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AI Regulation in Healthcare: New Paradigms for A Legally Binding Treaty Under the World Health Organization

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***Abstract*—*Our use and dependency to information and communication technology (ICT) creates undoubtedly new opportunities but also new risks. To ensure that ICT helps to promote healthcare and medicine worldwide, we necessarily need to address issues related to the implementation of Artificial Intelligence (AI) in healthcare. Human rights such as data privacy; ethics in the use of data; the digital gap or bias in AI are new challenges to tackle. According to the World Health Organization (WHO), AI promises to facilitate access to healthcare and medicine worldwide. Our postulation is that the current legal framework cannot regulate adequately the use of AI in healthcare. International cooperation is a prerequisite to ensure that all new risks and challenges associated with the use of AI in healthcare are tackled. A revision of the WHO International Health Regulations (IHR) is necessary as well as new coercive powers for the WHO to enable effective global public health policies.*

Keywords*—*AI; international cooperation; public health; data protection; human rights; privacy.

I. Introduction

ICT has transformed the way individuals may access healthcare. Our use and dependency to ICT creates undoubtedly new opportunities but also new risks [1]. To ensure that ICT helps to promote healthcare and medicine worldwide, we necessarily need to address issues related to the implementation of AI in healthcare. Regulating the use of AI is a prerequisite as tech companies cannot regulate themselves adequately. Human rights such as data privacy; ethics in the use of data; the digital gap or bias in AI are new challenges to tackle. According to the WHO, AI promises to facilitate access to healthcare and medicine worldwide [2]. Our postulation is that globalization and ICT have created new challenges for states and strengthening interstate cooperation throughout formal international cooperation mechanisms is a necessity. The international community has to agree on a series of international standards and legally binding instruments in the field of ICT and healthcare. The WHO is the right authority to monitor how states regulate the use of AI in healthcare as we can refer to the IHR adopted by the 58th World Health Assembly in 2005 through Resolution WHA 58.3 [3]. AI and other new technologies created a change of paradigm in how personal data may be used by both public and private actors. Regarding data protection, the European Union General Data Protection Regulation (GDPR) adopted in 2016 imposes a series of stringent obligations upon service providers processing, storing or sharing personal data. The GDPR is applicable in the field of AI as data will necessarily be processed [4]. The GDPR encompasses several key principles that apply to AI: data minimization, fairness and transparency, explainability, integrity, purpose limitation, and accountability to minimize the risks of potential harm to individuals caused by the use or misuse of personal data. The European Commission also made efforts to specifically regulate AI throughout its proposal – the Artificial Intelligence Act – released in April 2021 [5]. The main purpose of the Artificial Intelligence Act would be to protect individuals' safety and rights while using AI systems. Combined with the GDPR, this new EU regulation would regulate companies to actively protect privacy and prevent ethical concerns faced by AI users. EU regulations could serve as a law model for the elaboration of legally binding rules under the auspices of the WHO as many states today adopted laws in the field of data protection inspired by EU law [6]. Moreover, it can be argued that states have a general obligation of cooperation under the UN Charter, including health issues. Therefore, the WHO shall be granted coercive legal means to ensure compliance with international health law and especially the IHR which need to be amended by states parties to take into consideration AI and its use by states and private actors.

II. New Paradigm: The Adoption of a Legally Binding Treaty Under the WHO

The COVID-19 pandemic has highlighted the limitations of international law when it comes to

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the regulation of public health. New global trends in ICT and their impact on personal data and how it may be used demonstrate that states shall regulate adequately the use of AI. The WHO is today the most relevant international organization in the regulation of public health.

Bump et al. note that:

WHO is a manifestation of the advantages of cooperation and collaboration, and it consistently leads member states in ways that uphold its mission to advance the highest standard of health for all. In the pandemic, WHO has shown leadership in sharing information and in co-launching the Access to COVID-19 Tools (ACT) Accelerator, a global collaboration to accelerate development and equitable access to diagnostic tests, treatments, and vaccines [7].

