

Equitable access, appropriate quality. Twenty years after the Oviedo Convention

Acceso equitativo, con calidad adecuada. Veinte años después de la Convención de Oviedo

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Abstract

The right to protection of health, which includes access to health care services, is enshrined in many Declarations and other normative documents at the international level. The reference to equity is usually meant to deal with the constraint of available resources and not elude the reality of persisting inequalities. The reference to appropriateness is to underline the role of professional competence and scientific knowledge and progress in order to fit real needs, but also to optimize the use of resources. Article 3 of the Oviedo Convention aims at protecting both human rights and the dignity of the human being and still offers a fruitful starting point to elaborate on some of the most valuable conceptual and juridical tools that have been refined over these last decades to address this challenge: the principle of progressive realization, which can trigger and strengthen an emancipatory dynamic; the exercise of

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balancing principles, interests and goods both in the case law of Constitutional Courts and in policies; the concept of the core content of the right (entitlement) to health care services. These solutions are now confronted with the applications of new, unprecedented advancements of biomedical science, such as precision medicine. At the same time, the reference by the Convention to the jurisdiction of the Parties (the States) as the institutional framework within which obligations are undertaken needs to be further articulated against the global scope of the commitment to 'protect' human dignity and human rights.

Keywords: access to health care, dignity, equity, precision medicine, social responsibility, social rights.

1. Introduction

When the Oviedo Convention was signed, the reference to health had long since become mandatory in the vocabulary of human rights, together with that to the «inherent dignity» of all members of the human family as «the foundation of freedom, justice and peace in the world», to quote the Preamble of the Universal Declaration of 1948. The Constitution of the World Health Organization, which was signed in July 1946 by the representatives of 61 States, was a landmark, defining health as a «state of complete physical, mental and social well-being»¹ and establishing that «the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition». The reference to every human being implies that benefits of medical, psychological and related knowledge should be extended «to all peoples», also because «the health of all peoples is fundamental to the attainment of peace and security». According to Article 25 of the Declaration of 1948, everyone «has the right to a standard of living adequate

for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services». Together with the WHO Constitution, this was the starting point for further elaborations, at the global, regional and domestic level.² Some are legally binding instruments and some are non-binding.

As to Europe, and more precisely the Council of Europe, it was with the European Social Charter of 1961 that the challenge of social rights was fleshed out in all its breadth and with specific, detailed reference to health care.³ Everyone «has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable» and «anyone without adequate resources has the right to social and medical assistance» (Part I, 11 and 13). The Contracting Parties «undertake, either directly or in cooperation with public or private organizations, to take appropriate measures designed inter alia: 1. to remove as far as possible the causes of ill-health; 2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; 3. to prevent as far as possible epidemic, endemic and other diseases» (Part II, Art. 11). The Oviedo Convention, «bearing in mind» –among the most relevant texts– the International Covenant on Economic, Social and Cultural Rights of 1966, whose Article 12 was a decisive step to raise this commitment at the global level, seems indeed to be part of this history. It focuses on more specific issues related to the application of biology and medicine, but reaffirms that the Parties (the States), «taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality» (Art. 3: *Equitable access to health care*). We are on the same page, even though not with the same wording, with other documents that came after it, such as the Universal Declaration on Bioethics and Human Rights adopted in 2005 by the General Assembly of UNESCO and, remaining in Europe (the European Union), the

Charter of Nice of 2000.⁴ It is exactly the position of Art. 3 at the very beginning, among the General provisions of the Convention, that offers the key for a deeper insight into some choices and ideas which are neither obvious nor immediately clear as to their understanding and application. The goal to achieve, the method to follow, the actors to consider. What indications can be drawn to address the changes and challenges that we are confronted with twenty years after Oviedo?⁵

2. Two premises

The position of the article helps clarify two important premises. The first is one of the elements of the distinctiveness of the Convention, which aims at boosting the protection of human rights *and* the dignity of the human being. Of course, this does not amount to dismantling the continuity between the two concepts, which is at the very core of many international documents, starting with Article 1 of the Universal Declaration of 1948: «All human beings are born equal in dignity and rights». The first Chapter of the Charter of Nice is entitled to dignity, which is assumed as the ground and source of the rights and freedoms we are called on to respect, protect, fulfill. Article 3 of the UNESCO Declaration underlines the duty to fully respect «human dignity, human rights and fundamental freedoms». However, some tension can arise between rights as freedoms and dignity (it is worth observing that the latter was not mentioned in the Convention of 1950). The content and exercise of freedoms has to be consistent with the recognition and protection of universal, inherent dignity. Such commitment, in particular, does not coincide with the protection of whatever expression of self-determination and is the ground for setting some restrictions.⁶ Suffice it to mention, with respect to the Oviedo Convention, the limit of therapeutic purposes for interventions on the human genome (Art. 13), the provisions concerning research on embryos *in vitro* (Art. 18), and

