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## In defence of Helsinki and human rights

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The Declaration of Helsinki (DoH) is widely recognised as the leading authoritative source on ethical standards of medical research worldwide. Yet, in the past decade, different sources have questioned the authority of the DoH and its compliance with human rights, and argued for its replacement with UNESCO's Universal Declaration on Bioethics and Human Rights .

This paper argues that the tensions and alleged conflicts between Helsinki and human rights instruments are overstated, and that the latest version of the DoH is an important complement to human rights instruments in protecting the rights of disadvantaged populations and participants in biomedical research.

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Since its adoption by the World Medical Association (WMA) in 1964, the Declaration of Helsinki (DoH) has become embedded in national and international codes, laws and court judgements in cases involving allegations of abuse in clinical trials. Some critics have even suggested that the latest version of the DoH (2008) should be rejected and the principles governing research should be drawn instead from UNESCO's Universal Declaration on Bioethics and Human Rights (UDBHR).<sup>1</sup>

In response, this paper argues that the tensions and alleged conflicts between Helsinki and human rights instruments are overstated, and that the latest version of the DoH is an important complement to human rights instruments in protecting the rights of disadvantaged populations and participants in biomedical research.

### The case against Helsinki

In the past decade, revisions to the DoH have been criticised on two broad fronts. First, human rights groups have accused Helsinki of diluting universal ethical standards of care by allowing placebos to be used instead of the best proven treatment in developing countries. Critics say this 'dilution' introduces double standards – based on economics, convenience and efficiency – that should be anathema to any physician or patient.<sup>2</sup>

Secondly, the changes in paragraphs 29 and 30 of the 2004 version of the DoH, which were introduced partly in response to pressure from advocates of placebos as the 'golden' clinical and scientific standard, did not satisfy the US Food and Drug Administration (FDA).<sup>3</sup> For some years the FDA had viewed the DoH standards as too stringent, and endorsed drug developers' concerns that the requirement that drugs should be tested against the best current standard would make it harder to test their efficacy and drive up the cost of drug development. According to Robert Temple, director of the Office of Medical Policy of the FDA's Center for Drug Evaluation and Research, the WMA has been driven by concerns for 'social justice' rather than the 'ethics of clinical trials'.<sup>4</sup> Since 2004, the FDA has dropped the DoH in favour of the less exacting standards of the International Conference on Harmonisation of Good Clinical Practice.

More recently, there have been calls to reject the 2008 version of the DoH and replace it with the principled human rights framework of the UDBHR (2005).<sup>5</sup> The critics are associated with a South American bioethics network, Redbioetica, which operates under the umbrella of UNESCO. The UNESCO website describes Redbioetica as 'an organisation composed of institutions and investigators that serves as a new tool of interdisciplinary exchange of ideas to the subjects on bioethics in the region'. The website provides a list of the organisations involved, but no details of the members of the network.<sup>6</sup>

In 2010, the Declaracion de Cordoba was issued at the end of a conference held in Argentina and attended by researchers from 11 South American countries. The declaration criticises the 'weakening' of the benefit-sharing requirements in the 2008 version of the DoH, and the DoH's failure to uphold a universal and uniform standard of care in biomedical research trials. It calls for a shift to the UDBHR and, specifically, for research to be conducted under the principles on benefit sharing detailed in the UDBHR's Article 15.<sup>5</sup>

Overall, the criticisms point to an alleged gap, or worse, a failure by Helsinki to comply with international standards of justice and human rights in the conduct of clinical trials in developing countries.

Arguably, the proposal to demote Helsinki as the international, authoritative source of ethical principles on the conduct of medical research is very serious. It could have the unintended effect of destabilising and further weakening the rights of research participants in developing countries – a prospect which all the parties to this controversy will want to avoid.

I argue that support for Helsinki should be renewed, not abandoned, for three reasons: (i) the uncertain status of the UDBHR as a source of international law; (ii) upholding fundamental human rights does not require that universal standards of care should follow rigid and uniform templates on post-trial access to drugs and other benefits; and (iii) professional codes of practice, and Helsinki in particular, play a critical supporting role in ensuring that fundamental human rights are respected. Dialogue and co-operation, rather than institutional

and normative divisions, are essential for protecting research participants.

