Health risk of *Escherichia coli* exposure in fresh water beaches:

A Focused Practice Question

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Key Messages

1. A literature review was conducted to assess the risk of human illness associated with exposure to *Escherichia coli (E. coli)* present in untreated fresh recreational water at levels below 200 colony-forming units (cfu)/100 mL.

2. The risk of gastrointestinal (GI) illness associated with exposure to *E. coli* in fresh water beaches (through activities likely involving ingestion of water) at levels below a geometric mean of 200 cfu/100 mL is under 10 cases per 1000 bathers (1%).

3. The level of protection against GI illness corresponding to setting an *E. coli* guideline for fresh water beaches between 100 and 200 cfu/100 mL varies depending on the swimming-associated risk level deemed acceptable (from an illness rate of 0.7% to 1%, respectively).

1 Background

Peel region has four public fresh water beach sites (one spring-fed; three on Lake Ontario). The Ontario Public Health Standards (OPHS) under the Health Protection and Promotion Act mandates health units to monitor public beaches to prevent and reduce water-borne illness and injury related to recreational water use (1). Under the OPHS, the Beach Management Protocol outlines the requirement to conduct routine water sampling to assess water quality conditions at public beaches (2). Tests for levels of *Escherichia coli* (*E. coli*) are conducted as a water quality indicator for fecal contamination. Although beaches are monitored regularly, receiving timely results from the lab is a challenge as the turnaround time may take 2-4 days, which could hinder prompt notification of adverse conditions to potential beach users. Predictive beach modelling has been employed by some Ontario health units to overcome this delay. Peel Public Health is in the process of developing such a model with parameters including weather conditions, bather use, and threshold *E. coli* levels.

Research has shown that *E. coli* is a good indicator of gastrointestinal (GI) illness risk in recreational fresh water (3-6). For decades, *E. coli* has been the recommended indicator of the quality of recreational fresh water by Health Canada (7,8) and the U.S. Environmental Protection Agency (6,9) based on epidemiological studies. Health Canada has historically recommended a threshold of 200 colony-forming units (cfu)/100 mL for fresh water (7,8). Thus, many provinces have adopted this guideline. However, in Ontario, 100 cfu/100 mL has historically been the guideline (7,10) although the history behind this decision is not known (Tony Amalfa, Manager, Environmental Health Policy & Programs, MOHLTC, personal communication, 2014). Peel Public Health currently

adopts the Health Canada guideline (8) for recreational water quality. Under the Beach Management Protocol, water sampling of public beaches are conducted weekly during the beach season.

The discrepancy in *E. coli* standards across jurisdictions prompted a review of the scientific evidence. Thus, the purpose of this review is to determine the risk of human illness associated with exposure to *E. coli* in recreational fresh water below Health Canada's guideline of 200 cfu/100mL, and ultimately the science-based threshold for *E. coli* to inform predictive modelling.

2 Literature Review Question

What is the risk of human illness associated with exposure to *E. coli* present in untreated fresh recreational water at levels below 200 colony-forming units (cfu)/100 mL?

3 Literature Search

A literature search was conducted in January 2015 in Medline and Environment Complete. A complementary grey literature search was conducted during the same time period in Google Scholar and a variety of websites of environmental and/or health organizations in government. Searches were limited to synthesized research (reviews and guidelines) in the English language. Refer to Appendix A for the complete Search Strategy.

4 Relevance Assessment

The search results were screened for relevance by two reviewers based on the following:

Inclusion criteria:

- Fresh water bathing beaches (e.g. lake water) or untreated recreational water (including man-made, inland beaches)

- Synthesized research (e.g. reviews/guidelines)

- Human health effects (e.g. gastrointestinal or respiratory illness, skin/eye/ear infections)

Exclusion criteria:

- Marine water/ocean beaches

- Treated recreational water like swimming pools/spas

- Injury/drowning

- Ecosystem health

5 Results of the Search

Five articles from Medline and 13 grey literature articles were identified from the literature search. Following relevance assessment (based on title/abstract screening and full text review) by two reviewers, two guidelines (8,9) and a meta-analysis (11)

remained. Although the meta-analysis was cited in both guidelines, it was included because it provided a quantitative analysis of the *E. coli* threshold. Refer to Appendix B for the Literature Search Flowchart.

