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REPORT OF THE EXPERTS SCIENTIFIC WORKSHOP ON CRITICAL RESEARCH NEEDS FOR THE DEVELOPMENT OF NEW OR REVISED RECREATIONAL WATER QUALITY CRITERIA

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Workshop Chair:
Denise Keehner, USEPA

Workshop Experts:
Nicholas Ashbolt, USEPA
Thomas Atherholt, New Jersey Department of Environmental Protection
Michael Beach, Centers for Disease Control and Prevention
Bart Bibler, Florida Department of Health
Alexandria Boehm, Stanford University, California
Rebecca Calderon, USEPA
Jack Colford, University of California, Berkeley
Elizabeth Doyle, USEPA
Alfred Dufour, USEPA
Lee Dunbar, Connecticut Department of Environmental Protection
Lora Fleming, University of Miami School of Medicine and Rosenstiel School of Marine and Atmospheric Sciences, Florida
Charles Hagedorn, Virginia Tech
Joel Hansel, USEPA
Lawrence Honeybourne, Orange County Health Care Agency, Santa Ana, California
Donna Francy, U.S. Geological Survey
Roger Fujioka, University of Hawaii, Manoa
Toni Glymph, Wisconsin Department of Natural Resources
Mark Gold, Heal the Bay, California
Paul Hunter, University of East Anglia, U.K.
Dennis Juranek, Centers for Disease Control and Prevention (retired)
David Kay, University of Wales, U.K.
Sharon Kluender, Wisconsin State Laboratory of Hygiene
Erin Lipp, University of Georgia
Graham McBride, National Institute of Water and Atmospheric Research, New Zealand
Charles McGee, Orange County Sanitation District, California
Samuel Myoda, Delaware Department of Natural Resources
Charles Noss, USEPA
Robin Oshiro, USEPA
James Pendergast, USEPA
Mark Pfister, Lake County Health Department, Illinois
John Ravenscroft, USEPA
William Robertson, Water, Air and Climate Change Bureau, Health Canada
Stephen Schaub, USEPA

Mark Sobsey, University of North Carolina, Chapel Hill
Jeffrey Soller, Soller Environmental, California
Michael Tate, Kansas Department of Health and Environment
Peter Teunis, RIVM (National Institute of Public Health and the Environment), Netherlands
Gary Toranzos, University of Puerto Rico, Rio Piedras
Timothy Wade, USEPA
John Wathen, USEPA
Stephen Weisberg, Southern California Coastal Water Research Project
David Whiting, Florida Department of Environmental Protection
Richard Zepp, USEPA

Workshop Organizing Committee:

Shari Barash	USEPA
Rebecca Calderon	USEPA
Elizabeth Doyle	USEPA
Alfred Dufour	USEPA
Samantha Fontenelle*	USEPA
Mark Gibson*	ICF International
Patricia Harrigan	USEPA
Peggy Himes	Great Lakes Environmental Center
Rick Hoffmann	USEPA
Audrey Ichida*	ICF International
Beth Leamond	USEPA
Patrick McCool	Great Lakes Environmental Center
Charles Noss	USEPA
Kevin Oshima	USEPA
John Ravenscroft*	USEPA
Grace Robiou	USEPA
Cynthia Roberts	USEPA
Stephen Schaub	USEPA
Timothy Wade	USEPA
John Wathen	USEPA

* Workshop proceedings document managers

Appendix B includes a complete list of all persons who attended the workshop and their affiliations and contact information, including workshop experts, EPA resource personnel, and meeting support personnel (note takers, meeting facilitator, logistics staff).

Report cover photo credits:
Charles Hagedorn, Virginia Tech, Blacksburg
Lawrence Honeybourne, Orange County Health Care Agency, Santa Ana, California

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TABLES AND FIGURES

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ACRONYMS

7Q10	the lowest streamflow for 7 consecutive days that occurs on average once every 10 years
AWQC	ambient water quality criteria
ASABE	American Society of Agricultural and Biological Engineers
ATP	adenosine triphosphate
BEACH Act	Beaches Environmental Assessment and Coastal Health Act of 2000
BMP	Best Management Practices
CAFO	concentrated animal feeding operation
CDC	Centers for Disease Control and Prevention
cfu	colony forming unit
CSO	combined sewer overflow
CWA	Clean Water Act
DNA	deoxyribonucleic acid
DU	designated use
EHEC	enterohemorrhagic *E. coli*
EPA	U.S. Environmental Protection Agency
EU	European Union
FDA	U.S. Food and Drug Administration
FFU	focus forming units
GC/MS	gas chromatography-mass spectrometry
GI	gastrointestinal
GIS	geographic information systems
GM	geometric mean
HACCP	Hazard Analysis Critical Control Point
HEV	hepatitis E virus
HIV/AIDS	human immunodeficiency virus/acquired immune deficiency syndrome
HPLC	high performance liquid chromatography
HSPF	Hydrological Simulation Program-Fortran
ILSI	International Life Sciences Institute
IMS	immunomagnetic separation
ISO	International Organization for Standardization
L	Liter
mL	Milliliter
MPN	Most Probable Number
MST	microbial source tracking
NASBA	nucleic acid sequence based amplification
NEEAR	National Epidemiological and Environmental Assessment of Recreational Water Study
NOAA	National Oceanic and Atmospheric Administration
NPDES	National Pollutant Discharge Elimination System
NPS	non-point source program
NWS	National Weather Service
PCR	polymerase chain reaction
pfu	plaque forming unit

POP	probability of precipitation
POTW	publicly owned [wastewater] treatment works
QMRA	quantitative microbial risk assessment
qPCR	quantitative polymerase chain reaction
RCT	randomized controlled trial
RDS	relative standard deviation
RMSE	root mean square error
RNA	ribonucleic acid
SAFE	Swimming Advisory Forecast Estimate
SCCWRP	Southern California Coastal Water Research Project
SD	standard deviation
SETAC	Society of Environmental Toxicology and Chemistry
SRC	sulphite-reducing clostridia
SSM	single sample maximum
SSO	sanitary sewer overflow
STEC	shiga-toxin producing *E. coli*
SWMM	Storm Water Management Model
TMA	transcription-mediated amplification
TMDL	total maximum daily load
UAA	Use Attainability Analysis
U.K.	United Kingdom
URI	upper respiratory illness
U.S.	United States
USGS	U.S. Geological Survey
UV	ultraviolet light
WQS	Water Quality Standards
WHO	World Health Organization (United Nations)

INTRODUCTION

Purpose of the Workshop

Since the U.S. Environmental Protection Agency (hereafter EPA or the Agency) last published recreational water quality criteria in 1986, there have been significant advances, particularly in the areas of molecular biology, microbiology, and analytical chemistry. EPA believes that 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. To this end, EPA has been conducting research and assessing relevant scientific and technical information to provide the scientific foundation for the development of new or revised criteria. The enactment of the Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 (which amended the CWA) required EPA to conduct new studies and issue new or revised criteria, specifically for Great Lakes and coastal marine waters.

From March 26 through 30, 2007, EPA convened a group of 43 national and international technical, scientific, and implementation experts from academia, numerous states, public interest groups, EPA, and other federal agencies, at a formal workshop to discuss the state of the science on recreational water quality research and implementation.

The purpose of the workshop was for EPA to obtain individual input from members of the broad scientific and technical community 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-term. Near-term needs were defined as specific research and science activities that could be accomplished in 2 to 3 years so that results are available to EPA in time to support the development of new or revised criteria. The new or revised criteria, which would be available from EPA in roughly 5 years (2012), must be scientifically sound, protective of the designated use, implementable for broad CWA purposes, and when implemented, provide for improved public health protection. (See Appendix A for the full charge to the experts.) The Agency wants to develop this new or revised criteria in a highly participatory framework within the next 5 years based on the best available science.

Workshop Design

The *Experts Scientific Workshop on Critical Research and Science Needs for the Development of New or Revised Recreational Water Quality Criteria* was designed to be similar in organization and format to the Society of Environmental Toxicology and Chemistry (SETAC) Pellston Workshops, where technical experts in a particular subject area are invited to participate and evaluate current and prospective environmental issues. A Pellston-type workshop typically brings together between 40 to 50 technical experts from academia, business, government, and public interest groups. Experts are semi-sequestered for up to a week to facilitate focused discussions and individual and collaborative writing of a draft summary report by the end of the workshop. Subject leaders are then responsible for consolidating, editing, producing, and distributing the final (formal) workshop proceedings.

Participant Affiliation Balance

In addition to U.S. and international experts drawn from academia, public interest groups, and numerous state and other federal agencies, EPA selected several experts from within EPA to serve in the workgroups (see Appendix B for participant list). The 43 experts serving in 7 subject areas were supported by a total of 9 EPA resource personnel, 10 note takers, 3 logistics contractors, and a professional facilitator. The proper balance between EPA presence and outside experts was crucial for keeping the discussions on track with EPA's needs from the workshop while providing ample opportunity for the external experts to voice their opinions and intellectually explore topics of interest to EPA.

Agenda Overview

The workshop began on Sunday evening, March 25, 2007, with a logistics meeting for the workgroup chairs, EPA staff, and note takers. The plenary sessions on Monday served to orient participants regarding CWA §304(a) AWQC and EPA's needs from the workshop discussions and these proceedings. Monday afternoon the seven workgroups met for the first time to discuss interpretation of the charge questions (Appendix A). On Tuesday, all workshop participants met in a plenary session, which was followed by workgroup sessions throughout the day. The agenda facilitated and encouraged the workgroups to meet with each other to discuss common and overlapping issues. At the end of the day the workshop participants met again in plenary to hear report-outs from each workgroup chair that described their progress for the day.

Because the seven workgroup topics have many overlapping issues, it was important for the groups to communicate as needed so they could both stay informed of and build on each other's discussions. In addition to several joint breakout sessions, the workgroup chairs also shared all of their meals to discuss ongoing progress. On Wednesday, the workshop participants met once again in a plenary session to discuss overall progress followed by workgroup breakout sessions where each group continued discussions and began writing a draft workgroup report. The workgroups continued writing on Thursday. Friday morning, each workgroup turned in a 10 to 20 page draft report and their respective chairs provided an overview of each report regarding the major themes discussed and critical research needs in a final plenary session.

Seven Workgroup Topics

The seven workgroup topics are presented in seven chapters in this report. The relationships between these and other topics are graphically represented in Figure 1. In Figure 1 shaded boxes correspond to the seven workgroups. The alternatives boxes in Figure 1 refer to various possible indicators that a toolbox approach could provide for each of the CWA applications. The charge questions helped the workgroups to define the scope of their discussions. The experts were asked to provide their individual insights on the state of the science as well as critical path research that could be completed by EPA in the next 2 to 3 years. A short description of each workgroup and the tasks EPA asked them to discuss follows.

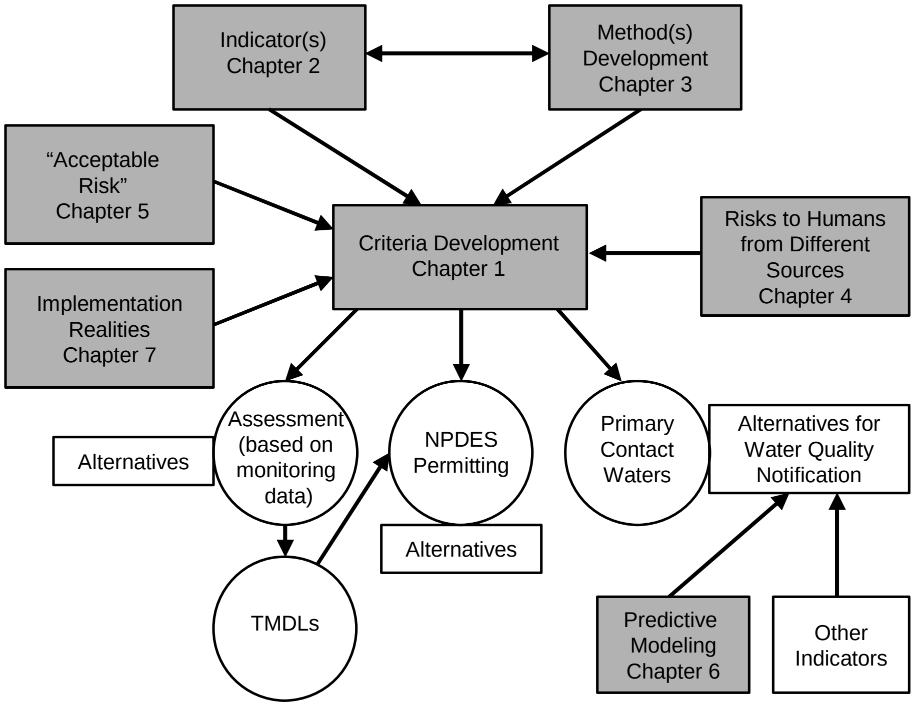

Figure 1. Flow Diagram of How the Workgroup Components Contribute to the Development of New or Revised Recreational Water Quality Criteria.

1. **Approaches to Criteria Development –** focus on a toolbox approach as well suggest other potential approaches for new or revised criteria development.
2. **Pathogens, Pathogen Indicators, and Indicators of Fecal Contamination –** discuss the strengths and limitations of indicators of fecal contamination, pathogen index microorganisms, and specific pathogens for development of new or revised recreational AWQC.
3. **Methods Development –** discuss methods for quantifying indicators and pathogens, such as culture-based methods, molecular-based methods (e.g., quantitative polymerase chain reaction [qPCR]), and faster culture-based methods and their applicability for AWQC.
4. **Comparing Risks to Humans from Different Sources –** discuss the relative risks of illness to humans in waters contaminated with human fecal material versus animal fecal material.
5. **Acceptable Risk –** discuss the level of risk to various populations that would be associated with numeric AWQC. EPA was interested in the science necessary to inform the policy decision regarding the target risk range and the process through which the policy decision could be reached.
6. **Modeling Applications to Criteria Development and Implementation –** discuss predictive modeling approaches and their potential applications in implementation of AWQC.

7. **Implementation Realities –** identify and consider factors that influence implementation of criteria for each of the CWA uses (beach monitoring and notification, development of National Pollutant Discharge Elimination System [NPDES] permits, assessments to determine use attainment, and development of total maximum daily loads [TMDLs].

Background

Clean Water Act §304(a) Recommended Criteria

What are EPA's Recommended §304(a) Criteria?

CWA §304(a) AWQC are (typically) expressed as numeric concentrations of pollutants. These are essentially the numbers that EPA recommends that States and Tribes adopt in setting their own Water Quality Standards (WQS) to protect waters for specified designated uses. State and Tribal WQS, once approved by EPA, are the effective standards used in CWA regulatory and non-regulatory programs. Figure 2 provides an overview of CWA WQS.

States and Tribes classify waters by their designated use,[1] which includes "primary contact recreation." States and Tribes typically define primary contact recreation to encompass recreational activities that could be expected to result in the ingestion of, or immersion in, a waterbody (such as swimming, water skiing, surfing, or any other recreational activity where ingestion of, or immersion in, the water is likely).

CWA §304(a):

- AWQC often are described as concentrations in the water column and generally have a time and duration component.
- AWQC could be expressed as an annual average concentration that should not be exceeded; a daily value or seasonal concentration that should not be exceeded; or a value that should not be exceeded, on average, more than one time every 3 years (for acute aquatic life criteria).
- AWQC are often associated with EPA-approved analytical methods. This is partly because without EPA-approved methods to measure concentrations in effluent, States are reluctant to adopt criteria in WQS that are then used in NPDES permits (see more below).

States typically adopt the recommended criteria into their WQS (i.e., regulations promulgated using state rulemaking processes [similar to Federal regulation development]).

What do States do with these EPA-recommended Numbers and how are they used by States?

Increasingly, because of the dynamics of State rulemaking processes and public and regulated community involvement, States are reluctant to adopt EPA's recommended criteria unless the

[1] CWA designated use (DU) classifications are narrative statements describing appropriate intended human and/or aquatic life and other quality objectives for waterbodies.

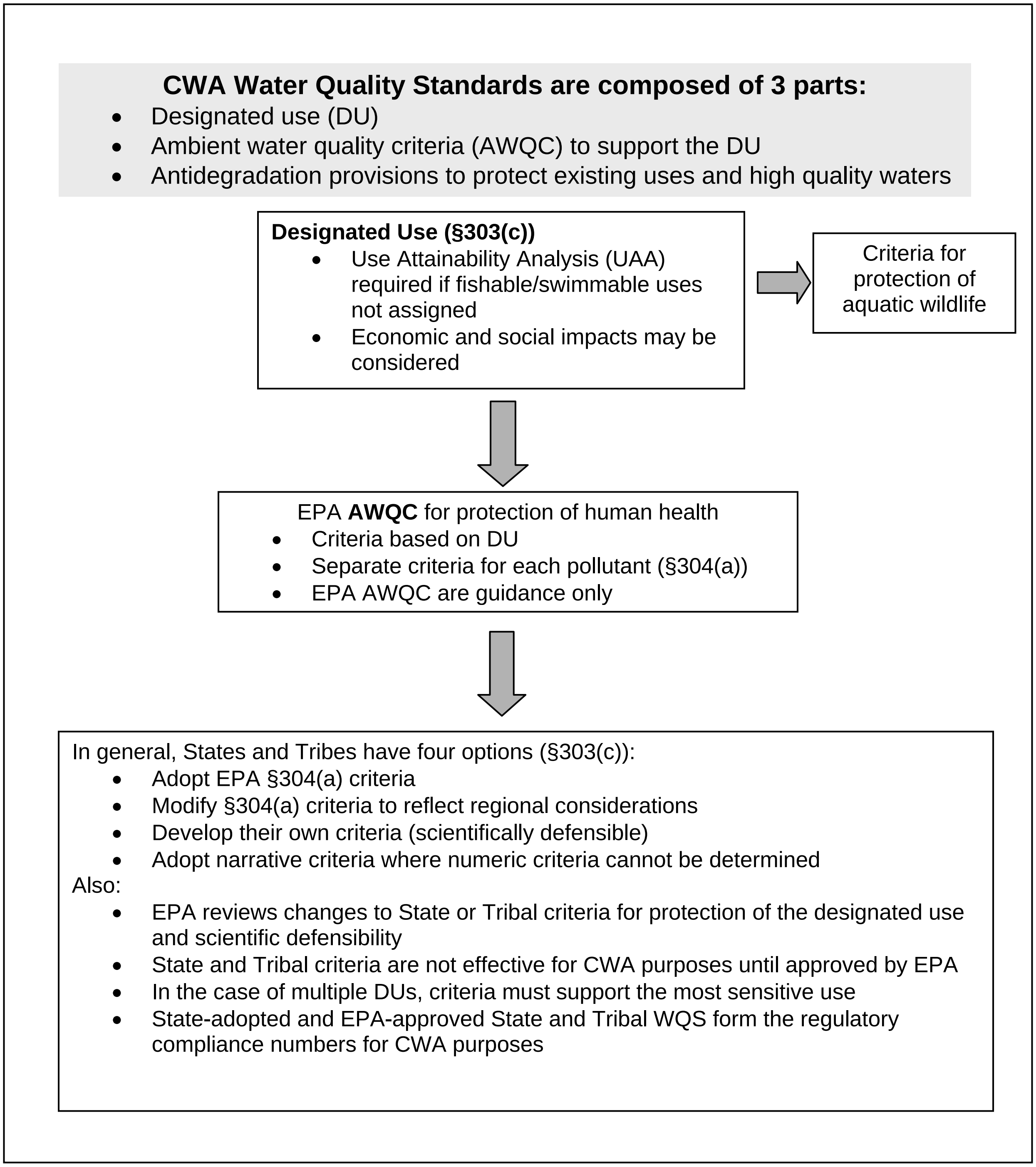

Figure 2. Clean Water Act: Water Quality Standards Overview.

underlying science supports the desired environmental result *and* the criteria can be implemented for all aspects of their CWA Programs.

Under CWA §304(a)(9), EPA is required to publish new or revised water quality criteria for pathogens and pathogen indicators (including a revised list of testing methods, as appropriate) for the purpose of protecting public health in coastal recreation waters. Coastal recreation waters are marine and Great Lake waters designated by States for use for swimming, bathing, surfing, or similar water contact activities. Under CWA §303(i)(1)(B), States are then required to adopt new or revised WQS for those pathogens and pathogen indicators for which EPA's new or revised criteria have been developed. States must submit these standards to EPA for approval or disapproval. EPA approves the standards if they are scientifically defensible and protective of the designated use.

Once approved, State WQS become effective for CWA purposes. This means that the State-adopted §304(a) criteria become regulatory standards and are used for several different CWA purposes, including the following:

- **§303(d) listings.** Under §303(d) of the CWA, States prepare lists of waters that are impaired and need TMDLs; States develop the lists every 2 years and submit them to EPA for approval. If States determine that waters are not meeting applicable water quality standards (whether from point or non-point sources of pollution), States are to identify those waters as "impaired" under §303(d).
- **TMDL calculations** for impaired waters must be prepared to implement the applicable State WQS.
- **NPDES permits,** which are issued after State WQS are in place for a pollutant, must have discharge limits as stringent as necessary to meet such WQS. EPA's analytical methods are often used to measure compliance with permit limits.
- **Public Notification at Beaches.** Under the BEACH Act of 2000, eligible coastal and Great Lakes States may apply for and receive BEACH Act grants for their beach monitoring and public notification programs. Those States use their recreational contact WQS to determine whether to close an area for swimming or issue a swimming advisory.

Toolbox Approach

EPA's recommended AWQC have to be applicable at a national level. A toolbox approach is under consideration because of the potential for greater flexibility in selecting situationally-appropriate indicators/methods and increased options for implementation, which is desirable for nationally applicable criteria. A toolbox allows for the use of varied techniques and approaches to achieve public health protection.

A preliminary working definition of the Toolbox approach for recreational water quality criteria might be the following:

> The toolbox approach is a set of potential microbiological (i.e., a microbe plus a specified enumeration method) and/or physico-chemical assays that could be employed alone, or in certain combinations, to protect and restore the recreational use of waters. The contents of the toolbox (the "tools") would be used by State public health and water quality agencies for beach advisory/closing program purposes and for all other Water Quality Standard related regulatory purposes under the CWA. The level of risk (or public health protection) would be the same regardless of which tool is used.

Although the toolbox concept allows a context for considering feasibility and applicability of different indicator and method combinations in developing new or revised recreational criteria under CWA §304(a), it is critical that there is an understanding of the relationship among the different methodologies for proper implementation of the criteria. For example, if EPA recommended one type of indicator for one set of uses (e.g., culturable enterococci) and also recommended the use of a DNA-based method (e.g., enterococci qPCR) for other uses, then there would have to be an understanding of the meaning of those multiple measures (i.e., linkage) in the context of the overall CWA §304(a) program. Without a clear understanding of the linkage and context of different methods the entire "toolbox" concept becomes unmanageable from a regulatory perspective.

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CHAPTER 1
APPROACHES TO CRITERIA DEVELOPMENT

Joel Hansel, Chair, USEPA
Mark Gold, Heal the Bay, California
David Kay, University of Wales, U.K.
John Ravenscroft, USEPA
William Robertson, Water, Air and Climate Change Bureau, Health Canada
Jeffrey Soller, Soller Environmental, California
David Whiting, Florida Department of Environmental Protection

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1.1 Benchmarks for Criteria Development

The workgroup was charged with answering 21 questions and providing a range of alternatives for the development of new or revised national recreational ambient water quality criteria (AWQC; see Section 1.5 for summary response). The following six potential approaches that could be used or adapted for an approach to develop new or revised criteria were initially discussed: (1) EPA's 1986 approach, (2) World Health Organization (WHO), (3) European Union (EU), (4) Hazard Analysis and Critical Point Analysis (HAACP), (5) Heal the Bay's Beach Report Card, and (6) EPA's Air Quality Index. The workgroup members concentrated the discussions on the three approaches that were deemed most appropriate for consideration in the context of Clean Water Act (CWA) Section 304(a) ambient water quality criteria (AWQC), namely, the WHO approach (with possible modifications), the EU approach (adopted 2006), and a modified version of EPA's 1986 criteria. Before the workgroup defined the approaches and determined the potential application of the three alternative approaches, workgroup members agreed that it was critical to identify desirable attributes or benchmarks for the criteria. The benchmarks or attributes that were identified are summarized below.

1. The criteria are health-based. The workgroup demonstrated a preference that the criteria be as directly as possible anchored to health effects demonstrated in epidemiology studies.
2. The criteria should demonstrate utility for and be compatible with all of the CWA §304(a) criteria (as amended by the Beaches Environmental Assessment and Coastal Health Act of 2000 [BEACH Act]) needs, including water quality assessment for public notification at beaches in a timely manner, assessment for impaired waters listings, development of total maximum daily load (TMDL) development and implementation, and development of National Pollution Discharge Elimination System (NPDES) permits.
3. The criteria should be scientifically defensible for application in a wide variety of geographical locations (climatic conditions), including fresh and marine waters, and temperate, subtropical, and tropical waters.
4. The criteria be sufficiently robust and flexible so that they can be configured to protect the public health of those exposed to recreational water impacted by sewage effluent, concentrated animal feed operation (CAFO) contaminated runoff, non-point sources (e.g., agriculture [non-CAFO], urban runoff) and waters not impacted by anthropogenic sources.
5. The criteria should be sufficiently robust and flexible so that they can be configured to provide regulators the ability to protect susceptible (sensitive) subpopulations such as children and immunocompromised individuals. Commonality was found among workgroup members that protecting the health of children was of paramount concern.
6. The criteria are associated (linked) with analytical methods that are reliable, robust, and provide reproducible results.
7. The criteria should protect primary contact recreation in freshwaters, marine waters, temperate, subtropical, and tropical waters equally. Similarly, the criteria should provide equal protection those exposed to effluent, urban runoff, and/or non-point source runoff impacted waters via primary contact recreation.

The workgroup members agreed that all seven of the above attributes are critical considerations for criteria development. In assessing the potential application of each of the proposed alternatives, it is important to keep in mind that criteria applied to these alternatives are assumed to be consistent with all of the above attributes (or at least most of them) before the final frameworks and criteria are developed. The likelihood that some of these attributes will not be met in the near-term seems to make the WHO or EU approaches more suitable for implementation.

The workgroup expressed the opinion that EPA should release the new or revised criteria and implementation guidance concurrently to provide clarity to States on how the criteria should be used for regulatory and public notification needs.

1.2 Integration of Workshop Components

A summary of the interactions between the various subject areas addressed in this workshop is presented in Figure 3. In Figure 3 shaded boxes correspond to the seven workgroups. The alternatives boxes in Figure 3 refer to various possible indicators that a toolbox approach could provide for each of the CWA applications. Briefly, the Pathogen/Pathogen Indicator workgroup proposes indicators that may have utility for criteria development (see Chapter 2). In doing so, they consulted with the Methods Development workgroup members (see Chapter 3) to assure that validated methods are or could be available and usable for the implementation of the proposed parameter. Different methods have different specificities for identifying whether the source of fecal contamination is human- or animal-based. The Comparing Risks workgroup provided information on the relative risks to human health from different sources of fecal contamination (Chapter 4). Once identified, the pathogen/pathogen indicator and the associated method are used during the criteria development process. Another critical component in the criteria development process is the identification of a risk level. Information from the Acceptable Risk workgroup (see Chapter 5) on how to develop “acceptable risk” thresholds is used in this context during the criteria development process. The Modeling workgroup discussed how predictive modeling can be used to inform criteria approaches and to provide information on water quality notification (Chapter 6). Once these pieces were integrated, an initial check was conducted against the suggestions and concerns of the Implementation Realities workgroup (see Chapter 7) members to help ensure that the potential for criteria development does not conflict with actual “on the ground” implementation.

As discussed in the Introduction to these proceedings, recreational AWQC are used for a number of purposes. First, these criteria are used to make assessment determinations under CWA §305(b) and §303(d).[2] Within this regard and depending on the framework, a number of alternate indicators or methods may be used to assist in making the determination as to the overall quality of a waterbody and the compliance with the underlying criteria. Second, these criteria are used to determine permit limits for NPDES permit holders and for TMDL purposes. Finally, these criteria are used to determine the acceptability of the water for direct primary contact recreation. Conceptually, alternative indicators, including models, could also be used for these purposes.

[2] http://www.epa.gov/owow/tmdl/tmdl0103/

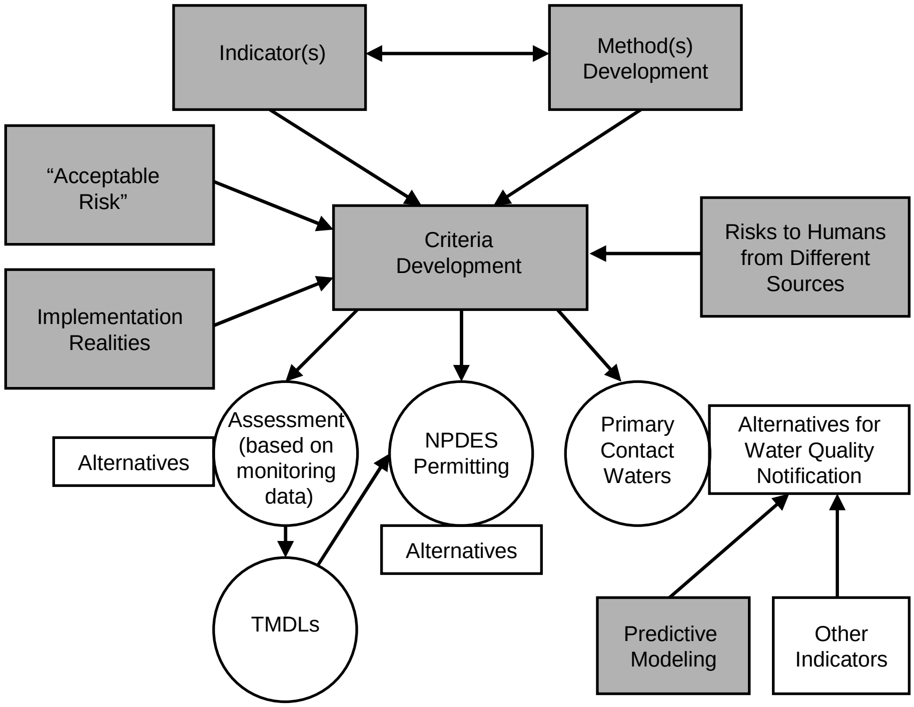

Figure 3. Flow Diagram of How the Workgroup Topics Contribute to the Development and Implementation of New or Revised Recreational Water Quality Criteria.

1.3 Summary of Currently Available Water Quality Criteria Setting Approaches

The three alternatives that were identified by the workgroup were a modified WHO approach, the EU approach, and a modified version of the EPA 1986 approach because all of these approaches are largely based on peer reviewed epidemiology studies and some version of each of these frameworks are in use currently in at least one country.

Workgroup members generally agreed that all three criteria development approaches are feasible providing the criteria meet the becnhmarl/attributes listed above. Although the workgroup briefly discussed other approaches such as the EPA's Air Quality Index, HAACP, and Heal the Bay's Beach Report Card approaches, none of these approaches were deemed to be appropriate for the desired purposes for a variety of reasons, including lack of applicability for criteria development.

1.3.1 WHO Approach for Water Quality Criteria Setting

The WHO has been concerned with health issues associated with recreational water environments for many years and has published several influential reports that represent a well accepted view among international experts (Prüss, 1998). The WHO approach provides a basis for standard setting in light of local and regional circumstances, such as the nature and seriousness of local endemic illness, exposure patterns, and competing health risks that are not associated with recreational water exposure.

The WHO approach is based on the perspective that recreational water quality and protection of public health are best described by a combination of sanitary inspection and microbial water quality assessments (the WHO [2003] Guidelines use enterococci as the fecal indicator of choice; see Table 1). This approach considers possible sources of pollution in a recreational water ("sanitary inspection category" in Table 1), as well as observed levels of fecal pollution ("microbial water quality assessment category" in Table 1), and combines them into a five-level classification scheme for recreational water environments. To date, the classification system has been used primarily to "grade" recreational waters and to provide an assessment for regulatory compliance purposes. This approach however, also could be adapted for other CWA §304(a) applications such as NPDES permitting and TMDL development.

The microbial water quality assessment criteria are based on a banded system, where the band divisions are equivalent to a risk of acquiring gastrointestinal (GI) illness for (A) <1 case in 100 exposures, (B) <1 case in 20 exposures, (C) <1 case in 10 exposures, and (D) >1 case in 10 exposures. The 95th percentile value was selected as an appropriate descriptor of the microbial probability density function because it is easily understood to be the probability of encountering

Table 1. WHO Classification Matrix for Integrating Microbial Water Quality as Measured by Enterococci Density with Sanitary Inspection Category.

		Microbial Water Quality Assessment Category (95th percentile intestinal enterococci/100 ml)				
		A ≤40	**B** 41–200	**C** 201–500	**D** >500	**Exceptional circumstances**
Sanitary Inspection Category (susceptibility to faecal influence)	**Very low**	Very good	Very good	Follow up[1]	Follow up[1]	Action
	Low	Very good	Good	Fair	Follow up[1]	
	Moderate	Good[2]	Good	Fair	Poor	
	High	Good[2]	Fair[2]	Poor	Very poor	
	Very high	Follow up[2]	Fair[2]	Poor	Very poor	
	Exceptional circumstances	Action				

Notes:

[1] implies non-sewage sources of faecal indicators (e.g., livestock), and this should be verified (section 4.6.2).

[2] indicates possible discontinuous/sporadic contamination (often driven by events such as rainfall). This is most commonly associated with Combined Sewer Overflow (CSO) presence. These results should be investigated further and initial follow-up should include verification of sanitary inspection category and ensuring samples recorded include "event" periods. Confirm analytical results. Review possible analytical errors (see section 4.6.2).

[3] In certain circumstances, there may be a risk of transmission of pathogens associated with more severe health effects through recreational water use. The human health risk depends greatly upon specific (often local) circumstances. Public health authorities should be engaged in the identification and interpretation of such conditions (section 4.6.5).

[4] Exceptional circumstances (see section 4.6.5) relate to known periods of higher risk, such as during an outbreak with a pathogen that may be waterborne, sewer rupture in the recreational water catchment, etc. Under such circumstances, the classification matrix may not fairly represent risk/safety.

SOURCE: WHO, 2003.

polluted water and focuses on water quality that is likely to cause illness (i.e., greater probability of illness associated with increasing density of human sources of fecal pollution). The WHO levels of risk for the bands described above were selected based on a series of science policy decisions in consultations with numerous international experts and were intended to be reasonable for both the developed and developing world. The expectation in the United States is that the "acceptable risk" (see Chapter 5) levels would be similar or more protective than the risk levels adopted by other developed countries. The methodology used to derive the 2003 WHO Guideline values is summarized in Appendix C.

The sanitary inspection category is intended to classify the risk of illness caused by fecal pollution in a recreational waterbody, although human fecal pollution will tend to drive the overall sanitary inspection category derived for an area. WHO experts believe that the three most important sources of human fecal contamination of recreational water environments for public health purposes are typically sewage, riverine discharges, and direct contamination from bathers. Sanitary inspections are required to address those sources as well as others, and inspections should take on a tiered approach, dependent on the level of perceived risk and its uncertainty. For example, if human and domestic fecal pollution is considered low based on land uses, but fecal indicator counts are relatively high, further exploration of the source(s) and their relative risks would be recommended. This higher level of examination (tier) may utilize more expensive methods and approaches and further cycles (tiers) of investigation as necessary. Based on the results of the sanitary inspections, recreational waters are ranked (from very low to very high) with respect to evidence for the degree of influence of fecal material.

1.3.2 EU Approach for Water Quality Criteria Setting

The EU broadly adopted the 2003 WHO Guidelines in formulating the 2006 Bathing Water Directive. A summary of the European Commission Directive is provided in Appendix D. The approach incorporates the following fundamental elements:

- The EU starts with the WHO risk assessment framework, but does not include the sanitary inspection category information for the purposes of recreational water classification. Instead, it uses only the microbial water quality assessment information to characterize the probability of exposure to human pathogens.
- The EU approach used the WHO microbiological criteria for marine waters and applied the same risk assessment framework to new epidemiological data to derive standards for fresh recreational waters.
- The EU approach allows sample discounting. Under discounting, numeric excursions above the water quality standards that are predicted and/or measured do not count against the waterbody for compliance determination (i.e., such values are discounted from the data set prior to calculation of the 95th percentile, but only 15% of scheduled samples can be so discounted). Sample discounting is allowed when a predictive model, source reduction plan, and communication management system are in place to inform the public about short-term pollution events derived during predictable conditions (e.g., rainfall).

The EU Bathing Water Directive (7/EU/EEC; dated February 15, 2006) is currently being translated by Member States for implementation (EP/CEU, 2006). The Directive establishes separate numerical microbiological criteria for fresh (inland) and marine (coastal and transitional) bathing waters for the 24 EU Member States (Table 2). The numerical values are based on epidemiological studies reported by Kay et al. (1994) and Wiedenmann et al. (2006)—the former was used by WHO in formulating their Guidelines (Kay et al., 2004; WHO, 2003).

Table 2. Numerical Microbiological Water Quality Assessment Classification for Fresh (Inland) and Marine (Coastal and Transitional) Bathing Waters for the 24 EU Member States.

Inland (Fresh) Waters			
Indicator	Excellent	Good	Sufficient
(Intestinal) enterococci (cfu/100 mL)	200*	400*	360**
E. coli (cfu/100 mL)	500*	1,000*	900**
Coastal and Transitional (Marine) Waters			
Indicator	Excellent	Good	Sufficient
(Intestinal) enterococci (cfu/100 mL)	100*	200*	200**
E. coli (cfu/100 mL)	250*	500*	500**

Notes: * = Based on a 95th percentile evaluation; ** = Based on a 90th percentile evaluation to reduce the risk of statistical anomalies when using a small data set, which also allows lower limit values for enterococci and *E. coli* densities in inland waters to be classified as sufficient versus good microbiological water quality.
Source: Adapted from EP/CEU (2006).

1.3.3 EPA 1986 Water Quality Criteria Setting

In the late 1970s and early 1980s, EPA conducted public health studies evaluating several organisms as possible indicators, including total and fecal coliforms, *E. coli*, and enterococci. The studies showed that enterococci and *E. coli* are the best predictors of GI illness (gastroenteritis) in sewage effluent-impacted freshwaters, while enterococci were the best predictor in sewage-impacted marine waters. Gastroenteritis describes a variety of diseases that affect the GI tract and are rarely life-threatening; self-limiting symptoms include nausea, vomiting, stomachache, diarrhea, headache, and fever. Based on these studies, EPA published a criteria document, *Ambient Water Quality Criteria for Bacteria – 1986*, recommending the use of these bacterial indicators in ambient water quality criteria values for the protection of primary contact recreation (US EPA, 1986). Table 3 summarizes the *Water Quality Standards for Coastal and Great Lakes Recreation Waters Rule* (US EPA, 2004) that requires States and Tribes to adopt the 1986 AWQC for Bacteria.

States and Tribes generally define their designated use of "primary contact recreation" to encompass recreational activities that could be expected to result in the ingestion of, or immersion in, water, such as swimming, water skiing, surfing, or any other recreational activity where ingestion of, or immersion in, the water is likely.

EPA derived standards that implied an acceptable excess illness probability of 0.8% in swimmers exposed in freshwater and 1.9% in swimmers exposed in marine waters. EPA's 1986 bacteria criteria document indicates the illness rates are "only approximate" and that the Agency based the 1986 values that appear in Table 3 on these approximations.

Table 3. Summary of EPA's 1986 Recommended Water Quality Criteria for Bacteria and 2004 Rule

Indicator	Swimming-Associated Gastroenteritis Rate per 1,000 Swimmers	Geometric Mean	Single Sample Maximum Allowable Density			
		Steady State Geometric Mean Indicator Density	Designated Beach Area	Moderate: Full Body Contact Recreation	Lightly Used: Full Body Contact Recreation	Infrequently Used: Full Body Contact Recreation
Freshwater						
Enterococci	8	33	61	78	107	151
E. coli	8	126	235	298	409	575
Marine Water						
Enterococci	19	35	104	158	276	501

Source: US EPA (2004).

EPA's 1986 bacteria AWQC document provides geometric mean densities as well as four different single sample maximum values (representing values below which an increasing percentage of single values are expected to fall if the geometric mean of samples from the waterbody is equal to the geometric mean criteria). The 1986 bacteria AWQC document categorizes the single sample maximum values based levels of beach usage as follows: "designated bathing beach" for the 75% (most conservative) confidence level, "moderate use for bathing" for the 82% confidence level, "light use for bathing" for the 90% confidence level, and "infrequent use for bathing" for the 95% confidence level. The lowest confidence level corresponds to the highest level of protection.

In the 1986 AWQC context, single sample maximum criteria are water quality assessment tools that provide a sense of when the water quality in a waterbody is not consistent with the AWQC. Insights based on single observations are very difficult because of the expected variability of fecal indicators. For instance, if the long-term geometric mean concentration of enterococci in the water at a marine beach is 35/100 mL and the log standard deviation is 0.4, then there is an 18% chance that the concentration of enterococci in a single sample would be over 158/100 mL. The higher the single sample maximum, the lower the probability that a single sample exceeding that value would occur as part of the normal random variability of samples (US EPA, 2006).

Since publication of the 1986 criteria, many States have expressed concern that the current fecal indicator/illness rate relationships identified in the epidemiology studies leading up to the 1986 criteria are not appropriate or representative of all U.S. waters. For example, States have concern that the most appropriate indicator in tropical waters may be different than in temperate waters, and that appropriate levels of indicators may be different in waters where human fecal waste predominates animal waste. Other identified issues are as follows:

- lack of clear, timely, and flexibile guidance regarding use of the single sample maximum values and differing risk levels;
- no EPA-approved analytical methods for use in wastewater for the indicator bacteria;

- lack of data to correctly assess the applicability of the 1986 bacteria criteria to flowing waters; and
- 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.

1.3.4 Summary of Proposed Criteria Development Approaches

Workgroup members developed a summary of the three proposed criteria development approaches, including strengths and limitations (Tables 4a and 4b).

Table 4a. Summary of Proposed Criteria Development Approaches: Strengths and Limitations

Criteria Approach	Science Supporting Approach	Strengths	Limitations
World Health Organization (WHO, 2003)	Fleisher et al., 1996 Kay et al., 1994, 2004 WHO, 1999 Wyer et al., 1999	• Flexible • Most comprehensive of available methods • Adopted by other countries • Incentives for beaches to upgrade • Allows more site appropriate protection of health	• Sanitary inspection component is qualitative; not quantitative • Greatest data needs • Would need to adapt potentially complex system to wide range of conditions in U.S. • Potential implementation issues
European Union (EP/CEU, 2006)	Fleisher et al., 1996 Kay et al., 1994, 2004 Wiedenmann et al., 2006 WHO, 1999, 2003	• Flexible • Relatively straightforward • Incentives for beaches to upgrade • Adopted by other EU Member States	• Discounting system has no direct precedent in the U.S. • Would need to devise robust and acceptable discounting scheme • Potential implementation issues
Current U.S. Criteria (US EPA, 1986)	US EPA, 1983, 1984	• Relatively straightforward • Currently in place in most states, new implementation issues less likely • Fewest data requirements	• Allows less flexibility • Single sample max (75^{th} percentile) has been criticized from implementation perspective • Credibility concerns in many parts of the U.S.

