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Editorial

The elusive effect of water and sanitation on the global burden of disease

Wolf-Peter Schmidt

Department of Disease Control, London School of Hygiene and Tropical Medicine, London, UK

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Introduction

About 2.5 billion people lack access to improved sanitation, and 1 billion have no access to any form of sanitation (UNICEF 2013). About 780 million people lack access to an improved water source, a figure that is based on a fairly generous definition incorporating little with respect to reliability, proximity and convenience of access (UNICEF 2013).

While the ancient Romans may already have been aware of it (Bradley 2012), water and sanitation came to be regarded as key to improve health in the growing cities of Europe and America in the late 19th and early 20th centuries. A number of notable observational studies were carried out that even with the limited epidemiological tools available at the time all but proved the direct link between water, sanitation and health (Snow 1860; Pringle 1910). By contrast, in the early days of development aid in the post-colonial era, water and sanitation were often not regarded as a health issue, but primarily provided with the aim of making people's life easier and enable developmental activities. Whoever tried to argue for more investment on health grounds was faced by a lack of epidemiological studies conducted in low-income settings, which led to a renewed interest in research from the 1970s.

Simple before/after and case-control studies to evaluate water and sanitation programmes

The studies on water and sanitation conducted in low-income settings since the 1970s were usually simple in design (Rubenstein *et al.* 1969; Aziz *et al.* 1990; Zhang *et al.* 2000, 2005; Azurin & Alvero 2007). Typically, a programme to improve water access would be implemented in one or two villages, with latrine construction and some form of hygiene education being provided at the same time. Disease (for example diarrhoea, schistosomiasis or soil-transmitted helminths) would be measured at baseline and then again after the intervention. A couple of not too distant villages with 'similar socio-economic conditions' would have been followed up as a control group. Allocation of the intervention was unlikely to be random. Villages might have received the intervention because they had many diseases or were the poorest in the region. They might have been chosen for having been the least or the most accessible, the politically most influential or the most neglected. The commonly small number of allocated villages enabled a close supervision of the intervention, assuring that everything was carried out according to plan. However, the within-village ('-cluster') correlation of disease meant that statistically not much could be made of any difference between intervention and control arm if there were <5 or 6 villages on either side. Accounting for the baseline levels of disease allowed strengthening the causal inference (Norman & Schmidt 2011), but only to some extent. Larger, randomised studies were deemed unfeasible given the logistical and engineering complexities involved, and the low budgets available at the time.

Given these constraints, case-control studies came to be seen as the most cost-effective way to evaluate the health impact of water and sanitation (Briscoe *et al.* 1985). If well done, case-control studies can be logistically efficient and as valid as cohort studies. The problem for the investigator lies in proving that his particular case-control study was carried out well, that is, that cases were adequately defined, the control group was sampled from the same source population as the cases, and confounding was adequately accounted for (i.e. no major confounders were left out or imprecisely measured).

Several case-control studies on water and sanitation came up with plausible results, suggesting reductions in diarrhoea by about 20–30% following an intervention, for example, (Daniels *et al.* 1990). Still, the studies usually fail to meet the inclusion criteria of systematic reviews, for example those following Cochrane guidelines, where for good reason, observational studies are viewed with suspicion, especially when included in meta-analyses.

Randomised controlled trials – adding to the uncertainty

In contrast to water supply and sanitation interventions, it is relatively straightforward to conduct large randomised controlled trials for hand washing and household ('point-of-use') water treatment (for example householders using a water filter or adding chlorine to their drinking water). These are interventions that can be delivered to and randomised at the level of single households, and do not require construction of hardware such as water pipes, sewerage or latrines. Many of them have attracted the interest of the commercial sector such as soap manufacturers or producers of water treatment devices, which has brought with it much research funding for this area.