6 Critical Appraisal

Two reviewers independently appraised the two guidelines using the AGREE II tool, and the meta-analysis using the Health Evidence Quality Assessment Tool for review articles. Discrepancies were resolved through discussion. Methodologies of the guidelines were obtained by directly contacting the authors (Teresa Brooks, Water & Air Quality Bureau, Health Canada, personal communication, 2015; Sharon Nappier, Microbiologist, Office of Water, US EPA, personal communication, 2015) and accessing supplementary documents (12). Following quality assessment, the meta-analysis (11) was rated strong and the two beach water guidelines from Health Canada (8) and the US EPA (9) were rated moderate.

7 Description of Included Reviews/Guidelines

Two beach water guidelines and a meta-analysis/systematic review were selected for inclusion. The meta-analysis (11) examined swimming as the exposure, and the two guidelines (8,9) focused on primary contact exposure to water, which include activities that likely involve ingestion of water (e.g., swimming, waterskiing, whitewater rafting). Both guidelines based their *E. coli* standards on geometric mean[1] values of water quality data.

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[1] Geometric mean is the average of the $\log_{10}$ sample values raised to the power of 10. It minimizes the very high or low values on the average. This calculation is used to average the *E. coli* levels in samples collected from recreational water.

The primary outcome examined in the included articles was GI illness, because it has been extensively studied and has formed the basis of the EPA and Health Canada's recreational water quality guidelines. Studies by the EPA and previous epidemiological studies have shown that criteria based on protecting the public from GI illness via fecal indicator bacteria will prevent most types of recreational waterborne illnesses (9). Compared with other adverse health effects that can be caused by fecal matter contamination including upper respiratory illness, rash, eye ailments, earache, and infected cuts, GI illness was found to have the strongest association. See below for the description of each included review/guideline.

1. **Do US Environmental Protection Agency Water Quality Guidelines for Recreational Waters prevent gastrointestinal illness? A systematic review and meta-analysis (Wade et al., 2003)** (11)

Results have shown that high *E. coli* levels in freshwater (ranging from 187-204 cfu/100 mL) were significantly associated with GI illness (RR=1.78; 95% CI: 1.45-2.20), whereas low *E. coli* levels (ranging from 45-170 cfu/100 mL) were not (RR=1.22; 95% CI: 0.99-1.51).

E. coli levels above EPA's guideline (US EPA, 1986) (see below) was significantly associated with GI illness (RR=1.81; 95% CI: 1.47-2.22), whereas levels below were not (RR=1.20; 95% CI: 0.97-1.48).

The fact that the meta-analysis was based on only five studies should be noted.

2. **Recreational Water Quality Criteria (US EPA, 2012)** (9)

Based on EPA's 1986 Recreational Water Quality Criteria (6) and studies conducted by the EPA to determine the GI illness rate (9), EPA's 2012 guideline recommends that levels of *E. coli* in fresh water (in a 30-day interval) not exceed either a geometric mean of:

126 cfu/100 mL based on an acceptable risk level of GI illness of 8 cases per 1000 bathers (the same guideline value recommended in 1986 (6),

OR

100 cfu/100 mL based on an acceptable level of risk of GI illness of 7 cases per 1000 bathers.

In addition to the geometric mean threshold, EPA also recommends that *E. coli* levels not exceed the corresponding statistical threshold value (STV; 90th percentile of the same water quality distribution) in greater than 10% of the samples in the same 30-day interval (Table 1). The STV accounts for variation in water quality measurements while restricting the number of samples allowed to exceed the STV.

EPA recommends that states make a risk management decision regarding illness rate, which would determine which set of guidelines to use (see Table 1 for comparison across guidelines).

Derivation of these guidelines was based on the equation originally developed in 1986 (6):

Seasonal risk of GI illness per 1000 persons = 9.397 (log10 *E. coli* concentration per 100 mL) – 11.74

GI illness is defined (based on the 1986 definition (6)) as: one or more symptoms within 8-10 days of swimming including vomiting, diarrhea with fever or disabling condition (remained at home, remained in bed or sought medical advice because of symptoms), or stomach ache or nausea accompanied by fever. Note that EPA now uses a broader GI illness case definition which includes these symptoms without requiring the occurrence of fever and a longer incubation time of 10-12 days. EPA calculated that 36 cases per 1000 bathers (2012 GI illness definition) is equivalent to 8 cases per 1000 bathers (1986 definition).