## UNESCO's Universal Declaration on Bioethics and Human Rights in international law

The UDBHR does not as yet have the status and authority of a legally binding document in international law. At this point, it is a statement of moral ideals and aspirations that merits serious attention because the document was issued by one of the UN agencies, but this is not sufficient to show that the moral ideals it states have the level of international support needed for it to be recognised as a source of law, let alone *the* authoritative, superior source of principles to guide the conduct of medical research in international law.

The legal threshold is high. The declarations or resolutions of UN agencies may acquire the status of a recognised source of international law if, over time, there is evidence that the norms they embody reflect 'international custom, as evidence of a general practice accepted as law'.<sup>7</sup> The International Court of Justice has interpreted this to mean that states have to follow the norm(s) out of a sense of legal obligation.<sup>8</sup> The Universal Declaration of Human Rights, adopted by the UN General Assembly in 1948, is the clearest example of an aspirational text which has acquired the status of international law.

Hitherto, Helsinki has become widely recognised as a standard-setting instrument for medical research worldwide, being embedded in numerous legislative texts and in the judgements of courts. Examples include the Clinical Trials Directive 2001, which is binding on all members of the European Union, and Judgments of the Supreme Court of Canada and US Federal Court. Various analyses are available.<sup>9,10</sup>

In contrast, the UDBHR has yet to secure widespread adherence among states, acting out of a sense of legal obligation, in order to gain recognition as a legally binding source of law. Hitherto, the mixed and contested reception of the UDBHR points to a lack of clear and widespread endorsement for the norms it enshrines.<sup>11-14</sup>

Therefore, rather than strengthening the rights of research participants in developing countries, calls to ditch Helsinki in favour of the UDBHR could weaken the internationally recognised standards of protection Helsinki sets out, in favour of a document which may or may not withstand the test of time as a legally binding source of law. Furthermore, it is by no means clear that the 2008 version of Helsinki is at odds with the UDBHR. On the contrary, a fuller understanding of the UDBHR and its place in the hierarchy of human rights instruments shows that the UDBHR requires neither rigid universal standards of care nor uniform templates of post-trial access to drugs and benefit-sharing, in order to comply with the protection of fundamental human rights in research.

## Fundamental human rights norms

The critics interpret the UDBHR as requiring rigid and uniform arrangements on post-trial access to drugs and other benefits. This, however, is questionable. The UDBHR itself, and its normative grounding and goals, have to be read consistently with the foundational human rights instruments cited in the text's Preamble – most notably the Universal Declaration of Human Rights (UDHR)

(1948) and the two legally binding treaties which followed, namely the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) adopted in 1966.<sup>15</sup> The UDHR contains two overarching fundamental rights that are particularly relevant to the controversies over Helsinki and UDBHR:

*Equal dignity of the human person.* All human beings are born free and equal in dignity and rights (Article 1 UDHR).

*Non-discrimination.* Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status (Article 2 UDHR).

These principles are reflected in the Preambles and several of the Articles in the ICCPR and ICESCR. For instance, respect for the inherent dignity of the human person is mentioned in the Preamble and Article 10 ICCPR and the Preamble and Article 13 (right to education) ICESCR.

Non-discrimination is expressly mentioned in several articles of the ICCPR, notably Article 4 (emergencies), Article 20 (limits on freedom of expression), Article 24 (rights of the child) and Article 26 (equality before the law). In the ICESCR, non-discrimination prominently opens the Covenant in Article 2, which imposes an overarching obligation of non-discrimination on member states in respect of *all* the rights contained in the ICESCR. Article 2 ICESCR requires 'that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status'.

The twin principles of the equal dignity of all persons and non-discrimination are in turn reflected in the list of civil, political, economic, cultural and social rights contained in the original UDHR and the Covenants. Johannes Morsink, the US scholar and author of the authoritative and seminal work on the UDHR, has persuasively argued that these rights are interconnected. He holds that these rights are normatively grounded in the drafters' shared view that protecting these rights is integral to facilitating human flourishing, individual self-realisation and the development of 'human capabilities'.<sup>16</sup> This also highlights the radical vision of human rights contained in the UDHR as a statement of entitlements, including not only the 'negative' civil and political rights of the enlightenment but 'positive' social, economic and cultural rights as well.<sup>17</sup>

Accordingly, and in the field of scientific research and health, the foundational moral and legal rights contained in the UDHR and the subsequent Covenants entail not only negative prohibitions on the conduct of research (Article 2 and 3 UDHR) but positive obligations too. This is reflected in the right of everyone to share in the benefits of scientific progress (Article 27 UDHR, Article 15 ICESCR).

