

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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of its guidelines, CIOMS provides a stronger statement on the need to involve the vulnerable in research. It also makes clear that it would then be for the researchers and research ethics committees to protect the rights and welfare of these vulnerable individuals or groups, essentially by ensuring that specific protections are in place. The previous version of the guidelines made reference only to vulnerable individuals, but not groups, and “special justification” is required in order to involve them in research (2). Two members of the CIOMS guidance working group sum up significant changes to vulnerability in the following manner (3):

*Just as the definition of vulnerability is context dependent, so is the delineation of special protections for groups considered to be vulnerable, including allowing for no more than minimal risks for research procedures that offer no potential individual benefits for participants, or requiring that the research be carried out only when it targets conditions that affect these groups. Researchers and research ethics committees should enable the participation of vulnerable individuals by protecting their rights and interests through special safeguards and protections.*

To cite Florencia Luna and Sheryl Vanderpoel (4), these two members of the CIOMS working group endorsed the view that categorical labelling of certain individuals or groups of individuals should be avoided. Their viewpoint is encapsulated in the commentary to guideline 15, where the following explanation has been proffered (1:p 57):

*The account of vulnerability in this Guideline seeks to avoid considering members of entire classes of individuals as vulnerable. However, it is useful to look at the specific characteristics that may render individuals vulnerable, as this can aid in identifying the special protections needed for persons who may have an increased likelihood of being wronged or of incurring additional harm as participants in research. Different characteristics may also co-exist, making some individuals more vulnerable than others. This is highly dependent on the context. For example, persons who are illiterate, marginalized by virtue of their social status or behaviour, or living in an authoritarian environment, may have multiple factors that make them vulnerable.*

It is unclear what “specific characteristics” and “multiple factors” could mean in the revised guidelines. More critically, the underlying notion of vulnerability seems to remain broadly unchanged, as the revised guidelines continue to typify certain classes of individuals as being more susceptible to harm on the basis of limited or inability to exercise voluntary choice. More broadly, CIOMS’s construction of vulnerability remains centred around a concern that research participants could be exploited as being merely means to an end. In the previous version of the CIOMS guidelines, vulnerable persons were defined as those who are incapable of protecting their own interests due to insufficient power, intelligence, education, resources, strength or other needed attributes to protect their own interests (2:p 64). As a general consideration, an

individual would at the outset be labelled as vulnerable if she or he belonged to a certain class of individuals conventionally understood to have “limited capacity or freedom to consent or to decline to consent” (2: p 64). These vulnerable classes would include children, persons with mental or behavioural disorders, the elderly and persons with serious or disabling diseases. In contrast, the revised guidelines attempt to avoid such a “labelling” approach, which has been criticised for at least two reasons. First, certain individuals are more likely to be excluded from research participation on the basis of their vulnerable status. This may occur even though a more holistic assessment would show that the limited or lack of voluntary decision-making capacity of these individuals alone would not render them any more vulnerable than other participants who are able to exercise voluntary choice<sup>1</sup>. Second, this “labelling” approach has also been criticised for being at the same time over-inclusive and thereby obscures its normative goal of averting or mitigating harm (5). Under the revised guidelines, researchers and research ethics committees are invited to assess who and how a person or group is vulnerable in terms of the likelihood of harm based on a number of characteristics, rather than through membership in a class of individuals conventionally labelled as vulnerable. However, the only generally applicable characteristic that the relevant commentary sets out continues to be rooted in the capacity to consent. This is followed by an enumeration of the standard categories of vulnerable persons that were – to varying degrees – discussed in the previous version of the CIOMS guidelines: individuals in hierarchical relationships, institutionalised persons, women and pregnant women. There is a further catch-all category of ‘other potentially vulnerable individuals’ that comprises a range of individuals: from those with limited access to care, to people who are politically powerless. The key message is straightforward though: so long as special protections are in place, vulnerable individuals or groups should not be excluded from research only because they are stereotypically considered to have limited means of, or are otherwise incapable of, exercising voluntary choice.