The EPA also provides states with the option of using beach action values (BAVs) corresponding to a 75th percentile value as a conservative precautionary tool for beach notification purposes. That is, any single sample exceeding the BAV could trigger a beach advisory.

States may also develop their own site-specific standards provided that they are scientifically defensible (based on their own epidemiological studies).

3. Guideline for Canadian Recreational Water Quality (Health Canada, 2012) (8)

Based on the derivation of EPA's 1986 *E. coli* guideline (6), Health Canada's latest guideline (2012) recommends a geometric mean of 200 cfu *E. coli*/100 mL in fresh water, which corresponds to an acceptable risk level of GI illness of approximately 10 cases per 1000 bathers (Table 1). According to Health Canada, results of its literature review concluded that there was insufficient evidence to suggest a revision of its existing *E. coli* guideline value.

In addition to the threshold geometric mean, Health Canada also recommends that *E. coli* levels not exceed the single sample maximum (SSM) concentration of 400 cfu/100 mL at a beach site. Additionally, Health Canada recognizes the limitations of monitoring indicator levels, as the absence of *E. coli* does not necessarily mean that pathogens are absent, and that it is just one aspect of a multi-barrier approach.

Health Canada's rationale for the acceptable level of GI illness risk was a risk management decision in consideration of potential health risks and benefits of recreational water use in terms of physical activity and enjoyment. According to Health Canada, this was a reasonable estimate of risk of illness likely experienced by users engaged in a voluntary activity, and suitably protective in the Canadian setting.

Table 1: Comparison of *E. coli* standards in fresh water and associated GI illness rate*

Guideline	GI Illness rate (# cases/1000 bathers)	Geometric mean (cfu/100mL)	Other threshold values (cfu/100mL)
US Environmental Protection Agency	7	100 (within 30-day interval)	320 (STV)
	8	126 (within 30-day interval)	410 (STV)
Health Canada	~10	200 (minimum 5 samples)	400 (SSM)

*1986 GI illness definition used to allow for comparability across guidelines.
STV: statistical threshold value (cannot be exceeded in > 10% of samples in 30-day period)
SSM: single sample maximum (cannot be exceeded at any beach site)

8 Synthesis of Findings

1) **Exposure to _E. coli_ levels above 126 cfu/100mL in fresh water beaches is associated with a higher risk of GI illness**

- Based on the meta-analysis of five studies, _E. coli_ levels above EPA's guideline of 126 cfu/100 mL was significantly associated with GI illness (RR=1.81; 95% CI: 1.47-2.22), whereas levels below were not (RR=1.20; 95% CI: 0.97-1.48). Additionally, high _E. coli_ levels in freshwater (ranging from 187-204 cfu/100 mL) were significantly associated with GI illness (RR=1.78; 95% CI: 1.45-2.20), whereas low _E. coli_ levels (ranging from 45-170 cfu/100 mL) were not (RR=1.22; 95% CI: 0.99-1.51).

2) **The risk of human illness (GI illness) associated with exposure to _E. coli_ in untreated fresh recreational water at levels below geometric mean of 200 cfu/100 mL is under 10 per 1000 bathers.**

- Health Canada's 2012 guideline found insufficient evidence to suggest a revision of its existing _E. coli_ geometric mean guideline value of 200 cfu/100 mL, which corresponds to a GI illness rate of approximately 10 cases per 1000 bathers.

- Based on additional primary research, EPA's 2012 guideline continues to report that a geometric mean _E. coli_ level of 126 cfu/100 mL corresponds to a GI illness rate of 8 cases of GI illness per 1000 bathers. Based on the same mathematical formula, an _E. coli_ level of 100 cfu/100 mL corresponds to a risk of GI illness of 7 cases per 1000 bathers. Furthermore, EPA recommends that states make a risk management decision regarding illness rate, which would determine which set of guidelines to use.

