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Assessing the Public Health Threat Associated with Waterborne Cryptosporidiosis: Report of a Workshop

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The following CDC staff members prepared this report:

David G. Addiss, M.D., M.P.H.
Michael J. Arrowood, Ph.D.
Mary E. Bartlett
Daniel G. Colley, Ph.D.
Dennis D. Juranek, D.V.M., M.Sc.
Division of Parasitic Diseases

Jonathan E. Kaplan, M.D.
Division of HIV/AIDS Prevention
National Center for Infectious Diseases

in collaboration with:

Robert Perciasepe, M.S.
James R. Elder
Stig E. Regli
Paul S. Berger, Ph.D.
Environmental Protection Agency

Assessing the Public Health Threat Associated with Waterborne Cryptosporidiosis: Report of a Workshop

Summary

In September 1994, CDC convened a meeting to address the public health threat associated with waterborne cryptosporidiosis. Representatives from 40 states and from regulatory and public health agencies, water utility companies, and advocacy groups discussed approaches to avoiding unnecessary boil-water advisories (i.e., statements to the public advising persons to boil water before drinking it) and preventing and controlling waterborne cryptosporidiosis. Work groups at the meeting addressed four issues: 1) surveillance systems and epidemiologic study designs; 2) public health responses when oocysts are detected in drinking water; 3) cryptosporidiosis in immunocompromised persons; and 4) water sampling methods and interpretation of results. The work groups defined the problems associated with these issues and developed strategies that could be used initially to manage these problems. The work group discussions were summarized, and the conclusions were provided as either a) summaries of current knowledge concerning that issue or b) suggested ways to obtain the information needed to develop useful recommendations. The work group conclusions are for consideration by persons and organizations who must assist with these issues and by those who seek to advance understanding of waterborne cryptosporidiosis.

INTRODUCTION

In 1993, an outbreak of cryptosporidiosis affecting >400,000 persons occurred in Milwaukee. The magnitude of this outbreak, coupled with its association with water obtained from a municipal water plant that was operating within existing state and federal regulations, emphasized the need for a) improved surveillance by public health agencies to detect and prevent such outbreaks and b) coordination among interested groups and agencies to respond appropriately to such outbreaks. It also stimulated efforts to develop regulatory standards for *Cryptosporidium* in drinking water. To assist CDC and state public health departments in providing guidance on these issues, CDC's National Center for Infectious Diseases (NCID) convened a workshop entitled "Prevention and Control of Waterborne Cryptosporidiosis: An Emerging Public Health Threat" on September 22–23, 1994. The purpose of the workshop was to assemble persons from a variety of disciplines to discuss ways to minimize the public health risks associated with waterborne cryptosporidiosis.

Invitations to the workshop were extended to CDC staff and representatives of state and local health departments, city and county water utilities, regulatory agencies, food and soft-drink industries, groups representing immunosuppressed persons, and other groups. The objectives of the workshop were developed on the basis of discussions

with these persons and organizations. The workshop agenda was designed to update participants regarding cryptosporidiosis and to separate into work groups to develop reports regarding four key issues: 1) surveillance and epidemiologic study designs; 2) public health responses when oocysts are detected in drinking water; 3) cryptosporidiosis in immunocompromised persons; and 4) water sampling methods, interpretation of data, and laboratory research priorities. Group leaders presented the work groups' reports during the final plenary session. Workshop organizers planned to publish these reports a) to summarize the public health issues associated with waterborne cryptosporidiosis; b) to suggest plans for responding appropriately to this threat; c) to suggest ways to develop the research base needed to determine the risks associated with *Cryptosporidium* oocysts in drinking water; and d) to stimulate discussions at all levels, especially at the local level, regarding prevention and management of waterborne cryptosporidiosis.

BACKGROUND

Cryptosporidium parvum has been recognized as a human pathogen since 1976. During 1976–1982, the disease was reported rarely and occurred predominantly in immunocompromised persons. In 1982, the number of reported cases began to increase as a result of the acquired immunodeficiency syndrome (AIDS) epidemic. Initially, the increase in incidence was limited to immunocompromised persons; however, outbreaks and sporadic infections in immunocompetent persons were identified with the aid of newly developed laboratory diagnostic techniques.

Cryptosporidium is a protozoan parasite transmitted by ingestion of oocysts that have been excreted in the feces of infected humans or animals. The infection can be transmitted through person-to-person or animal-to-person contact, ingestion of fecally contaminated water or food, or contact with fecally contaminated environmental surfaces. Several municipal waterborne outbreaks of cryptosporidiosis (*1–7*), including the 1993 outbreak in Milwaukee, have focused attention and concern on the potential for waterborne transmission.

Recent studies indicate that *Cryptosporidium* oocysts are present in 65%–97% of surface water (i.e., rivers, lakes, and streams) tested throughout the United States (*8–10*). Because *Cryptosporidium* is highly resistant to chemical disinfectants used to treat drinking water, physical removal of the parasite from water by filtration is an important component of the municipal water treatment process. However, many cities in the United States do not use filtration as part of their water treatment process, and no current method can guarantee complete removal of oocysts. The risk for transmission can be reduced by water filtration if the filters are properly operated and maintained.

