HUMAN RIGHTS BASED APPROACHES TO HEALTH CARE

BACKGROUND REPORT

Steering Committee for Human Rights
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This is a background report which provides an overview of the international human rights standards applicable to health care. Health care is understood to mean "the services offering diagnostic, preventive, therapeutic and rehabilitative interventions, designed to maintain or improve a person's state of health or alleviate a person's suffering,"[1] as well as related facilities, goods and information. Human rights are defined as the "rights inherent to all human beings, regardless of race, sex, nationality, ethnicity, language, religion, or any other status".[2] It should be noted that human rights are distinct from patients' rights as the former are universal standards accepted under international law as binding on all States which apply to all human beings irrespective of their status as patients. Patients' rights could be seen as a subset of human rights that is defined at the domestic level. The focus of this report is on the relevance of human rights for health care and on how international human rights standards can inform domestic patients' rights.

The human rights standards are organised by overarching themes and principles that cut across the interpretation and application of the relevant substantive human rights. The report includes but distinguishes between principles and standards that are part of international law having attracted general consensus on the one side and progressive developments of the law where divergences still persist on the other. The starting point and key underlying premise under international human rights law is that health care has to be undertaken in a manner that fully respects human dignity and human rights.[3] This is part of positive international law as evidenced by the fact that all major instruments in the field adopt a human rights-based approach to regulating biomedicine. These include, *inter alia*, the Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention on Human Rights and Biomedicine), the WHO Constitution,[4] the International Health Regulations of the WHO,[5] the UNESCO Declarations on the Human Genome and Human Rights, on Bioethics and Human Rights and on the Responsibilities of Present Towards Future Generations. These instruments refer in particular to the human rights principles of human dignity[6] and the prohibition against discrimination.[7] They also mention a few substantive human rights such as the right to life,[8] the right to personal integrity,[9] the right to respect for private life[10] and the right to health.[11] The right to benefit from science and its applications is also included in the survey as being increasingly and directly relevant to health care.

[1] Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, para. 24.
[2] UN definition available at: https://www.un.org/en/global-issues/human-rights .
[3] See CESCR, General Comment No. 17 (2005), E/C.12/GC/1712, para. 35 and General Comment No. 25 (2020), E/C.12/GC/25 on science and economic, social and cultural rights (General Comment 25), para. 81.
[4] WHO Constitution, Preamble, para. 3.
[5] WHO International Health Regulations, 2005, Art 3.
[6] UNESCO Declaration on Bioethics and Human Rights, Art 3(a); Universal Declaration on the Human Genome and Human Rights, Art 1 and 2(a).
[7] Universal Declaration on the Human Genome and Human Rights, Art 6 and UNESCO Declaration on Bioethics and Human Rights, Art 11.
[8] UNESCO Declaration on Bioethics and Human Rights, Art 2(c).
[9] Ibid, Art 8.
[10] Oviedo Convention Oviedo Convention on Human Rights and Biomedicine, Art 10.
[11] Ibid, Art 14(2).

1. ACCESSIBILITY

Accessibility is one of the most important aspects of both the right to health and the right to benefit from science, which are set out in the International Covenant on Economic, Social and Cultural Rights (ICESCR) and also part of customary international law, binding as such on all States. There is a general duty on States to provide equal access with respect to all economic, social and cultural rights.[12] This is evidenced by the wording of the relevant provisions in the Covenant. Article 12 ICESCR emphasises that *everyone* has the right 'to the enjoyment of the highest attainable standard of physical and mental health', that States ought to take steps 'to achieve the full realisation if this right', notably including 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.[13] Similarly, Article 15 ICESCR recognizes the right of *everyone* 'to enjoy the benefits of scientific progress and its applications' and requires States to take steps to achieve the full realisation of the right, including those necessary for the diffusion of science.

Specialised UN human rights treaties also provide for accessibility of health care with respect to specific protected groups, highlighting the understanding that equal access means access without discrimination on any grounds. For example, the UN Convention on the Rights of the Child requires States Parties to ensure access to "necessary medical assistance and health care to all children with emphasis on the development of primary health care".[14] Similarly, in the context of health, the UN Convention on the Rights of Persons with Disabilities imposes a duty on States to "[p]rovide persons with disabilities with the same range, quality and standard of free or affordable health care and programmes as provided to other persons, including in the area of sexual and reproductive health and population-based public health programmes" and to "[p]rovide these health services as close as possible to people's own communities, including in rural areas."[15] The UN Convention on the Elimination of All Forms of Discrimination against Women requires States to ensure access to women "to health care services, including those related to family planning" and further, to ensure access to "appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary".[16] The International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families imposes a duty on States to provide access to "any medical care that is urgently required for the preservation of their life or the avoidance of irreparable harm to their health on the basis of equality of treatment with nationals of the State concerned."[17]

These primary sources of international human rights law show a general consensus that accessibility means equal access to health care without discrimination on any ground. What is less clear is what are the minimum of services, goods and information included in this access. The ICESCR subjects to progressive realisation the creation of conditions that assure medical service and attention to all in the event of sickness, whereas the UN Convention on

[12] See e.g., General Comment 25, para. 37.
[13] See also Article 25 of the Universal Declaration of Human Rights (1948).
[14] UN Convention on the Rights of the Child, Art 24(b).
[15] UN Convention on the Rights of Persons with Disabilities, Art 25 (a) and (c).
[16] UN Convention on the Elimination of All Forms of Discrimination against Women, Art 12 (1) and (2).
[17] UN Convention on the Protection of the Rights of All Migrant Workers and Members of their Families, Art 28.

the Rights of the child emphasises in more assertive terms the development of primary health care for children. The UN Convention on the Rights of Persons with Disabilities is one of the most progressive instruments in requiring not merely equal but notably free and affordable access to health care. The question of whether accessibility requires more than equal and non-discriminatory access, i.e. equitable, affordable or even free access remains open and subject to debate where a stark division between the approaches of developed and developing States persists.

Accessibility is affirmed and significantly fleshed out in the General Comments of the Committee on Economic, Social and Cultural Rights on the relevant rights in the ICESCR. Whilst not legally binding, these comments are a highly authoritative interpretation of the ICESCR and often guide the practice of the States parties. General Comment No 14 on the right to health defines accessibility as having four dimensions:

- Non-discrimination: health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds;

- Physical accessibility: health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS…

- Economic accessibility (affordability): health facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households;

- Information accessibility: accessibility includes the right to seek, receive and impart information and ideas concerning health issues. …[18]

The Comment further clarifies that accessibility entails both equal and timely access to "basic preventive, curative, rehabilitative health services…; regular screening programmes; appropriate treatment of prevalent diseases, illnesses, injuries and disabilities, preferably at community level; the provision of essential drugs; and appropriate mental health treatment and care."[19] It imposes a special obligation on States "to provide those who do not have sufficient means with the necessary health insurance and health-care facilities, and to prevent any discrimination on internationally prohibited grounds in the provision of health care and health services, especially with respect to the core obligations of the right to health."[20] Notably, States have a further obligation to ensure equal access to health care and health-related

[18] CESCR General Comment No 14 The right to the highest attainable standard of health (2000), para. 12(b).
[19] Ibid, para. 17.
[20] Ibid, para. 19.

services provided by third, i.e. private parties by adopting the necessary legislation and other measures.[21]

It should be noted that not all of these aspects of accessibility are yet part of positive international law and that a number of them are still a progressive development. Indeed, according to the Committee on Economic, Social and Cultural Rights itself, the core of the right to health imposes obligations on States "to ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups", "to ensure reproductive, maternal (prenatal as well as post-natal) and child health care", "to ensure equitable distribution of all health facilities, goods and services" and "to provide … access to information concerning the main problems in the community, including methods of preventing and controlling them".[22] Given the affirmation of these core obligations in universally accepted instruments of the WHO, such as the Alma-Ata Declaration, as well as in the Programme of Action of the International Conference on Population and Development, they can be seen as obligations under general international law that are binding on all States.

