## How well does science support the QMRA process – An overview

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State-of-the-Science Symposium:
Fecal Source Identification and Associated Risk
Assessment Tools

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#### Why QMRA for Recreational Waters

- QMRA provides a scientifically accepted framework considering alternative water quality criteria
- ➤ QMRA can complement epidemiology studies to understand illness risks in recreational waters
- ➤ QMRA is specifically called out as option for site specific criteria in final 2012 RWQC

### What is QMRA?

- ➤ QMRA a formal, scientific process, analogous to chemical risk assessment of estimating human health risks due to exposures to selected infectious pathogens
  - <u>Problem Formulation</u>: Identify goals, regulatory and policy context, and develop conceptual models
  - <u>Analysis</u>: Document and evaluate exposure and health effects data
  - <u>Risk Characterization</u>: Compile information and data and put results into context

## Federal and International Organizations have a long history of using QMRA

- ➤ EPA has used risk assessment extensively for decades to establish human health criteria for a wide range of pollutants in water and other media
- QMRA has been applied to evaluate and manage pathogen risks for numerous scenarios - food, biosolids, drinking water, recycled water, and recreational waters.
- > QMRA specifically has been used
  - to inform policy making for drinking water and biosolids in the U.S. and
  - by U.S. and international governmental agencies to protect public health from exposure to microbial pollutants in food and water

#### **Considerations for Framing a QMRA**

- Which pathogen(s) (hazard identification)?
- ➤ How many pathogens are individuals or populations exposed to (*exposure assessment*) and from what scenarios (hazardous events)?
- > What are the adverse health effects of interest?
- What is the relation between exposure and health effects (*dose-response evaluation*)?
- How does variability (temporal, spatial, inherent) and/or uncertainty impact
  - Our understanding or interpretation of risk
  - Monitoring needs
- Do properties that are unique to microorganisms or infectious diseases such as person-person transmission and/or immunity need to be accounted for?
- What methods are appropriate / needed to characterize risk?

#### **QMRA** considerations

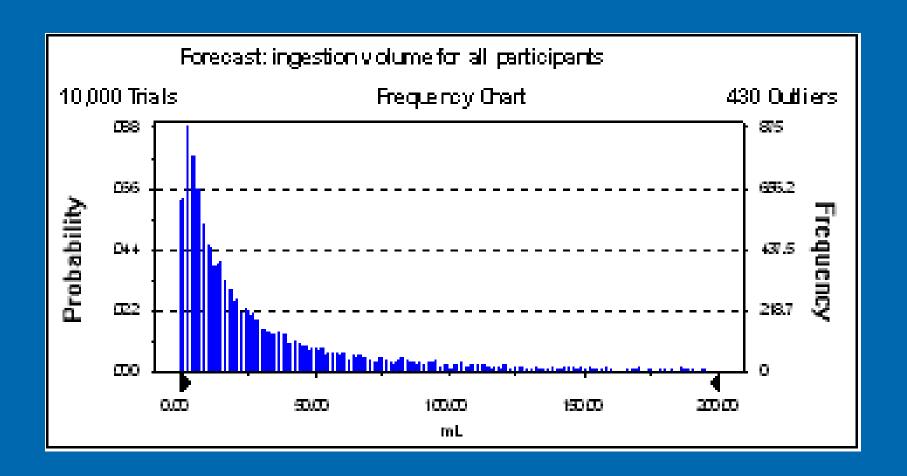
- > Pathogen specific (compared to epi studies)
- Works best when comparing relative risk of two or more scenarios
- > Exposure can be difficult to characterize
- Dose-response relationships are based on limited data
- Numerical simulation studies, need to be anchored to observable data to be widely accepted
- Have not been extensively applied for risk management of recreational waters

## What is the linkage between QMRA epidemiological studies for recreational waters

- > Recreational water epidemiology studies indicate
  - Rates of some adverse health effects are generally higher in swimmers than non-swimmers
  - FIB can predict GI illness, and in some cases AFRI
- Most epidemiology studies have focused on humanimpacted waters (primarily POTW effluent)
  - Notable exceptions Southern CA, South FL, New Zealand
  - Recreational water risks in waters impacted by sources other than those studied are not well understood
  - Even in human impacted waters, the primary etiologic agents are not well understood

- The etiologic agents are the intersection of QMRA and recreational water epidemiology studies
- > To estimate illness via QMRA, we need to understand
  - Exposure
  - Relationship between exposure and infection
  - Relationship between infection and illness