In the United States, all outbreaks of waterborne cryptosporidiosis detected from 1984 through 1993 occurred in communities where water utilities met state and federal standards for acceptable drinking water quality, and all surface water supplies implicated in those outbreaks had been filtered. These outbreaks indicate that utility compliance with Environmental Protection Agency (EPA) water treatment standards did not adequately protect against waterborne cryptosporidiosis. The EPA turbidity standards have been strengthened since the Milwaukee outbreak, and the finished (i.e., tap) water in Milwaukee at the time of the outbreak would not have met the new

standards. Nevertheless, recent reports of *Cryptosporidium* oocysts in fully treated (i.e., disinfected and filtered) municipal water that was meeting these new standards indicate small numbers of oocysts breached water treatment filters in 27%–54% of the communities evaluated (*11,12*).

The health risk associated with drinking filtered or unfiltered tap water contaminated with small numbers of *C. parvum* oocysts is unknown. Although researchers have recovered small numbers of oocysts from drinking water, current laboratory methods cannot reliably determine if these oocysts are viable or are infectious to humans. Moreover, research has not determined whether a) the number of oocysts usually present in drinking water is sufficient to cause illness in humans, b) immunosuppressed persons are more susceptible to lower doses of oocysts than are immunocompetent persons, or c) strains of *C. parvum* vary in virulence and infectious dose. The results of a study that used a *Cryptosporidium* strain derived from calves suggested that the infectious dose of oocysts to healthy human volunteers is small (i.e., a median infectious dose could be as few as 132 oocysts) (*13*). Other reports based on mathematical modeling algorithms indicate that some persons could become infected with a dose as low as one oocyst (*14*).

EPA has proposed a plan to collect data concerning a) the occurrence of several pathogens and chemicals in water and b) the ability of water treatment plants to remove these substances (*15*). The EPA plan—the Information Collection Rule (ICR)—will require utilities in the United States that both obtain water from surface water sources and provide service to ≥10,000 persons to test for *Cryptosporidium* oocysts in source water (and in some cases, finished water) for a period of 12–18 months (Appendix A). Almost all utilities are likely to detect oocysts in their surface source water on some occasions, and 24%–50% of utilities can expect to detect oocysts in their treated water (*16*). When low levels of oocysts are identified in treated water through testing required by the ICR, public health agencies and other local and state officials could be pressured to issue immediate boil-water advisories* or respond in other ways to the perceived public health threat, regardless of whether such measures are necessary. Local and state health departments and water utilities have expressed concern because current data are insufficient to determine the health risks associated with low-level oocyst contamination of fully treated drinking water.

WORKSHOP OBJECTIVES

The workshop was held to determine and address the public health concerns associated with waterborne cryptosporidiosis and to assess the potential public health, administrative, and economic implications of the ICR's *Cryptosporidium* testing component. Each of the more than 300 participants received background information regarding cryptosporidiosis and the ICR. The work groups had the following four specific objectives:

- To identify surveillance systems and epidemiologic study designs for assessing the public health importance of low levels of *Cryptosporidium* oocysts or elevated turbidity in public drinking water.

*Statements to the public advising persons to boil water before drinking it.

- To provide guidance for public health responses to the detection of *Cryptosporidium* oocysts in drinking water and to provide methods for notifying the public of potential risks for waterborne transmission.
- To identify and examine options for preventing waterborne transmission of *Cryptosporidium* to immunocompromised persons who use public water supplies.
- To evaluate and address a) water sampling methods for identifying *Cryptosporidium* oocysts, b) interpretation of data derived from these methods, c) the status of alternative methods of sampling, and d) laboratory research priorities.

Work Group I. Surveillance Systems and Epidemiologic Study Designs

Surveillance Systems

Local public health officials should consider developing one or more surveillance systems to establish baseline data on the occurrence of cryptosporidiosis among residents of their community and, where possible, obtain sufficient epidemiologic data to identify potential sources of infection. These baseline indices will be helpful in assessing whether oocysts that are found in drinking water are associated with any increases in the number of *Cryptosporidium* infections in the community. Such surveillance should be considered by all communities whose water utility provides service to ≥100,000 persons and whose water supply is derived from surface water. Although communities with populations of 10,000–99,999 persons will be required by the ICR to monitor their source water for *Cryptosporidium*, they will not be required to monitor their finished water. Nevertheless, those communities in which the water treatment process does not include filtration or in which the treated water quality indicates filtration does not adequately remove oocysts should also consider surveillance for cryptosporidiosis.

No single surveillance strategy can be recommended or would be feasible for all locations; therefore, communities should select a method that meets local needs and is most compatible with existing disease surveillance systems or ongoing special studies. Neither increased incidence of diarrhea nor *Cryptosporidium* infection in a community establishes water as the cause of infection. Any increased occurrence of either diarrhea or laboratory-confirmed *Cryptosporidium* infection detected by surveillance requires further epidemiologic investigation to identify the source(s) of infection.

This work group suggested the following seven approaches to surveillance, which are presented hierarchically by increasing order of the perceived effort and cost.

Make cryptosporidiosis reportable to CDC. Each state or city should report cryptosporidiosis cases to CDC's National Notifiable Disease Surveillance System. This measure was supported and approved by the Council of State and Territorial Epidemiologists (CSTE) in January 1995. Although such action might not improve diagnosis or reporting of cryptosporidiosis by physicians, it provides legal authority for collecting needed information. This type of surveillance is most likely to reflect the occurrence of cryptosporidiosis in immunocompromised populations because health-care providers are more likely to request that such patients who have diarrhea be tested for *Cryptosporidium*.