### **When is vulnerability not an issue?**

Despite its recognition that the meaning of vulnerability is context-dependent, the revised CIOMS guidelines do not go far enough in addressing situational and structural contributions to vulnerability. In its specific provisions on research involving five categories of individuals for instance<sup>2</sup>, the focus remains very much on voluntariness and on harm reduction. While these considerations are clearly important, there is little guidance on what minimum threshold of vulnerability is acceptable for research to take place and when changes in vulnerability for already vulnerable persons should be regarded as acceptable or not. CIOMS does provide a minimal-risk standard in Guideline 4, which requires that “risks in research must be compared to risks that an average, normal, healthy individual experiences in daily life or during routine examination.” (1:p 12) It does not however explain how differences in background risks should be accounted for in establishing the acceptable probability and magnitude of harm.

Vulnerability is a complex notion because it encapsulates overlapping interests and concerns that arise from our needs as human beings, commonly manifested in different types and levels of dependencies. Famously, Florencia Luna has proposed the metaphor of layers in representing vulnerability as not static, but contextual and variable. Her account emphasises vulnerability as having many sources, and each of these can add a layer of vulnerability on a research participant (6). Different analytics have been proposed in the literature on how vulnerability should be understood for the purpose of engendering ethically acceptable responses. For instance, the taxonomy of Mackenzie, Rogers and Dodds attributes vulnerability to three different sources (ie inherent, situational and pathogenic) and to two different states (ie dispositional and occurrent) (7). Such an approach makes explicit the different weight that could be attached to the different sources and states of vulnerability and the variety of ethical responsibilities that might ensue. In addition, this approach does not over-simplify the complexities that a contextually-embedded evaluation of vulnerability entails. Situational vulnerability may be confounded by the fact that the most ethically pertinent context is not always readily identifiable and it could be rendered more complicated by pathogenic (or structural) vulnerabilities that arise from institutional or system-level deficiencies. For instance, the outbreak of a previously unknown epidemic in an area ravaged by war and natural disaster gives rise to both situational and pathogenic vulnerabilities. Yet vulnerability can still be a useful analytic in ethical deliberation and action, through the explication of whether and how healthcare and research interventions should follow for populations in the affected area and who should have what responsibilities, as well as the ethical goals that should be prioritised. A holistic assessment of this nature could provide better guidance on whether research should be initiated on an already vulnerable population.

Apart from harm reduction, the revised CIOMS guidelines have surprisingly little to say about the ethical evaluation of differential changes in vulnerability. This concern was highlighted by Samia Hurst and others who have, like CIOMS, argued for an account of vulnerability as “an identifiably increased likelihood of incurring additional or greater wrong.”(8) Such an approach is similarly a move away from definitions of vulnerability as specific categories of people. But these scholars go further in proposing modes of evaluation as to when the sources and states of ‘vulnerability’ of certain individuals could be determined to be of ethical concern in that, on the whole, their moral claims are less likely to be met than if the sources and states were different(6:p 197). The moral obligation to avoid wrongdoing arises from a claim that some wrongs should be avoided or conversely, some claims are not to be denied. For Ruth Macklin (9), an inquiry should begin with an examination of the empirical facts and circumstances to explain why some individuals or groups are more prone to disease, illness, injury or harm than other groups. This is followed by the identification of specific characteristics or circumstances that render them

vulnerable and to assess the severity of their vulnerability. Finally, it must be considered what might be done to mitigate or prevent harms or wrongs to those who are vulnerable and to determine who has a responsibility to do so. In the same spirit, Lyn Horn has broadened the construct of vulnerability through a restatement of Kenneth Kipnis’ taxonomy of research vulnerability beyond (but still encompassing) a paediatric research population. Writing in the context of the South African mining industry, Horn proposes a series of overlapping and mutually non-exclusive questions in terms of typified epistemic components to conceptualise vulnerability in terms of cognition, juridical, deferential, medical, allocational, infrastructural and social (10, 11). Arguably, the revised CIOMS guidelines have not gone far enough to encourage researchers, research ethics committees and other stakeholders to reflect openly and critically on all aspects of their research identities, which could be multiple and shifting. As an analytic, vulnerability could be a means of re-thinking ethical commitments in terms of the day-to-day work of clinical trials and the relationalities that are encompassed (12). Broadening the conceptualisation of vulnerability should be an important means of rendering visible the needs of particular individuals that could, in turn, legitimise their involvement in research.

