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Topics Covered in Today's Presentation

- Objectives
- Background and historical perspectives for fecal-associated pathogens, health effects and use of fecal indicator organisms.
- Evolving understanding of risk from recreational waters.
- NEEAR studies
- 2012 Recreational Water Quality Criteria (RWQC)
- Five-year review
- Conclusions

KEEP OUT

SEWAGE CONTAMINATED WATER

EXPOSURE MAY CAUSE ILLNESS
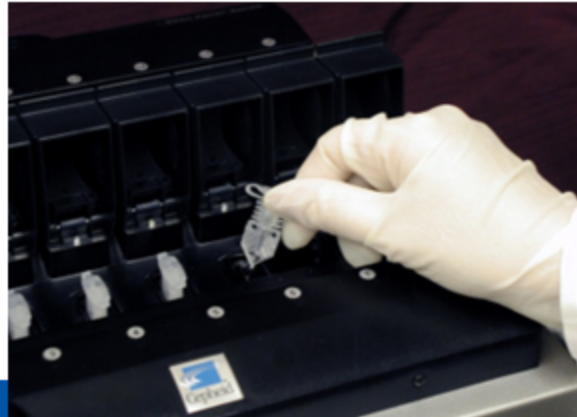
Objectives

- Describe US EPA's 2012 RWQC.

- Discuss the historical and current understanding of risk related to criteria.

- Describe the science used to develop criteria.

Examples of Waterborne Pathogens Associated with Feces

- Exposure to human feces-contaminated water is associated with illness and infection.
- GI illness is a common endpoint although some pathogens can cause infection in other systems.
- Some pathogens can occur in non-human or human fecal contamination, or both.
- EPA published a literature review in 2009 that identified studies of relevant zoonotic waterborne pathogens.*

*https://www.epa.gov/sites/default/files/2019-03/documents/review-zoonotic-pathogens-waters.pdf

Agent	Symptoms	Incubation	Duration
Campylobacter	Diarrhea, nausea, vomiting, cramps, fever	2-5 days	1 week
Pathogenic *E. coli* (e.g., STEC, E. coli 0157:H7)	Cramps, diarrhea (bloody), vomiting	3-4 days	5-7 days
Salmonella	Diarrhea, fever, cramps	1-3 days	5-7 days
Shigella	Diarrhea (bloody), fever, cramps	1-2 days	5-7 days
Norovirus	Diarrhea, vomiting, nausea, cramps	12-48 hours	1-3 days
Rotavirus	Fever, vomiting, diarrhea, cramps	2 days	3-8 days
Adenovirus	Respiratory, diarrhea, conjunctivitis, fever	5-8 days	1-2 weeks
Hepatitis A and E	Fever, abdominal pain, jaundice, fatigue, aches	28 days	4-8 weeks
Giardia	Diarrhea, gas, nausea, vomiting	1-3 weeks	2-6 weeks
Cryptosporidium	diarrhea (watery), cramps, nausea, vomiting, fever,	2-10 days	7 days

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Opportunities: Use of Fecal Indicator Organisms in Public Health

- Impractical to routinely monitor for all potential pathogens associated with fecal contamination.

- Non-pathogenic surrogates, culturable fecal indicator bacteria (FIB), have been used for over a century to monitor water quality and manage risk from exposure to human sewage contaminated waters (Dufour and Schaub, 2007; Boehm et al., 2009).

- FIB are found in high densities in sewage and the intestinal track of humans and other warm-blooded animals.

- Elevated levels in water can indicate the presence of fecal contamination.

- Easy to enumerate via culture and gene-based methods.

Challenges: Using Fecal Indicator Organisms

- Not specific to human fecal contamination (Boehm et al., 2009).
- Can persist/recover/regrow in the environment (Blatchley et al., 2007; Boehm et al., 2009; Dorevitch et al., 2010).
- Can have significant loading from non-fecal sources (Byappanahalli et al., 2006).
- Documented treatment differential in WWTPs (Kitajima et al., 2014).
- Do not correlate with pathogens (Wu et al., 2011).

Fecal Indicator Organisms, Recreational Water and the Evolving Understanding of Risk

- 1950s-1960s
  - Observed significant increase in gastrointestinal illness above 2300 total coliforms/100 mL (Stevenson, 1953).
    - Assumption of "zero-excess risk" below this level.
    - Total coliforms not specific to fecal contamination.
  - In 1968, the National Technical Advisory Committee (NTAC) translated the 2300 total coliform/100 mL level to 400 fecal coliforms/100 mL (Dufour and Schaub, 2007).
    - Ohio River data showed fecal coliforms were about 18% of the total coliforms.
    - NTAC applied a safety factor halving the fecal coliform value to 200/100mL.
    - In 1976, EPA published the PHS recommendations as the first federal ambient water quality criteria: GM 200 FC/100 mL with no more than 10% of samples above 400 FC/100 mL.
    - Assumption of "zero excess risk" at this level.

Fecal Indicator Organisms, Recreational Water and the Evolving Understanding of Risk

- **1970s-1980s**
  - EPA conducted epidemiological studies at marine (Cabelli/EPA, 1983) and fresh (Dufour, 1984) water beaches.
    - Defined gastrointestinal illness (GI) as Highly Credible Gastrointestinal Illness (HCGI) including vomiting; diarrhea with a fever or disabling, stomachache or nausea accompanied by a fever
    - Strongest associations observed between HCGI and enterococci (marine and fresh) and *E. coli* (fresh).

