

Dear Editor,

We applaud the work of Rishu and colleagues [1] in tracking the timelines to initiation of outbreak and pandemic observational research. Through this work they highlight the challenges in being prepared with a clinical research response in the next pandemic. Pandemics are unpredictable but also recurrent. Recent experience of Ebola and Zika outbreaks highlight the devastating impact these outbreaks have on the health, economy and security of communities for generations to come.

An effective clinical research response for an outbreak relies on expedience, co-ordination, co-operation and adaptability; and compels a shift in the current paradigm of research delivery [2]. We have been encouraged by noting shifts along these lines in areas of research regulation in Europe. For example, many ethics committees in Europe now facilitate expedited review of clinical studies. These channels could be accessed in the event of an outbreak. A new regulation governing intervention studies conducted in Europe [3], effective by October 2018, makes provision for a new category of research, recognizing that not all intervention research presents the same level of risk to participants. This may facilitate comparative effectiveness research during an outbreak. New approaches to obtaining informed consent may be suited to certain kinds of pandemic research [4]

However, there remain many bottlenecks preventing the expedient setup and conduct of clinical studies during an outbreak. Many of the delays to initiation of research arise from human behavior factors: reviewing protocols, agreeing data sharing arrangements and contract agreements. While regulatory mechanisms are important and necessary to ensure integrity of research conduct, we need new ways of thinking about how to enact these protections to expedite research during a pandemic outbreak. It is essential that we are able to use the scientific advances and innovations of our time to protect populations and treat illnesses.

References

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2. Lurie, N., et al., *Research as a Part of Public Health Emergency Response*. New England Journal of Medicine, 2013. **368**(13): p. 1251-1255.
3. European Parliament and Council, *Regulation (EU) No 536/2014 of the European Parliament and of the Council* E. Union, Editor. 2014, European Union: Official Journal of the European Union.
4. Grady, C., et al., *Informed Consent*. New England Journal of Medicine, 2017. **376**(9): p. 856-867.