### **Vulnerability should inform social value and advance social justice**

The framing of vulnerability by CIOMS as harm reduction or prevention is broadly consistent with other international normative documents, such as UNESCO's *Universal Declaration on Bioethics and Human Rights*. UNESCO recognises vulnerability as part of the human condition, but special vulnerability will impose a moral obligation on the state to protect the persons concerned. Article 8 of the Universal Declaration states (13):

*In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.*

The term “special vulnerability” has been explained by UNESCO's International Bioethics Committee as determinants that are caused by the internal states in individuals (such as less developed physical and mental states of children) and those that are caused by cultural, social, political, or environmental determinants (14).

Arguably, neither UNESCO nor CIOMS appear to go as far as the World Medical Association in presenting vulnerability as a rationale for research to involve “vulnerable” groups in order to alleviate health inequities that burden them. While the World Medical Association similarly calls for specifically considered protection for all vulnerable groups and individuals (15), it requires the research to be responsive to the health needs or priorities of the vulnerable group. In addition, the vulnerable group should stand to benefit from the research. Where research is conducted in low-resource settings, CIOMS

does indicate in the comment on Guideline 2, that the research must be responsive to the health needs or priorities of the communities or populations involved. Sponsors and researchers must also make every effort (1: p 3):

*...to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity.*

Commendably, CIOMS recommends that additional benefits such as investments in the local health infrastructure should be provided if this is necessary to ensure the overall fair distribution of the benefits and burdens of the research.

My sense is that CIOMS missed an opportunity to frame vulnerability as a means of holistic assessment or an analytic that could enable researchers to better consider and perhaps respond to social injustices. Some scholars already use the notion of vulnerability to move away from a purely risk-based approach, which they consider to be limited in scope and explanatory power (16,17). Rather than reduce the different "layers," considerations and factors associated with vulnerability into a uni-dimensional risk assessment exercise, vulnerability is presented as an interpretive framework within which social inequities that create greater exposure to risk of harms for particular individuals or group of individuals could be visualised and responded to. For instance, disasters are affected by social power structures which in turn generate unequal exposure to risk. This richer conception of vulnerability would enable researchers and research ethics committees to assess resilience or the social, economic and cultural abilities of particular individuals or groups to cope with changes or harms, beyond simply voluntariness, even if this is an important consideration.

Additionally, vulnerability need not be understood only in a negative sense, as susceptibility to harm. Instead, it could be understood as a condition for survival because it necessitates learning, innovation and responsiveness to external forces. In a variety of circumstances, flexible application of rules could well be critical for the smooth operation of normal functioning of technological systems and organisations (18). In other words, vulnerability could refer to the capacity to recover from existing inequities and harms and an opportunity to renew compromised capabilities, as well as the flexibility to develop new ones. Some provisions in the revised CIOMS guidelines 6 to 8, such as those that relate to community engagement and benefit sharing (2:pp 21-32), are relevant to this richer conception of vulnerability, although the existing provisions on vulnerability do not seem to support or encourage this.

### **Especially vulnerable children in health-related research**

A significant change in emphasis in the revised CIOMS guidelines is that children and adolescents must be included in health-related research unless a good reason justifies their exclusion. However, researchers and research ethics

committees must, among other requirements, ensure that: (i) the research might not equally well be carried out with adults; (ii) the purpose of the research is to obtain knowledge relevant to the health needs of children; (iii) a parent or legal representative of each child has given permission; (iv) the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and (v) a child's refusal to participate or continue in the research will be respected.

