Seven trials, seven question marks

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Biological plausibility suggests that sanitation, the safe disposal of human excreta, might reduce the risk of infectious diseases as diverse as diarrhoea, schistosomiasis, soil-transmitted helminths, trachoma, and filariasis.[1] Until 2013, only one randomised controlled sanitation trial had been reported (into trachoma, with equivocal results).[2] As a colleague pointed out, randomised trials into improved sanitation are like London buses. One waits for ages, and then several come along at once.[3-7] The study by Amy Pickering and colleagues[8] in this issue of *The Lancet Global Health* is the sixth sanitation trial published in the past 3 years, exploring the effect of community-led total sanitation on child diarrhoea prevalence and growth in rural Mali.

A key issue in public health intervention trials is adherence to the intervention. If an intervention does not achieve a reasonable change in sanitation coverage and use then there is little point in measuring the health effects. This aspect might distinguish the Mali trial[8] from the other trials. The sanitation trial in Indonesia achieved an increase in household sanitation coverage from just 60% to 64%.[3] The trial in Maharashtra, India, explored the effect of an intervention that increased coverage from perhaps 16% to 24%, an 8% difference.[5] Similarly, access to any form of latrine increased from just 57% to 65% in the Tanzania trial.[7] A 19% increase in latrine ownership was achieved in the trial in Madya Pradesh, India (from 22% to 41%),[6] a figure that was exceeded only by the trial in Orissa (from 9% to 63%).[4] However, in the Orissa trial,[4] nearly half of the constructed latrines were not functional 1 year after the intervention ended. Furthermore, evidence shows that in all three Indian sites, use of newly constructed latrines was low and open defecation continued, largely unabated. None of the early trials showed any effect on health, except for the one in Maharashtra[5] that suggested an improvement in child growth. In view of the low sanitation coverage achieved, this finding is implausible and might have been due to chance.

Pickering and colleagues[8] report an increase in private latrine ownership from 35% to 65%, access to any latrine was improved from about 66% to 90%, and self-reported open defecation seemed to decrease to about 10%. Their intervention seems to have been well accepted by the study population,[8] even though the quality of the latrines was probably, on average, inferior to the pour-flush latrines with water seal constructed at the Indian sites.[5] Sanitation is likely to be most effective if most of a neighbourhood or village practise it.[9] At low or intermediate coverage, open defecation by remaining households could keep environmental exposure to pathogens fairly constant, even for people using a latrine. Increases in sanitation coverage from about 60% to 90% (as in Mali[8]) might therefore have a greater potential to improve a population's health than increasing sanitation coverage from about 10% to 40% (as in the Orissa[4] and Madya Pradesh[6] trials). Disappointingly, no effect on the primary study outcome, the prevalence of diarrhoea in children younger than 5 years, was noted by Pickering and colleagues in Mali.[8] Instead the intervention was associated with a reduction in stunting. As a secondary outcome, this finding cannot be readily interpreted as an intervention effect. However, it also cannot be dismissed as biologically implausible, as was the case in the Maharashtra trial.[5] Irrespective of whether the modestly funded intervention in Mali improved health, it substantially improved sanitation access and the daily life of a poor rural population with a high demand for sanitation, as evidenced by the high pre-intervention latrine coverage. Compared with, for example, distribution of vitamin A tablets, improving sanitation is a worthy goal in itself independent of health effects.[10]

By contrast, the trials in India[5,6] show that if most of the target population has no demand for sanitation then even a well-funded campaign will not succeed, and to study health effects will be pointless. The reasons for India's traditionally low demand for sanitation are complex, probably including cultural, religious, caste, and gender issues. The Indian Government's ongoing attempts to force sanitation changes by offering increasingly generous subsidies alongside modest demand creation activities have been criticised.[11] Alternative approaches have so far only shown promise on a small scale.

All seven sanitation trials[2-8] published so far might underestimate the true health effect of sanitation because they were undertaken in rural villages, whereas sanitation interventions could be more effective in

dense urban slums. Completing a trial in this setting, however, would be difficult. Additionally, the timeline to implement and assess the interventions might have been unrealistically short to achieve a health effect. Improving sanitation takes years rather than months, but there are clear ethical and logistical barriers to undertaking longer-term trials.[10] Therefore, the study by Pickering and colleagues[8] might be as good as it gets, and their results provide much needed encouragement in this important area of public health. Additional evidence would be desirable, but might not be achieved.[10]

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I declare no competing interests.

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