Recommended health effects criterion for marine recreation waters.
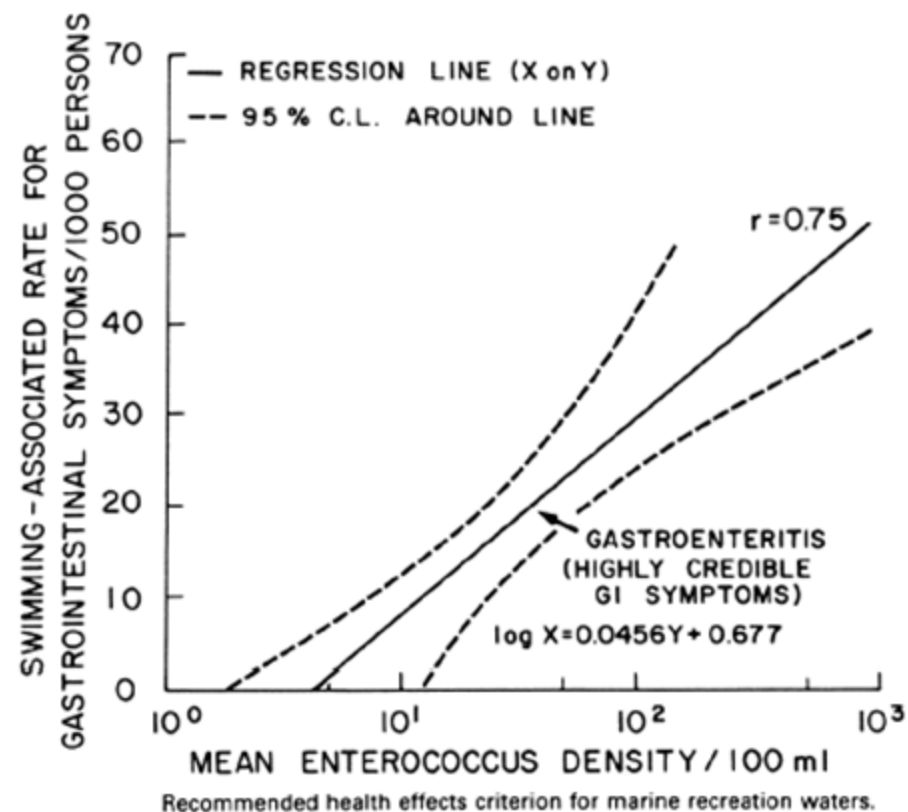
Fecal Indicator Organisms, Recreational Water and the Evolving Understanding of Risk

- On May 24, 1984, EPA proposed draft criteria based on the then new epidemiological results (OW-FRL-2593-1, FRN 49(102), 21987-21988).
  - New data demonstrated previous recommendations did not represent 'zero' excess risk.
  - 200 FC/100 mL represented 15 GI/1000 recreators in marine and 6 GI/1000 recreators in fresh.
  - Proposed draft criteria corresponding to those risk levels were 20 ENT/100 mL or 77 EC/100 mL in fresh and 3 ENT/100 mL in marine.
  - Public comments included concerns about implementing some of the proposed values because of the method level of quantification and background levels of indicator.

- Final 1986 Recreational Ambient Water Quality Criteria recommendations.
  - Translated 200 FC/100 mL into levels of enterococci and *E. coli* from the water quality data collected during the epidemiological studies, which then became the recommended water quality values.
  - The epidemiological relationships from Cabelli/EPA (1983) and Dufour (1984) were used to describe the level of HCGI associated with the water quality values (e.g., 8 HCGI/1000 in fresh and 19 HCGI/1000 in marine).

2000 BEACH Act Amendments

- Section 104(v) – directed EPA to conduct new studies
  - "an assessment of potential human health risks resulting from exposure to pathogens in coastal recreation waters…"
  - "appropriate and effective indicators for improving detection in a timely manner…"
- Section 304(a)(9) -- Requires EPA to publish new or revised criteria within 5 years and review every 5 years thereafter based on most recently available science.

The National Epidemiologic and Environmental Assessment of Recreational (NEEAR) Water Study

Research question:

Is there an association between illness and recreational water quality as measured by novel and rapid methods of determining water quality?

Selected publications:

Wade et al. (2006, 2008, 2010)

