

Schuklenk's critique of the CIOMS guidelines: All procedure, no substance

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In his article on the 2016 revision of the *CIOMS International Ethical Guidelines* (1), Udo Schuklenk criticises the guidelines but adds a few words of faint praise. His criticisms are primarily procedural, and comprise the following main points: the guidelines aren't really *ethical* guidelines; the process used by the work group that wrote the guidelines involves "appeals to authority"; the work group used a method of consensus to reach conclusions on controversial points; the work group consisted of twice the number of participants from the global North as from the global South, yet the guidelines are largely directed at low-resource countries. In this commentary, I reply briefly to these criticisms and make a few concluding remarks.

Why are the CIOMS guidelines not *ethical* guidelines? Schuklenk's main point is that the guidelines offer no (or only sketchy) ethical justification, which is the main function of ethical analysis. While I agree that ethical justifications are needed for guidelines to qualify as ethically sound or acceptable, I disagree that the guidelines provide no ethical justification. Most of the justification appears in the commentaries. Surely, one criterion for calling guidelines 'ethical' is that they make normative statements. All of the guidelines use normative terms, primarily "should" or "must", where the latter term connotes a strict obligation. That the guidelines are not written like an academic article submitted to a bioethics journal is obvious. They cannot and should not be expected to read like a publishable article written for scholars in the same academic field. There is no space here to provide examples of the justifications provided for the guidelines. Readers will have to look and judge for themselves.

Schuklenk claims that the guidelines "appeal to authority", and for that claim he uses an article in *JAMA* authored by Hans van Delden, the chair of the work group, and Rieke van der Graaf, a member of the work group and secretary for the committee (2). van Delden refers to the WMA's *Declaration of Helsinki* and UNESCO's *Universal Declaration on Bioethics and Human Rights* as "authoritative" documents. But van Delden doesn't maintain that what those documents say is accepted as an "authority" by the CIOMS authors. The use of "authoritative" in the sense of van Delden's comment is, for example, that many countries and

sponsoring organisations require adherence to the principles laid out in the Declaration of Helsinki. Member organisations of the World Medical Association can be presumed to be morally bound by the precepts in the Declaration of Helsinki. The Declaration is "authorized" by the votes of members of the World Medical Association at a meeting of the World Medical Assembly. So the use of "authoritative" in this context does not have the same meaning as "an appeal to authority" when someone defends an ethical judgment with the claim "So and so says so, therefore it's true." However, I do agree with Schuklenk's assessment of the UNESCO declaration as having "mediocre quality". That it is "virtually ignored by professional bioethicists" is less significant than that it is a vague set of statements that give little specific guidance. Perhaps it is "authoritative" only in the sense that it is issued by UNESCO, a United Nations organisation.

A related, but different criticism is Schuklenk's rather cynical assessment of CIOMS. What is this group? Whom does it represent? What is its "authority"? He writes: CIOMS "is in reality not much more than a naked emperor. It counts only 13 actual international organisations of medical sciences as its members, among them the International Society of Audiology" (why this slur on the latter organisation is a mystery). CIOMS was not created to provide an expanded version of the Declaration of Helsinki directed at resource-poor countries. For a description of the rationale and creation of CIOMS, see the article by Ehni and Wiesing (3). Until fairly recently, the World Health Organisation was considered a technical public health organisation and did not venture into areas that involved ethical judgments. That has changed substantially in recent years, but one of the functions CIOMS served was to address ethical issues on topics in which WHO had a stake. The CIOMS ethical guidelines over the years have been prepared "in collaboration with WHO." That was the case for the 1982, 1993 and 2002 CIOMS guidelines, and for the current revision, which had representatives from WHO present at meetings of the work group and involved multiple layers of careful review of the final draft of the guidelines.