the prohibition of financial gain from the human body and its parts (Art. 21). The decision to bring together and balance human rights (linked in Article 1 to fundamental freedoms) *and* dignity explains probably why the term *right* is used in few articles and why the focus appears often to be on the obligations to take, the measures and procedures to adopt, the scope of the respect and protection to ensure, that is what is due to every human being as such, even when they appear to consent to or express their will to commit acts which are in conflict with this responsibility.

Most of these restrictions became immediately controversial, as well as the content and meaning of dignity itself.⁷ The point to make is however that human dignity as *empowerment* and human dignity as *constraint* should be considered as two complementary concepts, as rights and duties or freedom and responsibility [5; 6]. It is against this background that a relevant distinction proposed in the comment on Article 1 of the Convention (*Purpose and object*) takes on its full meaning: rights and fundamental freedoms ought to be guaranteed to *everyone*, while protection of dignity and identity is required for *all human beings*. The rationale is that «unanimous agreement» lacked on the definition of *everyone* (in French *toute personne*) and «it was decided to allow domestic law to define them for the purposes of the application of the Present Convention». On the contrary, it was acknowledged that the essential value of dignity deserves respect «as soon as life began»: the more general expression *human beings* is referred to dignity in order to mark this difference [2, §§ 17-19; 7, pp. 82-83; 8, p. 330].

The second premise places in this context a methodological issue which is crucial for advocates of *social* rights as *positive* rights, especially considering that the Oviedo Convention is a legally binding text. Article 23 of the Convention affirms unequivocally that appropriate judicial protection will be provided «to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention».⁸ As to Article 3, however, the Parties are required only «to take appropriate steps to achieve this aim as far

as the available resources permit» and «the purpose of this provision is not to create an individual right on which each person may rely in legal proceedings against the State». It is rather about prompting the latter «to adopt the requisite measures as part of its social policy in order to ensure equitable access to health care» [2, § 26]. This distinction, which can be traced back to Article 2 of the two UN Covenants of 1966⁹ and makes the obligation of governments and parliaments at the same time broader and more challenging, without leaving room in any case for delays or lip service, needs two clarifications.

First, it is true that some of the provisions contained in the Convention, in particular those «formulating individual rights», are self-executing provisions and may therefore qualify as *directly applicable* under domestic law in many States. This is yet to reinforce and not to exclude the importance of that enactment of legislation which may be required for those provisions which contain more general principles «in order that effect be given to them in domestic law». Second, with specific reference to the efforts to ensure «a satisfactory level of health care», the commitment that States are called on to «may take many different forms and a wide variety of methods may be employed» [2, §§ 20 and 27]. By positioning access to health care among the General Provisions, the Convention affirms the idea that this remains an essential goal of all efforts to develop biology and medicine, looking at the standard of equality that appears necessarily entailed in the concept of dignity.

3. The goal to achieve

Tom Beauchamp and James Childress, in their *Principles of Biomedical Ethics*, propose a list of «some major candidates» for the position of principles of distributive justice: equal share; need; effort; contribution; merit; free-market exchanges [9, p. 261]. The decision to consider the commitment to guarantee equitable access to health

care as a commitment to meet *needs* is therefore not obvious, even though it could be quite easy to infer it from the recognition of the primacy of the right to life: protecting life implies necessarily protecting individuals' health from the consequences of their natural and socially conditioned vulnerability to suffering and disease. Article 3 of the Convention says nothing about the possibility of balancing needs against the *effort* or *merit* of complying with appropriate, healthy, virtuous lifestyles and individual choices, which can improve or worsen the differences (and consequently the needs) that both the lottery of nature and life spread among human beings. Of course, this is not to dismiss education and other drivers which are essential to boost health.

The wording is intentionally compact and concise: it sets a goal to achieve (access to health care of appropriate quality), the essential criterion to assess the appropriateness of care (needs), and the constraint that unavoidably impinges upon the State's ability to fulfill the obligation (resources). This is why *equitable* rather than unconditioned access is required. It goes also without saying that equity is not to be understood in the sense that someone, provided that *most people* are guaranteed access, could be prevented for whatever reason (including social and economic status) from having it. Unquestionably, *everyone* should have equitable access to health care of appropriate quality.

