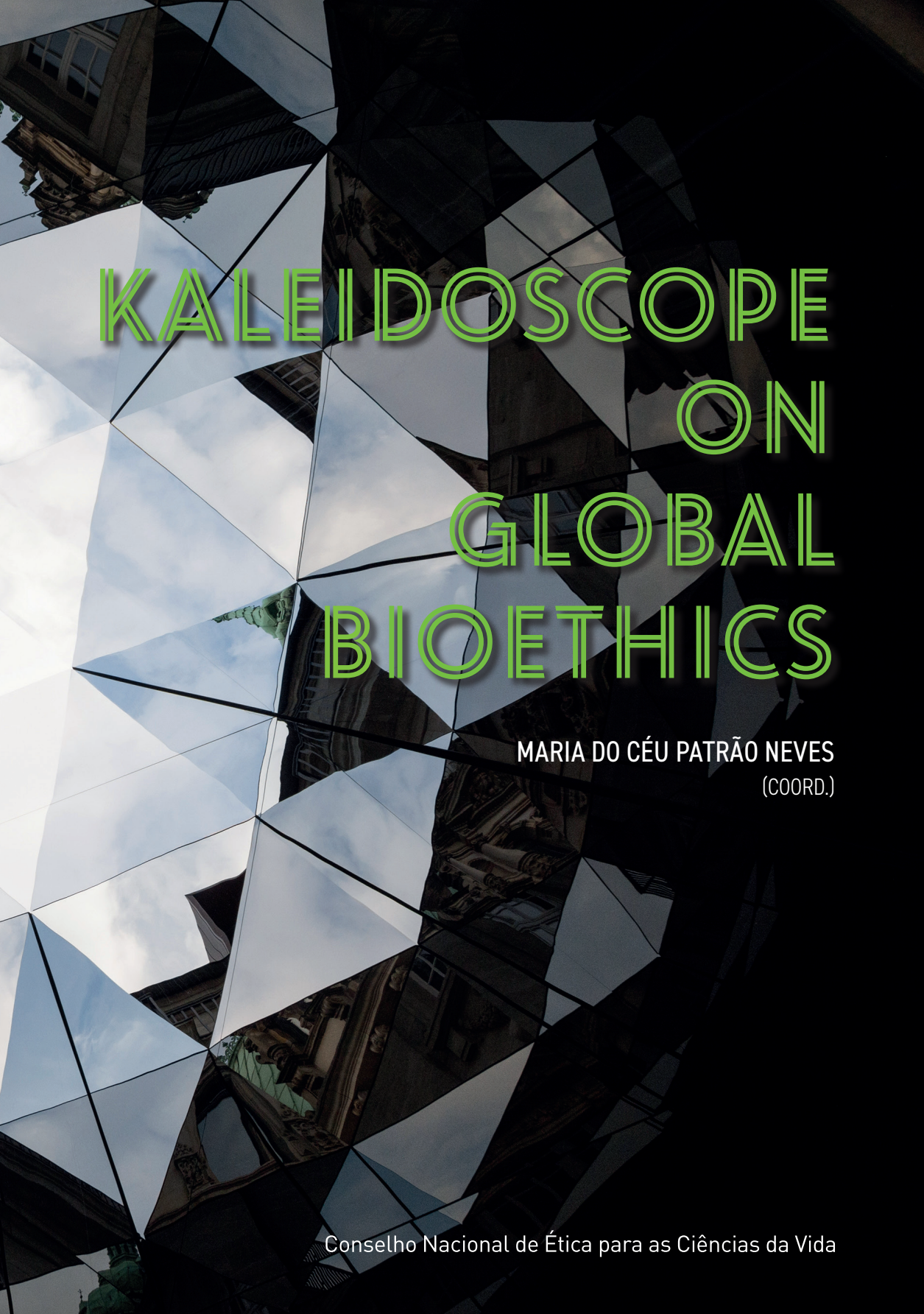

KALEIDOSCOPE ON GLOBAL BIOETHICS

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The Kaleidoscope of Global Bioethics

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The current publication was composed following the 13th Global Summit of National Ethics Committees which took place in Lisbon in September 2022, jointly organised by the Portuguese National Council of Ethics for the Life Sciences and the World Health Organisation, in close collaboration with UNESCO, under the motto "Health Justice: Health Care 4 All". The veritable kaleidoscope of perspectives presented at the Summit and to which the authors have now given substance fully illustrates the plurality of Bioethics in our days, in multiple regions of the world.

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BioEthics: dynamics of its diversification and globalization

M. Patrão Neves[1]

Bioethics has never been unitary or homogeneous, and these are features that persist to the present day. It is, in fact, this original and identity-oriented pluralism that, in a dynamic of decades, has contributed to the understanding of the apparent paradox between the growing diversification of bioethics and the consolidation of its globalisation. That said, the latter is not to be confused with its geographic expansion, but rather leads to an aspiration to unity.

A dual paternity[2]

Since its birth in 1970-1971, in the United States, when it was introduced in the academic, scientific and professional discourse in a significant and prevailing way[3], the neologism "bioethics" evidenced its dual paternity, thus attributing the same word with different features and scope.

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2 Expression suggested from the reading of Warren Reich, "The Word 'Bioethics': The Struggle Over Its Earliest Meanings, *Kennedy Institute of Ethics Journal*, 5 (1), 1995: 19-34, who explicitly refers to a "bilocated birth" of bioethics.

3 In this context, we are not referring to the very first formulation of the word 'bioethics', by Fritz Jahr, a German Protestant pastor, philosopher, and educator in Halle an der Saale, who, in 1927, publishes *Bio-Ethik: eine Umschau über die ethischen Beziehungen des Menschen zu Tier und Pflanze* (*Bio-Ethics: A Review of the Ethical Relationships of Humans to Animals and Plants*), because it did not have a direct influence on the emergence and structuring of what we now call "bioethics". However, the text then published in *Kosmos*, reflects an intellectual ambience and a philosophical orientation, demanding a new attitude of mankind towards the diversity of living beings, which gained expression in the first half of the 20th century and to which Potter will also belong.

For Van Rensselaer Potter, who coined the term in December 1970[4], bioethics designated a "science of survival", with relevant ecological meaning, by connecting the knowledge of living systems with that of values, comprising all living beings and ecosystems. This meaning became urgent when the post-World War II demographic explosion (Baby Boom) put unsustainable pressure on natural resources. For the obstetrician Andre Hellegers who, unaware of the previous use of the term, introduced it in July 1971[5] with an unprecedented use, bioethics designates a multidisciplinary approach, of an ethical nature, in assessing the impact of biotechnologies on human health, therefore limited to the clinical realm.

The history of bioethics unfolded from this medical meaning only to recover its original environmental significance in the 1990s. From then on, both connotations evolved under the concept of bioethics.

Generally speaking, BioEthics focuses on the phenomenon of life (*bios*), to the extent that it is or can be humanly (artificially) manipulated, and insofar it is justified that life is, or should be (*ethos*), artificially handled. Therefore, bioethics also refers to a transdisciplinary perspective and to a multidisciplinary practice – which reinforces, as already mentioned, its original heterogeneity.

A dual nature

The dual paternity of bioethics also reveals it to be, originally and indissolubly, of a theoretical-practical nature, that is, of a dual nature. In fact, bioethics, having been set on a practical level, i.e. from the identification of new problems in need of innovative solutions, has sought and acquired an epistemological status by virtue of the consistency achieved on the theoretical level in which the modalities of intervention, reasoned and coherent, were formulated.

For instances, if we travel back, for example, to 1962, and to the establishment of the first hemodialysis centre in the world – the Seattle Artificial Kidney Centre –, we learn that, at that time, the number of candidates in a life-threatening situation far exceeded the capacity to provide care, requiring a prioritization of patients which, in turn, called for non-clinical selection criteria. This process, from practice – in the obligation to prioritize patients – to theory – in the need to formulate objective and tendentially fair criteria –, was developed by the first

4 Van Rensselaer Potter, North-American and biochemical researcher in oncology, publishes the paper "Bioethics, the Science of Survival", in December 1970. This text would constitute the second chapter of the book *Bioethics: a bridge to the Future*, published in January 1971.

5 Andre Hellegers, obstetrician of Dutch origin, creates The Joseph and Rose Kennedy Center for the Study of Human Reproduction and Bioethics, on July 1st, 1971.

hospital ethics commission, in a time that we can consider as being the pre-history of bioethics.

Furthermore, if we consider separately both the level of practice and of theory, we recognize a clear heterogeneity. At the practical level, when we look at the cases or issues which have generated bioethics in different parts of the world, we find that they were quite diverse, in the common perspective of ethical concern in the face of the impacts of technological progress on human life[6]. In the United States, where bioethics originated, the major problem that triggered it was that of biomedical experimentation with human participants, and the growing public awareness of the atrocities committed against people and specific groups in the name of science. However, in the wake of the Nuremberg Trials and the establishment of the 10 principles legitimizing the participation of people in biomedical experimentation (1947), particularly the requirement of informed consent, there was a total neglect of these requirements in numerous biomedical research projects carried out in the United States. The public disclosure, in 1972, of the Tuskegee syphilis study and the persistent abuse of its vulnerable population was decisive for the emergence of a bioethical conscience, both at regulatory level – with the imposition of new rules for clinical research – and at institutional level – with the demand for the establishment of new institutions to guarantee the protection of research participants and ensure the quality of science.

In Europe, however, the vivid awareness of the human atrocities of the experimentation by Nazi doctors, but also of other similar earlier practices, dictated by a misplaced enthusiasm of scientific discovery, made the subject of human experimentation quite painful. Bioethics would emerge in Europe triggered by another reality: a surprising (almost magical) achievement of biotechnologies, in the generation of a new human life in a petri dish, through *in vitro* fertilization (IVF). We refer to the birth of Louise Brown in 1978 in the United Kingdom – the inappropriately named first test-tube baby. A few years later, in 1982, Amandine was born in France. Indeed, the issue of reproductive technologies was also decisive for the creation of national ethics commissions, not only *ad-hoc* but permanent, the first of which was established in 1983, in France[7].

Bioethics first developed in Asia under North American influence and in the wake of the modernization or scientificization of medicine. Nevertheless, a ra-

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6 The emergence of bioethics in different parts of the world is developed in M. Patrão Neves, "Bioética e Bioéticas", M. Patrão Neves, and Manuela Lima (cood.s), *Bioética ou Bioéticas na Evolução das Sociedades*, Coimbra, Gráfica de Coimbra/Centro Universitário São Camilo, 2005: 285--308.

7 The Comité *consultatif* national d›*éthique* pour les sciences de la vie et de la santé /CCNE was created by the President of the French Republic, François Mitterrand, following the birth of Amandine.

tional and secularly structured bioethics, anthropocentric and individualistic, progressing through increasingly restricted and technically-scientifically attested specializations, was poorly suited to this new geography. Of particular importance is the cultural and the community context, in which bioethical issues were debated, with respect for traditions, be it traditional medicine, the religiosity of peoples or the shared holistic conception of life. In Asia, bioethics has gradually assumed a profile marked by ethnocentrism and multiculturalism.

In South America, still resenting European colonization and with a long and diverse record of political revolutions, socio-political issues have become more relevant, in a clear distinction between "emerging problems" – new issues characteristic of a biomedical bioethics and related to the application of biotechnologies, such as reproductive biotechnologies – and "persistent problems"[8] – lingering social and political problems that bioethics is beginning to awaken to as it expands to different parts of the world and that reflects the specificity of the environment in which they emerge. The focus here is on the widespread access of populations hampered by poverty or illiteracy to the benefits of biomedicine. Bioethics, in South America, assumes a profile marked by social claims, often politically driven.

In Africa, the most powerful triggering element of bioethics was that of human experimentation, in the recruitment of African populations for the development of clinical trials – particularly in the scope of experimentation with vaccines against AIDS and hepatitis –, having a double standard of procedures as common practice, characterised by the suppression, in Africa, of the ethical and legal requirements that framed biomedical research in Western countries, to which was added the absence of benefits resulting from research for local populations, in a predatory attitude.

At the practical level, we have witnessed a thematic diversification of bioethics and, consequently, a progressive expansion of its domain, co-extensive with its development in the world.

Also at the specific level of theory we find, from very early on, a multiplication of perspectives of analysis of concrete bioethical problems. The process of theorization of bioethics began in 1979, with the publication of *Principles of Biomedical Ethics* by Tom Beauchamp and James Childress[9], who proposed four *prima facie* principles – autonomy, non-maleficence, beneficence and justice – to be applied to the resolution of ethical dilemmas in the context of everyday biomedical practice. This model of reflection and intervention in bioethics, later called princi-

8 Volnei Garrafa, and Dora Porto, Intervention bioethics: a proposal for peripheral countries in a context of power and injustice. *Bioethics*, 2003; 17 (5-6): 399-416.

9 Tom Beaucham, and James Childress, *Principles of Biomedical Ethics*, Oxford, Oxford University Press, New York, 1979.

plism, is still prevalent today under multiple expressions, insofar as it is still based on the enunciation of principles that the approach to ethical problems is framed.

Nevertheless, other theoretical and practical models quickly emerged in bioethics and entered into a dialogue that extends the present, adding new interlocutors, with new perspectives. Thus, while principlism adopts a top-down perspective in the application of principles to cases, other models advocate the importance of the inverse perspective, bottom-up in the standardization of procedures based on case analysis, as is the case with the casuistic model; still others emphasize the importance of virtues and the process of deliberation, in Aristotelian-inspired models; or the specificity of the clinical encounter and first-person narrative, in models of phenomenological and hermeneutic inspiration. Many other models were structured based on the common recognition of the need for a well-founded and solid theory, at the same time operational and effective, for the assessment of concrete cases and intervention, towards their satisfactory resolution.

At the theoretical level, we can confirm a multiplication of bioethical perspectives of analysis and, consequently, the construction of a broader and multifaceted vision of reality in its irrepressible dynamism, with growing inclusiveness and scope.

Meanwhile, we have also attested that bioethics, having been triggered by practical cases, quickly structured theories that substantiate, justify and advocate a standardized or normative action for other similar dilemmas, aiming for a fuller justice in the appreciation of a myriad of cases, concrete and unique, based on the same ethical criteria.

Institutional proliferation

This identity plurality of bioethics, which we have been successively pointing out, is reinforced by the genealogy of its institutionalization, that is, by the constitution of organisations dedicated primarily to it. Having emerged from a real need felt specifically at the professional and academic levels, but also in society at large, the institutionalization of bioethics begins with the creation of spaces, *fora*, for discussion groups, initially quite informal. From the outset the interconnection of different scientific and professional areas, namely medicine, theology and philosophy, is verified, as confirmed in the first bioethical institution, the Hastings Center, founded by theologian and philosopher Daniel Callahan and by the psychiatrist Williard Gaylin, in 1969. This is, to this day, an identity trait of bioethics advisory bodies. Personalities from different academic and scientific areas meet to discuss the best way to respond to the novel problems imposed on their professional practice by the biotechnological revolution. Later on, these discus-

sion groups were structured and developed into teaching and research centres, based in higher education institutions or in reference hospitals, well supported by specialised libraries.

These almost spontaneous think tanks were especially common in the Western world where bioethics was originally constituted. In other geographical-political spaces, this initial step in the broad development of bioethics did not take place. Far more frequently, its institutionalization began with the constitution of university and hospital centres.

This first type of bioethical institution, with very restricted scope, was followed by the establishment of clinical research ethics committees (initially termed Institutional Review Boards – IRB) and, later, by hospital ethics committees, dedicated to ethical issues within the scope of clinical care (initially termed Institutional Ethics Boards – IEB). In both cases, their constitution was originally dictated as a response to social contestation in relation to some mediatised cases of offenses committed against people in the context of biomedical research. Once again these institutions have arisen out of necessity, and always with a multidisciplinary constitution.

These first two types of ethics committees were implemented in multiple forms in different parts of the world: sometimes as distinct committees operating separately, as in the United States; sometimes as mixed or hybrid committees accumulating the function of both in a single body, as in many European countries; other times focusing only on the committee dedicated to clinical research, as is often the case in Africa.

The need to set up a multidisciplinary body to assess the foundations and regulate new practices in the context of biotechnological developments has also led to the establishment of national ethics committees, with the specific requirement of standardizing action guidelines. These national commissions were initially limited in mission and time (*ad-hoc*): the first to emerge was The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established in the United States with the mission of formulating ethical principles for human experimentation. It operated from 1974 to 1978, having produced the Belmont Report; later, in 1982, the Warnock Committee was established in the United Kingdom with the mission of regulating the use of reproductive technologies and having produced the Warnock Report in 1984. The national committees evolved from *ad-hoc* to permanent, given the persistent nature and wide range of bioethical problems that were multiplying and becoming more complex, as well as gaining a broader scope of intervention.

It is important, however, to underline that these national ethics committees are not always of the same nature in different parts of the world: while European countries tend to have two such advisory bodies – one focused on clinical re-

search and the other dedicated to public policies, with the common aim of unifying procedures – other continents tend to favour the constitution of a single national ethics commission for scientific research, similar to what also occurs with local ethics committees, in both cases favoring intervention at the research level.

Subsequently, in the wake of the commitment to standardize practices, ethics committees of international scope were also created, invariably dedicated to procedures to be adopted in the face of the new possibilities brought about by biotechnologies and structured on the basis of more broadly consensual ethical principles. We refer to: the current Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO), established in 1985 by the Council of Europe and which produced the only Convention in this area that became legally binding to all States that ratified it, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997)[10]; the European Group on Ethics in Science and New Technologies (EGE), created in 1991 by the European Commission, which regularly presents Opinions and Statements in various fields; and to two bodies created by UNESCO, the International Bioethics Committee (IBC), in 1993, and the Intergovernmental Bioethics Committee (IGBC), in 1998, which, among the Declarations produced, presented the Universal Declaration on Bioethics and Human Rights (2005)[11] adopted by the UNESCO. Opinions, Statements, Reports, Declarations, Conventions are all different types of ethical-legal documents (soft law) that these international bodies have produced on the most diverse bioethical issues, as they arise and require guidelines with maximum consensus, thus tending towards the unification of diversity.

In fact, bioethics has developed through a progressive diversification, also at the level of its institutions given their growing dissemination; paradoxically, this institutional proliferation has also progressed towards contributing to the unification of bioethics, in a process that, simultaneously, results in and reinforces the globalization of bioethics.

10 Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, https://rm.coe.int/168007cf98

11 UNESCO, Universal Declaration on Bioethics and Human Rights, https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights?hub=66535

Globalization of bioethics

Bioethics today is global – we say this without hesitation. And yet, the meaning of the statement is not unequivocal.

The expression "global bioethics" was introduced by the pioneer of bioethics Van Rensselaer Potter, in 1988, when he published *Global Bioethics, Building on the Leopold Legacy*[12]. Here, he somehow reiterates his initial proposal for the constitution of a new discipline or science that combines the knowledge of biology with various humanistic knowledge and that establishes "a system of medical and environmental priorities" that guarantees the survival of mankind. Potter, not taking from the relevance he had always attributed to the ecological dimension of bioethics, as its original design, began to refer also to the medical dimension, that shaped the history of bioethics and which he included in his view of "global bioethics". Indeed, for Potter "global bioethics" refers precisely to a conception of bioethics that encompasses its two historical dimensions: an "ecological ethics", related to the long-term survival of man as a species, and an "medical ethics", related to the well-being of the individual in the short term. This consists, chronologically, in the first meaning of "global bioethics" [13].

Nevertheless, Potter, in explaining the designation "global bioethics" refers explicitly to the theologian Hans Küng, who vulgarised the expression "global ethics", especially since 1990 with his work *Project for a World Ethics (Projekt Weltethos)*[14]. Here, Küng presents his fundamental thesis: it is urgent to develop a "global ethics" so that we can ensure the survival of mankind in the third millennium. The concern and commitment to build on of a new area of knowledge and practice which focuses on and promotes the survival of humanity in the future is the common project of Potter and Küng, even though their proposed pathways to achieve it are different. For Küng, this "global ethics" would present itself as a single *ethos*, as a set of principles, values, beliefs, ideals and utopias shared by all, or around which it would be possible to establish a binding consensus in order to guarantee not only peace among all peoples, but also an effective response, insofar as it is concerted, to the great problems afflicting humanity.

This goal of a "global ethics" could perhaps be realised in the specific field of bioethics through the common process of globalisation, which is often translated by the notions of "internationalisation", emphasising the growing involvement of

12 VanRensselaer Potter, *Global Bioethics, Building on the Leopold Legacy*, Michigan State University Press, 1988, 203 pp.

13 M. Patrão Neves, and Walter Osswald, *Bioética Simples* (Lisboa, 2014), systematize three different meanings of "global bioethics".

14 Hans Küng, *Projekt Weltethos*, München/Zürich, Piper, 1990.

professionals and academics from different countries, and of "universalisation", emphasising the identity of the same project being developed in various parts of the world. Global bioethics – in what will be its second meaning – is understood as a set of theories and practices that have been disseminated, expanded and implemented in numerous countries, or even throughout the world. This meaning accentuates the common aspects of bioethics in various geographical contexts, thus contributing to the construction of an identity for the expanding field of bioethics. However, although it favours its development in an increasingly wider area and takes into account the various contributions that different parts of the world can offer, this meaning adopts a standardizing perspective of bioethics, which is also sometimes denounced as homogenizing. In this sense, the unity attributed to an evolving academic-scientific, socio-professional and political-legal domain, which guarantees its identity, may also lead to the underestimation or even the suppression of specificities typical of different geo-cultural spaces and peculiar to different moral communities, which is a sometimes denounced as "Western bioethical imperialism".

These differences in the perception of bioethics and its development, arising from its implementation in different geo-cultural contexts are, conversely, intentionally and strongly accentuated in what has more recently been termed "local bioethics", that is, the ethical reflection specific to a geographic location or human community. In this second meaning, global bioethics would be merely the counterpoint to local bioethics.

It is important to advance towards the systematisation of a third meaning of global bioethics, understood as a superior point of view which, whilst taking into account the specificities of local bioethics, attempts to articulate them, without suppressing them, in a heterogeneous whole. This sense of global bioethics is set apart from the two previous iterations by the valorisation it places on the diversity of local bioethics and its respective contributions to thought and practice, that is more respectful of human beings in the diversity of their manifestations.

This perspective, which greatly enriches what we understand today as bioethics, risks, however, slipping into a purely eclectic level, thus failing to meet the challenge of the very same unity and coherence of thought and action that gives it validity and efficacy.

In truth, all different meanings of global bioethics are justifiable, and in themselves relevant and pertinent to a genuine and full understanding of bioethics: in the rigorous knowledge of its past, in the just interpretation of its present and in the perspicacious projection of its future. This being so, we should not ignore or neglect any of them, but rather promote their joint consideration, which only becomes possible if we understand global bioethics as an encompassing vision of the plurality of its developments in time and space – throughout its themes, pro-

tagonists, institutions, contexts –, in the demand for a unitary and integrating intelligibility that does not self-annihilate, but can be reinvigorated by its diversity.

It is not a question, then, of splintering bioethics into a plurality of heterogeneous meanings, or reducing it to a single homogeneous bioethics; nor is the alternative set between reducing plurality to unity and losing diversity or accepting plurality and losing identity. What matters is to discover or construct unity from and in diversity, in an irrepressible dynamic between its variables, like a kaleidoscope. This is what will most genuinely and fully correspond to the formulation of a global bioethics. Global bioethics is then that intelligible plurality of strands through which bioethics has evolved.

The development of global bioethics

Henk ten Have[1]

Introduction

The word 'bioethics' was introduced in the intellectual discourse in the early 1970s. The term was first used by Van Rensselaer Potter (1911-2001), an enthusiastic scientific researcher in oncology at the University of Wisconsin in Madison in the U.S.A. Around the same time, it was used by Andre Hellegers as the initial name of the first institute in this new area at Georgetown University in Washington, DC. The term 'bioethics' was quickly adopted and became widely used. In 1973, for example, Dan Callahan published "Bioethics as a discipline" (Callahan, 1973). In fact, it was an ideal term to designate a new movement, separate from the traditional medical ethics, and referring to an innovative discipline that was open to experts from a broad range of other disciplines.

From medical ethics to bioethics

For Potter, oncology is essentially an interdisciplinary field. In explaining cancer, it is necessary to go beyond the level of individual persons and beyond the medical perspective, since cancer is often associated with social conditions, life style and environmental influences. In the fight against cancer, there will be some limited progress at the individual level (in terms of alleviation of suffering and improved treatment) but much more can be accomplished at the level of populations (in terms of prevention of cancer, for example through restrictions on smoking). However, Potter realized that medicine and healthcare were facing more important problems (Potter 1971, p. 150). Although he did not systematically discuss them, he listed the priority problems as: population, war, pollution, poverty, politics and the negative side effects of the idea of progress. He regarded these problems as jeopardizing the survival of humankind, and their urgency induced in him a growing concern regarding the future. What was necessary, there-

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fore, according to Potter, was a new science of survival, a new discipline that he called 'bioethics'. This discipline should replace or supersede traditional medical ethics which is primarily focused on individual and medical perspectives, and mostly practiced and controlled by medical professionals alone.

From bioethics to global bioethics

The new discipline should bring together knowledge from different domains: biological knowledge or the science of living systems (hence "bio"), and knowledge of human value systems (hence "ethics"). The goal of this discipline would be wisdom. Already in his first publication on bioethics, Potter defined wisdom as "knowledge of how to use knowledge" for human survival and for improvement of the quality of life (Potter 1970, p.127). Wisdom is action-oriented; it is a guide for action.

The rapidity with which the word 'bioethics' was disseminated in the ethical but also in the public discourse surprised Potter. However, he also saw that it was used to demarcate the activities of ethics experts from the traditional discourse of medical ethics without incorporating a really new approach as he had advocated. He complained that, although using the word 'bioethics' suggested innovation, the ethical practice remained business as usual. Rather than a new approach, bioethics developed as an "outgrowth of medical ethics" (Potter 1988, p.1). First, it was solely concerned with the perspective of patients: how can their lives be enhanced, maintained, and prolonged through the application of medical technologies? Second, it was exclusively interested in the short-term consequences of medical and technological interventions as well as the prolongation of our current individual existence. Third, it was unrelated to social, cultural, political and environmental determinants of human life.

To emphasize that a broader and more inclusive approach in ethics is needed, Potter started to use a new term: 'global bioethics' (Potter, 1988). He used the idea of his former university colleague Aldo Leopold, an American pioneer in wildlife conservation that there are three stages in the development of ethics. In the first stage, ethics concerns the relations between individuals, in the second stage it focuses on the relations between individual and society, and in the third stage, which does not yet exist, ethics would deal with the relations of human beings with their environment, i.e., land, animals and plants. Potter was convinced that the rise of global bioethics heralded the emergence of Leopold's third stage of ethics.

Global bioethics

Global bioethics in the vision of Potter unites two meanings of the word 'global' (Potter 1988). First, it is a system of ethics that is worldwide in scope. Second, it is unified and comprehensive. Contemporary ethics discourse in healthcare is confronted with numerous new problems: poverty, hunger and malnutrition, migration, environmental degradation and climate change, war and violence, deficient governance, corruption and ethno-nationalism, organ trade, medical tourism, and pandemics. All these problems affect the whole of humankind, regardless of where people live. What is at stake is the health and survival of humanity, not simply individual health and wellbeing. Challenges not only cross borders but concern and threaten the planet as a whole. Even if such problems exist only in few countries, or emerge first in a specific region of the world, the way they are addressed will have consequences for other countries. Usually, the transactions and interconnections between developed and developing countries can either exacerbate or diminish the impact of such problems on society and culture. Often national legislation, regulation, or policies will not be sufficient but global cooperation and action will be required. Even if the moral values in specific countries and regions differ, a common ground has to be found as a world community in order to cope with these global challenges (Ten Have and Gordijn, 2014).

The global dimension of today's moral challenges requires a global perspective of bioethics. But it also demands a new and broader approach to ethics. This refers to the second meaning of 'global': bioethics as an encompassing and comprehensive approach, combining traditional professional (medical, clinical and nursing) ethics with ecological concerns and the larger problems of society. This implies more than simply declaring that today's problems are global and affect everyone. First, it requires interdisciplinary cooperation. Global problems as poverty, climate change and inequities in healthcare can only be addressed by obtaining and applying different types of knowledge. It is unavoidable to bridge the gap between science and humanities. Secondly, it requires that diverse perspectives must be used to explain and understand complex phenomena. Global problems can no longer be approached only from an exclusively Western or Eastern perspective. Healthcare will not be improved by simply importing and applying medication and technology; we need to understand the existing value systems. Various methods and theories will therefore be used in global bioethics. It also needs input from cross-cultural, empirical studies as well as philosophical analysis. This reflects the idea that the global and local levels in ethics are connected. Global bioethics principles need to be implemented at local levels which assumes that some principles will be more important than others when the local context is consid-

ered. For example, in developing countries, principles of justice, benefit sharing, and social responsibility are primary perspectives to examine moral issues, while in other countries with broad and inclusive healthcare systems, the principle of respect for autonomy will receive priority, although vulnerability will also be a major principle. Some principles such as the protection of the environment, and the protection of future generations will however be significant in all countries, given the global threat of climate change.

A global ethical framework

It has been suggested that global ethics is a two-level phenomenon (Kymlicka, 2007). At the abstract level there is the international human rights discourse defining a minimum set of standards agreeable to all. At the contextualized level, there is a multiplicity of different ethical traditions. These 'local' traditions define what is ethically required beyond and above human rights. The same distinction can be used for global bioethics. On the one hand, there is a set of minimum standards on which traditions and cultures agree; this is elaborated into specific bioethics principles in connection to international human rights language. On the other hand, there are many efforts to articulate more specific bioethics standards in the context of specific religious and cultural traditions. Members of these traditions also bring their views in the global debate through constructive dialogues and sometimes negotiations, so that the dialectic of global and local also helps to construct and produce global bioethics. Thus, the universal principles of global bioethics are the result of continuous and multilateral articulation, deliberation and production. This is exemplified in the *Universal Declaration on Bioethics and Human Rights* adopted by UNESCO member states in 2005 (Ten Have and Jean, 2009). The request to develop a common framework of ethical principles in bioethics was explicitly made by developing countries. They were afraid that with the rapid evolution and globalization of medical science and research they would insufficiently benefit from the advances and suffer too many harms and risks. A major concern was that international medical research and healthcare endeavors would proceed along double standards so that people in developing countries would receive substandard care and be involved in clinical trials without the ethical protection that exists in developed countries. The adoption of the Declaration shows that agreement could be reached on 15 global bioethics principles. However, these universal principles need to be interpreted and applied in specific local settings of different cultures and traditions. The abstract and contextualized levels are therefore interacting along bottom up and top-down lines of communication. Global platforms and local contexts mutually help each other to construct and

produce global bioethics. Thus, global bioethics is the result of continuous and multilateral articulation, deliberation and production.

Future challenges

Like many other international ethical standards in bioethics, such as the *Declaration of Helsinki* (1964) and the *European Convention on Human Rights and Biomedicine* (1997), the *Universal Declaration on Bioethics and Human Rights* (2005) is embedded in the human rights tradition, while it is unique as the first global instrument that endeavors to cover the entire field of bioethics (Andorno, 2007, 2009). Consequently, the future perspectives of global bioethics, thus framed, are closely connected with the prospects of the human rights tradition itself (Gordijn and Ten Have, 2014). The appeal to human rights makes a lot of practical sense in order to seek avenues for a more effective governance of global health since contemporary challenges are often crossing borders and demand international solutions. Additionally, bioethics and international human rights are held to have similar historical roots: World War II, the Nazi concentration camps and their follow-up events triggered the establishment of both (Annas, 2004, 2010; Baker, 2001). The challenge today is that human rights discourse is weakened. One reason is that theoretical lack of agreement persist as regards the justification of human rights, the anthropocentrism involved in the exclusiveness of human beings as the sole bearers of human rights, and the focus on rights without consideration of corresponding obligations. But perhaps the main reason is that many governments, and particularly autocratic regimes, do no longer respect human rights. In some cases, they argue that human rights should be regarded as Western imperialism, even though all governments or members of the United Nations have adopted international human rights law as a guiding framework for policy-making. In a significant number of countries, human rights activists are persecuted and imprisoned.

The globalization of bioethics furthermore demonstrates the ambivalent character of modern bioethics: the tension between academic scholarship and theoretical commitment on the one hand, and activism and practical engagement on the other. Bioethicists cannot avoid being involved in policy-making either at the local, national and international levels where bioethicists are involved in a wide range of activities that go beyond the exclusive domain of academic enquiry.

A final challenge is that in some countries bioethics has achieved a strong institutional base and a high level of sophistication, but in many other countries it has clearly not yet reached a full-fledged state of development. Efforts are needed to strengthen bioethics in most countries worldwide, so that global ethical standards

might be more effectively communicated and implemented. In the area of medicine, healthcare and the life sciences this can be done by promotion of bioethics education and capacity building. Existing initiatives such as the Ethics Education Program of UNESCO must be further expanded. Bioethics committees can play an important role in developing bioethics infrastructures. Since they use to be interdisciplinary bodies of expertise, committees can initiate and expand ethics education at various levels (for example, information and discussion sessions in secondary schools, and encouragement of universities to use the UNESCO resources and materials in ethics teaching) and in a range of disciplines. Health and well-being are in the interest of everybody so that the assumption is that every citizen in interested in learning about the advancements and possibilities of modern medicine. It is not merely the policy-makers who need to be advised, but the population as a whole that is in need of engagement and involvement.

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1. African Region
(AFR)

Bioethics: an African perspective

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The profile

Bioethics emerged largely from North American and Western European settings about 45 years ago, against a backdrop of set theories and principles that aimed to foster individual autonomy, privacy, mitigation of possible harms, and distributive justice (Barugahare, 2018; Scher, Kozlowska, 2018; Fayemi, Macaulay-Adeyelure, 2016). While these principles and ethical standards are intended to promote individual rights and interests and prevent exploitative practices, the nuanced understanding of health and health care from an African perspective highlights the need to integrate African thinking and values into the interventions for health dilemmas we face in Africa now. Part of the challenge is that Africa has been a popular research destination for researchers and funding agencies based in these Western block countries, given the rich diversity of African populations (Akintola, 2018). Given this importation of research activities into the continent and the limitations in the existing locally generated funding to support and build capacity, it is inevitable that research priorities and focal areas will be influenced by the world views and the decisions of these external researchers and funding agencies (outside of Africa). Numerous scholars in Africa and South America, in particular, suggest a different lens bioethics can play in addressing present issues and major challenges and mapping a future role in how it can change societies from a sociocultural, theoretical, legal, and indigenous healthcare perspective. See extensive work done by African scholars such as Behrens (2013), Moshabela, Zuma and Gaede (2016), Behrens and Wareham (2020), Aislan Vieira de Melo *et al.* (2021), Akpa-Inyang and Chima (2021) to name a few.

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Bioethics essentially involves both the normative and empirical aspects of moral issues and values and the application and implications of these to the healthcare environment. However, the concurrent consideration of the wider impact of socio-cultural influences on health decision-making cannot be ignored (Singh, Moodley, Cadigan, 2022). Hence, the scope and nature of bioethics in the South African context and across a wider African perspective must be grounded in the diverse cultural, religious, and other relevant settings and systems that invariably influence individual and collective decision-making. This means that understanding bioethics from an African perspective must take into account how different communities view health and illness, the human body and the sum of its parts (including blood and tissues), the transition between the living and the after-life, and the value placed on community and family influences on decision making (Akintola, 2018; Jegede, 2009; Diallo *et al.,* 2005). The related socio-cultural and religious values are underpinned by the ubuntu philosophy,[5] which expresses humanness and personhood through interconnectedness with other persons. This philosophy of Ubuntu fundamentally outlines that an individual is defined through their community and that authentic personhood can only be attained through being in a relationship or a community with others (Behrens, 2013). Thus, the focus is on the overall societal/common good for the affected village or population and defining what is of benefit to the community at large, as opposed to an individual. These value systems differ from those espoused in our current understanding of bioethics. It is, therefore, inevitable that the currently accepted principles and standards in bioethics would invariably clash with some local understandings and expectations of health for all and equality in health care. A clear example is a dominant approach of principlism to bioethics, which draws on the discipline of Western philosophy, and was exported to Africa. The problem with exporting principlism to Africa is that it is out of sync with African values that empathize with ubuntu, community, and solidarity over the autonomy and capabilities of individuals. We echo the sentiments expressed by Behrens (2013) that African bioethicists develop their version of principlism that incorporate Ubuntu, and other salient features of African ethics.

[5] The African philosophy of "ubuntu" – is a concept in which sense of self is shaped by relationships with other people. It is rooted on the premise that "a person is a person because of or through others. In practice, Ubuntu can be described as the capacity in an African culture to express compassion, reciprocity, dignity, humanity and mutuality in the interests of building and maintaining communities with justice and mutual caring. Ubuntu also means believing the common bonds within a group are more important than any individual interests, and therefore promotes solidarity and a community-centric ethos over individualism.

The challenges

While the context of understanding bioethics in an African setting differs significantly from the conventional bioethics context, the continent also bears the scars of historical injustices that continue to permeate the current delivery of health care. The African continent has seen numerous exploitative practices, such as exporting genetic resources and biosamples to other countries, with no benefit-sharing efforts being offered to local communities or researchers. The continent has a rich genetic history and population diversity, making it a lucrative destination for foreign researchers and clinicians. The appropriation of genetic material has characterized the global north-south and south-south divides because of poor resource capacity and inadequate researcher/stakeholder expertise within the affected countries (Akintola, 2018; Diallo *et al.,* 2005).

One example of exploitative practice within the continent is the mass exportation of biosamples during the 2014-2016 Ebola crisis. During the Ebola crisis in West Africa (Guinea, Liberia and Sierra Leone), about 50 000 samples were moved out of these countries to laboratories in other parts of the world because of the sub-optimal storage capabilities in the local facilities. However, once these samples were transferred out of these countries, local researchers had no further access to these samples (Moodley, 2019; Schopper *et al.*, 2019). This example has layers of exploitation that collectively indicate the challenges that have occurred due to weak country-level legislation and lapses in ethical oversight for the protection of individuals and community interests. Paradoxically, these highlighted issues also point to a fault line in how collaborations occur between researchers, clinicians, and other stakeholders within Africa and external to the continent (Moodley and Kleinsmidt, 2020; Moodley, 2020).

The recent COVID-19 pandemic reiterated the deep flaws and inequities in health care at a global level, especially in the face of a public health emergency (Singh, Cadigan, Moodley, 2021). The Centre for Global Health Inequalities Research (also known as CHAIN) and the EuroHealthNet, describe COVID-19 as a syndemic pandemic where the severity of the pandemic is amplified or exacerbated by the pre-COVID inequalities in health care provision, especially in disadvantaged and marginalized populations (EuroHealthNet, 2020). This is of particular interest to bioethics, given that countries such as South Africa have had to deal with the existing quadruple burden of disease against a backdrop of global inequalities in health care as a result of the COVID-19 pandemic. The African continent further suffered from delays in the initial access to COVID-19 vaccines amidst allegations of stockpiling and vaccine nationalism amongst high-income countries, while low and middle-income countries were placed low on the global vaccine priority list. These issues reflect distributive injustice at a global level and

are but some of the issues that contributed to eroded public trust at a community level. The skewed global prioritization of COVID-19 vaccines demonstrated the entrenchment of certain views and paradigms, including Africa's lack of socio-economic emancipation and political influence. These imbalances in power dynamics, which also exist between researchers and clinicians in the global north-south and south-south divide, must first be acknowledged and then addressed through the appropriate platforms. These power dynamics and the prevailing reliance on funding and research expertise outside of Africa could also explain why it is so difficult to develop and lead African initiatives in bioethics.

Additionally, the expertise in the South African research centres, honed from years of operating in an environment of high levels of infectious diseases such as HIV and TB, allowed the discovery of the Omicron variant early. The rapid, knee-jerk implementation and the subsequent travel ban/restrictions placed on the country, mainly by the countries in North America and Western Europe, were not aligned with the logic of travel restrictions to countries with high COVID-19 infection rates (Sippy, 2021). Instead, South Africa was singled out by the Western block countries at a time when the country had relatively low levels of infections compared to the US. This emphasizes the perpetuation of decision-making based on the deep global inequalities and prejudices that continue to permeate and impact the whole continent. At the same time, none of the major global bioethics consortia added their voice to speak against this unfavourable treatment that had serious implications for veracity and transparency related to scientific findings when such discoveries could be suppressed for fear of political backlash. The non-response of global and local bioethics leaders on this matter is an important point for further reflection and deliberation on such forums.

At the 13th global summit of National Ethics Committees held in Portugal in September 2022, the African region analysed that bioethics is an emerging and growing field in Africa. This is evidenced by a few African countries initiating the establishment of national ethics committees and frameworks for research ethics. The development of this field is, however, hindered by several challenges, including the lack of legal tools that provide for the establishment and recognition of structures and systems that govern bioethics, lack of capacity and insights to guide bioethics research and scholarship, and limitations of funding for training and operations of responsible committees. Generally, the health research ethics infrastructure charged mainly with reviewing and approving research protocols seems more developed than other ethics structures such as bioethics and clinical ethics committees. A view exists that international funding from the global north support capacity development in research ethics and the establishment of research ethics committees to approve the research they fund in Africa, and this has overshadowed the necessity for clinical ethics committees in Africa.

There is a clear need to build the field of bioethics, to expand the current expertise in response to the current scarcity of bioethicists. Very few institutions of higher education in Africa offer training programmes in bioethics, and most of them are located in South Africa. At the same time, where such training is offered, these are, at times, a result of educational/training grants received from the Western-block countries. While these grants are important to fuel investments in bioethics education, it becomes difficult for bioethics educators and researchers to critique the prevailing Western concepts and approaches that underline the current understanding of bioethics. The need to transform bioethics to a more African-sensitive approach also requires a shift in the mindsets of people who offer such training opportunities. These and other bioethics leaders must have louder voices so that when exploitative and discriminatory practices occur, they can be addressed rapidly and effectively.

The way forward (the future)

Collectively, these highlighted issues demand a review of how bioethics is positioned within the African continent. Bioethics in Africa must also be informed by contextual features distinct to the region to enable an effective and appropriate response to current and emerging challenges of moral significance. While pursuing identity is legitimate, it must factor in other competing considerations. This paper is not meant to be a guideline on bioethics but highlights the need for a paradigm shift in how we think and engage with bioethics in an African context, which is a diversion from the current focus on international ethics guidelines. The paper aims to emphasise a need for greater awareness among African clinicians, researchers, bioethicists, and other stakeholders from the global north and south to understand and engage with the local context of health care and research to make insightful and appropriate ethical decisions. Apart from the highlighted sociocultural considerations, the prevailing power dynamics between researchers and clinicians from the global north and south must also be acknowledged and debated at various bioethics platforms. There are no easy solutions to how these engagements can be facilitated. However, awareness and willingness to discuss these issues at different fora would be a good starting point for further deliberations. There is a need for ongoing communication, collaboration, and engagement with the relevant bioethics consortia across the globe. At present, a silo approach exists, yet much more could be achieved. A global networking forum that recognizes the nuances and peculiarities of the different contexts for bioethics could achieve greater dividends than the current fragmented processes. African moral perspectives can

contribute significantly to bioethics, and mainstream bioethical discourse must also recognize these important moral concepts.

Additionally, there is a need for locally developed curricula in bioethics education that are shaped and informed by contextualized real-world experiences, as highlighted earlier, so that scholars, clinicians, and researchers in Africa and outside of the continent are sensitized to these nuances that would ultimately impact research and health decision-making.

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The Nigerian National Bioethics Committee: Past, Present and Future

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Introduction

Bioethics has been given different definitions and the definitions have all tended towards health medical research, though by no means confined to this. This is understandable given what made bioethics popular globally. The attachment of bioethics to the Nazi war crimes during World War II, and the later multidisciplinary approach to allocation of scarce technological equipment in hospital settings, are the reasons bioethics is mostly seen as a field mainly to do with medicine. Bioethics indeed is much more than medicine, health-care or research. It is all encompassing cutting across every field and discipline. It is multidisciplinary, multifaceted, and ought to be viewed holistically as far as life is concerned. Bioethics is much more than physician-patient relationship or research–participant relationship. Therefore, a more comprehensive definition of bioethics would be as I coined it, the application of moral principles to the knowledge of human values in relationship to life.

As we all know, the concept of bioethics was first coined by Fitz Jahr in 1927 (Muzur & Rincic, 2011). He associated ethics primarily with life not just humans. Although, Fitz coined the term bioethics, bioethics was made popular by Van Rensselaer Potter. He foresaw the dehumanization of science and the need for a new discipline which would help re-establish ecological balance and protect natural resources. He was more concern with building a bridge between the natural sciences and the humanities (Muzur & Rincic, 2011).

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The beginning of Bioethics in Nigeria

Bioethics has been in existence in Nigeria since the 80's in the Federal Ministry of Health, but it was completely dormant (Ewuoso, 2016; NCHRE, 2007; Yakubu & Adebamowo, 2012). It only existed on papers, and there was also no formal training in research ethics (Ewuoso, 2016; Yakubu & Adebamowo, 2012). This could be as a result of poor political will, and lack of regulations and knowledge of research ethics on the part of the Nigerian authorities to promote health research in the country (Yakubu & Adebamowo, 2012).

The 1996 unethical Pfizer's cerebrospinal meningitis trial disaster in Kano State, Nigeria woke up the sleeping bioethics in the Federal Ministry of Health (Ewuoso, 2016). Pfizer capitalised on the absence of a functional research ethics committee at that time to conduct a phase 11 clinical trial of Trovafloxacin in Kano state, Nigeria. This unethical Trovan trial done by Pfizer is attributed to the direct cause of formal bioethics in Nigeria (Ewuoso, 2016). A major spur of bioethics came through Prof. Clement Adebayo Adebamowo who was instrumental to the writing of the Nigeria's National Code for Health Research Ethics, the reformation and re-establishment of the National Health Research Ethics Committee (NHREC) and the promotion, establishment, training and institutionalizing of a regime for registration of Institutional Health Research Ethics Committees in Nigeria (Malomo *et al.*, 2009). He also, through the funding from Forgaty International Center of the United States, National Institute of Health, introduced bioethics as a discipline in Nigeria, and also facilitated the training of many bioethics' scholars.

