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ASSET

share and move to face nasty bugs

Ethics and public health

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The ASSET FINAL EVENT
Share and move for mobilization and mutual learning at local, national and international levels on Science in Society related issues in epidemics and pandemics
Rome, 30-31.10.2017

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Many ethics inside bioethics

(Some) ethical values in bioethics

	Medical ethics	Research ethics	Public health ethics
Main focus	Patient	Society at large	Groups, populations
Key interactions	Individual physician and patient	Physician/researcher and patient	Agency/institution and community/population
Main values/principles	Autonomy, nonmaleficence, beneficence, justice	Autonomy, nonmaleficence, beneficence, justice, solidarity, reciprocity	Interdependence, community trust, solidarity, reciprocity, justice (harm reduction programs)
Required actions	Protect privacy, Informed consent, Economic rights	Ensure study value and validity (Randomization, Placebo arms, double blind), ethical review, informed consent	Restrict personal freedom, Contact tracing, Mandatory vaccinations, Mass culling of animals, etc.

ELSI issues in preventing and managing disease outbreaks

Public health:

- Prevention (health promotion, vaccinations)
- Preparadeness (surveillance)
- Response (social distancing, travel restrictions, quarantine, case isolation)

Medical interventions and medical research

- Resource allocation and prioritisation
- Ethical review of research during outbreaks
- Data sharing and benefit sharing

Prevention, health promotion

- Soft and hard paternalism: promoting healthy lifestyles, mandatory vaccinations, the «Nanny State» and the free rider problem.

Preparedness: Surveillance

- Surveillance is necessary to quickly identify and respond to a pandemic influenza outbreak. Surveillance strategies include rapid diagnosis, screening, reporting, case management reporting, contact investigations, and the monitoring of trends.
- The revised International Health Regulations (IHR) require member states to notify WHO of all events which may constitute a "public health emergency of international concern".

Surveillance ++

- Helps to create accountable institutions by providing information about health and its determinants
- When results are shared with populations and policymakers in a timely and appropriate manner, they can serve as a tool for advocacy.
- Contributes to reducing inequities; the needs of populations in which suffering occurs, particularly when this suffering is unfair, unjust, and preventable, cannot be addressed if these populations are not first made visible.

World Health Organization. WHO guidelines on ethical issues in public health surveillance. June 23, 2017.

http://www.who.int/ethics/publications/public-health-surveillance/en/

Surveillance --

Surveillance can involve practices such as name-based reporting, so it can trigger profound concerns about intrusions on privacy, discrimination, and stigmatisation, particularly in the absence of public trust that names will be secured and not inadvertently disclosed, or that aggregate data will only be released in a sensitive manner.

Balancing risks and benefits
Involve local communities
Protect confidentiality (how?)
Share results with public health authorities
Identify reasons not to share data

Global health ethics

Developing guidelines for public health surveillance

Background

Surveillance is one of the most fundamental activities of public health, involving different areas andpractices such as non-communicable disease registers, outbreak investigations, and health systems research. Public health surveillance raises multiple ethical issues concerning, among others, the use/non-use of informed consent or the provision/non-provision of standards of care.

WHO's work

In 2014 WHO launched a project to develop WHO Guidelines on Ethical Issues in Public Health Surveillance, and for this purpose established an international Guideline Development Group.

Response to outbreaks: liberty infringing interventions

- Decreased Social Mixing/Increased Social Distance
- Workplace and School Closings
- International Travel and Border Controls
- Isolation, quarantine
- Mass culling of animals

Liberty infringing measures

1) The harm principle should be met: there should be clear and measurable harm to others should a disease or exposure go unchecked or untreated.
2) Proportionality or least-restrictive means principle should be observed: public health authorities should prefer the least intrusive and burdensome policy that achieves their goals as well as, or better than, possible alternatives.
3) Reciprocity should be upheld as if society asks individuals to curtail their liberties for the good of others, society has a reciprocal obligation to assist them in the discharge of their obligations.
4) No discrimination should be made among persons or groups and the transparency principle should be respected, holding that public health authorities have an obligation to communicate clearly the justification for their actions and allow for a process of appeal.

Upshur R. The Ethics of Quarantine. Virtual Mentor 2003; 5(11);

Gostin LO, Markel H. Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law, and Ethics. J Law Med Ethics 2007; 35: 616–628.