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Study Design Highlights

- Prospective cohort
  - Household sample of beachgoers
  - Three interviews:
    - Enrollment
    - Beach interview
    - Telephone interview 10-12 days later
- Site selection
  - Effluent discharge nearby
    - Discharging population of at least 10,000
  - Range of FIB
  - Sufficient population
- Focus on water quality targets that can be quantified within a few hours
  - Quantitative polymerase chain reaction (qPCR) (TaqMan)
    - *Enterococcus* (all sites), *Bacteriodes* (marine), *Clostridia* (marine)
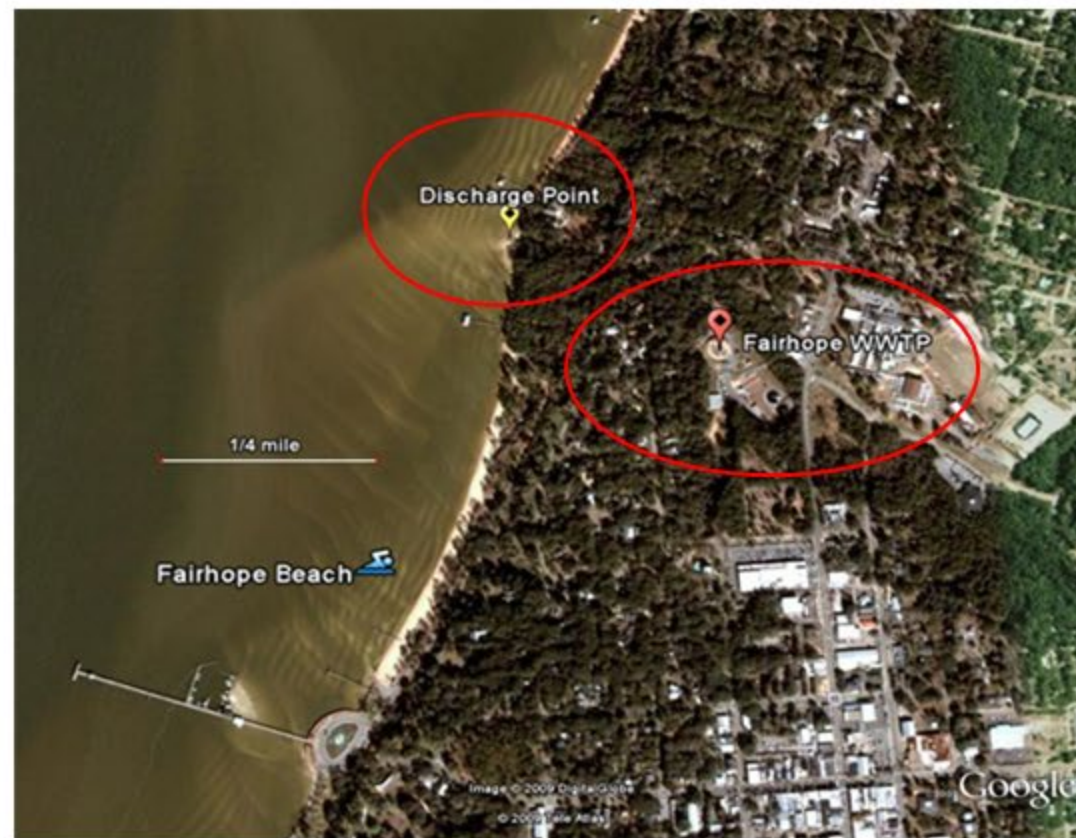 - Enterococcus culture (all sites); coliphage (one marine site).
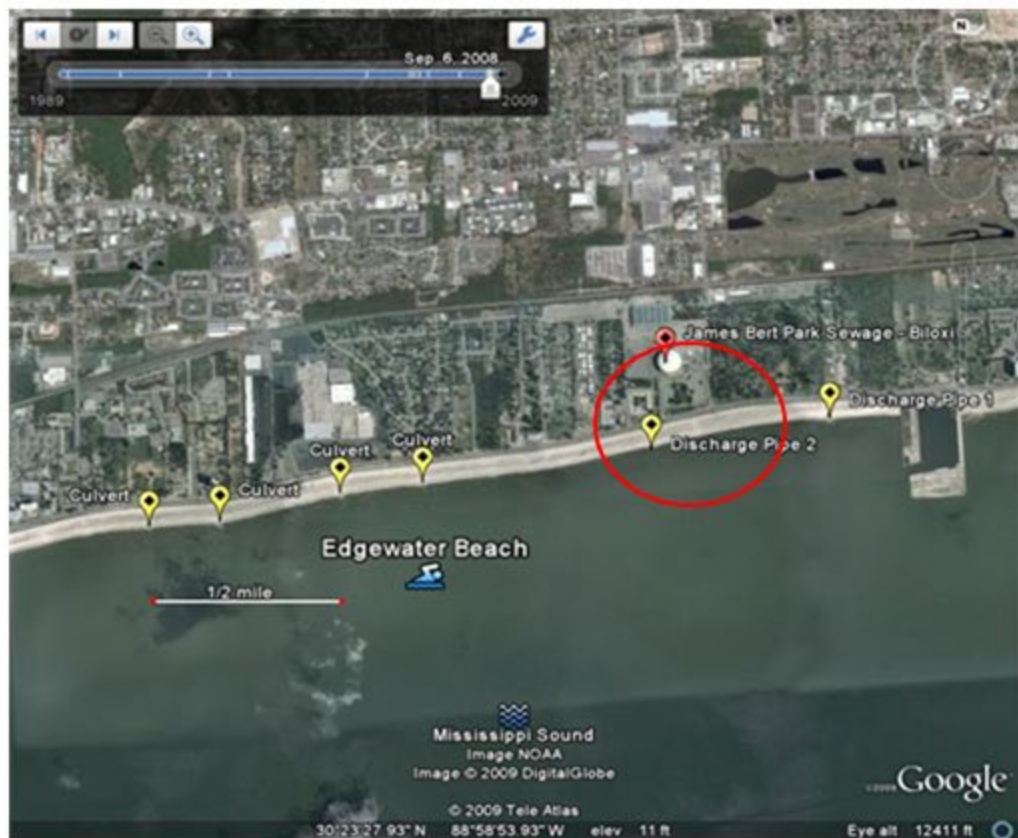
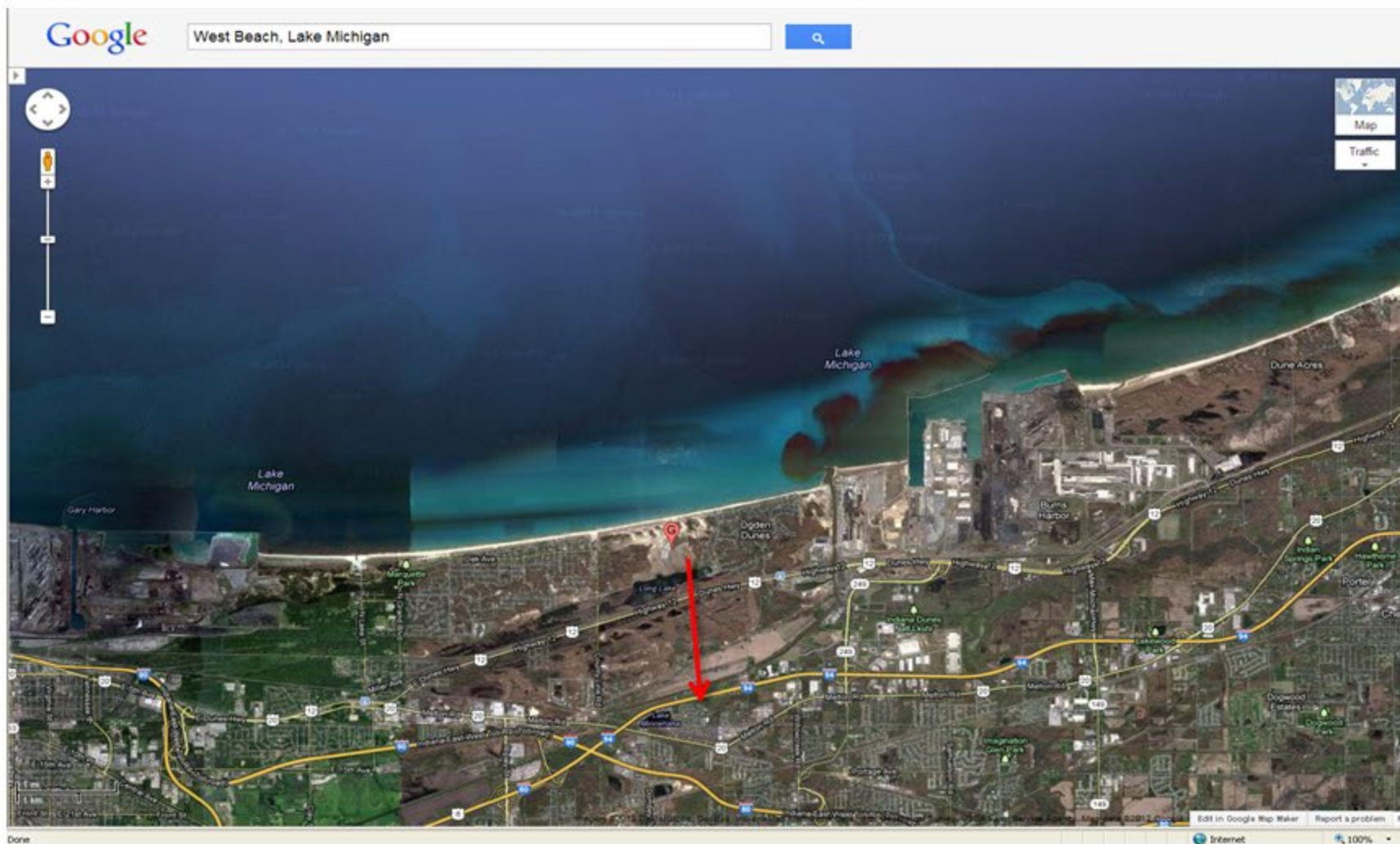# Study sites