The first bioethics body in Nigeria was the Society for Research in Bioethics. It was formed in 1996 with an intention for short-term training in bioethics (Malomo *et al.*, 2009). The University of Ibadan (UI), later introduced bioethics as a discipline in her master's programme. There is also a Centre of bioethics in Ibadan which succeeds the West African Bioethics Training Programme. It was established in 2004 by Professor Clement Adebayo Adebamowo through a grant from the Forgaty International Center (FIC) of the National Institute of Health (NIH), with an overarching goal of building bioethics in West Africa.

In 2006, a National Policy on Health Research was formulated. The policy mandated the establishment of a National Health Research Council, and a National Health Ethics Review Committee, which was to later regulate the Institutional Review Boards (IRBs) in the country (Idigbe, 2006: Malomo *et al.*, 2009). The National Health Research Ethics Committee was inaugurated, with Professor Clement Adebayo Adebamowo as its first Chairman (Malomo, 2009). More institutional health research ethics committees continued to be formed through the Centre of Bioethics in Ibadan.

Although the National Health Research Ethics Committee in Nigeria is the apex body for health research, it has a specific mandate which is strictly for health research as the name implies. Its mandate is specific, defined and confined, hence the need for a National Bioethics Committee in Nigeria, for an all-encompassing role. The aim of this paper is to understand the evolution of bioethics in Nigeria, the process and challenges of establishing a Nigerian National Bioethics Committee.

The process of establishing the Nigeria National Bioethics Committee

Nigeria being a member state of UNESCO since 1960, and a signatory to the 2005 UNESCO Declaration on Bioethics and Human Rights, is expected to have a National Bioethics Committee so as to implement the various standard setting instruments that have been adopted by UNESCO, and particularly because the declaration advocates for the establishment of an independent, multidisciplinary and pluralist ethics committees at National, Regional, Local or Institutional levels. (Have, Dikenou & Feinholz, 2011). According to UNESCO Assisting Bioethics Project Programme, the purpose of the National Bioethics Committee is to provide advice on ethical problems relating to research, development and application of scientific knowledge, formulate recommendations concerning guidelines and legislation, develop tools for standard setting, strengthen coordination and contacts among experts and institutions (*e.g.* through databases and networking) and foster debate, education and public awareness, and engagement in, bioethics (UNESCO ABC Project, 2008).

In 2009, at the expression of the government of Nigeria to set up a National Bioethics Committee, UNESCO organized and sponsored the first, preparatory National Bioethics Stakeholders meeting at the Hilton Hotels, Abuja, Nigeria. The main objective of this meeting was to provide the Nigerian authorities the information required to establish a National Bioethics Committee which is independent, multidisciplinary and pluralist with a broad mandate that could incorporate other entities. In 2017 UNESCO again organized and sponsored a second National Bioethics Stakeholders meeting at Kini Hotel, Akwanga, Nasarawa State. This time the main objective was to help guide the Nigerian authorities on the process of developing a National Bioethics Framework and Policy Documents necessary for the establishment of a National Bioethics Committee.

Two years later in 2019, the Nigerian Government through the National Biotechnology Development Agency (NABDA) organised and sponsored the third National Bioethics Stakeholders meeting in collaboration with the Nigerian National Commission for UNESCO (NATCOM-UNESCO). The main objective of

this meeting was to discuss bioethical issues bothering the country. Six thematic areas were identified, namely: Agricultural ethics, Defense and Security ethics, Educational ethics, Environmental ethics, Health ethics and Societal ethics. These thematic areas were headed by Technical Working Group Chairpersons who later assembled after the third National Bioethics Stakeholders meeting, to fine tune what over a hundred persons during the meeting put up, and thus developed and produced the National Bioethics Framework and the National Bioethics Policy Documents which Nigeria now has. The National Bioethics Documents are a prerequisite to establishing a National Bioethics Committee, because they would serve as guidelines for effective running of the National Bioethics Committee. The Nigerian National Bioethics Committee is expected to do the following:

- Act as advisory committee to government and policy makers on ethical issues bothering the country
- Review protocols that are not health-research related
- Act as an umbrella for other Ethics Committees in Nigeria

To make the Nigerian National Bioethics Committee truly national, the National Bioethics Documents were sent to the Federal Executive Council which is the highest executive arm of government in Nigeria for approval. This was done not only for the Bioethics document to be recognized as National documents, but also for the Federal Government to have a reason to fund the National Bioethics Committee. Fortunately, the Federal Executive Council on the 13th of May, 2022, approved the National Bioethics Documents for the establishment of a National Bioethics Committee.

Bioethics in Nigeria as compared to other African countries

Africa, South of Sahara has some approaches to interpreting and responding to the experience of nature in common, but in her rich diversity of history, and culture, the details are not of a homogenous field. Bioethics in Africa reflects this situation in terms of Beginning and Development, Institutionalization and Academic formation, Philosophising and Indigenous response, as well as Impact on the general society so far.

As earlier described, components of 'Bioethics' existed in the classical professions (particularly 'Scientific Medicine') as they were adapted from those in the homes of the colonial masters, and also with the religious bodies, especially the Roman Catholic Establishment, to the extent that the concerns of such bodies impinged on the practices of these bodies. We also showed how formal Bioethics in facilitation and capacity building derived much from the West. Through fur-

ther support, graduates of various Western institutions provided various degrees of training in their home countries and a number now have Postgraduate programmes in Bioethics.

Apart from Academic programmes, training of Human Research Ethics Committee members at local and national levels, as well as the use of Principles in Professional Codes are some ways in which Bioethics is getting into national lives at least at elite levels. Epidemics have underscored the importance of Public Health Ethics, while Climate change is underscoring Environmental Ethics. Documents towards the formation of National Bioethics Committees provide opportunity for foraying into other essential areas such as Ethical Issues in Society (with opportunities for including Ethical issues in Family, Politics, and Economics among others), Education, Agriculture, Technology, and Armed Forces among others. These are appropriate developments because HUMAN 'BIOS' is affected by these aspects of human reality and developments, as differing from the 'Bios' of lower animals or plants in their natural states.

Publications in learned journals have been mostly descriptive, especially highlighting the challenges to implementing 'RESPECT FOR AUTONOMY' in an African setting. Some critical works are at the Metaphysical, Ontological, and Epistemological levels (Coleman, 2017). These have sometimes met with the same discussions surrounding 'African Philosophy' but robust responses have usually been proffered (Metz, 2010). There seems to be a continuing need to 'neutrally' describe, define and discuss the ways Africans, like Orientals and Continentals for instance, have approached understanding and responding to Reality and their Existence, before further efforts to deploy or develop them. Meanwhile, through various channels, particularly as coordinated by UNESCO, Africans continue to participate authentically and validly in the global Bioethics discuss.

The Principles truly deal with common morals, in which all African communities participate in their particular ways. Bioethics, Human Rights and Freedoms are so intimate (Rheeder, 2016) that we might have expected societal rebirth, midwifed by Bioethics in Africa. Current affairs seem to deny that! It seems to us that a successful transplant of Bioethics, in its globalised masculine Principlistic mode, into African cultural environment with positive mutual adaptation, and flourishing needs to take cognisance of the following:

i) *Historical Gaps:* 'Liberty, Equality and Fraternity' are close enough to 'Autonomy, Justice, and Beneficence (with non-maleficence)'. Africans are yet to have their philosophical ('French') revolutions and civil rights discuss that would grant these goods TO ALL, and EQUALLY.

ii) *Traditional Ideology:* When life was brutal and short, due mostly to natural and external enemy assaults, groups bonded together with true love, trust and reliance, needed by all for safety, survival, and a modicum of flourishing. Then

there were traditional character building, cultic selection of roles, oversight and punishments as required. These would make any people idealistic in their expectations from neighbours, leaders, 'elders' and generally 'Authority' which must serve, protect, and grow others well in mutual interest. Africans remain trusting and relying on others especially in their 'group' or leaders from their 'group' even when traditional education, cultic selection; monitoring, sanctions, checks and balances have changed! This too in countries that are now capitalistic, democratic, and competition-driven; and when most others, especially in the Western world, are in the other extreme of cynical Realism about human nature and based expectations, and rules of engagement on such. Continental evidence seems to suggest that it is time Africans moved into Cautious idealism by interrogating 'Authority' and 'Claims' of neighbours.

iii) *Clan Vs Cosmopolis, Ethnos Vs. 'Civitas'*: Although, there are countries that bear the title of a Republic, most Africans and people of the developing societies including Africans, still feel, think, and live as in clans or its group forming a tribe with a common ethos of customs, values, and traditions. This impairs their capacity to transform into a Republic with its own life, structure, form and dynamics, determined solely by the constitution and laws derived from within it, in which values such as enunciated in 'The Principles' would be so valuable.

iv) *Conditions of Actualization:* Freedoms and Rights require both security and capacity (for bearing responsibility and for meeting obligations, respectively). They are both limited, in practice, by lack of security. Unless, therefore, a society can provide a minimum support to ensure security and capacity, these words are vacuous for the DEPENDENT individuals concerned. This is the experience of most people in developing societies.

It is clear from the above that, like Science and Technology, there may be a type of societal philosophy and fabric that can sustain the flourishing of the good at which Bioethics aims. All who are engaged in Bioethics in Africa may therefore need to pay attention to these facts, as found in the nature of Africans, in the interest of the populace they serve. Global and international dynamics as it impinges on nations' ability to implement 'the good' or 'the right', are real. These, however, are outside our present concerns.

In Nigeria, just like other African countries, research has shown that bioethics is still seen as a western thing, especially the aspect of autonomy in healthcare (Coleman, 2017). Africans generally have a communitarian kind of lifestyle where we believe that we all look out for each other (Andoh, 2011; Keymanthri *et al.*, 2020, Tangwa, 1996). In the health care system, Nigerians still believe that the care giver, in this case the physician has the utmost and final decision as regards their healthcare. It is believed that the physician would always act in the best interest of the patient. It therefore appears strange, in

such a context, when a physician asks a patient what choice of treatment he or she would prefer.

A physician who practices autonomy in the clinical setting is sometimes viewed as an 'incompetent' physician. It doesn't matter if the patient is educated or not. Our culture, tradition and religion greatly affect the practice of bioethics in Nigeria. Studies have shown that the practice of bioethics in Nigeria is not different from the practice of bioethics in other African countries (Coleman, 2017; Gbadegesin, 1993; Murove, 2005; Tangwa, 1996).

Coleman (2017) did a literature review on five African countries, Cameroon, Chad, Kenya, Nigeria and Republic of South Africa. He observed that all five articles lamented on the effect of colonialism and post-colonialism on the socio-economic and health status of their countries, as well as the dignity of its citizenry. The authors explored the dominant effect of western bioethics on the African way of life, and culture which is community centered as compared to the individual centered principlism framework which western bioethics advocates. They all observed that the African culture, tradition and religion interfere with the way bioethics is practiced in their individual countries (Coleman, 2017; Ikeagwulonu, Uneke & Uchejeso, 2021). Behrens (2017) also did a review of five articles from five countries, and interestingly all authors mentioned the intertwining of African culture with ethics. The African communitarian style of living is seen in the South African notion of Ubuntu; meaning I am because we are, or humanity towards others (Mbiti, 1996).

One thing common with all these authors who spoke about African bioethics is that they all agree that bioethics educational programme or training is a much needed one in our higher institutions (Andoh, 2011; Awujiusuk, 2014; Azetsop, 2011; Behrens, 2013; Gbadegesin, 1993; Mertz, 2010; Murove, 2005; Ogundiran, 2004; Onouha, 2017; Tangwa, 1996). Africans are not comfortable with the attempt to universalize western autonomy based on principlist theory or framework. It is believed that African ethics sterns from a common morality as opposed to individual morality ethics. They also observed that firstly, there is a need for ethics educational programmes for health professionals. Secondly, that lack of resources makes it difficult for health professionals to focus on clinical ethics despite being regarded as necessary and important (Andoh, 2011; Awujiusuk, 2014; Azetsop, 2011; Behrens, 2013; Gbadegesin, 1993; Mertz, 2010; Murove, 2005; Ogundiran, 2004; Onouha, 2017; Tangwa, 1996). It is our view that the African ideals will ultimately become more realistic, without necessarily compromising its caring ethos.

It is recommended that encouraging interested individuals and healthcare professional to engage in formal postgraduate bioethics educational programmes and including clinical ethics in bioethics curricular at undergraduate and post

graduate levels in health science education would help create awareness, improve capacity, and showcase the importance of bioethics (Andoh, 2013; Behrens, 2017; Ogundiran, Agunlanna & Malomo, 2017; Keymanthri & Landon, 2017; Keymanthri *et al.*, 2020; Monsudi *et al.*, 2015). While Monsudi *et al.* (2015) agree that bioethics educational programmes are needed for both physicians and non-physicians, they pointed out that traditional and cultural values hamper the practice of western bioethics as opposed to African bioethics. This raises the question, what is African Bioethics?

Challenges

Unfortunately, Nigeria is lagging behind in appropriating the benefits of Bioethics. This may be due to inadequate, awareness, advocacy, zeal and zest for supporting bioethics in Nigeria, on the part of the authorities concerned as well as the citizens. There is therefore a need for formal, systematic and continuous education, capacitation and integration of those in government and policy makers, as well as the citizens.

Conclusion

It took Nigeria over a decade, from 2009 to 2022 to come to terms with the need to establish a National Bioethics Committee. Lack of understanding is hampering the establishment of a National Bioethics Ethics Committee in Nigeria. Given the situation in Nigeria, it seems the reasons are multifactorial and complex. Capacity-building for the government, policy makers, media, and the entire citizen is required. Relevant legislation and effective regulatory measures need to be put in place for effective and vibrant National Bioethics Committee to be achieved. Bioethics expertise and infrastructure are seriously lacking in Nigeria.

What Next?

With the approval of the National Bioethics Documents for the establishment of a National Bioethics Committee in Nigeria, the next step is to constitute the members of the National bioethics Committee. We have drafted a skeletal modality of how the National Bioethics Committee should function. The constituted list would be sent to the President of Nigeria for his approval. Thereafter, a Memorandum of Understanding would be signed between UNESCO, and the Nigerian government. This would be followed by the training and inauguration of the National Bioethics Committee.

The way forward

The UNESCO Assisting Bioethics Committees (ABC) Project has the responsibility and opportunity, to keep investigating and enriching the nature of Bioethics and gaining the ever-increasing capacity to bring the gains of such to their society and humanity as a whole.

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Five Priorities for Research Ethics in Africa in light of the Covid-19 Pandemic

Caesar Alimsinya Atuire[1]

Introduction

In April 2020, as the populations of many countries were cowering under lockdowns imposed by national health authorities to curb the outbreak of the Covid-19 pandemic and scientists were struggling to find therapeutics and vaccines to limit the rising number of infections and deaths from the SARs-CoV-2 virus, many people were stunned by the news that French scientists were suggesting that Africans should become a testing ground for new health interventions because Africans do not have face masks, treatment, and resuscitation capacities ("Coronavirus: France racism row over doctors' Africa testing comments," 2020).

The news prompted indignation and strong reactions from within and outside the continent. Tedros Adhanom Ghebreyesus, the WHO Director General, responded, with strong words expressing his consternation about the Scientists' comments saying, "These kinds of racist remarks will not help. It goes against the solidarity… The hangover from colonial mentality has to stop. WHO will not allow this to happen." ("Africa will not be vaccine testing ground: WHO slams racist French medics," 2020).

Two years on, we can say that such ethical monstrosities were avoided during the trials that led to the successful production of Covid-19 vaccines. Amidst this success story of greater respect for research participants, the Covid-19 pandemic also revealed several important gaps, inequities, and inefficiencies in the research ethics and governance space in many African countries. Africans participated in trials and yet the continent was always at the backend of the queue in the allocation of lifesaving resources. When the president of South Africa, who was also the Chair of the African Union, together with the president of India, in November 2020 requested a temporary suspension of intellectual property rights on Covid-19 vaccines, their proposal was rejected or stymied by large global players including Bill Gates and the European Union (Usher, 2020). When South African researchers were diligent in sequencing the omicron variant and sharing the in-

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formation with the rest of the world, many high-income countries responded by imposing severe travel bans on countries in the Southern Region of Africa.

As Africa and the world reflect on building more robust responses to emerging and re-emerging health threats, the lessons learned from the Covid-19 pandemic will need to be taken seriously. In this chapter, I suggest five important issues that must be addressed, as necessary conditions, for building a research environment that can contribute to improving the health and livelihood of persons living on the African continent. These ethics and governance issues are data governance; research priority setting; capacity building; inclusion; and concluding remarks.

Data Governance

The importance of data sharing cannot be overemphasized when it comes to the prevention and management of major disease outbreaks. However, as Atuire & Bull (2022) point out, the data playing ground is not an even field. The collection, analysis, and use of data occur within a global health system that is already laden with power imbalances. Similar to what occurs with Africa as a producer of primary goods such as cocoa, crude oil, gold, and bauxite, the added value to data occurs elsewhere outside the continent and the benefits are not distributed equitably.

Looking at health research, what is striking from an ethical viewpoint is the value ambiguity that accompanies the various stages in the chain that leads to the production of a successful health intervention or product. The values that are predicated at the early stages include solidarity, transparency, and knowledge sharing. Funders of global health research like the Gates foundation insist on data sharing as a condition for funding (Anger *et al.*, 2022). Yet, when that data is used to generate knowledge and health interventions, a different set of values is applied to the product. In fact, as research draws towards the production of useful health intervention, one cannot but notice an increased silencing of the initial set of values of sharing, solidarity, and transparency, whilst other values such as private entitlements, profits, and ownership become louder.

African Ethics committees will need to address this issue by first, establishing functioning and empowered national ethics committees. A 2021 study by Hummel *et al.* of National Ethics Committees (NECs) found that only 15% of NECs corresponding to 19 were in the WHO African region which has 47 member states. This means that less than half of these have a NEC. Where Ethics committees exist, they often operate under serious constraints including, lack of clear SOPs, heavy workloads, a lack of sufficient capacity and funding, and a lack of independence (Silaigwana & Wassenaar, 2015). On the issue of data sharing, find-

ing a balance not just through protectionism, but rather through a framework that will ensure good data sharing and fair benefit sharing is an urgent need. Countries across the continent are individually introducing data governance laws, with differing levels of protection and protectionism. The international nature of major disease outbreaks requires a more harmonized regional or continental approach to data governance. Such a framework should factor benefit sharing into the conditions for equitable data sharing. Benefit sharing, which is a larger concept than direct reciprocity, asks the ultimate question about who benefits from research. The Africa Centre for Disease Control (CDC) which is leading the continent's drive towards a new era of health robustness is well positioned to lead the task of convening leading ethicists and policy makers from across the continent to design a framework that member States of the African Union could adopt.

Research Priority Setting

Linked to the previous point is the question of health research priority setting. The African Academy of Science, and later the Africa CDC issued a set of research priorities for Covid-19 (Research and Development Priorities for COVID-19 in Africa (Policy Paper), 2021). There has been no systematic monitoring of how these priorities were applied across the continent. In any case, much more than Covid-19 research priority setting, is the underlying issue of the choice of research priorities under non-emergency situations and how these are determined. Although member States of the African Union committed in 2007 to spending 1% of GDP on R&D, the regional average in 2015 was a mere 0.4% (Simpkin *et al.*, 2019). This means that research on the continent is driven by external funders whose priorities may not always coincide with local ones. Thus, for example, diseases and conditions that are endemic only to African countries run the risk of receiving less research funding support. An example is Mpox which has been endemic in parts of Western and Central Africa for at least five decades but did attract as much research funding until the disease started spreading among citizens of high-income countries.

The first ethical question of priority setting is about the right to equal concern, which requires that persons should be treated equally without regard to their persons or character or castes (Dworkin, 1977). Thus, health conditions that negatively affect people's lives and livelihoods anywhere in the world merit equal attention. Priority should not only go to those diseases that affect those who are economically well-off. Alongside the right to equal moral concern, what is becoming more evident – as in the case of Mpox and similar zoonotic diseases – is that no country can isolate itself by building health barriers. Travel, migration,

climate change, and other pathways in an ever more interdependent world come along with shared health concerns.

This of course does not mean that HICs have to foot the health bill of African countries at the expense of their own citizens. What it means is that a concerted global effort is required with countries assisting each other to address their health priorities. At the African level, actors, – continental, regional, health, and research institutions – would do well to identify and agree on the continent's health research priorities and engage as a collective with Funders and Research Institutions from outside the continent to determine what type of research needs prioritization.

Capacity Building

Capacity building has become a broad term for many types of health research interventions on the African continent ranging from investment in equipment, structures, and laboratories, to the training of personnel and the introduction of new courses and programmes in African institutions of higher education. Whereas it is true that many health systems in Africa lack the tools, systems and knowledge base to be able to monitor, prevent, and manage large disease outbreaks, and that this calls for enhancing local capacities as was done to improve the continent's capacity to test for Covid-19, there are some underlying ethical issues that need to be considered if the multiple initiatives of capacity building are to lead to greater fairness and equity for people living on the African continent.

Fanon (1986), in his famous book *Black Skins, White Masks,* asks the rhetorical question, was my freedom not given to me then in order to build a world of the You? Behind this question is the issue of agency linked to colonialism. The flag-planting era of European countries sharing dominion over African territories and people belongs to the past. Nevertheless, the colonial legacy, which we can aptly call coloniality lingers on in the governance system of many African countries. This system is premised on the specific moral wrong of colonialism which lies in the subtraction of communal and political agency of communities (Renzo, 2019). Not only is agency subtracted, but it is also replaced with an agency that prioritizes the interests of those at and near the centre of power whilst disregarding the interests of those considered to be at the periphery. Thus, looking at capacity building in health research, the question that arises is whether the capacities that are being built are to make people and structures capable of pursuing their own interests or serving the interests of those who are at the centre of such capacity-building initiatives. In the realm of ethics education, for example, one might ask, to what extent is there a colonizing element in establishing train-

ing for Research Ethics Committees premised on the ethical principles that fail to include indigenous ethical values and frameworks? A similar question could also be asked about what happened during the Covid-19 pandemic when African countries rushed to build their capacity to test for the virus through 'generous' donations of testing equipment only to realize that these came with an unaffordable high burden and dependence on the purchase of foreign-produced reagents.

What is required is an agency-centred reflection around the much-repeated notion of capacity building. In other words, capacity to do what and for whom? Continent-wide engagement and conversations to arrive at a consensus and issue guidelines would contribute in a significant way to Africa's quest for greater self-reliance in the health space. Initiatives around capacity building are sometimes perceived to be unsuccessful because of the endemic issues of the African continent like corruption, political instability, and institutional immaturity, among others. Important as these issues are, in my opinion, they cannot be adequately addressed without a careful unpacking of the types of capacities that are being built and whether these capacities are tailored towards fitting into established institutions and frameworks that are riddled with epistemic injustices.

Inclusion of understudied populations

At the early stages of the Covid-19 pandemic, alarming projections were made about how many African would die as a result of the outbreak. Among these was a gloomy prediction by Melinda Gates that deaths in Africa were going to be so many that dead bodies will be found on the streets ("Melinda Gates: Covid-19 will be horrible in the developing world," 2020). Fortunately, this has not happened, however, recent studies, for example, Struck *et al.*, (2022) in Burkina Faso, Ghana, and Madagascar suggest high levels of SARS-CoV-2 seroprevalence, reaching up to 55.7% in Bobo Dioulasso although less than 6% of the participants in the survey tested for Covid-19. Despite this high-level exposure to SARS-CoV-2 on the continent, the WHO Africa, concluded that "The continent differentiates itself from other regions by its high number of asymptomatic cases, with 67% of cases having no symptoms." (Over Two-thirds Of Africans Exposed To Virus Which Causes COVID-19: WHO Study, 2022).

Apart from the specific questions about how populations on the continent responded to the virus, the deeper issue that emerges is the dearth of true and updated knowledge about these populations and their immune systems. African populations are often understudied. This gap is present not only in the medical sphere but also in the socio-cultural domain. Hence, the imposition of impractical lockdown measures, designed for the middle and upper classes who have

larger homes, access to water, electricity, and money to stock up on food, revealed a dearth of understanding of the livelihoods of large sections of populations in many African countries.

Going ahead, a more concerted effort of inclusion is needed to engage with and better understand the biological, social, and cultural dimensions of people who, though epistemically marginalized, constitute large parts of the populations of many African countries. Indeed, the success of future health public health interventions and vaccination programmes depends to a large extent on how much health providers engage with and comprehend their own populations. Moreover, as the world draws towards a future 'Pandemic Treaty', the question of global surveillance is an important preventive measure. For such surveillance to be effective, much more biomedical and sociological research is needed, especially in places and spaces that up to now have been less studied.

Concluding Remarks

The importance of continental and regional collaborations in Africa cannot be overemphasized. A good example of how much the continent can achieve when countries learn to work together beyond national boundaries is the Africa CDC. Launched in 2017, in the aftermath of the 2014 Ebola outbreak in West Africa, the Africa CDC in 2019 was a small organization with fewer than 100 staff mainly in Addis Ababa. Yet this modest and young organization was able to coordinate the African response to the Covid-19 outbreak in key areas such as training of personnel, increasing testing capacity, and procurement of PPEs and vaccines (Makoni, 2020). Another positive example in this regard is the effort being made by the African Vaccine Regulatory Forum (AVAREF) to accelerate review processes through knowledge sharing between countries (Akanmori *et al.*, 2018). Through this initiative, AVAREF has generated harmonized clinical trial application forms and assessment templates to speed up review processes, harmonize standards, and reduce numerous duplications when doing research across countries through joint reviews (Humphreys, 2020).

Secondly, health ethicists in Africa frequently point to the fact that lack of funding is the key impediment to growth on the continent. Notwithstanding this impediment, some of the points I have highlighted above are issues than can be studied and pursued even with little resources. What is needed is a more structured in-depth appraisal of the current challenges and longer-term equitable planning for Africa to recover the agency required to attend to the health needs of its populations. Among the things that can be done to achieve this aim, is the strengthening of dialogue between local researchers and governments. Whilst

there is a wealth of research in many African universities, with few exceptions, this knowledge and data are rarely consulted when governments embark upon new projects. Health Ministries collect enormous quantities of data. Engaging local researchers to analyse this data and inform policymaking will go a long way to ensure that health policy choices are evidence-based. The overall point here is that, rather than appealing to a lack of resources as the primordial issue, many African governments -especially those in the middle-income bracket- could also take a more careful look at the optimal use of the resources available to them.

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2. Region of the Americas
(AMR)

Bioethics in Jamaica and the Caribbean Region

Derrick Aarons[1]

Introduction

Bioethics, the multi-disciplinary study of ethical questions and issues in life and human well-being, comprise a wide area of ethical discourse, including clinical ethics, professional ethics, research ethics, public health ethics, environmental ethics, and the standards that apply within these areas. The Caribbean region was introduced to many of the issues and topics prevailing in bioethics at the time when the 1st Caribbean Conference on Health Care Law and Ethics was hosted by Prof. Errol Waldron, former Dean of the Medical Faculty at the University of the West Indies in Barbados, in November 1993, with representatives attending from all over the Caribbean. Two years later, an Institutional Review Board (IRB) was formed at the Windward Islands Research and Education Foundation (WINDREF) in St. George's University, Grenada, and the 1st publication in the Caribbean on Research Ethics occurred at the end of 1995 [1].

That year, the Caribbean's 1st Masters in Bioethics graduate returned from bioethics studies in Canada and commenced authoring bioethics articles, giving lectures in the many issues in bioethics, providing expertise on the Ethical Committee of the Faculty of Medical Sciences at the University of the West Indies in Jamaica, and, in 2005, convened the Bioethics Society of the English-speaking Caribbean (BSEC) [2]. The subject of bioethics was also taught to medical students at the St. George's University, Grenada, W.I., while research was conducted at WINDREF [3] as well as at the campuses of the University of the West Indies.

During the subsequent decade, issues in health care ethics and research ethics were the dominant themes prevailing in bioethics at medical conferences, seminars, and biomedical meetings in Jamaica, Trinidad & Tobago, Grenada, Barbados, St. Vincent & the Grenadines, Antigua & Barbuda, St. Lucia, The Bahamas, Dominica, Belize, Guyana, Suriname, the British Virgin Islands, and the Turks & Caicos Islands [4]. Further, after initial planning by a steering committee for

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1 year, the National Bioethics Committee of Jamaica was established in 2006 and had its official launch in May 2009. At that time, Jamaica was only the 6th country in the world to have such a national bioethics committee formed under the sponsorship of UNESCO.

During that decade also, research ethics committees were instituted in several Caribbean countries, and in 2016, the Caribbean Public Health Agency (CARPHA) established a Caribbean-wide network of research ethics committees (CANREC). Over the last seven years, post-graduate training in research ethics for candidates from the lower and middle-income (LMICs) countries of the Caribbean has been provided by the Caribbean Research Ethics Education Initiative (CREEi), which is being funded by a Fogarthy grant, and all campuses of the University of the West Indies (Jamaica, Barbados, Trinidad & Tobago, and Guyana) currently have research ethics committees that meet and review research proposals, despite the absence of legislation or regulations for human subjects research in their respective countries [5].

Some current bioethical issues

The Covid-19 pandemic

Currently, countries of the Caribbean are slowly recovering in the aftermath of the Covid-19 pandemic, which challenged many ethical principles that should undergird health care delivery in our countries, including minimizing harm (non-maleficence), respect for the choices of individuals (autonomy), and justice (fair distribution of scarce resources – in particular medical supplies, human resources, and Covid-19 vaccines). Many of the ethical issues raised by infectious diseases in general (and the SARS Cov-2 infection in particular) are related to their powerful ability to engender fear in individuals and panic in populations [6]. The association of some infectious diseases with high morbidity and mortality rates, the acute onset and rapid course of many infectious diseases, and the communicability of infectious diseases thus all have strong undercurrent ethical issues.

Since infected individuals can threaten the health of other individuals and the society as a whole, public health care measures such as surveillance, isolation, and quarantine required the infringement on widely accepted basic human rights and liberties. Furthermore, during the pandemic, the interests of the general public took precedence over the interests of the individual patient or person, and the focus shifted from considerations of the individual to considerations of the 'collective' and the 'common good' [7].

The principles of bioethics require that a holistic approach in preparing for future pandemics be developed, and that every country in the Caribbean work

together (solidarity and cooperation) to address current shortfalls in health literacy, trust in science, equity in health, public health strategies and protection for vulnerable populations.

Emotional blunting

Another challenge currently facing some countries in the Caribbean is emotional blunting among their health care providers. This term refers to the reduction in the intensity of the provider's emotional response to the demands of health care, their affect and their desire to do good (beneficence). This became exacerbated during the Covid-19 pandemic, where care providers who were always in short supply within the Caribbean worked long hours without relief, along with inadequate medical supplies to address the needs of patients. The 'burn-out' suffered by many health care personnel (doctors, nurses, assistant nurses, allied health aides, porters, emergency medical technicians and responders) was not mitigated since no 'replacement staff' could be obtained.

This ethical quandary resulted in some neglect of individual patient's supportive health care needs, poor attitudes and inadequate communication, insufficient relief of pain and suffering in some health care settings, and scant attention to privacy and confidentiality matters within some government public hospitals. These issues also complicated already existing inadequacies within Jamaica's health care system, including insufficient access to basic health care and decreasing standards of secondary care, as well as deceptive advertisement and their effects on health within the society.

Bioethical considerations to minimize emotional blunting require that Caribbean governments adopt ethical approaches to healthcare rationing and the ratio of healthcare staff to patient populations. Mandatory periodic courses on the ethics of care and professionalism for all health care providers would also be beneficial in addressing the socio-emotional needs of patients within health care institutions.

Need for research regulations

No legislation or regulations for the protection of human participants in research exist in Jamaica, Trinidad & Tobago, Barbados, and countries of the Organization of Eastern Caribbean States (the OECS). Due to the comparatively low levels of literacy existing in Jamaica and a paucity of understanding for research methods and methodology, not all elements of the informed consent requirements have been met in some research projects, and despite the Caribbean Public Health Agency (CARPHA) lobbying since 2015 for draft regulations to be written for all member states by the Caribbean Community and Common Market (CARICOM), none have been written to date [8]. This reality leaves many inhabitants

vulnerable to exploitative research from within and outside the Caribbean region, with no legal means of redress.

The principles of human subjects' protection in international research ethics [9] require that all Caribbean governments immediately lobby for the model draft legislation approved by the Caribbean Community's Council of Human and Social Development (The COHSOD) in November 2015 to be circulated and that they implement the required legislation and regulations within their own countries with haste.

Human rights

The basic human right to privacy in sexual orientation; the right for women to be in control of their reproductive systems; and adequate societal provisions for the mentally ill and physically challenged are not given the recognition, prominence, or attention they should receive within many countries of the Caribbean. Further, issues such as homosexuality and abortion reveal the inequity and disparity existing within many Caribbean societies, since most countries currently have laws prohibiting homosexuality and abortion, and yet the 'privileged' within these societies are protected by the laws of privacy when they are involved in homosexuality or abortion, which their wealth allows them to obtain as they desire. Only the poor and vulnerable are discriminated by the current laws, as they cannot afford lawyers nor have the financial resources to have their wishes honoured.

The principles of bioethics and human rights [10] require that all Caribbean states recognize the fundamental rights of all human beings to human dignity and privacy, as well as the autonomy to make decisions regarding their own bodies. Further, that they are not subjected to stigmatization or discrimination, and so Caribbean countries should update their archaic legislations to reflect these requirements.

The use of cannabis/marijuana

Some Caribbean states have decriminalized the use of cannabis/marijuana, while some are currently contemplating doing so. However, in Jamaica (which decriminalized ganja/marijuana in 2015), no mechanisms currently exist for effectively reducing its access by the youth (under 18 years of age). Further, while breathalyzers for alcohol exist, no process exists to evaluate or test persons who drive under the influence of cannabis/marijuana resulting in motor vehicle accidents. Research has also shown that marijuana use can affect performance at work, which goes unmonitored.

Mill's harm principle would require that Caribbean states like Jamaica implement regulations that punish adults who facilitate the youth gaining access

to ganja/marijuana, and that collection of urine for subsequent ganja/marijuana testing be done at the site of motor vehicle accidents.

Environmental degradation

In the Caribbean, atmospheric pollution from burning sugarcane for harvesting and from cement plants and factories, deforestation, soil erosion, inadequate protection of streams and rivers from pollution by squatters on river banks, and asbestos exposure in squatter communities, are some of the specific environmental ethics issues that some of our countries face [11]. In recent years, there has also been a rapid increase in the construction of "mega-hotels" along the coast-line of some of our islands. The thousands of trees destroyed to facilitate these construction sites cannot be re-planted, and the land used cannot be re-claimed in the foreseeable future. These issues present formidable challenges for sustainable development in the Caribbean.

These harmful effects of human activity on the biophysical environment defy the principles of environmental ethics, which require that caring for and maintain the environment should be perceived as a public good. This requirement is underpinned by the concepts of *health maximization* (our obligations to maximize health in the population and through our interactions with the environment, for which we all are responsible), '*one health*' (which recognizes that humans, animals, and ecosystems are interconnected), and *proportionality* (ensuring that all human actions and interventions should have considerations of public health and the environment) [12], and so governments in the Caribbean should enact appropriate legislation and regulations to protect their environments, and heed the outcries of NGOs and environmentalists when they draw attention to environmental harm.

Conflicts of interest

Poor management of conflicts of interest commonly occur in the Caribbean region [13]. Public health personnel and organizations should not align themselves with corporate entities and industries whose products are high in sugar, salt, and fat, all of which contribute to chronic and non-communicable diseases. Health care personnel whose primary obligation concerns the best interests of their patients should not accept gifts from pharmaceutical companies seeking to have them prescribe their particular products. Specialists who receive honoraria from drug companies to address medical meetings are likewise conflicted when the disease condition about which they speak is amenable to a product produced by the particular sponsoring pharmaceutical company.

Clinical researchers who enrolled their own patients in research are also conflicted regarding the best interests of their patients and the possible outcome of

the research that could bring them fame, fortune, or promotion [14]. Institutions, organizations, members of the police and members of governments are also conflicted as various entities seek to influence them on specific matters.

The bias that is associated with 'conflict of interest' situations may permanently damage the public's trust as well as a person's reputation, and so whenever possible, persons in the Caribbean should always avoid situations of conflict of interest. When they cannot be avoided, persons should publicly disclose their conflict of interest, limit their involvement in the particular decision or situation, or be excluded from the work or particular situation altogether [13].

Some bioethics issues in the future

Preparing for the next pandemic

Based on lessons learnt from the Covid-19 pandemic, bioethics and bioethical principles can play a major role in preparing for the next pandemic. Bioethical considerations can make specific recommendations for actions in health emergencies aimed at local authorities (*e.g.*, local contact person; rapid communication mechanisms); institutions that are likely to conduct research during emergencies (*e.g.*, strategies for prompt and rigorous ethics review and monitoring); and the local scientific community (*e.g.*, develop generic research protocols for potential health emergencies) [15]. Through these bioethical structures, we can change our local societies to mitigate disasters and improve emergency responses to the greater benefit of local populations.

Bioethical considerations dictate that the principle of solidarity and cooperation (which were woefully lacking during the last pandemic) undergird the plans in preparation for the next pandemic, and leadership for this has been taken by the International Bioethics Committee (The IBC) of UNESCO, which has produced a preliminary draft Report on the subject to guide its 193 member states on the matter. Caribbean countries should adopt all the recommendations within the Report.

Social media and Telemedicine for the Caribbean

Bioethics may also play an important role in assisting to provide standards for the governance and regulation of data transfers across borders and jurisdictions. This will be particularly important for the protection of personal information and confidentiality, with harsh sanctions for those who breach its principles. For us in the health care environment, data coming to us via social media, and what we ourselves place over that space – must be comprehensive and evidence-based if the matter relates to health. It should combine the best available scientific knowl-

edge with our professional experience for the benefit of the individual patient as well as the health of the lay public [16].

Future health care may move towards the remote collection of data for diagnosing, monitoring, and supporting treatment. Collected data may be used to detect early warnings of diseases such as imminent heart attack, and make recommendations for appropriate behaviour. This could contribute to improved telemedical health care for persons living in remote regions and allow better communicative access to high quality health care. In the future, the smartphone could also be used for coordinating a person's health and for creating a health network that fosters autonomy and health literacy.

These processes could also provide a lot of new information quickly, in order to strengthen the evidence base for public health policies, thereby enabling better risk-adjusted prevention strategies for defined target groups. Consequently, in addition to strengthening regulations that currently exist regarding the protection of privacy and confidentiality, Caribbean countries should develop national laws to regulate social media as has been done in some eastern European countries to protect persons while facilitating the development of telemedicine and the beneficial aspects of social media.

The ethics of artificial intelligence

The convergence of Artificial Intelligence (AI), big data methods, and microsystems engineering makes AI-based algorithms for computational neuroscience one of the fastest growing fields of neuro-medical research [17]. AI algorithms in clinical neuroscience research may be used to detect early signs of Alzheimer's disease and mental illness, however, ethical issues such as incidental findings and privacy concerns, transparency and bias, and algorithm discrimination arise [18]. Continuous risk monitoring will be needed when AI medical devices are being researched or being used in research endeavours, and so responsive regulatory mechanisms must be in place [19]. Therefore, to protect the participants as these research projects emerge, robust and appropriate regulations for research involving artificial intelligence should be implemented across all Caribbean states, which would be in keeping with the research protections objectives discussed within the Caribbean Community and Commons Market (CARICOM) and approved for draft model legislation by the Caribbean Community's Council of Human and Social Development (The COHSOD) in 2015.

To achieve the aims and mission of bioethics, policymakers as well as members of the public must be sensitized to and further educated regarding the ethical considerations that should underpin personal actions as well as public policies in regards to health and the environment, resource allocation, research, and governmental decisions that affect the lives of individuals with adequate protections for those most vulnerable. This educational thrust as well as continuous lobby must come from those who understand or have been trained in some aspect of bioethics, to articulate the 'why' – the ethical rationale for specific beneficial courses of action.

This has been taking place increasingly over the past seventeen (17) years within the Caribbean through the formation in 2005 of the Bioethics Society of the English-speaking Caribbean [2], and through the graduates of the Caribbean Research Ethics Education Initiative, an educational programme that commenced in 2016. This growing cadre of bioethicists have been carrying out the aspirations of bioethics in the region, serving on various committees, tutoring, publishing, and lobbying at the administrative, institutional, and national levels to procure just outcomes in all concerns that affect the lives of their inhabitants. However, politicians and policymakers across the Caribbean should now incorporate their expertise and be guided by their sage advice in all relevant matters going forward.

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Bioethics as a Guiding Light: A View from the Latinamerican Region

Patricio Santillan-Doherty[1]

"Why have we gone blind, I don't know, maybe someday we'll get to know the reason, Do you want me to tell you what I'm thinking, Tell me, I believe we did not become blind, I believe we are blind, Blind who see, Blind who, seeing, do not see."

Blindness. J. Saramago, 1995.

Why bioethics: an introduction

As a plural and democratic society, Mexico has a recognized need of supporting the production of scientific knowledge via well-established methodology. Many efforts have been done in the last thirty years to achieve this important goal, mainly through government support of universities, academic organizations and research institutions. The National Council for Science and Technology has been an important factor in this endeavor mainly through financial support of institutions and research individuals. In spite of this, Mexico must increase this support to achieve the goal of reaching 1% of its Gross Domestic Product (1). The biomedical area is especially important since it makes up for the majority of the published research in our country.

Scientific knowledge proves or disproves the evidence with which we support the actions, treatments, programs, protocols taken to protect the right of access to adequate health in any country, including our own. This constitutes a moral imperative: to base all health decisions on sufficient and adequate evidence that can justify their implementation within the national health system. This view is sustained in our country and it is accompanied by the decision of implementing universal access to health (health for all), which is the number one priority of the National Health Program (2).

Therefore, science and technology become a very powerful entity which must be put under close scrutiny in order not to suffer the possible prophecy mentioned by Saramago (see above). Science and technology, introduced irreflexively

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within the health protection system, can be compared with the image of the blind minotaur used by Picasso in several paintings of his. Pictured as an extremely muscular being, Picasso's minotaur can be seen as an extremely powerful force who does not know which way to go because he is blind and requires the guidance of a small, innocent girl to avoid damaging those around him (you can see this in Picasso's "Blind Minotaur Led by a Girl Through the Night"). One cannot help to interpret this minotaur as a representation of science/technology while the innocent, little girl can be seen as bioethics; the techno-scientific force requires the adequate guidance of bioethical reflection. This is what the National Commission for Bioethics of Mexico and, I believe, of any other country, must represent. To be an agent which, even if blindness ensues, serves a guiding hand that leads us to a safe and beneficial shore.

During the beautiful and climate worthy month of September 2022, the Portuguese National Ethics Committee hosted the 13th Global Summit of National Bioethics Committees and as a corollary of this important reunion, a published recount of our own national/regional experiences in the field of bioethics become relevant in order to build a multifaceted view within the international community.

As part of the National System for the non-jurisdictional protection of human rights, the National Bioethics Commission (CONBIOETICA) has set forth a comprehensive strategy for the entrenchment of a culture of bioethics in health care and research. CONBIOETICA was established in our country with the mandate to guide state powers and nurture public opinion on the challenges of technological development, especially in the field of life and health sciences, as well as participating in the international deliberation on common challenges, in order to contribute to promoting good practices and preventing risks.

Origins

In the short history of bioethics in our country, several intellectual figures of philosophical and scientific thought have been involved in the development of this discipline. Dr. Ignacio Chávez – a renowned physician, considered the father of cardiology in Mexico –, expressed his concern about the dehumanization of medicine since 1958. However, the institutionalization of bioethics is associated with Dr. Manuel Velasco Suárez, whose writings show an early interest in medical ethics, respect for the dignity of patients and the social responsibility of the profession. In 1989, as Secretary of the General Health Council, Dr. Velasco promoted the creation of the "Study Group on Bioethics", which would lay the foundations of the National Commission.

The formal establishment of the National Bioethics Commission (NBC), was on March 30, 1992 in the Council Room of the Ministry of Health. In line with the interests of Dr. Velasco Suárez, the formalization of the Commission established attributions in matters related to medical ethics such as the dehumanization of services in medical institutions, addictions, organ transplantation, but at the same time including ethics in research, human rights, environmental sanitation, ecology, environmental pollution, demography, to as well as nuclear or chemical weapons. On October 23, 2000 –doctor's Day–, a presidential decree was issued ascertaining the creation of the Commission on a permanent basis, as governing body.

In 2005, Dr. Guillermo Soberón Acevedo took charge of the Executive Secretariat of the CNB. Under his management, the National Commission was reformed once again by presidential decree as a decentralized body of the National Health System, with technical and operational autonomy.

During the period of Dr. Manuel H. Ruiz de Chávez, the legal framework of the Commission underwent a significant modernization process. As a result, new provisions were introduced in 2011 in the General Health Law to mandate the establishment of a Hospital Bioethics Committee and a Research Ethics Committee, for every institution within de national health system (public, social and private sectors) under the supervision of the National Bioethics Commission. Also, during Dr. Ruiz de Chávez tenure, Mexico was honored to be host of the 10th Global Summit of National Ethics/Bioethics Committees (3).

We are proud of the fact that in 30 years we have evolved from a study group to a solid institution, with influence reaching throughout the whole country, for the promotion of ethical standards in all aspects related to health and healthcare, as well as serving as a consultative body on legislation, public policies and government programs.

Genesis of the NBC

As was mentioned above, the NBC was generated through the efforts of important medical personalities in our country who, in spite of being within the medical profession, recognized the area of bioethics as something much greater than a reduced concept of medical ethics and included the ethics of research in humans, the relation with non-human animal models as well as other living beings including and the environment.

Before the creation of the NBC, ethics was commonly deemed to be something within the sphere of religious groups. However, academic thinkers had been introducing strong arguments in favor of lay or secular principles with a

rational imperative through scientific and philosophic knowledge, always perfectible and non-absolute. The Mexican constitution establishes a non-religious secular government since its proclamation over 100 years ago and the creation of the NBC follows its mandate to promote secular/lay ethical thinking not with anti-religious implications but rather to curtail the imposition of dogmatic, absolute points of view within ethical discussion (4).

