Contact Recreation Use Attainability Analysis:

Microbial Risk Assessment (MRA) and Epidemiology Studies

Houston Area Bayous and Water Bodies Feasibility Study

This report includes opinions and recommendations of H-GAC and the Contact Recreation UAA Workgroup as stakeholders in addition to the information requested under TCEQ's grant to H-GAC.

Prepared by the Houston Galveston Area Council
In Cooperation with the
Texas Commission on Environmental Quality and the
U.S. Environmental Protection Agency

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DISCLAIMER

This document was reviewed in accordance with Houston-Galveston Area Council (H-GAC) policy for approved publications. It was prepared by H-GAC staff under a contract from the Texas Commission on Environmental Quality (TCEQ). H-GAC has prepared the report, with input from a panel of experts and stakeholders, two of whom represented TCEQ. The TCEQ made no comments to H-GAC's interim report or draft final report submitted under contract requirements in writing. Oral comments were received at workshop sessions. No official endorsement of the report is implied.

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TABLE OF CONTENTS

TABLES

ACRONYMS

AMSA	Association of Metropolitan Sewerage Agencies
ASM	American Society of Microbiology
AWQC	ambient water quality criteria
BEACH Act	Beaches Environmental Assessment and Coastal Health Act 2000
BMP	Best Management Practices
CART	Classification and Regression Tree
CAW	Chicago Area Waterways
CDC	Centers for disease control and Protection
cfs	colony forming units
Criteria	USEPA Water Standard Criteria for Contact Recreation - 1986
CSO	Combined Sewer Overflow
CWA	Clean Water Act
DNA	deoxyribonucleic acid
ESW	U.S. Environmental Protection Agency Expert Scientific Workshop
EU	European Union
FDA	Food and Drug Administration
GI	Gastrointestinal
GIS	geographical information system
HCGI	High Correlation Gastrointestinal Illness
HIV/AIDS	human immunodeficiency virus/acquired immune defense syndrome
H-GAC	Houston-Galveston Area Council
mL	Milliliter
MPN	Most Probable Number
MRA	Microbial Risk Assessment
MST	microbial source tracking
NCR	non-contact recreation
NPDES	National Pollution Discharge Elimination System
PCR	polymerase chain reaction
POTW	publicly owned (wastewater) treatment works
qPCR	quantitative polymerase chain reaction
RCT	randomized controlled trial
RNA	ribonucleic acid
SAC	stakeholder advisory committee
SD	standard deviation
SSM	single sample maximum
SSO	sanitary sewer overflow
SWMM	Storm Water Management Model
TCEQ	Texas Commission on Environmental Quality

TMDL	total maximum daily load
TNRCC	Natural Resource Conservation Commission
UAA	Use Attainability Analysis
URI	upper respiratory illness
U.S.	United States
USEPA	United States Environmental Protection Agency
WERF	Water Environmental Research Foundation
WQS	Water Quality Standards
WHO	World Health Organization
WWTP	Waste Water Treatment Plant

INTRODUCTION

The United States Environmental Protection Agency (USEPA) and the Texas Commission on Environmental Quality (TCEQ) propose revisions to water quality standards and implementation procedures with the intent to protect public health during contact recreation activities. Certain human illnesses (e.g. gastroenteritis) are associated with exposure to waterborne pathogens following contact recreation. TCEQ proposes to establish levels of microbial contamination that result in acceptable risks to the human population (Texas Surface Water Quality Standards, 30 TAC Chapter 307; TCEQ RG-194, January 2003).

The best human health policy comes from risk assessment based on research with sound scientific design, methodology, execution, and analysis. Epidemiology studies or Microbiological Risk Assessment (MRA), which draw upon epidemiology studies are useful tools for sound policy development. "The essence of microbial risk assessment is describing a system in which a microbial hazard reaches its host and causes harm…Risk consists of both the probability and impact of disease. In this way, risk reduction can be achieved in either dimension—by reducing the probability of disease or by reducing its severity."[1] TCEQ and USEPA seek to examine the feasibility of using the MRA model format with epidemiology studies or epidemiological studies alone to establish the effects of pathogen-containing urban surface waters on human health following various contact recreational activities.

The original USEPA Water Standard Criteria for Contact Recreation developed in 1986, has been criticized by many individuals and groups for lack of scientific validity. This includes comments from USEPA's own external review committees, Chicago Waterway System, Association of Metropolitan Sewerage Agencies, American Society of Microbiology, and Harris County in Texas, and the USEPA's 2007 Expert Scientific Workshop attendees. Criticism focuses on the underlying research, which forms the basis for the Criteria. Critics say the 1978-1982 epidemiology studies are poorly designed, use inadequate statistical analysis, and exhibit other problems associates with location (large lakes vs. urban bayous) and cohort population (no control) that cloud the studies validity. These concerns have not been addressed previously; the studies updated using modern science, or expanded to cover water bodies other than fresh water lakes. Addressing these difficulties offers the opportunity to use sound science and more modern research techniques to develop data to support a new or revised criteria.

Epidemiological studies or MRAs need to address three fundamental issues in urban water bodies. These are (1) the level and frequency at which pathogenic bacteria,

[1] Lammerding AM and Paoli GM. 1997. Quantitative Risk Assessment: An Emerging Tool for Food Borne Pathogens. *Emerging Infectious Diseases* 3(4). Retrieved on July 2, 2007 from http://www.cdc.gov/ncidod/EID/vol3no4/lammer.htm.

parasites, and viruses are found when bacterial indicators (*E. coli*) are identified, (2) the risk associated with incidental contact (primary and secondary recreational activities) to waters that contain human pathogenic bacteria, and (3) the levels of bacterial indicator contamination that indicate excessive risk for incidental contact and full body immersion following contact recreation. Such information is necessary for criteria development and should be applicable to similar scenarios in the state and other subtropical regions throughout the country.

Microbial risk assessment and epidemiological studies for contact recreational use of Houston urban bayous require addressing a number of basic questions before work can begin. First, what are the route, dose, and frequency of exposure of humans to pathogens in urban water bodies following different types of contact recreation? Unfortunately, it is difficult and expensive to measure waterborne pathogens directly. Surrogate pathogen indicators are used instead (e.g. *E. coli* and *Enterococcus)*. One must also consider the following questions. What is the relationship between the level of surrogate pathogen indicator detected to actual levels of waterborne bacteria, parasites, and virus human pathogens in urban water bodies? According to a number of studies in this region and across the country, 50-90% of indicator bacteria present in flowing water bodies are of non-human origin.[2, 3, 4, 5, 6] Are waterborne pathogens of non-human origin as virulent as those from human sources, or do criteria need to consider differential levels between the two in calculating human health risk? Can one identify the levels of risk-associated exposure to water containing pathogenic bacteria, parasites, and/or viruses from various types of recreational contact? Can an excessive human health risk from such recreation be determined based on establishing threshold levels of pathogen contamination and/or indicator bacteria? Finally, based on the determined health risk, what are the most appropriate public policy and regulatory criteria for addressing the health risk to the Houston-Galveston areas human population?

Two broad classes of recreational activities influence the exposure and dose of human pathogens following contact with urban water bodies. These classes include primary contact and secondary contact recreation. Primary contact includes full body immersion (e.g. swimming and diving). Secondary contact involves incidental exposure, which may occur during wading, fishing, canoeing, or other similar activities. Each of these activities requires definition. For example, what does "swimming" mean exactly? Estimates of the volume of water ingested range from 16-100 milliliters (mL) per "swimming" event, depending on the age of the individual. Consequently, what is the appropriate volume to use in risk assessment? Exposure to pathogens under marine situations would be different from fresh water ones, temperate lake exposure different from that in urban

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[2] Houston-Galveston Area Council. 2007. Failing septic system initiative. Houston: Houston-Galveston Area Council.

[3] PBS & J. 2007. Contact recreation use attainability analysis pilot study for Mill Creek in Austin County, Texas: Houston-Galveston Area Council.

[4] University of Houston, PBS & J, Texas A & M University-Corpus Christi. 2005. Total maximum daily loads (TMDL) in fecal pathogen bacteria on Buffalo Bayou and White Oak Bayou. Final Report. Austin, Texas: Texas Commission on Environmental Quality.

[5] Southam G. 1998. Source tracking identifies origins of waterborne pathogens. Arizona Water Resource s Newsletter. Tucson, A Z: University of Northern Arizona.

[6] Clark ML and Gamper ME. 2000. A synoptic study of fecal-indicator bacteria in Wind River. Bighorn River, and Goose Creek Basins, Wyoming, June-July 2000. Water-Resources Report 03-4055. Cheyenne, WY: US Geographical Survey.

subtropical bayous, and exposure to flood waters different from ambient conditions. Volume of ingested water and level of pathogens therein determines the dose and level of exposure of individuals. Dose and virulence of the particular pathogen are related directly to the potential of the individual to become ill following ingestion during recreational activity. Additional studies are need to quantify the dose of the pathogens, and whether they are ingested, aspired, or inhaled, by humans following primary or secondary contact recreational activities in urban bayous.

No studies are available which quantify levels of ingestion for secondary contact recreational activities either. How much water does a person ingest while fishing or canoeing? A person's hands will certainly be exposed to the water while baiting a hook or paddling, since hands will most likely touch mouths or eyes during those activities. However, they certainly will ingest less water under these activities than from a full body emersion. Quantifying the exact amount of the pathogen-containing water ingested, aspired, or inhaled during different recreational activities is difficult. However, it is a necessary component in determining the acceptable human health risk from secondary recreational contact with urban water bodies. It is also a necessary component of water quality criteria development.

In order to perform valid epidemiology studies, cohort populations for primary contact, secondary contact, non-contact, and controls are needed. Large numbers of individuals (7,000-10,000) divided equally between test and control cohort populations must be screened. Urban water bodies do not attract the large numbers of persons for contact recreation that lakes or beaches do. Preliminary surveys in this region at 10 sites along five major bayous indicate 212 swimmers were observed by survey respondents per summer season (June–August).[7] Thus, it may take 12 to 15 years to identify enough individuals in this category (2,500–3,500) to conduct a valid epidemiological study. According to this survey, the number of secondary contact recreators observed during a summer season was 1,287, which would require 2 – 3 years to complete an epidemiology study. Non-contact individuals would be much easier to find based on the estimate of 8,952 per summer season. Current epidemiological studies of urban water bodies in Chicago indicate 10,000 persons may need to be surveyed to obtain adequate numbers of individuals exposed to waterborne pathogens during contact recreational contact to conduct epidemiology studies.

Risk based epidemiological studies (MRAs) may offer the best opportunity for producing the type of data needed to set appropriate standards for urban water bodies. An MRA could use one of two types of epidemiological models, static and dynamic. The static model was developed to assess human health risk following exposure to chemicals. The dynamic model was developed to examine risk associated with infectious disease. While dynamic model studies are the most definitive means of assessing human risk, they are more costly. If a static model could yield the same level of data discrimination, cost-benefit analysis dictates its use. In certain scenarios, the two models are interchangeable,

[7] PBS & J. 2007. Contact Recreation Survey of Five Urban Bayous in Harris County, Texas. Houston: Houston-Galveston Area Council.

provided certain requirements are met. Unfortunately, urban water bodies do meet two of the three the criteria necessary for substituting the static model for the dynamic one. Urban water bodies do not have a zero rate of background illness/disease because of the prevalence of foodborne gastroenteritis in urban environments. The incidence of foodborne gastroenteritis is approximately 47/1000 persons in the United States,[8] which exceeds the EPA Criteria for waterborne illness of 8/1000. Thus, it would be very difficult to determine illness using the same endpoint, gastroenteritis, related to contact recreation in urban bayous because of the much higher rate/risk of illness associated with foodborne human pathogens. Additionally, the City of Houston Health and Human Services Department has no documented cases of gastroenteritis illness associated with contact recreation in Houston urban bayous in the past seven years (the time it began collecting the data) indicating apparent low risk to the human population. Further, the duration of infection and disease, in this case gastroenteritis, does not approach zero, as required for use of the static model. Rather is measured in days of illness. These two findings preclude use of the static model in urban environments in development of the most accurate level of risk associated with contact recreation.

Little data exists from preexisting studies for a number of parameters required for the conduct of the dynamic MRA. These include characterization of the Houston-Galveston region and its water bodies (28,000 miles of streams, bayous, creeks, drainage channels and ditches, etc.), destination distance, type of contact recreation activity (primary or secondary), frequency and duration of exposure, time of activity, exposure (contact recreation activity) to pathogens related to dose, age and susceptibility of participant, type of pathogen in urban water body, and incidence of gastroenteritis (background) among others. These data must be collected before the MRA can be conducted.

Additional factors considered when conducting a risk assessment include high flow issues, the need for an Institutional Review Board, non-human sources of bacteria, and the inability of urban bayous to meet water quality criteria as currently promulgated. High flow in water bodies alters the level of bacteria present. In urban settings in the Gulf Coast region, individuals, especially children, are likely to be exposed to urban water bodies under flood conditions. Swimming is unlikely, though not precluded. Many children enjoy splashing and playing in floodwaters contaminated by bacteria. Because the Criteria data came from large lakes, high flow was not addressed. It is an important consideration for development of new criteria for contact recreational activity. A recently completed H-GAC pilot study along Mill Creek in Austin County shows a 10-fold increase in pathogen indicator species (*E. coli*) after 10 days of rain.[9] These levels (approximately 3,000 vs. 300 MPN/100 mL) held true even in portions of the Creek where wastewater treatment plants (WWTP) did not exist; areas were bounded by natural areas and ranch land. Non-human rather than human fecal material is most likely the source of this increased indicator species load.

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[8] Mead P, Slutsker L, Dietz V, McCaig L, Bresee J, Shapiro C, Griffin P, and Tauxe R. 1999. Food-Related Illness and Death in the United States. *Emerging Infectious Disease*. Atlanta, GA: Centers for Disease Control and Prevention. Retrieved on May 29, 2007 from http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm.

[9] PBS & J. 2007. Contact Recreation Use Attainability Analysis Pilot Study for Mill Creek in Austin County, Texas. Houston: Houston-Galveston Area Council.

An Institutional Review Board, not required in the 1986 USEPA studies, must be included in the new study design and conduct. This is to protect the privacy of individual medical records required in determining risk in the population. This necessary and valuable process is time consuming and adds additional cost to the MRA.

Studies conducted over the past few years in a number of locations across the country show that the preponderance of surrogate pathogen indicators in water bodies (*E. coli* and Enterococcus) are of non-human origin. Species identified include dogs, cats, chickens, goats, cattle, wildlife, birds, and waterfowl. In December 2006, USEPA stated, "States and Territories must apply the *E. coli* and *Enterococcus* criteria to all coastal recreation waters. If, however, sanitary surveys and epidemiological studies show the sources of indicator bacteria to be non-human and the indicator densities do not indicate human health risk, then it is reasonable for the State of Territory not to consider those sources of fecal contamination in determining whether the standard is being attained. This is the approach taken in the 1986 bacteria criteria document. It would be reasonable for a State or Territory to use existing epidemiological studies rather than conduct new or independent epidemiological studies for every water body if it is scientifically appropriate to do so."[10] This indicates that states need to take into consideration the contribution of non-human pathogen indicator species to indicator level, as well as health risk associated to them in preparing criteria. Such information needs to be developed for the region. A secondary question arises in that the correlation between the level of pathogen indicator and actual pathogens present in water bodies (bacteria, parasites, and viruses) has not been established. Additional work is required.

The question of recreational contact use standard, primary vs. secondary, is also an important consideration in developing the new criteria. Approximately 2.85 million persons live within a quarter mile of the Houston area's 2,800 miles of urban water bodies.[11] By most accounts in urban environments, swimming and other primary routes of exposure are exceptions to the recreation use rule. If they do occur, it is a few individuals rather than a "beach-sized crowd." Secondary recreational activity that includes fishing, canoeing, and adult wading is more common. Criteria written for secondary contact would have more utility. Because of the dissimilarity in volume of water ingested, aspired, or inhaled between primary and secondary exposure, a different criteria for secondary exposure in urban bayous is needed. The distinct lack of data available for critical factors associated with secondary recreational contact in water bodies in an urban setting must be developed to set scientifically sound new criteria. It is interesting to note that although 2.8 million persons live within one-quarter mile of the 2,840 miles of Harris County water bodies, the City of Houston Health and Human Services Department has no apparent record of illness associated with recreational contact to urban water bodies in the past 15 years. According to preliminary results from a pilot telephone survey by H-GAC, potentially 200,000 persons have been exposed to waterborne pathogens through primary (swimming) contact in five urban watersheds. Studies performed by the Association of Metropolitan Sewerage agencies, under Sanitary

[10] USEPA. 2006.

[11] Houston-Galveston Area Council. 2007. 2035 H-GAC Forecast Program.

Sewer Overflow (SSO) water conditions, show the median infection estimate to be 1 illness in 10,000 exposures,[12] or 208 persons in Houston annually in a worst-case scenario. This draws into question developing a criteria based on a theoretical risk of illness to humans, when in actuality none may exist or if it does exist, it may be very low.

The USEPA 2003 Guidance document acknowledges, "animal fecal inputs and impairment of waters due to animals may be a health risk with pathogens such as *Campylobacter, E. coli 0157H7, Salmonella, Cryptosporidium,* and *Giardia,* which can originate from animals as well as humans and cause illness in humans."[13] H-GAC recently completed pilot studies on Mill Creek, the least impacted of any water body in the Houston-Galveston region. The area is primarily rangeland and natural areas, with a few small WWTPs. The East Fork of Mill Creek has no WWTP outfalls at all. Samples on both Forks and Main stem of Mill Creek exceeded Texas Surface Water Quality Standards for *E. coli* of 126 MPN/100 mL by two to four-fold under normal flow conditions. Under high flow conditions, exceedence was 25 fold. Thus, background levels of naturally occurring non-human species indicator bacteria exceed limits without significant human contribution. Put another way, even if all wastewater plants were eliminated from the Houston-Galveston area, the region's water bodies may not meet current united States Environmental Protection Agency (US EPA) Ambient Water Quality Criteria for Bacteria – 1986 (Criteria) for contact recreation in urban bayous. The Houston-Galveston area, located on a major flyway, with abundant wildlife, waterfowl, and family pets will be hard pressed to design practices to contain these sources of waterborne pathogens to allow for contact recreation in urban water bodies according to proposed new criteria. Without associated significant human health risk from exposure to waterborne pathogens following contact recreation, the human health benefit of the criteria is difficult to determine.

Recommendations are proposed to address the need for adequate water quality criteria, the area water body's inherent inability to meet those criteria, and the apparent very low risk of illness to the human population following contact recreation with urban water bodies. These include use of a microbial risk assessment with dynamic model, uniform definitions for primary and secondary contact recreation, separate criteria for secondary contact recreation, correlation of human pathogen levels with indicator species levels, determination of illness rate from most prevalent waterborne pathogens in subtropical urban bayous, encouragement of communication and planning between stakeholders on a national level, and adoption of the World Health Organization (WHO) approach for setting water quality criteria.

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[12] Association of Metropolitan Sewerage Agencies. 2004. *Characterization of the Potential Adverse Human Health Effects Associated with Combined Sewer Overflows and Sanitary Sewer Overflows – Limitations of AMSA Technical Memorandum.* Oakland, CA: EOA, Inc.

[13] Environmental Protection Agency. 2003. EPA 2003 Draft Guidance Document. 69 FR 67217, November 16, 2004, Section 3.4.1.

History: EPA Water Quality Standard - 1986

EPA's Ambient Water Quality Criteria for Bacteria – 1986 (Criteria)[14] establishes criterion for the upper limits for densities of indicator bacteria (*Enterococcus* spp. or *E. coli*) at swimming beaches. The basis for the Criteria are epidemiological studies conducted in the 1970s and 1980s.[15, 16, 17] One of the co-authors of the studies, V. J. Cabelli, states, "This criterion is based on the quantifiable relationship between the density of an indicator in the water and the potential human health risks involved in the water's recreational use."[18] The criterion is the subject of extensive review and criticism because of flaws in study design, data collection, and analysis, thought to affect the value of the criteria for protecting public health.

