Risk Assessment and Control of Waterborne Giardiasis

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ABSTRACT

Background: Waterborne giardiasis has been increasing in the United States with 95 outbreaks reported over the last 25 years. The Safe Drinking Water Act has mandated control of this pathogen.

Methods: A risk assessment model was developed to estimate risk of infection after exposure to treated waters containing varying levels of *Giardia* cysts. The model was defined by a dose-response curve developed from human feeding studies for *Giardia* and assumed 2L of water consumption per day. Data on concentrations and distribution of the organism in source waters were used to assess exposure after varying reductions achieved through treatment.

Results: In surveys reporting prevalence and levels of *Giardia* cyst contamination, average levels of cysts in surface waters ranged from 0.33 to 104/100L; from pristine watersheds (protected from all human activity) 0.6 to 5/100L. Yearly risks were 4.8×10^{-3} for systems using polluted waters and 1.3×10^{-4} for pristine waters with a 10^{-3} treatment reduction.

Conclusion: Public Health officials will need to work with the water industry to ensure a risk of less than 1/10,000 for source waters with 0.7 to 70 cysts per 100 liters through treatment achieving reduction of 10^{-3} to 10^{-5}, respectively, of *Giardia* cysts. (*Am J Public Health.* 1991;81:709–713)

Introduction

Giardia is the most frequently isolated enteric protozoan from populations worldwide and the most common pathogenic parasite in the United States.[1] Waterborne giardiasis has been increasing in the United States with 95 outbreaks reported over the last 25 years,[2] and *Giardia* is the most common identifiable etiological agent of all waterborne outbreaks. Bennet *et al.*[3] have also estimated that 60 percent of all *Giardia* infections are acquired through contaminated water.

Giardia cysts may be found in water as a result of the deposition of fecal material from both man and animals. Surveys of *Giardia* cyst levels in various waters indicate that 26–43 percent of the surface waters were contaminated with *Giardia* cysts ranging in concentrations from 0.3 to 100 cysts per 100L.[5–10] Sykora[9] has reported an average of 10^4 cysts/100L in raw sewage with an approximate reduction of 10^{-2} after treatment (152 cysts/100 L).

The Surface Water Treatment Rule has been promulgated to address the amendments to the Safe Drinking Water Act for controlling *Giardia* in treated drinking water.[4] This rule mandates that all surface waters be treated to achieve at least a reduction of 10^{-3} (99.9 percent removal) of *Giardia* cysts. Disinfection is required for all systems and filtration is required unless the system meets site specific criteria and has a protected watershed. The US Environmental Protection Agency (EPA) has also recommended that a treatment be provided to ensure that populations are not subject to risk of infection of greater than 1:10,000 (10^{-4}) for a yearly exposure, and that this is an acceptable level of safety for potable waters.

As the new regulations and rules come into effect, health departments will be called upon to ensure that the public is adequately protected against waterborne disease. Risk assessment is a tool by which health officials can communicate with the water industry by interpreting water quality surveys and assisting in defining the adequacy of treatment adhering to EPA's recommendations of potable water quality and acceptable public health risks. This will become particularly important as states implement the Surface Water Treatment Rule, evaluate new technologies, and determine what water management practices will impact public health.

This paper presents a risk assessment model that was used to estimate risk of infection due to waterborne exposure to *Giardia*. Dose-response curves were developed based on human infectivity studies, and data on the occurrence of *Giardia* cyst contamination in waters throughout the US were used to define the water treatment needed to reduce the risk of waterborne giardiasis.

Methods

To predict a potential public impact when the risk is small, models are used to estimate the risk after exposure. Haas reviewed three probability models for their ability to describe experimental dose-response data for humans after exposure to

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various enteric microorganisms.[11] Using the same approach, the simple exponential and beta distributed effectiveness models were evaluated for prediction of *Giardia* infectivity using experimental data developed by Rendtorff[12,13] in human feeding studies.