## Representative Exposure Data: Volume of Water Ingested During Recreation



Source: Dufour et al. 2006

#### **Pathogen Classes of Public Health Concern**

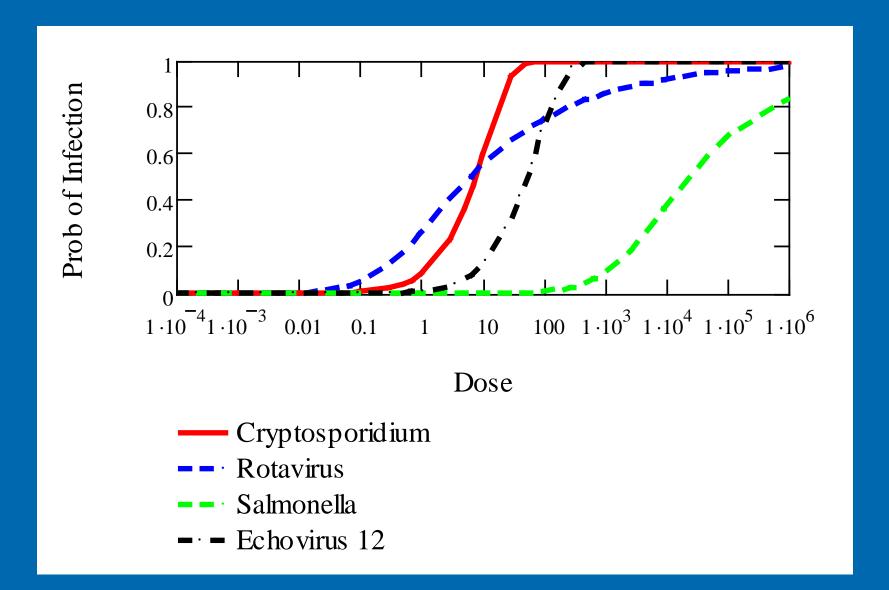
- Viruses
  - Rotavirus
  - Poliovirus
  - Echovirus
  - Adenovirus
  - Hepatitis A
  - Coxsackie virus

- Parasites
  - Cryptosporidium
  - Giardia
- Bacteria
  - Salmonella
  - Shigella
  - E. coli O157
  - Vibrio cholera
  - Campylobacter jejuni

## Reference Pathogens for Recreational Water QMRA

- In the US, there are 38.6M illnesses annually from known pathogens.
- > 24.8M illnesses are non-foodborne
- This set of eight reference pathogens accounts for >97% of non-foodborne illness from known pathogens in US.
  - Norovirus
  - Rotavirus
  - Adenovirus
  - Cryptosporidium spp.
  - Giardia lamblia
  - Campylobacter spp.
  - Salmonella
  - E. coli O157:H7

#### Representative Data: Dose-Response Relationships



# **Examples of Using QMRA to understand** recreational water risks

- Which etiological agent(s) cause illness during epidemiological studies
- Adding context for when epidemiological studies indicate equivocal results
- > Relative risks from non-human sources
- Mixed sources
  - mixed human (treated / untreated)
  - human / non-human sources

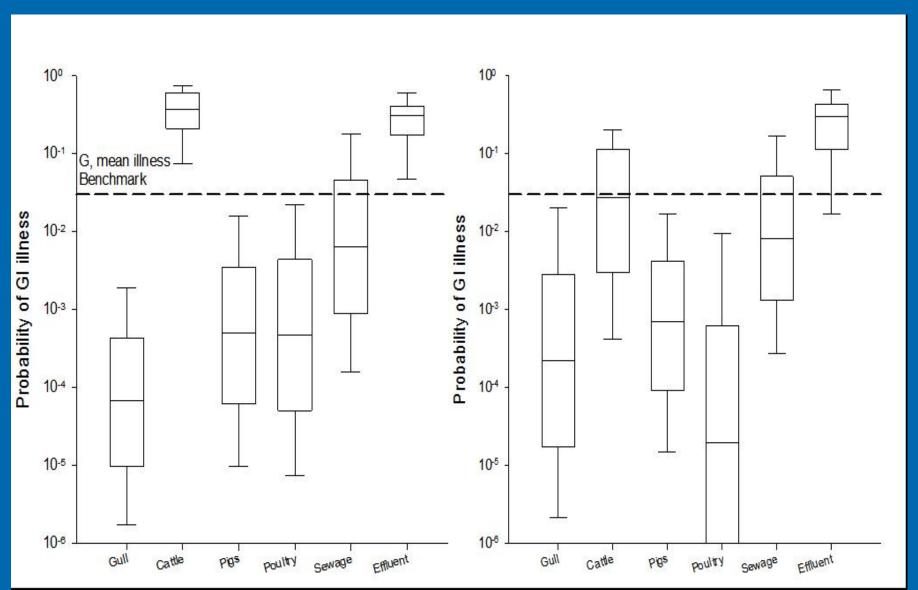
### Case Study: NEEAR Great Lakes Studies