Table 4b. Summary of Three Proposed Criteria Development Approaches: Benchmarks

Criteria Approach	Criteria Attribute	Approach Compatible with Attribute
World Health Organization (WHO, 2003)	Health-based	Yes
	CWA §304(a) applications	Most challenging – unclear how different grades for beaches would be interpreted with respect to impaired waters; for example, TMDLs would need to be considered.
	Geographic variability	Not with current indicator, ongoing research could fill gaps
	Point vs. non-point	No, epidemiological data would be needed
	Multiple subpopulations	Could be, but in current configuration children not analyzed separately
	Uniform risk across waterbody types	Yes
	Linked to method that is validated	Yes currently, but will also depend on future indicators
European Union (EP/CEU, 2006)	Health-based	Yes, but differential risks from different sources of fecal contamination is not included, thus, this approach is less health-based than WHO approach
	CWA §304(a) applications	Yes, but challenging for same reasons as WHO approach
	Geographic variability	Not with current indicator, ongoing research could fill gaps
	Point vs. non-point	No
	Multiple subpopulations	Could be, but in current configuration children not analyzed separately
	Uniform risk across waterbody types	Yes
	Linked to method that is validated	Yes currently, but will also depend on future indicators
Current U.S. Criteria (US EPA, 1986)	Health-based	Yes, but concern about single sample standard, also concerns that differential risks from different sources of fecal contamination are not included
	CWA §304(a) applications	Yes
	Geographic variability	No
	Point vs. non-point	No
	Multiple subpopulations	No
	Uniform risk across waterbody types	No, fresh and marine recreational waters have different "acceptable risks"; this could be addressed in new or revised criteria
	Linked to method that is validated	Yes currently, but will also depend on future indicators

1.3.5 Other Approaches Considered

As noted previously, the workgroup considered a number of other frameworks and approaches that might be applicable to criteria development, including the following:

- Hazard Analysis and Critical Control Point Principles (HACCP);
- Heal the Bay Beach Report Card; and
- EPA Air Quality Index.

The EU, EPA (1986) criteria, and the WHO approaches are already being used for the intended purpose, either in the United States or other countries. The other possible approaches listed above have not been applied in a regulatory framework for proposed water regulation and would need to be thoroughly assessed to determine their utility or applicability to derive recreational water quality criteria. The workgroup members felt that it was beyond their ability to conduct such an assessment at this time. One workgroup member noted that the Heal the Bay approach was never intended for use in all regulatory purposes and would not be recommended for such.

1.4 Summary of Critical Issues to be Resolved in Applying Available Water Quality Criteria Approaches

No matter which recreational water quality criteria development approach is selected, a number of research needs have to be met before criteria development can reach completion. Additional epidemiological studies that take into account marine waters, subtropical and tropical waters, urban runoff, and non-point sources of contamination will need to be completed in the next 2 to 3 years to provide the health effects data necessary if nationally applicable are to be developed. Further testing of quantitative polymerase chain reaction (qPCR) methods to detect enterococci and/or any additional proposed indicators under the conditions listed above also is critical. The epidemiological studies should also include (1) culture-based methods in addition to molecular methods for enterococci; (2) culture and molecular-based methods for *E. coli* in fresh water studies because national freshwater criteria and numerous States currently use *E. coli* in recreational criteria and including *E. coli* would maintain a level of consistency with the existing CWA §304(a) guidance; and (3) sensitive subpopulations to the extent feasible, including children at a minimum.

Other research gaps that can be filled in the next few years include, but are not limited to, fate and transport of molecular-based indicator organisms in wastewater treatment plants and in the ambient aquatic environment. Workgroup members expressed a significant concern about the issue of conservation of measurable genetic material throughout the treatment process because of the regulatory ramifications in the NPDES, water quality assessment, and TMDL programs of moving to molecular-based criteria.

Another research need is for effective predictive models for beach water quality forecasting to notify the public of the potential health risks of recreational water contact. The current use of single sample assessments using culture-based methods has proven to be largely ineffective for public notification of beaches purposes because of the time required for sample processing (i.e., sample transportation to a laboratory, 18 to 24 hour incubation time, and time required for results to reach and be evaluated by a decision maker). In addition to their development, the models need to be adequately field verified and calibrated. Ideally, regional models can be developed, but if predictive models can only be developed on a site specific basis over the next 3 years, the data needed to develop, field verify, and calibrate the models should not be cost prohibitive to collect. At a minimum, recreational beach managers should consider a simple, predictive rainfall model to more effectively protect public health.

Workgroup members emphasized that a sanitary investigation[3] approach to characterize drainages to primary contact recreational waters would prove useful for at least the WHO criteria development framework. A simple to implement, quantitative-based sanitary investigation, in conjunction with the health risk data from the proposed additional epidemiology studies, may enable the development of source specific risk parameters for criteria development. To clarify expectations for these surveys, a standardized and relatively simple approach would need to be developed that includes fecal bacteria source characterization (publicly owned [wastewater] treatment works [POTWs], storm drain outfalls, CAFOs, on-site wastewater treatment systems ["septic systems"], agriculture, etc.) on a drainage-wide basis, distance of sources to primary contact recreational waters, flow, developed area in the drainage, and the frequently high variability in water quality from day to day. Additional sanitary investigation components such as source identification and source tracking[4] may not need to be implemented unless there is a need in the regulatory process to implement a TMDL or to protect the public health of swimmers at chronically polluted beaches.

The following summary assumes that all of the approaches encompass and achieve the benchmarks outlined in Section 1.1 to the extent feasible.

1.4.1 Summary of Application of WHO Approach for U.S. Criteria Setting

The general framework described by the WHO (2003) would be applicable to U.S. criteria setting in the near-term given that the following research is conducted and science policy decisions are made:

[3] This is similar to Canada's "Environmental Health and Safety Assessment" in Appendix A of *Guidelines for Canadian Recreational Water Quality* (MNHW, 1992). Although the WHO (2003) uses the term "sanitary inspection," some workgroup members expressed concern that use of that specific term or the related term "sanitary survey" might imply adoption of all the protocols for sanitary inspections/surveys from other contexts. Thus, the term "sanitary investigation" was selected for use in these proceedings to minimize preconceived assumptions regarding the nature of the sanitary investigation and is used to refer to a quantitative approach to gauge watershed susceptibility to fecal influence. However, "sanitary inspection" is used when the WHO approach is described.

[4] Although there is not universal acceptance of definitions for microbial source tracking and microbial source identification, the Methods workgroup discussions assumed the following working definitions: source identification is determination of the type of animal (sometimes human versus nonhuman, sometimes more specific) that produced the fecal contamination. It does not include determining where in the watershed that material came from, but it does suggest what to look for upstream. Source tracking is determination of the actual source of fecal matter, such as a leaking pipe, a septic system, or a cow pasture. It typically involves using some of the marker techniques associated with source identification, but not necessarily. Source tracking can also be achieved through extensive spatial sampling with existing indicators or (for example) through use of dye tablets in septic systems.

1. Analyze epidemiological data to determine the values of water quality that correspond to the identified levels of "acceptable risk" for the indicator of fecal contamination using the selected method(s).
2. Identify a suitable indicator of fecal contamination or suite of fecal indicators (particularly for subsequent tiers of investigation). This information needs to be epidemiologically based.
3. Identify "acceptable risk" levels. Choosing an "acceptable risk" level is a policy decision that is informed by science (e.g., epidemiology studies). See Chapter 5 for a discussion of the process through which an "acceptable risk" level could be chosen.
4. Derive a quantitative sanitary investigation category rather than a qualitative process; also, the sanitary investigation should be standardized nationwide.
5. Statistically validate the linkages between different indicator/method combinations for different CWA §304(a) purposes to facilitate translation between the various indicator/methods.
6. Consider and develop a recreational water quality reclassification scheme, if appropriate. If such a reclassification scheme is appropriate, a management system would be necessary to facilitate implementation of beach advisories and to ensure informed choice regarding beach use.
7. Develop a public information management system and a beach signage provision. The purpose of these programs would be to represent bathing water characteristics derived from a "bathing water profile" and historical water quality.
8. Institute a monitoring program to acquire bathing water quality data for numerical compliance assessment purposes.
9. Release CWA §304(a) criteria guidance and associated implementation guidance concurrently.

To apply the WHO (2003) approach for future criteria setting, the following issues will need to be considered in detail and expanded:

1. Develop a process to determine how waterbodies get listed as impaired.
2. Determine the appropriate number of categories for microbial and sanitary investigation categories.
3. Possibly change several qualitative determinations in the framework (i.e., very good, good, fair) to less descriptive terms (i.e., Category I, Category II, etc.).
4. Develop a process for categorization of NPDES dischargers (consideration for default to most restrictive category).
5. Determine how to use different indicator/method combinations for CWA §304(a) applications and translate to each other to ensure equivalent levels of protection.
6. Determine whether health risks from nonhuman fecal sources are substantially different than from human sources.
7. Determine what is the most appropriate metric for expressing the water quality criteria (geometric mean, upper percentile, a combination of those and/or other)

8. Determine how to make water quality public notification decisions (this is likely a function of the indicator/method combination[s] that are employed and the strength of a predictive model).
9. Develop a well described and vetted quantitative sanitary investigation guidance; here the workgroup members suggested a tiered approach that allows for varying levels of effort based on likely benefit from the assessment (high and low risk should be easier to assess [i.e., beaches downstream from POTWs or urban catchments would be high risk, and beaches downstream of catchments with 100% natural sources would be low risk]). Although completion of the sanitary investigation does not need to be required, surface waters would default to the most restrictive criteria until such time as a completed investigation provides justification for changing the applicable criteria.
10. Develop a well described and vetted recreational water quality reclassification scheme.

1.4.2 Summary of Application of EU Approach for U.S. Criteria Setting

The general framework described by the EU (EP/CEU, 2006) would be applicable to U.S. recreational water quality criteria setting given the same research and science policy decisions as described above for the WHO except (1) a classification scheme based on a quantitative sanitary investigation would not be necessary because the sanitary inspection category is not used to determine the beach classification, and (2) it would not be necessary to determine whether health risks from nonhuman sources of fecal contamination are substantially different than from human sources, because the beach classification is based on microbial densities only..

To apply the EU approach for future criteria setting the same issues described above will need to be considered in detail and expanded, with the following exceptions:

1. Reform the microbial categories to fit U.S. waters, do not include the “sufficient” category of EU Directive EEC/7/2006.
2. Determine if a discounting scheme is necessary and appropriate (e.g., elimination of monitoring data for compliance purposes), and if so, then there is a need to determine how to make it most protective of public health.

1.4.3 Summary of Application of EPA 1986 Approach for U.S. Criteria Setting

The current EPA (1986) framework described previously would be applicable to new or revised U.S. criteria development with the following modifications:

1. Develop additional indicators and analytical methods that would be applicable to tropical and temperate waters and also for use in wastewater.
   a. Base additional indicators and methods on health risks (i.e., occurrence would be correlated with rates of illness from epidemiological studies).
   b. Ensure that the revised criteria framework specifies the appropriate indicator/methods combination for the various waters.

2. Consider more timely methods for beach monitoring and water quality notification. Currently, there is no scientific evidence supporting beach water quality determinations based on, at best, day-old (culture-based) data.
    a. If molecular-based methods are used, then fate and transport data for that indicator using that method would be needed.
    b. If molecular-based methods are limited to beach monitoring and water quality notification, then these methods must be linked somehow to the methods used for the other CWA purposes. Currently, very limited data are available for this purpose.
    c. If predictive modeling is used in water quality notification programs, the models need to be adequately field-verified and calibrated.
3. Risk threshold
    a. Any final recommendation for CWA §304(a) criteria must be health-based and derived from the available epidemiological data.
    b. If a single sample criteria is used, it should be of similar stringency to any other measure used (e.g., geometric mean) and the single sample criteria should account for the expected frequency of exceedance (e.g., if the single sample criteria is based on a 95th percentile, a 5% exceedance should be allowed without invoking compliance ramifications).
    c. Consider risk to sensitive subpopulations (e.g., children) in the determination of the risk threshold.
    d. The risk of illness should be the same for swimmers in all types of waters (i.e., marine, fresh, temperate, tropical, etc.) exposed to all types of fecal contamination sources (e.g., point, non-point).
    e. Secondary contact recreation waters:
        i. Acquire data to show health risks associated with limited, but defined levels of contact and/or incidental exposure.
        ii. Data can be from epidemiological studies or estimated using quantitative microbial risk assessment (QMRA).
        iii. Develop a more accurate descriptor of what constitutes secondary contact.
4. CWA §304(a) AWQC recommendations and associated implementation guidance should be released concurrently.

1.5 Summary of Response to Workgroup Charge Questions

See Appendix A for the complete (original) charge questions.

1. ***What approaches exist currently for setting limits of pollutants that may be relevant for developing nationally recommended recreational water quality criteria? Consider approaches used for other kinds of pollutants in water, in other environmental media, and by other countries as well as approaches being implemented by States. What are the pros and cons of each of these approaches?***

- European Union Revised Bathing Water Directive 2006/7/EC

- Hazard Analysis and Critical Control Point Principles
- Heal the Bay Beach Report Card
- EPA Air Quality Index
- EPA *Ambient Water Quality Criteria for Bacteria – 1986*
- WHO *Guidelines for Safe Recreational Water Quality Environments. Volume 1 Coastal and Fresh Waters*

The EU (EP/CEU, 2006), (US EPA) 1986 criteria, and the WHO (2003) approaches are already being used for the intended purpose, either in the United States or other countries. The other possible approaches listed above have not been applied in a regulatory framework for proposed water regulation and would need to be assessed to determine their utility or applicability to derive new or revised recreational water quality criteria.

2. *Which of these approaches is most applicable and appropriate for developing nationally recommended recreational water quality criteria in the near-term? Why is this approach on balance considered the most applicable and appropriate?*

Workgroup members identified the following critical benchmarks for water quality criteria development:

- Be applicable to human health effects;
- Fulfill the needs of Clean Water Act (CWA) and meet the associated regulatory purposes (monitoring, permitting, total maximum daily loads [TMDLs], and §303(d));
- Address geographic variability (i.e., tropical, subtropical, and temperate regions);
- Address potential differences between point and non-point sources of fecal contamination and associated risk;
- Consider risks to susceptible subpopulations, primarily children; and
- Be based upon methods that are reliable and reproducible.

Based on these benchmarks, workgroup members further identified three approaches for further consideration—European Union Revised Bathing Water Directive 2006/7/EC (EP/CEU, 2006), EPA *Ambient Water Quality Criteria for Bacteria – 1986*, and the 2003 World Health Organization *Guidelines for Safe Recreational Water Quality Environments. Volume 1 Coastal and Fresh Waters.* Table 4a summarizes the advantages and disadvantages of each approach and is provided in Section 1.3.4.

3. *For those approaches identified as applicable and appropriate, what is the science that supports the approach? Is that science sufficient and of adequate quality?*

Epidemiological research identified to support the best selected approaches was:

- European Union Revised Bathing Water Directive (2006/7/EC; EP/CEU, 2006)
  - Fleisher et al. (1996)

  - Kay et al. (1994)
  - Weidenmann et al. (2006)
  - Wyer et al. (1999)
- EPA *Ambient Water Quality Criteria for Bacteria - 1986*
  - US EPA (1983)
  - US EPA (1984)
- World Health Organization 2003 *Guidelines for Safe Recreational Water Quality Environments. Volume 1 Coastal and Fresh Waters*
  - Fleisher et al. (1996)
  - Kay et al. (1994)

All members of the workgroup agreed that the research reports listed above support the respective approaches but some members questioned whether the research identified above was adequate to meet all of the identified benchmarks. They also agreed that additional epidemiological and modeling work needed to be performed in order to successfully implement any of the approaches above for future new or revised recreational water quality criteria development in the United States.

4. ***Are there any critical research and science needs that should be addressed in developing or selecting an appropriate approach? Can this research be completed n time to be used in criteria development in the near term?***

The workgroup members identified the following research and science needs to support the suggested approaches.

- Information on the geographic applicability of fecal indicators for assessing health risks at tropical and subtropical fresh and marine recreational bathing areas impacted by point and non-point sources of fecal contamination (see Chapters 2, 3, and 4; research on sensitive subpopulations should also be incorporated into this need [see Chapter 5]);
- Ability to discriminate between human and nonhuman sources of fecal contamination;
- Information on sources of runoff (e.g., concentrated animal feeding operations [CAFOs]) from both marine and fresh recreational waters;
- How much water are bathers ingesting while swimming?; and
- Fate and transport of indicators (and pathogens) in the aquatic environment.

Workgroup members also identified the following possible long-term research needs:

- Comparison of prospective cohort and randomized control trial epidemiological studies;
- Identification of pathogens (viruses, bacteria, or parasites) responsible for GI illnesses at bathing beaches;

- Health impacts following exposures over multiple days;
- Significance of non-GI illnesses (dermal, aural, nasal); and
- Comparison of severity of illnesses related to exposure to human and animal (domestic and wildlife) fecal contamination (see Chapter 4).

Although workgroup members identified these long-term research needs there were some differences of expert opinion on the essentiality of these needs. In conjunction with these research needs, workgroup members also noted the necessity to clarify the objectives of environmental health assessments (sanitary investigations) and microbial source tracking methods.

5. ***Is a "toolbox" approach appropriate for developing new or revised recreational criteria in the near-term? Why or why not?***

The Approaches to Criteria Development workgroup members interpreted the concept of a toolbox approach differently. Some members believed that shifting from the current (US EPA, 1986) criteria approach to either the WHO (2003) or EU (EP/CEU, 2006) model approach would constitute a type of toolbox approach. For example, the sanitary investigation as used within the WHO approach could be considered to be an additional tool in the implementation of the new or revised criteria. Others believed the toolbox approach meant the use of alternative or additional fecal indicators or pathogen methods. In either case, the implementation of the toolbox approach was dependent upon additional epidemiological studies being conducted that may or may not be possible within the near-term (2.5 to 3 years).

Predictive models could be an integral part of the toolbox. Models that have been both validated and calibrated are critical for accurately predicting recreational waters that exceed criteria. Improved notification via forecasting models is likely to protect public heath better then the use of single sample criteria based on current indicators measured by culture methods.

6. ***What are the pros and cons of selecting a "toolbox" approach?***

There was commonality of workgroup member opinions in regards to several of the pros and cons related to the use of a toolbox approach.

Most of the workgroup members believed that a toolbox approach would help address some of the issues with geographic variability. For example, the use of different fecal indicators that demonstrate improved indicator/illness rate relationships in subtropical or tropical waters would reduce the likelihood of these waters inappropriately being listed as impaired under the CWA. The use of some form of sanitary investigations, as within the WHO (2003) approach, would potentially allow for discounting those waters that were identified as having limited or no anthropogenic fecal loading, thereby avoiding those waters being listed as impaired inappropriately.

The cons associated with a toolbox approach were primarily related to the current lack of data on the fecal indicator/illness rate relationships for additional methods. There was also some concern expressed about the difficulty in incorporating the toolbox approach to account for the use of different indicators for different CWA §304(a) needs. There was also concern about the feasibility of establishing requisite and defensible linkages between the various indicator/method combinations that could comprise the toolbox.

7. *What are the desired features or characteristics that would make a "toolbox" approach appropriate?*

Any additional fecal indicator or pathogen measure within the toolbox would need to have proven indicator/illness rate relationships, or at a minimum, have a linkage to another indicator that does. The characteristic of being interrelated (correlated) with each other would be of particular use, especially if one was going to be used to support one aspect of the CWA §304(a) needs and the other was being used to support another §304(a) need.

The toolbox approach should support more then just one aspect of the CWA §304(a) needs. Any of the tools within the toolbox should be validated, either by predictive modeling or by correlation to other tools within the toolbox. Additionally, if a management action is initiated on the results of a particular tool within the toolbox (e.g., a beach closure based on qPCR) the follow up action should also be based upon the same tool (beach opened based on qPCR), to the extent possible.

8. *Would a "toolbox" approach achieve additional public health protection as compared to another approach? Why or why not?*

Yes, as mentioned above, the additional tools within the toolbox could potentially improve the assessment of waters (e.g., reduce the listing of tropical or subtropical waters as impaired due to the poor indicator/illness relationship for these waters) or the appropriateness of beach advisories or closures.

9. *Criteria for secondary contact recreation could be part of a "toolbox." What approaches would be appropriate for developing criteria for secondary contact recreation?*

Workgroup members defined secondary contact as limited or incidental contact. As such, workgroup members believed that the same approach could be used for waters designated as secondary contact as used for primary contact, meaning that epidemiologically-based health data could be used to define acceptable exposure limits. QMRA could also be used for these purposes to supplement available epidemiological information.

10. *What are critical research and science needs in developing or selecting an appropriate approach for secondary contact recreation?*

Additional epidemiological studies may be needed under secondary contact conditions. These epidemiological studies should address the same data needs as those proposed in support of the primary recreation criteria. Alternatively, QMRA could be used if exposure data are available.

Can this research be completed in time to be used in criteria development in the near-term?

It is possible, but unlikely given the current demands for additional epidemiological work in support of the primary contact designated use. However, a QMRA study could be conducted during this timeframe.

11. *What are the implementation considerations of the different approaches for CWA purposes (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs?*

All three approaches—the (EPA) 1986 criteria, EU (EP/CEU, 2006), and WHO (2003) approaches—would require additional epidemiological studies to implement. Given additional epidemiological data with additional indicators, it is possible that each approach could potentially be implemented and could support multiple CWA §304(a) needs. As noted above, using multiple indicators for different purposes is a cause of concern.

Are there practical considerations that could preclude, or greatly limit, the use of an approach in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?

If future epidemiological studies do not identify additional indicator tools that would improve the indicator/illness relationship for a broader geographic range, the (EPA) 1986 model would be a much less desirable option than either the WHO (2003) or EU (EP/CEU, 2006) approach. Both the EU and WHO approaches apply a discounting scheme, so the failure of near-term epidemiological studies to identify more robust indicator tools does not preclude the implementation of these approaches for the development of new or revised recreational water quality criteria.

<u>Geographic Applicability</u>

1. Is a single criterion available that is appropriate for the diverse range of geographic conditions? Why or why not?

No. Different regions of the country have different potentials for regrowth, persistence, indicator/pathogen die off rates (UV exposure), and indicator/illness rate relationships. The literature supports the conclusion that additional indicators will be necessary to accurately identify those recreational waters that are at risk across all geographic regions of the country.

Workgroup members felt that future epidemiological studies should include additional indicators to improve the indicator/illness relationship across all geographic areas of the United States.

2. Is a toolbox approach appropriate for different geographical conditions? Why or why not?

Yes, for the reasons noted in the response to Question #1 above.

3. What would a "toolbox" that addresses geographical differences look like?

The toolbox might include alternative or additional indicators that better predict, either individually or in combination, the indicator/illness relationship. Alternatively, the toolbox might include environmental health and safety assessments (sanitary investigations) that allow for the discounting of waters that appear as impaired based upon the indicator results, but for which the impairment judgments are not supported by demonstrable impacts (elevated indicators from wildlife or sediment sources only). The toolbox approach also could be used to allow different indicators and be used for different CWA §304(a) purposes.

4. What are critical research and science needs in developing or selecting an approach that will appropriately factor-in diverse geographical conditions?

Additional epidemiological studies are needed that provide improved indicator/illness rate relationships for all regions of the United States. These additional epidemiological studies should focus on recreational waters that are under a variety of potential pathogen sources (e.g., sewage, urban runoff, non-point sources, non-anthropogenic sources). Where possible, the various potential sources of pathogens should be considered within a single epidemiological study rather than each being considered in separate studies. This might be possible by examining waters that have varying sources depending upon rainfall or climatic conditions. For example, California beaches that have urban runoff sources during wet weather but no known point or non-point sources during dry weather.

To pursue the 2003 WHO approach, a quantitative environmental health and safety assessment (i.e., sanitary investigation) tool would have to be developed in order to support the categorization of recreational waters as to their risk of potential fecal contamination. To have greater confidence in the WHO model, research is needed to determine if the notion that fecal contamination from non-anthropogenic sources is of lesser human health risk that anthropogenic sources.

Expression of Criteria

1. Given the diverse needs of the CWA programs and the overarching goal of protecting and restoring waters for swimming, what protection is provided by establishing a 30-day "average" value as the criteria?

There was some commonality of workgroup member opinion on this issue. Several members felt that the criteria would best be expressed as a geometric mean and/or a standard deviation or

95th percentile. Several members believed that these values would have to be site specific in order to be protective. If formatted correctly, an average value is as protective as any other single measure.

What additional protection (if any) is provided by a daily or instantaneous maximum value?

The added value provided by an instantaneous maximum value is dependent upon the indicator/illness rate association. Short-term variability associated with the current indicators limit the usefulness of single sample maximum values; however, using qPCR or other non culture-based methods may improve the utility of single sample values. Additional epidemiological data is needed to assist in making this determination. One problem is that the formulation of the current single sample maximum is such that it is more stringent than the geometric mean, and this has caused substantial confusion among States.

From a scientific standpoint, is one measure better scientifically than another for particular purposes (e.g., mean value for purposes of identifying waters and daily maximum for beach monitoring and notification purposes)? Why?

It depends on how the new or revised criteria are derived and the assumptions made about the variability in water quality. There is some scientific merit to the continued use of single sample maximum values for some CWA purposes. This is of particular interest with respect to public health protection; however, there was not agreement among the workgroup members on this point.

2. What are pros and cons of expressing the criteria differently for the various CWA program needs?

As currently used, single sample maximum values are not effective for beach monitoring purposes. This may change somewhat if the shift from culture-based methods to non culture-based methods improves the issues with variability and indicator/illness rate relationships.

There is potential to use single values, whether culture- or non-culture based, in predictive models for beach monitoring. The geometric mean, standard deviation, or 95th percentiles show promise for multiple CWA programs. So long as there is data from epidemiological studies that demonstrates the one expression of the criteria is equally as protective as another, there would be no problem with using different expressions of the criteria for different CWA purposes.

3. What are the implications of instantaneous or daily values for public health protection? If we don't currently have a good understanding of this, what are the critical research and science needs to answer the questions?

Currently there is very little data to support the use of instantaneous or daily values derived from culture-based methods from Day 1 to predict the need to post or close recreational waters on Day 2. There are recent epidemiological data (Wade et al., 2006) that indicates that qPCR (non culture)-based indicator methods may be effective for same day notification at some beaches.

Group members identified several critical research needs that would potential improve the utility of an instantaneous or daily value (see Chapter 1).

4. If EPA were to set criteria at a mean concentration over 30 days and not recommend a single sample maximum, do we understand the illnesses that could occur on a single day (where the level would still lead to compliance with the 30-day average)?

In general, workgroup members agreed that the probability of illness on any single day is not understood. Some reasons for this are as follows:

- the variance in water quality in any particular water body could be significantly different than the criteria from which it was derived;
- the variability of indicator could change between beaches and temporally; and
- if the exposure-response curve is based on a geometric mean, the interpretation of a single sample is difficult.

With research, a single sample maximum could be used to estimate the probability of illness on a particular day.

5. If the science is "not there," what are the critical research and science needs to answer this question?

Critical research and science needs centered on expanding epidemiological studies based on qPCR (and other indicators and methods) to other situations (e.g., example marine beaches or non-point pollution sources).

6. What are the implementation considerations for CWA purposes of failing to address (and addressing) differences geographically in the criteria and failing to include (and including) a single sample maximum value for (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs? Are there practical considerations that could preclude, or greatly limit, the usage in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?

To address this question it was separated into the following two components: (1) failing to address geographical differences, and (2) failing to include a single sample maximum for various purposes identified in the CWA.

(1) Failure to recognize that the current criteria may not be applicable to tropical and subtropical beaches could present an unacceptable risk to bathers in these recreational waters.

(2) Single sample maximum NPDES permits – compliance tools such as NPDES permits require single sample maximums and need to continue that approach.

Regarding States' designated use attainment, single sample maximum values are not necessarily required and in fact may not be necessary. These types of criteria could be useful for beach monitoring and water quality notification. Regarding TMDLs, single sample maximum values do not seem applicable for TMDLs for indicator bacteria.

1.6 Concluding Remarks

The workgroup members did not specifically prefer one criteria approach over another primarily because it is believed that additional data that will become available from epidemiological studies within the next 2 to 3 years and how those data will inform the criteria development process is not yet known. For example, it is not known what new information will be available based on new indicators and/or methods and how that information might inform a sanitary investigation component of a WHO-based criteria approach.

Further, it was the opinion of workgroup members that there may be differences in the ability to implement each of the three approaches if all of the various criteria attributes are not met. For example, workgroup members felt that the 1986 EPA approach with a new or different indicator and/or method would not be satisfactory if most or all of the criteria attributes were not met. Workgroup members also felt that the same set of circumstances may not preclude the use of the WHO or EU approach. With respect to the use of a toolbox-based approach where different indicators are used for different CWA §304(a) applications, workgroup members expressed concern about the feasibility of developing health-based linkages (as described above) as would be required by either the WHO or EU approaches. Thus, at this time, no workgroup member was definitively able to recommend one approach over another; however, the workgroup members agreed that the choice of approaches must be deferred pending the outcome of ongoing and near-term research.

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CHAPTER 2
PATHOGENS, PATHOGEN INDICATORS, AND INDICATORS OF FECAL CONTAMINATION

Nicholas Ashbolt, Chair, USEPA
Roger Fujioka, University of Hawaii, Manoa
Toni Glymph, Wisconsin Department of Natural Resources
Charles McGee, Orange County Sanitation District, California
Stephen Schaub, USEPA
Mark Sobsey, University of North Carolina, Chapel Hill
Gary Toranzos, University of Puerto Rico, Rio Piedras

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2.1 Application of Microbial/Biomarker Parameters

The charge of the Pathogen, Pathogen Indicators, and Indicators of Fecal Contamination workgroup was to identify critical research and science needs in the development of new or revised criteria for recreational waters, including total maximum daily load (TMDL) implementation, and National Pollutant Discharge Elimination System (NPDES) implementation using microbial and chemical indicators. The discussions were limited to constituents for which methods are currently available or expected to be available within the next 3 years and focused around the following four issues:

1. Fecal matter indicators (as surrogates for gastrointestinal [GI] and non-GI illnesses);
2. Pathogens and their index organisms (GI and non-GI illnesses);
3. Application of fecal indicators, pathogen index organisms, and pathogens in combination for criteria development; and
4. Application of all the above for all categories of waters, climatology, and geographical considerations.

Currently, implementation of ambient water quality criteria (AWQC) for the four Clean Water Act (CWA) applications require monitoring fecal bacterial indicators to assess the degree to which the water is contaminated with sewage and sewage-borne pathogens with respect to the accepted risk for exposure. Development of the existing (US EPA, 1986) AWQC for recreational waters were based on epidemiological studies that related concentrations of fecal indicator bacteria at recreational waters impacted primarily by point sources of human sewage.

Since development of the currently used 1986 AWQC, research has shown that this narrow health effects-based standard (i.e., epidemiological studies at beaches with point sources of human sewage) is limited in that it does not take into account differences in geographical conditions, ecology of microorganisms, and varying sources of fecal indicator bacteria. In this regard, the expected relationship between illness and indicator organism densities would be high if the source of contamination is human sewage, moderate if the source was a mixture of human and animal feces, or lower if the source is the result of replication of the indicator bacteria in the environment, such as in soil, sediments, storm drains, or on plants or aquatic vegetative matter. Initially, replication of fecal indicator bacteria was reported in tropical areas (e.g., Hawaii, Guam, Puerto Rico) but has now been documented in subtropical areas such as south Florida and even temperate areas (Great Lakes States). A further but untested complication in interpreting fecal indicator bacteria results may arise due to different rates of pathogen inactivation in the environment relative to fecal indicators across different geographic and climatic regions.

It is for the above reasons that experts in the field of microbial water quality generally agree that the principles of microbial ecology must be considered in water quality assessment. Understanding and applying these principles requires an assessment of the sources of fecal contamination, selection of the appropriate methods used to assess these sources, a connection between the intended AWQC application, and the fecal and/or pathogen indicator or pathogen measured and an analysis of that indicator's fate and transport. Because of this understanding, workgroup members suggested a tiered assessment of a watershed, starting with traditional fecal indicators (conservative measures), and progressing to select a suite of indicators of contamination (providing source specificity and contaminant load information). A characterization of contaminant inputs through a sanitary investigation of the watershed and the waterbody being assessed should be undertaken, specifically assessing hazardous events, such as rainfall-induced runoff or wastewater treatment failure. Key information would pertain to a cataloguing of point sources (e.g., sewage effluent) and non-point sources (e.g., animals, runoff, on-site septic systems, environmental regrowth) so that a comparative risk assessment can be made based on the concentrations of standard (traditional) monitoring fecal indicators (i.e., *E. coli*, enterococci) and the expected presence of human pathogens. This initial assessment should assist in understanding the relationship between the contamination and epidemiological studies (indicator levels and risks of illness) mentioned elsewhere in these proceedings. In order to select appropriate indicators, a tiered toolbox approach was preferred by workgroup members rather than promoting use of one particular indicator over another.

2.2 Tiered Toolbox Monitoring Approach

An initial cataloguing of fecal pollution sources should include a review of existing monitoring data and a sanitary investigation to assess contaminant levels and sources that impact a given recreational water site. Based on that information, the indicator used in monitoring or the predictive modeling tool most appropriate for each CWA AWQC application and contamination source would be selected for the situation. Water quality assessment for each recreational water site should begin with the simplest analyses and assessment and move on to the most appropriate (specific or targeted) indicator for that site or purpose. More refined tools to differentiate between human, domestic animal, or environmental sources of fecal contamination could subsequently be used if deemed necessary.

If a sanitary investigation determines that fecal pollution is human or animal origin, then *E. coli* or enterococci could be used in the tier one water quality assessment because many pathogens can be expected to multiply in human and animal intestines. If the source of the "fecal" indicator organisms is determined to be from the environment (i.e., from growth in soil/sand, sediment, or water), then *E. coli* and enterococci may be inappropriate because most pathogens are not capable of environmental multiplication. As a result, the monitoring for this tier would need to be a fecal organism/chemical that does not amplify in the environment, such as spores of *Clostridium perfringens* or male-specific (F+) coliphages measured by culture- or molecular-based methods, specific members of the *Bacteriodes* bacteria measured by a molecular method, or use of a chemical indicator of fecal material.

For a subsequent tier of monitoring, infectivity and/or molecular methods could be used for specific groups of pathogens such as, for bacterial pathogens (shiga-toxin producing *E. coli* [STEC] or *Salmonella*), for protozoa (*Cryptosporidium* or *Giardia*), and for representative human sewage-borne viruses (enteroviruses, adenoviruses, polyomaviruses, or noroviruses).

Location-specific data should be archived for potential use in future predictive modeling that might allow for management of site-specific fecal contaminants. Finally, if possible, archiving samples for further characterization and national comparison of new indicators, and/or pathogens and their respective methods would be advantageous assuming a national repository database and sample archive facility could be established.

Several non-GI illnesses have been associated with recreational uses of water but these are not addressed by monitoring for fecal indicator microorganisms or chemicals because the etiological agents for these waterborne diseases come from non-sewage sources. Examples include animal urine (*Leptospira* spp.), shedding from human skin (*Staphylococcus aureus*), or microorganisms that are naturally present in freshwater environments (*Aeromonas hydrophila*, *Naegleri fowlerii*, *Legionella pneumophila*). Further, several human pathogenic *Vibrio* species (*V. cholerae*, *V. vulnificus*, *V. parahaemolyticus*, *V. alginolyticus*) are indigenous to marine and brackish waters. Because reliable indicators have not been developed for non-GI etiological agents, the best approach to address aquatic non-enteric pathogens is to characterize the aquatic conditions that increase the risk for these pathogens. For pathogenic *Vibrio* spp., this includes saline waters of warmer temperature and waters that contain high levels of nutrients.

2.3 Parameters for Hazardous Event Pollution Monitoring

The first approach to investigate a hazardous event (sewage discharge, rainfall impact, etc.) would be to assay for fecal indicators (appropriate for a climatic/geographic area of concern, see Section 2.4). The primary indicators of fecal contamination are *E. coli* or enterococci; however, based on the classification from an initial sanitary investigation, alternatives may include *Clostridium perfringens* or F+ coliphages (dependent on a robust method being confirmed). These must be demonstrated to relate to a possible health outcome (see Section 2.4). When information is required on source characterization, then additional microbial indicators (see Section 2.5) are generally preferred over chemical biomarkers (see Section 2.7).

Focused sampling during and after higher risk periods is important when information from the sanitary investigation (which may include system models) is used to predict such risk. For these applications, the context of the likely pathogen group(s) should dictate the type of indicator to assay. For example, for rainfall in an area possibly impacted by on-site septic systems, viruses are considered the most mobile pathogen group so use of virus model organisms, such as the F+ coliphages, would be informative. For sites contaminated by concentrated animal feeding operations (CAFOs), reasonable pathogen index tests include shiga-toxin producing *E. coli* or *Cryptosporidium*. This approach assumes that some background level of the targeted group is known for the area of concern (see Section 2.8, research needs).

2.3.1 Microbiological Parameters

The Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 requires States with coastal or Great Lakes recreational waters to adopt the current (US EPA, 1986) criteria for *E. coli* and enterococci. In November 2004, EPA promulgated a final rule that put federal standards in place for the 21 coastal states that had not adopted the 1986 criteria or established criteria as protective of human health as EPA's 1986 criteria. However, these federal criteria apply only to coastal states and Great Lakes waters. In many cases, a fecal coliform-based standard still applies to many states having only inland waters. It is important to note that the results of the epidemiological studies used to generate the 1986 criteria for coastal and Great Lakes waters may not be directly applicable to all inland waters.

2.4 Traditional Fecal Indicators (Coliforms and Enterococci)

Consideration of the environmental context for which these traditional indicators are used is critical to the interpretation of the results. For example, wastewater treatment/disinfection may be effective in reducing the number of these traditional fecal indicators but ineffective in reducing/inactivating some pathogens of concern (Blatchley et al., 2007). Some industrial treatment systems may contain/enable replication of high number of “fecal indicators,” which are not necessarily associated with fecal sources (Degnan, 2007; Gauthier and Archibald, 2001). Ambient water and soils in tropical environments may be conducive to the growth of environmental strains of *E. coli* and enterococci (Fujioka and Byappanahalli, 2001). A similar situation was found in temperate Australian waters (Ashbolt et al., 1997; Barnes and Gordon, 2004; Davies et al., 1995) and these indicators have also been found to persist in U.S. beach sand/sediments (Whitman et al., 2006).

The range of strains of fecal indicators identified by traditional culture-based methods may differ from those identified by enzyme-based and quantitative polymerase chain reaction (qPCR [molecular])-based methods. Further, the strains more associated with fecal matter are not differentiated from the environmental strains by all of these methods. There are commercially available systems that can aid in the discrimination of strains; however, less expensive typing kits do not accurately provide such discrimination for environmental strains. It is important to note then when quantifying fecal indicator organisms, different methods target different strains. For example, cells stressed by wastewater disinfection processes may be enumerated using MPN (Most Probable Number) methods but excluded by methods enumerated by colony forming unit (cfu) methods. When current qPCR methods are used, both viable and non-viable cells are detected. In addition, the number of gene targets may vary per cell and therefore do not provide comparable information to culture-based results.

E. coli

Of the traditional fecal indicators (see also Appendix E, Text Box E-1), only *E. coli* has been shown in epidemiological studies to consistently relate to health outcomes for freshwater recreational water users (Cabelli et al., 1982; Wade et al., 2003; Wiedenmann et al., 2006). In marine/estuarine waters, *E. coli* is more readily inactivated than enterococci and appears to correlate less well to health risk than enterococci for saline water environments.

Subtyping of different strains of *E. coli* (library-dependent microbial source tracking methods) appears to be very site-specific if useful at all. Thus, it is not generally suggested as an effective way forward to separate environmental sources of *E. coli* from fecal sources across the United States (see Section 2.5).

Enterococci

The enterococci are the major group of fecal indicators that have a clear link to GI illness and upper respiratory disease in bathers in marine and fresh recreational waters (Kay et al., 2004).

There are, however, several shortcomings in the use of current methods for enterococci. Most importantly, there is a range of different *Enterococcus* spp. detected by current methods. Based on unpublished Californian studies (Stephen Weisberg, SCCWRP, personal communication, 2007), greater fecal specificity may result from specific identification and enumeration of *E. faecalis* or *E. faecium* or molecular-based methods targeting specific genes within these species (e.g., ribosomal RNA or enterococcal cell surface-associated protein and its gene *Esp*) (Lehner et al., 2005; Liu et al., 2006). However, no robust method is currently available that readily provides such information, nor has this concept been verified at other U.S. recreational water sites (Anderson et al., 1997).

2.5 Alternative Fecal Indicators

2.5.1 Bacteria

Clostridium perfringens

C. perfringens is a member of the sulphite-reducing clostridia (SRC), which are spore-forming anaerobic bacteria excreted in human and animal fecal matter, but unlike other SRC, do not appear to grow in the aquatic/soil environment. These bacteria have been used as fecal indicator organisms for decades. Australian and North Carolina studies show *C. perfringens* levels in humans comparable to levels found in dog and feral pig feces, but low levels in cattle, sheep, horses, and birds (Leeming et al., 1998; Mark Sobsey, University of North Carolina, Chapel Hill, personal communication, 2007). Importantly, because *C. perfringens* does not appear to grow in aquatic/soil environments, it has potential to be useful as a fecal indicator for tropical environments such as in Hawaii where growth of *E. coli* and enterococci in soil/sand, sediment, and water make those indicator organisms less useful (Byappanahalli and Fujioka, 1998; Hardina and Fujioka, 1991; Roll and Fujioka, 1997). For example, in ambient streams in Hawaii, concentrations of fecal coliforms, *E. coli*, and enterococci consistently exceed recreational Water Quality Standards due to contribution by extra enteric sources (Hardina and Fujioka, 1991, Luther and Fujioka, 2004). Thus, monitoring inland and coastal waters for *C. perfringens* provides reliable data for sewage contamination and is used by the Hawaii State Department of Health to confirm a sewage contamination event (Fujioka and Byappanahalli, 2001).

The presence of *C. perfringens* (spores) in water, therefore provides evidence of existing human/urban fecal contamination, which may reflect either recent or historical fecal contamination from humans or animals. Although methods have been available for some time, confirmation of a robust and consistent method approach should be developed. For example, the advantages of heat-treating samples (or not) to remove background vegetative cells and induce spore germination remains unclear.

The environmental resistance of *C. perfringens* spores has both advantages and disadvantages in their application as a fecal indicator, pathogen indicator, and as an indicator of wastewater treatment efficacy. Collectively, these make *C. perfringens* spores better indicators of persistent and treatment-resistant pathogens, such as *Cryptosporidium* oocysts (resistance to chlorine) and adenoviruses (resistant to UV radiation). However, they can be so persistent in the environment that they may not indicate the presence of pathogens coming from recent (contemporary) fecal contamination.

Recent studies on the partitioning of *C. perfringens* and other fecal indicator microbes in environmental waters, such as *E. coli* and coliphages, indicate differences in the extent of their association with settleable particulate matter (Characklis et al., 2005; Krometis et al., 2007). To date, limited data have been collected on any potential relationship between *C. perfringens* counts and recreator health outcomes (see Section 2.8).

Bacteroides

Bacteroides spp. are members of the normal microbiota of warm blooded animals and studies have shown them to be among the most prevalent genera in feces (Holdeman et al., 1976). Because they are strict anaerobes that grow in the GI tract of humans and animals, they do not survive for long periods of time under aerobic conditions (Kreader et al., 1998). However, their survival under different redox potential conditions (e.g., sediments) has not been thoroughly studied. Recent research based on molecular methods has demonstrated that some isolates may be strictly associated with human feces (Walters et al., 2007). If this is the case, these microorganisms also have the potential to be used for microbial source tracking (MST) applications.

Studies have indicated human versus bovine specificity in certain 16S rRNA genes therefore, 16S rRNA *Bacteroides* genes have been used as an index of human or animal contamination in Europe and the United States. The ability to differentiate sources of fecal contamination is very attractive when it comes to determining risk as a result of exposure via recreational waters. The molecular methodology has been shown to be robust and applicable in the United States and Europe, though it remains to be seen if this robustness holds across temperate versus tropical or subtropical zones of the world. Some results from Hawaii and Europe indicate that these methods may be useful under those climatic conditions (Betancourt and Fujioka, 2006; Seurinck et al., 2006). Either way, it is unclear whether quantification of human/animal fecal loads will be consistent or indeed possible using these molecular-based methods.

