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Chapter 2 Bioethics

Human genetic and biomedical research ethics at UNESCO and beyond

> Every scientific revolution brings with it a host of ethical and social questions. The so-called genetics revolution is no exception, giving rise to a broad international debate on how the undoubted benefits of progress in this area can be reconciled with certain core human values.
>
> (UNESCO 2002a: 1)

Bioethics

Bioethics as a field has evolved from two separate disciplines: medical ethics and moral philosophy. Concern for ethics in terms of patient welfare first appeared in the form of the Hippocratic oath, while moral philosophers have come to reflect on dilemmas faced by modern society alongside more abstract meta-ethics (Harris 2001: 1–2). Bioethics is now seen to cover a wide range of issues, including genetics, reproductive technologies and biomedical research. John Harris (ibid: 4) gives a succinct definition in his introduction to *Bioethics*, part of the *Oxford Readings in Philosophy* series: 'In short, bioethics investigates ethical issues arising in the life sciences (medicine, health care, genetics, biology, research, etc) by applying the principles and methods of moral philosophy to these problems.'

At international level, research ethics were first laid down in regulatory form in 1947, in the Nuremberg Code. This codification was a response to the human rights abuses that had taken place through experimentation on human subjects under the Nazi regime of World War II and enshrined a key principle in bioethics, that of informed consent: a person agreeing to take part in research should do so voluntarily and with sufficient knowledge and understanding of what is involved (Fluss 2004: 596–7; National Institutes of Health 2009). The Code also encompasses what have come to be known as the 'four principles' or 'Georgetown principles', formulated by philosophers Tom Beauchamp and James Childress in the 1970s, namely respect for autonomy, non-maleficence, beneficence and justice. Although contested, these principles provide a normative framework that is widely used by researchers and medical practitioners (Beauchamp 2001: 479–80; Holm 2001: 494–5).

There have been several further attempts to codify good research practice, to ensure, as far as possible, that the rights of those who take part in research are protected. In 1964, the World Medical Association produced the *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, which reflects the four principles. Updated regularly, most recently in 2008, this is generally considered the foremost document globally on medical research ethics (Carlson *et al*. 2004: 695; World Medical Association 2008). The 2008 version presents a significant change in that it binds physicians to its provisions above all other international and national ethical, legal and regulatory requirements (the 2000 version set itself above only national obligations) (Rid and Schmidt 2010: 143 and 145). The Council for International Organizations of Medical Sciences' *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS 2002) are intended to complement the Helsinki declaration. They give guidance on how its principles can be applied, particularly in developing countries. At other levels, many countries and research institutions have their own legal or regulatory instruments on bioethics, albeit usually based to a large extent on one or more of the international documents. The UNESCO declarations are the latest additions to this array.

Governance issues in bioethics

One of the main requirements of these various instruments will usually be that proposed research projects should be reviewed by a research ethics committee (REC). To ensure that a research project will be conducted ethically, RECs must determine whether the procedures for obtaining informed consent and the predicted risk/benefit ratio will be conducive to the protection of research participants, in terms of privacy, confidentiality, autonomy and safety (Benatar 2002b: 1134). How such concerns should be met has warranted renewed reflection in recent years, in the context of the growing frequency of research projects involving more than one country, including developing ones. The need to build capacity for ethical review in developing countries has also been noted. The extension of biomedical research beyond national borders renders international standards on bioethics necessary, so that research participants are

treated equally and fairly, whichever country they are in (Gevers 2001: 293; Benatar 2002b: 1135; Berlinguer 2004: 1087; Isasi and Knoppers 2006: 24).

Since these universal norms are likely to be realized in different cultures, it is important that their application be contextualized (Ateudjieu *et al*. 2010: 95). The Nuffield Council on Bioethics (2002: 51), an independent body based in the United Kingdom (UK), highlights the difficulties that ensue if sponsors fail to familiarize themselves with the cultural traditions of the countries in which they fund research. Solomon Benatar and Peter Singer (2000: 826) recommend that international researchers should be sensitive to local social, economic and political contexts, while Zulfiqar Bhutta (2002: 116) suggests that communities should be involved in decision-making about research to be conducted in their locales.

Elsewhere, Benatar (2004: 576) stipulates that contextualization should only go so far: 'respect for democracy should take precedence over the preservation of cultural traditions that undermine democracy and human rights'. Other ethicists would disagree, believing the idea that universal norms exist at all to be erroneous. 'Agreement at the level of general norms has no inherent practical significance since it is possible to derive markedly divergent policies and practices from the "same" principle, maxim, or moral intuition', writes Leigh Turner (2003: 195). He argues that historical and anthropological evidence for a common morality (including the notion of universal human rights) is scarce (ibid: 194 and 197). Similarly, modern bioethics has been criticized for deeming universal what some consider to be merely Western notions of ethics (Benatar 2004: 575).

Ruth Macklin (2003: 475) highlights the need for effective oversight of research: 'If a country lacks a mechanism for identifying and sanctioning researchers who violate laws, regulations, or fundamental ethical standards in carrying out the research, then all research subjects are potentially vulnerable.' Singer and Benatar (2001: 747), in an article on the World Medical Association's *Declaration of Helsinki* (the 2000 version), contend that building capacity in research ethics will have far more impact on ethical standards than 'revisions of this or any other research ethics code'. Similarly, Bhutta (2002: 117–18) argues that strengthening local capacity in bioethics is key to promoting ethical health research in developing countries. Benatar (2002b: 1136–8) also stresses the need for research to be effectively monitored once it has been approved. He and Christopher Vaughan (2008: 439) cite lack of resources and expertise as the two main barriers to effective ethical oversight in Africa. Several studies conducted over the last decade on African RECs and national bioethics committees bear this out (Kirigia *et al*. 2005; Kass *et al*. 2007: 28; Nyika *et al*. 2009: 189; Rwabihama *et al*. 2010: 248; Ijsselmuiden *et al*. 2012: 1).

Capacity within RECs is not the only issue. Joses Kirigia *et al*. (2005), Sylvester Chima (2006: 849), Nancy Kass *et al*. (2007: 29) and Jean-Paul Rwabihama *et al*. (2010: 248) all found that committees need national as well as international level guidelines and policies to steer them, which do not always exist in developing countries. In the context of genomics research, Dave Chokshi and Dominic Kwiatkowski (2005: 12) link the need for local capacity with the need to contextualize universal principles: 'Improving local capacity in bioethics in developing countries is essential to ensure that the philosophical principles of genomics ethics are informed by a practical understanding of what will work at the local level.' With regard to developing capacity for research itself, as well as its review, Bhutta (2002: 114) suggests that developing countries should be enabled to carry out research relevant to their needs. Petros Isaakidis *et al*. (2002: 4) assert that local researchers should play a substantial role in defining what these needs are, rather than have research priorities dictated to them by the global North. Kirigia and Wambebe (2006), in a review of health research policy in 10 African countries, recommended that governments should develop strategic plans for health research, in collaboration with stakeholders from the public and private sectors.

Medical research is largely market driven, to the detriment of those in poor parts of the world where infectious diseases are rife. Debates in research ethics thus spill over from micro level regulatory concerns to the broader issue of how inequalities of health between North and South should be addressed. Bhutta (2002: 118) deems these 'vital components of the same equation', as does Benatar (2001: 337): 'Medical research, health care, conditions of life around the world and how humans flourish may seem separate, but they are all interdependent. Taking such a comprehensive global perspective adds complexity to the task of crafting universal research ethics guidelines.' In 2000, in what was considered a radical article in the *British Medical Journal (BMJ)*, Benatar and Singer advocated 'a new, proactive research ethics', aimed at addressing the global health inequities they see as being the greatest ethical challenge (Benatar and Singer 2000: 826). Writing in *The Lancet* a few years later, Harold Varmus (2002: s4), former director of the National Institutes of Health (NIH) in the United States (US), expressed a similar view.

