WATER RESEARCH 47 (2013) 1181–1190

Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.elsevier.com/locate/watres

The joint effects of efficacy and compliance: A study of household water treatment effectiveness against childhood diarrhea

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ARTICLE INFO

Article history:
Received 16 May 2012
Received in revised form
26 October 2012
Accepted 21 November 2012
Available online 19 December 2012

Keywords:
Simulation model
Household water treatment
Diarrhea
Developing countries
Compliance
Adherence
Risk assessment

ABSTRACT

The effectiveness of household water treatment (HWT) at reducing diarrheal disease is related to the efficacy of the HWT method at removing pathogens, how people comply with HWT, and the relative contributions of other pathogen exposure routes. We define compliance with HWT as the proportion of drinking water treated by a community. Although many HWT methods are efficacious at removing or inactivating pathogens, their effectiveness within actual communities is decreased by imperfect compliance. However, the quantitative relationship between compliance and effectiveness is poorly understood. To assess the effectiveness of HWT on childhood diarrhea incidence via drinking water for three pathogen types (bacterial, viral, and protozoan), we developed a quantitative microbial risk assessment (QMRA) model. We examined the relationship between $\log_{10}$ removal values (LRVs) and compliance with HWT for scenarios varying by: baseline incidence of diarrhea; etiologic fraction of diarrhea by pathogen type; pattern of compliance within a community; and size of contamination spikes in source water. Benefits from increasing LRVs strongly depend on compliance. For perfect compliance, diarrheal incidence decreases as LRVs increase. However, if compliance is incomplete, there are diminishing returns from increasing LRVs in most of the scenarios we considered. Higher LRVs are more beneficial if: contamination spikes are large; contamination levels are generally high; or some people comply perfectly. The effectiveness of HWT interventions at the community level may be limited by imperfect compliance, such that the benefits of high LRVs are not realized. Compliance with HWT should be carefully measured during HWT field studies and HWT dissemination programs. Studies of pathogen concentrations in a variety of developing-country source waters are also needed. Guidelines are needed for measuring and promoting compliance with HWT.

1. Introduction

An effective intervention can be defined as one that reduces disease (i.e., is efficacious) and one that people use (i.e., they comply). For example, a drug or vaccine must be protective and people must take the drug or receive the vaccine; contaminated water must be correctly treated and people must drink the treated water. Both efficacy and compliance

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0043-1354/$ – see front matter
http://dx.doi.org/10.1016/j.watres.2012.11.034

must be evaluated when assessing the ability of an intervention to reduce illness; both are dynamic factors that can vary over time. Household water treatment (HWT) interventions are an interesting example that illustrates these two factors, where pathogen removal characterizes efficacy and behavior characterizes compliance. In this manuscript we examine the joint effects of 1) pathogen removal by a HWT device, and 2) the degree to which communities use the device. We focus on the protective effects of HWT against childhood diarrhea in developing countries, a leading cause of morbidity and mortality (Kosek et al., 2003).

Household water treatment (HWT) is a common strategy for reducing diarrhea in developing countries. HWT technologies most often used include chlorination, filtration, solar disinfection (SODIS), and boiling. Systematic reviews of field trials suggest that HWT is generally effective in preventing some diarrhea (Arnold and Colford, 2007; Clasen et al., 2009). However, lack of blinding and publication bias are important issues in the HWT literature that may exaggerate effectiveness (Hunter, 2009; Schmidt and Cairncross, 2009; Waddington et al., 2009).

Antimicrobial effectiveness of HWT is commonly measured by $\log_{10}$ reduction values (LRVs) from laboratory testing. Such tests use indicator organisms to represent the three main classes of waterborne pathogens: viruses, bacteria, and protozoan cysts. LRVs are a common metric for assessing different HWT methods (Sobsey et al., 2008; Sobsey and Brown, 2011). The United States standard for HWT "microbiological water purifiers" is LRVs of 6 for bacteria (99.9999% inactivation or removal), 4 for viruses, and 3 for protozoa (USEPA, 1987). The World Health Organization (WHO) recommends that "highly protective" devices have LRVs of 4 for bacteria, 5 for viruses, and 4 for protozoa (Sobsey and Brown, 2011). The WHO recommendations come from a quantitative microbial risk assessment (QMRA) assuming perfect compliance and an acceptable risk level of 10^{-6} disability-adjusted life-years (DALYs) for diarrheal disease from each pathogen type (Sobsey and Brown, 2011).