In Rendtorff's experiments, *Giardia* cyst doses ranging from 1 to 10^6 were fed to volunteers, and a positive response was measured by cyst excretion in the feces (Appendix). Laboratory dose-response studies generally appear to be conducted under conditions where the distribution of microorganisms in the administered dose may be regarded as Poisson. Under these conditions, if one microorganism is sufficient to cause an infection, and if host-microorganism interactions are constant, then the probability of an infection (P_i) resulting from ingestion of a single volume of liquid containing an average number of organisms (N) may be defined by a simple exponential equation.

$$P_i = 1 - \exp(-rN)$$

In this equation, r is the fraction of microorganisms that are ingested which survive to initiate infections ("host-microorganism interaction probability") (Appendix). In this particular case, the exponential model was statistically consistent with the Rendtorff data and r was calculated to equal −0.01982.

The 95 percent confidence limits to the parameter r in the exponential model were computed using a likelihood ratio technique. The resulting interval estimate for r is 0.009798–0.03582. This range was used in the preparation of Figure 1.

Exposure Estimates

Surface waters were classified into two categories: polluted waters contaminated by sewage and agricultural discharges; and pristine waters originating from protected watersheds without point source pollution or input from human activities. *Giardia* cyst levels were examined for the peak level of contamination from a single sample, average concentrations for each site, and average cyst levels for each water classification. Geometric means were calculated from the average concentrations from each site.[5–10] *Giardia* cyst levels were calculated as cysts/100 L as large volumes of water are routinely sampled for determining levels of contamination.

Using the exponential model, the potential risk of infection was determined with varying levels of *Giardia* cysts in drinking water. The model assumed the consumption of two liters of water per day, and exposure N in the formula was defined by numbers of cysts per liter times two liters. Levels of *Giardia* cysts found in polluted and pristine source waters and assumed levels of 10^{-3}, 10^{-4}, and 10^{-5} removal by treatment were used to estimate exposure in the model. Maximum daily risk was estimated using the peak level of contamination and yearly risk was determined using the geometric mean concentration of *Giardia* cysts for 365 days of exposure. Probability of infection was determined assuming a Poisson distribution of microorganisms in the drinking water,[11] i.e.,

> risk of contracting one or more infections = $1-(1-\Pr(N))^x$ where x = the number of days exposed and Pr(N) = the daily risk using the geometric average for N.

Data from five waterborne outbreaks of giardiasis were also evaluated for the *Giardia* cyst level of contamination detected in the drinking water and the attack rates in the exposed population.[14] This information was compared to the estimated infection rates developed by the exponential model after varying days of exposure.

Results

To ensure less than a daily risk of 10^{-4}, systems using source waters containing 250, 2,500 and 25,000 cysts per 100L would need to reduce the level of *Giardia* cysts by 10^{-3}, 10^{-4} and 10^{-5}, respectively, through drinking water treatment (Table 1). Examples of yearly risks for exposure to varying levels of *Giardia* cysts in drinking water are summarized in Table 2. To ensure less than a yearly risk of 10^{-4}, systems using source waters containing a geometric concentration of 0.7, 7.0 and 70 cysts per 100L would require a reduction of 10^{-3}, 10^{-4} and 10^{-5}, respectively, by treatment.

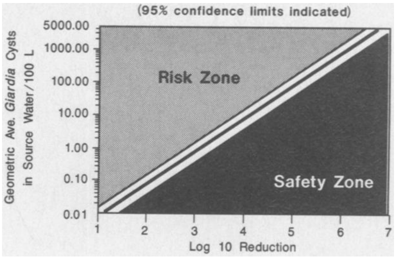

FIGURE 1—Log 10 Treatment Reductions for *Giardia* Cysts in Source Waters Yielding 10^{-4} Annual Risk (95% confidence limits indicated)

In surveys reporting prevalence and levels of *Giardia* cyst contamination in surface waters, average levels of cysts ranged from 0.33 to 104/100L. Eight of the areas where samples were collected from received treated sewage or agricultural discharges, however, the level of pollution was not documented.[5–10] In water samples originating from pristine watersheds (protected from all human activity) *Giardia* cyst levels averaged 0.6 to 5/100L. The percentage of positive samples did not vary dramatically from polluted to pristine waters (43 percent and 35 percent, respectively). Peak contamination in a single sample was 5.5 times higher from polluted waters than from pristine waters. However, geometric averages of cysts were 50 times higher for samples collected from polluted waters versus those collected from pristine waters.

