

## Estimates of endemic waterborne risks from community-intervention studies

Rebecca L. Calderon and Gunther F. Craun

### ABSTRACT

The nature and magnitude of endemic waterborne disease are not well characterized in the United States. Epidemiologic studies of various designs can provide an estimate of the waterborne attributable risk along with other types of information. Community drinking water systems frequently improve their operations and may change drinking water treatment and their major source of water. In the United States, many of these treatment changes are the result of regulations promulgated under the Safe Drinking Water Act. A community-intervention study design takes advantage of these "natural" experiments to assess changes in health risks. In this paper, we review the community-intervention studies that have assessed changes in waterborne gastroenteritis risks among immunocompetent populations in industrialized countries. Published results are available from two studies in Australia, one study in the United Kingdom, and one study in the United States. Preliminary results from two other US studies are also available. Although the current information is limited, the risks reported in these community-intervention studies can help inform the national estimate of endemic waterborne gastroenteritis. Information is provided about endemic waterborne risks for unfiltered surface water sources and a groundwater under the influence of surface water. Community-intervention studies with recommended study modifications should be conducted to better estimate the benefits associated with improved drinking water treatment.

**Key words** | community-intervention studies, drinking water, epidemiology, gastrointestinal disease, groundwater, microbes, surface water, waterborne disease, water filtration

### INTRODUCTION

This paper examines the available data from community-intervention studies to help develop a national estimate of waterborne disease risk in the United States. The general study design is discussed, and relevant, published studies of community drinking water interventions are reviewed. We discuss the specifics of each study, the principal results, and how data from these studies can quantitatively or qualitatively contribute to a national estimate of endemic water-

borne disease in the United States. Also described are two unpublished studies along with preliminary results provided by the investigators. Finally, we discuss the strengths and limitations of community-intervention studies and make recommendations for future research.

### THE CONCEPT: COMMUNITY-INTERVENTION STUDIES

Epidemiologic studies are usually classified as either observational or experimental. Community-intervention studies

**Rebecca L. Calderon** (corresponding author)  
US Environmental Protection Agency,  
MD-58a, Research Triangle Park,  
NC 27711,  
USA  
E-mail: [Calderon.rebecca@epa.gov](mailto:Calderon.rebecca@epa.gov)

**Gunther F. Craun**  
Gunther F. Craun & Associates,  
101 West Frederick Street  
Staunton, VA 24401,  
USA

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are considered quasi-experimental because they contain elements of both types of studies (Craun *et al.* 2006a). In observational studies, the conditions of the study and exposures are not controlled by the investigator. Through the ascertainment of disease and exposures in a population, either prospectively or retrospectively, associations between risk factors or exposures and the health effect of interest are evaluated. The results of several types of observational studies of endemic waterborne risks are described in this special issue (Craun & Calderon 2006). Observational study designs are also useful in the investigation of outbreaks and can help determine if the water was the cause of the outbreak. Outbreaks of waterborne disease in the United States are described by Craun *et al.* (2006b).

The experimental study can be conducted at the individual (e.g. clinical trials) or population level. Experimental studies involving the controlled exposure of individuals to known quantities of organisms have been conducted to determine dose–response information for a specific organism (Dupont *et al.* 1995). These results can be used as part of a microbial risk assessment for waterborne risks (Soller 2006). Randomized household-intervention studies at the population level are discussed and reviewed by Colford *et al.* (2006).

In community-intervention studies, the study parameters are not completely controlled by the investigator as they are in experimental studies. The investigators take advantage of natural experiments, incorporating basic design elements of observational studies. Water system interventions occur as the result of sociopolitical decisions or large scale environmental changes. Examples of opportunities for studying the contribution of microbial water contaminants to illness risks include changes made by water utilities in their source water, changes in disinfection practices, or addition of filtration usually as the result of drinking water regulation. Community-intervention studies employ a research design that has been used in a limited fashion in the last twenty years. The goal of these studies is to evaluate differences in illness rates before and after the intervention (e.g. change in water treatment). Similar to household-intervention trials, community-intervention studies estimate the number of cases of illness, if any, that were prevented as a result of the community intervention. The incidence of illness observed prior to the intervention or treatment change is compared to

the incidence after the intervention, and the attributable risk (AR) is computed. If the prior incidence is higher, the risk is reduced; the relative risk and population attributable risk would be less than unity indicating a benefit (Craun *et al.* 2006a). Since the outcome of interest is the benefit associated with the intervention, this measure can also be called the attributable benefit (Last 1995).