Though data from molecular techniques have shown that there is specificity in the human versus animal strains, the fact that both human and animal feces contain a diverse population of *Bacteroides* spp. may limit the usefulness of some detection methods. Methods that focus on one target may have reduced sensitivity as a result of the lower concentrations of a specific *Bacteroides* strain. Data have shown that *Bacteroides* spp. does not survive for long periods of time in the environment; thus, *Bacteroides* detected by qPCR in ambient waters includes a high percentage of inactivated microorganisms. The fact that qPCR detects both live and dead organisms needs to be considered when data are applied in different contexts (e.g., different AWQC applications). That is, qPCR detection is linked to the time the nucleic acid remains within the cell without being degraded. EPA data have demonstrated that the DNA remains undegraded for up to 20 days (Kevin Oshima, USEPA, Office of Research and Development, personal communication, 2007) in the inactivated unlysed cells. This may be equivalent to the survival of some enteric pathogens under environmental conditions. Thus, the presence of *Bacteroides* may have possible use as an indicator of health effects. Because the concentration of *Bacteroides* spp. in feces is much higher than other fecal bacteria, once the persistence of PCR-detected types is better understood, it may also be useful for TMDL applications, although this possibility needs further evaluation.

The molecular methodology for the detection of general and human-specific *Bacteroides* spp. is already being tested and has proven to be robust (Gawler et al., 2007; Walters et al., 2007). Thus, if detection methods are validated in the United States there is an excellent opportunity for short-term advances in quickly adapting the use of this alternate indicator for the rapid analyses of recreational waters and fecal source identification.

2.5.2 Bacteriophages

Coliphages

Bacteriophages (viruses) that infect *E. coli* and possibly other closely related coliform bacteria are called coliphages. There is a long history of research documenting the possible uses of phages as indicators of fecal contamination (Grabow et al., 1998). Coliphages were first proposed as indicators of the presence of *E. coli* bacteria and are taxonomically very diverse, covering the following six virus families: three families of double-stranded DNA viruses (*Myoviridae*, *Styloviriae*, *Podoviridae*), two families of single-stranded DNA phages (*Microviridae* and *Inoviridae*), and one family of single-stranded RNA viruses (*Leviviridae*).

Coliphages that infect via the host cell wall of *E. coli* are called somatic coliphages (including families *Myoviridae*, *Styloviriae*, *Podoviridae*, and *Microviridae*). Male-specific (also called F+) coliphages (*Inoviridae* and *Leviviridae*) infect by attaching to hair-like appendages called F-pili protruding from the host bacterium surface.

Somatic phages have been explored as fecal, treatment efficacy, and health effects indicators. However, little is known about the specificity of their occurrence in human or animal feces. Furthermore, their considerable taxonomic diversity and the lack of readily available and convenient methods to distinguish or specifically detect the different groups has made it difficult to determine which, if any, are effective fecal, treatment efficacy, or health effects indicators. In a recent study by Colford et al. (2007), somatic coliphages were not predictive of human health risks from bathing in marine recreational water largely impacted by non-point sources of fecal contamination. Furthermore, there is very little information on the sources and ecology of the somatic coliphages, especially for the different taxonomic groups. With rare exceptions, they are detected as a broad group with no effort to identify specific taxonomic groups or relate or attribute these different taxonomic groups to specific sources of human or animal fecal contamination or possibly non-fecal environmental sources.

Male-specific coliphages have been studied extensively as fecal indicators and for water/wastewater treatment/disinfection efficacy. Furthermore, F+ RNA coliphages can be distinguished genetically (via nucleic acid detection methods) or antigenically (via immunological methods), into four distinct subgroups: I, II, III, and IV. There is reasonably good evidence that Groups II and III are associated primarily with human fecal waste and that Groups I and IV are associated primarily with animal fecal waste (Furuse et al., 1975; Hsu et al., 1995; Osawa et al., 1981) in the United States. Male-specific coliphages have been included in some epidemiological studies of recreational water. In the recent study by Colford et al. (2007) at a marine recreational water site impacted primarily by non-point source fecal contamination, F+ coliphages were the only microbial indicator whose levels were associated with risks of swimming-associated illness.

Strengths of Coliphages as Indicators

Advantages of both somatic and F+ coliphages as fecal indicators include their (1) presence in relatively high concentrations in sewage; (2) relatively high persistence through wastewater treatment plants, compared to typical bacterial indicators like *E. coli* and fecal coliforms (coliphages may behave similarly to human viruses during wastewater treatment); and (3) ability to be detected in relatively small (100 mL) to medium (1,000 mL) volumes of fecally contaminated water.

Coliphages can be detected by relatively simple, affordable, and robust culture methods—several of which have been standardized and collaboratively tested as EPA, EU, and ISO (International Organization for Standardization) water methods. However, the EPA methods for somatic and F+ coliphages have been fully validated only for groundwater and not for ambient surface waters or wastewaters. Recent research also describes a rapid, simple, and affordable method to detect and group infectious F+ coliphages by short-term (3-hour) enrichment culture, followed by quick (<1 minute) detection of positive cultures by a simple immunological (particle agglutination) method scored by simple visual examination (Love and Sobsey, 2007). The method can be conducted in an MPN format to quantify concentrations of the different F+ coliphage groups (F+ DNA and F+ RNA Groups I, II, III, and IV).

These findings indicate that robust, simple, rapid, and low-cost F+ coliphage methods could be implemented within the 2 to 3 year time frame if correlations to health targets are observed in epidemiological studies. It would be valuable if water samples from upcoming EPA and SCCWRP (Southern California Coastal Water Research Project; see also Appendix F) marine recreational water epidemiological studies are collected and archived for analysis by these emerging qPCR methods once they are fully developed and validated. In addition, research is suggested to compare the performance of methods for rapid coliphage detection by short-term enrichment-particle agglutination and qPCR and to consider the advantages and disadvantages of these two methods for application to recreational water quality monitoring.

Limitations of Coliphages as Indictors

Although effective methods are available to recover, detect, and quantify coliphages, limitations and unsolved problems with these methods remain. The single agar layer method (EPA Method 1601) for enumeration of coliphages by counting plaques is limited to sample volumes of about 100 mL. Analyzing larger volumes is cumbersome and consumes considerable materials, such as Petri plates. Although the enrichment culture-spot plate method can be used to conveniently analyze sample volumes of up to 1 L, the method makes it more difficult to resolve coliphage mixtures when more than one type of coliphage is present in the enriched sample volume. In some cases, one coliphage will grow faster and to a higher concentration. This makes it difficult to detect and isolate minority coliphages that grow more slowly and to lower concentrations. However, detection of all of the different coliphages present as a mixture in enriched sample is possible by either nucleic acid or immunological (particle immunoagglutination) methods.

The ecology of both somatic and F+ coliphages remains poorly documented and inadequately understood. Information is lacking on bacterial host range, sources, occurrence, and behavior (survival, transport, and fate) in different geographical regions having different climates (temperate, subtropical, and tropical) and in waters and wastewaters of different microbial quality.

F+ coliphages can also be detected by molecular-based methods, including conventional and qPCR methods, according to recent studies. Careful review of these studies suggests that there may be deficiencies in the ability of these qPCR methods to detect the broad range of F+ DNA and F+ RNA coliphages and their subgroups. Nevertheless, research is now in progress to further improve F+ RNA qPCR by developing and performance-validating primer sets for all four genogroups of F+ RNA coliphages (Stephanie Friedman, EPA Environmental Effects Research Laboratory Laboratory, personal communication, 2007). Reliable methods have not been developed for genetic analysis and characterization of different somatic coliphage taxonomic groups.

Very few studies have been conducted to evaluate F+ coliphages as predictive indicators of human health risks from recreational use of water. The most extensive study was conducted by Colford et al. (2007). That study showed no health relationship for somatic coliphages, but a weak relationship for F+ coliphages examined by two different assay methods—an MPN version of EPA Method 1601 (enrichment-spot plate method) and EPA Method 1602 (saline agar layer plaque assay). However, these methods have not been performance characterized and fully validated for use in fresh and marine recreational waters according to EPA collaborative study protocols. Additional studies of this type are needed to clarify their potential criteria uses.

Bacteroides phages

Bacteroides phages, viruses that specifically infect *Bacteroides* spp., have been tested as indicators of fecal material in Spain and more recently in the U.K. The former used a method (bacterial host) that was tested in some labs in the United States but further efforts were not made as a result of the perceived difficulty in dealing with anaerobic methodology. Attempts to use the *B. fragilis* strain VPI 3625 showed low occurrence of these phages in the United States (Chung and Sobsey, 1993). Spanish data initially supported the use of *B. fragilis* HSP40, which is specific to phages that only occur in human feces. More recent British work indicated human specificity and high phage counts for a newer Spanish host *Bacteroides* (GB-124), thus providing the opportunity for determining human fecal contamination and virus transport using a rapid and inexpensive phage method (Ebdon et al., 2007).

Strengths of Bacteroides Phages as Indicators

The methods for the detection of *Bacteroides* spp. phages are inexpensive and their presence indicates human fecal contamination. In addition, there is research that indicates specific

Bacteroides hosts are susceptible to phages that are possibly useful for MST, which would be beneficial for its use for CWA §304(a) criteria (Chung and Sobsey, 1993; Ebdon et al., 2007).

Limitations of Bacteroides Phages as Indicators

The diversity of phages including their specificity for human host strains is not yet well characterized over a range of locations. This type of data could be easily obtained in 2 to 3 years, but if it is discovered that there is wide variability in their validity for MST, then their attractiveness for use in national AWQC would be reduced. Many laboratory personnel may not have the experience required to work with anaerobic microorganisms; however, little additional laboratory equipment would be required. Because detection methods have not been standardized in the United States, it would likely take several years to develop standardized methods for enumeration of *Bacteroides* phages in water samples.

2.5.3 EU Project Summary of Tracers

Several microbes and chemicals have been considered as potential tracers to identify fecal sources in the environment. However, to date, no single approach has been shown to accurately identify the origins of fecal pollution in all aquatic environments. In a European multi-laboratory study, different microbial and chemical indicators were analyzed in order to distinguish human fecal sources from nonhuman fecal sources using wastewaters and slurries from diverse geographical areas across Europe. Twenty-six parameters, which were later combined to form derived variables for statistical analyses, were obtained by performing methods that were achievable in all the participant laboratories and include the following: enumeration of fecal coliform bacteria, enterococci, clostridia, somatic coliphages, F+ RNA phages, bacteriophages infecting *Bacteroides fragilis* RYC2056 and *Bacteroides thetaiotaomicron* GA17, and total and sorbitol-fermenting bifidobacteria; genotyping of F+ RNA phages; biochemical phenotyping of fecal coliform bacteria and enterococci using miniaturized tests; specific detection of *Bifidobacterium adolescentis* and *Bifidobacterium dentium*; and measurement of four fecal sterols. A number of potentially useful source indicators were detected (bacteriophages infecting *B. thetaiotaomicron*, certain genotypes of F+ bacteriophages, sorbitol-fermenting bifidobacteria, 24-ethylcoprostanol, and epicoprostanol), although no one source identifier alone provided 100% correct classification of the fecal source. Subsequently, 38 variables (both single and derived) were defined from the measured microbial and chemical parameters in order to find the best subset of variables to develop predictive models using the lowest possible number of measured parameters. To this end, several statistical or machine learning methods were evaluated and provided two successful predictive models based on just two variables that provided 100% correct classification—(1) the ratio of the densities of somatic coliphages, and phages infecting *Bacteroides thetaiotaomicron* to the density of somatic coliphages and (2) the ratio of the densities of fecal coliform bacteria and phages infecting *B. thetaiotaomicron* to the density of fecal coliform bacteria. Other models with high rates of correct classification were developed but they required higher numbers of variables (Blanch et al., 2006).

2.6 Pathogens and Pathogen Indicators

Many beach regulators and scientists believe that there are significant opportunities to utilize specific pathogens or pathogen indices to better understand or characterize potential health risks from recreational exposures. Some reasons for not doing so, however, remain—especially that pathogen numbers are generally significantly lower and more variable than fecal indicator organisms. Nonetheless, pathogens could be utilized to accurately determine risks as there have been a number of studies that define actual human dose-response from oral exposures such as may be encountered during swimming. Enteric pathogens are found in raw and even treated sewage so there is merit in using them in water quality monitoring to assess the risks from exposure. Also, it is possible that an entire "class" of pathogen risks can be determined by the presence of an "index pathogen" representing that group. The current capabilities of molecular methods to detect, identify, and enumerate pathogens has increased regulators' and stakeholders' interest in seeing these applied to ambient water quality monitoring to better protect public health.

There are a number of criteria related capabilities that may be provided by use of specific pathogen or index pathogen monitoring, such as the following: (1) determination of specific pathogen residuals from sewage discharges, the data from which could then be used to conduct quantitative microbial risk assessment (QMRA) studies to assess relative levels of public health concern at a beach; (2) establishment of "model" pathogens and index pathogens that could be used to assess risks from new or reemerging pathogens (an example would be the use of a virus model to assess the recreational risks from avian influenza [H5N1] because this virus can be released from infected human and animal feces [especially waterfowl] and can directly or indirectly contaminate recreational waters); and (3) determination of levels of pathogens that can subsequently be used in QMRA studies to inform decision making relative to whether or not a beach should be closed or reopened after a closure.

There are currently two approaches to pathogen detection, identification, and enumeration, (1) the traditional culture-based techniques that are especially useful in determining viability of the sampled materials; and (2) the molecular-based methods (PCR, antibody-based, and metabolic-based) that generally cannot distinguish between viable and non-viable pathogens, but which may be quite useful in further differentiating or speciating pathogens in water samples. The culture-based methods are useful for recreational waters in that they can determine if there is a viable disease risk from exposure while the molecular methods may not be capable of discerning viability.

Moreover, the culturable isolate can be further characterized for the presence of human virulence genes and compared to clinical isolates in waterborne disease outbreaks. In contrast, molecular-based methods may not be capable of discerning viability although the presence of virulence genes can also be assayed by molecular methods. Because molecular methods do not recover the entire microorganism, further characterization of that microorganism is limited.

Specific tracking of host sources using molecular techniques for pathogens can be very useful in setting TMDLs, as it can help identify the source of the pathogen and its magnitude. Recent improvements in molecular science applications have brought about a capability to simultaneously sample and evaluate large numbers of pathogens (e.g., microarray technology). Microarray technology still requires high concentrations of pathogens for detection. However, ambient waters generally contain pathogen levels below the limits of detection and are unevenly distributed in the water matrix. Thus, research is needed to determine how to best apply these advanced technologies for characterizing enteric and non-enteric disease contaminants, their levels, and potential risks associated with their presence in recreational waters.

Workgroup members expressed some concerns about using either specific pathogens or pathogen class indices as a first tier monitoring requirement for infectious disease risks in a recreational water setting. First, pathogens are typically present in low concentrations in treated sewage, receiving waters, and also in recreational waters; therefore, high volumes of water need to be sampled, which is time consuming, costly, and contributes to analytical variability. Second, pathogen presence is typically sporadic in a community as many waterborne diseases may not be endemic, but are rather transient/episodic so they do not represent a constant contaminant source of fecal pathogens to monitor. Third, there is a variable component in terms of fecal contributions from humans and various animal sources in ambient waters that may have an impact on determining recreational exposure risks. Typically, a number of the bacterial pathogens (e.g., toxigenic *E. coli*, *Campylobacter*) are found in both humans and animals, but there may be differences in strain virulence or infectivity potential from different sources. Likewise, there are a number of protozoan pathogens that cross-infect animal species and humans (*Giardia* spp. and *Cryptosporidium parvum*). On the other hand, human enteric viruses have a much more limited host range and except for a potential few (e.g., hepatitis E virus [HEV]), animal sources of enteric viruses are not a major public health concern in recreational waters. Lastly, it is important to note that at any given time only a small portion of the human population may be infected and excreting any specific pathogen or index pathogen. Thus, large wastewater treatment systems may always contribute a small level of pathogens of concern while septic systems or small treatment systems may not have enough contribution from the infected population to ensure that those effluents would contain specific pathogens of concern to use as a routine measure of contamination—even if the disease organisms are endemic in the population. Also, many types of pathogens are associated with a seasonality or periodicity to their occurrence in a given population.

It is reasonable to use specific pathogens or their index organisms (or model organisms) in a toolbox or tiered approach to monitoring if considered as other than as a first tier measure of fecal contamination. In a toolbox approach, the determination of the presence and concentration of specific pathogens or their index organisms could be useful to characterize risks once it has been determined that there is a trigger level of fecal contamination at a given recreational water site. Dose-response data for a number of the primary pathogens from oral exposures is available and these data would help more narrowly define exposure risks for a detected pathogen. Because of the costs, time for analysis results, and expertise needed to test specific pathogens or index organisms, these measurements would be the last set of measurements applied to monitoring of recreational sites for determining potential sources. The specific pathogen monitoring tools for other AWQC applications (e.g., TMDLs) could allow States to determine sources and concentrations of the pathogens for particular upstream contamination events. Also, pathogens could be incorporated into future NPDES permit limits and be used in the future to assess wastewater treatment plant discharges for specific pathogens of concern downstream and to provide a better understanding of the efficacy of treatment and disinfection processes.

2.7 Chemical Biomarkers of Fecal Contamination

Various shortcomings have been identified in relying solely on indicator bacteria or pathogen/index microorganisms for CWA criteria uses. Methods for MST in aquatic environments have been developed and discussed above that distinguish animal from human sources in the United States and in Europe (Blanch et al., 2006). However, for some specific tiered approaches in sanitary investigations, certain chemical biomarkers of sources may provide timely or higher resolution information in fecal source tracking. Some of the most promising are discussed below.

2.7.1 Fecal Sterols

The most commonly known fecal sterol, coprostanol (5β-cholestan-3β-ol), is largely produced in the digestive tract of humans and dogs by microbial hydrogenation of cholesterol (Leeming et al., 1996). The term "sterols" is generally used for all sterols and stanols (i.e., "fecal sterols") and is also a more specific term denoting a steroidal alcohol with at least some degree of unsaturation.

Two pathways have been proposed for the biotransformation of cholesterol to coprostanol, one in the gut and the other in natural sediments. The α-configured form (cholestanol) is the most thermodynamically stable of the reduction products and is found ubiquitously in the environment; whereas coprostanol is largely of fecal origin, but some reisomerization can yield low levels in natural sediments. Both forms are easily resolved by gas chromatography-mass spectrometry (GC/MS) analysis.

An important advance in using these fecal sterols has been the realization that it is critical to measure both the ratios and absolute concentration of at least four of these related compounds to attribute fecal source contributions between humans, herbivores, and birds (Ashbolt and Roser, 2003). Coprostanol alone has never really been embraced as an indicator for sewage pollution because its presence is not considered as indicative of a health risk due to multiple sources and low level environmental production in sediments.

The fecal sterol biomarker technique offers many diagnostic and quantitative advantages when used in conjunction with traditional techniques for detecting sewage pollution. When careful data interpretation is undertaken, fecal sterol analysis, although expensive and complex, has resolved problems of source attribution in urban and rural environments not possible with use of traditional fecal indicator bacteria and coliphage assays (Roser and Ashbolt, 2007).

2.7.2 Caffeine

Caffeine has been extensively examined as a tool for assessing human influence on aquatic systems. Although caffeine is metabolized when consumed, a small amount (<10%) of ingested caffeine remains intact when excreted (Peeler et al., 2006). Most work in the past decade has focused on heavily polluted systems and efficiency of caffeine removal in sewage treatment plants, although with improvements in techniques and the lowered detection limits, the scope of application has broadened to include stream, wetland, estuarine, and groundwater systems.

A major disadvantage is that caffeine is often present in the urban environment from numerous plant species debris as well as from human "dumping" of coffee wastes. Further, the current methods used (specific extraction and GC/MS analysis) are relatively complex and expensive. Nonetheless, based on the recent work of Peeler et al. (2006) in southwest Georgia, caffeine appears immediately below wastewater discharge sites and within towns, but not in rural watersheds. Overall, aquatic concentrations of caffeine are typically less than for fecal sterols, but caffeine tends to stay in solution, whereas the sterols associate with fine particulates.

2.7.3 Optical Brighteners and Other Sewage Markers

Recent sewage contamination may be readily identified in waters by the presence of ammonium, turbidity/particle counts, phosphate, odor, and a range of organics present. Depending on the sensitivity and AWQC applications, some of these analytes may provide value in fecal source identification.

One relatively inexpensive and sensitive fecal source identification method is fluorometry (Hartel et al., 2007). Fluorometry identifies human fecal contamination by detecting optical brighteners (also called fluorescent whitening agents) in water. Optical brighteners are compounds added primarily to laundry detergents, and because these brighteners emit light in the blue range (415 to 445 nm), they compensate for undesirable yellowing in clothes (Kaschig, 2003). In the United States, 97% of laundry detergents contain optical brighteners (Hagedorn et al., 2005). Because household plumbing systems mix effluent from washing machines and toilets together, optical brighteners are associated with human sewage in septic systems and wastewater treatment plants. However, in order to use optical brighteners to detect human fecal contamination properly, they must be combined with use (counts) of fecal indicator bacteria. For example, effluent from a wastewater treatment plant contains optical brighteners, regardless of how effective the treatment processes have been at removing or inactivating pathogens. Thus, data on the presence of optical brighteners without accompanying data on viable fecal indicators does not provide information on the potential health risk from pathogens.

However, results of studies that have combined fluorometry with counts of fecal bacteria have been contradictory. Although various reports have documented a strong fluorescent signal and high numbers of fecal enterococci, cases of no correlation between fluorometry and counts of fecal bacteria have also been reported (Hartel et al., 2007). One key confounder has been the presence of organic matter that fluoresces and interferes with fluorometry. Yet, this interference can be reduced by adding a 436-nm emission filter to the fluorometer, which may reduce background fluorescence by over 50%. As long as the fluorometer used is equipped with a 436-nm filter, it appears that targeted fecal indicator sampling combined with fluorometry can be a relatively inexpensive method for identifying human fecal contamination in water.

In summary, chemical biomarkers appear to have niche applicability for those with the resources and expertise to use them and where such biomarkers are advantageous, such as where other less expensive MST options have shown to be unsatisfactory or provide ambiguous results.

2.8 Research Needs

2.8.1 Near-term (1 to 3 Years)

1. Validate the range and species or sub-species diversity qPCR assays identify, and how they may relate to health outcomes for recreational exposures (also using archived epidemiological study material) (**high priority**).
    a. Example priority list of organisms: enterococci, *Bacteroides*, *C. perfringens*, *E. coli*, F+ RNA coliphages, and somatic coliphages
2. Investigate the potential for speciation of enterococci to identify fecal-specific (preferably human) from environmental strains, then apply results to future MST and epidemiological studies (**high/medium priority**).
3. Ensure that archived samples (collected from epidemiological/specific studies) are suitably sorted and stored (to maintain their integrity) for future viability as well as molecular-based method comparison or validation studies for candidate indicators/methods (**high priority**).
4. Validate *C. perfringens* (SRC) assay's robustness over a range of water and sediment sample characteristics and correlate health effects relationships to this indicator (**high priority**).
5. Determine if there are *Bacteroides* analytical targets that are human-specific and validate their use over a range of geographic areas, diverse populations, climates, and water quality conditions to correlate levels to health targets (**high priority**).
6. Conduct health and epidemiological studies with as wide a range of microorganisms (indicators/MST organisms) as possible to identify risk correlations for a range of pathogens/indicators (including bacteriophages) from various nonhuman sources; at a minimum would include *E. coli*, enterococci, enterococci-qPCR, coliphages, *Bacteroides*-PCR, *C. perfringens*; where possible, *Bacteroides* phage GB-124, enterohemorrhagic *E. coli* (EHEC); and check for absence of human Norovirus-qPCR, adenovirus-qPCR, Pan-enterovirus-qPCR, polyoma viruses (**high priority**).
7. Conduct health and epidemiological studies with microorganisms from nonhuman sources such as *Leptospira* spp. in fresh and *S. aureus* and pathogenic *Vibrio* spp. in marine recreational waters and determine appropriate indicators for these pathogens (**medium priority**).
8. Conduct epidemiological studies incorporating the measurement of pathogens of interest (along with indicators) as monitoring tools in sewage in order to determine the correlations of the occurrence of these pathogens to indicators, and to better understand their association with diseases at downstream recreational locations. For instance, while it is strongly suggested that enteric viruses are major contributors to illness from swimming, there have not been prospective epidemiological studies to actually support this association. Use serology (also consider collecting saliva and possibly fecal

samples) to help identify the etiological agents from sewage that are impacting on recreational water sites (**high priority**).

   a. Conduct similar studies in recreational waters (above refers to studies in sewage) (**medium priority**).

9. Systematically identify and evaluate more reproducible, accurate, and cost effective methods to sample and identify priority pathogens or their index organisms (including the total adenoviruses, [e.g., Groups A-F and adenovirus 40/41], but also JC virus, and Norovirus) in ambient waters (**medium priority**).
10. Determine if there are any appropriate sewage associated bacterial pathogens that can adequately serve as an index of any of the currently known sewage-borne bacterial organisms to use on a more routine basis in recreational water criteria. For example, determine if monitoring recreational waters for *Salmonella* spp. bacteria and phages of *Salmonella* can fulfill the criteria of a pathogen index for sewage-borne bacterial pathogen can be developed (**medium/low priority**).
11. Conduct microbial fate and transport studies to determine relationships between traditional and new fecal indicators, index pathogens, and priority pathogens in treated effluents and in downstream recreational waters to compare and validate their applicability for specific criteria uses (**high/medium priority**).

2.8.2 Longer-term Research Goals

The research below may take longer than 2 to 3 years of research to complete. These are *not* presented in order of priority.

1. Review archived samples to look for trends in evolution of viruses (new or cyclic re-emergence of viruses) and the efficacy of current indicator targets used by molecular methods for health based correlations.
   a. Develop predictive models to understand the conditions that promote the emergence or re-emergence of new pathogens.
2. Continue to conduct additional epidemiological studies on non-point sources of fecal contamination and assess illness relationships to pathogen/indicators.
3. Continue to conduct sewage surveillance for pathogens as a means of public health surveillance and informing pathogen monitoring programs for CWA purposes.
4. Develop robust method for speciation of enterococci with a view to identify fecal-specific (preferably human) from environmental strains; then apply to future MST and epidemiological studies (assuming initial studies suggest that this should be explored further).
5. Conduct studies on beaches to characterize the usefulness of total adenoviruses (Groups A-F), adenovirus 40/41, JC virus, and Norovirus to meet recreational water quality criteria purposes.
6. Conduct health/epidemiological studies to identify a range of pathogens/indicators from various nonhuman sources of fecal contamination.

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CHAPTER 3
METHODS DEVELOPMENT

Stephen Weisberg, Chair, Southern California Coastal Water Research Project
Alfred Dufour, USEPA
Charles Hagedorn, Virginia Tech
Sharon Kluender, Wisconsin State Laboratory of Hygiene
Erin Lipp, University of Georgia
Robin Oshiro, USEPA

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3.1 Introduction

The Methods Development workgroup focused on addressing the following four key questions:

1. What are the attributes and criteria for deciding whether a new method or indicator is ready for adoption by EPA?
2. What kinds of studies are necessary to quantify those attributes?
3. Are there any new indicators/methods for which those studies have been conducted and that are ready for adoption?
4. What studies (or modifications to planned studies) are most critical for EPA to implement in the next 3 years to support adoption of new methods/indicators in a criteria development framework?

A critical starting point for the workgroup members was recognition that the evaluation of methods and/or indicators needs to be considered in context of the Clean Water Act (CWA) applications in which they would be used. The following five primary uses were identified by workgroup members:

- Routine beach monitoring to support public health warning notification systems;
- Routine beach monitoring data to support total maximum daily load (TMDL) decisions;
- Rapid methods to track the progress of a sewage spill as it moves downstream or downcoast to improve the beach closure determinations;
- Compliance assessments conducted at the terminus of National Pollutant Discharge Elimination System (NPDES) discharge pipes; and
- Trends assessments to determine whether water quality conditions at a site are changing over time.

The workgroup focused on the first two applications beacause members felt that they are most relevant to EPA's desire to redefine their current recreational water quality criteria. However, several workgroup members also recognized the relevance of the other applications so a short section is included (see Section 3.7) that illustrates the similarities and differences in the method evaluation process for these other CWA uses.

For water quality notification systems, two principal issues were identified that need to be addressed. The first is that current laboratory measurement methods require up to 24 hours to enumerate indicator bacteria. Contaminated beaches remain open during this processing period, but indicator bacteria may already have returned to acceptable levels by the time laboratory results are available and warning signs are posted. Continued advances and improvements in molecular- and immunological-based techniques provide new opportunities for measuring bacteria more rapidly. Although current (traditional/standard) methods rely on bacterial growth and metabolic activity, these new methods allow direct measurement of cellular attributes, such as genetic material or surface immunological properties. By eliminating the necessity for a lengthy incubation step, some of these methods have the potential to provide results in less than 4 hours, enabling managers to take action to protect public health (i.e., post warnings or close beaches) on the same day that water samples are collected. This assumes that samples can be processed at the beach or that the time required for transportation to a laboratory is brief. For same day posting to be achieved, the results of the tests also have to be delivered to and evaluated by beach managers in a timely manner.

The second issue workgroup members identified is that present standards used to evaluate recreational water quality data are based on a "one-size-fits-all model," relying on use of a single indicator (e.g., enterococci at marine beaches) and a single standard for all recreational waters. There is growing recognition that enterococci measured on the beach may derive from many sources, including humans, domesticated animals, indigenous wildlife (including shore and migratory birds), and regrowth in sand, sediments, or on biofilms. The health risk to humans varies depending on which of these sources is responsible for the measured enterococci. As such, existing warning systems do not provide an equal level of health risk protection at all beaches. Moreover, the costly cleanup processes associated with the TMDL programs are not necessarily focused on the beaches that represent the greatest public health risk. There are additional concerns that cleanup activities, and associated costs, are being targeted at beaches where enterococci concentrations that exceed standards result from natural sources and processes.

EPA could consider two means of adjusting their criteria framework to address one-size-fits-all concerns. The first adjustment is to develop additional indicators to replace, or to augment in a tiered fashion, the existing enterococci indicator as it is now used at marine beaches (US EPA, 1986). These new indicators would be more specific to human sources and better related to human health risk than the existing indicator.

The second potential adjustment is to adopt a framework similar to that of the World Health Organization (WHO, 2003), in which watershed characterization studies are used to adopt site-specific standards. These site-specific standards would be based on perception of health risk resulting from the types of fecal sources in the watershed and the proximity of those sources to the beach. The Methods workgroup members felt strongly that source identification methods needed to be a key tool in characterizing risk and that further evaluation of source identification methods needed to be conducted if they are to be used in this context.

This chapter is organized around describing the approach that would be used for assessing methods/indicators in the following three contexts: (1) replacement of existing methods with more rapid methods, (2) replacement of existing indicators with those that are more specific to human sources of fecal contamination, and (3) determination of source identification methods that can be used to characterize risk in the development of site-specific standards. Within each section, the adequacy of evaluations of methods/indicators is discussed and the most immediate research activities that would provide the greatest benefit to EPA for modifying monitoring and/or indicators within the next 5 years are highlighted.

3.2 Classes of Indicators

The evaluation of methods is a critical element in bringing new technology to the measurement of water quality. Current evaluation protocols were developed for cultural methods for enumerating bacterial indicators of fecal contamination. The evaluation usually included method attributes regarding the performance of the method, such as specificity, accuracy, and precision. Further evaluation that addressed how the method performed in and between laboratories included multi-laboratory testing that determined how robust a method might be (i.e., how poorly can the method be performed and still produce useful results?). The question that arises is whether the current protocols for evaluating membrane filter culture-based methods are suitable for evaluating new methods that are being proposed for measuring water quality. Some of the new or alternative methodologies that are available for testing water quality include molecular-based methods, such as quantitative polymerase chain reaction (qPCR), nucleic acid sequence based amplification (NASBA), and transcription-mediated amplification (TMA). These methods amplify nucleic acid sequences to high levels such that they can be easily detected. Other methods use antibodies to which fluorescent compounds are attached. The fluorescent-tagged antibodies then attach to specific microbes and are “counted” in a flowcytometer. The preceding methods “count” dead and live bacteria and thus differ significantly from currently used quantitative cultural methods.

Some recent methods do measure viable microbes in an indirect manner. For example, enzyme-based methods measure substrate utilization employing compounds that fluoresce when metabolized by specific bacteria. Comparison of the fluorescence to a standard curve allows a “count” to be established. Another method measures adenosine triphosphate (ATP) using a bioluminescence measuring instrument to determine the amount of ATP that is produced only from viable bacteria.

In the current context, there are indicators available or in late stages of development that are ready for evaluation to determine if they are appropriate for use in routine beach monitoring. Some can be measured with the technology described above while others can be measured with currently available methodologies.

Leading candidates are indicators and detection methods that can be used to replace current culture-based indicators of water quality (i.e., enterococci and *E. coli*). For instance, nucleic acid sequences from enterococci have been used to measure the density of enterococci in bathing beach water. Some aspects of the performance of this method have been completed. As described above, enterococci have also been quantified using a fiber optic/fluorescent antibody detection method, an enzymatic/substrate method, and a method that measures ATP. None of the latter methods have been evaluated with respect to either their performance characteristics or for robustness. Similarly, molecular-based methods that measure viruses (e.g., adenoviruses) that might replace currently used indicators of recreational water quality have not had their performance evaluated. If these indicators are shown to be effective in their performance, they will be candidates for use in epidemiological studies to determine how well their densities in recreational waters relate to swimmer health.

Another class of microbes and other analytes are related to identifying the source of fecal contamination that might affect beach microbial water quality. Other markers include genes such as the *Esp* gene from enterococci, which might be specifically associated with human feces; male-specific (F+) coliphage that can indicate whether water has been contaminated by humans or animals; and chemical markers such as optical brighteners, caffeine, coprostanol, and urobilin that may be associated with human use or are the end-products of human metabolism (see also

Chapter 2). Optical brighteners are measured quite easily with a spectrofluorometer, while caffeine, coprostanol, and urobilin require more complex instrumentation, such as a high performance liquid chromatography (HPLC) instrument. Measuring genomic markers is less complicated and does not require a thermocycler to perform a PCR test. The varied nature of these source identification markers may require modification of the performance evaluation criteria to accommodate the different characteristics of these source specific analytes. For instance, the range of applicability and practicality may be more important than the accuracy and precision characteristics of these chemical or genomic source identification approaches.

The last class of indicators that may be ready for evaluation as indicators of fecal contamination are those that may have been rejected previously, for whatever reason, but should be considered again because of the availability of new information about their occurrence in water or because of new methods for their detection. Other potential indicators may be candidates because they are species within a group indicator, such as the enterococci and clostridia, and individual species may better indicate the quality of a waterbody. It is likely that this class of indicator will fit well into the current paradigm for characterizing microorganisms that might be used for routine recreational water quality monitoring.

3.3 Evaluating New Methods for Existing Indicators

Workgroup members felt that after a method passes defined performance criteria, it must be evaluated for its application as an equivalent (or superior) water quality tool compared to the current assays. An example of when this approach might be used is the transition from culture-based enterococci detection to detection by a rapid (molecular-based) assay.

The workgroup identified two major approaches to conduct this evaluation, (1) determining the relationship to health risks based on epidemiological studies or (2) establishing equivalency to an existing water quality tool.

3.3.1 Health Risk Evaluation

Workgroup members felt that determining the relationship to health risk is the best approach to evaluating a new method. An epidemiological study that can associate human risk with a new method is the preferred approach. The new detection method will ideally show an improved relationship to illness and will therefore be more protective of public health than the current approach that relies on indicator detection. Likewise, if the new method offers other improvements over the existing method (e.g., more rapid, less costly, etc.), then its relationship with human health should be at least as good as the current indicator.

The health risk evaluation should also be used when the target of the new method differs significantly from the current system. For example, a culture-based enterococci assay does not measure the same thing as a polymerase chain reaction (PCR)-based assay, which detects DNA rather than culturable (viable) cells. In these cases, a direct comparison of methods (as described below) may not be appropriate or possible.

3.3.2 Establishing Equivalency between New and Standard Methods

The equivalency validation approach assumes that for methods with similar targets (e.g., viable cells), the performance of the new method can be compared to that of the existing method without the need to determine health risk directly. Given the cost and time involved in large scale epidemiological studies, the equivalency approach can be performed for many new methods. The EPA should determine how dissimilar the method targets can be and still be evaluated by this approach. For example, cellular activity-based assays (e.g., immunomagnetic separation and ATP bioluminescence [IMS/ATP]) and membrane-filtration assays both measure viable cells, even though the end points are different. The workgroup members suggested that this activity-based assay is similar enough to be evaluated through equivalency validation. This level of flexibility is important because of the limited number of epidemiological studies that can be carried out in the near- or long-term.

The current EPA (2003) protocol, *EPA Microbiological Alternate Test Procedure (ATP) Protocol for Drinking Water, Ambient Water, and Wastewater Monitoring Methods*, provides a suitable vehicle for performing these evaluations. The EPA recommends approval of a proposed method if it is similar or better than the approved method (the “gold standard”) for 80% of the matrices tested. Currently, only culture-based methods can be included as an alternate test procedure; therefore, consideration should be given by the EPA on the comparability of other methods (as mentioned above).

Along these lines, California has adopted equivalency validation between methods with different targets (i.e., culture-based versus PCR-based). This protocol, *Beta Testing of Rapid Methods for Measuring Beach Water Quality* (SCCWRP, 2007), provides guidelines for comparing between methods. Similar to EPA, this validation compares method performance between multiple sample types and laboratories and also sets acceptable variability between results at 0.5 log (based on within method variability previously reported [Griffith et al., 2006; Noble et al., 2003]). Additionally, the precision should be equal to or better than for the existing methods.

Many workgroup members felt that EPA’s protocol is too prescriptive because it disallows applications for methods that are not culture-based. In the future, for example, should the IMS-ATP test be found to have a health risk-based association, EPA should consider allowing its comparison to culture-based methods since both assay for live organisms, albeit not exactly via the same mechanism (membrane-filtration colonies or Most Probable Number [MPN] results versus ATP occurrence). By the same token, workgroup members felt that the California protocol was too relaxed in that genetic methods were compared to culture-based methods for the purposes of acceptance of the former. Because these methods do not measure the same targets (DNA versus membrane-filtration colonies), this was perceived as comparing “apples to oranges” as the criteria for making such comparisons are not yet well established.

3.4 Performance Criteria

Regardless of which of the two evaluation approaches is chosen (health risk-based or method equivalency-based), performance criteria for the method should be completed, and preferably before using the method in an epidemiological study to obtain heath risk-based association data.

Workgroup members consider the following to be the major parts of performance criteria: repeatability, accuracy, specificity, sensitivity, robustness, range of applicability, and practicality. These performance criteria are summarized below.

Repeatability asks the question: if a test is repeated, will the results be the same? Note, this does not take into account the degree of error with regard to how well the test does at identifying its target (accuracy). For example, if a person is throwing darts at a target, repeatability is the measure of how often the darts hit a specific place. Repeatability does not measure whether one hits the center of the target or not—that is accuracy (see more below). Repeatability is sometimes referred to as precision and can be expressed both on an absolute scale (i.e., standard deviation) and on a relative scale (i.e., relative standard deviation [RSD]). The RSD (sometimes referred to as coefficient of variation) is calculated as the standard deviation divided by the mean, expressed as a percent. For the purpose of summarizing data, both standard deviations and RSDs should be calculated. Generally, RSDs are most appropriate for summarizing precision when variability increases as concentration increases. To provide an indication of the effect of multiple matrices on precision, standard deviations should be calculated separately for each matrix as well as for the method over all matrices. In addition to within and among matrix/matrices for repeatability, it is important to test intra- (within lab) and inter-laboratory (among labs) repeatability to ensure consistency.

Accuracy measures the degree to which the method identifies its target. It is defined as the degree of agreement between an observed value and an accepted reference value. Accuracy includes random error (precision) and systematic error (recovery) that are caused by sampling and analysis. Using the above dart example, this would be the number of times that the dart hits the “bulls-eye.”

Specificity includes the false positive and false negative rates. The false positive question asks if the method is significantly more likely or less likely to detect non-target organisms or other sample constituents that would be reported as the target organism by the analyst when compared to the reference method. To assess whether the false positive rates are significant, replicates known to contain non-target organisms that could be falsely identified as the target organism should be analyzed. The determination that the samples do not contain the target organism should be based on a third independent standard method. For example, if the target organism is cultured *E. coli*, the test should be used against, at a minimum, other enterobacteria, and, depending on what the test is, potentially Gram positive organisms as well. If the test is for genetic material, then the primers and probes should be tested against GenBank to look for potential false positives from non-*E. coli* species with the same sequences. Specificity also asks the false negative question regarding whether the new method is significantly more or less likely to exhibit non-detections for samples with the target organism or to exhibit results that are biased low when compared to the reference method. To assess whether the false negative rates are significantly different between methods, replicates known to contain target organisms should be analyzed. As in false positive studies, the determination that the samples do not contain the target organism should be based on a third independent standard method. For example, if the target organism is genetic material from *E. coli*, then a method for culturable *E. coli* can be used.

If the culture method is able to detect *E. coli*, then the genetic method should, in general, also detect *E. coli*.

Estimates of false positive and negative rates as percentages can be calculated as follows:

1. false positive rate = # false positives/(# of true negatives + false positives) × 100%; and
2. false negative rate = # false negatives/(# true positives + false negatives) × 100%.

The sensitivity of a test is the analytical detection limit of the test (the smallest amount detectable using the method). For chemical methods, the sensitivity may be defined as the minimum amount of a particular component that can be determined by a single measurement with a stated confidence level. Generally, these refer to instrument analysis; thus, it is the lowest quantity of a substance that can be distinguished from the absence of that substance (a blank). For microbial methods, sensitivity is the limit of detection of a particular method. In general, methods are not used at this level since confidence around that level is lower and more subject to user error.

The robustness of a test is the degree to which the method can perform in the presence of incorrect inputs or stressed conditions. More simply, how poorly can a method perform and still produce useful results? For example, does the method perform as intended in the hands of a semi-novice user (e.g., a qPCR method performed by a person familiar with molecular-based methods including PCR but not qPCR)? If the test is for cultured microorganisms, can it detect stressed organisms in ambient waters (e.g., the EPA *E. coli* methods have a 2-hour resuscitation step at a lower temperature for stressed organisms)? Robustness is not a measurable attribute per se but must be considered and applied for overall method performance.

The range of applicability should also be considered as it answers the question: is the test reliable on a nationwide basis (e.g., does it work equally well in temperate and tropical climes, in the Great Lakes and other inland waters, etc.), in the presence of inhibitors (e.g., turbidity, alkalinity, organics [humic acids]), and in a variety of matrices (e.g., sewage, septic tanks, urban runoff, agricultural waste, known animal sources)? In general, the range of applicability does not apply to matrices other than the one for which the test was designed; that is, a recreational water quality method should not be expected to perform equally well for sewage sludge. Like robustness, this is not a measurable attribute but must be considered and applied for overall method performance.