9 Limitations and Gaps

- Only five studies were included in the meta-analysis of studies of *E. coli* levels in fresh water beaches (Wade, 2003). There was also evidence for borderline publication bias.

- Limitations to note of the literature review conducted by Health Canada (Health Canada, 2012) include the absence of clear inclusion criteria, and lack of a systematic approach to assessing the quality of the included studies.

- Another limitation recognized by Health Canada was that the absence of *E. coli* does not necessarily mean that pathogens are absent, as it is meant to act as an indicator of fecal contamination in water (Health Canada, 2012).

- The EPA's updated guideline (US EPA, 2012) was based on additional studies of enterococci, which have not been quality appraised. The *E. coli* guideline threshold was not directly re-validated through these studies.

- Both EPA's and Health Canada's *E. coli* guidelines are based on risk of illness in the general population. Although EPA recognized that children may be at higher risk of illness, there was inconclusive evidence that children exhibited a significantly different illness response than the general population (US EPA, 2012).

- All research findings are limited to primary contact exposure to beach water (where ingestion of water is likely such as swimming).

10 Recommendation

It is recommended that the acceptable risk level of GI illness corresponding to setting the *E. coli* guideline level in recreational fresh water be set to match the background rate of GI illness associated with recreational activity at beaches in Peel region if data are available. The risks and benefits of the decision to set a particular illness risk level must be considered as appropriate to the nature of Peel's population and beach sites.

References

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(2) MOHLTC. Beach Management Protocol, 2014. 2014; Available at: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/beach_management.pdf. Accessed April 6, 2015.

(3) Prüss A. Review of epidemiological studies on health effects from exposure to recreational water. Int J Epidemiol 1998;27(1):1-9.

(4) United States Environmental Protection Agency (US EPA). Implementation guidance for ambient water quality criteria for bacteria (May 2002 draft). 2002.

(5) Zmirou D, Pena L, Ledrans M, Letertre A. Risks associated with the microbiological quality of bodies of fresh and marine water used for recreational purposes: summary estimates based on published epidemiological studies. Arch Environ Health 2003;58(11):703-711.

(6) US EPA. Ambient Water Quality Criteria for Bacteria-1986. 1986; Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/upload/2009_04_13_beaches_1986crit.pdf. Accessed April 6, 2015.

(7) Ministry of National Health and Welfare. Guidelines for Canadian Recreational Water Quality. 1992.

(8) Health Canada. Guidelines for Canadian Recreational Water Quality, third edition. 2012; Available at: http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/guide_water-2012-guide_eau/index-eng.php. Accessed April 6, 2015.

(9) US EPA. Recreational Water Quality Criteria. 2012; Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/index.cfm. Accessed April 6, 2015.

(10) Public Health Ontario (PHO). Public Health Inspector's guide to the principles and practices of environmental microbiology. 4th ed. 2013.

(11) Wade TJ, Pai N, Eisenberg JN, Colford JMJ. Do U.S. Environmental Protection Agency Water Quality Guidelines for Recreational Waters prevent gastrointestinal illness? A systematic review and meta-analysis. Environmental Health Perspectives 2003;111(8):1102-1109.

(12) US EPA. Report of the Experts Scientific Workshop on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria. 2007;

Available at:
http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/upload/2007_06_26_criteria_recreation_experts_expertsWorkshop.pdf. Accessed April 6, 2015.