When designing an epidemiologic study of endemic waterborne risks, several important concerns must be addressed. Endemic gastrointestinal illnesses are rarely seen by the medical community in the United States. Since the majority of gastrointestinal illnesses are not confirmed through the medical care system, other methods of illness detection must be developed. In assessing the drinking water risks, investigators must also study other risk factors and exposures including food, person-to-person transmission, contact with animals, foreign travel and recreational water contact. These exposures may present greater risks for gastrointestinal illness than drinking water exposures. Relatively large populations may be required in observational studies to obtain sufficient statistical power to detect an association between endemic gastrointestinal illness and waterborne exposures, and observational studies may not be economically or technically feasible to assess small risks, especially when it is difficult to ascertain gradients in exposures to microorganisms in drinking water. Although water quality will vary seasonally and the effectiveness of treatment is affected by operational practices, it is anticipated that waterborne microbial events will be low-level and sporadic. Ideally, sufficient waterborne exposure gradients to conduct a study can be obtained through changes in water sources or water treatment. Dramatic changes in waterborne microbial exposures may occur when water sources are changed or treatment is added (Craun 1988). Such an improvement in the microbial quality of drinking water should increase the probability that a community-intervention study will be able to detect a change in endemic illness, if one occurs.

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## REVIEW OF COMMUNITY-INTERVENTION STUDIES

Our review focuses on studies conducted in countries with a relatively high quality water supply and municipal water

treatment. Studies in developing countries are not directly relevant to a national estimate of waterborne disease in the United States and are not included in this review. However, a recent review of intervention studies in less developed countries is of interest (Fewtrell *et al.* 2005). Fewtrell *et al.* describe interventions that significantly reduced the risks of diarrheal illness. Water quality interventions were found to be more effective than previously thought, and multiple interventions (e.g. improved drinking water and sewage disposal) were no more effective than interventions with a single focus.

The review is divided into studies conducted or sponsored by the US Environmental Protection Agency (EPA) and studies conducted by investigators in other countries in the last ten years. Six studies were reviewed (Table 1). The studies evaluated acute gastroenteritis illness (AGI) risks presumably related to microorganisms, but the illness definitions differed among the studies. Studies in the United States considered self-reported gastroenteritis. In Australia, one study considered the number of requests for analysis of gastroenteritis-related fecal specimens as an indicator of AGI; the other study considered hospital and emergency room visits for gastroenteritis. In North West England, the health effect of interest was laboratory-confirmed, symptomatic cryptosporidiosis. In all of the studies, the risk was assessed for the general population, and no studies specifically evaluated sensitive subpopulations (e.g. immunocompromised).

### Studies in the United States

As a means to evaluate the role of microbes in drinking water, EPA's Office of Research and Development initiated a program of identifying communities affected by the 1989 Surface Water Treatment Rule (SWTR) (USEPA 1989). The SWTR (published 29 June 1989 and effective 31 December 1990) requires that water systems filter and disinfect water from surface water sources to reduce the occurrence of unsafe levels of microbes. Potential study communities were identified by reviewing and verifying existing information about communities that were planning to meet the requirements of the SWTR by adding water filtration. Candidate communities were evaluated by water quality data, proposed construction schedules, and demographic

information. Three communities were identified through this process, and studies were conducted when water treatment changes were scheduled.

The general approach to collecting illness information about waterborne AGI is the diary method. Study participants keep contemporaneous records of symptoms and illness events, and investigators maintain frequent contact to ensure diaries are maintained. The diary method used for all three US studies was similar to that used in the Canadian household-intervention drinking water studies (Payment *et al.* 1991, 1996) and in a US recreational water health study (Calderon *et al.* 1991). A similar diary method was also used by Colford *et al.* (2002; 2005a, b).

### Community 1 (Calderon 2001)

In June of 1996, EPA began an epidemiologic study in Massachusetts to assess improvements in the quality of health that might be associated with water filtration. The water supply was a series of three connected reservoirs with relatively few point sources of sewage contamination. There was significant agriculture on the watershed including a commercial buffalo farm. Source water samples were negative for *Cryptosporidium* and *Giardia*. Water treatment changed from chlorination-only to a facility that used ozone, granular filtration, and chlorination. Although this was initially to be a pilot study, sufficient information was collected about water quality and health to assess waterborne gastroenteritis risks.