Monitor sales of antidiarrheal medications. Local pharmacies often have computerized data bases containing the number of medications sold daily. The development of an information exchange between local pharmacists and state or local public health officials is a cost-effective and timely way to detect increases in diarrheal illness in some communities. In addition, these data bases can provide historical data that can serve as an indicator of baseline sales rates for antidiarrheal medication.

Monitor logs maintained by Health Maintenance Organizations (HMOs) and hospitals for complaints of diarrheal illness. HMOs and hospitals have computerized systems for logging telephone calls regarding patient illnesses. Information entered promptly into a computerized data base can effectively monitor both complaints of diarrhea and severity of gastrointestinal disease in a community. These data are particularly useful if the local medical-care facility records zip code numbers for persons who are ill, because waterborne illness associated with inadequate water treatment affects persons residing throughout the water distribution area.

Monitor incidence of diarrhea in nursing homes. During outbreak investigations, data from nursing homes have implicated drinking water as the source of community infection. Diarrheal illness rates in residents of nursing homes that use municipal drinking water can be compared with illness rates in residents of other nursing homes in the same community that use a different water source (e.g., well water). Because nursing staff usually record the frequency and characteristics of bowel movements for each resident, such data also can be used for other surveillance purposes. Substantial efforts by the local or state health department might be needed to review and extract the relevant data from patient records, which could differ in format by nursing home. If this measure is employed, health departments also should establish a baseline for the population comprising nursing home residents, which usually experiences more gastrointestinal problems than the general population.

Monitor laboratory data for *Cryptosporidium*. Most laboratories do not look for *Cryptosporidium* in stool specimens submitted for routine parasitologic examination. To obtain this information, health-care providers usually must request specifically that stool specimens be examined for *Cryptosporidium*. Because health-care providers who treat patients who have AIDS are more likely to suspect cryptosporidiosis as a diagnosis in such patients who have diarrhea, they are more likely than other health-care providers to request specific testing for *Cryptosporidium*. Thus, current laboratory-based surveillance for cryptosporidiosis would more likely detect an increased number of *Cryptosporidium* infections in patients who have AIDS than in immunocompetent patients in the general population. To more accurately determine the occurrence of *Cryptosporidium* infection in the general population, health-care providers must be aware of the public health importance of obtaining data on the occurrence of cryptosporidiosis, and they should be encouraged to submit stool specimens for persons who have symptoms compatible with the disease and to request *Cryptosporidium* testing. In addition, the cost of the additional laboratory testing for cryptosporidiosis in immunocompetent patients presents an obstacle, especially because specific therapy will not necessarily be implemented as a result of a confirmed diagnosis. Some HMOs and laboratories might be able to provide computerized

reports of all *Cryptosporidium* diagnoses. However, substantial delays might occur between the completion of the test and the entry of data into a computer.

Monitor tap water in selected cities. Intensive surveillance in a sample of six to 10 cities known to have *Cryptosporidium* oocysts in their finished water can provide a method for assessing how often a temporally related increase in diarrheal illness or *Cryptosporidium* diagnosis occurs during the first week or first 2 weeks after oocysts are found in drinking water. Health departments and public officials in other cities can use information derived from analysis of the data generated at these sites as a basis for local decision making and for educating the public about the public health risks associated with similar levels of oocyst contamination of their water supplies. Health officials in cities participating in this intensive surveillance would need to implement thorough surveillance techniques for recording diarrheal illness and laboratory-confirmed *Cryptosporidium* diagnoses, and they should monitor finished water for *Cryptosporidium* oocysts more frequently than required by the ICR. In addition to identifying small outbreaks, these studies could be used to compare the effectiveness of different surveillance methods (including those described previously) and to identify cases of cryptosporidiosis for possible inclusion in epidemiologic studies that could further define the risks for waterborne cryptosporidiosis. A detailed plan for developing intensive surveillance and funding for such activities should be developed by representatives from CDC, EPA, CSTE, and water utilities.

Make immediate epidemiologic assistance available. Rapid initiation of epidemiologic investigations might be necessary when disease surveillance or water quality data indicate that the public might be at increased risk for cryptosporidiosis. Although some states and cities could implement such investigations independently, many could not and would need technical and financial assistance. Rapid response teams based at CDC and EPA should be organized so they would be available to respond to such events. These teams also could assist states in responding to outbreaks of cryptosporidiosis. These investigations should emphasize a) assessment of the morbidity and mortality in various immunocompromised populations, b) appropriate and rapid environmental testing for *Cryptosporidium* oocysts, c) rapid identification and evaluation of potential sources of water contamination (e.g., sewage), and d) a thorough engineering assessment of the water utility's equipment and treatment processes.

Epidemiologic Study Designs

The ICR does not include financial or strategic support for assessing possible health risks that might be associated with the occurrence of small numbers of *Cryptosporidium* oocysts in source or finished water. Moreover, the ICR's proposed laboratory method for testing water for *Cryptosporidium* does not include the recovery efficiency and precision necessary for conducting true dose-response–type studies. For example, the same specimen tested several times by the same laboratory could yield counts ranging from 0 to ≥30 oocysts per 100 L of water. Furthermore, laboratories cannot determine reliably whether oocysts that are identified in a specimen are still living and capable of causing disease in humans. (See Work Group IV. Water Sampling Methods and Interpretation of Results.) This work group proposed

the following study designs for comparing *Cryptosporidium* infection in exposed and unexposed groups. These suggestions were based on the assumption that a more reliable test will be available in the future or that studies could be designed without the need to quantify precisely the number of oocysts present in drinking water.