Like many commentators, Benatar and Singer (2000: 824) referred to the '10/90 gap': in 1990, approximately 90 per cent of annual health research funding was concentrated on only 10 per cent of the global disease burden. Similarly, a

well-known study by Médecins Sans Frontières and the Drugs for Neglected Diseases Initiative showed that of the 1,556 drugs marketed between 1975 and 2004, only 21 are for diseases mainly affecting the global South (Chirac and Torreele 2006: 1560). The figures have changed significantly for the better in the last 20 years, through the efforts of, *inter alia*, the World Health Organization (WHO), The Wellcome Trust, NIH, the European Union and the Bill and Melinda Gates Foundation, but the 'gap'remains symbolic (Benatar and Singer 2010: 194; Global Forum for Health Research 2011; Ijsselmuiden 2012: 74). In a follow-up to their *BMJ* paper, Benatar and Singer (2010: 195) acknowledged the improvements, but maintained that 'the global medical research agenda remains skewed away from the needs of poor people'.

While those in developing countries have, until recently, seen relatively little benefit from medical research, they may well have participated in it. Factors including open access to patients, lower costs and fewer regulations conspired to produce what Benatar has termed a 'research sweat shop' (Benatar 2001: 337; Emanuel *et al*. 2004: 930). Some people in countries with poor healthcare provision may have become research participants in order to receive treatment to which they would not normally have had access (Nuffield Council on Bioethics 2002: 4). Giovanni Berlinguer (2004: 1087) has thus warned against medical research becoming a new form of exploitation. But if research in developing countries was to stop, for fear of abusing vulnerable populations, even fewer resources would be devoted to addressing their health concerns than is currently the case (Macklin 2003: 478; Clarke and Egan 2008: 44). The challenge is to develop means by which ethical research in developing countries can continue and grow.

Benatar and Singer (2000: 826), in their *BMJ* article, suggested as criteria that any proposed research should be relevant to the host country and likely to be of long-term benefit. In the 2010 follow-up they called for intensified efforts to ensure that research promotes social justice, through improved research capacity and healthcare in poor countries (Benatar and Singer 2010: 194–6). 'Benefit sharing' agreements, by which funders and researchers commit to sharing any gains from scientific or technological research with participants or the wider community, whether directly in terms of profit or product or indirectly through capacity building and healthcare provision, may be one way to achieve this (UNESCO 2005s: article 5). Berlinguer (2004: 1088) summarizes the need for such measures as follows: 'Benefit-sharing and equal access to advances in biomedical science are now urgent and *universal* issues' [italics added].

Genetics and genomics

The term 'genomics' derives from the word 'genome'. A genome is the sum total of all the DNA (deoxyribonucleic acid) in any given individual or organism. DNA is made partly from four chemicals or bases, adenine, guanine, cytosine and thymine (abbreviated to A, G, C and T), which are sequenced in pairs along a genome. The human genome, for example, contains around 3 billion base pairs (Metcalfe *et al*. 2001: 71; US Department of Energy Office of Science 2011). Humans have approximately 99.9 per cent of their genome in common with each other, with differences in the remaining 0.1 per cent being responsible for genetic variation between individuals (Schmidt 2001: A26).

Genes are particular sequences of DNA within the genome that determine certain characteristics of an organism, such as eye colour and contribute to others, such as health and behaviour (Metcalfe *et al*. 2001: 8). There are just over 20,000 genes within the human genome, accounting for less than 2 per cent of the genome's DNA (Richards and Hawley 2011: 421 and 427). Some of the residual DNA supports genes by, for example, activating them at the correct time (Metcalfe *et al*. 2001: 105–6). Geneticists have now discovered 'some sort of function' for around 80 per cent of the genome, but there is much still to learn (Maher 2012: 46).

Geneticists can determine the order in which base pairs appear in a genome through a process called DNA sequencing. The end result is a 'map' of where each gene is positioned, as well as the supporting and non-functioning DNA. The most famous example of DNA sequencing is the Human Genome Project, which published drafts and a completed version of the human genome sequence in 2000, 2003 and 2006 respectively (US Department of Energy Office of Science 2006).

Some are keen to draw a clear distinction between genomics and genetics, as follows:

> Genomics is the comprehensive examination of an organism's entire set of genes and their interactions (as distinct from genetics, which is the study of a single gene or a small number of genes to determine specific gene roles in diseases or physical characteristics of an individual).

(Smith *et al*. 2004: 385)

Since, however, a genome contains genes (as well as the other types of DNA) the terms are often used somewhat interchangeably. In 2004, for example, the World Health Assembly, the decision-making body of the WHO, adopted by resolution WHA57.13 the following definition: 'genomics is the study of genes and their functions, and related techniques' (WHO 2004: 21). Similarly, the Human Genome Organisation describes itself as 'the international organization of scientists involved in human genetics' (HUGO 2012). For the sake of simplicity, this book henceforth uses 'genetics' as a collective term for both genetics and genomics.

Genetics in developing countries

Genetics has the potential to transform health and healthcare, in both developed and developing countries. As knowledge of both the nature and functions of the human genome increases, genetic influences on human disease patterns will be identified (Giallourakis *et al*. 2005: 399). While the principal cause of many diseases may be environmental, a growing pool of molecular data has led to the belief that there is a genetic component to almost all human diseases. A decade ago Kwiatkowski (2002: 1) predicted,

> For example, genetic variation may partly explain why one child develops fatal cerebral malaria, or kwashiorkor, while other children living in the same compound are equally exposed to malaria parasites and to poor diet but do not develop these severe clinical syndromes. A huge amount of scientific effort is now being put into investigating the many different genetic factors that influence susceptibility to common diseases, in the hope that this will provide fundamental insights into molecular pathogenesis and ultimately lead to better methods of disease prevention.

Infectious diseases such as malaria, HIV/AIDS and tuberculosis may involve several hundred genes, interacting both with each other and environmental risk factors. Genome-wide research enables the study of these complex diseases, affording valuable information concerning the molecular and cellular basis of disease in the search for effective vaccines and treatments (ibid; Kwiatkowski 2000: 1062).

Benatar (2002a) questions whether biotechnology will really help the poor, if drugs that have already been developed have not been made available to the very many people in the global South that need them. With Gopal Sreenivasan, he advocates a more holistic approach, predicting that scientific advances in biotechnology will have little impact if broad disparities in wealth and health are not addressed with equal enthusiasm (Sreenivasan and Benatar 2006: 3). This was also the finding of a 2002 WHO report entitled *Genomics and World Health*. The report, which received considerable attention worldwide,[1] stated that 'the science of genomics holds tremendous potential for improving health globally', but stressed the importance of 'fundamental overarching strategies to improve health', such as poverty alleviation, health systems development and education, alongside genetic science (WHO 2002: 3). Thus the value of any investment in genetics must be assessed relative to current approaches to healthcare and medical research, such that these more conventional mechanisms are not neglected (WHO 2003: 1–2).

The report also cautioned that it would take time for the possible health benefits of genetic research to come to fruition and that, because these are likely to be expensive, they have the potential to increase disparities in health. This was all the more concerning because most developing countries did not have 'either the technological capacity or skill base to reap the potential benefits of genomics research and apply them to their health care needs'. Hence the report recommended that developing countries should develop clinical genetic services, which would be the simplest means of building the necessary capacity, as they use well-established DNA technologies. These services would also enable early intervention to control hereditary diseases such as sickle-cell anaemia, which is particularly prevalent in sub-Saharan Africa (WHO 2002: foreword, 6, 83, 187 and 189). A 2010 WHO consultation on community genetics in low and middle income countries found that provision is still inadequate (WHO 2010: iv).