The Criteria uses a small set of site-specific static model epidemiology studies performed from 1973 through 1982 at a limited number of fresh and marine water beaches. *E. coli*, *Enterococcus*, fecal coliform, and total coliform geometric mean density levels, were determined. For the freshwater criteria, data were collected during the summers of 1979 and 1980 at two beaches on Lake Erie and at two beaches on Keystone Lake, a large lake in Oklahoma. A "polluted" freshwater beach (*E. coli* geometric mean density ranging from 47 to 236) was paired with a non-polluted beach (*E. coli* geometric mean density ranging from 23 to 137) in each lake. Density was calculated from culturing fecal bacterial indicators, *Enterococcus* spp., or *E coli.* The "polluted" beach was within an unspecified distance from a point source, with discharge volume unknown. Swimmer, non-human, or other non-point sources of pathogen contamination were not considered. Additional data were collected in 1982 at the polluted beach on Lake Erie.

Gastroenteritis illness was assessed in swimmers and non-swimmers at the beach (neither category nor criteria specifically defined). Results relied on self-reporting without medical verification, increases the potential bias as does media reports about the study. A control, persons who did not swim and did not go to the beach, was not included. Neither sanitary survey nor epidemiological surveillance was conducted as part of the monitoring program. Confounders (e.g. food and drink, age, sex, history of certain diseases, drug use, personal contact, additional bathing, sun socioeconomic factors, etc.) were not controlled. Gastroenteritis was self-determined and covered a period up to seven days after the swimming event. The incidence of gastroenteritis for swimmers was statistically significantly elevated above that for non-swimmers (P=<0.05) in only two of nine

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[14] Environmental Protection Agency. 1986. Ambient Water Quality Criteria for Bacteria – 1986. U.S. Environmental Protection Agency, EPA-440/5-84-002. Cincinnati, OH.

[15] Cabelli V, Dufours A, Levin M, Habemann P. 1976. The Impact of Pollution on Marine Bathing Beaches: An Epidemiological Study. Middle Atlantic Continental Shelf and the New York Bigh: Proceedings of the Symposium, American Society of Limnology and Oceanographers, 3-5 November 1975. New York, NY and Lawrence KS: American Society of Limnology and Oceanography: 424-432.

[16] Cabelli VJ, Dufour AP, Levin MA, McCabe LJ, Habermann PW. 1978. Relationship of Microbial Indicators to Health Effects of Marine Bathing Beaches. *Am. J. Public Health.* 69(7):690-696.

[17] Cabelli VJ, Dufour AP, McCabe LJ, Levin MA. 1982. Swimming Associated Gastroenteritis and Water Quality. *American Journal of Epidemiology*. 115(4)606-616.

[18] Cabelli V J. 1983. Health Effects Criterion for Marine Recreational Waters. U.S. Environmental Protection Agency, EPA-600/1-80-031. Cincinnati, OH.

sampling events (22%). These two events formed the basis for development of the criteria using regression analysis. Interestingly, after plotting data for swimmers and non-swimmers, the rates both had a correlation of 0.67, indicating that exposure to contaminated lake water through contact recreation was not necessarily a factor in the illness observed. Data reported for certain study populations) e.g. limited age groups or regions with certain endemicities) are *a priori* not transferable to populations with other characteristics who recreate near the water.

A companion study was performed for marine beaches in New York City (1973, 1974, and 1975), Lake Ponchartrain (1977 and 1978), and Boston Harbor (1978). The incidence of gastroenteritis for swimmers was significantly elevated above that for non-swimmers ($P < 0.05$) in seven (7) of eighteen (18) sampling events (38%). These seven events formed the basis for development of the criteria.

Based on this set of studies, the acceptable swimming associated gastroenteritis (illness) rate is 8/1000 swimmers for freshwater and 19/1000 for marine water, which translates into a steady state geometric mean indicator density of 126 and 35 CFU per 100 mL respectively, for *E. coli* and *Enterococcus* spp. as indicator organisms. Because of these studies, the USEPA recommended the establishment of *E. coli* and *Enteroccocus* spp. as the preferred indicator organisms.

In 2000, USEPA proposed a guidance plan for implementation of their ambient water quality criteria based on the 1986 document and its underlying data for swimming contact at beaches, broadening its application for the protection of human health relative to other types of water bodies and other types of recreational contact. Authority was based on the Beaches Environmental Assessment and Coastal Health Act of 2000 (BEACH Act), an amendment to the Clean Water Act. A draft USEPA Guidance document was issued in 2003, and promulgated in 2004 (69 FR 67217, November 16, 2004). These criteria were to maintain the same level of protection to the human population afforded under the Criteria. In response, TCEQ, then called Texas Natural Resource Conservation Commission (TNRCC), also began the process of re-evaluating the Texas criteria.

Review: USEPA Water Quality Criteria for Bacteria-1986 (Criteria)

The Criteria was reviewed by a number of groups, including the USEPA, in preparation for development of new criteria to establish an acceptable incidence of illness/disease associated with exposure to pathogen containing water bodies during various forms of contact recreation. From the beginning, the criteria have been criticized by reviewers with concerns over the study design, quality, and quantity of data, and method of statistical analysis. Many reviews, including those chosen by USEPA, judge the criteria inadequate or flawed by scientific standards and offer a variety of suggestions and proposed research necessary to protect the public's health adequately. A collection of the most recent and broadly based reviews is summarized on the following pages.

USEPA External Peer Review of Standard

In 2003, EPA charged three statistical analysis experts in microbiology and epidemiology to examine the 1986 Water Quality Criteria. Drs. Joseph Eisenberg, Charles McGee, and Mark Sobsey were asked to address "major issues associated with the approach used to determine the appropriate risk level range for recreational users of water bodies." Their review addresses the following questions: (1) "Given the constraints of the data available, is the risk analysis in *Implementation Guidance for Ambient Water Quality Criteria for Bacteria* appropriate, (2) is it scientifically defensible to extrapolate the relationship (in terms of linear regression or other quantitative means) between bacterial indicator density and illness rate for fresh waters beyond the 1% risk level, and (3) how much further could one extrapolate and what would be the rationale for extrapolating further?"[19] Comments can be divided into concerns about the limitations of quantity and quality of data and analysis approach and execution.

Limits of Quantity and Quality of Data

- "The question was whether water quality variations (temporal and spatial) can be explained by systematic patterns or is variability simply the result of random error." (Data may "not provide reliable national estimates of the relationships between human exposures to pathogens….")
- Bias in data collection and data analysis is not taken into account. For example, the few study sites "do not adequately represent some other sources of fecal contamination that can impact bathing water and carry pathogens, such as non-point sources of human fecal contamination … or non-human fecal contamination sources, such as waterfowl and animal agricultural waste."
- "Non-control for confounders (e.g. food and drink intake, age, sex, history of certain diseases, drug use, personal contact, additional bathing, sun, socio-economic factors) may influence the observed association."

Flawed Analyses of the Microbial Data

The EPA Peer review group indicates the "analysis of the microbial data is limited and probably flawed."

- Use of geometric mean for estimating dose exposure may not be appropriate because it may underestimate the average level of exposure. The arithmetic mean might be a better choice because it provides an average exposure over time.
- Variability and uncertainty of data makes the extrapolation of the relationship between bacterial indicator density and illness rate beyond the 1% risk level scientifically indefensible.
- One cannot estimate a cut-off using higher doses without also measuring both highly infectious organisms and less infectious organisms, which was not done in this study.
- Only one simple log-linear regression model was used as opposed to regression multivariate analysis methods. Statistical tests, which allow for use of the log 10

[19] Versar Inc. 2004. Comments Summary Report: External Peer Review of EPA Analysis of Epidemiological Data from EPA Bacteriological Studies. Washington D.C.: Environmental Protection Agency.

distribution, were not conducted. Bootstrapping or a Monte Carlo style approach might have mitigated the situation if log-normality was violated.

In summary, EPA's three statistical experts indicate the Criteria are scientifically flawed in the areas of quality and quantity of data, study design, and analysis of results.

Chicago Waterway System

As is the case with many water bodies in urban environments, swimming and other primary routes of exposure are exceptions to the recreation use rule. Persons rarely swim in urban rivers, bayous, or streams, and if they do, it is a few individuals rather than a "beach-sized crowd." Secondary use, including fishing, canoeing, and adult wading, is more common.[20] However, access to the water bodies is often limited in urban settings decreasing the number of persons exposed. This could result in a low number of cases of illness being reported to urban health departments.

Urban waterways, such as the water system in Chicago, are generally classified as secondary recreational contact water bodies. The Illinois Environmental Protection Agency (IEPA) is conducting a Use Attainability Analysis (UAA) to determine the feasibility of reclassifying the Chicago Area Waterways for primary contact recreation, which would require development of more stringent water quality standards along the line of the proposed changes in Criteria. In 2006, The Metropolitan Water Reclamation District of Greater Chicago, Research and Development Department commissioned an expert review committee to address the utility of the USEPA's Criteria and 2003 Guidance to secondary contact recreation in urban water bodies.[21] Concerns were focused primarily on the study design and lack of data to address critical factors associated with secondary recreational contact in water bodies in an urban setting.

USEPA Study-Based Concerns

- USEPA sites for freshwater were large lakes. The applicability of these data to urban bayous, rivers, and streams remains to be determined. Substantial differences between lakes and urban bayous exist when one considers sedimentation, re-suspension, use by bathers, potential source contamination, agricultural runoff, and urban runoff. These factors will affect risk levels in the human population.
- Site specific data collected in the USEPA studies have limited utility because of the geographical separation of the sites (fresh water - Oklahoma and Ohio, salt water - Lake Ponchartrain, Boston Harbor, and New York City) and the different time periods (seasons and years), which introduce high variability.

[20] Secondary contact recreation is defined as incidental contact where the probability of ingesting appreciable quantities of water is minimal. Examples include fishing, commercial and recreational boating, canoeing, kayaking, wading by adults, and limited body contact associated to shoreline activity. The risk level for secondary contact recreation is 14-15 illnesses per 1000 swimmers, which is 5 times the primary geometric mean (630 colonies per 100 mL) for primary contact.

[21] Metropolitan Water Reclamation District of Greater Chicago. 2006. Expert Review Report Regarding United States Environmental Protection Agency's Water Criteria for Bacteria -1986: Application to Secondary Contact Recreation. 2006-38. Chicago, IL. Metropolitan Water Reclamation District of Greater Chicago.

- USEPA studies did not use a control group, individuals who did not visit the beach. Additionally, confounding factors (e.g. age, gender, health status, race, economic status, and nutrition) were not considered.
- Eye, skin, respiratory, eye or ear infection routes were not considered.
- No attempt was made to quantify the actual level of exposure (i.e. length of time in the water, extent of contact with the water, amount of water ingested) in the USEPA studies, which make extrapolation of the standard to secondary contact problematic. The relationship between indicator organism and specific pathogen is very likely to be different in urban streams as opposed to a lake beach setting.
- Criteria for fresh water are base on data from only two of nine sampling events.
- Use of an "un-weighted log-linear regression to fit the epidemiology studies was not the most appropriate statistical model. The log-logistic model produces a better fit, and additionally there is a possible non-linearity in response, which is difficult to test with the small number of data points."
- Virtually no scientific data are available that characterize secondary contact to use as a base for criteria for secondary contact recreation exposure, either in freshwater or marine situations.

Criteria-Based Concerns

- "The USEPA 1986 criteria are not risk based but rather are based on a small set of site specific epidemiology studies that are conducted at bathing beaches."[22]
- USEPA has not developed a microbial risk assessment based approach to setting the recreational water quality criteria. Reliance on epidemiological studies alone assumes "similarity of use and exposure scenarios, and water quality and environmental conditions." Water quality and environmental conditions are not the same in subtropical urban environments as they are in the cold water Great Lakes.
- Concentrations of *Enterococcus* spp. and *E. coli* form the basis of the bacteria standards. These do not differentiate between human, non-human, and environmental (e.g. soil, water, sand, plants) sources of bacteria. It is noteworthy that this is the same criticism used to replace the old total coliform and fecal coliform indicators in an earlier USEPA criterion.[23] Whether or not these are, the correct indicator species for determining human health risk remains to be determined.
- The standard relies on the hypothesis that there exists an approximate trend for human-source pathogens such that the presence of a higher-level indicator species correlates with a higher level of pathogens in urban bayous. This hypothesis has yet to be tested and validated.
- The USEPA criteria rely on a hypothesis that a five-fold increase in gastroenteritis over the primary contact guidelines is an acceptable level of human health risk for secondary exposure in an urban setting. There is no scientific basis for this factor in the original USEPA study or justification for extrapolating primary contact data to secondary contact situations. Further investigation is required.

[22] IBID
[23] IBID

- There is inconsistency between the USEPA 2004 guidance document and the U AA Stakeholder Advisory Committee (SAC) identifying kayaking as primary or secondary contact recreation.
- The primary contact USEPA statistical model is not directly applicable to secondary contact water quality standards, a fact "acknowledged by USEPA in their 2003 Guidance document (Pages 40-41)."[24]
- The USEPA 2003 Guidance document acknowledges, "animal fecal inputs and impairment of waters due to animals may be a health risk with pathogens such as *Campylobacter, E. coli 0157H7, Salmonella, Cryptosporidium* and *Giardia*, which can originate from animals as well as humans and cause illness in humans." If the indicator bacteria come from animals, the risk to human health as indicated by human illness will be much lower.

Association of Metropolitan Sewerage Agencies

The Association of Metropolitan Sewerage Agencies (AMSA) also reviewed USEPA's proposed rule for Water Quality Standards (July 9, 2004; 69 Fed. Reg. 41720).[25] The AMSA questions the validity of the Criteria because of scientific flaws in the original studies and the lack of subsequent studies to confirm the criteria. Additional comments include the lack of guidance and EPA-test methods that hamper criteria implementation, USEPA's interpretation of "Single Sample Maximum (SSM)," application in Combined Sewer Overflow (CSO) impacted waters, applicability to new dischargers to relocated discharge outfalls, and economic impact analysis deficiencies. Comments are as follows.

Scientific Validity Concerns.
AMSA highlights concerns for the narrow testing periods and limited testing sites in the original study. None of the data in the 1986 report has been confirmed by additional studies in the ensuing 20 years. There are also concerns for the study design biasing the results. Although nine testing periods were used for data collection only two (22%) showed a statistically different illness rate between swimmers and non-swimmers. All illness was self-diagnosed with the possibility that all incidences of illness came form the same family unit. Finally, the study does not consider non-human sources of bacteria contamination. Technology has advanced to the point where it is possible and economically feasible to determine bacterial source. New studies and research are recommended using up-to-date methods. While statutory deadlines for the BEACH Act do not allow extensive testing, new standards should be as "careful and responsible" as possible given the limitations of the data upon which the Criteria are based.

Single Sample Maximum.
How will Single Sample Maximum be defined? One possible interpretation is that it is a single value never to be exceeded. AMSA disagrees with this interpretation, as it is inconsistent with other USEPA guidance, including the 1986 criteria, which uses geometric mean. Part of AMSA's concern is based on the inherent difficulty in the nature

[24] IBID
[25] Kirk K. 2004. Letter with Comments to Water Quality Standards for Coastal and Great Lakes Recreation Waters. August 9. Cleveland, OH. Association of Metropolitan Sewerage Agencies.

of bacteria sampling, detection, and enumeration, which can vary greatly from one single sample to another. The BEACH Act requires that new promulgated criteria be "as protective of human health" as the 1986 criteria. The 1986 criteria document itself states the following, "…it is the long term geometric mean bacterial density that is of interest. Because day-to-day fluctuation around this mean, a decision based on a single sample (or even several samples) may be erroneous, i.e. the [single] sample may exceed the recommended mean criteria even though long-term geometric mean is protective, or may fall below the maximum even if this mean is in the non-protective range."[26]

American Society for Microbiology

In 2004, USEPA requested comment from the American Society of Microbiology (ASM) on the USEPA's proposed rule for protecting human health based on the Criteria. ASM is the "largest single life science society with more than 42,000 members including scientists in academic, industrial, clinical, and government institutions, working in areas related to basic and applied research, the prevention, and treatment of infectious diseases, laboratory and diagnostic medicine, the environment, and water, and food safety."[27]

The organization believes "serious human health risks can arise from exposure to fecal contamination in recreational waters." It encourages the USEPA to "fully evaluate relationships between indicator species and health risks, and to incorporate a more complete understanding of indicator species ecology, microbial source tracking and sample statistics to provide adequate public health safety in coastal and Great Lakes recreational waters." ASM identifies seven specific issues with the proposed rule as follows:

- Acceptable levels of risk are determined for gastroenteritis only and should be expanded to include other diseases associated with exposure to pathogen-contaminated water during recreational activities.
- A limited number of bacterial indicator species determines human health risk. Their ecological behavior is not fully elucidated, which may confound predictions of illness risk. Other indicators such as bacteriophages might be more reliable.
- Pathogens are associated with waterborne disease, yet there is no specific monitoring protocol for the pathogens. Risk of illness from waterborne pathogens is dependent on "type of contact, exposure time, pathogen concentrations in contaminated water, pathogen survival in receiving waters, and pathogen transport from source to contact point, and the level of the individual or population susceptibility to waterborne pathogens." These factors are not considered in the original USEPA studies in the 1970s and 1980s.
- Pathogen distribution and dynamics associated with disease are not considered. Source contamination variations can be considerable, for example, "combined sewer overflows … seasonal variation in sewage discharge disinfection, pathogen

[26] EPA 1986, pg. 9.

[27] Berkelman R. 2004. Letter to Water Quality Standards for Coastal and Great Lakes Recreation Waters, Proposed Rule. August 2, 2004. American Society for Microbiology. Retrieved on July 2, 2007 from http://www.asm.org/Policy/index.asp?bid=29781.

accumulation in sediment and sands," rainfall events, flooding, and non-human sources. Consider all factors in determining the most appropriate strategies and use of available funds.

- More appropriate statistical models are available than geometric mean and soft system methodology (SSM), which thinks the term 'the problem' as inappropriate because it might narrow the view of the situation.
- Use of arithmetic mean is a "more accepted practice in other areas of applied public health microbiology." Sampling frequency, data analysis, and management factors using this statistical analysis would "determine the most appropriate parameter(s) for use in establishing acceptable or unacceptable levels of fecal contamination."
- Addressing contamination from non-human sources of fecal pathogen contamination is necessary for sound regulation, requiring microbial source tracking and species identification, especially between wild, domestic and agricultural sources. Exclusion or exemption may not be advisable because, for example, "wildlife, such as waterfowl harbor known human-source pathogens *Salmonella* spp. and *Campylobacter* spp. In urban water bodies, where significant microbial contamination comes from non-human sources, their exclusion from the criteria may leave the human population at substantial risk for illness related to exposure to waterborne pathogens.
- Microbiological methods, which require 24 hours to complete could result in regulatory action after the particular situation has abated, e.g. rainfall events. "Rapid microbial methods, use of rainfall data, and other management tools (e.g. other geohydrographical data) may act as predictive tools for making management decisions about beaches."

Harris County, Texas

The TCEQ proposed revisions of the Texas Surface Water Quality Standards, 30 TAC Chapter 307. In 2006, the Harris County Attorney supplied written comments on behalf of Harris County Public Health and Environmental Services – Environmental Public Health Division, Harris County Storm Water Quality Section, and Harris County Flood Control District.[28] Harris County contains approximately 1,500 water bodies totaling approximately 2,840 miles in length. These water bodies are diverse in character ranging from Barker Reservoir to the Houston Ship Channel to the Galveston Bay Estuary. Harris County has a population of nearly 3.5 million persons. The Harris County comments address include standard-specific and site-specific concerns about the applicability of the standard to Harris County.

General Criteria. Many different factors are present in the Houston area, which make a "one size fits all standard" difficult to apply. Water quality in the Harris County area is affected by a flat topography that allows for little aeration of surface water, hydrology that includes major seasonal flooding, slow flow in the drainage conduits, a large

[28] Patel SR. 2006. Letter to Ms. Sidney Tiemann, Texas Commission on Environmental Quality. Preliminary Comments for Review and Revision of the Texas Surface Water Quality Standards 30 TAC Chapter 307. Harris County Attorney's Office. March 1, 2006.

population of resident and migratory birds that introduce bacteria into waterways, and subtropical climate.

Use Activity Baseline. Baseline use is determined as the use of the water body on or after November 25, 1975. Evidence as to the designated use on or about that date may be difficult to ascertain due to background or other conditions. While this is an admirable goal, it may not be feasible. Developing arbitrary "presumed uses," without study and analysis, is not supportable methodology.

Site-Specific Standards. Harris County supports site-specific standards, which account for differing conditions within its jurisdiction. This involves a use attainability analysis to evaluate how the surface water is used, if it is an existing use, natural background levels of microbial contaminants, hydrological and environmental parameters, and "uncontrollable" conditions. Otherwise, standards might be implemented, which may not improve water conditions or attain the "use" desired. TCEQ itself indicates that "Site-specific criteria do not apply to those instances in which surface waters exceed criteria due to natural phenomena, including seasonal changes (30 TAC 307.7[a])."