Matching the goal to achieve with the condition of available resources places us at the crossroads of the debate concerning *social* rights, which imply for individuals not only respect and protection of freedoms, but also entitlements to services and benefits.¹⁰ The *institutionalization critique* and the *feasibility critique* are being used over and over again¹¹ and may easily overlap. The objection on the lack of effective, *strong* justiciability, in particular, can be brought back to Kelsen, who proposed a radical argument against the existence of rights *before* law, which should then recognize, sanction and protect them. The argument builds on two assumptions. First, a right «is nothing but the correlative of a duty»: it is the legal order to

determine that «course of conduct to which a certain individual is obligated» and, at the same time, «a corresponding behavior of another individual to which –as it is usually termed– this other individual has a right. In this sense, to every obligation there corresponds a right». Secondly, the essence of an individual right as a *legal* right is a «power granted by law», i.e. the power which «consists in the fact that the legal order attaches to the expression of the individual's will that effect at which the will is directed» [12, pp. 77 and 81]. As long as the *power* depends on available resources, it seems unavoidable to conclude that no obligation *stricto sensu* may be imposed by the legal order upon individual agents nor the State: the mutual, *justiciable* implication right/obligation is unattainable.

Looking at the Oviedo Convention, as I have already underlined, the counter-argument to the brute statement that «a basic human right to the delivery of health care, even the delivery of a decent minimum of health care does not exist» [13, p. 336], is to predicate on a more flexible and dynamic political-institutional approach, which includes Courts but is not limited to them. This is a crucial task to perform for the most influential contemporary theories of justice, which keep looking at the idea of at least «basic health care assured for all citizens» as one of the important requirements to achieve democratic peace and its stability [14, p. 50]. John Tobin, aiming at elaborating a «social interest theory of rights» as an alternative both to the reference to a comprehensive theory and the idea that no agreement is possible,¹² underlines the interconnection of the legal, political, and moral dimension and points out two premises. First, «it is not simply the interest that must be justified but also the *actual* content of the obligation or duty», keeping in mind, as John Eekelaar explains, that a «distribution of power» is always at issue [15, pp. 54-55]. Secondly, «it is not only the interests of a beneficiary that ground a right it is also the interest of the duty bearer to determine the scope and content of the obligation», so that «the interests of the broader community» be bolstered [15, p. 58]. Bringing together the commitment to protect everyone's

rights *and* the commitment to protect the dignity of human beings implies bringing together the idea of interest *and* the idea of some *shared* good, as difficult as the task may appear and actually be. Article 14 of the UNESCO Universal Declaration on Bioethics and Human Rights, for instance, defines explicitly health as a «social and human good». It is against this background that equity is to pursue and assess, focusing on the approaches which are the most used to develop actions and strategies consistent with the provisions of the Oviedo Convention: progressive realization; the method of balancing principles, interests and goods both in policy-making and Courts; the definition of an essential core content for the goal of providing everyone with access to health care of appropriate quality.

4. Progressive realization

The reference to equity entails the acknowledgment that some inequality is consistent with the principle of justice. According to the General Comment by the Committee on Social Economic and Cultural Rights to Article 12 of the Covenant of 1966, a *disproportionate burden* for the poorer households as compared to richer ones sets the threshold to not cross with respect to the economic accessibility to (affordability of) health facilities, goods and services [16, § 12 (b)]. Equitable access, so we read in the Explanatory Report to the Oviedo Convention, «implies effectively obtaining a satisfactory degree of care», but is not «synonymous with absolute equality» [2, § 25]. However, it is the *inherent* equality of all human beings which is at stake in every discourse on fundamental rights and dignity. A first way to not yield to the constraint of resources as a verdict of powerlessness and accept the standard of equity without dismissing equality is the attempt to highlight the dynamic of progressive feasibility. A *manifesto* (Feinberg) as well as an *aspirational* (O'Neill) view of rights «can be action guiding» [17, p. 10; 18]¹³ and trigger an emancipatory dynamic, which involves both institutional (States

are called on to take measures to the maximum of their possibilities) and feasibility benchmarks and «does not crumble merely because further social changes may be needed at any point of time to make more and more of these acknowledged rights fully realizable and actually realized» [11, p. 384]. Therefore, we should focus on the idea of gaps to be filled rather than the un-surmountable difference between what is actually enforceable by the means of at-hand judicial remedies and a generic call to orientate policies and individual and collective behaviors towards the realization of some good.