The impact of the NBC in public policy can be evaluated by the fact that as of this year, 1243 Hospital Bioethics Committees and 438 Research Ethics Committees have been registered and are under its surveillance. Also, Bioethics Commissions in 31/32 of the states that conform the Mexican Federation (5). Participation in public policy is discussed below. Education and training in bioethics is done through collaboration with universities such as the National Autonomous University of Mexico, the Autonomous University of Queretaro, the University of Guadalajara, Anahuac University and the Metropolitan Autonomous University; but also with medical institutions of the National Institutes of Health in Mexico.

Challenges in the operation of the National Health System

The challenges of the National Health System make up a complex web –from structure and organization to its operation. The historic disarticulation of the subsystems of health represents a considerable obstacle to offering equitable access to health services at the federal level based on internationally endorsed quality standards.

For more than 20 years, the universalization of the right to health protection in Mexico has been a long-felt aspiration and the present government has implemented actions directed to reach that goal on the short run (6). Special attention has been directed towards mental health (reconverting its management to include a first level approach and reducing discriminatory practices) as well as access to sexual and reproductive health (which has slowly evolved within different federal states against resisting forces represented mainly by religious views) (7). The COVID pandemic has slowed the implementation of universal access to health, however different programs have been able to start off in spite of the challenge of reconverting many institutions to cope with gravely ill patients infected by the SRAS-COV-2 virus. Provisions were made to deal with the need of producing sound medical evidence to justify health care actions; for example, the National Institutes of Health in accordance with the Secretary of Health office issued recommendations on the evaluation of unproven treatments through research protocols using a centralized scientific and ethical revision system, as well as considerations for special groups (such as children and others). CONBIOETICA pub-

lished a pronouncement regarding bioethics during the pandemic in which the main points were: 1) to recognize the difficulties of adequate planning in face of uncertainty; 2) respect for persons and protection of vulnerable groups (which implies the recognition of severe social heterogeneity); 3) developing the highest standards of care possible under pandemic conditions (including epidemiological societal control, medical attention for patients and protection measure for health care workers; special support for health innovation and research and; 5) the promotion of a spirit of solidarity and agreement within the society at large (8).

Since the pandemic, new challenges have arisen, affecting the National Health System, such as the modernization of infrastructure to strengthen fundamental functions in public health and improve response capacity, or the strengthening of the production and distribution chain of medicines and health supplies to ensure the continuity of vital services and treatments. Furthermore, the change in the category of Covid-19 from pandemic to endemic is not minor, but implies a change in the cultural paradigm, in which public health should be positioned as a fundamental value for coexistence, from the way in which we carry out studies to work and entertainment.

Public Policy

The state, as promoter of the development and well-being of society, has the obligation to control and monitor public policies, in order to ensure their effectiveness and efficiency. In this respect, the strengthening of the National Health System requires continuous monitoring of its operation, in order to identify deficiencies and promote their solution.

Among the mechanisms implemented to strengthen government action, it is important to consider the non-jurisdictional protection of human rights, which is not limited to the attention to complaints or the issuance of recommendations, but rather refers to the transversal obligation of state authorities to promote, respect and guarantee human rights.

For more than 11 years, the international framework of human rights has been recognized in our country as a higher standard of law – with a hierarchy equivalent to the *Magna Carta* itself –; however, its introduction into the constitutional text is insufficient in itself to ensure the development of our society in conditions of equity and unconditional respect for human dignity throughout the territory. The vision offered by the human rights framework entails a paradigm shift on the very structure of society and the ordering of the entire government body, as well as collaboration with international bodies, which has constituted a long and difficult transition process for our country.

The role of the Commission today

In the case of our country, bioethics has positioned itself as a fundamental support to guide health institutions and personnel with regard to the ethical and moral challenges involved in the provision of healthcare services and research with human beings, in line with the highest standards of quality and therapeutic safety, within a framework of equity and distributive justice.

CONBIOETICA is responsible for the oversight of bioethics in everyday clinical work through the registration, evaluation and capacitation of institutional Hospital Bioethics Committee, as well as scientific research endeavours reviewed and supervised by the Ethics in Research Committee which are mandated under Title V of our General Health Law which is of national observation within the Republic. Guidelines exist as to the formation, function and what is expected from these important committees (fig. 1) (9, 10).

Mexico is a federation of states each of which constitute their own democratically elected governments. The National Commission establishes working alliances with its counterparts at the state level through the State Bioethics Commission (SBC) of each member of the national federation. These State Bioethics Commissions serve as bioethical consultants to their own governments and responsible for the promotion of which training and education in their geographical area. The first SBC was created in 2003 and since then all other states have complied with the exception of one (of a total of 32 states) (11).

The National Commission fosters Bioethics not only as a common moral paradigm to combine efforts among diverse stakeholders, but also as facilitator of public policies. By framing a public policy or legislation within a moral vision, the various stakeholders are induced to evoke their own responsibilities in these terms and conduct themselves by ethical principles, above other interests. In this sense, the incorporation of bioethics in public policies contributes at least in the following three aspects: the generation of common understanding around a public problem and its impact, within a framework of secularism; the design and establishment of social participation mechanisms; as well as the management of uncertainty.

When adopting a regulation and imposing its observance, the instances of the federal executive and the representatives of the legislative power must refrain from transforming their own conception of morality into regulations, taking into account the needs of those who are directly affected by government interventions. In this sense, bioethical analysis offers a promising approach to assess prospectively the potential of a policy to meet the needs of society.

Accounting for the great sociocultural diversity of Mexico, the development of the national infrastructure in bioethics has aimed since its inception at the

establishment of State Bioethics Commissions in each of the 32 federal entities that make up our country, to contribute to the development and application of bioethics in health care and scientific research, as well as for the professionalization and teaching of bioethics in the field of medical sciences, humanities and other related areas.

The model of the institutional infrastructure in bioethics of our country, although unique in its class at a global level, only represents the reflection of the characteristic institutional model of our country: federalism. Thus, the National Bioethics Commission, as governing body, has been a promoter of the strengthening of the regulatory framework in health, especially in relation to some of the most controversial aspects of medical practice, such as assisted reproduction, research with groups in conditions of vulnerability, aspects regarding a dignified death or the regulation of marijuana, among others.

In order to learn about the main problems and possible bioethical dilemmas that arise in the field of medical care, health research and care for the environment in the different regions of the country, Regional Bioethics Councils were instituted in 2019 as a space for deliberation, generation of common understanding, exchange of experiences and coordination among stakeholders.

In addition to managing the registration and monitoring of bioethics committees, CONBIOETICA acts as an advisory body on health, scientific innovation and human rights. In this sense, it issues positioning statements on emerging ethical challenges and legislative gaps in health, as well as technical opinions on regulatory projects and initiatives, with an interdisciplinary and intersectoral approach, in order to contribute to the strengthening of health services.

The National Bioethics Commission has stood out throughout its history as a space for joint participation and the generation of alliances in order to address the challenges posed by the advancement of science and the evolution of our society. It exercises participatory leadership in health and human rights, maintaining close ties with non-governmental organizations and higher education, public and private, in order to strengthen its programs and strategies.

NBC and the Latinamerican region

The first National Bioethics Commissions created in the latinamerican region were in Cuba (1997) and Haiti (1999) which were initiated as national committees on bioethics. In Mexico, as mentioned at the beginning of this chapter, the installation of the National Commission of Bioethics was signed in 1992, however, it was not until 2005 that a Presidential Decree established its creation as a decentralized body agency of the Health Ministry with technical and operative autonomy.

Within the Latinamerican region UNESCO promoted in 2003 the creation of the Latinamerican and Caribbean Bioethics Network (Red Latinoamericana y del Caribe de Bioética), which later on took as reference the Universal Declaration on Bioethics and Human Rights approved by UNESCO in 2005. Most countries in the region have a National Bioethics Commission/Committee or something similar (mostly related with research ethics and review (see Table 1).

As member of this Network, the Mexican commission participates in an exchange of views on bioethical issues of global interest, contributing to common understanding and consensus building and helping other nations to strengthen their own bioethical institutions. For instance, the commission collaborates with the Latin-American Federation of Institutions on Bioethics and fosters the Commitment of San Salvador, an agreement promoted by UNESCO to support the development of national ethics and bioethics commissions in Latin American countries (12).

Final message

The National Commission for Bioethics of Mexico has a staff of around fifty employees in charge of different aspects of registration, evaluation, supervision, capacitation, promotion, coordination and other activities. All staff members embody a "bioethical culture" which is continuously reflected in their work. We are proud of this. We believe it is an important message that must be continuously transmitted to our society. We believe that it is within each member of our society must develop a bioethical culture understood as the awareness within the general society of the existence of principles and values that interact with our actions, some of which require maximization and others that must be viewed as a minimum which must be defended (i.e.: Human Rights). The final purpose is to create a small but powerful light that can serve as guidance to the scientific, technological and operative "minotaur" of our health system, to be able to walk safely; and to walk in a beneficial way within our society, respecting persons and avoiding possible harms or injustices. To be able to walk along side our society without complying with Saramago's prophecy of "seeing without seeing". Bioethics is the guide that makes us become able to see where we have to see.

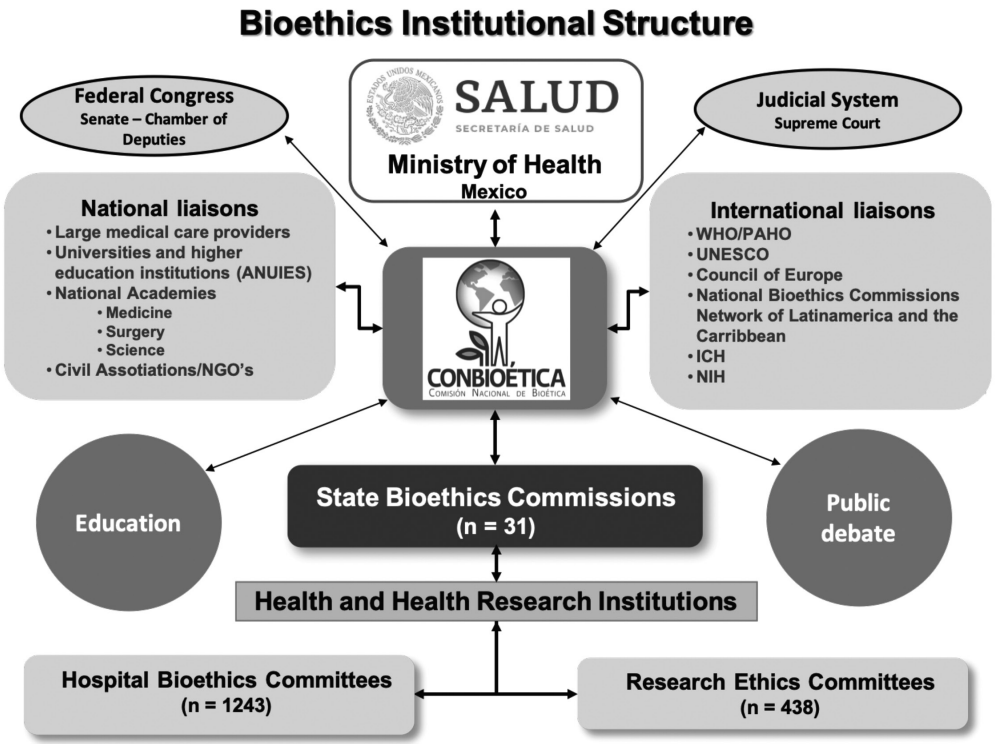

Figure 1 – Institutional structure of bioethics in Mexico. The National Bioethics Commission is a decentralized body that depends of the Secretary of Health with the responsibility to promote, register and oversee Hospital Bioethics Committees and Research Ethics Committees in coordination with State Bioethics Commissions. It acts as advisor to the Federal Government as well as State Governments (through State Bioethics Commissions); it also advises the Federal Congress (Chamber of Deputies and Senate) as well as the Supreme Court. It establishes working relationships at the national and international level. Finally, it promotes public debate on different bioethical topics and contributes to academic education on bioethical principles.

Country	Creation	Year	Denomination	Dependence
Argentina*	Ministerial resolution	1998	National Committee for Ethics in Science and in Technology	MoScTI
Barbados**	Ministerial resolution	1998	IRB within University	MoH/UoWI
Bermuda**	Research Governance Framework	2008		MoH
Bolivia	Ministerial resolution	2003	NBC	MoH
Brasil	Law project Ministerial resolution**	2005 2016**	National Bioethics Council National Commission on Research Ethics**	Exec Power

Country	Creation	Year	Denomination	Dependence
Chile	Law	2006	National Bioethics Committee	Exec Power
Colombia	Law	2010	National Bioethics Council	MoP/MoE
Costa Rica*	Ministerial resolution		NBC	MoH
Cuba	Academic resolution	1997	National Cuban Ethics Committee	CAS
Dominican Republic	Administrative disposition S/D	2000** 2003 2009	National Council on Health Bioethics** Dominican Consultive Council for UNESCO	Exec. Power NC-UNESCO
Ecuador	Ministerial resolution	2012	National Health Ethics Committee	MoPH
El Salvador	Ministerial resolution	2009	NBC of El Salvador	MoH
Guatemala*	Ministerial resolution	2018	National Committee on Health Ethics	MoH
Haiti	Ministerial resolution	1999	National Bioethics and Person Protection Committee	MoH
Jamaica	Ministerial resolution	2009	NBC of Jamaica	NC-UNESCO
Mexico	Ministerial resolution Ministerial resolution Presidential decree	1989 1992 2005	Study Group on Bioethics NBC NBC (decentralized body)	MoH
Nicaragua**	n/a	n/a	Institutional Ethical Review Committee	MoH
Panama*	Ministerial resolution Law	2014 2019	National Committee for Bioethics of Research	MoH
Paraguay	Ministerial resolution	2017	NBC	MoH
Peru*	Ministerial resolution	2020	National Transitory Committee for Research Ethics	MoH
Uruguay*	Presidential decree		Nat. Research Ethics Commission Commission for Bioethics Integral Quality of Health Delivery	
Venezuela	Ministerial resolution	2010	National Commission for Bioethics and Health Biosecurity	MoPPFH

Table 1 – Creation of National Bioethics Committees (NBC) or their similar according to local denomination in several Latinamerican countries (data taken and modified from reference 14 (available at: https://repositorio.unbosque.edu.co/handle/20.500.12495/3337).

* Data taken from (accessed 12-14-2022) https://uchile.cl/dam/jcr:fdc5bc16-0787-4e16-adbc-80db0cb31ff9/04-comisionesnacionalesbioetica.pdf

** Data taken from (accessed 12-14-2022) https://www.gob.mx/cms/uploads/attachment/file/665991/2020_International_Compilation_of_Human_Research_Standards.pdf and https://www.cavehill.uwi.edu/researchethics/docs/uwi_policy_research_ethics_oct.aspx

MOScTI: Ministry of Science, Technology and Innovation; MoH/UoWI: Ministry of Health/University of West Indies: MoH: Ministry of Health or equivalent; Exec Power: Executive Power (sic); MoP/MoE: Ministries of Protection and Environment respectively; CAS: Cuban Academy

of Sciences; NC-UNESCO: National Commission established with UNESCO; MoPH: Ministry of Public Health; MoPPFH: Ministry of Popular Power for Health; n/a: not available.

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Strengthening national research ethics systems in the Americas to improve its ethics preparedness and response to emergencies

Sarah Carracedo, Carla Saenz[1]

Since its creation in 1993, the Regional Program on Bioethics of the Pan American Health Organization (PAHO) – which serves as the Regional Office for the Americas of the World Health Organization (WHO) – has strengthened capacity in bioethics in the Region (1). During the 28th Pan American Sanitary Conference in 2012, PAHO Member States resolved to advance bioethics and integrate ethics in all health-related activities, primarily in research and public health (2-3). During the 56th PAHO Directing Council in 2018, the outcomes of this 2012 regional mandate were assessed, and PAHO Member States decided to escalate their efforts to integrate ethics into various areas of health (2-4). Regarding research ethics, Member States drew attention to the fact that, despite the significant progress achieved, some challenges remained for the Region, such as the establishment of research ethics systems capable of ensuring that research is always conducted ethically (4).

To promote a systemic approach to research ethics (i.e., taking a comprehensive view of research ethics that considers all relevant aspects of research and fosters coordination with all research stakeholders), PAHO's Regional Program on Bioethics devised a strategy that includes two lines of action: *(1)* strengthening research ethics systems to ensure all research is ethical; and *(2)* strengthening ethics preparedness for emergencies. For each line of action, corresponding objectives and indicators were developed (table 1) (5-7).

Table 1 – Objectives and indicators of PAHO's strategy to strengthen research ethics systems

Objective	Indicator
Line of action 1: *Strengthening research ethics systems*	
Adopt ethical standards for research with human participants in accordance with international guidelines	1. Number of countries with legislation or other legally binding instrument governing health-related research with human participants that is consistent with international ethical standards, including requirements for ethics review by an independent committee

[1] Regional Program on Bioethics, Department of Evidence and Intelligence for Action in Health, Pan American Health Organization

Objective	Indicator
Establish effective mechanisms for the ethics oversight of research	2. Number of countries with a national body tasked with the oversight of ethics review committees, including establishing mechanisms for registration, training, and compliance
Enhance ethics capacity among researchers and ethics review committees	3. Number of countries with policies that support research ethics training for investigators and ethics review committees
Advance transparency in research	4. Number of countries requiring the prospective registration of clinical trials in accordance with WHO standards
	5. Number of countries with policies on responsible conduct of research
Line of action 2: *Strengthening ethics preparedness for emergencies*	
Strengthen the capacity to conduct research ethically during emergencies	6. Number of countries with established procedures to do thorough accelerated ethics review of research during emergencies

PAHO evaluates countries' research ethics systems using these indicators in order to understand their current situation, tailor technical cooperation plans to each countries' needs, and identify progress. PAHO's Regional Program on Bioethics actively supports countries throughout the process of fulfilling the indicators, *e.g.*, developing national research ethics policies in accordance with international ethical standards and considering the countries' needs, advocating for their approval, facilitating national consultations, coordinating with key stakeholders, and supporting the implementation of the policies approved. PAHO is committed to periodically reviewing and updating its indicator-based strategy to strengthen research ethics in the Region. This approach can also be used in other countries or regions to catalyze research ethics.

In a recent study, PAHO's indicators were used to assess 22 countries in the Latin American and the Caribbean region (7). The results show that most of the countries already achieve two indicators: 1) having legally binding instruments governing health-related research involving human beings, and 2) having a national body responsible for the oversight of research ethics committees (RECs). The indicators that still require more work to achieve are those related to the responsible conduct of research and the establishment of procedures for the rapid ethics review of research during emergencies (table 2). Regarding this last indicator, it is important to note that the study did not include the measures taken specifically in response to the COVID-19 pandemic.

Table 2 – Number of countries that achieve PAHO's indicators

Indicator	Achieved	Partially achieved	Not achieved
Existence of legally binding instruments for health-related research with human participants in alignment with international guidelines	12	9	1
Existence of a national body responsible for the oversight of research ethics committees	12	7	3
Existence of policies that support research ethics training for investigators and ethics review committees	7	10	5
Existence of the requirement of the prospective registration of clinical trials in accordance with WHO standards	1	12	9
Existence of policies on the responsible conduct of research	1	2	19
Existence of established procedures to conduct thorough accelerated ethics review of research during emergencies	1	2	19

Ethics preparedness and response to health emergencies

The COVID-19 pandemic has stressed the importance of improving countries' ethics preparedness and response to emergencies, which includes the capacity to conduct research ethically. Countries in the Region that experienced the 2016 Zika virus outbreak had already recognized the value of conducting ethical research in emergencies. Indeed, this public health emergency of international concern led to the consensus that research is an essential component of the response to health emergencies, and that it must be conducted in adherence to international ethical standards, which includes being reviewed by RECs in a rapid yet rigorous process (8).

When WHO declared the COVID-19 pandemic, PAHO quickly escalated its existing work strengthening the Region's ethics preparedness for emergencies, issuing ethics guidance aimed at catalyzing ethical research (9-14). At first, the support provided by PAHO was mainly focused on the establishment of mechanisms to ensure accelerated yet rigorous ethics review and monitoring processes of RECs (10, 11). Ten countries of Latin America rapidly adapted their research ethics review processes in line with PAHO's recommendations to streamline the review of COVID-19 studies and ensure their adequate monitoring (15).

However, challenges remained in the Region to conduct ethical research in response to the COVID-19 pandemic. For instance, despite the considerable number of clinical trials conducted in countries of Latin America and the Caribbean studying the safety and efficacy of interventions to prevent and treat COVID-19, a trend toward small and repetitive studies incapable of producing meaningful conclusions was identified (16). Additional prominent challenges in the Region included the monitoring of ongoing research in the context of rapidly emerging evidence, and the emergency use of unproven interventions outside of research. PAHO thus produced guidance on both topics and worked closely with health authorities and other relevant stakeholders to support their implementation. PAHO also held several regional dialogues throughout the pandemic, which have also included RECs, health authorities and investigators, to share experiences and discuss what has worked and what continues to pose challenges (17). The goal of these dialogues was to identify the lessons learned from COVID-19, and the pending agenda for the Region to improve its ethics preparedness and response to future health emergencies. This regional reflection led to PAHO's publication: *Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda* (18).

Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda was published in Spanish in June 2022 and subsequently in English, Portuguese and French. The publication revises and integrates prior guidance documents for emergencies issued by PAHO, includes the lessons learned during the COVID-19 pandemic, and develops final recommendations to improve ethics preparedness and response in emergencies, as well as to strengthen research ethics in general (table 3). A summary version of the publication has also been published in Spanish, English, Portuguese, and French (19).

Table 3 – Chapters of PAHO's publication: *Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda*

Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda	
Chapter 1	Lessons learned from the Zika outbreak and challenges during the COVID-19 pandemic
Chapter 2	How can trust in research conducted in emergencies be strengthened? Transparency and public engagement
Chapter 3	How to ensure that the ethics review and monitoring of research conducted by research ethics committees are agile yet rigorous in emergencies
Chapter 4	How can the ethical acceptability of research be ensured in response to emerging evidence?

Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda	
Chapter 5	How can the ethical use of unproven interventions outside of research be ensured in health emergencies?
Chapter 6	How to ensure that data and samples are shared ethically for future research
Chapter 7	Final recommendations

The publication's final recommendations are divided into recommendations for action, which can be implemented immediately, and recommendations to conceptualize the specific actions needed. In both cases, the recommendations may apply specifically to health emergencies or may be relevant for both emergency and non-emergency situations. All the recommendations constitute the pending agenda for the Region and establish the stakeholders in charge of their implementation or further conceptualization.

For example, for health emergencies, the responsibilities of health authorities are to establish a strategy for the ethical oversight of emergency research, coordinate research efforts, and get involved in the research conducted in response to emergencies from the beginning to ensure their populations benefit from the research's potential benefits. Along with international organizations and the scientific community, health authorities should also develop generic research protocols for potential health emergencies.

Most of the recommendations have been conceived for emergencies and ordinary situations in order to foster research ethics in general. For instance, health authorities should always require the registration of clinical trials in registries that feed WHO's International Clinical Trials Registry Platform (ICTRP) and make public all studies involving human participants that have been approved (20). RECs are tasked with the responsibility of establishing communication mechanisms to inform the public about the studies they are supervising. Health authorities and RECs should incorporate virtual tools into their processes, as well as mechanisms for agile coordination between the actors involved in research, and allow alternative ways of carrying out informed consent processes, so they are not restricted to face-to-face processes. Another important recommendation resulting from the regional reflection on the experience during the COVID-19 pandemic pertains to recognizing the contribution of members of RECs, whose time and dedication is indispensable to conduct rigorous reviews promptly. Research institutions that establish RECs should compensate their members, financially or through another appropriate mechanism.

In order to put these recommendations into practice, PAHO continues providing support to relevant stakeholders. Issuing ethics guidance does not suffice to ensure such guidance is actually followed. PAHO's Regional Program on Bio-

ethics works closely with Member States on the implementation of ethics guidance and encourages the development of trusting relationships established prior to the emergency, as it facilitates the implementation of ethics guidance during emergencies. Advancing ethics preparedness and response to health emergencies in the Region is an ethical imperative to which PAHO and its Member States are truly committed.

From the COVID-19 pandemic to the Monkeypox (mpox) emergency

On July 23, 2022, WHO declared the outbreak of mpox as a public health emergency of international concern. By November 14, 2022, 52.875 confirmed cases had been reported in the Region of the Americas. (21). Building on the COVID-19 pandemic experience, ethics has been embedded in PAHO's response to the mpox emergency from the beginning. For instance, PAHO's Incident Management System includes ethics as a formal component in the response to mpox, and the Regional Program on Bioethics has worked in coordination with PAHO's response teams on several topics, including the emergency use of unproven outside of research (MEURI framework), and the ethical criteria for equitable vaccine allocation.

Following the recommendations issued by WHO in relation to mpox (22), MEURI protocols for tecovirimat have been developed where clinical trials could not be initiated. In this sense, PAHO's Regional Program on Bioethics has provided support to ensure that the exceptional access to tecovirimat in view of its possible benefit is monitored to protect people and contribute data to the generation of evidence in accordance with the relevant ethics guidance (14, 23).

Additionally, PAHO's Regional Program on Bioethics has been actively engaged with PAHO's Revolving Fund for Access to Vaccines. The Revolving Fund has provided access to most vaccines used in Latin America and the Caribbean for more than 40 years (24), and access to mpox vaccines was approved by Member States in August 2022 (25). To ensure equitable access to these vaccines, ethical criteria for allocation and a plan to operationalize them through the Revolving Fund have been developed with the support of PAHO's Regional Program on Bioethics. To date, 130,000 doses of third-generation mpox vaccines have been secured for Latin America and the Caribbean (26).

Final considerations

Strengthening research national ethics systems in the Region of the Americas is an ongoing responsibility of Member States and PAHO. Prior health emergencies, including the COVID-19 pandemic, have shown that lessons to improve the capacity of the Region to conduct ethical research in response to health emergencies do get learned. As described in *Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda*, Latin America and the Caribbean have actively taken action to advance the conduct of ethical research during the pandemic. However, further efforts are needed – as evidenced by the recommendations in the document – to be better prepared for potential emergencies in the future (18). PAHO's Regional Program on Bioethics will continue to support Latin America and the Caribbean in the strengthening of regional capacities to ensure that research involving human participants is always conducted in adherence with the highest ethical international standards, and that ethics is integrated in all the other areas of work in health.

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Brazilian Bioethics: A Struggle for Social Justice, Health, and Democracy

Elda Coelho de Azevedo Bussinguer[1]

Early Concerns

The Covid-19 pandemic, the most serious health crisis ever experienced in the world, intensified in Brazil by the tragic handling of the process by a government uncommitted to life, health, and ethics in politics and public affairs, which endangered our already fragile and still recent democracy, imposing on Brazilian Bioethics a necessary critical and protagonist position in the struggle for Social Justice, especially Health, and Democracy.

The dystopic condition through which the country went and still goes through worked as a driving force for the strengthening and repositioning of the country's Bioethics, compelled to assume a prominent place in the conduction of a national movement in defense of Democracy and the Unified Health System (SUS).

The Brazilian Society of Bioethics (SBB), an organization representing Brazilian bioethicists founded in 1995, did not avoid the presented challenge. It played a significant role in the formation of a large social movement known as Front for Life (Frente pela Vida), in coordination with other civil society entities.

To prevent the memory of the struggles of Brazilian Bioethics from fading with time, it is necessary to record some of its actions that can be recalled in the process of constructing hope and the future.

This text neither aspires to be exhaustive nor undertakes to present all the historical landmarks on which the nation's bioethics are founded. However, it briefly reflects the Brazilian Bioethics approach to the previously mentioned struggles for Public Health, Democracy, and Social Justice.

[1] President of the Brazilian Society of Bioethics.

From 1990 to 2022: Public health in Brazil as the center of bioethical concern

In its nearly three decades of existence, particularly after the establishment of the SBB, Brazilian bioethics has carved out an identity field that has brought it very close to the struggles for democracy, particularly in the field of public health.

The first Brazilian bioethicists were connected to the Brazilian Sanitary Reform movement, which continues to fight for the protection of SUS to this day.

This text is consistent with this viewpoint. As a privileged observer of the actions of the Brazilian Society of Bioethics, due to the active participation in the process of building its recent history, as a member of the Scientific Council in the 2017-2019 management, Vice-President in the 2019-2021 management, and current President of the SBB in the 2021-2023 management, it is certain that the analysis and the recording are, in some way, committed to the author's view and perspective.

According to our historical records, the country's incorporation into the thematic field did not occur until the early 1990s. Nonetheless, we must consider Resolution N.º 1/1988 of the National Health Council, whose purpose was the ethical regulation of research involving humans, as an effective initial milestone, even though it was initially modest and had limited impact.

The country's redemocratization, accompanied by the expansion of participation spaces, was crucial to the emergence of the bioethical debate.

The 1993 publication of the first volume of the Bioethical Journal by the Federal Council of Medicine under the editorship of Professor Sergio Ibiapina Ferreira, a member of SBB, is noteworthy for its significance and leadership.

Through this journal, which quickly gained recognition in the scientific community, and as a result of its high capillarity, Bioethics and its themes more closely related to the clinical field gained prominence and became the subject of debates at congresses, seminars, and in scientific journal articles. As a result, Bioethics became a field of study and introspection.

Even though the publication of the journal occurred in 1993, it was the result of intense debates and articulations that allowed its creation by the physicians' organization, which is traditionally more conservative and technical in nature.

On February 18, 1995 (Rego *et al.*, 1995), the Brazilian Bioethics Society (SBB) was founded, which was unquestionably a significant historical event for the advancement of Brazilian bioethics.

The institutionalization of Bioethics, through the formation of a scientific society that brought together scholars and researchers from diverse backgrounds, brought coherence and progress to the field. It has enabled other accomplishments, such as the biennial systematization of national congresses and the es-

tablishment of regional congresses, which allowed the expansion and capillarity essential to its consolidation process.

In addition to its natural functions related to the promotion of Bioethics by involving professionals and institutions, SBB has been supporting the Research Ethics Committees and the Hospital Bioethics Committees, encouraging the teaching and research in the field, participating in public hearings when debating issues related to bioethical conflicts, such as the interruption of pregnancy of anencephalic fetuses, the defense of the non-criminalization of pregnancy interruption, and the use of embryonic stem cells in scientific research, among others, participation as Amicus Curie in Public Civil Cases, in addition to various explanations to the press, through published articles and interviews.

The national congresses, held in various regions of the country, have contributed to the expansion of Brazilian Bioethics by broadening its professional thematic and technical scope. In its 27 years of existence, the Society for Bioethics and Biomedical Ethics (SBB) has organized fourteen national congresses with the participation of professionals from diverse fields, demonstrating the inter- and transdisciplinary nature of bioethics.

Based on these accomplishments, several Bioethics Specialization Courses have been offered, leading to the development of Master's and Doctoral Programs.

The Master's Program in Bioethics at So Camilo University Center began in 2002, and the doctoral program in 2010. These courses were discontinued in 2019, but they played a significant role in the country's scientific output and bioethicist training.

In 2004, the Professorship in Bioethics at the University of Brasília (UnB) was recognized by UNESCO, and in 2008, the Coordination of Superior Level Staff Improvement (Capes) – a foundation linked to the Brazilian Ministry of Education and whose task is to expand and consolidate the post-Graduation *Stricto sensu* – created the Master's and Doctoral's Courses in Bioethics at UnB.

In 2005, the SBB established the Brazilian Journal of Bioethics, which has been coordinated and managed by the same Professorship since its inception.

In an innovative initiative, in 2010, Capes authorized the creation of the Post-Graduation Program in Bioethics, Applied Ethics, and Collective Health (PPGBIOS), an association between Oswaldo Cruz Foundation (Fiocruz), Federal University of Rio de Janeiro (UFRJ), State University of Rio de Janeiro (UERJ), and Fluminense Federal University (UFF). This program, which was derived from a collective project, brought something that was already present in the Brazilian Bioethics model, namely the close relationship between Bioethics studies and Collective Health.

In 2013, Capes sanctioned the master's Course in Bioethics at the Pontifical Catholic University of Paraná, which has been instrumental in the research and

training of Bioethics masters in the country's southern region. In the most recent quadrennial evaluation of Capes, the program achieved concept four, allowing it to argue for the creation of a Doctorate and demonstrating its scientific maturity.

It should be noted that after October 2005, with the approval of the Universal Declaration on Bioethics and Human Rights by Unesco, the SBB invested in the promotion of the Declaration by holding courses and events aiming to implement a culture based on the principles of the Declaration in several institutions.

Notable is the convergence between Brazilian bioethicists, via the Brazilian Society of Bioethics, and Portuguese bioethicists, via Professor Maria do Céu Patro Neves, president of the National Ethics Council for Life Sciences. (CNECV).

During the Covid-19 pandemic and considering the serious violations of Fundamental Rights perpetrated by the government in conducting the health crisis, the SBB, in collaboration with Abrasco, Cebes, Rede Unida Institution, and the National Health Council, teamed up to form and conduct a broad front called the Front for Life (Frente pela Vida).

This movement unites hundreds of civil society organizations linked to the democratic field in defense of life and health, reiterating the Sanitary Reform movement's maxim that health is democracy and democracy is health. Professor Dirceu Grecco, who was president of the Brazilian Society of Bioethics at the time, and later Elda Bussinguer, the current president, strengthened SBB's participation, demonstrating the institution's current direction.

Created and constituted in 2020, right at the beginning of the pandemic, when the defenders of SUS noticed the disregard with which the federal government treated and directed the actions aimed at facing the pandemic crisis, the Front for Life movement brought together civil society institutions and movements in defense of Health, Life, and Democracy, building a National Plan for Facing Covid-19.

This movement has expanded as the Federal Government promoted constant bioethical violations aiming at the deinstitutionalization of the State apparatus, especially with the technical disempowerment of the Ministry of Health and its militarization, distancing itself from the doctrine and organization principles of SUS, perpetrating multiple violations of the principles of the Universal Declaration of Human Rights, "such as its article 14, which prescribes social responsibility and health as the pursuit of the highest level of health possible as a Fundamental Right (Bussinguer, 2021).

The SBB, along with Abrasco, Cebes, Rede Unida Institution, and the National Health Council, has defended SUS and equal access to vaccines against Covid-19 countless times.[2]

[2] Documents available in the institutional webpage SBB-https://sbbioetica.org.br

The future of brazilian bioethics is already being built

Brazilian Bioethics became more consistent in the early 1990s, right after the re-democratization of the country and the promulgation of the Constitution of 1988, a period in which global Bioethics was already in its review phase (Garrafa, 2012), with criticism of principialism and concern with issues related to facing social and health issues, such as the universalization of health care, social exclusion, equity, among others, such as the allocation of scarce resources.

These three decades have paved the way for the realization that Democracy, Health, and Social Justice are essential and fundamental themes for bioethical reflection and bioethical practice, particularly in light of the Latin American context.

The SBB is an entity committed to the process of social emancipation that seeks to reflect and establish the indispensable guidelines for the adoption of ethical standards capable of guaranteeing spaces of freedom and sustainable individual and collective development, capable of maintaining the necessary hygiene to guarantee Democracy and Social Justice.

The VI World Congress on Bioethics, held in Brasilia in 2002, brought together national and international experts to debate the theme "Bioethics: Power and Injustice," which resulted in the publication of a new book (Garrafa and Pessini, 2004) with the same title, compiling the theses that were discussed at the event.

We now have an important epistemological collection from a Brazilian and Latin American perspective, compatible with a reality that still lacks debates on bioethics and colonialism and the realization of fundamental human rights, twenty years after this event. Intervention Bioethics and Protection Bioethics contribute to Brazil's robust scientific output (Garrafa *et al.*, 2006; Feitosa *et al.*, 2015). According to Schramm (2017): "the protection bioethics (BP) is a proposal that emerges at the beginning of the XXI Century in the scope of bioethics built in Latin America and in the context of researchers' attempts to think the conditions of possibility of a sanitary bioethics, concerned with public health policies, so that they are morally legitimate, socially fair (equitable) and also respectful of Human Rights, after noticing the limits of traditional bioethical tools, essentially applied only to interpersonal conflicts of moral agents and patients involved in biomedicine practices."

Conversely, it is possible to understand, from Dora Porto and Volnei Garrafa's (2005, p. 115) lessons, that intervention bioethics "intends to legitimize, in the field of the study of moralities and the application of ethical values, a broad perspective that involves the social aspects of the production of diseases, contributing to the construction of a critical bioethics that can be applied in peripheral countries, and especially in Brazil".

Not dissociating itself from other themes important to Bioethics, such as those related to biotechnological advance and its unfolding, Brazilian Bioethics continues to focus on themes related to persistent problems – understood as those "situations that are historically persistent in the evolutionary process of humankind which keeps on repeating themselves, despite the world's current stage of development. Also known as bioethics of everyday situations: that occur every day and should no longer occur" – and emerging – which, on the other hand, can be understood as those "that have emerged historically over the last few decades, as a result of scientific and technological development. Also called bioethics of situations related to the limits or boundaries of development" (Garrafa, 2012, p. 749) – in collective public health, such as underfunding, violence, racism, LGBTQIA+-phobia, hunger, and social inequality, considering their intersectionalities and perspectives, of inter and transdisciplinary confrontation.

The strengthening of the National Commission on Ethics in Research (Conep) and the entire REC/Conep system, which ensures social control and adequate protection of research subjects, remains a daily political battle to be waged in the legislative sphere, educational institutions, and research institutions.

The creation of a National Bioethics Council, a law proposal that has been pending in Congress for nearly two decades, is one of the most urgent and significant challenges facing Brazilian bioethics in the coming years. The lack of Bioethics representation in the National Congress and Executive has made it difficult to discuss, negotiate, and approve this project. There are strong indications and expectations that the approach of bioethicists in strategic positions in the current government will simplify negotiations, thereby increasing the likelihood that the law project will be approved.

Considering the necessary struggle for the effectiveness of fundamental human rights in Brazil as an indispensable condition for the realization of democracy, with the reduction of economic and social asymmetries that currently divide the nation and make it impossible to reach a level of civilization compatible with the peace that we want to achieve, Brazilian Bioethics shall continue to play a relevant role in the sense of stimulating academic, professional, and social debate in order to establish the promotion and consolidation of egalitarian values through the dissemination of educational and professional strategies that guarantee spaces of freedom, autonomy, and awareness of Rights.

The approximation with the Bodies of the Brazilian Justice System, especially the Judiciary, the Public Ministry, the Attorney General's Offices, and the Public Defender's Offices, constitutes a strategic project of the Brazilian Bioethics Society, to promote the principles and values of the Universal Declaration on Bioethics and Human Rights of Unesco, seeking endorsements and spaces for reflection on the major themes and ethical dilemmas to be faced in the coming decades, espe-

cially those related to Revolution 4.0 and its impacts on social and institutional relations, especially considering the principles of privacy, autonomy, freedom, and equality.

The Bioethics Committees of the Brazilian Bar Association, which is still playing a modest role, considering the number of professionals currently practicing advocacy in the country, is within SBB's strategic project for the expansion of Bioethics in the country, considering the need to incorporate the theme, in a transversal manner, in the legal education and courses, in the pursuit of a less dogmatic education and more based on principles and values compatible with the Constitution and the Democratic State of Law.

In a similar vein, the SBB has included in its strategic planning for the next few years a massive campaign aimed at increasing the exceedingly small number of hospital bioethics committees. This action should be consolidated into the possible formation of a dedicated Committee within the organization.

SBB understands that the weakening of institutional and personal relationships resulting from the political process that is now ending and that has put at risk the health and life of Brazilians, with attacks on SUS, the Environment, Science, and Democracy, should be an object of concern and investment by Lula's Government which took office on January 1st, 2023, considering that the bioethical values contemplate a necessary coexistence/tolerance with the different beliefs and ways of being and living, not being able, however, to ignore the limits of tolerance and its impossibility of being practiced before the aggression to Democracy and with absolute respect to life, health, and the Dignity of the Humane Individual.

The new democratic winds that are announced in the country, with promises of progress about respect to social interests and the implementation of public policies that aim to guarantee the universalization of the Rights to health and education, as a priority, must open privileged spaces for Bioethics to act. These spaces should be occupied intending to materialize a culture based on the principles of the Universal Declaration of Bioethics and Human Rights.

The Front for Life, one of the most significant and fruitful recent areas of action of the SBB, has consolidated partnerships with the major Brazilian institutions and social movements, making the institution and its values known, and will continue to be a space for action during the next administration.

It is necessary to consider that the fight for Democracy must continue with the challenge of recovering the spaces and rights lost during the validity of the anti-democratic project implemented by the government that was defeated in the elections and that represented delay, retrocession, and death for almost 700 thousand people by Covid-19, hunger for 33 million Brazilians, and around 20 million unemployed.

The expansion of bioethical research in the country, with the formation of a Brazilian, Latin American bioethical thought that considers our anti-colonial struggle and the intersectionality of our problems and vulnerabilities, depends on the expansion of shared spaces of investigation that allow the approximation of researchers and institutions, aiming at the construction of new epistemological bases of support and consolidation of theoretical and methodological bases already in an advanced stage of development.

The approximation with Portuguese-speaking countries, so often intended and initiated, is currently directed toward the construction of a Lusophone Platform for Bioethics, which will allow the development, expansion, and construction of a field of bioethical knowledge with a high potential for expansion and contribution to the nations that share the same linguistic pattern.

Throughout the past three decades, Brazilian bioethics has evolved from a perspective of struggle and defense of Democracy, Social Justice, Collective Health, and SUS, in particular towards the 17 UN Sustainable Development Goals[3], in order to address the unacceptable global disparities.

The United Nations describes the goals as "an urgent call to action by all countries, both developed and developing, in a global partnership." They make it clear that eradicating poverty and other deprivations must be coupled with strategies that improve health and education, reduce inequality, and stimulate economic growth – all while combating climate change and preserving our oceans and forests.

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Re-Invigorating Notions of a Bioethics Council for Canada in a New Era of Biomedicine

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Introduction

Expert committees, commissions, and councils have existed for centuries, with Western examples dating back to the 14thC. (la Compagnie du Gai Savoir in Toulouse). These groups gained prominence in the 17thC. with the founding of the British Royal Society and French Academy of Sciences and developed further in the 18th and 19th C. with the British "Royal Commission" and the USA "Blue Ribbon Commission" models that advised governments on relevant topics. Two centuries later, in the early 1970s, all-too-often tragic events in clinical care and health research stimulated the formation of committees in the growing field of bioethics. Hospital clinical ethics committees and research ethics boards gained prominence for their capacity to provide guidance to the institutions in which they existed. At the same time, national-level committees also emerged to provide science and ethics advice and input to policy discussions occurring in countries, and across regions.

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Canada's opportunity to establish a national body that could have a far greater reach than local committees or boards was detailed by Baudouin *et al.* (1990), who, writing for the Law Reform Commission of Canada, noted the gap in Canada. Against a backdrop of a nearly 40-year history of national commissions or councils in the USA, pan-Europe, Asia and Australia, they argued that a national body tasked with the responsibility to advise the government was necessitated "by an urgent requirement for coordination of and consistency in the country's scientific and ethical activities" (Baudouin *et al.*, 1990, p. 49).

Over the past two years, we have been motivated to revisit this call and explore the value of a dedicated national entity for bioethics advice for Canada with a focus on current-day needs. In this Opinion, we examine the contemporary imperative and processes for expert engagement, and deliver recommendations for implementation. Indeed, given ever-emerging ethical issues such as those related to the COVID-19 pandemic, emerging biotechnologies, artificial intelligence, and climate change, the urgency could not be greater.

Reimagining Canadian Bioethics

The Law Reform Commission of Canada was abolished in 1993; the recommendations of Baudouin *et al.* (1990) were never implemented. Other groups and commentators picked up the torch, but in carrying it into the national and international conversation, a patchwork approach rather than a single entity approach resulted. For example, over 30 years, specialized committees and groups have been struck to address bioethics issues in Canada, including the Royal Commission on New Reproductive Technologies (1989 –1993), the Tri-Council Working Group on Ethics (a joint effort of previous Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada), the National Council on Bioethics in Human Research, Interagency Advisory Panel on Research Ethics, CIHR Standing Committee on Ethics, Committees of Parliament, and the Genome Canada GELS Program. Canada has also been represented on regional and global bioethics committees, including the UNESCO International Bioethics Committee, World Health Organization expert panels, and in co-producing the OECD Responsible Research and Innovation Toolkit.

Complementing the work of these groups, ethical issues are often raised, discussed, and assessed on the national agenda through House of Commons and Senate of Canada committees. They are also addressed within professional associations and organizations, such as the Tri-Council funding agencies, courts at various levels, the Council of Canadian Academies, the Royal Society of Canada,

and the Canadian Academy of Health Sciences. They receive diverse attention from the media depending on the topic and level of tension associated with an issue or debate.

Unlike a centralized body with targeted receptors, the current structure involves many actors working toward both common and parallel objectives, and with distinct frameworks, levels of funding, timelines, and for a plurality of receptors. Canada's federalist system, marked by distinct federal and provincial/territorial governments, laws, and responsibilities, adds to the complexity of national coordination.

Laying the Groundwork: What Do We Know?

In the USA in particular, the establishment of bioethics commissions by both Congress and through Presidential Executive Order set an initial standard for how public ethics advisory bodies could be used to develop guiding principles, recommend actions to inform policies, and in rare cases, to investigate (as occurred with the US Advisory Commission on Human Radiation Experiments).

By the end of the 1980s, national bioethics commissions and similar bodies existed across the world and can now be found on every continent except Antarctica. They self-organize in a Biannual Summit with a secretariat provided by the World Health Organization. No two commissions are identical. Their mandates have evolved beyond ethical issues in research to take on broader issues in health policy, science and technology, and engineering. However, ethical issues in research remain an enduring issue. Some respond only to direct requests for advice from their government, while others have the authority to identify their own agenda.

A large body of literature explores the role of national bioethics bodies (NBBs) on a global scale (see, *e.g.*, Meslin, 2003, 2008; Eiseman, 2003; Lee, 2017; Davis, 2010; Schwartz, 2017). Many countries locate their commissions outside of government, such as the United Kingdom, which often relies on the Nuffield Council on Bioethics. Others locate their commissions inside government by reporting to an executive office, department or, less often, to a legislature. Some countries, like France, have standing committees not tied to a particular government in power. Others are time limited. Yet despite these variations, they share common features: they focus on ethical issues in their broadest sense; they are multidisciplinary, they draw on diverse academic and professional expertise and experience; and, their work is visible and accountable to the public. In the literature, capacity-building among NBBs has been identified as a tool for networking as well as a way to develop new NBBs in countries that lack them (Gefenas & Lukaseviciene, 2017).