Recruited families were asked to provide information about AGI by recording symptoms of illness in their diaries each day. An additional questionnaire was used to collect information about other potential sources of microbial exposures such as food, recreational water, animals, children in diapers, contact with other sick people, travel and other recreational activities (e.g. camping, hiking). Recruited families were followed for nine months (July 1996–March 1997) before filtration began. After filtration and an interval of three months, families were followed again in the same-season months (July–December 1997). A total of 1191 individuals, comprising 316 families, were enrolled into the before phase. For the after phase enrollment a total of 910 individuals in 254 families were enrolled.

The key endpoint of interest was credible gastrointestinal illness (CGI) defined as nausea and abdominal cramps;

**Table 1** | Summary of study designs

	<b>Calderon (2001)</b>	<b>Frost et al. (2006)</b>	<b>Kunde et al. (2006)</b>	<b>Goh et al. (2005)</b>	<b>Hellard et al. (2002)</b>	<b>McConnell et al. (2001)</b>
Study design	Cohort	Cohort	Cohort	Case-control	Ecologic	Ecologic
Outcome measure	Individuals	Individuals	Individuals	Individuals	Ecologic	Ecologic
Exposure measure	Ecologic	Ecologic	Ecologic	Ecologic	Ecologic	Ecologic
Study area	United States	United States	United States	United Kingdom	Australia	Australia
Study population	Families with one child age 2–10	Families with one child age 2–10 or adult > 65	Families with one child age 2–10	Residents of study area with no foreign travel or contact with other case-patients <sup>1</sup>	Residents of study area	Residents of study area
Dates of study	1996–1997	2000–2001	2001–2002	1996–2002	1974–1980	1991–1997
Length of follow-up	Four months	Six months	Five months	NA	Four years and two years	One year
Source water quality	Unfiltered surface water	Unfiltered surface water	Groundwater under influence	Unfiltered surface water	Undisinfected surface water	Undisinfected surface water (7 systems) Chlorinated surface water (10 systems)
Intervention	Conventional granular filtration	Conventional granular filtration	Membrane filtration	Membrane filtration	Chlorination	Chlorination ( <i>n</i> = 3) Filtration ( <i>n</i> = 10) Chlorination & filtration ( <i>n</i> = 4)
Outcome definition	CGI (symptoms)	CGI (symptoms)	CGI (symptoms)	Clinical diagnosis cryptosporidiosis	Emergency room & hospital admissions for AGI	Rate of fecal specimens analyzed in study area
Intervention benefit: risk (95% CI)	RR = 1.8 (1.5–2.2) before vs. after	NA	NA	IRR = 0.207 (0.099–0.431) after vs. before	Admissions: OR = 1.067 (0.724–1.212) ER visits: OR = 0.99 (0.84–1.18) OR = 0.96 (0.81–1.13) before vs. after	NA

NA: Not available.

CGI = Credible gastrointestinal illness.

<sup>1</sup>Residents with no travel outside the study area and no contact with other household members who had diarrhea or cryptosporidiosis.

vomiting alone; or a soft or liquid stool (two or more per day). This definition is similar to the definition used in the Canadian studies (Payment *et al.* 1991, 1996) but is slightly more restrictive, as only a single episode of diarrhea had to be reported daily in the Canadian studies. It is less restrictive, however, in that the Canadian subjects were asked to distinguish between soft stools and bloody or liquid stools.

A reduction in CGI was associated with an improvement in water quality from the filtration. The only water quality parameter to change significantly was turbidity, and a major reduction in drinking water turbidity was seen after the introduction of filtration. Poisson regression analysis indicated significantly higher CGI rates (RR = 1.8; 95% CI 1.5–2.1) in the before-filtration phase compared to the after-filtration phase ( $n = 316$  families before and 254 families after filtration). Higher CGI rates (RR = 1.8; 95% CI 1.5–2.2) were also observed when the analysis included only those families that participated in both phases ( $n = 99$  families). As expected, age was a significant variable, with children experiencing a higher incidence of CGI; family size was also a significant predictor of illness. The youngest group (less than 6 years of age) had the highest rates of CGI, and the largest reductions in CGI episodes were found for the youngest group and young adults 11–20 years of age. The attributable risk (AR) for CGI (for all families) was calculated using  $\{[p(RR - 1)]/[p(RR - 1) + 1]\} \times 100$ . The AR associated with unfiltered surface water is 34%; filtration resulted in a 34% reduction in CGI.