Freshwater beaches

Marine beaches

Examples of study sites and discharges

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Examples of study sites and discharges

NEEAR Health Outcomes Assessed

- NEEAR Gastrointestinal illness (NGI)
  - Diarrhea (3 or more loose stools in a 24-hour period); Vomiting; Nausea and stomach-ache; Nausea or stomach-ache and impact on activity.
  - Broader definition of illness compared to HCGI.
  - Viral GI Infections often produce mild or no fever.
  - Longer follow up period (10-12 days)

- Upper respiratory illness (URI)
  - Any two: sore throat, cough, runny nose, cold, fever

- Skin rash

- Eye irritations (watery eye or eye infection)

- Earache

NEEAR studies: Key Results

- Molecular-measures of FIB were associated with GI illness among swimmers.
  - Dose dependent associations established
  - Body immersion swimming exposure

- Data for non-GI illnesses assessed did not exhibit dose-dependent associations with water quality measures

- ENT qPCR associations with NGI were stronger and more consistent than for culture-based ENT (e.g., odd ratios were not statistically significant).
  - *Freshwater AOR: 1.36 (p=0.0006)*
  - *Marine AOR: 2.56 (p=0.007)*

- 8:00 AM samples also statistically associated with GI illness

2012 US EPA Recreational Water Quality Criteria

- Included HCGI to NEEAR-GI translation = ~4.5x (Wymer et al., 2011)
- Single criteria for marine and freshwater based on an illness rate
  - 7-8 HCGI ≈ 32-36 NGI
- Statistical Threshold Values, Beach Action Values provided
- *Enterococcus* qPCR provided as an option with guideline values
- Section 6 provides tools to support evaluating and managing recreational waters (sanitary surveys and predictive modeling) and for considering alternative criteria (Quantitative Microbial Risk Assessment (QMRA), epidemiology studies, method performance)
- Technical Support Materials for implementation guidance.

Source: US EPA Recreational Water Quality Criteria (2012)
https://www.epa.gov/wqc/recreational-water-quality-criteria-and-methods

2012 US EPA Recreational Water Quality Criteria

Table 4. Recommended 2012 RWQC.

Criteria Elements	Estimated Illness Rate (NGI): 36 per 1,000 primary contact recreators Magnitude			Estimated Illness Rate (NGI): 32 per 1,000 primary contact recreators Magnitude	
	GM (cfu/100 mL)[a]	STV (cfu/100 mL)[a]	OR	GM (cfu/100 mL)[a]	STV (cfu/100 mL)[a]
Indicator Enterococci – marine and fresh	35	130		30	110
OR					
E. coli – fresh	126	410		100	320
Duration and Frequency: The waterbody GM should not be greater than the selected GM magnitude in any 30-day interval. There should not be greater than a ten percent excursion frequency of the selected STV magnitude in the same 30-day interval.					

[a] EPA recommends using EPA Method 1600 (U.S. EPA, 2002a) to measure culturable enterococci, or another equivalent method that measures culturable enterococci and using EPA Method 1603 (U.S. EPA, 2002b) to measure culturable E. coli, or any other equivalent method that measures culturable E. coli.

Table 6. Values for qPCR in marine and fresh waters.