The majority of data for the pristine waters was developed from a study by

TABLE 1—Estimated Daily Risk of *Giardia* Infections from Various Levels of Cyst Contamination in Drinking Water Using an Exponential Risk Assessment Model

Worst Daily Risk Pr(N)	Cyst Exposure	Maximum Cyst Concentration in Finished Water per 100L	Maximum Cyst Concentration in Source Water Per Level of Treatment Reductions 10^{-3}	10^{-4} Cysts/100L	10^{-5}
$10^{-3.5}$	0.015	0.75[a]	7.5×10^2	7.5×10^3	7.5×10^4
10^{-4}	0.005	0.25	2.5×10^2	2.5×10^3	2.5×10^4
$10^{-4.5}$	0.0015	0.075	75	7.5×10^2	7.5×10^3
10^{-5}	0.0005	0.025	25	2.5×10^2	2.5×10^3

[a] Levels of cysts detected during waterborne outbreaks of giardiasis.

TABLE 2—Estimated Yearly Risk of *Giardia* Infections from Various Levels of Cyst Contamination in Drinking Water Using an Exponential Risk Assessment Model

Yearly Risk $1-(1-Pr^a (N))^{365}$	Average Daily Cyst Exposure for a Year	Geometric Mean Cyst Concentration in Finished Water per 100L	Geometric Mean Cyst Concentration in Source Water Per Level of Treatment Reductions		
			10^{-3}	10^{-4}	10^{-5}
			Cysts/100 L		
$10^{-3.5}$	4×10^{-5}	2×10^{-3}	2.0	20	200
$10^{-4.0}$	1.4×10^{-5}	7×10^{-4}	0.7	7.0	70
$10^{-4.5}$	4×10^{-6}	2×10^{-4}	0.2	2.0	20
10^{-5}	1.4×10^{-6}	7×10^{-5}	0.07	0.7	7.0

[a] Pr = Daily Probability of Risk

TABLE 3—Potential Levels of Cysts in Treated Drinking Water and Probability of Infection

Source Water	Reduction by Treatment	Geometric Cyst Levels per 100L in Drinking Water	Yearly Risk[b]	With Peak Contamination Cysts/100L in Drinking Water	Daily Risk
Polluted 33 cysts[a]/100L	10^{-3}	0.033	4.8×10^{-3}	0.625	2.5×10^{-4}
	10^{-4}	0.0033	4.8×10^{-4}	0.062	2.5×10^{-5}
	10^{-5}	0.00033	4.8×10^{-5}	0.006	2.5×10^{-6}
Pristine 0.9 cysts[a]/100L	10^{-3}	0.0009	1.3×10^{-4}	0.114	4.6×10^{-5}
	10^{-4}	0.00009	1.3×10^{-5}	0.0114	4.6×10^{-6}
	10^{-5}	0.000009	1.3×10^{-6}	0.0011	4.6×10^{-7}

[a] geometric average
[b] $Risk = 1-(1-Pr(N))^{365}$

Ongerth, *et al.*[6] The Tolt, Green and Cedar watersheds in the State of Washington were extensively sampled with 222 samples collected. The averages reported in the publication included a 22 percent recovery adjustment for method efficiencies. The data from the Ongerth study[6] used in this paper did not include such adjustments since the data used from other studies[5,7–10] did not take into account adjustments for recovery efficiencies.

Daily and yearly risks were developed for the peak cyst level and the geometric average, respectively, for the two water categories (Polluted and Pristine). The data are shown in Table 3. Yearly risks ranged from 4.8×10^{-3} for systems using polluted waters with a 10^{-3} treatment reduction to 1.3×10^{-6} for pristine waters with a 10^{-5} treatment reduction. Between 10^{-4} and 10^{-5} reduction with treatment would be required for polluted waters to achieve a similar risk as pristine waters treated for a 10^{-3} removal of *Giardia* cysts. For daily risks for waters containing peak levels of *Giardia* cysts, the differences were not as dramatic between systems using polluted versus pristine source waters. The peak daily risk was approximately five times greater in systems using polluted versus pristine waters receiving similar treatment for removal of cysts.