Accessibility is further clarified in the most recent General Comment No 25 on the right to benefit from science as entailing that "States parties *should* ensure that everyone has equal access to the applications of science, particularly when they are instrumental for the enjoyment of other economic, social and cultural rights" and that "information concerning the risks and benefits of science and technology *should* be accessible without discrimination."[23] It is notable that the Comment uses hortatory terms and thus does not impose strict obligations but rather makes recommendations. However, the General Comment uses mandatory language when defining accessibility in the context of the right to sexual and reproductive health, requiring that "States parties must ensure access to up-to-date scientific technologies necessary for women in relation to this right."[24] By way of examples, the Comment sets out, this time in hortatory terms, that "States parties *should* ensure access to modern and safe forms of contraception, including emergency contraception, medication for abortion, assisted reproductive technologies, and other sexual and reproductive goods and services, on the basis of non-discrimination and equality."[25] The Comment also recommends that "States *should* promote scientific research, through financial support or other incentives, to create new medical applications and make them accessible and affordable to everyone, especially the most vulnerable."[26]

According to the CESCR, the core access obligations imposed by the right to benefit from science include the obligation of States to "[e]liminate laws, policies and practices that unjustifiably limit access by individuals or particular groups to facilities, services, goods and information related to science, scientific knowledge and its applications", "[e]nsure access to those applications of scientific progress that are critical to the enjoyment of the right to health" and "[e]nsure that in the allocation of public resources, priority is given to research in areas where there is the greatest need for scientific progress in health… and the well-being of the

[21] Ibid, para. 35.
[22] Ibid, paras 43 and 44.
[23] General Comment No 25 on article science and economic, social and cultural rights (2020), para. 17 (emphasis added).
[24] Ibid, para. 33.
[25] Ibid (emphasis added).
[26] Ibid, para. 67 (emphasis added).

population, especially with regard to vulnerable and marginalized groups".[27] The Committee further emphasises that "States parties have a duty to prevent unreasonably high costs for access to essential medicines…from undermining the rights of large segments of the population to health"[28] and that "States parties have a duty to make available and accessible to all persons, without discrimination, especially to the most vulnerable, all the best available applications of scientific progress necessary to enjoy the highest attainable standard of heath".[29] Overall, General Comment No 25 interprets accessibility as equal access without discrimination adding an element of equity when requiring that States prevent unreasonably high costs for accessing essential medicines.

Accessibility is interpreted most progressively in the area of sexual and reproductive health care. According to the CESCR, it entails physical accessibility of health facilities, goods, information and services "available within safe physical and geographical reach for all, so that persons in need can receive timely services and information";[30] affordability of both publicly and privately provided sexual and reproductive health services, as well as "[e]ssential goods and services, including those related to the underlying determinants of sexual and reproductive health, must be provided at no cost or based on the principle of equality to ensure that individuals and families are not disproportionately burdened with health expenses."[31] It is recommended that States provide people without sufficient means with the support necessary to cover the costs of health insurance and access to health facilities providing sexual and reproductive health information, goods and services.[32] Last but not least, accessibility includes access to information, which encompasses "the right to evidence-based information on all aspects of sexual and reproductive health, including maternal health, contraceptives, family planning, sexually transmitted infections, HIV prevention, safe abortion and post abortion care, infertility and fertility options, and reproductive cancer."[33]

Examples of actions that would violate the States' obligations to provide access to sexual and reproductive health include criminalising: abortion, non-disclosure of HIV status, exposure to the transmission of HIV, transgender identity and expression.[34] States would also violate their obligation to provide accessible health care with respect to sexual and reproductive health if they allow third party providers to impose practical or procedural barriers to health services through physical obstruction of facilities, dissemination of misinformation, imposition of informal fees and authorisation requirements, including parental, spousal and judicial authorisation requirements for access to sexual and reproductive health services and information, including for abortion and contraception; biased counselling and mandatory waiting periods for divorce, remarriage or access to abortion services; mandatory HIV testing; and the exclusion of particular sexual and reproductive health services from public funding or foreign assistance funds.[35] Another example of a violation would take place where a State fails to guarantee access to the full range of contraceptive options.[36]

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[27] Ibid, para. 52.
[28] Ibid, para. 62.
[29] Ibid, para. 70.
[30] General Comment No 22 on the right to sexual and reproductive health (2016), para. 16.
[31] Ibid, para. 17.
[32] Ibid.
[33] Ibid, para. 18.
[34] Ibid, para. 40.
[35] Ibid, paras 41 and 43.
[36] Ibid, para. 62.

Examples of actions that States should undertake to ensure universal access without discrimination to sexual and reproductive health care include providing access to "a full range of quality sexual and reproductive health care, including maternal health care; contraceptive information and services; safe abortion care; and prevention, diagnosis and treatment of infertility, reproductive cancers, sexually transmitted infections and HIV/AIDS, including with generic medicines" and to "physical and mental health care for survivors of sexual and domestic violence in all situations, including access to post-exposure prevention, emergency contraception and safe abortion services".[37] States are under a positive obligation to take measures to eradicate practical barriers to the full realisation of the right to sexual and reproductive health, which notably include the disproportionate costs and lack of physical and geographical access to sexual and reproductive health care, as well as ensuring that health care service providers are equitably distributed throughout the State.[38] Another positive obligation in the field is for States to guarantee both universal and also equitable access to affordable health services, goods and facilities.[39] Accessibility also entails ensuring access to effective and transparent remedies and redress in cases of violation of the right to sexual and reproductive health, including administrative and judicial mechanisms.[40]

Turning to accessibility in regional human rights instruments, Article 3 of the Convention for the Protection of Human Rights and Dignity of the Human Being with Respect to the Application of Biology and Medicine (the Oviedo Convention) is progressive in specifying that access to 'health care of appropriate quality' ought to be not merely equal but also 'equitable'. The Explanatory Report to the Oviedo Convention clarifies that "equitable" means "the absence of unjustified discrimination" and although not synonymous with absolute equality, it "implies effectively obtaining a satisfactory degree of care."[41]A similar requirement for equitable access in relation to genetic screening programmes for health purposes is set out in the Additional Protocol concerning Genetic Testing for Health Purposes.[42] As seen above, the majority of general international human rights instruments only provide for equal and non-discriminatory access to health care with only some of the general comments recommending that access should also be equitable and affordable.

Another example of a progressive development of human rights on a regional level can be found in the EU Charter of Fundamental Rights, which in Article 35 provides for a separate right of everyone to 'access to preventive health care and the right to benefit from medical treatment'. According to the Commentary of the Charter, the key innovation of the provision is giving access to preventive health care.[43] Further, not defining what type of access should be given was a deliberate choice given the practical difficulties in guaranteeing substantive equality of access to health care for all citizens.[44]

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[37] Ibid, para. 45.
[38] Ibid, para. 46.
[39] Ibid, para. 49 (c).
[40] Ibid, para. 49 (h).
[41] Explanatory Report to the Oviedo Convention, para. 25.
[42] Additional Protocol to the Oviedo Convention concerning Genetic Testing for Health Purposes, Art 19 (e).
[43] Commentary of the Charter of Fundamental Rights of the European Union, EU Network of Independent Experts on Fundamental Rights (2006), pp 308 et seq.
[44] Ibid, p. 310.