Element	Estimated Illness Rate (NGI): 36/1,000 primary contact recreators Magnitude			Estimated Illness Rate (NGI): 32/1,000 primary contact recreators Magnitude	
	GM (cce per 100 mL)	STV (cce per 100 mL)	OR	GM (cce per 100 mL)	STV (cce per 100 mL)
qPCR[a]	470	2,000		300	1,280
Duration and Frequency: The waterbody GM should not be greater than the selected GM magnitude in any 30-day interval. There should not be greater than a 10 percent excursion frequency of the selected STV magnitude in the same 30-day interval.					

[a] EPA Enterococcus spp. Method 1611 for qPCR (U.S. EPA, 2012b).

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US EPA Five-Year Review of RWQC

- Purpose: Assessment of the Need to Revise the 2012 RWQC.

- Required by the BEACH Act.

- 1st Recreational Review (2017): https://www.epa.gov/sites/default/files/2018-05/documents/2017-5year-review-rwqc.pdf

- 2nd Recreational Review: *ongoing*
  - Process: Literature search on specific topics including -
    - Health studies (epidemiological studies, QMRA, outbreak reports)
    - Children's health and exposure
    - Alternative surrogates and enumeration methodologies
    - Fecal source identification
    - Antimicrobial resistance

Data Integration: NEEAR and CA Epidemiological studies

- Combined data set -13 beaches, >80,000 observations, 360 beach days, ~5,000 water samples- provided opportunity for further analysis
- Arnold et al. (AJPH, 2016)
  - Children health risks
- Benjamin-Chung et al. (Epidemiology, 2017)
  - Coliphage- associations with swimming-associated illness
- DeFlorio-Barker et al. (JESEE, 2017)
  - Children exposure- volumes of water ingested
- Wade et al. (PLOS One, 2022)
  - Additional analyses of children's risk
  - Impact of source of fecal contamination and swimming exposure intensity

Wade et al. (2022): New Assessment of Children's Risks

- Compare associations between enterococci CFU and qPCR CCE and health endpoints for various sites, fecal sources, exposure and age categories

- Use previously developed models (logistic regression), accounting for possible confounders such as underlying health conditions, contact with ill people, consumption of risky foods, other swimming, etc.

- Test differences to see if risks differ in children compared to adults

- Odds ratios – expressed here as increase in risk of illness per log increase in enterococci, among exposed group.

Wade et al. (2022): Key parameters

Parameter	Definition
Illness outcome	▪ Gastrointestinal illness (NEEAR-GI) ▪ Diarrhea ▪ Vomiting ▪ Severe gastrointestinal illness ▪ Respiratory illness ▪ Cold ▪ Sore throat ▪ Rash
Swimming exposure	▪ Any contact with water ▪ Body immersion ▪ Swallowing water ▪ At least 30 minutes in water ▪ At least 60 minutes in water
Water quality indicator	▪ Enterococcus qPCR-CE[a] (geometric mean-daily average) ▪ Enterococcus CFU[b] (geometric mean- daily average)
Age category[c]	▪ All ages ▪ 12 and under ▪ 10 and under ▪ 6 and under ▪ 4 and under ▪ 13 and over ▪ 18 and over
Source/site	▪ All sites ▪ Sites with likely human source ▪ Sites with likely human source, excluding tropical site ▪ All NEEAR sites ▪ NEEAR point source sites ▪ NEEAR core sites (excluding tropical and non-point source site)

Wade et al. (2022): Site classification

| Category	Sites	
All sites	Avalon Beach Boquerón Beach Doheny Beach Edgewater Beach Fairhope Beach Goddard State Park Beach Huntington Beach	Malibu Beach Mission Bay Silver Beach Surfside Beach Washington Park Beach West Beach
Human impacted	Avalon Beach (ground water discharge above median)[b] Boquerón Beach Doheny Beach (berm open)[a] Edgewater Beach Fairhope Beach	Goddard State Park Beach Huntington Beach Washington Park Beach West Beach Silver Beach
Human impacted (excluding tropical)	Avalon Beach (ground water discharge above median)[b] Doheny Beach (berm open)[a] Edgewater Beach Fairhope Beach	Goddard State Park Beach Huntington Beach Washington Park Beach West Beach Silver Beach
All NEEAR	Boquerón Beach Edgewater Beach Fairhope Beach Goddard State Park Beach Huntington Beach	Silver Beach Surfside Beach Washington Park Beach West Beach
All NEEAR- point source	Boquerón Beach Edgewater Beach Fairhope Beach Goddard State Park Beach	Huntington Beach Silver Beach Washington Park Beach West Beach
NEEAR- core sites	Edgewater Beach Fairhope Beach Goddard State Park Beach	Huntington Beach Silver Beach Washington Park Beach West Beach