Water samples were collected and *Giardia* cyst levels were determined during the investigation of five waterborne outbreaks of giardiasis. Attack rates varied from a low of 0.5 percent in the Houtzdale and Pittston outbreaks to a high of 16 percent in the Ft. Plain outbreak. The level of cyst contamination ranged from 0.6 to 21 cysts/100L. Generally the lower levels of contamination were associated with lower levels of infection in the population. The data are shown in Table 4.

All five outbreaks were associated with unfiltered chlorinated surface waters. Three factors primarily influenced the attack rate for infection: first, the level of contamination; second, the level of cyst viability and inactivation through chlorination; and third, the length of exposure to the population whose prior exposure to *Giardia* (and potential immunity) was unknown. Much of this detail is not known. The exponential risk model was applied to the known cyst levels from the outbreak and infection rates were estimated for varying days of exposure. It is unlikely that there was a single day of exposure or that the exposure was equal to the duration of the outbreaks. If one uses intermediate times of exposure, five to 10 days, the infection rates developed by the model ranged from 0.1 to 7.7 percent.

Discussion

Many regulatory and public health agencies have accepted risk assessment models to evaluate the importance of chemical pollutants in water. How well these models reflect reality depends on the accuracy of the model for characterizing the independent variables, assumptions, and the data used to develop the dose-response curves and exposure.

The most essential component to the risk model described in this paper is the dose-response curve. *Giardia* species/strains are known to have a low infectious dose. Rendtorff and Holt demonstrated in 1954 that ingestion of as few as 10 cysts was capable of initiating infection in two volunteers. It must be kept in mind that infection was measured by cyst excretion and illness was not determined. Asymptomatic *Giardia* infections may range between 39 percent and 76 percent for children less than five years of age and adults, respectively.[15,16] Symptomatic infections, however, have been reported at a rate of 50 percent to 67 percent and as high as 91 percent.[17] Chronic giardiasis may also develop in as many as 58 percent of the population infected.[18] Thus the illness to infection ratio is highly variable. We addressed only infection in this analysis of risk.

Another important issue regarding the dose response curve based on the Rendtorff data is uncertainty about infectivity due to strain variation and the immune response to infection by different populations. The Rendtorff data are derived from one *Giardia lamblia* strain and one relatively small sample population. The confidence interval around the probability of infection does not take these uncertainties into account when using the model as a predictive tool.

Assuming the dose response relationship derived from the Rendtorff data is representative, we may be overestimating

TABLE 4—*Giardia* Cyst Contamination of Drinking Waters during Waterborne Outbreaks of Giardiasis and the Relationship to an Exponential Risk Model

		Outbreak Data		Estimated Infection Rates[b] after Exposure for (Days)				
Outbreak	Duration (days)	*Giardia*[a] Cysts/100L	Attack Rates %	1	5	10	30	60
Pittsfield	30	21	3	0.84	3.9	7.7	21	38
Ft. Plain	60	19.5	16	0.78	3.8	7.5	21	37
Houtzdale	?	2.4	0.5	0.09	0.4	0.9	2.7	5.2
Pittston	?	0.87	0.5	0.03	0.1	0.3	0.9	1.8
Wilkes-Barre	?	11	9	0.4	2.0	3.9	11.3	21
		0.6	1	0.02	0.1	0.2	0.6	1.2

[a] Data received from Dr. Judith Sauch, Environmental Protection Agency, Cincinnati, OH.[14,15]
[b] Estimated from the exponential risk model.

risks based on the assumption that all cysts are viable and all cysts in water are species which infect humans. In addition, the 2L of tap water consumption may represent overestimation of exposure, depending on individuals consumption of other beverages. However, the underestimation of risk may be of greater concern due to underestimation of exposure by the inefficiencies of the methods for detection of *Giardia* cysts in water.

In spite of its limitations, the model can be used to examine waterborne outbreak data and disease surveillance data associated with various exposure routes. Epidemiological data, may be even more insensitive and inaccurate. Attack rates for waterborne outbreaks, defined by the number of illnesses in the exposed population, are developed using a variety of methods; they do not take into account unreported cases or asymptomatic infections, and may include individuals who were not exposed. Estimation of infection based on attack rates is probably understated.