Surveys of stool specimens. Studies designed to compare the prevalence of laboratory-confirmed *Cryptosporidium* in stool samples obtained from two populations (i.e., one group exposed to water contaminated with oocysts and the other group not exposed) or in the same population (i.e., before and after exposure to contaminated municipal drinking water) are difficult to conduct. A demographically similar control group that has not been exposed to contaminated drinking water must be identified, and an adequate number of persons must participate in the study. Because the background prevalence of cryptosporidiosis is expected to be minimal (i.e., ≤1%–2%) in persons unexposed to contaminated water, large sample sizes are required to detect twofold to fivefold increases in stool positivity rates in the exposed population. The sample size must be large enough to show the statistical validity of a negative result (i.e., to indicate that the health risks are below an established level). For example, if the background *Cryptosporidium* stool positivity rate is assumed to be 1% in persons not exposed to contaminated water, the sample size required to detect a twofold increase in prevalence among exposed persons (at a confidence level of 95% and a power of 80%) is 4,500 persons (i.e., 2,250 persons in both the exposed and unexposed groups). A more manageable sample size of 650 persons is calculated if the detection of a fivefold or greater increase (i.e., an increase from 1% to 5%) in stool positivity is desired. However, negative results from a study using this smaller sample size would not exclude the possibility that exposure to oocysts in the contaminated water resulted in a substantial, but lesser, number of *Cryptosporidium* infections (e.g., a twofold to threefold increase in the stool positivity rate).

Surveys of serologic specimens. Conducting a survey of serologic specimens instead of stool specimens to detect differences in *Cryptosporidium* antibody prevalence rates in exposed and unexposed populations could facilitate the epidemiologic assessment of health risks attributable to waterborne transmission of oocysts. A reliable assay that could distinguish between previously and recently acquired *Cryptosporidium* infection would enable investigators to survey relatively large populations, especially if blood already collected for other purposes could be tested. A sample size of 625–750 persons, with 50% of the sample comprising persons exposed to contaminated water and 50% comprising persons not exposed, is needed to demonstrate that a ≥10% increase in antibody prevalence in the exposed population is statistically different from the background prevalence in the unexposed population. This sample size is based on the assumption that the prevalence of anti-*Cryptosporidium* antibody detectable by enzyme-linked immunosorbent assay (ELISA) is 20%–30% in residents of communities that are not exposed to *Cryptosporidium* in drinking water.

Use of a Western blot test or other tests instead of the ELISA for serologic testing could result in a different sample size calculation because of different background rates of seropositivity. High priority should be placed on pilot testing current serologic methods to better define the sensitivity and specificity of these methods for

identifying *Cryptosporidium* infection and to review the extent to which these methods distinguish recently acquired infections from those acquired previously.

Case-control studies. Case-control studies are designed to test the association between a given exposure and an infection rather than establish a difference in the actual infection rate as described previously. Case-control studies require that a method be developed to a) identify persons (i.e., case-patients) who have laboratory-confirmed cryptosporidiosis, b) identify one or more groups of uninfected persons (i.e., those in the control group) who are representative of the population from which the case-patients are drawn, and c) identify (by using an epidemiologic questionnaire) the exposures to infection that are more common among case-patients than persons in the control group. Although the exposure of predominant interest is exposure to tap water, the questionnaire must be developed to enable evaluation of the relative contributions of other possible sources of exposure.

The case-control study design can assess the sources of exposure to low-incidence diseases; compared with population-based studies described previously, this design usually requires a substantially smaller sample size. To exemplify these sample size requirements, it can be assumed that persons drinking tap water are at greater risk for exposure to *Cryptosporidium* than persons drinking only specially selected or treated bottled water. As an example, 90% of case-patients in this study design drink tap water (i.e., 10% drink only bottled water), and only 80% of controls drink tap water. A sample size of 438 persons (i.e., 219 case-patients and 219 controls) is needed to demonstrate that this 10% difference in exposure to tap water is unlikely to be caused by chance alone (confidence level=95%, power=80%). Similarly, if 95% of case-patients and 90% of controls drink tap water, the desired sample size would increase to 948 (474 case-patients and 474 controls).

In most case-control studies, locating several hundred persons in a community who have laboratory-confirmed cryptosporidiosis is difficult. Theoretically, case-patients can be enrolled in a study even if their diagnosis of cryptosporidiosis was made 1–2 years previously; however, the memories of such patients could be affected by recall bias (i.e., they could have difficulty recalling when or if they had certain types of exposures to *Cryptosporidium* [e.g., through contaminated recreational water, contact with children who wear diapers, sexual contact, visiting a person who had diarrhea, or brief travel to other cities that have greater risk for waterborne infection]). Recall bias also can affect the memories of persons in control groups; therefore, investigators should strive to enroll in the study those persons whose illness was diagnosed recently. For patients who have AIDS, a recently diagnosed *Cryptosporidium* infection might not represent a recently acquired infection.

A case-control study also can be conducted in communities in which most neighborhoods receive tap water from surface water sources but some neighborhoods receive well water. In this situation, users of well water could be considered unexposed. However, investigators must be able to identify persons who receive well water at their residence but who might work or attend school in an area served by surface water. Such persons should be considered as exposed to *Cryptosporidium*.

