The 2016 CIOMS guidelines and public-health research ethics

J R Williams, PhD

School of Epidemiology and Public Health, Faculty of Medicine, University of Ottawa, Ontario, Canada

Corresponding author: *J R Williams (jrewms@yahoo.com)*

In November 2016, the Council for International Organizations of Medical Sciences (CIOMS) published its revised *International Ethical Guidelines for Health-related Research Involving Humans*. In relation to earlier versions, the scope of the new guidelines has been expanded to include public-health research. While successful to some extent, the document does not take into sufficient account the differences between public-health research and other types of health research. It is silent on some issues of importance to public-health research, such as its definition, health inequities and novel research methodologies. Its treatment of some other issues, including the need for research-ethics committee approval, consent, community involvement and dissemination of research results, are deficient in some respects. The guidelines that are particularly applicable to and useful for public-health research deal with social value, the health needs of communities and populations, community engagement, disasters and disease outbreaks, cluster randomised trials and data sharing. Much further development of the foundations and applications of public-health research ethics is needed to inform future revisions of the guidelines and of other international and national research-ethics documents.

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On 29 November 2016, the executive of the Council for International Organizations of Medical Science (CIOMS) approved the newly revised version of *International Ethical Guidelines for Health-related Research Involving Humans*.[1] This document combines and replaces the 2002 CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects* and the 2009 CIOMS *International Guidelines for Ethical Review of Epidemiological Studies*. It was produced by an expert working group that met numerous times between September 2012 and June 2016.

Public-health researchers have often complained that both international research-ethics guidelines such as the Declaration of Helsinki and the CIOMS documents, and most, if not all, national guidelines and regulations, do not take sufficient account of the differences between public-health research and other health-related research.[2] The primary aim of these documents is the protection of individual research participants and, to a lesser extent, communities, whereas public-health research prioritises health promotion and disease prevention among populations over protection of individuals.[3] When reviewed by research-ethics committees (RECs), public-health protocols are often judged by the same standards and criteria as clinical trials, even when these are clearly inappropriate.

Do the 2016 CIOMS guidelines deal adequately with the ethical aspects of public-health research? In what follows I argue that although they are partially successful in this regard, they are silent on some important public-health research issues, and problematic on others.

Ethical issues on which the guidelines are especially useful

In some respects the 2016 document represents a significant advance over previous versions, and contains much useful information for public-health researchers. The following guidelines are particularly applicable to public-health research:

- Guideline 1, 'Scientific and social value and respect for rights', states that 'all research is [to be] carried out in ways that uphold human rights, and respect, protect and are fair to study participants and the communities in which the research is conducted.' There was no guideline on social value in previous versions, and the commentary on this guideline makes explicit mention of public health in relation to social value.
- The new guideline 7, 'Community engagement', does not mention public health as such, but is clearly applicable. The commentary provides a broad definition of 'community' that 'consists not only of people living in the geographical area where research is to be carried out; it also comprises different sectors of society that have a stake in the proposed research, as well as subpopulations from which research participants will be recruited'. However, the guideline and commentary do not include community approval of or consent to research as an aspect of engagement, and they leave important questions unasked (see below).
- The new guideline 20, 'Research in disasters and disease outbreaks', is clearly relevant to public-health research. It reflects the great amount of ethical analysis of responses to recent pandemics of severe acute respiratory syndrome (SARS), avian influenza and Ebola[4,5] and, to a lesser extent, of earthquakes and weather-related disasters, although there is no mention of wars.
- Another new guideline, 21, 'Cluster randomised trials', is likewise of major concern to public-health research, since those randomised are 'groups of individuals (clusters), communities, hospitals, or units of a health facility'. However, the guideline's primary focus, as throughout the entire document, is on individual members of these groups, whether patients or healthcare workers.

- Guideline 24, 'Public accountability for health-related research', calls on researchers to share their data, thereby echoing previous demands from those engaged in public-health research.[6]

Ethical issues on which the guidelines are silent

What public-health research is

Whereas medical research has well-established methodologies, such as clinical trials, that differentiate it from medical practice, it is sometimes difficult to determine whether a public-health activity is research or something else, such as programme evaluation or quality improvement, and the guidelines do not address this issue.

Health inequities

Although the first guideline is entitled 'Scientific and social value and respect for rights', neither the guideline nor its commentary mentions health inequities, a major concern of public health.[7]

Novel research methodologies

The guidelines do not mention the evaluation of research methodologies that are unfamiliar to members of RECs, such as those employed by some public-health researchers.[8,9] The commentary on guideline 23 requires RECs to 'either carry out a proper scientific review, verify that a competent expert body has determined the research to be scientifically sound, or consult with competent experts to ensure that the research design and methods are appropriate'. However, the guideline provides no criteria for making such a judgement.

Ethical issues on which the guidelines are problematic

To what extent are the guidelines applicable to public-health research?

On the one hand, the preface states that 'the current scope is confined to the classic activities that fall under health-related research with humans, such as observational research, clinical trials, biobanking and epidemiological studies.' Although this list may not be intended to be exhaustive, it is unclear whether all public-health research is included within 'classic activities'. Just below, however, the preamble claims that 'the ethical principles set forth in these guidelines should be upheld in the ethical review of research protocols. The ethical principles are regarded as universal.' (Unlike the 2002 version of the guidelines, this one does not name its ethical principles, nor is there any definition or discussion of ethics.) This statement, and others found throughout the document, suggest that all health-related research activities, including public-health research, are subject to the same principles and procedures for ethics review.

When is REC approval required?