In contrast, compliance, the extent to which persons (or a population) use a HWT method, is often poorly defined and poorly measured. Compliance (sometimes referred to as adherence) has many dimensions. Individuals might reject a HWT method because of cost, difficulty using HWT, or taste of treated water. Well-established theory regarding adoption of new technologies indicates that 10%–20% of a community will not use the new technology, even after acceptance by most of the community (Rogers, 2003). Furthermore, preventive practices (such as HWT) have difficulty spreading because the benefit (e.g., cases of diarrhea averted) is a 'non-event'; therefore, the benefit gained is not obvious to the user (Rogers, 2003). HWT devices might simultaneously be used frequently and inconsistently. For example, someone might drink treated water at home, but untreated water while working. During a HWT field trial in rural Congo, nearly all households sometimes drank untreated water (Boisson et al., 2010).

Although the variable and incomplete nature of compliance is widely recognized, it is mostly unmeasured or incompletely measured by field trials. A review of 30 field trials of water quality interventions found that 7 did not report compliance, and 9 measured compliance by "occasional observation" only (Clasen et al., 2009). Furthermore, consumption of treated water was never directly measured (Clasen et al., 2009). Studies that report compliance find that communities rarely use HWT devices 100% of the time. For example, a meta-analysis of HWT chlorination studies indicated a median of 78% of samples having detectable free chlorine (range 36–100% over 12 studies) (Arnold and Colford, 2007).

Compliance is difficult to measure and is subject to various biases. Participants might be more likely to comply by virtue of knowing that they are part of a study (Hawthorne effect) (McCarney et al., 2007). Participants in a study might also report that they use an intervention more frequently than they actually do (Dharod et al., 2007). Compliance might increase during a trial because study personnel remind people to use HWT (deliberately or not). Field trials over longer periods show lower HWT effectiveness against diarrhea; decreasing compliance over time is one explanation (Hunter, 2009). It is particularly difficult to determine the amount of untreated water that HWT users consume outside the home.

Despite not being well measured, compliance clearly influences the ability of HWT to prevent diarrhea, because HWT can only be effective if people use it (Duflo et al., 2007). Field measurements of LRVs tend to be lower than laboratory-measured LRVs for many reasons, such as differing water quality or suboptimal maintenance of HWT devices (Sobsey et al., 2008). Nonetheless, the benefits from HWT might be eroded by slight noncompliance. For example, a risk assessment of diarrheal infection from intermittent treatment by a Ugandan water treatment plant estimated that water treatment failure for 1 day per year increased the annual probability of enterotoxigenic *Escherichia coli* (ETEC) infection via drinking water from 0.001 to 0.1 (Hunter, 2009).

The relationship between compliance and LRVs (which measure efficacy) can be illustrated with a simple mathematical example:

$$d = u(1-c) + uc10^{-L} \quad (1)$$

where d is the dose of pathogens consumed, u is pathogens per liter of untreated water, c is compliance (the proportion of drinking water treated), and L is the LRV of the HWT method. Assuming that source water contains 10,000 pathogens per liter, 5 LRVs of pathogens are inactivated, and 1% of drinking water is untreated, then 100 pathogens are ingested for each liter of water ingested. For LRVs of 4, 3, 2, and 1, the numbers of pathogens consumed are, respectively: 101, 110, 199, and 1090. The dose (and therefore the infection risk) is very similar for LRVs of 3 or higher, and the largest incremental benefit is from LRVs of 1 and 2; we therefore hypothesize that incomplete compliance results in marginal reductions in diarrheal disease as LRVs increase. If this hypothesis is true, then the current WHO recommendations for LRVs from HWT must be considered in the context of compliance. In this manuscript we test this hypothesis in more detail, using a quantitative microbial risk assessment (QMRA) model to examine the joint effects between device efficacy (measured by LRVs) and compliance (measured by how often the device is used). In doing so, we provide a more complete framework for evaluating the effectiveness of HWT interventions.