Kelsen himself acknowledges that the theory of the priority of rights, though logically untenable as a scientific description, «is of the utmost political significance» as a political ideology, whose purpose is to influence the formation of law through the assumption that the legal order cannot create (or abolish) «but merely guarantee rights» [12, p. 80]. The idea of an open dynamic between rights and guarantees has been taken up with the aim of dismantling the fixed compartmentalization of civil and social rights. Fundamental rights consist in both negative and positive expectations, to which prohibitions of infringement and obligations to provide services and benefits correspond. These prohibitions and obligations can be termed *primary guarantees*, while the obligations to remedy and sanction judicially the infringements of rights, that is the violations of their primary guarantees, can be termed *secondary guarantees* [20, pp. 10-11]. It is true that the existence of adequate guarantees cannot be taken for granted, but this in no way implies the non-existence of rights. We should rather acknowledge, looking at these strict prohibitions and obligations to the maximum of available resources, the astonishing uncoupling of norms and reality and fill, or at least reduce, a gap which delegitimizes our systems not only politically, but also juridically. The argument of non-justiciability is being dispelled in the recent case law at several levels and through different dispositions and it is exactly with respect to the right to health (together with social security and suitable salary) that judicial protection is being extended. Last but not least, these rights, apart

from the issue of their justiciability, count as «guiding principles for the juridical system, which are largely used for the solution of disputes by the jurisprudence of Constitutional Courts» [20, pp. 31-32].

5. Balancing principles, interests, goods

Robert Alexy, articulating the standard definition of rights as a «three-point relation» (the beneficiary or *holder*, the *addressee*, and the subject-matter or *object*), defines social constitutional rights as entitlements in the narrow sense, that is «rights of the individual against the State to something which the individual could obtain from other private individuals, if only he had sufficient financial means, and if only there were sufficient offers on the market» [21, pp. 120 and 334-335]. However, it can always be the case that for the State itself available resources come out to be insufficient. Alexy's solution builds on a structural distinction. Norms are divided according to three criteria: 1. norms «granting *subjective* rights» or «merely objective norms binding the State»; 2. *binding* or *non-binding* norms (programmatic statements); 3. norms establishing «*definitive* or *prima facie* rights and duties», that is rules or principles. Needless to say, «binding norms granting definitive subjective entitlements give the strongest protection, while non-binding norms imposing a merely objective *prima facie* duty of the State to provide goods give the weakest». Along this line from the strongest to the weakest, balancing is ever more required, keeping in any case the premise that «the power of the principle of budgetary competence on the part of the legislature is not unlimited. It is not an absolute principle» [21, pp. 335-336; 344].

The case law of the Italian Constitutional Court over these last decades provides a meaningful, concrete example of the balancing approach with respect to health.¹⁴ In the Judgment no. 455/1990, the recognition of the right to health as a primary and fundamental

right, that imposes full and exhaustive protection, was already associated with the clear distinction between two kinds of juridical relations that the right refers to. With regard to the defense of personal integrity against attacks or injuries, the right to health is a right *erga omnes, immediately* guaranteed by the Constitution and directly justiciable. The right to medical treatments, like all rights to services and benefits, is a *conditioned* right, in the sense of a programmatic provision. Under this second point of view, the realization of the right to health is therefore to be achieved «gradually, after a reasonable balancing with other interests and goods which are acknowledged an equal constitutional protection and the real, objective possibility to have at disposal the necessary resources». This concept of a right which is «financially conditioned» and can be limited in practice by insufficiency of resources has been reaffirmed many times.¹⁵

Binding norms granting definitive subjective entitlements are obviously a matter for Courts. The commitment to boost nonbinding norms imposing a merely objective *prima facie* duty intersects with a broader approach, aiming at encouraging and strengthening the «many different forms» of the effort to ensure a satisfactory level of health care that the Explanatory Report refers to. Suffice it to mention Article 14 of the Universal Declaration on Bioethics and Human Rights, which sets a landmark as to the extension of the principle of social responsibility to the field of bioethics: «The promotion of health and social development for their people is a central purpose of governments that all sectors of society share». This is to underline: *a.* the awareness of the many social determinants of health (education, housing, work conditions, environment, institutions); *b.* the role of those non-legal practices, such as a culture of solidarity, bottom-up practices of social engagement, whistleblowing on different kinds of exclusion or discrimination, which boost the effectiveness of legal binding norms, help their implementation and in many cases anticipate them, influencing policy-makers also with respect to allocation of resources; *c.* the importance of

giving «the general ethical status of human rights its due, rather than locking up the concept of human rights prematurely within the narrow box of legislation – real or ideal» [11, p. 366]. In this perspective, even a programmatic provision is far from being just wishful thinking and triggers valuable behaviors and choices at the individual, collective and eventually institutional level. The broader the scope for balancing the tools of legal coercion, the more decisive may be the role of social responsibility.