Workgroup members felt that practicality should also be considered when considering a method. This issue is largely addressed in Chapter 7 (Implementation Realities workgroup). However, four main issues were considered important enough to be mentioned here—capital cost, training cost, per sample cost, and additional sampling requirements. Capital costs include the upfront costs such as equipment purchase and the actual space required for the test. For example, when performing genetic testing, aside from the equipment needed (e.g., platform [specific machine], laminar flow hoods, dedicated pipettors), space is needed, ideally in separate rooms, for reagent preparation (material not containing any genetic materials). Space is also needed for the two types of sample preparation, those containing high target sequence DNA concentrations such as DNA standards and calibrator samples, and those containing expected low target sequence DNA concentrations (e.g., filter blanks and water samples)—the latter of which should also be in separate laminar flow hoods. Training costs are those incurred prior to routine testing so that the user can perform the test within the performance criteria of the test; these may include participation in a workshop for hands-on experience or completing a training module. The other two issues regard routine use of the test. A high per sample cost may become an issue if a large volume of tests need to be completed on a routine basis. Additional sampling is generally an effort that results from rapid testing. For example, if an early morning sample yields, after 4 hours, a positive result resulting in beach closure, it may then lead to additional sampling to determine if the beach still needs to be closed in mid-afternoon. It should be noted that many laboratories (at least in California) do not object to capital or training costs, but take issue with a high per sample cost or with additional sampling requirements.

3.5 Evaluation Process for Alternative (New) Indicators

Currently, recreational water quality is assessed with a single indicator with a single threshold (i.e., a “one-size-fits-all” approach). Under consideration is the implementation of alternative indicator(s) that are better associated with human health risk than the enterococci. These alternative indicators could theoretically replace the current standard but still be used in a one-size-fits-all approach or could be targeted for specific applications (e.g., one indicator may be best associated with risk in tropical marine waters, another in temperate marine waters, and another in freshwaters). Regardless of the final implementation, any new proposed indicator will need to be vetted through performance based standards.

The system of approving an alternative indicator will follow the same process as outlined for the assessment of any indicator or method, although there will be key differences.

- Any proposed indicator and/or method should be evaluated for the following performance characteristics:
  - repeatability (i.e., precision);
  - accuracy;
  - sensitivity;
  - specificity (false positive/false negative);
  - robustness;
  - range of applicability; and
  - practicality.
- *After* performance characteristics have been demonstrated and the indicator and associated method has been *determined to have adequate performance*, it then should be evaluated for its use and application in a water quality criteria, including:
  - relationships to health risks must be established based on epidemiological studies covering an array of beach types and/or geographic areas; and
  - because of lack of comparable standards, a new indicator cannot be evaluated based upon equivalency to an existing method.

This approach would establish the basis for alternative (new) indicators, and leads into the possibility that such indicators could also serve in a role as source identifiers.

3.6 Evaluating Source Identification Methods – Proficiency and Evaluation

When bacterial levels in recreational waters exceed adopted State Water Quality Standard, the potential risk to the public health requires local authorities to post advisories or close swimming areas, risking significant losses in local revenue. The goal of microbial source tracking (MST), as applied to U.S. waters, is to accurately identify the contributors and, if possible, the relative proportions of fecal pollution from all potential sources, or at least the major contributors. Proper use of MST can assist watershed managers in implementation of best management practices (BMPs) that can reduce fecal inputs, thereby limiting or reducing public health risk.

Two major classes of microbe-based and one class of chemical-based MST methods are currently being developed and utilized in surface waters across the world (Blanch et al., 2006; Stoeckel and Harwood, 2007). Although there has been significant progress in the MST field over the past decade, variability among performance measurements and validation approaches in laboratory and field studies has led to a body of literature that is very difficult to interpret, both for scientists and for end users (Stewart et al., 2003; Stoeckel et al., 2004). This section lists and defines/describes performance characteristics that should be uniformly applied across MST studies, although selection of which criteria from the following list to use will vary somewhat based on the target. All methods and MST projects need to include some considerations for representative sampling, sampling frequency, sample volumes required, and the number and choice of source categories. Although the use of a toolbox approach has been important in MST studies, there is a desire to develop an appropriate tiered approach to avoid costs and time from using multiple methods simultaneously. Within the MST community, and largely as a result of the method comparison studies, library-independent methods are currently the priority, while chemical-based methods appear to be desirable for rapid screening and presence-absence tests (with perhaps quantification in the future). Library-based methods still have a role in MST, but only in those circumstances where detailed information is needed, such as many TMDL-based studies.

3.6.1 Library-independent Methods (also Reported as Sample-level Classification)

Examples (not comprehensive) include both molecular approaches (*Bacteroidales*, *E. coli* toxin, *Enterococcus Esp* gene, direct measurement of source-specific viruses (polyoma, adenoviruses, enteroviruses, phages, etc.) and microbe-based approaches (*Clostridium perfringens* [alternative indicator], source-related clostridia, source-related enterococci, sorbitol fermenting bifidobacteria [human], *Rhodococcus copraphilus* [grazing animals], human-specific bacteriophages, phage typing, etc.).

Method evaluation includes the following eight performance criteria:

1. Accuracy is defined as the true positive or success rate—if a method identified the presence of the target in 98 out of 100 blind samples, the accuracy would be 98%;
2. Rates of false negatives and false positives of the target are used to describe specificity;
3. The analytical detection limit of the test is used to describe sensitivity;
4. The level of target-host specificity and the range of target-host distribution;
5. Efficiency of recovery of the target from different environments;

6. The reproducibility of analytical results, both inter- and intra-laboratory;
7. The suitability of marker detection (and/or quantification) to meet study-specific objectives; and
8. Detection of several of the above, especially #4 and #5, can be referred to as robustness.

3.6.2 Non-microbial Methods (also Called Chemical Methods)

Examples of non-microbial indicators include, but are not limited to, optical brighteners, host-derived DNA (e.g., eukaryotic mitochondrial DNA), fecal sterols/stanols, and source-specific fecal compounds such as caffeine and pharmaceuticals for humans.

The performance criteria in numbers 1 through 8 above, excluding #4 and #5, apply to non-microbial methods. For chemicals, the analytical detection limit of the test is usually applied to describe both sensitivity (#3) and the efficiency of recovery of the target from different environments (#5).

3.6.3 Library-based Methods (also Called Isolate Matching)

Examples of library-based methods include but are not limited to both molecular approaches (pulsed-field gel electrophoresis [PFGE], ribotyping, PCR with different primer sets, etc.) and phenotype-based approaches (antibiotic resistance analysis [ARA], biochemical, etc.).

The performance criteria in numbers 1 to 3 from library-independent methods (above) are applicable for library-based methods. In addition, the following four criteria apply:

1. Jackknife (also reported as holdout or cross-validation) analysis and the pulled-sample test (recently described as internal proficiency) should be done on each and every library (Stoeckel and Harwood 2007);
2. Library should shave clones removed to reduce redundancy, based on the precision of the typing method;
3. External proficiency or blind tests to determine both size and representativeness of the library should be done as the library is developed; and
4. The benefit-over-random statistic should be used when accuracy is determined, and should be performed on both the library and the external proficiency (or blind) set.

3.7 Modifications to the Evaluation Process When Indicators are used for Other Applications

Indicators are used in many different contexts. Routine beach monitoring, the most time-critical use of indicator bacteria is described extensively in other chapters of these proceedings. This section briefly addresses other (secondary) uses of indicators. Another use of indicators is as an early warning system that would provide evidence for an imminent human health risk, such as a sewage spill. They can also provide evidence of returning to acceptable ambient water quality conditions as designated by the criteria. It is important that the methods be highly specific and robust. Because of the potential for illness in exposed populations, it is extremely important that this use of an indicator be associated with great specificity and robustness. Specificity in this case refers to the ability of a method to detect an indicator with certainty that the indicator is not giving a false positive response (i.e., an organism or analyte that responds similarly to the target organisms, but is not the target organism). Similarly, target microbes that do not provide a positive response are indicated as false negatives and too many of these could result in a false sense of security that would be highly unacceptable from a public health perspective. Robustness in this case means that the method can be abused and still function properly. Methods of this type are usually used under extreme conditions where the correct result must be obtained in a very short time period.

Another use of indicators is for compliance monitoring purposes, such as monitoring sewage treatment effluent for EPA's NPDES Program. Important characteristics for indicators used for such compliance monitoring are precision and specificity. The precision is necessary because sewage treatment plants would receive a fine(s) if limits of the permit are exceeded. The specificity, both false negative and false positive responses, are important for the same reason mentioned above and may influence the way beaches are managed.

Trend assessments are used to determine whether water quality conditions at a site are changing with time. The most important characteristic is precision that contributes to the ability to detect small changes over time (i.e., whether the water quality is decreasing or improving over time). If the water quality decreases then bathing may no longer be allowed. Conversely, if the water quality improves sufficiently then bathing may be re-allowed.

3.8 Research Needs

Several lines of research should be pursued in order to implement improved methods for (1) rapid detection of current water quality indicators, (2) implementing alternative indicators that are more protective of public that the current indicators, or (3) determining source (human or nonhuman) at beaches. This set of research priorities is based upon the current state of available methods and the projected feasibility of implementation in near-term (1 to 3 years) and mid-term (2 to 5 years) or longer timeframes. Although these are listed in priority order, the workgroup members felt that they largely expand on efforts that EPA or its potential partners have already initiated and all are achievable in the next 3 years. Appendix G summarizes currently planned measurements for use in the upcoming Doheny and Malibu Beach (California) epidemiology study.

1. Systematic evaluation of performance criteria for library-independent source identification methods (for use in source characterization [i.e., human versus nonhuman fecal contamination] and in MST) (timeline: 1 to 2 years).

   Workgroup members felt that EPA should fast-track studies to evaluate the performance criteria of source-specific microbial targets.

   A series of controlled trials representing a variety of geographical areas should be conducted to evaluate promising methods. Studies should include samples spiked with known source fecal matter from multiple hosts as well as environmental samples collected from areas with known dominant sources of fecal contamination. Samples should be assayed by the test methods in several laboratories using blinded controls. These protocols would be similar to those used in the Griffith et al. (2003) studies that EPA co-sponsored approximately 5 years ago, but which need to be updated as new methods have developed and existing methods refined.

Although there are many potential methods that could be included in such studies, the workgroup members identified the following as the most important:

1. enterococci *Esp* gene;
2. *E. coli* virulence genes;
3. human enteric viruses (molecular detection);
   a. DNA-based – adenoviruses and polyomavirus;
   b. RNA-based – enterovirus and norovirus;
4. *Methanobrevibacter smithii* (*nifH* gene);
5. *Clostridium perfringens*;
6. coliphage; and
7. *Bacteroides* human-specific markers.

The last two methods are also being planned for use in EPA's upcoming (2007) health risk (epidemiological) study. The workgroup members felt that the coliphage and *Bacteroides* methods are more advanced than the others and endorses their inclusion in source identification studies.

In coordination with trials over various geographic areas, candidate methods should also be evaluated from the perspective of persistence of genetic or chemical or microbial targets in both primary and secondary habitats (sediments) over longer time periods (multi-year). Although this may be a longer term goal, eventually all methods that appear to be suitable for use regulatory or management-level decisions will need such to be examined over time periods sufficiently long so that there is confidence that the desired targets do not change, or that changes can be captured and dealt with if they do occur.

2. Evaluation of chemical indicators for human sewage (timeline: 2 to 3 years).

Several possible chemical markers of sewage have been reported and have the potential to be used in a rapid to real-time assessment of source. Coordinated studies to evaluate the performance criteria over multiple labs are needed to implement these assays.

The following analytes should be included in near term evaluation studies:

1. optical brighteners;
2. coprostanol; and
3. caffeine.

At least one multi-laboratroy evaluation study of optical brighteners is currently being developed by individual investigators (Hartel et al., 2007).

3. Continued evaluation of rapid assays for the detection of enterococci in human health risk (epidemiological) studies (timeline: 1 year and beyond).

   Rapid detection of current water quality indicators are proposed to allow same day evaluation of water quality. To implement these assays, continued evaluation of the health risk relationship is needed. For qPCR (*Enterococcus*), more epidemiological studies from a range of beach types are needed before implementation. Additionally, other rapid assays for enterococci have been developed and should be evaluated in upcoming and future epidemiological studies.

   Methods under consideration for enterococci detection include the following:

   Immediate (timeline: 1 to 2 years):
   - qPCR (detection of DNA); and
   - TMA (detection of RNA).

   Mid-term (timeline: >2 years; require additional performance evaluation):
   - IMS/ATP (detection of activity);
   - RAPTOR^{TM} (antibody-based detection)[5]; and
   - enzymatic detection.

4. Evaluation of alternate indicator candidates in human health risk (epidemiological) studies (timeline: 1 year and beyond).

   Potential alternate indicators (i.e., to replace enterococci and *E. coli*) that have already been vetted for performance criteria should be included in any future epidemiological studies of recreational waters to determine their relationship with health risk.

   The following indicators should be evaluated within the next two years:

   - *Bacteriodales* human specific markers; and
   - F+ coliphage (antibody).

   Other candidates indicators should be added for evaluation as they meet required performance criteria (as listed above)

5. Optimization of sampling, recovery, and processing methods for efficient concentration, processing and detection of rapid, alternative or host specific indicators (Time line: 1 year and beyond).

[5] http://www.resrchintl.com/raptor-detection-system.html

Additional methods need to be optimized for source specific microbial targets. Studies should address issues such as optimization of sample volume, processing/concentration methods, and extraction/purification methods (especially for targets expected to occur at low numbers in the environment).

Furthermore, research addressing straightforward techniques to enumerate *Enterococcus faecium* and *faecalis*, rather than the larger *Enterococcus* group that is presently measured, are needed as the individual species are more likely to be associated with human sewage/feces. Performance-based criteria tests are also needed for these species.

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CHAPTER 4
COMPARING RISK (TO HUMANS) FROM DIFFERENT SOURCES

Dennis Juranek, Chair, Centers for Disease Control and Prevention (retired)
Rebecca Calderon, USEPA
Jack Colford, University of California, Berkeley
Elizabeth Doyle, USEPA
Graham McBride, National Institute of Water and Atmospheric Research, New Zealand
Samuel Myoda, Delaware Department of Natural Resources

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4.1 Introduction

Fresh and marine recreational waters and beaches may be impacted by human and/or animal feces from point and non-point sources. Studies have recently been completed by EPA on assessing rapid water quality indicators and their ability to predict swimming-associated illness at freshwater beaches impacted by publicly (and privately) owned (sewage/wastewater) treatment works (POTW) systems. Similar EPA studies are currently planned (starting summer of 2007) to assess the risk of illness for people who swim in marine recreational waters impacted by POTW systems (point sources of fecal contamination). Thus, in the near future additional information should be available on risk of illness for bathers at marine beaches largely impacted by human sewage. Plans are also underway by the Southern California Coastal Water Research Project to assess swimming risks at least one marine beach that is impacted by non-point source sewage that likely contains a mixture of human and animal feces. However, there remains a paucity of data on the risk of illness for swimmers at beaches exclusively (or primarily) impacted by feces from animals. The absence of such data makes it difficult to interpret the health significance of the frequent and persistent elevated fecal indicator levels in such waters that have been attributed to animals in many locations throughout the United States.

It is widely believed that human feces pose a larger health risk than animal feces to swimmers and other primary contact recreational water users. This belief derives from the basic concept that virtually all enteric pathogens of humans are infectious to other humans, while relatively few of the enteric pathogens of animals are infectious to humans. Possible exceptions are bird flu virus and swine hepatitis E virus (HEV). Workgroup members regarded the evidence for swine HEV transmission by water to be very weak and felt that it could disregarded in terms of risk assessments during the next 2 to 3 year EPA planning period. Bird flu was discounted as a major concern for swimmers because it was felt that if an outbreak of bird flu was recognized in birds or humans in the United States, early public health recommendations would include directives for people not to swim in waters that might be impacted by bird or human feces, including chlorinated public pools.

Counterbalancing the concept that animal feces may pose a lower risk is recognition that animals do harbor many bacterial and protozoan pathogens that pose a human health hazard and that some of these pathogens, such as enterohemorrhagic *E. coli* (EHEC), can cause serious, potentially life-threatening illness in humans. In addition, animal feces are often directly deposited in freshwater that receives no treatment before reaching bathing areas. The concentration of both feces and pathogens may be sufficiently high at beach locations at various times to pose a significant health risk to swimmers.

The bottom line is that there are few data to demonstrate whether animal feces pose a lower, greater, or equivalent health risk to bathers than human feces. If there is a difference, it would be helpful to know the magnitude of that difference in order for EPA to make appropriate public health recommendations. The only way to get a better sense of the health risk for swimmers posed by animal feces is to conduct targeted studies. Some types of studies (epidemiological and quantitative microbial risk assessment [QMRA] studies) would produce quantitative estimates of risks while others (fate and transport, pathogen loads in water, etc.) would provide supporting information or stand alone qualitative information about risk.

It is recognized that there are many different types of animals and that the pathogen risks posed by feces from these animals are different. These differences, as well as the different pathways (point, non-point, fecal deposition on land versus in water, etc.) that feces reach bathing areas, have to be taken into account in weighing risk. Workgroup members approached the issue by developing Table 5 in order to rank the likely risks from different sources of fecal contamination and to help prioritize which bather/animal-fecal-risk interface studies should be undertaken first.

The initial workgroup member discussion focused on assessing the universe of pathogen sources of interest to recreational waters. Workgroup members developed a table (Table 5) in which the major sources of fecal contamination categories are in rows. The major rows are wildlife, agricultural animals, domestic animals (pets), human/sewage, and what the workgroup termed "secondary environments" (i.e., soil, sand, and sediments). The wildlife row is subdivided into aquatic birds and all others. The agricultural animals are divided into poultry and other (largely comprised of domestic livestock such as cattle, sheep, and pigs). The human/sewage is divided

Table 5. Comparing Risks (to Humans) from Different Pathogen Sources.[a]

Source	Viruses	Protozoa	Bacteria	
Wildlife				
Aquatic birds	N	L	L-M	
Other (e.g., deer)	N	M	M	#2 priority
Agricultural animals				
Poultry	N	N	M-H	
Other (e.g., cattle, sheep)	N	M	M-H	#1 priority
Domestic animals				
Pets (e.g., dogs, cats)	N	L	L	
Fecal shedding by bathers				#3 priority
Adults	L	L	L	
Children	H	H	H	
Sewage				
No treatment (combined sewer overflows)	H	H	H	
No treatment (separate storm sewer overflows)	?*	?*	?*	
Secondary treatment**	H	H	M	
Plus chlorine**	H	H	L	
Plus UV	M-H (L with increased energy)		L	
Secondary environments***	L	L	M	

[a] Does not have an explicit fate and transport component
* Risk largely depends on amount of human feces present
** Focus of most (U.S.) recreational water epidemiological studies
*** Sediment suspension and contact with beach sand

N = estimated no or negligible risk, L = estimated low risk, M = estimated medium risk, H = estimated high risk into untreated sewage, secondary treatment sewage, chlorinated sewage, and UV-treated sewage. Fecal shedding by bathers (adults and children) is considered separately.

The columns are defined by broad microorganism groups of viruses, protozoan and bacteria. By an expert opinion process (within the workgroup) each cell of the table was given a risk estimate of no (zero) or negligible risk (N), low, medium, and high (L, M, H). The types of characteristics discussed included infectious dose, numbers of pathogens per gram of stool from infected animals, implication of source in waterborne disease (extended discussion on foodborne disease and vector-borne disease), persistence and survival in the environment and finally an assumption that sources are in close proximity to a primary contact recreational area. The N, L, M, H risk designations in the table cells represent the workgroup's "best guesses" and assumed that animal feces was deposited in freshwater relatively closed to bathing sites. The workgroup did not specifically address pathogen "die-off" associated with fecal deposition on land (spring/summer temperatures resulting in pathogen drying, transport from soil to water affects on viability, etc.). It was felt that many of these types of data are available and that the table could be updated with real data at a later date as a separate project. It was recognized that updating the table with published data might change the values in one or more risk rankings of the table cells.

With rare exception, viruses are species-specific. Essentially, all enteric oral/fecally transmitted viruses that infect humans are of human origin. For all of the animal viral sources of pollution, the viral cells were given a zero or negligible risk (indicated by "N" entries in Table 5). All the human sources were given a high risk estimate with the exception of UV-treated sewage. UV-treated sewage at current levels has up to a 0.5-log reduction of viruses and hence this cell was assigned a medium risk. More energy intensive UV irradiation may provide up to a 4-log viral reduction and result in a low risk ranking. Sentinel viruses for this group include enteroviruses, hepatitis A virus, norovirus, rotovirus, and adenoviruses. The major protozoan pathogens of concern are *Giardia* and *Cryptosporidium*. Given the current knowledge of infectious dose, the long survival in the environment, many of the animal cells within the table were given a low, low-to-medium, or medium risk level. As with the viruses, all the human cells within the table were given a high risk rating with the exception of UV-treated sewage. The bacteria had similar ratings to the protozoa ranging from low-to-medium and again, the human sources were all assigned a high ranking with exception of chlorine- and UV-treated sewage that received a low risk ranking.

Bather density was divided into adults and children (recognizing that children could be divided into specific age groups) with the assumption that hygiene and accidental fecal discharges were much more likely to occur in children than adults. Thus, for adults, a low risk ranking was assigned across the columns and a high risk ranking was assigned for children.

Based on the few studies done on secondary environments, viruses and protozoa were given a low risk rating, while bacteria were given a medium rating.

In developing Table 5, workgroup members noted the following discussion points:

1. Current epidemiological literature suggests that the symptomatic profile of swimming-associated illnesses indicates primarily viral illnesses.
2. Certain pathogens such as EHEC have a low probability of occurrence but are associated with severe a health outcome.
3. Information available to the workgroup suggested that nonhuman fecal sources impacted freshwater sources more than marine water sources.
4. Combined sewer overflows (CSOs) were considered as untreated sewage.
5. Separate storm sewer overflows initially were put in the domestic animal row but subsequent discussion of recent studies suggested that they could have a human component in many communities.

In discussing the future research needs related to the development of new or revised recreational water quality criteria, the workgroup members defined the ultimate goal to be a determined quantitative risk estimate for each fecal source (row). The benchmark by which risks should be compared is the secondary and chlorine treated sewage row that is currently the focus of recently completed EPA National Epidemiological and Environmental Assessment of Recreational (NEEAR) epidemiological studies for freshwater and the planned marine water studies. The following research projects were suggested to meet that objective of determining a sound and defensible risk estimate for each row of Table 5.

4.2 Summary of Workgroup Discussions and Reflections on Workgroup-specific Charge and Questions

The charge to the workgroup was to consider the impact of waterborne pathogens from various sources, both human and nonhuman, on the health risk resulting from exposure to fecal contamination in recreational waters. Workgroup members considered the impact of the issue on beach monitoring and notification and the classification of waterways as impaired. The discussions were wide-ranging. Discussions began with the consideration of the relationship of likelihood of illness due to nonhuman sources to likelihood of illness predicted by the use of epidemiological data from human exposure to POTW-impacted waters using fecal indicators. Possible approaches to modifying the application of regulatory approach using considerations of infectivity to pathogens among species were debated. The location of fecal sources relative to the site of monitoring and the potential of animals to move off-site were also discussed. These topics are all reflected in the potential research activities proposed and discussed in this chapter.

Six charge questions were provided to the workgroup (see Appendix A) to help stimulate discussion, and to identify key issues for consideration. A brief synopsis of responses to the questions is presented below.

- *Question 1: Is setting criteria based on a treated human point source such as a POTW protective, under-protective or overprotective of other potential sources of human pathogen? Why or why not? Are there data to support this conclusion?*

Whether the criteria are protective would depend on the effectiveness of treatment in reducing the levels of pathogens and the relative reduction in indicator organisms. Secondary wastewater treatment with chlorination could provide a false sense of security for protozoa and viruses. This reflects the higher degree of effectiveness of chlorine in killing/deactivating bacteria relative to viruses and protozoa. Given that current indicators are bacteria and would be reduced to a greater extent than viruses and protozoa, low indicator levels might suggest that waters impacted by POTWs were relatively pathogen-free when they still contained a significant virus and protozoan load. Data are available to characterize the relative effectiveness of disinfection techniques across classes of waterborne pathogens and indicator organisms.

- *Question 2: Based on the "state of the science," what conclusions or assumptions are reasonable to make about risks to humans exposed to human fecal contamination, non-point source contamination from animal sources, and mixed sources (e.g., combined sewer overflows [CSOs] and (separate) storm sewer overflows)?*[6]

Workgroup members felt that it is reasonable to assume that exposure to fecal contamination from untreated human waste posed the highest risk. Treated sewage was judged to be of lower concern, although it was more similar in risk to untreated human waste than to nonhuman sources. In general, treated and untreated sewage should be treated similarly for the purposes of evaluating risk. Discussion of CSOs led to the conclusion that they should be considered similarly to untreated sewage in terms of public health concern. Although separate storm sewer overflows were initially considered to be similar to animal waste in nature, there was a recollection of data in the literature (Haile et al., 1999) noting the occurrence of a significant occurrence of human pathogenic viruses in stormwater effluent and associated health effects merits further investigation. Aquatic avian sources were considered to be of low public health concern. Other wildlife and agricultural animal (including poultry) feces were deemed to be of moderate concern.

- *Question 3: To what extent is it reasonable to apply risk estimates from POTW-influenced beaches to non-POTW beaches? Do we understand scientifically whether this would lead to overprotection? What science would be important to understanding this?*

A portion of the answer to this question is reflected in the responses to Questions 1 and 2 above. The propensity to over- or under-protect would depend upon the source of the waste impacting the site. Non-point sources that largely reflect nonhuman sources of fecal contamination would probably be overprotected by studies in POTW-impacted locations. Mixed sources or untreated human sources may be inappropriately characterized by the POTW-dominated data. The workgroup's generalizations are reflected in Table 5. Addressing the public health significance of CSOs and separate storm sewer overflows are problematic because of the site-specific nature of the extent to which they vary by site characteristics. Although the importance of dilution of pathogens and indicator organisms in runoff events was discussed, no conclusion was reached about its significance.

[6] It is important to note that the workgroup was specifically charged (see Appendix A) to address (separate) storm sewer overflows and not sanitary sewer overflows, the latter of which are often discussed in conjunction with CSOs and commonly using the acronym "SSO." For this reason, workgroup members decided to not use the acronym SSO anywhere in the chapter.

- *Question 4: Assess whether there is a possibility of overprotection due to a compounding of risks from multiple factors (such as the current definition of gastrointestinal [GI] illness [i.e., no fever]; more sensitive molecular-based methods; assuming that POTW risks = nonhuman fecal contamination source risks, etc.).*

This question was referred to the Acceptable Risk workgroup (see Chapter 5).

- *Question 5: How should EPA evaluate risk that may have a low probability of occurrence but a significant risk, if it occurs?*

This question was considered by workgroup members to be unlikely to be adequately represented by completed epidemiological studies due to the low incidence (or detection) of pathogens that are associated with severe health outcomes. However, this important public health issue might be addressed using quantitative microbial risk assessment (QMRA) methods or by using large-volume filtration in future epidemiological studies.

- *Question 6: What are the key data gaps and uncertainties needed to support criteria development in the near term?*

The research needs and their prioritization are presented in a separate section (4.4). Epidemiological studies were given a high priority, with QMRA as an important adjunct. Additional epidemiological studies were encouraged by workgroup members because the data produced directly measure outcomes of interest (e.g., GI illness) and the data produced are more directly comparable to data being obtained for human health risks at marine beaches largely impacted by human sewage. Thus, epidemiological studies were preferred to the extent that they were possible and were viewed as an anchor for QMRA studies. However, it was recognized that it may be difficult to find freshwater recreational sites with sufficient bather activity to provide adequate sample sizes for an epidemiological study. If suitable sites cannot be found, then modeling the risk using QMRA techniques based on available epidemiological information would provide quantitative risk estimates that could help with short-term decision making on health risks. Similarly, if pathogen-source combinations in Table 5 cannot be conducted, it may be possible to use QMRA to provide quantitative risk estimates.

4.3 Options for Approaches and Implementation Considerations

The considerations in the followings section are not applicable to the current U.S. approach (i.e., US EPA, 1986; see also Chapter 1) because there is no way to take into consideration the charge to this workgroup on comparing risk to humans of fecal contamination from different sources. The following considerations are applicable to both the European Union (EP/CEU, 2006) and WHO (2003) approaches to criteria development. The sanitary investigations are important for the topics discussed by this workgroup. Simultaneous use of multiple indicator organisms or a tiered approach may be necessary.

4.4 Research Needs

1. Prioritize the next generation of studies. The purpose of these studies is to (1) revisit the ratings using a more through literature review and (2) gain as much information as currently exists on the magnitude of the fecal pathogen source problem across the United States.
    a. Quantify the magnitude of difference in the risk of illness from different exposure sources (see Table 5) to see if they are different from POTW-impacted waters.
        i. Initial estimate of risk – populate the table with infectious dose data and likely number of organisms excreted in stool per gram to characterize fecal source rank.
        ii. Magnitude across the United States
            1. Number of impaired waters
            2. Number of beaches affected by the sources (number of affected bathers if available)
        iii. Identify potential fresh and marine recreational sites for each of the fecal pathogen sources (rows) for future epidemiological studies. Priority should be given to freshwater sites.
2. Identify and characterize potential sites for future epidemiological studies using the following sources of information:
    a. National Pollution Discharge Elimination System (NPDES) – provides location of all point source dischargers and their levels of discharge
    b. CWA §303(d) list and §305(b) reports
    c. Sanitary investigations and microbial source tracking to confirm site characterization
    d. Compile information (via literature review and/or site-specific) about pathogen loads in non-point source water impacted by all sources of fecal contamination (human and animal), characterizing with respect to pathogens and indicators in freshwater versus marine water.

4.4.1 Epidemiological Studies

Workgroup members agreed that epidemiological studies are the most desirable approach to define and quantify health risks to humans swimming in fecally contaminated waters. Although many epidemiological studies have been previously conducted at point source-impacted beaches, very few such studies have been published on non-point source-impacted recreational waters. The relationship between current water quality indicators and health outcomes that is currently used in regulating beaches was developed from studies at point source-impacted beaches where water quality indicator levels correlated with swimming-associated illness (US EPA, 1986). It is plausible that the relationship between water quality indicators and health is different at non-point source-impacted sites since indicator levels may be high due to animal (e.g., birds, other wildlife) or other sources that do not increase the risk of human illness. Some workgroup members felt that it is appropriate to conduct epidemiological studies at non-point source-impacted sites to better define risk and guide future regulations.

Some workgroup members noted that epidemiological studies cannot be performed in all of the various types of non-point source-impacted waters for which there is a need to know risk. In many of these types of sites, other techniques (such as QMRA) will necessarily have to be used (see Section 4.4.2). The choice of the specific sites (beaches, rivers, lakes) in which to conduct epidemiological studies could be guided by the risk rankings developed in Table 5. These rankings include the types and concentrations of pathogens present, the number of affected waters across the United States, the number of people who are exposed to such sites, and the number of sites affected by regulatory restrictions under the CWA §303(d) guidelines.

Two principal study designs have been used in prior beach epidemiological studies—the randomized controlled trial (RCT) and the prospective observational cohort. The RCT has been primarily used in European studies and the observational cohort in many countries. Workshop participants discussed the relative strengths and limitations of each study design. With respect to the issue of health risks in non-point source-impacted waters, the workgroup members actively discussed the advantages of each design and felt that each had merit. Because of the required sample size (i.e., number of swimmers) is much less for an RCT, workgroup members could envision situations in which an RCT could be employed in future non-point source epidemiological studies. Workgroup members did note that in the United States it would be more likely for such an epidemiological study to receive human subjects approval if the enrollment scheme were altered from the RCT that has been used in several European studies. In Europe, subjects are typically recruited and enrolled in the studies at sites distant from the beach and then brought to the study sites. Workgroup members discussed an alternate design for consideration in the United States; specifically, enrolling willing persons who are about to enter the water and randomizing them to either swim or not swim that day. As in all epidemiological studies, aggressive exposure measurements of the water ingested and measures of water quality (e.g., indicators of fecal pollution) to which the swimmer is exposed would be critical. In non-point source sites where adequate numbers of swimmers could be enrolled, the prospective cohort design could be used for epidemiological studies. Workgroup members felt that it would be very helpful at some point to use both study designs simultaneously on one beach. This would allow for a direct comparison of the results and help guide future epidemiological studies.

1. Epidemiological studies (**highest priority is to conduct studies at beaches impacted by different types of non-point sources of fecal contamination [see Table 5]**)
    a. Randomized control trials (for consideration at beaches with low numbers of bathers)
        i. European design should be modified for use in the United States (suggestion – randomize people about to swim into groups that will swim or not swim)
        ii. Potential problem – identifying appropriate numbers of participants may be more difficult for inland (predominantly fresh) recreational waters than marine waters
        iii. Estimated necessary sample size – 1,500 people/site
    b. Prospective observational cohort study
        i. Potential problem – identifying sufficient numbers of participants may be more difficult for inland recreational waters than marine waters

ii. Estimated necessary sample size – 5,000 to 10,000 people/site (200 to 400 people/day)
iii. Wide range of exposures needed

4.4.2 Quantitative Microbial Risk Assessment

Several workgroup members advocated for QMRA studies in developing new or revised recreational ambient water quality criteria (AWQC). In part because QMRA can be used to rank the relative risks of different situations, such as sites impacted by animal versus human fecal wastes, and where no direct epidemiological information is available. QMRA studies can also be instructive in recreational areas where such studies have already been completed.

QMRA is increasingly used to characterize risk to humans from exposure to contaminated water when engaging in "contact recreation," especially swimming, but also other forms of water contact such as water skiing. It translates the environmental occurrence of pathogens and the volume of water that individuals are exposed to into a probability of infection or illness. Inputs with known variability are described by statistical distributions from which many random samples are taken, often using a "Monte Carlo" calculation procedure, to derive a risk profile.[7]

The following four step process is used: (1) identifying the important pathogens ("hazards"); (2) determining human exposures to contaminated water, via ingestion or inhalation; (3) characterizing dose-response, using data available from clinical trials, illness surveillance, and outbreak data; and (4) mathematically characterizing the risks and communicating risks and attendant uncertainties.

For step 1, a suite of sentinel pathogenic microorganisms should be considered for each situation as they are considered to cover the range of illnesses that could arise in the United States, such as the following:

- viruses – norovirus, Hepatitis A virus, caliciviruses, enteroviruses, rotavirus, adenoviruses;
- bacteria – EHEC, *Campylobacter* spp., *Salmonella* spp., *Shigella* spp.; and
- protozoa – *Giardia* cysts, *Cryptosporidium* oocysts.

The setting for each site of interest will dictate which of these pathogens should be used. For example, a recreational site impacted only by animal wastes should not need to include viruses. Adenoviruses will need to be included where aerosols may be inhaled (e.g., by water skiers).

For step 2, information on water ingestion and exposure rates, along with duration of the recreational activity, are combined with the concentration of pathogens in the water to obtain a

[7] EPA's Office of Water has developed a "complete draft" of a Protocol for Microbial Risk Assessment based on the EPA-ILSI (ILSI, 2000) *Revised Framework for Microbial Risk Assessment* (http://www.ilsi.org/file/mrabook.pdf) and which is consistent with the chemical risk assessment paradigm. The Agency has initiated a review to insure it meets risk assessment needs for all water-based media. Contact Stephen Schaub, EPA Office of Water (see Appendix B), for information on the Protocol for Microbial Risk Assessment.

dose—all these variables being described by statistical distributions. Information on the origin, quantity, and fate and transport of wastes deposited on a land surface and into waterways is of prime importance in determining the distributions of pathogens in the water that is subsequently ingested or inhaled.

For step 3, several dose-response analyses have been reported and may be used, albeit with caution. In particular, the form of the "dose" used in a clinical trial needs to be made consistent with the form used to describe the dose ingested or inhaled.[8] Also, uncertainty in the dose-response equation, in the form of credible intervals, can be captured by the calculation process.

In step 4, risk profiles may be derived, in the form of a cumulative distribution function—this will be particularly useful for examining the risks associated with rare but highly significant illness (e.g., EHEC). This also enables uncertainty measures to be calculated. Comparing relative risks for different sites should be done by comparing risk profiles, rather than by comparing single risk "numbers."

1. QMRA provides a range of possible illnesses or risks, allows comparisons across all fecal pathogen sources (see Table 5), and number of illnesses by a modeling approach (**highest priority is to conduct assessments at beaches impacted by different types of non-point sources [see Table 5]**). There was discussion among workgroup members regarding the strengths and limitations of conducting QMRA versus epidemiological studies (see Eisenberg et al., 2006); QMRA:
    a. Is a potential alternative, adjunct, or precursor to epidemiological studies
    b. Can evaluate infection and illness
    c. Could evaluate sentinel (index) pathogens such as:
        i. Bacteria (EHEC, *Campylobacter, Salmonella, Shigell*a)
        ii. Protozoa (*Giardia, Cryptosporidium*)
        iii. Viruses (norovirus, Hepatitis A, caliciviruses, enteroviruses, rotavirus, adenoviruses)
    d. Can consider inhalation as an additional route of exposure if data are available
        iv. Adenoviruses
2. QMRA is a good way to compile information (via literature review and/or site-specific) about pathogen loads in source waters impacted only by animal sources (with an emphasis on freshwater) and to characterize pathogens and indicators.

4.4.3 Etiologic Agents

Workgroup members felt it important to emphasize that there is a glaring lack of knowledge about the incidence with which specific pathogens cause swimmer-associated illnesses at both non-point source- and point source-impacted beaches. Identification of such pathogens as the actual cause of illness in swimmers would provide important information for developing new or

[8] For example, a rotavirus clinical trial will report dose as FFU (focus forming units); there may be many virus particles for each FFU.

revised recreational AWQC (or State Water Quality Standards) to enhance the protection of public health. In order to go forward with currently available technologies, the diagnosis of viruses could be made by exclusion of bacterial and protozoan pathogens causes of illness. Additionally, such information would be essential inputs into QMRA models to be used at recreational sites (or types of sites) where epidemiological studies cannot be conducted due to expense or insufficient numbers of swimmers. Because advances in modern techniques in microbiology now make a more complete identification of specific pathogens possible, workgroup members felt that the epidemiological studies currently underway and planned provide a unique opportunity to collect specimens (stool, saliva, and/or blood) from swimmers (and non-swimmers as controls) with which to identify the responsible waterborne pathogens. Such data would be complementary to the data collected in studies of pathogen occurrence in water that are presented elsewhere in this chapter and these proceedings. Workgroup members suggested that both types of pathogen occurrence information (in humans, in water) be collected during future epidemiological studies in order to minimize cost and maximize the utility of the information.

1. Identify etiologic agents of swimming-associated illness.
2. Pilot approaches for identifying etiologic agents in planned and ongoing epidemiological studies.
3. Classify etiologic agents in ill swimmers by broad groupings (i.e., viral, bacterial, protozoan).
4. Develop and evaluate sample collection techniques (stool, salivary antibodies, blood).

All of the above could be done as an adjunct to epidemiological studies.

4.4.4 Fate and Transport

Because direct pathogen detection is not feasible on an ongoing basis, a surrogate measure relating water quality conditions to human health risk is required. When developing the appropriate indicator(s) to use in this approach, knowledge of the fate and transport characteristics of the pathogens and indicator(s), both individually and as they relate to each other is critical.

Individually, fate and transport is significant because only those pathogens that are present and viable in a given waterbody pose a potential public health risk. These pathogens are typically divided into the following three major categories: viruses, bacteria, and protozoa. Because the microbiological characteristics of each of these groups are significantly different, it is not unreasonable to assume that their fate and transport characteristics will vary (perhaps significantly) as well.

The most simplistic route of pathogen transport is direct deposition. Once the pathogen(s) (assumed to be carried in the feces of warm blooded mammals) is excreted over or in the water, the question is twofold—how long will the pathogen be viable and available (i.e., persist in the water column).

Indirect deposition of feces introduces a more complex situation. First, the fecal properties of different mammals can vary substantially. One of the primary differences (aside from pathogen and indicator density) is moisture content. That is, very "wet" feces is more likely than "dry" feces to introduce pathogens into the aquatic environment. After defecation, the distance of the feces from surface water plays an important role as well. Driven by precipitation and transported primarily via surface runoff, the pathogens are typically washed into the surface water either by sheet flow or are collected and discharged through a storm water collection system. During this transport, they are subjected to a variety of environmental factors—including, but not limited to, UV disinfection, predation, temperature—that affect the proportion that will ultimately end up in surface water in which people are recreating.

Another category of indirect deposition includes point source discharges, such as POTWs, CSOs, concentrated animal feeding operations (CAFOs), and other NPDES permitees. In addition to the issues identified above, the effect of the treatment processes that these effluents are subjected to plays a role in fate and transport of the pathogens.

Resuspension from sand, soil, or sediment (i.e., secondary environments) can also play an important role in pathogen fate and transport. There may be a reservoir of indicator(s) and/or pathogens that could be reintroduced into the water column. Additionally, regrowth of either the indicator(s) or pathogens could represent a source and/or confound the risk assessment/prediction.

Ideally, the indicator(s) chosen as the surrogate for the pathogens will have the same fate and transport characteristics of the pathogens themselves. However, since this is unlikely, it is important to know and relate the characteristics that are specific to the indicator(s) and the pathogens so that the measurement of the indicator can be correlated to the concentration of the viable pathogens in the water and ultimately to public health risk.

A number of studies have been published on the fate and transport of many waterborne pathogens and current indicator organisms. Therefore, a literature review to identify any data gaps so that additional studies may be designed and also to inform QMRA studies would also be useful.

1. Conduct fate and transport studies for indicators and sentinel (index) pathogens.
2. Conduct literature review to identify data gaps and to inform QMRA.
3. Identify indicators that have the similar fate and transport characteristics as pathogens.
4. Should include assessment of risk of pathogens and indicators being resuspended from sand, soil, and sediments (secondary environments).

4.4.5 Determine the Occurrence of Pathogens in Impacted Recreational Waters

The pathogen occurrence and pathogen concentrations in water impaired by animal feces in one or more non-point study site(s) (e.g., beach impacted by [non-CAFO] agricultural animal runoff; Table 5, priority #1) could be compared with pathogen load in planned POTW-impacted marine epidemiological studies. It is also proposed that investigators consider using high-volume, tangential-flow water filtration methods that were recently developed for assessing bioterrorism threats to drinking water. This technology was designed to simultaneously capture very low concentrations of viruses, bacteria, and parasites in 10 to 100 L of water using a single collection apparatus (filter and pump). Although the equipment and pathogen recovery methods were initially designed to work on finished drinking water, there has been additional research to adapt the process for use on raw water supplies. The raw water application of this technology may be sufficiently understood for its employment in current or planned studies within the next 2 to 3 years. If the methods have not yet been adequately evaluated for this purpose, EPA may wish to encourage fast tracking their development for use in recreational water epidemiological and related field studies. Use of the large volume filtration tools might also be helpful to assess risks associated with low probability events that have serious health consequences (e.g., EHEC).

1. Determine the occurrence of pathogens in affected waters using the high volume filtration currently being developed for counter bioterrorism purposes.

4.4.6 Bather Studies

Bathers themselves can be a source of both indicator organism and pathogens in recreational waters (Elmir et al., 2007). Workgroup members suggested the following studies to determine the magnitude of this problem and/or the conditions at recreational sites in which this would be a problem.

1. Conduct additional studies on the impact of bathers on levels of indicator organisms and as a source of infectious pathogens for other bathers.
2. Develop better tools for assessing bather density.
3. Incorporate bather density into the study design and analysis of future recreational water epidemiological studies.
4. Conduct additional studies on human shedding in a controlled setting with a focus on young children.
5. Incorporate bather contribution to indicators and pathogens in QMRA studies.

4.4.7 Additional Research (Either Short- or Long-term Depending on EPA Priority-setting)

The following research would also enhance many of the ongoing and future efforts described in this chapter and elsewhere in these proceedings.

1. Include epidemiological data in predictive modeling efforts. This would broaden the use of both epidemiologic and modeling data. Many recreational epidemiological studies collect an extensive set of environmental data. Whether this is sufficient to accomplish environmental modeling is unknown. Both modelers and epidemiologists should discuss the feasibility of this effort.
2. Develop a method for accurate exposure assessment among swimmers. Exposure assessment in terms of water contact and quantity of water swallowed or inhaled is an area of potential misclassification in observational epidemiologic studies. The following would improve exposure assessment in epidemiologic studies:

a. Develop individual sampling devices.
b. Develop methods and conduct studies to determine the quantity of water ingested and inhaled in recreational settings. Consider studying secondary recreational contact for potential comparison.