The African Charter on Human and Peoples' Rights provides for the right of everyone to enjoy the best attainable state of physical and mental health, which obliges States to ensure that people receive medical attention when they are sick.[45] The African Commission on Human and Peoples' Rights has given a number of progressive interpretations of this provision, including asserting the obligation of States to give access to "adequate medical attention in the event of sickness or accident",[46] to "a social security system which provides for minimum coverage of health",[47] to "access to medical care",[48] to "an effective and integrated health system which is responsive to national and local priorities, and accessible to all",[49] to "affordable health facilities, infrastructure, goods and services to all without discrimination", to "equitable distribution of all health facilities, goods and services and measures to ensure physical access by all"[50] and at "reasonable distances."[51] In relation to specific diseases which pose particular challenges in the region, the African Commission also called on States to "guarantee free access to anti-retroviral drugs"[52], to make "affordable and comprehensive health care available to African governments for urgent action against HIV/AIDS"[53] and to provide "prompt access to…the appropriate and affordable treatment within twenty-four hours of the onset of symptoms [of malaria]".[54]

Soft law instruments too provide for accessibility, often requiring equitable and affordable access. For example, the UNESCO Universal Declaration on Bioethics and Human Rights defines as one of its aims "to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries".[55] It recommends "access to quality health care and essential medicines, especially for the health of women and children".[56] The UN Agenda for Sustainable Development contains a number of accessibility of health care recommendations too, particularly the achievement of universal health coverage including access to essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines to all;[57] access to quality health care, ensuring universal access to sexual and

[45] African Charter on Human and Peoples' Rights, Art 16.
[46] State Party Reporting Guidelines for Economic, Social and Cultural Rights in the African Charter on Human and Peoples' Rights on National Periodic Reports (2011).
[47] Ibid.
[48] Resolution on Access to Health and Needed Medicines in Africa, ACHPR/Res.141, 24 November 2008.
[49] Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter on Human and Peoples' Rights, para. 62.
[50] Ibid, para. 67.
[51] General Comment No 2 on Article 14(1)(a), (b), (c) and (f) and Article 14 (2) (a) and (c) of the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, 28 November 2014, paras 29-30.
[52] Concluding Observations on the Cumulative Periodic Reports of the Republic of Angola, February 2014, para. 29.
[53] Resolution on the HIV/AIDS Pandemic Threat against Human Rights and Humanity, ACHPR/Res. 53, 7 May 2001.
[54] Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter of Human and Peoples' Rights, para. 67.
[55] UNESCO Universal Declaration on Bioethics and Human Rights, Art 1(f).
[56] Ibid, Art 14(a).
[57] UN GA Resolution 70/1 (2015) Transforming our World: the 2030 Agenda for Sustainable Development, Goal 3.8.

reproductive health care services, including family planning and integration of reproductive health.[58]

Accessibility was emphasised during the COVID-19 pandemic when the WHO called on States to provide "universal, timely and equitable access to, and fair distribution of, all quality, safe and efficacious and affordable health technologies and products…required in response to the COVID-19 pandemic" and "access to safe testing, treatment, and palliative care for COVID-19".[59] Last but not least, the Council of Europe's Resolution on Equal Access to Health Care calls on Member States to ensure that the cost of care does not hinder access to care, including through the promotion of generic drugs; to ensure accessibility of health care facilities and health professionals throughout the territory; to ensure that pregnant women and children have full access to health care irrespective of their status and to guarantee physical accessibility of vaccines, especially for marginalised groups and people in remote areas.[60]

International human rights courts have affirmed certain aspects of accessibility as part of positive international law, including an obligation to ensure access to essential health services and drugs;[61] the right of persons infected by HIV/AIDS to access good quality goods, services and technologies for HIV prevention, treatment, care and support, including medicines;[62] the right of cancer patients to appropriate free medical treatment, including anti-cancerous medication;[63] the right of pregnant women to access information about their health and the health of their foetus, including the right to genetic testing where provided for in domestic law and the right to access to lawful abortion.[64]

Overall, it is well established that accessibility of health care requires States to provide equal access without discrimination to facilities, goods, services and information. It is increasingly well established that accessibility includes four dimensions: non-discrimination, physical accessibility, economic accessibility and the accessibility of relevant health information. What remains controversial is whether access to health care should also be equitable and what this entails in practice.

[58] Ibid, Goal 3.7.
[59] WHA Res 73.1 (2020) COVID-19 Response, paras 4 and 7(7).
[60] Council of Europe Resolution 1946 (2013) Equal Access to Health Care, paras 6 -7.
[61] *Case of Cuscul Pivaral et al v Guatemala*, IACtHR, Judgment of 23 August 2018, Series C No 359, para. 105.
[62] Ibid, para. 108.
[63] *Panaitescu v Romania*, ECtHR (2017).
[64] *RR v Poland*, ECtHR (2011), paras 157 and 210.

2. AVAILABILITY

The standard of availability is closely connected to but distinct from accessibility. It refers to the presence and distribution of all health care facilities, goods and services, to the provision of essential drugs and to the elimination of geographical disparities that often exist within the same State.

General Comment No 14 on the right to health defines availability as:

> Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party. The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party's developmental level. They will include, however, the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs, as defined by the WHO Action Programme on Essential Drugs…[65]

A similar definition of availability is the one provided by the African Commission on Human and Peoples' Rights:

> The availability of the rights, which requires that the state should ensure that the necessary goods and services needed to enjoy the rights are practically available to the individual, regardless of how this is achieved…. This requires that the goods and services provided to the individual are sufficient to meet all the requirements of the rights protected.[66]

The Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights requires States to make primary health care available to all individuals and families in the community.[67]

The UN Convention on the Rights of Persons with Disabilities imposes an obligation on States to "[p]rovide those health services needed by persons with disabilities specifically because of their disabilities, including early identification and intervention as appropriate, and services designed to minimize and prevent further disabilities, including among children and older persons".[68]

According to General Comment No 25 on the right to benefit from science, availability "means that scientific progress is actually taking place, and that scientific knowledge and its applications are protected and widely disseminated. States parties should direct their own resources and coordinate actions of others to ensure that scientific progress happens and that

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[65] General Comment No 14, para. 12 (a).
[66] Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter, para. 3(a).
[67] Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, Art 10(a).
[68] UN Convention on the Rights of Persons with Disabilities, Art 25(b).

its applications and benefits are distributed and are available, especially to vulnerable and marginalized groups."[69]

In the context of sexual and reproductive health, according to General Comment No 22, availability entails:

> An adequate number of functioning health care facilities, services, goods and programmes should be available to provide the population with the fullest possible range of sexual and reproductive health care. This includes ensuring the availability of facilities, goods and services for the guarantee of the underlying determinants of the realization of the right to sexual and reproductive health, such as safe and potable drinking water and adequate sanitation facilities, hospitals and clinics.
>
> Ensuring the availability of trained medical and professional personnel and skilled providers who are trained to perform the full range of sexual and reproductive health care services is a critical component of ensuring availability. Essential medicines should also be available, including a wide range of contraceptive methods, such as condoms and emergency contraception, medicines for abortion and for post-abortion care, and medicines, including generic medicines, for the prevention and treatment of sexually transmitted infections and HIV.[70]

It also requires States to provide medicines, equipment and technologies essential to sexual and reproductive health, including based on the WHO Model List of Essential Medicines.[71]

In terms of availability in soft law instruments, the Universal Declaration on the Human Genome and Human Rights requires that "[b]enefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all".[72] The UNESCO Universal Declaration on Bioethics and Human Rights recommends making available "new diagnostic and therapeutic modalities or products stemming from research".[73] According to the UN Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care, "[a]ll persons have the right to the best available mental health care, which shall be part of the health and social care system."[74]

Overall, it seems increasingly well-established that States have to make practically available to their population health care facilities (be they public or private), goods (particularly essential drugs), services and information. These ought to be adequate to enable individuals to enjoy the right to health, including reproductive and mental health. However, the precise character and the scope of what ought to be made available is unclear and may well vary from State to State depending on its development and available resources, as well as between different groups of the population, where vulnerable and marginalised groups might require a greater degree of availability.

