

industry, and venture capitalists to work on predefined goals—including the Millennium Development Goals.

I declare that I have no conflicts of interest.

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1 Kassim-Lakha S, Bennett J. Philanthropic funding for health in Pakistan. *Lancet* 2013; **381**: 2236–37.

Authors' reply

We are grateful for the considerable interest that our Series on Health Transitions in Pakistan has provoked.

We concur with Naeem Jafarey and colleagues that there is a mismatch between the production of physicians through the medical educational system in Pakistan and public health needs. As indicated in our Series, this is a function of multiple factors including poor governance of medical education, limited opportunities and initiatives to deploy physicians in areas of maximal need, and absence of retention regulatory mechanisms. We agree with the need to focus the national medical curricula on priorities for Pakistan, in line with recent recommendations.¹ However, a mere change in curriculum or undergraduate education and training in primary care settings is unlikely to produce change without the requisite changes in public policy.² In recommending a shift towards primary-care-centred undergraduate medical education, Jafarey and colleagues question the fundamental premise and prerequisites of undergraduate training in Pakistan. This view is still an important subject of debate.³

Muhammad Qureshi and colleagues lament the scarcity of clinician scientists in Pakistan and their importance in national development. They recommend the initiation of MD/PhD training programmes. Notwithstanding the merits of this proposal, there is no clear consensus on this as a national priority, nor funding—as underscored by Jafarey and colleagues. In fact the entire funding and oversight of science education

and research in Pakistan is in dire need of revamping and restructuring.⁴ Therefore, we need a clear career pathway for clinician scientists, adequate funding for research, and mechanisms to ensure that appropriate research will find its way to policy and action. Mere production without the demand and absorption capacity might be counterproductive.⁵

Aitzaz Bin Sultan Rai calls for greater engagement by the international and national philanthropic bodies and foundations in supporting health research in Pakistan. National philanthropic organisations and the Pakistani diaspora support health initiatives in Pakistan and we believe that this scant funding should be targeted for health care. A proportion might be targeted for monitoring and evaluation of such initiatives but funding health research should be a function of global and national science funding bodies.

We concur with the ethos of the correspondents in that there is a need for fundamental rethinking of supportive mechanisms, ambience, production, and utilisation of health professionals in Pakistan. This was the basis for our call-for-action,² and we take this opportunity to underscore again the need for concerted action.

We declare that we have no conflicts of interest.

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Reconsidering the Declaration of Helsinki

The World Medical Association (WMA) working group on the revision of the Declaration of Helsinki is grateful to Ezekiel Emanuel for his interest and comments on the Declaration of Helsinki (May 4, p 1532).¹ He was invited by the working group to one of the expert conferences on the Declaration of Helsinki in Cape Town, South Africa, in December, 2012, as a keynote speaker, where he provided us with thoughtful input and advice.

The WMA is respectful of Emanuel's views and opinions, and has carefully considered input from him and many other experts and international organisations from all over the world in the development of a new draft revised version of the Declaration.

This new version, which unfortunately was not referenced in Emanuel's article, was published on the WMA website. We feel that this new version provides several important improvements, including: improved readability by reorganising and restructuring the document with subheadings, more protection for vulnerable groups, more protection for participants by including the issue of compensation for the first time, more precise and specific requirements for post-study arrangements, and a more systematic approach to the use of placebos, but no weakening of the ethics of placebo use.

The final decision on a revision of the Declaration of Helsinki is up to the General Assembly of the WMA and will be made in a transparent and democratic manner by voting. This is the only acceptable way to give the Declaration authority within the WMA and it is—in the best sense of the word—a political and thoroughly democratic decision. This political process is the appropriate one for a Declaration that a professional organisation such as the WMA has to adhere to. Most of the other guidelines Emanuel refers to were adopted by

For the **Lancet Series on Pakistan** see <http://www.thelancet.com/series/health-transitions-in-Pakistan>

For the **World Medical Association website** see <http://www.wma.net>

institutions in exactly this same way—through a voting process. This does not lessen the ethical validity of the final version of this document or any of the others he has referenced.