	Health Based Approach			POTW Effluent Based Approach		
			Estimated mean		·	Estimated mean
	Illness rate /1000	Infection Rate /	concentration	Illness Rate /	Infection Rate /	concentration
Pathgoen	swimmers	1000 swimmers	(organisms/L)	1000 swimmers	1000 swimmers	(organisms/L)
All	30.6	Unknown	NA	30.6	Unknown	NA
Rotavirus	4.8	13.6	0.7	0.3	0.7	0.04
Norovirus <sup>1</sup>	17.1	276.9	32.3			
	17.1	28.6	2.1	29.7	49.5	3.8
Adenovirus	4.8	9.5	0.7	0.3	0.5	0.04
Cryptosporidium	0.3	0.7	0.2	0.2	0.5	0.15
Giardia	2.2	4.9	7.6	0.01	0.03	0.05
Camplyobacter	0.6	24.6	1.0	0.1	3.8	0.4
E. coli O157:H7	0.01	0.05	0.2	0.001	0.01	0.01
Salmonella	0.09	0.44	122	0.0003	0.001	0.4

- 1. Genome copies per liter
- 2. First row is based on assumption of dose dependent illness given infection, second row is based on fixed proportion of illnesses regardless of dose. Both rows are based on data presented in Teunis et al 2008

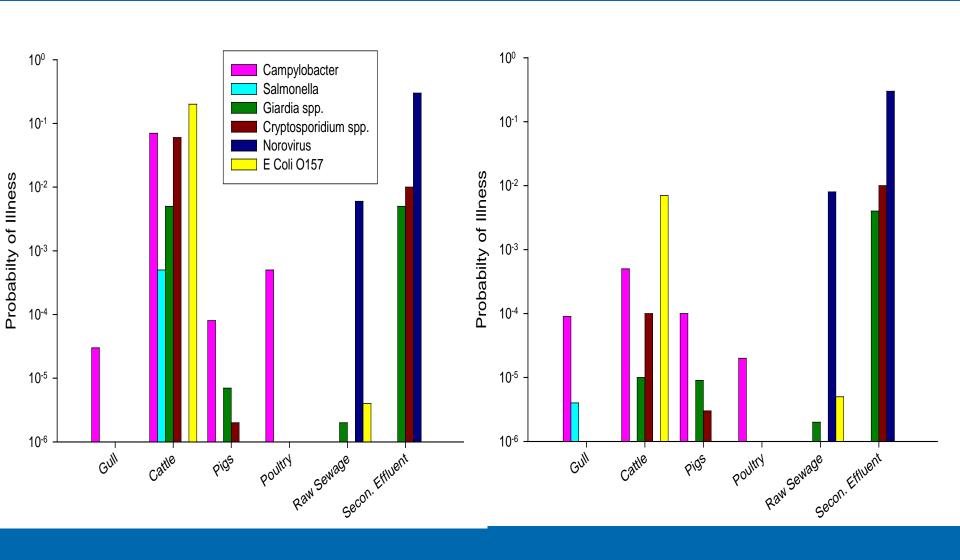
## Case Study: Relative Risks from Various Animal Sources

ENT E. coli



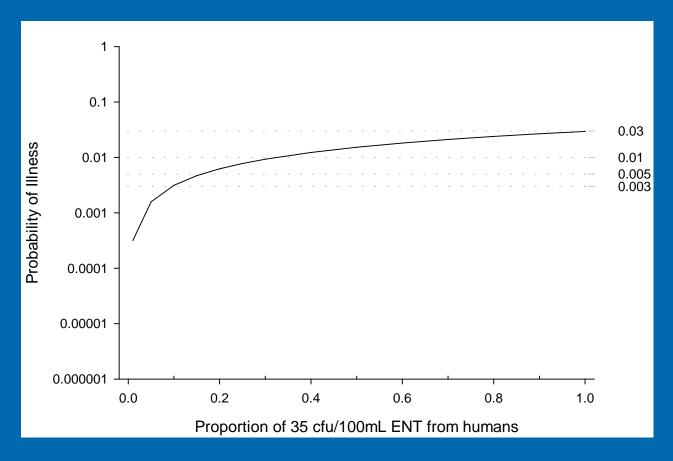
## Relative Contribution of Reference Pathogens for Risks from Various Animal Sources

ENT E. coli



#### Case Study: Mixed Sources of Contamination

- ➤ Purpose: Evaluate how the source of fecal contamination can influence the potential for adverse human health effects from recreational activities
- Approach: Examine various scenarios of mixed fecal sources and estimate the probability of GI illness as the proportion of FIB from the fecal sources varies
  - Human source mixed with a non-pathogenic (environmental) source
  - Pig source mixed with a non-pathogenic source
  - Human source mixed with pig source
  - Human source mixed with chicken source



Numerically higher, but equivalently protective, sitespecific water quality standards could be developed for recreational waters that are impacted by low levels of human fecal contamination

#### **Final Thoughts**

- We have a solid framework to consider recreational water risks via QMRA
- > Some of the next challenges to consider relate to how to determine relative contributions of important sources
- These tools could prove to be very useful allocating resources to waters that can have greatest public health benefit