Efforts made by the WHO during the COVID-19 pandemic could be duplicated in other fields related to global health especially the use of AI by both public and private actors. How can the international community address the risks associated with the use of AI in healthcare? What can the WHO do to guarantee equal access to new technologies and protect fundamental rights such as privacy [8] and data protection? According to the WHO, *"[e]quitable access to health products is a global priority, and the availability, accessibility, acceptability, and affordability of health products of assured quality need to be addressed in order to achieve the Sustainable Development Goals, in particular target 3.8*" [9].

ICT creates an unprecedented situation in interstate relations since the end of the World War II in 1945. AI can indeed facilitate access to healthcare. It has always been a crucial issue for the international community [10], especially for developing countries [11]. However, the current legal regime applicable to global health does not protect sufficiently personal data and privacy [12]. A new paradigm is an absolute necessity in order to reshape international health law and international cooperation to efficiently address all risks associated with the use of AI in healthcare. This new paradigm is the adoption of a global answer throughout the implementation of new international rules by states to facilitate cooperation and regulation of the use of AI in healthcare. The IHR (2005) could be used by States Parties to improve the degree of response to threats to privacy and the confidentiality of medical secrets of patients posed by ICT today; and also to participate in the adoption of international standards such as the protection of ICT users as covered by the GDPR 2016 [13] and increase interstate cooperation. WHO members could rely upon the IHR and EU regulations – the GDPR and the proposed Artificial Intelligence Act – in efforts to negotiate new legally binding rules. Today, under the IHR, one of the limitations is that bilateral and multilateral cooperation are only encouraged. Additionally, WHO members shall provide a comprehensive set of rules to facilitate interstate cooperation and involve the private sector in these efforts.

Healthcare is today recognized as a global public good [14]. It can also be argued that the Internet and all new ICT trends constitute global public goods [15]. As a consequence, the international community must help to provide new technologies to developing countries and facilitate their implementation, especially in the field of healthcare. Here again, a parallel could be made with the COVID-19 pandemic and the necessity to regulate more efficiently global health [16]. Some authors studied the theory of global public goods and how it could be applied to COVID-19 vaccines to develop further international cooperation [17]. Indeed, the doctrine traditionally used to consider public health as a global public good, "*with a particular emphasis on the control of infectious diseases*" [18]. Global public goods – here, AI for better access to healthcare – could be implemented in a legally binding treaty signed under the auspices of the WHO. State members will have obligations to cooperate and assist each other as the ultimate goal is to facilitate access to healthcare especially in developing countries.

III. The General Obligation of Cooperation with the WHO Under the UN Charter Regarding Health Matters

Under the UN Charter, Members have a legally binding obligation to cooperate in matters representing a threat to international peace and security but also to the development of peaceful interstate relations, especially in the field of economic and social matters [19]. This duty of cooperation is at the core of international law. Some authors argue that such obligation can be assimilated to a hard law principle of international law [20]. The UN International Law Commission listed the obligation to cooperate among peremptory norms of *jus cogens* [21]. To support such position, research and traditional concepts demonstrate that the obligation to cooperate is hard law in international water law [22].

Can the obligation to cooperate in health matters be considered as a mandatory principle in international law? Our postulation is that such a duty to cooperate should necessarily be transposed into the field of international health law and be implemented in situations where the use of AI may pose risks on privacy, data protection but also access to healthcare. New technology should facilitate access to healthcare and not create any further inequalities especially for developing countries. WHO members do have a general obligation to cooperate not only in the

peaceful settlement of disputes but also in health matters in the spirit of the UN Charter.

Coordinated actions between the General Assembly of the UN and the WHO could be implemented in order to conduct a global answer through what is a hard law principle, namely the duty to cooperate. Here, the WHO will guide and ensure that state members do comply with their obligations such as implementing a defined set of international standards in order to guarantee the respect of fundamental rights and ensure that developing countries can also implement new technology which has proven to provide a better access to healthcare. To this effect, the UN General Assembly may adopt a new Resolution and refer to the general duty to cooperate in health matters and especially the use of ICT and AI in healthcare and call for a coordinated answer that will be led by the WHO. Efforts to modify the IHR should be made as they will create new obligations for states and create a truly global response to mitigate risks associated with the use of AI in healthcare.

