How to ethically conduct clinical research during public health emergencies

May 21 2018, by Shilo Rea

Credit: Carnegie Mellon University

Following the 2014-2015 Ebola outbreak in West Africa, the U.S. National Academy of Sciences, Engineering and Medicine established a committee to assess the clinical trials conducted in Guinea, Sierra Leone

and Liberia. In a report entitled "Integrating Clinical Research into Epidemic Response: The Ebola Experience" the committee outlined ways to facilitate rapid, well-coordinated responses to future public health emergencies.

Carnegie Mellon University's Alex John London, a prominent bioethicist, served on the National Academies committee and has co-authored a viewpoint article in *PLOS: Neglected Tropical Diseases* on the ethics of clinical research during public health emergencies.

"The latest outbreak of Ebola in the Democratic Republic of the Congo is a tragic reminder that public health emergencies are often unpredictable, complex situations. It is critical that stakeholders recognize the lessons that we have learned from the 2014-2015 outbreak," said London, the Clara L. West Professor of Ethics and Philosophy in the Dietrich College of Humanities and Social Sciences.

The paper describes the committee's key findings and conclusions, including:

- Conducting research and clinical trials during outbreaks is necessary to determine which interventions actually advance the humanitarian mission of minimizing mortality and morbidity.
- To learn how to improve care, research must be designed to generate evidence that can support reliable inferences about safety and efficacy.
- The standard of clinical equipoise, which requires the existence of genuine uncertainty or disagreement in the expert medical community about the interventions being tested in a clinical trial, is applicable to research conducted in a public health emergency and should play a key role in determining when randomization is permissible during an emergency health situation.
- Effectively communicating reliable scientific information to

local communities, including uncertainty about the effectiveness and safety of investigational treatments, is an essential component of ethically responsible research.

- Communication and engagement strategies must be initiated early, ideally during interepidemic periods so that reliable, ethically acceptable research can be organized, reviewed and launched when the next outbreak strikes.
- Sustained coordinated international support for health systems in low- and middle-income countries is crucial. This will help mitigate concerns that frontline caregivers in these areas have over supplies and resources being directed towards research.

More information: Alex John London et al, Ethics of randomized trials in a public health emergency, *PLOS Neglected Tropical Diseases* (2018). DOI: 10.1371/journal.pntd.0006313

Provided by Carnegie Mellon University