Although the subsequent treaties and obligations are directly addressed to member states, Morsink argues that due to the nature of the international legal order there is no such restriction on the range of duty holders in the UDHR. Who the duty holders may be in relation to the discharge of each particular right will vary and may include both state and non-state actors. For instance, in the case of the right

to education, duty holders may include parents, the community or the state. But as regards the nature of the obligations and their enforceability, there is an important distinction between the dual regime of human rights covered by the ICCPR and the ICESCR.

## The UDBHR: A hybrid of negative and positive rights

The duties falling on member states that have ratified the ICCPR necessarily entail the adoption of national policies, laws and regulations to facilitate the protection and fulfilment of the rights. States whose organs (police, army, government officials) violate the rights contained in the ICCPR can be referred to the Human Rights Committee, which has jurisdiction to monitor the implementation of the ICCPR and hear individual complaints.<sup>18</sup>

By contrast, economic, social and cultural rights are not directly enforceable. When the two covenants were adopted, it was acknowledged that the extent to which social and economic rights could be fulfilled would vary tremendously depending on the social and economic national context.<sup>15</sup> Thus the legal obligation that the ICESCR imposes on member states is to take steps 'towards achieving progressively the full realisation of the rights' (Article 2).

These steps, including the setting of targets and the means to achieve them, have to be evidenced in regular reports submitted to the UN's Committee on Economic, Social and Cultural Rights (CESCR).<sup>19</sup> As of 2008, the committee can hear individual complaints where member states acceded to the ICESCR, which grants the committee competence to receive and consider communications (GA resolution A/RES/63/117). But there is no sign that states are in a rush to recognise the committee's jurisdiction. To date there are only 8 ratifications, including by Bolivia, Ecuador, El Salvador, Slovakia and Spain, and 40 signatures from UN member states.

The UDBHR comprises a hybrid mix of the rights contained in the two covenants. Arguably, the elaboration of the normative content and nature of the legal obligations (hypothetically) attached in international law to the rights detailed in the UDBHR depends on whether the right in question falls within the general umbrella of civil and political rights in the ICCPR or the social and economic rights in the ICESCR.

For instance, Articles 5 and 6 of the UDBHR enjoin respect for autonomy, and the individual's right to choose and consent to medical treatment and research. These are a species of civil and political rights broadly relating to Article 7 ICCPR, which stipulates an absolute prohibition on torture and medical research without consent: 'No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.'

These articles could be read to entail that states have an obligation (i) to take steps to prevent human rights contraventions by corporations that have their main office under their jurisdiction, and (ii) relating to the conduct of research which would be illegal in one country, but which owing to lack of legal protections is possible in another.<sup>20</sup> In practice, because international law norms do not have automatic legal force in national laws, victims of wrongs arising from trials

conducted in Nigeria have had to pursue a remedy in negligence in US courts, a process that can be extremely protracted and onerous for the victims.<sup>21</sup> For instance, in *Abdullahi v. Pfizer Inc.* (January 2009) the US Court of Appeal, second circuit, held by a majority of 2:1 that US corporations are liable under the Aliens Tort Statute for breaches of international law committed abroad.<sup>22</sup>

By contrast, 'positive' rights that elaborate on the social and economic rights contained in the ICESCR, such as the right to health (Article 14) or benefit sharing (Article 15) UDBHR, do not impose absolute obligations on states, but variable obligations towards progressive realisation of the rights. Accordingly, it is implausible to read Article 15 UDBHR as requiring states to adopt a rigid and uniform template or standard on the conduct of clinical trials irrespective of local considerations.

Certainly, the rights of research participants in a disadvantaged country will be violated if the design of the trial involves *discrimination* against the host population. This can happen either when placebos are used instead of best current treatment, and/or because post-trial care is offered to other populations in the same or comparable trials *without any reasonable justification*, i.e. as in the HIV trials that originally prompted this debate.<sup>23</sup> However, the use of placebos *per se* does not necessarily amount to a breach of human rights or a failure to confer a benefit. Indeed, when placebos are used in trials to find cheaper alternatives to existing, unaffordable formulations, the use of a placebo may even be justified as conferring a benefit on the local population, if the resources required for a trial against the 'current' best proven treatment and the extended time frame would result in more lives being lost or harm being suffered.