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CHAPTER 5
ACCEPTABLE RISK

Paul Hunter, Chair, University of East Anglia, U.K.
Michael Beach, Centers for Disease Control and Prevention
Lora Fleming, University of Miami School of Medicine and Rosenstiel School of Marine and Atmospheric Sciences, Florida
Peter Teunis, RIVM (National Institute of Public Health and the Environment), Netherlands
Timothy Wade, USEPA

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5.1 Introduction

This workgroup was primarily charged to reassess the extent to which existing microbiological criteria protect the health of swimming populations, and whether or not this is appropriate for current U.S. society. In particular, the workgroup was asked to consider the case of vulnerable (susceptible or sensitive) subpopulations and whether current levels of public health protection are sufficient for these people. The workgroup was also asked to consider whether it would be possible that improvements in recreational water quality criteria would be sufficient to improve public health protection for drinking water, recreational water, or consumption of shellfish.

Group members decided to organize the main questions under the following headings:

- Whether the term "acceptable risk" is still the most appropriate term.
- Public involvement in "acceptable risk" decisions
  - To whom should any risk from recreational water contact be "acceptable"?
  - How can we get public involvement in the decision making process over what is and what is not "acceptable"?
  - How best to communicate risk with and educate the general public about risks from recreational water.
- "Acceptable risks" to the general population
  - Whether the current methods for assessing risk from recreational water exposure are sufficient and if not, what new methods may be appropriate?
  - Whether risks differ between marine and freshwaters and whether it is "acceptable" to have different levels of protection for people bathing in these different waters.
  - Whether the current approach, based on protecting people from enteric illness is sufficient, or whether "acceptable risk" decisions need to take into account non-enteric illness.
  - Whether risks are different to people swimming in tropical, subtropical and temperate waters.
- "Acceptable risks" for vulnerable subgroups
  - Define the main vulnerabilities.
  - Determine what risks are greater in vulnerable subgroups and whether general recreational water standards are sufficient to protect these groups.
- What are the current levels of protection from existing criteria?
- Potential synergies for health protection between revised recreational water criteria and standards for drinking water and shellfisheries.

5.2 Main Conclusions and Observations

5.2.1 Whether the Term "Acceptable Risk" is Still the Most Appropriate Term

There was commonality amongst the workgroup members that the term "acceptable risk" is flawed and should be avoided during the process of creating recreational water criteria. The term "acceptable" was felt to elicit responses related to "acceptable to whom?" and had the connotation that swimmers accepted the risk and there was some level of informed decision making during the process. Although a variety of suggestions for replacing "acceptable" were elicited (e.g., tolerable, appropriate, excess, increased), no agreement on terminology was reached. However, workgroup members felt that any new term should be simple, easily understood, and inclusive rather than paternalistic in nature. Workgroup members also felt that EPA should develop a policy that includes public interaction during the criteria development process.

This approach to determining "acceptable risk" should be broadly inclusive of impacted groups (e.g., swimmers, taxpayers who pay for beaches to be open) throughout the process. This would mean that EPA's decision making and criteria development process should include information on how impacted groups would determine the level of "acceptable risk" and how those risks and the concept of protective criteria would be best communicated. This would require that EPA's criteria development process (1) be clear, transparent, and communicated to all stakeholders; (2) factor in and include input and data collected from impacted groups; (3) include a data-informed communication package to educate impacted groups when the new criteria are released; and (4) develop a plan for assisting state and local authorities with future communication of the concepts of "acceptable risk" and the meaning of beach closures and advisories to the public. Such an effort would require collaboration with sociologists and anthropologists to assess risk perception and risk communication research and apply this to development of appropriate assessment tools for determining key elements necessary for criteria development, release, and interpretation. Rapid integration of this information into ongoing EPA criteria development would be expected to build or improve partner involvement and acceptance of the new criteria.

5.2.2 Public Involvement in "Acceptable Risk" Decisions

Including public involvement in the criteria setting process would require that impacted groups are first informed about the process and then information solicited about how these groups make "acceptable risk" decisions and how tolerant these groups would be of risk associated with recreational swimming area use. Key research questions include the following: (1) What does the public understand currently? (2) What does the public think of when one uses the term "acceptable risk"? (3) How does the public interpret existing criteria and beach closures/advisories? (4) How does/should EPA communicate this risk? and (5) What level of risk would the public accept? The voluntary nature of recreational swimming needs to be clearly explained and put in context with other routinely and voluntarily accepted risks (e.g., driving to the beach, eating at local restaurants, smoking). The breadth of illness associated with swimming and types of illness to be reduced by new or revised recreational water quality criteria needs to be clear. Workgroup members felt that current criteria were not well understood by the public or beach managers so that indicator cutoff values (i.e., beach closures) connoted zero risk and "safe" water rather than an understanding of the concept of "acceptable risk." These groups should be allowed to provided input on factors used in the decision making process (i.e., reduction of illness in children being a decision point). Workgroup members appreciate that EPA will ultimately be making the decisions and setting criteria but felt that a more informed and communicative path for this decision making is critical to future acceptance of these new or revised criteria.

Workgroup members suggested that EPA conduct the following activities:

1. Begin building a transparent communication plan to inform impacted groups about ongoing criteria development.
2. Rapidly initiate studies to assess how impacted groups understand and perceive the risks associated with recreational water use and what level of voluntary risk would be "acceptable," followed by evaluation of final communication materials.
3. Develop a multi-year plan to communicate the criteria development process to impacted groups and a communication plan for educating impacted groups about the new criteria.
4. Assist state and local officials in developing data-based risk communication plans for communicating information on criteria interpretation and beach closures/advisories to the public.

5.2.3 "Acceptable Risk" Levels for the General Population

Method for Assessing Risk

Workgroup members identified epidemiological (both randomized control and prospective observational cohort designs) and quantitative microbial risk assessment (QMRA) studies as the main methods for assessing risk. Some workgroup members noted that while QMRA is widely used and relied on by EPA for drinking water applications, it does not seem to be as widely used for recreational waters (with the exception of the work done by Jeffrey Soller). To broadly evaluate the gastrointestinal (GI) illness risk associated with the numerous potential pathogens found in recreational waters, epidemiological studies were viewed as more appropriate, although workgroup members believed the EPA should investigate expanding the role of QMRA (see also Chapter 4). One distinction noted was that although epidemiological studies are good at assessing the generally common and self-limiting risks associated with swimming in fecally-contaminated waters, they are not well-suited for investigating rare but potentially severe (and potentially life-threatening) illnesses that may be associated with recreational water exposure such as enterohemorrhagic *E. coli* (EHEC). For these special cases, workgroup members felt QMRA approaches may be the best way to assess risk and address potential outbreak situations.

Other cases where QMRA could be useful would be for evaluating specific risks associated with specific waterborne pathogens (although not necessary rare) such as *Cryptosporidium*, Norovirus, and *Shigella*. A third method that has not yet been widely applied to assess risk from recreational waters is dynamic infectious disease modeling (with the exception noted above). These models are a form of QMRA, but specifically account for factors such as the immune status of the population (susceptible, infected, immune), rates of secondary transmission of illness, and other parameters.

Workgroup members also noted that epidemiological studies can identify illness, but not infections, whereas QMRA studies can predict infections, but have more uncertainties associated with translating infections into an estimation of illness. Although epidemiological studies provide valuable results, there may be some confusion in their interpretation and application; for example, most studies of recreational waters to date have been conducted at beaches with known human sources of fecal contamination and results may not apply to other sites. EPA needs to clearly explain the purpose of such studies (current, planned, and previous studies), their focus, and limitations.

Marine versus Freshwater

Workgroup members did not see any reasonable rationale for different "acceptable risk" levels in marine and fresh recreational waters. Although the current "acceptable risk" levels based on EPA's *Ambient Water Quality Criteria* [AWQC] *for Bacteria – 1986* are different for fresh and marine waters (gastroenteritis rate of 8 per 1,000 swimmers in freshwaters and 19 per 1,000 in marine waters), workgroup members believed this to be an arbitrary decision that was not well founded. Workgroup members agreed that there could be different indicators, or different levels for the same indicator across marine and fresh recreational waters, but those levels should relate to the same estimate of risk. Furthermore, justifying differences in risk to the public and stakeholders based on type of water would continue to be confusing and problematic.

There was some further discussion about how to account for differences in baseline levels of illness that could exist across locales and whether use of a relative risk scale instead of an excess (or attributable risk) scale may be a better way of addressing such differences. There is a distinct difference between doubling an absolute risk versus doubling a relative risk (see Section 5.2.5).

Enteric versus Non-enteric

Workgroup members felt that criteria based on pathogen indicator levels derived to protect against GI illness would not necessarily protect against all non-enteric illnesses, with the possible exception of certain upper respiratory illnesses (URIs) transmitted via the fecal-oral route. At least one study (Fleisher et al., 1996) observed exposure-response relationships with fecal streptococci (enterococci) and URI; workgroup members believed there was potential for pathogens causing such illnesses (e.g., adenoviruses) to be transmitted via fecally-contaminated waters. The workgroup members felt that most causes of other non-enteric illnesses (e.g., rash, earache) were most likely to be caused by environmental or naturally occurring conditions and/or pathogenic microorganisms unrelated to fecal contamination (e.g., *Naegleria* infection, non-cholera *Vibrios*) and therefore would not be explicitly controlled by criteria based on protection for GI illness (WHO 2003).

There was uncertainty about EPA's role in protecting against such illnesses, particularly those that are not anthropogenic. However, there are some risks that were unclear. For example, cyanobacteria concentrations can be influenced by nutrients and human impact, and may also be a cause of swimming-associated skin infections, respiratory infections, or long-term chronic conditions such as liver cancer (Chorus and Bartram, 1999; Fleming et al., 2002).

Workgroup members felt that earaches (*otitis externa* or "swimmers ear") were probably the most debilitating of the commonly occurring swimming associated non-enteric illnesses. However, they also felt that there was no evidence that such infections (often caused by *Pseudomonas*) were associated with fecal indicator bacteria, and therefore AWQC or State Water Quality Standards based on fecal indicators would not afford public health protection for those illnesses. Workgroup members also felt that other indicator bacteria, or other types of indicators, are not currently available to protect swimmers from most non-enteric illnesses.

Workgroup members agreed that when a beach was closed due to fecal contamination then potential non-enteric swimming associated illnesses would also be prevented, although this would be inadvertent and it is not clear how often or under what circumstances this would occur (e.g., Do currently used indicators correlate with the presence of cyanobacteria or *Pseudomonas*?).

Tropical and Subtropical versus Non-tropical Recreational Waters

Workgroup members identified the possibility that tropical and subtropical recreational waters may have to be approached differently from temperate waters because of issues such as regrowth and significant spatial or temporal variability of both indicator organisms and pathogens in the water and soils, substantially different ecosystems and climatic conditions (including heavy rains), and possibly the presence of a greater range of "exotic" pathogens. In addition, persons may experience longer term seasonal exposures in tropical and subtropical recreational waters due to the warm waters throughout the year. Finally, it is highly likely that the background rate of GI diseases is higher in tropical and subtropical populations (Payment and Hunter, 2001).

It is important to note that workgroup members believe that people in tropical and subtropical areas should not be exposed to greater health risks from exposure to recreational waters than people in more temperate areas.

Relative risk measures, unlike excess risks, express risk as a proportion of baseline risk and thus correct for varying background levels. Workgroup members discussed other ways to describe risk in place of an "acceptable risk" framework, including illnesses prevented as a result of implementing criteria (as done by the U.S. Food and Drug Administration [FDA]). Workgroup members felt that there was need for risk communication in this area so that risks are fully and accurately communicated.

5.2.4 "Acceptable Risk" Levels for Vulnerable Subgroups

Definitions

In considering vulnerable human populations with regards to the health risks from exposure to recreational water, workgroup members distinguished between two major categories of vulnerability, (1) persons at different life stages, and (2) persons with suppressed immune function.

What is Different?

Life stage connotes that for a variety of reasons, humans vary in their level of vulnerability to the health risks associated with exposure to recreational water over their life span. In particular, the discussion focused on the possible increased vulnerability of children, pregnant women (and their fetuses), and the elderly. Workgroup members felt that children are at a greater increased risk compared to all other life stages because of their behavior and possibly because of naïve immune status. Because all members of the population pass through life stages, classifying childhood as a life stage instead of simply a subpopulation strengthens the argument for explicitly considering children when developing AWQC. Regarding behavior, children probably have higher exposures; that is, they are more likely to consume both marine and freshwater. Moreover, young children have significant hand-to-mouth and fecal-oral behavior that may lead to the consumption of contaminated substances. Very young children may also be more vulnerable to pathogens in recreational waters because they have never been exposed to these pathogens previously. Of note, preliminary, unpublished data from recent studies by EPA (NEEAR; Timothy Wade, EPA Office of Research and Development, personal communication, 2007) as well as results from other published studies appear to demonstrate an increased risk of GI illness and possibly respiratory illness for children from exposure to recreational waters, although this has not yet been formally reviewed.

Pregnant women (and their fetuses) and the elderly may be at increased risk for more severe consequences from acquiring GI diseases from exposure to recreational waters. Pregnant women and their fetuses may be at greater risk from certain recreational water pathogens (e.g., coxsackie B virus associated with fetal infection when acquired close to delivery, and enterovirus associated with certain fetal malformations). Furthermore, pregnant women may be at increased risk for significant dehydration and its consequences if they do acquire a GI infection resulting from contact with recreational water. Finally, although the elderly were believed to be less exposed due to decreased high intensity swimming behavior, it might be possible that the decreased immune function associated with increasing age might make them more vulnerable to infection and illness.

Workgroup members also identified a potentially large subpopulation of persons with suppressed immune function, ranging from persons with HIV/AIDS to persons undergoing chemotherapy and using other immunosuppressive medications. Of note, a portion of the latter subpopulation could be completely unaware of their suppressed immune function. As a group, persons with suppressed immune function would be at increased risk compared to the healthy population of acquiring diseases from a range of opportunistic pathogens found in recreational waters, such as *Cryptosporidium*, *Toxoplasma*, and *Vibrio parahemolyticus*. Furthermore, persons with suppressed immune function may be at increased risk of more severe consequences from these diseases as well as from the effects of dehydration—a secondary ramification of GI diseases.

Tourists and visitors were identified by workgroup members as a unique potentially vulnerable group to increased health risks associated with exposures to recreational waters. Similar to small children, these people may be previously unexposed to the range of pathogens in a new recreational water environment, and as such, more susceptible to both acquiring the infection and disease—possibly with more severe health consequences. Given that many of these people are on vacation, they may experience greater exposure to recreational waters.[9] Further, given that significant tourist travel is to tropical and subtropical areas, there may be additional risks from a range of exotic pathogens and potentially unique ecosystem conditions found in tropical and subtropical recreational waters.

[9] Tourists may spend long periods of time in the water over several days, whereas local users may have shorter exposures that are spread further apart.

Overall, workgroup members believed that the apparent increased risk for children for acquiring GI and possibly other diseases from exposure to both fresh and marine recreational waters should drive the health risk assessment of any future recreational water criteria development efforts, assuming the current and future research continue to demonstrate their apparent increased risk. Workgroup members emphasized that future recreational water criteria set on health risks and exposures of adults would not be sufficiently protective for children. As mentioned previously, because of differences in susceptibility between adults and children (and other subpopulations as well) a given numeric criteria translates to different risk levels for each subpopulation. Therefore, it is impossible to protect adults and children equally. The workgroup members felt that data on children should be explicitly considered for deriving the "acceptable risk" level in the development of new or revised recreational water quality criteria, with the understanding that the associated risk level for adults would then be even lower.

Workgroup members felt that the increased risk to immunosuppressed people should not be an important factor in setting any future recreational water criteria because the factors associated with the increased risk of disease in this vulnerable subpopulation are not controllable or achievable through management of recreational water sites. Rather, an emphasis should be made on improved risk communication with immunosuppressed groups and health care professionals to inform them about risks associated with recreational water use and, in consultation with their health care provider, assessment of the need to avoid recreational water exposure.

5.2.5 What are the Current Levels of Protection from Existing Criteria?

It is not certain how accurate the current levels of protection are. "Magic" numbers like 8 or 19 cases of gastroenteritis in 1,000 swimmers can "take on a life of their own," increasing the risk of distraction from the basic objective—providing best effort to protect swimmers. This provides a compelling reason for not deriving and using a single numeric value for the targeted risk for new or revised AWQC. Risk levels from preliminary unpublished data from the EPA NEEAR study seems to agree with WHO (2003) B category waters (i.e., 1 illness per 20 swimmers) (see Table 1, Chapter 1; Timothy Wade, EPA Office of Research and Development, personal communication, 2007). Pathogens associated with threshold indicator levels in current (US EPA, 1986) AWQC may differ from those in 2007; the population established in 1986 also may have different susceptibility due to differences in immunity to current pathogens in 1986 versus 2007. Aside from protection against enteric illnesses, it seems likely that enterococci levels below current standards also provide some protection against upper respiratory tract infections.

Instead of absolute levels of risk, workgroup members felt that the preventable fraction is a better measure for the level of protection. This includes information on the background level of risk against which the risk associated with recreational water use must be compared. Presence of other major exposure routes may mask any beneficial effects of lowering risks due to recreational bathing. Thus, an absolute reduction in illness from recreational water may not be reflected in a similar reduction in total cases in the community if people simply become infected by other transmission routes. On the other hand, disease reduction may be even greater if secondary cases are also prevented. Most recreational water exposures are experienced by a minority of the population who are repeatedly (chronically) exposed.

It is also possible that part of the primary contact-associated infections is caused by bather-to-bather transmission. This independent, direct fecal contamination would be unaffected by monitoring programs designed to limit sewage contamination. Further studies are needed to understand the role of bather shedding in disease transmission and microbial water quality indicator levels.

In a trade-off situation, acceptability of risk is partially determined by its source; that is, pathogen-shedding by fellow swimmers is difficult to control and may be more readily accepted than contamination by treated sewage effluent or agricultural runoff, whose risks are usually considered less acceptable. More important than trying to enforce compliance with a fixed standard level of risk, is the need to work toward continual improvement in public health associated with recreational water use.

5.2.6 Potential Synergies for Health Protection between New or Revised Recreational Water Criteria and Standards for Drinking Water Sources and Shellfish Harvesting Waters

Workgroup members considered that any change in recreational water criteria that led to improved public health protection would not negatively impact on the risks from drinking water or shellfish consumption. However, some workgroup members did express concern about any change that would encourage further recreation in waters intended to be used for drinking water production or for shellfish harvesting. When people bathe they invariably contaminate the water to some extent with potential pathogens. Such pathogens may then be concentrated within shellfish or contaminate drinking water supplies and pose a health risk to others.

5.2.7 Areas of Discord

Although workgroup members accepted that the phrase “acceptable risk” was widely used, they realized that there were difficulties in its general acceptance. However, no alternative to the phrase was thought to be “acceptable” to all workgroup members. Although the phrase “tolerable risk” is now being used more frequently internationally, it was still not tolerated by all members of the workgroup.

5.3 Research Needs

1. ***Risk perception studies to inform the risk communication strategy for the criteria rollout and focus groups to evaluate the risk communication strategy***
    a. Assess public understanding of relative versus absolute risk.
    b. Key research questions include the following: (1) What does the public understand currently? (2) What does the public think of when one uses the term “acceptable risk”? (3) How does the public interpret existing criteria and beach closures/advisories? (4) How does/should EPA communicate this risk? and (5) What level of risk would the public accept?

2. ***Define the data and conditions where a directed monitoring program would be necessary to protect against certain non-enteric (non-GI) illness.***

a. Such research would probably require pathogen-specific studies, and a possible role for QMRA.

3. ***EPA should investigate expanding the role of QMRA, particularly for investigating rare but potentially severe (and life-threatening) illnesses that may be associated with recreational water exposure such as EHEC (e.g.,* E. coli *O157:H7).***
   a. Define data needed for the QMRA modeling for special/outbreak cases and also for background/regular situations.
   b. Engage EPA experts in QMRA in recreational water research.
   c. Explore approaches to integrate QMRA (and/or dynamic modeling) to better understand recreational risk, especially situations with rare, but potentially severe outcomes.

4. ***Conduct methodologic comparisons in tropical and subtropical recreational waters and if appropriate, conduct epidemiological studies.***

   Methodological and ecological studies need to be conducted in tropical and subtropical recreational waters because of issues such as regrowth, significant spatial and temporal variability of both indicator organisms and pathogens in the water and soils, substantially different ecosystems and climatic conditions (including heavy rains), and possibly a greater range of exotic pathogens. These studies would determine the impact of these environmental factors on the use of proposed indicators organisms to be used for monitoring and regulatory purposes. Depending on the results of these studies, assessment of the need for epidemiologic studies specifically in tropical and subtropical recreational waters should be performed. This information will be essential to determine whether the same recreational water criteria as used elsewhere in the United States are also appropriate in these waters. Information on risks in such waters will help ensure appropriate risk communication to healthcare providers, public and environmental health managers, and residents of and visitors to tropical and subtropical areas concerning the risks of tropical and subtropical recreational waters.

5. ***Ensure that future epidemiological studies obtain data on and existing studies are reviewed for risk to children.***

   Children appear to be at increased risk for acquiring GI illness and possibly other illnesses from exposure to recreational waters; therefore, workgroup members felt future recreational water criteria should be based on the health risk to children. If existing standards are deemed not to provide sufficient protection to children then additional information will be needed to establish new or revised criteria that are thought to provide sufficient protection. Such information will also be essential to provide risk information to parents and others responsible for children.

6. ***Review prior data to evaluate whether additional epidemiological studies are needed to determine the risk of severe disease to pregnant women and their fetuses, to the elderly, and to immunosuppressed individuals.***

   There is evidence that pregnant women (and their fetuses), the elderly, and immunosuppressed people may suffer more serious disease and/or more serious health consequences from recreational bathing waters. If these data show that there may be increased risks, then the incorporation of these subpopulations as specific target populations in future epidemiological studies should be considered. Information on risks in such waters will help ensure appropriate risk communication to healthcare providers, public, and environmental health managers, and these potentially increased risk groups from recreational waters.

7. ***Determine how risks in tourists and visitors differ from those in residents.***

   There is some evidence that risk may be greater for tourists and visitors than for residents local to a recreational water; thus, current estimates may underestimate the actual risk and so give inappropriately lax criteria (Payment and Hunter, 2001). Consideration should be given to the design and implementation of future epidemiological studies to address risk in tourists and visitors. It may also be possible to review data from previous studies to determine if there are increased risks to tourists. Information on risks in such waters will help ensure appropriate risk communication to healthcare providers, public, and environmental health managers, and tourists with exposure to recreational waters.

8. ***Ecology of swimming-related waterborne pathogens, including studies on the role of bather shedding on transmission of illness and microbial water quality indicators***

   Further studies are needed to understand the role of bather shedding in disease transmission and microbial water quality indicator levels. How efficiently are pathogens transmitted through swimming or bathing? This could be an experimental study, partly, augmented by epidemiology (serology, or microbial source tracking in a small study population).

9. ***How many illnesses are prevented by beach closures?***

   Studies of the number of illnesses prevented by beach closures would be primarily a modeling/statistical exercise. First, the procedures/modeling assumptions should be agreed upon. It could be done relatively easily in a QMRA-type of study.

Table 6 provides a summary of how each workgroup member ranked the above research needs in relation to overall importance (1 to 5), relevance to EPA, and estimated time needed to complete the project.

Table 6. Research Needs and Rankings from Five "Acceptable Risk" Workgroup Members.

Description	Importance					Relevance to EPA					Near- and/or Long-term				
Conduct risk perception studies to inform the risk communication strategy for the criteria rollout and focus groups to evaluate the risk communication strategy (#1)	5	5	5	5	5	5	5	5	5	5	N and L	N	N	N	N
Assess public understanding of relative versus absolute risk (#1)	1	2	1	3	3	1	1	1	3	3	N and L	N	N	N	L
Define the data and conditions where a directed monitoring program would be necessary to protect against certain non-enteric (non-GI) illness (#2)	3	3	2	3	3	3	3	2	3	3	N and L	N	L	N	L
Define data needed for the QMRA modeling for special/outbreak cases also for the background/regular situation (#3)	3	4	3	3	5	3	4	3	3	5	N and L	L	N	N	N
Engage QMRA in recreational water research (#3)	2	3	3	3	5	2	3	4	3	5	N and L	N	N	N	N
Explore approaches to integrate QMRA (and/or dynamic modeling) to better understand recreational risk, especially situations with rare, severe outcomes (#3)	4	2	4	3	4	4	2	4	3	4	N and L	L	N	N	N
Conduct future epidemiological studies in tropical and subtropical bathing waters (#4)	4	4	2	5	5	4	4	2	5	5	N	N	N	L	L
Ensure that future epidemiological studies obtain data on and existing studies are reviewed for risk to children (#5)	5	4	5	5	5	5	4	5	5	5	N	N	N	L	N
Review prior epidemiological studies to determine the risk of severe disease to pregnant women and their fetuses (#6)	2	2	1	3	5	2	2	2	5	4	L	L	L	L	L
Review prior epidemiological studies to determine the risk of severe disease to the elderly (#6)	1	2	1	3	5	1	2	2	5	4	L	L	L	L	L
Review evidence about whether or not immunosuppressed individuals are at increased risk from recreational bathing waters (#6)	4	3	1	4	5	4	3	2	5	3	L	N	N	N	N
Determine how risks in tourists and visitors differ from those in residents (#7)	4	5	2	4	4	4	5	2	4	5	N	N	L	N	L
Conduct studies on the role of bather shedding on transmission of illness and microbial water quality indicators (#8)	5	5	5	4	5	5	5	5	5	5	N	N	N	L	N
Determine the ecology of swimming-related waterborne pathogens (#8)	3	4	3	5	3	3	4	3	5	5	L	L	L	L	L
Determine how many illnesses are prevented by beach closures?(#9)	4	4	4	5	3	4	4	4	5	5	N and L	N	N	N	N

Scoring for importance: score 1 not at all important to 5 highly important
Relevance to EPA: score 1 not at all relevant to 5 highly relevant
For time: N (within next 2 to 3 years); L (within next 10 years)

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CHAPTER 6
MODELING APPLICATIONS FOR CRITERIA AND IMPLEMENTATION

Alexandria Boehm, Chair, Stanford University, California
Donna Francy, U.S. Geological Survey
Mark Pfister, Lake County Health Department, Illinois
John Wathen, USEPA
Richard Zepp, USEPA

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6.1 Introduction

The Modeling workgroup was charged with determining how models might be incorporated into future recreational water criteria development and implementation. Workgroup members did not explicitly consider total maximum daily loads (TMDLs) in the discussion because models are already being used in TMDLs for pathogens throughout the United States. The discussion focused on what was generally felt to be the most important novel applications of models in new or revised recreational ambient water quality criteria.

In the context of recreational water quality criteria, a perfect model would allow prediction of fecal indicators, pathogens, or risk as a function of source presence and strength relative to physical, chemical, biological, and human variables.

There is limited understanding regarding the sources of microorganisms and their fate and transport in the aquatic environment, so the use of deterministic, process-based models (see Appendix G) in criteria development and implementation is not practical for most U.S. water quality managers within the next five years (2012). Rather, **simple heuristic, statistical models that do not necessarily require an understanding of processes and mechanisms are more realistic for criteria development and implementation within the next 5 years.** This is not to say that substantial research should not go into refining understanding of sources, fate, and transport of pathogens and pathogen indicators and their spatial and temporal variability in water and sediments. Thus, workgroup members suggested that a substantial research effort go into understanding these processes in watersheds and near-shore waters as this will have profound impacts of development of future ("next generation") recreational water quality criteria (see Section 6.5).

Workgroup members saw two roles for models in the development and implementation of near-term (five years) new or revised criteria: (1) recreational water quality notification models and (2) models to support sanitary investigations (hereafter referred to as "sanitary investigation models" for simplicity). Recreational water quality notification models are already in use in the Great Lakes and have proven to be effective and popular with the public (Francy and Lis, 2007; Olyphant, 2004; Whitman, 2007). There are a handful of sanitary investigation tools and models that are accessible to recreational water managers throughout the country (e.g., DigitalWatershed, the BASINS3 system). The main focus of this chapter is water quality notification models because these are easily accessible to a wide range of recreational water managers in the near-term. However, because workgroup members viewed the sanitary investigation model as an area of near-term research activities and investigation, with possible applications in the near-term development of new or revised criteria and/or implementation, discussion of sanitary investigation models was included as well.

6.1.1 Water Quality Notification

Numerous research studies in the peer reviewed literature show that a single sample standard implemented in conjunction with assays that require incubation longer than a few hours results in less accurate management decisions (Francy and Darner, 2006; Hou et al., 2006; Kim and Grant 2004). That is, by the time results from analysis of a water sample are available and a water quality notification is issued, the microbial water quality may have changed. This is due to the inherent variability in indicator bacteria levels over timescales shorter than a day (see Figures 4a and 4b), as measured by culture-based assay, both with selective membrane-filtration media and

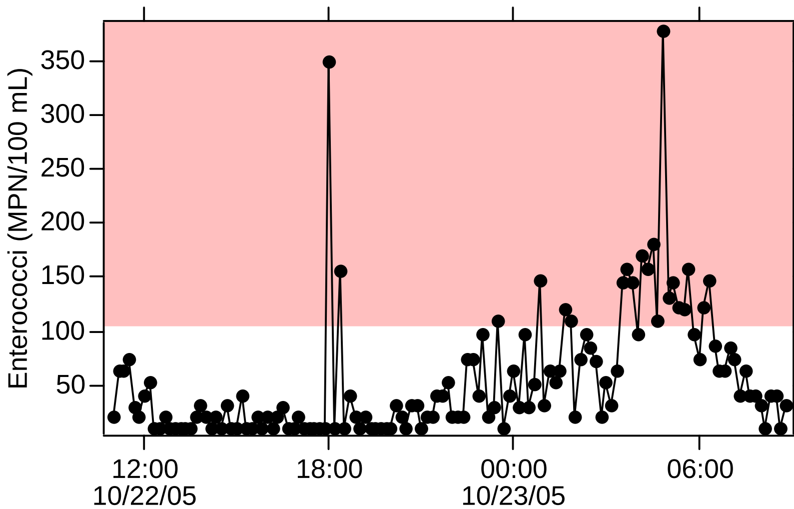

Figure 4a. Enterococci (MPN/100 mL) Sampled Every 10 Minutes at a Beach in California. (The reference background denotes the range of single sample exceedance.) SOURCE: A.B. Boehm, unpublished data (ENTEROLERT assay).

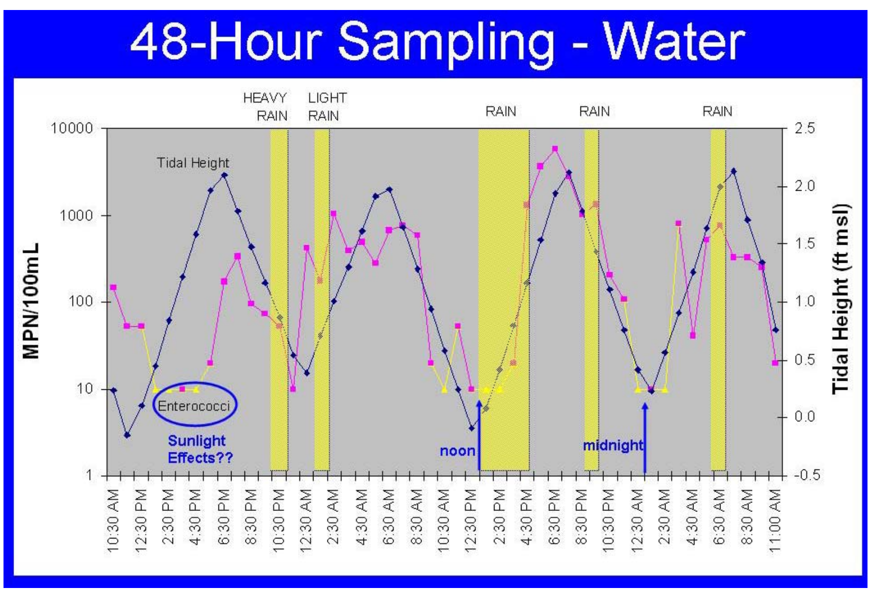

Figure 4b. Subtropical Marine Beach (Miami, Florida): 48 hours Sampling. SOURCE: Amir Abdelzaher, Samir Elmir, Lora Fleming, Kelly Goodwin, Helena Solo-Gabriele, John Wang, Mary Wright, University of Miami, personal communication, 2007.

defined substrate technologies such as Quanti-Tray (IDEXX, Westbrook, Maine). Note, variability in indicator levels as measured by nucleic acid-based assays (like quantitative polymerase chain reaction [qPCR]) has not been well characterized in the peer reviewed literature. The variability in Figures 4a and 4b is not unusual in environmental waters because "patchiness" is an inherently natural phenomena. **A water quality notification model can be used to augment monitoring data and provide more timely and accurate recreational water quality notification to better protect the public from exposure to waters not in compliance with water quality criteria or standards.**

Summary of near-term research needs (i.e., the next 2 to 3 years) specific to **water quality notification** include (see Section 6.5 for further information) the following:

1. Day-to-day water quality notifications should not be issued using a single sample standard in conjunction with a microbial assay that takes longer than a few hours due to time-lag notification errors as discussed above. Simple, heuristic or statistical water quality notification models are one way to improve water quality notification accuracy.
2. Immediate research needs include the following:
    a. Testing whether models can be used to predict health outcomes during upcoming epidemiological studies in California and in Alabama and Rhode Island and retrospectively for the Great Lake epidemiology study in the Great Lakes (Wade et al., 2006) (that is, risk = f[temperature, tides, waves, etc.]);
    b. Developing and testing simple notification models on different recreational water types with a wide range of sources and geographical locals;
    c. Exploring the feasibility of developing regional models that apply to more than one recreational water;
    d. Training recreational water managers; and
    e. Creating a user-friendly portable package for developing local models.

6.1.2 Sanitary Investigation

Quantitatively determining the potential for a waterbody to be impaired with human pathogens is essential if the European Union (EU; EP/CEU, 2006) or World Health Organization (WHO, 2003) approach to criteria development is undertaken (i.e., sanitary investigation is integrated into the criteria). This potential could be determined using a "toolbox approach" in conjunction with water quality notification models or sanitary investigation models. In the first case, the water quality notification model results can be used to learn about the factors that influence water quality in recreation waters; for example, high rainfall and wave action from a given direction and of a given height might lead to greatest impairment. The occurrence of these environmental conditions can be used to trigger sampling for "toolbox" approaches such as analyses for human-specific or bird-specific markers and human pathogens to "rule in" or "rule out" high probability of human pathogen presence. In the second case (sanitary investigation models), simple, quantitative sanitary investigation models that relate watershed attributes to probability of human pathogen impairment may be developed.

Summary near-term research needs (i.e., the next 2 to 3 years) specific to **sanitary investigation models** include (see Section 6.5 for further information) the following:

1. Simple, heuristic or statistical models that correlate watershed activities (presence of wastewater/sewage treatment plant effluents, agricultural activities, and domesticated animals) and attributes (slope, soil type, climate, soil moisture) can be used to determine the susceptibility of a waterbody to pathogen impairment.
2. Research should be conducted to better understand how watershed activities and attributes relate to pathogen presence in streams and receiving waters and include the following:
    a. factors that modulate septic tank impact on waterbodies;
    b. factors that modulate contributions of animal wastes to pathogen and pathogen loads to waterbodies;
    c. sources in urban landscapes (e.g., broken/leaky sewer pipes, combined sewer overflows [CSOs], runoff); and
    d. effect of meterological factors (e.g., rainfall, evapotranspiration, etc.) on non-point sources.

6.2 How Models are Currently Being Used

6.2.1 Sanitary Investigation Models

Sanitary investigation models that explore the relationship between land use, watershed attributes, and water quality are already in place and have been used in TMDL implementation (criteria implementation); however, they have not been specifically applied to criteria development. Creating a TMDL-like model for a waterbody prior to impairment may be viewed as proactive rather than reactive. Such models in use include deterministic models like Hydrological Simulation Program-Fortran (HSPF) and Storm Water Management Model (SWMM) for watershed loading, and CE-QUAL models for pathogen fate and transport (US EPA, 2002). Feedback from some environmental engineers and consultants who apply these models to pathogen and fecal indicator transport suggests they provide highly uncertain predictions for pathogen and indicator concentrations and fluxes (Ali Boehm, Stanford University, personal communication, 2007).

If sanitary investigation models are to be used for criteria development (i.e., prioritizing or discounting procedure for various type of sources), then models that are quantitative yet simple must be available to managers who do not have the resources to run full-scale simulations. These quantitative simple models need to relate land use activities and patterns to the likelihood of human pathogen presence. The ability to rule in or rule out the presence of human pathogen sources in a watershed would be useful to recreational water managers—especially if the EU or WHO approach to criteria development is undertaken. The relationship between land use patterns and microbial water quality has been investigated quantitatively along the California coast (Handler et al., 2006), lakes of South Carolina (Siewicki et al., 2007), North Carolina (Mallin et al., 2000), and Georgia (Fong et al., 2005; Vereen et al., 2007). In Australia, the relationship between land use and watershed attributes and pathogens and pathogen indicators has been applied to numerous catchments using what is termed "pathogen catchment budgets (PCBs)" (Ferguson and Croke, 2005; Ferguson et al., 2007). A sanitary investigation model, for example, might indicate that a completely undeveloped watershed with no agriculture has very low probability of producing runoff containing human pathogens and could potentially place a water body in a "low concern" tier in criteria similar to the EU or WHO approaches (see Tables 1 and 2, Chapter 1). Such models are being developed and used in the U.K. for criteria implementation and development (David Kay, University of Wales, U.K., personal communication, 2007; Kay et al., 2005, 2007).

6.2.2 Water Quality Notification Models

Water quality notification models that are most commonly used are simple heuristic models that relate rainfall to water quality. More complex models currently in use for informing advisory and closure decisions are exclusively statistical models that are used in conjunction with historical water quality data. The models draw on a body of past recreational water monitoring water quality data and temporally-associated physical parameters. The models are developed by assessing and exploring data for parameters that correlate most strongly with variations in water quality detected over the course of monitoring for pathogen indicators. Promising variables are selected, regression models are tested, and the models are refined on the basis of the results obtained using single variables and/or sets of variables.

Another type of "model" for water quality notification is the Heal the Bay Beach Report Card grading system (http://www.healthebay.org/brc/statemap.asp), which provides grades for water quality that are updated daily and formulated using more than one water quality measurement. Given the major uncertainty and variability in measured microbial water quality (e.g., Figures 4a and 4b), this is highly preferable compared to using a single sample to drive public water quality notifications.

One workshop participant (not from the Modeling workgroup) suggested that neural network models be used to model water quality for notification. Neural networks relate independent variables to a dependent variable non-linearly and have been used to model fecal coliforms in some waterbodies (Kumar and Jain, 2006; Neelakantan et al., 2002). However, the Modeling workgroup members agreed that neural network models would not be accessible to the majority of U.S. recreational water quality managers and public health officials in the near-term (5 years). In addition, neural network models have not been used previously for water quality notification, so they are probably not going to be useful in the near-term. They are, however, worth examining in the future.

Simple statistical models have been developed for Great Lakes and West Coast recreational waters that link fecal indicator concentration with meteorological and water quality data/information, and include the following:

- water quality and dynamic hydrologic variables (e.g., water temperature, turbidity, currents, wave height, tide level or range, lake height);
- optical property data (e.g., UV and visible irradiance, light scattering, cloud cover);
- meteorological parameters (air temperature, wind speed/direction, rainfall, pressure); and

- other factors (e.g., bird counts near a recreational water, number of swimmers in the water, video counts of swimmers and wildlife, flow/discharge from a storm drain or nearby creek).

These models have been used very successfully in three states in the Great Lakes to predict the likelihood of exceedance of the current (US EPA, 1986) indicator bacteria criteria for public water quality notification. The models have been shown to be effective in predicting indicator concentrations for compliance and for making timely public health decisions relative to recreational water advisories and beach closures.

The short-term predictions derived from these statistical models have been referred to as "nowcasting." Nowcasting has been described in the peer reviewed literature (Boehm et al., 2007; Francy et al., 2002, 2003; Hou et al., 2006; Nevers et al., 2005). The variables that are used to correlate with indicator concentrations vary depending on the type of setting of the recreational water. Among the descriptive variables assessed to date, turbidity, rainfall, tides, and wave height have been found to be among the most highly-correlated. The success of these models has been evaluated by their effectiveness in predicting days when current EPA limits have been exceeded and comparing predictions with bacteria concentrations from monitoring on a given day.

Statistical tools such as Swimming Advisory Forecast Estimate (SAFE) and SwimCast (http://www.earth911.org/waterquality/) for Lake Michigan and nowcasting models for Lake Erie are being used to warn the public about potentially unhealthy conditions in recreational waters. Project SAFE is a statistical model used for the five recreational waters in Lake and Porter Counties that extend to the west of the Burns Ditch outfall (Ogden Dunes, West, Wells Street, Lake Street, and Marquette Beaches). These beaches are directly affected by contaminants in the Burns Ditch outfall, particularly during prevailing north wind conditions. Project SAFE models provide a far better real-time estimate of *E. coli* counts than advisories based on single sample monitoring, and are generated for the five beaches simultaneously. Similar applications are being developed for other Great Lakes recreational waters. Another instance of statistical model use is the Ohio Nowcast system. The U.S. Geological Survey (USGS) and Cuyahoga County Board of Health are implementing a pilot Nowcast project to test the use of a statistical model at Huntington Beach, Bay Village, Ohio (Francy and Lis, 2007). Nowcast was used as a tool for recreational water closure decisions for the first time in Ohio in 2006. If the testing goes well, the Nowcast model will be used in subsequent years at other Lake Erie recreational waters.

In all cases where models are being used in the Great Lakes, the modeling is being used to augment microbial water quality monitoring that is being continued as required by the *National Beach Guidance and Required Performance Criteria for Grants* (US EPA, 2002). In Lake County Illinois (SwimCast) all recreational waters are monitored each day in the morning and 5 days per week in the afternoon at locations used for obtaining data for statistical modeling. In Indiana (SAFE model) recreational waters are monitored once a week. In Ohio (Nowcast) monitoring occurs 4 days per week at most Lake Erie recreational waters; and at Huntington Beach, monitoring was increased to 7 days per week during 2006 to provide a large data set to test the accuracy of the Nowcast system.

Hou et al. (2006) and Frick and Ge (submitted) have taken other important steps in developing useful statistical tools for use in recreational water quality notifications. Currently used models are based on long time-series records because models developed from large data sets are generally considered better than models developed from smaller data sets. However, large data sets are developed over time, so this approach is "static." Because conditions at recreational waters are highly dynamic and change from year-to-year and as the season progresses, these authors' models use a dynamic approach in which the descriptive variables are updated periodically.

6.2.1 Communication of Modeled Information to the Public and Recreational Water Managers

Information on modeled projections of water quality has been communicated to the public through the use of a range of communication media and in a variety of information formats. Internet postings, radio spots, and local signs have all been employed in communicating the output of regression model-based advisories. Model outputs intrinsically include an estimate of error. This is expressed in the Nowcast program in a manner similar to the familiar weather forecast probability of precipitation (POP). That is, the likelihood of an exceedance of water quality standards for a given day is expressed as a percentage. In SwimCast, the modeled estimate of fecal indicator concentrations is provided with the average prediction and the upper and lower bounds of the 99th percent confidence limit of the projected figure. Because the value of that number to the general public is limited, a risk explanation is reported based on this statistical prediction in terms of a text description (e.g., low risk if entire confidence interval is below the single sample maximum criteria).