Research points to best practices as well as the impacts of NBBs. For example, some view the primary exercise of NBBs as policy advisers (Schmidt & Schwartz, 2016), and some also see them playing a role in public education surrounding bioethical issues. Through public deliberation (Dresser, 2017) and associated efforts to uncover perspectives on bioethical topics, NBBs can serve a role as public educators (Lee, 2017).

A wide swath of literature also explores the factors required for a NBB to be effective. In such an exploration, Köhler *et al.* (2021) concluded that NBBs "must be legally mandated, independent, diverse in membership, transparent and sufficiently funded to be effective and visible." Others argue that NBBs with a mandate centred around advice that are comprised of experts, as opposed to expert bodies with a mandate for policymaking, are better able to distil the interests of the wider public due to their capacity for reasoned deliberation (Dodds & Thomson, 2006).

There are now more than 150 national bioethics commissions around the world from which Canada might draw examples of structures and processes it may wish to emulate. These commissions, organized as the Global Summit of National Bioethics Commissions, meet biennially at the same time as the International Association of Bioethics. The topics it has confronted in the past 30 years would easily occupy the agenda of a national body, for example, pandemics, artificial intelligence, communication and public trust, brain and neuroscience, and environmental change, among many others.

Advancing a Made-in-Canada Initiative

As a group of experts with an interest in this area, we held two consultations with members of the international and Canadian academic bioethics and science, technology, and society (STS) communities to discuss the interests of Canadians (Table 1). The international consultation was guided by three questions:

1) What is the historical and political context of ethics bodies in the country you represent?[2]
2) How were these ethics bodies established?
3) What were the successes and failures of these ethics bodies, and what advice might you give for establishing a new body today?

Seven participants, selected for their prior or current leadership positions on national bioethics bodies, described examples of successful NBBs, reasons for

[2] Members of the international consultation represented Canada; Tasmania; the United States; Mexico; the United Nations Educational, Scientific and Cultural Organization (UNESCO); Japan; Netherlands; and, Germany.

their creation, pressing concerns, as well as lessons learned. Among successes, they pointed to groups such as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the iconic Belmont Report it authored, which has had lasting impacts on bioethics. Drivers for the creation of NBBs were described as including constitutional or legally charted mandates.

There was also an emphasis on interdisciplinary representation (*e.g.*, ethics, law, technology, economics, political philosophy, STS, and environment) and a dynamic discussion that emphasized cooperation and consensus building. Among top priority concerns for a Canadian NBB, participants identified pandemics, environmental degradation, and the affordability of pharmaceuticals. They also cautioned that NBBs could become politicized and ignite public debate that threatens the goals of a political party or administration. They spoke to the importance of being receptive and collaborative in the approach to dealing with global issues, having organizational autonomy, a clear agenda, and a sustained independent budget. The opportunity for capacity-building was regarded as a bonus for such an initiative.

Participants also spoke of different models for NBBs around the world. For example, Japan's Expert Panel on Bioethics, a branch of the Japanese Council for Science, Technology and Innovation, was discussed. Established in 2001, Japan's Expert Panel on Bioethics has dealt with issues ranging from human cloning and chimera research to human genome editing. Moreover, Japan's Expert Panel on Bioethics, through close connection to various government ministries, has routinely succeeded in having its recommendations adopted in policymaking. This Panel also highlights the importance of involving the public in ethical decision-making to capture the range of perspectives and sectors of society impacted by bioethical issues.

The German Ethics Council, a legally enshrined advisory body, is a second example. By law, members of the German Ethics Council are interdisciplinary and must represent different societal and religious groups. Of the Council's 26 members, half are appointed by the government and half are appointed proportionally by parliament. While this nomination strategy was designed to be less political than having the government nominate members alone, some scholars argue that the joint appointment mechanism actually enhances politicization because the public is aware when a specific political party nominates a member to the Council. That said, in an official sense, the work of the Council is independent, as are its members.

The Netherlands Scientific Council for Government Policy also highlights a successful example of an advisory body that requires the government of the day to respond publicly to reports and recommendations of the Council.

A second consultation focused on the Canadian landscape specifically. Here the guiding questions were:

1) Does the idea of a bioethics council for Canada resonate with your scholarship and leadership?
2) What should the Working Group be thinking about in terms of expertise and implementation, and what should it avoid?
3) What are the next steps to increase exchange and uptake in the broader bioethics community?

Overall, the seven participants – selected for the roles they have played in Canadian bioethics – noted their support of an effort to create a Bioethics Council of Canada (BCC). Some spoke to challenges associated with the creation of a NBB while also noting the overdue nature of such a body. Participants noted the challenges of creating a fully bilingual organization, avoiding overlapping mandates with specialized committees already in existence, and the absence of Indigenous bioethicists in Canada.

Therefore, some participants questioned how a NBB could be representative of the Canadian population and how non-traditional and distinctly Canadian ways of thinking could be incorporated. Much like participants in the international consultation, Canadian participants also noted the need to avoid insularity in favour of a global enterprise. At the same time, they noted the need to create a clear mandate and purpose for any NBB. They emphasized that next steps focus on the organizational positioning of a BCC, the scope of bioethics tackled by such a body, and how political polarization could be reconciled to create a unified and representative enterprise.

Valuable though these findings may be, context matters. The decision of a country to establish a committee, including its scope, authority, and membership, reflects important national values and priorities. Through its extensive history with various bioethical entities, Canada has demonstrated its awareness of the ethical issues that arise in health, science, and society, as well as its need to move to the next stage. It is time for Canada to enhance its approach towards bioethical challenges and take Canada to the next level of scientific and ethical excellence.

The Work Ahead

Through a series of meetings beginning in 2020, we reaffirmed the importance of a unified approach to bioethics and science, technology, and society in terms of critical ethical thinking, scholarship, guidance, and action on a national level. Our efforts coincided with the motion to create a Standing Committee for

Science and Research in the House of Commons, the 25th such standing committee—only one of which includes ethical issues in its mandate.

In a 2021 piece published in *The Conversation*, we discussed how the motion to create such a Standing Committee emphasizes the relative lack of bioethical presence in Canada's government apparatus and its negative implications. Here we argue again that a centralization of normative guidance would strengthen Canada's ability to allow its citizens to "benefit from the advancement of science and its applications" as promulgated in the Universal Declaration of Human Rights, as well as enhance its global presence and leadership in ethics, science, and health. Indeed, by moving away from the prior *ad hoc*, topical, or opportunistic approach to bioethical issues, multi-sectorial, expert and stakeholder guidance can be incorporated efficiently and flexibly into policy at all levels.

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3. South-East Asian Region
(SEAR)

Ethical Issues around Covid-19 Vaccine Research in India

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Covid-19 pandemic has led to enormous morbidity and mortality in many parts of the world including in India. In order to combat the disease and save lives, the world saw an unprecedented race against time for finding the right therapeutics and novel candidate vaccines that would impart protection from infection, disease or transmission (1). Vaccine development has historically been time consuming often requiring decades of research before reaching the public. However due to the urgency imposed by the pandemic, huge funding available, new technologies made available, vaccine research was fast tracked across the world and including in India. Laboratories worked in a time bound manner; involving inactivated/ recombinant/ live attenuated / protein/ or RNA/ DNA based vaccines. However, the accelerated research was seen with a lens as evidence to generate safety and efficacy data is considered to be time consuming (2).

The Indian Council of Medical Research (ICMR), New Delhi, is the apex body in India for the formulation, coordination and promotion of biomedical research and is one of the oldest medical research bodies in the world. It has not only attempted to address the growing demands of scientific advances in biomedical research, but also involved in developing ethical guidance and policy to guide the conduct of biomedical and health research in India. The first National Policy on ethics was created way back in 1980 which was revised and converted to a more detailed guidance in 2000 and further revised in 2006 and 2017. In April 2020, ICMR came up with its latest guidelines to help ethics committees review research during the pandemic. ICMR has set up a Bioethics Unit to serve as an ethics advisory unit and to guide development and timely updation of national ethical guidelines, policies, reports, other supplementary documents and tools in order to address ethical aspects of biomedical and health research. It also serves as the secretariat for the Central Ethics Committee on Human Research (CECHR) and carry out ethics review of nationally important complex issues. Further it builds capacity of ethical review in institutions across the country and creates networks in the areas of ethics related to biomedical research. Further

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ethics committee now require a registration with the National Authorities as an essential requirement.

The ICMR Ethical Guidelines, 2017 discuss the ethical requirements for undertaking any biomedical and health research including vaccines trials are now mandated under law to be followed for any Biomedical and health research in India (3). Further the ICMR National Guidelines for Ethics Committees, 2020 released during Covid-19 Pandemic provided direction to ethics committees regarding updated requirements for research carried out during this period (4). Further Clinical Trials are regulated under the New Drugs and Clinical Trial Rules, 2019 which provide the ethical requirements for conducting a trial (5). All of these documents highlight the need to uphold ethical values and ensure participant protection. There are some landmark decisions contained in these documents which are very unique to India, such as, the requirement to have an external person (non-affiliated) to serve as the Chairperson for an ethics committee. This provision ensures that the ethics committee members are in a position to voice their concerns without any fear of higher institutional authority and function independently. Secondly it is legally binding in India to provide medical management in case a research participant suffers from an injury, even if causality is undetermined. Further the regulatory agency has provided a timeline for reporting of serious adverse events, causality assessment and provided a formula for calculation of compensation to be paid in case the injury is found to be related to participation in research. Therefore, every research undertaken must plan to make budgetary provisions to take care of these costs and seek insurance policies before implementation.

In the beginning, the world was totally unprepared to handle the Covid-19 pandemic. The disease was novel, and there was incomplete information, inadequate preparedness to conduct robust science, reluctance to support research in fast-track mode, lack of public trust, allegations about probable compromises on the quality of research, doubts about heightened risks to the research participants, etc. (6). These challenges imposed serious ethical dilemmas in undertaking Covid-19 vaccine research in the country related to scientific, political, social and ethical issues. This paper attempts to highlight some of these ethical challenges in undertaking Vaccine research involving humans.

Scientific Validity

Research has to be scientifically robust. It was a critical time when research was being fast tracked, and there was no time to invest in ensuring details in well written vaccine trial protocols or the informed consent forms, or looking at

site preparations and infrastructure to support the research. The scientific challenges encountered during the period were very challenging, for research ethics committees referred to in this paper as ethics committee. These ethics committees reviewing research protocols had a difficult time determining if the clinical trials with new vaccines be continued when a successful candidate vaccine was approved and was available. Similarly, there were concerns, if blinded placebo control trials should be continued or whether there was a need to switch to open label studies. There were discussions about using adaptive trial designs or the stepped wedge cross over designs, which being novel methodologies were not well understood by many. There was incomplete information, gaps in the review processes as well as funding mechanisms. Compromises in scientific review especially in respect of vaccine studies cannot be acceptable as it has wide implications on the implementation of the vaccination program and public trust. There was demand for improved transparency in the review and approval processes at the highest level. Every Vaccine trial is required to be registered on the Clinical Trial Registry of India Platform which is an online platform accessible to all (7). This brought in some transparency, but still left room for many more questions about reporting of research results, accuracy and research integrity. The principle of utility means that the best values may be provided to the people despite situations and the benefits to be accrued need to be maximised. The indigenously prepared vaccines were found to be safe, efficacious, cost effective, and beneficial as required routine cold chain already available across India. Vaccine rollout in a clinical trial mode without completion of Phase 3 did raise lot of concerns around scientific deliberations and proactive approaches and better transparency would have helped in reducing vaccine hesitancy. A decision was taken to provide the vaccines free of cost so that there would be no financial burden on the public and any economic harm can be avoided. Considering the fact that the covid-19 morbidity and mortality was higher amongst elderly or those with co-morbidities, and therefore in order to save more lives, this group was identified to receive vaccine in the initial phase. There was an incomplete knowledge set available in view of prior experience, incomplete information about scientific validity, long term effects, values and incomplete evidence for public health decisions. Therefore, ethics committees needed a lot more deliberations, to come to consensus to make difficult decisions while undertaking benefit risk assessments. It was well realised that the challenges need to be tackled in public interest, without making any compromises on the core ethical values for a greater good for the society, to approve new methods and technologies, in a fast-track mode.

Informed Consent Process

An informed consent process is integral to provide due information before receiving a voluntary agreement from the participant for any given research. The information has to be communicated in the simplest of manner to explain the details of the study, the risk and benefits, procedures to be followed and other relevant information and decisions be taken without any undue pressure or coercion. ICMR National Guidelines for Ethics Committees, 2020 released during the pandemic have suggested that novel methodologies can be adopted by researchers to facilitate informed consent process during the lockdowns. The importance of utilizing audio/ visual aids or electronic tools to seek consent with appropriate documentation has been highlighted (4). As soon as vaccine trials were announced, several vaccine study sites reported that many volunteers turned up in the hope to be amongst the first ones to receive protection from the deadly disease. Therapeutic misconception was high and vaccines (though experimental) were seen as a magic portion to save lives. There was lack of clarity in the public understanding of experimental vs approved vaccines, since many of the vaccine were granted an emergency use authorization (EUA) even before the trials were completed and results published. Recent reports have suggested that India's Covid-19 Vaccination Program saved millions of lives (8). But on the other hand, at other sites, there were concerns related to obtaining and documenting informed consent (9). It is time that scientific community makes better investments to make informed consent truly voluntary where participants or their communities are engaged in a meaningful manner and there are measures to build trust between the stakeholders. An online e-program was developed namely, Covid Vaccine Intelligence Network (Co-WIN) application for improved access to information, availability of vaccination sites, booking appointments, and generating vaccination certificates. The vaccination was voluntary and protected individual autonomy to an extent to decide and have a choice to choose the center as per available vaccine. Further even during the roll out of vaccination in the very initial phase, it was made voluntary to come forward for vaccination and receive the same after a written informed consent process. Further fact sheets were disseminated and those who received vaccines were closely followed up over the telephone for any adverse events. These measures were taken in order to protect autonomy and rights of the people and protect them from any undue harm. In addition, a landmark decision was taken in India to make budgetary provisions to pay compensation in case of any harm caused due to vaccination in the initial phases of its implementation and roll out (10).

Vaccine Research in Pregnant Women, Children, Vulnerable Persons

Traditionally clinical trials exclude persons or group who are determined to have diminished autonomy and are vulnerable. The same practice was followed for Covid-19 vaccines trials, where the pregnant women and children were excluded from participation in the initial phases of vaccine research/ trials, due to safety related concerns. The principle of Non-Maleficence or to 'do no harm' requires that the pregnant and lactating mothers or children be excluded from clinical trials in order to protect them from harm that was possible due to experimental vaccines. While other public health researchers have concerns that when the vaccine was approved and become available to general public, it could still not be administrated to pregnant women and children across all ages, since, the safety and effectiveness of the vaccines remained to be tested in these groups. It was noted that unvaccinated children were reservoirs and passively transmitting the infection to others around them. Therefore, the vaccine remained inaccessible to pregnant women and children for a long time and they were denied of their right to receive the benefits of vaccination early on (11). The unresolved debate on whether vaccine trials need to be carried out concurrently in adults and children continues. Children have been excluded citing concerns of safety, and there is need for more discussion to understand the conditions and requirements that would encourage timely research in children with the due safeguards and monitoring (12). Use of experimental vaccines in children or in women during pregnancy provides the prospect of imparting protection for both mother and child, however this can be debated as there have been only a limited number of studies documenting the efficacy and safety of vaccines leading to an ethical dilemma in assessing the benefits and risks. The principle of equity requires one to set priorities to provide equitable access to all without discrimination. The high-risk groups were prioritised in the vaccination drives and access to vaccine was for all without any discrimination between rich or poor, socially marginalised, tribal or other vulnerable population group.

Safety Reporting

Vaccine trials require very vigorous adverse event or serious adverse event reporting and monitoring. However, in case of Covid-19 vaccine trials, there was very limited safety data available. During this period emergency use approvals were granted even before all phases of the trials were completed and, therefore understanding the safety aspects of vaccines was particularly challenging. Thus, the risk related to experimental vaccination was largely unknown. Further there

was no understanding about the long-term effects, duration of protection, and especially related to high-risk groups or vulnerable persons or those with co-morbidities, geriatric population, pregnant women or children. In addition, there was a risk of contracting infection, if the vaccine turned out to be ineffective. In order to overcome these challenges a meticulous procedure for follow up was created and further, a series of webinars, online as well as physical trainings were arranged for the healthcare work force on various aspects of safety reporting down to the block level health care workers. Adequate healthcare infrastructure was further created for delivering care and undertaking safety reporting. Co-WIN application had in built provisions to ask the recipients about any adverse event and to report the same. Skilled manpower and suitable logistic delivery platforms were available to ensure fulfillment of the principle of beneficence and protection of persons. The trials reported that the risks or discomforts were mostly mild, such as fever or pain or those that were related to anxiety, and resolved in 3-4 days (13). India has a strong Adverse Event Following Immunization (AEFI) monitoring mechanism in place. However, there was flooding of speculations and misleading claims, information on social media creating the scare of adverse events, leading to fears and vaccine hesitancy (14).

Psychological health and safety of Health Care Workers

Covid-19 affected the mental health of people in a significant way. They were exposed and vulnerable to various socio-economic changes, has fear related to vaccination and its long term affects. The ICMR Ethical Guideline discusses the need to focus on mental health issues and psychological needs of both people and the researchers during the pandemic. The guidelines discuss about the importance of ensuring respect, empathy, compassion, to those who become positive with infection and guidance to institutions to make provisions for emotional support and wellbeing. The health care workforce dealing with highly infectious material required appropriate protection gear as well as training on handling, storing or sharing the highly infectious samples across labs. The National Guidelines for ethics committees reviewing research during the Covid-19 pandemic released in April 2020 discuss about the need for self-protection, use of PPE kits as well as appropriate waste disposal for wellbeing (4). Despite the initial hesitation, the momentum of vaccination caught up and enormous efforts were made by government agencies to educate and communicate information which led to positive outcomes and overall, an improvement in the mental health status (15).

Transparency and Accountability

Knowing that vaccines usually take years to develop, with the accelerated research, there was a perception that the vaccine may not be safe or effective. The regulatory processes for approval came under close scrutiny. Public demanded complete transparency in the decision-making processes. There was demand to post the names of all members of the expert committees involved in policy and decision making, requirements to declare conflicts of interest, posting of minutes of meetings in the public domain and follow-up action plans to be available on website for easy access to all. The public rightfully wants all stakeholders to be responsible and accountable. ICMR acted on this and launched a vaccine portal, which is a website collating all available and updated information about Covid-19. This was in order to provide transparency in the R&D process and to serve as a repository of all information related to vaccine development in India (16). These steps were important in building societal trust. However, much more efforts are needed to improve transparency. The regulatory decisions are often taken in closed doors meetings should also involve public as an important stakeholder in the deliberations and decision making. To ensure the principle of accountability and fairness, all efforts were made to find improved ways to communicate in a timely and objective matter, presenting available data or evidence to keep the public informed with honesty and make all efforts to communicate in the most simplistic manner for understanding. These initiatives are important in reducing vaccine hesitancy and improving confidence for decisions being taken at the policy level.

Importance of Communication

There was a realization how communication needs to take the center stage in order to cater to the needs of the communities. At different time periods, the disease forced the public to experience an emotional turmoil, such as 'fear', 'anger', 'depression', 'desperation' and 'anxiety'. These emotions could rather have been, 'satisfaction', 'confidence' or 'hope' if, there had been better communication. Often the communication received is partly skewed, or presents a one-sided perspective, or fake news driven by political motives, or sensationalized by media. News channels running 24x7 fueled this fire and created stories over factual information. WHO labelled the epidemic of misinformation causing confusion as an 'Infodemic' as it travels much faster leading to risk taking behaviors (17). There was a felt need to engage better with communities and people directly and for media to act more responsibly. Further the scientists need to learn to communicate

better and share information in a timely manner. India has high speed internet connectivity to the remotest part of the country which needs to be better utilized for sharing right information in a timely manner. Research needs a lot of investments and to have the capacity of not only dealing with the crisis situations but also having in place appropriate methods to inform and communicate better with the stakeholders so that right information and perspectives can be presented and understood. Truthfulness, honesty and empathy are critically important principles for an effective and ethical communication. Message content to be shared for public consumption must be understandable in lay language, honest and open. However, there were major challenges in form of rumors or scary information to create panic among the public. The Government of India left no stone unturned and held weekly Press Information Bureau (PIB) meetings and provided timely updates along with data presented as power point presentations/ graphs etc. which was live telecasted on national television to keep the public informed. Further the websites provided the guidelines, training modules, videos, etc. on their websites for easy access to the public. Various social media platforms in both electronic and print mode were utilized to broadcast and inform the public. Regarding fake news and warn the public from time to time. These measures were found to be useful and helped to reduce misunderstandings, unnecessary conflicts and helped to improve communication. Further a Communication Strategy was prepared by the Ministry of Health and Family Welfare, Govt of India which provided a detailed direction to these efforts (18).

Governance of Research

ICMR Ethical guidelines have suggested preemptive preparation for undertaking research in emergency situation such as these COVID-19 pandemic. Ethics preparedness can help in the conduct of research with improved outcomes while safeguarding the people (19). The government set up website to provide updated information on every new initiative. Several 'Make in India' and 'Atma Nirbhar Bharat' (which means self-reliance) initiatives were supported by the government to overcome the challenges through innovation and self-reliance to meet the priority needs of the country (20). The regulatory agencies further made every effort to streamline review processes with expert committees to ensure timeliness of reviews so that the vaccine trials could be promptly initiated without much delay for regulatory review. The regulation also contains clauses that allow emergency use authorization (EUA) in order to facilitate expedited vaccine development under exceptional conditions.

In India, a new drug approved outside the country can be given a waiver from conduct of clinical trial if there is an emergency such as an epidemic or disaster or for patients suffering from rare diseases for which treatments are not available on a case-to-case basis. Therefore, in such rare instances, unapproved drugs which are not available in Indian markets can be imported in small quantities by a medical institution for treatment related to life-threatening diseases or those with for unmet medical needs in India. Hence, there is a defined regulatory framework for import or manufacture of unapproved new drugs for compassionate use (21) However, there was a lack of understanding on regulation amongst not only practitioners but researcher as well. Initially only the two indigenously developed vaccines received the regulatory approval and were made available to the public as they were temperature stable not requiring very low temperature cold chain. Vaccine studies were not done in many other vaccines which required stricter cold chain support and would be unaffordable and inaccessible in the remote areas (22). Various Government agencies and departments set up Research consortiums, and National Task Force Studies in order to develop an integrated process for an effective vaccine to combat Covid-19. Support was extended to industry, academia, scientists and institutions to join hand Further India joined hands with the world in ACT Accelerator, CEPI, joined hands with neighboring countries for building science diplomacy for technological advancement and acceleration of indigenous vaccine development efforts. Multipronged approaches and efforts need to ensure vaccine manufacture and supply within the country and to low- and middle-income neighbouring countries dependent on India for the vaccine such as Nepal, Bhutan, Myanmar, Bangladesh, Maldives, Seychelles, Mauritius on a gratis basis. India emerged as global leader in advocating against vaccine nationalism and providing vaccines to different countries. India supplied COVID-19 related medical assistance, since the beginning of COVID-19 pandemic and under the Vaccine Maitri Programme supplied 723.435 lakh doses of COVID vaccine to about 94 countries (23). The underlying values for this work relate to the Principle of distributive justice ensuring fair selections and allocations of the available but limited resources, while involving and engaging with the diverse members from the community. Further these initiatives have helped India in its resolve towards the principle of equity and access to people. In the fight against the COVID-19 pandemic during the second wave, support in the form of COVID related equipment and medicines were received from more than 50 countries. These included supplies from foreign governments, private companies, Indian associations abroad, etc. (24).

Conclusion

The importance of implementing the principles of ethics came to the fore as India fought against Covid-19 infections. For the first time it was seen that there was a global requirement to prepare a safe and efficacious vaccine that could be administrated to all age groups right for new born to children, young and old adults, pregnant or nursing women and even geriatric population or those with co-morbidities. The various initiatives taken to combat Covid-19 underlined the bioethics principles to an extent, and taken in the best interest of public however more robust and open discussions around values and principles in ethics would have improved these responses further.

The vaccines trials conducted in India had their own set of challenges and issues and there are many lessons learnt during this time. However, being a large country with socio-economic, political, religious and cultural diversity, the efforts needed more ethical deliberations to ensure fairness. The political parties used the pandemic as an opportunity for self-promotion and fault finding for others leading to confusion and lack of public trust. There were concerns related to inclusion and accessibility to benefits for everyone, and especially those residing in remote areas or those who belonged to certain communities such as tribal population groups with limited access and awareness. The policies and decisions at the highest level were guided by transparent and fair procedures however there is much room to improve this further. Lessons have been learnt to ensure autonomy of persons and having better community engagement programs, better communications and preparation of advocacy material before enrollment of participants. Further handling of conflicts of interests, being transparent and accountable require appropriate disclosure since they raise serious questions on the outcomes of research and questions regarding integrity of findings. More and more participatory approaches and collaborations are required in order to undertake better research studies. It is now clear that there can be no compromises on the quality of science, rights or safety of participants even in an emergency situation. The meetings can be expedited, the procedures can be fast tracked, however, in no way the rights, safety and wellbeing of the participants can be compromised. The researchers need to work towards reducing bias and restoring public trust. The core ethical principles addressing issues and concerns raised in research around vaccines revolved around the principles of autonomy, beneficence, non-maleficence, justice including distributive justice and also around the ethical values of ensuring equity, fairness, utility, transparency, accountability, affordability and easy access. A safe and efficacious vaccine development and implementation involves both hard science as well as soft science focusing on ethical aspects to ensure processes leading to a good vaccine.

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Bioethics in South-East Asia Region

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WHO South-East Asia Region (SEAR) comprising of 11 countries[2] is home to over a quarter of world's population (nearly 2 billion people) with a substantial cultural and religious diversity both within and between countries. It has some of the largest countries in the world (India, Indonesia and Bangladesh) and some of the smallest island countries (Maldives and Timor-Leste). As per World Bank's income classification 2022, most countries are categorized as lower middle-income countries except Thailand and Maldives which are designated as upper middle-income countries (World Bank, 2022). The region bears disproportionate burden of tuberculosis having nearly half of new cases and more than 40% of all deaths from TB. It also has one of the highest burdens of childhood malnutrition manifested as wasting, stunting and underweight. At the same time, it is experiencing an expanding epidemic of noncommunicable diseases accounting for almost two-thirds of all deaths.

Though the debate on medical ethics is old as Indian civilization with some evidence in Charaka Samhita and Sushruta Samhita[3] of ancient India, the discipline of bioethics-a 'value' based approach to development and evaluation of public health policies and clinical care decision-making--is still evolving in the Region. While ethical issues related to policies related to population control measures and dual practice of health care providers in public and private sector in a Region characterized by one of the highest levels of private health care service utilization (and private health care expenditures) and income inequities that reflect in inequities in access to health care are long standing, additional ethical issues related to emerging infections (such as HIV/AIDS. COVID) and public health measures used to control them continue to emerge. Finally, rapid advances in science and technology (assisted reproduction, ICU technologies and end-of-life care, use of data and social media, gene editing, stem cell technology, and artificial intelli-

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[2] Bangladesh, Bhutan, Democratic Republic of Korea India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste.

[3] Sushruta and Charaka Samhita are two foundational texts on Ayurveda (Indian traditional medicine) that have survived from ancient India.

gence), promotion of market economies and globalization has made discussions on bioethics more urgent. In addition, many countries in the Region are putting increasing emphasis on local production of drugs, vaccines and diagnostics, especially in the context of pandemic and emerging diseases, which makes developing sound and efficient governance mechanisms for ethical conduct of research even more urgent.

Most member states adopted bioethics standards to address pressing administrative and practice issues (*e.g.* to take care of negligence and malpractice issues or to take patient consent before any procedure on him). Colonial legacy has also influenced as the legal systems and medical acts adopted by newly emerging nations in the Region were inherited from the past (Kasturiaratch *et al.*, 1999). For example, in most of the countries the practice of establishing medical councils and nursing councils to regulate the medical profession derives from their colonial legacy. Many countries have taken a legal approach to address the bioethical issues and enacted laws to regulate related practices for example abortion laws, organ transplantation, medical practice (informed consent, professionalism), human research subject protection and human reproduction.

Research ethics

Most developed aspect of bioethics in the Region seems to be in the domain of research ethics. This is mainly because of push from external research funders, as much of the initial research was donor driven. Many external research collaborators ad funders required review and approval of the proposals from local institutional ethics review committees, where none exist initially. This requirement led to export of similar research ethics governance mechanisms (in the form of monitoring by an institutional ethics review committees). Most of the member states have a national-level body under the overall authority of Ministry of Health or equivalent that sets standards or provides other capacity building support for ethical conduct of research. For example, Nepal has National Health Research Council (NHRC) (1991) and Bangladesh has Bangladesh Medical Research Council (BMRC) (since 1972) and India has Indian Council of Medical Research (ICMR)[4] (since 1949) that perform these functions. Smaller countries such as Bhutan and Maldives have national health research unit or focal persons within the Ministry of Health. Many of these national bodies (*e.g.* ICMR, BMRC, NHRC) also house national Ethical Research Review Committees that directly review specific research proposals but also set standards, monitor and provide guidance to other

[4] ICMR evolved from Indian Research Fund Association established under British in 1911, which was redesignated as ICMR in 1949.

institutional review committees operational in the country. Some Member States (*e.g.* Bangladesh and Nepal) have developed systems of registration of the institutional review committees operational in the country and regularly monitor their activities. However, the independence of these committees, including capacity to review proposals remains questionable and should be assessed.

Initiatives in Research ethics in Asia

Many international, regional, and national conferences are being regularly organized that are providing opportunities to raise awareness of the ethical challenges in health research in the Region.

The Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP)

FERCAP was formed in Thailand in the year 2000 under the umbrella of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) as a project of the World Health Organization (WHO) Special Training and Research Programme in Tropical Diseases (TDR)[5]. It aimed at fostering improved understanding and better implementation of ethical review of behavioral and biomedical researches in the region. It is currently affiliated with and holds office at the Faculty of Allied Health Sciences, Thammasat University, Thailand. Its major projects involve capacity building and education for research ethics committees in Asia, and developing models of good research ethics review in Asia and the Western Pacific with clear specification of processes and accountabilities. It organizes annual international conferences and different training programs.

Challenges in research ethics

The research ethics oversight is still getting institutionalized, and it remains to be fully demonstrated if the current mechanisms are actually adding value in term of improving either the research quality and protecting the human research subjects. The practice is still evolving and needs substantial standardization and appreciation of its value by the researchers who still see this as an administrative burden rather than a support to improve the research quality. Changing the situation will require action on multiple fronts – integration of ethics in the professional development curricula, increasing awareness among researchers and general population and improving the efficiency of the Committees and increas-

[5] https://www.sidcer-fercap.org/pages/home.html as accessed on January 9, 2023.

ing financial investment in this area. There are still issues of suboptimal research infrastructure that makes ethics review of protocols inadequate or slow with little value addition (Reyes, 2012). Widespread poverty, high levels of illiteracy and inadequate access to health services are other challenges which may cause participants difficult to make informed decision about their participation, and hence greater need for providing formal safeguards.

In addition, there is still a debate about application of universal principles of research ethics (*e.g.* beneficence, justice and respect for research participants) in the context of the region given substantial cultural and religious diversity, with some arguing one-size-fits-all approach of research ethics is not viable by presenting ethical practices from the South Asian perspective (Dahal, 2020). Others have also suggested that research in these socio-culturally diverse contexts may present unique ethical challenges for researchers.

From research ethics to broader bioethical issues

While research ethics is getting substantial attention at least in term of establishing the formal research ethics committees etc. at Ministry of health level and at research institutions (universities or teaching hospitals) level, the governance mechanisms to address other bioethical issues are still non-existent in most countries in the Region as explained later.

One of the key governance mechanism proposed for managing bioethics issues is establishment of national ethics (or Bioethics) Committees that provide recommendation and guidance to the governments and public, thereby ensuring that public policies are informed by ethical issues (Kohler *et al.*, 2021). UNESCO in its 2005 declaration urged countries to develop independent, multidisciplinary and pluralistic national ethics committees (UNESCO, 2005).

However, as of now, most of the Member States in SEAR do not have an overarching National bioethics committee (NECs) whose mandate goes beyond research ethics and which acts as single point of contact for all the bioethics issues ranging from medical/clinical ethics, public health ethics, ethical issues in surveillance, new health technologies, etc. For example a survey of National ethics committees in early 2018 by WHO (Kohler *et al.*, 2021), noted NECs only in India (National Bioethics Committee in the Ministry of Science and Technology, department of Biotechnology), Indonesia (National Bioethics Commission of Indonesia), Sri Lanka (National Committee on Ethics in Science and Technology). (WHO, 2023). In other countries, such as Bangladesh, Bhutan, Nepal, Timor-Leste, these are primarily national 'research' ethics committee concerned primarily with research ethics. One of the major barriers to establish them to find

a natural home in the government bureaucratic system and an agency that may be held responsible, given the multi-disciplinary nature of these committee. Lack of public demand may be another factor. Increasing demand, and active civil society advocating addressing key bioethical issues outside the legal framework may push the government to establish these committees.

A large-scale qualitative study in six of the SEAR Member States described the ethical dilemmas faced by physicians in relation to range of clinical issues in big urban hospitals (WHO, 2000). The study tried to distinguish between the technical medical dilemmas and the ethical dilemmas. One of the findings was that financial constraints play an important role for discussion of most ethical dilemmas. An overwhelming majority of the respondent physicians received no formal training in medical ethics as part of medical studies or in their subsequent careers.

Most member states have adopted the principles of universal health care and access based on human rights and health equity frameworks, as they either strive to provide universal 'free health care' through publicly managed and publicly funded health care systems or through social health insurance systems (*e.g.* Indonesia, Maldives and Thailand). The clinical ethics issues are addressed under a charter of patient rights and medical misconduct domains. For example, National Human Rights Commission in India prepared a Charters of Patient Rights, to be implemented by National Ministry of Health and Welfare for provision of proper health care to patients by the clinical establishments[6]. In addition, the consumer protection law in India includes a "health consumer" (Kasturiaratch *et al.*, 1999).

The ethical discourse on specific issues such as abortion, sex-selective induced abortion, and biomedical research involving human subjects is influenced by changes in socio-political scenarios, influence of outside agencies and the colonial legacy. A recent review (Pratt *et al.*, 2014) of literature on health and ethics from four largest Asian countries including India and Bangladesh from WHO SEAR noted that bioethical literature mainly focused on informed consent and revealed norms in clinical decision-making that include physician paternalism, family involvement in decision-making and reluctance to provide information that may upset patient. The review recommended that scholars from these countries seek to enter into a bioethics dialogue with the potential to enrich and inform "international" frameworks.

[6] https://main.mohfw.gov.in/sites/default/files/PatientCharterforcomments.pdf as accessed on January 9, 2023.

Addressing new emerging areas requiring bioethics lens

Digital transformation of health is impacting all health systems and inexorably changing health services and delivery of care, as well as how individuals manage their health and interact with the health system. This raises a number of important ethical questions and dilemmas, such as those relating to the collection and use of personal data, equity and the digital divide, changes in the clinician-patient relationship, the application of algorithms and potential harms that may arise, and patient autonomy and consent. Ethical approaches are needed to ensure that the design and implementation of digital health interventions enhance health outcomes and advance equity, quality, and accessibility. A new emerging area is application of artificial intelligence for delivering health care, though this is still in infancy in the Region, mainly in the form of personal wearable health technologies. National Ethics Committees have an important role to play in building understanding, and identifying and assessing ethical issues associated with the use of digital technologies in health.

A detailed assessment needs to be undertaken as to how the ethical issues in digital health are understood by policymakers and how the key ethical questions are included in policy discussions.

Initiatives in Bioethics in Asia

Many international and regional conferences have been organized that had provided opportunities to raise awareness of the bioethical issues in the Region.

From 1997-1999, an integrated research cum training project to promote teaching of and practical application of medical ethics in clinical decision and health policy making was undertaken in the six of the eleven countries of the Region (Kasturiaratch *et al.*, 1999). The project carried out a baseline study of ethical values in the large teaching hospitals, preparation of a teaching module on health ethics, and promotion of health ethics through national workshops.

As part of implementation of its 2005 declaration, UNESCO provides support through the *Assisting Bioethics Committees programme* by working with ministries and government to establish committees in countries requesting assistance.

Asia Pacific Network of National Bioethics/Ethics Committees (AP-NEC)

APNEC provides a platform for Member States from WHO SEAR and Western Pacific Region (WPR) to exchange ideas, build support, and foster regional collaboration and driving sustainable action on regional priority issues in health ethics. Senior officers in the MOH or another government agency responsible for

health ethics policies and programmes or senior members of NECs or an equivalent group participate in APNEC Regional meetings.

WHO provides secretarial support in collaboration with UNESCO for this network. The regional Network is expected to organize regional meeting once every two years, and bring together national ethics committees, as well as ethics/bioethics focal points in governments, from around the world to share their thoughts and experiences in relation to bioethical issues. The Republic of Korea held the inaugural AP-NEC meeting in 2017 that explored how to promote health ethics in the Sustainable Development Goals, while the second meeting in 2019 in New Zealand dwelled on the theme of reducing inequities through solution-oriented Bioethics.

Since early 2020, APNEC has met on a regular virtual basis as a 'COVID-19 Working Group' to discuss priority ethics issues and enhance the role of NECs in the response. Bangladesh, India, Nepal, Sri Lanka and Thailand have been particularly active participants.

Next steps

Given the demographic and socio-cultural complexity including that of health care system of the Region, new bioethical issues are expected to emerge continuously in the form of new disease and measures used to control them (*e.g.* COVID pandemic), the ethics of neglected tropical diseases (including their elimination and eradication), and exploding new technologies and ambition of the some of the countries to emerge as leaders in local development of drugs, vaccines and diagnostics. Some of the next steps to promote bioethics will be mainstreaming it in national medical and nursing education curricula and promote its practical application in clinical-decision making and public health policymaking through research and teaching. Governance structures needs to established and/or strengthened to provide a formal platform to facilitate dialogue on bioethical issues involved in research, clinical decision-making and health care as well in public health policies.

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4. European Region
(EUR)

Ethics as our compass for responsible biomedical and health research

Hervé Chneiweiss[1]

Created in 1964, the French National Institute for Health and Medical Research (Inserm) is one of the main European research organizations dedicated to biological, medical and human health research. It is positioned along the entire pathway from the research laboratory to the patient's bed, from basic research to clinical research. On the international scene, it is the partner of the largest institutions involved in the challenges and scientific progress of these fields.

From 1964 on the Inserm Ethics Committee (IEC) was the driving force behind biomedical ethics in France until the creation of the National Consultative Ethics Committee (CCNE) in 1982, settled at Inserm headquarter leading to close IEC. It was re-created in 1999 at the request of Inserm scientists that felt a lack of tools to lead the reflection on the ethical questions raised by basic biomedical research and health research as they are developed by Inserm groups whereas CCNE is more oriented on the ethics of societal questions raised by the use of life science technologies (in example: opening medically assisted reproduction technics to same sex couples and women alone or the ethics of the end-of-life are not topics relevant for IEC since they do not correspond to research led in the institute). IEC is composed of 16 to 20 members nominated for a renewable 3-years mandate, with gender parity, less than half from Inserm, less than half biologists or physicians and foreign members. IEC role is to anticipate the impact of biomedical discoveries, both on the practice of research and their societal consequences. The IEC's vocation is to be an actor in the dialogue between the scientific and medical community and the society. In this sense, contributing to the organization of public debates and promoting the dissemination of knowledge are part of the commitments and missions of the IEC. IEC dialogs with and helps the work of other ethics bodies such as CCNE.

I will share here the vision of bioethics and its impact as I can see it as president of the IEC since 2013, but also as a former member of CCNE (2013-2017) and former member and past-president of the International Bioethics Committee of UNESCO (IBC, 2013-2021, 2019-2021).

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The COVID-19 pandemic as a prime example of the need for bioethics

The COVID-19 pandemic that we have been experiencing since the beginning of 2020 is a perfect example of the importance and the stakes of bioethics. Ethics as a universal compass has been the mantra of both the IEC and the IBC during this crisis, and this mantra has even become the title of the recently created IBC newsletter. In both cases, the ethics committees continued their work of reflection and advice. Through interventions in the media (1) or statements (2, 3, 4, 5), we have stated loud and clear that no health emergency can disregard the ethical values essential to the respect of human dignity and human rights. We have said and implemented that all public health decisions must be based on solid scientific facts, even in situations of uncertainty, which must encourage the promotion of research that will remove the unknown and the doubt. We have said that the urgency of clinical trials calls for an adjustment of practices, and in particular an acceleration of procedures, but we have refused any exceptionalism that would have led to a deterioration in the quality of our expertise procedures or to a reduction in the level of protection of persons taking part in research. We have opposed trials that have not been approved by regular research assessment committees, research ethics committees or personal protection committees. We have called for clear, open and transparent information. We have called for careful consideration of the full consequences of containment measures. We have seen how these measures create new situations of vulnerability, in particular for women and the elderly, but also for children deprived of schooling. We underlined the interest of digital methods to model the epidemic and trace contacts, but warned against the multiple risks of exclusion or discrimination of health passport techniques. Finally, we asked that vaccines be recognized as global public goods, i.e. that no one be excluded and that the use of some does not exhaust the resource for others. The temporary waivers on patents on messenger RNA vaccines was one of the levers for action, but not the only one, given the issues of access and distribution. It is difficult today to assess the precise impact of our actions that were supported at the highest level of international organization including UNESCO and WHO DGs (common declaration 24th Feb 2021). It would have been incomprehensible and undignified to say or do nothing in such a context. Sadly, selfishness and short-view of some European governments delayed for more than one year adoption of such measures at WTO, creating a dramatic distrust for vaccines, not only COVID-19 ones, in many African countries.

Activities and impact of the IEC

The IEC is composed of about twenty people appointed for a three-year term with renewal by thirds after a draw. It is composed of equal numbers of men and women, Inserm/non-Inserm, biology-medicine/humanities and social sciences, including lawyers and philosophers, and we have two foreign members and a representative of patients' associations. Since 2013, the IEC publishes 4 to 5 Opinions each year, freely available in open access on our website (6) or on the HAL open archives (7). We observe an average of 200 monthly consultations of IEC Opinions and communications on HAL and more than 5000 views of IEC pages on inserm.fr for the year. Among our instruments of visibility and interaction with our colleagues at the Institute and with a wider public, an annual meeting open to all allows us to discuss the ethics of a current issue that has been the topic of a recent Opinion and to debate the work-in-progress of the Committee's various working groups. Thanks to the hybrid format (face-to-face and videoconference), more than 300 people participate each year and the recording is then posted on our YouTube channel where it is viewed more than 500 times.

The IEC and embryo research

Some topics have been the subject of several Opinions. This is the case of research on the human embryo, on embryonic stem cells and on embryonic models for scientific use (EMSU). Our views are to promote responsible research identifying the real ethical issues, including the need to improve our basic knowledge of early human development, and the need to make more efficient medically assisted reproduction. We noticed that the legal (Conseil d'Etat), ethical (Etats Généraux de la Bioéthique) and legislative (Parliament office for scientific and technology assessment, OPECST) work preliminary to the last revision of the bioethics law in France (August 2, 2021), frequently cited our opinions and that the new legal framework of research on the human embryo on the one hand and on human stem cells on the other hand (embryonic or reprogrammed) corresponds essentially to our recommendations.

The IEC and genome editing

Another area where the IEC has had a national and international impact is genome editing. The IEC was among the first in 2015 to publish an ethical opinion on the different issues of genome editing, both in humans, animals and plants. It

should be noted here that in its 2015 report on genetics, the IBC UNESCO also took a position on human genome editing and in particular called for refraining from any heritable modification in the current state of knowledge.

The opinion of the IEC was the starting point for a dialogue with some twenty European partners, which laid the foundations for a common opinion (8). Continuing our dialogue with Latin American, African and Indian partners, this led us to propose the creation of an international NGO to promote ethical and responsible research in genome editing, ARRIGE (9), created in Paris in March 2018 and which is now pursuing its work independently even if the IEC still faithfully supports ARRIGE.

Our commitment in this field has also led us to become a partner of the international initiative Global Citizen Assembly (10) whose objective is to organize a citizen deliberation in ten different countries, followed by a deliberation of the delegates of each country and a restitution in the summer of 2023 to the United Nations Secretary General. We have established a partnership with the Regional Ethical Spaces to organize this deliberation in the fall of 2021 in 8 French regions. More than 300 citizens, including many young people (16-17 years old) thanks to the mobilization of philosophy and biology teachers, participated in this consultation over 5 days. The final restitution will be the basis of the French delegation's contribution to the global deliberation.

It is also thanks to this intense activity that I had the honor of being invited to be part of the WHO expert panel on Governance of Human Genome Editing in February 2019 to develop an international program of governance of human genome editing techniques and this report, in 3 volumes (11) covering the framework of the reflection, the governance program and recommendations was published in July 2021.

The IEC and Health Research in the South

The IEC working group dedicated to these issues has published several Opinions concerning the ethics of research conducted in collaboration with partners in the Souths, "s" as situations are diverse depending on the country and the research topic. More recently, this working group is interested in healthy volunteers involved in biomedical research. This has led to the organization of a two-days' workshop at UNESCO in Paris on February 15 and 16, 2022. The VolRethics initiative (Ethics and Healthy Volunteers in Medical Research) aims to develop an international consensus and good practice guidelines for biomedical research involving healthy volunteers. Several additional regional meetings (12) are now taking place to get an inclusive document.

Ethical issues raised by the collection and processing of massive health data

This working group was created at the end of 2020 because of the questions raised by the French government's decision to entrust the hosting of data from the National Health Data System (SNDS) collected by the Health Data Hub (HDH) to Microsoft. The IEC working group was quickly led to broaden its reflection to a wider set of ethical issues raised by the "massive" collection and processing of data that may be closely or remotely related to health data ("dataification" of research, respect for the rights of people who entrust their data, etc.). The stakes of public health but also those of privacy rights are enormous and the GPDR only partially meets these stakes. The group's work in 2021 led to a progress report published in January 2022 recognizing the importance of sharing data and the development of public health policies but pinpointing ethical issues related to informed consent, broad consent for use of personal health data being not satisfactory, and privacy protection, the US company in charge of data storage being allowed to transfer data out of GDPR-regulated EU. This reflection seems to be all the more important as the HDH is now in charge of carrying the European infrastructure for massive health data collection.