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[69] General Comment No 25, para. 16.
[70] General Comment No 22, paras 12-13.
[71] Ibid, para. 49 (g).
[72] Universal Declaration on the Human Genome and Human Rights, Art 11(a).
[73] Universal Declaration on Bioethics and Human Rights, Art 21(1)(c).
[74] UNGA Resolution 46/119 (1991) The protection of persons with mental illness and the improvement of mental health.

3. QUALITY

Quality relates to the standard of health care required, including the use of trained and skilled health care personnel, of scientifically approved drugs, the incorporation of new and safe technology, the provision of scientifically accurate information and more generally, the accordance of health care with generally accepted scientific principles and standards, as well as with relevant and up-to-date information. The standard of quality directly corresponds to the objective of guaranteeing patient safety.

General Comment No 14 on the right to health defines quality as meaning that "goods and services must also be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation."[75] The ESC's reporting guidelines on the right to health under the ICESCR require States to report on the measures taken to ensure "[t]hat drugs and medical equipment are scientifically approved and have not expired or become ineffective" and that "[a]dequate training of health personnel, including on health and human rights."[76]

General Comment No 25 on the right to benefit from science provides that "[q]uality refers to the most advanced, up-to-date and generally accepted and verifiable science available at the time, according to the standards generally accepted by the scientific community. This element applies both to the process of scientific creation and to access to the applications and benefits of science. Quality also includes regulation and certification, as necessary, to ensure the responsible and ethical development and application of science. States should rely on widely accepted scientific knowledge, in dialogue with the scientific community, to regulate and certify the circulation of new scientific applications accessible to the public."[77]

General Comment No 22 on the right to sexual and reproductive health requires that the facilities, goods, information and services in this area must be "evidence-based and scientifically and medically appropriate and up-to-date" which requires trained and skilled health care personnel and scientifically approved and unexpired drugs and equipment.[78] Notably, "[t]he failure or refusal to incorporate technological advances and innovations in the provision of sexual and reproductive health services, such as medication for abortion, assisted reproductive technologies and advances in the treatment of HIV and AIDS, jeopardizes the quality of care."[79]

The Oviedo Convention on Human Rights and Biomedicine defines quality of health care in terms of adhering to the relevant professional obligations and standards when undertaking health interventions and research.[80] According to the Explanatory Report to the Convention, quality must be of a fitting standard in light of scientific progress and be subject to continuous assessment.[81] The Additional Protocol to the Convention concerning Genetic Testing for

[75] General Comment No 14, para. 12 (d).
[76] CESCR, Guidelines on Treaty-Specific Documents, Art 12, para. 56 (c) and (d).
[77] General Comment No 25, para. 18.
[78] General Comment No 22, para. 21.
[79] Ibid.
[80] Oviedo Convention on Human Rights and Biomedicine, Art 4.
[81] Explanatory Report to the Oviedo Convention, para. 24.

Health Purposes clarifies further that quality refers to meeting the "generally accepted criteria of scientific validity and clinical validity", the implementation of quality assurance programmes and monitoring in health care facilities and ensuring that persons providing genetic services are appropriately qualified.[82]

According the UN Principles for the Protection of Persons with Mental Illness, mental health care "shall always be provided in accordance with applicable standards of ethics for mental health practitioners, including internationally accepted standards such as the Principles of Medical Ethics adopted by the United Nations General Assembly."[83]

The requirement of quality of health care seems to be well-established in international human rights law. It includes the quality of health care goods, technologies, services, information and personnel. The measure of quality is that of up-to-date, generally accepted and verifiable evidence-based science, of internationally accepted scientific but also ethical standards. Quality includes not only the final health care services and goods but also the processes of their regulation and certification.

4. ACCEPTABILITY

Acceptability requires providing health care, including all facilities, goods, information and services, in a manner respectful of social and cultural norms, including those of individuals, minorities, peoples and communities. Acceptability is one of the more recently developed human rights standards of health care.

General Comment No 14 on the right to health sets out that:

> All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned…[84]

Similarly, the Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter define acceptability as ensuring that "health systems respect cultural differences, and ethnic diversity, while encouraging members of vulnerable and disadvantaged groups to study medicine and public health and to join the system as service providers".[85]

According to General Comment No 25 on the right to benefit from science, "Acceptability implies that efforts should be made to ensure that science is explained and its applications are disseminated in such a manner as to facilitate their acceptance in different cultural and social contexts, provided that this does not affect their integrity and quality."[86]

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[82] Additional Protocol to the Convention on Human Rights and Biomedicine, Art 5.
[83] UNGA Resolution 46/119 The protection of persons with mental illness, Principle 9(3).
[84] General Comment No 12, para. 12 (c).
[85] Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter, para.67(z)(aa).
[86] General Comment No 25, para. 19.

Similarly, in the area of sexual and reproductive health, "[a]ll facilities, goods, information and services related to sexual and reproductive health must be respectful of the culture of individuals, minorities, peoples and communities and sensitive to gender, age, disability, sexual diversity and life-cycle requirements."[87] Notably, this cannot be used to justify the refusal to provide tailored facilities, goods, information and services to specific groups.[88]

Whilst new, the acceptability of health care seems to have become increasingly well established at both the international and regional levels. It is not entirely clear, however, what it entails in practice beyond the general requirement of health care being respectful of cultural, ethnic and other differences.

5. EQUALITY AND NON-DISCRIMINATION

The human rights standards of equality and non-discrimination are closely linked to the standard of accessibility discussed above. The key differences are the emphasis being on prohibiting discrimination based on specific characteristics or with respect to specific groups, as well as the scope of the standard that goes beyond access. Equality and non-discrimination are increasingly interpreted by the CESCR as requiring not only legal and formal equality but also substantive equality with respect to health care.[89]

According to General Comment No 14, "the Covenant proscribes any discrimination in access to health care and underlying determinants of health, as well as to means and entitlements for their procurement, on the grounds of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, physical or mental disability, health status (including HIV/AIDS), sexual orientation and civil, political, social or other status, which has the intention or effect of nullifying or impairing the equal enjoyment or exercise of the right to health."

The comment emphasises further that: "States have a special obligation to provide those who do not have sufficient means with the necessary health insurance and health-care facilities, and to prevent any discrimination on internationally prohibited grounds in the provision of health care and health services, especially with respect to the core obligations of the right to health. Inappropriate health resource allocation can lead to discrimination that may not be overt. For example, investments should not disproportionately favour expensive curative health services which are often accessible only to a small, privileged fraction of the population, rather than primary and preventive health care benefiting a far larger part of the population."[90]

According to General Comment No 3 on the nature of States Parties' obligations, even in times of severe resource constraints, the vulnerable members of society must be protected by the adoption of relatively low-cost targeted programmes.[91]

[87] General Comment No 22, para. 20.
[88] Ibid.
[89] General Comment No 22, para. 24.
[90] General Comment No 14, para. 19.
[91] General Comment No 3 Nature of States Parties' Obligations, para. 12.