Information on beach water quality can be provided to the public through a tiered approach. The first tier involves communicating a red or green light; that is, simply informing the public on whether or not the recreational water is currently posted with a water quality advisory. The second tier is to provide additional information for those who desire to be more informed and could include posting the measured water quality, environmental water quality data, and the resultant numerical prediction on a website. The third tier is to provide detailed information on the Nowcast system and explain how statistical models are developed and tested, which can also be provided on a website or summarized in fact sheets distributed to the public at the recreational water. A tiered system allows the recreational water user the ability to choose their desired level of information.

Effective communication to the recreational water manager and state and local public health agency representatives is essential for acceptance of a Nowcast or similar system. Presenting the science behind statistical modeling in a simple and concise manner at periodic workshops and meetings is the first step toward gaining acceptance. Because the Nowcast system is different from conventional water quality notification systems already in place (i.e., using the previous day's measured bacterial indicator concentration), local officials may be apprehensive in accepting the new technological approach. Thus, demonstrating to local agencies that the Nowcast system provides a more accurate assessment of water quality conditions may be required before acceptance and implementation is achieved.

6.3 Advantages and Disadvantages of Modeling

The main advantage of modeling for water quality notification is that modeling can provide accurate and timely notification of water quality, whereas day-to-day monitoring cannot. Such modeling may be as simple as a heuristic model or a letter grade for recreational water. More complex models, such as those already in place in the Great Lakes, use multiple regression modeling or similar tools.

An advantage of using a simple sanitary investigation model that relates land use activities and patterns to microbial water quality is that a manager may be able to rule in or rule out the presence of human pathogen sources in a watershed to relax criteria, as is proposed in the EU (EP/CEU, 2006) and WHO (2003) approaches to criteria development.

6.3.1 Advantages of Modeling

- Statistical/regression fecal indicator estimation models are relatively easy to create for an individual with knowledge of statistics and may in some cases only require one variable to adequately describe/predict the pathogen indicator. Several government or private entities currently maintain hydro-meteorological equipment and sensors (e.g., USGS, National Oceanic and Atmospheric Administration [NOAA]) with readily accessible real-time data via the Internet, which could be used at no cost to the recreational water quality manager if deemed appropriate for the specific recreational water. Collected descriptive variables can either be continuous or categorical. Once developed and put into place, statistical models are also easy to use with minimal training required for the recreational water managers and operators.
- Predictions from a sanitary investigation model may allow managers to rule in or rule out human pathogen sources in their watershed and hence relax water quality criteria using an EU or WHO criteria approach. Land use and watershed attributes may be readily available for incorporation into such a model (e.g., Digital Watershed, see http://www.iwr.msu.edu/dw/).
- Water quality notification predictions may be made "near" real-time if required data elements (input variables) exist. This alleviates the delay currently experienced by culturable methods (18 to 24 hours for *E. coli* or at least 24 hours for enterococci). Even with the advent of rapid qPCR (molecular-based) methods, there will continue to be time associated with collection, sample preparation, analysis, and results evaluation. For example, sample preparation adds an estimated minimum of 2 hours in addition to the analysis time. In addition, only the most intensively used waterbodies will likely be monitored with a frequency that will make the best use of the timely results from the use of these methods.
- Collection and analysis delays for both culture- and non culture-based methods currently have and potentially will continue to result in false negative (Type II) advisory/closure errors (e.g., contaminated recreational waters remain open). This is due to the inherent variability of fecal bacteria densities—even over time scales as short as every 10 minutes (see Figures 4a and 4b). Statistical models created for various recreational waters in the Great Lakes have been successfully used to correctly advise/notify the recreational water user of current fecal indicator conditions. Proper public notification should result in

improved public health outcomes and is the major benefit of statistical modeling. It has been well received (instills confidence) by the public and recreational water managers and operators at currently used recreational water locations.

- For recreational waters that have daily (or multiple day per week) monitoring of a fecal indicator and other hydro-meteorological data, costs for creating a statistical model will be low relative to other monitoring/advisory costs. For many recreational waters, initial model creation will require additional water quality monitoring for fecal indicators because it is imperative that the data set on which the model is based include a full range of fecal indicator concentrations for the specific location. However, once the statistical model is created and is validated, the need for daily or weekly monitoring could be reduced, potentially reducing monitoring costs.
- Once the statistical model has been created, both the data-element collection and actual prediction can be automated using current technologies. Although automation initially increases costs (i.e., equipment and programming), personnel costs should be reduced over time.
- Many recreational waters are monitored infrequently due to economic reasons or logistical issues (e.g., difficulty of sampling on weekends). Statistical modeling, if relatively automated, will improve water quality notification activities at these locations, often during highest use days.
- When associated variables become known during model development, a deeper understanding and knowledge of the potential reasons driving increased fecal indicator concentration should assist the recreational water operator (and other interested parties) with future assessments and sanitary investigation work. Simple linear relationships can help to identify potential sources of fecal indicator bacteria (i.e., waterfowl counts versus *E. coli* measurements) and can be used to help design monitoring and microbial source tracking studies.
- Currently used statistical models are based on recreational water quality criteria and thus meet Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 and recommended Clean Water Act (CWA) §304(a) single sample maximum allowable fecal indicator density requirements. Because previous studies have demonstrated that the currently-used bacterial indicators are statistically associated with acute GI illness, predictions based on these pathogen indicators should be protective of public health.
- Statistical models could possibly be used to forecast poor conditions at recreational waters using forecasted descriptive variables available from NOAA.
- The statistical approach is flexible and could be applied to prediction of other criteria besides the current culturable *E. coli*- and enterococci-based criteria. However, new data would be required to calibrate the models if the criteria changes and this could be a disadvantage (see more below).

6.3.2 Disadvantages of Modeling

- Because water quality notification models are based on real-time data, prediction accuracy may be diminished by poorly collected or inappropriately maintained equipment. Quality assurance and quality control procedures must be in place for all required input data elements. Recreational water managers and operators (or other individuals) must be diligent in ensuring that proper collection and data management techniques are used.

- Because current water quality notification models utilize statistical techniques, a relatively large (n = 75) and rigorous data set is required to develop the model. Both dependent and assumed descriptive variables should be collected at least 3 to 4 days/week during the recreational water season (if possible). Additionally, the data set should contain a variety of sampling events to capture temporal variability (morning and afternoon) and under both wet and dry weather conditions. It is also necessary to attempt to sample and collect the full range of fecal indicator concentrations for a specific recreational water to help ensure accurate future predictions.
- Politicians, government officials, recreational water operators and managers, and the public may be apprehensive to accept the concept or the need for a modeling-based water quality notification system. Initial support may be difficult to obtain and a local "champion" would be beneficial to advance the concept. The workgroup members noted that once a model is created and accurate predictions are demonstrated, this apprehension would lessen substantially over time.
- Statistical water quality notification models are based on previously collected data and historical associations. Unanticipated events such as sewage spills, large increases in wildlife populations, changes in shoreline from extreme weather events, or new non-point sources of fecal contamination may reduce the predictive ability of the model. If numerous under- or over-predictions occur, additional data collection activities would be warranted to determine whether the model would need to be modified.
- Statistical water quality notification models appear to be most useful at recreational water locations that have occasional but infrequent exceedances of current bacterial water quality criteria. Recreational waters with consistently low or high fecal indicator concentrations may be very difficult to model. Additionally, the need for modeling will be harder to justify as currently accepted monitoring designs may be a preferable and cheaper method.
- Simple statistical models, whether for recreational water quality notification or sanitary investigations, are generally not sufficient for use as deterministic models (e.g., bacterial fate and transport) or to provide load estimates for use in developing TMDLs.
- Current statistical water quality notification models are based on recreational water criteria and thus meet BEACH Act and recommended CWA §304(a) single sample maximum allowable fecal indicator density requirements. However, if ambient water quality criteria for bacteria change, all currently used statistical models will need to be modified to reflect and predict the new criteria. This will result in new costs in the redevelopment and modification of an existing model to incorporate the changed relationships of predictive variables to indicator concentrations. In addition, because fecal indicators are used to predict health risk, the model is only as good as the indicator used.
- There is some confusion as to whether a model output should be measured against a single sample standard and/or a 30-day geometric mean standard. Input from workshop participants revealed that these criteria are used differently around the country with monitoring data. Output from water quality notification models should be used with the

single sample standard and not the 30-day geometric mean standard because it is not clear that model outputs should be averaged for comparison with the 30-day geometric mean standard. Guidance needs to be provided on this issue if new or revised recreational water quality criteria will support the use of models.

- Because water quality is inherently variable, even over a 10-minute scale (see Figures 4a and 4b), how to collect data to develop and validate models needs to be carefully considered. In the Great Lakes, composite sampling is conducted. Guidance for any new or revised criteria that recommend models would need to address this.
- There was some concern from the Implementation Realities workgroup that recreational water advisories or closures instigated by model output would count against them for CWA §303(d) listings or other CWA applications. Guidance for any new or revised criteria that recommend models would need to address this concern.
- Models are site-specific and must be developed for various recreational sites, the same way water quality monitoring must be conducted at specific sites.
- Sanitary investigation models have not been used before for water quality criteria development.

6.4 Model Development and Evaluation

6.4.1 Initiating Model Development for Water Quality Notification

Prior to initiating statistical model development at any recreational water site, a review of all past monitoring and watershed data should be completed. In some cases, enough data may exist to analyze associations between the environmental variables and indicator densities. For example, some states and local agencies collect data on air and water temperature, rainfall, amount of algae wrack, and/or tide level during compliance water monitoring. This type of ancillary data can be used to develop preliminary models and determine if any relationships between indicators and readily available environmental variables exist. This may guide additional monitoring needs and variables to be assessed. As always should be the case, strict quality assurance and quality control practices are to be followed to ensure that a high quality data set has been or will be collected. Additionally, a good understanding of the potential sources and extent of fecal contamination should be determined to aid in choosing sample locations and frequencies. This type of information can be obtained from recently conducted sanitary investigations, historical observations from local water resource managers, and/or visits to the recreational water site.

6.4.2 Model Development for Water Quality Notification

Statistical models have relatively easy to obtain data needs. Data collection should include observations that cover the range of hydrometerological conditions that are expected to impact the recreational water. Sampling should be conducted, at the very least, by collecting at least two recreational seasons of data. A minimum of one recreational season will be necessary for model creation, while the second is used to gather additional data and for model evaluation. Water should be collected four or five times each week and the data set should contain a variety of sampling events to capture temporal variability (morning and afternoon) under both wet and dry weather conditions. It is also necessary to attempt to sample and collect the full range of fecal indicator concentrations for a specific recreational water to ensure accurate future predictions. If current monitoring is conducted on a weekly or monthly basis, serious consideration should be given to increasing data collection requirements as it will take a much longer time period (i.e., 5 years) to develop the model. Generally, a relatively large (n = 75) and rigorous data set is required to develop a water quality notification model. Recreational locations that have consistent good or bad water quality are not good candidates for statistical models. Rather, sites with mixed water quality conditions are the best candidates for statistical models. A representative sample of the waterbody (multiple point grab samples or composite samples for larger recreational areas) should be analyzed for concentrations of fecal indicator bacteria, such as *E. coli* and enterococci, determined by use of an EPA-recommended method.

The descriptive variables for each recreational waterbody will differ from site-to-site. More precise and frequent measurements may lead to better statistical models but also lead to increased costs. However, increased equipment use does lead to automated processes, greater reliability of measurements, and reductions in personnel time.

Water quality notification models use a variety of descriptive variables and all are based on statistical correlations between descriptive variables and indicator organisms. Wave height has been shown to have a positive association with fecal indicator bacteria at some beaches and thus is often included as an independent variable in water quality notification models. Wave height can be estimated visually, measured with a graduated rod, or with pressure transducers. Wave height estimates can also be obtained from an off-site external source, such as a NOAA buoy. Turbidity has also been proven to be a useful factor for use in predictive models. Turbidity can be measured with a field turbidimeter or in situ by use of a turbidity sensor. Models of marine recreational water sites may also include tides (Boehm and Weisberg, 2005; Hou et al., 2006). Insolation, a measure of solar radiation, has been shown to be a useful predictor for fecal indicator bacteria models, since fecal indicator bacteria are sensitive to sunlight (Boehm et al., 2002). Insolation can be measured using a pyranometer on site or provided by external sources (such as NOAA). Rainfall, as well as wind speed and direction, have been included in predictive models. These data can be measured in situ using a weather station or obtained from a reliable source such as operating meteorological stations, which are often located at airports (NOAA, 2007). Streamflow rates from nearby tributaries (USGS, 2007) and effluent discharge rate information from wastewater treatment plants may also be useful factors for inclusion in a predictive model. The number of birds at the recreational water might also prove useful factors for inclusion in a model. Some models presently in use in the Great Lakes for water quality notification use the amount of biological wrack or algal mats as model inputs. Overall, the factors/variables included in a model will be site-specific. A thorough review of factors that might be included in a water quality notification model is outlined in Boehm et al. (2007). Water quality notification models that are most commonly used are simple heuristic models that relate rainfall to water quality (Ashbolt and Bruno, 2003).

Two types of output may be produced by statistical models. The first and obvious output is the predicted microbial concentration and its associated confidence limits. A second output variable is the probability of exceeding an appropriate target value; for example, the probability of exceeding the single sample maximum recreational water quality criteria (Francy and Darner, 2006). Either output may be used to issue advisories or closings of a recreational water site.

6.4.3 Data Needs for Simple Sanitary Investigation Model Development

Because the sanitary investigation model has not been implemented previously for water quality criteria development, data needs are based on characteristics that are important to models used for TMDL implementation. A waterbody manager would need data on land use within a watershed, types and numbers of domesticated and wild animals, publicly (and privately) owned (wastewater) treatment works (POTW) discharges and their degree of treatment and effluent characteristics, number and types of on-site septic systems, type and age of sewage infrastructure, presence of CSO and sanitary sewer overflows (SSO) systems, soil characteristics, and watershed slope. At minimum, such a model could generate a quantitative score of "very likely" to "not probable at all" regarding the possibility of having human pathogens present.

6.4.4 Cost Estimates

There is a wide range of cost estimates for the development, validation, and maintenance of statistical model programs. For all programs, the assumption is that an indicator monitoring program is already in place for the recreational water and computer hardware and statistical software are available. The following are 3 examples of costs for statistical modeling programs for 2 recreational seasons (60 observations per season), starting from the least to most expensive programs.

1. Using existing data from other sources, such as meterological data from the National Weather Service (NWS) and wave height data from NOAA. Expenditures include data compilation and model development (200 hours of computer time).
2. Using existing meterological data from other sources, measuring turbidity, wave heights, and number of birds at the time of sample collection. Expenditures include the purchase of a turbidimeter and standards ($1,200), field measurements (30 hours), and data compilation and model development (200 hours).
3. Installing in situ site-specific instruments for measurements of wave heights, turbidity, wind direction and speed, and rainfall amounts. Expenditures include the purchase and installation of equipment (a one-time cost of $15,000 to $20,000), maintenance of equipment ($2,000/year for replacement and manufacturer calibration of equipment and 80 hours), and data compilation and model development (200 hours).

6.4.5 Understanding the Uncertainty and Measuring Success of Statistical Models

The natural complexity of environmental systems means that it is difficult to develop complete mathematical descriptions of relevant processes, including all of the intrinsic mechanisms that govern their behavior. Model evaluation is defined as the process used to generate information to determine whether a model and its analytical results are of sufficient quality to serve as the basis for decision making (CREM, 2003). Once a statistical model is constructed, it is important to describe its usefulness or success. A regression model is built using a "training" data set comprised of dependent and independent variables (Boehm et al., 2007). The ability of the model to predict the dependent variable using independent descriptive variable inputs within the training data set can be described by a root mean square error (RMSE). A coefficient of determination (R^2) can also be used and is interpreted as the percent of the variation of the independent data set described by the model. However, the workgroup members agreed that this was not the best metric for evaluating model performance. A third metric for testing the performance of a model is to examine the number of Type I and Type II errors that result. Assuming the null hypothesis is that a recreational water is in compliance with a water quality regulation and should be open to the public, a Type I error occurs when a recreational water is closed or posted with a warning when it should not be (i.e., false positive), while a Type II error occurs when a recreational water is not posted or closed when it should be based on the water quality regulation (i.e., false negative). These two types of errors can be summed to determine the total errors. The number of such errors is a function of the specific policy used by recreational water managers in making water quality notification and closure decisions.

Model evaluation must be conducted using a data set with which it was not trained before it can be applied as a predictive tool. Model evaluation is defined as the process used to generate information to determine whether a model and its analytical results are of a quality sufficient to serve as the basis for a decision (CREM, 2003). It can only be completed if an appropriate evaluation data set of independent and dependent variables not used to train the model is available. The success of a model during evaluation is described by the root mean square error of prediction, which has the same mathematical formation as the RMSE. The number of Type I and II errors, as well as the total error rate is also calculated. The model's performance is then compared with the current method for assessing recreational water quality (i.e., using the previous day's measured bacterial indicator concentration).

At a Lake Michigan recreational waterbody during 2004 (Olyphant, 2004; Pfister, 2007), swimmers were exposed to a health threat without warning on three occasions and kept out of the water when it was safe on only one occasion when a water quality model was used to make recreational water closure decisions. In contrast, swimmers would have been exposed to a health threat without warning on 19 occasions and kept out of the water when it was safe on 12 occasions if daily morning monitoring data alone had been used to notify the public of health risks.

Because every model contains simplifications, predictions derived from the model can never be completely accurate and the model can never correspond exactly to reality (CREM, 2003). After model validation (e.g., those that have been shown to correspond to field data), an additional year of data can be added to the model development process and a new model with another year of data is developed for use in subsequent years.

The information about model evaluation presented above is an overview. The peer reviewed literature should always be examined for new ideas and thoughts about model evaluation.

6.5 Research Needs

Research needs for simple, statistical models are categorized below regarding near-term activities (2 to 3 year horizon) of immediate relevance to implementation and development of new or revised rcriteria in recreational waters to long-term research activities, such as elucidation of processes affecting pathogen/indicator fate and transport, development of non-point source models for catchments or watersheds, and deterministic models for TMDL development. There were differences of opinion among workgroup members about how important TMDL model development is for the long-term for criteria development and implementation.

6.5.1 Near-term Research Needs (2 to 3 years)

There is an immediate need to conduct research for development of models that can be used for water quality notification. Statistical (or empirical) models are most promising for this purpose because they are relatively cheap and simple, and readily accessible to most recreational water quality managers (see Chapter 7). Statistical models link microbial concentrations with meteorological and water quality data/information. Recent research has lead to the development of useful statistical models for some Great Lakes recreational beaches (Francy and Darner, 2006; Francy et al., 2003; Frick et al., 2005; Olyphant, 2005; Whitman and Nevers, 2004; Whitman et al., 2006) and marine coastal beaches (Hou et al., 2006). Although these statistical models have successfully predicted criteria exceedances under a variety of environmental conditions, statistical modeling studies must be extended to a variety of other recreational waters to evaluate fully the utility of this approach.

Near-term research needs for water quality notification include the following:

1. Day-to-day water quality notifications should not be issued using a single sample standard in conjunction with a microbial assay that takes longer than a few hours due to notification errors. Simple, heuristic or statistical water quality notification models can help avoid notification errors (**all 5 workgroup members [5/5] agree**).
2. Immediate research needs include the following:
   a. Testing whether models can be used to predict health outcomes during upcoming epidemiology studies at Doheny Beach (California) and in Alabama and Rhode Island, and as well as the already completed epidemiology studies done in the Great Lakes (described by Wade et al., 2006) (**high priority [5/5]**);
   b. Developing and testing simple notification models on different recreational water types with a wide range of sources and geographical locals (**high priority [5/5]**);
   c. Exploring the feasibility of developing regional models that apply to more than one recreational water (**low priority [5/5]**);
   d. Training recreational water managers (**high priority [3/5]**, **low priority [2/5]**, there was disagreement on whether this belonged on the research list);
   e. Creating an excellent user-friendly portable package for developing local models (**high priority [5/5]**); and
   f. Developing dynamic predictive modeling methods (refers to models where variables are constantly updated over time) (**high priority [2/5]**, **medium priority [2/5]**, **low priority [1/5]**).

1. Linking statistical models to health effects. One approach would be to concurrently conduct modeling studies along with planned epidemiological studies that will be conducted by EPA and the Southern California Coastal Water Research Project during the upcoming year in California, Alabama, and Rhode Island. In addition to measurements of microbial concentrations, appropriate data for model development should be collected during the epidemiological studies (e.g., turbidity, irradiance, wind speed/direction, wave height, tides, temperature).

Another approach would be to retrospectively develop statistical models for sites of past epidemiological studies in the Great Lakes, where appropriate data relevant to statistical modeling have already been collected (or can be obtained from existing meteorological data). For example, statistical models have been developed for Huntington Beach, Ohio, and West Beach, Indiana—both of which are sites of past NEEAR epidemiological studies (Haugland et al., 2005; Wade et al., 2006).

2. Developing statistical models for different types of recreational waters. To test the feasibility of the statistical modeling approach, research is needed in recreational waters that are impacted by different sources of biological contaminants (non-point or point sources such as POTWs) and that are described by a wide range of meteorological and water quality variables. Waters that are significantly impacted by POTWs or non-point agricultural sources will be accorded the highest priority in site selection because past studies have shown that these sources are most likely to adversely affect human health. Sites located in the following regions should be considered for this research:

- West Coast (open ocean and confined beach);
- East Coast (open ocean and confined beach);
- Gulf Coast;
- inland lakes/reservoirs;
- rivers with designated primary contact recreational use; and
- tropics and subtropics.

3. Dynamic approaches to statistical modeling. Currently used models are based on long time-series records that take at least 2 years to obtain. The regression constant and coefficients are held constant when the model is used to predict (generally Nowcast) conditions. Once established, the models are changed only at the end of season to incorporate new data. Other recent research suggests that model performance may be improved by using a dynamic approach in which the descriptive variables are updated periodically with data generated within a limited recent period—usually on the order of 30 to 60 days. Using the dynamic modeling approach, the predictions of bacterial concentrations have been significantly improved (Frick and Ge, submitted; Hou et al., 2006) and the time period for model development may be reduced. An alternative approach would be the development of a sliding seasonal band of data using multi-year data from the period surrounding the date of interest. Additional research is required to refine this approach, either though use of previously obtained data sets or data obtained at sites that will be used for the first two activities (i.e., linking statistical models to health effects and developing statistical models for different types of recreational waters).

4. Communicating and training modeling techniques. Various activities can improve the communication of modeling techniques and results to the public and training recreational water managers, including the following:

- creating a user-friendly portable package for developing local models;
- training for running statistical models for recreational water managers; and
- including recreational water managers on the decision process and polling them regarding their perception of its usefulness/feasibility.

Training is an important component towards acceptance and implementation of statistical models by recreational water managers and public health agencies. In a November 2003 workshop held as part of the Great Lakes Beach Association Annual Conference in Green Bay, Wisconsin, recreational water managers expressed as a high priority the need for informed training on statistical models and other recreational water monitoring activities. Similarly, training is being provided by EPA Region 5 on statistical model and sanitary survey (investigation) development in April 2007 at the request of recreational water managers.

5. Explore the feasibility of developing regional models (e.g., for southern Atlantic coast recreational waters). At present, simple water quality notification models are site-specific. The feasibility of using a regional scale model that predicts water quality regionally, within a large waterbody, for example, should be explored.

Near-term research needs (next 2 to 3 years) for sanitary investigation models include the following:

1. Simple, heuristic, statistical/conceptual models that correlate watershed activities (e.g., presence of treatment plant effluents, agricultural activities, domesticated animals) and attributes (e.g., slope, soil type, climate, soil moisture) can be used to determine the probability of a waterbody having inputs of human pathogens (**all [5/5] agree**).
2. Research in the near-term should be carried out to better understand how watershed activities and attributes relate to pathogen presence in streams and receiving waters, including the following:
    a. factors that modulate septic tank impact on waterbodies (**high priority [1/5] medium priority [1/5]**, **low priority [3/5]**);
    b. factors that modulate contributions of animal wastes to pathogen and pathogen loads to waterbodies (**high priority [5/5]**);
    c. sources in urban landscapes such as broken/leaky sewer pipes, CSOs, stormwater and urban runoff (**high priority [5/5]**); and
    d. effect of geographical and climatic setting on non-point source delivery (**high priority [5/5]**).

6.5.2 Longer-term Research Needs (8 to 10 years)

A variety of research needs are required to be able to develop an excellent model that would allow prediction of fecal indicators or human pathogens. Additionally, important sources, and fate and transport processes will need to be elucidated. These research needs will require a longer time horizon for completion and are summarized below.

1. **Processes that affect fate and transport of pathogens and fecal indicators for incorporation into deterministic models and improving statistical models indicators.** This long-term research effort involves the development of data and descriptors of processes that are required in deterministic models that predict fate and transport effects on pathogen concentrations in recreational waters. Process information can also be used to help define appropriate variables to use in statistical models. Such research would focus on partitioning of microorganisms to suspended and bottom sediments and sands, mortality of pathogens and indicators, zooplankton grazing on fecal indicators and pathogens, and the possibility of bacteria proliferation in the environment. Some of these processes are shown in Figure 5. In addition to these processes, a better understanding of mobilization of pathogens and pathogen indicators from sources within a watershed (i.e., from animal feces) and source strength from POTWs and CSOs are needed (**high priority[5/5]**).

2. **Research on GIS layers relevant to modeling.** In order to develop viable models, recent and relevant GIS data need to be readily available and usable for models (e.g., POTW locations, recent land use categories, storm sewer locations). Digital Watershed

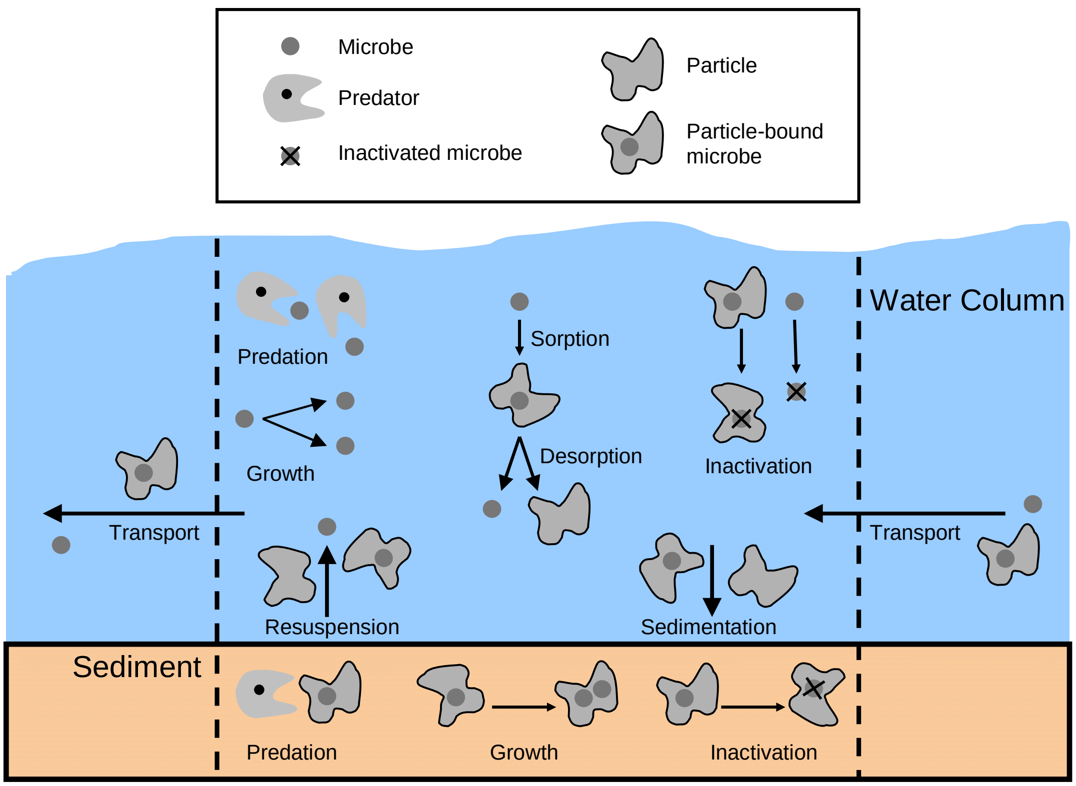

Figure 5. The Possible Fates of Microbes (Fecal Indicators and Pathogens) in Environmental Water and Sediment (the fate of nucleic acids may be different; this figure does not include those sources). SOURCE: Adapted from Olivieri et al. (2007).

is one example of a GIS-based software that can be used to provide inputs for deterministic models such as L-THIA (**high priority [1/5]**, **medium priority [4/5]**, **[1/5]** does not think this is a research need).

3. **Combining deterministic models with statistical models.** This research involves using outputs from deterministic models as inputs for statistical models that would be used for water quality notification and sanitary investigation purposes (**high priority [0/5], medium priority [5/5]**).

4. **Forecasting using statistical models.** This research will seek to expand current efforts (e.g., by Frick and Ge, submitted) to use forecasted variables (such as wind speed and direction, precipitation, wave height, and turbidity, if available) to forecast concentrations of biological contaminants in recreational waters (**high priority [2/5]**, **medium priority [1/5]**, **low priority [2/5]**).

5. **Development of deterministic models of pathogen and fecal indicators for criteria implementation and development** (**high priority [3/5]**, **medium priority [2/5]** there was concern that these would not be really used by recreational water managers and that this is already being done if resources permit).

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CHAPTER 7
IMPLEMENTATION REALITIES

Lee Dunbar, Chair, Connecticut Department of Environmental Protection
Thomas Atherholt, New Jersey Department of Environmental Protection
Bart Bibler, Florida Department of Health
Lawrence Honeybourne, Orange County Health Care Agency, Santa Ana, California
Charles Noss, USEPA
James Pendergast, USEPA
Michael Tate, Kansas Department of Health and Environment

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EPA requests that experts consider implementation realities when providing input to all specific and general questions throughout this document.

The Implementation Realities workgroup members were charged with providing input to EPA and the experts participating on the other six workgroups concerning the practical implications of incorporating any proposed changes to the recreational bacteria criteria into State Water Quality Standards (WQS) and subsequent impacts on existing water quality management programs. To this end, the workgroup members met frequently with and actively participated in the deliberations of the other workgroups over the course of the workshop. Implementation issues and concerns are therefore incorporated into the individual workgroup chapters throughout these proceedings. This chapter provides a summary of the major areas of concern identified by the Implementation Realities workgroup during the deliberations resulting from the workgroup's internal discussions as well as discussions with other workshop participants.

At the most basic level, the success of implementing any new initiative depends on providing resources and guidance that are adequate to accomplish the stated objectives. Where additional effort is needed, either additional resources must be obtained or existing resources must be diverted from other activities. Workgroup members attempted to evaluate resource needs as a critical component of implementing new bacteria criteria across a broad spectrum of programmatic responsibilities from conducting necessary research to educating stakeholders and gaining acceptance of the public and regulated entities of program changes, to actual impact on the day-to-day implementation of water quality management programs.

The results of the discussions are presented in three sections. First, an evaluation of the four principal program areas where recreational bacteria criteria are currently employed: (1) water quality beach notification and advisory programs; (2) National Pollutant Discharge Elimination System (NPDES) permitting, including regulation of wastewater treatment facilities, urban stormwater, and combined sewer overflow and sanitary sewer overflow (CSO/SSO) discharges; (3) monitoring and assessment programs required for compliance with Clean Water Act (CWA) §303(d) and §305(b) purposes; and (4) development of total maximum daily loads (TMDLs) for waters identified as not meeting State WQS. The second section provides an evaluation of the implementation concerns that must be addressed that relate specifically to three potential approaches for the development of new or revised recreational water quality criteria. The third and final section identifies the specific areas of research that workgroup members considered to be most critical to facilitating implementation efforts.

7.1 Application to Specific Program Areas

7.1.1 Beach Monitoring and Water Quality Notification Programs

The objective of this program is to provide accurate and timely information to the public regarding the health risks associated with participating in recreational activities at marine and freshwater beaches. Significant concerns have been expressed regarding both the accuracy and timeliness of the information currently provided.

The most pressing need for regulatory authorities who conduct beach monitoring programs is to get better information to the public as quickly as possible regarding the safety of the recreational water. There is currently a minimum 24 hour delay between the time when a water sample is collected, tested, and when the results of the test are available. Thus, decision makers only know what the quality of the bathing water was like yesterday.

"Rapid Tests"

Research in the past few years has resulted in the development of molecular-based tests that can provide results in just a few hours following the initiation of the test compared to 24 hours for the currently used culture-based tests.

Rapid tests have several benefits. They shorten the time from when an unsafe water condition occurs (an "exceedance") to when the test reveals the existence of an exceedance. This provides a capability to shorten the time it takes to post an advisory or to close the beach during unsafe conditions. The reduced test period thereby reduces the public health risk. The shorter test period also shortens the time it would take to remove the advisory and/or reopen the beach when water quality returns to a safe condition. Thus, the period of "loss of beneficial use" is also reduced. Because test results can be obtained in a shorter period, it is possible that they could be used to aid fecal pollution source identification efforts such as in identifying a problem in a specific location by enabling more samples to be analyzed in a shorter period of time.

Although there is a desire to use the new, rapid tests in beach monitoring programs, several issues related to their use must first be resolved. First and foremost, it must be shown that these new "molecular" methods provide a level of human health protection equal to or above that provided by the currently used tests. States need to know that there is a beneficial reduction in illness to justify the costs of adopting and implementing a new test methodology.

While rapid tests are sometimes referred to as "real-time" tests, they are not in fact real-time tests as there is still a delay of several hours between water sampling and test results. The public may still be exposed to potentially unsafe water for some period of time, albeit likely a shorter time period compared to current culture-based methods used to measure indicator organism levels. The rapid tests will not shorten the time required to collect water samples and deliver them to the test laboratory (typically 4 to 5 hours or longer), nor will they shorten the time required to convey test results to the appropriate authorities and the public (1 to 2 hours or more).

Many States only have the resources to sample periodically (e.g., weekly, monthly) as opposed to daily. The new tests are not likely to provide authorities with resource savings sufficient to analyze water quality more frequently. However, the ability to obtain test results faster may raise the expectation of the public or regulatory mangers that, since the tests are faster, additional samples can or should be collected and tested—even when this may not be possible due to resource constraints. Taking full advantage of the benefits associated with more rapid tests will likely require additional resources for increased monitoring.

Before any new test can be used broadly, the EPA will have to adopt and validate a standardized method for its use. State and local public health officials use the results of monitoring to make health-based decisions to close or open a beach, or to issue or lift a beach advisory. These officials need to know that the analytical method they use provides reliable results; therefore, they only endorse methods that have already been validated by EPA.

Further, to be able to bring a faster test into routine use, issues related to test equipment, training, laboratory capacity, and certification of laboratories will need to be resolved. The initial capital cost and any ongoing operation and maintenance costs need to be calculated and compared to that of the currently used tests. Regardless of how "good" the more rapid tests are, if they are too expensive, regulatory authorities may not be able to afford them.

In addition, because the test endpoints of molecular-based tests are different than culture-based tests, a new regulatory scheme may need to be adopted to accommodate the new water quality criteria. See the discussion in Section 7.1.2 for further information on this topic.

For the public and local authorities, a period of time may be required to gain "acceptance" of the new indicator.

In general, any change in current monitoring practices (e.g., sampling type, frequency, location) necessitated by a change in recreational water quality criteria will need to be carefully considered relative to benefits offered because it will involve resource issues and many implementation concerns.

Predictive Modeling

Changes in microbial indicator counts in recreational waters are typically controlled to a large extent by a variety of meteorological and water quality factors. Data for many of these factors (e.g., wind, rainfall, etc.) can be obtained in real or near-real time. By monitoring and identifying which of these factors control indicator count changes, it is possible to create "predictive models" (see Chapter 6). Such models are essentially mathematical equations that have the "controlling" meteorological and/or water quality parameters as components. A "robust" model that is validated by comparison of predicted indicator concentrations to a sufficient number of actual concentrations is able to successfully predict, within a stated degree of precision, when unsafe water conditions will exist more accurately than the currently used culture-based assays are able to do.

Predictive modeling offers great promise because it estimates when there may be a problem *prior* to the bather exposure. The use of predictive models may also reduce the need for rapid testing. Furthermore, they can be employed daily, providing information beyond that available from periodic microbial monitoring. However, it is important to note that predictive models are not themselves criteria. Predictive models are tools that can be used to evaluate compliance with criteria.

Models are only as good as the data used in their construction. If critical data are not available, a valid model cannot be developed until those data are obtained. As discussed in Chapter 6, the amount of data, especially microbial monitoring data, required to develop a predictive model within a stated confidence level may be significant. In general, model development may require significant time and resources depending primarily on the availability of data on indicator densities and associated predictive variables (e.g., antecedent rainfall, wind direction, wave height, etc.).

Currently developed predictive models appear to be site-specific. A predictive model developed for one beach or location is not likely to be usable at other beaches or locations because the effect of a predictive variable such as wind direction on indicator densities will be different at each beach. Therefore, for each "problem" beach or location, a separate model (i.e., set of predictive equations) is likely to be required.

Competing financial resources may make modeling a low priority. For example, limited funds may have to be used for higher priority tasks such as improving impaired waters (e.g., fecal source identification).

Any proposed use of modeling results for compliance purposes is likely to present implementation difficulties. Model results may not be always accepted as "proof" of a water quality standards violation because of the inherent uncertainty associated with model results. That is, regulators are likely to require actual monitoring data rather than modeling output for compliance purposes, particularly if non-compliance may lead to legal enforcement action. Regulators as well as members of the public often perceive monitoring as accurate and modeling as estimates.

Statistical models are currently used in some States to assess compliance with their water quality standards for purposes other than beach monitoring. If there is a change in the criteria (as would occur if a new indicator is adopted) then corresponding model would have to be modified, which would require additional resources.

It is important to note that modeling should not supplant routine water quality monitoring, which will always be needed to detect unanticipated events such as a sewer line break. Thus, regular monitoring provides an ongoing, direct measure of microbial water quality. Monitoring also provides data to help improve the precision of model predictions.

General Considerations

Workgroup members felt that any new or revised recreational water quality criteria need to allow for a binary (pass/fail) decision (e.g., close or not close a beach), must be a numeric, and must be based on a health risk determination for water quality notification/closure purposes. The criteria for reopening a closed beach or removing an advisory should be the same as that used for the initial closure or advisory. New or revised criteria must be expressed in a way that the authorities using the criteria are able to fully explain the criteria and their health risk basis, in a readily understandable way to the public.

New or revised criteria should have some "flexibility"; for example, there may be State-specific circumstances and the criteria will need to be able to be used in all such circumstances. At the same time, the new or revised criteria need consistency so that the public has confidence that their health is being protected.

Any new or revised criteria should be tied to a specific method unless “equivalency” of the new method to a previously used (and validated) method can be demonstrated to facilitate implementation (see Chapter 3 for further information).

The development of guidance to implement new or revised criteria should occur simultaneously with the development of the criteria. The implementing authorities will need assurance that the new criteria will be effective in ensuring that public health goals are met.

Finally, the successful implementation of new or revised criteria will very likely result in the need for increased funding for microbial source tracking (see also Chapters 2 and 3) and for beach management programs.

7.1.2 NPDES Permitting Programs

The purpose of the NPDES permitting program is to insure that point source discharges of pollutants to waters of the United States achieve the statutory required level of treatment and do not cause waters to exceed State WQS after discharge. This is accomplished by imposition of the more stringent of either technology-based or water quality-based limits on discharge quality and mandating discharge monitoring at a frequency adequate to insure compliance with permit limits and conditions.

Tiered Approach

Water quality criteria might be expressed in a tiered approach; that is, that the criteria include multiple attributes, each of which apply for a specific purpose. With respect to NPDES permits, the tiered approach should be workable as long as one attribute of the criteria is specifically developed for NPDES requirements. This would necessitate choice of a pathogen indicator that achieves NPDES needs (see more below).

In addition, NPDES effluent limits are developed with an implicit exceedence rate. NPDES permitting guidance for water quality-based effluent development is based on a wasteload allocation that is calculated based on an exposure condition that represents the upper 99th percentile of conditions (e.g., conditions occurring under rare low flows such as the 7Q10 [the lowest streamflow for 7 consecutive days that occurs on average once every 10 years]) when point source discharges have the greatest impact on water quality conditions. As a result, it is important that water quality criteria include an allowable exceedance frequency to facilitate permit limit derivation. This is particularly important for deriving permit limits for pathogen indicators in wet weather conditions because the flow conditions at the time of discharge can be extreme and represent rarely occurring situations.

Pathogen Indicators

Changes in pathogen indicators from the current ones (*E. coli* and enterococci) will significantly affect implementation, especially if the change results in a different indicator being used for TMDL modeling than for permitting or uses an indicator that cannot reflect the efficacy of wastewater (sewage) treatment practices (disinfection). At a minimum, the indicator used for

NPDES permitting needs to be sensitive to disinfection so that the permitting authority can determine that the NPDES regulated facility is adequately disinfecting its discharge. If the indicator cannot do so, then there will be a need for different indicators for ensuring the discharge achieves water quality standards and the wastewater is properly disinfected. Another way to accomplish this is to develop an approach that translates between the various indicators.

Analytical Methods

There is concern that molecular-based methods may not adequately verify that wastewater disinfection has been effective. This concern is based on research that shows the qPCR (quantitative polymerase chain reaction) signal does not decrease post-chlorination. Many State public health codes require disinfection of human waste and the analytical method used for NPDES permitting needs to be able to measure disinfection. As a result, a molecular-based method may not be suitable to fulfill all NPDES needs.

It is also important for implementation that the analytical methods be tested in a wastewater matrix and approved for use in wastewater. NPDES regulations require that effluent monitoring be conducted using either an EPA-approved analytical method or an analytical method specified in the permit. In the latter situation, the permit documentation needs to defend the use of the method. However, many States do not have the technical experience to defend analytical methods or have legal restrictions on the use of alternative methods and thus must rely solely on use of EPA-approved methods.

Resources

Many NPDES regulated dischargers conduct analysis of their wastewater on-site. The existing laboratory expertise of these dischargers may not be sufficient to conduct analyses for new pathogen indicators (e.g., molecular-based methods). The start up cost of purchasing equipment for conducting the new analyses and additional training for staff poses a resource drain for both the dischargers and the regulatory authority that must provide oversight. Should the dischargers choose to contract out their laboratory analysis, they will need to pay to ship the samples to the contract laboratories, which is also a resource drain.

Finally, many states require that laboratories be certified for analysis with certification being specific to the parameter being analyzed. Therefore, States will need to amend their laboratory certification program to include the new pathogen indicators. This is also a resource drain on States.

7.1.3 Monitoring and Assessment for CWA §303(d) and §305(b)

The purpose of this program is to provide an accounting of the condition of the Nation's waters, identify those that do not meet current State WQS for focused mitigating action, and to track progress in improving the overall quality of the Nation's water resources.

Assessment and listing based on the current ambient water quality criteria (AWQC) have disproportionately focused State resources on what are often perceived as minimal to nonexistent public health issues. States have expressed frustration at being effectively handcuffed by strict application of the criteria and the inability to adjust assessment findings based on other data indicating the health risk is significantly lower than implied by the criteria exceedance. Such factors include evidence that elevated indicator levels are not due to human sources of fecal contamination and hydrologic factors that preclude recreational exposure, such as during or immediately after high rainfall events. Areas where improvements can be made in the new or revised criteria and implementation guidance associated with the criteria includes monitoring, criteria, guidance, and (inland) flowing waters.

Monitoring

Workgroup members felt that new or revised recreational AWQC must include a clear discussion regarding linkages between an advisory/closure decision at a beach and assessment of use attainment. Beach advisories/closure decisions may, but need not necessarily, be linked to such assessments. There may be instances where beach advisories or notifications are made based on models, or special circumstances (such as sewer line breaks) that should not be counted as non-attainment for assessment purposes. In a similar vein, if the beach advisory regulations are more stringent than State WQS, the advisory in and of itself should not constitute non-attainment unless the State chooses to list that beach as impaired on that basis.

