

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 sign-post some of the key considerations and to provide a starting point for discussion. Each summary includes details of relevant publications on the topic.

Contents

Animal research ethics	2
Artificial gametes	3
Biotechnology and globalisation	4
Dual-use technologies	5
Food culture	6
Gender selection	7
Germline gene therapy	8
Global health inequalities	9
GM Insects	10
Health tourism in the UK	11
Innovative therapies	12
Longevity	13
Non-invasive prenatal testing	14
Participant-led research	15
Social care robots.....	16
Suppressing the extra chromosome in Down's syndrome.....	17
Targets for diagnosis.....	18
Wearable health monitoring technologies	19
Cross-cutting themes	20

Animal research ethics

Overview

Animal research in the context of the 'animal as patient' can fall into two broad categories. First, there is the use of animals in 'n=1' research, where the primary intention is to develop treatments for humans, but where the animal may also benefit. Secondly, there is the use of animals in research that is not directed at human health interests. This second category could include research on the health and treatment of domestic animals, increasing production from livestock, and improving sports animals' performance. Increasingly, clinical research is being conducted within private veterinary practices by individual practitioners. Unlike veterinary research institutions, these practitioners do not normally have access to ethics review committees, and there is relatively little guidance available regarding best practice.

Ethical issues

A key ethical issue that arises within the field of animal research is the question of what moral value should be attributed to animals. Does this value depend on the species concerned, or its worth to humans (e.g. pets, working animals, livestock, or sports animals)? Some ethicists, such as Peter Singer, argue that animals have rights, which confer duties on humans and dictate how animals should be treated. Even if we don't assign rights to animals, we may still feel that there are limits to how they can be treated.

Different issues can arise depending on the context in which the research is conducted. First, there is the concern that 'n=1' research may undermine research governance frameworks that would normally apply to research conducted on animals for the benefit of humans. By framing the research in terms of treating the animal, it may not necessarily fall under animal research regulations. The second area of concern is the potential for conflicts of interest. Researchers may be subject to a number of different, and sometimes competing, motives for conducting their research. These may include promotion of animal welfare; commercial interests; direct requests from a pharmaceutical company to test a new drug; academic success; or following pathways set by research in humans. Veterinary surgeons may also be faced with a conflict of obligations between treating the animal and addressing the needs of the owner. For example, research may aim to enhance an animal's performance, such as producing more efficient livestock or faster racehorses, rather than improving the animal's health. Some of these endeavours may stem from a human perspective of what is desirable.

Lastly, there is the issue of consent. This is usually given by the owners but they are often unaware of what occurs once the animal is taken away for the procedure. Furthermore, owners may not realise that some practitioners use treatment appointments as an opportunity for research. For example, superfluous tissue, such as blood samples, may be used for research without specific consent having been given. Practitioners themselves may be unclear as to how much information is required in order for the owner's consent to be valid.

Policy implications

Currently, the need for ethical review depends on whether the proposed action is part of recognized veterinary clinical practice or research. Any research involving animals that has the potential to cause pain, suffering, distress or lasting harm falls under the Animals Scientific Procedures Act 1986 (ASPA), and therefore requires a Home Office licence and compulsory ethical review. However, Home Office authorization is unlikely to be required if the research is part of recognized veterinary practice and consent is given. Irrespective of whether it is part of standard practice or not, ethical approval is increasingly becoming a requirement prior to securing funding for research or publication. The question then becomes how best to provide ethical review in this context. Potential options include: collaboration with colleagues in research institutes with ethics committees; purchase of ethical review services from institutions; establishing a national independent body under the RCVS; or the setting up of ad hoc ethical review processes by veterinary surgeries.

Relevant reports

RCVS/BVA (2013) *Ethical review for Practice-based research*. A report of a joint RCVS/BVA working party.

Centre for Health and Ethics (2012) [Health policy in consideration of good care for animals and environment](#).

RCVS (2011) *Research into Practice – Practice into Research*. Bonner report.

Mellanby R (2011) Promoting Clinical Research in Practice *Journal of Small Animal Practice* **52**: 557-8.

Artificial gametes

Overview

In 2011, [researchers in Japan](#) created fully functioning sperm from mouse embryonic stem cells, which were subsequently used to fertilise mouse eggs *in vitro* and produce healthy offspring. This development has raised the possibility of deriving artificial gametes (AGs) from human stem cell lines at some point in the future. The resultant source of gametes could offer numerous possibilities for both stem cell research and assisted reproductive technology, such as enabling infertile couples to have genetically related children without the need for donor gametes.

Ethical issues

The ethical issues that arise depend to some degree on whether the technology is being used for research purposes or treatment. In the context of research, there is the question of the moral status of the embryos created for such purposes. It has been suggested that the use of AGs may alleviate some of the ethical, religious and political objections to the use of human embryos and gametes for research. However, is there any moral difference between destroying an embryo generated from artificial gametes in order to obtain stem cells, and destroying an embryo donated for research for the same purpose? In the context of fertility treatment, AGs could offer a huge breadth of scope for people to have genetically related offspring regardless of age, gender, relationship status or sexuality. For example, AGs may create the potential for same-sex couples to have children that are genetically related to both parents. It may even be possible eventually for a child to have more than two genetic parents, or just a single genetic parent (although doubts remain regarding the feasibility of ever producing 'male eggs' or 'female sperm'). Some have viewed this prospect as having the potential to democratise reproduction and end infertility, as well as a possible solution to the current shortage of donor gametes. However, others have raised concerns regarding the increased medicalisation of conception and pregnancy. It is clear that advances in this field have the potential to challenge our very notion of infertility, which is imbued with social meaning and choice as well as biological factors, by enabling those not currently viewed as 'infertile' to become genetic parents. It also highlights the distinction between genetic parenthood and social parenthood. Why is genetic relatedness to one's offspring so important? Why do some people prefer medically assisted reproduction over adoption or donor conception, and how far should we go in accommodating the desire for genetic parenthood?

A fundamental concern in this area is the well-being of the potential children born using AGs and the safety of the technology. Some have argued that this technology will lead to the creation of 'human embryo farms', and that the knowledge that they have been conceived in such a way could be psychologically damaging to children. Would these children risk being viewed differently by society, or labelled as 'artificial' in some way? Others argue that children have a right to have a biological mother and father, and a natural biological heritage. However, what is meant by 'natural' in this context, and why is natural presumed to be better? Will being genetically related to two parents of the same sex fundamentally alter the experience of childhood? What impact would this technology have on our current conceptions of parenthood and the moral relationships within families? This technology could also have huge implications for our sense of genetic control, with some people fearing that it could lead to unwitting parenthood. Currently, our gametes can only be accessed by sexual or surgical intervention, which is governed by strict ethical and legal constraints. However, the ability to create AGs from non-reproductive cells, such as skin cells that we have shed, would dramatically reduce this control. Would children conceived from unwitting genetic parenthood have a right to know their 'parents'? Lastly, there are concerns that this technology could be used for 'in vitro eugenics' and as a tool for human enhancement by utilising selective crossing techniques to create a child with a desired genotype. Some claim that this will promote the commodification of children with parents trying to ensure that their offspring meet certain 'specifications', and may undermine the presumption of moral equality among human beings.

Policy implications

Currently, the [Human Fertilisation and Embryology Act 2008](#) permits the use of AGs for research but not for treatment. The question for policy makers is whether this position will need adapting in the future if further research demonstrates that the use of this technology is both possible and safe for treatment services. This may raise further questions regarding eligibility for therapy and whether there would need to be limits to its application. Furthermore, how would we protect the rights and interests of the human sources of cells from which gametes are derived? And would the current position of determining responsibility for financial support based on genetic tests no longer be tenable?

Relevant reports

The Hinxton Group (2008) [Consensus Statement: The Science, Ethics and Policy Challenges of Pluripotent Stem Cell-Derived Gametes](#).