Schuklenk takes a swipe at the use of WHO's Guidelines Review Committee, and clearly misunderstands its function. This is not, as Schuklenk maintains, yet another "appeal to authority": "In this case it is an appeal to the authority of an opaque committee (yes, another committee) at the World Health Organisation. This Committee is called, you could not invent a better name, the Guidelines Review Committee. It approved the CIOMS revision process....So, in essence, unknown people of an unknown WHO committee assure us that all is well with CIOMS procedures." Ten years ago, an article in the *Lancet* reviewed and criticised a number of scientific guidelines issued by WHO (4). The article noted WHO's method of using

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experts in the formulation of scientific recommendations and found that the recommendations were not sufficiently evidence-based. According to the WHO website, "The GRC was established by the Director General in 2007 to ensure that WHO guidelines are of a high methodological quality and are developed through a transparent, evidence-based decision-making process" (5).

Basically what the GRC demands is that proposed guidelines have undergone systematic reviews of the relevant scientific literature. In the case of the CIOMS committee drafting ethics guidelines, questions arose both on the part of committee members and the head of the Guidelines Review Committee regarding just what documents or "systematic reviews" the CIOMS work group could produce to meet the requirements. In the very nature of the ethics literature, controversy and disagreements exist. Nevertheless, as van Delden describes briefly in the introductory section of the guidelines, "The GRC acknowledged that many of the 'review questions' may not require a full 'systematic review' and quality assessment but the process of retrieving information needed to be documented.... The final draft of these Guidelines was reviewed by the Secretariat of the GRC, which concluded that since these Guidelines are related to values and moral principles, they were exempted from GRC review" (6). In sum, there was no "appeal to authority" at WHO regarding the content of the CIOMS guidelines. Schuklenk is right that WHO should be more transparent in its disclosure of committees and processes at the organisation. It is not known for its transparency, and that is an area where serious reform is needed.

Further, in support of his contention that the CIOMS guidelines are not *ethical* guidelines, is Schuklenk's statement that the document is "an eminently political document where votes took place and compromises were reached, and where consensus was the name of the game". What guidelines or group reports that end with recommendations can do otherwise? Whether it is reports on ethical matters by Presidential or other governmental commissions, expert committees convened by the World Health Organisation, the Nuffield Council, or any other non-governmental body, the groups authoring such reports must reach consensus. To call them "political" is an error, as the authoring groups are not beholden to a single political point of view, nor are they financed by a sponsor with a political agenda in the usual sense of that term. True, they strive to be policy documents, which Schuklenk rightly calls the CIOMS guidelines. A group can come to conclusions or adopt recommendations only by consensus or vote. Moreover, any individuals who would refuse to accept a consensus or majority vote on a policy document should refrain from agreeing to serve on such a committee. Such individuals should stick to writing their academic papers for scholarly journals.

On the matter of representation of members, Schuklenk criticises the composition of the work group because members from the global North outnumber those from the global South. He notes that there were no members from China or Central America. Of course, there were no members from

most countries in the world. He correctly points out that it would have been especially useful to have representation from South Africa. I would agree that the African membership on the committee lacked balance, despite the excellence of the two members, both of whom were from French-speaking West Africa. East Africa was not represented, although much research is carried out in countries like Uganda and Tanzania. But despite the shortcoming of the lack of balance between global North and global South, what's the point here? It is surely not the case that all people from the global South "think alike," or have the same ethical viewpoints or experiences. One member from any country or region surely does not "represent" the region in any meaningful sense. This points to an inconsistency in Schuklenk's own criticisms. In discussing the composition of the work group and the inclusion of a member representing the perspective of a research participant, he calls the latter "close to nonsensical. Unless past research participants have been surveyed on the issues the guidelines are concerned about, and the results of that survey were represented by said members, it simply is not the case that 'the perspective of research participants' was represented. What was represented was the perspective of said member of the authoring committee, no more, no less". Arguably, the same could be said for the members from Senegal, Burkina Faso, India, and Brazil. Moreover, among those four members, there was no greater agreement on some controversial ethical issues than existed among members of the global North, and on some issues there was greater alliance among particular members from North and South. Schuklenk's point about the perspective of research participants applies equally well to membership from countries and regions of the world.