Levels of cysts ranging from 0.6 to 21/100L detected in waters were associated with outbreaks of disease. *Giardia* cyst levels found in drinking waters averaged 0.19/100L during non-outbreak conditions and were rarely above 1/100L.[19] Based on the data in Table 4, it appears the model may be useful in estimating probability of infection. The greatest limitation of the model may be the underestimation of infection and disease through the use of cyst concentrations in water without taking into account method efficiencies, peak contamination levels, and duration of exposure.

By applying information on *Giardia* cyst levels to Figure 1, public health agencies, regulatory agencies, and water utilities can evaluate the adequacy of current treatment of a drinking water supply, the need for more effective treatment, or the type of treatment needed in developing new water supplies.

Public health workers must not only have an understanding of waterborne disease. The implications of new regulations, watershed protection, and water treatment on indigenous potential waterborne infections in the population must also be understood. Standard methods are available to assess *Giardia* cyst contamination in water. Health agencies can utilize such data in a risk assessment, cost-benefit approach to establish rational policies for public health protection. □

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APPENDIX

For the purpose of modeling, it was assumed that the cysts have a random distribution in water and that a Poisson distribution would govern the probability of any given exposure.[11] The risk of infection was defined as a function of the exposure (N organisms) and the interaction of the host and pathogen. The parameters characterizing this interaction (r) were determined using the human infectivity data set. The data set for the experimental infection and development of the model areshown in Table A-1. The single-hit exponential equation for the probability of infections is shown in Table A-2. The constant characterizing the host-cyst interaction with the best fit values to the data set is also presented. An average r value (that fraction of microorganisms that are ingested which survive to initiate infection) for the exponential model was computed by determining the value of r at each dose. The chi square goodness of fit test was used to evaluate the appropriateness of the model for the data set.The single hit exponential model was used toevaluate the risk of waterborne giardiasis. Low level contamination of drinking water with *Giardia* (0.5 cysts/100L)would result in a potential infection rate of 0.02 percent in the exposed population using the exponential model while at high levels of contamination, (100 cysts/100L) a 3.9 percent infection rate was determined (Table A-3).

TABLE A-1—Data Set for Experimental Infection for *Giardia* Cyst Exposure

Cyst Dose	Volunteers' Response Positive[a]	Volunteers' Response Negative	Percent with Positive Response	Predicted Number of Positives[b]
1	0	5	0	0.098
10	2	0	100	0.359
25	6	14	30	7.809
10^2	2	0	100	1.724
10^4	3	0	100	3
10^5	3	0	100	3
3×10^5	3	0	100	3
10^6	2	0	100	2

[a] Positive response denoted by cyst excretion.
[b] Based on function p = 1−exp(−0.0198N)
Source: Rendtorff[12,13]

TABLE A-2—Best Fit Distribution Parameters for *Giardia* Infection Probability

Model	*Exponential Model*
Equation	$p = 1 - \exp(-rN)$
Constant(s)	$r = (-.01982)$
Expected probability of infection from an average dose of 1 cyst	0.0198
Number of infections in a population of 100, each exposed to 1 cyst	2

*95% confidence intervals for r = 0.009798–0.03582.
Source: Haas[11]

TABLE A-3—Potential Risk of Infection in *Giardia* Contaminated Drinking Water Using an Exponential Risk Assessment Model

Giardia concentration in water Cysts/100L	*Giardia* concentration in water Cysts/L[a]	Daily Risk	Percent Infection
0.5	0.005	2.0×10^{-4}	0.02
0.8	0.008	3.2×10^{-4}	0.032
1	0.01	4.0×10^{-4}	0.04
5	0.05	$2\ \times10^{-3}$	0.2
10	0.1	4.0×10^{-3}	0.4
15	0.15	6.0×10^{-3}	0.6
20	0.2	8.0×10^{-3}	0.8
50	0.5	2.0×10^{-2}	2.0
100	1	3.9×10^{-2}	3.9
200	2	7.7×10^{-2}	7.7

[a] Assume consumption of two liters of drinking water per day.