The existing international legal framework allows us to consider that the WHO can monitor the implementation of this general obligation of cooperation.

IV. The Necessity to Provide the WHO with Coercive Legal Means to Ensure Compliance with International Treaties and the International Health Regulations

Today, the WHO has no enforcement powers [23] and its inability to act of its own reflects the shortcomings of international law. Obviously, legal tools exist and written rules akin to codes of conduct allow states with gaps in their health regulations to adopt a number of international standards. However, this is only a mitigative measure subject to the goodwill of states. The limitations of the WHO have been addressed by researchers [24]. Moreover, the WHO has been criticized by commentators for its "rather restrained role in creating new norms under its Constitution" [25]. Despite the fact that the WHO has a recognized expertise and a constitutional mandate to tackle health related issues on a global scale such as pandemics and global health crises, it only provides soft rules such as guidelines and recommendations to state members. As noted by Gostin et al., "*[t]he WHO's most salient normative activity has been to create 'soft' standards underpinned by science, ethics, and human rights. Although not binding, soft norms are influential, particularly at the national level where they can be incorporated into legislation, regulation, or guidelines*." [26]. In international law, soft rules are necessary as they allow the international community to reach a consensus on certain matters, and they simplify the adoption of a formal treaty, for example. However, strong answers are essential in specific situations as many state members may decide not to actively cooperate with other members or international organizations. As discussed, ICT is on the rise. AI offers new opportunities in terms of access to healthcare but also new challenges that require positive action and the implementation of compulsory rules by states. This applies to the WHO. Consequently, the WHO should be granted a real normative power throughout a set of legally binding rules. The IHR have been considered as a fundamental development in international law [27]. These regulations are an existing legal tool that can provide the WHO outstanding attributions to regulate the cross-border activity of Tech companies. The current version of the IHR entered into force in 2016 [28]. Article 2 WHO IHR, which is related to purposes and scope of the WHO – one of the most important provisions – states that "*the purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade*" [29]. It is also worth referring to Part II of the IHR related to Information and Public Health Response, especially Articles 12 [30] and 13 [31]. These provisions give important powers to the WHO but there are no enforcement powers in situations where WHO members refuse to cooperate nor coercive measures that can be taken against such states.

Globalization also created a fundamental obligation for states to cooperate not only in situations threatening international peace and security but also public health. The international community acknowledged that there is a correlation between international economic law and development since decades [32]. The same should apply to international health law: economic and sustainable development cannot be achieved without a fair access to healthcare and by controlling adequately the use of AI. The duty to cooperate in health matters is a fundamental component of the new international economic order.

V. CONCLUSION

The current legal framework shows us the limitations of international health law, especially regarding the role played by the WHO. This international organization has been designed as the key player in the regulation of public health with legal tools negotiated for decades. However, the international community has to acknowledge that a new paradigm is necessary today due to globalization and the emergence of Tech companies which are able to offer their services on a global scale. Indeed, there is now a shift in how we can access healthcare and how data can be processed, stored or shared. The WHO shall

have new coercive and normative powers to address issues [33] related to access to healthcare and the use of AI. Ultimately, AI shall facilitate access to healthcare and provide better health systems according to the UN Sustainable Development Goals [34].

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[17] *See generally* Gordon Brown & Daniel Susskind, International Cooperation During the COVID-19 Pandemic, 36 OXFORD REV. ECON. POL'Y (SUPPLEMENT ISSUE 1) S64 (2020).

[18] *Id*. at S65-66. International cooperation should allow states to facilitate research and development of new medicines and their equal access.

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[30] *Id*. at 14. Article 12 Determination of a public health emergency of international concern states that: "1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations."

[31] *Id*. at 15. Article 13 Public health response states that: 1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.

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