Site-Specific Uses and Criteria. A subtropical water body is one where "non-pathogenic strains of fecal coliform and *E. coli* are almost universally present, without direct association with human-source pathogens found in cooler waters in other regions of the State and throughout the United States. Non-pathogenic strains of indicators organisms (*E. coli*) are nearly ubiquitous (in subtropical regions), and are subject to re-growth in the natural environment. There does not appear to be a good relationship between the presence of pathogens and the presence of indicator organisms in those conditions." An indicator species, which more closely reflects the presence of human-source pathogen, is needed to identify the actual threat to public health.

Site-Specific Uses and Criteria for Classified Streams.

Harris County believes the criteria of 126 colonies/100 mL for *E. coli* is not applicable in this area. There is no epidemiology evidence of a public health threat in the County or City of Houston. Scientific evidence and local conditions supports a high level of non-pathogenic strains of indicator *E. coli*, which may result in a level of *E. coli* unrelated to human-source pathogen load and human health risk.[29]

USEPA – Experts Scientific Workshop 2007

Many scientific advances have occurred since the Criteria were completed in 1986, particularly in the areas of "molecular biology, microbiology, and analytical chemistry. (US)EPA believes that these new scientific and technical advances need to be factored into the development of new or revised Clean Water Act (CWA) Section 304(a) criteria for recreation."[30] Towards these ends, USEPA "convened a panel of 43 national and

[29] IBID

[30] United States Environmental Protection Agency. 2007. Report of the Expert Scientific Workshop on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria. Washington DC: United Stats Environmental Protection Agency.

international experts in the scientific, technical, and implementation from academia, numerous states, public interest groups, USEPA, and other federal agencies, at a formal workshop to discuss the state of science on recreational water quality research and implementation. The purpose of the workshop was for (US)EPA to obtain input … on the 'critical path' research and science needs for developing scientifically defensible new or revised CWA §304(a) recreational ambient water quality criteria (AWQC) in the near future."[31]

Evaluation of the Criteria includes the following concerns:

- Illness rate of 0.8% in swimmers exposed in fresh water and 1.9%^ in swimming exposed in marine waters are only "approximate" and the EPA based the 1986 values on these approximations.
- The single sample maximum criteria are based on single observations, which are very difficult because of the expected variability of fecal indicators.
- States are concerned that Criteria are not appropriate or representative of all U. S. water bodies. Tropical waters may be very different from temperate waters.
- Appropriate levels of indicators may differ in waters where human fecal waste is predominating to animal/avian waste or vice versa.
- "Lack of clear, timely, and flexible guidance use of the single sample maximum values and differing risk levels.
- No EPA-approved analytical methods for use in waste water for the indicator bacteria.
- Lack of data to assess correctly the applicability of the 1986 criteria to flowing waters.
- Lack of data to quantify the risk associated with contributions from nonhuman sources of fecal contamination as well as lack of flexibility to adjust the criteria for water bodies that do not receive human sources of fecal contamination."[32]
- Secondary contact recreational uses are not addressed.

Modifications to Criteria Needed. Workshop attendees determined that the USEPA 1986 Criteria might be applicable in the development of the new USEPA criteria if the following are taken into consideration.

- "Address the difference between tropical and temperate waters
- Use additional base indicators and methods of assessing health risks to correlate occurrence with rates of illness form epidemiological or microbial risk assessment studies.
- Specification of appropriate indicator/methods combination for the various water bodies.
- More timely methods for beach monitoring and water quality notification.

[31] IBID.
[32] IBID.

- Risk threshold must be health-based and derived from available epidemiological data.
- If a single sample criteria is used, it should account for the expected frequency of exceedence
- Risk assessment should be sensitive to subpopulations (e.g. children)
- Risk of illness should be the same for all swimmers in all types of water bodies (marine, fresh, temperate, tropical, etc.) exposed to fecal contamination point or non-point in origin), rather than the current Criteria, which is different for fresh and marine water bodies.
- A more accurate descriptor of what constitutes secondary contact needs to be developed.
- Health risks for secondary contact recreation in water bodies (limited, but defined levels of contact and/or incidental exposure) should be determined
- Health risk assessment for secondary contact recreation exposure can be determined by quantitative microbial risk assessment or epidemiological studies."
- USEPA should approve state criteria if they are scientifically defensible and protective the designated use."

Consensus

Comments addressed toward the Ambient Water Quality Criteria for Bacteria – 1986 are unanimous in concerns about lack of control, study design that introduces bias in test subject population, biased statistical analysis, localized results, and limited quantity of data. Additional concerns include lack of consideration of background levels of pathogens, relationship/correlation of indicator species to human-source pathogens, subtropical climate differences, water body type, hydrology, non-human sources of pathogens and/or background microbes.

Microbial Risk Assessment Models

Two models currently predominate in Microbial Risk Assessment (MRA), static and dynamic. Based on the chemical risk assessment technique, static risk assessment is focuses on the individual and assumes a single exposure event to the pathogen. The dynamic model is population based, includes secondary exposure, and incorporates infectious disease parameters.

The Environmental Research Foundation (WERF) conducted an evaluation of MRA techniques and applications in 2004.[33] "This investigation evaluates methodologies used for microbial risk assessment (MRA) with respect to their applicability for reclaimed water uses," with the intent to "refine and/or extend the most appropriate techniques

[33] Water Environment Research Foundation (WERF). 2004. Evaluation of Microbial Risk Assessment Techniques and Applications. Alexandria, VA: Water Environment Federation. 164 pages.

and/or models" as predictive tools. [34] It has five major components: literature collection, categorization, and review; risk assessment model identification; model (static and dynamic) evaluation using simulations and case studies; three-state water reclamation regulation examination; and criteria identification for future computer interface to increase utility of the database. Although this study examines the risk to exposure to reclaimed water, conclusions are applicable to most water bodies, including urban ones.

Microbial Risk Assessment Literature Review

Development of the literature database included a review of 1,100 articles, abstracts, reports, and books, which were examined for pertinence, leaving 200 for classification and categorization.

Risk assessment techniques and two models (static and dynamic) were identified, which are generally used in estimating public health risk from exposure to waterborne pathogens via reclaimed water applications. The models, using either absolute or relative risk, are based on different perspectives of the complexity of scientific risk assessment. The static model focuses on individual risks using a format developed for chemical risk assessment. The dynamic model uses population risk as its endpoint, following the infections disease risk format, which includes a number of variables. The static model is most often used because it requires a more limited data, is less complicated and therefore easier to manage. This investigation attempts to "differentiate between the conditions under which the models predict similar and substantially different risk assessments." Numerical simulations (500,000) with three hypothetical scenarios follow. Exposure/pathogen combinations are identified through case studies where the less complicated static model can be utilized: risk of exposure from recreational impoundment (rotavirus), on a Golf Course (*Cryptosporidium* spp.*)* and in an agricultural reuse application (*E. coli* O157:H7).

Another aspect of the report examines landscape irrigation and reclamation regulations in Arizona, California, and Florida in a "constraint analysis to identify how risk assessment techniques may assist (or hinder) current and future regulatory issues related to reclaimed water." Finally, the investigation identifies criteria for a "user-friendly computer interface that will allow regulatory and/or municipal agencies/utilities to take advantage of the identified methodologies for microbial risk assessment."

The literature review covers publications in the field from the early 1980s through 2002. Online searches were conducted using Current Contents, Medline, Melvyl (University of California), Biosis, and ISI's Web of Science. The investigation provides an extensive bibliography and synopsis of over 200 articles, dividing them into the following categories: general risk analysis, overview/broad perspective, exposure models, water microbiology, predictive microbiology with quantitative microbial risk assessment, epidemiology studies, and quantitative microbial risk assessment (point estimates, distributions, and extension of standard techniques).

[34] IBID

Of the 200 articles found to be most pertinent, the “broadest level of distinction was between direct estimates of risk or illness using epidemiologic data and indirect estimates using models." Direct estimates require “collection of infection or disease outcome data, such as prospective studies or outbreak investigations, which might be categorized as actual risk. Indirect estimates utilize exposure data, which is put into a mathematical model to calculate risk." Most of the studies utilized an indirect or static model based on primary exposure used in classical chemical risk assessment. Only a few studies used the dynamic model, which incorporates secondary transmission, immunity, and population dynamics (e.g. infectivity) of pathogens within the environment. The dynamic model more closely approximates actual conditions in the environment, exposure to pathogens, and health outcome in the population than the static model.

Most articles do not discuss risk assessment methodologies from the standpoint of (1) “how risk assessment may be used for particular applications, (2) methods used to characterize water quality related to microbiological agents, or (3) the characterization of exposure.” However, taken as a body of information, it appears that “direct methods are best used to assess the public health impact associated with a specific and known (or identifiable) exposure pathway" under prescribed conditions (e.g. no background microbial contamination). The methods in most of these articles "do not provide regulatory and management information for making decisions regarding changes in environmental conditions" or exposure to a specific waterborne pathogens.

Model Development

This investigation evaluates the “applicability of microbial risk assessment (MRA) techniques identified during the literature review for estimating the public health risk from exposure to pathogenic microorganisms via reclaimed water application.” Two methodologies predominate, static and dynamic.

Based on the chemical risk assessment technique, static risk assessment is individually focused, and assumes a single exposure event to the pathogen. It uses direct exposure (environment-to-person), dose-response factors, assumes negligible potential for secondary transmission, and negligible immunity to infection. The static model has two epidemiological states: a susceptible state and an infected or diseased state. The assumption is that the susceptible individuals are exposed to pathogens from reclaimed water. The probability of infection or disease is a function of the quantitative dose of the pathogen, which is determined by (1) the concentration of pathogens at the exposure site, (2) the volume of water ingested, and (3) the number of organisms that can withstand the host’s local immune response. The “probability of infection is often multiplied by the number of exposed individuals to estimate the expected number of infected individuals for the exposure scenario under consideration.”

Dynamic risk assessment is based on the infectious disease risk assessment technique and population focused. It uses both direct and indirect (person-to-person) exposure and dose response function coupled with considerations for possible immunity, incubation, and

asymptomatic infection. The dynamic model is actually a group of epidemiological states, which include secondary (beta) factors. At any given time, only a portion of the population is susceptible, and only those susceptible to infection can become infected following exposure. The probability that a susceptible person moves into an exposed state is governed by the dose of the pathogen, infectivity of the pathogen, and the number of infected/diseased individuals with whom the person has come into contact. Thus, as in the static model, dose-response is an important function of the model. Individuals are considered infected if they are shedding pathogens in their feces and/or exhibit relevant clinical symptoms such as diarrhea, and/or vomiting.

The similarities between the two models include influence of concentration of pathogen(s), volume of water ingested, and dose-response parameters. The primary difference between the two is that the static model omits many of the properties unique to an infectious disease process: proportion of population exposed; frequency of exposure; duration of incubation, infectiousness, disease, and protection, probability of symptomatic response, person-to-person transmission potential, and background concentration level.

Model Evaluation

"The purpose of the model evaluation was to determine if conditions exist under which one model is more appropriate than the other in assessing the public health risk associated with exposure to pathogens from a reclaimed water source." The static model is easier to manage, but omits many parameters distinct to infectious diseases. The dynamic model is a more comprehensive mathematical characterization of risk than the static type, but it requires a considerable amount of data to complete the assessment. Under some scenarios, the static and dynamic models yield similar results, or the best of both models. These include (1) the background concentration of the pathogen in the population is zero or unimportant, (2) the duration of infection and disease approaches zero, and (3) infection and/or disease do not confer immunity or the duration of immunity approaches zero. This investigation set out to determine under which scenarios these factors could be met allowing the two models produce similar levels of public human health risk.

Model Evaluation Factors. To differentiate between those conditions under which the static model may be used, those under which the dynamic model may be use, or the conditions under which both models predict similar risk, over 500,000 simulations were performed. Both exposure-dependent factors (concentration of pathogen in water, volume of water ingested, proportion of the population exposed, and frequency of exposure), and pathogen-dependent factors (dose-response parameters; duration of incubation, infectiousness, disease, and protection; probability of symptomatic response, potential of person-to-person transmission, and background concentration level of pathogen in the environment) were examined for viruses (Enteroviruses, rotavirus, and caliciviruses), protozoan parasites (*Cryptosporidium parvum, Giardia lamblia)* and bacteria (Salmonella, *E. coli* 0157:H7, and *Shigella*). "A sensitivity analysis was then conducted to determine what parameters in the model affected the predicted difference in infection incidence between the two models."

Model Parameters. Appropriate values for each of the pathogen-dependent variables were determined from the literature for each pathogen of concern. Minimum (Min), median (Med), and maximum (Max) representative values were obtained for each parameter. Composite values were identified for each group. The minimum composite was the lowest value found in the Min values, the median composite value was the median of all values for the particular parameter, and the Max composite value was the highest value for the parameter. The composite values are used in the simulations.

Min, Med, Max values were also determined for the exposure-dependent parameter values. These values were based on reported data and best professional judgment to the extent necessary.

Simulation Strategy. "A series of numerical simulations were run to explore the range of feasible parameter combinations for exposure to a representative range of pathogenic microorganisms via reclaimed water applications." The dynamic disease model used 11 parameters in the simulation, while the static model uses three. Three levels for each parameter (Minimum, median, and maximum) in both models where examined. Thus, there are 177,147 possible combinations for the dynamic model. The output of each simulation was expressed as the incidence of infection or disease[35] per 100,000 attributed to exposure for each parameter combination.

A subsequent computation determined the difference in incidence of disease between the two models (results from the static model minus results from the dynamic model) for each parameter combination.

Exposure intensity, the proportion of the population exposed, times the frequency of exposure, was categorized as low (3/100,000), medium exposure intensity (1/1000) and high exposure intensity (1/10).

Organism ingestion, where the dose represents the number of organisms ingested via the exposure under consideration were set at low dose (1/100,000,000) medium dose (1/10,000) and high dose (1/1)

Levels of tolerance for the difference in predicted incidence of disease between the two models were set at the following: Threshold A =<10/100,000 per year. Threshold B =< 1/100,000 per year, and Threshold C =< 0.01/100,000.

"A Classification and Regression Tree (CART) sensitivity analysis was performed to determine what parameters in the model affected the incidence most strongly and to classify the low and high outputs of incidence" as well as prioritized them.
Model Evaluation Results. CART sensitivity analysis was conducted where the difference between the two models are considered to be low (10/100,000, 1/100,000, and

[35] "For the static model, the incidence of infection or disease is defined as the number of individuals moving from susceptible state to infected/diseased state. For the dynamic model, the incidence of infection or disease is defined as the number of individuals entering either a diseased state or a carrier state."

0.01/100,000). Approximately 45% of the 500,000 simulations were less than 0.01/100,000, about 60% were less than 1/100,000, and approximately 70% were less than 10/100,000. "The results of the sensitivity analysis suggested that the parameters that most strongly affected the difference in predicted incidence between static and dynamic models are, in order of decreasing importance:

- Dose of pathogen;
- Exposure intensity;
- Dose response beta[36];
- Dose-response alpha; and
- Duration of infection.

Approximately 177,000 static model simulations show that a large percentage of the simulated resulted in extremely low infection levels, about 2.75 cases in the whole population in the United States (0.0009/100,000). According to the Centers for Disease Control and Prevention, the incidence of foodborne diseases in the whole population of the United States is 4,700/100,000 or 47/1000.[37]

Model Evaluation Discussion. In order to determine the utility of either the static or the dynamic model, one first identifies the threshold tolerance level for the infection/disease, which in this case is gastroenteritis. "If the difference in predicted incidence is less than the threshold level, the static model applies…If the predictive levels of incidence in the static and dynamic models differ by more than the predetermined threshold level, the dynamic model would be the best choice." Graphical summaries of model evaluation are provided in the study, to elucidate this conclusion more fully.

"As the tolerable level of predicted incidence increases (from 0.01/100,000 to 1/100,000 to 10/100,000 per year) the static model becomes appropriate for more combinations of three parameters." However, one should be mindful that this investigation is an "extrapolation of these results to routes of exposure, pathogens, and/or other variant models not investigated, including levels of incidence difference. Conclusions from these extrapolations must be used cautiously. In actuality, they are applicable within the specific bounds at a specific time and set of specific conditions under investigation.

Microbial risk assessment is inherently pathogen specific. Cumulative impact to exposure to multiple pathogens is expected to occur. However, this factor is not explicitly addressed in this study. Additionally, the disease endpoint in this study was taken to be gastroenteritis, which typically supplies dose-response data in relation to the heath outcome. There are more serious disease states, which occur from exposure to pathogenic organisms. This investigation may very well underestimate cumulative health risk to the public.

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[36] In two parameter biomedical models, dose-response alpha refers to the intercept in a linear regression model, while dose-response beta refers to the slope in the model.
[37] Mead P. 1999.

The results from this investigation show that a less complex microbial risk assessment (static model) can provide guidance to utilities and managers regarding reclamation water uses. However, risk managers should use caution, as risk issues are "typically complex and the possibility of transient infectious agents circulating in the environment requires thoughtful consideration …Characterizing the risk associated with a particular exposure scenario for a particular pathogen may not be sufficient for regulatory decision-making purposes; monitoring, data collection, and health surveillance will continue to be important components of public health protection."

Case Studies

Case Studies include an overview of the particular scenario, beneficial use summary, hydrology, water treatment facility effluent water quality; virus loading, identifying parameter ranges (e.g. specific parameters and reference values including exposure- and pathogen dependent), pathogen source, environmental contact potential, and a summary of the dose pathogen in the exposure. Dose-response parameters are obtained using regression analysis and used to determine the appropriate MRA model for each case study when case-specific parameter values are compared to reference values. The most appropriate risk assessment methodology for each case study assessment depends on the difference between the models that is tolerable to the risk manager. Put another way, the incidence of disease/infection acceptable within the framework of the case study determines the choice of model. If the level of risk is 10/100,000 or greater the static model should be used; otherwise the dynamic model is the best choice.

Case Study A: Risk of Exposure to Rotavirus in a Recreational Impoundment. In this scenario, the impoundment has a capacity of 2,500 acre-feet with surface area of 80 acres. It is located on the outskirts of a 250,000-population city and surrounded by parkland. Approximately 80,000 residents use the impoundment annually, with the greatest use in summer for swimming and wading. There are no bovine or equine creatures in the immediate vicinity. Impoundment inflow comes from a 50/50 blend of pristine river water and effluent from the local wastewater treatment facility. Virus loading from infected individuals can be significant is not included in the case study. "In one investigation the mean amount of fecal material shed per bather was estimated at 0.14 gram, with reported concentrations of enteric viruses in feces of infected individuals ranging from 10^5 to 10^{12} per gram (Flewett and Woode 1978).[38] This is a significant deficiency. However, the authors believe this omission makes determination of the MRA model less complicated. The most appropriate risk assessment methodology for this case study assessment is a static model and depends on the difference between the models that is tolerable to the risk manager. Put another way, the incidence of disease/infection acceptable within the framework of the case study determines the choice of model. If the level of risk is 10/100,000 or greater the static model should be used; otherwise the dynamic model is the best choice.

Case Study B: Risk of Exposure to *Cryptosporidium* spp. in a Golf Course. This case study examines the use of reclaimed water in two of 10 golf course ponds on two 18-hole

[38] Flewett TH and Woode GN. 1978. Rotaviruses. *Archives of Virology*. 75:1-23.

public golf courses built on a former landfill. The courses are open 7 days a week year round from dawn to dusk, with approximately 400 golfers on site each day. The property is surrounded by residential, open space, and light industrial uses. A variety of wildlife lives on the golf course. Approximately 350,000 gallons of reclaimed water flow into the ponds each day year round. The treatment plant produces chlorinated secondary effluent for reclaimed use. Literature indicates that the "concentration of *Cryptosporidium* spp. in disinfected secondary effluent ranges from 0.0004 to 0.3 oocytes per liter.[39, 40] In this scenario, "a dynamic model would be more appropriate because either the person-to person transmission or immunity affects the assessment sufficiently such that predicted levels of incidence in the static and dynamic models differ by more than the predetermined threshold level (10/100,000)."

Case Study C: Risk of Exposure to *E. coli* O157:H7 in an Agricultural Reuse Application. This case study is more hypothetical than the previous two. The source for reclaimed water is chlorinated secondary effluent, which is used for irrigation on strawberries. The study assumes the fruit is consumed on the day of irrigation. "Interpretation of findings indicates that the static model could be employed under any of the tolerance levels for incidence difference between the static and dynamic models."

