timeless](#) project, a joint venture between the LSE, the Wellcome Trust, and Liminal Spaces, aims to educate and encourage debate about SEF and fertility. The Progress Educational Trust ran an [event](#) on SEF in June 2016. Media articles appear regularly highlighting [new developments](#) such as a brand new clinic in the US dedicated solely to egg freezing – a new model that could potentially be brought to the UK.

Can the Council offer a distinctive contribution?

The [European Society of Human Reproduction and Embryology](#) published a comprehensive [report](#) in 2016 which includes a detailed summary of the ethical issues. The Council could add to this, exploring the issues further, engaging members of the public, providing a platform for anyone with an interest to debate the issues, and providing guidance to policy makers on which areas may require legislation and guidance.

Sports science

Whilst sports science is a broad discipline, the central issue identified here concerns the use of performance enhancing techniques (PETs) in sport. It can also involve the study of the impact of sport on health.

Are there recent scientific, legal or social developments?

The World Anti-Doping Agency (WADA) published a new [World Anti-Doping Code](#) in 2015, and continues to update its [prohibited list](#). Gene [doping](#), which is the process of altering an athlete's genetic makeup by injecting DNA, is also receiving attention. It is unclear whether or how widely it is in use, but it is on the WADA prohibited list, and the International Olympic Committee (IOC) will reportedly use a new [test](#) to retroactively check samples from the Rio 2016 Olympics for one type of gene doping.

Are there complex ethical issues?

It is unclear what counts as 'unacceptable' enhancement. What is the difference between intense training to enhance your performance, and the use of the latest (permitted) technology, compared to the use of PETs? There is also an apparent lack of consistency in what PETs are prohibited. Understanding why doping is deemed to be 'wrong' may be helpful, but it is also unclear: it might, for example, be argued that PETs are unsafe (for example, because they are not subject to 'standard' drug trial protocols). Yet safety is a reason in itself to regulate enhancements, and there are other things that are arguably equally as risky that we allow – such as the participation in high contact sports. Another answer might be that enhancements are 'unnatural'. Being unnatural however does not immediately indicate that something is wrong or bad (neither does being natural indicate that something is right or good – see discussion in Council's recent project on [naturalness](#)). Perhaps it is because PETs bring an unfair advantage to those who use them. But what about the people who have a natural genetic advantage: in what way is that a level playing field? A further answer might appeal to the 'spirit of sport', which is a difficult concept to define. [Suggestions](#) appeal to the particularly human nature of sport, and the fact that there is a particular skill or strength involved. Defining what is human is difficult, especially when there is a continuous strive to be better. Locating the relevant skill or strength may also be difficult, especially if benchmarks can be moved. This difficulty leads [some](#) to argue that there is nothing inherently wrong with PETs, and that PETs should be legalised, but with safety informing regulation. Other issues include the acceptability of retroactive testing, and liability. Should athletes alone take responsibility for doping, or should the medical professional or coach also be (partly) liable? This links with concerns about the role of medical professionals in sports, and the conflict they face between basic medical ethical guidelines and sports environments, identified in the Council's 2014 [Background Paper](#).

Is there a potential policy impact?

Policy makers need to consider the appropriate response to PETs. There are two contrasting options (as well as the middle ground currently held): PETs could be legalised, and regulated according to different measures (e.g. safety); or could be [criminalised](#), as previously considered. Either option would require changes at an international level, as the UK Anti-Doping (UKAD) body has to adopt WADA's World Anti-Doping Code. This could be timely as a recent Special National Anti-Doping Organizations (NADO) [summit](#) called for an overhaul of WADA. UKAD already has an educational prevention programme which might be furthered, especially considering the cost effectiveness compared to developing and implementing anti-doping testing. The role and responsibilities of medical professionals, particularly in relation to PETs, might also be considered.

Is it a subject of public concern?

There is considerable public interest in sport, and concern about doping, evidenced by the [wealth of stories](#) in the media. Spectators are portrayed as being 'betrayed' by doping athletes, and there is a concern that young athletes and amateurs will be encouraged to use PETs, e.g. through sports supplements, something that is being monitored by the [MHRA](#).

Is the consideration timely?