Test G & Harris J (2005) Ethics and synthetic gametes *Bioethics* **19**: 146-66.

Biotechnology and globalisation

Overview

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. The industries associated with biotechnology include agriculture, pharmacology and bioengineering. The effects of the mechanisms of globalisation on such industries raise significant ethical and policy issues. 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. At the same time, the increase in global competence in biotechnology raises the possibility of internationally directed projects, such as large scale geo-engineering.

Ethical issues

Ethical issues to consider with respect to biotechnology and globalisation include: weighing the potential harms and benefits from biotechnology; ensuring fair access; ensuring just treatment of workers in biotechnological industries; protecting cultural integrity and national sovereignty; and determining the appropriate role for private companies and market forces in public health and biotechnology. 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. Countries may find themselves losing a skilled workforce to international biotechnology companies, without receiving the benefits of research. Furthermore, the aggressive expansion of multinationals within a country may skew the educational priorities of the native population. Lesser developed countries may find that these processes leave them dependent on continued investment by foreign-controlled companies and thus economically vulnerable. Large-scale cooperative biotechnology projects raise questions of our relationship to the natural world. Should we make permanent and radical changes to the environment in order to meet human needs, or to satisfy non-essential preferences? If so, when are such changes warranted? The globalisation of the biotechnology sector also raises concerns regarding the equitable distribution of risks and benefits derived from such technology, and might present challenges to our notion of solidarity.

Policy implications

Effective policy may require a better understanding of the process of globalisation, the mechanisms by which it works, and its likely or possible outcomes. Allowing market forces solely to dictate the shape of biotechnological industries is neither feasible nor desirable. Instead, a policy of responsible research and innovation is needed, which guides research to meet the needs and ambitions of society, and better reflect its values, as well as ensuring equitable benefit sharing of the results of biotechnology. This will require mechanisms for effective coordination between national and international governments and corporations. Issues with generic and counterfeit prescription medicines highlight difficulties in ensuring quality control, and in seeking redress for breaches of national or international regulations. Policymakers must also address the role of intellectual property rights in biotechnology, in order to constrain biopiracy without restricting innovation.

Relevant reports

Falkner R (2013) *The handbook of global climate and environment policy* (London: Wiley-Blackwell).

Nuffield Council on Bioethics (2012) [*Emerging Biotechnologies: Technology, choice and the public good*](#)

International Assessment of Agricultural Knowledge, Science and Technology for Development (2008) [*Agriculture at a crossroads*](#).

Newell P (2003) Globalization and the Governance of Biotechnology *Global Environmental Politics* **3(2)**: 56-71.

Glasner P and Rothman H (2001) New genetics, new ethics? Globalisation and its discontents *Health, Risk & Society* **3(3)**: 245-59.

Council of Europe (1999) *International conference on ethical issues arising from the application of biotechnology* (Oviedo: Spain).

Dual-use technologies

Overview

Traditionally, the term dual-use technology (DUT) has been used to denote a technology that has both civilian and military applications. However, it is also used to refer to scientific research that is intended to do 'good' but may be misused for malicious purposes, such as acts of bioterrorism. This idea of the 'dual-use dilemma' first entered modern consciousness with the role of atomic research in the creation of nuclear weapons. Recent advances in genetics, neuroscience and synthetic biology have heightened these issues. The combination of an increasingly globalised world, the availability of scientific equipment and knowledge, and the threat of global terrorism, make the dangers inherent in DUTs more pressing than ever. At the same time, it must be recognised that many beneficial civilian (or peaceful) technologies have arisen from research with militaristic (or hostile) aims.

Ethical issues

The chief ethical issues to do with DUTs turn around the values of scientific knowledge on the one hand, and global security on the other. It is an open question whether either security, or the pursuit and dissemination of scientific knowledge, are intrinsically (rather than merely instrumentally) valuable. Supposing each to be valuable in their own right, there remains substantial disagreement over how to resolve conflicts between them. Is there a right to security, and if so, what degree of risk is consistent with its observance? To what extent can scientists disclaim responsibility for the potentially harmful uses of their research? On the other hand, can unforeseen or unintended beneficial consequences of research justify an otherwise ethically dubious research programme? How far ought individual scientists, or the scientific community as a whole, consider the potential social ramifications of their work when deciding how to proceed? Insofar as DUTs involve foreseen but unintended consequences of an activity, there are clear parallels with the 'doctrine of double effect'.

Policy implications

It is generally agreed that we should aim for policy that strikes a balance between the goal of promoting scientific progress (and the goods that this entails) and the goal of protecting security. Given the globalised nature of scientific enterprise, and the potentially global ramifications of the weaponisation of biotechnology, international coordination is necessary. The EU has implemented [legislation](#) that governs the export of dual-use items and technology. However, questions remain regarding the degree to which governments should interfere in scientific practice, such as limiting the content of a publication, its timing or its distribution. Control over the areas of research and the dissemination of its products may occur at any of a number of different levels. These include regulation by individuals themselves, professional associations, publishers, research committees, funding boards, governments, or extra-governmental organisations. In America, for example, the [National Science Advisory Board for Biosecurity \(NSABB\)](#) is a federal advisory committee that addresses issues related to biosecurity and dual-use research. The scientific community is generally in favour of voluntary self-governance, arguing that autonomy is essential to scientific progress and that governmental interference would be both unethical and counterproductive. Against this, it has been argued that scientists lack both the independence and the knowledge required to make decisions about the security implications of their research.

Relevant reports

Baum S and Wilson G (2013) The ethics of global catastrophic risk from dual-use bioengineering *Ethics in Biology, Engineering and Medicine* (forthcoming).

Royal Society (2012) [Brain waves 3: neuroscience, conflict and security](#) (London: Royal Society).

Miller S, Selgelid MJ and van der Bruggen K (2011) *Report on biosecurity and dual use research: a report for the Dutch Research Council* (The Hague: Dutch Research Council).

Parliamentary Office of Science and Technology Postnote (2009) [The Dual-Use Dilemma](#).

Atlas RM and Dando M (2006) The dual-use dilemma for the life sciences: perspectives, conundrums, and global solutions *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* **4(3)**: 276-86.

National Research Council (2004) *Biotechnology in an age of terrorism* (Washington DC: National Academies Press).

Food culture

Overview

A diet containing the right amount of nutrients is important for maintaining health and preventing malnutrition (including both under- and over-nutrition). These conditions can have a dramatic impact on a person's quality of life, as well as imposing high economic and social costs on countries of all income levels. In the UK, it is estimated that 3 million people suffer from under-nutrition, whilst one in four adults is obese. However, people may have differing views as to what constitutes a healthy diet, and there may be many factors that guide a person's choice in relation to food. In 2016, the Wellcome Trust will conduct a UK-wide [public engagement initiative on food and drink](#), which will focus on the links between environment, nutrition and health, including issues surrounding food production, transport, packaging, storage, shopping, cooking, eating, and waste.

Ethical issues

A key question in this area relates to people's attitudes to food and what influences their perceptions of a 'good' choice. Some draw a distinction between 'natural' and 'artificial' foodstuffs, often perceiving the former to be a better option. This is reflected in the food industry itself, such as with the production and marketing of organic foods. Products marketed as such are often more expensive than similar conventional options, although it is debatable as to whether they differ in terms of nutritional content. Furthermore, the labelling of these foods can lead to confusion amongst consumers who might view the terms 'organic', 'natural', 'GM-free' or 'whole food' as interchangeable, or might be unclear as to the standards required to receive certification. Similarly, some people may hold the view that food that has been cooked from raw ingredients at home is preferable to ready-made meals bought from the supermarket. However, what is the difference between a natural food and an artificial one, and can this distinction be clearly defined? Even if a distinction can be made, does it always follow that a natural food will always be the healthier option (consider the marketing of [Coca-Cola Life](#) as a 'natural' option)? There may also be other considerations aside from the nutritional content that may influence a person's choice. Consumers are increasingly interested in how their food has been produced, including the impact on the environment, whether it has been grown locally, and issues surrounding animal welfare. Attitudes to food may also differ significantly between different cultures. However, with globalization has come the exportation of 'Western' models of food consumption to developing countries, which some believe is responsible for the growing prevalence of obesity in these countries. This raises the issue of food imperialism and the question of who should decide what constitutes a good choice in relation to food.