However, the revised CIOMS guidelines do not sufficiently account for the source of vulnerability of children and adolescents as arising in the context or situation in which children may be placed, rather than in the inherent nature of childhood, or in innate aspects of research with children. As the recently published report of the Nuffield Council on Bioethics explains (19), classifying a group as vulnerable, rather than a situation as creating vulnerability, does not facilitate a robust evaluation of the actual vulnerability of any particular member of that group. Where obtaining permission of a parent or legally authorised representative is concerned, there is also little guidance on what should legitimately be considered. On this point, Katharine Wright indicates that the Nuffield Council has avoided the term "best interests," on the grounds that the use of "best" unhelpfully implies that only one possible course of action is justifiable, while this will rarely be the case in research participation. Instead, the Nuffield Council developed the concept of a "fair offer" to describe what an ethics committee should be aiming to secure on behalf of potential participants (20).

There may be situations where the decision of young persons to participate in research should suffice. Phaik Yeong Cheah and Michael Parker explain that children are not always vulnerable in terms of their limited capacity to voluntarily participate in research (21). Particularly in low-income settings or disaster areas, a significant number of mature minors is precluded from research participation because their parents are unavailable or refuse to provide consent, even though the children themselves are agreeable and could potentially benefit from research participation. Where research is important, meets international scientific and ethical standards and has been approved by relevant ethics committees, and where the information is presented in a way that is accessible to children, these children should be allowed to consent for themselves in these very limited circumstances. While such a proposed arrangement should be adequate in meeting the requirements of the CIOMS revised guidelines, a more robust conception of vulnerability would arguably encourage (if not require) researchers to implement the research in a manner that would improve the capabilities of these children as participants, and possibly local capacities also by supplementing or removing socio-economic or structural limitations. For instance, a study illustrates how the responsiveness of a malaria Quinact trial to the socio-economic vulnerabilities of its child participants in the Democratic Republic of Congo was not confined to harm reduction, but encompassed a number of culturally appropriate measures that were directed at alleviating systemic inequities (22).

When the social value of the research is compelling and cannot be conducted in adults, CIOMS indicates that a research ethics committee may permit a minor increase above minimal risk. While researchers should ensure that the research is responsive to the health needs or priorities of communities or populations because they subsist in a low-resource setting, CIOMS's definition of social value does not require efforts to alleviate social injustice. In contrast, Sergio Litewka and Kenneth Goodman argue that researchers and sponsors need to do more (23). In some Latin American countries emerging from decades of political unrest, civil wars and corruption, a significant number of children is homeless and prone to sexual abuse and human trafficking. All research carried out with this particularly vulnerable population must not only adhere to strict ethical safeguards, but should also attempt to alleviate the pathogenic vulnerabilities of their participants. Rather than to read the above discussion as imposing an additional and potentially onerous responsibility on researchers who work with especially vulnerable individuals, I have noted in the previous section of this paper that other provisions in the revised CIOMS guidelines already require such considerations and actions, albeit in a disjointed manner. The criticism of this paper is that, in confining the provisions on vulnerability to consent and harm-reduction, the revised CIOMS guidelines do not go far enough to enable a more holistic visualisation of vulnerability, particularly the implicit social injustices.

## Conclusion

While the intent may be for the revised CIOMS guidelines to be read and applied in their entirety, clearer guidance needs to be provided on how the various analytics and ethical goals engendered could be applied. There is no reason why vulnerability as an analytic should be limited to voluntariness and harm reduction (or prevention). Surely vulnerability is implicit to the determination of social value and perhaps enabling individuals and groups to become less vulnerable should be an ethical goal for health research. In addition, the potential of a more positive framing of vulnerability remains at this point unharnessed. To focus only on protection without at the same time promoting innovative change and resilience undermines the very motivation that spurs the research enterprise.

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## Conflict of interest

The author knows several members of the CIOMS authoring committee well, and has worked with some of them on journal editorials or projects.

## Notes:

<sup>1</sup> If vulnerability is to be understood as an increased risk of exploitation, or being unfairly taken advantage of, then a research participant could be vulnerable even if she or he is able to exercise voluntary choice. ( See: Wertheimer A. *Exploitation in clinical research*. In: Emanuel EJ, Grady C,

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<sup>2</sup> *These being adults without decision-making capacity, children and adolescents, women, pregnant and breastfeeding women, and those in disasters or disease outbreaks.*

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