Wade et al. (2022): Children's Health Outcomes

Odds ratios for diarrhea associated with a 1 log increase in Ent qPCR CCE
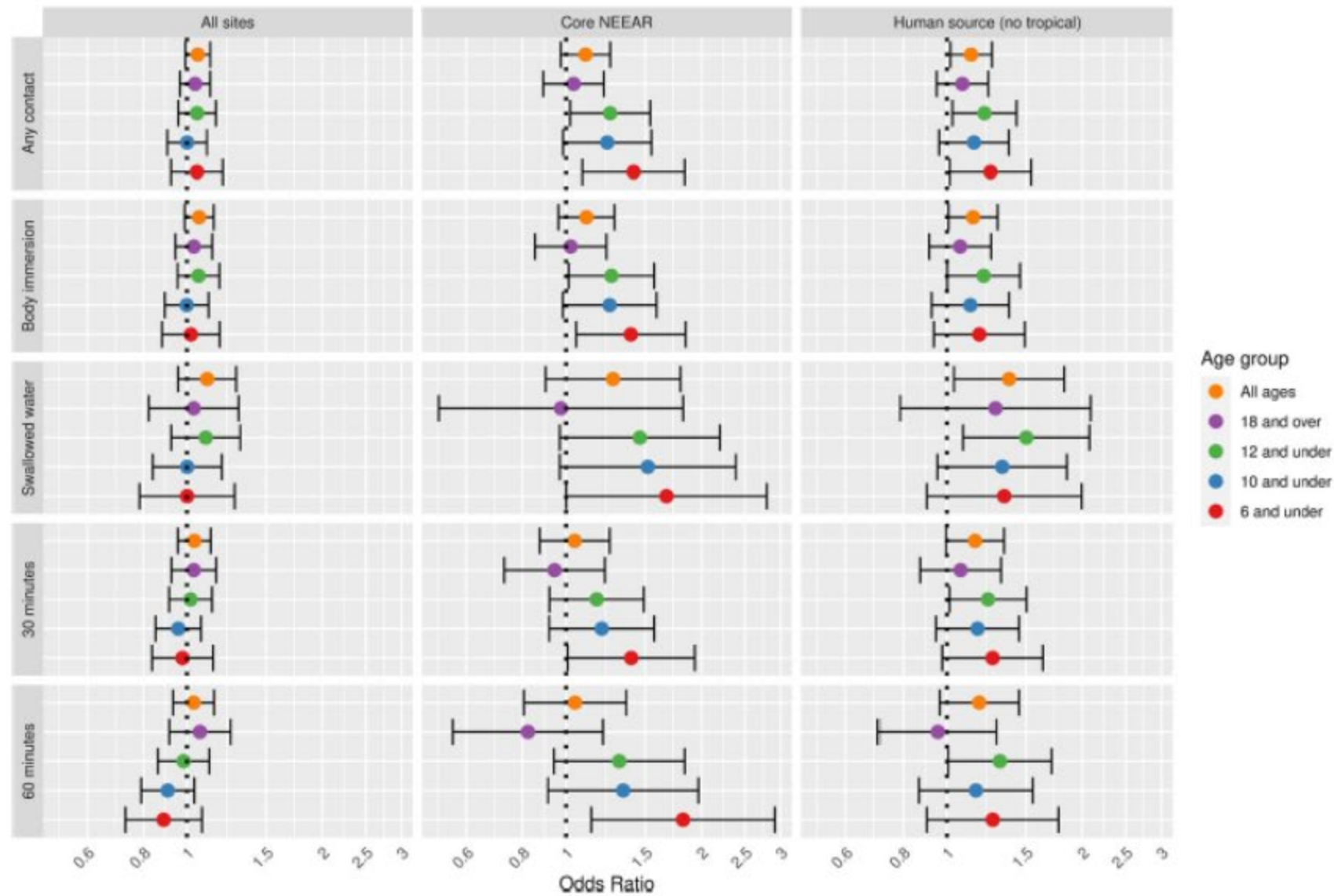
(among exposed group)
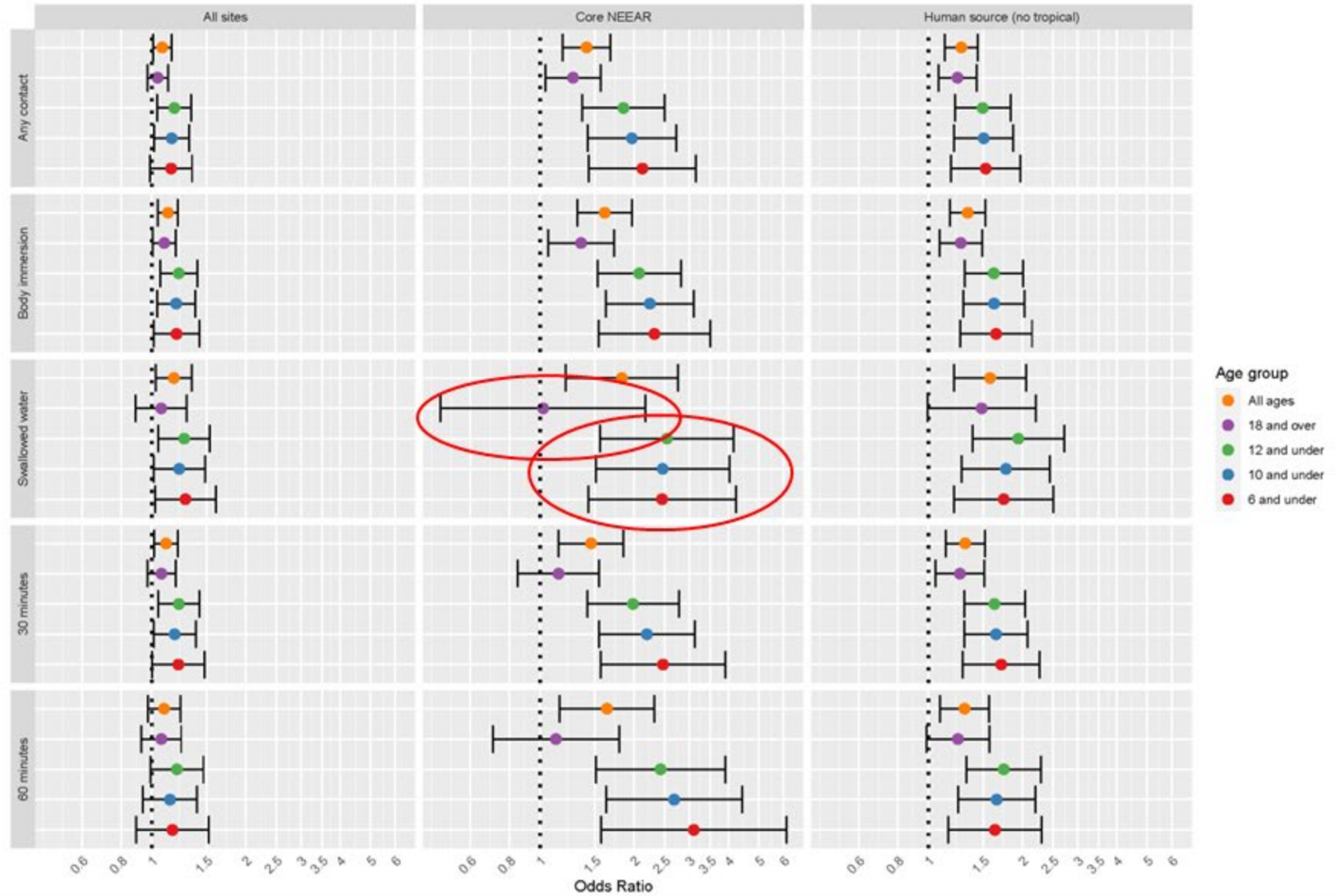
Wade et al. (2022): Children's Health Outcomes