Guidelines 10 and 23, which deal with this matter, are at best unclear and arguably inconsistent, especially with regard to public-health research. No. 23 states: 'All proposals to conduct health-related research involving humans must be submitted to a REC to determine whether they qualify for ethical review and to assess their ethical acceptability, unless they qualify for an exemption from ethical review (which may depend upon the nature of the research and upon applicable law or regulations)'. The commentary on this guideline includes the following paragraph on exemptions from review: 'Some studies may be exempt from review. For example, when publicly available data are analysed or the data for the study are generated by observation of public behaviour, and data that could identify individual persons or groups are anonymized or coded, the study may be exempt. Health-systems research may be exempted from review if public officials are interviewed in their official capacity on issues in the public domain'. It is unclear whether the researcher has the authority to decide if a study qualifies for exemption from REC review or whether this is the prerogative of the REC.

A similar problem is found in guideline 10, 'Modifications and waivers of informed consent', which states unequivocally: 'Researchers must not initiate research involving humans without obtaining each participant's individual informed consent or that of a legally authorised representative, unless researchers have obtained explicit approval to do so from a research ethics committee'. However, the commentary on this guideline states: 'When a study is performed under a public-health mandate or by public-health authorities, such as disease surveillance, normally neither ethical review nor a waiver of consent is needed because the activity is mandated by law'. The commentary compounds this ambiguity where it says: 'Although the extent and limits of data collection are determined by law, researchers must still consider whether, in a given case, it is ethical to use their authority to access personal data for research purposes'. No criteria are given for making this determination.

Consent

The primary focus of public-health research is human populations and the institutions that provide healthcare, rather than individual research participants. Populations include ethnic groups, residents of a specific geographical location, an identifiable group either affected by or susceptible to some health condition, a virtual community sharing a common interest and connected on the internet, etc. The guidelines do mention research on populations, but their main concern is individual research participants, as is evident in their numerous entries on consent.

Throughout the document 'consent' applies only to individuals. In guideline 7 on 'Community engagement', there is no mention of community consent for research, although the co-operation of the community is usually very important, if not essential, for research to proceed. Moreover, RECs need to decide whether researchers have to give the community an opportunity to consent to the dissemination of the results of the research as a condition for their agreement to participate in a study.

Three new guidelines deal with problematic aspects of consent that arise in public-health research. The very lengthy guideline 20, 'Research in disasters and disease outbreaks', requires that 'the individual informed consent of participants is obtained even in a situation of duress, unless the conditions for a waiver of informed consent are met'. The last of these conditions from guideline 10 – that the research would not be feasible or practicable to carry out without the waiver or modification, the research has important social value, and the research poses no more than minimal risks to the participants – may be impossible to fulfil in disasters and epidemics. When there are entire populations affected by an earthquake or outbreak of infectious disease, different interventions can be implemented, and evaluated afterwards to determine which were more effective

in alleviating the health effects of the disaster. It would often be impossible to obtain individual consent from all those involved in the interventions.[10]

Guideline 21, 'Cluster randomised trials', is more permissive in allowing exceptions to individual informed consent. The guideline authorises researchers, sponsors, relevant authorities and RECs to 'determine whether it is required or feasible to obtain informed consent from patients, healthcare workers, or community members in certain studies' and to 'determine whether requiring informed consent and allowing refusal to consent may invalidate or compromise the research results'. However, the commentary on the guideline withdraws this discretion from researchers, and stipulates that for such research, a waiver or modification of consent must be obtained from a REC.

Guideline 22, 'Use of data obtained from the online environment and digital tools in health-related research', deals mostly with privacy. Where it does mention consent it reverts to what seems to be a requirement for individual consent to use online personal health-related data: 'Researchers should inform persons whose data may be used in the context of research in the online environment of: the purpose and context of intended uses of data and information; the privacy and security measures used to protect their data, and any related privacy risks; and the limitations of the measures used and the privacy risks that may remain despite the safeguards put in place'. Although this statement uses 'should' rather than 'must', it is arguably too restrictive. Much public-health data, including official statistical reports, can be obtained from conventional media sources such as newspapers and the internet. Even though the data may identify individuals or communities, there should generally be no need to obtain their consent. Whether this applies to data from so-called social media (Facebook, Twitter, etc.) is unanswered in the guidelines.

Community involvement

Although the new guideline 7 deals explicitly with this topic, it leaves several questions unasked. How can researchers, especially those from outside, gain the trust of the population, especially if the population has had negative experiences with previous researchers? If the researchers, or their assistants, are from within the population, how can they avoid a conflict of interest between the requirements of the research and the needs or desires of population members? Who owns the results – the researchers or the population, or both? Does the population have a right to participate in the interpretation of the data? Can it veto the dissemination of results that could stigmatise it? A REC needs to be assured that the researchers have considered these issues and have a sound plan to deal with them before the project is approved.

Dissemination of research results

Guideline 24, 'Public accountability for health-related research', requires researchers to 'prospectively register their studies, publish the results and share the data on which these results are based in a timely manner'. The commentary on this guideline states: 'Researchers and sponsors have an obligation to register their studies before they actually start'. As desirable as this may be, it is not feasible for most public-health research. There is no public-health research equivalent of the various clinical-trial registries where proposed studies can be listed and, in some cases, their results can be summarised.

Conclusion

Public-health researchers can be pleased that CIOMS has recognised that the ethics of research applies to their field just as much as to other types of health-related research. They will likely be concerned, however, that the differences between their needs and those of other health researchers are not sufficiently accounted for in the revised guidelines. This is understandable, considering the relative underdevelopment of public-health research ethics compared with other health-research ethics, which benefits from a huge literature and multiple international and national guidelines and regulations. One can hope that the new CIOMS guidelines will spur all those involved in public-health research ethics to intensify their efforts to develop both the theoretical foundations and the practical applications of this field, so that the next revision of the guidelines, and of other international and national research ethics documents, will be as useful for public-health research as for all other health research.

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