### Community 2 (Frost *et al.* 2006 – preliminary)

The second community intervention study was conducted in two cities in the state of Washington. The first city is served by two surface water supplies. The area of primary interest (Site A) was affected by a change in water treatment from chlorination-only to treatment by ozone, high-rate anthracite filtration, and chlorination. Site B (a different source water supply but the same city) was served by a chlorinated, unfiltered surface water with no change in water treatment for the entire study period. Both of the surface water sources for Site A and Site B come from well-protected watersheds with no evidence of sewage contamination from human or domestic animals. To control for community variation in gastroenteritis rates, the study design included a

demographically similar, nearby community (Site C) served by chlorinated groundwater sources. As in the Massachusetts study, families with children between the ages of 2 and 10 or an adult over the age of 65 were recruited. The same daily diary method was used. Several categories of illness were defined based on the reported symptoms: diarrhea (at least two episodes of soft or loose stools); gastrointestinal illness (nausea, vomiting, or abdominal cramps); and highly credible gastrointestinal illness (HCGI). HGGI was defined as having one of the following: (1) vomiting or liquid diarrhea, or (2) nausea or diarrhea combined with abdominal cramps. The number of households (individuals) that completed both the before and after phases of the study were: Site A 277 (711), Site B 164 (363) and Site C 124 (289). The families were followed for six months (June 2000–November 2000) before the change in drinking water treatment for Site A and were followed again in the same six month period (June 2001–November 2001) in the following year. In a preliminary analysis, the incidence of gastrointestinal and diarrheal illness for all three sites was found to be comparable in the before- and after-filtration phases. The preliminary analysis also found that the occurrence of illness in the before phase was predictive of illness in the after phase. For example, participants that reported three or more diarrhea episodes in the before phase had a five-fold higher risk of diarrhea episodes in the after phase compared to those participants who had less than three episodes in the before phase. Analyses are ongoing.

### Community 3 (Kunde *et al.* 2006 – preliminary)

A third study evaluated enteric disease risks in two south Texas communities using the same diary method and illness definition as previously described for Community 2. For drinking water, Site A uses spring water sources that are under the direct influence of surface water (GWUDI). In June 2002, membrane filtration and improved drinking water disinfection facilities were completed. Before then, the spring water was treated only by chlorination. A second community in which water treatment was unchanged served as a control (Site B). Site B uses a surface water source with clarification and mixed media granular filtration treatment. Families were recruited from both communities and were asked to maintain daily health

diaries for five months before and the same five month period after the treatment change in Site A. Initially, 160 families from the intervention community and 142 families from the control community agreed to participate. The number of families (individuals) that completed both phases of the study were 52 (165) and 37 (99) for the intervention and control communities respectively.

During the before phase of the study, Site A had a significantly higher diarrheal illness rate than Site B. After filtration was installed at Site A, the two communities had comparable diarrheal illness rates. A preliminary analysis found that diarrheal illness rates in Site A decreased after filtration. Similar to the study in Community 2, an association was found between reports of illnesses in the before- and after-filtration phases. After adjusting for illness risks in the before phase, the diarrheal illness risk among participants over age 35 was significantly reduced after membrane filtration. Analyses are ongoing.

## Studies in England and Australia

### Goh *et al.* (2005)

The incidence of sporadic cryptosporidiosis among 106 000 residents of two local government districts in part of the Lake District National Park in the northwest area of England before and after installation of membrane filtration of public water supplies was compared to that of 59 700 residents of the Lake District whose public water supplies remained unchanged. A case of sporadic cryptosporidiosis was defined as a resident who had diarrhea (3 or more loose stools in a 24-hour period) and had a stool specimen positive for *Cryptosporidium* oocysts. Cases were excluded from the study, if within 14 days of illness onset, they had traveled outside the country, stayed outside the study area for these 14 days in other areas of the UK, or had contact with another household member who had diarrhea or cryptosporidiosis. During the period before filtration (1 March 1996–29 February 2000), 153 cases were reported for an incidence rate of 8.44 cases per 100 000 person-years. After filtration (1 March 2000–31 August 2002), 22 cases were reported (3.31 cases per 100 000 person-years). A national outbreak of foot and mouth disease in livestock during 2001 was associated with a decline in sporadic human cryptosporidiosis in all regions of the

United Kingdom. The authors concluded that, despite the confounding effect of the foot and mouth epidemic, membrane filtration of the public water supply was effective in reducing the risk for sporadic human *Cryptosporidium* infection in this population. Results from a Poisson regression model indicated that membrane filtration was associated with an estimated 79% reduction in cryptosporidiosis (incidence RR = 0.207, 95% CI = 0.099–0.431) after adjustment for the foot and mouth disease epidemic and water source.