Ambient Water Quality Criteria

Alternative AWQC or methodologies that more precisely define health risk would be highly useful in improving assessments—in particular indicators of human versus nonhuman pathogens. The criteria and implementation guidance need to recognize the potentially lower risk of pathogens from nonhuman sources and provide a way for addressing and discounting pathogen and indicator data not associated with anthropogenic sources of fecal contamination.

The criteria must also be sufficiently flexible for assigning attainment of use based on limited data sets, particularly for inland waters. Often, States only collect data on a monthly, bi-monthly, or annual basis and compare these data to previously collected data to assess trends. The problem will be exacerbated for assessment purposes if new or revised criteria are adopted. It could take years to develop a statistically significant data set.

If the format of the new or revised criteria requires a specific number of samples to be collected in a set timeframe, States will be challenged as they are with the current criteria (e.g., 5 samples over a 30-day period). Criteria that allow assessment samples collected at any frequency to be statistically manipulated to the appropriate exposure frequency would allow States to maintain their current monitoring approaches while appropriately applying the criteria.

Also, for ease of State implementation, new or revised criteria need to allow for some reasonable excursion frequency. Criteria expressed as a percentile value (e.g., cannot exceed criteria more than x% of time) would provide an incentive to conduct additional sampling so as to not have the assessment rely on one or two samples and would facilitate implementation for assessment purposes.

If the European Union (EU; EP/CEU, 2006) or World Health Organization (WHO, 2003) approach for criteria development is followed, there needs to be a clear distinction between the criteria that is needed to protect human health and what is considered to be supplemental guidance. For instance, is it possible to have a "good" beach or a "very good" beach and still be considered non-impaired? Apparently, "good" meets the criteria while "very good" is a desired higher level of microbial water quality. Such discussion should be in supplemental guidance rather than in the criteria.

If a rapid method is selected as the indicator, the speed of a rapid method offers no additional benefit relative to assessment, unless the rapid method provides more precision/better protection to benefit public health. Therefore, a rapid method may offer the benefit of more rapid water quality notification, but has little positive effect on the overall assessment process that is conducted on data collected over a 2 year period.

Workgroup members expressed concerns with establishing a new or revised recreational water quality criteria linked to a sanitary investigation. If a WHO-type criteria model is chosen that includes use of a sanitary investigation to modify the criteria and allow for nonhuman sources of fecal contamination, the frequency of performing that investigation would need to be identified in assessment guidance. There was a strong preference among workgroup members that the frequency be longer than the two year assessment cycle for State's issuance of assessment information pursuant to §303(d) and §305(b) of the federal CWA. The available information for the sanitary investigation did not specify the frequency for repeating such investigations.

Lastly, for assessment purposes, there needs to be some way to translate between previously used indicators and any new indicator(s) so information from past monitoring is not lost. If a "translator" is not available, it might take several years to build up enough information to conduct a statistically valid assessment for pathogen indicators.

Guidance

If new criteria indicator/methodology combinations are adopted, issuance of guidance for implementation will be imperative. With the likelihood of rapid molecular-based test methods, sanitary investigations, and so on, guidance will need to accompany the criteria to help States understand how to apply the new or revised criteria and thus achieve State acceptance.

Flowing Waters

Flowing freshwaters (e.g., streams, rivers) present some unique challenges that have not been addressed with previous epidemiological studies of recreational waters. Therefore, if new or revised criteria include application to flowing freshwaters, consideration needs to be given to an allowance for different values/applications of the criteria to reflect the differences in hydrologic regime (e.g., extreme high flows) through one of the following:

- higher criteria that applies in extreme events; or

- changes to the use/criteria when the use is not taking place (e.g., when recreation is unlikely to occur such as during winter months or during or immediately after heavy rainfall).

Lastly, an indicator applicable to flowing freshwaters needs to be identified. As stated elsewhere in these proceedings, *E. coli* appears to be a more appropriate freshwater indicator of fecal contamination than enterococci. *E. coli* are a subset of fecal coliform bacteria while enterococci bacteria are a separate group of enteric bacteria. More recent water quality data generated using *E. coli* can be more easily compared to earlier water quality data generated using fecal coliform bacteria than can more recent water quality data generated using enterococci bacteria.

7.1.4 Total Maximum Daily Load Program

The purpose of this program is to establish the maximum pollutant load that a specific waterbody can assimilate and apportion that load among sources of that pollutant to the waterbody, leading to the development of a management plan that when fully implemented will result in reducing those loads to the extent that State WQS are achieved and maintained.

TMDLs for bacteria designed to achieve consistency with the current (US EPA, 1986) criteria are typically difficult to develop and explain to stakeholders because expressing pollutant loadings of bacteria or pathogens in terms of mass is nonsensical. Pathogens or pathogen indicators are not measured as mass but rather as cell counts (e.g., colony forming units [cfu]). Developing wasteload allocations for point sources and load allocations for non-point sources in mass units does not make sense to the vast majority of TMDL practioners and those responsible for implementing bacteria TMDLs. For this reason, alternative means of expressing loading reductions (e.g., "percent reduction," "load duration curve-based," "reference watershed" methods) have been used by many States. TMDL development for waters impaired by excessive indicator bacteria densities is further complicated in that the necessary load reductions are typically strongly linked to hydrologic factors and intermittent sources such as stormwater runoff. Establishing a static steady-state design condition, as is frequently done for other types of pollutant impairments, is not possible for bacteria due to the significant wet weather event-driven characteristics of many bacteria-impaired waters.

Workgroup members viewed criteria expressed in numerical terms as a practical necessity to implementing any revised recreational use criteria in TMDL programs due to the need to quantify loadings. Implementation realities dictate that the criteria be expressed in terms that facilitate calculation of an acceptable daily loading under a range of hydrological conditions. The criteria has to be a number (as opposed to a category/classification) to make implementation in TMDL programs feasible. The workgroup experts expressed a diversity of opinions over the benefits of a geometric mean or other statistic versus single sample maximum criteria with specified exceedance frequency for water quality assessment and TMDL purposes. Some prefer use of single sample maximum (SSM) while others prefer geometric mean largely reflecting current practice in their particular State. If the new or revised criteria are expressed as a single value, the benefits of allowing for that value to be exceeded at some stated frequency for TMDL and assessment purposes cannot be overstated. EPA should expect intense resistance from Sstates if future criteria guidance proposes criteria expressed as a "never to be exceeded" value.

An acceptable exceedance frequency is critical to facilitate design of treatment requirements and best management practices (BMPs) to implement the TMDL as well as accounting for rare extreme event-driven conditions not practical to mitigate. Providing States (and other stakeholders) with evidence that the criteria incorporate flexibility to accommodate the variability inherent in bacterial densities in natural systems would greatly facilitate acceptance and subsequent implementation efforts.

Criteria that distinguish between human and nonhuman sources of fecal contamination would also make TMDL development significantly easier. The ability to make allocation decisions would be enhanced and public acceptance of the TMDL implementation requirements would be achieved much more readily if additional confidence could be provided in estimates of source category loading. Further, the ability to adjust TMDLs based on more accurate source separation and to make allowances that “discount” the contribution of certain lower risk sources (e.g., non-anthropogenic) or sources from which the contributed risk may be lower (e.g., wildlife) would encourage States to move forward to adopt the criteria into their WQS. If the criteria or implementation protocol includes a sanitary investigation there should be guidance provided to encourage consistency in sanitary investigation methodologies among States. This guidance might be a combination of minimum expectations and general framework for what constitutes an acceptable sanitary investigation. A mandate to provide confirmation of investigation results through alternative means (e.g., microbial source tracking, use of more human-specific indicators) may also be acceptable provided the cost and technical difficulty are not prohibitive or use of this additional step is only required in selected instances where the results of the investigation are not conclusive.

7.1.5 Important Differences Between Workgroup Members as to Views/Observations

Workgroup members had a diversity of opinions over the benefits of a geometric mean-based as opposed to AWQC based on SSM for certain water quality assessment and TMDL purposes. Some preferred the use of a SSM-based standard, while others preferred the use of a geometric mean-based standard. One of the times of potential concern is when an individual sample result may be over the SSM but the data set does not exceed the geometric mean. The concern is that some event may have occurred during that time and the public could potentially be at risk; however, it is also possible that the result is a one-time occurrence and the public is not at a greater risk than at other locations that meet the geometric mean-based criteria.

7.2 Evaluation of Alternative Approaches for Criteria Development

This section describes the implementation considerations for each of the three alternative approaches for the development of new or revised recreational water quality criteria that were proposed and discussed at the workshop (see Chapter 1). Some of the concerns regarding implementation that are common to all three approaches include the following:

- level of discriminatory power/sensitivity of a method;
- if rapid method is used, difficulty in implementation in some places (e.g., holding time); and

- if site-specific epidemiological studies are needed, most States will be unlikely to fund these studies.

Many of the above concerns, as well as the concerns described in the following sections, would be eliminated if the following statements were true:

- epidemiological studies demonstrate that indicator organisms are sufficiently correlated to human health risk;
- studies provide a scientific basis for discounting risk to human health from wildlife sources of fecal contamination;
- criteria included flexibility to account for the reduced exposure (and thus, lower risk) of use at extreme conditions (e.g., high flow);
- relationships between advisories and impairments were more clearly defined in EPA guidance;
- level of disinfection necessary to provide adequate pathogen reduction/inactivation in human sewage was determined; and
- criteria applied for NPDES purposes included flexibility to account for wet weather conditions.

7.2.1 WHO Approach

The WHO approach provides a range of risk levels and accounts for differences in relative risk resulting from site-specific considerations of sources of indicator organisms based on the results of a sanitary inspection performed prior to the assessment of monitoring results. The following implementation concerns are not specific to any specific application of the WHO model, but rather reflect the general use of this approach.

The WHO (2003) approach to criteria development relies on identification of the potential for human sources of fecal contamination to impact a beach or other recreational water area. Many pathogens are host-adapted and so human fecal sources may contain many pathogens not found in feces from non-human animals (e.g., *Salmonella typhi*, *Vibrio cholerae*, *Cryptosporidium hominis*, *Entamoeba*, many viruses). Thus, it is essential to have available a reliable methodology to distinguish between human and natural sources (e.g., wildlife only) of pathogens for use of the WHO model. As part of this, the methodology should also be able to either quantify that the risk from natural sources is low or provide some way to characterize the risk from natural sources as being acceptable. It is important to characterize or quantify the risk from natural sources rather than to completely discount it because this risk needs to be included in beach advisory decisions. For example, if pathogens from sea lions pose a risk to humans, then it is important to post an advisory on a beach where sea lions reside. However, it would not be necessary to consider this risk in determining impairment because sea lions are a “natural” source and most environmental agencies would not view development of a plan to eliminate sea lions as consistent with their overall mission.

It is also important to be able to quantify the risk from domestic animals and livestock and include this risk if a WHO-based approach is pursued. Although these sources of fecal contamination are nonhuman in nature, these animals live in close proximity to humans and may carry human (zoonotic) pathogens in their feces(e.g., *E. coli* O157:H7, *Cryptosporidium parvum*; see also Strauch and Ballarini, 1994). Use of the WHO model will require including the likelihood of these sources impacting beaches and other recreational water areas. As a result, it becomes important to quantify risks of exposure to fecal material of these animals.

The WHO approach appears to be amenable for use with multiple pathogen indicators (e.g., the toolbox). If multiple pathogen indicators are used in application of the WHO model, then all the considerations related to use of both molecular and culture methods that were discussed for each CWA application above apply. In addition, if multiple WHO model tables are used, it may be advantageous to develop separate tables for lakes and flowing waters because exposure in these two situations are different.

There are several implementation issues that arise if the WHO model is applied using a qPCR analytical method. The first issue is the capacity of States and NPDES dischargers to adopt and use a qPCR method, as initially, there may be insufficient laboratory capacity to conduct the method. Specific concerns with respect to NPDES facilities are discussed in the preceding Section (7.12) on the NPDES permitting program. Additionally, it is reasonable to expect that the initial costs per sample will be substantially higher than for the currently used culture-based methods, which poses an additional cost to States and NPDES facilities.

The second implementation issue with respect to qPCR is its apparent inability to confirm that disinfection is being properly applied. As discussed previously, NPDES permits need to both assure that WQS are achieved and that State disinfection requirements are being met. If qPCR method is used to apply the WHO approach, then another indicator using culture-based methods will be needed in NPDES permits to demonstrate adequate disinfection.

Another implementation issue is the use of sanitary investigations based on the WHO approach. However, the protocols for a sanitary investigation should not be overly prescriptive to the point of making the investigation resource-prohibitive. There is a need to define the minimum elements of a sanitary investigation to ensure that it is reliable. Application of the criteria needs to invoke trust by the public. If there is too much variety in sanitary investigations, then the public will perceive that the investigations have no technical rigor and which will undermine use of the WHO model. In addition, States will need to develop the capacity to conduct sanitary investigations on every waterbody with recreational uses, which constitutes a resource burden. Finally, States need sufficient time to conduct sanitary investigations by the time the new or revised criteria are adopted into their WQS.

The WHO approach includes columns that characterize different risk (see Table 1, Chapter 1). Two of the columns include water characterizations of "very good" but are associated with different risk. The model should be applied with only one "acceptable risk" level. If there is more than one acceptable category of good, it implies there is more than one "acceptable risk" level. This makes it difficult to explain to the public, difficult to enforce, and difficult to make decisions on the lower risk level. Any further distinction between "good" and "very good" outcomes should be voluntary.

It is possible that States will issue advisories in situations that are not considered as CWA impairments. This can occur when a state public health agency wants to impose a higher degree of protection than the state environmental agency, or at beaches where there are wildlife sources that pose risk. It is uncertain how such a situation would work with the WHO model, and this would need to be developed.

The WHO model uses ranges of pathogen densities. This allows States to select which specific value to use, and thus result in inconsistencies on thresholds to close or open beaches between various states. It is much more preferable for the criteria to specify one threshold rather than a range. However, it was discussed that while the range may be difficult to implement in a regulatory fashion, it may more realistically describe the precision of epidemiological-based criteria applied to a wide range of waters coupled with the precision of indicator measurement.

Finally, it appears that empirical models of pathogen densities can be used with the WHO model, as long as one threshold is used rather than a range.

7.2.2 EU Approach

The EU approach provides defined criteria at a single risk level but allows for adjustment of the assessment result based on a sanitary investigation performed following review of monitoring results.

Like the WHO (2003) approach, the EU (EP/CEU, 2006) model uses sanitary inspections; however, unlike the WHO approach, the EU model uses the inspections to rationalize that monitoring results above the criteria levels do not indicate an elevated risk to human health. Thus, the rigor of any type of sanitary investigation that may be required for an approach based on the EU approach seems to be greater than for WHO-based approaches (i.e., requires a more detailed site assessment). A workgroup participant indicated that for some waters a desktop GIS-based methodology could constitute a sufficient sanitary survey for many bathing waters (Paul Hunter, University of East Anglia, U.K., personal communication, 2007).

As was the case for the WHO model, there are implementation concerns regarding the time and capacity for conducting sanitary investigations, and the ability to distinguish between risks from human and nonhuman sources of fecal contamination. Specifically, States will need to know how good are the techniques to distinguish between risks from human and nonhuman sources, and what is the degree of risk from nonhuman sources. Thus, the discussion of the WHO approach on these topics likewise applies to the EU approach.

As one way to implement the EU model, EPA could use a “pristine” watershed as a baseline. In this situation, EPA would look at pathogen indicator counts at baseline flows and use these values to determine how to adjust concentrations.

The EU model process presents opportunities to be more transparent to the public than the WHO approach. States could seek public involvement in determining how to conduct the sanitary investigation/discounting process.

One impediment to implementation of the EU approach is how domestic and agricultural animals are addressed. It appears that these sources can be excluded; however, these fecal contamination sources may have a potential risk to human health.

The EU model characterizes beaches using the 95^{th} percentile of a set of microbial water quality data. This seems to prevent making short-term decisions for beach closure or reopening unless beach managers use some sort of predictive modeling. This is an implementation concern given the aforementioned (see Chapter 6) data needs of models. Not all recreational water sites can currently develop a model due to limited data. If there is no model, then decisions would likely be based on a data set over a period of time, rather than a specific data point, which would require interpretation for beach monitoring for closing or opening decisions.

Like the WHO approach, the EU approach includes columns that characterize different risk (see Table 2, Chapter 1). The model should be applied with only one “acceptable risk” level. If there is more than one acceptable category of good, it implies there is more than one “acceptable risk” level. This makes it difficult to explain to the public, difficult to enforce, and difficult to make decisions on the lower risk level. Any further distinction between “good” and “very good” outcomes will make implementation difficult in some jurisdictions.

7.2.3 Existing U.S. Model – 1986 Criteria

The existing model provides defined criteria at a single risk level but does not provide for adjustment based on other sources of information such as sanitary investigations or source identification.

The original basis for the (EPA) 1986 criteria were freshwater and marine water epidemiological studies conducted at a limited number of sites with restricted geographic extent and waterbody type (lake beaches and marine beaches). Therefore, a concern exits that single value criteria may not be applicable to all waters across the United States—for instance, inland flowing waters, tropical waters, or freshwaters under tidal influence. In the development of new or revised criteria, epidemiological data or quantitative microbiological risk assessment (QMRA) for as wide a variety of fresh and marine waters as is possible should be used.

If single value criteria are to be developed, as was the case for the 1986 criteria, it is vital to use as many indicators as necessary to best characterize the microbiological quality of the water. There is a variety of opinion as to the most appropriate indicators for fresh and marine waters. However, there is evidence that *E. coli* is the most suitable indicator for flowing freshwaters while enterococci, either by culture- or molecular-based methods, is most suitable for marine waters; however, the workgroup did not reach a common opinion on the evidence.

A major criticism of the 1986 criteria was the lack of approvable test methods for wastewater effluent. If new indicator organisms or test methods are identified for the new criteria, approved test methods must be developed for all potential needs such as NPDES permitting and ambient water quality monitoring.

The 1986 criteria provide minimal implementation guidance. Due to most States' interpretation of the criteria in their WQS, the criteria tend to be treated as requiring compliance at all times and in all waters. This interpretation has caused considerable problems in the assessment and TMDL arenas. Any new or revised criteria must include implementation guidance that allow for methods to address issues such as extreme flows and nonhuman sources of fecal contamination.

EPA needs to provide more scientific data and information to States for implementation of pathogen indicator criteria. States have concerns regarding the effectiveness of existing sewage treatment capabilities on new indicator organisms. In switching from enterococci or *E. coli* as an indicator, there is concern that disinfection designs may not meet permit limits based on the new indicator criteria. This issue needs to be addressed by EPA so that the State programs will have consistent, valid, and scientifically defensible responses when these concerns are raised during the implementation of new WQS.

7.2.4 Alternative Approaches

Two additional potential approaches to consider in the development of new or revised recreational water quality criteria include the following:

1. An alternative hybrid approach could blend the single value criteria with facets of the WHO (2003) and EU (EP/CEU, 2006) models to allow for demonstration of mitigating (or discounting) factors to be completed by a fixed date after criteria adoption. This has the advantage in preventing waters from being CWA §303(d)-listed based solely on excursions above a single value criteria. If the water was ultimately listed, it could be de-listed at a later date if it were demonstrated that mitigating factors prevented designated use attainment.
2. The largest implementation concern with the single value (EPA) 1986 criteria is regarding assessment. An alternative approach to developing new criteria could incorporate the existing 1986 criteria with the following implementation provisions:
    - a provision to discount non-compliance with the single value criteria after investigation of the contributing watershed to confirm the absence of nonhuman sources and lower risk than implied by the criteria exceedance;
    - criteria/use inapplicability during extreme high flow events; and
    - a process to exclude natural sources of fecal indicator organisms (i.e., indicators specific to human sources are not present), according to the corresponding risk to human health.

7.3 Research Needs

Research is clearly needed to provide support for implementing any alternative approach to criteria development, expression, or application. A key concern is the role research results play in the ability of State and federal regulators to explain and gain public acceptance of changes in existing CWA programs. Opportunities to leverage the value of individual research programs by employing data collection designs that may be useful to answer multiple questions should be exploited.

7.3.1 Near-term (Next 1 to 3 Years)

Beach Monitoring

1. Provide a quantitative protocol to identify the types of nonhuman sources of fecal contamination. For example, other than molecular-based fecal source identification techniques, are there methods (e.g., sanitary investigations) to track nonhuman sources such as waterfowl, dogs, horses, and other anthropogenic sources? The WHO and EU approaches to criteria development provide for "discounting" exceedances if it can be determined they are of nonhuman origin through a sanitary inspection. If risks from nonhuman sources can be adequately quantified, sanitary inspections could be used to support decision making.
2. Determine the risk from different types of nonhuman sources of fecal contamination (e.g., domestic and indigenous wildlife). Although the new or revised criteria would need to address all potential risks, a delineation of the categories of risk made available to the public would improve water quality notification and informed consent aspects of implementation. Specifically, the perceived risk associated by the public with elevated concentrations of indicators derived from indigenous sources (e.g., deer, birds) may be more acceptable than sources of domestic origin (e.g., cattle, poultry). The public may wish to make an informed decision about usage relative to specific pathogens such as enterohemorrhagic *E. coli* (EHEC) that are potentially associated with agricultural land usage.
3. Determine under what conditions a sanitary investigation would be sufficient (as opposed to microbial source tracking). This research is most important if the WHO and EU approaches are being considered.
4. Identify minimum elements that a sanitary investigation should include. Again, the focus should be on the minimum elements necessary for a reliable sanitary investigation. If the requirements for a sanitary investigation are too onerous, they will become resource-prohibitive and of minimal value. Assess the reliability, accuracy, and validity (etc.) of the various types of sanitary investigations. Without some sort of standardized investigation criteria, inconsistencies will result in the implementation of the criteria and create potential variances in health risk levels at beaches.
5. Predictive modeling offers the prospect of benefits to beach management that are sufficiently significant such that it should be explored further. An identification of data needs is required for such models. For water quality notification purposes, models should be developed and calibrated to assure a minimum confidence level.

NPDES

1. Conduct studies to develop a methodology to compare the correlation of the culture-based methods and the qPCR (molecular-based) method. Identify how or where the same level of protection can be provided, even if implementation is different. Any requirement to use non culture-based methods may have significant impacts on NPDES permit monitoring programs. Non culture-based methods may not adequately assess treatment processes or determine permit compliance.

2. Develop an improved understanding of disinfection using the different indicators. Determine how well each indicator is in measuring disinfection effectiveness, including determination of the viability of the organisms (pathogens and indicators) following various disinfection processes (e.g., chlorination, UV light).
3. Determine risks of exposure from intermittent microbial pollution discharges, CSOs, urban runoff, and concentrated animal feeding operations (CAFOs).
4. Evaluate the effectiveness and cost of stormwater and agricultural BMPs as related to pathogens and microbial contaminants. This evaluation should be made in concert with epidemiological studies/QMRA analyses that will determine the risk from different types of sources (urban and agricultural runoff, indigenous and domestic animals, regrowth).
5. Evaluate the efficacy, costs, and benefits of disinfection for the purposes of supporting eventual promulgation of a disinfection rule. It is anticipated that disinfection could eventually be promulgated as a mandatory treatment technology nationwide as it already is in many States. Specifically, research is needed to support levels of disinfection necessary to provide adequate pathogen reduction/inactivation.

Use Attainment

1. Research to determine the risk from different types of nonhuman sources of fecal contamination (e.g., domestic and indigenous) is needed to better quantify the risk from nonhuman sources so that when implemented at recreational waters, those risks are better accounted for.
2. Develop criteria or methodologies that more precisely define the health risk associated with pathogen exposure in recreational waters.

Overall

1. Conduct research so that monitoring using indicators can help to distinguish human from nonhuman sources of fecal contamination.
2. Conduct epidemiological/QMRA studies on flowing recreational waters. Current (1986) criteria were based on epidemiological studies conducted in relatively static waterbodies. Additional studies are needed to assess risks in flowing waters. This has significant implications for criteria development for inland U.S. waterways.
3. Need to better understand the health-basis for allowable exceedance frequency. Additional explanation is needed to justify percentile criteria differences between WHO, EU, and EPA (1986) criteria development approaches (e.g., use of 95^{th} or 90^{th} percentile).
4. Conduct research to better understand how to measure the impact of regrowth and persistence in sediments of indicator bacteria on water quality. The source of some problems of high pathogen indicator levels may at times be due to regrowth rather than urban runoff, animals, birds, biofilms, ocean circulation, etc.

7.3.2 Long-term (Beyond 3 Years)

NPDES

- Develop a viability assay for the viral and protozoan portion of effluent.

Overall

- Develop methodologies that are pathogen-specific.

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APPENDIX A: CHARGE TO THE EXPERT WORKGROUP MEMBERS

PURPOSE

The purpose of the Pellston-type[1] Experts Scientific Workshop on Critical Research and Science Needs for the Development of Recreational Water Quality Criteria is for EPA to obtain individual input from members of the broad scientific and technical community on the "critical path" research and science needs for developing scientifically defensible new or revised Clean Water Act (CWA) §304(a) recreational water quality criteria in the near-term.[2]

BACKGROUND

An important goal of the CWA is to protect and restore waters for swimming. Section 304(a) of the Act directs EPA to publish "advisory water quality guidance on the effects of the presence of pollutants in water on health and welfare." These recommendations are referred to as §304(a) criteria. Under §304(a)(9) of the CWA, EPA is required to publish water quality criteria for pathogens and pathogen indicators to protect swimmers from illnesses associated with pathogenic microbes in coastal and Great Lakes waterbodies.

In adopting new or revised water quality standards, States must adopt criteria that are scientifically defensible and protective of the use, but they have flexibility to do so by adopting EPA's recommended criteria, adopting criteria to reflect site-specific conditions, or adopting other criteria that are scientifically defensible. In the case of criteria EPA publishes under §304(a)(9), States with coastal and Great Lakes waters are required to adopt EPA's new or revised criteria for pathogens and pathogen indicators into State Water Quality Standards (WQS).

Once adopted into State WQS, water quality criteria express the desired ambient condition of the water to protect a designated use. State WQS are used for various CWA purposes or programs that identify and address the sources of pollution with the goal of attainment of the criteria, including National Pollutant Discharge Elimination System (NPDES) permits, water body assessments to determine use attainment, and development of Total Maximum Daily Loads (TMDLs). In addition, these WQS used by States in beach monitoring and water quality notification programs.

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[1] A workshop similar in organization and format to the Society of Environmental Toxicology and Chemistry (SETAC) Pellston Workshops where technical experts in a particular subject area are invited to participate and evaluate current and prospective environmental issues. A Pellston-type workshop brings together between 40 to 50 technical experts from academia, business, government, and public interest groups. Experts are sequestered for a week and expected to contribute to a summary report. Subject leaders are then responsible for consolidating, editing, producing, and distributing the workshop proceedings.

[2] Near-term requirements: in order for EPA to develop criteria in the near-term, the indicators/methods/tools upon which they are based must be currently available, have undergone scientific peer review and validation, and ready for day-to-day implementation in State public health/environmental laboratories within the next 2 to 3 years. New or revised criteria must be based on indicator/methods that are easy to use and interpret.

Historically, EPA's recommended criteria for protecting people who recreate in water have been based on fecal matter in recreational waters. In the 1960s, the federal government recommended using the indicator bacteria, fecal coliforms, as the primary contact recreational[3] criterion. In the late 1970s and early 1980s, EPA conducted public health studies evaluating several organisms as possible indicators, including fecal coliforms, *E. coli*, and enterococci. The studies showed that enterococci are a good predictor of gastrointestinal (GI) illnesses in fresh and marine recreational waters, and *E. coli* is a good predictor of GI illnesses in fresh waters. As a result, EPA published in 1986 revised criteria (*EPA's Ambient Water Quality Criteria for Bacteria – 1986*[4]*)* for primary contact recreation recommending the use of *E. coli* for fresh recreational waters (criteria set as a geometric mean of 126 colony forming units [cfu]/100 mL) and enterococci for fresh and marine recreation waters (criteria set as geometric means of 33/100 mL in freshwater and 35 cfu/100 mL in marine water). These recommendations replaced EPA's previously recommended bacteria criteria for fecal coliforms of 200 cfu/100 mL. EPA's criteria recommendations use "indicator" bacteria. Most strains of *E. coli* and all enterococci do not cause human illness (that is, they are not human pathogens); rather, they merely indicate fecal contamination, and the assumption is that pathogens co-occur with incidences of fecal contamination.

Since EPA issued its recreational criteria over 20 years ago, there have been significant scientific advances, particularly in the areas of molecular biology, microbiology, and analytical chemistry. EPA believes that these new scientific and technical advances need to be factored into the development of new or revised CWA §304(a) criteria for recreation. To this end, EPA has been conducting research and assessing relevant scientific and technical information to provide the scientific foundation for the development of new or revised criteria. The enactment of the Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 (which amended the CWA) required EPA to conduct new studies and issue new or revised criteria, specifically for Great Lakes and coastal marine waters.

OVERALL CHARGE TO THE EXPERTS

Experts are asked to provide their individual knowledge and insight that will help EPA define the critical path research and science needs, recognizing the "state of the science" and the reality that research that cannot be completed within 2 to 3 years will not be helpful in EPA's near-term criteria development efforts. Experts should focus their efforts at this Workshop on identifying near-term research and science needs that will allow EPA to publish new or revised criteria in roughly 5 years. (While EPA understands that experts may wish to offer perspectives on research and science needs for the development of future or "next generation" criteria, this is not the primary purpose of this Workshop.) "Next generation" criteria refer to criteria EPA may publish in the longer term; that is, in approximately 10 to 15 years, pursuant to CWA §304(a)(9)(B). Section 304(a)(9)(B) directs EPA to review and, as necessary, revise the §304(a)(9) criteria 5 years after EPA publishes the initial criteria, and every 5 years thereafter.)

[3] Primary contact recreation includes activities that could be expected to result in ingestion of water or immersion. These activities include swimming, water skiing, surfing, and other activities where contact and immersion in water is likely.

[4] US EPA. 1986. *Ambient Water Quality Criteria for Bacteria - 1986*. EPA440/5-84-002. Washington, DC: US EPA.

Although not the focus of this Workshop, EPA is aware of stakeholder concerns regarding implementation issues associated with the existing (EPA) 1986 criteria and the desire on the part of some stakeholders for EPA to address these issues in the interim (i.e., before EPA publishes a new or revised recommended criteria). In recognition of these concerns, experts in the "Implementation Realities" Workgroup are encouraged to identify aspects of the 1986 criteria which have been cited as problematic, and, to the extent that these issues can be remedied through new or revised criteria, offer individual input for EPA to consider in the criteria development efforts.[5]

The new or revised criteria must be scientifically sound, protective of the designated use, implementable for broad CWA purposes, and when implemented, provide for improved public health protection. By scientifically sound, EPA means that the criteria must be based on the science and peer reviewed studies available at the time the criteria are developed. By protective of the use EPA means that the criteria must establish the desired ambient condition of the water to protect the designated use (e.g., primary contact recreation) given to the waterbody. EPA's new or revised criteria must also serve the broad purposes for which CWA criteria are intended, including beach monitoring and water quality notification programs, development of water quality based effluent limits for National Pollutant Discharge Elimination System (NPDES) permits, waterbody assessments to determine use attainment, and development of total maximum daily loads (TMDLs), where needed. Lastly, the new or revised criteria, when implemented, should also provide for improved public health protection and States must be satisfied that the underlying science is sound and that the numeric values of allowed pollutant in recreational waters will achieve the desired environmental result.

On the last day of the Workshop, the chairs for the individual breakout topic groups will provide EPA with sections of a draft Expert Report. Each of these sections will summarize the individual input provided by the experts and collected by the Chairs throughout the week's discussions. The Chairs will be asked to summarize commonalities and differences in the input provided by participants, and list out the projects and activities that the individual experts identified as critical to the development of new or revised CWA §304(a) criteria in the near-term, recognizing that research that cannot be completed in 2 to 3 years will not be useful in near-term criteria development efforts. (The workgroup chairs may also summarize any research and science needs identified by the experts for developing "next generation" criteria.)

The draft Report will include a summary of expert views on the following topics: appropriate pathogens or pathogen indicators, along with available and appropriate methods; single versus "toolbox" criteria approach; implementation issues; and most importantly, identification of critical technical issues and uncertainties that could be addressed with near-term research.

EPA contractual support will be available to the Chairs during the workshop to provide assistance in preparing the draft Report. After the workshop, EPA contractual support will be available to the Chairs to finalize their component of the Report in 1-month's time. EPA will use

[5] To the extent that experts come to some conclusion on how to better implement the 1986 criteria, EPA intends to track these issues separately in order to not depart from the primary purpose of the meeting which is to obtain input on critical research needs for the development of the near-term criteria.

the Report as it develops a critical path science plan that will guide research activities over the next 2 to 3 years.

Presented in the following sections of this document are key questions on seven major overarching issues pertaining to criteria development and implementation. A threshold issue that impacts the deliberations of all groups is whether EPA should consider a fundamental change in its approach to recommending recreational criteria; for example, switch from a single criterion in all places to a diversified toolbox or tiered approach, using multiple criteria, or several tools supporting a single criterion, or some other combination.

Break-Out Group #1: Approaches to Criteria Development (See Chapter 1)[6]

Single versus "Toolbox" Approach: A single criterion and/or method may not adequately address all CWA needs. One approach for new or revised criteria may consist of several "tools" (i.e., indicators, methods, intrinsic geographic factors, etc.) to fulfill all of the specific CWA needs. For example, it could involve using molecular methods and rainfall models for beach monitoring and water quality notification, and possibly other method-indicator combinations for other CWA uses—provided that all criteria and methods are comparable in terms of level of protection provided. For example, the definition of an impaired recreational water in terms of the number of people that would get sick when the water is not in compliance cannot differ from the illness rate that triggers a beach advisory or closing.

The following set of questions is intended to guide a robust discussion among the experts in this group. The results of this discussion will improve the understanding of the advantages and disadvantages of various approaches to criteria development.

1. *What approaches exist currently for setting limits of pollutants that may be relevant for developing nationally recommended recreational water quality criteria? Consider approaches used for other kinds of pollutants in water, in other environmental media, and by other countries as well as approaches being implemented by States. What are the pros and cons of each of these approaches?*
2. *Which of these approaches is most applicable and appropriate for developing nationally recommended recreational water quality criteria in the near-term? Why is this approach on balance considered the most applicable and appropriate?*
3. *For those approaches identified as applicable and appropriate, what is the science that supports the approach? Is that science sufficient and of adequate quality?*
4. *Are there any critical research and science needs that should be addressed in developing or selecting an appropriate approach? Can this research be completed in time to be used in criteria development in the near-term?*
5. *Is a "toolbox" approach appropriate for developing new or revised recreational criteria in the near-term? Why or why not?*
6. *What are the pros and cons of selecting a "toolbox" approach?*

[6] Because breakout group numbers do not correspond to chapter numbers in these proceedings, chapter numbers are referred to for easier reference.

7. *What are desired features or characteristics that would make a "toolbox" approach appropriate?*
8. *Would a "toolbox" approach achieve additional public health protection as compared to another approach? Why or why not? If unknown, what science would need to be completed in order to determine whether a "toolbox" approach would achieve additional public health protection?*
9. *Criteria for secondary contact recreation could be part of a "toolbox." What approaches would be appropriate for developing criteria for secondary contact recreation? Would this approach be different from that used to develop primary contact recreation criteria? Why and why not?*
10. *What are critical research and science needs in developing or selecting an appropriate approach for secondary contact recreation? Can this research be completed in time to be used in criteria development in the near term?*
11. *What are the implementation considerations of the different approaches for CWA purposes (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs? Are there practical considerations that could preclude, or greatly limit, the use of an approach in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?*

Geographical Applicability: Options for ensuring criteria are appropriate in a diverse range of recreational waters include EPA recommending geographically different approaches, numbers, or indicators, applicable to different regions (e.g., fresh and marine waters, coastal and inland waters, tropical/subtropical and temperate waters) or types of waterbodies (e.g., lakes and flowing waters).

1. *Is a single criterion available that is applicable for the diverse range of geographic conditions? Why or why not?*
2. *Is a "toolbox" approach appropriate for different geographical conditions? Why and why not?*
3. *What would a "toolbox" that addresses geographical differences look like?*
4. *What are critical research and science needs in developing or selecting an approach that will appropriately factor-in diverse geographical conditions?*

Expression of Criteria: EPA is currently assessing the degree to which criteria should be expressed as the mean concentration over a period of time (e.g., 30 days) and/or as a daily or instantaneous maximum value.

1. *Given the diverse needs of the CWA programs and the overarching goal of protecting and restoring waters for swimming, what protection is provided by establishing a 30-day "average" value as the criteria? What additional protection (if any) is provided by a daily or instantaneous maximum value? From a scientific standpoint, is one measure better scientifically than another for particular purposes (e.g., mean value for purposes of identifying impaired waters and daily maximum for beach monitoring and notification purposes)? Why?*

2. *What are pros and cons of expressing the criteria differently for the various CWA program needs?*
3. *What are the implications of instantaneous or daily values for public health protection? If we don't currently have a good understanding of this, what are the critical research and science needs to answer these questions?*
4. *If EPA were to set criteria at a mean concentration over 30 days and not recommend a single sample maximum, do we understand the illnesses that could occur on a single day (where the level would still lead to compliance with the 30 day average)?*
5. *If the science is not there, what are the critical research and science needs to answer this question?*
6. *What are the implementation considerations for CWA purposes of failing to address (and addressing) differences geographically in the criteria and failing to include (and including) a single sample maximum value for (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs? Are there practical considerations that could preclude, or greatly limit, the usage in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?*

<u>Break-Out Group #2: Implementation Realities (See Chapter 7)</u>

Although EPA wants the experts to consider implementation realities when providing input to all general and specific questions throughout this document, the following set of questions are intended to guide a robust discussion among the experts about implementation issues and how science and research could ease implementation.

1. *What are the essential implementation considerations as EPA develops new nationally recommended recreational water quality criteria for CWA purposes: (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs?*
2. *What are the major lessons learned in implementing the (EPA) 1986 criteria? What worked well and not so well? How could we avoid repeating past "mistakes" that lead to delays in adoption or difficulties in implementing these criteria?*
3. *Which approaches to criteria development have the most potential for success in implementation when new or revised criteria are adopted into State water quality standards? Why?*
4. *What are general features or characteristics that would make new or revised criteria easy to interpret and implement for states when adopted into State water quality standards? Why?*
5. *Would a "toolbox" approach be easier or more difficult to interpret and implement? What are desirable characteristics of a "toolbox" criterion from an implementation perspective?*
6. *If new or revised criteria are provided as a range of values instead of a single value, what implementation concerns are triggered (e.g., can a range of values be used when developing NPDES permit limits or TMDL calculations)?*

7. *What are critical path research and science needs that would enhance implementation of new or revised criteria in the near-term?*

Break-Out Group #3: Pathogens, Pathogen Indicators,[7] and Indicators of Fecal Contamination (See Chapter 2)

Indicator Approach: EPA previously developed criteria based on indicators of the potential presence of human pathogenic organisms; that is, based on indicators of fecal contamination. Other possible approaches such as pathogen index microorganisms and specific pathogens are discussed below.

The following set of questions is intended to guide a robust discussion among the experts toward the identification of critical research and science needs in the development of criteria based on pathogens, pathogen indicators or indicators of fecal contamination. It is essential that this group focus discussions on only those pathogens, pathogen indicators or indicators of fecal contamination where methods are ready now for day-to-day use in State public health and environmental labs or where methods will be ready for day-to-day use in these labs within the next 3 years.

A. Fecal matter indicators (as surrogates for gastrointestinal and non-gastrointestinal diseases):

1. *What are the benefits and shortcomings for continuing to implement the current fecal indicators (*E. coli *and enterococci) to meet each of the CWA §304(a) criteria uses (beach notification, TMDLs, NPDES permits, listing of impaired waters) to protect swimmers health from (a) gastrointestinal disease? (b) upper respiratory tract disease? (c) other diseases (skin, ear, eye disease)? Should other CWA §304(a) uses be tied to health outcomes?*
2. *Are there other microbial fecal indicator(s) that can be used to better meet each of the CWA §304(a) criteria uses and provide improved protection against diseases (e.g.,* Bacteroides *spp.,* Clostridium perfringens, *coliphages or other phages)? Why?*
3. *Are there any chemical biomarker fecal indicators (e.g., fecal stanols, detergents, whiteners, caffeine) that can be used to better protect public health and meet all CWA purposes than the current indicators of fecal contamination?*
4. *What critical research would improve or widen the selection of fecal indicators available for the criteria?*

B. Pathogens and their Index organisms (gastrointestinal and non-gastrointestinal disease):

1. *Would a specific pathogen or index microorganism approach present an improvement in health protection over fecal indicators for each CWA use if applied as §304(a) criteria? If yes, then see question #2. If no, what research could be done to support this*

[7] A specific pathogen belonging to a broader group of pathogens which would serve as a surrogate for the presence and/or health risks for that group (e.g., *Cryptosporidium* serving as a surrogate for all parasitic protozoa); or an indicator microorganism whose presence is correlated to the presence of a broad group of pathogens (e.g., spores of *Clostridium perfringens* serving as a surrogate for human or dog parasitic protozoa).

approach? (also for skin, upper respiratory tract, ear, eye disease criteria considerations)

2. *What are the advantages and disadvantages of this approach?*
3. *What might be the most appropriate pathogens or index organisms? Why?*
4. *What data support a dose-response relationship between a particular pathogen or its index in recreational water and any disease outcome?*
5. *The BEACH Act requires that EPA conduct research and develop new or revised water quality criteria for "Pathogens and Pathogen Indicators." The Act defines a pathogen indicator as a substance that indicates the potential for human infectious disease. How might the term "index microorganism" relate to the statutory term pathogen indicator?*
6. *What is the critical research to make the selection of pathogen/ index organisms available for the new or revised criteria and for the next generation criteria?*

Application of Alternatives: The following two sections present some possible applications of a mix of approaches that may increase the potential to improve monitoring, better express health risks from swimming exposures, and be more comprehensive in their use to meet all criteria needs and provide more efficient and cost effective procedures.

C. Application of fecal indicators, pathogen index organisms, and pathogens in combination for criteria:

1. *If none of the above three groups of surrogates can meet all CWA §304(a) criteria needs, is there any combination of the three that would provide an acceptable criteria approach?*
2. *What specific combined applications would have merit in meeting criteria needs?*
3. *Would the combined applications best utilize an analytical toolbox approach or a tiered analytical approach?*
4. *Would the criteria endpoint reflect a general gastrointestinal disease target or a dose response estimate base on more limited disease symptoms reflecting the metrics used?*
5. *What research is important to make the selection of combinations available for the new or revised criteria and the next generation criteria?*
6. *Can adoption of the WHO/Annapolis Protocol approach[8] that combines sanitary reconnaissance survey information along with microbial assessment to develop surrogates of fecal contamination (predictive modeling) on the day to manage water advisories provide improved health gains over current criteria? Are there sufficient examples of this approach to develop new/improved use of indicators/surrogates in the near term?*

[8] WHO (World Health Organization). 2003. *Guidelines for Safe Recreational Water Environments. Volume 1 Coastal and Fresh Waters*. Geneva, Switzerland: WHO.

