

NEJM Perspective: 'Studying 'Secret Serums'—Toward Safe, Effective Ebola Treatments'

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Conducting clinical studies of agents to treat Ebola and allowing compassionate use of those agents are not necessarily mutually exclusive, writes Georgetown University Medical Center's (GUMC) Jesse L. Goodman, M.D., M.P.H., in a perspective piece published Wednesday in the *New England Journal of Medicine*.

In "Studying 'Secret Serums'—Toward Safe, Effective Ebola Treatments," Goodman describes the Ebola virus as "one of the world's most feared pathogens." The latest Ebola outbreak that began in West Africa in Dec. 2013 has infected more than 2,200 people and killed more than 1,200 to date, according to the World Health Organization. There are no approved treatments for the disease.

Goodman says that studies of, and access to, promising Ebola treatments can and should be expedited, but that care should also be taken to avoid harm, which could potentially derail the needed public health response.

"... the consequences of unforeseen harm, both to [patients](#) and public trust, from premature or ill-advised widespread use of an experimental therapy that proves unsafe could be substantial and jeopardize both the outbreak response and efforts to develop treatments," he writes.

Goodman advocates for the completion of basic safety studies in a small number of healthy humans before, or, for the most promising agents, at

least contemporaneously, with treating very sick, unstable Ebola patients. "If an experimental product is used first in acutely ill, unstable patients, it may be impossible to recognize even severe adverse effects such as organ failure and death if such events are commonly part of the disease itself."

Goodman notes that while controlled trials will be needed to determine which experimental medicines can truly help patients, early access may also be appropriate outside clinical trials. "When sufficient doses of an unproven but promising therapy become available, it may be reasonable to consider administering it both within [clinical trials](#) and for 'compassionate use,' particularly in places where trials cannot be conducted, provided that all patients can be adequately monitored."

Goodman also points out that it is possible that high quality supportive medical care may reduce mortality from Ebola infection, an issue that should be studied. Such care, while challenging in resource poor environments, could be brought to bear even before expensive and untried experimental medicines are likely to be available, he says.

Finally, Goodman stresses the need for building a functional public health infrastructure globally and in a sustainable way to prevent and contain outbreaks, to take care of sick patients and to perform urgently needed clinical studies. "When it comes to infectious diseases, we are increasingly one world and dependent on each other for knowledge, safety, and security," he says.

Provided by Georgetown University Medical Center

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