The Rio 2016 Olympic and Paralympic Games have brought a number of doping scandals to light. An independent [report](#) conducted for WADA exposed state-sponsored doping programmes in Russia, leading to a number of athletes being [banned](#) and controversy over the handling of the case. Since September 2016 athletes' confidential data on Therapeutic Use Exemptions (TUEs) held by WADA has been [released](#) by hackers, calling into question the potential abuse of TUEs and the security of such data. The government has also recently conducted a [consultation](#) on the duty of care sport has towards participants.

Can the Council offer a distinctive contribution?

There have been little neutral ethical analyses of the issues surrounding PETs, and so the Council is in a unique position to contribute to the debate. It can offer a platform to research the underlying ethical questions relating to the moral status of enhancements in sport from a neutral perspective. This would form a starting point for (re)considering the more specific questions such as, which enhancements should be banned and how they should be regulated.

Suppressing the extra chromosome in Down's syndrome

Research on the silencing of the extra copy of chromosome 21 has led to speculations that a chromosomal therapy for Down's syndrome could be developed in the future.

Are there recent scientific, legal or social developments?

In July 2013, a team of scientists from the University of Massachusetts Medical School published [research](#) detailing a method of silencing the third copy of chromosome 21. Using genome editing techniques the team were able to insert a XIST transgene into chromosome 21 which induced chromosome-wide transcriptional silencing of one copy of chromosome 21 in an *in-vitro* model. This was announced as a first major step towards 'chromosome therapy' for Down's syndrome. The therapy may not block all gene expression in the extra chromosome however. Scientists have also identified signalling pathways as [possible therapeutic targets](#) in mice models of Down syndrome and shown improvements in cognitive function.

Are there complex ethical issues?

Poor health is not inevitable in people with Down's syndrome and most children will now go to a mainstream school. [Studies](#) have shown that people with Down's syndrome are happy with their lives and like who they are. Life expectancy for those with Down's syndrome has also increased substantially and is now around 60 years in the developed world. However, individuals with Down's syndrome are at increased risk of developing a number of health conditions (such as congenital heart disease, duodenal atresia and early-onset Alzheimer's disease) and will all have some degree of learning disability.

Some argue that a chromosomal therapy could benefit individuals with Down's syndrome, and that if such treatments are available, then people have a right to access them. Particularly in areas of the world where people with Down's syndrome are more likely to experience discrimination, or where socio-economic resources are less, it may be very important to enable individuals to lead more independent lives. Yet there has also been criticism of the focus on 'curing' Down's syndrome, rather than aiming to facilitate and support individuals with the condition in their daily lives. [Some](#) view disability as an important aspect of an individual's identity, and are concerned that the idea of a cure further perpetuates the notion that a life with Down's syndrome is less valuable, leading to increased stigma and discrimination towards those living with the condition. Many people hold the view that Down's syndrome is associated with particular facets of personality (such as being more open, caring and humorous) and that people with Down's syndrome have much to contribute to society. Some go as far as to dispute whether Down's syndrome is in fact a disease at all. This also raises wider questions about how society benefits from diversity and the opportunities for compassion and solidarity to which it may give rise.

Is there a potential policy impact?

There will need to be further regulation of genome editing techniques as they become increasingly available in the future as well as widespread public consultation as to whether therapies to 'cure' Down's syndrome or other chromosomal disorders are in the interests of society. Policy makers may also need to review whether limited funding resources should be directed towards such research or not.

Is it a subject of public concern?

About 775 babies are born with Down's syndrome each year in the UK, and all pregnant women are routinely offered prenatal screening for Down's syndrome. Currently up to 90% of women who are diagnosed with a baby with Down's syndrome during pregnancy will choose to terminate. A recent BBC2 documentary entitled '[A World without Down's Syndrome?](#)' questioned the impact of non-invasive prenatal testing (NIPT) on the number of terminations and the effects of making NIPT available on the NHS. The documentary sought to challenge the view that Down's syndrome is a catastrophe for families and that instead individuals with Down's syndrome are simply 'types' of people with many admirable qualities. Indeed some people believe that we would be worse off in a world without Down's syndrome and there are [organisations](#) that campaign on this issue. The documentary received widespread media attention and sparked public debate on the topic.

Is consideration timely?

The research into a chromosomal therapy for Down's syndrome is still at a very early stage, and may not be available for many years, if at all. However, considering that such research is currently underway, it may be timely to discuss the future implications of this and other 'cure-directed' therapies for Down's syndrome.

Can the Council offer a distinctive contribution?