Like the WHO report, bioethicists Abdallah Daar and Singer have warned that biotechnology could widen the gap between rich and poor. In a 2001 article in *Science*, they campaigned for an increase in investment, infrastructure and expertise to enable developing countries to capitalize on the promise of biotechnology and thus prevent a 'genomics divide' (Singer and Daar 2001: 87). Although the number of studies on non-Western populations (particularly African ones) is still comparably low, the last decade has seen an increased interest in genomics in developing countries (Hardy *et al*. 2008b: S23; Séguin *et al*. 2008: 487; de Vries and Pepper 2012: 474). The African Ministerial Council on Science and Technology (AMCOST), established in November 2003 to coordinate and implement the science and

technology programmes of NEPAD (the New Partnership for Africa's Development) and the African Union, under *Africa's Science and Technology Consolidated Plan of Action*, sees great potential in genetics (and the life sciences in general) to fight diseases such as malaria and contribute to poverty reduction and economic growth (NEPAD 2005).

AMCOST has also identified factors that could constrain the development potential of genetics and biotechnology, including insufficient scientific and technical capacity, infrastructure and funding. To address these, NEPAD established the African Biosciences Initiative in 2005, consisting of four regional networks of centres of excellence (NEPAD 2005; NEPAD Office of Science and Technology 2005: 7–9 and 2006: 5–6). In August 2007, a High-Level African Panel on Modern Biotechnology (set up, like AMCOST, under the auspices of the African Union and NEPAD) suggested that each African region should specialize in a particular area of biotechnology through 'long-term "biotechnology missions"', reflecting existing expertise. Southern Africa could thus focus on health biotechnology and East Africa on livestock (Juma and Serageldin 2007: iii and xvii).

The most prominent programme on human genetics in Africa is the Human Heredity and Health in Africa Initiative (H3Africa), sponsored by The Wellcome Trust and NIH (de Vries and Pepper 2012: 475). This grew out of a proposal for an African Genome Project at the 2007 meeting of the African Society of Human Genetics (Newport and Rotimi 2009: 251). The initiative has a budget of USD 70 million for 2012–19 and aims to 'catalyse' genomics research in Africa, through investment in infrastructure, training, research projects and clinical services, in existing institutions and new centres of excellence. Collaborative networking will also be key. The ultimate goal is to improve health, by increasing understanding of the genetic and social determinants of communicable and non-communicable diseases common in Africa (H3Africa 2011; H3Africa Working Group 2011: 1–2).

Why genetics needs governance

Human genetic research, like biomedical research in general, stretches beyond national borders: 'An orders-of-magnitude increase in scale of genetic data collection has created the need for establishing diffuse international partnerships, sometimes across developed- and developing-world countries, with ramifications for assigning research ownership, distributing intellectual property rights, and encouraging capacity-building' (Chokshi and Kwiatkowski 2005: 1). While genetics holds great promise, then, it also carries new ethical dilemmas, concerning both individuals and communities, which require international governance. Governance at national level may also be an issue. The WHO report *Genomics and World Health* found that many developing countries did not have regulatory, ethical or policy frameworks in place to deal with genetics (WHO 2002: 187–8).

One general concern in genetics is to balance freedom of research with individual rights. Anne-Marie Duguet (2001: 203) expresses this concern thus:

> An acknowledged principle in our democratic societies, freedom in research, is viewed as inherent to freedom of thinking and it is therefore accepted that its finalities be unrestricted. However, genetic research explores a very sensible domain. Indeed, what is under investigation is a person's intimate inheritance, origins, future and progeny.

Fears of discrimination on the basis of the information their genome contains may render some people reluctant to participate in genetic research. Thus confidentiality must be protected (Reilly 2000: 489; Anderlik and Rothstein 2001: 404–5). A complicating factor is that, while each person's genome is unique, it also carries information about their families (and possibly communities) (Knoppers 2002: 86). This has consequences for how far someone's right to autonomy should allow them to control personal genetic information (Laurie 2001: 1).

Other issues requiring guidance include the transfer of samples and data across national borders and the ensuing implications for ownership, particularly given the increase in international research projects. This affects developing countries disproportionately, as they have less capacity for in-house analysis. Standardization of procedures would enable both better protection of individual rights and further transnational research cooperation (Godard *et al*. 2003: S104). One trailblazer is the MalariaGEN project, a network of malaria researchers across 21 countries. The project has set up rigorous materials transfers agreements between partners, as well as training for young researchers from all sites and the development of software enabling data analysis from anywhere in the world, without the need for expensive infrastructure (Parker *et al*. 2009: e1000143; de Vries *et al*. 2011).

Chokshi and Kwiatkowski (2005: 1) capture a major dilemma in genetic research with the question, 'What is the structure of an equitable and fair system for distributing the financial and scientific rewards of research?' Some

scientists are concerned that the patenting of gene sequences, including human ones, could be detrimental to both scientific advancement and healthcare provision (Andrews 2002: 803). Researchers may be reluctant to share findings for fear of precluding possible patents, while the cost of licence fees for gene-based products could render some treatments unaffordable. Others argue that, without the legal protection of intellectual property, there will be little incentive for companies to invest in research (Schmidt 2001: A29). The human genome itself is in the public domain, but data on the products derived from the information therein may not be. Richard Dahl (2001: A32) writes, 'the mapping of the human genome opens huge potential markets for pharmaceutical and biotechnologic product developments, which take time and money. The question is, how much patent protection should those efforts enjoy?'

Some are concerned with the idea of gene sequencing at a more fundamental level. Eike-Henner Kluge argues that the patenting of human genes is 'ethically indefensible and amounts to an unjustified appropriation of a general human heritage' (Kluge 2003: 119). The characterization of the human genome as the 'common heritage of humanity' (HUGO Ethics Committee: 2002) promotes the idea of benefit sharing (Knoppers and Chadwick 2005: 77). Who exactly deserves to benefit is complicated, however, given that several parties will have contributed to the process of deriving a gene-based health product, from those who have given genetic samples, through to those who take it to market. Chokshi and Kwiatkowski (2005: 10–11) give the following example:

> It is … unclear who deserves to gain financially from, for instance, the discovery of a novel anti-malarial molecule from studies of national genetic diversity. Any of at least five groups can make a claim: the subjects themselves, the health professionals who diagnosed and treated them, the epidemiologists who managed the study, the geneticists who produced the result, and the company that makes the end product. As Chadwick and Berg have pointed out, while our moral intuitions may sympathize most with the subjects' claim, it is the scientists who have actually made the subjects' samples 'valuable'.

They thus advocate a broad approach to benefit sharing in genetics:

> If we assert first that the reference human genome sequence belongs to mankind and second that, given the positive-externality effects of vaccines and therapies for infectious diseases, research is of potential benefit to all, it follows that the aims of benefit-sharing should shift from purely local interests to broader interests.
>
> (Chokshi and Kwiatkowski 2005: 11)

Between 2001 and 2006, Daar and Singer, with colleagues at the Toronto Joint Centre for Bioethics, promoted the idea of a global governance mechanism to ensure the benefits of genomics are enjoyed equitably. This was to sit outside the traditional intergovernmental structures of the UN, which were seen to be too slow-moving to keep pace with genomic innovation. The proposals went through various iterations, from a commission on genomics and global health, to a network-based Global Genomics Initiative. The idea was to bring together stakeholders from various sectors – industry, academia, governments and civil society – to promote global dialogue, collaboration and norm-setting (Singer and Daar 2001; Acharya *et al*. 2004a and 2004b; Dowdeswell *et al*. 2003, 2005 and 2006). Although the initiative never formally took off, Daar, Singer and colleagues (now at the Sandra Rotman Centre for innovation in global health at Toronto) continue to publish widely on ways to promote science and technology, including genomics, for development. Ruha Benjamin (2009: 346) credits the Centre with establishing the field of public health genomics, stating, 'Through tremendous visibility and strategic collaboration, this relatively small group of health policy entrepreneurs is playing a principal role in the growing political will among governments to sponsor genomic initiatives and implement genomic sovereignty legislation' (that is, legislation to protect the DNA of their populations).