Involvement of the IEC in research in ethics

The IEC has had the opportunity to get involved in several European research projects developing ethics in new fields of research. The latest one, currently underway, is the HYBRIDA project, selected in the H2020 SwafS-28-2020 call. Its objectives are to investigate the ethical issues associated with research on organoids and related technologies. The IEC is responsible for leading the elaboration of "Operational Guidelines for researchers and Code of conduct on organoids". Organoids are new biological objects which generates many uncertainties on their nature (natural self-organized structure or artifact produced by cellular engineering), on their regulatory framework and on their uses (for example in the framework of toxicological studies, will they soon be able to replace animal experimentation as a pre-clinical stage?). Some organoids, such as complex organoids associating several structures corresponding to various areas of the nervous system (cerebroids) raise particular ethical questions: could they one day suffer? Could they one day reach a form of consciousness? A first version of the Operational Guidelines and of the Code of Conduct was submitted in October 2022. It proposes an interactive set of files to provide the Minimal Information for the Use of Organoids (MIAOU) aims to foster trust among researchers through transpar-

ency on the origins, the method to obtain, the reproducibility and robustness of results and preventing misconducts such as misnaming. It also contains a guideline with a precise list of questions (Echoes) to check for evaluators and Research Ethics Committees. This draft is available on request and will be now submitted to test by the various actors of the field to yield the final version in the end of 2023.

Involvement of the IEC in teaching ethics

The IEC also regularly participates in training activities (Inserm high potential executives, annual day of the association of biology professors, training in hospitals and clinics that request our services, etc.) by delegating one of its members.

Launch of a priority program within Inserm

The IEC is one of the promoters of the program "The Organization for Ethical and Responsible Inserm Research (Lorier)" developed within the framework of Inserm's 2021-2025 strategic plan. This program aims to reinforce and maintain the highest international standards of ethics, integrity and transparency in its medical and health research activities, and to consolidate through its action the pact of trust between society and scientific actors in medical and health research. It covers issues of ethics, integrity, deontology, reproducibility, open science, research quality and responsible research.

The work of the IEC in the wider bioethical context

Being helpful for our community is our primary goal through provision of a tool-box to think the ethical issues raised by our research activities. As science is a global activity, our works should also be situated in a wider context. It seems clear that we have recently been at origin of several international actions as described above: genome editing oversight and research with healthy volunteers to give two successful examples with impact at the level of UN agencies such as UNESCO and WHO and the foundation of an international NGO, ARRIGE. Because of my personal position in both committees, IEC influenced IBC and vice et versa. This had also some impact on activities in ethics of neurotechnologies at OECD, UNESCO and Council of Europe. Because of our various activities, we were also invited in several EU funded research projects in ethics: TRUST and HYBRIDA to take two successful applications. It is already something for a group of less

than 20 people, fully benevolent and acting as IEC members in addition to their professional activities. In the future we will continue to search for interactions with other ethics committees to promote the role of ethics as a universal compass.

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The Nuffield Council on Bioethics

Dave Archard[1]

Profile

The Nuffield Council on Bioethics (NCoB) was established by the trustees of the Nuffield Foundation in 1991, and since 1994 it has been funded jointly by the Foundation, the Medical Research Council and Wellcome. It is independent of Government and determines its own programme of work. Its original defining remit was to examine and evaluate the social, legal and moral issues arising from important developments in medical and biological research. It now understands itself as identifying, analysing, and advising on ethical issues in science and health so that decisions in these areas benefit people and society.

The NCoB comprises three elements: a Council of Members drawn from various disciplines and backgrounds that drives the intellectual function of the organisation by deciding on priority areas and on the direction, function and membership of the NCOB, being in particular responsible for developing the five-year Strategic Plan, for keeping abreast of developments in relevant areas of research, and for identifying appropriate topics and outputs; an Executive that works to support the Council in delivering its programme of work by conducting appropriate research, drafting documents, and organizing relevant activities and meetings; and a Funding Board, drawn from the organization's funders together with external experts, which is responsible for reviewing and challenging the work of the Council and Executive, providing assurance that the Council is operating within its remit and is committing expenditure in line with the terms of the grant and the goals of the Strategic Plan.

The NCoB is not committed to any particular approach to ethics nor is its work informed by any one moral theory. Nevertheless, we are guided by the following and long-standing core values underpinning how we work:

Rigour: Our approach to ethical analysis is multidisciplinary and deliberative. We draw on a wide range of expertise and experience and use the best available evidence.

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Independence: We set our own agenda and select our own topics, methodologies and outputs. We do not represent any particular group or view.

Relevance: We explore things that matter to society so we can support real-time policy developments and debates and anticipate those coming down the line.

Transparency and inclusiveness: We are open about how we conduct our work and we engage with a wide range of different voices and views. We are committed to increasing the diversity of the people we work with and creating safe and welcoming spaces for deliberation. Our outputs are designed with a view to accessibility to all audiences.Thus, some of our outputs are short briefing notes – for example on surrogacy – where in summarising the main ethical and legal issues we aim to inform and assist policy makers; others, such as blogs, are more personal statements of views intended to provoke general discussion; and our longer major Reports will be of use both to policy makers and a broader informed audience of interested stakeholders.

At the heart of our organizational work Is a Horizon Scanning function maintained by both Council and Executive. This seeks to anticipate scientific developments and health trends that pose fundamental ethical questions to society; we thus look ahead to developments and trends in science and health that are at the intersection of scientific innovation and societal challenge. These are at the forefront of any ethics policy agenda both in the United Kingdom and beyond. In the future we will work primarily within our priority areas – discussed below.

We produce a range of outputs and publications that are relevant, timely, appropriate to a topic identified as important and such that we can make a distinctive contribution to a proper understanding of the issues in question. We thus produce major Reports, shorter background documents and rapid response policy briefings, consultation responses, commissioned essays, opinion pieces and blogs.

Although independent of Government we act effectively as, and are widely viewed as, the national bioethics committee of the United Kingdom. Our immediate focus is hence policy within the UK. Nevertheless, our work has global reach and we play an important role in various international fora of national ethics committees.We attend and participate in the the EU National Ethics fora, and hold an annual meeting with the French Comite National d'Ethique and the German Deitscher Ethikrat to share work and plan collaborative projects. Beyond that, our international work includes a major collaborative series of colloquia with Chinese colleagues in ethics and law who are responsible for shaping relevant legislation and wish to draw on Nuffield Council experiences and practical advice.

The United Kingdom has a rich and diverse bioethical landscape with a variety of organizations, professional bodies, academic centres and individuals contrib-

uting to public debate on bioethical issues. The NCoB seeks to build connectivity across that landscape, to ensure that there is a shared understanding of the value of ethics in science and health policy making, and that ethics can play its proper role in that policy making.

Issues and challenges

The NCoB has always sought, and will continue to seek, to play a leading role in the identification of those key issues that arise at the intersection of scientific and social changes, and to ensure that policy making reflects a proper, informed understanding and evaluation of those issues. The work of the Council is always taken seriously. As a good recent example, our published Report on Genome editing and Farmed Animals was widely discuissed in the media and quoted as a key text by both Government and Opposition spokespersons in Parliament during the debates on the Genetic Technology (Precision Breeding) legislation.

Nevertheless, we have now identified for the immediate future three priority areas on which we will focus in our work. This focus will not be to the exclusion of responses to other matters that fall within our remit and merit attention. These priority areas are:

Reproduction, parenthood and families: Innovations in human reproduction will challenge our traditional understanding of reproductive options and choice. These include developments that seek to enhance or work alongside existing assisted reproductive technologies and those that offer new opportunities for people unable to conceive or carry biologically-related children. Amongst the most striking are the development of artificial gametes, the possible creation of 'synthetic' embryos, and on the distant horizon the prospect of ectogenesis through artificial womb technology. We will explore the regulatory framework surrounding all of these developments, as well as broader cultural and social questions about the nature of gender, the constitution of the family and our understanding of parenthood. We will, thus, produce work on surrogacy against the background of a forthcoming legal review, and contribute to the debates around any changes in the Human Fertilisation and Embryology legislation.

The mind and brain: Technologies that intervene in the brain, such as brain-computer interfaces, offer the potential to help many neurological conditions, like Parkinson's, stroke, and chronic pain. Although there are many possible benefits, the potential unintended consequences require careful consideration. The unique status of the brain as the principal organ of the mind raises ethical and social concerns around personal identity and autonomy, moral responsibility, and free will, which are not seen in the context of other biomedical technolo-

gies. The potential for non-therapeutic applications give rise to further questions about the ethics of cognitive enhancement and dual use, while the emergence of the field of 'neurorights' calls for greater consideration of rights to cognitive liberty and mental privacy and integrity.

We also note the potential use of brain scans and the resulting neuroscientific data in the criminal justice system, for example assessing competency to stand trial, criminal culpability, witness credibility, the risk someone will commit a crime or reoffend, and for lie detection purposes. Such technology even if proven to be reliable, would raise a host of ethical issues relating to coercion to undergo scanning, the framing of criminal responsibility, and the possibility of new interventions for criminals being developed.

The environment: Human health is closely connected to the health of other animals and the environment. Environmental hazards such as food contaminants and air pollution have been linked to serious illnesses, including cancer, depression and heart disease. Climate change affects the social and environmental determinants of health – clean air, safe drinking water, sufficient food and secure shelter. Responses to climate change fall into two main categories: mitigation (reducing and limiting greenhouse gas emissions); and adaptation (adjusting to current or expected effects of climate change). These responses raise considerations of justice as to how responsibility for action is to be distributed, as well as a balancing, including an equitable distribution, of the harms and benefits of different strategies (trade-offs between mitigation and adaptation strategies).

New and emerging uses of technology, such as geoengineering, present various ethical challenges around the balance of benefit and harm, equity of access, and concept of naturalness and technological solutionism.

Conversely, activities that promote human health, such as medical procedures, can have damaging effects on the environment. The One Health approach advocates sustainable healthcare policies where protecting the environment is considered an integral part of protecting human health. This requires balancing benefits and risks to humans, to non-human animals and to our shared environment.

Future role in changing society

Our commitment is to 'embed ethics' in all relevant areas of decision-making that concerns our defining remit, namely those that arise from issues at the intersection of scientific and social change, and to do so in a manner that ensures all benefit,

We can realise that commitment by anticipating scientific developments and health trends that pose fundamental ethical questions to society, by undertaking

and communicating our rigorous ethical analysis of those questions in a way that is clear and relevant to decision-makers and the public, by demonstrating the value of ethics to society and decision-makers, and by building connections across the national bioethics community to strengthen the voice of bioethics in policy and broader public debate.

We occupy a unique position as the recognised national bioethics committee and with an established reputation, both nationally and internationally, for our past work on key issues. Yet our commitment to influence decision-making requires working with others, Thus, it is important to engage with a range of individuals and organizations and to do so in a variety of ways. Such public engagement ensures that our work is informed by an understanding of what matters to people and our extensive and ongoing consultation with relevant experts ensures that our work is robust and appropriately informed. This engagement also works the other way by ensuring that we maximise our influence and can encourage the uptake of recommendations.

Our key audiences include Government (Departments and official agencies), regulators, policy and health organizations, communities of individuals with lived experience of relevant issues, journalists and the media, industry, health professionals, researchers, and research funders.

Impact on policy requires proven expertise, and we draw both from our own Council Membership and Executive team, as well work with external subject leaders and professionals on specific projects. Research evidence and expert advice is crucial to demonstrating that our analysis and recommendations have a clear evidence base or robust supporting argumentation.

We also strive to collaborate and form partnerships with relevant organizations. For instance, we are completing a joint project on Artificial Intelligence and genomics with the Ada Lovelace Institute to examine how AI is transforming genomic science and what such a transformation could mean for people and society.

We worked with the Universities of Oxford, Bristol, Edinburgh, and London to establish a UKRI-funded Ethics Accelerator, a collaborative effort to harness the work of the academic bioethics community that it might influence public debate and policy decision-making.

To ensure policy impact we will embed ethics directly in decision-making by being represented on official bodies. For instance, the Chair of the NCoB is a member of the United Kingdom's National Genomics Board which is responsible for overseeing and implementing the national genomics strategy.

We will undertake appropriate policy work that is commissioned by Government, such as a project on disagreements between parents and clinicians concerning the treatment of children.

Finally, we will seek, where we can, to undertake major public engagement exercises that influence policy. For instance, we published a substantial report on genome editing of farmed animals and worked with other organizations to produce a public dialogue on this topic. This work, as noted earlier, was extensively reported and cited in Parliamentary debate during the passage of relevant legislation.

We will also lead a major public engagement project in the form of a citizens' jury on the important issue of assisted dying, where there is an urgent need for legal clarification and where public attitudes can significantly influence the decision-making. A Citizens' Jury comprises 12-24 people representative of the demographics of a given area or society, coming together to deliberate on an issue (usually one clearly framed question) over a period of time. These are particularly effective on "value-laden and controversial questions, where knowledge is contested and there might be important ethical and social repercussions. In this way we hope to inform and structure a critical debate on a major issue.

References

For more on our recent work, who we are and what we plan to do, see our web page: https://www.nuffieldbioethics.org/

Bioethics in Central and Eastern Europe
Learning from the Past, Facing New Challenges

Jozef Glasa[1]

1. Introduction

This brief essay aims to reflect upon an already vast and increasingly complex field of bioethics developing in a culturally and historically rich, and very heterogenous region of countries, sometimes, non-geographically, called *Central and Eastern Europe* (*CEE*). For this essay, we shall understand CEE as comprising the European countries of the former Euro-Asian 'Soviet bloc', that have been liberated in the early 1990-ies from the so-called 'communist' (or 'real socialist') totalitarian auto- or plutocracies of the 'Cold War' era. These surprising and mostly unexpected developments were enabled after the falling of the infamous 'Iron Curtain', built in the aftermath of World War II (WWII) between then increasingly antagonist 'Soviet' and 'Western Europe' (WE) blocs. Thus, a rather long-time unexperienced freedom, democracy, and novel entrepreneurship have suddenly been re-introduced into the CEE countries and their societies.

Since then, more than three decades of very complex, unprecedented economic, political, cultural, and social advancements in CEE countries brought in a lot of positive progress and, after those very painful transitional years or decades, also much sought economic and social prosperity, as was increasingly the case before arrival of the disastrous Covid-19 pandemic. Unfortunately, many of these hard-earned gains are being cut away at present both due to the troublesome consequences of the pandemic, but even more because of the effects of the horrendous, fratricidal war of aggression waged against Ukraine by the Russian Federation on February 24, 2022.

Albeit most of the hard 'transitional work' had to be done by the CEE peoples and professionals themselves, multiple help in almost all possible aspects of these complex efforts and developments, given by the scores of individual people, or-

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ganizations, and institutions stemming from the 'Free World' (mainly WE, USA), was crucial. On a larger, institutional scale, this indispensable help materialised within the 'accession processes' of the 'candidate CEE countries' to the European Union (EU). The profound reforms and changes required to enter the 'EU club', affecting all of the most important sectors of the transitioning, still rather fragile 'new democracies', pushed these CEE countries up and forward within the scales and speeds they would have been unable to achieve otherwise.

Bioethics, at least as me and many of my colleagues from its founding generations in CEE probably would see it, was, somehow, from its almost invisible advent into the very complex and dynamic cultural, professional, educational, and scientific CEE realities, both a sign of the new era and, increasingly, also an active part of those unprecedented changes taking place, in particular in the CEE countries' biomedical research, medicine, nursing, and health care sectors. (8) Including in the related legislative, educational, and public debate developments. This entailed, to a very considerable extent, also an extensive international collaboration and exchange among the CEE bioethicists themselves, including those from Russia, Ukraine, and Belorussia, as well as with their colleagues in WE, USA, and beyond. (2, 19)

2. Establishing Bioethics in CEE

Filling in the 'Post-Totalitarian' Vacuums, Fostering Renewal

Soon after the fall of the 'communist' totalitarian regimes in CEE, rather vast moral and cultural vacuums left behind by the disgraced Marxist-Leninist (M-L) ideology became visible. It was even more so because of the now dismissed, but previously very hard, debilitating grip M-L ideology exercised both upon everyday peoples' lives, but, especially, upon the societies' sectors of education, humanities, all kinds of research, culture, and arts. What a sad, Orwellian (20) picture that was, continuing for long-long decades. Therefore, all of a sudden arrival of freedom took almost all by a big surprise. To many, it was bringing in never-before-known opportunities, genuine joyful feelings of hope, and newly found and freely accepted (but ultimately rather short-lived) social cohesion. (14)

Indeed, with exception of the former Soviet Union countries, with almost no experience ever of a functioning democracy, after 40 years of the post-WWII totalitarian developments in CEE, people with real-life democratic experience and memories of a non-ML 'normalcy', were then mostly about to enter their retirements. Still, they were able, to some extent, to inform the people of the current and the newly coming, younger generations. Also, they tried hard, sometimes to no avail, to offer their personal experience and genuine 'totalitarian era' life

stories as warning pointers within the quickly evolving everyday realities. Unfortunately, the real damages, deeply smashing and yet unhealed wounds and scars left behind from the previous totalitarian times in both individual and collective identity, psyche, and cultures were yet to be learned to have been much worse, crippling, deeper, and long-lived than anyone could ever have imagined.[2] Indeed, the newly achieved freedom had become rather difficult to understand, handle, and use for the good – the individual, and common. (10) Nobody seemed to be sufficiently prepared for this.

The newly opened vacuums, however, were to be soon and rather quickly filled in. By a wide variety of contents to be provided by different protagonists of various, sometimes rather contradictory ways of thought, stemming from a plethora of backgrounds and educational – professional milieus. Both of domestic and international origin. (16)

Bioethics in CEE, from its very beginning, was to be an interesting part of the ongoing, rather quiet, but immensely profound cultural and moral developments (or attempted 'revolutions'). (2, 3, 4) The major, almost uniting, original aims of these efforts were to bring about the needy moral, intellectual, cultural, and somewhere also spiritual renewals, deemed to be the *sine qua non* prerequisites for the successful developments toward free, democratic, and prosperous CEE societies. (9, 10) Soon on, however, these rather noble goals and enthusiastic ideas were put under many troublesome challenges, because of some less fortunate developments and some new CEE realities.[3] (13)

Protagonists of the Early CEE Bioethics

Interestingly, the people to step into the early bioethics developments in CEE were stemming from rather different professional and cultural backgrounds. (10, 14)

An important, albeit not too numerous group, was comprised of intellectuals, sometimes gathered in small groups, formerly dissenting against the ruling M-L pseudoscience and ideology. They were developing their philosophical, theological, environmentalist, or other studies in almost clandestine conditions, in privacy,

[2] It is safe to acknowledge that those are still at the core of many of the problems seen in CEE even in our days.

[3] Indeed, the 'young, rather unexperienced democracies' in CEE were (and still are) prone to fall for dangerous populistic, semi-totalitarian, and somewhat oppressive or tightened societal models, fostered by pressures of the actual real-life problems and disillusions, emotions-filled nostalgias for the past, and still rising support for the 'strong leaders', expected to just 'put all things right and in order' (and quickly).

sometimes risking everything in publishing the so-called 'samizdats'[4], while some of them achieved considerable intellectual and moral quality and distinguished scholarship.

A special subcategory of this group entailed the clandestine intellectual groups of various prohibited religious orders or communities (including underground theology faculties and priestly seminaries). They were often able to reach out (with considerable risks) to young people, especially students, 'to keep up the torch of hope and free thought' in those very adversarial circumstances. Some of their clandestine pupils, inspired by this life-orienting experience, chose to pursue careers in humanities, including bioethics.

Importantly, the inner space of functioning families, despite all untoward outer pressures, served as a much cherished, relatively safe, sometimes almost clandestine place for free thought and expression, for intellectual and spiritual resilience or resistance. Indeed, there were scores of true 'prisoners (and even martyrs) of conscience'.

Interestingly, there was also another, rather different group: university teachers and research professionals in humanities, originally almost totally ruled by the M-L ideology. They were somehow able to professionally 'survive' and later flourish at some universities or research institutes. Some of these academics successfully became active in the bioethics field, even internationally, claiming their newly found 'liberal' or 'humanistic' backgrounds.

After setting open the previously barred CEE's intellectual and cultural 'doors and windows', the CEE area of intellectual inquiry became quickly frequented by scholars, enthusiasts, and various professionals stemming from the other side of the former 'Iron Curtain'. Their interest was genuine, if sometimes a bit misled by certain prejudices or misunderstandings, but usually very respectful and good willing. They were also bringing in a lot of useful and free professional help.

Last but not least, there was a group of young, incoming scholars of new generations, who experienced still shorter parts of their early careers spoiled by M-L ideologies and were increasingly able to use the newly accessible opportunities of travel and study abroad. Sometimes at very renowned academic centres in WE, and overseas. Their enthusiasm, curiosity, intellectual and language capabilities – as well as most generous and honest, albeit sometimes rather demanding attitudes, enabled them to grow quickly, and became an important manpower inflow into the field of humanities, including bioethics. With their refreshing youthful open-mindedness, criticism, and creativity.

[4] Samizdats – self-edited and secretly printed and distributed journals, brochures, and even book series.

Early International Help and Collaborations

Besides the help and contributions to CEE bioethicists provided on an almost individual basis, as highlighted above, there were, already early on, several initiatives and useful programs made available to them by various organizations or institutions from abroad (WE and overseas).

One of the early, but far-reaching activities that helped to start and develop bioethics in and for the CEE region, was the unique CEE Program of the Hastings Center (NY, USA), launched in the early 1990-ties. (16) It brought a handful of talented, mostly younger scholars from CEE countries to stay for a couple of weeks at the Center to experience 'how bioethics was done there'. Moreover, some of the newly emerging CEE bioethics groups or centres were invited to join the Center's broadly international 'Goals of Medicine' Research Project. Its conferences, some of them held in CEE, were among the first opportunities for future CEE bioethicists from different countries to meet, become colleagues and friends, and to discuss enthusiastically their newly discovered, dynamic discipline, which was to become their life-long hobby or a truly professional commitment. Soon on, they were able to organise their own meetings and initiatives, emulating what they were able to see and learn.

There were, later on, similar activities sponsored by other European or even oversea bioethics centres and some intergovernmental bodies. Among those making a huge difference for the CEE bioethics development, were the work and various activities of the Council of Europe (CoE) Steering Committee on Bioethics (CDBI),[5] including the ones of the Standing Committee on National Bioethics Committees and Similar Bodies (COMETH).[6]

The same could be stated about various initiatives and programs related to the bioethics field run by the departments of the European Commission (EC). Examples may include the meetings of the National Ethics Committees' (NECs') (and similar bodies') chairs and secretaries (later on transformed into today's NEC Forum), opinions-producing work and outreach activities of the European Group on Ethics of Science and New Technologies (EGE), the programs and other activities of the EC Department of Science and Society, including the pivotal activities aimed to 'embed bioethics' into the Framework Program, and subsequent research programs funded by the Commission (EC) (at present, the Program

[5] CDBI was established in 1992 to follow the activities of the CoE's *Ad hoc* Committee on Bioethics (CAHBI) existing since 1985. At present, it exists as the CoE's Steering Committee on Human Rights in the Field of Biomedicine (CDBIO). Additional information available at the CDBIO webpage at https://www.coe.int/en/web/bioethics/home

[6] COMETH, working closely with CDBI, helped to establish and develop national bioethics committees or similar bodies in countries where these had not been yet established.

'Horizon Europe'[7] (2021-2027)), and organising both ethics evaluation of biomedical research proposals and ethics monitoring of the approved research projects. Strongly encouraged and gradually increasing participation of CEE bioethics experts and centres provided excellent, highly valuable, and helpful educational and research collaboration opportunities.

Establishing CEE Bioethics Institutions

Within the collaborations and exchanges entailed in the scores of bioethics activities, only partially outlined above, the protagonists of bioethics in CEE – with a lot of enthusiasm and effort, sometimes operating in very limited conditions ('almost non-existent', usually starting from scratch), were able, in a step-by-step manner, to establish the necessary bioethics institutions, such as the ethics committees (research, clinical, and 'national' (NECs)) (11, 12), academia teaching and research centres (5, 6), professional journals, and organising scores of professional bioethics meetings, domestic and international. Thus, establishing important institutional foundations of bioethics in their respective countries, and in the CEE region.

Very soon, via the already mentioned international collaborations, they were also able to contribute to the bioethics activities and research going on in Europe and even in a broader international square. For a limited time, there even existed the CEE Association of Bioethics (approximately 1999-2002) (22), which was originally meant to become part of the International Association of Bioethics (IAB). Its activities, regrettably, were terminated rather early, due to the lack of necessary operational resources.

Keeping the Pace with Contemporary Bioethics

Importantly, bioethicists stemming from, living, and working in CEE countries, take an active part in today's bioethics works and initiatives – domestic, European, and overseas. They aim to provide scholarly contributions to its present discussions, activities, and quandaries. (17, 18) They seem to be rather well-posed to provide interesting, innovative points of view, including those stemming from their distinctive historical and professional experiences.

However, with quickly increasing CEE – WE interconnection and speeding of multilayer and multifaceted globalization developments, affecting the lives and cultures of their respective societies and academic communities, the styles of work and kinds of problems dealt with by the CEE bioethicists – both in the professional (i.e., scientific, research, educational, publishing), organizational, and

[7] Additional information is available at the official Program Horizon Europe website at https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

existential (i.e., questions on how to 'survive' the sometimes rather stern conditions for humanities in today's academic and broader worlds) realms – seem to be increasingly similar to those of their colleagues from WE, USA, or from the other, rather well off, developed nations around the Globe. (21)

This seems to be true also for rather vast and multifaceted sets of bioethics (and biolaw) issues they are supposed to deal with. Both in their academic research, and in more or less visible public squares – domestic, and international. Thus, coming into, and contributing to the developments within the already huge, and prospectively growing knowledge body of international ('Global') bioethics, and its applications.

3. Present Issues and Challenges for CEE Bioethics

Issues of Content

The growing field of bioethics in CEE countries gradually, sometimes unexpectedly, had firstly been engaged with scores of ethical issues brought in by the transitional processes in CEE medicine, health care provision, and life sciences research. (15) These resulted in the need for rather quick development of (and 'bioethics input' into) substantive numbers of new legislations, deemed necessary for the successful transitioning from the totalitarian, state-owned, planned, and run health care, education, and (biomedical) research and development systems, toward the freer, democratic, and pluralistic ones.[8]

Interestingly, up till nowadays, the CEE societies – and bioethicists, have been considerably engaged (sometimes deeply entrenched) in dealing with the 'classical bioethical issues', such as those involved in abortion, human reproductive medicine, euthanasia, end-of-life care, physician-patient relationship, shadowy out-of-the-pocket patients' payments (i.e., tipping, or corrupting health care professionals), patients' rights, accessibility of health care and others. (2, 14)

In parallel, bioethics problems dealt with in the international professional and political arenas were increasingly brought to the CEE bioethicists' considerations. These had to be adequately addressed also in CEE countries, not least because of the said developments of the respective national public policies and internationally compatible domestic legislations (especially important for the 'EU candi-

[8] I.e., not dominated anymore by the outgoing totalitarian M-L ideology and power structures. These efforts included legislating for the first time on some of the practical issues in biomedicine and health care provision, loaded with strong or constitutive bioethics components. These processes, running with smoother or bumpier courses ever since their unexpected beginnings in 1990-ies, are still ongoing, trying to meet the steadily incoming 'challenges of the day'.

date countries' during their accession processes to achieve full EU memberships). (21)

A strong interest of the CEE researchers and research institutions in active participation in international research and development activities quickly brought in the need to have the respective national parts of international projects of biomedical research, including clinical trials, reviewed by independent (research) ethics committees. These *sine qua non* type requirements were important for establishing, developing, or improving such domestic ethics review structures, including the development and conduct of necessary education and training activities. (1, 7, 12) Therefore, research ethics issues were of strong interest ever since.

The broadening of the scope of ethical evaluation and reasoning from originally predominant ethical problems of medicine and health care towards engaging with ethical issues related to new technologies, broader life sciences, and the environment, have become visible also in CEE, including establishing more specialized local or national (research) ethics committees, as well as novel bioethics research projects, programs, or centres.

Moreover, via participation in high-quality international research or educational projects and in various international bodies, CEE bioethicists were able to engage directly in important international ethical discourses.

When Disasters Struck

The seemingly 'normal developments' of CEE bioethics, however, have been put under considerable strain during the last two-three years. This has been due to the consequences of two consecutive, already global disasters: the Covid-19 pandemic, and the war in Ukraine.

The first of the catastrophes – the Covid-19 pandemic, brought unprecedented rises in both morbidity and mortality also into CEE countries, and led to serious depletions of already limited human and material resources, predominantly suffered in health care sectors. Those were temporarily unable to cope, leading to situations, where triage procedures for Covid-19 and other patients had to be implemented at the local, regional, or national levels. On top of the public health and healthcare disastrous developments, all sectors of the CEE societies did suffer greatly. In these situations, bioethicists in most of the CEE countries were able to actively join the common efforts of combating those unprecedented, daring situations.[9](8)

[9] *E.g.*, by taking part in the national consultative or managerial 'pandemic teams', providing professional advice in situations of very complex, demanding decision-making done in the conditions of scarcity, great pressures, quick changes, and gut-wrenching uncertainty. Rather often, usually as members of their countries' NECs or leading academic institutions, they were able to produce

Since February 24, 2022, however, the terrible consequences of the fratricidal war in Ukraine were quickly superimposed upon the CEE countries and their communities that still had not been able to recuperate from the multiple, multisectoral, and multifaceted crises brought about by the pandemic. Very unfortunately, the piling breaches of any sound morality and law '*inter arma*', perpetrated mostly by the aggressor, amount nowadays to blatant war crimes, horrible violations of the Geneva Conventions, and horrendous crimes against humanity. All this is happening upon the broadest, shattering scale. The economic consequences are already bringing in miserable poverty and multilayered insecurity. The refugees' crisis, so far extraordinarily managed both by Ukraine bordering CEE nations (esp. Poland, Slovakia, Romania, Moldova), who take most of it, as well as by several WE countries and others, is huge, and its long-term untoward consequences are yet at least unclear.

These developments do have serious, much unpredictable influence on the evolving moral, cultural, and political realities in struggling CEE (and WE) societies. The emerging trends toward increasing populism, nationalism, political and social fragmentation, and moral and intellectual degradation of the public squares are alarming. As is the ideologization of public debate, science, and research. Thus, repeated running of the communities or peoples in CEE (and elsewhere) into the 'old' dead-ended or otherwise dangerous avenues cannot be easily prevented.

Public Engagement and Relevance

In so diverse, and dynamically evolving situations, just briefly sketched above, including the genuine existential struggles of the societies both in CEE and WE (and globally), the possibilities of some reasonable and useful contributions of bioethics and its active representatives to cogent solutions finding or, at least, to clearer conceptualizations of the ethical issues and ethically loaded problems involved, may seem rather limited.

However, notwithstanding all untoward odds, there seems to exist a rather strong conviction, shared by many, that bioethics and bioethicists in CEE (and WE, and elsewhere) must just not give up. Despite often facing the situations of being side-lined, not listened to, or, sometimes, even silenced by various ideologically or politically motivated pressures.

Indeed, bioethics – in CEE and elsewhere – must not abandon its original mission: to work tirelessly for making the present and future world at least a bit better, safer, and more joyful place. To foster genuine individual and common good, humane flourishing, and true societal development.

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public statements or opinions on practically important ethical issues involved in the development and implementation of 'pandemic-related' public policies and legislations.

Therefore, its 'agents' – nowadays' bioethicists, may want to understand themselves again as being called up not only to deepen and broaden their ethical inquiry efforts and to engage in the important present and near future intellectual discourses and discerning work. Importantly, they must also be prepared to go into the public square and to approach, in their undeniable expert capacities, the societal decision-making structures. Bringing in sound reason and well-founded arguments to enlighten difficult, sometimes truly existential societal quandaries. Including those arising from the exponentially speeding and growing scientific, technical, and technological progress. Only then, bioethics and its active representatives in CEE (and elsewhere) would keep up their unshattered professional and societal relevance, as well as the real possibilities to influence the said complicated, sometimes dangerous, and highly dynamic processes to their possibly good and somewhat safer outcomes.

Long-Term Sustainability and Development

The said difficult situations and developments in CEE (and elsewhere), in the wake of still ongoing disasters of the latest years, put considerable strains upon the provision of personal and material resources for various sectors of the 'societies under pressure'. As the states, societies, and their respective communities increasingly struggle to meet their basic needs and to provide the needed goods and services to their members, the necessary allocations to 'seemingly not-so-vital' societal sectors may be put into jeopardy.

These untoward developments may also include the waning support of culture, research, and education in humanities, possibly favouring the 'necessary goods and services' producing sectors. This may translate itself into diminishing possibilities for young professionals of entering the bioethics field, as well as sustaining (not to mention developing) the existing university or other academic bioethics institutes or centres. Thus, the real professional capacities in bioethics, so successfully developed in CEE (and elsewhere) during the previous decades, may in some places be put into decline, or may even be lost.

These considerable risks are already being seen to materialize in some CEE countries that are, in most of the vitally important aspects of their economic, cultural, research, education, and political realities, much more fragile and vulnerable than their WE counterparts. The unprecedented 'brain drain' of young, prospective professionals, leaving for better (and so far, also much safer) living and working conditions in the WE countries ('Golden West'), or overseas, is quickly leaving behind scores of deepening and broadening holes or gaps that are not at all easily dealt with, filled in, or bridged.

The said developments are mostly beyond the effective reach of bioethics protagonists to allow their meaningful mitigation. So, despite the interest and need

for genuine bioethics expertise and professional advisory work may increase (as the novel bioethics problems will arise, being themselves more difficult to understand and deal with), keeping and development of bioethics capacities, including the achievement of professional qualifications and opportunities to work in the field, may need an extra personal effort and even stronger 'professional devotion'.

These truly existential problems of bioethics and bioethicists in CEE (and elsewhere) will need to be appropriately dealt with by the present and incoming bioethics leaderships – and the societies and communities, where they live and work – to enable the necessary sustainable developments. And, at the same time, to keep the fundamentally needed professional independence in the possibly increasingly ideologized academic and societal milieus.

4. Possible Future Perspectives

Approaching the last part of this essay, let us consider possible perspectives bioethics and its protagonists have in CEE countries, while it and them being already well networked into the formidable field of international or even global bioethics, and, hopefully, at the same time not losing its and theirs possibly distinctive characteristics, ways of thinking, approaches, and attitudes to bioethics issues, stemming from its and their professional memories, works, and rather difficult developments during the demanding periods of the former societal transitions.

We must acknowledge that many important factors of possible future CEE bioethics developments are locked today under the dense fog of uncertainty regarding the overall political, even military, economic, cultural, and also religious developments resulting from the current and near-future CEE (and WE and global) developments in the said volatile, dynamic, and rather dangerous realms. These include the seemingly serious risk of building up again the new 'Iron Curtain' in Europe (with possible novel 'metastases' around the Globe) alongside the newly cut divisions introduced by the inexcusable, barbaric war in Ukraine.

Thus, the real-life conditions for the future existence and possible positive developments of bioethics in CEE (and beyond) are hard to predict, and less so to guarantee. We are left here at best with a strong hope, or belief, that these determining European and Global developments will ultimately turn to the good side – the looming existential disasters for the Continent and the Globe (i.e., for Mankind as a whole) being averted, and the positive, genuinely good developments ensue. Those, as seen during the said transition processes in CEE, will not be possible without a strong moral/ethical overhaul in all sectors of the CEE (and other) societies and communities of the nearer or more remote future. Thereby,

bioethics and its protagonists, if well, adequately intellectually and morally prepared, may become again integral and very useful parts of these necessary and truly positive changes. Therefore, sustaining and developing the professional and institutional bioethics capacities in CEE (and elsewhere) has never been more relevant and necessary. As well as the genuine day-to-day professional work of bioethicists at various academic and other important places within the said CEE (and other) societies and communities.

5. Conclusions

Bioethics in the CEE countries has developed – during the previous three to four decades of a more freely, often much demanding, transitional political, social, cultural and economic developments seen in this formidable, historically and culturally rich and distinct European and World region – into a well-established academic and real-life practice-oriented discipline with already impressive recent history and experience of the self-standing professional, research, and educational work, and of rather strong public engagement on the local, national and international level, working since its beginnings within strong international networks of collaboration and exchange. Thus, being already a distinct and fruitful part of the international or Global bioethics endeavour. Hopefully, in the nearer and more remote future, the CEE bioethics will be able to contribute, distinctively and creatively, to positive developments in both the discipline itself, as well as to finding good, truly beneficial solutions to the present and new ethical quandaries the growing, and possibly well-maturing Mankind will face, while walking its far-reaching, risky, but ultimately successful paths on this Earth (and beyond).

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5. Eastern Mediterranean Region
(EMR)

Supporting Bioethics in the EMR: WHO Perspectives

Ahmed Mandil[1]

While traditional medical ethics is principally focusing on healthcare, the focus of bioethics is mainly society oriented and usually limited to ethical questions related to health research and application of biotechnology in medicine and biology (Nordic Committee on Bioethics, 2002). On the other hand, research ethics ascended to address ethical concerns arising from conducting research on human subjects (European Commission, 2010). The key ethical principles of health research codes include objectivity, integrity, openness, respect for intellectual property, confidentiality, and responsible publication (Resnik D).

Since the 1990s, the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) have worked closely with UNESCO/Arab States in supporting development and fostering of National Ethics / Bioethics Committees in the Eastern Mediterranean Region (EMR) via different activities including capacity building activities, conducted meetings as well as having standing UNESCO membership of the Eastern Mediterranean – Research Ethics Review Committee (RERC). Examples of meetings include conducting Regional Bioethics Summits (Muscat, Oman 2017; Cairo, Egypt 2019), planning for a third one during May 2023 in Muscat Oman in coordination with the National Ethics Committee in Oman. Moreover, representatives of several National Ethics / Bioethics Committees participated in the recent "13th Global Summit on National Ethics Committees", which was hosted by the "Portuguese National Council of Ethics for the Life Sciences" during September 2022. They represented such committees from Egypt, Iran, Lebanon, Morocco, Oman, Pakistan, Saudi Arabia and Tunisia. The Region is also looking forward to participation in the upcoming Summit planned to be held in San Marino during 2024. Moreover, WHO/EMRO conducted several capacity building activities on research ethics as well as ethics in implementation research, which were conducted in collaboration with Institute Pasteur of Tunis on almost annual basis during 2015-2022. Examples of jointly organized capacity building activities included national "research ethics workshops" in Bei-

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rut, Lebanon (2017) and Damascus, Syria (2019) as well as a regional "workshop on ethics in implementation research" at WHO/EMRO, Cairo, Egypt (2019).

WHO/EMRO supported development of WHO Collaborating Centers (WHO-CC) on bioethics in the EMR, now hosted by 3 institutions in Iran (Center of Medical Ethics, Tehran University of Medical Sciences) since 2020; Lebanon (Salim El-Hoss Bioethics and Professionalism Program, American University of Beirut & Medical Center) since 2021 and Pakistan (Centre of Biomedical Ethics and Culture, Sindh Institute of Urology & Transplantation) since 2019. These WHO-CCs have been active in support of different bioethics-related activities in the EMR, especially during pandemic response (2020-2022) *e.g.*, jointly planned and conducted virtual webinars (on equity) and capacity building activities. Examples include a webinar on: "Fair, Equitable and Timely Allocation of Covid-19 Vaccines in the Arab States/ Eastern Mediterranean Region", jointly coordinated by WHO/EMRO, UNESCO/Arab States and the League of Arab States, 6 December 2021; and a hybrid seminar on: "Scientific and Ethical Challenges in Human Reproduction: Perspectives from EMR" coordinated by CBEC and WHO/EMRO, 12-13 December, 2022.

In addition, the Eastern Mediterranean Health Journal (EMHJ), the flagship public health journal of WHO/EMRO, has formulated and online published ethical guidelines for scientific conduct of research on human subjects and sharing its outcomes with the scientific community. The document is titled: "EMHJ Guideline on Ethical Conduct and Publication of Health Research" (https://www.emro.who.int/emh-journal/authors/emhj-guidelines-on-ethical-conduct-and-publication-of-health-research.html), and based on international guidelines including those provided by the Council for International Organizations of Medical Sciences (CIOMS); World Medical Association's Declaration of Helsinki; Committee on Publication Ethics (COPE); the World Association of Medical Editors (WAME), and the International Committee of Medical Journal Editors (ICMJE).

In 2012, WHO published its "strategy on research for health" (WHO, 2012) emphasizing 4 pillars of: priorities (meeting health needs); capacities (strengthening health research systems); standards (good research practice); and translation (evidence to practice). Similarly, the 2013 World Health Report (Research for universal health coverage, WHO, 2013) emphasized the role of WHO in advancing research that addresses the dominant health needs of countries and setting norms and standards for proper conduct of research. To ensure the scientific rigour and ethical conduct of health research recommended for WHO funding, the Eastern Mediterranean – Research Ethics Review Committee (EM-RERC) was established back in 2007 (WHO, 2015). The Committee was reformulated in 2021 to include external (from Egypt, Iran, Lebanon, Pakistan, Palestine, Sudan, Tunisia, UNESCO standing membership) as well as in-house (WHO/EMRO)

members representing its different overall areas of work, including: Science, Information & Dissemination; Health Systems; Communicable Diseases; Noncommunicable Diseases & Mental Health; Healthier Populations; and Health Emergencies. Its primary function is to "review the protocols of all health research projects involving human subjects and disease surveillance activities submitted to WHO for funding in the Region" in order to safeguard the dignity, integrity, human rights, safety and well-being of all the human participants. The RERC also has the authority to verify that ongoing studies comply with WHO policies and regulations for the conduct of health research in the Region. To enhance observing ethics in health research and medical practice in the EMR, attention was given to ensuring compatibility of the Committee's work with international guidelines for health research, including the Council for International Organizations of Medical Sciences (CIOMS)-WHO and UNESCO guides. Additionally, updating the ethical review process took place through critical review of the currently used checklists for the review of submitted research proposals and sections on research on vulnerable groups including minors (under 18 years) and pregnant women as well as research during emergencies were added.

The EM-RERC recommends developing/enforcing national laws and regulations which govern bioethics and related research, urging vigilance by editors of scientific journals to avoid fraud and falsification of outcomes of health research, developing / accrediting national bioethics committees which could oversee the work of institutional committees, establishing ethical review committees according to need, establishing national registries for clinical trials and research, regulating pharmaceutical companies' contributions to clinical studies and ensuring a rigorous ethical review process on different levels (institutional, national, regional).

WHO/EMRO coordinates different Calls for Proposals via its "Research Promotion & Development" unit, Science, Information & Dissemination Division. These include Calls for "Research in Priority Areas in Public Health (RPPH)"; Tropical Disease Research – Impact Grants Scheme (TDR-IGS); Special Calls for: COVID-19 Research, Migration Health Research; International Health Regulations & Health Security Preparedness. More information could be accessed at this weblink: https://www.emro.who.int/rpc/grants/ . Challenges for conducting and coordinating such Calls include: sustainability of funding for research grants; completing WHO requirements for contractual agreements; obtaining national / institutional ethical clearance which is pre-requisite for processing WHO's grants; receiving technical / financial review at designated times as per contractual agreements; ensuring sharing research outcomes with the scientific community.

WHO/EMRO aims to continued encouragement / soliciting research on public health priorities in the Region, especially on crises and emergencies, use the

expertise of current global WHO collaborating centers for bioethics-related matters (especially hosted by EMR institutions), support development of a regional WHO-CC network on bioethics and support capacity-building activities in bioethics/ethical conduct of health research. Special consideration also is given to conduct capacity building activities to address the existing gaps in ethics in medical practice and health research in EMR.

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Lebanese View on Bioethics: Past, Present, and Future Challenges

Michel Daher[1]

Background

Lebanon is a country in the Eastern Mediterranean region which is the cradle of the three major monotheistic religions, Judaism, Christianity and Islam. It is important to remind that Lebanon was one of the first countries to adopt the Universal Declaration of Human Rights of the United Nations (UDHR UN1948) where in its first Article it says: "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood". Dr. Charles Malek, the official delegate of Lebanon to the UN, was the Secretary General of the Committee who drafted the Declaration which was presented to the UN for approval. In this old picture, we can see the 3 members of the committee: Mrs. Eleanor Roosevelt (United States), Professor Rene Cassin (France), and Dr. Charles Malek on the left (Lebanon).

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Since then, the unprecedented progress in biomedical sciences and technology has been accompanied by profound transformations in the concepts of health and disease, health systems and health care organization and practices. A broad range of ethical dilemmas, which could not be adequately managed by the classical ethical principles, has accompanied those transformations.

This process generated a growing interest in the ethical aspects of the medical and healthcare practices, not only among professionals but also among the whole society. At the same time, this situation represents a challenging task for the medical schools and institutes of health professionals' education requiring a comprehensive outlook and effective management.

Bioethics became a debatable topic in Lebanon among the health professionals and the public opinion in the 80s following a series of bioethics seminars during local congresses (Middle Eastern Oncology Congress in 1982, 1984, 1986, 1988) organized by the Lebanese Cancer Society where the Ethical issues at the end-of-life, the ethics of palliative care, communication with patient in advanced disease, were discussed and recommendations suggested to the policy makers.

In the early 90s, an important forum took place at the Lebanese Order of Physicians about the Ethics Education and a program proposed. The Faculties of Medicine of both the American University of Beirut, and Saint Joseph University started an undergraduate course in ethics, including the Code of Medical Ethics and Bioethics. The 5 other faculties of Medicine and Medical Sciences and the Faculty of Health Sciences, and Schools of Nursing created successively during the following decades also adopted an undergraduate Ethics and Bioethics curricula. In parallel, many conferences, symposia and seminars were organized discussing hot topics in this field (Ethics of End-of-Life care, Ethics of Research on Human subject, Organ Donation, Education of Bioethics in Universities, Patients' Rights), and promoting the creation of a National Ethics/Bioethics Committee.