6. The core content of the right and obligation

In General Comment No. 14, the Committee on Economic, Social and Cultural Rights recalls not only that some components of the right to health care are legally enforceable, such as, in many national jurisdictions, the principle of nondiscrimination in relation to health facilities, goods and services, but also the statement, made in General Comment No. 3, concerning the core obligation for the States «to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care». The list of core obligations that, according to the Committee, stem thereof is quite long and comprehensive.¹⁶ It is also emphasized that «it is particularly incumbent on States parties and other actors in a position to assist» to provide international assistance and cooperation «which enable developing countries to fulfill their core and other obligations» [16, §§ 43-45].

At the domestic level, it is again the case law of the Italian Constitutional Court to offer an illustrative example of this approach, looking at the principle of gradual implementation of onerous reforms, the distinction between conditioned and unconditioned rights, and «the discovery of the “minimal/essential content” of “second generation” rights» [22, p. 122]. However, the consideration of available resources should never become an excuse to squeeze

the *irreducible core*¹⁷ of the right and eventually the notion itself of equality. The Essential Levels of Care (Livelli Essenziali di Assistenza: LEA) have been introduced in this perspective.¹⁸ According to Legislative Decree No. 502/1992, they should be uniform and comply with the criteria of respect for dignity, health needs, equity, quality, appropriateness, cost-effectiveness. The commitment to «overcome territorial imbalances in social and health care conditions» (Law No. 833/1978, Art. 3), in particular, is now to assess against the complex relation between State and Regions set in Art. 117 of the Constitution, as revised in 2001. Health protection is a matter of concurring legislation. That means that the State maintains the power to set the «fundamental principles», while other legislative powers are vested in the Regions. Many disputes have been raised before the Constitutional Court to set the balance between these concurring powers. What is relevant, is the explicit assumption of the idea of essential levels as a criterion for defining and limiting the State's responsibility for equality of all citizens. Provided that the essential levels are attained (which is far from being true in many cases),¹⁹ the Regions keep their freedom to do and give more, so that the logic of the LEA risks to turn once again into that of inequality, at least with regard to «inessential» aspects.

The essential levels approach is being challenged ever more also by the reshaping of the pivotal concept of appropriateness. According to a quite obvious definition, *appropriate* treatment is the one which fits the patient's needs according to evidence-based scientific standards, considering his or her particular condition and on the premise of informed consent. We are also long used, especially in contexts where the recognition of a constitutional right to health care is under the pressure of financial constraints, to the reinterpretation of therapeutic appropriateness in terms of expenditure restraint [23, p. 23]. The so-called *precision medicine* is now introducing a radically new approach, in order to offer this person the treatment that he or she really needs. It is no longer simply about looking at the person in a narrative or holistic perspective, on the premise that every patient

is different from any other. Precision medicine, defined as «an approach to disease treatment and prevention that seeks to maximize effectiveness by taking into account individual variability in genes, environment, and lifestyle» [24, p. 6], is triggering a change in the culture and practice of medicine. The impact is likely to be spectacular with respect to prevention (susceptibility to diseases) as well as treatment (the right dose of the right drug). However, it will require to loosen more and more the link between appropriate quality and standardized protocols. Promises are great. At the same time, some ethical concerns deserve careful consideration. Together with respect for privacy, training of medical personnel in front of unprecedented responsibilities for communication of data and counseling, protection of patients once, for instance, they become aware of their non-responsiveness to a certain treatment, the cost and affordability of precision medicine can also be a challenge and «providing equitable access to it may be difficult even within a single country». In any case, «cost-benefit analyses are needed to ascertain which procedures have clinical utility and validity and for what diseases» [25, § 68]. The essential levels will not be a *one fits for all* standard.