Another issue that arises in this area is the question of who is ethically responsible for ensuring that a population receives a nutritious diet. It could be argued that government has a role to play, whether that be by 'nudging' people towards healthier choices or imposing tighter regulations. Some argue that the food industry should do more to produce healthier food, whilst others advocate the view that the individual should be free to make informed choices regarding their own diet. However, there are concerns from some quarters regarding the 'freeness' of a person's choice, especially considering the powerful impact of advertising and the confusion that often surrounds food labelling.

Policy implications

Food labelling regulations in the UK have been criticized for being too complex and subject to a number of reforms and parliamentary acts. However, following an EU-wide review of both general and nutrition labelling legislation, the [Food Information for Consumers Regulation](#) was adopted in 2011. This new regulation, which will replace current UK law from 2014, aims to simplify and consolidate existing legislation. A key policy question is to what extent governments should be involved in promoting healthy eating habits. Is greater regulation of the food industry required or should consumers be free to make their own choices? How do governments ensure that people receive sufficient information in order to make an informed choice whilst avoiding confusion from too many mixed messages?

Relevant reports

Food Ethics Council (2014) [Telling people what to eat: A moral imperative or a step too far?](#)

Sustainable Food Supply Chains Commission (2014) [The long and the short of it.](#)

FAO (2013) [The State of Food and Agriculture: Food systems for better nutrition.](#)

Center for Science in the Public Interest (2010) [Food Labelling Chaos: The case for reform.](#)

Gender selection

Overview

There are a variety of methods that can be utilized to control the sex of offspring with varying degrees of success. These include sperm sorting, preimplantation genetic diagnosis (PGD), and prenatal sex diagnosis during pregnancy. In the UK, gender selection is prohibited unless it is for the purpose of avoiding a child being born with a sex-linked genetic disorder. Couples who wish to pursue sex selection for non-medical reasons must therefore seek treatment abroad, such as the [Fertility Institutes](#) clinics and [Genetics & IVF Institute](#) in America.

Ethical issues

There are a number of arguments that are raised against allowing gender selection for non-medical reasons. First, there is the view that choosing a child's sex interferes with divine will or the intrinsically virtuous course of nature. However, this would appear to prohibit all forms of gender selection, including those for medical reasons, and it is not clear what distinguishes an acceptable intervention from an unacceptable one if it is conceded that in some sense all medical treatments are 'unnatural'. Some oppose gender selection for non-medical reasons on the grounds that it treats the child as a means to another's ends since it is aimed at benefiting the parents rather than the child themselves. This view is based on the respect for the future child's value as a person, which precludes the exercise of control by parents over the sex of the child. Some argue that children may be psychologically harmed by the knowledge that they were chosen for their sex or that parents may try to mould them to fulfil their expectations. Concerns are also raised that allowing the practice of sex selection will reinforce societal patterns of gender inequality and discrimination, especially towards women. This argument is premised on the assumption that there are underlying sexist motives for choosing a child's gender based on preconceived gender role expectations. It is claimed by some that this could result in a distortion of the sex ratio, particularly in countries with strong culturally mediated gender preferences. Lastly, it is claimed by some that allowing the practice of gender selection will lead to the wider adoption of 'designer babies' and the further commodification of children. Some fear that this will promote a consumerist attitude towards children, with parents trying to ensure that their offspring meet certain 'specifications' and to control an inherently unpredictable process.

Those in support of gender selection often argue on the grounds of protecting procreative autonomy; that there is insufficient justification to restrict people's right to self-determination in what many people regard as a fundamental aspect of their lives. Advocates of this view often raise the question of who exactly is being harmed by gender selection and the non-identity problem. Essentially, is any harm that is caused by choosing a child's sex so severe that it would be better if the child did not exist? Are these two outcomes even comparable? Some virtue ethicists attempt to circumvent this problem by avoiding questions of harm to the child. Instead, they argue that a virtuous parent would accept their children regardless of their sex, so choosing gender would not be to act virtuously, even if the child is not harmed. Therefore, gender selection is wrong because it is not in accordance with the parental virtue of acceptance. However, it is unclear whether this view prohibits all forms of gender selection, or just for non-medical reasons.

Some institutions only provide sex selection in the context of 'family balancing'. This is because it is assumed that the parents do not prefer one sex over the other, but rather are aiming for an equal representation of genders in their family. In response to this, some hold that this is still based on sexist preconceptions about anticipated gender-specific behaviours.

Policy implications

In 2003, the Human Fertilisation and Embryology Authority (HFEA) conducted a public consultation on the permissibility of sex selection for non-medical reasons. The HFEA found that there was considerable public opinion against this practice and concluded that gender selection should only be permitted where there is a risk that a woman will give birth to a child with a serious gender-related condition. This policy position is given statutory footing in the [Human Fertilisation and Embryology Act 2008](#). The question for policy makers is whether this position needs to be expanded to allow gender selection for non-medical reasons, and if so, whether there should be any limits to these grounds. Furthermore, what bearing would the allowing of gender selection have on the permissibility of controlling other characteristics of one's offspring, such as hair or eye colour?

Relevant reports

International Human Rights Clinic, University of Chicago Law School, National Asian Pacific American Women's Forum, Advancing New Standards in Reproductive Health (2014) [Replacing Myths with Facts: Sex-selective abortion laws in the United States](#).

WHO (2011) [Preventing gender-biased sex selection](#).

HFEA (2003) [Sex selection: Options for regulation](#).

Germline gene therapy

Overview

Germline gene therapy refers to any procedure which involves the modification of the genetic material in germ cells for therapeutic purposes. It involves intervening in the reproductive process before conception has taken place. Within such techniques we may distinguish between those which target mitochondrial DNA (mtDNA) and those which target nuclear DNA (nDNA). Germline gene therapies can involve either the manipulation of genetic material (e.g. the insertion of one or a few genes) or its outright replacement. Examples of the former include procedures such as cytoplasmic transfer and gene knockout therapy; of the latter, pronuclear transfer, maternal spindle transfer, somatic cell nuclear transfer and nuclear transfer. Some of these procedures involve therapeutic human cloning.

Key ethical issues

The key ethical issues to consider with such techniques include the following: the overall balance of potential harms and benefits of the procedure; the identity of individuals affected by gene therapy; the (disputed) right to 'genetic integrity' and its relation to 'human dignity'; respect for the autonomy of the affected individuals; difficulties in establishing informed consent; justice and the possible effects on third parties and society; definitions of parenthood; and the dangers of possible 'slippery slopes' towards reproductive cloning and genetic 'enhancement'. Disability rights campaigners have questioned whether it is ethical to *screen out* certain heritable conditions for a number of reasons. They argue that the experience of disability can contribute to a person's sense of identity, and that there are inherent problems in making value-based judgements about which conditions should be targeted for therapy and what is considered genetically 'undesirable'. This raises questions about what are identity determining characteristics, which is especially relevant in terms of recent research into the genetic determinants of mental illness. These ethical issues are heightened by the fact that germline gene therapies affect all future generations of offspring. Given the possibility of unforeseen downstream effects, determining when the overall potential benefits outweigh the harms is problematic. Furthermore, since gene therapies apply to future persons, and arguably alter the identity of the individual who comes into existence, applying concepts of harm and consent to the affected parties is difficult.