### Hellard *et al.* (2002)

This study evaluated the effect on community gastroenteritis associated with water disinfection in Melbourne, a city of over 3 million people. Two major reservoirs supplied almost 90% of the drinking water for the study area. The watershed areas that supply these reservoirs are closed wilderness catchments. Chlorination began in one reservoir in May 1976 and the other in June 1978. Prior to chlorination, fecal coliforms were regularly identified. After chlorination, fecal coliforms were rarely detected. Data on hospital admissions and emergency room visits for gastroenteritis at Melbourne's major children's hospital were analyzed between 1974 and 1980 inclusively, and the influence of chlorination on the rates of gastroenteritis was examined. An admission was classified as being due to gastroenteritis if it fitted the International Classification of Diseases codes either ICD 8 000-009 or ICD 9 001-009. The severity of the illness was measured by the duration of the hospital stay. Emergency room gastroenteritis was defined by presentation due to gastroenteritis, regardless of whether a pathogen was identified. No statistically significant difference was found in the number of admissions (OR = 1.067; 95% CI = 0.724–1.212) before and after chlorination of the water supply or duration of the admission. There was no statistically significant difference for gastroenteritis-related emergency room visits following chlorination of each surface water source (OR = 0.99; 95% CI 0.84–1.18 in 1976 and OR = 0.96; 95% CI 0.81–1.13 in 1978). The authors concluded that water was not a dominant contributor to the burden of gastrointestinal disease as measured by hospital admissions in the community. However, they also noted

that the study design was not capable of detecting small (<20%) reductions in the rate of gastroenteritis.

### McConnell *et al.* (2001)

This study evaluated whether there was a measurable decline in fecal specimens submitted for gastroenteritis-related symptoms following the introduction of water treatment in two states of Australia between 1992 and 1996. The investigators compared rates for the analysis of fecal specimens for gastroenteritis one year before and one year after the improvement of water treatment in 17 communities with a population greater than 1000 persons. The water systems used surface water sources subject to contamination from animals and, in some cases, human sewage. Filtration was added to 10 systems that had previously only disinfected the water. In seven surface water systems there was no existing water treatment; four systems added disinfection and filtration, and three systems added disinfection. The rate of fecal sampling varied from a reduction of 55% to an increase of 198%. There were marked changes in water quality such as turbidity and the detection of *E. coli* and total coliforms following treatment, but there was no significant correlation between these changes and changes in the rate of fecal specimens. The authors concluded that any reduction in endemic gastrointestinal illness as a result of the introduction of water treatment was likely to be small as a percentage of all gastroenteritis. The authors also acknowledged several limitations of their study. The ecological design was relatively weak at detecting small changes in disease incidence, and the fecal specimens, which were used as a surrogate measure for the incidence of gastrointestinal illness, represented only a small proportion of the actual cases of gastrointestinal illness in the community.

### STRENGTHS AND LIMITATIONS OF COMMUNITY-INTERVENTION STUDIES

Investigators who design and analyze community intervention must take into consideration not only many of the generic methodological and practical issues that arise in most epidemiologic studies but also several special challenges presented by a change in exposure for an entire

community rather than for selected individuals. Koepsell (1998) reviewed the design of community-intervention studies and provided the following advantages of these studies in assessing changes in risk:

- Community interventions reach people in their “native habitat” rather than people who volunteer for study in an artificial setting or clinic. For community-intervention studies no artificial conditions or specialized conditions are required for houses, workplaces or schools. For changes in water quality, the change is seamless in that, other than for changes in aesthetics, no other discernable changes are experienced by the population.
- Targeting everyone in a community or area will change exposures for all and, thus, may prevent more cases of disease than targeting just high-risk individuals in a study. In considering why community-intervention studies are appropriate for assessing the health benefits associated with drinking water improvements, the broader “population” strategy is aimed at everyone rather than just those at “high risk” (e.g. boil water for immunocompromised). The net effect is an overall reduction of illness in the population.
- Environmental modifications may be easier to accomplish than large-scale voluntary behavior change and, thus, may present better opportunities to conduct studies. The community environment can be an important determinant in disease risk. Modifying the environment in which people live can be more expedient and reach more people than attempting to induce voluntary behavior change on a mass scale. Providing potable water at the community level is far more effective at reducing waterborne disease than having individuals rely on household treatment.
- Some intervention modalities are unselective by nature (e.g. water treatment improvements). The improvement of drinking water quality automatically affects everyone in the community. No individual behaviors need to be modified nor is the provision of water selective. All members of the community water system receive the improved product.
- Community-intervention studies can be logistically simpler and less costly on a per-person basis than other study designs. Other intervention studies often sort the

population into risk groups from high to low. Elimination of the sorting process reduces the program cost and complexity. In addition, interventions aimed at individuals or households also add a complexity and cost as each household intervention must be initiated and then monitored.

A major advantage of community-intervention studies is that, in addition to monitoring health effects of the intervention for individuals (Figure 1), you can also evaluate changes in population health risks based on other traditional sources of disease surveillance that are typically conducted on a community basis. For microbial-related enteric disease, these include hospital admissions, positive clinical specimens, ambulatory care visits and nurse hotline calls. These health measures represent a decreased numbers of cases on the disease pyramid when compared to symptomatic illness, as they are more severe (Craun *et al.* 2006a). However, none of the studies reviewed in this paper presented multiple types of illness data to allow a comparison of the rates of endemic AGI with more traditional sources of medical surveillance (clinical specimens or hospitalizations). Future studies should consider the possibility of collecting multiple types of data to compare the relationship between medical and population surveillance especially for self-reporting of AGI symptoms.

A major data gap is an understanding of the etiologies of the symptomatic illnesses considered in the epidemiologic studies. As noted by Craun *et al.* (2006a), microbial-associated AGI can be caused by a number of microorganisms from bacteria and viruses to protozoan parasites. It is

notable that there has been minimal utilization of biological specimens to determine the etiology of the endemic AGI events being studied. If available, this information can be used to help determine the variation in the occurrence of waterborne pathogens by season, by drinking water sources, or by treatment parameters.

While the known list of waterborne pathogens is quite diverse, it is believed that other waterborne pathogens remain to be identified. Drinking water treatment is targeted to reduce or remove most known enteric pathogens, especially those that may be most resistant to water disinfectants. Identification of the pathogens responsible for waterborne AGI would help clarify the efficacy of current water treatment for newly identified pathogens. This information can also help public health officials identify sources of microorganisms that might require strategies beyond treatment (watershed management, distribution system integrity). Future studies should attempt to identify the etiology of endemic waterborne AGI.

A major issue of concern is the community-level variation of illness. Community-level variation is related to the basic idea that diseases do not occur at random in populations but vary systematically in relation to person, place and time. Community variation has been well documented and geographic differences are the source of hypotheses. The design of community-intervention studies needs to take community variation into consideration. This was a key issue in the progression and design of the EPA studies. While the first study in Massachusetts was a single community, subsequent studies included both intervention and non-intervention communities to evaluate community variation.

Another concern is the random assignment of individuals into an exposure group. This is possible in experimental studies and ensures comparability of the exposed and non-exposed groups in terms of possible confounding factors. Randomization was not an option for the intervention community given the requirements of the SWTR, and as noted earlier, some interventions are unselective by nature. Although the selection of a control community can be randomized, selection is limited given the need to match communities. Since investigators had a very limited role in selecting either intervention or control communities for study, selection bias is of minimal concern for the US studies. Given the similarity in design and collection of data

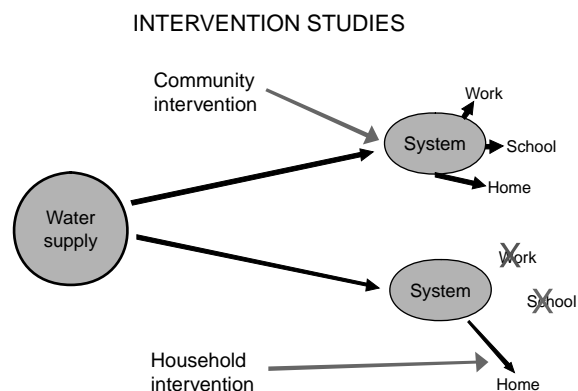


Figure 1 | Community versus household interventions.



among the US studies, a combined examination of the data would allow evaluation of community variation as well as other population aspects that may be important in studying gastrointestinal disease. Comparison of population enteric illness rates should also be made with other studies such as the FOODNET cross sectional survey (Roy *et al.* 2006) and the Iowa household-intervention study (Colford *et al.* 2006).