The UNESCO Bioethics Programme

UNESCO (the United Nations Educational, Scientific and Cultural Organization) is a long-standing agency of the United Nations, comprising 195 member states. It was founded in 1945, aiming to 'build peace in the minds of men' through education, science, culture and communication. Its remit has now expanded to include poverty eradication, sustainable development and intercultural dialogue, in line with the Millennium Development Goals. It has a mandate to advise member states on developing national capacities (UNESCO 2007f; UNESCO 2011e). UNESCO 'functions as a laboratory of ideas and a standard-setter to forge universal agreements on emerging ethical issues' (UNESCO 2011q). The ethics of science and technology is a priority within Social and Human Sciences, one of UNESCO's five

specialized sectors. UNESCO aims to consolidate the universal values of justice, freedom and dignity, while acknowledging pluralism: 'scientific and technological progress must be placed in a context of ethical reflection rooted in the cultural, legal, philosophical and religious heritage of all our communities' (UNESCO 2012j).

The UNESCO Bioethics Programme,[2] part of the Division of Ethics and Global Change, began in 1993 with the formation of the International Bioethics Committee (IBC). Then Director-General of UNESCO, Federico Mayor, decided that the organization should set up this committee so that it could 'reply to the main ethical preoccupations raised by advances in the life sciences' (UNESCO 1994). An Intergovernmental Bioethics Committee (IGBC) followed in 1999. Each committee has 36 members, the former made up of independent experts and the latter of representatives from selected member states (UNESCO 2012b). UNESCO also provides the secretariat for the UN Inter-Agency Committee on Bioethics, established in 2001 (UNESCO 2011a). Beyond UNESCO Headquarters in Paris, many of UNESCO's activities are administered through National Commissions in each member state (UNESCO 2004m: 6).

One of UNESCO's key activities is the setting of international standards, on which member states can subsequently draw to establish regulatory or legal frameworks at national level. Koïchiro Matsuura, Director-General of UNESCO from 1999 to 2009, expressed the need for standards within science and technology in terms of transnational practices and benefit sharing:

> Present-day scientific practices cross national borders. Hence the imperative need to take action together at the international level – not to erect barriers against these practices, but to provide the necessary oversight so that the benefits of science may be enjoyed by all humanity. …
>
> (UNESCO 2004n: 10)

UNESCO sees itself as particularly well-suited to standard setting in bioethics, as the only UN organization with competencies in both human and social sciences (ten Have 2005: 745; UNESCO 2012k). Publications, speech transcripts and the UNESCO website all emphasize its unique or leading role in this field. As science and technology advance, its 'ethical watch mandate' becomes more and more pertinent (UNESCO 2012b).

The UNESCO declarations

In recent years UNESCO has produced a series of declarations on bioethics and genetics: the 1997 *Universal Declaration on the Human Genome and Human Rights* (UDHGHR), the 2003 *International Declaration on Human Genetic Data* (IDHGD) and the 2005 *Universal Declaration on Bioethics and Human Rights* (UDBHR). These declarations have stemmed from the tremendous increase in the profile of genetics and the extension of biomedical research beyond national borders. The three declarations are to be 'treated integrally'; indeed, there is much common ground between them (UNESCO 2005a: 3). As a set, they prescribe how human genetic and biomedical research can be conducted ethically and encourage capacity building and knowledge sharing in science and ethics, particularly between North and South.

The IBC's first task was to prepare an international instrument on the human genome (the eventual UDHGHR). It appointed a Legal Commission to propose what form and substance the instrument should take, which met regularly between April 1994 and December 1996. An international consultation was launched in May 1995. After receiving a progress report in November 1995, the twenty-eighth UNESCO General Conference requested that a draft declaration be developed, to be finalized by a committee of government experts appointed by member states (as per established protocol within the UN). The resultant draft was adopted 'unanimously and by acclamation' at the twenty-ninth General Conference, in November 1997. A year later the UDHGHR was endorsed by the UN General Assembly (UNESCO 1999a: IV, 1–2 and 67).

The UDHGHR was adopted in order to facilitate a balance between progress in genetics and protection of human rights. The preamble states:

> The General Conference, … recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasizing that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics, proclaims the principles that follow and adopts the present Declaration.

(UNESCO 1997)

Although the declaration covers human genetic data in a general sense, it was felt that their collection, processing, storage and use needed to be addressed more specifically and as a matter of urgency. Growth in the number of human genetic databases and international research programmes, increasing private sector involvement and the need to protect vulnerable populations were all contributing factors to this decision. The IBC had already produced two reports on this subject when the Director-General requested in May 2001 that it look into drafting an international instrument thereupon. The thirty-first General Conference endorsed the initiative the following November and the IBC duly set up a drafting group. After widespread written and verbal consultations and further scrutiny by various UNESCO bodies – the IBC, the Executive Board (elected by the biennial General Conference and constituting 58 member states), an intergovernmental meeting of experts and a working group – the draft IDHGD was adopted 'unanimously and by acclamation' on 16 October 2003, at the thirty-second General Conference, as 'an extension of and means of implementing' the UDHGHR (UNESCO 2000a; UNESCO 2002a; UNESCO 2003c: 1 and 3; UNESCO 2012i).

In 2001 the General Conference had invited the Director-General to look into the possibility of elaborating a universal instrument on bioethics. On the basis of the IBC's subsequent report, the 2003 General Conference declared the setting of universal standards in bioethics to be 'imperative and desirable' (Berlinguer 2004: 1088). The drafting process for the UDBHR was launched in January 2004. As with the previous two declarations, a drafting group was appointed and an extensive consultation process initiated, involving UNESCO, member states and other stakeholders. It was decided that universal guidelines on 'all issues' in bioethics were needed (UNESCO 2003h: 2; UNESCO 2004o; UNESCO 2005q).

The UNESCO website (2012e) has for several years defined bioethics as follows:

> Stem cell research, genetic testing, cloning: progress in the life sciences is giving human beings new power to improve our health and control the development processes of all living species. Concerns about the social, cultural, legal and ethical implications of such progress have led to one of the most significant debates of the past century. A new word has been coined to encompass these concerns: bioethics.

The final text of the UDBHR contains no reference to issues such as stem cells, however, because they proved too controversial to enable consensus. Thus the original aim proved over-ambitious. Illustrating a complete reversal, a 2005 report described the IBC's final draft text as 'far from attempting to resolve all the existing bioethics issues' (UNESCO 2005h: 7). Henk ten Have, Head of UNESCO's Division of the Ethics of Science and Technology (the predecessor to the Division of Ethics and Global Change) from 2003 to 2010, explained, 'Research into stem cells and cloning does not for now affect the lives of most people. They remain a hope for the future, but right now, people are dying because of poor health conditions. We must concentrate on this problem' (Tousni 2006). Rather than trying to address the large and ever-growing number of specific bioethics issues, he wrote in 2006, the declaration provides a 'basis' or 'frame of reference' for states developing legislation or policies on bioethics (ten Have 2006: 341). The declaration was adopted 'by acclamation' by the General Conference, on 19 October 2005 at its thirty-third session (UNESCO 2005r).