Schuklenk has confined his critique of the CIOMS process to procedural matters, as he explains in his introduction: "This paper will avoid the temptation to produce a point-by-point discussion of the new guidelines. It will also avoid the temptation – it's a big temptation – to produce rebuttals to guidance points that I think are both ill-informed and misguided (such as Guideline 20 on research in disasters and disease outbreaks)". He could have made the point about his focus in the paper without his swipe at Guideline 20. With all of his emphasis on providing justifications of ethical statements, it is simply unfair to claim that a particular guideline is ill-informed and misguided without saying more. The members of the work group who were mainly responsible for Guideline 20 have published on the topic and served on other committees and fora devoted to research in disasters and epidemics. I await Schuklenk's giving in to temptation and providing his own rebuttals to guidance points that he thinks are ill-informed and misguided. Then we can begin to talk about some genuinely substantive ethical matters.

Process and procedures are important, however. Of great importance is ensuring that members of such groups have no conflicts of interest. On that score, all members of the CIOMS working group met the test. Schuklenk's critique leaves us with the question: are there any credible "authorities" or for that matter, non-authoritative groups or organisations that could

issue international ethical guidelines on research with human beings? Clearly, governmental organisations can do so for their own populations but not for other nations. Schuklenk is critical not only of the “authority” of CIOMS to issue guidelines, but also that of the WMA. He does not say whether UNESCO could count as “authoritative,” but he makes clear what he thinks of its Declaration. As for the WHO, it is a public health organisation, one of the United Nations family of organisations (like UNESCO). If WHO appointed an expert committee to draft ethical guidelines for research, and the guidelines were vetted by its Guideline Review Committee using its rigorous methodological and procedural criteria, would that count as appropriately “authoritative” for Schuklenk? If so, why should not the WHO’s collaboration with CIOMS similarly count? And if not, it seems that no organisation could qualify as a proper body to issue international ethical guidelines for research. The CIOMS guidelines should be judged by their content and the justifications provided in the commentaries, not by the status of the organisation that issued them.

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CIOMS guidelines remain conservative about vulnerability and social justice

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Abstract

This paper begins by considering how the revised CIOMS guidelines have progressed beyond a mere labelling approach in the handling of vulnerability. However, progress is limited as the guidelines remain fixated on voluntariness and harm reduction or prevention. Although these are important considerations, vulnerability could also serve as a robust analytic for the evaluation of situational and pathogenic (or structural) contributions to susceptibilities to harm. They could also provide better guidance on how to differentiate among varying types and degrees of harm, rather than merely noting their presence. The paper concludes by considering vulnerability in relation to especially vulnerable children in health research.

Introduction

While the fourth edition of the *International Ethical Guidelines for Health-related Research Involving Humans* (1), recently revised by the Council for International Organization of Medical Sciences (CIOMS), is not primarily focused on vulnerability, an invaluable opportunity is nevertheless missed in framing the notion more positively and in ways that better enable researchers to address concerns of social justice. This paper begins by considering how vulnerability in the revised CIOMS guidelines has been progressive in moving beyond a mere “labelling” approach. However, progress is limited as the guidelines remain fixated on voluntariness and harm reduction or prevention. Although these are undoubtedly important considerations, vulnerability could also serve as a robust analytic for the evaluation of situational and pathogenic (or structural) contributions to susceptibilities to harm. They could also provide better guidance on how to differentiate among varying types and degrees of harm, rather than merely noting their presence. The paper concludes by considering vulnerability in relation to especially vulnerable children in health research.

Vulnerability in the revised CIOMS guidelines

Vulnerability remains an important reference point in the revised CIOMS guidelines on health-related research involving humans. In comparison with the previous version

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