Constraint Analysis for Existing Reuse Regulations

Regulations and/or public policy may constrain or support the expansion of the use of reclaimed water. Many of these constraints and concomitant concerns apply to urban water bodies as well. Constraint occurs when regulations "no longer reflect a reasonable interpretation of 'good science.'" Microbial risk assessment is one of the tools, which might mitigate the use of regulations where the regulation supports requirements that do not enhance public health and safety from waterborne pathogens, even though considerable implementation costs have been expended. However, "established standards should not be changed without good cause or without considering and understanding the health of regulatory objectives on which they are based."

Water reuse regulations for non-restricted landscape disinfection are examined for three states, Arizona, California, and Florida. They are providing herein to provide background for decisions to be made on choice of model for determination of relative risk in urban water bodies. Standards for the three states, which relate to filtered water quality (turbidity) and disinfection requirements in addition to microbiological water quality (total or fecal coliform) are compared. All three states use media-filtration and chlorination for wastewater treatment.

Summary of Water Reuse Regulations for Non-restricted Landscape Irrigation. Water quality requirements for wastewater reclamation vary, dependant on the end use of the water and the level of exposure to humans. All three states allow reclaimed water use for similar purposes. In Arizona, this includes irrigation of food crops; recreational

[39] Rose JB, Huffman DE, Riley K, Farrah SR, Lukasik JO, and Hamann CL. 2001. Reduction of Enteric Microorganism as the Upper Occoquan Sewage Authority Water Reclamation Plant. *Water Environment Research.* 73(6):711-720.
[40] York DW, Menendez P, and Walker-Coleman L. 2002. Pathogens in Reclaimed Water: The Florida Experience. *2002 Water Sources Conference.* Pages 1-16.

impoundments; residential, school, and open access landscape irrigation; and spray irrigation of orchards or vineyards. California allows additional specific uses for golf courses, industrial applications (e.g. cooling towers), and food crops where edible food comes in contact with the reclaimed water. Florida lists reclamation uses as residential lawns, golf courses, cemeteries, parks, landscape areas, highway medians, and other areas of similar public access. By extension, one would expect water quality requirements for different contact recreation activities (primary or secondary) to vary depending on the contact activity and the urban water body type.

One of the difficulties in developing regulations from static model risk assessment is that it is based on exposure to chemicals in the environment. Pathogens are not specified in regulations in the same way as chemicals, by an absolute threshold. Analytical methods to detect a particular pathogen may not exist, are too expensive, able to process a sample before it degrades, or be able to handle the demand. In lieu of monitoring the pathogen, most regulations control the treatment process, which is supposed to decrease or alleviate the pathogen. This is achieved by specific design parameters, performance standards for a water quality surrogate, in this case total or fecal coliform.

Arizona requires "no detectable fecal coliform in four out of seven samples, with no sample exceeding 23 coliforms/100mL. Florida requires 75% of the samples collected in a 30-day period to be below detectable levels, with no sample exceeding 25 fecal coliforms/100mL. Both states specify microbiological criteria in terms of median and maximum levels. California, which uses total rather than fecal coliform, requires a "median 2.2 total fecal coliform/100mL based on a running 7-day calculation. Only one sample in any 30-day period can exceed 23 total coloforms/100mL, and no sample may exceed 240 total coliforms/100mL. California's requirements in the coliform standard are the most restrictive, followed by Arizona, and Florida.

Differences in disinfection standards most likely will result in a different risk endpoint for public health concerns. Risks proposed by different exposures to reclaimed water also produce differences in level of risk.

Use of Microbial Risk Assessment and Water Reuse Regulations. All three of the state regulations examined are performance-based. Regulations based on performance standards do not consider if following their implementation and enforcement, there is a resultant decrease in the relative human health risk from exposure to waterborne pathogens. The regulations require monitoring for a surrogate microbe for pathogenic microorganisms, but there is only a tenuous understanding of the relationship between the monitored water quality parameters and the pathogens of human health concerns. At some point, this deficiency should be taken into account in the regulatory process. The current utility of Microbial Risk Assessment comes in its ability to provide comparison of benefit between alternative wastewater treatment processes, for example the use of ultraviolet light as an alternative to chlorination.

MRA is also useful in the development of new water regulations. It serves as a tool to correlate regulatory options to the "help ensure that the desired level of public health

protection is achieved in a quantitative fashion. In a perfect world, zero chance of becoming ill from a waterborne pathogen might be possible. In this present world, some level of risk associated to exposure of an antagonist is the only option. MRA can also be used in a benefit analysis for risk manager enabling them to make informed decisions about new or additional water treatment achieving the chosen level of acceptable risk.

Interface Criteria Development

The final component of this investigation examined criteria for a computer interface, which would allow regulatory and/or municipal agencies/utilities to use MRA and model evaluations to establish risk to public health requiring action. Desirable software attributes (e.g. ease of use, flexibility, online access, and understandable output), model evaluation components (e.g. pathogen of interest, concentration of pathogen, volume ingested, and population exposed), identifiers, incidence predictors, and specific tolerances were discussed. An Excel platform was deemed desirable for the static model because of easy use. A platform for the dynamic model remains to be determined. "Given the substantial variability and uncertainty of microbial risk assessment parameter values, interpretation of the risk characterization results from a complex risk assessment is often quite difficult." During software development, both input and output must be considered

Consensus

While a less complex microbial risk assessment (static model) can provide guidance to utilities and managers regarding recreational contact with urban bayous, the static model should be used with caution. Risk issues are "…typically complex and the possibility of transient infectious agents circulating in the environment requires thoughtful consideration.…Characterizing the risk associated with a particular exposure scenario for a particular pathogen may not be sufficient for regulatory decision-making purposes; monitoring, data collection, and health surveillance will continue to be important components of public health protection."[41] The dynamic model with epidemiologic study is thus the analysis of choice for MRA in an urban environment.

Epidemiology Study Model

Epidemiology is the study of the cause, distribution, and management of disease in human populations. Epidemiology studies also require adequate study design. Study design must take into account the type and cause of the disease (waterborne pathogen), in addition to the distribution of the disease in the exposed population following secondary recreational activity in an urban water body, so that the disease can be managed thru through regulations and public policy. However, essential elements characterizing baseline parameters are required before designing an epidemiological study. These

[41] WERF. 2004.

elements include (1) characterization of the region, (2) characterization of water bodies studied, (3) background levels of pathogens, (4) exposure through recreational use, and (4) regional background of disease/illness associated with waterborne pathogens. Some of these parameters are currently know, others are not.

Cohort Study Protocol Design

A "cohort" is a group of subjects followed together over time with measurements of potential predictor variables at the beginning and with the ascertainment of at a subsequent outcome (case). Cohort studies describe the incidence of certain events over time (e.g. "Y" incidence per 1,000 cases) and analyze associations between risk factors and those outcomes, which infer a causal factor. There are three general types of study protocols for evaluating contact recreational exposure to human-source pathogens in urban waters: retrospective cohort studies, prospective cohort studies, and randomized prospective trials. Each of these protocols has their advantages and disadvantages.

Retrospective Cohort Studies. A retrospective or historic cohort study examines the medical records of a chosen population or group of individuals who experiences certain conditions and outcomes and looks for possible exposures in their history that may have contributed to their condition or outcome. In the retrospective cohort group, baseline measurements, follow-up, and outcomes all happened in the past. Advantages include lower cost, and less time. Retrospective Studies have an additional advantage over the case-control studies; in that, all of the subjects who developed the outcome (cases) and all those who did not (controls) come from the same population.[42, 43] Several small cohort groups with secondary contact present themselves in urban bayous (e.g. county flood control district workers, Clean Rivers Program monitors, TCEQ monitors, USGA monitors).

Disadvantages include inability to control the nature and quality of measurements made (accuracy, completeness, etc.) and data may not include all-important parameters needed to answer the question. In the case of illness associated with exposure to pathogens in urban water bodies these deficiencies include (1) the need for a group of seriously ill subjects caused by exposure to pathogens during secondary contact with urban bayous, (2) the inability to produce a credible dose response curve required in health based standards design, (3) the inability to differentiate between incidence of endpoint illness caused by test pathogen and background incidence of endpoint illness, when background incidence of illness greatly exceeds test case, and (4) absence of human illness data associated with exposure to area water bodies in the City of Houston. It is worth noting that a cohort study cannot definitively prove cause and effect, only correlation.

Prospective Cohort Studies. A prospective cohort study follows chosen population or group of individuals over time that has the same exposure and compares them for a particular outcome or case (e.g. gastroenteritis) in the present or at a future time.

[42] University of Michigan. Unknown. Cohort Studies Following Groups of Subjects over Time. Retrieved August 5, 2007 from http://www-personal.umich.edu/~seonaeyo/CH7.HTML/tsld008.htm.
[43] Dallal GE. 2007. Some Aspects of Design. Retrieved on August 8, 2007 from http://www.tufts.edu/~gdallal/STUDY.HTM.

Advantages include design strategy is more able to clearly define the incidence and investigation of the potential causes of a condition before data is collected (e.g. using a selection of a broad range of participants after voluntary swimming). Time sequence strengthens the inference between factor and outcome (incidence of illness). One is able to assess and measure variables to a degree of completeness and accuracy. Prospective studies also allow investigators to follow the antecedents of disease. There is high applicability to water quality standards because it follows an actual human illness or disease.

Disadvantages include high expense. "Associations found can sometimes be misleading because of confounding variables associated with both predictor and outcome of variables." [44] Often statistical analysis must be used to strengthen results by measuring all confounding variables and adjusting for their effects, which is what is required in determining illness associated with exposure to pathogens in urban water bodies following contact recreation. In this regard, disadvantages in assessing illness in this scenario include (1) the precise measurement of the level of waterborne pathogen during exposure for each swimmer is not possible, (2) the need for a large number of subjects to get a statistically valid dataset (estimated to be 3,000 – 5,000 at a minimum), and (3) the inability to differentiate between incidence of endpoint illness caused by test (water borne) pathogen and background incidence of endpoint illness (from food borne pathogens), when background incidence of illness greatly exceeds test case as occurs in the Houston area.

Randomized Prospective Trials. An essential characteristic of a randomized prospective trial is that it compares an exposure group to placebo group. A study population is divided into groups using a randomization procedure, with a single, and more likely, a double blind procedure (neither researcher nor test subject knows the placebo group) to collect the data. One group performs secondary contact recreation activities under specific conditions in a water body containing a human waterborne pathogen at a defined level. The placebo or control group (single or double blind) performs the same secondary contact recreation activity, but without pathogens in the water. If the controls are sufficiently rigorous, it should be possible to conclude that any statistically significant observed illness (e.g. gastroenteritis) has indeed been caused by exposure to the waterborne pathogen.

Advantages include the removal of self-selection bias, better definition of exposure to each subject, more precise measurements of water quality to which subjects are exposed, and the numbers of subjects needed are smaller than Prospective Cohort study. Disadvantages are many. They include the ethical dilemma of asking subjects, potentially children to expose themselves to water bodies containing human-source pathogens as well as the high cost and complexity of the studies. The inability to differentiate between incidence of endpoint illness (gastroenteritis) caused by waterborne test pathogen and background incidence of endpoint illness caused by food borne pathogens is problematic, because the background incidence of illness from food borne

[44] University of Michigan.

pathogens far exceed the exposure level from water borne pathogens. this makes quantifying relative human health risk difficult.

National Epidemiology Study

Organizations like the Water Environment Research Foundation (WERF) have expressed an interest in conducting studies on a national scale using standard protocols. Interviews conducted on a small scale in local watersheds could then be pooled with data collected from similar areas around the country to produce a more statistically valid study. There are many problems that are readily apparent with epidemiological studies in certain types of water bodies. There may be large differences in topography, climate, soil types, age of infrastructure etc. that may interfere with the results. However, such a definitive study should include regions that contain both water bodies that do and do not meet criteria for contact recreation.

Suitability of Protocols in Literature

Staff has reviewed over 30 epidemiological studies conducted from 1953 to 2006. Twenty-one of those studies are summarized in Table 1. Most protocols are not suitable for individual urban watersheds in the Houston-Galveston area.

Table 1: Review of Epidemiology Studies in the Literature

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Van Asperen 1998	Event study of 827 Triathletes and 723 Biathletes (cyclists) as control group to evaluate risk of Gastroenteritis from exposure to fecal pollution.	Netherlands - 2 sport seasons	Freshwater	Full body contact vs. control with no contact	E. coli, thermo-tolerant coliforms, fecal strep, *Enterococcus*-retroviruses, F-specific RNA phages, *Salmonella, Campylobacter*, *Aeromonas, Plesiomonas shigelloides, Pseudomonas aeruginosa & Staphylococcus aureus*	Gastrointestinal ailments	Intense water quality monitoring to assess exposure to fecal indicators. Questionnaires used to collect data on occurrence of health complaints and potential compounding factors	Attack rate rises when geometric mean concentration of thermo-tolerant coliforms >= 220/100mL OR geometric mean concentration. of *E coli* >= 355/100mL. Below threshold, attack rates similar to control. Swimmers 2x more likely to experience Gastroenteritis than control	EU imperative standard of <= 2000/mL indicator is inadequate to protect health
Balarajan V. 1991	Prospective survey of 1883 recreators, all ages and sex, with various degrees of exposure, ranging from none, wading, surfing, swimming, diving	UK - 3 weeks	Marine	Range of full body contact to no contact	Total coliform, Fecal coliform, Fecal *Streptococcus*	Eye, Ear, Nose, Throat, Respiratory Illness, Gastrointestinal ailments	2101 patients Interviewed at beach, follow-up telephone interview of 1883 for sore/red eyes, ear infection, runny nose, sore throat, respiratory symptoms [wheeze, cough], GI symptoms [nausea, vomiting, stomach cramp, diarrhea - 3 + loose stools/24 hrs]. Sea water monitored at selected sites & times for different indicators	Risk of GI illness increased with degree of exposure and was greatest among 15 – 24 year old age group. If background risk of illness for the non-exposed population is 1.00, waders risk = 1.25, swimmers = 1.31, surfers/divers (total immersion) = 1.81.	Dose-response relationship identified b/w exposure & illness. No significant difference b/w residents and day-trippers. (insufficient number of day-trippers for analysis)

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Cabelli V. 1983	Prospective epidemiological study to develop water quality criteria for marine recreational waters based on the determination of acceptable risk.	USA - 8 years for the 3 separate studies (1972 - 1978)	Marine	Full body contact vs. control with no contact	*Enterococcus*	Eyes, Ears, Highly credible gastrointestinal ailment (HCGI), Upper respiratory tract,	Beach interview on weekends to recruit participants - NY, Boston harbor, Lake. Ponchartrain. No mid-week swimmers. Single exposure. Phone or personal interview follows up to 8-10 days after exposure. Swimming means head immersion. 3-4 samples collected on day of exposure - chest high depth.	Swimming exhibits risk of GI illness. Increased risk of gastroenteritis with greater exposure to polluted waters. High correlation between frequency of GI illness & distance to WWTP. *Enterococcus* is best indicator of human pathogens in marine water. *E. coli* is good indicator in freshwater. Direct linear relationship between High Credible GI illness & *Enterococcus*, while frequency. of GI symptoms strong association with distance to known WWTP outfalls.	Swimming in marginally polluted marine bathing water is significant route for transmission of GI illness. Children, Hispanic & low - middle income socioeconomic groups. most susceptible.
Dufour, AP 1984	Prospective epidemiological study to determine relationship b/w swimming-associated GI illness & water quality in freshwater contaminated by sewage effluents. Also to determine best indicator bacteria & appropriate criteria for freshwater.	USA - 3 yrs (1979, 1980, 1982)	Freshwater	Full body contact vs. control with no contact (non-swimmers include no head immersion)	*E coli*, *Enterococcus* & fecal coliforms	Highly credible gastrointestinal illness, total GI illness, respiratory ailments.	Beach interviews on weekends followed by telephone interview 8-10 days after exposure. Swimming means head immersion. Family units selected when possible so one adult could respond for many individuals.	High GI illness associated with high density of fecal indicator bacteria. Strong correlation between *E. coli* or *Enterococcus* & swimming-related GI illness. Either indicator is suitable to measure risk of swimming associated illness. Bacteria die-off rates different in marine & freshwater environments, which can cause an underestimation of human pathogens.	Criterion developed for marine bathing waters not applicable to fresh bathing water.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Durand R. 1989	Study of 2,642 visitors to investigate the gastrointestinal effect of using recycled non-potable water [treated wastewater and runoff] to irrigate parks -- compared with irrigation with potable water.	USA - 3 yrs (1984-1987)	Parks	Secondary contact (golf, soccer)	Total coliform, Fecal coliform, *Fecal streptococci, Salmonella, Shigella*	Gastrointestinal ailments	Data collected by telephone surveys of randomly selected park visitors. "Credible symptoms" of GI illness [*stomach discomfort, diarrhea, vomiting, cramps, fever, weight loss, gas, blood in stool*] documented. Irrigation water sampled for indicator bacteria and other biological pathogens.	No significant difference between subjects exposed to recycled vs. potable water. Association found between morbidity when Fecal coliform or *Fecal Streptococcus* >= 500/mL and when Total Coliform >= 3000/mL. GI illness increases with exposure to wet grass, whether irrigated by potable or non-potable water.	Parks may be irrigated with recycled water provided indicator levels remain below critical values.
Dwight R.H. 2004	Cross-sectional survey to compare health symptoms experienced by surfers at a beach near a highly urbanized area - North Orange County (NOC) and a rural beach in Santa Cruz County (SCC)	USA - 2 Surfing Seasons (1998-1999)	Marine	Full body contact (surfing in coastal waters)	Not Reported	Eye, Ear, Nose, Throat, Highly credible Gastrointestinal ailments, Significant respiratory disease, Skin, Fever	Over 2 years, survey at surfing beaches in NOC & SCC. Frequent surfers questioned about GI illness last 3 mos. Regression analysis by County, water exposure, gender, age, occupation, education, income, political views, concern water quality. Limited utility because of dependence on respondents memory & no contemporaneously measure water quality	Risk of illness increased with every additional 2.5 hours of exposure. Urban surfers had 2x the symptoms as rural surfers. Confirms findings of direct association between pollution levels in run-off waters with an urban land use, high population density & a large amount of impervious surface in a watershed.	Discharging untreated urban run-off directly into recreation waters can pose health risks.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Fleisher J. 1996	Prospective cohort study to Identify dose-response relationship among bathers exposed to domestic sewage polluted marine water and to calculate risk of non-enteric illness (Acute Febrile Respiratory illness, eye, ear, skin ailments)	UK - 4 summers (1989-1992)	Marine	Full body contact vs. control with no contact	Fecal coliform, *Fecal streptococci,* Total coliform, Total *Staphylococci, Pseudomonas aeruginosa*	Eye, Ear, Nose, Throat, Respiratory illness, Skin ailments	1216 volunteers 18+ yrs old, randomly assigned to contact or control group. 548 bathers with 10+ minutes exposure. Water Sampled @ 3 depths for Total coliform, Fecal coliform, Fecal *streptococcus*., Total *Staphylococci, Pseudomonas aeruginosa*	Dose-response relationship exists b/w level of exposure to fecal strep & risk of respiratory illness. Exposure to increased levels of fecal coliform predictive of ear ailments. No significant difference in eye or skin ailments observed between test & control group. Exposure threshold to risk of illness estimated at 60 Fecal *Streptococcus* organisms/100 mL for febrile respiratory illness & 100 Fecal coliform organisms/100 mL for ear ailments.	Findings suggest that the use of a single illness or indicator organism to establish marine standards for recreational water quality is incorrect.
Stevenson 1953	Three prospective cohort studies at comparative sites, determine health effects of exposure to polluted recreational H2O. Sites were Two beaches on Lake Michigan, two beaches on Long Island Sound, one beach on Ohio River & swimming pool in Kentucky	USA - one swim season?	Marine, Freshwater & Pool	Full body contact vs. control with no contact	Total coliform	Ear, Nose, Throat, Respiratory illness, Gastrointestinal ailments	Intense public outreach about the ongoing epidemiology study. Health and Human Services in study areas given calendars to keep daily record of swimming events and illness. Eye, ear, nose, throat, GI ailments and skin irritation. Water sampled regularly to obtain average figures for water quality - Coliforms per 100mL. Swimming not defined as head immersion.	Most swimming done by ages 10-19 years old, then 5-9 year olds. Least swimming by participants 44 + yrs. Morbidity rate greater for swimmers vs. non-swimmers. Illness increased with swim frequency & density of pollutants. Strong correlation between increase in GI illness and water quality observations of 2700 coliforms/mL	Suggests that most strict bacteria water quality criteria may be relaxed without health effect. [**Considered to be deficient in design - Cabelli, 1983]