Research in emergency situations

Collaborative partnership

- Involve local communities and stakeholders in planning, conducting, and overseeing of trials
- Ensure fair benefits from the conduct or results of trials (eg, contribute to strengthening health systems, help to ensure availability of any proven treatments or vaccines)

Social value

- Ensure data are valid and robust
- Disseminate knowledge

Scientific validity

- Plan trials in view of all relevant data (eg, preclinical, compassionate use)
- Ensure that trials realise scientific objectives (eg, randomly assign participants to experimental interventions with supportive care or supportive care with placebo control)
- Ensure that trials are feasible (eg, adequate infrastructure to monitor participants and collect data)

Fair selection of study population

- Be transparent about selection criteria and ensure criteria are consistently applied
- Select study population to ensure scientific validity (eg, exclude patients with severe Ebola to reduce confounding of side-effects)
- Avoid prioritisation of well-connected and well-off individuals

Rid A, Emanuel EJ. Ethical considerations of experimental interventions in the Ebola outbreak.
Lancet 2014;384(9957):1896-9

Research in emergency situations

Favourable risk–benefit ratio

- Evaluate the risks and potential benefits to participants based on all relevant data
- Minimise risks to participants (eg, provide supportive treatment, monitor for side-effects, establish data and safety monitoring boards)

Independent review

- Ensure public accountability through ethical review or oversight
- Ensure public accountability through transparency and, as appropriate, reviews by other international and non-governmental bodies

Informed consent

- Disclose information and obtain voluntary and informed consent in culturally and linguistically appropriate formats
- Implement supplementary community and familial consent procedures if appropriate
- Ensure freedom to refuse or withdraw

Respect for recruited participants and study communities

- Monitor for and treat medical disorders (eg, side-effects and research-related injuries arising from the trial)
- Protect the confidentiality of recruited and enrolled participants
- Provide enrolled participants with relevant information in the course of the research study
- Provide compensation for research injuries
- Inform participants and the study community of the results of the research

Rid A, Emanuel EJ. Ethical considerations of experimental interventions in the Ebola outbreak. Lancet 2014;384(9957):1896-9

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Ethics of Clinical Science in a Public Health Emergency: Reflections on the Role of Research Ethics Boards

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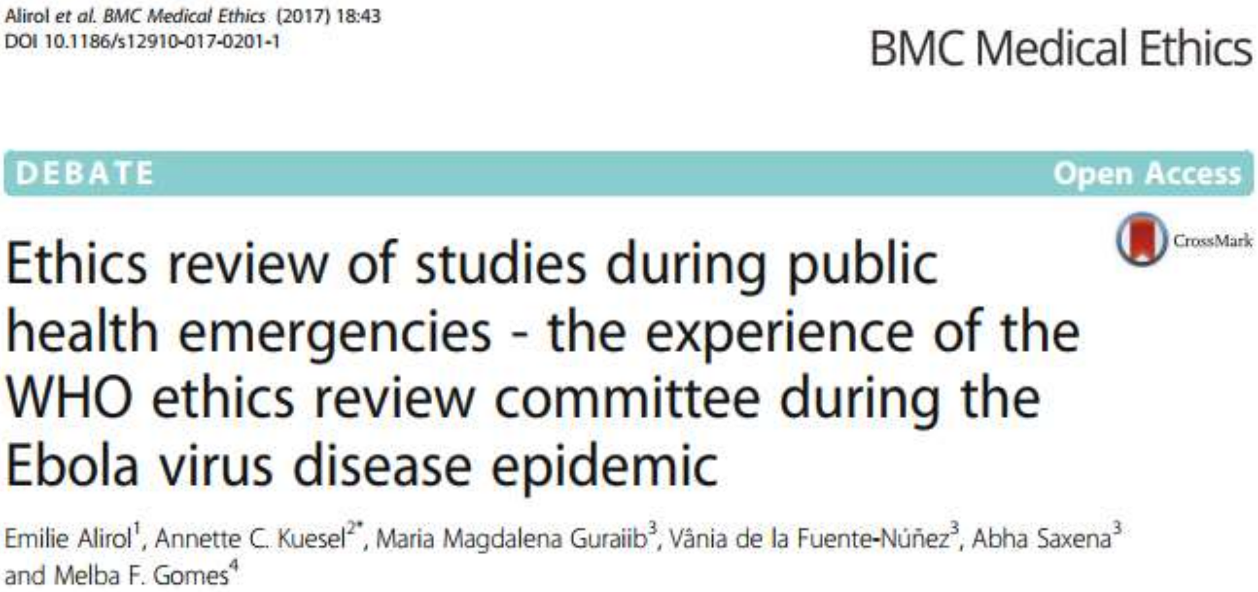
- The ethical questions raised involve groups of persons rather than single individuals.
- The response to sudden public health emergencies needs to be both effective and extremely prompt; the time required to implement most research protocols is not compatible with emergency situations
- The challenge is thus to reconcile emergency conditions with the need for research and respect for the basic ethical principles involved.

How can we ensure that RECs warrant the best protection for participants without undue waste of time?

When «expedited review» should be preferred?