Whilst many of the questions this research raises may be addressed within the current council projects on [NIPT](#) and [genome editing](#), there may be scope for a spin-off project to look more closely at the notions of 'disease' or 'disorder' which have been attributed to Down's syndrome and to bring together expert and public opinion on this. The Council might consider a larger project looking at the impact of new genetic technologies on conditions involving learning disability or behavioural disturbance (such as autism, ADHD). This would follow-on from previous work on [mental disorders and genetics](#) and [genetics and human behaviour](#). Or it may be interesting to consider more broadly the topic of personality and how new biomedical advances might restrict the range of personality variations in the future.

Whole genome sequencing of newborns

The advances in genome sequencing technologies have made it increasingly quick and cheap to generate data on the entire sequence of the human genome. This has led to the prediction that sequencing will become available as a 'once-only' test at the start of life and will largely replace* existing newborn screening programmes.

Are there recent scientific, legal or social developments?

The existing UK newborn blood spot screening programme helps identify several rare but serious diseases including cystic fibrosis and sickle cell disease with a heelprick test. In January 2015 a new set of rare inherited metabolic diseases was included in the blood spot programme. The US-based [BabySeq](#) project began in 2015 and is the first randomised, controlled trial to measure the harms and benefits of newborn genomic sequencing. The US National Institutes of Health in the US committed \$25 million to projects investigating the use of newborn genomic sequencing; evidence perhaps of very real hopes to introduce this technology in the near future.

Are there complex ethical issues?

As it stands newborn screening is conducted without explicit written consent and is seen to be part of routine care of newborns in the UK. The NHS chooses to test for conditions which meet the [Wilson and Junger](#) criteria for screening, in that, among other things, we understand the natural history of the conditions and we have interventions available. The introduction of whole genome sequencing could alter the fundamental aim of newborn screening and it remains to be evaluated whether whole genome sequencing would be in the best interest of the newborn. It offers the potential to identify a much broader range of conditions, not all of which will be necessarily predictable or treatable. Informed consent for such testing would hence be important and counselling parents with the results of the tests may pose particular ethical dilemmas, in particular because we are asking parents to consent on behalf of their children. This raises questions as to whether it is beneficial for the child or the family to have this information and when and how the data should be released to the parents or the individual. Following [Feinberg](#)'s principle of a child's right to an open future, there is an argument that genetic testing should be delayed until a person is old enough to make an informed choice.

Sequencing would not only identify children affected with certain conditions but also the carriers of a combination of genetic variants which may never cause a significant disease or for which we are currently unable to establish the relationship between genotype and phenotype. This risks children being labelled as 'affected' with a condition with potential consequences of parental anxiety, overtreatment, stigma and health insurance hurdles. The issue begs the larger societal question as to whether we ought to obey the 'technological imperative' to employ the most sophisticated form of technology that is available to us.

Is there a potential policy impact?

In the first instance these services are likely to become available in the private sector and will require appropriate regulation. Ultimately the NHS is likely to be faced with the decision of whether to introduce whole genome sequencing as a form of newborn screening; whether this is likely to be cost-effective or appropriate remains to be answered. Policy makers will also need to consider the role of the information generated from newborn screening in acting as a biometric that can be used to identify and track individuals and their relatives.

Is it a subject of public concern?

There has been considerable public scrutiny about the use of residual blood spots for biomedical research. A recent [study](#) looking at parental attitudes to using whole-genome sequencing found concerns that genetic risk information could be inaccurate or cause worry, concerns about privacy and storage of results, and a call for parents to have a meaningful role in the newborn screening process, including being consulted about screening.

Is the consideration timely?

Predictions have been made that the implementation of sequencing technologies in newborns will become routine within a decade.

Can the Council offer a distinctive contribution?

The current Council [project](#) on non-invasive prenatal testing (NIPT) is already seeking to address whether providers of NIPT should be subject to any limits when developing antenatal genetic tests or whole genome sequencing. It would be informative to look at the ethical differences between providing this information antenatally as opposed to in the newborn period. A new project might explore the value of an open future as weighed against knowing about one's own, or one's child's, future health. It would be helpful to provide recommendations as to whether sequencing should be used to look at a limited list of conditions or whether whole genome sequencing is appropriate. The Council could be in a unique position to gauge public opinion on the issue and to ensure these voices are heard in any future changes to the newborn screening programme.

*Some conditions within the newborn screening programme such as congenital hypothyroidism are not usually genetic conditions and the present screening methods can therefore not be wholly replaced by sequencing techniques