General Comment No 25 on the right to benefit from science emphasises that "States parties are under an immediate obligation to eliminate all forms of discrimination against individuals and groups in their enjoyment of economic, social and cultural rights. This duty is of particular importance in relation to the right to participate in and to enjoy the benefits of scientific progress and its applications because deep inequalities persist in the enjoyment of this right. States must adopt the measures necessary to eliminate conditions and combat attitudes that perpetuate inequality and discrimination in order to enable all individuals and groups to enjoy this right without discrimination, including on the grounds of religion, national origin, sex, sexual orientation and gender identity, race and ethnic identity, disability, poverty and any other relevant status."[92]

In the context of sexual and reproductive health care, equality and non-discrimination require a tailored approach towards the distinct sexual and reproductive health needs of particular groups, as well as the barriers they face.[93] A key example are the needs and rights of persons with disabilities who "should be able to enjoy not only the same range and quality of sexual and reproductive health services but also those services which they would need specifically because of their disabilities. Further, reasonable accommodation must be made to enable persons with disabilities to fully access sexual and reproductive health services on an equal basis, such as physically accessible facilities, information in accessible formats and decision-making support, and States should ensure that care is provided in a respectful and dignified manner that does not exacerbate marginalization."[94] Particular steps are also required with respect to ensuring access to sexual and reproductive information, goods and health care to prisoners, refugees, stateless persons, asylum seekers and undocumented migrants given their vulnerabilities.[95] Arguably, these should extend to providing health care, goods and services to these often marginalised groups more generally.

The UN Convention on the Rights of Persons with Disabilities requires States to prevent discriminatory denial of health care or health services on the basis of disability.[96]

The African Commission on Human and Peoples' Rights defines equality in its Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter as ensuring the "provision of basic social services (such as…health care) and equitable access to resources to members of vulnerable and disadvantaged groups."[97]

Soft-law instruments too provide for equality and non-discrimination. The Universal Declaration on the Human Genome and Human Rights requires that "[n]o one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."[98] There is also increasingly a requirement for inter-generational equity recommending that States give

[92] General Comment No 25, para. 25.
[93] General Comment No 22, para. 24.
[94] Ibid.
[95] Ibid, para. 31.
[96] UN Convention on the Rights of Persons with Disabilities, Art 25(f).
[97] Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter, para. 33.
[98] UNESCO Universal Declaration on the Human Genome and Human Rights, 1997, Art 6.

due regard to the impact of life sciences on the rights of future generations, including their genetic constitution.[99]

The prohibition against discrimination is a cornerstone principle of international law from which no derogation is permitted, even in time of emergency. Equality is its corollary principle. Both are well established and binding on all States. There is some uncertainty, however, with respect to the interpretation of equality with legal or formal equality being generally accepted but substantive equality, i.e. equality in practice being much more difficult to achieve. There is a growing international consensus that States have an obligation to help achieve substantive equality for vulnerable and marginalised persons in the context of health care.

6. CONSENT

The free, prior and informed consent to health care interventions is one of the cornerstones of modern human rights law codified in Article 7 of the International Covenant on Civil and Political Rights on the prohibition against torture and inhuman and degrading treatment, providing that "no one shall be subjected without his free consent to medical or scientific experimentation". The principle of consent is a direct corollary of the principles of human dignity and autonomy.[100] According to the UN Special Rapporteur on the right of everyone to the highest attainable standard of health:

> The right to informed consent is a fundamental element of the right to physical and mental health. Informed consent involves a voluntary and sufficiently informed decision, and serves to promote a person's autonomy, self-determination, bodily integrity and wellbeing. It encompasses the right to consent to, refuse or choose an alternative medical treatment.[101]

The UN's Committee on Economic, Social and Cultural Rights has emphasised that special attention ought to be given to the protection of women's free, prior and informed consent in treatments or scientific research on sexual and reproductive health,[102] as well as the need for genuine consultation to obtain the consent of indigenous peoples when using their knowledge or in relation to health care policies that have impact on them.[103] The importance of clear and transparent evaluation and communication of risks to allow for properly informed consent is also emphasised in the context of health-related research and applications that carry risks for the participants.[104] Examples of violations of the principle of free, prior and informed consent include State laws and policies that perpetuate coercive medical practices, that censor or withhold information or that present inaccurate, misrepresentative or discriminatory

[99] UNESCO Universal Declaration on Bioethics and Human Rights, Art 16.
[100] See e.g, CESCR General Comment No 25 (2020), paras 19 and 22.
[101] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (2018) A/HRC/38/36, para. 25.
[102] CESCR General Comment No 25, para. 33. See also Protocol to the African Charter on the Rights of Women in Africa, Art 4.
[103] Ibid, para. 39. See also Principles and Guidelines on the Implementation if Economic, Social and Cultural Rights in the African Charter on Human and Peoples' Rights (Nairobi), para. 44.
[104] Ibid, para. 71.

information related to health.[105] Other examples would be non-consensual medical treatment, experimentation and forced sterilisation.[106]

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine Art 5 sets out the general rule that:

> An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
>
> This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
>
> The person concerned may freely withdraw consent at any time.

According to the Explanatory Report to the Oviedo Convention, consent is free and informed "if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone" and where the information is "sufficiently clear and suitably worded for the person who is to undergo the intervention. The patient must be put in a position, through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aim and methods of the intervention against its risks and the discomfort or pain it will cause."[107]

The Oviedo Convention contains special rules on the protection of persons who are not able to consent requiring that medical interventions are carried out only when they are in their direct benefit and with the authorisation of their representative or a legally designated authority.[108] According to the UN General Comment on the right of the child to the enjoyment of the highest attainable standard of health, "States should review and consider allowing children to consent to certain medical treatments and interventions without the permission of a parent, caregiver, or guardian, such as HIV testing and sexual and reproductive health services, including education and guidance on sexual health, contraception and safe abortion."[109] Similarly, the UN Convention on Persons with Disabilities imposes an obligation on States to require that health care professionals provide care on the basis of the free and informed consent of persons with disabilities.[110]

Persons with a serious mental disorder may be subjected to treatment of their disorder only where a serious harm would to their health would likely result without the treatment.[111] According to the European Court of Human Rights, '[i]n the sphere of medical assistance, even where the refusal to accept a particular treatment might lead to a fatal outcome, the

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[105] CESCR, General Comment No 22 (2016), para. 58.
[106] African Commission on Human and Peoples' Rights, Communication No 227/99, *Democratic Republic of Congo v Burundi*, Rwanda, Uganda, 29 May 2003, para. 88.
[107] Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, paras 35-6.
[108] Oviedo Convention, Art 6.
[109] General Comment No 13 on the right of the child to the enjoyment of the highest attainable standard of health (2013), para. 31.
[110] UN Convention on the Rights of Persons with Disabilities, Art 25(d).
[111] Oviedo Convention, Art 7.

imposition of medical treatment without the consent of a mentally competent adult patient would interfere with his or her right to physical integrity contrary to article 8'.[112]

Furthermore, where consent cannot be obtained in an emergency situation, medically necessary interventions may be carried out for the benefit of the health of the individual.[113] Similar provisions regarding the general rule on consent and the special rules on persons who are not able to consent can be found in the Additional Protocol to the Oviedo Convention concerning Genetic Testing for Health Purposes.[114]

The EU Charter of Fundamental Rights also requires the free and informed consent of the persons concerned in the fields of medicine and biology as part of the right to integrity of the person.[115] A similar approach has been adopted in the interpretation of Article 8 of the ECHR on the right to respect for private and family life. According to the European Court of Human Rights 'a medical intervention in defiance of the subject's will gives rise to an interference with respect for his or her private life, and in particular his or her right to physical integrity'.[116]