Finally, and after many attempts with policy makers, the Lebanese National Consultative Committee on Ethics was created on May 15, 2001 by the Prime Minister by virtue of the Decree No. 63 /2001.

The Lebanese National Consultative Committee on Ethics (LNCCE/CCNLE)

CCNLE

اللجنة الاستشارية الوطنية اللبنانية لأخلاقيات علوم الحياة والصحة

Comité Consultatif National Libanais d'Ethique

Lebanese National Consultative Committee on Ethics

The Lebanese National Consultative Committee on Ethics (LNCCE), Le Comite Consultatif National Libanais d'Ethique (CCNLE), was created by the Ministry Council in 2001, Decree No: 63/2001 (15/5/2001), recognized of public interest. it comprises 22 members (all volunteers), appointed by the President of the Council of Ministers, of different disciplines and backgrounds (sociologists, physicians and other health professionals, legal experts, men of religion, philosophers, researchers, and other academics). Its primary mission is to provide advice, draft decrees and laws on ethical and social issues raised by the progress of science in the fields of biology, medicine and health, propose recommendations and guidelines, and promote education. It can be sought by the President of the Republic, the President of the Parliament, any governmental committee, institutions of higher education, public or private centers whose activities might have ethical implications in the field of health and medicine, or self-referral.

The work within the LNCCE/ CCNLE is carried out by three bodies:

- The Plenary Committee, a deliberative body that meets monthly to discuss and debate opinions, guidelines, draft laws, and other projects underway. The LNCCE operates in accordance with its bylaws, which provides for a quorum of half the Committee members for the adoption of any of its projects;
- The Executive Committee, comprising the President, Vice President and Secretary General, whose role is to ensure the proper functioning of LNCCE work and implement the decisions, guidelines, draft laws, revised or submitted by the Plenary committee;
- The sub-committees or working groups in each problematic issue in the field of bioethics referred to the LNCCE for opinion is first studied by a working group composed of members of the Committee who can call upon experts from outside the LNCCE, if needed, to provide insight on the subject matter. After the study and deliberation phase, the members of the working group write a report to be discussed by the Plenary Committee for final decision. Meetings of both the Plenary Committee and Sub-Committees take place behind closed doors in the premises of the Grand Serail, or in the office of the LNCCE. The decision is sent to the requesting body (Ministry Council, Parliament, Institute, or any other governmental committee) as advice, recommendations, guidelines, or a draft law. Important opinions are communicated to the public at large through the media as well as by means of press conferences.

Since its creation, the Committee has met regularly each month at the Grand Serail inspired by its Vision and Mission:

- The Vision – The committee aspires to become a leading independent institution, recognized by the Lebanese society as a national and international

reference in the field of life sciences and health ethics, working for the promotion and development of such a culture.
- The Mission – the Committee's mission is to conduct studies and provide advice, guidelines, and recommendations on ethical issues related to individuals or groups and raised by research and applications in the field of life sciences and health.

Implementation and Role of the Lebanese National Consultative Committee on Ethics (LNCCE/CCNLE)

In recent years, we have witnessed a wave of innovation in health technologies driven by new medical breakthroughs, novel scientific approaches and the rise of digital health technologies. Pioneering methods of drug development and disease diagnosis, the rise of 'big health data', and new means of providing networked care have led to predictions that world health systems are on the edge of transformation. While much of the promise held in these technological innovations remains to be fully realized, the rise of new health technologies is accompanied by a profound shift in the way individuals – whether as patients, citizens or consumers – engage with matters of health. Individuals and collectives are participating in new and unprecedented ways in the conduct of health research, health policy, and health practice.

In light of these transformations, the LNCCE has focused its activities in different directions:

— **As legislation** achievements, the LNCCE studied and proposed a draft law on Genetic Testing which was adopted on 14 October 2003 (Law No 625/2003). The aims of this law is to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data. Any collection, processing, use and storage of human genetic data, human proteomic data and biological samples shall be consistent with the international law of human rights. Genetic testing should be done only after a genetic counselling with signature of a free and informed consent. Privacy of individuals and the confidentiality of human genetic data should be protected.

— The following year, it elaborated and proposed a draft law on Patients' Rights and Informed Consent (Law No 574/2004).

— It also reviewed and worked for the adoption of the Law no. 240 of 2012 amending some articles of the Code of Medical Ethics- No. 288 of 1994.

— **Proposition of Decrees:** to the Ministry of Public Health (MOPH) for the creation of Medical Ethics Committees in the hospitals for control of eth-

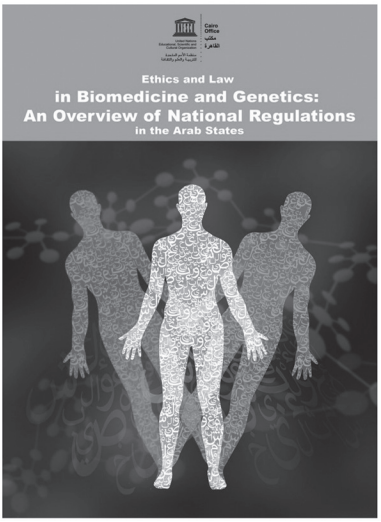
ical issues and research on human subjects; a proposition of Decree for regulating the Clinical Trials which was issued in March 2002 (MOPH Decree No 32/ 2002); a proposition of decree on a mechanism for the creation of accredited Institutional Review Boards/ Research Ethics Committees in the universities and hospitals (Decree No 141/2016). A proposition of a decree on the use of Stem Cells and Biobanking (Decree No 79, issued on 1st Feb 2017. In 2016, a draft decree was submitted and approved by the MOPH establishing Institutional Review Boards (IRB) in hospitals in order to monitor the medical research and clinical trials. It includes the purpose of the research, the written informed consent, the protection of the human subject, the research on minors and subjects under tutorship.

— **As recommendations:** the LNCCE submitted to the MOPH a recommendation on Medical Futility on 23 Oct 2002 (MOPH Decree No 100/ 2002): pain relief, accompanying the patient and a good palliative care is the best alternative to medical futility;
— An amendment of the Law 109 – 16 Sept 1983, concerning Organ Donation was proposed and adopted. A National Committee for Organ Donation and Transplantation was created under the auspices of the Ministry of Public Health to meet with the candidates and review the files: related donors are favored, avoid any commercial deal or financial compensation.
— Other recommendations were submitted upon request from various officials: general principles as to the experimentation of new drugs on human beings, recommendations against any kind of human cloning (20002, and 2017), recommendations on Uterine Transplant to be done only under a strict research protocol (2018); recommendations on assistance and care for persons in end-of-life situations (Dying with dignity 2018); recommendations on the use of Marijuana only for medical purposes; recommendations on the prohibition of human genetic editing; recommendations on the export of human biological samples outside Lebanon (2019)…
— Two draft **laws** are now proposed to the National Assembly of Deputies for review and adoption: Law on Reproductive Technology and Research on the Embryo, and the Law on Rights of the Psychiatric Patient.
— Since its creation, the LNCCE has developed a good **relationship** with the Lebanese Order of Physicians and Nursing, the local scientific societies, the the National Council for Scientific Research, and the local NGOs. Several joint educational Symposia, Panels, Workshops.
— The Lebanese National Consultative Committee on Ethics (LNCCE) has long-standing **relations with various international and regional organizations**, with which it cooperates on Bioethics issues. These organizations include the United Nations Educational, Scientific and Cultural Organiza-

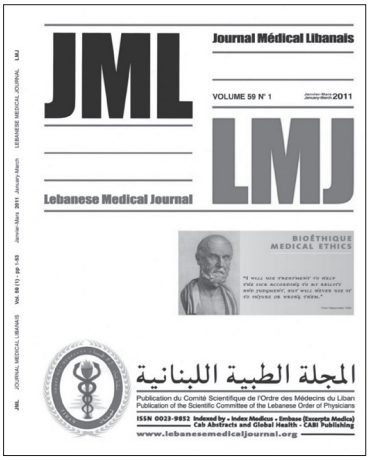
tion (UNESCO), the World Health Organization (WHO), the Arab League Educational, Cultural and Scientific Organization (ALESCO), the Standing Committee on Scientific and Technological Cooperation (COMSTECH), and the Islamic Educational Scientific and Cultural Organization (ISESCO). A double contribution with the Arab League in Cairo was done in reviewing and amending these documents: the Arab Declaration on Organ Donation and Transplantation (Cairo, 2015), and the Arab Declaration on Human Cloning (Cairo, 2015).

— The Committee has also established strong relations with a significant number of Bioethics Committees throughout the world such as the French National Consultative Ethics Committee (CCNE) and the Tunisian National Committee of Medical Ethics (CNEM) and many others.

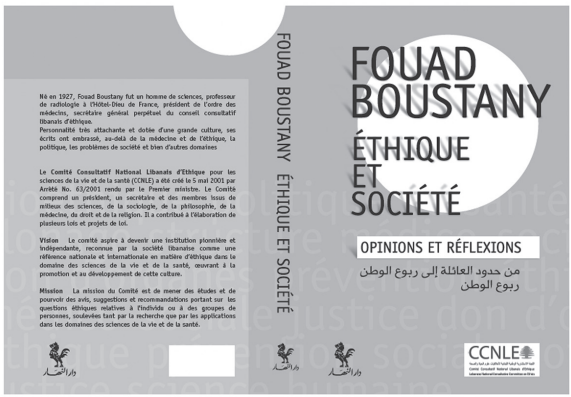
— **Several Publications** of the LNCCE and its members were done: Annual reports, on the activities and achievements of the LNCCE; report on Ethics and Law in Biomedicine and Genetics in the Arab States by Prof. Fouad Boustany- submitted to the UNESCO and adopted as an official document (see cover page of the publication).



— A special issue on Ethics in Palliative Care in Lebanon in the Lebanese Medical Journal and a special issue on Bioethics in Lebanon were published (see cover page).

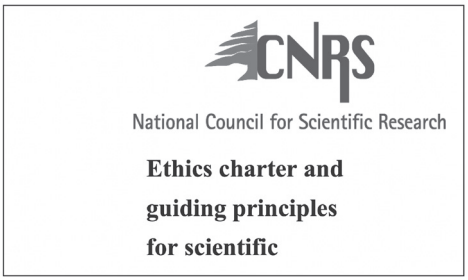


— A book titled "Ethique et Société" par Prof Fouad Boustany was edited and distributed. (see cover page)



— Some important **local activities:** Ethics Teacher Training Course in Beirut, Lebanon from 8-11 June 2015 in collaboration with the UNESCO; Symposium on Pain and Palliative Care on Saturday 28 March 2015, in Beirut, Lebanon; International Congress on Medical Ethics, May 21-23, 2015, Beirut, Lebanon in collaboration with the WHO and UNESCO; 2nd National Congress on Organ Procurement and Transplantation, May 14-16, 2015; LNCCE participates in "Droit et Ethique" seminar organized by ESA; Series of lectures on Ethics and Palliative Care- Feb 27-28, 2015.
— A joint publication in 2 languages with the National Council for Scientific Research titled "Ethics charter and guiding principles for scientific research in Lebanon/ Charte des principes éthiques en recherche scientifique au Li-

ban was published in Mai, 11, 2016 and adopted by both the WHO and the Unesco.(see cover page)



— During the Covid-19 pandemic (April 2020), the LNCCE/CCNLE received a request from the Secretary General of the Ministry Council to propose "Recommendations and General Guidelines for Ethical Healthcare Decision-Making in Lebanon in case of high number of Covid-19 cases going beyond the available medical resources". The LNCCE/CCNLE discussed the issue and drafted guidelines to assist healthcare institutions and professionals who are in the front lines for making critical and morally challenging decisions while caring for patients during the COVID-19 pandemic. These challenges will be compounded should the number of infected patients rise exponentially and clinical care will have to be provided in situations of severely limited resources.
— Finally, it is important to note that the LNCCE was represented in all of the last 6 **Global Summits** with active participation and contributions from its delegates (8th GSNECs in Singapore; 9th GSNECS in Tunis in 2012, 10th GSNECs in Mexico in 2014; 11th GSNECs in Berlin in 2016; 12th GSNECs in Senegal in 2018; 13th GSNECs in Lisbon in 2022. (see picture Lisbon 2022)

Challenges for the Present

The LNCCE/CCNLE has been trying to continue its work with varying degrees of efficiency through lack of budget and a political unrest and vacuum, which has been prevalent in the past decade. However, it mostly failed to have its previously mentioned draft laws studied and ratified by the Parliament as the latter was not meeting. Obstacles we are facing escalated in 2019, with the Lebanese people widespread demonstrations that oftentimes prevented the secretariat from reaching our offices. This was followed by COVID, the lockdowns, the rapidly and drastically deteriorating economic situation and Beirut port blast, which left the committee without offices. Meanwhile, the LNCCE has been trying as much as possible to continue its endeavors in the bioethics field through working and communicating online. It has been allocated a new office but the lack of budgeting for its secretariat or even for having power is still not allowing it to resume its work properly.

Challenges for the future

Bioethics Education: During the past decades, we have witnessed an increasing interest in bioethics education. The How should medical education respond to those transformations in an adequate manner and at the same time maintain its professional values? Considering that the main goal of medical education is the integral formation of physicians who are devoted to the ethical and moral values of the profession, medical educators must develop learning objectives for educational programs that would clearly reflect those values. Bioethics is now taught in almost every Lebanese medical school and nursing school. We still need competent teachers who can help clinicians learn bioethics and accept this important responsibility to provide practical advice as an integral part of good clinical medicine. At the same time, they should adopt relevant educational strategies that could lead to the translation of the values into deep convictions expressed later in the daily professional conduct and practice.

Genetic Testing: During the past decade, many laboratories for genetic testing have been established in university hospitals and private clinics in Lebanon. These tests include chromosome studies, genotyping, human leukocyte antigen (HLA) analysis, genetic tests for medical research, genetic tests for judicial purposes (legal medicine, DNA fingerprinting, etc.), and for the diagnosis of mutations in monogenic or polygenic diseases.

All abovementioned tests are regulated under Law No. 625 /2004) concerning human genetic tests. We believe that an amendment of this law has become necessary due to the rapid evolution of the above-mentioned procedures.

Assisted Reproductive Technologies: This issue is regulated in Lebanon by the Draft Law on Assisted Reproductive Technologies and the Code of Medical Ethics. Diverse ART activities began in Lebanon between 1980 and 1985. They include: artificial insemination by injecting sperm into a woman's uterus and fallopian tube, IVF, and introducing inseminated eggs to the uterus or fallopian tubes. The draft law submitted by the CCNLE was immediately adopted by the Ministry of Health. However, it faced many obstacles from the Council of Ministers who wanted to consult the different Lebanese religious denominations on the subject, since some of those denominations prohibit ART except when practiced on married couples.

Informed Consent: This issue is regulated in Lebanon under several laws and guidelines. The consent to medical care applies also to the participation in clinical research. Therefore, in case the patient was not in a state that allows him to express his/her will, participation would require the consent of a trusted person.

Research Involving Human Subjects: In Lebanon, this issue is well regulated under several laws and guidelines. Indeed, Law No. 574 (2004) pertaining to patient's rights and informed consent tackles in its first chapter the subject's right to access of information. Inspired by the Nuremberg Code (1947), the Helsinki Declaration (1964), and the more recent CIOMS Guidelines (2016), and in recognition of the increasing number of medical faculties and university hospitals in Lebanon, the CCNLE found it necessary to propose a draft Decree on guidelines for creating and ruling IRBs, and obtaining accreditation from the Ministry of Public Health based on these guidelines.

Medical practice

Medical practice is regulated in Lebanon under several laws and decrees, the most important of which is the Code of Medical Ethics of 1994, amended by the Law No. 313/ 2001. It is worth mentioning that the Lebanese Order of Physicians sent an update of this code to the parliament for approval.

Final Word

The CCNLE is well established and recognized committee in Lebanon; its opinion in the field of bioethics is sought and respected by the different Lebanese

authorities, institutions, universities, etc. Its past achievements, locally as ratified legislation, published studies and organized seminars on bioethics education, and internationally as active participation in the most important Congresses, Summits, Seminars and other events in the bioethics field, bear witness to the LNCCE's dedication to tackling first-hand bioethics issues in Lebanon, keeping up with the developments taking place regionally and internationally and upholding its vision and mission. However, its work has been hindered drastically in the past decade due to the lack of budgeting; the Political instability and vacuum delayed the approval of already elaborated legislation and recommendations, which are becoming obsolete and in need for review.

The ambitions of the LNCCE run far and wide with regards to what it seeks to achieve in a field that is essential for the protection of the community, and provision with a decent quality of life; it also continues to hope to get back the circumstances that would allow it to resume its work with its usual efficiency by quoting Marie-Curie:

"I never see what have been done; I only see what remain to be done."

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Pakistan and Bioethics: Observations and Reflections

Farhat Moazam[1]

"We are the children of our landscape;
it dictates behavior and even thought
in the measure to which we are responsive to it"

Lawrence Durrell, *Justine*

As a physician with a longstanding interest in cross-cultural ethics, I have observed and been involved in the progress of bioethics in Pakistan over several decades. What follow are my reflections and a brief overview of the emergence and progress of modern bioethics in Pakistan, and the inherent challenges in a country with different norms and values, healthcare systems, and socioeconomic realities from those of America where this discipline was born. I will also refer to ongoing efforts in the Center of Biomedical Ethics and Culture (CBEC) of the Sindh Institute of Urology and Transplantation (SIUT) in Karachi to shape bioethics education which is contextual and relevant to existing ground realities (1).

About Pakistan

The Islamic Republic of Pakistan has more than 220 million people of whom 97% are Muslims and the rest a mixture of Christians, Hindus and Zoroastrians. It is classified as a Low Middle Income Country (GDP per capita US $1,500; Portugal $24,200; USA $69,200). The overall literacy rate is 58% but considerably lower in women and residents of the provinces of Baluchistan and Pakhtunkhwa. The country has many ethnic subcultures, several mother tongues (the national language is Urdu), different socioeconomic groups, and a variety of education systems from the religious to the modern.

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Pakistani citizens nevertheless share many characteristics of a deeply interdependent "collectivistic" culture that shapes notions of the "self" and its relationship to others in personal and professional domains (2). For many in Pakistan, the family, rather than the individual, is the social and moral unit of society, duties to kin are prioritized over personal rights and interests, elders are perceived as repositories of wisdom to guide important decisions, and religious values are essential components of the moral life.

Bioethics arrives in Pakistan

With the explosive advances in medical sciences and biotechnology in the latter half of the last century Pakistan, like other Low- or Middle-Income Countries (LMICs) in the region, experienced increasing medical specialization, tertiary level medical services, and a shift towards privatization of health care systems. Physicians began to confront complex moral dilemmas in practice similar to those being faced in developed countries. These included complex decisions about provision of ICU care/ventilatory support in the face of medical futility, appropriate management of terminally ill patients, saving extremely premature neonates, initiation of organ transplantation, etc. These were compounded in a country with understaffed and overburdened public healthcare institutions, limited resources and the absence of national health insurance schemes.

During the 1980s, Pakistani physicians and surgeons who had trained in the West were returning home to practice acquired advanced medical and surgical skills. They brought back with them "Principlism" elaborated by American philosophers Tom Beauchamp and James Childress in their book, *Principles of Biomedical Ethics* (3). In this view, balancing four secular, philosophical principles – respect for autonomy, beneficence, non-maleficence and justice – provides "the common morality" applicable universally irrespective of local cultural values to address ethical dilemmas of modern medicine. The four easily memorized principles remain popular in medical fields, including in the USA (4), and continue to remain the dominant bioethics paradigm internationally (5).

In effect, medical professionals imported and transplanted the four principles into Pakistan. To a great extent, bioethics in Pakistan is still led by medical professionals, is largely medical rather than multidisciplinary in its nature, and practical rather than theoretical in its orientation. This contrasts with a multidisciplinary American bioethics with philosophers, theologians, lawyers, social scientists in key roles, and its strong antiauthoritarian ethos (including against medical practitioners and researchers) and emphasis on the rights and liberty of patients to make their own choices.

Brief overview, Bioethics and Pakistan

The first formal introduction of bioethics to medical students occurred in the Aga Khan University (AKU) in the late 1980s by an American physician chairing the department of community health sciences (6). Ethics sessions were subsequently introduced for postgraduate resident trainees and in the university's nursing curriculum. Initially the focus was on the four principles but over time, clinical faculty (I was chair of the AKU department of surgery then) began to incorporate "real" cases in the teaching sessions to highlight the importance of local contexts in shaping ethical dilemmas and influencing decision making processes.

Awareness of the importance of medical ethics spread rapidly in medical institutions and research and clinical ethics workshops, conference lectures and talks became popular. At the same time, a parallel stream emerged led by physicians who perceived this "secular," western approach as alien to Muslim values, advocating instead religious (Islamic) ethics based on opinions and teachings of Muslim *ulema* (scholars) and *fuqaha* (jurists) for guidance in medical decisions. The Pakistan Islamic Medical Association (PIMA) continues to a leading role in organizing ethics workshops and conferences emphasizing Muslim values and "Islamic View Points."(7).

At the national level, in 2002, the Pakistan Medical and Dental Council (PMDC), the certifying body of the country, stipulated that bioethics be incorporated in the curricula of all medical colleges (8). It also issued its Code of Ethics for physicians (revised in subsequent years) which included the four philosophical principles but also emphasized the importance of "Islamic bioethics" without however, engaging with the inherent tensions between the two. The response to PMDC's recommendation that specific hours of the curriculum be dedicated to teaching medical ethics has been uneven so far. Whereas a few medical institutions have complied, many in the government sector lack teachers with appropriate ethics background to make this possible.

Ongoing political turbulence in the country complicated matters further. In 2019, the new government dissolved the PMDC through a controversial Presidential Ordinance replacing it with the Pakistan Medical Commission (PMC). In October of this year, the National Assembly of the current government in power passed a bill to reconstitute the PMDC but the final outcome of this is awaited.

In 2004, the Ministry of Health took an important step by establishing the National Bioethics Committee (NBC) of Pakistan with a multidisciplinary membership. In the initial years the NBC managed to achieve a modicum of success in enhancing this discipline nationally. It formulated national guidelines for ethical interactions between healthcare professionals and the pharma industry, and also

prepared a detailed guidance document for the collection, usage, and export of human biological materials in the country (9).

The Healthcare Ethics Committee (HCEC), one of NBC's subcommittees, undertook the responsibility of running workshops in the country's provinces to build capacity in research and clinical ethics. This was relatively successful until the passage of 18th Amendment to the Constitution which shifted education from the Federal to Provincial governments. The HCEC also developed a detailed national bioethics curriculum with an accompanying handbook, to help institutions incorporate this subject into the dental and medical undergraduate curricula. Unfortunately, once again due to changes at the federal and provincial government levels in the last decade (beyond the scope of this essay to describe) this document has not yet been approved by the PMDC to make it a mandatory requirement.

NBC's second subcommittee, the Research Ethics Committee (REC), reviews and provides ethical clearance to research undertaken in Pakistan which is either foreign or government funded or involve interprovincial projects. This is a daunting task in a country in which good research is essential yet institutional mechanisms ensuring ethical research remain either weak or absent outside of some exceptions. Nevertheless, as research still remains under the federal government the REC remains very active. Recently it successfully developed a well-functioning rapid turnaround review process in response to the COVID 19 pandemic.

Challenges for bioethics in Pakistan

There is growing realization among healthcare professionals and institutions that robust bioethics education at all levels, and implementation of ethics in practice and research, are crucial and essential for welfare of the general public. The progress so far has been fragmented, compounded by an absence of coherent, systematic and sustained efforts by a government in constant flux.

There has been a substantial increase in institutional ERCs in Pakistan driven by the need to meet requirements for funding, multinational collaborations, and publications in reputable journals. What is required is the establishment of a national ERC/IRB accreditation body to oversee and monitor ethical reviews conducted at institutional levels (10). Pakistani researchers are involved in multinational, foreign funded, collaborative research, including some involving genetic materials obtained from illiterate rural populations, factors that heighten the importance of such a body (11).

Equally important will be to address conceptual issues pertaining to bioethics education in Pakistan, make a largely physician driven movement inclusive

to other fields especially social sciences. Bioethics education should be "functional," relevant and contextual to cultural and social realities of Pakistani lives (12). There is dawning realization of the paradox of delivering lectures on secular, abstract principles about autonomous individuals making independent choices, while caring for patients and families living with profound interdependencies and a moral compass guided by religion (13). In Pakistan, and other countries in this region, traditions, cultural norms and religious values remain important for many to make sense of life and death (14). As with Principlism, it will be important to engage critically and constructively with these aspects within decision making processes.

Through its programs for healthcare professionals, since 2006, CBEC is working on meeting some of these challenges. "Real" clinical and research scenarios are preferred for class discussions and students encouraged to present ethical dilemmas they face at work. A multidisciplinary approach is employed employing faculty with medical, social, religious, and legal backgrounds in discussions about common clinical dilemmas. This allows students to move beyond unhelpful theoretical debates that categorize bioethics into airtight compartments of secular/rational versus religious/beliefs, liberal versus traditional, universal versus relative compartments, and so on (15).

In light of my involvement with this discipline for over two decades, and using CBEC outcomes as a barometer, the future for bioethics in Pakistan is promising despite the challenges I identify. For example, many among the more than 110 alumni of CBEC to date are now undertaking steps in their parent institutions – introducing ethics to undergraduates and trainees, initiating/strengthening ERCs, conducting workshops in research and clinical ethics, giving talks in national/international conferences, and publishing their experiences in international and national journals (17 in the year 2021 alone) and in the local press. Many have also been elected to serve on the REC of the NBC.

Despite significant challenges, Pakistan is slowly but steadily building core capacity to take bioethics forward in Pakistan and also to enrich the international bioethics community through its programs and publications.

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6. Western Pacific Region
(WPR)

The starting point for institutional bioethics in Aotearoa New Zealand

Nic Aagaard[1] and John McMillan[2]

The establishment of New Zealand's legislated bioethics committees and other key protections and legislation to protect people was born from unethical research. In 1987 Women's Health Action founders Sandra Coney and Phillida Bunkle published an article titled 'An unfortunate experiment at National Women's Hospital' in a monthly local magazine (1). The article outlined an unethical study at National Women's Hospital, the country's premier women's hospital at the time. The study started in 1966 and involved following women with major cervical abnormalities without definitively treating them. This occurred without the women's knowledge or consent. Twenty years on, many had developed cervical cancer, and some had died.

The revelations led to public outrage and ultimately to a government-led inquiry. This inquiry led to the establishment of Aotearoa New Zealand's national bioethics committee in 2001. Named the National Advisory Committee on Health and Disability Support Services Ethics (NEAC), it is also known by its Māori name; Kāhui Matatika o te Motu (which translates as 'National Ethics Group').

The members of NEAC are appointed by the Minister of Health and bring expertise in ethics, health and disability research, health service provision and leadership, public health, epidemiology, law, Māori health and consumer advocacy. The Ministry of Health provides Secretariat support to NEAC. New Zealand also has separate national ethics committees for Assisted Reproductive Technologies, and Health and Disability Research.

NEAC issues guidelines (2) that set out the ethical standards that must be met by researchers when they undertake health and disability research. These guidelines are also used by ethics committees that review research study proposals – they are responsible for checking that each study meets the ethical standards set out in NEAC's guidelines.

NEAC also issues advice on ethical issues in health care and disability services, including public health ethics and clinical ethics.

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[1] Manager of Ethics at the Ministry of Health in New Zealand.

[2] Chair of NEAC.

Resource allocation and equity

For example, in 2021 NEAC published Ethics and Equity: Resource Allocation and COVID-19. NEAC recognise that in an emergency like COVID19, it is even more important that the New Zealand government upholds these obligations. NEAC produced a Framework that supports the health system in meeting its obligations under Te Tiriti, by helping it to draw on the principles of Te Tiriti and their implications for resource allocation decisions.

Supporting the New Zealand health and disability system to meet its obligations under Te Tiriti is necessary if we are to ensure iwi, hapū, whānau and Māori communities are active partners in preventing, mitigating and managing the impacts of a pandemic or public health emergency on those communities.

As Te Tiriti recognises Māori have the right to determine their own destiny (tino rangatiratanga) and that without self-determination Māori cannot achieve full equity with their fellow citizens (oritenga), ethical guidance must include both Māori ethical principles as well as procedural guidance on how to ensure Māori are involved through all decision making.

Health research standards

In the context of setting Standards for Health and Disability Research, the New Zealand bioethical research standards start from a recognition that there are significant inequities in health outcomes between Māori and other New Zealand populations.

Both currently and historically there has been unequal access to health and disability services, and differences in the quality of care, Māori receive compared to other groups in Aotearoa New Zealand. The persistent and significant health inequities for Māori have been longstanding and are a breach of Te Tiriti, and are avoidable, unethical and unjust.

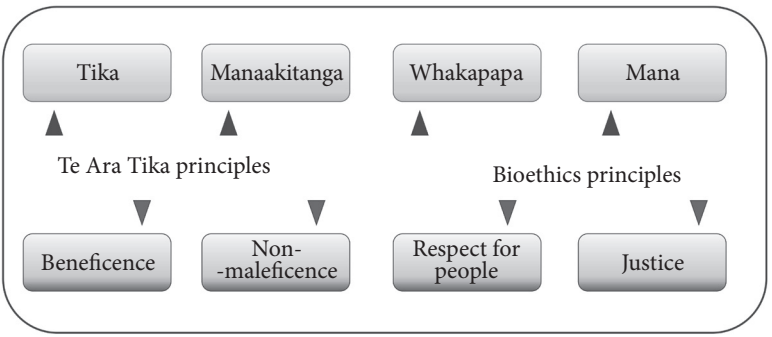
The reasons for these inequities include racism and the historical and persistent consequences of colonisation, whereby Māori were subjected to dispossession of their land; appropriation of resources; alienation from their culture; and the disruption of their traditional relationships, responsibilities and practices. Importantly, there is a recognised inequality of access to the determinants of good health, such as: economic security, good-quality housing, safe and secure employment, good-quality education and freedom from racial discrimination.

This substantiates NEAC's focus on eliminating Māori health inequities and honouring Māori health aspirations in the ethical review of all health research.

This approach broadens the concept of health and presents a challenge – as it represents a move away from a diagnostic notion of health and care, to one that is holistic, pragmatic and wellbeing focused.

The Standards address this by recognising that all research in New Zealand is of interest to Māori. This is further reflected in the partnership of principles. The National Ethics document sets out two sets of principles that collectively form the basis for these standards: Te Ara Tika principles and bioethics principles. Te Ara Tika is a set of Māori ethical principles that draws on a foundation of tikanga (Māori protocols and practices); 'Te Ara Tika' means 'to follow the right path' and is used in this document as a generic set of principles commonly shared by many generations and communities of Māori; however, they have application to all people in Aotearoa New Zealand. Te Ara Tika principles are tika, manaakitanga, whakapapa and mana.

The bioethics principles that appear here have been used in many sets of human research ethics guidelines, which have carefully established and developed their implications.



These Standards do not ethically or conceptually prioritise either of the two sets of principles. No assumption is made that they cover the same ground in all cases. However, they do have important common ground in one sense: they involve knowledge discovery through respectful and rights-based engagement between researchers, participants and communities to advance health and wellbeing. From a theoretical position, NEAC's approach proposes that different and sometimes inconsistent values and principles of ethics create *prima facie* obligations. This means that wherever they are relevant, they are significant, but a particular value or principle may sometimes have to be sacrificed to realise another value or principle, judged to be of greater weight or significance in the circumstances. From a psychological standpoint, people will often

feel a variety of ethical values pulling them in different directions. NEAC believes that good decision-making involves recognising, rather than ignoring, these tensions.

When used together, the two sets address ethical positions of different societies, thereby strengthening ethical discourse in New Zealand. These two sets of principles are the ethical sources of the more specific standards set out in the following chapters. For example, the guideline that participants give their informed consent to participate comes from the principle of respect for people, and from the principles of mana and manaakitanga.

The Standards also recognise that all studies may produce benefits for Māori but may also present risks of harm. All research has the potential to support Māori achieve their health and wellbeing aspirations. All researchers in New Zealand therefore must consider the degree to which they can contribute to improving Māori health outcomes. Guidance on engagement and consultation is provided to support this approach, and key ethical issues are described to support New Zealand researchers.

Current ethical challenges in Aotearoa New Zealand

Achieving equity is an important goal that raises many ethical issues and challenges.

Pandemics and other public health emergencies often have the biggest impact on marginalised communities. They highlight and exacerbate existing inequities within the health system. Equity recognises that different people with different levels of advantage require different approaches and resources to achieve equitable health outcomes – a one size fits all approach' approach to the pandemic would therefore exacerbate existing inequities.

Measures taken in a pandemic must acknowledge the principle of intergenerational equity, which considers the concept of fairness for a cross-section of different generations, including future generations. It may, for instance, encompass the right for different generations to attain a high standard of living. Actions taken in the present can affect the rights of later generations, and decision-makers should take these potential consequences into account – especially where there is a risk of potential harm.

NEAC recognises that multiple ethical principles may need to be considered in ethical decision-making. It may be that, in some circumstances, decision-makers can accommodate different ethical principles at the same time (for example equity and intergenerational equity). For example, for some elective surgeries, prioritising those with the most need and achieving the most benefit might be

considered in tandem. However, in a pandemic (as in many other contexts), ethical values and principles can conflict.

In the context of the COVID-19 response, it may not be possible to achieve equity and to benefit the most people at the same time. As an example, in the case of ICU beds or ventilators, a clinician might make a decision to treat those with fewer comorbidities first, considering this to be the best way of saving as many lives as possible, or getting the most out of the resources. Yet this decision may undermine equity, as some groups (for example, Māori and disabled people) tend to have more comorbidities than other groups.

In prioritising the ethical principle of equity, it supports a view of COVID19 as a syndemic, rather than a pandemic. This approach recognises that response to the pandemic is not only a case of containing an infectious disease, but also a case of responding to biological and social interactions between conditions and states that affect an individual's vulnerability to worse health outcomes. Viewing COVID19 as a syndemic provides a holistic, broad focus which looks at social determinants of health like education, employment, housing, food and environment.

When we address COVID19, we must also address co-morbidities and conditions such as hypertension, obesity, diabetes, cardiovascular and chronic respiratory diseases and cancer. Co-morbidities and conditions are preventable and can often occur as a result of systematic inequities within the health and disability system. This creates an imperative for a focus on equity as an ethical principle in the integrated response to COVID19 and the relational impacts of the wider health system.

Increased risk through unequal distribution and exposure to the determinants of health, and what this means in the context of targeted support and resource allocation

In NEACs work, it recognises that there is an unequal distribution of power and resources and differentiated access and exposure to determinants of health. Research persistently shows that Māori, Pacific peoples and people from lower socioeconomic demographics experience worse health and die younger than other New Zealanders. Refugees, migrants and the Lesbian Gay Bisexual Transgender Queer or Intersex (LGBTQI) community also have health disparities that should be recognised.

Disabled people are of equal value and have the same rights as all other New Zealanders. Yet an underlying, pervasive and often unquestioned devaluing of disabled people exists; this is called 'ableism'. When ableism intersects with ageism and/or racism, classism and sexism, it can compound discrimination and

result in specific human rights violations, deprioritisation in access to resources and poorer-quality health services.

NEAC's advice and guidance recognises these considerations and aims to address them.

The future of bioethics

NEAC are committed to ensuring bioethics in New Zealand is underpinned by a commitment to achieving health equity, and that the health sector and government have a strong ethical foundation for decisions that affect every New Zealander. Adopting Te Whare Tapa Whā – a shared model of health and wellbeing – Within the context of health in Aotearoa New Zealand, there have been many models developed to address health and wellbeing. However, in developing recent pandemic ethics guidelines, NEAC have chosen to use Te Whare Tapa Whā to explain health and wellbeing.

Te Whare Tapa Whā is a Māori model of health and wellbeing developed by Tā (Sir) Mason Durie in 1984 (3). While it was developed to articulate a Māori conception of health and health services, it is relevant to the health of all New Zealanders. Te Whare Tapa Whā is a metaphor based on the four pillars of the wharenui or meeting house. Each of the four tapa (sides of the house) represent an element that is necessary to build health and wellbeing, with all elements working in harmony.

Some areas NEAC are working on to strengthen the ethical considerations in research are through supporting New Zealand Agencies to ensure the legal and ethical framework for research with adults who cannot provide their own informed consent is clear and robust and underpinned by ethics.

For public health, NEAC aim to strengthen New Zealand's pandemic preparedness, ensuring actions taken are effective and ethical. Whakapuāwaitia e tatou kia puāwai tatou means Ethical Guidance for a Pandemic. the draft publication is separated into six chapters:

- Chapter 1 outlines a shared foundational approach to responding to a pandemic.
- Chapter 2 introduces a set of six ethical principles and a framework for decision-making in a pandemic.
- Chapter 3 explores how these ethical principles might operate before a pandemic (readiness and reduction of risk).
- Chapter 4 explores how these ethical principles might operate during a pandemic (response).

- Chapter 5 explores how these ethical principles might operate after a pandemic (recovery).
- Chapter 6 provides insight into what these ethical principles mean for New Zealanders with disabilities.

The draft guidelines use six ethical principles that weave Maori and Western principles, and are demonstrated using New Zealand sign language, one of the official languages of New Zealand.

NEAC recognise how many challenges and ethical issues are presented by historical injustices and advances in technology, and are developing a framework that aims to ensure prioritisation of advice, with the limited resource and time they have, that ensures a transparent and justifiable focus on key ethical challenges in New Zealand. Te Ara Tika means to follow the right path, and NEAC are committed to ensure New Zealand continues to do so. New Zealand will continue to support and develop bicultural principles, frameworks and can contribute to global bioethics by sharing our experiences and learnings.

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National Bioethics Committees in Asia
Focusing National Bioethics Committee of Republic of Korea

Bong Ok Kim[1]

In Asia, bioethics is not an area that receives much attention at the national level. Therefore, the activities of the National Bioethics Committee are not so prominent in the countries in the region. In this paper, I would like to briefly examine the current status of the National Bioethics Committees in Asian countries such as Singapore, Japan, and China, and review National Bioethics Committee of Korea in more detail.

The Singapore Cabinet established the Bioethics Advisory Committee (BAC) in December 2000 and has been making efforts at the national level to deal with bioethics in the field of biomedical science [1]. It works to solve ethical, legal, and social problems arising from the field of biomedical science and gives public education related to bioethics. Since Singapore aims to develop biomedical science as a key pillar of the economy, national efforts to prevent bioethical problems in this field are essential.

Bioethics initiatives in Japan have been operated mainly by the Science, Technology and Innovation Committee Cabinet Office [2],which was changed from Council for Science, Technology and Innovation founded in 2013. The Committee is attended by the Prime Minister, who is the chair of the meeting, as well as the relevant ministers and expert members. The Science, Technology and Innovation Committee of Japan aims to establish a comprehensive strategy related to science and technology to respond to the national and social issues in a timely and appropriate manner. Main activities of this Committee are: 1) research and deliberation on basic policies for science and technology 2) budget and resource allocation for research and deliberation on science and technology, 3) evaluation of nationally important R&D, and 4) deliberation activities on comprehensive environmental improvement to promote innovation creation through practical application of R&D results.

In the wake of the "CRISPR babies" scandal in July 2019, China deliberated and voted on the formation of the National Science and Technology Ethics Committee and this committee is currently being operated. The committee was established focusing on gene-editing technology in the beginning, currently it also

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deals with overall life science and technologies such as cloning technology, cell therapy, heterogeneous transplantation, mitochondrial replacement, and nanotechnology, etc. [3]. Through this committee, China strives to standardize various scientific research activities, including improving the system norms pertaining to national science and technology and the governance mechanisms, strengthening ethical supervision, and specifying the relevant laws, regulations, and ethics review rules.

1. The birth of the National Bioethics Committee of Korea

Just after a painful experience of the ethical violation in a research, on human embryonic stem cells by cloning, which was published in the journal *Science* in 2004 by a Korean veterinarian researcher[2], the National Bioethics Committee of Korea (NBCK, the Committee) was established in 2005 as one of the Presidential committees of Korea based on the Bioethics and Safety Act. The Act was initially passed in a hurry in 2004 and amended partially several times till 2020. The main chapters of this Act are:

1) National Bioethics Committee and Institutional Bioethics Committee
2) Human Subject Research and Protection of Human Subjects of Research
3) Embryo, Production and Research
4) Human Materials Research and Human Material Banks
5) Gene Therapy and Testing.

The National Bioethics Committee of Korea(NBCK) was established in order to ensure bioethics and safety, thereby contributing to promoting citizens' health and improving their quality of life by preventing the violation of human dignity and values or the infliction of harm on human body in the course of researching on human beings, human materials, etc. or of handling embryos and genes, etc.

NBCK is expected to review the items such as

1) establishment of basic national policies on bioethics and safety, 2) affairs assigned to joint institutional review boards and joint operation of IRBs, 3) exemption from the deliberation on human subjects research projects, 4) making and preservation of records and disclosure of information on human subjects research, 5) researches permitted to use surplus embryos, 6) categories, subject-matter, and the scope of research, 7) research on somatic-cell cloning embryos, 8) exemption from the deliberation on a human materials research project, 9) restrictions on

[2] Hwang, Woo-suk announced that he had succeeded in cloning human embryo and cultivating therapeutic stem cells for the first time in the world in February 2004 and it was known to be a fraud and a serious bioethical violation in research soon after.

genetic tests, and 10) other matters tabled by the chairperson of the National Committee, deemed likely to substantially affect society in connection with bioethics and safety. The National Bioethics Committee of Korea is comprised of at least 16 and not more than 20 members, including one chairperson and one vice chairperson. The chairperson is appointed by the President among the members, and the vice chairperson shall be elected by and among the members.

The NBCK is comprised of the following members: 1) the Ministers of Education, Science and ICT, Justice, Trade, Industry and Energy, Health and Welfare, and Gender Equality, 2) not more than seven persons commissioned by the President among persons who have abundant expertise and experience in research on biological science, medical science, or social science, 3) not more than seven persons commissioned by the President among representatives of religions, ethics circles, judicial circles, civic groups (referring to nonprofit, non-governmental organizations) or women. 4) The NBCK has two secretaries, who are the Minister of Science and ICT and the Minister of Health and Welfare; and the latter serves as senior secretary; 5) In order to support the affairs, including the management of administrative affairs of NBCK the Minister of Health and Welfare may designate a specialized institution related to bioethics and safety, so that the institution serves as a secretariat, as prescribed by Ordinance of the Ministry of Health and Welfare. 6) Korea National Institute for Bioethics Policy which was established in 2011 has been designated to support NBCK. And 7) the term of the members in the Committee is three years.

2. Activities of the National Bioethics Committee of Korea

NBCK has five standing specialized committees on special areas such as; 1) bioethics and safety policy, 2) embryo, 3) human material, 4) gene and 5) protection of human subjects of research as they are written in the Act.

The specialized committees work to strengthen the efficiency of NBCK's operations and the appropriateness of deliberation by providing professional opinions and advice on issues that require a professional review of NBCK's agenda.

For the issues which are not written in the Act, *Ad hoc* committees have been organized to review the issues timely and they were; 1) institutionalization of stopping meaningless life-sustaining treatment, 2) declaration of respect for life, 3) basic policies on bioethics and safety and currently, 4) priority in treatment in Intensive Care Unit.

Some of the issues reviewed by the Committee can be summarized as follows;

Somatic cell cloning

In early 2000s, as Korea experienced the serious bioethical issue on Hwang's research in somatic cell cloning embryos, legislation was facilitated regarding the methods of handling the embryos before inactivation. Bioethics and Safety Act was passed, implemented and amended with reinforced gametocyte research, with improved IRB system to prevent researchers from further bioethical violation. The Committee investigated, reported, and deliberated on the bioethical problems of Hwang's case.

Lower level legislation of Bioethics and Safety Act followed and somatic cell cloning embryo research was subjected to be reviewed.

Genetic testing

Genetic disorders for which genetic testing of embryo or fetus are permitted were reviewed. The methods of reasonable limitation in genetic testing were reviewed.

Reasonable improvement plans of genetic testing, guidelines for genetic testing of embryo and fetus and limitation of the number of embryos in extra-corporeal embryo transfer were reviewed.

Institutionalization of decisions on life-sustaining treatment

Ad hoc committee for institutionalization of decisions on life-sustaining treatment on dying patients was established in NBCK in 2013. The recommendations by the Committee was submitted to the National Assembly of Korea and the "Act on hospice and palliative care and decisions on life-sustaining treatment for patients at the end of life" was passed in 2016.

The Life-sustaining Treatment Decisions System, which has been in effect since 2018, respects the right to self-determination of patients who are in the process of dying, does not provide unwanted life-sustaining treatment, and provides dying care to help them face a comfortable death.

However, the availability of hospice care, as a way of end-of-life care, is still limited in Korea, meaningless life-sustaining treatment are not uncommon in hospitals even though patient expressed his or her own decisions beforehand. Currently, in 2023, NBCK is proposing amendments of the Act to allow people to write life-sustaining treatment plan earlier, to make decisions to institutionalize stopping meaningless life-sustaining treatment of the unknown patient without surrogates and to broaden the medical institution ethics committees in medical institutions and to give mandatory education for the physicians who are in charge of end-of -life care of patients.

Declaration on Respect for Life

Ad hoc committee for establishment of the Declaration on Respect for Life was organized in NBCK in 2015 and operated including Korean consciousness survey on respect of life. Declaration on Respect for Life was announced.

Reponses to Covid 19

The Committee reviewed government's responding system to Covid-19 and made special recommendation to set up a special committee for Covid-19 in public IRB to facilitate Covid-19 research in 2021. NBCK Chair's Statement on the bioethical issues related to Covid-19 pandemic was announced.

NBCK established an *Ad hoc* committee on "Priority in treatment in intensive care unit" in early 2022 to be better prepared for the next pandemic which we might not be able to avoid. In December 2022 a forum was held with the same title to share the result of the discussion with public.

Direct-to-Customer(DTC) gene testing system

The Committee reviewed Direct-to-Customer(DTC) gene testing system and made recommendations to government to carry forward to make improvement in the system including amendment of the law for accreditation of DTC gene testing facilities, consumer guidelines and periodic inspection of the gene testing facilities.

