Process of obtaining ethical approvals during epidemics

Tom Lutalo, PhD

November 24th, 2020

Outline

- Critical ethical questions during epidemics
- Some ethical considerations
- Submission requirements during epidemics
- Guidelines used during the review
- Fast-track review
- The Approval and monitoring

Some critical ethical questions in epidemics

- Who will get priority access to medications, vaccines and intensive care unit beds?
- What obligations do health-care workers have to work notwithstanding risks to their own health and the health of their families?
- How can surveillance, isolation, quarantine and social-distancing measures be undertaken in a way that respects ethical norms?
- What obligations do countries have to one another with respect to pandemic planning and response efforts?
- Are the cases due to the pandemic a vulnerable population?

Ethical considerations

- Most ethical issues related to research during epidemics are the same as those already addressed in general ethics guidelines governing biomedical research
- Ethical deliberations must take place within the context of the applicable national and international guidelines governing research involving human subjects
- Reviewers should base their decisions on the best available evidence at any given time
- There is a need to streamline the ethics review process and to establish appropriate, flexible mechanisms and procedures for ethical oversight not limited to traditional REC systems

Submission and review during epidemics

- Full Research protocol
- A Risk Management Plan (RMP)
- Evidence of collaboration between data sources
- All submitted via established channels during the epidemic
  - e-communication to REC secretariat
  - e-submission (sometimes with standard number of hard copies)
- Document research procedures as guided by epidemic specific guidelines
- e-review by REC members
- e-communication/discussion to/with PI/Study lead
- Normal submission fee structure

National Guidelines for Conduct of Research During Coronavirus Disease 2019 (COVID-19) Pandemic

Safe Drugs Save Lives

Ethical considerations during review (1)

- scrutinize competency of investigators
- scientific merit and soundness of the study design
- 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
- the inclusion of quarantined or isolated individuals and migrant populations

Ethical considerations during review (2)

- evaluation of anticipated risks and benefits
- maintenance of confidentiality and privacy of personal data and information
- safeguards for biobanks and intellectual property
- respect for autonomy and informed consent
- fair and equitable benefit-sharing and distribution
- community engagement
- declaration of conflict of interest

What's new with epidemics?

- changes in perceptions of risks, benefits and trust especially in patient-provider relationship
- need for attention to organizational values like accountability and transparency
- need for timely generation of knowledge
- there may not be sufficient time for standard ethics review processes

Flexibility

- Some protocols undergo full REC review because of significant risks to individuals or populations under study

- Majority adopt a fast-track review process (7-14 days)

  - no dropping or narrowing ethical principles
  - adjust the balance between in-person and electronic communications by REC members
  - use of pre-emergency repositories of study protocols or protocol parts which could be submitted to RECs for ethical pre-screening
  - Rolling (contemporaneous) review of protocols or parts of protocols=> prevent rigid protocols that could repeatedly be abandoned as new information emerges

  - the creation of special emergency research RECs (national/regional) or joint review committees (for scientific merit and ethical review)

  - In some cases, greater reliance on retrospective rather than prospective ethics review with safeguards (eg population surveillance measures, disease control and prevention, and program development and evaluation)

Public health practice

- Stakeholders should formulate plans to ensure that such activities receive appropriate and timely ethical review
- Review by special committees with appropriate expertise and experience to examine procedures and methods specific to a public health practice
- Training modules for research ethics committees and public health professionals should be created to support this goal

Approval and monitoring

- If there is a joint review, a re-review by REC of record follows
- e-communication of REC approval to PI and hard copy follows
- PI submits to regulatory authority/authorities
  - UNCST, NDA
- Institute Risk Management oversight team
- Institute biosafety team
- Scheduled monitoring by REC/Regulatory Authorities

References

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2. *Guidelines for defining public health research and public health non-research*. Atlanta, GA, United States Centers for Disease Control and Prevention, 1999 (http://www.cdc.gov/od/science/regs/hrpp/researchdefinition.htm)

3. Uganda National Guidelines for Research Involving Human Participants; https://www.academia.edu/35380180/Uganda_National_Guidelines_for_Research_Involving_Human_Participants

Thank you