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The Authors Respond

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To the Editor

In his thoughtful response to our article, Arnold¹ raised several important points. We agree that many community trials should define compliance at the community-level. Performing an instrumental variable (IV) analysis on an infectious disease outcome with compliance defined at the individual-level may be problematic,² as was nicely illustrated by their directed acyclic graph. In our study, aside from the consideration of meeting the IV assumptions, defining compliance at the cluster-level had biological plausibility. The water, sanitation, and hygiene (WASH) interventions were implemented at the cluster-level and each of the individuals in a cluster should theoretically have had access to those cluster-level WASH components. The transmission pathways for soil-transmitted-helminths further underscores the relevance of defining compliance at the cluster-level, as compliance to WASH reduces infective eggs across the cluster-level environment and all individuals from a given cluster are exposed to that cluster-level environment.

In complex and multi-faceted field studies, defining compliance is rarely straightforward, and we admit to a “pragmatic compliance definition.” Instead of using our equal-weight analysis, we would have preferred a definition that weighed the WASH components based on each of their individual contributions to health, where the parameters were informed by meta-analyses or the broader literature, and where interdependencies were considered between different WASH components (e.g., handwashing requires water).^{3,4} Due to a paucity of school-WASH studies in the literature, we found little empirical support to inform such complex weighting. While more complex weighting might have been better for our particular analysis, the ideal IV analysis would require a study with multiple WASH intervention arms, and then multiple instrumental variables could be employed to assess the impacts due to varying WASH combinations.

There is indeed a need for further development of compliance definitions for interventions that are multifaceted, time-varying, and/or implemented at the cluster-level. Compliance to these types of interventions is more likely to be measured across a continuous spectrum, so

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Conflicts of Interest

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compliance definitions will need to move both methodologically and linguistically beyond binary categorizations (e.g., complier vs. not). The structural nested model framework is robust and should allow for these more complex adherence definitions, but also has a different interpretation than other IV frameworks, such as the principal stratification framework. The effects we produced using structural nested models are actually different than the complier average causal effect. The complier average causal effect conditions on being a ‘complier,’ a latent principal stratum that is unobserved, and is defined as a person who would always comply with their assigned treatment regardless of the treatment assignment. The effect from a structural nested model is conditional on *observed* adherence, where the adherers (e.g., $A=1$) might also include people (or schools in our case) who were assigned to the control group but were observed to be adhering (e.g., ‘always-takers’). While structural nested models may allow for robust adherence definitions, traditionally used terms such as ‘adherence’ and ‘compliance’ must also be relaxed linguistically to allow for incremental adherence *levels* and also for ‘adherence’ by individuals who might have already been ‘adhering’ to the interventions before the study ever started.

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References

1. Arnold B. Estimating the effect of school water, sanitation, and hygiene improvements on pupil health outcomes. *Epidemiology*. 2016; 28:xxx. Re.
2. Halloran ME, Struchiner CJ. Causal inference in infectious diseases. *Epidemiology*. 1995; 6(2):142–51. [PubMed: 7742400]
3. Garn JV, Mwandawiro CS, Nikolay B, Drews-Botsch CD, Kihara JH, Brooker SJ, Simiyu EW, Okoyo C, Freeman MC. *Ascaris lumbricoides* Infection Following School-Based Deworming in Western Kenya: Assessing the Role of Pupils’ School and Home Water, Sanitation, and Hygiene Exposures. *Am J Trop Med Hyg*. 2016; 94(5):1045–54. [PubMed: 26903608]
4. Bor J. Commentary: Can’t WaSH Without Water: Instrumental Variables Evidence from a Randomized Trial. *Epidemiology*. 2016; 27(5):761–4. [PubMed: 27276026]