All three UNESCO declarations aim to promote human dignity, human rights and fundamental freedoms in the context of bioethics and genetics, while at the same time embracing principles of responsibility, solidarity, equality and justice, as affirmed in the preamble of each. They cover both medical and research ethics; article 5 of the UDHGHR refers to 'research, treatment or diagnosis affecting an individual's genome', for example (UNESCO 1997). Each contains articles on informed consent, risks and benefits, confidentiality, freedom of research, ethics committees and bioethics education and training. The IDHGD (2003) and the UDBHR (2005) also cover transnational practices and the monitoring and management of research. As well as these general provisions, the two genetics declarations include principles specific to their context; both, for example, condemn discrimination on the basis of genetic characteristics and genetic reductionism. The UDHGHR (articles 1 and 4) also disallows reproductive cloning and states that the human genome, the 'heritage of humanity', in its natural state should not enable financial gain (UNESCO 1997).

The declarations also contain several principles that are particularly pertinent to developing countries. The UDHGHR (1997, article 17) promotes research on genetically influenced endemic diseases, while the UDBHR (2005, articles 6(3), 8 and 12) endorses community engagement, the protection of individuals and groups of special vulnerability and

due regard for cultural diversity and pluralism. All three display a strong commitment to benefit sharing, knowledge exchange and capacity building. Article 18 of the UDHGHR, for example, reads:

> States should make every effort … to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.
>
> (UNESCO 1997)

Article 18 of the IDHGD (2003) is very similar, the only difference being that it reads 'human genetic data and human proteomic data' rather than 'human genome, human diversity and genetic research' (UNESCO 2003b).

The UDBHR (2005) is different again, as follows (article 24 (2)):

> Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related knowhow and the benefits thereof.
>
> (UNESCO 2005s)

The UDBHR also directly addresses inequalities of health. Article 14, on social responsibility, pertains to social and economic rights as bioethical issues. Citing the promotion of health and social development as 'a central purpose of government', it states that progress in science and technology should advance access to healthcare, nutrition, water and improved environmental and living conditions and reductions in marginalization, illiteracy and poverty (ibid). These were considered important elements of the proposed declaration from an early stage. The IBC's 2003 report on the possibility of a new bioethics instrument notes, 'Our global society must face the responsibility to use science and technology to promote public health and to equalize access to healthcare and medicines' (UNESCO 2003h: 4). (Berlinguer was rapporteur to the working group that compiled the report.)

Relation to other bioethics instruments

UNESCO's status as an intergovernmental UN agency is a key factor in its justification for its bioethics activities. Noëlle Lenoir, Chair of the IBC from 1993 to 1998, claims that UNESCO played a 'major role in laying the foundations of international bioethics' through the UDHGHR (1997), in a paper titled 'The first legal and ethical framework at the global level' (Lenoir 1998–9: 546). The UNESCO website describes the UDHGHR as having been 'the only international instrument in the field of bioethics' at the time of its endorsement by the UN General Assembly in 1998 (UNESCO 2012b). Similarly, Koïchiro Matsuura, then Director-General, declared in June 2005 that the UDBHR would 'close a wide gap at the international level' (UNESCO 2005m: Annex II, 1–2) and ten Have (2006: 342) has described the governmental commitment enshrined in the bioethics declaration as its 'innovative dimension'. All this implies that ethics guidelines produced by professional organizations, such as the World Medical Association (WMA) and the Council for International Organizations of Medical Sciences (CIOMS), are not truly 'inter-national', because they have not been agreed by nation-states (although CIOMS is in official relations with the WHO). Yet, where the WMA's *Declaration of Helsinki* is formally directed at physicians or researchers, the CIOMS guidelines, like the UNESCO declarations, are intended to be used in the designing of national policy on biomedical research ethics, particularly in developing countries.

Unusually, the UDBHR (2005) notes these non-UN documents in its preamble. The declaration is also considered unique in scope, as it is not confined to medical or research ethics (UNESCO 2005h: 6). Justice Kirby, who chaired the UDBHR drafting committee, purports, 'It lifts the eyes of bioethicists from the patient's bedside and the hospital ward to a new insistence on the relevance to the bioethics discipline for society, the community, humanity, all living beings and the biosphere' (Kirby 2010: 794). ten Have (2006: 341) goes even further:

> The Declaration on Bioethics thus opens perspectives for action that reach further than just medical ethics and reiterates the need to place bioethics within the context of reflection open to the political and social world. Today, bioethics goes far beyond the code of ethics of the various professional practices concerned. It implicates reflection on the evolution of society, indeed world stability, induced by scientific and technological

developments. The Declaration on Bioethics paves the way for a new agenda of bioethics at the international level.

UNESCO and human cloning

After three declarations within a decade, at the end of 2005 UNESCO decided to take a 'normative pause' and instead concentrate on supporting the implementation of the existing declarations at regional and national levels (UNESCO 2005a: 4). It was not long, however, before it started to think about a fourth instrument. Despite ten Have's words about the limited relevance of stem cell research and cloning to the majority of the world's population, in 2008 the IBC set up a working group to examine whether there was any call for an international convention on human cloning.

What is cloning?

Human cloning inspires strong views, but also confusion about what exactly the term means and why the practice appears to be universally condemned. There are two types of cloning: 'reproductive' cloning and 'therapeutic' or 'research' cloning. None of these terms are strictly accurate scientifically, but are widely used. They derive from when the only means of cloning were embryo splitting and somatic cell nuclear transfer (SCNT). SCNT is the process by which a single nucleus from a somatic (body) cell is transferred into an enucleated egg. The resulting embryo can be used for either reproductive or research purposes. Reproductive cloning sees the embryo being implanted into a female for gestation. Dolly the Sheep was the first mammal to be cloned by this method in July 1996. Therapeutic cloning sees the embryo being harvested rather than gestated, to glean stem cells (embryonic stem cells or ESCs). These cells are pluripotent, meaning they have the capacity to develop into various types of specialized cells. They occur naturally only in the early stages of embryonic development. Stem cells harvested from a cloned embryo are likely to be particularly useful in therapeutic terms, because they will be compatible with the originator's immune system (Wilmut *et al*. 1998: 21; Bowring 2004: 402–3; Isasi *et al*. 2004: 628; UNU-IAS 2007: 6).

Therapeutic cloning is seen to have great potential as a means of replacing damaged tissue and organs, but it remains controversial on several fronts. Some oppose the utilitarian creation of embryos purely for research, while others are concerned about the risks to egg donors. The strongest objection is to the destruction of embryos entailed in harvesting, on the grounds that they are morally equivalent to human persons. For those who believe human life begins at conception, even therapeutic cloning is reproductive (Isasi *et al*. 2004: 628; Lo *et al*. 2010: 17). In 2006 a new method was developed that avoids destroying embryos, by reengineering somatic cells to become pluripotent (induced pluripotent stem cells or iPSCs). This may circumvent the moral objections to therapeutic cloning by SCNT, but it opens up new possibilities for human reproductive cloning, through tetraploid complementation (a method used to clone mice) and artificial gamete production (Meyer 2008: 851; Lo *et al*. 2010: 16; UNESCO 2010g: 2).