Intervention cohort studies. In an intervention cohort (i.e., prospective) study, the researchers a) try to control, either randomly or nonrandomly, who is exposed to tap

water from a surface source during a specified time period and b) monitor for the occurrence of cryptosporidiosis in the exposed and unexposed populations. The unexposed group is composed of persons who drink either well water, high-quality bottled water, or adequately filtered water. A major advantage of this study design is that researchers have greater ability to demonstrate whether the exposure is associated with infection or disease. This type of study, however, is not appropriate for the investigation of low-incidence diseases (e.g., communitywide incidence of cryptosporidiosis) because large sample sizes are needed.

Study design summary. The most feasible study design to use when investigating waterborne cryptosporidiosis in nonoutbreak settings might be a cohort study that incorporates a serologic test for rapidly identifying seronegative persons. Two groups (i.e., an exposed and an unexposed group) could be retested 6–12 months after the initial test. Half the cohort of seronegative persons could be given *Cryptosporidium*-free water to drink, and the other half could drink tap water from a surface source. Alternatively, the cohort could contain persons residing in an area of a larger city in which some residents use municipal surface water and some use a nonsurface water source (e.g., a well). Persons who develop diarrhea could either be screened for *Cryptosporidium* infection by stool examination or evaluated serologically for infection soon after illness, or both tests could be used. Sample size considerations are the same as those for population surveys.

Work Group II. Public Health Responses

This work group focused on identifying methods and messages for notifying agencies, advocacy groups, and the public of potential risks for waterborne *Cryptosporidium* transmission and on providing guidance for public health responses when oocysts are detected in drinking water.

Boil-Water Advisories

A boil-water advisory is a public health measure that, if implemented promptly, can successfully reduce the risk for potentially serious diarrheal and other waterborne diseases among persons whose water supply has been contaminated by microbial pathogens. However, boil-water advisories also might be associated with adverse effects, including economic losses (e.g., increases in energy use and/or losses to the food, beverage, and tourism industries), erosion of public confidence, diversion of public health resources, and burn injuries resulting from unintentional contact with boiling water. These factors and available information regarding the level of risk for cryptosporidiosis in a community must be considered carefully before issuing a boil-water advisory.

A task force should develop general guidelines for implementing and lifting boil-water advisories to assist local agencies in deciding when boil-water advisories should be implemented. A balanced approach is recommended. Finding low levels of *Cryptosporidium* oocysts in finished water should not be the reason for issuing a boil-water notice for the general public, unless the decision is supported by other data that suggest water quality is not acceptable. Supportive information could include raw water turbidity and fecal coliform counts, particle counts or turbidity measurements on individual filters, treatment plant effluent, and epidemiologic information

confirming increases in diarrheal disease in the community. Because a low number of oocysts in treated water should not be the only reason for issuing an advisory, the continued presence or absence of oocysts should not be the sole criterion for deciding if municipal water is safe to drink.

Information Dissemination and Education

Public health officials, water utility officials, health-care providers, immunosuppressed populations, and the general public should be provided information on *Cryptosporidium* and drinking water before the ICR is implemented. A task force should be created with representatives from federal, state, and local public health agencies, water treatment utilities, public officials, health-care providers, immunosuppressed populations, and the general public; the goal of this task force should be to develop and distribute educational materials to explain the relationship between the parasite *Cryptosporidium*, drinking water, and the ICR. A high priority should be placed on educating immunosuppressed persons, who are at increased risk for severe cryptosporidiosis if they become infected. Immunosuppressed persons should be provided information about how to reduce the risk for cryptosporidiosis, regardless of the source of transmission, and about measures they can take to ensure their drinking water is safe (see Work Group III. Cryptosporidiosis in Immunosuppressed Persons).

Before the ICR is implemented, local public health officials and water utility officials should develop coalitions with other groups (e.g., health-care providers and members of advocacy groups for immunosuppressed persons) to discuss the public health implications of the ICR. These coalitions should develop plans for communicating important public health information, and they should decide what specific action, if any, will be taken if *Cryptosporidium* oocysts are detected in municipal water. The coalitions should agree on the criteria for, and logistical issues relevant to, issuance of a public notification or boil-water advisory.

Work Group III: Cryptosporidiosis in Immunocompromised Persons

No current data indicate that immunocompromised persons are more likely than immunocompetent persons to acquire cryptosporidiosis during waterborne outbreaks. However, immunocompromised persons who have HIV/AIDS, patients receiving treatment for cancer, recipients of organ or bone marrow transplants, and persons who have congenital immunodeficiencies are at greater risk than are immunocompetent persons for developing severe, life-threatening cryptosporidiosis if they become infected. Therefore, all immunocompromised persons should be educated and counseled about the ways that *Cryptosporidium* can be transmitted (e.g., sexual practices involving fecal exposure, contact with infected adults or with infected children who wear diapers, contact with infected animals, drinking or eating contaminated water or food, and exposure to contaminated recreational water).

All persons, especially immunocompromised persons, should avoid drinking water directly from lakes or rivers. Because water can be ingested unintentionally, immunocompromised persons should be advised that swimming in lakes, rivers, or public swimming pools also can place them at increased risk for infection.