The principle of consent is set out in numerous soft law instruments in the field of health too.[117] The principle of consent was codified in the1947 Nuremberg Code in response to the medical experiment atrocities during World War II. The Code emphasises that voluntary consent is "absolutely essential" and clarifies that this means that "the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."[118]

The principle of consent has been interpreted and applied in case law. For instance, the Inter-American Court of Human Rights addressed it in the case of *I.V. v Bolivia* concerning forced sterilisation in the absence of an emergency situation and without the informed consent of I.V. The Court held that:

> States have the international obligation to obtain informed consent before performing any medical act based, above all, on the autonomy and self determination of the individual, and as part of respecting and ensuring the dignity of every human being, as

[112] *Jehovah's Witnesses of Moscow v. Russia*, No. 302/02, 10 June 2010, para. 135; *Pretty v. the United Kingdom*, No 2346/02, ECHR 2002-III, para. 63; *Glass v. the United Kingdom*, No 61827/00, ECHR 2004-II, paras 70–72.
[113] Oviedo Convention, Art 8.
[114] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes, Art 9 and 13.
[115] EU Charter of Fundamental Rights, Art 3.
[116] See e.g., *X v. Finland*, No 34806/04, ECHR 2012, para. 212; *Glass v. the United Kingdom*, No 61827/00, ECHR 2004-II, para. 70; *Y.F. v. Turkey*, No 24209/94, ECHR 2003-IX, para. 33; *Jehovah's Witnesses of Moscow v. Russia*, No 302/02, 10 June 2010, para. 135; *Shopov v. Bulgaria*, No 11373/04, 2 September 2010, para. 41.
[117] WMA Declaration of Helsinki 1964, paras 25, 26 and 37; Universal Declaration on the Human Genome and Human Rights 1997, Art 5; UNGA 46/119, Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Healthcare (1991), Art 5 and 11; UNESCO Universal Declaration on Bioethics and Human Rights, Art 6.
[118] Nuremberg Code, para. 1. See also para. 9.

> well as their right to personal liberty. This means that the individual may act according to his or her own wishes, and ability to consider choices, take decisions and act without the arbitrary interference of third parties, all of this within the limits established in the Convention. This is so, especially, in cases of female sterilization, because such procedures entail the permanent loss of reproductive capacity. The need to obtain informed consent protects not only the right of patients to decide freely whether they wish to submit to a medical act, but is also an essential mechanism to achieve the respect and guarantee of different human rights recognized by the American Convention, such as to dignity, to personal liberty, to personal integrity – including health care and, in particular, sexual and reproductive health care – to private and family life and to raise a family.[119]

In *Elberte v Latvia,* the European Court of Human Rights found that Latvia's law on the operation of consent with respect to tissue removal which allowed for the removal of tissue from the body of the applicant's deceased husband without her knowledge or consent lacked clarity and the necessary safeguards against arbitrariness thus violating the right to respect for private and family life and the prohibition against inhuman and degrading treatment.[120] The case of *Nevmerzhitsky v Ukraine* concerned the lack of consent of a detained person who was force-fed without strict medical necessity. The Court concluded that this conduct constituted degrading treatment.[121]

7. PRIVACY AND THE PROTECTION OF PERSONAL INFORMATION

The right to privacy is well-established in international human rights law, being set out in Article 12 of the Universal Declaration of Human Rights, in Article 17 of the ICCPR, in Article 22 of the UN Convention on the Rights of Persons with Disabilities, as well as in Article 16 of the UN Convention on the Rights of the Child. It is also included in a number of regional human rights treaties, such as Article 8 of the ECHR and Article 11 of the American Convention on Human Rights. The EU Charter of Fundamental Rights contains separate provisions on the right to private life in Article 7 and on the protection of personal data in Article 8, both of which have been interpreted as aspects of privacy in practice and in case law.[122]

The right to privacy imposes both negative and positive obligations on States. The negative obligations are included in all surveyed treaties and require the protection of individual autonomy from arbitrary or unlawful interference.[123] The positive obligations are emphasised in the UDHR, the ICCPR and the Human Rights Committee's General Comment No 16, which require the State to protect privacy through the law.[124] According to General Comment No 16, a further positive obligation is imposed on the State to guarantee the right to privacy "against all such interferences and attacks whether they emanate from State authorities or from natural or legal persons".[125]

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[119] Case of *I.V. v Bolivia*, Judgment of 30 November 2016, Ser C No 329, para. 165.
[120] *Elberte v Latvia,* Application No 61243/08, Judgment of 13 January 2015.
[121] *Nevmerzhitsky v Ukraine*, Application No 54825/00, Judgment of 5 April 2005, paras 87 et seq.
[122] See HRC, General Comment No 16, para. 10.
[123] See Art 12 UDHR and Art 17 ICCPR.
[124] UDHR, Art 12; ICCPR, Art 17(2); General Comment No 16.
[125] General Comment No 16, para. 1.

Human rights courts and treaty bodies have interpreted the right to privacy to include: the regulation by law of "[t]he gathering and holding of personal information on computers, data banks and other devices, whether by public authorities or private individuals or bodies" and ensuring that "that information concerning a person's private life does not reach the hands of persons who are not authorized by law to receive, process and use it, and is never used for purposes incompatible with the Covenant";[126] the right to have personal health data treated with confidentiality;[127]the physical and psychological integrity of the person;[128] the prohibition against forced medical treatment and examinations;[129] the right to personal autonomy and self-determination, including the right to make decisions about one's body;[130] as well as the right to information with respect to risks to one's health.[131]

The right to privacy and to protection of personal data also finds expression in international instruments regulating health and human rights. The Oviedo Convention affirms the right of everyone "to respect for private life in relation to information about his or her health".[132] Similarly, the Additional Protocol to the Oviedo Convention concerning Genetic Testing for Health Purposes affirms the right to protection of personal data derived from genetic tests, the right to access any information derived from such tests that is about their health, as well as the right not to be informed.[133] The International Health Regulations of the WHO contain a detailed provision on the confidential treatment and anonymisation of personal data disclosed for the purposes of managing public health risks.[134]

Last but not least, the right to privacy and to protection of personal data is reflected in soft law instruments in the area of health. The UNESCO Declaration on Bioethics and Human Rights affirms the right to privacy and to confidentiality of personal information.[135] It requires further that "such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law."[136] The Universal Declaration on the Human Genome and Human Rights that requires that "[g]enetic data associated with an identifiable person and stored and processed for the purposes of research or any other purpose must be kept confidential in the conditions set by law."[137] Other soft law instruments including the right to privacy include the WMA Declaration of Helsinki[138] and the UN Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care.[139]

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[126] Ibid, para. 10.
[127] General Comment No 14, para. 12(b) and General Comment No 22 on the right to sexual and reproductive health, para. 18.
[128] *X and Y v The Netherlands*, ECtHR, Ser A No 91, paras 22, 30.
[129] *Glass v UK*, ECtHR, Reports 2004-II 25, paras 70-2.
[130] *Pretty v UK*, ECtHR, 2346/02, paras 61 and 67.
[131] *Guerra and Others v Italy*, ECtHR, Reports 19980I 211, para. 60.
[132] Oviedo Convention, Art 10.
[133] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes, Art 16.
[134] WHO International Health Regulations, Art 45.
[135] UNESCO Universal Declaration on Bioethics and Human Rights, Art 9.
[136] Ibid.
[137] Universal Declaration on the Human Genome and Human Rights, Art 7.
[138] WMA Declaration of Helsinki, para. 24,
[139] UNGA 46/119 (1991) Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care, principle 6.

