WHO Guidance on Ethics & infectious disease outbreaks

Dr Andreas Reis and Ms. M. Guraiib

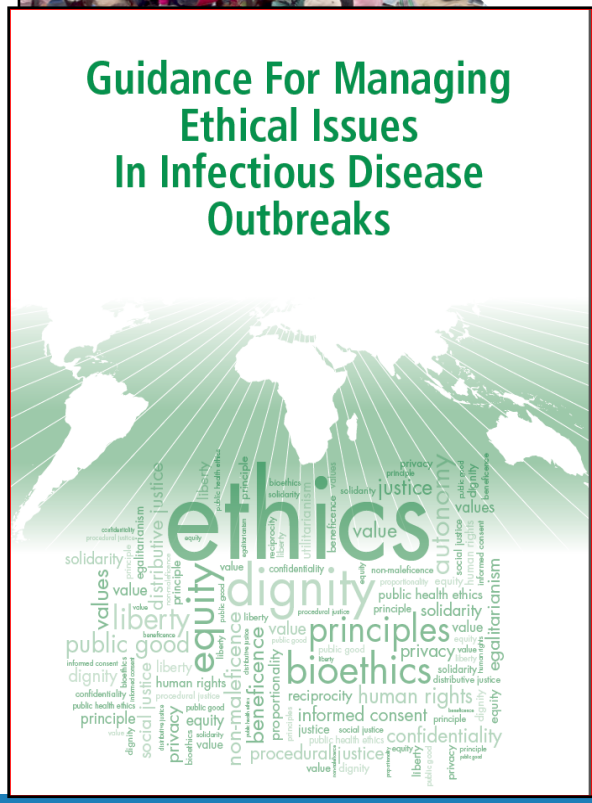
Global Health Ethics

WHO Geneva

World Health Organization

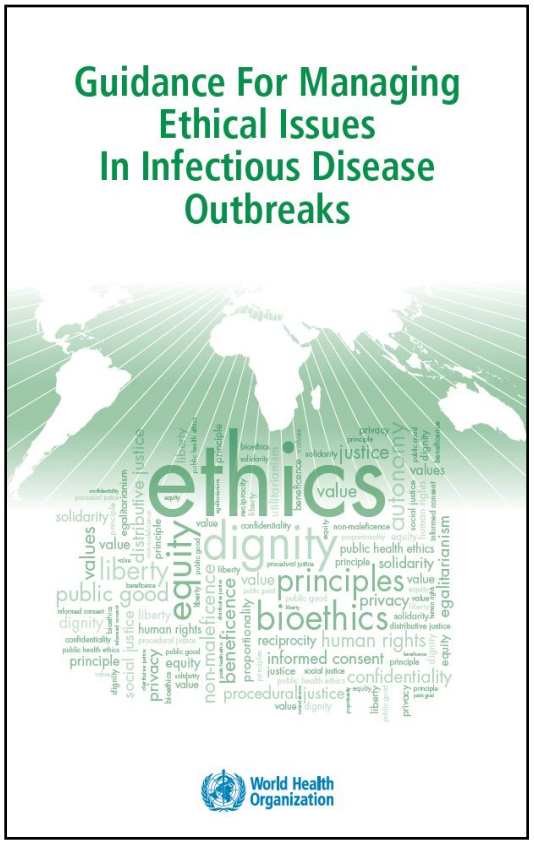
Infectious Disease Outbreaks

- WHO has been working in the area of Ethics & outbreaks for many years

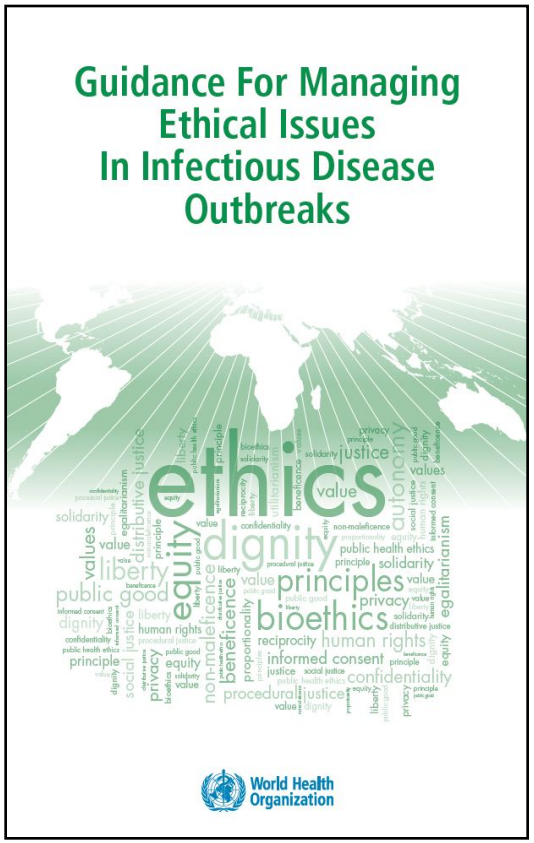


World Health Organization

Guidance for Managing Ethical Issues in Infectious Disease Outbreaks, 2016



Pregnant women



P.42: **Sex- and gender-inclusive research strategies** — "Researchers should make efforts to ensure that studies do not disproportionately favour a particular sex or gender, and that **women who are or might become pregnant are not inappropriately excluded from research participation.** During an outbreak, research on experimental treatments and preventive measures should seek to identify any sex- or gender-related differences in outcomes."

World Health Organization

CIOMS: INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS

- CIOMS 2016

Guideline 18: WOMEN AS RESEARCH PARTICIPANTS

" Women in many societies have been excluded from research. … In particular, women who are biologically capable of becoming pregnant have been traditionally excluded from clinical trials of drugs, vaccines and medical devices owing to concern about undetermined risks to the fetus (see Guideline 15 – Research involving vulnerable persons and groups). Although the presumption against including women has changed in recent years, they are still excluded in many cases without adequate justification. Much remains unknown about the safety and efficacy of most drugs, vaccines, or devices used by women in medical practice, and this lack of knowledge can be dangerous."

CIOMS: INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS

- CIOMS 2016

Guideline 19: Pregnant and breastfeeding women as research participants

"A direct consequence of the routine exclusion of pregnant women from clinical trials is their use of medications (both prescription and non-prescription) lacking data from clinical trials about the potential individual benefits and harms to themselves, their fetuses and their future children. Therefore, after careful consideration of the best available relevant data, it is imperative to design research for pregnant and breastfeeding women to learn about the currently unknown risks and potential individual benefits to them, as well as to the fetus or nursing infant."

ERC Experience

- Potential inclusion of pregnant women is a frequent issue during ERC deliberations
- Risk-benefit analysis often challenging
- ERC has often recommended the inclusion of pregnant women and children < 5 years