Policy implications

From a policy perspective, important questions are raised about what regulatory framework is appropriate in regards to germline gene therapies. In 2012, the Council produced a report on the specific issues that arise from the modification of mtDNA. In that report, the Working Party concluded that modification of the mitochondrial genome does constitute germline gene therapy, but that there is a distinct material boundary between mtDNA and nDNA modification, which would enable regulators to provide a clear legal distinction. [Regulations](#) to allow the use of mitochondrial replacement techniques for the prevention of mtDNA disorders were approved by Parliament in February 2015 and will come into force from 29 October 2015. The key question for policy makers following the approval of these regulations is whether the germline modification of the nuclear genome should also be permitted in certain circumstances.

Relevant reports

HFEA (2014) [Third scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception: 2014 update](#).

HFEA (2013) [Mitochondria replacement consultation: Advice to Government](#).

Nuffield Council on Bioethics (2012) [Novel techniques for the prevention of mitochondrial DNA disorders: An ethical review](#).

Parker M (2012) *Ethical problems and genetics practice* (Cambridge: Cambridge University Press).

Bredenoord AL, Dondorp W, Pennings G and De Wert G (2011) Ethics of modifying the mitochondrial genome *Journal of Medical Ethics* **37(2)**: 97-100.

UNESCO (2003) [Report of the IBC on pre-implantation genetic diagnosis and germ-line intervention](#) (Paris: UNESCO).

The President's Council on Bioethics (2002) [Human cloning and human dignity: An ethical inquiry](#).

World Health Organization (2002) [Genomics and world health: Report of the Advisory Committee on Health Research](#) (Geneva: World Health Organization).

American Association for the Advancement of Science (2000) [Human inheritable genetic modifications: Assessing scientific, ethical, religious, and policy issues](#).

Global health inequalities

Overview

Global health inequality refers to the disparity in health outcomes and access to healthcare amongst the world's populations. Common measures of health inequality include life expectancy, maternal and infant mortality, morbidity rates, and self-reported quality of life. Health inequalities, whether at a local, national or international level are largely man-made and reversible. Research has shown that there is a strong correlation between the level of economic development of a country and its population health indicators. Therefore, a general inequality exists between the health outcomes of lesser and greater economically developed countries (LEDCs and GEDCs, respectively).

Ethical issues

The case for reducing global health inequality is supported by a number of ethical principles, including those of equitable distribution of resources and collective justice, healthcare as a human right, and the good of promoting human flourishing. The ethical issues that arise with global health inequalities include: determining whether health equality should be measured in terms of access or in terms of outcomes; clarifying when such inequalities become unfair or unjust; determining to what extent GEDCs have a responsibility to address them; and establishing what interventions are necessary and permissible for each (state or non-state) actor. Benefits must be provided with a view to long-term sustainability, in a way which is culturally sensitive and non-paternalistic. Since such help incurs opportunity costs, potential benefits and risks of a given intervention must be weighed. However, decisions must be mindful of the tension between considerations of utility, and of the inherent dignity and human rights of the affected individuals. It remains an open question as to how useful (if at all) the concept of solidarity is in explaining our obligations to reduce global health inequalities.

Policy implications

Improving health outcomes in deprived areas raises important policy challenges. A key issue is establishing what the roles of the various actors involved should be, including that of global organisations, governments, NGOs, corporations, and individuals. Coordination between these different groups is necessary if remedial work is to be effective. There is a danger that major philanthropic organisations and NGOs may, though good-intentioned, skew research and international development priorities in ways that are counterproductive. Furthermore, large-scale interventions by non-local entities can have unforeseen effects on the cultural and economic well-being of a region. Effective policy must tackle structural inequalities and the underlying social causes of poor health outcomes if long term gains are to be made. This may include changes in both the built and natural environments, as well as economic, cultural and social changes. In certain respects, the health model in LEDCs may be more efficient than its counterparts in GEDCs. The distribution of aid is therefore a reciprocal arrangement, involving benefits to GEDCs as well as the intended recipient of aid (e.g. experience for medical staff, learn about novel contexts, and gain local knowledge). Policy makers face the challenge of devising mechanisms that allow these benefits to be used effectively.

Relevant reports

WHO (2013) [Research for Universal Health Coverage](#). The World Health Report 2013.

European Commission (2013) [Health inequalities in the EU](#). Final report of a consortium.

Royal Society (2012) [People and the planet](#) (London: Royal Society).

International Federation of Red Cross and Red Crescent Societies (2011) *Eliminating health inequities: every woman and every child counts* (Geneva: International Federation of Red Cross and Red Crescent Societies).

UN Department of Economic and Social Affairs (2009) [Implementing the Millennium Development Goals: Health Inequality and the Role of Global Health Partnerships](#). Committee for Development Policy Note.

World Health Organization (2008) [Health equity through action on the social determinants of health](#) (Geneva: World Health Organization).

GM insects

Overview

Genetically modified (GM) insects are produced by altering or inserting new genetic material into the DNA of insects. This technology is viewed by some as a potential control method to reduce the harm caused by insect-borne diseases, and prevent damage to crops and livestock from pests. For example, [Oxitec](#) has developed a [GM mosquito](#) that is designed to mate with wild females and produce progeny that die as late larvae or pupae. The aim of this research is to combat the spread of the dengue virus by reducing the mosquito population that acts as a vector for the virus. This mosquito has been trialled in the Cayman Islands, Malaysia, Brazil, and Panama, and was approved for [commercial release in Brazil](#) in April 2014. The company has also applied to carry out field trials of its [GM olive fly](#) (a major pest of olive trees) in [Spain](#).

Ethical Issues

Some view the issue of GM insects as purely a matter of risk-benefit analysis. Proponents of the technology consider it a useful tool in the fight against insect-borne diseases and for pest control. Possible benefits of GM insects include fewer effects on non-target species than pesticides, the ability to cover areas that may be inaccessible to conventional methods, and the reduction in the amount of insecticides and other potentially harmful chemicals being used. However, concerns have been raised regarding the release of GM insects into the environment, including the development of resistant pathogens or insects, the elimination of one species leading to the dominance of another, the transfer of the inserted genes into other species (horizontal gene transfer), and the potential harmful effects of GM insects on human health and the ecosystem. Some maintain that the technology should not be implemented until it can be demonstrated that there is no risk to humans or the environment (the so-called precautionary principle). However, this level of certainty is often unachievable in practice. A further problem foreseen with GM insects is that it may be very difficult to restrict their spread once they have been released into the environment. This may have important implications for consumers who wish to avoid contact with genetically modified organisms (GMOs).

A fundamental question in the field of genetic modification more generally is whether there is an intrinsic ethical issue in genetic engineering. Some view GM technology as inherently 'unnatural', or that it is 'playing God'. As such, it is argued, the technology is morally wrong and should not be promoted regardless of the potential benefits. This viewpoint implies that there is an intrinsic value in the genetic integrity at organism and ecosystem level which humans should not interfere with. However, one problem with this stance is that the distinction between what is considered 'natural' and what is considered 'unnatural' is far from clear. Cross-species DNA transfer has been found to occur in nature, and the same genetic changes that are engineered in GMOs are observed in conventional breeding methods. To some extent, any human endeavour, including traditional farming practices, can be viewed as an interference with nature. Furthermore, because the changes in GMOs are arguably more targeted and controlled, some suggest that it should be considered safer, and therefore potentially more desirable, than natural processes.

Policy implications

There are no specific regulations for GM insects in the EU. Instead, the [Deliberate Release Directive 2001/18/EC](#) governs the release of all GMOs into the environment for research or commercial purposes.¹ Under this Directive, EU member states must reach a qualified majority to approve any release following a scientific assessment by the [European Food Safety Authority](#) (EFSA). However, in the past, the implementation of this Directive has been largely concerned with the cultivation of GM crops and food products. One question for policy makers could be whether there is a need for separate regulations specifically formulated for GM insects. In particular, the ability of insects to cover long distances and cross international borders means that any regulation will need to take account of transboundary movement. Policy makers would also need to decide whether the interests of states, or individual consumers within states, that want to remain GM insect-free should be protected, and if so, how.