International human rights courts have further clarified the right to privacy and to confidential information in case law. The European Court of Human Rights emphasised in a line of case law that the "protection of personal data, in particular medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention."[140] The Court found that the failure of a health authority to establish a register for securing confidential personal medical data against unauthorised access was a breach of the right to privacy.[141] The ECtHR also confirmed that a hospital refusal to give photocopies of medical records constitutes a breach of the right to privacy under Article 8 of the ECHR.[142] The denial of timely access to prenatal genetic tests is another example of violating Article 8 of the ECHR.[143]

8. PRIMACY OF THE INDIVIDUAL AND NO HARM PRINCIPLE

The primacy of the individual is inherent in all international human rights instruments, which emphasise the protection of human dignity and individual rights, limiting the interference by the State on the basis of a narrow set of recognised public interests and subject to strict conditions of necessity and proportionality.[144] Human rights instruments in the area of health and health care contain express provisions on the primacy of the human being providing that in the case of conflict, the interests and welfare of the individual shall prevail over the sole interest of science or society.[145]

The primacy of the individual also applies in the context of medical research. The WMA Declaration of Helsinki provides that medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the individuals involved.[146] A similar provision can be found in the Nuremberg Code.[147]

The primacy of the individual is linked to the principles of no harm and maximising benefits in the context of medical interventions. For example, according to the Universal Declaration on the Human Genome and Human Rights:

> No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.[148]

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[140] *I. v Finland*, Application No 20511/03, ECtHR 2008, para. 38.
[141] Ibid, para. 46.
[142] *K.H and Others v Slovakia*, Application No 32881/04, ECtHR 2009, paras 44-58.
[143] *R.R. v Poland*, Application No 27617/04, ECtHR 2011, para. 188.
[144] See e.g., Art 4 ICCPR and Art 15 ECHR.
[145] Oviedo Convention on Human Rights and Biomedicine, Art 2; Additional Protocol to the Oviedo Convention concerning Genetic Testing for Health Purposes, Art 3 and UNESCO Universal Declaration on Bioethics and Human Rights, Art 3(2).
[146] WMA Declaration of Helsinki, para. 16.
[147] Nuremberg Code 1947, para. 10.
[148] UNESCO Universal Declaration on the Human Genome and Human Rights, Art 10.

The Oviedo Convention on Human Rights and Biomedicine adopts a proportionality approach in requiring that scientific research on a person may only be undertaken if, *inter alia*, "the risks which may be incurred by that person are not disproportionate to the potential benefits of the research".[149] The UNESCO Declaration on Bioethics and Human Rights recommends that in applying and advancing scientific knowledge and technologies, the benefit to affected individuals such as patients should be maximised and any possible harm ought to be minimised.[150] Similarly, the Protocol to the African Charter on the Rights of Women in Africa obliges States to prohibit all forms of harmful practices which negatively affect the human rights of women and which are contrary to recognised international standards, such as female genital mutilation.[151] Harmful practices are defined as "all behaviour, attitudes and/or practices which negatively affect the fundamental rights of women and girls, such as their right to life, health, dignity…and physical integrity".[152] The Principles for the Protection of Persons with Mental Illness include the no harm principle as part of the standard of care, requiring that:

> Every patient shall be protected from harm, including unjustified medication, abuse by other patients, staff or others or other acts or physical causing mental distress discomfort.[153]

Some instruments combine the no harm principle with the maximisation of benefits. For instance, the UNESCO Declaration on Bioethics and Human Rights stresses that the applications of research in genetics and medicine concerning the human genome "shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole."[154] The requirement in the Oviedo Convention on Human Rights and Biomedicine that genetic interventions ought to be undertaken only for preventive, diagnostic or therapeutic purposes and provided that their aim is not to introduce any germline modification, can be read in similar vein.[155]

According to the UN Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, "first, do no harm" is a principle of medial ethics that ought to be respected.[156]General Comment No 25 on the right to science defines 'unacceptable harm' as "(a) threatening to human life or health; (b) serious and effectively irreversible; (c) inequitable to present or future generations; or (d) imposed without adequate consideration of the human rights of those affected."[157] The Committee on Economic, Social and Cultural Rights recommends that the benefits of science to affected individuals should be maximised and any possible harm, minimised through reasonable protection and safeguards.[158] According to the Committee, when an action or policy might lead to unacceptable harm and in the absence of full scientific certainty, the no harm principle requires

[149] Oviedo Convention on Human Rights and Biomedicine, Art 16(ii).
[150] UNESCO Declaration on Bioethics and Human Rights, Art. 4 Benefit and Harm.
[151] Protocol to the African Charter on the Rights of Women in Africa, Art 5.
[152] Ibid, Art 1(g).
[153] UNGA Res 46/119 Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care, Principle8(2).
[154] Oviedo Convention on Human Rights and Biomedicine, Article 12(b).
[155] Ibid, Art 13.
[156] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (2020), para. 65.
[157] Ibid, para. 56.
[158] CESCR, General Comment No 25 on article 15, para. 19.

that actions are taken to avoid or minimise unacceptable harm.[159] States are also required to implement laws and policies that prohibit conduct from third parties that cause harm to the physical or mental integrity of individuals or undermine their full enjoyment of the right to health.[160]

9. PREVENTION

The duty to act with due diligence in preventing harm to the individual and their human rights is increasingly incorporated in human rights law.[161] Article 12 of the ICESCR on the right to health imposes an obligation on States to take steps for the prevention of epidemic, endemic, occupational and other diseases.[162] The UN Convention on the Rights of the Child requires States to develop preventive health care and guidance for parents.[163] Similarly, according to the EU Charter of Fundamental Rights, everyone has the right of access to preventive health care.[164] One of the central purposes of the WHO International Health Regulations is the prevention of the international spread of disease.[165]

The Committee on Economic, Social and Cultural Rights sees giving timely access to basic preventive health services;[166] regular screening programmes;[167] preventing third parties including individuals, groups and corporations from interfering with the right to health by regulating their activities;[168] implementing immunization programmes and other strategies to control infectious diseases, as well as the prevention of sexually transmitted diseases as measures that States ought to take to give effect to their obligation under Article 12 ICESCR.[169] General Comment No 25 on the right to benefit from science identifies technological and human rights impact assessments as tools for identifying risks relating to the process and use of scientific applications, including medical ones.[170] According to the authoritative interpretations of human rights treaty bodies, the duty of prevention in the context of health also includes encouraging States to foster research on the prevention of genetically based and influenced diseases, both rare and endemic ones;[171] preventing unreasonably high costs for access to essential medicines;[172] the application of the precautionary principle to the protection of the participants in scientific research;[173] improving early warning mechanisms based on sharing timely and transparent information between States on emerging epidemics

[159] Ibid.
[160] CESCR, General Comment No 22 on the right to sexual and reproductive health, para. 42.
[161] See e.g., Convention on Preventing and Combating Violence against Women and Domestic Violence, 11 May 2011, Art 5.
[162] ICESCR, Art 12(c)
[163] UN Convention on the Rights of the Child, Art 24(2) (f).
[164] EU Charter of Fundamental Rights, Art 35.
[165] WHO IHR, Art 2 Purposes and scope. See also Art 19(2) General obligations.
[166] CESCR, General Comment No 14 on the right to health, para. 17.
[167] Ibid.
[168] Ibid, paras 33 and 51.
[169] CESCR, Guidelines on Treaty-Specific Documents to be Submitted by States Parties, Art 12 ICESCR.
[170] CESCR, General Comment No 25, para. 56.
[171] UNESCO Declaration on the Human Genome and Human Rights, Art 17.
[172] CESCR, General Comment No 25 on the right to benefit from science, para. 62.
[173] Ibid, para. 71.

