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

Patrik Hummel¹, Katherine Littler², Andreas Reis²

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 contingent 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 All³.

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