There are similarities and differences between household- and community-intervention studies (Figure 1). Both studies consider source water, treatment, and distribution system risks, but the community system changes water exposures for all members of the community. The major difference is the lack of control for water consumption outside the home in household-intervention studies. These studies do not account for exposures outside the home (school, office, restaurants) or, in the case of point-of-use devices and bottled water, compliance with their use. Exposure patterns to drinking water, especially for ingestion, are unknown, but a study in New York suggests that it is difficult to avoid tap water exposures outside the home (Davis *et al.* 1998). However, as noted earlier, household-intervention studies offer the advantage of randomization of exposure for study participants. It would seem that both types of studies should be conducted to take advantage of their strengths. Thus, we recommend that investigators consider the possibility that a household-intervention trial and a community-intervention study might be conducted simultaneously.

Epidemiologists usually evaluate a body of evidence by considering results from different study designs conducted by different investigators in different locations. This is appropriate for endemic waterborne risks. Risks from community-intervention studies should be compared with the risks observed in experimental and observational studies.

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## SUMMARY AND CONCLUSIONS

What can community-intervention studies tell us about the incidence, prevalence, or risk of waterborne AGI in the United States – quantitative or qualitative? Studies outside the United States considered cases identified by medical surveillance. The US studies considered self-

reported gastrointestinal illness. A reduction in risk was observed in two of the four published studies. A study in England found that membrane filtration of surface water was associated with an estimated 79% reduction of laboratory-confirmed cryptosporidiosis, and a study in Massachusetts found that granular filtration of surface water was associated with an estimated 34% reduction of self-reported gastrointestinal illness.

Two studies in Australia found no significant decreases in gastroenteritis associated with water treatment. However, gastroenteritis was defined differently from that in the US studies, and the changes in water treatment are generally not applicable to US water systems. In one study, hospital admissions and emergency room presentations for gastroenteritis were compared before and after chlorination of surface water sources. In the other study, investigators compared the number of requests for analysis of gastroenteritis-related fecal specimens before and after water treatment in 17 surface water systems. In 10 water systems that were previously disinfected, filtration was added, but the remaining seven systems were previously untreated.

To inform the national estimate of waterborne endemic AGI in the US, we have available results from Massachusetts, but only preliminary results are available from the other two study sites. In Texas, diarrhea risks were reduced after the addition of membrane filtration to a GWUDI. In Washington State, no decreased diarrhea risk was observed after the filtration of a high quality surface water source with a well-protected and restricted watershed.

The applicability and generalizability of the community-intervention studies reviewed here is limited given the availability of relevant studies and the current state of analyses. Studies outside the United States considered cases identified by medical surveillance. However, the results do provide insight into the potential range of benefits that may be associated with improved water treatment of certain water sources.

Important in interpreting the information is evaluating the statistical power of the study and deciding how representative the current results are in terms of the study design, a specific geographic location, time period, or type of water source or treatment. For example, if no benefit was associated with improved water treatment, was the study

able to detect a relatively small change in gastrointestinal illness that might be due to drinking water?

We recommend that the results of community-intervention studies be considered along with results from other studies in estimating a population attributable risk for waterborne gastrointestinal illness for the US population. Even with the current data from observational studies, outbreaks and intervention studies, the national estimate would likely be quite uncertain. Thus, community-intervention studies should continue to be conducted. Future studies should consider other changes in drinking water treatment, a design that nests a household-intervention study within a community intervention, the collection of multiple types of health endpoints (medical surveillance as well as symptomatic illness), and the identification of specific pathogens as the cause of symptomatic illness.

## DISCLAIMER

The views expressed in this paper are those of the individual authors and do not necessarily reflect the views and policies of the US Environmental Protection Agency. The paper has been subject to the Agency's peer review and approved for publication.

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