International collaborations

NBCK participated in the 10th Global Summit of National Ethics/Bioethics Committees held in Berlin, Germany. Asia Pacific National Ethics Committees(AP-NECs) was organized and NBCK hosted the first AP-NECs meeting in Seoul, Korea in October, 2017 with the theme of "Promoting Health ethics in the 2030 Agenda for Sustainable Development Goals". In collaboration with Korea National Institute for Bioethics Policy the Committee participated actively in the AP-NEC working group on Covid-19. NBCK participated in the 13th GS of NECs in Lisbon, Portugal in 2022.

NBCK has been participating in the joint meetings of International Bioethics Committee (IBC) and World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) organized by Intergovernmental Bioethics Committee (IGBC).

3. Current issues and major challenges

The Committee reached an agreement in the necessity to reposition National Bioethics Committee in relation to government and public. Operational guidelines of the Committee was established. NBCK established Basic Policies and Implementation Plans on the Bioethics and Safety (2020).

Regular meetings of the Committee are held biannually and NBCK members from the private sectors meet monthly in a roundtable format. Ministers usually do not attend the regular meetings even though they are tabled to participate. As a senior secretary of NBCK the Minister of Health and Welfare used to be the only minister to be present at the regular meetings. Most of the politicians are not interested in the ethical issues and the Committee has only a little political influence.

Budget is limited to operate the Committee with more openness to public, more meetings and expansion of functions. There are relatively strong control over the Committee by the government ranging from appointment of the members to the decision of the issues reviewed by the Committee. Therefore the committee is partially independent.

Currently the Committee has been busy to make recommendations for amendment of Bioethics and Safety Act. There have been two separate research projects, which are still in progress, to design framework of the amendment as the processes are complicated.

However, the new government which took power in June, 2022 has a plan to scale down the Committee from a Presidential Committee to one of the committees under Ministry of Health and Welfare, which is in the opposite direction from the plans established by the Committee in 2020. The new regime emphasizes budget reduction and administrative efficiency with this change even though the Committee should embrace science, technology, education, justice and gender equality, etc. as well as health and welfare.

Meanwhile, the Korean Associations for Bioethics[3] are currently consulting with each other to gather opinions and feedback on the government's actions and steps to maintain and improve the status of bioethics in Korea. Experts in bioethics are working hard to make their voices heard to prevent from passing this bill in the National Assembly.

With increasing public awareness of the Life-sustaining Treatment Decisions System, Korean society became interested in well-dying, and discussions related to the end of life, such as death with dignity and euthanasia, have emerged as social issue. Recently a new proposal on the bill on physician-assisted-suicide was

[3] Korean Bioethics Association, The Korean Society for Medical Ethics, Korean Association of Medical Law, Academic Network for Future Medicine and Humanities, etc.

submitted in 2022 by a lawmaker. The Committee has not made open discussion on this topic yet as the committee agreed to delay as we are not ready to discuss it yet in Korea. Systems of End-of-Life care and hospice care, which are very limited now, need to be discussed further with public and be made accessible to more people who need this special care.

4. Future roles of the National Bioethics Committee of Korea

Started from the bioethics and safety in researches, National Bioethics Committee of Korea is expected to support Korean people and government to ensure bioethics and safety, thereby contributing to promoting citizens' health and improving their quality of life by preventing the violation of human dignity and values or the infliction of harm on human body in the course of living as well as researching.

As Basic Policies on Bioethics and Safety was established in 2020 the current Bioethics and Safety Act should be amended accordingly. As society develops, we experience emerging conflicts related to bioethics and safety. Emphasizing public participation and 'bioethics for everyone policy' the National Bioethics Committee of Korea should be reinforced with higher positioning and less government influences.

The directions of amendment of Bioethics and Safety Act should be; 1) higher and stronger positioning of National Bioethics Committee of Korea, 2) new roles of NBCK with increased public participation, openness and clarity, 3) more autonomy of the Committee in selecting the issues for discussion and review independently (less governmental influence), 4) legal baseline for strategic accomplishment of public bioethics and bioethical conflict management, 5) genetic and health information are the personal information which need to be protected bioethically, 6) As current Act has too many details in some areas it may be separated into one Basic Bioethics Act plus several acts for special areas in more detail, and 7) Are there any issues of bioethics and safety which are left out from any other Acts? 8) Can we share our experiences in Korea internationally?

Along with the efforts to make amendments of the Bioethics and Safety Act, National Bioethics Committee of Korea will work continuously with professionals, citizens, students, government and legislators to make Korean society a better place to live in terms of bioethics and safety.

First, the National Bioethics Committee of Korea will expand opportunities for active engagement and communication of social members (citizens, researchers, etc.) as responsible agents along the way of making bioethics-related policies and forming social norms. At the same time, the Committee will support and

empower them so that they can conduct sufficient deliberations based on diverse bioethics perspectives. Second, the Committee will manage unpredictable risks of emerging biomedical sciences and biotechnology due to their complexity and uncertainty through objective evaluation and monitoring based on accurate information. With appropriate safety measures for each technical characteristics the Committee will build and support the environment in which researches can be conducted and managed without causing unnecessary conflicts or concerns.

Finally, the Committee will continue to make efforts to promote democratic deliberation and mature public bioethics based on the common values of "respect for human life" and "human dignity" and implement them in all areas.

In Asia, bioethics has not been positioned in the mainstream in politics or academia. Nevertheless, bioethics is rather considered as an essential partner that must accompany development of biomedical technology in Asian countries, such as Singapore, China, Japan, and Korea. Recently, its status is getting higher and higher day by day, with exceptions in Korea. Nevertheless, it remains to be seen how independently an opinion can be expressed when it is greatly influenced by the government in many ways, including the composition and budget of the committee, like in Korea. Therefore, it is important to have an independent position away from the influence of the government in order for bioethics to have a more expanded discussion and firm position in Asia than it has now. And the Asian bioethics network needs to be more active as in the other regions of the world. It is also important to have a place where bioethics committees and bioethics experts from each country can regularly discuss and exchange information based on networks such as AP-NEC operated by the Western Pacific region of World Health Organization. Respecting the unique cultural characteristics and diversities, level of development and value system of each country, the principal issues and directions of development in bioethics need to be shared regionally and globally with more international collaborations.

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Bioethics in Singapore

Roy Joseph[1] and Lee Eng Hin[2]

Profile

Bioethics development in Singapore is characterised by a close collaboration between healthcare professionals, scientists, the health authorities and the society with societal good as the yardstick and the use of education, policies and regulation. In Singapore formalized Bioethics began in January 1994 with the establishment by the Ministry of Health of the National Medical Ethics Committee (NMEC) to provide advice on specific local clinical ethical issues, potential local issues based on international trends, identify prevailing issues related to public health, medical practice and research, to develop ethical codes of conduct for doctors and to form sub-committees to deal with specific issues (1).The intention of its formation was in November 1993 declared by the statement of the Minister of Health during the parliamentary debate on "Affordable Health Care ". At an operational level, the importance given from much earlier on to the upholding of ethics can be seen by the establishment in 1905 of the Medical Council of the Straits Settlements under the Medical Registration Ordinance and the simultaneous commencement of the Medical School. The purpose was to legalise the status of the then 219 medical practitioners, prevent the unqualified from posing as medical doctors, deal with professional misconduct, formalise medical education and increase the number of doctors. It can be reasonably inferred that these developments were driven by the ethical principles of desiring to minimize harm and enable healthcare needs to be better met (2).

Under the Medical Registration Act 1970, the duty of the Medical Council was expanded to uphold the reputation and standing of the profession. Doctors were expected to be competent in the discharge of their responsibilities and to be honourable in relation to their patients and this was largely dependent on the

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individual doctor's character, conscience and upbringing. To assist the doctor, the council, about a decade later, published a guide to its functions and operating rules (although not referring to ethical principles), listing the types of offence and misconduct that may become the subject of disciplinary action (3). Subsequently the Medical Council in 1995 published its first Ethical Code and Guidelines. Developments in medical practice and research have prompted two revisions, in 2002 and 2016. The third revision is in progress. The Code and Guidelines serve well the profession, enabling minimum standards to be exceeded and aspirational standards strived for. Throughout the document, there is reference to the relevant ethical principle.

In the early years an ethical sensitivity and professionalism was imparted to students through an informal curriculum of opportunistic and contextual teaching in the wards and clinics by clinicians. Colleagues report senior clinical staff taking time to explain on the basis of ethical principles why, in a particular patient, certain actions were taken or not taken. Such teaching and learning continue today and retains its importance. The large volume of patients naturally generated a wide variety of ethical issues, and this proved sufficient for about 70 years. The current generation of the nation's senior medical practitioners and faculty are products of this informal curriculum.

In the mid-1970's a formal curriculum was introduced to better prepare students for the complex ethical issues and the challenging practice environment arising from the rapid development of medical science, clinical and health services and clinical research. In our first Medical School, now named as the Yong Loo Lin Medical School, this took the form of a short series of lectures delivered by clinicians on common ethical issues like securing informed consent, upholding patient confidentiality and privacy, respecting the autonomy of persons and end of life care. In 1995, the teaching was broadened to formal activities in both Years 3 and 4. In Year 3, it was 2 Core lectures in Ethics during the Medicine posting. In Year 4, formal teaching was delivered in the Community Health, Obstetrics and Forensic Medicine postings. The following topics were covered – Ethical and legal aspects of medical practice, genetic diseases, genetic manipulation, termination of pregnancy, assisted reproduction, litigation, medical examination, medical errors, professional negligence, and professional secrecy.

In 2000, the Physician Development Programme was introduced to Year 1 students. This allowed exposure to patients in the wards and enabled tutors to elaborate on the nature of the ethical basis of the doctor-patient relationship and the development of attitude and skills required for interprofessionalism. In 2008, 2 years after its inception in the Medical School, the Centre for Biomedical Ethics developed and introduced the Health Ethics, Law and professionalism curriculum. This was a longitudinal tract that aimed for continual and spiraled learning

through formal learning activities across all 5 years of the medical undergraduate programme. It was structured to achieve professional identity formation through reflective practice and integrated learning. The Core elements included knowledge of the ethical, professional, and legal foundations of the duties of clinicians to patients, family members, interprofessional colleagues and other stakeholders. This curriculum is now in the process of being refined to foster more opportunities for the individual student to practice ethical reasoning. In addition, it will aim to bring a closer alignment of the competencies that will be acquired by the end of the undergraduate programme with the competencies that will be required of first year house officers. Much of the learning will now be part of the clinical posting and will have co-teaching by ethicists and clinicians and be based on ethical issues that the students will identify in the patients they are learning clinical medicine from. The two other medical schools in Singapore – Duke-NUS Medical School and the Lee Kong Chian Medical School also have formal curricula in medical ethics, law and professionalism that extends longitudinally across all the years of study. These have similar aims.

The medical professional organisations in Singapore – the Singapore Medical Association, the Academy of Medicine and the College of Family Physicians promote the continuing professional development of its members through providing a variety of learning and training activities that are affordable, readily accessible and have significant content in Bioethics. Recognising the importance of this aspect of the development of the medical professional, the Singapore Medical association established in 2000 a dedicated Centre for Medical Ethics and Professionalism (4). Overall continuing development is ensured through the need to meet minimum number of training hours to be eligible for professional practice license renewal. In the pipeline is the need for these developmental activities to include learning in the professional, legal and ethical domains.

In the National Medical Ethics Committee (NMEC), a diversity of perspectives is ensured by the presence of doctors from different specialties, and non-doctors including nurses, social workers and persons with legal and sociology backgrounds. The latter responsibility is currently undertaken by the Singapore Medical Council. Its earliest recommendations led to the establishment of Hospital Ethics Committees (4). This was followed by the issuing of the nation's first Ethical Guideline on research involving human subjects (5). The NMEC has subsequently issued guidelines on the management of a variety of ethical issues arising in clinical practice. In addition, it has provided its views on specific ethical issues. These include among others, human organ and tissue transplantation, termination of pregnancies with foetuses having lethal malformations, medical treatment of high-risk infants, psychiatric practice, advanced care planning, collaborating with patients in clinical decision making, decision making at the end-

of-life, advertisements related to medicines, aesthetic medicine and bone marrow donors (3). More recently during the Covid 19 pandemic, it engaged the Clinical Ethics Committees (formerly known as 'Hospital Ethics Committees') to ascertain the ethical issues that were being experienced on the ground, how these were being addressed in order to establish ethically framed processes that could be used in the future. Not surprisingly, the most common dilemma was the management of a patient or family member who was reluctant to abide by a policy that limited their freedom of choice. A less frequent issue but very distressing for all concerned was the inability to meet the social needs of our dying patients, even those who did not require isolation.

In 2000, the Singapore Government declared a Biomedical Science Initiative as one of the nation's key economic drivers and formed a Life Sciences Ministerial Committee. This Committee in the same year established the Bioethics Advisory Committee (BAC) to address the potential ethical, legal, and social issues arising from biomedical sciences research in Singapore, and to advise and make recommendations to the Government. In the decade that followed, the BAC examined and reported on the Ethical, Legal and Social issues arising from research involving Human Stem Cells, Reproductive and Therapeutic Cloning, Human Subjects, Genes, Genetic Testing, Personal Information, Donated Human Eggs and Guidelines for Institutional Research Boards. Public consultations were an integral part of each of the investigations.

The findings and recommendations within these reports have contributed to forming the basis of the ethical foundations of the rapidly expanding biomedical research that was occurring in Singapore (6). These include the establishments of the National Research Foundation to coordinate and research activities of different agencies, the Institutional Review boards (IRB) at the National University of Singapore and the National Healthcare Group of medical institutions. Later another IRB was established in the Singhealth Group. This was accompanied by the Ministry of Health issuing National Guidelines for IRB'S and Directives to Healthcare institutions on research involving oocytes and gametes. During this period the following were also enacted The Human Cloning and Other Prohibited Practices and, the Mental Capacity Acts. All these developments also led to the nation being positioned to host in July 2010, the 8th Global Summit of National Bioethics Advisory Bodies and the 10th World Congress.

A National Advisory Committee for Laboratory Animal Research (NACLAR) was established in 2003 by the National Parks Board to ensure the establishment of best practices in accordance with scientific, ethical, and legal principles. The Committee in 2004, published the Guidelines on the Care and Use of Animals for Scientific Purposes. The guidelines are a national guide that sets out the responsibilities of all parties involved in the care and use of such animals and are

based on the fundamental principles of Replacement, Reduction and Refinement. The guidelines stipulate that all proposed use of animals for scientific purposes must be evaluated and monitored by an Institutional Animal Care and Use Committee (IACUC). It also requires that all animal research facilities have to operate in accordance with the Guidelines in order to qualify for licensing from the Animal and Veterinary Service (AVS) of the National Parks Board. The second edition of the Guidelines were published in 2022 and it has an additional section on Occupational Health and Safety (7). The additional section provides guidance and standards for protecting the health of those who care for and use animals.

Building capacity and advancing scholarship in Bioethics is the responsibility of the Centre for Biomedical Ethics in the Yong Loo School of Medicine of the National University of Singapore. The Centre works to develop understanding, capacity for good judgement and sound ethical practice in the context of healthcare provision, biomedical science, and health related policy. It helms the undergraduate curriculum in Health ethics, Law and Professionalism of the medical school, has established a networking and training platform for the nation's Clinical, Transplant and Research Ethics Committees. A separate programme of the Centre focuses on bioethical research, promotes sound practices and provides support and ethics expertise to policy makers engaging in ethics-related research. The Centre is also a WHO Collaborating Centre, supporting the latter's work in health ethics, law and policy. More recently it has established a Paediatric Ethics Programme. The Asian Bioethics Review, the journal published by the Centre aims to encourage scholarship in all aspects of Bioethics, especially those with a relevance to the region (8).

The Ministry of Health has been contributing to the development of bioethics through initiating and facilitating cooperation and collaboration among health professionals and their related organisations, scientists, researchers, and the public service administrators. The medium is through customised Advisory Committees who always have as one of their responsibilities, ensuring the ethical appropriateness of all aspects of a proposed health service development. The Advice is considered when a policy is being developed. Policies are transmitted to stakeholders through Advisories, Directives, Regulations and Acts. The most recent Act is the Healthcare Services Act (HCSA), 2020. This is a service-based licensing regime that aims to provide regulatory clarity, strengthen governance and accountability, enhance safeguards for patient safety and welfare and continuity of care in healthcare services that are not provided by the government. It also requires licensing of new and innovative patient need centred services. Examples are services that provide Cell, Tissue and Gene Therapy, Clinical Genetic and genomic diagnoses, Hyperbaric oxygen therapy and Telemedicine.

Issues

Despite the described developments in bioethics literacy among health professionals, researchers and the public, the great pace of growth in the scientific, technological, and clinical domains has resulted in a knowledge, skill and attitude gap persisting in both the professionals and the public and the resulting ethical issues. Areas where significant ethical issues will develop are human reproduction, genetic diagnosis and manipulation, ageing, chronic diseases, neurological conditions, end of life care, public health and in the use of Big Data and artificial intelligence for promoting and restoring health. Details of the ethical issues that are arising from research and treatment in these areas have been detailed in a recent monograph published in 2021 by the BAC (9). Of added concern is the greying of the distinction between research and innovative medical care and the need for ethically appropriate and practical solutions to enable research to be translated into care.

To address the gap, the Ministry of Health has in 2019 established a Health Ethics Capability Committee to oversee the implementation of existing and new training roadmaps for registered healthcare professionals. The Committee is to periodically update the clinical ethics competency framework for these professionals. It will also review the specialised relevant competency needs and training programmes for Hospital/Clinical Ethics Committees, Transplant Ethics Committees and Institutional Review Boards that review applications for human biomedical research. Anticipating widening needs, the reviews will also include other ethics review committees that may be set up in the future.

Our nation is multi-cultural and multi religious. This results in the presence of diverse perspectives and belief in existential aspects of life and a greater readiness to its public expression. There is the need to foster safe expression without compromising a common societal good. Hence ethical issues need to be addressed and resolved in an inclusive manner and not politicised (10). This requires an enlightened engagement process. We have over the last two decades been engaging the public and seeking their inputs and considering these when drafting recommendations (11). The BAC has also exploited the digital and public space through its website, social media posts and the Bioethics Corner in the National Library and another in the Singapore Science Centre (12).

A related challenge is the need to consider international and regional perspectives when resolving local ethical issues. There is a need to contribute to, secure and understand the regional and international perspectives of bioethical issues. To address this the BAC has increased its exposure and active participation into the region and internationally through an active involvement in the UNESCO Bioethics Programme through membership in its International Bioethics Com-

mittee and the Inter-Governmental Bioethics Committee (13). To foster a regional collaboration, the BAC has established the Asian Bioethics Network in June 2021.

Role

The National level ethics committees have been instrumental in the development of Bioethics in Singapore and they will continue to have an ongoing and larger role. Their contributions as described above will be enhanced with greater connections and collaborations with each other, the public and the international community.

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The Philippine Health Research Ethics Board (PHREB)

Leonardo de Castro[1]

Profile

The Philippine Health Research Ethics Board (PHREB) was created by the Department of Science and Technology (DOST) in 2006 through DOST Special Order No. 091, s. 2006. It acquired status as a legally mandated national policy-making body for health research ethics upon the institutionalization of the Philippine National Health Research System through the Republic Act 10532, signed on May 07, 2013.

PHREB's mandates are detailed as follows:

- Formulate and update guidelines for the ethical conduct of human health research;
- Develop guidelines for the establishment and management of ethics review committees (IRBs) and standardization of research ethics review;
- Monitor and evaluate the performance of institutional ethics review committees in accordance with procedures outlined in a prior agreement;
- Promote the establishment of functional and effective ethics review committees;
- Provide advice and make recommendations to the PNHRS Governing Council and other appropriate entities regarding programs, policies and regulations as they relate to ethical issues in human health research;
- Initiate and contribute to local and international discourse on ethical issues in human health research; and
- Network with relevant local, national and international organizations.

Because it has no full-time members, PHREB carries out its mandate through the following committees, which have been vested with specific functions:

1. The Committee on Standards and Accreditation (CSA) assists in the establishment of functional and effective research ethics committees (REC)

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across the country that are adherent to the universal principles of protecting human participants in research. It is also responsible for the implementation of the policies and guidelines set by PHREB with regard to REC accreditation and makes certain that the standards in ethics review are upheld by all RECs in the Philippines through monitoring and evaluation.

Like other Asian bioethics regulatory bodies that implement their work through RECs/Institutional Review Boards (IRB), the PHREB performs its review tasks through RECs/IRBs. These RECs/IRBs also serve to promote demographic fairness. The PNHRS law and before it the administrative order creating the Philippine Health Research Ethics Board provided demographic fairness by requiring the presence of at least two female members for declaration of quorum. There must also be at least two "non-scientific" members as a requirement for quorum. Non-scientific members are those without formal academic training in the sciences. The presence of IRBs/IRCs also serves as a safeguard that local publications are consulted about foreign/external research protocols that can take advantage of their vulnerabilities.

There are currently 87 PHREB-Accredited RECs across 12 of the 17 regions of the Philippines.

2. The Committee on Information Dissemination, Training, and Advocacy (CIDTA) develops guidelines for the establishment and management of RECs and standardizes research ethics review by providing the necessary competencies through the conduct of ethics training to researchers, REC members, research coordinators of institutions, and other stakeholders.

   The PHREB-CIDTA conducts an average of 63 training-workshops every year, with about 1500 participants, which include researchers, REC members, faculty members, and administrative personnel, among others.
3. The Committee on Networking (CON) ensures cooperation and collaboration with local, national, regional, and international agencies and organizations in promoting and safeguarding the rights and well-being of human participants in research, and promoting the ethical conduct of health research and public health ethics activities. The committee is helping national agencies establish their own RECs.

   The PHREB works hand in hand with the National Commission on Indigenous Peoples, National Commission for Culture and the Arts, and the National Museum of the Philippines to ensure that Indigenous People are represented by their own kind in the informed consent process.
4. The Committee on Patient, Family, and Community Engagement in Health Research (CPFCE) ensures that the policies of PHREB encompass the pro-

motion and safeguarding of the rights and welfare of human participants in research.

To assist PHREB in a comprehensive and consistent implementation of its policies to protect the rights, safety, and welfare of human participants in health and health-related research, it needs regional arms. The pertinent provision of the PNHRS Law allows PHREB to monitor the accreditation processes, ethics training dissemination, patient engagement mechanisms, and advocacy in all the regions of the country.

Initially, the DOST Special Order No. 248 s. 2017 established the Regional Ethics Monitoring Board (REMB) in three regions, namely Ilocos (Region I), Western Visayas (Region VI), and Davao (Region XI). Each serves as the regional arm of PHREB in implementing policies and directions in health research ethics, each with their own CSA and CIDTA.

The REMBs are lodged within existing regional DOST, DOH, and CHED offices or any designated institution with the following functions:

- Information dissemination, training and advocacy of PHREB;
- Monitor the performance of RECs in their respective regional areas.
- Submit annual reports to PHREB;
- Assist in the development of quality assurance in review of RECs in the region;
- Assist in the implementation of policies and directions for health research ethics set by PHREB;
- Perform other functions or tasks as deemed necessary by PHREB.

An *Ad Hoc* Committee for the Updating of the National Ethical Guidelines is established every five (5) years to review and update the existing ethical guidelines. This Committee may tap other experts that could review and provide updates to the specific guidelines.

The PHREB also organizes a National Conference every two years to provide a venue for research ethics committees, researchers, and other stakeholders to discuss and learn about updates on health research ethics.

The National Ethics Committee (NEC), the predecessor of PHREB, addresses the identified gaps in the health research ethics review structure in the Philippines and assists in improving the quality of ethics review in the country. Established in 1984 to promote ethics review in health research, the NEC was temporarily phased out in 2010 because of the overlapping functions with PHREB and the increasing number of institutional research ethics committees that conduct ethics review. However, due to the pressing need for a national body to review research of national impact, it was reactivated in 2013 through DOST-PCHRD Special Order No. 146.

Issues

The PHREB has come a long way in performing its functions, though it still faces many challenges.

One prevailing challenge is the shortage of research ethics experts in the country, and this small pool consists of either experts in their retirement or developing experts whose interest in research ethics are secondary to their primary professions. This affects not only the PHREB itself, but all research ethics committees in the country.

Compensation for being a member of a research ethics committee is also quite minimal and often fails to motivate early to mid-career academics or medical practitioners to dedicate time and resources to become research ethics experts.

Second, at the onset of the COVID-19 pandemic in 2020, community quarantines and stay-at-home orders hindered the operations of PHREB, specifically those of the CIDTA and CSA. Functions that are accomplished in person such as trainings and accreditation activities were suspended while the world, including the PHREB Secretariat, transitioned to virtual platforms. RECs also faced similar issues during this time, resulting in the postponement of scheduled trainings for its members or its application for reaccreditation. As a result, the number of trainings done during 2020 were significantly lower than in 2019, and the accreditation of many RECs expired, thus reducing the number of PHREB-Accredited RECs in 2020 and 2021.

However, the PHREB Secretariat quickly adapted to conducting trainings and accreditation activities through online platforms, resulting in an increased number of trainings and accreditation visits later in 2021.

Another issue that affects the operations of RECs, and thus the number of accredited RECs, is the high turnover rate of staff secretariat. Institutional memory suffers and there is no proper endorsement of documents and pending activities, especially when it comes to the PHREB-accreditation status of the REC.

Finally, the PNHRS law is not seen to provide PHREB with effective 'police powers' to penalize erring researchers or research ethics committees. Though uncommon, there are some researchers who do not abide by the ethical guidelines set by the PHREB and its accredited RECs. On the other hand, contract research organizations and some researchers come to PHREB at times to request penalties for RECs that are non-compliant to their own Standard Operating Procedures. Nonetheless, PHREB invokes its legal mandate to implement guidelines consistent with national policies and laws, and international guidelines which includes the World Health Organization's (WHO) broad definition of health. As such, it seeks to provide steadfast guidance that can be quite useful in times of emergency.

Vision

The Philippine Health Research Ethics Board envisions a culture that respects, protects, and promotes the rights, dignity, and well-being of research participants, upholds research integrity and inclusive, collaborative, and ethical research for achieving the best possible health outcomes of all Filipinos.

In support, PHREB aims to bring awareness and knowledge on research ethics to all academic, research, and funding institutions in the country, through dialogues with institutional heads, national and interregional conferences, and advocacy campaigns.

The Committee on Patient, Family, and Community Engagement produces informational materials and organizes campaigns to help patients and communities understand their rights and responsibilities as research participants and/or research sites, respectively. It also assists the Committee on Information Dissemination, Training and Advocacy (CIDTA) in producing informational materials for community representatives who are potential REC members. These informational materials and activities are disseminated to the regions through the Regional Ethics Monitoring Boards.

These multi-committee information dissemination and advocacy campaign activities ensure that all stakeholders, including researchers, implementing and funding institutions, members and potential members of RECs, participants and potential participants of researches as well as their communities, are aware of the ethical standards that must be upheld in conducting research.

PHREB also seeks directly to assist Research Ethics Committees (REC) in building their capacity and competence in conducting ethics review by giving targeted trainings on ethics review and concrete operational concerns.

Currently, CIDTA provides Continuing Research Ethics Trainings, on specific topics, according to the needs of the requesting institution or REC, or the recommendation of the CSA. Some of these have to do with Conflict of Interest (COI) and Informed Consent. There are also Standard Operating Procedure (SOP) Workshops that focus on the REC's development of their own SOPs. Additionally, a Practical Training Course for REC Chairs and Staff is provided to pre-identified RECs during the PNHRS Week Celebrations every second week of August.

PHREB has also started to implement an observership program for newly established RECs wherein they have an agreement with a well-established REC, for the members or staff secretariat to observe how the well-established REC runs and operates, on condition that the participants sign Confidentiality and Conflict of Interest declarations.

We have similarly been implementing interregional conferences for RECs, both well-established and newly-established ones, to supplement those that are

held during the yearly PNHRS Week Celebration and the Biennial PHREB National Conference. Thus, we are able to ensure that we continuously communicate and learn from one another, especially those regarding the best practices that the new RECs may adapt and practice, as well as the common issues that we face, as we come up with possible solutions together.

At the global level, PHREB continues to take an active role in the Regional Asia-Pacific Network of National Ethics Committees through its regular participation and influence on the regional agenda. PHREB is also taking the opportunity to influence the agenda for regional ethics promotion and awareness building at this time when the presidency of the International Organization for Education in Ethics is in the Philippines.

7. International institutions

Health Ethics & Governance at WHO: The importance of the Global Summit of National Ethics Committees

Patrik Hummel[1], Katherine Littler[2], Andreas Reis[2]

Introduction

WHO celebrates its 75th anniversary in 2023. Since its establishment in 1948, the mission of the World Health Organization has been to deliver health care for all, with its constitution stating 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." This ambitious goal of health for all, or providing universal health coverage (UHC) for everyone, has been one of the main goals of WHO in the past decades. Following WHO's constitution (World Health Organization, 1946), the Declaration of Alma Ata in 1978 made a strong push for primary health care (PHC) as the key for attaining the goal of Health for All (*Declaration of Alma-Ata*, 1978). The World Health Reports of 2008, 2010 and 2013 all focused again on the centrality of primary health care and Universal Health Coverage (World Health Organization, 2008, 2010, 2013), just like the Salalah Declaration on UHC and the Astana Declaration on PHC in 2018 (*Declaration of Astana*, 2018; *Salalah Declaration on Universal Health Coverage*, 2018).

And fundamentally, the pursuit of UHC, or Health for All, is an ethical aspiration. As Margaret Chan, the former WHO Director-General declared 10 years ago: "*I regard universal health coverage as the single most powerful concept that public health has to offer.... It operationalizes the* highest ethical principles *of public health. It is a powerful social equalizer and the ultimate expression of fairness*" (Chan, 2013, as cited in Reis, 2016). And more recently, Dr Tedros, WHO's current DG, stated: "For me, the key question of universal health coverage is an ethical one. Do we want our fellow citizens to die because they are poor? Or millions of families impoverished by catastrophic health expenditures because they lack financial risk protection?" (Ghebreyesus, 2017). Thus, the central goal of WHO, the attainment of Health for All, is inextricably linked to an ethical ambition.

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Health Ethics & Governance is at the heart of WHO's Program of Work

WHO's 13th Program of Work (2019-2023) is an ambitious program (World Health Organization, 2019). It defines a set of interconnected strategic priorities, ensuring healthy lives and promote well-being for all. In particular, it formulates the triple goals of the "three billions": One billion more people better protected from health emergencies, one billion more people enjoying better health, and one billion more people benefitting from universal health coverage. One of WHO's six core functions is to "articulate ethical and evidence-based policy options" and it declares that "WHO will work to ensure that all policies, public health interventions and research are grounded in ethics" (World Health Organization, 2019).

Particular importance is given to ethical issues in new and emerging scientific disciplines and Universal Health Coverage, where both the opportunities and risks to global health are noted. WHO's Member States recognize that it is crucial to proactively address ethical issues to ensure that Universal Health Coverage is enhanced and not undermined by novel technologies: "WHO's normative guidance will be informed by developments at the frontier of new scientific disciplines such as genomics, epigenetics, gene editing, artificial intelligence, and big data, all of which pose transformational opportunities but also risks to global health" (World Health Organization, 2019).

Thus, WHO's Member States recognize the Organization's key function to ensure that new technologies will benefit everyone, and not further exacerbate existing inequities. "WHO is uniquely positioned to understand and tackle proactively the ethical, regulatory, professional and economic implications and to provide independent guidance with universal legitimacy to ensure that UHC is enhanced and not undermined by new scientific frontiers." This has been a strong mandate for WHO's Health Ethics and Governance Unit to undertake work on the ethical aspects of new technologies, for example in the areas of human genome editing and artificial intelligence for health.

Importance of Global Summit of National Ethics Committees

The Global Summit of National Ethics Committees plays a key role for WHO in fulfilling its mandate on Health Ethics & Governance. The Summit is the central platform for deliberation and exchange between National Ethics Committees worldwide (Bouësseau *et al.*, 2011; Ruiz de Chávez Guerrero & Pina, 2015; Deutscher Ethikrat, 2018). It takes place every two years since 1996 and is coordinated by WHO and UNESCO. The WHO Health Ethics & Governance Unit serves as the Permanent Secretariat of the Summit since 2004 (Köhler *et al.*, 2021).

National Ethics Committees (NECs) provide expertise and guidance on ethical questions in medicine, biomedical research, and public health (Mali *et al*., 2012; Hummel *et al*., 2021; Hummel & Reis, 2021, 2023). The composition of these Committees is almost always multidisciplinary "to ensure a multitude of views and opinions" (Köhler *et al*., 2021) is considered, for example with representatives from medicine, policy, law, theology, ethics, and civil society organizations. The deliberations of National Ethics Committees lead to reports, opinion pieces, and recommendations to policy-makers and the public. The range of outputs varies from reflective work on bioethical concepts and contexts of application, to frameworks for responsible research and innovation, to more directive, specific recommendations on the application of new biotechnologies in practice (Schmidt & Schwartz, 2016; Montgomery, 2017; Hummel *et al*., 2021) Committees began publishing such documents since the 1970s, and there has been a marked increase in the publication volumes since the early 1990s (Hummel *et al*., 2021). Besides policy advising and providing guidance on bioethical issues, many Committees strive to serve as catalysts for public discourse. They map the state of the art, mediate between controversial positions, facilitate the expression of diverse views, take the perspectives of both experts and laypeople seriously, and consider both when formulating recommendations (Dodds & Thomson, 2006).

There are various reasons why the Global Summit is an important platform for National Ethics Committees (Hummel & Reis, 2021, 2023). The scope of bioethical challenges rarely aligns with national borders. Instead, many of them have a global dimension. The Covid-19 pandemic is only the most recent illustration of the transnational connectedness of key issues in biomedical research, public health, and the life sciences more generally that have important ethical dimensions. Many other developments and innovations raise both ethical challenges and opportunities that can be managed effectively only through joint action. Whether it is research ethics in international trials, questions around the responsible development and access to assisted reproductive technologies, the deployment of artificial intelligence in health and beyond, the equitable distribution of scarce vaccines, planning and preparedness for the next pandemic, the regulation of technological interventions such as gene drives or modifications of the human genome – coordination between countries is indispensable for arriving at effective measures and making meaningful progress in governance.

In view of such interconnectedness, National Ethics Committees identify as their stakeholders not only domestic policy-makers and the public, but also the international community (Montgomery, 2017) in particular National Ethics Committees from other countries (Deutscher Ethikrat, 2023) with whom cooperation on challenges that transcend the domain of particular nation states is

indispensable. The Global Summit is a key venue to initiate and deepen such cooperation and to facilitate continuous exchange of perspectives, arguments, and latest evidence. It serves as an "essential tool for international dialogue and consensus-building" (Bouësseau *et al.*, 2011).

In the years between Global Summits, many Committees meet at regional summits (World Health Organization Regional Office for the Eastern Mediterranean, 2017; World Health Organization Regional Office for the Western Pacific, 2019) such as the European Forum of National Ethics Committees co-organized by the European Commission (*26th Forum of National Ethics Councils (NEC) and the European Group on Ethics in Science and New Technologies (EGE)*, 2020), and even sub-regional meetings between National Ethics Committees of neighboring countries (Deutscher Ethikrat, 2020) in order to focus on current challenges, ongoing work, best practices in the respective region, and to shape the interplay between regional and global perspectives.

Such dialogue is all the more important in view of the significant pluralism amongst National Ethics Committees. One difference concerns their scope. Some Committees are generalistic bioethics committees that work on a broad range of topics, from conceptual, theoretical, and foundational work to concrete applied issues in all domains of bioethics. Other Committees have a much narrower focus and work solely on the ethics of biomedical research, typically by reviewing proposed research studies and sometimes also by informing research-related policy activities (Fuchs, 2005; Köhler *et al.*, 2021; Hummel *et al.*, 2021). While there are internationally recognized research ethics standards such as the Nuremberg Code, the Declaration of Helsinki, and the CIOMS Guidelines of the Council for International Organizations of Medicine, it is essential to conduct national and local ethics reviews in order to interpret, substantiate, and apply recognized international standards in a context-sensitive way (Hummel & Reis, 2021, 2023). In fact, the genesis of these standards themselves was partly shaped by National Ethics Committees – the Global Summit 2014 was an important occasion for the CIOMS Working Group to seek feedback from National Ethics Committees on the refinement of the guidelines (The Council for International Organizations of Medical Sciences, 2016).

Further differences between National Ethics Committees concern their formal constitution, mode of operation, degree of independence, *e.g.*, from their national government, and political and value systems in the countries they represent. Some Committees are part of governmental ministries, others are independent, nongovernmental organizations. Most Committees are permanent institutions, but some are set up only for a given legislative period (Capron, 2017) or on an *ad hoc* basis. While some Committees enjoy sufficient resources, others report that they lack necessary means to operate effectively and face challenges, *e.g.*, around

independence and funding (Köhler *et al*., 2021). There are salient clusters in focal topics across most Committees, for example research ethics and ethics review processes, ethical aspects of genetic technologies, organ transplantation, assisted reproductive technologies, and ethics at the end of life. Committees' works and positions are further shaped by distinctive country perspectives and priorities (Hummel *et al*., 2021).

From the start, the Summit was also intended as a venue for facilitating capacity building and for promoting the establishment and training of National Ethics Committees in countries that are currently without such a Committee, or in which Committees experience obstacles of various kinds. As recent empirical investigations (Köhler *et al*., 2021) indicate, such obstacles pertain to the availability of means for sustainable, effective, and transparent operation, i.e., the consistent production of outputs, their accessibility to all stakeholders, and their consideration and uptake by policy-makers. These issues are highly continent upon the political environment in which the respective Committee is located and the means and capacities it has been equipped with. Consequently, the Summit has been a forum for initiatives to learn from each other's experiences, challenges, and solutions in order to develop coordinated approaches. In this way, the Summit facilitated the dissemination and access to capacity building initiatives such as UNESCO's impactful Bioethics Programme (UNESCO, 2010; Bagheri *et al*., 2016) and associated activities at national levels (Langlois, 2014; Gefenas & Lukaseviciene, 2017) which led to the establishment of many new National Ethics Committees in countries that so far lacked such an institution.

In November 2019, 47% of National Ethics Committees were located in countries classified by the World Bank as high-income countries, 10% were located in low-income countries. These Committees were geographically distributed across all WHO regions: 44% were located in Europe (EURO), 18% in the Americas (PAHO), 15% in Africa (AFRO), 11% in the Western Pacific (WPRO), 6% in the Eastern Mediterranean (EMRO) and 5% in the South-East Asia (SEARO) region (Hummel *et al*., 2021).

Recent Summits

The theme of the 12th Global Summit held in Senegal in 2018 had been "Bioethics, sustainable development and societies", reflecting the United Nations sustainable development goals. One of the three sub themes of that Summit was focused on health emergencies and resilience, remembering that this Summit came on the back of the aftermath of the Ebola pandemic in West Africa. Who at that time would have thought that this topic would rise to such importance in early

2020 through COVID-19? Another theme revolved around the issues associated with the electronic data era which is an expanding field, especially given the convergence with AI. The third theme of social justice and civil society, is still critically important to the way we respond to health and scientific challenges. In view of these reflections and debates, participating countries adopted a "Call for Action" (Global Summit of National Ethics Committees, 2018) highlighting the need for international attention and coordination with regard to ethical aspects of these themes. This shows how in addition to networking and exchanging experiences, the Summit is a platform for Committees to identify global priority topics (Hummel & Reis, 2021, 2023). On the basis of such declarations, National Ethics Committees align their activities, lay the foundation for joint action, and engage stakeholders accordingly.

In fact, there is a real thread that has run through the last three Global Summits from the 2016 Summit which was held in Germany through to the 2022 Global Summit in Lisbon. That is the focus on pandemic preparedness and response, which clearly remains as important as ever, especially as Member States of WHO are now engaged in negotiating a pandemic treaty (World Health Organization, 2023). This is clearly a topic and area that it is important that National Ethics Committees continue to take an interest in going forward, especially as we move from response to preparedness.

The recent 13th Summit, under the theme of "Health Justice and Health Care for all", focused on a range of current issues and concepts: from crisis to collectivism to communitarianism, to commonality, to coordination, to solidarity, to trust, to mistrust, to social media, to the effects of social Media, to the "infodemiology", to demography, to climate change, to migration, to populism, to tribalism, to access and lack thereof, to Innovation to equity or lack thereof, to education, to literacy, to being prepared to not being prepared, or to being prepared again, to learning lessons or not learning lessons, to the importance of our community, the Global Ethics Community. The national ethics and the regional ethics community are called upon to tackle the breadth of these challenges in a changing world, from the macro to the micro level.

Unlike that Summer in Senegal in 2018, participating countries did not develop a "written call to action", but there was still a clear sense throughout the meeting that National Ethics Committees have a key role in helping society to reflect on and discuss these major challenges, to advise, and to engage. Organizations such as WHO and UNESCO have a key role to play in supporting Committees to do this.

As became apparent during the meeting, representatives perceive a translation and implementation problem. A common theme was that many struggle with how to effectively embed ethics in policy and decision making. As it happens,

ethicists are not alone as this struggle which is not particular to the ethics community; it happens with scientists as well. Still, there was agreement that the commitment highlighted by the Portuguese hosts in the opening ceremony is one of the foundations the global community must continue to build on to come full circle.

Future importance of Global and Regional Summits of National Ethics Committees

Especially since Covid-19, there is a larger need than ever to jointly advocate for the recognition of the importance of bioethical issues when addressing and preparing for current and future challenges. On the one hand, the pandemic has led to increasing levels of public attention to the activities of National Ethics Committees, which play even more prominent roles in guiding policy and assessing research projects than before. As one indication, the number of requests to National Ethics Committees has increased sharply in many countries and a large number of statements have been published in a relatively short time (Hummel & Reis, 2021, 2023). In line with this, and resonating with the foundations of UHC outlined at the outset, in various statements at different stages of the pandemic the WHO Director General has used normative language and referred to ethical concepts to describe what is at stake, *e.g.*, when framing vaccine equity as a moral imperative and cautioning against catastrophic moral failures as a consequence of vaccine nationalism (World Health Organization, 2021). He urges policy-makers and implementers to "keep ethics at the heart of decision-making" as it is "fundamental in every area of health" (World Health Organization, 2022).

On the other hand, there is a continuous need to promote and foster the effective translation and sustainable embedding of bioethical expertise into policy-making (World Health Organization, 2022). While systematic evidence on the experiences of Committees during the pandemic is still to be gathered and analyzed, there are anecdotal reports about pressures related to issues such as turnaround times, outcomes of review processes, and the assessment of unproven treatments. Increased numbers of requests to Committees also meant that workloads often grew disproportionate to the size and funding of many Committees. In terms of capacity building, especially Committees that operate under scarcity of funding faced challenges in assessing increasingly complex, large, and adaptive trial designs. Going forward, one of the key issues to debate at future Global Summits is how the global community can work towards resilient structures, including at the level of National Ethics Committees, to better prepare for the next global health emergency.

As we move to the next Global Summit in San Marino in 2024, we need to not only think about the valuable lessons we can build on from previous Summits but how we can amplify the value of National Ethics Committees on shining a light on, debating and discussing some of the toughest issues our societies are struggling with. At WHO, we are committed to supporting this invaluable network in line with WHO's mandate on Ethics and Governance to promote Health for All[3].

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The Role of the Council of Europe in Bioethics

Ritva Halila[1]

The Council of Europe is an intergovernmental organization set up in 1949. It aims at protecting human rights and strengthen pluralist democracy, European cultural identity and peace. Bioethics has been part of its work from 1970's. In 1982 in its recommendation 934 (1982) (1) on genetic engineering the Parliamentary Assembly asked the Council of Ministers for a preparation of an international agreement on bioethics. The Parliamentary Assembly was then aware on public concern about the use of new scientific techniques for genetic engineering techniques, and therefore asked the Committee of Ministers to draw up a European agreement to protect and respect human rights in the field of biomedicine. In 1985 the Committee of Ministers set up the *Ad hoc* Committee of experts on Bioethics (CAHBI), which became in 1992 the Steering Committee on Bioethics (CDBI). These Committees were responsible for the intergovernmental activities of the Council of Europe in the field of bioethics, and in this field in preparation of numerous Recommendations for the adoption by the Committee of Ministers, such as Recommendation (92)3 on genetic testing and screening for health care purposes (2) and Rec (92)1 on the use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system (3) by CABHI, and Recommendation on human tissue banks and on screening as a tool of preventive medicine, by the CDBI (4, 5), and preparation of the Convention on Human rights and Biomedicine, known also the Oviedo Convention, the only binding international treaty in this field. The Oviedo Convention was adopted by the Committee of Ministers on 6th November 1997, and it entered into force on 1st of December, 1999. By now, 36 Member States of the Council of Europe have signed the Convention, and 29 have ratified it. The additional Protocols on the Prohibition of Cloning Human Beings, Transplantation of Organs and Tissues of Human Origin, Biomedical Research and Genetic Testing for Health Purposes were prepared and adopted since then. In 2012 the CDBI became the Committee on Bioethics (DH-BIO), a subordinate body of the Steering Committee on Human Rights (CDDH). In 2022 the Committee became the Steering Committee for

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Human Rights in the fields of Biomedicine and Health (CDBIO). As a steering committee, the CDBIO works under the authority of the Committee of Ministers, but still works in close collaboration and regular exchange of views with the Steering Committee on Human Rights. In accordance with its status of steering committee, the CDBIO holds regular exchange of views in order to evaluate its activities and advise by the Committee of Ministers and the Secretary General on future priorities in its sectors including possible new activities. Also, it will conduct intergovernmental work on human rights protection in the fields of biomedicine and health.

The DH-BIO has also prepared a draft additional protocol to protect the rights of mental health patients in involuntary care and subject to involuntary treatments. In addition to that, the CDBIO has started preparation of recommendation on voluntary services in mental health with which the use of involuntary services in mental health care could be avoided. The DH-BIO and now CDBIO has also published Compendium, a guide for good practices to promote voluntary measures in Mental Health Services. The work on recommendation on voluntary care should be finalised by the end of 2024 (6).