Appendices

Appendix A: Search Strategy

Appendix B: Literature Search Flowchart

Appendix C: Data Extraction Tables

Appendix A: Search Strategy

Database: Ovid MEDLINE(R) <1946 to January Week 3 2015>
Search Strategy:
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1   Water Microbiology/ (27654)
2   Water Pollutants/ (12834)
3   exp Water Pollution/ (20362)
4   Escherichia coli/ (226627)
5   Escherichia coli Infections/ (25729)
6   Swimming/ (13352)
7   Recreation/ (5128)
8   Bathing Beaches/ (855)
9   beach*.ti,ab. (4102)
10   recreational water.ti,ab. (391)
11   exp Gastrointestinal Diseases/ep, et, mi, pc [Epidemiology, Etiology, Microbiology, Prevention & Control] (214673)
12   gastrointestinal illness.ti,ab. (713)
13   GI illness.ti,ab. (54)
14   Diarrhea/ep, et, pc [Epidemiology, Etiology, Prevention & Control] (17322)
15   Disease Transmission, Infectious/ (6047)
16   Communicable Diseases/ep, et [Epidemiology, Etiology] (6839)
17   Health Status/ (60306)
18   health effect*.ti,ab. (15949)
19   human health.ti,ab. (19014)
20   health outcome*.ti,ab. (20194)
21   ear infection.ti,ab. (572)
22   eye infection.ti,ab. (248)
23   skin infection.ti,ab. (1329)
24   11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 (350613)
25   6 or 7 or 8 or 9 or 10 (22677)
26   escherichia coli.ti,ab. (206620)
27   "e. coli".ti,ab. (98765)
28   4 or 5 or 26 or 27 (317561)
29   24 and 25 and 28 (66)
30   remove duplicates from 29 (66)
31   limit 30 to (english language and humans) (51)
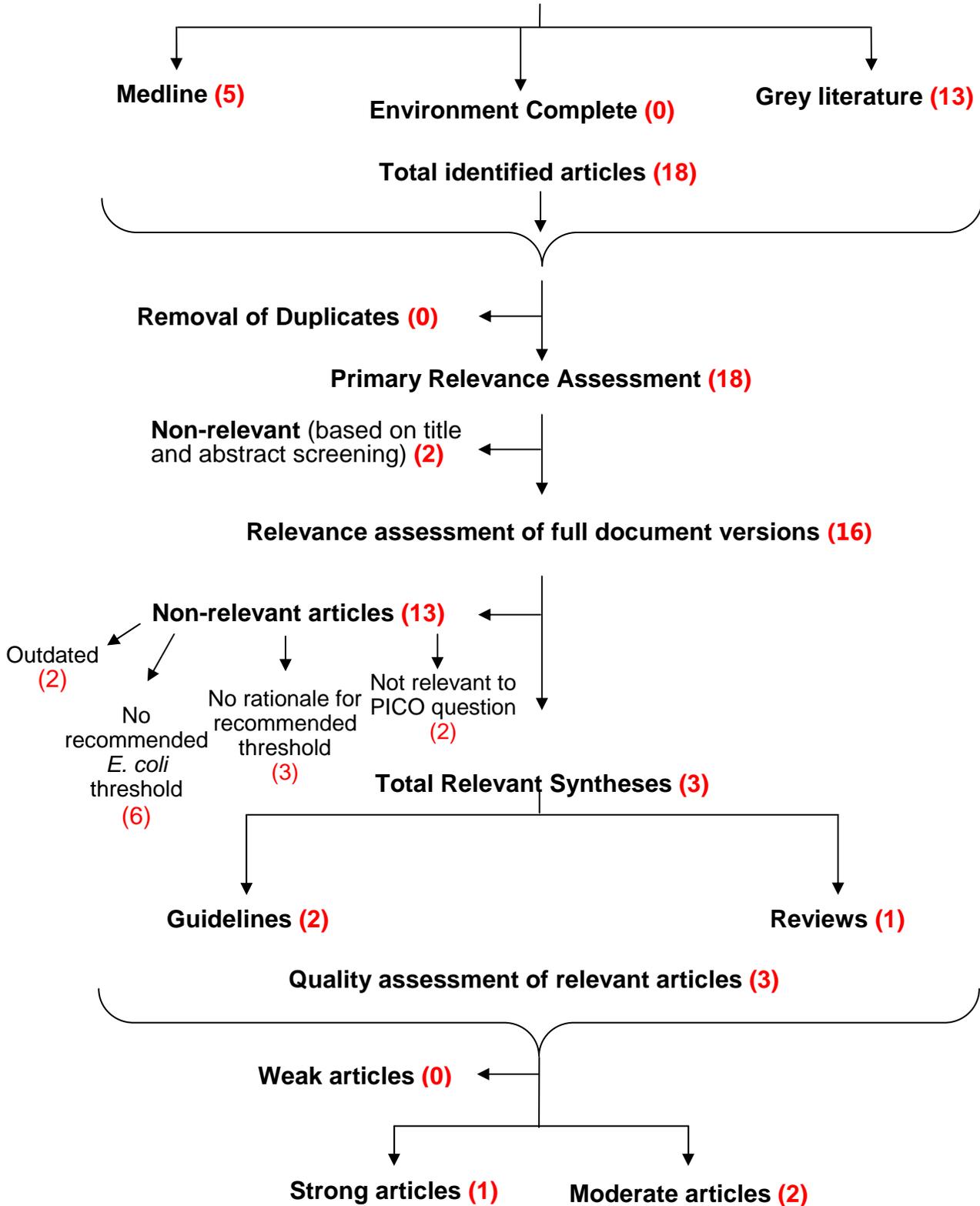32   limit 31 to "review articles" (5)