Odds ratios for NGI associated with a 1 log increase in ENT qPCR CCE
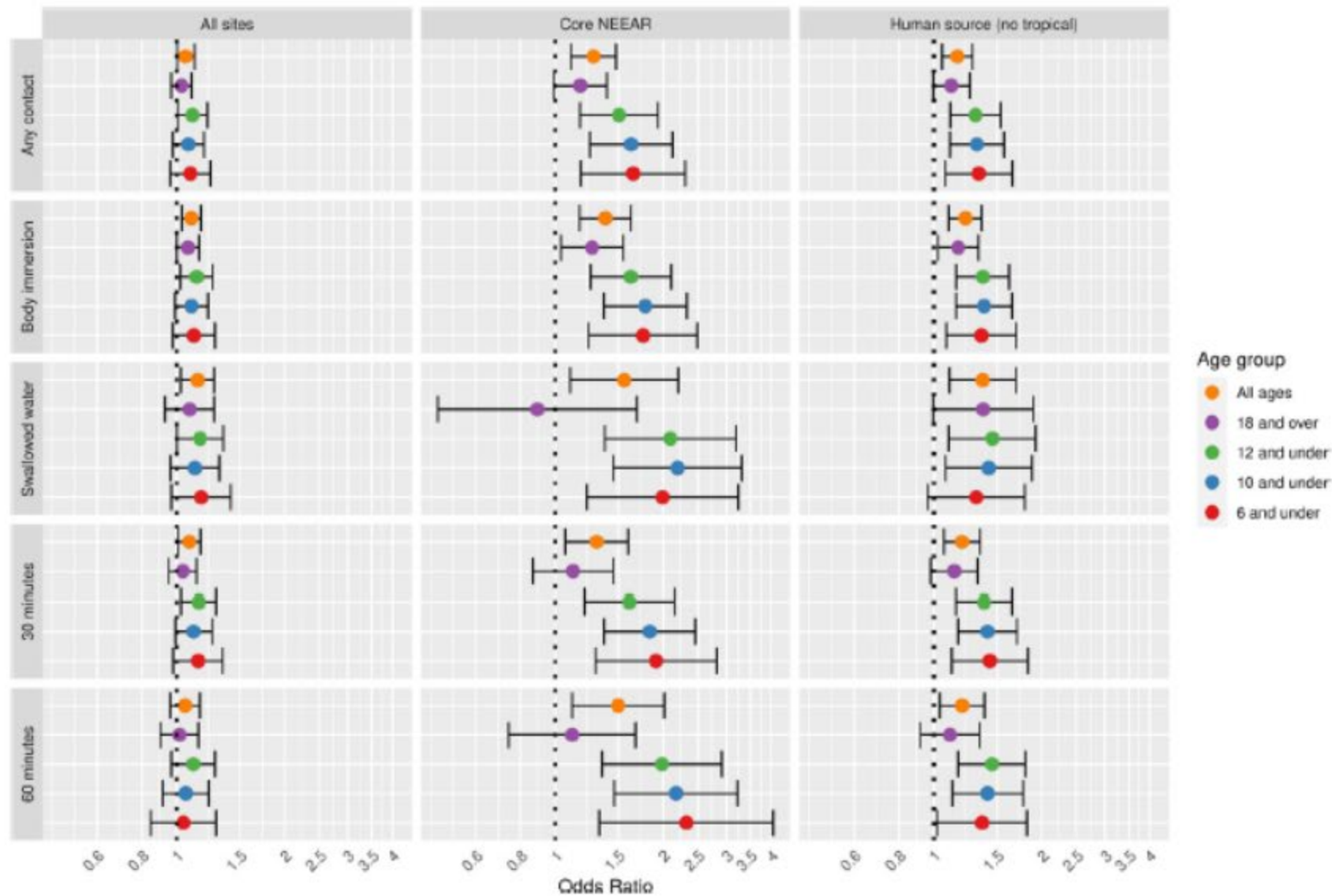
Wade et al. (2022): Children's Health Outcomes