In terms of the frequency of revision, it is WMA policy to review documents on a regular basis and revise them whenever it seems appropriate in order to meet current and future challenges. The Declaration of Helsinki is therefore a living document which has been adapted over time in response to developments in medical research.

Emanuel also notes that the Declaration of Helsinki primarily addresses physicians. As an international representative organisation of national medical associations, the WMA has no mandate to formulate duties for members of other professions. However, WMA can invite other professional groups to support the Declaration and adhere to its principles, and it can also invite experts from other professions to join the consultation during the revision process. It is important not to confuse the mandate of an organisation, the authorisation within this organisation, and the openness of deliberation.

The working group invited all of those interested in the public consultation process to comment on the draft revised version of the Declaration. These comments were used to develop a new draft version, which was discussed at the end of August, 2013, by a large international audience at a WMA stakeholders meeting in Washington, DC. By working collaboratively with all our partners, we have been able to develop a new and stronger document, which has been submitted for discussion and approval by the WMA General Assembly in October.

We declare that we have no conflicts of interest. RP-P is Chair of the World Medical Association Declaration of Helsinki working group. All authors are members of the World Medical Association Declaration of Helsinki working group.

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- 1 Emanuel EJ. Reconsidering the Declaration of Helsinki. *Lancet* 2013; **381**: 1532–33.

Undoubtedly Ezekiel Emanuel's proposal¹ improves the structure, logic, and clarity of the Declaration of Helsinki. However, in his revised Declaration of Helsinki,¹ article 7 addressing the placebo issue reproduces the old text of the Declaration (article 32). This is disappointing because it is time to clarify the appropriate use of placebo, even if only in general terms. The ethical principle should be: use placebo only if there is proven uncertainty about the existence and/or efficacy of alternative interventions.

It is potentially misleading to say that placebo can be used for "compelling and scientifically sound methodological reasons".¹ It is difficult to understand what those reasons might be. One reason could be the need to prevent biocrep in non-inferiority trials, which, however, have been challenged as unethical per se.² Most three-arm trials with a placebo control group are also weak on ethics—with few exceptions.³

The use of placebo when comparators are available always implies consequences for patients who are deprived of useful treatments for controlling their symptoms or improving their disease outcomes. For example, the use of placebo instead of interferon- β or glatiramer in the trials of new agents against multiple sclerosis has resulted in a number of relapses that could have been avoided.⁴

The revised Declaration of Helsinki should allow the use of placebo only if it fully respects patients' interests.

I declare that I have no conflicts of interest. I thank Judith Baggott for her assistance with editing.

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Author's reply

It was a great honour to be invited to give advice and recommendations to the World Medical Association (WMA) on its latest revision of the Declaration of Helsinki. My article reflected my advice to the WMA.¹

The WMA heeded advice on the need for labels to make the document more readable and coherent.² There are improvements in the latest proposed revision, but many problems remain and some are compounded.

First, the main purpose of the recommendation for labels is to give the document a systematic coherent structure, to have one section logically flow from the others. The labels used and their ordering by the WMA in its latest proposed revision fail to provide any conceptually logical framework.

Second, many of the flaws—and contradictions—I pointed out are largely retained. The document aspires to universality and yet is addressed to physicians, although it retains requirements around publication for non-physicians. A document on human subjects research makes recommendations on the treatment of the environment.

Third, new flaws are added. The WMA in paragraph 19 now specifies that the key criterion of being a member of a vulnerable population is that a person is at increased risk compared with the normal population. But the Declaration then specifies that the basis of the risk is determined by the ability to consent.

The Declaration states that some populations are particularly vulnerable, need special protection, and have an increased likelihood of incurring additional and greater harm.



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These include those who cannot give or refuse consent for themselves and those who might be vulnerable to coercion or undue influence. All vulnerable groups need specifically considered protection.