This work group suggested that immunocompromised persons can take the following specific measures to help reduce the risk for waterborne cryptosporidiosis:

Boiling Water Before Use

During waterborne outbreaks or other situations in which a community boil-water advisory is issued, immunocompromised persons should boil water for 1 minute to eliminate the risk for acquiring cryptosporidiosis. Using submicron, personal-use filters (i.e., home or office types of water filters) or high-quality bottled water also can reduce the risk for transmission. However, boiling water is the most certain method of killing *Cryptosporidium* oocysts.

Using Water Filters

Only microstraining filters capable of removing particles ≤1 μm in size should be used by immunocompromised persons and other persons who choose to use a personal-use filter (i.e., home or office water filters) to reduce the risk for transmission of *Cryptosporidium*. Filters in this category that provide the greatest certainty of *Cryptosporidium* removal include those that produce water by reverse osmosis, those labeled according to filter manufacturing industry standards as "Absolute" 1 μm filters, and those labeled as meeting American National Standards Institute (ANSI)/NSF (formerly the National Sanitation Foundation) International standard #53 for "Cyst Removal."* The "Nominal" 1 μm filter rating is not standardized, and many filters in this category might not reliably remove oocysts. Filters that only employ ultraviolet light, activated carbon, or pentiodide-impregnated resins are not effective against *Cryptosporidium*. Not all filters advertised as effective against *Giardia* are effective against *Cryptosporidium*. Because bacterial overgrowth on filters can be an additional health risk (*17*) and oocysts are likely to concentrate on the outside of filter cartridges, persons should carefully follow the manufacturer's instructions for filter replacement and use. Immunocompromised patients should either have someone else change the used cartridges or use disposable gloves if they themselves change the cartridges.

Using Bottled Water

Many brands of bottled water adequately reduce the risk for cryptosporidiosis and, thus, provide a reasonable alternative to boiling tap water. However, labeling of bottled water is not standardized with regard to the manufacturing practices used to test for and remove or kill *Cryptosporidium* oocysts. The origin, microbial flora, and treatment of water before it is bottled vary considerably between bottled water companies and between brands of water produced by the same company. Label information on bottled water often does not provide the consumer with the information needed to identify the lowest-risk product. In general, bottled water obtained from underground sources (i.e., springs or wells) is less likely to be contaminated with *Cryptosporidium* oocysts than bottled municipal water derived from rivers or lakes. Water from underground sources is unlikely to contain oocysts if it is protected from possible contamination that results from intermittent mixing with surface water and it has been consistently free of coliform bacteria when tested. Because the water bottling industry neither uses a labeling standard for bottled water that reflects the degree of well or spring protection from contaminants nor lists results of coliform testing at the source,

*NSF International certifies water filters according to the ANSI/NSF International Standard #53: Drinking Water Treatment Units—Health Effects. To obtain information regarding the current status of any water filter, contact NSF International, 3475 Plymouth Road, P.O. Box 130140, Ann Arbor, MI 48113-0140. Telephone (800) 673-8010.

consumers might have to seek this information directly from company representatives. Persons who use bottled water as an alternative to tap water that has been boiled must carefully research and choose their supplier.

The absence of coliform bacteria in municipal tap water, in tap water treated with submicron filters, or in finished bottled water does not guarantee that the water came from an uncontaminated source (i.e., water negative for *Cryptosporidium* oocysts) or that it has been treated adequately to remove oocysts. Treating water before bottling by distillation or reverse osmosis filtration, regardless of the source (e.g., well, spring, and municipal tap water), ensures removal of oocysts if they are present. Similarly, water that has been passaged through an "Absolute" 1 μm or smaller filter or through a filter labeled as meeting ANSI/NSF International standard #53 for "Cyst Removal" before bottling will provide almost the same level of oocyst removal. However, bottlers using "Nominal" 1 μm filters as the only *Cryptosporidium* treatment barrier might not reliably remove oocysts. Use of the word "Microfiltration" on the label does not ensure that filters are effective against *Cryptosporidium*. Although ozonation of water can kill *Cryptosporidium* oocysts in experimental conditions, research has not established the appropriate concentration and contact time that are effective against oocysts in bottled water. Municipal tap water that is bottled after treatment with charcoal to remove the chlorine taste or after short-term exposure to ultraviolet light offers no additional protection against *Cryptosporidium*.

Determining Risk for Cryptosporidiosis in Nonoutbreak Settings

The magnitude of risk for acquiring cryptosporidiosis from drinking water in a nonoutbreak setting is uncertain and can vary considerably by city depending on the quality of the water source used by utilities and on the quality of water treatment. Current data are inadequate to make a general recommendation that immunocompromised persons in the United States boil or avoid drinking tap water in nonoutbreak settings. However, immunocompromised persons should be advised that the risk for waterborne transmission is possible and that they can choose to reduce their risk for waterborne cryptosporidiosis by using precautions similar to those recommended during outbreaks. Immunocompromised persons should consult their health-care provider before making such a decision.

Immunocompromised persons and other persons who choose to use a personal-use filter or bottled water during an outbreak or nonoutbreak situation should be aware of the difficulties in selecting the appropriate product, the lack of enforceable standards related to oocyst destruction or removal, the cost, and the life-style changes that are necessary to consistently use these products for all water consumed. Preliminary data from outbreak investigations indicate that persons who did not consistently use bottled water or filters were as likely to become ill as those who did not use such products (CDC, unpublished data).