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Prieto M.D. 2001	Prospective cohort study to assess health outcome of bathing in sewage-polluted water polluted with sewage & to determine best microbial indicators most clearly related to swimming-induced illness.	Spain - one swim season (July 1 to September16)	Marine	Full body contact vs. c ontrol with no contact	Total coliforms, Fecal coliforms, Fecal streptococci, *Staphylococcus aureus, & Pseudomonas aeruginosa*	Eye, Ear, Acute respiratory illness, Gastrointestinal ailments & Fever	Subjects randomly selected in survey at 4 beaches – f/b telephone interview within 7 days of exposure. Water sampled contemporaneous with survey. Three of the beaches classified as "relatively polluted." .	Bathers had higher incidence of GI, skin & upper respiratory. tract symptoms than non-bathers but difference not statistically significant. No difference due to head immersion. Freq. of symptoms similar in both men & women but decreased w/ age. Visitors had higher incidences of illness than residents did but no significant difference between bathers & non-bathers. Increased risk associated with total coliforms levels of 2500 - 9999/mL.	Results suggest that Total coliforms are best predictors of the analyzed illnesses - differs from findings of other studies.
Soller J. 2003	Quantitative microbial risk assessment to determine if the addition of tertiary treatment during the winter season substantially reduces the risk of viral gastroenteritis among bathers in fecal-contaminated recreation waters (San Joaquin River).	USA - 7 yrs (1996 - 2002)	Freshwater	Full body contact [simulated]	Enteric viruses [rotavirus - simulated]	Viral Gastroenteritis [simulated]	Numerical [Monte Carlo] simulation of gastroenteritis cases based on integrated hydraulic & disease transmission models. Input variables included exposure assessment [daily & seasonal distribution of recreators], estimates of viral count attenuation & WWTP pathogen removal efficiency.	Illness due to background exposure approximately 1000-x illness due to exposure to microbial waters. Marginal risk of GI ailment attributable to effluent decreased as treatment efficiency increased. Reduction in viral gastroenteritis after tertiary treatment about 4 avoided cases /100,000 recreation events. Most significant factors are virus shedding by bathers & WWTP removal efficiency.	Risk of viral gastroenteritis w/ secondary treatment is below risk level acceptable by USEPA standards. Risk decreases by up to 50% w/ tertiary treatment.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Sinton, L.W. 1993	Review of USEPA criteria for marine & fresh recreational waters. Comparison with findings in other regions and the implications for New Zealand (NZ), especially considering the large animal to human ratio that exists in NZ.	General literature review of Epidemiological studies	Not Applicable	Not Applicable	Fecal coliform and Fecal *Streptococcus - Enterococcus* and *Escherichia coli*	Not Applicable	Not Applicable	Care should be taken in adopting USEPA standards for NZ. Studies elsewhere suggest EPA results not universally applicable b/c of regional differences. US effluents from WWTP are treated w/ Chlorine unlike in NZ. UK practice closer to NZ but agree with USEPA that *Enterococcus & E Coli* more closely model disease occurrence than Fecal coliform	While evaluating international standards, evaluate local conditions that may require modified approach
Cheung, W 1990	Prospective cohort study of the epidemiological study of beach water. First epidemiological study in subtropical waters.	Hong Kong - 2 swim seasons (1986 - 1987)	Marine	Full body contact vs. Control with no contact	*E. coli, Klebsiella, Fecal Streptococcus, Enterococcus, Staphylococci, Pseudomonas aeruginosa, Candida albicans,* Total fungi	Eye, Ear, Nose, Throat, Respiratory illness, Gastrointestinal & Skin ailments, Fever	Weekend survey of 18,741 beach goers at 9 beaches over 2 swim seasons. Follow up telephone interview 7-10 days after exposure. Swimmers spent average of 1.3 hrs in water. Swimming defined as total immersion. Water sampled every 2 hrs. Beaches close to sewage outfalls, agricultural runoff, & storm drains.	Incidents of gastrointestinal, ear, eye, skin, respiratory, fever & total illness greater among swimmers than non-swimmers & higher in more polluted waters. Swimmers < 10 years old significantly higher rates of GI, HCGI, skin, respiratory, fever, & total illness. *E. Coli* was best indicator of gastroenteritis & skin problems. *Staphylococcus* showed high correlation with ear, respiratory & total illness but not GI	*E. Coli* best indicator of swimming-related illness. *Staphylococcus* may supplement *E. coli* for ear, respiratory & total illness.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Ferley J.P 1989	Retrospective study to assess the relationship b/w swimming related morbidity & bacterial quality of recreational waters.	France - 1 Summer	Freshwater	Full body Contact	Total coliform, Fecal coliform, *Fecal Streptococcus, Aeromonas* spp., *Pseudomonas aeruginosa*	Eye, Ear, Nose, Throat, Respiratory illness, Gastrointestinal & skin ailments, fever	5737 tourists in 8 holiday camps questioned retrospectively about illness and swimming habits in preceding week. Water quality readings were aggregated.	Weighted linear regression analysis. Bathers experienced more incidents of morbidity than non-bathers did. Gastrointestinal ailments most common. Fecal *streptococcus* correlated best with GI morbidity. Fecal coliform not good predictor of GI morbidity risk. Skin ailments greater among bathers than non-bathers do.	Main question is how to define 'acceptable' risk. Study provides strong epidemiological data on which to base microbiological standards.
Corbett, J 1993	Cohort study to determine the health risk of swimming at Sydney beaches. 70% of Sydney's wastewater is discharged into the ocean.	Australia - 1 Summer (1989)	Marine	Full body contact vs. Control with no contact	Fecal coliform. Fecal *Streptococci*	Respiratory, gastrointestinal, eye, ear symptoms, fever, cold, diarrhea	2,839 participants >15 years old recruited on 12 popular beaches, weekends, holidays + 1 week day. Follow up telephone interview 7-10 days after recruitment. Water samples collected AM & PM on interview days. Swimming is head immersion. Fecal contamination 'low' if geometric mean <=300 cfu/100 mL, with no single sample > 2000 cfu/100mL.	2 variables stood out - swimming duration & density of indicator bacteria. Swimmers almost 2x as likely to experience ill health as non-swimmers. Swimmers who spent > 30 minutes in water 4.6 x more likely to develop symptoms of GI illness. Linear relationship between all reported symptoms except GI ailments.	In Sydney beaches, Fecal coliform better predictor of reported symptoms than Fecal *streptococcus* possibly because of different survival rate as effluents not chlorinated & Australian oceans warmer than North . America.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Wade, T.J. 2006	Prospective cohort study of recreators at 2 lake beaches to evaluate the ability of the rapid water quality assessment method (Quantitative Tasman PCR or QPCR) to predict the health effects of exposure to pathogens in contaminated recreational waters.	USA - 1 summer	Freshwater (Great Lakes beaches)	Range of Full body contact to no contact	*Enterococcus*, Bactericides	Gastrointestinal ailments	5,667 individuals in study. Initial interview at beach followed by phone call 10-12 days after exposure. Collected info on all ailments but focus on GI illness defined as diarrhea, vomiting, nausea & stomach ache. Water samples taken 3 times daily on each study day.	Bathers reported higher incidences of GI illness than non-swimmers. Risk greater with head immersion. Strong correlation between *Enterococcus* level and risk of GI illness, especially with increased time in water. A 10-fold increase in *Enterococcus* resulted in a 1.43 increase in risk of GI illness but w/ > 2 hrs in water, a 2.89 increase in risk predicted. No significant association between bactericides & GI illness.	QPCR is viable tool to predict GI illness in freshwater. Further studies advocated.
Siegfried, PL 1985a	Prospective cohort study to examine the relationship b/w exposure to contaminated recreational waters and the incidence of swimming related illness.	Canada - 1 summer	Freshwater (Great Lakes beaches) - 1 summer	Range of Full body contact to no contact	Total *Staphylococcus*, Fecal coliform, Fecal *Streptococcus*, Heterotrophic bacteria, *Pseudomonas aeruginosa*	Respiratory illness, Gastrointestinal ailments	4,537 participants interviewed on weekends at 10 Ontario beaches. [2,743 swimmers]. Family units randomly selected. Baseline health checked. Follow up within 7-10 days by phone or mail to document health conditions of the respondents. Water samples taken contemporaneously. Counts of persons on beach, in water & heads submerged.	Swimmers had substantially higher morbidity rates than non-swimmers. Respiratory, GI, ear, & skin symptoms also higher for swimmers but ear infections occurred predominantly where heads were submerged. Highest morbidity rates among swimmers < 20 years old. Small correlation between Fecal *Streptococcus* and GI illness but best correlation between *Staphylococcus* density & GI illness	Findings consistent with Cabelli and Stevenson.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Petrel, L 1992	Prospective cohort study of water quality and disease attack rates in fresh water	United Kingdom -	Freshwater	Primary/Secondary contact (canoeists) vs. no contact (spectators)	Total coliform, Fecal coliform, *Fecal Streptococci*, Total *Staphylococci, Salmonella,* Enteroviruses	Eye, Ear, Nose, Throat, Skin, Respiratory illness	Two whitewater canoeing slalom channels with different amts of microbial contamination - lowland stream with high Enteroviruses concentration & moderate Fecal coliform concentration. Upland stream with no Enteroviruses and moderate Fecal coliform concentration. Waterside survey follows up by telephone interview for symptoms.	Canoeists at lowland site had higher incidences of GI & upper respiratory illness than unexposed study subjects did. (3x - 4-x increase in risk).	Study suggests that risk of morbidity from contact w/ disease-causing agents in fresh-water may be better measured by counting virus rather than bacteria levels.
Edema, G 1995	Pilot study to determine the relationship between microbiological water quality parameters and occurrence of health complaints among tri-athletes. Prelude to larger study.	Netherlands	Freshwater	Full body contact vs. Control with no contact	*E. coli*, Thermo-tolerant coliforms, Fecal Streptococcus, Enteroviruses, & retroviruses, F-specific RNA phages, *Salmonella, Campylobacter, Aeromonas, Plesiomonas shigelloides, P. aeruginosa & Staphylococcus aureus*	Respiratory illness, Gastrointestinal ailments, Skin,	Participants enrolled at 2 different sporting competitions. 314 tri-athletes (swimmers) & 81 bikers (non-swimming controls) surveyed. Follow up health data collected by questionnaire a week after exposure. Water samples were collected during the swimming event & evaluated for the concentration of pathogenic organisms.	Swimmers experienced incidences of illness at over 2x the rate of non-swimmers, but health risk for all groups of illness not significantly different b/w the two groups. Geometric. mean concentration of indicator bacteria relatively low and Enteroviruses present at concentrations of 0.1/1. Key feature - homogeneous population. of athletes & simultaneous exposure to pathogens	Study design suitable for a complete study to be carried out later.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Turbo, D 2003	Study to create a model that simulates historic incidence rates of gastroenteritis in swimmers based on Enterococcus densities.	USA - 31 months	Marine	Full body contact vs. Control with no contact	*Enterococcus*	Highly credible gastrointestinal illness (HCGI) [vomiting, diarrhea, nausea, or stomachache, accompanied by a fever]	Historical Enterococcus density data collated & beach attendance estimated from life guard/fire dept records. A Highly Credible GI risk curve was applied to the historical Enterococcus counts to get a risk factor for each sampling location. RF multiplied by No. of bathers yielded an estimate of the HCGI cases over the study period. (Cabelli)	Majority of HCGI cases occur in summer even though peak concentration. of Fecal *Enterococcus* is in late winter/early spring. Illness rates highly sensitive to the relationship between Enterococcus density and HCGI risk. Daily risk level fluctuated throughout the study period.	Characterization of Enterococcus density & HCGI risk is useful predictor of health effects of recreational activity in marine beaches.
Hailer, RW 1999	Cohort study to determine health risk associated with exposure to untreated urban runoff from storm drains in marine recreation waters. [Follow up study to previous investigation that found human fecal waste in storm water collection system].	USA - 1 summer	Marine	Full body contact	Total & fecal coliforms, *Enterococcus & E. coli,* Enteric viruses.	Upper respiratory & gastrointestinal ailments, fever, chills, ear discharge, vomiting, coughing with phlegm	15,000 bathers interviewed at beach with follow up telephone interview 1-2 wks after exposure. Measures of exposure include distance from storm drains. Water quality analyzed for indicator & pathogen bacteria & viruses.	Incidents of fever, HCGI, ear discharges etc. were significantly greater among bathers who swam near storm drains than bathers > 400 yards away. When tot. coliform > 1,000 cfu/100 mL, risk of ill health increases w/ lower total coliform to Fecal coliform ratio, but decreases with higher ratios. Risk also higher when enteric viruses found in water. Strong association between bloody diarrhea & *Enterococcus*.	Health concerns due to storm drains identified. "No Swimming" warning signs posted near storm drains in Santa Monica Bay.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
Colcord, J.M. 2005	Cohort study to determine public health risk of swimming-related illness due to exposure to recreational waters w/ non-point sources as dominant fecal input source. Attempt to develop new methods for measuring traditional bacterial indicators (QPCR), new bacterial indicators (bactericides), and viruses (somatic & male-specific pâté, adenovirus, Norwalk-like virus)	USA - 1 summer (2003)	Marine	Full body contact vs. Control with no contact	*Enterococcus*, Fecal coliforms, Total coliforms	Gastrointestinal ailments, HCGI, respiratory, skin, eye, ear, fever.	8,797 participants completed the study. Recruited at 6 beaches-weekends & holidays. Follow-up telephone interview 10-14 days later. Swimmers (any contact) = 4,971. Water quality monitored hourly during beach interviews. Multivariate analysis to measure health outcomes and degree of exposure + level of contamination.	Skin rash & diarrhea significantly elevated among simmers. Diarrhea greatest among children 5-12 year olds. Higher among Caucasians. Risk of illness uncorrelated with bacteria levels or length of exposure. Significant association between male-specific Coliphage & HCGI-1/HCGI-2, nausea, cough, fever. No pathogenic or Norwalk-like virus was detected. One sample contained adenovirus.	WQ thresholds not predictive of risk where bacterial source mainly non-human fecal. Nucleic acid-based technique provides faster, cheaper & more specific results than culture-based technique.

AUTHOR	DESCRIPTION	LOCATION - STUDY PERIOD	MILEU	EXPOSURE	INDICATOR	SYMPTOMS	METHODOLOGY	FINDINGS	CONCLUSION
City of Chicago 2007	Microbial Risk Assessment to quantify health impact of not disinfecting effluents from water plants & to develop appropriate protective standards for proposed secondary contact recreation use of Chicago Area Waterways (CAW) – Incidental Contact Recreation (ICR) & Non-Contact Recreation (NCR)	USA	Freshwater	Lake recreators, CAW recreators, Unexposed recreators	Total culturable viruses, *Adenovirus, Caliciviruses* , Viable *Cryptosporidium parvum*, Viable *Giardia lamblia*, *Salmonella*, *Pseudomonas aeruginosa, E. coli*, Fecal coliforms, *Enterococcus*	Skin, eye, respiratory symptoms, acute GI symptoms.	Dry & Wet weather sampling to analyze levels of microorganisms . Hazard identification, exposure assessment, dose-response assessment, & risk characterization. Model development to predict risk of illness resulting from different levels of exposure to CAW.	Published findings & empiric observations input to probabilistic risk simulation model to determine dose-response assoc. Risk of illness calculated, based on recreation type, location, duration of exposure, ingestion rate. Overall risk of GI illness low compared w/ EPA guidelines of 8 per 1000. Greatest risk from *E. coli*; receptor type & exposure duration most important inputs.	Proposed CAW standards for recreation season: **ICR**-30 day geometric mean 1030 cfu/100mL *E. coli* based on 10 illnesses per 1000; **NCR**-30 day geometric mean 2740 cfu/100mL *E. coli* based on 14 illnesses per 1000

Number of Test Subjects

In urban water bodies, it is very difficult to collect data from the numbers of individuals that would be needed to get statistically sound results. A sufficient number of individuals must be available in test, cohort, control, and placebo groups. There are three different test categories:

- Primary contact- full body immersion
- Secondary or incidental contact
- Non-contact

Literature review of epidemiology studies shows between 850 to more than 3,000 individuals in study groups are needed to collect the statistically valid data. A current study in Chicago began using 7,000 individuals in several cohort populations. It is estimated that nearly 10,000 persons may be necessary to obtain an adequate number of individuals exposed to urban water bodies to complete epidemiology studies. The initial estimated cost of this study was $2.5 million. Costs are currently at $3.75 million.

In the Houston area, high numbers of individuals from the non-contact group are certainly available. These include walkers, joggers, bicyclists, park users, etc., that are recreating in areas adjacent to urban streams but never actually coming into contact with the water. High numbers of individuals from the other two categories, full body immersion and incidental contact, are difficult to find. People use the urban streams for these types of recreation in insufficient numbers to obtain a statistically significant, valid study.

A random telephone survey conducted by H-GAC of Houston residents in five urban water bodies (Sims, Brays, Buffalo and White Oak Bayous, and Cypress Creek) produces interesting results.[45] The survey showed for ordinary residents, 8 per cent have utilized urban water bodies for swimming and 15 percent of the people have utilized urban water bodies for wading, fishing, and other forms of secondary activities. The estimated population of the five urban watersheds is 2,536,303, thus nearly 203,000 people may have been exposed to water borne pathogens via primary recreational activities and become ill. With indicator bacteria levels in Houston's urban bayous routinely five times the contact recreation Criteria (126 cfu/100mL)[46], why has the City of Houston's Health and Human Services Department recorded no illness associated with recreational contact with water borne pathogens in urban bayous since 1992? The risk of illness appears to be very low under primary contact conditions. For secondary contact, 380,000 may have become ill potentially, a far greater number.[47] (See later Section in this paper on Other MRA and Epidemiology Study Considerations – Low Level of Illness/Disease Associated with Contact Recreation in Houston Bayous for further discussion.)

A companion telephone survey of 134 members of the Bayou Preservation Association (BPA), a group knowledgeable about the environment and character of urban water bodies, was also conducted. Of the BPA members surveyed, approximately 2 per cent had been swimming in

[45] Creative Consumer Research. 2007. Recreation Usage, Attitude and Awareness Telephone Study. Houston: Houston-Galveston Area Council.

[46] cfs = Colony forming units.

[47] City of Houston. 2007.

urban water bodies and 35 per cent had used urban water bodies for some form of secondary recreation activities.

Designated beaches (lake or gulf), swimming areas, and marinas allow more access for the public and provide a better opportunity for prospective studies. Unfortunately, opportunities for large numbers of persons to congregate in the undertaking of contact recreation do not exist in urban water bodies. Rural areas also have limited public access because most access to waterways requires the transit of private lands. With limited public access in rural areas, the ability to conduct prospective studies is also compromised.

What recreational activities occur in urban water bodies in the Houston area? H-GAC has conducted a Contact Recreational Survey of people utilizing five urban bayous in Houston (Sims, *Brays*, Buffalo, White Oak, and Cypress Creek).[48] The survey is coupled with interviews of "recreation participants" using the water bodies for primary (swimming, children wading) or secondary (fishing, canoeing, wading) types of contact recreation or non-contact recreation types of activities (jogging, bicycling, walking, picnicking etc). This survey not only gives H-GAC a chance to utilize the interview instrument under development for the UAA but also provides a good foundation for understanding recreational use of Houston's urban bayous, and ultimately forms the basis for appropriate risk assessment study design.

Based on current City of Houston Health and Human Services Department (HHSD) data, there was insufficient incidence of gastroenteritis associated with waterborne pathogens to provide numbers of affected individuals for epidemiology studies from 1992 until the present. In 2000, HHSD added specific questions related to exposure to water bodies to its intake questionnaire given to those individuals who had been reported to HHSD with positive results for reportable pathogens, including *Shigella, Vibrio, Cryptosporidium, Picornaviruses*, etc. Persons are reported by physicians or hospitals. In addition to its own database, the City of Houston has access to citywide pharmacy over-the-counter sales of anti-diarrhea and flu medication database, and other electronic databases to identify hospitals and zip codes where a gastroenteritis outbreak may be occurring.