In addition to binding legal documents, the Committee has produced guidance to various areas in health care, for example to end-of-life issues (7), emerging technologies (8), prohibition of financial gain (9), and public debate (10), just a few to mention as examples. Many of these topics have originated from the discussions of the committee, either to elaborate further ethical principles or the articles of the Oviedo Convention, as in the case of the guide on prohibition of financial gain, and the guide to public debate in Human Rights and Biomedicine. The development of medicine has been enormous, and emerging technologies, such as genomic editing, neurotechnology, big data and artificial intelligence, raise questions whether the ethical issues, and also solutions for concerns, are the same as in health care in general. The purpose of the guide on the decision-making process regarding medical treatment in end-of-life situations was to serve as a useful tool for professionals, patients and their families, to help for the development of practices and as a basis for discussions about difficult and sometimes problematic decisions in the end-of-life situations. It was also intended to facilitate the implementation of the principles of the Oviedo Convention. During the Covid-19 pandemic, the DH-BIO published several documents about equal access to vaccines (11), and following that approved a draft recommendation for the adoption of the Committee of Ministers on equal access to medicines and medical equipment in the situation of scarcity in November 2022 (12). The Committee has also produced educational tools on bioethical issues for schools, and e-learning course on bioethics for human rights educational course for legal and health professionals (HELP) (13).

The work of the CDBIO is based on the Oviedo Convention and its additional protocols, which have their basis on the Convention of Human Rights. Basic ethical principles included in the articles of the Oviedo Convention are nowadays an important and integral part of health care practices, such as equity in access to health care, autonomy of a patient (consent), information to patients about benefits, risks and possible harms, rights of those who are not able to consent, obligation for member states to foster public debate, and rights of the research participants. During the last years the CDBIO has focused on many of these issues, published recommendations and guidance, and arranging seminars, round tables and educational events on specific issues and their relevance to the Oviedo Convention and ethical principles. All documents produced by the committee are public and have been published in the web pages of the Committee (14).

Why legal instruments?

The Oviedo Convention is still the only legally binding international document in the field of bioethics. Since the adoption, many countries have written national legislation on the rights of patients. Finland was among the first countries in the whole world to have the Act on the Rights of Patients, already in 1992 (15), followed by many other countries already during 1990´s. Legally binding instruments are tools for courts, for example the European Court on Human Rights (ECHR), to evaluate the fulfilment of the rights of patients on case-by-case basis or have they been infringed in some ways(16). The ECHR has even used the Articles of the Oviedo Convention in their decisions concerning Member States that have not signed or ratified the convention[2].

The Committee follows regularly the impact of its work by regular questionnaires to the member states on different areas. The Committee of Ministers also requires the Steering Committees to monitor their work and development in their field in the Member states. The CDBIO also follows the work of the ECHR and its decisions. The CDBIO works actively in improvements in the field of bioethics especially in new member states (DEBRA project) arranging seminars and courses to health care and legal professionals.

Examples of the recent and ongoing work of the CDBIO

While preparing its Strategic Action Plan, the DH-BIO collected items to four "pillars" or sections it considered as the basis of the Plan. As these sections", governance of technologies, physical and mental integrity, equity in health care and co-operation and communication. The first, governance of technologies, embeds

[2] see ECHR decisions, for example https://rm.coe.int/090000168073644f

human rights in the development of technologies that have an application in the field of biomedicine, such as gene editing technologies, applications of neurotechnologies, and artificial intelligence in healthcare. Public dialogue is needed for democratic governance, equality in access to new technologies and needed health care. Good governance is needed for the realization of other sections, integrity and equity, in healthcare. The fourth section, co-operation and communication with other Council of Europe instruments and international organisations in this field is important to maximize efficiency and ensure that the committee makes a unique contribution to the challenges presented to it.

The four pillars were discussed in the committee meetings, and delegates were asked to contribute and make suggestions of items for the following years, based on the accepted SAP structure. The items chosen, some of them presented here, were among these suggestions.

Guide to health literacy

The DH-BIO planned in its strategic action plan to draw a guide to health literacy, because understanding prevention, diagnostics and therapies of complex diseases abilities to get adequate information and understand it is even more important. Health literacy is a significant determinant of health and a constituent of avoidable and unfair health inequalities. Limited health literacy relates closely to adverse health outcomes whereby health literacy becomes a critical social determinant of health. Low socio-economic status, low education, adverse health behaviors, poor self-reported health, and increased use of services correlate with limited levels of health literacy. The ability to understand, and thus participate into decision-making concerning one´s health is more compromised among persons belonging to language minorities, persons with communication challenges, persons with disabilities, and minors, just a few to mention. However, health literacy is also content- and context-related and it relates to low-income, medium-income and high-income countries alike.

The DH-BIO started its work by nominating two experts, Kristine Sorensen and Leena Paakkari, to prepare a technical report on issues concerning health literacy. In their report health literacy was defined in this context, and subsequently key challenges were highlighted. The working group started the work on a draft guide based on the report in November 2021, and final version of the guide was approved by the CDBIO in November 2022 after consultation of the experts in February-March 2022.

This guide is intended for decision-makers, health professionals and health providers to help them identify the needs of individuals in accessing healthcare.

The guide contains practical examples how to improve health literacy in different population groups. While health literacy entails people´s knowledge, motivation and competencies to access, understand, appraise and apply health information in order to make judgments and decisions in life concerning health, disease prevention and health promotion, the health literacy is an essential part of a person´s ability to improve his or her health and welfare. Health literacy also helps people to seek help in need, and get more easily in contact with health care professionals. Health literacy is an important determinant of health and a constituent of avoidable and unfair health inequalities. A strong socio-economic gradient has been identified which indicates how low socio-economic status, low education, adverse health behaviours, poor self-reported health, and increased use of services correlates with limited levels of health literacy. Health literacy gaps can lead to inequities between countries and between different population groups within countries.

The intention of preparing the Guide was also to give examples how the health literacy can be improved, what are the gaps, how to decrease inequalities in health, and how to find persons in greatest health needs.

The CDBIO adopted the Guide during its second meeting in November 2022. The guide is informative and easy to use, and it contains practical examples how to improve health literacy in certain situations and of different patient and age groups. It has been intended to be actionable online resource that can be updated easily. This guide can be found in the web pages of the CDBIO (17)

Draft guide to the participation of children in decision--making processes regarding their health

As one goal of the Strategic Action Plan of the Committee, the DH-BIO established a working group together with the CDENF, the Steering Committee for the Rights of the Child, for strengthening the ability of children to participate in decision-making on their own health. For this aim a consultant, professor Annagrazia Altavilla, was nominated to write a background document on legislation concerning children´s rights on this area, and issues concerning decision-making in health among minors in health care and health research.

Allowing children to participate in decisions regarding their health may help them develop competence, confidence, self-efficacy and responsibility, leading to their empowerment and greater participation in their own lives. In turn, this contributes to fostering their self-esteem, developing self-caring and participation skills that are necessary for long-term self-management as well as to promoting health-seeking behavior, satisfaction, health-related quality of life and overall welfare.

Although legislation concerning self-determination of minors, and the role of their parents vary in European Countries, it is possible to increase the children´s ability to participate their health care decisions. The guide contains many examples how children and adolescents have been taken in participatory processes, to discussions concerning their health care, and also to design and evaluate both research and care.

The working group was established by nominations of members of the group by both committees, to prepare a guide with also good practices from different countries. The guide is targeted to health care professionals, while they are in key role in empowering the child to participate. Children who participate in individual decision-making processes on issues relevant to their health are likely to be more informed, feel more prepared, to learn how to better manage their condition and treatments on their own and experience less anxiety about the unknown.

This guide has been processed consulting both committees, stakeholders and children. Good practice examples have been collected from the members of the two committees, and by a questionnaire sent to stakeholders in member states. The guide should be finalized by the end of 2023. It will be actionable online resource in a form that can be updated easily.

Ethical issues in neurotechnology

The DH-BIO organized a round table on ethical issues in neurotechnology in collaboration with OECD and UNESCO. OECD had previously published recommendation on responsible innovation in neurotechnology, and the UNESCO-IBC had published a report on the ethical issues of neurotechnology.

In this round table in November 9th, 2021, attention was raised to human rights issues raised by the applications of neurotechnologies in the biomedical field. The purpose was also to assess the existing human rights framework to address them with a view to prevent abuses and misuses while promoting innovations and applications beneficial for human health, and identify avenues for actions to contribute to responsible innovations in the field.

After setting the scene proposal on existing rights and specific new neuro rights were assessed. Several rights were found to be at stake, *e.g.*, integrity, freedom of persons, and discrimination.

In conclusions of the report on this round table, the rapporteurs state that "while specific "neuro"-rights may well be important in the future, it may be premature to embark upon creation of such rights at this juncture. There is no clear consensus regarding the conceptual-normative boundaries and terminology of neurorights. Divergences exist in relation to how these rights are interpreted,

named, and conceptually articulated. Moreover, there is a risk that elaboration of new rights could lead to accusations of rights inflation which poses the risk of undermining existing fundamental rights, and thus far, proposed "neuro-rights" could be encompassed under many existing human rights instruments and articles." (18). Instead, the rapporteurs suggest multi-level governance of this field. Multi-level governance should aim at creating a normative eco-system in which innovations and applications of neurotechnologies are value based and inclusive.

For future actions the rapporteurs suggest promoting neurotechnology literacy, and public dialogue, activities that the CDBIO has worked also before and published guides in these areas. Future work with OECD and UNESCO/IBC the CDBIO could seek to develop an Interpretative Guide to Adapting Existing Human Rights to neurotechnologies to guarantee that the protection of human rights is a guiding consideration throughout the entire process of research, development, and application.

In future actions with the OECD, it is important to raise public awareness around neurotechnologies and to facilitate an inclusive societal deliberation on how such technologies should be deployed and regulated. In further support of a multi-level governance approach, the Committee, in collaboration with other stakeholders could develop an Interpretative Guide to Adapting Existing Human Rights to neurotechnologies to guarantee that the protection of human rights is a guiding consideration throughout the entire process of research, development, and application.

The impact of the CDBIO in international ethics network

The CDBIO is a part of the organization of the Council of Europe. The protection of human rights is a central part of its work. The CDBIO gets its mandate and assignment from the Committee of Ministers that is the highest decision-making body of the Council of Europe. The work of the CDBIO reflects also the work of other bodies of the Council of Europe, such as the Parliamentary Assembly (PACE) and the European Court of Human Rights (ECHR). Much of its work is done in collaboration with other committees, such as Committee on Prevention of Torture (CPT), and Committee on Artificial Intelligence (CAI), just a few recent collaborations to mention. The CDBIO has constant collaboration with the European Commission, WHO, UNESCO, and OECD. Many of the delegates have connections to national ethical advisory boards in their home countries.

What is the impact of the CDBIO in this kind of global ethics network? The Oviedo Convention, prepared by the predecessors of the CDBIO is a basis for legislation on patients´ rights in Europe and also other parts of the world, and still

is the only binding treaty in this field. To increase the impact of the Oviedo Convention and its Additional Protocols, the CDBIO and the Committee of Ministers do have continuous discussions with the representatives of the Member States about obstacles of signing or ratifying them. The reasons for ratification and not ratifying the convention vary from a county to another. The ratification of the Oviedo Convention is a precondition to sign and ratify an additional protocol, and therefore the number of signatures and ratifications of additional protocols is lower than the Convention.

The committee has expertise in wide field of bioethics, and connections to other sectors of the Council of Europe, its member states and their ethics advisory bodies, and other international organisations. The ever more complex health care ethics issues, technical development, aging, globalization, diverging values within and between societies and global threats force us to work even more closely together, and share thoughts for better understanding, more visibility in societies, and better protection of human rights in health care, especially of those in most vulnerable situations.

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The European Group on Ethics in Science and New Technologies

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Travelling home from the 13th Global Summit of National Bioethics Committees in Lisbon in September 2022, it was hard not to be inspired. A conversation that I had with another participant over coffee sums up the sentiment: "There is a major shift going on in bioethics", my colleague shared their impression of the summit. "Hardly anyone talks about informed consent. It is all about collectives". What this colleague meant is not that anyone suggested that individual autonomy had become less important. Such a view would certainly be mistaken: At a time when people's human rights are openly infringed in so many places, protecting individual rights could not be more important. Rather than suggesting that the role of individual rights was changing, what my colleague was referring to were the broadening and diversification of perspectives and approaches in bioethics. While bioethics continues to pay attention to individual rights and interests, many of the problems that bioethicists – and bioethics committees more broadly – seek to (and need to) tackle at this moment in time require structural and collective solutions. The increasing attention that bioethicists all over the world now pay to social and economic inequities is not merely a reflection of concerns about justice or injustice done to individuals, but it also shows greater awareness of the need to change the social, political, and economic institutions and structures that shape these injustices and inequities in the first place. Doing so requires deliberation, not only about how each person can be given her fair share, but also on what kind of society we want to live in.

Another reason for the Global Summit's extensive attention to collective practices and values – such as solidarity, for example – was the geographical diversity of participants. Many participants came from countries where bioethics – and political and social philosophy more broadly – are rooted in a relational understanding of people and societies. This, in turn, has led to a stronger inclusion of communal and collective values (*e.g.* Owusu-Ansah & Mji, 2013; Frimpong-Monsoh & Atuire, 2019; Rainie *et al.*, 2019) – something that also feminist bioethicists and theorists have long been fighting for (*e.g.* Sherwin & Stockdale, 2017;

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Scully, 2021). Such emphasis on communal and collective values does not, as is sometimes misleadingly argued, mean to assume that the public good trumps the rights, liberties, and needs of individual people. What a relational understanding entails, instead, is to see people whose identities, needs, and interests are shaped also by their relations to others (Mackenzie & Stoljar, 2000; see also Prainsack, 2018), rather than treating them as atomistic individuals. What collective values such as solidarity do, thus, is to overcome approaches that treat individual and collective goods, and individual rights and public interest, as dichotomies (EGE, 2022). Individual and collective goods are not a zero-sum game where one must give for the other one to gain. More often than not, they require each other. As the EGE puts it in our most recent statement on 'Values in times of crisis: Strategic crisis management in the EU',

> While […] there are situations in which individual rights and interests can be in opposition to public interest and the broader common good, they are not in opposition to each other *in principle*. […R]ather than asking how we should ideally 'balance' individual rights and the public interest, we need to ask how we can make sure that everyone's basic needs are met also in a crisis, and how everyone receives the best support possible. (EGE, 2022:8)

In the early 2000s, the Finish philosopher and bioethicist Matti Häyry noted that solidarity is often seen as a particularly (continental) European value and contrasted with the supposedly 'American "autonomy and justice" approach', whereby the latter 'is often seen as overemphasising the role of individuals as consumers of health services' (Hayry, 2005: 199; see also Hayry, 2004). According to Häyry, this was not so much because the Four Principles, autonomy, justice, beneficence, and non-maleficence, represented particularly American values *as such*. Instead, Häyry argued, the dominant interpretations of these four values were couched in an American philosophical tradition. Only about ten years later, Bruce Jennings diagnosed a 'relational turn' in bioethics, which he described as an approach that 'correct[s] the excessive atomism of many individualistic perspectives' (Jennings, 2016: 11). Such a relational approach, according to Jennings, rejected the idea that people can be abstracted from their social and natural environments – that is, from their 'ecological place', as Jennings put it (2016: 13). Here, Jennings already pointed at another aspect that would become increasingly important in the following decade: The acknowledgement of the great extent to which the lives and practices of humans are intertwined with those of non-human species (Gibb *et al*., 2000). Approaches such as One Health (*e.g.*, Gibbs, 2014; Mackentzie & Jeggo, 2019) and Planetary Health (*e.g.*, Horton

et al., 2014; Horton & Lo, 2015) – with different nuances and focus points – call for a responsible stewardship of natural resources that supports a good life for all living beings, including those that will live in the future. They represent a paradigm shift in the sense that they do not suffice with a programmatic diagnosis that 'everything is connected', but they deduct new ways of acting upon the world.

This acknowledgement of the interconnectedness of humans with each other and with other species is closely connected to a rise of complexity thinking in other areas. Also here, complexity thinking is not tantamount to the simple assumption that 'everything is connected', or that things are complicated. A combustion engine is complicated – because of the way in which individual parts need to slot into one another in precise ways. But a combustion engine is not complex. Its behaviour can be predicted if one knows its individual elements and how they interact. The behaviour of a complex system, on the other hand, cannot be predicted. It results from the interaction of its individual elements and from things that these interactions create – including the interactions of these elements with other, environmental factors. In the case of a group of friends going on a weekend trip together, no observer – not even someone who knows each individual in this group – can predict how the weekend will go. This is because the behaviour of the group emerges through the interactions of the individual members with each other and with their natural and artefactual environment during that weekend. A group of people is a complex system.

Many of the current challenges that bioethics is concerned with – including the impacts of climate change on (human and other species') health – benefit from perspectives and approaches that harnesses complexity. Complexity thinking does not mean that we should throw our hands into the air and resign to fatalism as we cannot control complex systems anyhow. Instead, it means to change the way we think about our own interactions with the world. Rather than assuming that we can control – or even aspire to control – our human and natural environments, we need to listen and learn more before we act. To paraphrase Nicole Curato (2019) and Andrew Dobson (2010), this means not only to listen to those who already speak, but to listen out for those whose voices are not yet heard. Hendrik Wagenaar and I (2021) have suggested the metaphor of gardening as a way to act upon complex problems. The metaphor of gardening stands in stark contrast to the notion of engineering which has guided solutions to many big societal problems in many places of the world so far. The concept of engineering is closely associated with many of the achievements of the last 200 years: electrification, pharmacology, information and communication technologies, and machines revolutionising agriculture, transport, and education. Its spell reaches far into the 21st century, where we continue to set our hopes in engineering solutions

for a wide variety of societal challenges such as battling disease or fighting climate change (think of the European Green Deal having been introduced as 'Europe's man on the moon moment').

But engineering hinges upon precision and the ability predict – to calculate precisely – how a tool or machine or system will behave and the impact it has on the particular slice of the world on which it operates. This, in turn, means that the engineer needs to not only know all the elements and factors that can impact the operation of the machine and the system, but she also needs to be in control of them. But we cannot be 'in control' of the planet. Neither can we be in control of human health, or the climate. No matter how much engineering has helped to increase health, prosperity, and progress in the world, and how helpful the engineering metaphor has been in driving home that human ingenuity and perseverance can successfully tackle the most difficult challenges, in connection with the complex challenges that we are currently grappling with – ranging from pandemics to wars to climate change, it sends the wrong message. Instead of more engineering, we need more gardening.

A good engineer should have a high level of logical and analytic thinking, a knack for math, and a focus on problem solving. A good gardener, however, needs different skills: the ability to observe, 'listen to' (sometimes, quite literally), and learn from nature (*e.g.* Kimmerer, 2013). Gardening is not mastery, but relation. Despite the most well informed and precisely planned attempts to create a garden in a specific design, it is impossible to plan a specific outcome at a drawing board and merely 'implement' it. Because the gardener cannot control all the elements that will have bearing on the outcome, she needs to work with a certain level of uncertainty. She cannot foresee know how the temperature, the wind, the insects, parasites, and other factors that shape and inhabit a garden will behave. A gardener is tending to a garden rather than engineering it. She is in a dialogue with her environment. She can sow the seeds, plant the seedlings, or tear out the weeds, but she can never fully master the garden.

Bioethics should be part of this turn to 'gardening'. Most of the issues that we are grappling with cannot be addressed with solutions quick-fix, technological solutions, or those that tackle individual behaviour. We need to change not one thing but many. We cannot do this without having a new concept of how things not only hang but also develop together, and of our place, as humans, in this interconnected web of flows, energy and materiality.

What does this mean for scholarship and the practice of bioethics? First of all, as Atuire and Bull (2022: 68) argue, we need „a revisitation of the frameworks and conceptions of health, research and ethics to ensure first that they are not unjust towards indigenous knowledge systems, and that they are open enough to include both indigenous and foreign knowledge systems". There is much left to do

at the level of epistemic justice (Fricker, 2007). Second, at the level of practice, it requires questioning whether our arguments and recommendations, but also our own practices help to change the structures and practices that are destructive for people and the planet, or whether they help to reinforce these structures – and actively listen out for marginalised positions and voices when making these assessments. We also need to reconsider some practical aspects of the way we work. Who are we helping if we fly across the globe to give a talk, and at whose cost? For me personally, the Global Summit in Lisbon has been a time of hope and inspiration, and also a reason for a critical assessment of my own assumption and practices. For the EGE, with its commitment to a broad and pluralistic approach to bioethical problems, it has been an honour and privilege to be part of the Summit. Our members, who participated as speakers, chairs, and in various other roles, are grateful to the organisers for such an incredibly rich event – we leave the summit with a strong sense of purpose, and an awareness of the importance of the road ahead of us.

The EGE provides the European Commission with high quality, independent advice on all aspects of EU legislation and policies where ethical, societal and fundamental rights issues intersect with the development of science and new technologies. It is an independent advisory body of the President of the European Commission, founded in 1991. Its most recent statements and opinions can be accessed at

https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics_en#ege-opinions-and-statements

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Navigating novel ethical challenges in the era of disruptive technologies: the role of the European Commission's ethics review mechanism

Mihalis Kritikos[1], Dorian Karatzas[2]

Over the last 15 years, the European Union (EU) has filled an important gap in the ethical governance of research and innovation. By making adherence to ethical principles a binding legal requirement for funding research proposals at the supranational level (within Horizon Europe, its Framework Programme for Research[1]) and by setting up a multi-stage ethics review mechanism, the European Commission has managed to determine the bounds of ethical research in all major scientific fields.

More specifically, the Horizon Europe programme requires for all funded research to comply with ethical principles (including the European Code of Conduct for Research Integrity) and relevant EU and international legislation (including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights). In order to effectively address the ethics and integrity dimensions of funded activities, the Commission has developed a comprehensive, multilevel Ethics Appraisal Procedure: all activities considered for EU funding are systematically assessed by specialised experts and multi-disciplinary expert panels before the Grant Agreement is signed. In addition, whenever needed the projects may be assessed and assisted during their lifetime, through dedicated Ethics Reviews or Checks.[3]

The role of the European Commission in this sensitive domain of research governance has been two-fold: on the one hand safeguarding the compatibility of its review procedures with the relevant EU norms and international best practices

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[3] For more details on the procedure and the ethics issues assessed during the proposal evaluation, please consult the Horizon Europe Programme Guide (https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf) or the How to complete your ethics self-assessment guidance (https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf)

and on the other respecting the traditional competences of the Member States in all matters of ethical gravity as well as the autonomy of local ethics committees and of institutional review boards. As a result, this special positioning of the European Commission's ethics appraisal mechanism requires synchronization with all relevant international legal, regulatory and institutional developments and in parallel an active participation to and exchanges with European networks such as the European Network of Research Ethics Committees (EUREC)[4] and coordination of the National Ethics Council (NEC) Forum.[5]

The Horizon Europe *ad hoc* ethics expert panels are currently facing new challenges that stem from the emergence of a broad range of disruptive technologies such as artificial intelligence, gene editing, robotic technologies and data science research to name a few. That is unsurprising given that ethics handbooks and committee structures are traditionally using bioethics instruments and even vocabularies. For example, the traditional principles of respect for human autonomy, harm prevention/ non-maleficence, beneficence, and justice/equity appear not always fit-for-purpose as they do not seem to address the challenges of transparency/explainability/auditability. At the same time, the value of concepts such as informed consent appears of limited value when it comes to big data research that raises questions of agency and identity, augmentation and bias.

As segments of these newly emerging technologies are increasingly being developed and used in global research but normative frameworks, policy options and best practices for the ethics review and oversight of AI-enabled studies are currently lacking, there is an imminent need to identify the relevant governance gaps and required changes that need to be addressed including those related to the role and responsibility of research ethics committees (RECs) and ethics policy advice bodies such as the National Ethics Councils.

As the current governance framework cannot accommodate a priori all the new ethical challenges associated with the deployment of a set of disruptive technologies, the Union's approach has gradually become hands-on and vigorous. In fact, efforts are currently focused on the strengthening of the capacity of ethics review processes to cope with unchartered ethical challenges that pose new risks to the protection of our fundamental rights. These include challenges that stem for example from various forms of data re-use and the often unpredictable and tentative nature of big data research and unforeseeable risks and concerns that range from privacy and bias to the threat to democracy and the protection of fundamental rights. Among the key concerns are research activities that do not involve traditional 'research participants' or where there are no established practices or legal obligations to undergo ethics review especially in the case of

[4] http://www.eurecnet.org/index.html

[5] https://www.ccne-ethique.fr/en/node/474

research analysing data produced as a by-product of people's use of technological devices and services, and other categories of non-personal data.

Coping with these challenges include the EU funding of research in domains where there are emerging ethics governance needs,[6] fostering partnerships with international actors in the domains of ethics and research integrity and upskilling/reskilling research ethics experts. Ensuring the trustworthiness and reliability of ethics reviews for research involving innovative technologies also includes the development of a series of special Guidance Notes for research applicants/beneficiaries,[2] ethics reviewers, and local committees and last but not least the design of specialized training and education actions that will better prepare the research community for the ongoing and future challenges.

Within this frame, the Commission services are putting special emphasis on the training of young researchers, the exchange of good practices in addressing special ethical challenges and the development of practical guidance for researchers, expert reviewers and research managers. These policy actions will not only help researchers navigate the maze of various norms and procedures but also empower them to act in a responsible manner when exploring new technological avenues of ethical magnitude. In an effort to create a "one stop shop" for all these activities, the European Commission has supported the development of the "Embassy of Good Science"[7], a dedicated web site where the results of EU funded projects can be found, shared and used by universities, research institutions, citizen associations and the research community.

In view of the ongoing deployment of data-intensive technologies and the convergence of transformative technologies, the development of an operational governance framework that could allow our researchers, innovators, academics and students to multiply their synergies in critical domains of research ethics and integrity is of outmost importance. This framework could entail the development of effective regulatory pathways and ethics roadmaps, the continuous support of research teams with advice and guidance and eventually the monitoring all possible ethics impacts during the actual implementation of research in real life settings. Towards this direction, the Commission's ethics review process is further enhanced with the development of dedicated ethics checks that take place throughout the implementation of highly-complex and sensitive research projects in the domain of new and emerging technologies.

In addition to ensuring the protection of research participants and facilitating the integration of ethical concerns into research projects and protocols from the

[6] EU to invest €13.5 billion in research and innovation (europa.eu) and wp-11-widening-participation-and-strengthening-the-european-research-area_horizon-2023-2024_en.pdf (europa.eu) in particular pages 103,108 and 134

[7] The Embassy of Good Science

conception phase, guidance is also urgently needed for the operationalization of AI ethical principles (in a non-technical manner) in various contexts and domains. Towards this direction, several guidance notes that focus on issues such as AI bias and fairness, the need for reconceptualising informed consent and ethical audits in the frame of digital technologies and the ethics of cybersecurity are currently under preparation by specialised expert groups of interdisciplinary character under the supervision of the European Commission. These guidelines are expected to incorporate ethical reflection into the relevant research design frameworks and further facilitate the ethical assessment and auditing of research projects and outcomes. They are also expected to include mechanisms to assess 'ethics readiness levels' in correspondence to the relevant 'technology readiness levels' and to develop the relevant mechanisms and toolboxes that will enable the embedding of ethical considerations throughout the lifetime of a research project.

The Commission is also putting forward an ethics-by-design approach and is funding a series of research projects that aspire to provide policy-makers, researchers and research ethics committees with new toolboxes, assessment criteria and training material. These include the development of new ethics assessment and audit methodologies, self-assessment tools, practical guidelines and performance/compliance benchmarks in new areas of scientific inquiry and technological innovation and the release of a Guidance on 'Ethics by Design and Ethics of Use Approaches for AI'[8] that will further facilitate the implementation of the ethics by design approach. This particular Guidance Note that builds on the work of the results of the EU-funded SHERPA[9] and SIENNA[10] projects is premised on the basis that development processes for AI and robotics systems can be better described using a generic model containing six phases: 1) Specification of objectives, 2) Specification of requirements, 3) High-level design, 4) Data collection and preparation, 5) Detailed design and development and 6& Testing and evaluation.

It needs to be mentioned that according to the ethics by design-approach ethics concerns need to be integrated and addressed in the design and development phase or else as early as possible offering an additional tool for tackling ethical challenges ab initio. To implement this approach, the Commission has introduced a process for evaluating the trustworthiness of all AI-based applications used and/or developed as part of activities funded by Horizon Europe.

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[8] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf

[9] Project Sherpa – Shaping the Ethical Dimensions of Smart Information Systems a European Perspective (project-sherpa.eu)

[10] Start – SIENNA (sienna-project.eu)

A great part of these initiatives is inspired by the EU Guidelines on Trustworthy AI[3] and are taking place against a proliferation of new ethical guidelines and codes developed worldwide that aspire to protect people online and offer them a new set of rights that could protect them as participants to research frameworks. The EU Guidelines enable AI systems to be lawful, ethical and robust and prescribe four principles (respect for human autonomy, prevention of harm, fairness and explicability) and seven key requirements 1) human agency and oversight, human agency and human oversight), 2) technical robustness and safety, 3) privacy and data governance, 4) transparency, 5) diversity, non-discrimination and fairness, 6) societal and environmental wellbeing and finally, 7) accountability.

This ground-breaking EU initiative highlights the need for promoting the following principles: putting people and their rights at the centre of the digital transformation; supporting solidarity and inclusion; ensuring freedom of choice online; fostering participation in the digital public space; increasing safety, security and empowerment of individuals and promoting the sustainability of the digital future. These EU-wide initiatives are expected to enable the ethics processes to better inform policy choices about the socially sustainable uses of new and emerging technologies and support the researchers in incorporating ethical considerations into their research, thereby contributing to the protection of human rights in the research domain and the promotion of EU values when technologies are designed and deployed.

At the same time, the Commission's efforts are focused on preventing ethics reviews and assessments from becoming a red-tape mechanism, especially as the ex-ante-model of traditional ethics oversight might not be apt to deal with new challenges, for example stemming from various forms of data re-use and the often unpredictable and tentative nature of big data research and unforeseeable risks. The Commission is also investigating how the ethics committee structures should evolve in the context of the ever-changing technological landscape by taking into account the need for multidisciplinary expertise, and timely interventions.

These initiatives are taking place also against the backdrop of intense negotiations for the final shaping of the EU Act on AI[11] that is expected to introduce a new form of risk governance for all AI applications. The upcoming Act, that is the first law on AI by a major legislator worldwide, aims at integrating ethics and research integrity norms into the EU-funded research ecosystem, as part of a responsible research and innovation policy narrative, and more importantly, as a component of the EU responsible for research appraisal structures and mechanisms. This legislative proposal is extremely important from an ethical viewpoint as it introduces a human-centric and risk-based approach on the basis of which AI practices are classified as particularly harmful (that need to be banned), high-

[11] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206

risk (those systems that pose significant risks to the health and safety or fundamental rights of individuals), low-risk or limited-risk and is expected to operationalize the European Commission's 'Ethics guidelines for trustworthy artificial intelligence.'[12] The eventual adoption of the proposed AI Act will provide a robust legal framework for the protection of all people from harmful uses of AI systems and the promotion of trustworthy and human-centric AI in Europe and beyond.

Beyond the AI Act, there are several important initiatives in the pipeline that aim to facilitate the access to and use of digital data, such as the Data Governance Act and the proposals for a Data Act and the European Health Data Space. Meanwhile, the EU has been a frontrunner in the formulation of normative frameworks that aim at safeguarding human rights and freedoms in the context of digital innovation, and has committed to incorporate those values into international research collaboration. The recently adopted Declaration on European digital rights and principles, which will complement existing rights, such as data protection, ePrivacy, and the Charter of Fundamental Rights[13] also stands out as it is expected to enhance further the human-centric design and deployment of new and emerging technologies.

Ultimately, the eventual adoption of the Act in combination with the gradual operationalization of the EU Guidelines on Trustworthy AI will pave the way for a more human-centric approach to the design of these transformative technologies that will place people at the center of the ongoing digital and ecological transformation. Promoting the ethical design of these transformative technologies at the EU level as a prerequisite for achieving excellence in research and innovation could also serve as a global point of reference when it comes to their trustworthy and inclusive design, deployment, and uptake.

Given the multiple crises that our societies are facing, a paradigm shift in the ethical governance of research is more than necessary. This shift should be based on a clear commitment to the principles of solidarity, fairness and equity and ethics standards we hold dear but also on inclusive and equitable international cooperation in R&I to help us address, together with our international partners, the daunting global challenges that we face – the energy crisis, climate change, digital divide and food security.

In fact, lawmakers and international organisations around the world are also actively putting forward legislative proposals and technology governance frame-

[12] AI HLEG (2019). High-Level Expert Group on Artificial Intelligence. Ethics Guidelines for Trustworthy Artificial Intelligence. Brussels: European Commission. Available online at: https://www.europarl.europa.eu/cmsdata/196377/AI%20HLEG_Ethics%20Guidelines%20for%20Trustworthy%20AI.pdf

[13] https://digital-strategy.ec.europa.eu/en/library/european-declaration-digital-rights-and-principles

works that could improve the ability of the long-established ethics review structures to ensure the embedment of human rights in the development of digital technologies and to protect 'digital rights' and 'digital principles' in the context of international research while research frameworks become increasingly datafied and algorithmic driven.

Within this frame, the Commission's effort to promote inclusive and equitable research partnerships in the domain of the ethical governance of research could prevent potential ethics dumping phenomena (in the shape of export of research practices in countries with a different or weaker ethical and legal framework) and enhance the institutional capacity of local ethics structures across the world to tackle new and emerging ethical challenges across the entire technological spectrum. To this end, the European Commission supported the preparation of the Global Code of Conduct for Research in Resource Poor Settings,[14] currently a reference document in the Horizon Europe Application Evaluation process and recently adopted by Nature Publishing as a reference document.[15]

What is more, the research community and policy-makers need to safeguard that research ethics and integrity structures remain the backbone of excellence and trust and that issues such as the responsible conduct of research, the accuracy and reliability of data, the protection of privacy as well as of other fundamental ethical principles remain an essential part not only of the international policy debate on responsible research and human rights but also of the actual modus operandi of the entire research and innovation ecosystem.

More specifically, in the frame of the going digital transformation, special attention needs to be paid to the gatekeepers of responsible research that is local, regional and national ethics committees. These epistemic communities must remain at the epicentre of the design and implementation of research and the deployment of technological products as their opinions constitute an important point of reference in our ethical governance ecosystems and offer an important mental compass to all research stakeholders. Within this frame, new policy and institutional initiatives need to be taken to identify new ways of enhancing the ability and empowering traditional ethics committees to safeguard the embedment of human rights in the development of digital technologies, to remain 'relevant' during the lifetime of the research endeavour and to protect 'digital rights' and 'digital principles' in the context of international research.

In order to achieve these ambitious and necessary goals, the ethics structures need to be adequately supported both in terms of human resources and access to expertise but also access to appropriate ethics "lifelong" learning and education. Additional efforts need also to be made to achieve inter-institutional, inter-dis-

[14] Home – Global Code of Conduct.

[15] Nature addresses helicopter research and ethics dumping.

ciplinary and international collaboration when governing and assessing research from an ethical and research integrity perspective given the transnational and disruptive character of the ever-growing ethical risks.

In addition, research institutions and Universities must provide well supported ethics and integrity environments were researchers in all stages of carrier development will be able to purse their tasks in an environment that is conducive to responsible research practices. As an important step towards creating such "safe" environment for researchers, the European Commission has supported the development Ethics and Integrity Standard operating procedures and promotion plans[16] and will continue to support work in this area.

In conclusion, there is an urgent need to discuss and identify effective ways of shaping an inclusive and multi-level ethical framework that will address all major societal concerns and enhance the level of protection offered to both researchers and research participants. That way, we may develop the ability that is necessary to tackle the growing challenges associated with the growing datafication of our societies and the need to reclaim data sovereignty, ensure that human rights apply online just as they do offline and create an inclusive, sustainable and robust culture of responsible design, development and deployment of disruptive technologies.

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[16] SOPs4RI – Promoting excellent research.

UNESCO, Bioethics and its Application into Policy

Ames Dhai[1]

Introduction

The field of bioethics has significantly expanded from the 1970's. Progress in the life sciences could be considered a double-edged sword. It gives human beings new power to improve health, wellbeing and control the development processes of all living species. At the same time, concerns about the social, cultural, legal and ethical implications of such progress arise. UNESCO considers bioethics as the term that encompasses these concerns. Hence, bioethics goes much further than professional codes of ethics. It necessitates reflection on societal changes and also on global balances and imbalances brought about by advancements in science and technology. Initially challenging questions like "How far can we go?" emerged. However, other equally if not more complex issues have also surfaced rapidly (1).

UNESCO, as the principal agency of the United Nations in bioethics plays a critical role in promoting universal bioethical norms and principles. In addition, it assists countries in the translation of those principles to concrete policy outcomes for their citizens. UNESCO's involvement in promoting internal reflection in the life sciences started in the seventies. UNESCO continues in its commitment to building, reinforcing and strengthening robust linkages and networks among ethicists, scientists, policy-makers, judges, journalists, and civil society and, in this way, it assists Member States in developing and implementing sound and reasoned policies on ethical issues in science and technology.

In this article, pertinent contributions from UNESCO in promoting the field of bioethics will be highlighted. UNESCO standard setters that have pioneered normative action will be described.

Promoting bioethics

Ways in which UNESCO has contributed towards advancing bioethics include developing programs for the establishment and consolidation of National Bioethics Committees and an Ethics Education Program. The latter comprises a Core Curriculum in Bioethics, an Ethics Teacher's Training Course and establishing

[1] Chair of the UNESCO International Bioethics Committee (IBC).

and linking networks to promote the teaching of Bioethics. Hence UNESCO's Bioethics Program ties together three key areas of work: standard setting, global reflection and capacity-building. Standard setting is achieved via UNESCO'S Declarations in the domain of bioethics. These documents have been pivotal in the development of many regional and national legal instruments. Global reflection is attained through the International Bioethics Committee (IBC) whose mandate is to guide policymakers in the application of the ethical principles, in sometimes complex and multi-faceted fields. Capacity-building is implemented through the use of educational and technical assistance for bioethics committees so that robust national bioethics infrastructures are built around the world. In the next section UNESCO's key standard-setters will be described.

Unesco and standard-setting in bioethics

The following UNESCO Standard-setters are the forerunners that establish normative action:

- Universal Declaration on the Human Genome and Human Rights (1997) (2);
- International Declaration on Human Genetic Data (2003) (3);
- Universal Declaration on Bioethics and Human Rights (2005) (4);
- Declaration of Ethical Principles in relation to Climate Change (2017) (5);
- Recommendation on Science and Scientific Researchers (6);
- Recommendation on the Ethics of Artificial Intelligence (7).

Universal Declaration on the Human Genome and Human Rights (1997)

On 11 November 1997, the Universal Declaration on the Human Genome and Human Rights (UDHGR) was adopted unanimously and by acclamation at UNESCO›s 29th General Conference. The United Nations General Assembly endorsed the Declaration in 1998. The UDHGR draws from the universal principles of human rights as affirmed in UN instruments, in particular in the Universal Declaration of Human Rights (1948), the International United Nations Covenant on Economic, Social and Cultural Rights (1996) and on the International United Nations Covenant on Civil and Political Rights (1966). It underscores the importance of promoting and developing research and its consequences that are ethical and within the framework of respect for human rights and fundamental freedoms as science and technology advance in the fields of biology and genetics. That research and its resulting applications on the human genome herald extensive possibilities for progress in improving the health and wellbeing of individuals

and of humankind as a whole is emphasised. The UDHGR commences in Article 1 by affirming that the human genome is symbolically the heritage of humanity because it underlies the fundamental unity of all members of the human family, while recognising their inherent dignity and diversity. Therefore, the human genome must be protected as it is passed on to future generations and scientific advances require human rights considerations. The Declaration has been cited in many academic and popular journals and has been referred to in many national and regional legislation on medicine, privacy and genetic research.

During the past few decades, several new techniques that have the potential to radically and significantly intervene in human genetic material have been developed. These possibilities extend to include human genome editing. Serious concerns regarding the implications of human genome editing have been raised, especially if this is applied to the germline, introducing heritable modifications, which would be transmitted to future generations. This unease is shared by many, including scientists, despite it being one of the most promising scientific undertakings. Based on the guidance from *inter alia* the UDHGR, the UNESCO International Bioethics Committee (IBC) affirmed that interventions on the human genome should only be for preventive, diagnostic or therapeutic reasons and without enacting modifications for descendants and called for "a moratorium on genome editing of the human germline." (8)

The International Declaration on Human Genetic Data (2003)

Genetic databanks have been steadily increasing over the last three decades. Some of these databanks contain over a million records. Several, which contain genetic information on almost the entire population in the country, have been established and are being maintained at a national level and. While genetic data can be used for medical diagnosis, disease prevention and population genetics studies we must remember that each person's genetic heritage is unique. Hence, forensic science and the judicial system also use them for identification purposes. Because of concerns that human genetic data could be used against human rights and freedom, there arose a call for international guidelines on this subject from governments, non-governmental organizations, the intellectual community and society in general. Therefore, as a means of addressing these concerns, the International Declaration on Human Genetic Data (IDHGD) was unanimously adopted at UNESCO's 32nd General Conference on 16 October 2003. The Declaration reaffirmed the principles established in the UDHGR together with the principles of equality, justice, solidarity and responsibility. In addition, respect for human dignity, human rights and fundamental freedoms, in particular free-

dom of thought and expression, including freedom of research, and privacy and security of the person were affirmed. It was underscored that these principles must underlie the collection, processing, use and storage of human genetic data. Hence, any collection, processing, use and storage of human genetic data, human proteomic data and biological samples need to be consistent with the international law of human rights.

The Universal Declaration on Bioethics and Human Rights (2005)

UNESCO has contributed to the formulation of basic principles in bioethics in particular through the Universal Declaration of Bioethics and Human Rights. (UDBHR). When the Declaration was adopted in 2005, it was the first time in the history of bioethics that Member States committed themselves and the international community to respect and apply the fundamental principles of bioethics. The overarching endorsement is that of the rules governing respect for human dignity, human rights and fundamental freedoms. More importantly, the UDBHR gives credence to the interrelationship between ethics and human rights in the sphere of bioethics. Over the years UNESCO has affirmed its standard-setting role in bioethics by identifying universal principles based on shared values to guide scientific and technological development and social transformation.

The objectives of the Declaration include that of promoting equitable access to medical, scientific and technological developments together with wide and rapid dissemination and sharing of knowledge emanating from these activities. The sharing of benefits, with particular attention to the needs of developing countries are also established. It is affirmed that a central purpose of governments is that of promoting health and social development for their people. Because the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction, progress is necessary to advance access to quality health care and essential medicines, especially for the health of women and children. Health is essential to life itself and hence it is a social and human good. To realise the principles, professionalism, honesty, integrity and transparency in decision-making must be promoted. Some other points to note in the Declaration include the need to foster bioethics education and training and this could be included in the activities of bioethics committees. The importance of bioethics education, both at global and local levels cannot be adequately emphasised. This education will assist with informing public engagement. Why do we need public engagement? To allow for the promotion of trust, legitimacy and ownership of decisions. Decision-makers need to be trustworthy by ensuring early engagement with stakeholders. Decision-making processes must be ethi-

cal, transparent and conducted with integrity. While the UDBHR was adopted in 2005, it remains highly relevant in how we tackle ethical issues that unfold by the day. This was evidenced quite starkly during our current COVID-19 pandemic, and also previous ones.

Declaration of Ethical Principles in relation to Climate Change (2017)

The UNESCO Declaration of Ethical Principles in relation to Climate Change (DEPCC) communicates the grave concerns of UNESCO Member States with regard to climate change creating morally unacceptable damage and injustice. When 195 member states affirmed the Declaration on 13 November 2017, at the 39th session of UNESCO's General Conference they simultaneously called for global partners to rally together and implement these principles. This Declaration sets out a shortlist of the globally-agreed ethical principles that should guide decision-making and policy-making at all levels and help mobilize people to address climate change. The ethical guidance of this UNESCO Declaration is supposed to complement states' other multilateral efforts including negotiated commitments under the United Nations Framework Convention on Climate Change, and scientific assessments organized by the Intergovernmental Panel on Climate Change. According to the Declaration "prevention of harm" is one of the important ethical principles in relation to climate change. Hence there is a need to anticipate harm from climate change, avoid it and where not possible, then to minimize it with the use of climate mitigation and adaptation policies and actions. Other ethical principles in the Declaration include scientific integrity, solidarity, sustainability, justice and equity and a precautionary approach.

Recommendation on Science and Scientific Researchers (2017)

The Recommendation on Science and Scientific Researchers is important in standard-setting because it codifies the goals and value systems by which science operates, together with emphasizing the need to support and protect science in order for it to flourish. The Recommendation was adopted at UNESCO's 39th General Conference on 13 November 2017. It significantly expanded the scope and reach of the Status of Scientific Researchers Recommendations (1974), which it now supersedes.

Recommendation on the Ethics of Artificial Intelligence (2021)

The Recommendation on the Ethics of Artificial Intelligence (AI) was adopted in November 2021 by UNESCO's 193 Members States at its General Conference. It is the very first global standard setting instrument on AI. Not only will it protect and promote human rights and human dignity in the sphere of AI, but it serves as an ethical guiding compass and a foundational global normative instrument, so that robust respect can be built and sustained for the rule of law in the digital world. The Recommendations take into account *inter alia* that AI technologies are developing very rapidly resulting in challenges to their ethical implementation and governance in a culturally diverse world. Cultural diversity must be protected and respected in all contexts and in particular that of AI. While the positive implications of AI are recognised and embraced, it has cautioned that AI has the power to disrupt local and regional standards and values. This Recommendation approaches the ethics of AI as a systematic, normative reflection. It uses a holistic, comprehensive, multicultural and evolving framework of interdependent values, principles and actions in order to give guidance to societies, the environment and ecosystems. An ethical standard is set in order for AI technologies to be accepted or rejected. Ethics is considered from the perspective of a dynamic basis for normatively evaluating and guiding AI technologies.

Conclusion

Bioethics has an international dimension and decisions regarding ethical issues in healthcare, the environment and other relevant spheres not only have an impact on individuals, but also on families, groups or communities and humankind as a whole. Moral sensitivity and ethical reflection are integral to all that we do, and in particular to our academic and research endeavours. Moral and ethical values allow for the creation of a distinction between right and wrong. While the rightness of social fairness cannot be disputed, often fairness is absent. This was starkly evident again during the pandemic with resource poor countries being last in the queue as rich countries splurged in their shopping spree for vaccines and treatments. UNESCO ethics and human rights instruments go a long way in taking forward not only fairness, but also respect for human dignity, equality, justice, solidarity and responsibility, amongst other entrenched bioethical principles.

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