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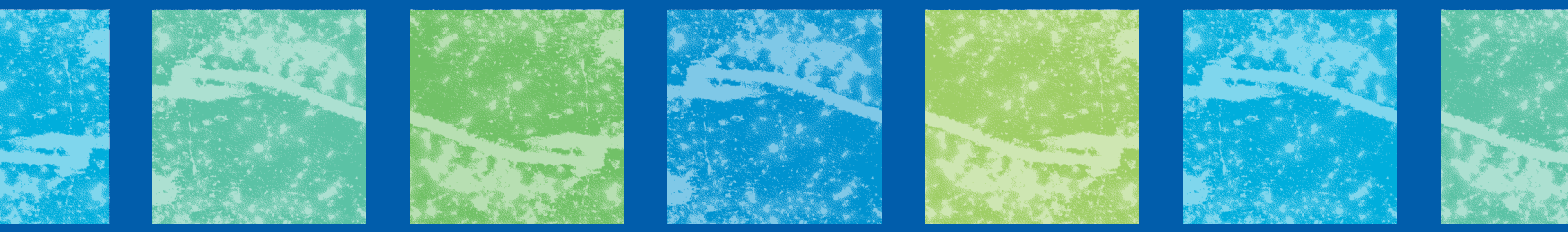
Research Ethics in International Epidemic Response

WHO Technical Consultation

Geneva, Switzerland
10–11 June 2009

MEETING REPORT



World Health Organization

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Executive summary

- Most of the ethical issues related to research in public health emergency situations are the same as those already addressed in general ethics guidelines governing biomedical research. Differences during an emergency include such things as changes in perceptions of risks, benefits and trust which must be taken into account in the ethics review process; a heightened need for attention to organizational values like accountability and transparency; and the fact that, as a practical matter, there may not be sufficient time for standard ethics review processes which in many countries can sometimes take months.
- Despite these differences, even in an infectious disease emergency or other crisis situation, the principles and values embodied in international and national ethics guidelines, as well as human rights instruments, must be upheld.
- In many countries, most research with human participants must undergo prospective ethical review by a research ethics committee (REC), while activities characterized as public health or clinical practice are not subject to this requirement. However, distinguishing between research and practice is complicated by the fact that there is a significant area of overlap in these activities in terms of methodology, systematization of investigation, and the outcome of producing generalizable knowledge.
- Despite the conceptual problems of distinguishing between research and non-research, the distinction is deeply ingrained in many countries' regulatory structures and is unlikely to be changed any time soon. However, this does not mean that all research must undergo full REC review, nor does it mean that activities that fall outside local or international definitions of research should escape ethics review entirely.
- The ultimate goal for public policy should be to ensure that most, if not all, emergency public health activities are subject to some form of ethical oversight, whether or not those activities are formally characterized as research. The specific nature of the oversight should be commensurate with the activity's objectives, methods, risks and benefits, as well as the extent to which the activity involves vulnerable groups.
- To achieve this goal, it is crucial to streamline the ethics review process and to establish appropriate, flexible mechanisms and procedures for ethical oversight not limited to traditional REC systems.
- While some crucial emergency health research should still undergo full REC review because of significant risks to individuals or populations under study, a "fast-track" review approach should also be adopted. However, review should not be expedient to the point of dropping or narrowing ethical principles.
- Options for promoting fast-track review of emergency research include adjusting the balance between in-person and electronic communications by REC members; the use of pre-emergency repositories of study protocols or protocol parts which could be submitted to RECs for ethical pre-screening; the creation of special emergency research RECs, perhaps on a national or regional level; and, where there is no other feasible option, greater reliance on retrospective rather than prospective ethics review, with safeguards to address non-compliant or sub-standard research ethics conduct.
- Public health activities that are classified as practice may raise important ethical issues. Stakeholders should formulate plans to ensure that such activities receive appropriate and timely ethical review. One option to consider, at least in some

situations, is review by special committees with appropriate expertise and experience to examine procedures and methods specific to a public health practice. For activities that do not warrant committee review, or in countries that choose not to institute a committee review structure, public health practitioners can be equipped with tools to help them assess whether their planned activities comport with principles of public health ethics. Training modules for research ethics committees and public health professionals should be created to support this goal.