Ethical review in emergency situations



Alirol *et al. BMC Medical Ethics* (2017) 18:43
DOI 10.1186/s12910-017-0201-1

BMC Medical Ethics

DEBATE

Open Access

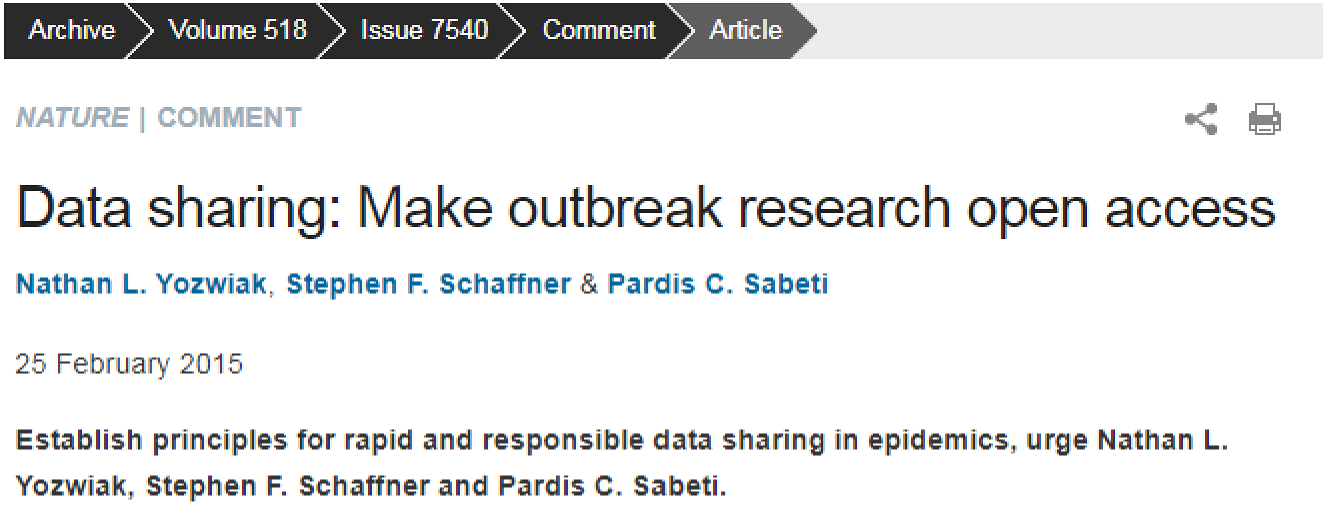
CrossMark

Ethics review of studies during public health emergencies - the experience of the WHO ethics review committee during the Ebola virus disease epidemic

Emilie Alirol[1], Annette C. Kuesel[2*], Maria Magdalena Guraiib[3], Vânia de la Fuente-Núñez[3], Abha Saxena[3] and Melba F. Gomes[4]

Conclusions: To accelerate study approval in future public health emergencies, we recommend: (1) internally consistent and complete submissions with information documents in language participants are likely to understand, (2) close collaboration between local and international researchers from research inception, (3) generation of template agreements for data and sample sharing and use during the ongoing global consultations on bio-banks, (4) formation of Joint Scientific Advisory and Data Safety Review Committees for all studies linked to a particular intervention or group of interventions, (5) formation of a Joint Ethics Review Committee with representatives of the Ethics Committees of all institutions and countries involved to strengthen reviews through the different perspectives provided without the 'opportunity costs' for time to final approval of multiple, independent reviews, (6) direct information exchange between the chairs of advisory, safety review and ethics committees, (7) more Ethics Committee support for investigators than is standard and (8) a global consultation on criteria for inclusion of pregnant women and children in interventional studies for conditions which put them at particularly high risk of mortality or other irreversible adverse outcomes under standard-of-care.

Data sharing, benefit sharing



NATURE | COMMENT

Data sharing: Make outbreak research open access

Nathan L. Yozwiak, **Stephen F. Schaffner** & **Pardis C. Sabeti**

25 February 2015

Establish principles for rapid and responsible data sharing in epidemics, urge Nathan L. Yozwiak, Stephen F. Schaffner and Pardis C. Sabeti.

Benefits of sharing

A swift and effective response to emerging infectious diseases demands that researchers have ready access to the latest data on the pathogens responsible. There is still a long way to go to ensure this.

One health, one bioethics?

More different ethics

- Enviromental ethics
- Animal ethics

in many cases, the causal connections between human, animal and environmental health will often also lead to trade-offs, where, for example, protecting animal health and welfare may have negative consequences for human quality of life, or vice versa.

Ethical Promises and Pitfalls of OneHealth

Marcel Verweij, Bernice Bovenkerk

Public Health Ethics, Volume 9, Issue 1, 1 April 2016, Pages 1–4,
https://doi.org/10.1093/phe/phw003
Published: 04 March 2016