Relevant reports

WHO-TDR & Foundation for the National Institutes of Health (2014) [Guidance framework for testing of genetically modified mosquitoes](#).

Parliamentary Office of Science and Technology POSTnote 483 (2014) [GM Insects and Disease Control](#).

Macer D (2005) [Ethical, legal and social issues of genetically modifying insect vectors for public health](#). *Insect Biochemistry and Molecular Biology* 35: 649-60.

¹ A draft directive amending 2001/18/EC is currently being debated by the European Parliament and Council. However this is likely to be only relevant to the cultivation of GM crops.

Health tourism in the UK

Overview

'Health tourism' is an umbrella term which encompasses a number of different practices. Popular use of this phrase in the media refers to individuals who are not usually resident in, or citizens of, the UK who seek to access NHS services. Thus the term 'health tourists' may be used to cover those who travel to the UK for the sole purpose of seeking medical treatment or care on the NHS, as well as those such as asylum seekers, migrants without leave to remain, and temporary visitors, who may also have cause to use the NHS. Thus the debates surrounding 'health tourism' are closely related to debates around access to public services by those who are not permanently resident in the UK, and around the extent to which the state has a duty to provide for individuals who are not citizens of the UK or the EU. The term may also be used in a much wider sense, as a synonym for (planned) international 'medical tourism' or 'medical travel': these wider issues are covered in a separate entry on medical travel.

Ethical issues

Non discriminatory universal access to healthcare, free at point of need is one of the founding principles of the NHS. Whether this principle should be applied to non-British and non-EU citizens is the source of some debate. On the one hand, temporary visitors and illegal migrants do not contribute through the taxpayer system towards public services - they are therefore obliged to pay for any non-emergency treatment they require (unless they come from countries with reciprocal healthcare agreements with the UK). In the current economic climate, with pressure on the DH to make 'efficiency savings' of around £20 billion, financial pressures on the NHS are becoming increasingly acute, and there are concerns that the use of NHS resources to care for those who are not normally resident in the UK could have a significant adverse impact on those who are.

On the other hand, it has been argued that the cost generated by temporary or illegal migrants accessing NHS services is a very small fraction of the total NHS budget. Having a healthcare system that is universally accessible is arguably an ethical obligation of a state; people should not be discriminated against based on their country of origin. From a rights based perspective, individuals should have a right to access healthcare whether or not they are able to afford it. Furthermore, it may be much more cost effective to invest in preventative medicine, including that provided by primary care services: restricting access to primary care may simply increase the burden on other parts of the health service through emergency and long term admissions for chronic and unmanaged health problems. Restricting access to healthcare also puts clinicians in a difficult ethical position, by requiring them to make judgments about their patients' personal circumstances despite their primary professional duty of care towards each individual patient.

Policy implications

In July 2013 the coalition government launched a consultation on migrant access to healthcare services. It recommended changes so that non EEA temporary migrant workers would have to contribute a flat levy towards the cost of their care if they did not have private health insurance. Illegal migrants and non EEA patients would be charged for accessing primary as well as secondary care services. It is likely that these, or similar policies will be adopted in the UK, after the government signalled its intention to do so in the Queen's speech. However, the plans remain controversial, particularly those that will require GP practices to record the immigration status of prospective patients. The proposed reforms have been criticised by the chair of the RCGP, and the BMA has indicated it will oppose the guidelines.

Relevant reports

Lunt et al (2014) [Implications for the NHS of inward and outward medical tourism: a policy and economic analysis using literature review and mixed-methods approaches](#) *Health Services and Delivery Research* 2:(2).

Hanefeld J, Lunt N, and Smith R (2013) Health tourism and the NHS: facts of fiction *The Lancet* **382(9890)**: e2.

Department of Health (2013) [Sustaining services, ensuring fairness: a consultation on migrant access and their financial contribution to NHS provision in England](#).

The Guardian (3 July 2013) [Health tourism: how much does it cost the NHS?](#).

Innovative therapies

Overview

An innovative therapy (IT) is a newly introduced or modified therapy with unproven effects. The Declaration of Helsinki allows for unproven interventions to be used in circumstances where proven interventions do not exist or have been ineffective, so long as the unproven intervention offers hope of saving life, re-establishing health or alleviating suffering. 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. Furthermore, an IT is generally aimed at helping a particular patient, or group of patients, whereas the primary purpose of research is to acquire knowledge. However, the distinction between treatment and research is not always clear. IT is not a singular concept, but rather a spectrum of interventions, ranging from procedures without precedent (e.g. use of a novel untested intervention) to slight variations in practice (e.g. modifying dosage or minor changes to a surgical technique) to using conventional treatments in novel contexts. As such, innovation can be seen as a standard feature of care, with doctors tailoring treatment to particular patient needs. However, innovative treatments can also differ little from research when they involve a radical deviation from accepted best practice. These nuances raise important questions surrounding governance and the ethical principles that should underpin IT.

Ethical issues

IT raises a number of ethical issues that are common to both medical practice and research: respecting patient autonomy; ensuring informed consent; truth telling; and balancing the potential benefits and harms to the individual. In addition, IT may raise further concerns when the border between research and treatment is less clearly defined. Physicians involved in IT will need to be aware of the potential conflict that may arise between the goal of furthering medical knowledge and the welfare of the individual patient, and the potential for this conflict to undermine trust in the doctor-patient relationship. Patients (and their families) may feel 'objectified' if doctors view their condition as a subject for 'experimentation' (and potentially, for professional development via publication). Other patients may view the ability to participate in experimental therapies in a positive light if they view 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 risks inherent in a procedure. Withholding potential 'rescue' therapies that might improve prognosis or quality of life on the basis that they are experimental is contentious. Finally, 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'.

Policy significance

IT raises a number of issues for effective policymaking. The BMA is clear that unproven remedies or new techniques should not be used without ethical overview or independent assessment. A key question, therefore, is how the independent review of an IT could best be achieved, and whether existing models used for research governance, such as research ethics committees, are appropriate in this context, or whether a new form of assessment is required. 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 whether a 'one size fits all' type of regulation is the best solution to the spectrum of interventions that may fall under the umbrella term 'IT'. Lastly, there is the question of whether a database would be required to 'capture the learning' gained from the use of ITs, and how this might be structured.

Relevant reports

Chan TE (2013) Legal and regulatory responses to innovative treatment *Medical Law Review* **21(1)**: 92-130.

Eyadhy AA and Razack S (2008) The ethics of using innovative therapies in the care of children *Paediatrics and Child Health* **13(3)**: 181-4.

Stenck N (2007) *ORI Introduction to the responsible conduct of research* (Washington DC: Department of Health and Human Services).

World Medical Association (2001) [Declaration of Helsinki: ethical principles for medical research involving human subjects](#).

Longevity

Overview

Gerontology is the study of the social, psychological, and biological aspects of aging. Although people in the developed world now enjoy longer life expectancies than previous generations, some researchers are still seeking ways to extend the human lifespan further. The [SENS Foundation](#) and [Human Longevity Inc](#) are two such organizations that are attempting to utilize recent advances in the field of genomics to extend the healthy human lifespan. However, at the same time, there remain huge differences in life expectancy between different parts of the world. In the context of medical practice, society's commitment to enable people to live for as long as possible, combined with advancements in the technological capability to do so, has led to increasing pressures on healthcare staff to keep people alive at all costs. There are also concerns that society has become less accepting of death, and that there is a growing reluctance to talk about it. Initiatives, such as '[Death Cafes](#)', have been implemented in response to this perceived problem.