D. Applications of all the above for all categories of waters, climatology, and geographical considerations:

1. *Will the choices of individual, combined, or tiered fecal indicators, index organisms or pathogen indicators, or pathogens selected from above be capable of working for each or all of the following:*
   a) *Freshwaters (flowing and lakes/ponds)? Marine waters? POTWs? TMDLs?*
   b) *Temperate waters? Tropical waters?*
   c) *High matrix waters (high in solids)? Special conditions?*
2. *What science or research is important in the near term to make the determination in Question D1?*

Break-Out Group #4: Methods Development (See Chapter 3)

The 1986 criteria are based on a culture method (EPA Method 1600) for the detection of fecal indicators in ambient waters. The Agency has been considering the use of newer methods, such as qPCR and faster culture-based methods, for inclusion in new or revised criteria. EPA is interested in input on what other methods or tools are available and should be considered for developing criteria/standards that would meet all CWA purposes.

The following set of questions is intended to guide a robust discussion among the experts toward the identification of critical research and science needs in the development of detection methods for the new criteria. It is essential that this group focus discussions on those methods (and pathogens, pathogen indicators or indicators of fecal contamination) that are ready now for day-to-day use in State public health and environmental labs or would be ready for day-to-day use in these labs within the next 3 years.

1. *Are there quantitative methods other than membrane-filtration/Most Probable Number (MF/MPN) methods that measure active organisms that EPA should consider for water quality criteria development?*
2. *Are there data to support other molecular methods for beach microbiological monitoring purposes? Which molecular methods are most fully developed in your view?*
3. *Are there data to support other methods targeting non-microbiological surrogates of beach fecal pollution? Which methods are most fully developed in your view?*
4. *How important is time-to-results in method selection from the perspective of public health protection?*
5. *What further work needs to be done to ensure that the qPCR method or other promising (molecular) methods are considered valid for all CWA purposes?*
6. *What are the pros and cons of the use of molecular methods in each of the CWA applications?*
7. *If some tools are available for certain CWA uses only (e.g., for beach monitoring and notification) how could other methods be "linked" to the qPCR method so that they are scientifically sound and easily implementable? If only qPCR has been validated through epidemiological studies to predict health effects, what other studies could be done to link qPCR to other methods/indicators that may be more appropriate for §304(a) uses?*

8. *Depending on the method used, how could contamination at the beach be linked to all potential fecal sources of contamination? If the source of the contamination was a treated point source, could the method be linked to the necessary source to address the contamination?*
9. *Current culture-dependent methods and qPCR are linked to health risks using epidemiological studies. How would future methods (resulting from rapid technical advances) be calibrated to health risks without new epidemiological studies?*
10. *What applications of water quality criteria would culture methods, including EPA Methods 1600 and 1603, be most suitable for and why?*
11. *What further work needs to be done to ensure that other culture methods are considered for CWA regulatory purposes? If the science is not there, what are the critical path science or research needs to be used in this aspect of criteria development in the near-term?*
12. *What new methods and analytical technologies may be useful to begin to investigate in order for these to potentially be available in the development of "next generation" criteria (i.e., 10 or more years in the future)?*
13. *Can other tools (e.g., models, sanitary surveys) be developed to enhance the insight provided by water quality indicators?*
14. *What characteristics of analytical methods are essential for the methods used in both wastewater and ambient water?*
15. *What are implementation considerations for CWA purposes (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs? Are there practical considerations that could preclude, or greatly limit, the usage in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?*

<u>Break-Out Group #5: Comparing Risks (to Humans) from Different Sources (See Chapter 4)</u>

New or revised criteria should be protective of waterborne organisms that are pathogenic to humans whether the source is human waste or animal waste. The following set of questions is intended to guide a robust discussion among the experts toward the identification of critical research and science needs to better understand the relationship between the risks posed by exposure to human and animal wastes in recreational waters so that this may be considered in the development of new criteria.

1. *Is setting criteria based on a treated human point source such as a publicly (or privately) owned (sewage/wastewater) treatment work (POTW) protective, under-protective or overprotective of other potential sources of human pathogen? Why or why not? Are there data to support this conclusion?*
2. *Based on the "state of the science," what conclusions or assumptions are reasonable to make about risks to humans exposed to human fecal contamination, non-point source contamination from animal sources, and mixed sources (e.g., combined sewer overflows and storm sewer overflows)?*

3. *To what extent is it reasonable to apply risk estimates from POTW-influenced beaches to non-POTW beaches? Do we understand scientifically whether this would lead to overprotection? What science would be important to understanding this?*
4. *Assess whether there is a possibility of overprotection due to a compounding of risks from multiple factors (such as the current definition of GI illness [i.e., no fever]; more sensitive molecular methods; assuming that POTW risks = non-human source risks, etc.)*
5. *How should EPA evaluate risk that may have a low probability of occurrence but a significant risk, if it occurs?*
6. *What are the key data gaps and uncertainties needed to support criteria development in the near term?*

<u>Break-Out Group #6: Acceptable Risk (See Chapter 5)</u>

Population to be Protected: EPA is currently reassessing the extent to which criteria protect swimming populations, including some vulnerable subpopulations (e.g., immunocompromised individuals, elderly, and children) against various types of waterborne diseases (GI and non-GI) caused by pathogens.

The following set of questions is intended to guide a robust discussion among the experts toward the identification of critical research and science needs to better understand what protections new criteria would provide and for what populations/subpopulations.

1. *Is the science there now to understand the degree and extent of protection that nationally recommended criteria for the general population would provide to vulnerable subpopulations (e.g., immunocompromised individuals, elderly, and children)? Is the science there now to understand whether nationally recommended criteria (based on the types of epidemiological studies EPA and others have conducted to date) provide protection against all types of major waterborne diseases? If not, for which subgroups, pathogens, and waterborne illnesses is the science lacking? What types of studies would be needed to answer these types of questions about the degree of public health protection provided by nationally recommended criteria?*
2. *What methodologies or approaches for assessing human health risk or hazard should EPA consider as it develops new criteria? Why?*
3. *What are the pros and cons of using GI illness rates associated with differing levels of fecal contamination as the foundation for developing nationally recommended criteria?*
4. *Is there any scientifically-based reason to establish different "acceptable" risk levels for fresh water versus marine water?*
5. *Is the phrase "acceptable risk" from the (US EPA) 1986 criteria the best terminology or should we consider other terminology (e.g., tolerable or appropriate risk level)?*
6. *What science, if any, would be helpful to EPA in making decisions about what amount and type of human illness from recreation should be considered acceptable?*
7. *What is the level of human health protection provided by the implementation of the 1986 criteria? Is it really no more than 8 to 10 GI illnesses (with fever) per 1,000 in fresh water and 19 GI illnesses (with fever) per 1,000 in marine waters, or, are we really*

protecting people from more than GI illness (with fever)? What science is needed to understand what protection is provided by the implementation of the 1986 criteria?

Protection of Humans from Drinking Water and Fish and Shellfish Consumption: EPA is currently assessing the degree to which recreational criteria can and should be developed to not only protect people from illnesses associated with recreation, but also to protect people from illness caused by drinking contaminated recreational water or consuming fish and shellfish found in contaminated recreational water.

1. *Will criteria that protect swimmers from swimming-related illnesses caused by pathogens also protect people who drink the water or eat fish or shellfish from the same water? Is the science sufficient to support a determination that recreational criteria will also protect drinking water uses and shellfish uses?*
2. *What additional science is needed to ensure that recreational criteria protect people from illnesses associated with recreation and also protect people from illnesses caused by drinking contaminated recreational water or consuming fish and shellfish found in contaminated recreational water?*
3. *Is the science there now to understand and characterize the degree of protectiveness for all these elements?*
4. *If the science is not there, what are the critical path science or research needs to address this?*

<u>Break-Out Group #7: Modeling Applications for Criteria Development and Implementation (See Chapter 6)</u>

Predictive modeling may be useful as a tool to help with the development of site-specific recreational water quality criteria, and the implementation of criteria. Presently, EPA is not considering models in its plans for new or revised criteria in the near-term. However, in recognition that some states and municipalities currently use models effectively in beach notification programs, EPA solicits input from experts regarding the potential use of models as tools to aide implementation of the new or revised criteria, and further requests input on critical research and science needs in this area for future criteria development.

1. *What potential role could estimating techniques (or models) play in criteria development? In the setting of site-specific criteria for recreational waters?*
2. *What potential role could estimating techniques (or models) play in implementing nationally recommended criteria for recreational waters?*
3. *What are advantages and disadvantages of using models, instead of direct measurement (monitoring), in water quality management? And in particular, in management of recreational waters?*
4. *What factors should be considered in integrating modeling with current monitoring regimes, or in changing monitoring regimes to include or support modeling?*
5. *What is the "state of the science" in modeling to support recreational water quality criteria development and implementation?*

6. *What model evaluation procedures are used to insure the quality of predictive models for recreational water quality?*
7. *How does uncertainty in modeling compare to uncertainty in monitoring? How can uncertainty be accurately represented and considered in risk analysis and public health decisions?*
8. *Do differences in the nature of the respective uncertainties inherent in modeling versus monitoring require different means of addressing these uncertainties? For instance, issue an advisory on the basis of modeled results, but clear the advisory only on the basis of sampling.*
8. *What models would be most useful for certain "uses" of criteria (i.e., beach notification, assessment, permitting, TMDLs)? How would modeling be used together with monitoring to cover all "uses" of criteria?*
9. *In models that are currently being used to predict levels of indicator bacteria, how are advisory/closure decisions being made using model results, and how are the results and/or the risk being communicated to the public? Do paradigms currently exist that would be applicable to the communication of modeled information on likely water quality?*
10. *Given the differences between fresh water and marine water environments in terms of physical predictive factors, what are the respective challenges of the two environments relative to developing predictive models? What are the differences in data requirements, likely effectiveness of models, and resources required to develop and implement useful models for the full range of intended purposes?*
11. *What are the critical path research and science needs EPA should pursue to further enhance the capabilities and effectiveness of models in the development/implementation of new or revised criteria? Why?*
12. *What critical path research and science needs EPA should pursue to consider modeling in the development of next generation criteria? Why?*

APPENDIX B: PARTICIPANT LIST

Experts by Workgroup

Approaches to Criteria Development

Joel Hansel, Chair
Mark Gold
David Kay
John Ravenscroft
William Robertson
Jeffrey Soller
David Whiting

Pathogens, Pathogen Indicators, and Indicators of Fecal Contamination

Nicholas Ashbolt, Chair
Roger Fujioka
Toni Glymph
Charles McGee
Stephen Schaub
Mark Sobsey
Gary Toranzos

Comparing Risk (to Humans) from Different Sources

Dennis Juranek, Chair
Rebecca Calderon
Jack Colford
Elizabeth Doyle
Graham McBride
Samuel Myoda

Modeling Applications to Bacteria Criteria Development and Implementation

Alexandria Boehm, Chair
Donna Francy
Mark Pfister
John Wathen
Richard Zepp

Implementation Realities

Lee Dunbar, Chair
Thomas Atherholt
Bart Bibler
Lawrence Honeybourne
Charles Noss
James Pendergast
Michael Tate

Methods Development

Stephen Weisberg, Chair
Alfred Dufour
Charles Hagedorn
Sharon Kluender
Erin Lipp
Robin Oshiro

Acceptable Risk

Paul Hunter, Chair
Michael Beach
Lora Fleming
Peter Teunis
Timothy Wade

Contact Information – Experts (Alphabetical)

Nicholas Ashbolt (Chair)
USEPA
513-569-7303
Ashbolt.Nick@epa.gov

Thomas Atherholt
New Jersey Department of Environmental Protection
609-984-2212
tom.atherholt@dep.state.nj.us

Michael Beach
Centers for Disease Control and Prevention
770-488-7763
mjb3@cdc.gov

Bart Bibler
Florida Department of Health
850-245-4240
Bart_Bibler@doh.state.fl.us

Alexandria Boehm (Chair)
Stanford University, California
650-724-9128
aboehm@stanford.edu

Rebecca L. Calderon
USEPA
919-966-0617
calderon.rebecca@epa.gov

Jack Colford
University of California, Berkeley
510-642-9370
jcolford@berkeley.edu

Elizabeth Doyle
USEPA
202-566-0056
doyle.elizabeth@epa.gov

Alfred Dufour
USEPA
513-569-7330
dufour.alfred@epa.gov

Lee Dunbar (Chair)
Connecticut Department of Environmental Protection
860-424-3731
lee.dunbar@po.state.ct.us

Lora Fleming
Departments of Epidemiology and Public Health and Marine Biology and Fisheries, University of Miami School of Medicine and Rosenstiel School of Marine and Atmospheric Sciences, Florida
305-243-5912
LFleming@med.miami.edu

Donna Francy
U.S. Geological Survey
614-430-7769
dsfrancy@usgs.gov

Roger Fujioka
University of Hawaii, Manoa
808-956-3096
roger@hawaii.edu

Mark Gold
Heal the Bay, Santa Monica, California
310-451-1500
mgold@HealTheBay.org

Toni Glymph
Wisconsin Department of Natural Resources
608-264-8954
Toni.Glymph@Wisconsin.gov

Charles Hagedorn
Virginia Tech
540-231-4895
chagedor@vt.edu

Joel Hansel (Chair)
USEPA
404-562-9274
hansel.joel@epa.gov

Lawrence Honeybourne
Orange County Health Care Agency,
Santa Ana, California
714-433-6015
lhoneybourne@ochca.com

Paul Hunter (Chair)
University of East Anglia, U.K.
+ 44 1603 591004 / 593061
Paul.Hunter@uea.ac.uk

Dennis Juranek (Chair)
Centers for Disease Control and
Prevention (retired)
770-457-2056
ddjuranek@comcast.net

David Kay
University of Wales, U.K.
+44 1570 423565
dvk@aber.ac.uk

Sharon Kluender
Wisconsin State Laboratory of Hygiene
608-224-6262
hesk@mail.slh.wisc.edu

Erin Lipp
University of Georgia
706-583-8138
elipp@uga.edu

Graham McBride
National Institute of Water and
Atmospheric Research, New Zealand
+64 7 8560726
g.mcbride@niwa.co.nz

Charles McGee
Orange County Sanitation District,
California
714-593-7504
CMCGEE@OCSD.COM

Samuel Myoda
Delaware Department of Natural Resources
& Environmental Control
302-739-9939
Samuel.Myoda@state.de.us

Charles Noss
USEPA
919-541-1322
noss.charles@epa.gov

Robin Oshiro
USEPA
202-566-1075
oshiro.robin@epa.gov

James Pendergast
USEPA
202-566-0398
pendergast.jim@epa.gov

Mark Pfister
Lake County Health Department, Illinois
847-377-8028
MPfister@co.lake.il.us

John Ravenscroft
USEPA
202-566-1101
ravenscroft.john@epa.gov

William Robertson
Water, Air and Climate Change Bureau,
Health Canada
613-957-1505
Will_Robertson@hc-sc.gc.ca

Stephen Schaub
USEPA
202-566-1126
schaub.stephen@epa.gov

Mark Sobsey
University of North Carolina, Chapel Hill
919-966-7303
sobsey@email.unc.edu

Jeffrey Soller
Soller Environmental, Berkeley, California
510-847-0474
jsoller@sollerenvironmental.com

Michael B. Tate
Kansas Department of Health and
Environment
785-296-5504
MTate@kdhe.state.ks.us

Peter Teunis
RIVM (National Institute of Public Health
and the Environment), Netherlands
+31 30 274 2937
Peter.Teunis@rivm.nl

Gary Toranzos
University of Puerto Rico, Rio Piedras
787-773-1743
gatoranzos@uprrp.edu

Timothy Wade
USEPA
919-966-8900
wade.tim@epa.gov

John Wathen
USEPA
202-566-0367
wathen.john@epa.gov

Stephen Weisberg (Chair)
Southern California Coastal Water Research
Project
714-755-3203
stevew@sccwrp.org

David Whiting
Florida Department of Environmental
Protection
850-245-8191
David.D.Whiting@dep.state.fl.us

Richard Zepp
USEPA
706-355-8117
zepp.richard@epa.gov

Contact Information – EPA Resource Personnel (Alphabetical)

Shari Barash
202-566-0996
barash.shari@epa.gov

Samantha Fontenelle
202-566-2083
fontenelle.samantha@epa.gov

Patricia Harrigan
202-566-1666
harrigan.patricia@epa.gov

Rick Hoffmann
202-566-0388
hoffmann.rick@epa.gov

Denise Keehner (Workshop Chair)
202-566-1566
keehner.denise@epa.gov

Beth Leamond
202-566-0444
leamond.beth@epa.gov

Kevin Oshima
513-569-7476
oshima.kevin@epa.gov

Cynthia Roberts
202-564-1999
roberts.cindy@epa.gov

Grace Robiou
202-566-2975
robiou.grace@epa.gov

Lauren Wisniewski
202-566-0394
wisniewski.lauren@epa.gov

Contact Information – Support Personnel (Alphabetical)

Note Takers

Alexis Castrovinci
ICF International
703-934-3313
acastrovinci@icfi.com

Kristine Cornils (Implementation Realities)
ICF International
(202) 257-4591
kcornils@icfi.com

Mark Gibson
ICF International
703-934-3242
mgibson@icfi.com

Audrey Ichida
ICF International
703-934-3154
michida@icfi.com

Rebecca Kauffman
ICF International
781-676-4011
rkauffman@icfi.com

Joseph Keithley
ICF International
703-934-3438
jkeithley@icfi.com

Michelle Moser
ICF International
703-934-3887
mmoser@icfi.com

Ami Parekh
ICF International
703-934-3173
aparekh@icfi.com

Laura Tuhela-Reuning
ICF International
(740) 965-1999
lmtuhela@owu.edu

Kerry Williams
ICF International
703-218-2707
kwilliams@icfi.com

Facilitator

Jan Connery
ERG
781-674-7322
Jan.Connery@erg.com

Logistics

Patrick McCool
GLEC
231-941-2230
pmccool@glec.com

Peggy Himes
GLEC
231-941-2230
phimes@glec.com

Malkia Perry
ERG
703-633-1646
Malkia.Perry@erg.com

APPENDIX C: TRANSLATION OF EPIDEMIOLOGY TO DISEASE BURDEN BY WHO AND EU

In a series of five international expert consultations that took place between 1996 to 2001, the World Health Organization (WHO), together with partner organizations, including the EPA, the Commission of the European Communities, and a group of independent experts, have developed a methodology for expressing the exposure-risk relationship for recreational water. This approach is outlined in detail in Chapter 4 of the WHO's (2003) *Guidelines for Safe Recreational Water Environments. Volume 1 Coastal and Fresh Waters* (see also Kay et al., 2004). The broad framework is summarized below as a basis for burden of disease calculations.

Stated briefly, the approach is based on the following two assumptions:

1. that the statistical distribution of the fecal indicators (i.e., given a sufficiency of samples through a compliance period such as a bathing season) which predict illness in recreational waters is described by a $\log_{10}$-normal probability density function (pdf); and
2. that the pdf for any beach can be combined with the dose-response curve to produce a unique disease burden for a specific location.

Given a fixed dose-response curve, the relative disease burden (or proportion of the exposed population that becomes ill) for any beach, region or jurisdiction can be calculated from the parameters of the pdf, principally its geometric mean (GM) value (i.e., the mean of the $\log_{10}$ transformed bacterial counts) and the standard deviation (SD) of the $\log_{10}$ transformed bacterial counts. The mathematical basis of these calculations is outlined in WHO (2003), while Kay et al. (2004) and Wyer et al. (1999) provide a discussion on the impacts of different GM and SD assumptions.

Figure C-1 illustrates a theoretical pdf for any beach. The cleaner the water, the further to the left the peak of the pdf will be. Figure C-2 provides the dose response curves reported in Kay et al. (1994) that were used in deriving the standards in WHO (2003). Plot C-2a is projection of the dose-response curve beyond the actual data range of >157 (intestinal) enterococci per 100 mL. In fact, the projection of this relationship to exposures above about 150 enterococci would not be justified because the empirical data acquired during the U.K. randomized sea bathing trials was restricted to lower exposures. Figure Plot C-2b assumes that the excess probability of illness does not continue to increase as enterococci exposure increases above the levels experienced in the sea bathing trials. This was chosen as the dose-response curve in the derivation of the 2003 WHO Guidelines as a pragmatic approach. It should be recognized, however, that it may represent an underestimate of the true disease burden if the curve does not, in fact, flatten as suggested in this diagram.

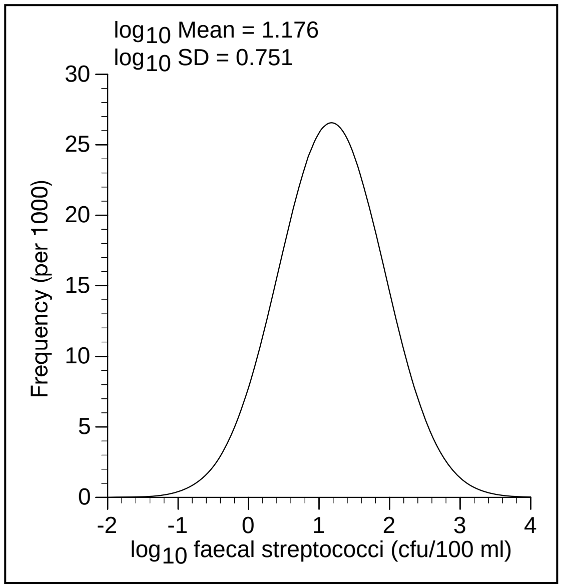

Figure C-1. A Probability Density Function of Fecal Indicator Distributions Measured at a Recreational Water Showing Probability of Exposure (Y Axis) versus Log10 Fecal Streptococci Concentration (later termed enterococci).

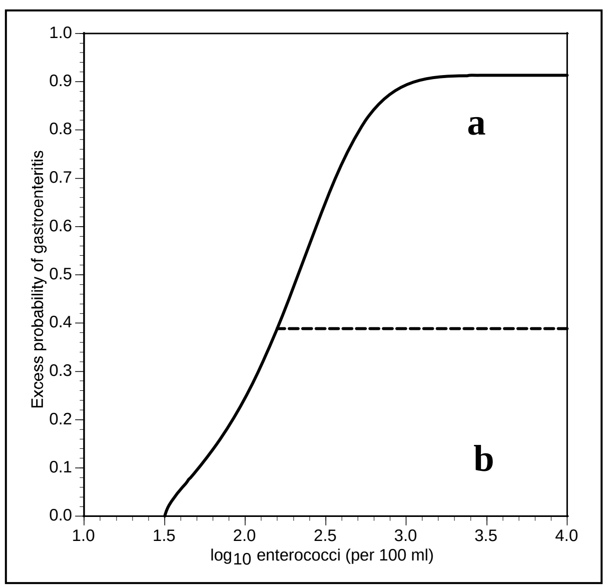

Figure C-2. The Dose-response Relationship Derived From Kay et al. (1994) (a) and the Functional Form Used to Derive the 2003 WHO Guideline Values (b). See Kay et al. (2004) for a more detailed explanation.

Figure C-3 combines the pdf of Figure C-1 with the dose-response curve of Figure C-2 to produce a relative disease burden prediction as a proportion of the exposed population. The mathematical basis of this process is provided in Kay et al. (2004).

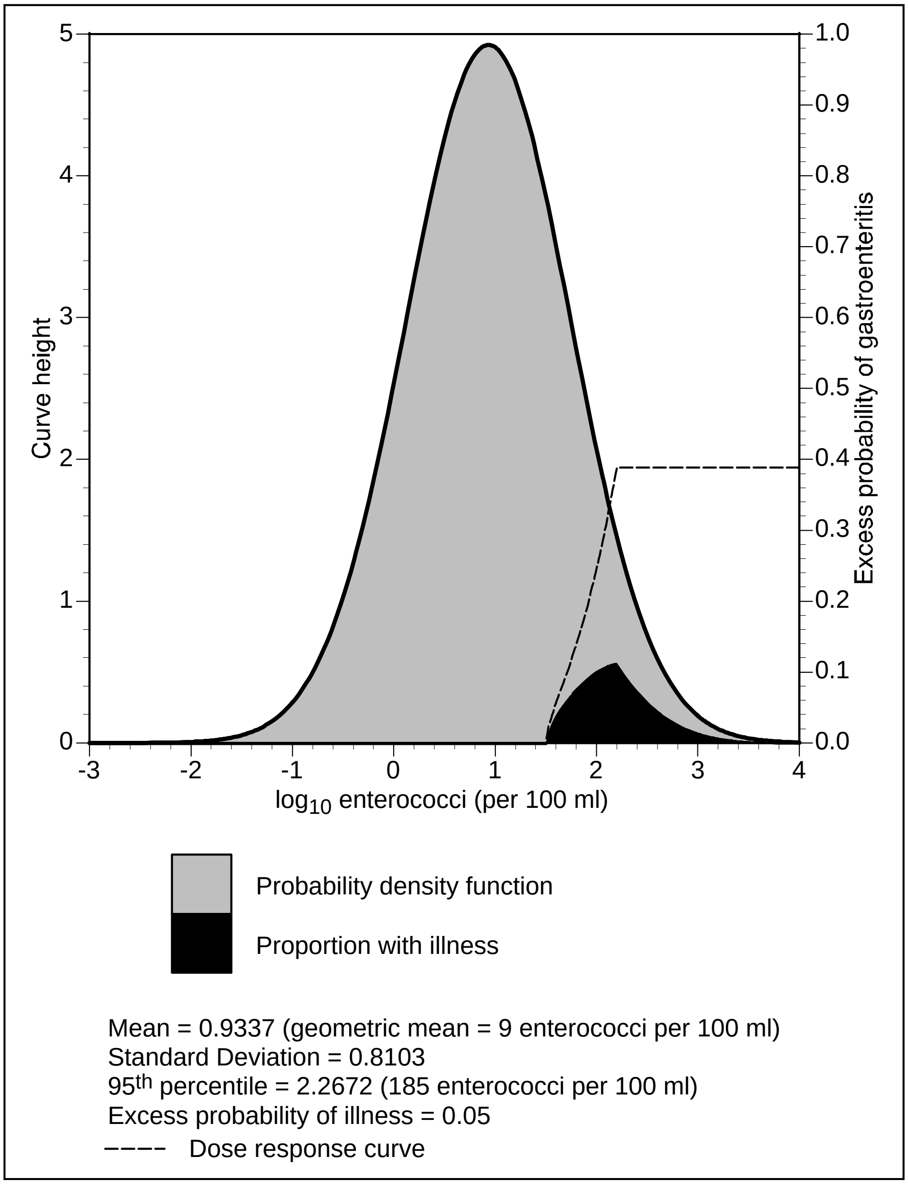

Figure C-3. Combining the Dose-response Curve and the pdf to Produce a Relative Disease Burden Assessment for any Beach or Region.

The computation of gastrointestinal (GI) illness rates in the population is accomplished as follows. The pdf is described by:

$$y = \frac{1}{s\sqrt{2\pi}} e \frac{-(c-m)^2}{2s^2}$$

Where c is the $\log_{10}$ transformed enterococci concentration, y is the normal curve height, and m is the mean enterococci concentration. The associated probability of exposure across a given range of enterococci concentration (i.e., c_a to c_b,) for a given distribution is expressed by:

$$\Phi(c) = \int_{ca}^{cb} y_{dc}$$

which is the area under the normal pdf curve between the limits c_a and c_b. The proportion of bathers with GI illness is then calculated from the area under the curve described by:

$$z = py$$

where p is the probability of GI illness (gastroenteritis) from the dose-response relationship with the upper limit set at 158 enterococci per 100 mL; that is:

$$p = 0.20102\sqrt{(c - 31.9) - 2.3561}$$

and z is the corresponding proportion of the normal curve height, y. The associated probability of GI illness across the range of enterococci concentrations, c_a to c_b, is then expressed by the following integral:

$$\Phi(c) = \int_{ca}^{cb} z_{dc}$$

For the WHO (2003) Guidelines derivation, the integration of these areas was performed using iterative algorithms as outlined in Khabaza (1965). The algorithm was checked against standard tabulations of the normal pdf curve (Lindley and Miller, 1968) and an accuracy of at least four significant figures was obtained over the specified range of the normal pdf.

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APPENDIX D: SUMMARY OF THE EUROPEAN COMMISSION DIRECTIVE

Revised Bathing Water Directive (EP/CEU, 2006)

The Directive sets out requirements for the following:

(a) the monitoring and classification of bathing water quality;
(b) the management of bathing water quality; and
(c) the provision of information to the public on bathing water quality.

It is meant to apply to identified European Union (EU) bathing waters used by "large numbers" of bathers which must be assessed against the criteria in Table 2 in Chapter 1 of these proceedings (using the previous 3 or 4 years of sampling data) though establishment of a sampling program to acquire data from each bathing water at locations where a bathing water "profile" suggests the greatest risk of pollution and/or the greatest numbers of bathers might be expected (Article 3.3b). Member States must monitor each bathing water in accordance with a monitoring calendar established at the start of the bathing season (Article 3.4). The monitoring calendar can be suspended during "abnormal" conditions and samples taken during "short term pollution" may be disregarded (Article 3.6) provided that Member States comply with the additional provisions outlined below.

Bathing waters are legally required to achieve "sufficient" microbiological status by 2015 (Article 5.3), although the numerical values will be reviewed in 2008 (Article 14).

However, bathing waters classified as "poor" in Table 2 may still remain in compliance with this Directive provided that Member States shall ensure that the following conditions are satisfied (Article 5.4a (i-iv)):

> adequate management measures, including a bathing prohibition or advice against bathing, with a view to preventing bathers' exposure to pollution and identification of the causes and reasons for the failure to achieve "sufficient" quality status is undertaken by Member States; and adequate measures to prevent, reduce or eliminate the causes of pollution; and in accordance with Article 12, alerting the public by a clear and simple warning sign and informing them of the causes of the pollution and measures taken, on the basis of the bathing water profile.

Member States must establish their bathing water profiles by March 24, 2011, which will be reviewed as specified in Annex III of the Revised Bathing Water Directive.

Article 12 further describes information which must be made available to the public at the bathing water and communicated promptly by means of a sign, which includes:

- the current bathing water classification and any bathing prohibition or advice against bathing;

- a general description of the bathing water, in non-technical language, based on the bathing water profile established in accordance with Annex III;
- in the case of bathing waters subject to short-term pollution: notification that the bathing water is subject to short-term pollution;
- an indication of the number of days on which bathing was prohibited or advised against during the preceding bathing season because of such pollution, and a warning whenever such pollution is predicted or present;
- information on the nature and expected duration of abnormal situations during such events;
- whenever bathing is prohibited or advised against, a notice advising the public and giving reasons;
- whenever a permanent bathing prohibition or permanent advice against bathing is introduced, the fact that the area concerned is no longer a bathing water and the reasons for its declassification; and
- an indication of sources of more complete information in accordance with paragraph 2.

In addition, "Member States shall use appropriate media and technologies, including the Internet, to disseminate actively and promptly the information concerning bathing waters referred to in paragraph 1 and also the following information in several languages, when appropriate" (Article 12.1 and 12.2).

Where a bathing water is subject to short-term pollution the public should also be informed on the following (Article 12.4d):

- conditions likely to lead to short-term pollution;
- the likelihood of such pollution and its likely duration; and
- the causes of the pollution and measures taken with a view to preventing bathers' exposure to pollution and to tackle its causes.

Member States are required to disseminate this knowledge using geo-referenced information and signage at bathing waters beginning March 24, 2008.

Member States are free to simply use the numerical standards in Table 2. However, they may take advantage of the opportunity to discount samples collected during short-term pollution events provided they have produced a bathing water profile and have complied with the requirement to provide public information specified in Article 12, which requires real time water quality prediction. No more than 15% of planned samples that are predicted to be of poor quality (i.e., resulting in public advisories) can be discounted in this manner prior to the calculation of the compliance statistics.

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Bathing Water Quality and Repealing Directive 76/160/EEC. *Official Journal of the European Union* L64: 31-51. Available at: http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2006/l_064/l_06420060304en00370051.pdf.

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APPENDIX E: INDICATOR TERMINOLOGY

Table E-1. Definitions for Indicator and Index Microorganisms of Public Health Concern.*

Group	Definition
Indicator	A group of organisms that demonstrates the efficacy of a process, such as total heterotrophic bacteria or total coliforms for chlorine disinfection
Fecal indicator	A group of organisms that indicates the presence of fecal contamination, such as the bacterial groups fecal coliforms or *E. coli*; thus, they only infer that pathogens may be present
Index and model organisms	A group/or species indicative of pathogen presence and behavior respectively, such as *E. coli* as an index for *Salmonella* and F-RNA coliphages as models of human enteric virus behavior in the environment
Pathogen indicator	A specific pathogen belonging to a broader group of pathogens which would serve as a surrogate for the presence and/or health risks for that group (e.g., *Cryptosporidium* serving as a surrogate for all parasitic protozoa), or an indicator microorganisms whose presence is correlated to the presence of a broad group of pathogens (e.g., spores of *Clostridium perfringens* serving as a surrogate for human or dog parasitic protozoa)

*See Text Box E-1 for definitions of microbial groups (adapted from Ashbolt et al., 2001).

Text Box E-1. Definitions of Key Fecal Indicator Microorganisms

Coliforms: Gram-negative, non spore-forming, oxidase-negative, rod-shaped facultative anaerobic bacteria that ferment lactose (with β-galactosidase) to acid and gas within 24 to 48 hours at 36±2°C. *Not* specific indicators of fecal pollution.

Fecal coliforms: coliforms that produce acid and gas from lactose at 44.5± 0.2°C within 24±2 hours, also known as thermotolerant coliforms due to their role as fecal indicators.

Escherichia coli (E. coli): thermotolerant coliforms that produce indole from tryptophan, but also defined now as coliforms able to produce β-glucuronidase (although taxonomically up to 10% of environmental *E. coli* may not). Most appropriate group of coliforms to indicate faecal pollution from warm-blooded animals.

Fecal streptococci (FS): Gram-positive, catalase-negative cocci from selective media (e.g., azide dextrose broth or m Enterococcus agar) that grow on bile aesculin agar and at 45°C, belonging to the genera *Enterococcus* and *Streptococcus* possessing the Lancefield group D antigen.

Enterococci: all fecal streptococci that grow at pH 9.6, between 10° and 45°C, and in 6.5% NaCl. Nearly all are members of the genus *Enterococcus*, and also fulfil the following criteria: resistance to 60°C for 30 minutes and ability to reduce 0.1% methylene blue. The enterococci are a subset of fecal streptococci that grow under the conditions outlined above. Alternatively, enterococci can be directly identified as micro-organisms capable of aerobic growth at 44±0.5°C and of hydrolysing 4-methlumbelliferyl-β-D-glucoside (MUD, detecting β-glucosidase activity by blue florescence at 366nm), in the presence of thallium acetate, nalidixic acid, and 2,3,5-triphenyltetrazolium chloride (TTC, which is reduced to the red formazan) in the specified medium (ISO/FDIS 7899-1 1998).

Sulphite-reducing clostridia (SRC): Gram-positive, spore-forming, non-motile, strictly anaerobic rods that reduce sulphite to H_2S.

Clostridium perfringens: as for SRC, but also ferment lactose, sucrose and inositol with the production of gas; produce a stormy clot fermentation with milk; reduce nitrate, hydrolyse gelatine, and produce lecithinase and acid phosphatase. Bonde (1963) suggested that all SRC in receiving waters are not indicators of fecal pollution; thus, *C. perfringens* is the appropriate indicator.

Bacteroidales: a family of strictly anaerobic bacteria present in the guts of warm-blooded animals. The family to which *Bacteroides* belongs.

Bacteriodes: Gram-negative, mainly straight *Bacteroides* species that are: (a) obligately anaerobic, chain saturated, anteiso-methyl, and iso-methyl branched acids, (b) saccharolytic, producing acetate and succinate as the major metabolic end products; (c) contain enzymes of the hexose monophosphate shunt-pentose phosphate pathway; (d) have a DNA-base composition in the range 40-48 mol% GC; (e) membranes contain sphingolipids, and contain a mixture of long-chain fatty acids; (f) possess menaquiones with MK-10 and MK-11 as the major components; and (g) contain *meso*-diaminopimelic acid in their peptidoglycan. This definition restricts the *Bacteroides* to the following ten species: *B. fragilis*, *B. thetaiotaomicron*, *B. vulgatus*, *B. ovatus*, *B. distasonis*, *B. uniformis*, *B. stercoris*, *B. eggerthii*, *B. merdae*, and *B. caccae*, with *B. fragilis* as the type strain. The *Bacteroides*, along with *Prevotella* and *Porphyromonas*, form one major subgroup in the bacterial phylum Cytophaga-Flavobacter-Bacteroides. This phylum diverged quite early in the evolutionary lineage of bacteria, and thus the *Bacteroides*, although Gram-negative organisms, are not closely related to the enteric Gram-negatives such as *Escherichia coli.*

Bacteriodes phages: Those viruses (bacteriophages) that use *Bacteroides* as a host for replication.

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APPENDIX F: SUMMARY OF MEASUREMENTS CURRENTLY PLANNED FOR THE DOHENY AND MALIBU BEACH (CALIFORNIA) EPIDEMIOLOGY STUDY

Table F-1. Summary of Measurements Currently Planned for the Doheny and Malibu Beach (California) Epidemiology Study.

Indicator	Method	Investigator
Traditional		
Enterococci	IDEXX	South Orange County Wastewater Authority (SOCWA)
Enterococci	Membrane-filtration (MF)	SOCWA
Fecal coliforms	MF	SOCWA
E. coli	MF or IDEXX	Southern California Coastal Water Research Project (SCCWRP)
Total coliforms	MF	SOCWA
Rapid Traditional		
Enterococci	Quantitative polymerase chain reaction (qPCR)	Noble
Enterococci	qPCR	Stewart
Enterococci	PCR-Luminex	Stewart
Enterococci	Transcription-mediated amplification/nucleic acid sequence-based amplification (TMA/NASBA)	Moore
Enterococci	Immunomagnetic separation (IMS)	Bushon
E. coli	qPCR	Noble
E. coli	IMS	Bushon
E. coli	IMS	Jay
Marker Genes		
Entero-Raptor, *Esp* gene	qPCR-Raptor	Harwood/Lim
Enterococci *Esp* gene	qPCR	Scott
E. coli virulence genes	qPCR	Sadowsky
Bacteroides human marker	qPCR	Field
Bacteroides human marker	qPCR	Wuertz
Phage		
Phage	Culture	Stewart
Phage	Culture	Sobsey
Rapid phage	Antibody	Sobsey
Human Virus		
Adenovirus	qPCR	Sobsey

Indicator	Method	Investigator
Enterovirus	qPCR	Stewart
Hepatitis A virus	qPCR	Fuhrman
Norovirus	qPCR	Stewart
Norovirus	qPCR	Sobsey
Polyomavirus	qPCR	Harwood
Community Profiling		
Bacteroides thetaiotamicron	Sequencing	Moorthy
Heliobacter pylori	Sequencing	Moorthy
Campylobacter jejuni	Sequencing	Moorthy
Clostridium perfringens	Sequencing	Moorthy
Salmonella enteritica serovar Typhimurium	Sequencing	Moorthy
Shigella dysenteriae	Sequencing	Moorthy
Shigella flexneri	Sequencing	Moorthy
Shigella boydii	Sequencing	Moorthy
Bacterial Markers		
Bacteroides thetaiotamicron	qPCR	Noble
Bacteroides thetaiotamicron	PCR	Leddy
Multiple methanogens	PCR	Ufnar
Methanobrevibacter smithii	PCR-Luminex	Stewart
Methanobrevibacter smithii	qPCR	Stewart
Legionella spp.	qPCR	Gast

APPENDIX G: DEVELOPMENT OF DETERMINISTIC MODELS

The discussion of the modeling workgroup members included the present and future use of statistically-based models. This relates to the fact that they are currently being used to supplement monitoring information and can be implemented in a resource-effective manner in existing beach advisory programs. In general, deterministic models have not been included in the main part of this discussion (see Chapter 6) because it was the common opinion of the workgroup members of the modeling workgroup that their application represents a longer-range measure that might be considered in the context of research and development beyond the 2 to 3 year (near-term) window envisioned by the current criteria development effort; however, there were differences of opinion on the importance of this relative to development of new or revised recreational water quality criteria.

Although not discussed in detail at this workshop, deterministic process-based models represent an entire range of additional modeling tools that could be used to inform water quality criteria development and implementation over the range of criteria framework options that have been discussed during the course of this conference. Applications of such models to beach environments are discussed in the EPA report *Review of Potential Modeling Tools and Approaches to Support the BEACH Program*, (US EPA, 1999). They range from those that are simply based on precipitation to newer models that consider other factors such as sediment resuspension, hydrodynamics, microbial growth and decay, and non-point source basin scale inputs. For example, a process-based deterministic model has been recently used to predict fecal indicator concentrations in coastal reaches of southern Lake Michigan (Liu et al., 2006) and Huntington Beach, California (Boehm et al., 2005; Grant et al., 2005). Deterministic models also are being used in the development of total maximum daily loads (TMDLs) for pathogens and in evaluations of non-point and sources of biological contaminants in watersheds.

In this appendix, deterministic models for evaluating pathogens in watersheds are briefly discussed. TMDLs often have to consider non-point sources from watersheds. This discussion is not intended to be comprehensive; rather, it is designed to illustrate the range of tools available to this area of consideration.

Commonly used TMDL models allow users to discretize the watershed spatially and bacteria loads spatially and temporally, although this capacity is limited. As discussed in ASABE (2006),

> the models are also limited in their ability to simulate bacterial life cycles and bacteria concentrations. Even with their limitations, these models are useful when developing TMDLs if for no other reason than their use provides educational opportunities for both stakeholders and modelers throughout the TMDL process. The load duration method of developing TMDLs provides a good representation of overall water quality and needed water quality improvement, but intra-watershed bacteria contributions must be determined through supplemental sampling or through subsequent hydrologic and water quality modeling. Identified research needs include improved bacteria source characterization procedures and supporting data, and specific modeling advances.

New models are now becoming available for evaluating non-point sources of pathogens derived from watersheds and catchments.

- The L-THIA model (http://www.ecn.purdue.edu/run-off/lthianew/) combined with GIS-referenced inputs from Digital Watershed are being used as tools to evaluate runoff of fecal coliform and fecal streptococcus (enterococci) in watersheds. Digital Watershed (http://www.iwr.msu.edu/dw/) allows the user to view the watershed tributary to any given point in the continental United States, on an 8-digit or (in parts of the Midwest) a 12-digit HUC code level of detail. L-THIA calculates the surface and groundwater impacts of current land use, land use changes and potential best management practices (BMPs) for quality and quantity for the bacteria. L-THIA will be directly linked to STORET water quality and SSURGO soils databases within a year. In the Midwest it is also available as a web-based GIS tool at the 12-digit HUC code level through the watershed delineation tool at http://pasture.ecn.purdue.edu/~watergen/.
- The SPARROW model (SPAtially Referenced Regression on Watershed attributes) (http://water.usgs.gov/nawqa/sparrow/index.html) is being used to investigate the sources and fate of fecal contamination in streams and to assess the effects of the spatial resolution of the stream network and landscape data on model parameters and predictions. SPARROW has been used to evaluate the following indicators: fecal coliforms, *E. coli*, *C. perfringens*, somatic coliphage, F+ RNA phage, and the bacterial pathogen *Campylobacter*. The explanatory data for the SPARROW models include land use and other data that describe the climatic, hydrologic, and physical conditions of the catchments. The models also reveal the effects of climate, soils, and instream processes on the transport of fecal contaminants.
- LSPC is the Loading Simulation Program in C++, a watershed modeling system that includes streamlined Hydrologic Simulation Program Fortran (HSPF) algorithms for simulating hydrology, sediment, and general water quality on land as well as a simplified stream transport model. LSPC has been used in Alabama for developing pathogen TMDLs (see http://www.epa.gov/athens/wwqtsc/Toolbox-overview.pdf and http://www.epa.gov/ATHENS/wwqtsc/html/lspc.html).

In addition to these models, a 1999 EPA report describes other potential models that can be used for evaluating non-point sources of biological contaminants from catchments. These include, for example, HSPF. HSPF is one of the models that is included in the BASINS3 watershed model system that is maintained by EPA (http://www.epa.gov/waterscience/BASINS/).

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