A large number of randomised trials were conducted – often with spectacular results, suggesting a 30–50% reduction in self-reported diarrhoea (Curtis & Cairncross 2003; Clasen *et al.* 2007; Ejemot *et al.* 2008). One study from Pakistan found that childhood pneumonia diagnosed by non-clinical staff was reduced by 50% if people washed their hands (Luby *et al.* 2005). One study found that hand washing or household water treatment alone is as effective as combined water and hygiene interventions (Luby *et al.* 2006). The results of these studies attracted great interest, propelling, for example, hand washing promotion to the top of the list of single most cost-effective interventions to improve health in low-income settings (Laxminarayan *et al.* 2006). Consortia were established to promote hand washing and household water treatment at large scale, such as the Private Public Partnership for Handwashing (Curtis *et al.* 2005) or the WHO's network for household water treatment (WHO 2013). Hand washing and household water treatment, two seemingly simple health behaviours, came to be regarded as the best answer to diarrhoeal diseases since the widespread adoption of oral rehydration. To some extent, hand washing and household water treatment received attention because it was relatively easy to conduct randomised controlled trials. Water access and sanitation, being much more fundamental interventions that are likely to be associated with a whole range of health and developmental benefits, looked rather old school by comparison: 'We used to drill wells in the 70s but now we enable households to take health into their own hands!' By focussing on hygiene and household water treatment, donors expected to obtain results quickly, and more cheaply than by supporting complicated engineering projects, involving drilling and engaging with governments.

The trials giving rise to such hopes had one problem that became increasingly difficult to ignore: almost all of them were unblinded and used self- or carer-reported diarrhoea as primary outcome measure. There is usually little bias in a trial using an unblinded intervention if the outcome is objective (Savovic *et al.* 2012). It is also acceptable that a trial uses a subjective outcome if treatment allocation is effectively blinded. It is the combination of lack of blinding and use of a subjective outcome such as self-reported diarrhoea that causes bias. Hand washing cannot be blinded, but interestingly, several household-level chlorination trials were conducted that did use self-reported diarrhoea as primary outcome, but were adequately blinded. These trials did not show a 50% reduction in diarrhoea: they showed no reduction in diarrhoea at all (Schmidt & Cairncross 2009). And there were other signs that the unblinded trials were severely biased: a household water treatment trial in Colombia demonstrated a 25% reduction in diarrhoea despite only 30% of the trial population using the product (Reller *et al.* 2003). A trial in Ethiopia testing a personal portable filter found a similar diarrhoea reduction despite good evidence that virtually the whole study population had long given up touching the device (The author tried it – it is unusable) (Boisson *et al.* 2009). Bias could explain even the largest observed impacts on disease in studies that were neither blinded nor used a reasonably objective primary outcome.

By moving from case-control studies to the seemingly more rigorous randomised control trial as the preferred study design, researchers in the field may have produced effect estimates that were 'all an illusion' (Schmidt *et al.* 2009). The former were prone to selection bias and confounding; the latter subject to observer and responder bias. The act of randomisation after informed consent when carried out at the household level almost precludes an unbiased response in symptom-based questionnaire surveys – the standard method of assessment. It seems that the severity of responder and observer bias in unblinded trials outweighed even the risk of confounding and selection bias in observational designs.

Trials are almost impossible in settings where they are most needed

In recent years, the interest in public health in low-income settings gained momentum, partially fuelled by the Millennium Development Goals. More public and private funds for research became available. Governments of low-income and donor countries and many funding organisations accepted the principle that water and sanitation are necessary cornerstones for public health. Yet they demanded evidence as to the magnitude of this effect and in particular the relative cost-effectiveness of investing in particular interventions. Unlike in previous decades, village-level cluster-randomised trials on a large scale became financially possible. Of note, funders and researchers alike avoided sanitation trials in urban areas, where the impact on disease and well-being is likely to be greatest, as the logistical and engineering constraints of cluster randomisation in cities were deemed insurmountable. Likewise, there were no serious attempts to conduct large cluster-randomised trials on improved water access in rural mountainous or dry areas where water access is likely to be most beneficial. It was perhaps assumed that villagers and local politicians may not agree to any delay in receiving water access just for the sake of science – everyone wants water now. Further, the challenges of laying pipes or drilling bore holes in difficult or dry terrain proved little amenable to randomisation.

The sanitation trials ended up being carried out in rural settings, usually within ongoing large-scale programmes such as the Total Sanitation Campaign in India. Again most trials used self-reported diarrhoea as primary outcome, but village-level randomisation (with household consent restricted to health surveillance, not intervention delivery) offered the opportunity to make health surveillance visits appear unconnected to the intervention, reducing the potential for bias. Indeed, bias turned out not to be the driving methodological problem – the problem was time.