Ethical issues

Is there intrinsic value in living longer? Is longer life something we should aim for because life is itself a basic good? Is there a fundamental difference between the desirability of living as long as possible within the limits of the average life expectancy, and the desirability of living beyond those (arbitrary?) limits? It may be asserted that the first is concerned with something that we have a right to maintain, whilst the second is concerned with enhancement, to which the concept of right is ill-suited. However, John Harris argues that saving a life and delaying its end are morally equivalent; if we have a moral duty to save a life, we also have a moral duty to extend the human lifespan indefinitely. This touches on the concept of the value of life and what is considered important. Is it the quality of an individual's life, which is in itself inherently difficult to assess, or the number of years lived that is important? Should old age be viewed as a disease that should be treated if possible, or a normal aspect of life?

Any new technology that leads to significant lengthening of the human lifespan is likely to be very expensive, at least initially, and therefore will only be available to the wealthy, exacerbating existing inequalities between the rich and the poor. The fortunate few who could afford the therapy would have significantly longer lives, and more opportunities to amass wealth or political power. Given that there are already vast differences in mortality and morbidity rates between different populations in the world, can we morally justify investing in research to extend life further in those who have already more life than others? What are the goals of such research and for whom is it being developed? Are longer life expectancies only better for the individual who lives longer, or is a society whose members live longer a more desirable society? Any discussion along these lines would also need to take account of the possible detrimental effects that would result from people living considerably longer. This would include the problem of progressively less space and resources available for future generations, necessitating longer inter-generational gaps.

Policy implications

The UN predicts that life expectancies will continue to creep upwards, albeit at a slower pace. Although it is likely to be some time before the technology needed to dramatically extend the human lifespan is readily available, research aiming to achieve this is already underway. The challenge for policy makers then would be how to regulate this technology should it become available. Presently, the problem is one of resource allocation; should we be investing in technologies that potentially extend the human lifespan, but at the expense of improving the health and quality of life within the current life expectancy. Another question for policy makers is the impact of NHS targets on our idea of longevity, and whether the emphasis on mortality rates promotes the view that death can only be a bad outcome. Has this resulted in doctors and the healthcare system finding it increasingly difficult to allow people to die?

Relevant reports

House of Lords Select Committee on Public Service and Demographic Change (2013) [Ready for Ageing?](#) Report of Session 2012-13.

Alexandre Kalache (2013) [The Longevity Revolution: Creating a society for all ages](#). Adelaide Thinkers in Residence Report.

ILC-UK (2011) *Living Beyond 100: A report on centenarians*.

Non-invasive prenatal testing

Overview

Non-invasive prenatal testing (NIPT) is an emerging technology that uses the analysis of cell-free foetal DNA (cffDNA) in maternal blood to screen for Down's syndrome and other chromosomal abnormalities. It is increasingly being viewed as a desirable alternative to current prenatal screening protocols because it is considered more accurate at estimating the chance of a baby being born with a disorder. It is also predicted that, as the technology improves and the costs of sequencing and analysis decrease, the scope of prenatal screening will significantly expand in the near future beyond common autosomal aneuploidies. Indeed, several [commercial companies](#) already offer NIPT as a screening test for certain sex chromosomal disorders, such as Turner and Klinefelter syndromes, and deletion syndromes (e.g. Cri-du-chat).

Ethical issues

NIPT has a number of perceived benefits over current prenatal screening protocols, including being able to be performed earlier in pregnancy and reducing the risks associated with invasive procedures, such as amniocentesis and chorionic villus sampling (CVS). However, some commentators have raised concerns that this perceived 'ease of use' might itself create problems, such as the 'routinisation' of testing and abortion, and increased uptake of testing 'just for information'. The development of NIPT could potentially lead towards screening for other genetic disorders, including clinically less severe abnormalities and late-onset conditions, as well as testing for sex and non-medical traits. This could have a number of implications. First, the expanded scope of testing might hinder the ability of women or couples to make an informed choice by complicating the decision-making process. There would be a greater burden on pre-test counselling to account for the possibility that abnormalities might be revealed that the parents were not sufficiently prepared for. There is also the question of whether there is a 'right not to know', including the right of the future child to choose later whether they wish to know or not (what Joel Feinberg has referred to as a child's 'right to an open future'). Furthermore, there is the issue of storage and updating of information once the child has been born as the interpretation of the data will gradually evolve as time goes on. This raises questions as to who is responsible for this, and when, how and to whom the information should be communicated to if additional insight is obtained in the future. Testing for non-medical or cosmetic traits (e.g. sex determination, or hair and eye colour) is often opposed on the grounds that it would lead to the commodification of children and could result in the trivialisation of abortion decisions. This also raises fundamental questions about our concept of 'normalness'. In medicine, there is an obvious desire to prevent ill-health and disease. However, in striving for this pursuit, there is a risk that a perception of what is normal becomes idealised, and therefore desirable, and any deviation from this norm is stigmatised and rejected.

An important consideration surrounding prenatal testing more generally is the disability rights critique, which argues that any form of prenatal screening involves an implicit value assumption that some conditions give rise to a lower quality of life and that this sends a discriminatory message regarding those living with a disability. Some fear that the widespread practice of NIPT might exacerbate this problem further by substantially reducing the prevalence of a condition. This might subtly alter society's attitudes towards disability, as well as the acceptability of continuing an affected pregnancy. This in turn could have an adverse effect on the support available to affected individuals and their families, and increase stigma surrounding the disorder.

Policy implications

NIPT raises a number of important questions for policy makers. First, there is the question of whether there should be restrictions on what screening should be offered for. For example, should it be limited only to serious congenital and childhood disorders? If so, who would decide what is considered serious enough to warrant screening? This consideration is likely to become even more pertinent as the technology evolves. Secondly, there is the question of who should be offered the test: everyone who wants it or just those considered high risk? Currently in the UK, NIPT is only offered by commercial laboratories. This raises the question of how private enterprises that offer direct-to-consumer testing should be regulated. In particular, how would regulators ensure that adequate information and counselling is being provided to women or couples seeking these services? Finally, there is the issue of the information derived from NIPT being used as a basis for discrimination by secondary users, such as employers or insurers, and how this could be prevented.

Relevant reports

European Society of Human Genetics & American Society of Human Genetics (2014) *NIPT: Challenge of responsible innovation in prenatal screening* [Draft version – Final report not yet published].

Health Council of the Netherlands (2013) [NIPT: dynamics and ethics of prenatal screening](#). Publication no.2013/34.

National Consultative Ethics Committee for Health and Life Sciences (2013) [Ethical issues in connection with the development of foetal genetic testing on maternal blood](#). Opinion no.120.

PHG Foundation (2009) [Cell-free fetal nucleic acids for non-invasive prenatal diagnosis](#). Report of the UK expert working group; and Appendix III: [Ethical, legal and social issues arising from cell-free fetal DNA technologies](#).

Participant-led research

Overview

The recent proliferation in digital technology and online social networks has enabled individuals to become more active in monitoring their own health. This has also facilitated the formation of communities engaged in pursuing health research projects, including self-experimentation, self-surveillance, analyses of genomic data, and genome-wide association studies. [PatientsLikeMe](#), for example, is an online health data sharing platform which enabled patients with ALS who had experimented with lithium carbonate to report their experiences. The results from this analysis, which showed no effect, were later corroborated by a larger clinical trial.

