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Experts warn the Ebola epidemic could return with a vengeance

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Health experts have warned that a greater flexibility must be brought to medical trials to combat diseases like Ebola to avoid facing another nightmare outbreak.

The rapidity and spread of the Ebola outbreak and the urgency of a response led to many challenges not least of which was to advise those managing people on the ground of the best way to treat the illness and which treatments might be effective.

The conventional design of medical trials may have been too time consuming, and demand recruitment of too many patients for what was a very urgent situation. The experts have urged a greater flexibility be used in future.

One of the experts, Professor Sanjeev Krishna, of St George's University of London's Infection and Immunity Institute, said: "The challenges posed by the current Ebola outbreak affect all types of interventions. These include difficulties in evaluating new potential drugs, vaccines and diagnostics especially when the numbers of individuals who are infected can change quickly from day to day or week to week.

"To design really useful and informative trials that can give results to change practice in this and any future outbreaks, we suggest highly flexible, but nevertheless, powerful designs that can adapt to changing patterns of infection and mortality."

Writing in the prestigious medical journal *The Lancet Infectious Diseases*, the medical experts and academics say: "Even if somehow the present epidemic is eventually contained (over a time course that is currently uncertain), the world will still be largely unprepared for the next epidemic that could strike again at any time in an equally explosive manner."

The Ebola outbreak that has devastated parts of west Africa represents an unprecedented challenge for research and ethics. Estimates from the past three decades emphasise that the present effort to contain the epidemic in the three most affected countries (Guinea, Liberia, and Sierra Leone) has been insufficient, with more than 24 900 cases and about 10,300 deaths, as of March 25, 2015.

Faced with such an exceptional event and the urgent response it demands, the use of conventional randomised controlled trials (RCT) for Ebola-related research are considered by some to be both unethical and infeasible. Others suggest that potential interventions should be assessed in non-randomised studies on the basis of compassionate use - giving patients what doctors think might work. However, these non-randomised studies might not yield valid conclusions, leading to large residual uncertainty about how to interpret results. It can also waste scarce intervention-related resources by not answering fundamental questions about their value, making them unethical in some people's eyes.

Scientifically sound and rigorous study designs, such as adaptive RCTs, could provide the best way to reduce the time needed to develop new interventions and to obtain valid results on their efficacy and safety while preserving the application of ethical precepts. They should be included in the tool-kit against emerging infections.

More information: "Are adaptive randomised trials or non-randomised studies the best way to address the Ebola outbreak in west

Africa?" *The Lancet Infectious Diseases*. DOI: 10.1016/s1473-3099(15)70106-4