Epidemiology Baseline Parameter Requirements

Based on the issues raised in the expert panel reviews of the Ambient Water Quality Criteria for Bacteria – 1986 and issues raised by meetings with local epidemiologists, there are a number of parameters or confounders that need to be analyzed prior to developing a protocol for implementation of an MRA. These include characterization of the region and its water bodies; destination distance from recreator's residence to activity location; type of recreation activity (primary, secondary, and/or non-contact): frequency, duration, time of day, season and ambient conditions during activity; exposure to pathogens, age and susceptibility of participant; species of pathogen (bacteria, parasite, and/or virus), and incidence of gastroenteritis (background and exposure).

[48] Creative Consumer Research. 2007.

Characterization of Region

The H-GAC Gulf Coast Water Quality Management Planning Region follows the southeast Texas coastline from Bolivar Island to Palacios, reaching inland to the piney woods of Huntsville and Lake Livingston in the north, westward through Columbus to Weimar, and eastward through Anahuac to Winnie. The region encompasses approximately 12,500 square miles in 13 counties including Austin, Brazoria, Chambers, Colorado, Fort Bend, Galveston, Harris, Liberty, Matagorda, Montgomery, Walker, Waller, and Wharton. According to the 2000 Census the region's population numbers 4,854,454, an increase of 957,312 people (25%) since 1990 (U.S. Census Bureau 2000 Census). Forecasts project an increase in population of 40% over the next twenty years with the greatest growth expected in Harris, Brazoria, Fort Bend, Galveston, and Montgomery Counties.[49]

Land use in the region is diverse, ranging from urban development to grazing lands and piney forest, from prairies to coastal wetlands and estuaries. The H-GAC region is comprised of varied types of water bodies: Galveston Bay and its complex estuarine system, the San Jacinto River and its associated watershed of bayous and creeks, which flow into the Houston Ship Channel; the Trinity, Brazos, San Bernard, and Colorado River watersheds; Lakes Conroe, Houston, and southern Livingston; and Wallisville Reservoir. There are approximately 27,400 miles of rivers, streams, creeks, bayous, tributaries, canals, channels, tributaries, flood control structures, ditches and shore line in the 13-county Houston-Galveston Area Council region, which drain over 9.130 square miles.[50] Almost the entire population of the Houston metropolitan area (4 million people) resides within half a mile of a water body (3,547,086 persons).[51]

Characterization of Water Bodies.

What type of water body receives primary and/or secondary recreational use? Geospatial parameters (e.g. bayou, flood control channel, gulf, estuary, or lake) are important in study design and data collection. Whether the water body is fresh, salt, or tidal water in composition also affects the type, presence, frequency, and virulence of waterborne pathogens. Another consideration for epidemiology studies or MRA is the location of the water body. Is it urban or rural? Each has characteristic sources, which contribute to the level of waterborne pathogens. Possible sources of bacteria and viruses include wastewater treatment plant (dominate source in urban areas), storm water discharge, developed acreage, septic systems, industrial outfalls, wildlife, agricultural animals dominant source in rural areas), and domesticated pets. Finally, other man-made confounding factors such as channels, some with hard-armored (concrete) sides affect water velocity and conveyance. These in turn affect the water bodies and the level of pathogens therein.

Destination Distance (Residence to Activity Location). The type of recreational activity in urban water bodies is determined by proximity to the water body, characteristics of the water body, and activity. The closer people live to an urban water body, the more likely activity is to occur. The type of activity is a function of the character of the water body – lake, swift moving water, shallow ephemeral stream, estuary, or wetland – along with the needs of the participant.

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[49] Houston-Galveston Area Council. 2004. 2025 Regional Growth Forecast. Houston: Houston-Galveston Area Council.
[50] Houston-Galveston Area Council. 2007. How's the Water: 07 Basin Highlights. Houston: Houston-Galveston Area Council.
[51] Houston-Galveston Area Council. 2007. 2035 Regional Growth Forecast.

Water body type is an important factor in determining how far people will travel to utilize it for recreational purposes. People travel to water bodies to participate in particular activities. For example, White Oak Bayou is likely to receive neighborhood resident use only, perhaps fishing, since there are few amenities, boat launches, and/or parks along its banks. Buffalo Bayou reaches 22 miles from Barker and Addicks reservoir birding areas to Downtown Houston, Allen's Landing, and the "Blue Bayou," before concluding in the Houston Ship Channel, which flows to Galveston Bay. A variety of activities (e.g. birding, canoeing, dragon boat races, fishing, art activities etc.) draws users from the surrounding 50-mile area. Clear Lake, adjacent to major birding sites, Space Center Houston, and fine marinas and water-based activities that draw visitors from across the state. Where Galveston Bay is a national and international destination because of its estuaries, birding activities, and marine activities. These parameters need quantification for inclusion in study design, as they will affect the ability to follow test participants.

Type of Contact Recreation Activity. Determining the type of contact recreation that is occurring in an urban water body is critically important for accurate risk assessment. The type of use is related directly to exposure and by corollary dose response. There are two categories of contact recreation use, primary and secondary, plus one category for non-contact recreation.

Primary Contact Recreation is defined as significant risk of ingestion of water or full body emersion; examples include wading by children, swimming, water skiing, diving, surfing, scuba diving, and subsistence fishing. Each of these activities must be clearly defined. For example, what does "swimming" mean exactly? Estimates of volume of water ingested range from 50 -100 mL per "swimming" event. Ingestion in fresh water is assumed greater than salt water. All other factors being equal, young children are assumed to have the greatest exposure.[52] Risk level for freshwater primary contact recreation according to the Criteria is eight illnesses per 1000 swimmers (Geometric mean: 126 colonies of *E. coli*). Risk levels for primary contact with saltwater are 1.9 illnesses per 1000 swimmers (Geometric mean of 35 colonies of *Enteroccocus*).

Secondary Contact Recreation is defined as incidental contact where the probability of ingesting appreciable quantities of water is minimal. Examples include fishing, commercial, and recreational boating, canoeing, wading by adults, playing in the sand by the water, and limited body contact associated to shoreline activity. Secondary contact assumes parts of the body, primarily the hands, come in direct contact with the water body, but inhalation might also occur through splashing, waves, and wind. Additional contact may occur through handling paddles, fishing tackle, fish, canoes, or kayaks.

Quantification of the exact amount of pathogen-containing water ingested or inhaled (milliliters) is difficult though necessary to determine appropriate risk to human health from secondary contact.

The risk level for secondary contact recreation is 14-15 illnesses per 1000 swimmers, which is 5 times the primary Geometric mean (630 colonies of *E. coli*). This designation is proposed for assignment only where a use attainability analysis has been conducted consistent with 40 CFR

[52] Alexander LM, Haven A, Tennant A, Morris R. 1992. Symptomatology of Children in Contact with Seawater Contaminated with Sewage. *Journal of Epidemiology and Community Health*. 46:340-3444.

131.10 that further demonstrates there is no reasonable potential for primary contact recreation uses to occur.

Non-contact Recreation (NCR) is incidental contact where the probability of ingesting appreciable quantities of water is minimal. It also includes any type of contact recreation considered unsafe for reasons unrelated to water quality or recreation prohibited in water bodies for safety reasons (i.e. Houston Ship Channel.) Examples include fishing, commercial and recreational boating, biking, running, walking, dining at riverside restaurants, and picnicking as well as limited body contact incidental to shoreline activity. Risk level is the same as for secondary contact, five times the primary contact recreation geometric mean (630 per 100 mL, a risk level between 14 - 15 illnesses per 1000 swimmers.

Frequency and Duration of Activity. Risk is a function of frequency and length of exposure to the antagonist. Those exposed to a human waterborne pathogen have different levels of risk depending on whether or not the exposure is daily, weekly, monthly, or yearly. Is exposure intermittent, of short duration (e.g. fishing) or more lengthy (swimming)? Those who live within the immediate proximity of the water body will most likely have the greatest risk with regard to frequency and length of exposure. Seasonal variation in activities, for example, children on summer vacation, is also a factor. Study design requires that each of these factors be clearly defined.

Time of Activity and Ambient Conditions. When does the activity occur? Determining seasonal variations, air/water temperature, time of day, weekday, weekend, and holiday, are important parameters for epidemiological study design. What is the ambient level of pathogens in the water body? Data is available for many regional water bodies through the Clean Rivers Program database maintained by H-GAC to assist in study design. For a specific study, proximity to septic system, wastewater treatment plant, and bacteria levels in a water body after rainfall would also be important.

Exposure to Pathogens – Contact Recreational Use of Urban Water Bodies

Exposure is a key component of risk assessment. The greater the exposure to pathogen-containing water body, the greater risk, seen as a function of type of activity, frequency at which the exposure was taken, rate at which the exposure occurs, duration of the exposure (acute or chronic), and the route of the exposure. In water-based activities, the primary route of exposure is assumed oral ingestion, although exposure to body parts, including dermal, eyes, ears, mouth, throat, inhalation, and aspiration may also occur.

Age of Participant. This is the most significant factor in considering ingestion of water from a water body for use in the dynamic MRA model. Children (preschool, elementary age), teenagers, young adults, adults, and older persons are assumed to ingest different amounts of water when performing the same activity. Active young children wading in shallow water may consume proportionally more water than a swimming adult may, though this difference remains to be quantified. Any MRA must consider this factor in determining dose response, route of ingestion, and infectivity.

Susceptibility of Individuals. Persons particularly at risk of infection are infants, some elderly or immunocompromised people such as those undergoing chemotherapy for cancer; those who have undergone organ transplants; those who are undergoing treatment with steroids; and people with AIDS or other immune system disorders. AIDS patients may have asymptomatic or self-limited symptomatic infections, and may be unable to clear parasites, such as Cryptosporidium, and the disease may produce a prolonged and fulminated clinical course contributing to death.

In Houston, investigations revealed that 8 of 35 (23%) Houston Cryptosporidiosis cases were positive for HIV.[53] Suspected waterborne transmission of pathogens (from contaminated drinking water or contact recreation) or prolonged diarrhea in AIDS patients or history of animal contact warrant investigation. [54] [55]

Pathogens in Water bodies. According to the Centers for Disease Control and Prevention (CDC)[56], a relatively small number of waterborne pathogens are of public health concern, responsible for illness in humans (e.g. gastroenteritis, and fever). These include viruses (Enteroviruses such as Norwalk-like viruses rotavirus, and caliciviruses), protozoan parasites (*Cryptosporidium parvum, Giardia lamblia)* and bacteria (*Salmonella, E. coli* 0157:H7, and *Shigella*). Persons can be exposed to waterborne pathogens in a variety of ways, including drinking water, and to a lesser extent, contact recreation.

In the urban Houston area, the most prevalent human waterborne pathogens causing illness, in order of incidence, are *Cryptosporidium*, *Vibrio* (salt water), *Shigella*, Enterobacteria, *Picornaviruses*[57], which causes Hepatitis A, and Coliphage. Route of exposure is contaminated drinking water rather than contact recreation. Different waterborne pathogens prevail in rural settings because of the changed source type of human-source pathogen contamination. These would include agricultural and wildlife sources, with a decrease in human contamination from malfunctioning wastewater treatment plants and collection systems.

Because disease/illness symptoms (gastroenteritis) of waterborne pathogens are identical to those for foodborne pathogens, one must consider the background level of foodborne organisms in study design so that the causative affects of the waterborne pathogens can be differentiated from those of foodborne pathogens, which are far more prevalent. The most prevalent foodborne pathogens in the Houston area, in order of incidence of illness, include *Salmonella, Shigella, Cryptosporidium,* Enterobacteria, *Vibrio, Picornaviruses,* which causes Hepatitis A, Coliphage, and *Listeria*.

There is little information available in the literature concerning the ambient level of these human disease-causing pathogens in urban water bodies. Another consideration is how rainfall affects the level of waterborne pathogens.

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[53] City of Houston Health and Human Services Department. 2007. Unpublished results.
[54] Heymann DL MD. Editor. 2004. *Control of Communicable Diseases Manual* , 18 Edition. New York: American Public Health Association.
[55] National Center for Infectious Disease. 2007. Infectious Disease Information. Retrieved on August 2, 2007 from www.cdc.gov/ncidod .
[56] Mead et al. 1999.
[57] Picornaviruses are small, nonenveloped viruses containing a single positive strand RNA genome. They are divided into two groups, the Enteroviruses (Poliovirus, Coxsackievirus and Echovirus) and the Rhinoviruses.

A confounding study design factor is the lack of correlation between the surrogate pathogen (*E. coli or Enterococcus)* monitored by ambient and test studies to the level of pathogen present. Will showing a level of "X" surrogate indicator pathogen equate to a level "Y" of a specific waterborne pathogen, which in turn, relates to the possible number of persons becoming ill. It is possible that a statistical analysis (e.g. Path analysis or Structural Equation Modeling) might be useful tools for linking these factors. Other factors yet to be determined are the viability of each of the pathogen under waterborne conditions along with its rate of infection. Low levels of a certain pathogen may result in greater risk to exposed human than higher levels of another, especially in urban situations.

Cryptosporidium. Illness from the protozoan *Cryptosporidium parvum* is most often associated with a contaminated drinking water source. The clinical case definition for Cryptosporidiosis is an illness "characterized by diarrhea, abdominal cramps, and loss of appetite, low-grade fever, and nausea and vomiting. Infected persons may be asymptomatic. General malaise, fever, anorexia, nausea, and vomiting occur less often. The disease can be prolonged and life threatening in the severely immunocompromised."[58]

Laboratory confirmation is usually completed by identifying oocysts in stool or intestinal fluid or by microscopic examination of small-bowel biopsy specimens. In addition, microbiological techniques may be used. These include ELISA (to detect oocysts or sporozoite antigens) or PCR (to detect DNA from the protozoan).[59]

The disease was made a nationally notifiable disease in 1995 with the classification of probable and confirmed cases. The definition of the case reporting was updated and the classification of cases changed in 1998 to confirm symptomatic and confirmed asymptomatic. A confirmed, symptomatic case is a laboratory confirmed case associated with one of the symptoms such as diarrhea with upset stomach and abdominal pain and a slight fever. A confirmed, asymptomatic case is a laboratory confirmed cases associated with none of the symptoms described above. [60]

Cryptosporidium is found in untreated surface water, swimming and wading pools, daycare centers, and hospitals. A person may become ill following infected with as few as 30 microscopic oocysts. *Cryptosporidium* is a leading cause of persistent diarrhea in developing countries. Fecal-oral route is the mode of transmission. This transmission may be from person to person, animal to person, waterborne, or foodborne.

Although *Cryptosporidium* is infectious, there has never been an outbreak of cryptosporidiosis in Houston, based on City of Houston records. During the review period 2000-2004, sixty cases were reported to the Health and Human Services Bureau and only 35 were confirmed Houston cases. The incidence rate during this period is 2.46/1,000,000 for male and 1.12/1,000,000 for female, and with male to female ratio of about 2:1 (table 1). None of these was related to exposure from contact recreation in urban water bodies. Among these 35 cases, 11 cases (32%)

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[58] Heymann DL. 2004.

[59] Center for Disease Control and Prevention. 1997. Case Definitions for Infectious Conditions under Public Health Surveillance. MMWR 46(No. RR-10) Atlanta, GA: Center for Disease Control and Prevention. Retrieved on August 2, 200t from www.cdc.gov/epo/dphsi/casedef.

[60] IBID.

had HIV and/or AIDS. The data showed July to September had the most cases during this period.[61]

The number of Houston confirmed cases (35) in the period of 2000-2004 increased in comparison with the 15 confirmed cases of the period 1995-1999. However, in general, the incidence rate of Houston from 2000-2004 is still lower than that of the entire US population and about the same as Texas' incident rate (except for 2002).[62]

For the purpose of study design, knowledge of the relationship between levels of surrogate pathogen and actual levels of *Cryptosporidium* in the particular water body is important to ascertain.

Incidence of Gastroenteritis. Gastroenteritis (GI) illness is defined as any of the following: diarrhea (three or more loose stools in a 24-hour period), vomiting, nausea and stomachache, and nausea or stomachache that affects regular activity (inability to perform regular daily activities). This is consistent with the recent studies (Wade et al. 2006,[63] Colford et al. 2002[64]). According to the Centers for Disease Control and Prevention, the incidence of diseases from exposure to foodborne pathogens in the whole population of the United States is 47/1,000.[65] EPA sets the acceptable rate of swimming gastroenteritis (illness) associated with primary recreational contact (swimming) rate as 8/1000 for freshwater and 19/1000 for marine water. Thus, a higher level of illness from food sources is tolerated as opposed to waterborne sources. Since the symptoms related to incidence/disease from exposure to foodborne pathogens are very similar to symptoms associated with pathogens from waterborne pathogens, an epidemiological study to differentiate between the two would require additional design criteria. The incidence of incidence/disease from waterborne pathogens may very well be indistinguishable from the more prevalent foodborne pathogen incidence/illness in an epidemiological study.

A study conducted by the Association of Metropolitan Sewerage Agencies using a microbial risk assessment numerical simulation based on 150 literature articles indicated that for *Salmonella* illness from exposure to the most likely volume, judged 1 mL, of Sanitary Sewer Overflow (SSO) water show the median infection estimate to be one illness in 10,000 exposures.[66] An SSO is considered a worst-case scenario and is similar to exposure to raw sewage. It greatly exceeds ambient microbial levels.

Even in this extreme situation, estimated risks attributable to *Cryptosporidium* shows median infection estimates of one infection in 10,000 exposures. *Giardia lamblia*, not a prevalent pathogen in Houston water bodies, show median infection estimates of one infection in 10

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[61] Guerrant RL. 1994. *Cryptosporidiosis*, an Emerging, Highly Infectious Threat. *Emerging Infectious Diseases* Vol. 3 No. 1 Jan.-Mar.
[62] City of Houston. 2007.
[63] Wade TJ, Calderon RL, Sams E, Beach M, Brenner KP, Williams AH, Dufour AP. 2006. Rapidly measured Indicators of Recreational Water Quality Are Predictive of Swimming-Associated Gastrointestinal Illness. *Environmental Health Perspectives* 114(1):24-28.
[64] Colford JM Jr., Rees JR, Wade TJ, Khalakdins A, Hilton JK, Ergas, et al. 2002. Participant blinding and gastrointestinal illness in randomized, controlled trial of an in-home drinking water intervention. *Emerging Infectious Di*sease 8(1):29-36.
[65] Mead P et al. 1999.
[66] Association of Metropolitan Sewerage Agencies. 2004. *Characterization of the Potential Adverse Human Health Effects Associated with Combined Sewer Overflows and Sanitary Sewer Overflows – Limitations of AMSA Technical Memorandum.* Oakland, CA: EOA, Inc.

exposures. Rotavirus and cumulative enteric virus infections associated with an SSO event show median infection estimates of one infection in 100 exposures and one infection in 10 exposures respectively. [67] According to the City of Houston, these are not prevalent either. For primary contact recreation, volumes of 50 to 100 mL may be consumed, leading to much higher incidence rates (1/100 or 1/1).

As specified by EPA, the acceptable swimming associated gastroenteritis (illness) rate is 8/1000 for freshwater and 19/1000 for marine water. This equates to approximately one illness for every 100 recreational swimming events and results in a "maximum allowable density of indicator bacteria that increases as the potential number of exposed individuals increases."[68] At least in the case of *Salmonella*, the exposure from a SSO event is close to the EPA allowable rate. Since an SSO is typically an infrequently occurring, worst-case scenario. Ambient conditions in water bodies in the region are expected to have a lower risk.

A recent Water Environment Research Foundation (WERF) review of 200 articles studying MRA in reclaimed water, using approximately 177,000 static model simulations show that a large percentage of the simulations resulted in extremely low infection levels, about 2.75 cases in the whole population in the United States per incident (1/100,000,000). These studies would provide the lower rate of infection/disease from waterborne pathogens.

Other MRA and Epidemiology Study Considerations

Low Level of Illness/Disease Associated with Contact Recreation in Houston Bayous

The most common waterborne pathogens in contaminated drinking/well water in the area are *Cryptosporidium, Vibrio* (salt water), *Shigella*, Enterobacteria, *Piconarvirus*, and Coliphage. The most common pathogens found in urban water bodies in the Houston-Galveston area are not known, but assumed to include these pathogens. Type and characteristics of pathogens along with exposure route and rate/duration of exposure are critical factors in determining human health risk. For example, if there is very little exposure to pathogens because persons do not participate in primary contact recreation in the urban water bodies, there is a very low incidence of illness, and therefore very low risk. Conversely, if there large numbers of persons participating in primary contact recreation, potential exposure to pathogens in urban water bodies is higher, and the human health risk would be much higher.