In a nonoutbreak setting and during periods when finished water quality is within EPA standards, no single indicator of municipal water quality (e.g., minor fluctuations in turbidity, particle size counts, or discovery of low numbers of oocysts) is considered sufficient for issuing or rescinding a boil-water advisory for immunocompromised persons. (See discussion on boil-water advisories, Work Group II. Public Health Responses.)

Work Group IV: Water Sampling Methods and Interpretation of Results

The ICR and related immunofluorescence methods for detecting *Cryptosporidium* oocysts in source and finished drinking water are subject to limitations that affect the interpretation of the results. This work group assessed several of these limitations, including the following:

Labor Required

The ICR techniques are labor intensive and require a lengthy processing time; furthermore, their use requires expertise in microscopy and parasitology. Thus, the tests are costly and depend on the degree of quality control of the laboratory.

Distinguishing Characteristics of Infectiousness

The assays do not effectively differentiate viable (infectious) or viable (but noninfectious) oocysts from nonviable oocysts.

Species Identification

All isolates of *C. parvum* submitted thus far to participating laboratories for testing have yielded positive results using the ICR standard assay. However, oocysts of other species have also been detected with this assay, including *Cryptosporidium wrairi* (guinea pig), *Cryptosporidium meleagridis* (turkey), and an unnamed species that affects quail. Some isolates of *Cryptosporidium muris* (cattle) react to the reagent, whereas isolates of *Cryptosporidium baileyi* (chicken) do not react (*18*; CDC, unpublished data). If *C. muris* and *C. baileyi* isolates that do react with the reagent are present in a sample, they can be differentiated from *C. parvum* by oocyst morphology and size. Depending on microscopic image quality and analyst expertise, *C. parvum* oocysts might be difficult to distinguish from the larger *C. baileyi* oocysts. Although the assay reagents show adequate specificity for *Cryptosporidium*, nonspecific reactions or cross-reactions with algae or other particles have been observed. Although a positive result indicates the potential presence of *Cryptosporidium* oocysts, these oocysts might not be infectious to humans. For these reasons, *Cryptosporidium* testing results cannot be the only criterion considered when making public health decisions. Other measures that should be considered when assessing public health risk include treatment plant efficiency and water quality data, epidemiologic information, surveillance information, and previous occurrence data. Strain (i.e., virulence) differences between *C. parvum* isolates cannot be assessed by current identification methods.

Recovery Efficiency

The ICR methods have an erratic recovery efficiency; therefore, low levels of oocysts in water might not be recovered and the results of oocyst counts for the same specimen could vary. Recovery efficiency and sensitivity are influenced by the characteristics of the water sample (e.g., reduced by highly turbid source water or water with high algal content). Water-sample volume and level of analyst or laboratory expertise also affect recovery efficiency and sensitivity. Consequently, water contaminated with *C. parvum* could yield negative test results.

Level of Technical Expertise Required

The level of laboratory expertise is particularly critical. EPA has sponsored a preliminary assessment of commercial laboratory proficiency using the immunofluorescence method for low turbidity waters that has been proposed by the American Society for Testing and Materials (ASTM) (*19*). This assessment has demonstrated substantial laboratory-to-laboratory variability in the identification and reporting of *C. parvum* oocysts and *G. lamblia* cysts from experimentally contaminated (i.e., "spiked") test samples. *C. parvum* oocyst recovery efficiencies ranged from 1.3% through 5.5% (average: 2.8 %). False-negative (55%) and false-positive (18%) results also were reported. However, not all laboratories uniformly applied the ASTM assay during this assessment (i.e., several laboratories had modified this assay).

Use of Standardized Techniques

Studies that evaluated tap or raw water sediments spiked with *C. parvum* oocysts have reported oocyst recoveries of 42.0%–89.9% (*10,20*). Efforts to compare the results of these and other studies have been complicated by the use of slightly different methodologies. Nevertheless, reported recovery efficiencies for spiked samples varied fivefold to fiftyfold, and the results from raw source water or finished drinking water samples will probably be as variable. The decision to implement the *Cryptosporidium*-specific portion of the ICR will be made partially on the basis of the results of a planned performance evaluation trial with the ICR method.

Need for Alternative Methodologies

Alternative methods or modifications to existing methods have been reported or are being developed. None of these alternatives currently supplant or improve the current ASTM or ICR methods, and research needs to continue on the development of alternative methodologies. Such methodologies are needed to better meet public health objectives for assessing the health significance of oocysts in drinking water, and they should enable water treatment operators to test and react to the presence of oocysts in source or finished water within hours.

WORK GROUP CONCLUSIONS

These work group conclusions are the summarized suggestions from the proceedings of each work group, as presented by the work group leaders at the concluding plenary session of the workshop, and they were drafted with multiple opportunities for open input from all participants. The workshop formalized the awareness that current knowledge of *Cryptosporidium*, particularly waterborne cryptosporidiosis, is minimal. This level of knowledge does not provide a scientifically sound basis for many essential decisions regarding the public health risks associated with the infection. This report provides, on the basis of available information, potential strategies for managing cryptosporidiosis. Moreover, these discussions assist with focusing researchers on possible ways to attain the information needed to better understand the risk factors associated with waterborne cryptosporidiosis, thereby enhancing the eventual development of effective prevention strategies.

Surveillance Systems and Epidemiologic Study Designs

Local, state, and national public health agencies should cooperatively initiate and develop surveillance and epidemiologic investigations to assess the public health significance of low levels of *Cryptosporidium* oocysts in public drinking water.

