Crises are no excuse for lowering scientific standards, say ethicists

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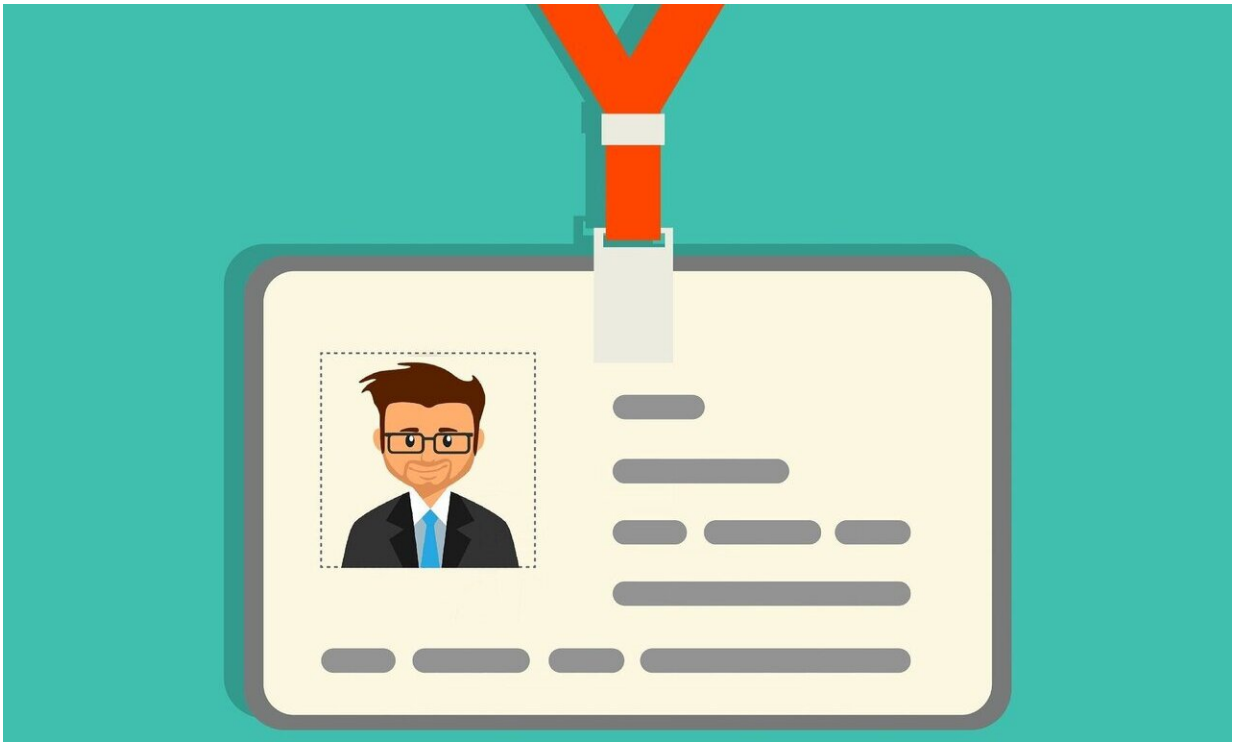

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Ethicists from Carnegie Mellon and McGill universities are calling on the global research community to resist treating the urgency of the current COVID-19 outbreak as grounds for making exceptions to rigorous research standards in pursuit of treatments and vaccines.

With hundreds of clinical studies registered on ClinicalTrials.gov, Alex John London, the Clara L. West Professor of Ethics and Philosophy and director of the Center for Ethics and Policy at Carnegie Mellon, and Jonathan Kimmelman, James McGill Professor and director of the Biomedical Ethics Unit at McGill University, caution that urgency should not be used as an excuse for lowering scientific standards. They argue that many of the deficiencies in the way medical research is conducted under normal circumstances seem to be amplified in this pandemic. Their paper, published online April 23 by the journal *Science*, provides recommendations for conducting clinical research during times of crises.

"Although crises present major logistical and practical challenges, the moral mission of research remains the same: to reduce uncertainty and enable care givers, health systems and policy makers to better address individual and public health," London and Kimmelman said.

Many of the first studies out of the gate in this pandemic have been poorly designed, not well justified, or reported in a biased manner. The deluge of studies registered in their wake threaten to duplicate efforts, concentrate resources on strategies that have received outsized media attention and increase the potential of generating false positive results purely by chance.

"All crises present exceptional situations in terms of the challenges they pose to health and welfare. But the idea that crises present an exception to the challenges of evaluating the effects drugs and vaccines is a mistake," London and Kimmelman said. "Rather than generating permission to carry out low-quality investigations, the urgency and scarcity of pandemics heighten the responsibility of key actors in the research enterprise to coordinate their activities to uphold the standards necessary to advance this mission."

The ethicists provide recommendations for multiple stakeholder groups involved in clinical trials:

- Sponsors, research consortia and health agencies should prioritize research approaches that test multiple treatments side by side. The authors argue that "master protocols" enable multiple treatments to be tested under a common statistical framework.
- Individual clinicians should avoid off-label use of unvalidated interventions that might interfere with trial recruitment and resist the urge to carry out small studies with no control groups. Instead, they should seek out opportunities to join larger, carefully orchestrated studies.
- Regulatory agencies and public health authorities should play a leading role in identifying studies that meet rigorous standards and in fostering collaboration among a sufficient number of centers to ensure adequate recruitment and timely results. Rather than making public recommendations about interventions whose clinical merits remain to be established, health authorities can point stakeholders to recruitment milestones to elevate the profile and progress of high-quality studies.

"Rigorous research practices can't eliminate all uncertainty from medicine," London and Kimmelman said, "but they can represent the most efficient way to clarify the causal relationships clinicians hope to exploit in decisions with momentous consequences for patients and health systems."

More information: A.J. London at Carnegie Mellon University in Pittsburgh, PA el al., "Against pandemic research exceptionalism," *Science* (2020). science.sciencemag.org/cgi/doi … 1126/science.abc1731

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