A telephone survey of individuals in five major urban watersheds in the Houston area indicates that 8% of those queried had observed individuals swimming in the bayous.[69] Based on the population living within these watersheds (2.5 million), one would expect 200,000 persons to

[67] WERF. 2004.
[68] IBID
[69] CRC. 2007.

have been swimming. Levels of indicator bacteria exceed Criteria in all of these watersheds. Considering the Criteria threshold (8/1,000), one could expect to see approximately 1,600 cases of illness severe enough to report, following primary contact recreation in these bayous.

In the past 7 years, the City of Houston Health and Human Services Department received approximately 10,000 individual incident reports of communicable illness. A review of the incident reports and summaries (weekly, monthly, and annual) showed no incidence of illness associated with contact recreation activities in urban water bodies from 2000 (first year of addressing this association by specific question on the intake form) to the present. In fact, the Department believes no incidence of illness associated with contact recreation to water bodies in the past 15 years.

During this workgroup process, Harris County Flood Control District (HCFCD) indicated it had examined its employee records dating back several decades for incidence of illness associated with secondary, and occasional primary contact, with urban water bodies. Preliminary review has not identified a single case of illness associated with this occupational exposure, which would present a greater risk to human health than occasional recreational contact. It would be interesting to review HCFCD records in detail along with those of other entities whose workers come in contact with urban water bodies on a regular basis (e.g. TCEQ, EPA, United States Geological Survey, Texas Parks and Wildlife Department, etc.) to determine what if illness related to exposure to urban water bodies occurs.

There are several possibilities for the observed apparent very low incidence of illness, which might correlate to very low risk of illness from exposure to pathogens in urban water bodies following primary or secondary recreational contact. The rates of infectivity could be low or pathogens are present in insufficient numbers to cause illness (indicator bacteria levels bare no relationship to the actual number of human pathogens present). Low incidence could be a function of recreators not swimming in urban bayous at all. This would mean that even though pathogen levels of indicator bacteria may exceed Criteria, the overall risk to the human population is low because use is low. Alternately, low incidence of illness could occur because persons do not contact water bodies during periods of high indicator bacteria levels (e.g. high flow).

It could be that human primary contact exposures to pathogens under lake conditions (basis of 1986 Criteria), pose very different and much higher health risk than secondary exposures in urban bayous. Very low incidence of illness could also mean that the majority of recreational activities are secondary in nature and carry a much lower risk of infection.

Another possible explanation is that symptoms of illness were present, but were not serious enough to warrant seeking medical attention. Alternately, even though the reporting process follows CDC guidelines, there could be underreporting of disease or missed records in the region. Many urban areas have large low-income populations that are the least likely to visit a doctor, clinic, or hospital when ill. It could also be that illness from exposure to pathogens in urban water bodies is masked by the background incidence of foodborne illness.

It is possible that the level of indicator bacteria does not show a linear correlation with the level of pathogens actually present in urban water bodies. Some pathogens survive within very narrow temperature gradients or under very specific conditions. If these are not present in urban bayous, pathogens do not survive or reproduce. Thus, compared to the level of indicator bacteria present, the actual level of pathogens capable of infecting humans may be low.

Others suggest that because of the low incidence of primary contact recreation in the whole population and the possible negative bias in reporting, one would expect to see a low incidence of illness, which correlates with low health risk following primary contact recreation in urban water bodies.

Therefore, while all available data suggest that the overall risk of contracting illness from contact with urban water bodies following primary contact during recreational activities appears to be very low, further scrutiny of the available region's health department and occupational records is warranted. The conduct of MRAs will be needed to determine actual risk level.

Despite hypotheses to the contrary, the fact remains that all current data assessing human health risk from exposure to urban water bodies following contact recreation activities in the Houston-Galveston area indicates the risk is apparently very low. This includes City of Houston data, which was collected in accordance with CDC policy for reporting communicable diseases. Area epidemiologists agree with this finding. Development of new criteria must take the apparently low risk factor into account. While MRA studies are costly, they may be a viable option to determining which hypothesis is valid. MRA studies should be conducted as soon as possible.

Background Level of Illness from Human-source pathogens - Foodborne vs. Waterborne

According to the Centers for Disease Control and Prevention (CDC), a relatively small number of waterborne pathogens are of public health concern, responsible for illness in humans (e.g. gastroenteritis, and fever). These include "Norwalk-like viruses and rotavirus (Human Viruses), *Cryptosporidium parvum* and *Giardia lamblia* (Protozoa) and *Salmonella* spp. and *Shigella* spp. (Bacteria)." The probability of infection varies depending on the organism, exposure, and the individual. Nationally, the incidence of illness associated with waterborne pathogens in reclaimed water is 2.75 cases in the whole population of the United States (0.000009/1000).[70] This is significantly below the EPA Criteria actionable level of 8/1000 illnesses per primary contact exposure.

When the EPA Criteria were established in 1986, illness from foodborne pathogens was not a serious problem in the United States. Times have changed. According to the CDC, the incidence of foodborne diseases in the entire population of the United States is 4,700/100,000 population or 47/1000.[71] At this rate of illness, it would be difficult to differentiate illnesses associated with foodborne pathogens from that associated with waterborne pathogens (8/1,000

[70] Mead. 1999.
[71] IBID

Criteria threshold) found in urban water bodies. A robust monitoring program designed to discern the difference between the two would be required. However, it is also feasible that the incidence of illness associated with waterborne exposure to urban water bodies following primary or secondary contact is rare and cases have not as yet been identified. This implies low risk to human health under contact recreational exposure to urban water bodies.

High Flow Issues

Hurricanes, tropical storms, and torrential rains, all of which cause flooding of its water bodies, frequent the Houston-Galveston region. Additionally, Texas has a broad range of climates, habitat, and topography. High flow may definitely impede access to a water body just by the sheer danger of being swept away. Alternately, in streams where there is little or no flow most of the time, periods of high flow may produce enough water to attract children to the water body. In other cases, high flows may produce whitewater conditions that may be attractive to canoeing or kayaking enthusiasts, thus increasing the number of people using the water body for contact recreation than normally might be present. Consideration of high flow on a case-by-case basis seems the most reasonable way to address the issue of human-source pathogens.

Periods of high flow can also contribute to very high bacteria levels from both human and non-human sources. SSO can become more prevalent and storm water is more likely to carry high levels of bacteria from the land surface.

Recently completed H-GAC pilot studies on Mill Creek (East Fork, West Fork, and Main Stem) show significant increased levels of bacteria following 10 days of rain.[72] Pathogen indicator bacteria (*E. coli*) levels at these locations were generally in the range of 200 to 400 cfu/100 mL.[73] Flow for the West Fork (9.3 cfs), East Fork (14.7 cfs), and Main Stem Mill Creek (78.2 cfs) was determined. This increase to 15.9; 95.48; and 36.11 cfs respectively. Indicator bacteria levels increase 10 to 25 fold, with levels of 2,876; 3,348; and 3,588 MPN/100 mL respectively. It is noteworthy that the level of indicator bacteria increased in East Fork to a greater degree than the other water bodies, even though it has no wastewater treatment plant along its reaches. It is bounded by natural areas and ranchland.

Institutional Review Board

Studies utilizing human subjects, in which an individual and his/her health information may be identified, are entitled to protection in accordance with federal regulations and ethical requirements. Study design, questionnaires, and materials must be reviewed and approved by an Institutional Review Board (IRB) comprised of individuals with expertise in assessing the risk to the individual associated with participating in the study. All verbal participants must also provide informed consent before enrollment. If an organization does not currently have an IRB, one must be established or a contractual arrangement established with an entity, which has an established IRB and who is willing to provide review and oversight. There are a number of universities and medical schools in the area with IRBs or Human Use Review Boards who might

[72] H-GAC. 2007. Mill Creek Study.

supply this service or act as a partner for the study. Arrangements and IRB review might add additional time and cost to the study, but is necessary to protect test subjects.

Non-human Sources of Bacteria

EPA's current position on addressing non-human sources of bacteria is found in the final rule promulgating EPA's water quality criteria for bacteria for coastal recreation waters. In an attachment to a December 20, 2006 EPA Region 6 letter, Region 6 provided an option to limit application of bacteria criteria in waters affected by non-human sources. Region 6 stated that "while this rule is specific to coastal waters, the policy regarding the application of bacteriological criteria in waters impacted by non-human sources applies to inland freshwaters as well: 'States and Territories must apply the *E. coli* and *Enterococcus* criteria to all coastal recreation waters. If, however, sanitary surveys and epidemiological studies show the sources of indicator bacteria to be non-human and the indicator densities do not indicate human health risk, then "it is reasonable for the State of Territory not to consider those sources of fecal contamination in determining whether the standard is being attained." A UAA would simply state that inability to meet the standard is due to high natural levels of wildlife or non-human derived indicator bacteria. This is the approach taken in the 1986 bacteria criteria document. It would be reasonable for a State or Territory to use existing epidemiological studies rather than conduct new or independent epidemiological studies for every water body if it is scientifically appropriate to do so.'"

Preponderance of Pathogens in Urban Water Bodies from Non-human Sources. *Escherichia coli* is used both as a predictor of the presence of waterborne human pathogens and as a measure of whether or not a water body meets State of Texas criteria for contact recreation. Water quality data, stakeholder discussions, and field reconnaissance indicate that potential sources of *E coli* loading falls into four basic types: natural, agricultural, residential, and urban. Examples of these sources in these categories include migratory birds, wildlife, chickens (cooped and free ranging), goats, dogs, cats, family pets, failing septic systems, and emergency bypasses from municipal wastewater treatment plants. The potential for all of these exists in the Houston-Galveston urban water body environment. Additionally, other non-point source pollutants like trash, pesticides, sediment, and soils affect indicator bacteria levels.

Identifying indicator bacterial sources is complicated by *E. coli* subspecies composition variability, geographic location, collection time, rainfall, habitat, and re-growth. In the case of bacterial source tracking (BST) methods, a commensurately large host-origin control database is required to encompass these compositional changes for greater reliability. Sample collection must be at collected at multiple locations under variable sampling conditions coupled with rigorous statistical analysis.

There is a growing body of evidence indicating 50 - 80% of surrogate indicator bacteria (*E. coli* and Enterococcus) in urban water bodies are of non-human origin. Underlying pathogens would similarly be from non-human sources.

H-GAC Study - Westfield Estates. H-GAC recently completed a pilot study in a community in northeast Houston, along Halls Bayou, which was chosen for the study because it is served by

on-site wastewater treatment facilities (septic tanks) with a high rate of failure. The pilot study indicated the preponderance (65%) of indicator bacteria were from non-human sources.[74] The study showed *E. coli* and Enterococcus bacterial contamination at all eighteen sites examined in the community and the five in Halls Bayou, at levels significantly above State criteria for recreational activity, ranging from 6 to 600-fold. Bacterial sources were identified as human (16%), dog (33%), and chicken (17%), and unknown (34%). The level of unknown source of bacterial contamination is significant. Characterization of bacterial contamination source risk factors is essential to the development and implementation of a correction strategy, since correcting bacterial contamination from only a single source, e.g. human, will not significantly reduce bacterial contamination in the community. It is also essential in determining risk associated with exposure to pathogens for designing an MRA and developing water quality criteria. As in the City of Houston Health and Human Services Department surveys, there is no evidence that persons in the community have become ill from exposure to contaminated water bodies during contact recreation. No primary or secondary contact to the water body was observed during sampling.

Contact Recreation Use Attainability Analysis Pilot Study for Mill Creek, Austin County, Texas by Houston-Galveston Area Council. Recently completed H-GAC pilot studies on Mill Creek (East Fork, West Fork, and Main Stem); the least impacted water bodies in the region exceed State of Texas criteria by two to four-fold, generally in the range of 200 to 400 cfu/100 mL. These streams have a limited amount of humans living around them. During one sampling period, significant increased levels of bacteria were detected following 10 days of rain.[75] Indicator bacteria levels increase 10 to 25 fold, with levels of 2,876, 3,348, and 3,588 MPN/100 mL respectively. It is noteworthy that the level of indicator bacteria increased in East Fork, with no wastewater treatment plant, surrounded by ranchland and natural areas, to a greater degree than the other water bodies, even though it has no wastewater treatment plant along its reaches. Significant numbers of indicator bacteria must be from non-human sources. This must be considered in the development of new criteria.

Total Maximum Daily Load (TMDL). Information developed in a UAA study is useful for establishing new contact recreational human health risk thresholds under the Clean Water Act (CWA) §304(a) criteria. Once approved by EPA, state standards may be used for several CWA purposes, including §303(d) listings, TMDL calculations, National Pollution Discharge Elimination System (NPDES) permits, and pubic notification at beaches. TMDL calculations for impaired waters listed under §303(d) must be prepared to implement applicable state WQS. Under the Clean Water Act §303(i)(1)(B), States are required to adopt new or revised water quality standards (WQS) for pathogen indicators for which EPA has developed new criteria.

A TMDL is the maximum amount of bacteria a water body can assimilate without exceeding the Water Quality Criteria for designated use for contact recreation. This maximum daily load is also called the maximum load capacity. It is a function of waste load capacity (WLC), load allocation capacity (LA), and the chosen margin of safety (MOS).[76]

[74] Houston-Galveston Area Council. 2007. Failing Septic System Initiative. Houston: Houston-Galveston Area Council.
[75] H-GAC. 2007. Mill Creek Study.
[76] University of Houston. 2006. Total Maximum Daily Load Final Report Summary. February.

The WLC contributors include wastewater treatment plant (WWTP) discharges, biosolid release, some on-site sewage systems, wet weather WWTP overflows, storm water system discharges, bayou sediments, dry weather storm sewer discharges, and wastewater collection/conveyance leaks and some other non-human sources (animals, wildlife, livestock, and avian creatures).

Recently concluded controversial TMDL studies for Buffalo and White Oak Bayous in Houston suggest that the majority of indicator bacteria come from storm water system discharges.[77] In preliminary results, with a very limited set of samples, a significant number of indicator bacteria in storm water discharge would be expected to be of non-human origin. According to this limited study, the second highest discharge of indicator comes from WWTP discharges, by a factor of 10,000 fold less than storm water system discharges in Buffalo Bayou. Levels of indicator bacteria are twice as high in White Oak Bayou as those in Buffalo Bayou. According to the limited TMDL studies, the average daily load of indicator bacteria in Buffalo Bayou is 28,700 billion indicator bacteria per day and 99,000 billion indicator bacteria per day in White Oak Bayou. There are a number of stakeholders who strongly disagree with the allocation of source of indicator bacteria between storm water and sanitary sewer contributions. Additionally, these studies used a relatively small number of bacterial source tracking samples. Some stakeholders do not agree that storm water is the predominant contributor to elevated bacteria levels in urban water bodies. They are in the process of spending their own resources to determine if in fact these figures are correct.

This report does not attempt to resolve issues with the TMDL work in the Houston-Galveston area. However, within the context of the charge for the report, to evaluate the feasibility of MRA or epidemiology studies to determine human risk following recreational contact, the TMDL results are indeed surprising. Despite huge numbers of bacteria present in urban bayous, there have been no recorded incidences of illness associated with contact recreation in Houston urban water bodies, according to the City of Houston Health Department in a population of over 3 million persons. Several reasons are possible. Illness is a function of exposure, level of pathogens ingested, and immunocompetency of the individual, and virulence of the pathogen. Perhaps few people are exposed. Perhaps waterborne pathogens are not as virulent as their foodborne counter parts. Perhaps the level of indicator bacteria is not related to the level of infective pathogens in the water body. Addressing these questions is critical to developing a scientifically sound criteria and whether or not a significant public health risk actually exists in urban bayous.

From these studies, it is clear that there are multiple sources of indicator bacteria, both human and non-human, which must be addressed during the risk assessment process. Additional cohort populations will need to be added to the study to determine the risk of illness from exposure to the most prevalent pathogens.

This rate of illness must be correlated with primary vs. secondary recreational activity in the selected urban water body. If the sources of indicator bacteria are confirmed to be non-human and the non-human indicator densities do not indicate human health risk, then according to USEPA's December 2006 letter, it is reasonable for the State of Texas not to consider those sources of fecal contamination in determining whether the water quality criteria is being attained.

[77] IBID

The criteria would have to be adjusted upward to include the non-human pathogen indicator species in criteria requirements, the criteria values would need to be adjusted upward. The surrogate pathogen indicator level would be inflated by the number of non-human pathogen species, which might be less virulent than the human species. In that case, the use attainability level of 126 MPN/100mL might be raised to 1,200 or 12,000 to account for the higher number of non-pathogenic bacteria. Additionally, the applicability and or relationship of a bacteria indicator species to other human pathogens (e.g. parasites, bacteroides, and viruses) remain to be determined.

Urban Bayou Inability to Meet Water Quality Criteria

In the Houston-Galveston area it may be difficult for urban bayous to meet indicator bacteria levels for contact recreation no matter what criteria is developed. A variety of confounding factors occur including the magnitude of indicator bacteria from non-human sources, high flow conditions, the relationship of indicator bacteria to actual level of pathogen, and issues associated with flowing sub-tropical water bodies.

According to the TMDLs, the greatest contributor to the level of indicator bacteria in Buffalo and White Oak Bayou is storm water system discharges.[78, 79] These TMDL studies have been disputed by some stakeholders. Storm water contains indicator bacteria from non-point sources including those of non-human origin, WWTP overflows, and leakage from sanitary sewer lines. Not all of these sources are controllable in a subtropical climate subject to regular severe flooding. Storm water contributes significant amounts of non-human indicator bacteria into urban water bodies from a number of sources. The Houston-Galveston region is on a major migratory flyway. Urban pets, especially dogs, contribute significantly to indicator load. In the Dallas-Fort Worth Metroplex, 1.2 million pets produce about 900,000 pounds of waste per day (56 dump truck loads).[80] There are also contributions from urbanized wild animals. It will be difficult to design methods to reduce the level of indicator bacteria produced by migratory birds and family pets such that these non-human indicator bacteria do not find their way into urban bayous.

However, based on the limited TMDL studies and other Bacterial Source Tracking Studies (BST) in other parts of the country, the most significant contributions of indicator bacteria does come from non-human sources (50-90%).[81,82,83,84,85] In many studies, the contribution of indicator bacteria from non-human sources is so significant that even if all the obvious sources of human-source indicator bacteria (WWTPs) were removed, urban water bodies would still not be able to meet current Criteria for contact recreation. That is not to say that the frequency of

[78] University of Houston. 2004.
[79] University of Houston. 2005.
[80] Gillette B. 2006. You're . Dogs Waste Could be an Environmental Hazard. CBS 11 Garland, Texas. April 20, 2006. Retrieved April 24, 2006 from http://cbs11tv.com/local/local_story_110182747.htmL .
[81] PBS & J. 2007. Mill Creek Study.
[82] University of Houston. 2005.
[83] Southam G. 1998.
[84] Clark ML and Gamper ME. 2000
[85] Houston-Galveston Area Council. 2007. Failing Septic System Initiative.

WWTPs monitoring, especially unannounced, should not be increased or that current regulations might not be tightened to reduce contamination by indicator bacteria from identifiable human sources. Simply, focusing on correcting problems with WWTPs may not reduce indicator bacteria levels enough to allow urban bayous to meet Criteria requirements for contact recreation. Further bacterial source tracking studies are needed to resolve this issue.

A final criteria would need to take these factors into account along with the low level of risk to human health associated with primary contact following recreational activities in urban water bodies.

Protocol Requirements

Benchmarks for Criteria Development

Before defining approaches and applications for development of a new water quality criteria, desirable attributes or benchmarks for the criteria must be considered. The USEPA Expert Scientific Workshop 2007 lists seven benchmarks desirable in the process. Houston-Galveston Area Council supports and agrees with these benchmarks.

- "The criteria must be health based.
- The criteria should demonstrate utility for and be compatible with all of the CWA §304(a) (as amended) needs, including notification at beaches, for development of TMDLs and NPDES permits.
- The criteria should be scientifically defensible for application in a wide variety of geographical locations (climate conditions), including fresh and marine waters, and temperate, subtropical, and tropical waters.
- The criteria should be sufficiently robust and flexible so it can be configured to protect the public health to those exposed to recreational water impacted by sewage effluent, concentrated animal operation contaminated runoff, non-point sources, and waters not impacted by anthropogenic sources (and non-human sources of fecal contamination).
- The criteria should be robust and flexible so it can be configured to provide regulators the ability to protect susceptible (sensitive) subpopulations such as children and immunocompromised individuals.
- The criteria should be based on analytical methods that are reliable, robust, and provide reproducible results.
- The criteria should protect primary contact recreation in freshwaters, marine waters, and temperate, subtropical, and tropical waters equally. Similarly, criteria should provide equal protection to those exposed to effluent, urban runoff, and/or non-point source runoff impacted waters via primary contact recreation.[86]

World Health Organization (WHO) Approach

Adoption of the World Health Organization (WHO) approach for water quality setting has direct applicability to criteria development for contact recreation in urban water bodies. It provides

[86] USEPA. 2007. Expert Scientific Workshop. P 11.