Public Health Responses

Discovering *Cryptosporidium* oocysts in low levels in finished water should not be the only reason for issuing a boil-water advisory. Additional support for such an advisory should include other data indicating that the water quality is unacceptable. A task force should be created to develop general guidelines for implementing and lifting boil-water advisories and to assist local agencies in deciding when boil-water advisories are necessary. A coordinated local-to-national effort should be made before implementation of the ICR to provide information concerning *Cryptosporidium* and drinking water to public health officials, water utility officials, health-care providers, immunosuppressed populations, and the general public. Such information should include appropriate prevention strategies.

Cryptosporidiosis in Immunocompromised Persons

A coalition or task force should be established that will place high priority on educating immunocompromised persons about cryptosporidiosis because of the increased risk for severe disease if they become infected. This group should provide information to immunocompromised persons that explains how to reduce the risk for cryptosporidiosis, regardless of the source of transmission, and about specific measures they can take to further reduce the risk for waterborne transmission.

Water Sampling Methods and Interpretation of Results

Current methods are limited with regard to detecting oocysts in source and finished drinking water. These technical limitations restrict the ability of public health officials to practically interpret data on the occurrence and public health importance of *Cryptosporidium* in drinking water. Research should be accelerated to develop alternative, dependable methods for detecting *Cryptosporidium* in drinking water.

AFTERWORD

In November 1994, as a result of the workshop, NCID initiated the Working Group on Waterborne Cryptosporidiosis. This group is a coalition of agencies and organizations that meets biweekly by teleconference to discuss concerns about cryptosporidiosis. The group has convened smaller task forces that are developing information to help local and state public health departments, health-care providers, water utilities, and regulatory agencies address many of the strategies proposed in this report. Additional information concerning the Working Group on Waterborne Cryptosporidiosis can be obtained by calling (404) 488-7750 or (404) 488-7769.

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APPENDIX A

Summary of EPA's Information Collection Rule

The purpose of the Information Collection Rule (ICR) is to improve drinking water quality by obtaining information concerning the occurrence of microorganisms and chemicals in public drinking water and the ability of water treatment plants to remove these microorganisms and toxins. In addition, information concerning disinfection byproducts (DBPs) will be collected to support the development of improved DBP standards. The ICR was developed through a negotiated rule-making process and was originally intended only to assist in developing new DBP standards. However, participants in the ICR negotiations agreed that better microbial standards would also be needed to prevent increases in microbial risk while public water systems made treatment changes to comply with new DBP standards. Existing microbial standards for systems using surface water supplies require one level of treatment for *Giardia* (99.9% removal) and viruses (99.99% removal), regardless of the quality of the source water. A key concern among the ICR negotiators was that systems with poor-quality source waters that only minimally meet these standards would not provide adequate treatment while controlling DBPs.

A major objective of the ICR is to obtain national occurrence and water treatment data for *Giardia*, *Cryptosporidium*, viruses, and indicator organisms in water. Another major objective is for each public water utility to estimate the concentration of *Giardia* and *Cryptosporidium* in its source water. These estimates can then be used to determine the level of treatment required to comply with possible new regulations proposed from the negotiations. ICR occurrence data will enable water utilities both to comply with new DBP standards and to determine more quickly the appropriate levels of microbial treatment that are needed.

TABLE A-1. Information Collection Rule (ICR) microbial monitoring summary*

Population of community served by water utility	*Giardia*	*Cryptosporidium*	Viruses	Coliforms	Fecal coliforms or *Escherichia coli*
10,000–99,999 persons	Every 2 mos at water intake for 12 mos.	Every 2 mos at water intake for 12 mos.	Not required.	Every 2 mos at water intake for 12 mos.	Every 2 mos at water intake for 12 mos.
≥100,000 persons	Monthly for 18 mos at water intake. If during the first 12 mos the estimated concentration is ≥1/L,† then finished (tap) water must be monitored.	Monthly for 18 mos at water intake. If during the first 12 mos the estimated concentration is ≥1/L, then finished water must be monitored.	Monthly for 18 mos at water intake. If during the first 12 mos the estimated concentration is ≥1/L, then finished water must be monitored. The entire 18 mos of monitoring is not required if viruses are not detected during the first 12 mos or if the source water meets certain exemption criteria.§	Monthly for 18 mos at water intake. If during the first 12 mos the estimated concentration is ≥1/L, then finished water must be monitored.	Monthly for 18 mos at water intake. If during the first 12 mos the estimated concentration is ≥1/L, then finished water must be monitored.

*The Environmental Protection Agency is proposing the ICR to improve drinking water quality by obtaining information concerning the occurrence of microorganisms and chemicals in public drinking water and the ability of water treatment plants to remove these substances. Information concerning disinfection byproducts will be collected to support the development of new standards. ICR pathogen monitoring does not apply to any water utility that purchases all of its water from another water utility. All ICR monitoring is to occur in consecutive months. If a water utility has more than one water source, each individual source or blended source must be monitored. The ICR might also require monthly monitoring for *Clostridium perfringens* and coliphage.

†One organism per liter of water.

§Virus-monitoring exemption for good-quality source waters: based on monitoring that occurs 5 days per week beginning 4 months before ICR promulgation and 2 months after promulgation, the water utility can discontinue virus monitoring if total coliforms are <100/100 mL or fecal coliforms or *E. coli* are <20/100 mL in 90% of the intake samples.

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