7. Within their jurisdiction

The Parties to the Oviedo Convention undertake obligations within their jurisdiction, which is quite obvious with regard to the «necessary measures» to take in internal law that Article 1 refers to. This distinction within/outside crosses the difference between negative and positive rights and the consequence, to paraphrase Alexy and recall the Kantian distinction between perfect and imperfect duties, seems to be a strong contrast between the strictness of the obligation for the State to provide effective and immediate judicial remedy in case of infringements upon negative rights *within its jurisdiction* and the much looser and generic commitment *to*

do something for other peoples which lack very often access to even basic levels of health care. Some authors challenge not only the practical feasibility, but the idea itself of a *universal* normative framework: the attempts to establish *global* bioethics, such as the UNESCO Declaration of 2005, are dismissed as examples of the «general vacuity of its principles» [26, p. 3].

The Oviedo Convention entails however many issues, which are by all evidence to consider against their global scope (and potential market): interventions on the human genome, protection of persons undergoing research, organ and tissue removal for transplantation. Together with the policies developed by the States, the concept itself of social responsibility and the role of actors involved should be broadened accordingly and the most promising approach is probably the one which brings together three premises.

First, the *moral* recognition of the equality of all human beings. This remains the contribution offered by the human rights tradition and cosmopolitanism, which share «the aspiration to live beyond specific, bounded horizons», allow «a broader solidarity without boundaries» and refuse the idea that human well-being be defined by «a particular location, community, culture or religion». Cosmopolitanism, in particular, is growing at three levels: *a.* subjective, that is «increasing global consciousness»; *b.* objective, that is «expanding global jurisprudence; multiplication of global organizations»; *c.* political, that is «limited sovereignty of nations; growing importance of civil society». In order to avoid the clash of different identities and narratives, Henk ten Have proposes a two-level model, for which bioethics can provide a valuable test: at the global level general principles and «a set of standards agreeable to all» should be defined to guide the aspirations of the global community; at the local, operational level, the common principles need to be interpreted and applied in a way consistent with «different ethical views and moral cultures» [27, pp. 107, 111 and 101]. From this perspective, human rights can offer at least a kind of conceptual umbrella for inclusive frameworks based on pragmatic yet essential agreements,

along the line –to provide just one illustrative example– of Jacques Maritain’s contribution to the preparatory work for the Declaration of 1948. An agreement of minds is difficult to imagine between people «who come from the four corners of the globe». However, as soon as we shift from *speculative* to *practical* ideology and basic principles of action, it is possible to find out «a sort of common denominator, a sort of unwritten common law». The condition is to not ask *why* [28, pp. I-II].

The second step concerns a reshaping of the *political-institutional* framework of justice. It is necessary to go over the traditional yet misleading opposition between cosmopolitans and statistes, with the former conceiving global justice as «domestic justice writ large» and the latter opting «for an account of international morality consisting of principles of mutual assistance and respect between internally well-ordered political communities» [29, pp. 2-3]. An alternative to leaving to *humanitarianism* rather than *justice* (understood as linked to coercive relations which protect persons’ right to freedom) the duty to help and assist those in need can be built on a multi-faceted approach to the notion of *coercion*: together with *interactional* coercion, that is «coercion exercised by an agent (be it a collective or an individual)», we ought to consider *systemic coercion*, that is «coercion exercised through a system of rules supported by a large enough numbers of agents». These rules –this is the crucial point– can be both formal and informal and this observation «has important implications for our thinking about justice in the global realm, where there clearly are pervasive systems of formal and informal social rules but no overarching, state-like, group agent» [29, pp. 14-15 and 18]. In this perspective, we can say that access to quality health care is a case of the more general issue of considering international policies and strategies as a matter of *governance* not less than interaction between *governments*. Governance refers both to formal and informal organizations and mechanisms, to horizontal and non-hierarchical widespread political processes as opposed to those, typically hierarchical, which distinguishes the State’s authority

and power of direct sanction [30, p. 71]. In this context, soft law can also be key, as well as an approach from below entailing «broader vision of governance and globalization based on a common framework of shared values and objectives; inclusion and participation of more actors and stakeholders; evolvement of new practices inspired by different forms of leadership» [27, p. 155].²⁰

Last but not least, an integration of the call for meaningful yet generic commitments with more specific targets is always advisable, so that these targets can be monitored and progressively refined and updated. Let's take the example of the right of the child to adequate pre-natal and post-natal care and medical services, affirmed in Principle 4 of the Declaration of the Rights of the Child of 1959 and then further elaborated in Article 24 of the Convention on the Rights of the Child adopted and opened for signature in 1989. The commitment, for instance, to take appropriate measures «to diminish infant and child mortality» is obviously commendable and worth encouragement. The effort to reduce in all countries, by 2030, the «neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births», which is one of the targets included in the UN 2030 Agenda for Sustainable Development, gives a concrete and therefore verifiable content to the idea of the basic, essential standard of protection that every human being should be entitled to. In the absence of that, it is easier to transform the principle of progressive realization into an excuse to indefinitely put off the commitment.