Arguments for and against human reproductive cloning

Since the cloning of Dolly the Sheep made human reproductive cloning seem feasible within the near future, a plethora of authors – mainly bioethicists and lawyers rather than scientists – have argued for and against the development of this technology. Those in favour take a liberal position, in the name of reproductive freedom. They also see cloning as a promising means to combat infertility. Those against are concerned for the psychological health of the clone and society more broadly. Where there is near universal consensus is on the safety issue (Galton and Doyal 1998: 279; J. Robertson 1998: 1372 and 1410; de Melo-Martín 2002: 248; Cheshire *et al*. 2003: 1010; Gogarty 2003: 84; Harris-Short 2004: 333; Tauer 2004: 209). Most scientists and philosophers agree that, as technology stands, it would be unethical to attempt human reproductive cloning. Fears for the physical health of both the clone and the mother are grounded in the poor record in animal cloning. Dolly was the only one of 277 attempts to survive to birth. Success rates in mammals remain very low and genetic abnormalities are common (Elsner 2006: 597). Even if these issues could be resolved, say some, there would still be moral objections to cloning (Cheshire *et al*. 2003: 1010; Polkinghorne 2004: 593).

Fears for the psychological health of a human clone are rooted in two related concepts. First, having a unique identity is seen as an inherently human quality, which a clone would be unable to enjoy. Second, they would be denied their right to ignorance (as articulated by Hans Jonas), or to an open future (Joel Feinberg), if they knew about the life of the person from whom they were cloned, or were expected by their 'parents' to conform to a particular life pattern (J. Robertson 1998: 1411 and 1415–16; Burley and Harris 1999: 110; de Melo-Martín 2002: 249–50; Gogarty 2003: 85; Harris-Short 2004: 344; Tauer 2004: 209; Tannert 2006: 239; Mameli 2007: 87; Morales 2009: 43). These fears are seen by several scholars as speculative, with no basis in science. Nestor Morales (2009: 48) has reviewed analogous

psychological studies (of twins, for example) and concluded that there is no evidence that individuals produced through reproductive cloning 'could display the characteristics of their donors to the extent of compromising uniqueness'. To believe otherwise, say the critics, is to engage in a crude genetic determinism that does not take sufficient account of environmental factors.

A clone would not be an exact copy of their 'original' in all respects, but would simply have the same genetic code, as do 'identical' twins, who are considered to have unique personalities nevertheless. Since environment plays an important part in development, 'time-separated twins' would be less similar than monozygotic twins, whose psychological well-being is not of major concern (Harris 1997: 353–4; Brock 1998: 152; J. Robertson 1998: 1415; de Melo-Martín 2002: 249–50; Pearson 2006: 658; Camporesi and Bortolotti 2008: e15; Morales 2009: 44–45; Ahlberg and Brighouse 2010: 541; Aloni 2011: 57). But the time delay is the significant factor, say Evelyne Shuster (2003: 520) and David Jensen (2008: 620), not least because of the implications for notions of parenthood if one's mother or father is also one's genetic 'twin'. For Christof Tannert (2006: 239), by contrast, the important point is that the similarity between monozygotic twins has occurred by chance rather than deliberate decision.

Inmaculada de Melo-Martín (2002: 251), like Justine Burley and Harris (1999: 111), argues that policies should not be based on public misunderstandings about what cloning really entails. Finn Bowring (2004: 405) agrees that the problem lies in a false premise rather than the probable impact of cloning on identity *per se*, but believes this will lead to genetic determinism all the same:

> The effects of eugenic technologies like human cloning are mediated by a cultural attachment to genetic determinism which both underpins and is consolidated by those same technologies. The problem is not that the autonomy and uniqueness of individuals will be lost, and hence they will be undeserving of the respect and dignity normally accorded to human beings. It is, rather, that the respect, love and recognition ideally expressed by adults towards the child will be subverted by their expectation that they have ordered a predetermined product, and this expectation will in turn promote the misrecognition or repression of the child's attempts to assert its autonomy and uniqueness.

John Robertson (2000–01: 41) sees these concerns as based on a misreading of parental motivations, at least in the case of an infertile couple who simply desire a genetically similar child, rather than to dictate the every move of their offspring. Any danger of psychological harms could thus be minimized through information and counselling. Joyce Havstad (2010: 74 and 76) agrees with Bowring that misconceptions of reality or fact have real consequences, which cannot be ignored, but also suggests information and monitoring as a means to mitigate these. A further counter-argument to Bowring is that there have always been parents who try to influence their children in an overbearing or less than perfect way, without this warranting interference in parenting styles (Harris 1997: 358; Camporesi and Bortolotti 2008: e15; Ahlberg and Brighouse 2010: 542).

Concerns about identity and 'human-ness' also extend to the societal level. Some believe reproductive cloning would violate human dignity (GAEIB 1997: 351; Cheshire *et al*. 2003: 1011; Shuster 2003: 522–3; Harris-Short 2004: 352). A somewhat nebulous concept, human dignity encompasses ideas of intrinsic worth, self-determination and autonomy. Many equate it with Immanuel Kant's categorical imperative that people should always be treated as ends not means; that is, they should not be commercialized or instrumentalized (S. Robertson 1998: 282; Tannert 2006: 239). Shuster (2003: 524) has suggested that cloning could lead to a new form of slavery, in the form of 'genetic bondage'.

The very mechanics of cloning are also seen as a threat to humanity. Reproductive cloning would be different to other forms of assisted reproductive technologies because it would mimic asexual rather than sexual reproduction and thus be 'unnatural'. If part of being human is that one is the unique and unplanned result of the combination of two separate chromosomes, then reproductive cloning would mean nothing less than a redefinition of what it means to be human (J. Robertson 1998: 1410; S. Robertson 1998: 282; Cheshire *et al*. 2003: 1011; Häyry 2003: 456–7; Shuster 2003: 521; Aloni 2011: 56). This distinction between the natural and the unnatural has been criticized as arbitrary. As David McCarthy (1999: 99) points out, marriage between racial groups has been deemed unnatural by some jurisdictions in the past. John Polkinghorne (2004: 597) similarly reminds us that much of routine medicine is unnatural.

Another societal level threat that cloning is perceived to carry is reduced human genetic diversity (Gogarty 2003: 84; Aloni 2011: 5). Jaime Ahlberg and Harry Brighouse (2010: 541) refute this possibility, as it is predicated on the highly

unlikely scenario of vast numbers of clones with the same genetic code being created. In the eyes of several bioethicists, the idea of an army of clones is unfeasible, futile and the stuff of science fiction. The reality will be far more mundane, with cloning being the last resort for such a small number of (honourably intentioned) people that the impact on genetic diversity will be negligible (Harris 1997: 356–7; Harris-Short 2004: 359; Elsner 2006: 596; Camporesi and Bortolotti 2008: e15). Furthermore, they argue, we cannot ban behaviours or techniques because they might be open to abuse. If we did this consistently, the implications for human society would be enormous (Harris 1997: 356; McCarthy 1999: 99; Camporesi and Bortolotti 2008: e15).

Reproductive freedom, or procreative autonomy, is one of the key arguments in favour of allowing human reproductive cloning. If safety issues can be resolved, this principle would allow people to use cloning technology as and when they wish – to replace a dead loved one, for example (Harris 1997: 358; J. Robertson 1998: 1381 and 1391; de Melo-Martín 2002: 253–4; Häyry 2003: 450; Harris-Short 2004: 333; Tauer 2004: 209; Aloni 2011: 68). Authors differ on how broadly the right to reproductive freedom should be interpreted. Dan Brock (1998: 143) and Havstad (2010: 73) frame it as a negative right to non-interference in one's reproductive choices, not a positive right to reproductive assistance. Sonia Harris-Short (2004: 334) finds a similar reading of states' obligations in international human rights law (the International Covenant on Civil and Political Rights and the Convention on the Elimination of All Forms of Discrimination against Women, for example). She thus concludes that there is no reproductive right to cloning: 'under international law, no one has an absolute right to procreate in any way they choose' (Harris-Short 2004: 359). In a US context, John Robertson (1998: 1441) argues for a constitutional right to fertility treatment, to include cloning if and when this becomes feasible. Cheshire *et al*. (2003: 1011), by contrast, also writing from a US perspective, contend that reproductive liberty is not an inalienable right, nor is it a purely private matter. In the case of cloning, they argue, individual autonomy does not outweigh the public interest.