- There is a critical need for capacity building in the ethical review of public health research and practice. Researchers, public health agencies and other stakeholders should work together to develop short courses, degree programmes and other training modalities. Funding agencies should direct appropriate support to these efforts.

Background

Pandemic influenza preparedness and response raises many ethical questions. Upon request by Member States, in December 2007 WHO published a global guidance document entitled *Ethical considerations in developing a public health response to pandemic influenza* (*1*). This guidance document addressed the following issues:

- priority setting and equitable access to therapeutic and prophylactic measures;
- isolation, quarantine, border control and social-distancing measures;
- the role and obligations of health-care workers during an outbreak of pandemic influenza;
- developing a multilateral response to an outbreak of pandemic influenza.

Since the publication of this document, it has become apparent that there is a need for additional guidance on a subject that was not addressed in the previous work, namely the ethical issues that arise while doing research in infectious disease outbreaks. Notably, in a workshop in Uganda in 2008, several ministries of health representatives identified the lack of guidance in this area as a gap in the previous WHO document. The importance of filling this gap has been highlighted by the recent emergence of influenza A (H1N1).

In response to the request for additional guidance, WHO's Global Influenza Programme and the Ethics and Health team jointly convened a technical consultation on "Research Ethics in International Epidemic Response". This meeting brought together experts of international organizations, government agencies and ministries, professional medical associations, academic and research institutions, as well as staff of various WHO departments and regional offices to:

- identify and elucidate the ethical issues related to clinical and public health research and related activities during infectious disease outbreaks;
- provide WHO with urgently needed guidance in this area, with specific focus on the question of whether and how prospective ethical review should take place for these activities;
- provide practical guidance to public health practitioners and researchers in the field.

The discussion occurred in the context of the current influenza A (H1N1) event, which was declared a "pandemic" on 11 June 2009, the second day of the meeting. It was noted during the meeting, however, that the suggestions and approaches developed by the group could be extended to other infectious disease emergencies as well.

Existing ethical guidance and relevance to epidemic response

1. Participant presentations and discussions covered a broad range of ethical issues related to international response to epidemics, including: the standard of care as applied in different local and multinational research contexts; the appropriate use of placebo-controlled trials; exploitation and protection of vulnerable groups, including quarantined or isolated individuals and migrant populations; fair and equitable benefit-sharing and distribution, especially between sponsor and host countries (which typically means developed and developing countries respectively); just prioritization of public health responses; evaluation of anticipated risks and benefits; maintenance of confidentiality and privacy of personal data and information; safeguards for biobanks and intellectual property; and respect for autonomy and informed consent.
2. As a starting point of the discussion, the group agreed that, even in an infectious disease emergency or other crisis situation, the principles and values embodied in international and national ethics guidelines must be upheld.
3. Participants agreed that most of the ethical issues related to research in emergency situations are not unique to emergencies. Rather, the same [illegible] human subject research. These include questions of informed consent, risk–benefit assessment, confidentiality, community engagement, etc. Members noted, however, that many existing research ethics guidelines emphasize issues related to clinical studies, with less attention to public health research. In general, the field of research ethics would benefit from greater attention to the ethics of public health activities.
4. The group noted that ethical issues in an emergency differ from other situations in several ways.

   ■ Emergency situations affect perceptions of risks, benefits and trust, and these changed perceptions, especially in the patient-provider relationship, must be taken into account in the ethics review process.

   ■ There is a heightened need for attention to organizational values like accountability and transparency.

   ■ The timely generation of knowledge is a practical matter of importance. The normal processes used to ensure the scientific and ethical validity of such efforts may not react fast enough; for example, there may not be sufficient time for standard ethics review processes, which in many