Ethical issues

Any research involving humans must be preceded by a careful assessment of the potential risks and expected benefits to the individuals concerned, as well as the scientific validity of the proposed investigation. The other central consideration is to ensure that informed consent is given where appropriate to ensure that participation is voluntary. However, unlike traditional research, individuals involved in participant-led research (PLR) may potentially be both the researcher and the participant, presenting unique challenges. First, how would the risk-benefit analysis be conducted, and by whom? One option may be to allow the participant-researchers themselves to assess the level of risk involved and determine whether this is acceptable, placing a strong emphasis on the respect for individual autonomy. However, there may be limits to how much risk individuals should be allowed to expose themselves to. Furthermore, patients involved in self-experimentation may conduct a distorted risk assessment leading to unacceptable risk-taking, and they may be subjected to coercion and peer pressure by fellow participant-researchers who are keen to recruit more people. Secondly, how would the consent of participants be ensured in PLR? Is consent even relevant in this context? Some view PLR as self-empowering of patients, and a mechanism by which the wider public can steer priority setting in research by pursuing topics that have been ignored by industry and other major stakeholders. It may also reduce concerns regarding the potential ulterior motives of researchers and the risk of exploitation. However, questions may be raised as to the accuracy and quality of the information that patients receive in PLR, and whether this is sufficient for them to make an informed choice. There is also the issue of the security of personal information shared online and how this equates with the capacity for people to control their own health data to whatever end they see fit.

Policy implications

The practice of PLR raises important questions for policy makers: can it be conducted responsibly, and can it achieve the required scientific rigour? Existing regulatory frameworks and current research ethics review processes will need to be evaluated to determine how suitable they are to the practice of PLR. If not, the challenge for policy makers will be to devise regulations that are applicable in the context of PLR when individuals are potentially both the researcher and the participant. This framework will need to strike a balance between protecting potential participant-researchers and empowering patients who wish to pursue this research. Policy makers will also need to address the question of where liability resides in PLR, and who is responsible should things go wrong. Lastly, there is the problem of how to avoid research protocol violations, such as patients taking off-label medicines when they are supposed to be on the placebo arm, and patients in randomised control trials sharing their side-effects in an attempt to 'unblind' themselves.

Relevant reports

Vayena E & Tasioulas J (2013) Adapting standards: ethical oversight of participant-led health research *PLoS Medicine* **10**(3).

Economist Intelligence Unit (2012) [The patient-led R&D strategy](#).

DoH (2005) [Research Governance Framework for Health and Social Care](#) [2nd Edition].

Social care robots

Overview

Social care robots are one strategy being explored as a way of addressing the ever-increasing cost of providing social care to an aging population. They are also viewed by some as a way of improving the quality of life of older people and enabling them to continue to live independently in their own homes. For example, the [Mobiserv project](#) has designed a 'social companion robot', which aims to support independent living and promote the well-being, nutrition and safety of older people. It is able to prompt a person to exercise, eat and drink, and take their medication, as well as providing control of home lighting and heating. [Toyota](#) has developed robots that assist people with limited mobility, and the [Strands](#) project is developing a robot in conjunction with an Austrian care home provider.

Ethical issues

One of the foremost concerns is that the use of social care robots could lead to less human interaction and social isolation of the elderly. Furthermore, it could be argued that our need for the care of others, such as during childhood, sickness, and old age, moralises us. It highlights our interdependence, and the reciprocity, over time, of our needs. By turning to robots for our care, we risk 'demoralization'; a severing of the ties that bind us. Another issue is whether people would trust the technology. People would need to feel comfortable with the presence of robots in their homes and attending to their needs before the technology could be widely adopted. Some people may feel that the constant presence of a robot leads to a loss of household privacy, whilst others may perceive a robot as less intrusive than another person, especially in potentially embarrassing circumstances. Lastly, the safety of the technology would have to be ensured before it could be introduced into people's homes. This includes the physical harm that might arise from robot malfunction or improper use, as well as the potential for psychological harm caused by issues of attachment or dependency on the technology.

There are also more theoretical concerns that may arise in the future as robots become more advanced. Some people have questioned whether we would need to afford rights to robots if they were ever to develop the potential for robotic autonomy or consciousness. Would we then have a duty to treat them ethically?

Policy implications

An important question for policy makers would be how to take into account the wishes of potential users. For instance, would people be afforded any choice between having a robot or a person as their carer? And what impact would the introduction of social care robots have on the current workforce? Another important consideration is the question of liability. Who is in control and at what point a duty arises? Who is responsible if something goes wrong? This is likely to involve layers of liability, including designers, programmers, medical staff, and potentially even the user. One option might be to use existing legal frameworks for product liability and negligence. However, difficulties arise in the context of sophisticated systems that can evolve in a dynamic manner, building upon interactions with humans and the environment. These evolutionary capabilities cause difficulties in the development of guidelines and principles, as they would need to cover potentially unforeseeable consequences of the design process. Another area for policy makers to be involved would be the confidentiality of any private information that is shared with the robot by the user and how this would be stored. Who would be able to access this information, and in what situations and why?

Relevant reports

Nesta (2014) [Our work here is done: Visions of a robot economy.](#)

Robotics Virtual Organisation (2013) [A Roadmap for US Robotics: From Internet to Robotics.](#)

European Commission (2012) [Public Attitudes Towards Robots.](#) Special Eurobarometer 382 Report.

Suppressing the extra chromosome in Down's syndrome

Overview

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. Trisomy on chromosome 21 causes the clinical features associated with Down's syndrome, including developmental delay, learning difficulties, and a characteristic physical appearance. Individuals with Down's syndrome may also suffer from a number of complications, including immune and endocrine system dysfunction, congenital heart defects, and dementia. However, it is important to note that not all individuals experience these complications and that Down's syndrome exists on a spectrum of severity. Normally, an RNA gene called XIST² silences one of the 2 X chromosomes in female cells in early development. The team mimicked this process by inserting the XIST gene into affected cells in vitro. It is thought that this development could facilitate further research into the condition, and may potentially pave the way for chromosomal therapy of Down's syndrome in the future (although this possibility remains highly speculative at present). Preliminary research is being carried out on mice that aims to silence the Trisomy on chromosome 21 in mouse embryos. Whilst chromosome therapy for humans is not likely to be available for some time, there are a number of ethical and social issues that it raises that warrant analysis.

Ethical issues

One of the key ethical issues of silencing the extra copy of chromosome 21 is whether or not this is in fact desirable. With social and educational support, individuals with Down's syndrome can lead meaningful and fulfilling lives. There are criticisms of the medical model of disability which focuses on curing or fixing disability and impairment; as opposed to a social model which aims to facilitate and support individuals in their day to day lives. Disability can also form part of an individual's identity and ideas about personhood. There are also issues concerning prenatal chromosome therapy in general, such as reducing genetic and social diversity, and making decisions on behalf of future persons whose wishes are unknown.

In favour of chromosomal therapy are arguments that such treatments have the potential to improve the quality of life of individuals with Down's. From a rights-based perspective, for example, it could be argued that if such treatments are available, people have a right to benefit from them. Parents in particular may feel that they have a duty to reduce 'genetic harm' to their offspring. This raises the question of what constitutes genetic harm; many children are born with genetic abnormalities and anomalies, or are subject to damage in utero. The question of degree and 'severity' of genetic damage is contested. Some fear that prenatal genetic manipulation could be used to screen out undesirable traits for eugenic purposes, whilst others argue that this is already being done to a certain extent through terminations based on foetal anomaly screening programs (in the UK, 91% of women who receive an antenatal diagnosis of Down's terminate the pregnancy).³ If made available, chromosomal therapy may further perpetuate the idea that a life with Down's syndrome is worth less than a 'normal' life; and could lead to increased stigma and discrimination towards those with the condition.

Policy implications

Chromosomal therapy is a very novel concept; it is still in the experimental stage and may not be available to patients for many years (if at all). However, considering that the research is currently being conducted, it may be prudent for policy makers to begin considering the future implications now should this therapy ever be realised. One of the key questions is whether chromosomal therapy should be made available, and the social and ethical ramifications of doing so. This research has the potential to produce a number of developments, from an enhanced ability to study the genetic factors involved in Down's syndrome to potential treatments for the complications of the syndrome, to possibly even the 'treatment' of the syndrome itself. Each of these may involve different issues and so may require individual analysis. Furthermore, this research is likely to have implications for other chromosomal and genetic disorders aside from Down's syndrome.