Closely linked with the reproductive freedom argument is the hope that reproductive cloning could help infertile couples and others who are unable to conceive 'naturally' (lesbian or gay couples, for example), or who are carriers of conditions such as Huntington's disease, to have genetically related children (Harris 1997: 357; J. Robertson 1998: 1378 and 1445; de Melo-Martín 2002: 253; Häyry 2003: 449; Harris-Short 2004: 333; Tauer 2004: 209; Pearson 2006: 658; Havstad 2010: 72; Aloni 2011: 22). Neil Levy and Mianna Lotz (2005: 232) and Robert Sparrow (2006: 308) cite the potential to combat infertility as the strongest argument there is for reproductive cloning. If cloning is the only means by which an individual or couple could have a genetically related child, the argument that they should be able to use this technology to exercise their reproductive freedom is much stronger than a general appeal to autonomy and does not carry the usual concerns of parental narcissism or clonal armies taking over the world. Several authors support the use of cloning as an infertility treatment if scientific concerns about the safety of the procedure can be addressed (J. Robertson 2000–01: 35; Strong 2008: 130). Going ahead even with a higher than normal chance a child could be born with birth defects or abnormalities might not be unethical, unless the child's life would not be worth living (J. Robertson 2000–01: 40; Elsner 2006: 597 and 600; Lane 2006: 135). The 'life worth living' argument has also been applied against concerns about psychological harms to the clone (Burley and Harris 1999: 113; Havstad 2010: 74).

Some ethicists counter the argument for cloning as a fertility treatment on the grounds that, like the arguments about identity and uniqueness, it is based on a genetic fallacy (Sparrow 2006: 308). Levy and Lotz (2005: 232) believe that the importance attached to genetic relatedness is a societal construct. If environmental factors are at least as important as genetic ones in determining a person's identity, as those in favour of cloning argue, how can cloning to enable parents to have genetically similar children be justified? J. Robertson (1998: 1373), who supports reproductive cloning (if safe), recognizes this tension:

> The desire to clone arises precisely because genes are viewed as highly important, if not crucial, in making people who they are. Assigning significance to genes, however, risks becoming a crude form of genetic essentialism or determinism. At the same time that one grants genes their due, one also must guard against expecting too much from them.

Implications for regulation and research

With very few exceptions, philosophers and scientists are agreed that human reproductive cloning should not currently be allowed: 'Unlike many other areas of reproductive technology and indeed biotechnology, the practice has been near unanimously condemned by the scientific, medical, ethical, and general communities' (Gogarty 2003: 84). As Roger Brownsword and Matti Häyry point out, however, this consensus is a 'happenstance convergence'

(Brownsword 2004–5: 538), or a 'happy constellation' (Häyry 2003: 459) that masks the conflicting principles bubbling under the surface. There is a fundamental difference in outlook between those who oppose reproductive cloning on safety or pragmatic grounds and those who see it as inherently wrong. John Robertson falls into the first category. In an oft-cited paper of 1998, in which he systematically reviewed the arguments for and against cloning, he concluded that a complete ban on human reproductive cloning could not be justified. He wrote, 'When carefully analyzed, the alleged harms of cloning tend to be highly speculative, moralistic, or subjective judgments about the meaning of family and how reproduction should occur' (J. Robertson 1998: 1441). Yet the view that cloning should be allowed once safety concerns have been resolved is itself speculative, as it is premised on a hypothetical level of sufficient evidence that attempting human cloning would carry an ethically acceptable degree of risk (Galton and Doyal 1998: 279).

de Melo-Martín (2002: 246–7) claims that arguments both for and against reproductive cloning fail to stand up to scrutiny, because they ignore context. The reality, she says, is that we live in a world where overpopulation, poverty and ill-health are rife:

> When one reads analyses of this technology, one has the impression that we live in a society where our most serious and pressing problems are the pleas of infertile people, or the requests of those who want to replace their dead loved ones; a world where genetic disease is the main cause of preventable deaths, where individuality is threatened, where one of the worst things that can happen to children is that their parents have too many expectations because of their genetic make up, and where resources are all but limited.
>
> (de Melo-Martín 2002: 264)

Sparrow (2006: 318) similarly argues that moral arguments against cloning are not strong enough to trump reproductive autonomy, but asks whether pursuing cloning research would be an ethical use of scarce resources. Others baulk at the expense, given the lack of scientific or medical justification for the risks involved (GAEIB 1997: 351; Gogarty 2003: 85). McCarthy (1999: 98) contends that the 'it's expensive' argument usually masks moral objections, but for Rosalind McDougall (2008: 259), like Sparrow, the expense is in itself a moral issue. She claims that investing in reproductive cloning would be an affront not to the dignity of the clone, but to the dignity of all those who are deprived of their basic rights and liberties through ill-health. Myfanwy Williams (2009: 331) directly counters this claim, citing the fact that we cannot know what the fruits of research will be. The question of how to balance meeting basic needs with the possibilities technological advancement brings goes far beyond the cloning debate, to the very heart of the scientific endeavour.

How human cloning is currently regulated

Given the albeit strained consensus that human reproductive cloning would be unethical under current conditions, it might be expected that this would be reflected in international and national laws. This is only partially the case. Many countries, but by no means all, have enacted legislation to ban reproductive and/or therapeutic cloning. Often this legislation refers to SCNT rather than cloning more generally and thus does not cover the newer technologies (Lo *et al*. 2010: 16). At regional and international level, in the wake of Dolly, several measures were brought out. UNESCO's 1997 *Universal Declaration on the Human Genome and Human Rights* (UDHGHR) is unequivocal: 'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted' (UNESCO 1997: article 11). The WHO passed resolutions in 1997 and 1998 stating that human reproductive cloning is contrary to human dignity and urging member states to prohibit it (WHO 1998: 1). The Council of Europe's *Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings*, adopted in 1998, similarly prohibits reproductive cloning in all circumstances (articles 1 and 2), as does the European Union's 2000 (amended 2007) *Charter of Fundamental Human Rights* (article 3). None of these constitute an absolute ban, however: the UDHGHR, as a declaration, is by definition non-binding, the Council of Europe's Protocol has been ratified by only 21 of its 47 member states (Council of Europe 2012) and the European Union (EU) Charter applies to its members only when enacting EU law (Europa 2010). This hole in the international canon prompted the UN General Assembly to look towards a binding convention in 2001. The end result was the *United Nations Declaration on Human Cloning* of 2005.

The circumstances surrounding the adoption of the *UN Declaration on Human Cloning* have been thoroughly documented by several authors (Isasi and Annas 2003 and 2006; Arsanjani 2006; Cameron and Henderson 2008). In 2001, in response to claims by some scientists that they would soon attempt human reproductive cloning, France and

Germany proposed a convention to ban the reproductive cloning of human beings to the UN General Assembly. They decided on the UN rather than UNESCO, which had already proscribed the practice in its 1997 UDHGHR, because of its wider membership (crucially, the US was not at the time a member of UNESCO) and its status as the premier global legislative forum. Moreover, as cloning is cross-cutting, touching on science, ethics, health and human rights, they felt it could not be dealt with fully by any one of the UN's specialized agencies (Isasi and Annas 2003: 405; Arsanjani 2006: 164–5; UNU-IAS 2007: 16; Cameron and Henderson 2008: 153). It was expected that drafting and adopting a convention would be a relatively straightforward endeavour, as there was consensus among member states that human reproductive cloning was undesirable (Arsanjani 2006: 166; Cameron and Henderson 2008: 157). What followed was four years of dispute and discord, as rival factions fought their corners. The divergence was not over reproductive cloning, but therapeutic cloning (or, more specifically, whether there is really a significant difference between these two procedures, as both involve human embryos).