The perceived sanitation needs in many rural low-income populations are driven by convenience, traditions and culture. A farmer may perceive defecating in the open on the way to his field as convenient and refreshing compared with a claustrophobic and smelly latrine. For a newly married daughter-in-law, going to the fields may be the only opportunity in the day to get out of the house and meet friends. A bad latrine design may easily lead householders to perceive a latrine as a source of infection rather than a way to prevent it. These are not just deeply held beliefs and superstitions that hinder the progress of mankind: in many rural settings, they make perfect sense. Nevertheless, people are willing to give up open defecation if they can get access to an attractive looking, solid latrine that is easy to clean, does not smell and comes at an affordable price (Watershed/USAID 2004; Jenkins & Curtis 2005). To establish a sanitation market offering good products and to persuade people that a latrine can make their life easier, cleaner and healthier, or even be a sign of social status, requires time – time that researchers conducting an RCT do not have.

For example, a recent trial from Indonesia reported that 16% of intervention group households had built a latrine over the 2-year trial implementation period, compared with 13% in the control group, a difference the authors somewhat optimistically described as a 30% increase in the rate of toilet construction (Cameron *et al.* 2013). A large World Bank funded trial in rural Maharashtra, India, achieved a bare 8% difference in latrine coverage between intervention and control villages (Hammer & Spears 2013). Why this trial found a substantial increase in height-for-age (an outcome that is slow to change) at 18 months remains unclear. Before considering 'sanitation externalities and children's human capital', one may want to look at data quality. A good sanitation marketing campaign may require 5–10 years to achieve a marked increase in latrine coverage with the potential to impact on health. It would be hard to design an RCT where a control group would be deprived of access to sanitation for such a long period of time.

The 'best available evidence'

Given the severe constraints in implementing water and sanitation trials, especially in settings where they would be most informative, it seems unlikely that we will get useful health impact estimates in the near future. The feasibility of trials alone can bias public health decision-making. The predominance of drug therapy in contemporary medicine is likely in part a consequence of the relative ease of obtaining hard evidence from double-blind drug trials, as opposed to methodologically inferior evidence for other potentially important treatments such as physiotherapy.

It is often said that in the absence of evidence from randomised trials, we need to go with the 'best available evidence'. As there is no evidence from trials or cohort studies on the effect of sanitation on *mortality*, various authors have used ecological analyses as the next best option, for example by comparing state-level mortality and sanitation coverage across different states of India (Boone 2005), making use of national census data and population-based health surveys. For example, a multi-country comparison found that almost all variation in child mortality is due to health care, mothers' child care knowledge and treatment-seeking behaviour, and none due to water and sanitation (Boone & Zhan 2006). By contrast, two studies using similar data found that sanitation 'can statistically explain a large fraction of international height differences' (Spears 2013) and that – within India – changes in sanitation coverage explain a substantial proportion of between district differences in child mortality (Spears 2012). India may be colourful but that is nothing compared with econometric analysis. While applying the 'best available evidence' may not always lead to military invasions in search of a smoking gun, the consequences in the field of public health can be dire, too.

It is difficult to escape the conclusion that the literature on the impact of water, sanitation and hygiene is unreliable in its entirety, and in any case, it only represents results from those trials and studies that are feasible – they would not be there, otherwise. Meta-analyses do little but average biased estimates. Conducting a meta-analysis without being able to include urban sanitation trials and rural water access trials is a bit like reviewing the effect of insecticide-treated bed nets on malaria based on studies from Norway.

The Global Burden of Disease Study – the ultimate number game

No evidence may be better than bad evidence. However, influential studies such as the Global Burden of Disease study (GBD) cannot do without data. A recent publication of the GBD including a comparative risk assessment of burden of disease and injury attributable to various risk factors suggested that inadequate access to water and sanitation accounts for only 0.9% of the global burden of disease (Lim *et al.* 2012). To some extent, this figure reflects how the world has changed since the 1990s when water and sanitation were believed to account for about 6.8% of the global burden of disease. Globally, child mortality has come down, and life expectancy has increased with non-communicable disease becoming more dominant. The estimated number of deaths in children under five attributable to diarrhoea has fallen from more than 2 million in the 1990s to perhaps 700 000 per year (Walker *et al.* 2013). Focussing largely on diarrhoea (Engell & Lim 2013), the recent GBD estimates that the number of disability adjusted life years lost due to inadequate access to water and sanitation has more than halved since 1990, from 52 to 21 million, as has the number of deaths (from 716 000 to 337 000).