8. Conclusions

The general provision set in Article 3 of the Oviedo Convention is to update considering the new developments of scientific knowledge in the biomedical field, the inequalities that always entail risks of inequity, the growing responsibilities as to the global challenges concerning health. An integrated approach is therefore

required, aiming at increasing available resources (not only financial means), improving social determinants of health, adopting policies consistent with the priority of equitable access to quality health care, balancing this priority with other principles, interests and goods, setting concrete and verifiable targets to reach. The shrinkage of public resources in many countries, in coincidence with growing needs of ageing population, cannot be an excuse to weaken the obligation. At the international level, this frontier of *sharing* is key for development to be sustainable and inclusive.

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¹ As it is well-known, this definition has been criticized by many authors as too broad, all-embracing, out-of-reach and inflated. Daniel Callahan, for example, observed that the reference to complete well-being (mental as well as social), risks to turn whatever kind of human problem into a *health* problem, making «the medical profession the gate-keeper for happiness and social well-being. Or if not exactly the gate-keeper (since political and economic support will be needed from sources other than medical), then the final magichealer of human misery» [1, p. 81]. At the same time, however, he acknowledged the attractiveness of bringing together «the good of the body and the good of the self», impelling the analyst «to work toward a conception of health which in the end is resistant to clear and distinct categories, closer to the felt experience» [1, p. 77]. These remain the drivers of an open debate.

² The Italian Constitution, which was adopted at the end of 1947, by affirming in Article 32 the obligation for the Republic to safeguard health as a fundamental right of the individual and as a collective interest and to guarantee «free medical care to the indigent», provides an illustrative example of the inclusion of this right among the constitutional essentials.

³ The focus of the Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 was on *civil* rights. The reference to health, starting with Article 5 and then in Article 8, 9, 10 and 11, was to specify the conditions that allow the restriction of the right to liberty and of some fundamental freedoms, be it the case of lawful detention «for the prevention of the spreading of infectious diseases» or of the protection «of health or morals» with respect to private and family life, freedom of thought, conscience and religion, freedom of expression, freedom of assembly and association. The freedom of movement, which was explicitly recognized in 1963 by Protocol No. 4, can also be restricted for the same reason. It is worth observing that the Oviedo Convention, in Article 26, limits the grounds

for restrictions to those that are prescribed by law and necessary in a democratic society «in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others». As it is pointed out in the Explanatory Report, the protection of the patient's health is not mentioned and «it seemed preferable to define this exception in each of the provisions expressly alluding to it» [2, § 155]. The Explanatory Report, even though it is not an authoritative interpretation of the Convention, was written under the responsibility of the Secretary General of the Council of Europe taking into account the discussions held during its preparation and the remarks made by Delegations and offers useful observations and insights to better understand the text.⁴ Article 35 of the Charter states that «everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities». Many other documents should obviously be added before and after the Oviedo Convention. They refer to health with different wordings. The right «to the enjoyment of the highest attainable standard of health», recalling literally the WHO definition, is recognized in the Convention on the Rights of the Child of 1989 (art. 24) and the Convention on the Rights of Persons with disabilities of 2006 (art. 25). We find the same goal, with a slight modification to the text, in the Alma-Ata Declaration of 1978 («the attainment of the highest possible level of health») and the African Charter on Human and Peoples' Rights of 1981 («the best attainable state of physical and mental health»). As to the content of the concept, the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights «Protocol of San Salvador» of 1988 perfectly overlaps with the definition proposed by the WHO Constitution (art. 10), while the African Charter on the Rights and Welfare of the Child of 1990 adds «spiritual health» instead of «social well-being» to the physical and mental components (art. 14). With specific reference to possible forms of discrimination, the right to health is included in the International Convention on the Elimination of all Forms of Racial Discrimination of 1965 (art. 5), the Convention on the Elimination of all Forms of Discrimination against Women of 1979 (art. 12) and the International Convention on the Protection of All Migrant Workers and Members of Their families of 1990 (arts. 28, 43 and 45). The Ljubljana Charter of 1996, looking at health care reforms in the European context, is centered on the principle that they «should first and foremost lead to better health and quality of life for people» and acknowledges that «the improvements in the health status of the population are an indicator of development in the society» (arts. 2 and 3). Starting with the Ottawa Charter for Health Promotion of 1986, the WHO Global Health Promotion Conferences have fleshed out the principles and priorities of this commitment. The Shanghai Declaration of 2016 reaffirms «health as a universal right, an essential resource for everyday living, a shared social goal and a political priority for all

countries», underlining at the same time that «health and wellbeing are essential to achieving the United Nations Development Agenda 2030 and its Sustainable Development Goals».