Relevant reports

Jiang J, Jing Y, Cost G, et al. (2013) Translating dosage compensation to trisomy 21 *Nature* **500**: 296-300.

Malek J (2010) Deciding against disability: does the use of reproductive genetic technologies express disvalue for people with disabilities? *Journal of Medical Ethics* **36**: 217-21.

Reynolds TM (2003) Down's syndrome screening is unethical: views of today's research ethics committees *Journal of Clinical Pathology* **56(4)**: 268-70.

² 'XIST': X-inactive specific transcript; which is an RNA gene on the X chromosome.

³ Morris JK and Springett A (2013) [The national Down's syndrome cytogenetic register for England and Wales: 2011 annual report](#).

Targets for diagnosis

Overview

The setting of targets within healthcare is viewed by some as an effective way of raising clinical standards. The national [Quality and Outcomes Framework](#) (QOF), for example, financially rewards general practices for meeting certain clinical indicators. In the past, these targets have largely been concerned with optimising a patient's management once they have received a diagnosis. However, in 2012, the UK government set a target to improve dementia diagnosis rates to two-thirds by 2015 based on prevalence estimates. Part of this initiative has involved offering financial rewards to GPs for assessing patients at risk of dementia. Furthermore, NHS England has recently implemented the [Dementia Identification Scheme](#), which will pay GPs £55 for every person diagnosed with dementia until March 2015 (although it is currently doubtful that this scheme will be continued past this). This policy has raised wider questions regarding the practice of setting targets for diagnosis rates.

Ethical issues

A major concern with the proposal to financially reward doctors for making a diagnosis is that it risks undermining the trust that is essential for the doctor-patient relationship. Receiving a diagnosis can have a huge impact on a person's life. Normally, this decision is based on clinical need, and is viewed as being in accord with the patient's interests because it facilitates further investigation and treatment for a problem that the patient has presented with. However, any financial incentive to make a diagnosis may influence a doctor's decision-making. This potential conflict of interests could result in the loss of confidence among patients that their doctor is acting in their best interests.

There are many benefits to receiving a timely diagnosis. It can lead to better understanding for patients and their families, empower people to make their own choices, facilitate access to support services, and enable advance care planning. For this reason, some take the view that any measure aimed at reducing the time before someone receives a diagnosis should be welcomed, particularly for conditions where the percentage of people diagnosed with the disorder is felt to be very low. However, these benefits must be balanced against the potential harms of promoting more diagnoses, such as the unnecessary distress from an incorrect diagnosis, or the stigmatization that is attached to certain conditions. Not everyone may agree that the potential benefits outweigh the harms. A further crucial issue is whether the healthcare service infrastructure in place is able to cope with a dramatic increase in the number of people being diagnosed with a disorder and the potential treatment options available to them.

Policy implications

An important question for policy makers is whether the making of a diagnosis should be considered differently from other areas of healthcare provision which are already subject to targets and financial incentives. If so, what other strategies could be adopted to improve diagnosis rates? Diagnoses can also result from screening programmes. These initiatives are first evaluated by the UK National Screening Committee (UK NSC) according to a number of [criteria](#) before being implemented. It has been suggested that the practice of using targets for diagnosis is a form of screening, but without being subject to the same requirements (the UK NSC concluded in 2009 that screening for dementia should not be offered, although this is currently under [review](#)). This raises the question as to whether targets for diagnosis should be subjected to a similar standard of criteria as for screening.

Relevant reports

Brunet M, '[Targets for dementia diagnoses will lead to overdiagnosis](#)' (2014) *BMJ* 348, p.2224.

All-Party Parliamentary Group on Dementia (2014) [Building on the National Dementia Strategy: Change, progress and priorities](#). APPG Report.

Department of Health (2012) [Prime Minister's challenge on dementia](#) – *Delivering major improvements in dementia care and research by 2015*.

Wearable health monitoring technologies

Overview

Wearable health monitoring technologies incorporate a range of devices that enable care provision to take place outside of traditional healthcare settings. For example, a number of companies are developing 'smart clothes', which will be able to measure a range of physiological signs. In 2010, [researchers](#) at the University of California developed underwear that allow the continuous monitoring of soldiers' vital signs, and [OMsignal](#) is currently marketing shirts that record heart rate and respiration rate. Predicting health problems before they happen is viewed as an important potential application of this technology. The EU is funding an international smart clothing research project called [MyHeart](#), which aims to help prevent heart disease, and a company called [Footfalls and Heartbeats](#) is working with the University of Nottingham to develop smart socks that could assist in predicting the onset of diabetic foot ulcers by measuring blood flow.

Ethical issues

There are a number of ethical issues that could arise with the development of wearable health monitoring technologies. First, there is the issue of trust. Before these technologies could be widely adopted in the context of healthcare, both medical professionals and patients would have to trust that the device is safe to use and is able to accurately report a person's vital signs. It has been suggested that the use of personal monitoring devices could be useful in the care of older people and enable more individuals to remain independent at home. However, some have raised concerns that this could inadvertently lead to social isolation of already vulnerable members of society because carers and medical personnel may feel that it allows them to visit less frequently. Furthermore, constant monitoring in the home could lead to the 'medicalisation' of the home environment, and promote the perception among users that they are frail or unwell.

Wearable health monitoring technologies have the potential to become personalised to the user, and could even be designed to provide behaviour-modulating feedback. For example, [one company](#) is developing smart clothes that aim to help prevent falls via targeted early alerts to encourage a change in behaviour. Devices could also be designed to prompt users to make healthier choices about diet and exercise. This potential ability to alter habits and behaviours raises questions about how permissible it is for this technology to influence our lives. Furthermore, health monitoring technologies that automatically alert medical staff in the case of an emergency may take the decision of whether to call for help or not out of the hands of the user, resulting in a loss of self-determination. It may lead to a perception of reduced responsibility amongst users for their own health if they believe that the device will alert someone else if something is wrong.

Concerns have also been raised about the issue of data privacy and the risk that any information collected could be misused if adequate controls are not in place. For example, insurance companies or employers may wish to acquire the information to monitor people in their daily activities and require them to act in certain ways that will benefit their health.

Policy implications

A key question for policy makers will be how to adequately protect potential users of the technology. First, there is the question of data privacy and how to ensure that any personal information recorded is protected from misuse by third parties. Currently in the UK, the [Data Protection Act 1998](#) governs how personal data is to be lawfully processed, although the European Council and Parliament are currently debating [proposals](#) for the reform of data protection legislation. Secondly, there is the issue of how to protect users from undue influence from companies who may seek to alter a person's behaviour for commercial gain. Furthermore, would patients in the UK be offered a choice between wearable health monitoring devices or more traditional follow-up with a medical professional if the former is deemed to be more cost-effective? Policy makers will also need to decide where liability would lie if an intervention (or lack of intervention) is based upon inaccurate reporting from a device.

Relevant reports

Mittelstadt B et al (2014) The Ethical Issues of Personal Health Monitoring *International Journal of Technoethics* 5: 37-60.

Cross-cutting themes

Council might also like to consider the possibility of working on one of a number of broader cross-cutting bioethical themes. Suggestions put to Council include:

- **Justice.** A report on justice might use a 'case-study' approach, looking for example at distribution between rich and poor countries, or within the UK healthcare system; another approach might focus on intergenerational justice. Is justice best understood as a 'virtue'?
- **Autonomy:** could include changing models in decision-making such as more 'relational' approaches to autonomy.
- What is meant by '**normalness**'? (potentially to be reviewed as part of the cosmetic procedures project; alternatively might include consideration of sex/gender and intersex individuals)
- **Dignity:** and how the term is understood in different settings or legal systems (potentially could include issue of existence in MCS).
- Further **neuroscience** studies: e.g. human identity, what is 'normal' behaviour, addiction, neuropsychology.
- **Privacy**
- **Influences of different voices** in the bioethics policy area: for example how faith groups contribute to debates on bioethics.