This paragraph on vulnerable population is now confused. The inability to give or refuse consent in and of itself does not place a subject at higher risk of harm. It is a physical or environmental condition, such as having renal failure or inability to follow the protocol, that typically places people at higher risk of harm.

Silvio Garattini's comments can be seen as absolutist. The problem with this position is that many people do not benefit from currently available interventions. Unfortunately, given the world's level of global health assistance, nothing we do will get many people in poor countries the world's best standard of care in a foreseeable time. Even with all the attention to HIV/AIDS over the past decade, only 9.7 million people out of 26 million clinically eligible have access to antiretroviral therapy. These millions of HIV-positive people will continue to lack access to treatment for the foreseeable future despite our best efforts.

The fundamental ethical question is whether we prohibit research that might ameliorate their situation even if it does not result in providing them the world's best standard of care. Absolutists declare that research into ameliorating technologies are unethical because they are not the best. The absolutists condemn people who cannot get the best to whatever they currently have with no improvement.

Someone who believes in the principle of progress over perfection will recognise that sometimes it is necessary to conduct research on treatments that improve the situation but are not the best available in the world. Progress over perfection is a better standard to guide research in certain situations than the absolutist stand that condemns billions to their current state of poor health in

the name of wanting to guarantee them the world's best care—even when there is no chance of getting them that best care. This is hardly an ethically tenable position.

I declare that I have no conflicts of interest.

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- 1 Emanuel EJ. Reconsidering the Declaration of Helsinki. *Lancet* 2013; **381**: 1532-33.
- 2 World Medical Association. Declaration of Helsinki. Draft revised text for public consultation, 15 April – 15 June 2013, annotated version. http://www.wma.net/en/20activities/10ethics/10helsinki/15publicconsult/DoH-draft-for-public-consultation_annotated.pdf (accessed Aug 8, 2013).

Section 136 and police custody

A *Lancet* Editorial (June 29, p 2224)¹ advocated policy changes so that no-one is remanded in police custody solely for being ill. Section 136 of the 1983 Mental Health Act authorises police officers in England and Wales to take people suffering from a mental disorder to a place of safety for assessment. Detention in police stations under Section 136 is still common, despite guidance of the Code of Practice.² The most frequent reason for detention (57 of 70, 81%) was the perception of a risk of suicide or self-harm.³

In France, when police officers are informed that someone presents a high risk of suicide, they must call for emergency medical services. A physician takes the decision to transfer the person to hospital. Any person suffering from mental disorder and needing immediate care is examined by a psychiatrist. In Paris, the Psychiatric Ward of the Police Prefecture allows police officers to get a psychiatric assessment for individuals with mental health needs who threaten their own safety or that of others, whether or not they have committed a crime and are kept in police custody. Any arrestee might, at their request, be

examined by a doctor during custody.⁴ A police officer, as part of their duty of protection, can also request a medical examination. Despite these legislative protections, many mentally ill patients are detained in custody, and 4–8% of French male prisoners suffer from severe mental illness.⁵

We declare that we have no conflicts of interest.

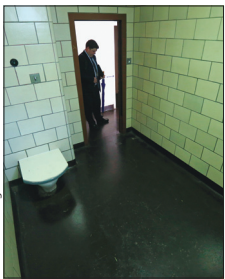
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Department of Error

Frood A. *Global Alliance for Chronic Diseases tackles diabetes*. *Lancet* 2013; **382**: 1014—In this World Report (Sept 21), the last sentence of the third paragraph should have read: "The GACD is an alliance of some of the world's biggest publicly funded research organisations, ranging from the UK's Medical Research Council to the Chinese Academy of Medical Sciences and the European Commission." The last sentence of the sixth paragraph should have read "Projects will last 2–5 years and around £20 million will be spent, most of it outside of the UK where it is administered from University College London." These corrections have been made to the online version as of Oct 11.



Andrew Winning