⁵ The International Conference organized by the Committee on Bioethics (DH-BIO) under the auspices of the Czech Chairmanship of the Committee of Ministers (*20th Anniversary of the Oviedo Convention: Relevance and Challenges*), which was held on 24-25 October 2017 in Strasbourg, offered a fruitful opportunity both to celebrate this anniversary and look forward to further developments.

⁶ In this perspective, it is indeed correct to say that human dignity «is a limit of self-determination» and should rather be linked, following Kant, to the concept of autonomy and its universality [3, pp. 235-241].

⁷ Starting with Bentham's harsh criticism against «nonsense upon stilts», human rights and in particular social rights have also undergone similar objections. With specific reference to the right to health, Thérèse Murphy labels as *devastating* the critiques addressing the lack of a persuading account of its conceptual foundations (Daniels) and the vacuity of the concept (Griffin) [4, p. 2].

⁸ Unlawful, because the Convention itself, as it always happens in this kind of documents, permits some «restrictions to the free exercise of the rights it recognizes» [2, § 142].

⁹ While in the case of civil and political rights States will ensure «that any person whose rights or freedoms as herein recognized are violated shall have an effective remedy» by «competent judicial, administrative or legislative authorities», in the case of economic, social and cultural rights each State Party is called on to take steps to the maximum of its available resources «to achieving progressively the full realization of the rights».

¹⁰ The right to health contains both *freedoms* and *entitlements*. Freedoms include «the right to be free from non-consensual medical treatment, such as medical experiments and research or forced sterilization, and to be free from torture and other cruel, inhuman or degrading treatment or punishment». Entitlements include, among other things, «the right to a system of health protection providing equality of opportunity for everyone to enjoy the highest attainable level of health», «the right to prevention, treatment and control of diseases», «access to essential medicines», «equal and timely access to basic health services» [10, pp. 3-4].

¹¹ For the presentation of these critiques and a first account of possible counterarguments see , e.g., Amartya Sen's reflections included in his book on the idea of justice [11, Chapt. 17].

¹² Tobin quotes Raz, Griffin, Sen, Buchanan and Hessler, and Beitz as points of reference of this approach and Cass Sunstein for the definition of the international legal instruments which recognize the right to health as examples of «incompletely theorized agreements» (Chapt. 2). The question remains open whether to simply dismiss debates on comprehensive theories or keep it alive in a different arena [15].

¹³ It is worth reminding that Joel Feinberg introduced this expression looking at a special manifesto sense of *right*, that is the idea of claims embedded in natural, unfulfilled needs, which are not correlated with another's duty: «such claims, based on need alone, are “permanent possibilities of rights”, the natural seed from which rights grow» [19, p. 67].

¹⁴ The case of Italy is very interesting, because it signed the Oviedo Convention in 1997 and adopted in 2001 a Law for its ratification and execution (Law No. 145/2001), but had not yet deposited the instrument of ratification at the beginning of 2017. Checked on 17 May 2017 at http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=Uqns3llq.

¹⁵ See, e.g., Judgments No. 218/1994, 304/1994, 309/1999, and 248/2011.

¹⁶ For some authors the list is indeed too long and comprehensive, «unprincipled and impractical», «so onerous that few, if any states are likely to be persuaded to adopt such an approach» [15, p. 117]. As an alternative, Tobin proposes an approach which distinguishes «minimum core obligations of conduct» and «minimum core obligations of results».

¹⁷ See Judgment No. 309/1999, but also No. 509/2000 and 252/2001.

¹⁸ In the literature, the adjective that is more commonly used is “basic” (standards, levels, services). Both concepts are confronted with a fundamental question. A life-saving treatment can be complex and expensive. It is essential (of crucial importance) for the person who needs it. At the same time, nothing less than what is basic (life itself) is at stake, even though the resources that are required are far from minimal. Where to set the bar?

¹⁹ The DPCM (Decree by the President of the Council of Ministers) *Definizione e aggiornamento dei livelli essenziali di assistenza (Definition and updating of the Essential Levels of Care)* was published on the «Gazzetta Ufficiale» on 18/3/2017 (n. 65).

²⁰ Social movements and NGOs, civil society, media should be among the driving forces.

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