Some states felt that if only reproductive cloning were to be outlawed, this would implicitly endorse therapeutic cloning (that is, the creation and destruction of embryos), which would be unacceptable for those who believe human life begins at conception. Pragmatically, they worried that allowing therapeutic cloning could create a 'slippery slope' towards reproductive cloning and that it would be difficult to prevent rogue researchers implanting embryos that had originally been created for research purposes. There were also concerns about the impact on women, particularly in developing countries, who might be enticed to undergo risky procedures in order to produce large numbers of eggs for money. The US and Costa Rica led this faction, which grew to almost 70 states, including Kenya, Nigeria, Zambia and several other developing countries (Isasi and Annas 2003: 408–10; Isasi and Annas 2006: 61; Arsanjani 2006: 167–72; Cameron and Henderson 2008: 160–3).

Commentators differ on how interested or involved developing countries were in the debate. According to Nigel Cameron and Anna Henderson (2008: 171), these countries were 'particularly vocal' regarding the exploitation of women. Led by Tanzania and Nigeria, they also successfully lobbied for the inclusion of an article that resembles in spirit Article 14 of the UDBHR (2005) on social responsibility, encouraging states to consider 'the pressing global issues such as HIV/AIDS, tuberculosis and malaria, which affect in particular the developing countries' when allocating research funding (United Nations 2005a; Isasi and Annas 2006: 65). Rosario Isasi and George Annas (2006: 62) put this down to the political manoeuvring of the US and Costa Rica, which used this issue to broker the support of developing countries for a comprehensive ban. For Mahnoush Arsanjani (2006: 178), the inclusion of this article, which makes no mention of cloning, demonstrates the 'remoteness' of the issue for many developing countries.

On the other side, feelings ran equally strong. Those states in favour of therapeutic cloning would not countenance a holistic ban. This smaller group, led by the UK and Belgium, argued for an immediate international prohibition of reproductive cloning, to prevent unscrupulous scientists finding sanctuary in states without appropriate jurisdiction, to be followed by further measures on therapeutic cloning as and when these could be agreed. This option, in turn, was unacceptable to those in favour of a complete embargo. Realising proceedings were at deadlock, in November 2003 the Organization of the Islamic Conference proposed discussions should be postponed for two years, in the hope that consensus might be possible at a later date. (There had already been a year long pause in negotiations in 2002–3 (Isasi and Annas 2003: 410–12; Arsanjani 2006: 172).) The General Assembly agreed to a delay of one year. As stances remained firm after the hiatus, in November 2004 it decided to opt for a declaration rather than a convention, in the vain hope that states would be able to agree on a non-binding instrument (Isasi and Annas 2003: 413; Isasi and Annas 2006: 62).

The *UN Declaration on Human Cloning* was adopted by the General Assembly on 8 March 2005, but by no means unanimously. Only 84 voted in favour, with 34 against and 37 abstentions. (Later, seven states informed the UN Secretariat they had intended to vote in favour, one that they would have voted against and two that they would have abstained.) The reason why so many states felt they could not support the declaration was its ambiguous wording (Arsanjani 2006: 165–6 and 176). The declaration calls on states to 'prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life' (United Nations 2005a). The UK confirmed that it had voted against the declaration because it 'can be interpreted as a call for a total ban on all forms of human cloning. We cannot accept such an ambiguous declaration, which may sow confusion about the acceptability of that important field of research' (United Nations 2005b: 4–5). Nikola Biller-Andorno (2005: 63), in a *Journal of Medical Ethics* editorial, reports that an insider said the declaration was 'ambiguous enough to please everybody', but this strategy clearly backfired, given the ambivalent voting.

That the declaration is ambiguous is disputed by some authors. This depends on whether one reads the phrase 'inasmuch as' to mean 'to the extent that' or 'because' (note that the French and Spanish translations of the declaration use the former sense). Arsanjani (formerly Director of the Codification Division of the UN's Office of Legal Affairs) believes the phrase was used deliberately to enable selective interpretation (Arsanjani 2006: 178), but Cameron (who advised the US delegation in 2002) and Henderson disagree. They maintain that the legislative intent of the General Assembly was clear and thus the only legitimate interpretation is to see the declaration as a comprehensive ban on all forms of cloning (Cameron and Henderson 2008: 195). Similarly, the *UN Chronicle* (United Nations 2005c: 28) states that, at the final vote, the General Assembly had 'urged Member States to prohibit all forms of human cloning, including cloning of human embryos for stem cell research'. A more subjective reading would mean that the declaration allows states to engage in reproductive cloning if they do not see this as violating human dignity (Cameron and Henderson 2008: 195). In sum, the end result was highly unsatisfactory – a weakly worded document that enjoys only ambivalent support from states. It is seen as too weak to either prevent renegade research or support legitimate scientific investigation (Isasi and Annas 2006: 63).

UNESCO enters the fray

UNESCO's decision to investigate the possibility of a convention on human cloning came on the back of a 2007 report by the United Nations University's Institute of Advanced Studies (UNU-IAS), entitled *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance*. One option identified by the report was that the IBC take up the issue of cloning regulation. Another was, 'Dissemination, discussion and debate on cloning issues at the international level, such that all countries including the developing and least developed countries can participate and put forward their concerns regarding this new technology' (UNU-IAS 2007: 26). Koïchiro Matsuura, Director-General of UNESCO, requested that the IBC examine the report. The IBC duly formed a Working Group on Human Cloning and International Governance for 2008–9. The Group's task was to 'explore whether the scientific, ethical, social, political and legal developments on human cloning in recent years justify a new initiative at international level', rather than to analyse ethical or scientific aspects of human cloning *per se* (UNESCO 2008d: 1).

In its September 2008 interim report, the Working Group recommended a legally binding convention to ban reproductive cloning (UNESCO 2008h). It redrafted the report in the light of discussions at the IBC and joint IBC–IGBC sessions in October 2008 and, in the final version (2009), recommended intensified international dialogue on the issue, rather than a convention (UNESCO 2009e: 7–8). The Working Group continued its work in 2010–11, but the IBC was unable to agree to its draft 'final statement', which again recommended a ban. The topic has now been all but abandoned, as it will simply be monitored by one or two IBC members under the IBC's Work Programme for 2012–13 (UNESCO 2011f: 4; UNESCO 2012m). Chapters 4 and 5 explore what led to this outcome and its implications.

Human genetic and biomedical research clearly has the potential to contribute towards addressing the pressing global problem of inequalities of health between North and South. If this potential is to be realized ethically, adequate protection of individual research subjects must be ensured. On a grander scale, sufficient resources will be needed to fund research directed towards the health needs of developing countries and the provision of any interventions consequently developed. Aside from external factors, UNESCO's efficacy in meeting these challenges will depend partly on its systems of decision-making and implementation. The next chapter asks what insights international relations theory might offer into how successful UNESCO's endeavours are in this regard.

Footnotes

1 The report generated commentaries in the journals *Science* and *Nature Genetics*. It was also announced in newspapers around the world, including *The New York Times, The Washington Post, The Toronto Star, Financial Times, Agence France Presse, New Straits Times* (Malaysia), *The Independent* (The Gambia) and *Africa News* (as revealed by a search of the database Nexis UK, 23 February 2007).

2 For simplicity, the term 'Bioethics Programme' is used throughout the book. At one time it was known as the 'Bioethics Section', led by a Chief of Section. In 2012 it became the 'Bioethics Team', led by a Team Leader, although its homepage still refers to the 'Bioethics Programme'.

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