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CDC CLEARANCE PROCESS CONSTITUTES AN OBSTACLE TO PROGRESS IN PUBLIC HEALTH

We wholeheartedly concur with your recent Editorial, "The CDC Clearance Process: An Obstacle to Progress in Public Health." Furthermore, we admire the courage of the authors who speak so frankly about a public donor. The three of us are based at the University of Washington and entered into a cooperative agreement with the Centers for Disease Control and Prevention (CDC) in 2010 to measure the effects of the US government program for AIDS Relief (PEPFAR) on the non-HIV health system in Uganda.

The CDC prepared the protocol prior to selecting the academic partners (the University of Washington, along with our subcontractor, Makerere University in Uganda), suggesting methods were cleared in advance. Even so, the initial paper we produced, "Did PEPFAR Investments Result in Health System Strengthening? A Retrospective Longitudinal Study Measuring Non-HIV Health Service Utilization at the District Level," took in excess of a year to process through CDC clearance (September 2013 through October 2014). We estimate no fewer than 12 reviewers at CDC examined our

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paper, and rarely were the names of examiners revealed to us without extensive and repeated inquiry. It is now sitting with a journal, where additional review is taking place. Years later, we will see the results of an article that should be informing current policy. Although our CDC funding has long since expired, we nonetheless are still slogging through the clearance process on the remaining manuscripts from the project. Some potential manuscripts are likely to die of their own weight, with our African colleagues entirely discouraged about the prospects of a timely return on their work.

We concur with the recommendation to limit CDC review to a single author and would add that CDC review not extend beyond 30 days. The CDC should trust its own scientists to work in collaboration with academic scientists in a responsible manner, leaving review to scientific peers selected by journal editors.

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Contributors

All of the authors contributed equally to this letter.

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THE CDC CLEARANCE PROCESS: SUPPORTING QUALITY SCIENCE

In their recent editorial, Blank and Jemmott raise concerns about the value and efficiency of the Centers for Disease Control and Prevention (CDC) clearance review policy for scientific manuscripts, in particular as the policy applies to manuscripts led by non-CDC authors. CDC appreciates the concerns raised by the authors. CDC values the partnerships and collaborations that it has with the many non-CDC scientists with whom we work and reaffirms its commitment to its responsibility of providing timely, high-quality scientific information.

To fulfill that commitment, CDC has in place a process for review of manuscripts authored and coauthored by CDC professionals that seeks to ensure scientific rigor and accuracy, and to coordinate relevant expert input across the agency.² Additionally, CDC's review process ensures adherence to certain federal laws and policies, including the Office of Management and Budget Final Information Quality Bulletin for Peer Review, which provides directives and guidance on the appropriate use by federal agencies of disclaimers when a publication does not represent official government policy.³

The scope and breadth of CDC reviews are at the discretion of supervisors and are determined by the scope and breadth of the research, complexity of the science issues, and likely impact of scientific findings. While the extent of review and possible need for approval by multiple CDC organizational units may add to clearance times, we strive to minimize the time and number of reviewers. Over the past year, the median clearance time for manuscripts tracked in our electronic system (n=3206) has been 22 business days.

CDC believes that the intent and purposes of its clearance policy are appropriate. Nevertheless, we acknowledge that there is always room for improvement. CDC will review its current policy to ensure that it supports both the quality of scientific information that the public health community expects and timely reporting. We welcome this opportunity to explain the spirit behind our processes and be reminded that CDC's

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research is used every day in making health decisions for people across the nation and the globe. \blacksquare

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