Still, there are reasons to question the figures. The relative contribution of a single risk factor to the global burden of disease depends on many factors such as (i) the relative risk between exposed and unexposed groups, (ii) the definition of what 'exposed' and 'unexposed' means, (iii) the size of the exposed population, and (iv) the number and effects of competing risk factors included in the assessment. As shown above, the relative risk of the poor access to water and sanitation is uncertain, especially in settings where they matter most. Perhaps, the most arbitrary decision to be made, however, concerns defining the 'unexposed' control group. The GBD defines it largely based on the criteria of the Joint Monitoring Programme (JMP) (WHO 2014) that aim to measure the progress of the Millennium Development Goals, pragmatically categorising water and sanitation access as either 'improved' or 'unimproved'. The JMP definition of 'improved access' was never meant to constitute a 'gold standard' or a 'theoretical-minimum-risk exposure' (Lim *et al.* 2012) that ideally everyone should have. A water source may be defined as improved if it takes a 30-min uphill walk to collect the water at a source that only works 4 days per week. A smelly pit latrine that each day produces 2000 culicine mosquitoes able to transmit filariasis (Maxwell *et al.* 1990) may be defined as improved. By contrast, the control group for high blood pressure (the globally leading risk factor) was defined as 110–115 mmHg systolic, a range at the low end assumed to be associated with the lowest risk of all possible values. The equivalent control group for water access would probably be 'a tap in the house that provides safe water 24 h a day, every day', and for sanitation, a 'household and all its neighbours having access to a private flush latrine connected to a sewer or septic tank'. Choosing more stringent criteria for the control group obviously results in higher relative risks. Further, the definition of 'exposed to poor access to water and sanitation' impacts on the estimated size of the globally exposed population. A generous definition of improved water access that ignores reliability and distance inevitably reduces exposure prevalence. Finally, the competing risk factors included in the GBD merit attention. The large number of cardio-vascular risk factors included in the GBD not only reflects the widespread occurrence of cardio-vascular disease, but also the widespread occurrence of cardio-vascular disease research, where epidemiologists go fishing with a large net (Beaglehole & Magnus 2002; Ioannidis 2007). Water and sanitation may affect many different conditions such as diarrhoea, soil-transmitted helminths, schistosomiasis, respiratory infection, trachoma, lymphatic filariasis, urinary tract infection and back pain (Hunter *et al.* 2010; Mara *et al.* 2010), many of which are not accounted for by the GBD. By reducing the overall pathogen load in the environment (possibly a key factor for diarrhoea in poor settings (Taniuchi *et al.* 2013)), better water and sanitation access may improve gut function, immunity and nutritional status (Humphrey 2009; Ryan 2013). However, little research has been carried out on causal pathways through which water and sanitation may impact on health, a challenge even with a large research budget. In addition, by contributing to education and socio-economic development (Black & Fawcett 2008), water and sanitation (unlike blood pressure drugs) are likely to produce long term, indirect health effects, which will be almost impossible to quantify.

Investing in water and sanitation despite lack of evidence

Even if there was no health impact, the educational, developmental and gender-related benefits of water and sanitation access are large enough to merit investment. The World Bank, in a moment of institutional wisdom during the 1980s, declared that investments in water and sanitation could be economically justified on the basis of time savings alone (Churchill *et al.* 1987). However, the lack of reliable health impact data remains an obstacle in the health policy arena. New research methods including microbial source tracking and molecular methods may in the future shed more light on gastro-intestinal transmission pathways and the role of water and sanitation (Jenkins *et al.* 2009; Taniuchi *et al.* 2013). For now, accepting the often fatal methodological flaws in quantifying health effects of water and sanitation may be an intellectual challenge, but perhaps a necessary step. We may at some point be forced to get out for a bit and walk through an urban slum during the wet season. The lack of high-quality trials on urban sanitation or rural water access should not stop us from opening our eyes – the oldest form of impact assessment. This may sound fantastical, but perhaps, only to the ears of a 21st century academic. There are scientifically plausible and less plausible beliefs. To say that homoeopathy can cure the tubercular *miasm* inherited from one's grandfather may sound esoteric to some. It is not esoteric to believe that water and sanitation are upstream interventions, likely to have a broad impact on well-being and health (Hunter *et al.* 2010; Mara *et al.* 2010). Whether we like it or not, it could be that beliefs, not randomised controlled trials, will determine whether children in slums will continue to wade through open sewage, and whether school-aged girls in the hills will continue to spend most of their mornings fetching water.

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Corresponding Author Wolf-Peter Schmidt, Department of Disease Control, Faculty of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, Keppel St, London WC1E 7HT, UK. Tel.: +44-20-7636 8636, E-mail: Wolf-Peter.Schmidt@lshtm.ac.uk