Thus, the minimalist, cost-benefit ratio approach that Temple advocates need not be in breach of human rights. However, it falls short of the expectations set out by Farida Shaheed, the UN Special Rapporteur, on Article 15 of the ICESCR in her report of 24 May 2012.<sup>24</sup> She specifically cites Article 15 of the UDBHR as a useful starting point, noting that 'benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries'. Shaheed describes 'multiple forms' of benefit sharing in paragraph 67 of her report: 'special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research; access to quality health care; provision of new diagnostic and therapeutic modalities or products stemming from research; support for health services; access to scientific and technological knowledge; and capacity-building facilities for research purposes.'

In this light, it is difficult to see how the qualified and nuanced wording of Articles 17, 32 and 33 of the DoH may be inconsistent with the obligations entailed by fundamental human rights instruments, notably Article 15 ICESCR and Article 15 UDBHR.

Article 17 HoD entails a commitment to ensuring protection of 'disadvantaged or vulnerable population(s) or community(/ies)'; stipulating that medical trials involving such populations are only justified where the research both addresses their health priorities *and* they stand a 'reasonable likelihood' of benefitting from it. Article 32 explicitly delineates the two scenarios in which using placebos is acceptable: firstly, in instances where no current proven treatment exists, the use of placebos are justified in furthering research.

Secondly, placebos are permitted where necessary for determining 'the efficacy or safety of an intervention', and receiving placebos must not put patients at risk of 'serious or irreversible harm'. Article 32 concludes with the warning that 'Extreme care must be taken to avoid abuse of this option.'

Article 33 of the 2008 DoH states: 'At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.' Thus, without using the language of 'rights', Article 33 nevertheless acknowledges these rights of participating patients.

## Codes of ethics and human rights

The fundamental human rights set out in human rights instruments are of a general nature, and do not detail the obligations entailed by a right or the means of ensuring its protection. Therefore, far from being a superfluous addition to human rights instruments, ethical codes of practice are essential. These codes elaborate detailed ethical standards which are developed and maintained by discipline-specific professional organisations. For example, the American Association for the Advancement of Science (AAAS) has convened a Science and Human Rights Coalition initiative on Article 15 ICESCR, which demonstrates how productive links may be developed between professional codes of ethics and human rights.

The DoH extensively lists specific ethical obligations attending the conduct of medical research, making it a necessary and important supplement to the human rights instruments whose weight and standing comes from decades of practice. UNESCO's Bioethics Declaration has a long way to go to acquire equivalent credibility. Furthermore, the continued involvement and co-operation of millions of physicians on the ground is critical to ensure that the rights of research participants are protected.

However, there are disputes over the relative status and authority of human rights instruments *vis-à-vis* professional codes of practice, as well as divisions between UN agencies (UNAIDS, WHO, UNESCO, ECOSOC, WIPO) and their respective declarations and norms. These disputes create confusion and uncertainty and allows key stakeholders to pick and choose which standards suit them best, at the expense of those already suffering grave inequalities.

Bioethics is a novel expansion of UNESCO's mission and competences in the field of education, science and culture. It has the potential to intersect with the mission and competences of other UN agencies in the areas of biomedical research, health and intellectual property rights, as well as the mission of non-governmental organisations and professional associations which have historically worked to promote ethics in scientific research. An important example of a recent initiative to revisit the UN Millennium goals which intersects with Article 15 UDBHR is the Framework Convention on Global Health. This framework aims to set up norms for the enforcement of positive rights, to achieve more normative uniformity.<sup>25</sup>

Collaboration and dialogue between these institutions is crucial to ensure human rights are respected, as well as transparency about

who UNESCO chooses to sponsor under its 'Bioethics' umbrella and engage in dialogue with, and why. At the time of writing, UNESCO is sponsoring one regional South American network, Redbioetica. There is no indication of why and how UNESCO has opted to sponsor this particular network and what criteria were applied to determine which members may be included or excluded. The worst-case scenario for disadvantaged populations in developing countries is for international organisations to work at odds with each other, and develop fragmented, overlapping and inconsistent norms.

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