to prevent them from becoming pandemics;[174] the prevention of infertility, reproductive cancers and HIV, including with generic medicines;[175] the prevention of unsafe abortions;[176] providing preventive measures for endemic diseases such as tuberculosis and malaria;[177] free and regular medical checks and screening for pregnant women and children;[178] screening for illnesses responsible for high premature mortality rates;[179] the prevention of mental disorders in children;[180] the prevention of maternal mortality and morbidity;[181] the taking of proper preparations and provision of adequate facilities to protect the experimental subject against the possibilities of injury, disability and death;[182]and the prevention of non-communicable diseases.[183]

The procedural obligations relating to risk assessment and management that stem from the duty to act with due diligence in preventing harm are commonly incorporated in instruments dealing with human rights in the context of biomedicine. For example, the Universal Declaration on the Human Genome requires rigorous assessment of the potential risks but also of the benefits pertaining to the individual's genome prior to any research, treatment or diagnosis that involves it.[184] The UNESCO Declaration on Bioethics and Human Rights emphasises not only the need of risk assessment but also of adequate risk management in relation to medicine, life sciences and associated technologies.[185] Related to this, it recommends that States give due regard to the impact of life sciences on future generations.[186]

The rights of future generations are a concept that reflects long-term prevention in the course of numerous generations. According to the UN Declaration on the Responsibilities of the Present Generations Towards Future Generations, in the field of the human genetics the rights of future generations entail a basic obligation to ensure that scientific and technological progress do not impair or compromise the preservation of the human species.[187] UNESCO declarations in the field provide for a mix of obligations and recommendations to give due regard to the impact of life sciences on the rights of future generations so as not only to safeguard but also to promote their rights.[188] The Preamble of the Oviedo Convention emphasises the beneficence aspects of the obligation in requiring "that progress in biology and medicine should be used for the benefit of present and future generations".[189] The Universal Declaration on Bioethics and Human Rights defines as one of its objectives the dual

[174] Ibid, para. 82.
[175] CESCR, General Comment No 22 on the right to sexual and reproductive health, para. 45.
[176] Ibid, para. 49 (e).
[177] CESCR, General Comment No 19 on the right to social security, para. 13.
[178] Form for the Rreports to be submitted in pursuance of the 1961 European Social Charter and 1988 Additional Protocol adopted by the Committee of Ministers, 2008, para. 2.
[179] Ibid.
[180] General Comment No 15 on the right of the child to the enjoyment of the highest attainable standard of health (2013), para. 39.
[181] Ibid, para. 51.
[182] Nuremberg Code, para. 7.
[183] UN GA Res 66/2 on the Prevention and Control of Non-communicable disease (2011).
[184] Universal Declaration on the Human Genome and Human Rights, Art 5.
[185] UNESCO Declaration on Bioethics and Human Rights, Art. 20 Risk Assessment and Management.
[186] Ibid, Art. 16 Protecting Future Generations.
[187] UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations, 12 November 1997, Art. 6.
[188] Universal Declaration on Bioethics and Human Rights, Art. 16 and UNESCO Declaration on Science and the Use of Scientific Knowledge, para. 39.
[189] Oviedo Convention, Preamble, para. 1.

obligation to safeguard and promote the rights of present and future generations.[190] The UN Declaration on the Rights of Future Generations requires that "[t]he present generations have the responsibility of ensuring that the needs and interests of present and future generations are fully safeguarded."[191] As a minimum, the present generations *should* strive to ensure the continuation of humankind with due respect for the dignity of the human person.[192]

Overall, the duty of prevention in relation to health care includes risk assessment and management, close health care monitoring through regular examinations and screening programmes, the taking measures of timely measures that limit or delay the development of the disease, the prevention of the spreading of infectious and non-communicable diseases, the prevention of epidemic and endemic diseases and the provision of preventive health care with special care for vulnerable groups, including the disabled, mothers and children.

10. PARTICIPATION IN HEALTH-RELATED DECISION MAKING AT THE LEVEL OF THE INDIVIDUAL AND THE PUBLIC

International human rights law instruments increasingly recognise a right to participate in health-related decision making both at the level of the individual and also the public. The Committee on Economic, Social and Cultural Rights stresses the importance of "the participation of the population in all health-related decision-making at the community, national and international levels,"[193] including in political decisions relating to the right to health taken at both the community and national levels.[194] It requires States to develop a participatory national framework law for the realisation of the right to benefit from science and its applications as part of the core obligations under the right.[195] Similarly, the Preamble of the Oviedo Convention on Human Rights and Biomedicine recognises "the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto".[196] Article 28 requires that:

> Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

The UNESCO Declaration on Bioethics and Human Rights too lists as one of its aims the fostering of "multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole"[197] and recommends that "[o]pportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be

[190] UNESCO Declaration on Bioethics and Human Rights, Art 2(h).
[191] UNESCO Declaration on the Responsibilities of the Present Towards Future Generations, Art. 1.
[192] Ibid, Art 3.
[193] CESCR, General Comment No 14 on the right to health, para. 11.
[194] Ibid, para. 17.
[195] CESCR, General Comment No 25 on the right to science, para. 52.
[196] Oviedo Convention on Human Rights and Biomedicine, Preamble, para. 14.
[197] UNESCO Universal Declaration on Bioethics and Human Rights, Art 2(e).

promoted."[198] In the field of genetics, States are encouraged to facilitate "an open international discussion, ensuring the free expression of various sociocultural, religious and philosophical opinions."[199]

The right to participate in health-related decision making extends to the groups that would be specially affected by the decisions in question. For example, the Committee on the Rights of the Child requires States to ensure that adolescent girls and boys have the opportunity to participate actively in planning for their own health and development.[200] Similarly, indigenous peoples "have the right to be actively involved in developing and determining health…programmes affecting them".[201] The WHO Alma-Ata Declaration stresses that individuals "have the right and duty to participate individually and collectively in the planning and implementation of their health care."[202]

The Inter-American Court of Human Rights discussed individual participation in health-related decision making in the case of *I.V. v Bolivia* emphasising the special relationship between doctor and patient "characterised by the asymmetry in the exercise of power by the physician based on his special professional knowledge and ethics".[203] The Court observed a paradigm shift in this relationship towards shared decision-making based on the principle of consent:

> The Court notes that, in the practice of medicine, recognition of informed consent as an expression of the autonomy of the individual in the sphere of health has signified a paradigm shift in the physician-patient relationship, because the model of informed and free decision-making has evolved to focus on a participatory process with the patient, rather than the former paternalistic model where the physician, as the expert in the matter, was the one who decided what was best for the person who needed a particular treatment. From this perspective, patients are empowered and collaborate with the physician as the main actor in the decisions that must be taken with regard to their bodies and health, rather than the passive subjects of this relationship. The patient is free to choose alternatives that physicians may consider contrary to their advice, and this is the most evident expression of respect for autonomy in the sphere of medicine. This paradigm shift is reflected in various international instruments which refer to the right of the patient to freely accede to a beneficial medical act or allow it to be performed, without any type of violence, coercion or discrimination, after having received appropriate and timely information prior to taking the decision.[204]

Overall, it is increasingly recognised that both the individual and the public ought to be given a chance to participate in health-related decision making and that there is a corresponding obligation on States to enable such participation.

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[198] Ibid, Art 18(3).
[199] UNESCO Universal Declaration on the Human Genome and Human Rights, Art 21.
[200] CRC, General Comment No 4 Adolescent health and development, para. 31(d).
[201] United Nations Declaration on the Rights of Indigenous Peoples, Art 23.
[202] WHO Alma-Ata Declaration, para. IV.
[203] *Case of I.V. v Bolivia*, IACtHR, Set C No 329 (2016), para. 160.
[204] Ibid, para. 161.