- Basis for standard setting in light of local and regional circumstances.
- Evaluates the nature and seriousness of local endemic illness.
- Examines exposure patterns.
- Considers competing health risks that are not associated with recreational water exposure.
- Uses sanitary inspection (survey) and
- Uses microbial risk assessment.
- *Enterococcus* as a fecal indicator.
- Five-level classification scheme for recreational water environments. [87]

Data Needs

The following table summarizes the information and data needed to conduct an MRA or epidemiology study (Table 2) in the Houston-Galveston Area. Priority ranking is determined by the relative order in which the data must be collected, not its importance in development of criteria.

Funding Needs

A list of the studies that should be undertaken to perform an adequate MRA for the Houston-Galveston area is provided in Table 2. The studies are ranked by priority in terms that the data must be acquired, not the relative importance of the study to overall risk assessment. It is not possible to determine the cost of each of these studies at this time. A detailed budget will need to be worked out, which would be protocol specific and outside the boundaries of this report. The Contact UAA Workgroup is hesitant to provide specific dollar values until protocols are finalized.

Substantial funding will be required for the conduct of an MRA Study, most likely in the amount of millions of dollars. It is doubtful any single source could provide the necessary funds. TCEQ, Harris County, the City of Houston, Storm Water Quality Joint Task Force, EPA, and private organizations (e.g. WERF) are likely contributors to complete the study. Considerable interagency cooperation is necessary to put funding into place.

[87] USEPA. 2007. Expert Scientific Workshop pg. 14.

Table 2 - Summary of Needs to Complete MRA Study

Category	Need	Availability of Data	Priority	Comments
Environment	Characterization of the Region	Yes	1	H-GAC in-house databases from 2035 Forecast and Clean Rivers Program, and Water Quality Plan
Environment	Characterization of Water Bodies (not associated with pathogen identification)	Most	1	H-GAC In-house Database - Clean Rivers Program (CRP)
Pathogen	Determination of Pathogen Distribution in Ambient Water Conditions, including seasonal variation	Partial	1	Pathogens from human and non-human sources, habitat, type of water body and hydrologic conditions, suspended solids, source of pathogen (bacterial, parasite, and viral) contamination
Pathogen Environment	Determination of Pathogen Distribution in High Flow Water Conditions	No	3	Pathogens from human and non-human sources, habitat, type of water body and hydrologic conditions, suspended solids, source of pathogen (bacterial, parasite, and viral) contamination
Individual	Destination Distance	Partial	3	Distance from residence to contact recreation activity. H-GAC In-house databases. Calculations required
Individual	Survey - Type of Contact Recreation	No	1	Urban water body uses: Primary or Secondary
Individual	Survey - Time, Season, Frequency and Duration of Activity	No	1	

Category	Need	Availability of Data	Priority	Comments
Individual	Characterization of Contact Recreation Participant	No	2	Age, gender, immunocompetency/susceptibility to pathogen infection,
Pathogen	Characterization of Waterborne Pathogen in Urban Settings	No	1	Top five pathogens causing illness/disease following exposure to water bodies during contact recreation: primary and secondary
Individual Risk	Exposure to Pathogens - Contact Recreational Use of Urban Water Bodies	No	2	Determination of route, amount of water ingested, amount of pathogen present following exposure
Pathogens	Waterborne Pathogen Level under High Water Flow Conditions	No	3	Thunderstorms, flash floods, tropical storms, and hurricanes; includes bacteria, virus, and parasites
Environment Pathogen	Non-human Sources of Pathogens (bacteria, parasites, and virus)	No	1	Some work with indicator and pathogens

Category	Need	Availability of Data	Priority	Comments
Individual	Background Level of Gastroenteritis	No	2	Foodborne and other non-waterborne pathogens
Individual Risk	Incidence of Gastroenteritis following Exposure to Urban Water Bodies	No	3	Primary and Secondary contact recreation. Exposure through various routes
Risk Individual	Institutional Review Board	No	2	Requires arrangement with currently existing IRB
All	Protocol Development - MRA	No	2	
Individual Pathogen Risk	Protocol Development-Epidemiology Study	No	2	Prospective
All	Assessment Procedures	No	1	
Risk	Determination of Health Risk from Contact Recreation	No	3	Primary and Secondary
Risk	Development Recommendations for Criteria for Secondary Contact Recreation	No	3	
Environment	Determination of Ability of Urban Water Bodies to Meet Criteria	No	3	
All	Cost - Benefit Analysis of Criteria Implementation	No	3	
All	Estimate of Cost of Meeting Criteria in Urban Water Bodies	No	3	
All	Developing Funding Sources	No	1	Consortium of Harris County, the City of Houston, Joint Task Force, EPA, TCEQ and private organizations (e.g. WERF)

Recommendations

H-GAC addresses several questions posed by TCEQ for attaining scientifically sound water quality criteria for bacteria for contact recreation use of urban water bodies in the region. These include: appropriateness of current standards for contact recreation, feasibility of establishing standards for secondary recreational contact, evaluation of protocols and assessment procedures, ability of urban water bodies in the gulf coast region to meet current contact recreation standards, cost-benefit of MRA and epidemiology studies, and quantification of human health risk from exposure to pathogens (human and non-human origin) during contact recreation activities in urban bayous.

Appropriateness of Current Standards for Houston-Area Bayous

Comments on the Ambient Water Quality Criteria for Bacteria – 1986 are unanimous in concerns about lack of controls, study design that introduces bias in test subject population, biased statistical analysis, localized results, and limited quantity of data. Additional concerns include lack of consideration of background levels of pathogens, relationship/correlation of indicator species to human-source pathogens, subtropical climate differences, and water body character, and hydrology, non-human sources of pathogens and/or background microbes. Based on the lack of sound scientific investigation, current contact recreation standards are inappropriate for water bodies in a wide variety of locations, including the Houston area.

Further studies are required to establish a valid standard, which will adequately protect humans from exposure to human-source pathogens during contact recreation in urban bayous.

Secondary Use Standards for Urban Bayous

In urban environments, swimming and other primary routes of exposure are exceptions to the recreation use rule. This may explain in part why the City of Houston Health and Human Services Department has not documented cases of gastroenteritis associated with recreational contact with urban bayous. Persons rarely swim in urban rivers, bayous, or streams, and if they do, it is a few individuals rather than a "beach-sized crowd." Secondary recreational activity that includes fishing, canoeing, and adult wading is more common. Moreover, access to the water bodies is often limited in urban settings decreasing the number of persons exposed. Additionally, there are virtually no scientific data available that characterizing secondary contact to use as a base for criteria for secondary contact recreation exposure, either in freshwater or marine situations. A different standard for secondary exposure in urban bayous deeds development in order to protect the public from the most likely risk, if indeed one exists after exposure to urban water bodies following recreational activities.

There is a distinct lack of data available for critical factors associated with secondary recreational contact in water bodies in an urban setting. Quantification of the actual level of exposure (i.e. length of time in the water, extent of contact with the water, amount of water ingested) needs to be determined for secondary exposure to urban water bodies. Further, the relationship between indicator organism and specific pathogen is very likely to be different in urban streams as opposed to a lake or beach setting. Urban water bodies need their own secondary standard.

A microbial risk assessment based approach to setting the recreational water quality criteria needs to be developed. Reliance on epidemiological studies alone assumes "similarity of use and exposure scenarios, and water quality and environmental conditions." Water quality and environmental conditions are not the same in subtropical urban environments as they are in the cold water of the Great Lakes.

Concentrations of *Enterococcus* spp. and *E. coli* form the basis of the bacteria standards. These do not differentiate between human, non-human, and environmental (e.g. soil, water, sand, plants) sources of bacteria, conditions which significant in the regions urban water bodies. Data does not exist to substantiate an approximate trend for human-source pathogens such that the presence of higher indicator species indicates a higher concentration of pathogens also exists.

The USEPA criteria rely on a hypothesis that a five-fold increase in gastroenteritis over the primary contact guidelines is an acceptable level of human health risk for secondary exposure in an urban setting. Justification for extrapolating primary contact data to secondary contact situations requires additional data and scientific analysis.

The USEPA 2003 Guidance document acknowledges, “animal fecal inputs and impairment of waters due to animals may be a health risk with pathogens such as *Campylobacter, E. coli 0157H7, Salmonella, Cryptosporidium,* and *Giardia,* which can originate from animals as well as humans and cause illness in humans." Several recent studies indicate that 50 – 80% of *E. coli* in Houston urban bayous may come from non-human sources. Does this enhance or lessen the human health risk of illness following exposure to urban water bodies after secondary recreational contact? Further studies are needed need to resolve this issue.

Sampling Protocols and Assessment Procedures

Appropriateness of Current Protocols and Procedures. The literature contains many flawed studies, which use the static model for MRA. Some have proposed continued use of the static model to determine relative risk to the human population for illness following exposure to human-source pathogens during contact recreation in urban bayous. The static model is certainly less costly because of lower data requirements. The three conditions under which the static and dynamic models produce similar results are (1) the background concentration of the pathogen in the population is zero or unimportant, (2) the duration of infection and disease approaches zero, and (3) infection

and/or disease do not confer immunity or the duration of immunity approaches zero. Urban bayous do not meet conditions 1 and 2, and the background level of gastroenteritis is not zero in the Houston metropolitan area. A quantifiable level of gastroenteritis exists in the test population following exposure to foodborne pathogens and waterborne (not associated with contact recreation) pathogens.

Additionally, the duration of disease/illness can last several days or longer. It is not zero. Based on City of Houston data, the incidence of foodborne illness is much higher than any associated with exposure to waterborne pathogens. Use of the static model along with flaws in earlier epidemiology studies does not provide a scientifically sound basis for promulgating regulations.

Utility of Epidemiology Study Performed in Conjunction with MRA

Epidemiology is the study of the distribution and determinant factors affecting the health and illness of populations and the application of these studies to control of human health problems and preventative medicine. It uses evidence-based methodology for identifying risk factors for disease with the goal of uncovering relationships between exposure to a specific agent and changes in health status of individuals and the exposed population. "Epidemiological studies can never prove causation; that is, it cannot prove that a specific risk factor actually causes the disease being studied. Epidemiological evidence can only show that this risk factor is associated (correlated) with a higher incidence of disease in the population exposed to that risk factor. The higher the correlation the more certain the association, but it cannot prove the causation."[88]

Epidemiology studies require a large number of persons in several cohort groups. Based on preliminary findings for the UAA, it will be virtually impossible to secure the 5,000 or more individuals necessary to perform a statistically valid prospective epidemiology study for urban water bodies used in secondary recreational contact. However, when used as part of an MRA, more limited epidemiology studies offer the best information to assist in determining public health policy and water quality criteria and standards, even though their independent utility is limited. For example, one could follow small groups such as the annual Buffalo Bayou (Houston) dragon boat racers, approximately 200 persons. Another small group conducts fly fishing classes on Sims Bayou. The frequency could be noted and possibly ingestion rates determined for each group, along with food intake, length of exposure, and illness. Results would be used to calibrate the local MRA dynamic model and/or assist other localities with similar test population activities.

MRA Protocol Choice – Dynamic Model. Use of the dynamic model with addition of expert recommendations to correct flaws in earlier epidemiology studies provides a scientifically sound basis for promulgating regulations. This model is a costly endeavor because current literature information is inadequate. Considerable effort will be required to acquire necessary data to use as a scientifically sound basis for the development of appropriate criteria.

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[88] Extension Toxicology Network. 1993. Epidemiology. Retrieved on July 2, 2007 from http://pmep.cce.cornell.edu/profiles/extoxnet/TIB/epidemiology.htmL.

Cost - Benefit of MRA or Epidemiology Study. There are no elements in ordinary life that have zero risk of some harm befalling an individual. Public policy dictates setting a threshold level of number of cases of gastroenteritis associated with exposure to recreational activity in urban water bodies before action. In the case of human health risk associated with exposure to waterborne pathogens in urban bayous, the apparent absence of identifiable illness begs the question as to whether or not sufficient evidence is available to determine human health risk on which to base development of the criteria. If human health risk is present, is it a level where something should be done about it? A small quantifiable risk may be present acknowledged in a criteria but changed from a management action to and advisory such as, "If one wants to be completely safe from getting sick from bacteria in the bayou, don't swim in it, just as you don't walk outside in a thunderstorm so you will not be hit by lightening."

The incidence of gastroenteritis associated with foodborne exposure to human-source pathogens poses a far greater risk to human health than illness from waterborne pathogens in urban water bodies. Public policy determines the level of risk acceptable to society and how funds should be allocate to manage this risk.

Meeting Contact Recreation Standards

Studies are currently underway to ascertain whether the least impacted watersheds in the area can meet contact recreation criteria. Least impact means few if any WWTPs, little urban development, and few on-site septic systems. Indicator bacteria levels in these watersheds would be from wildlife, birds, soil, and other naturally occurring sources. If these watersheds cannot meet the Water Quality Criteria, attempting to meet criteria in urban water bodies would be extremely difficult.

Recent pilot studies on a least impacted water body in the Houston-Galveston area, Mill Creek, showed current standards exceedence by two to three-fold. The study was completed under wetter than normal conditions in June and July 2007. Mill Creek is located in rural Austin County, approximately 50 miles northwest of Houston. Only two small WWTP (less than 100,000 MGD) are located on the Creek and a single five-lagoon WWTP serving 300 persons on its West Fork. The East Fork of Mill Creek has no WWTPs. Exceedence ranged from 250 to 400 MPN/100mL on the Creek and its branches, including the East Fork.

Human Health Risk: Contact Recreation Exposure, Human-source Pathogens and Urban Water Bodies

All AWQCB reviewers recommend a full evaluation of relationships between indicator species and health risks along with incorporating a more complete understanding of indicator species ecology, microbial source tracking, and sample statistics to provide

adequate public health safety[89] in urban water bodies in the Houston-Galveston and surrounding areas.

Based on current City of Houston Health and Human Services Department data, the risk of illness from exposure to human-source bacteria from contact recreation is very low. It may be difficult to determine given the far greater incidence of foodborne illness with similar symptoms.

Coordinate Project Development and Implementation Nationwide

A number of studies determining parameters necessary for MRA determination are planned or underway across the United States. For example, the Chicago Water Authority plans a controlled study to determine the amount of water ingested during various types of primary and secondary recreational activities. This study will be performed in a swimming pool monitoring using cyanuric acid.[90] This compound stabilizes chlorine in swimming pool water and is easily detectable in human urine. Results would be directly applicable to all MRA and/or epidemiology studies in the country. Characterization of various parameters associated with Houston-Galveston urban water bodies might be applicable to other subtropical regions, while studies conducted in northern regions be applicable to risk assessment in the Great Lakes and Atlantic states. Coordination of studies and results by USEPA, its regional offices, and/or other entities (e.g. WERF) would provide less duplication and better utilization of limited resources of time, staff, and funding.

Conclusion

Reviewers, including USEPA's own peer review group and workshop participants agree that the Ambient Water Quality Criteria for Bacteria – 1986 is based on inadequate epidemiology studies. Study design in the Criteria is flawed, with lack of control cohort populations who neither swam nor frequented the beach. Statistical analysis was not strong. In fact there is no statistical difference in illness in the swimmer cohort and the beach recreator (non-swimmer) cohort ($R^2 = 0.67$ in both cases). USEPA and TCEQ are to be commended in their efforts to develop new criteria based on sound science. Based on this feasibility study, which contains some data from pilot studies, H-GAC draws the following conclusions at this time:

1. Epidemiology studies alone are not recommended.
    - It will be difficult and time-consuming (years) to find sufficient numbers of persons (7,000 to 10,000) to assess illness from exposure to waterborne pathogens following contact recreation (primary or secondary)

[89] Berkelman R. 2004.

[90] Meeting with Metropolitan Water Reclamation District of Greater Chicago. 2007. Urban Water Body Risk Assessment. February 28, 2007. Chicago, Il.

- The City of Houston does not have record of any illness associated with exposure to urban water bodies dating back to 1992. This may indicate incidence of illness is rare.
- Background level of illness (gastroenteritis) from foodborne pathogens is significantly greater than the Criteria level. It is doubtful the incidence of illness associated with exposure to waterborne pathogens following contact recreation in urban water bodies will be discernable form the foodborne illness.

2. Microbial risk assessment (MRA) using the dynamic model is recommended to commence within 1 year.
    - The model is based on infectious disease parameters rather than chemical ingestion.
    - Since data on some of the parameters required to conduct the MRA are not available, the study will provide information characterizing the environment of urban water bodies, information characterizing the pathogens associated with illness from exposure to urban water bodies, characterization of individuals involved in contact recreation, as well as characterize risk.
    - MRA requires a small study population.
    - It requires fewer participants in cohort pathogens and evaluates environmental and human parameters.

3. Urban water bodies exhibit an inherent inability to meet water quality criteria.
    - Significant levels of indicator bacteria coming from non-human sources, which are not easily controlled, are present.
    - The least impacted steams in the region, with few if any wastewater treatment plants along their recesses contain levels of indicator bacteria 2 to 4-fold above current Criteria during wet conditions and 25-fold increase following 10 days of rain.

4. A uniform definition for primary and secondary contact recreation is necessary.

5. A separate criteria for secondary recreation is necessary

6. Levels of human pathogen in urban water bodies must be correlated with the level of indicator or surrogate pathogen chosen.

7. The actual illness rate associated with the top five waterborne pathogens in a subtropical region must be correlated with the level of indicator bacteria in urban water bodies associated with both primary and secondary recreational contact.

8. Historical aerial photography and Geographic Information Systems (GIS) coupled with census data may assist in determining background and historical uses of urban water bodies.

9. Bacteria indicator species levels over varying flow regimes should be assessed as predictive tools for determining water body closures.

10. Health risk associated with exposure to waterborne pathogens following exposure to urban water bodies is apparently very low.
    - Based on current levels of indicator bacteria in Houston area urban bayous, 21/1000 cases of GI illness are expected.
    - No recorded incidence of GI illness associated with exposure following contact recreation in a population of 3.2 million persons in the Houston area in the past 7 years according to the Houston Department of Health and Human Services.
    - Background incidence of food borne GI illness is 47/1000 and a higher incidence than expected from bacteria levels in urban bayous, posing a higher risk to human health than GI illness associated with recreational contact to urban water bodies.

11. Planning, communication, and coordination between USEPA, its regions, and state authorities (e.g. TCEQ) is necessary
    - Stronger data sets and tools will be developed from which to develop national criteria are necessary.
    - It will avoid costly and time-consuming duplication of effort on many agencies working on projects throughout the country.
    - Peer review can be coordinated.
    - Stakeholder input can be shared
    - Some studies must be conducted locally. A cold-water lake has different characteristics than a sub-tropical bayou.

12. Adoption of the World Health Organization (WHO) approach for water quality setting has direct applicability to criteria development for contact recreation in urban water bodies. It provides
    - Basis for standard setting in light of local and regional circumstances.
    - Evaluates the nature and seriousness of local endemic illness.
    - Examines exposure patterns.
    - Considers competing health risks that are not associated with recreational water exposure.
    - Uses sanitary inspection (survey) and
    - Uses microbial risk assessment.
    - Five-level classification scheme for recreational water environments. [91]

MRA and/or epidemiology work (in other regions) cannot be completed in a vacuum. Coordination on a national level is needed to make the best use of limited resources. For example, it is not necessary for every one involved in risk assessment to identify characteristics and parameters for canoeing. If one agency is looking at canoeing, another entity could be looking at ingestion rates, and still another group completing a

[91] USEPA. 2007. pg. 14.

different parameter from the priority list. Granted, some confounders must be studied on a local basis. For example, bacterial re-growth in sub-topical Houston is different from that in temperate Boston. TCEQ would do well to coordinate with USEPA and the EPA regions to determine which of the above priority parameters are best conducted in the Houston Region. If EPA is developing a national criteria for Water Quality for Contact Recreation, sound science dictates it be based on nationally generated data. Extensive coordination is needed by USEPA its regions, state and local authorities, and stakeholders to determine studies planned, underway, and completed to avoid duplication. The Houston-Galveston region looks to TCEQ and USEPA to provide leadership in establishing appropriate criteria to protect the public from unacceptable risk from exposure to urban water bodies following primary or secondary contact recreation.

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