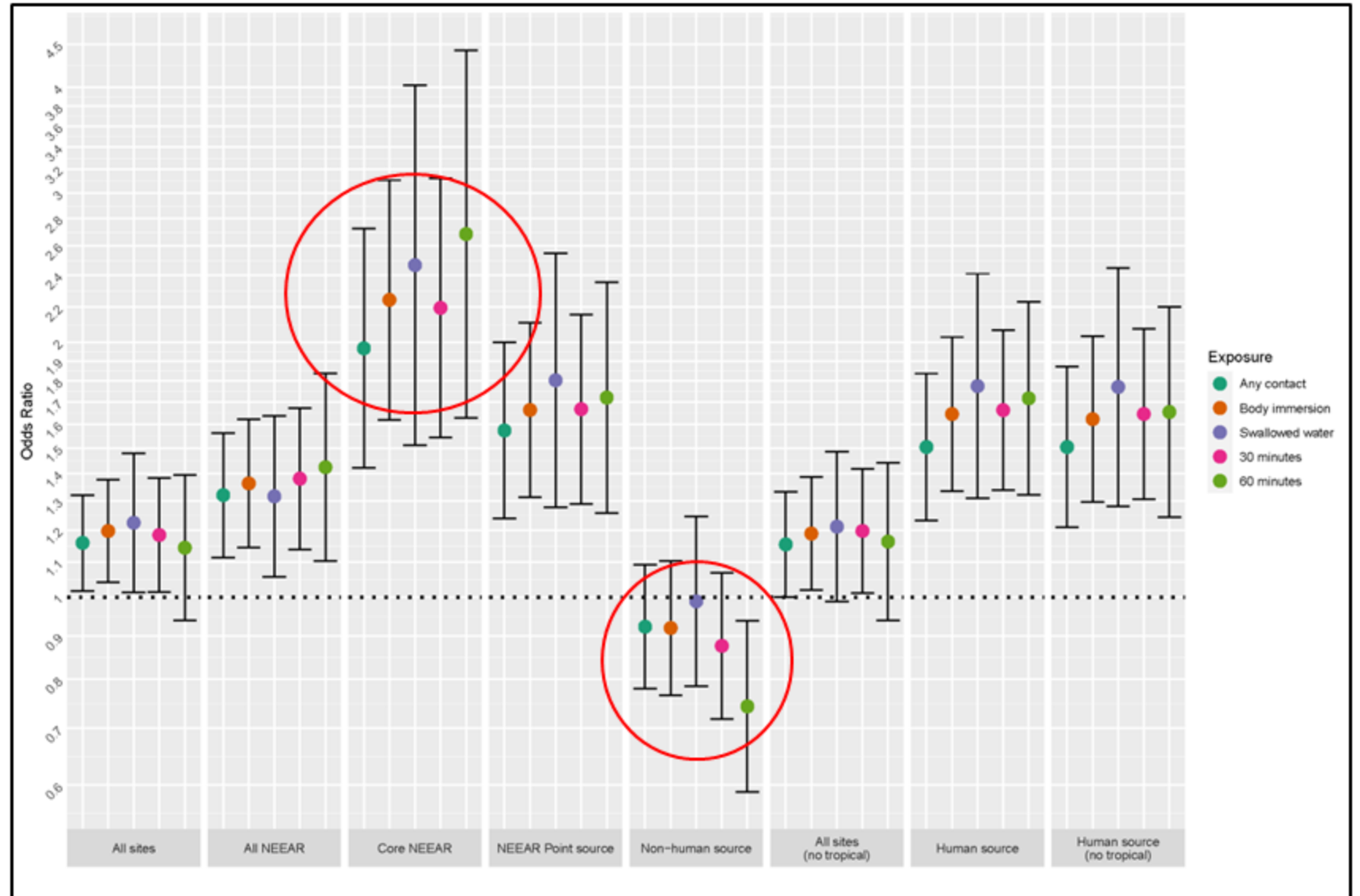Odds ratios for NGI associated with a 1 log increase in ENT CFU

Wade et al. (2022): Source of contamination

Odds ratios for diarrhea associated with a 1 log increase in Ent qPCR

(among children 10 and under in exposed group)

- Human impacted sites driving risk

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Wade et al. (2022): Key Findings

- Diarrhea was more strongly associated with ENT than other health endpoints, including NGI.

- Associations with ENT qPCR were strongest and statistically significant among children under several different exposure scenarios.
  - Associations were weaker (not significant) among ENT CFUs with borderline statistical significance observed for children 6-years and under.

- Children were also at statistically significant greater risk for "severe" GI illness.
  - Resulting in missed activities, hospital visit, or lasting more than 3 days.

- Stronger associations observed at sites impacted by human fecal contamination – source matters.

- Strongest association at "Core" NEEAR sites.

- Stronger associations observed with higher exposures.

Conclusions

- Science continues to advance our understanding of risk in recreational waters affected by fecal contamination.

- Considerations when interpretating culturable FIB data includes their source and the source(s) of fecal contamination.

- Sanitary surveys* and other tools can be used to understand fecal sources.

- Additional tools have been developed to characterize potential risk (e.g., QMRA) and measure fecal contamination (e.g., gene-based methodologies, source identifiers).

*US EPA's sanitary survey app: https://www.epa.gov/beach-tech/sanitary-surveys-recreational-waters

Extra Slides

Sites

Beach	Location	Year	Notes	Number enrolled
West Beach	Indiana Dunes State Park, Lake Michigan	2003	Freshwater, Great Lakes	2,877
Huntington Beach	Bay Village Ohio, Lake Erie	2003	Freshwater, Great Lakes	2,840
Silver Beach	St. Joseph Michigan, Lake Michigan	2004	Freshwater, Great Lakes	10,921
Washington Park Beach	Michigan City Indiana, Lake Michigan	2004	Freshwater, Great Lakes	4,377
Edgewater Beach	Edgewater, Mississippi	2005	Marine, Gulf Coast	1,351
Fairhope Beach	Fairhope, Alabama	2007	Marine, Gulf Coast	2,022
Goddard State Park Beach	Goddard State Park, Rhode Island	2007	Marine, Atlantic	2,977
Surfside Beach	Surfside, South Carolina	2009	Marine, Atlantic	11,159
Boquerón Beach	Boquerón, Puerto Rico	2009	Marine, Atlantic, Tropical	15,726
Malibu Beach	Malibu, California	2009	Marine, Atlantic	5,674
Doheny Beach	Dana Point, California	2007-2008	Marine, Pacific	9,303
Mission Bay	San Diego, California	2003	Marine, Pacific	8,076
Avalon Beach	Catalina Island, California	2007-2008	Marine, Pacific	6,149