Note: A search of the Environment Complete database was also conducted by adapting

the Medline search terms. A search by author Wade, TJ (from US EPA) was also

conducted in Medline.

Grey Literature Databases/Websites

Google Scholar, National Institute for Health and Care Excellence (NICE), guidelines.gov, the United States Environmental Protection Agency (US EPA), Centers for Disease Control (CDC), World Health Organization (WHO), European Union (EU), the International Triathlon Union, National Collaborating Centre for Environmental Health (NCCEH), Canadian Institute for Public Health Inspectors (CIPHI), National Association of County and City Health Officials (NACCHO), and provincial/federal health authorities (including Alberta Health Services, Manitoba Health, and Ontario Ministry of Health and Long-Term Care (MOHLTC), Public Health Ontario (PHO), Health Canada, and Public Health Agency of Canada (PHAC))

Appendix B: Literature Search Flowchart

What is the risk of human illness associated with exposure to *E. coli* present in untreated fresh recreational water at levels below 200 cfu/100 mL? (Jan. 2015)

Medline (5)

Environment Complete (0)

Grey literature (13)

Total identified articles (18)

Removal of Duplicates (0)

Primary Relevance Assessment (18)

Non-relevant (based on title and abstract screening) **(2)**

Relevance assessment of full document versions (16)

Non-relevant articles (13)

Outdated (2)

No recommended *E. coli* threshold (6)

No rationale for recommended threshold (3)

Not relevant to PICO question (2)

Total Relevant Syntheses (3)

Guidelines (2)

Reviews (1)

Quality assessment of relevant articles (3)

Weak articles (0)

Strong articles (1)

Moderate articles (2)

18

Adapted from: healthevidence.org *Keeping Track of Search Results: A Flowchart*. [Retrieved January 13, 2010]

Appendix C: Data Extraction Tables

Items reviewed	**Review #1 of 1:** Do U.S. Environmental Protection Agency (EPA) Water Quality Guidelines for Recreational Waters prevent gastrointestinal illness? A systematic review and meta-analysis.
General Information & Quality Rating	
Author(s), Date, Country	Wade et al., 2003, U.S.
Quality rating	Strong (using Health Evidence tool by the Environmental Health Critical Appraisal Club; n= 10)
Objective(s) of review	• Quantify the association between microbial indicators of recreational water quality and gastrointestinal illness • Evaluate the potential for gastrointestinal (GI) illness below current U.S. EPA guidelines. Note: The remainder of this table focuses on the association between *E. coli* levels in fresh water and GI illness.
Details on methodology	
Number of included primary studies	27 total (five relevant)
Types of studies	Prospective cohort, prospective studies during recreational events (athletic or organized recreational), randomized controlled trials, cross-sectional
Search period	1950-2003
Search sources	• Databases including Medline, BIOSIS, EMBASE, old Medline • Grey literature (doctoral dissertations, reports, conference proceedings, and other unpublished studies)
Inclusion/exclusion criteria	Inclusion: Human; English language abstract; at least one measure of microbial water quality reported; at least one measure of health potentially associated with water quality; all types of health outcomes (focus on GI illness); focus on epidemiologic studies that quantified relationship between water quality indicators and GI illness under endemic (non-outbreak) conditions Exclusion: Exposure to chlorinated water sources; no reporting of relationship between water quality and human health; studies that only examined infection (i.e., as measured by serology) and examined only typhoid and/or polio; risk assessments, case series, case reports, descriptions of outbreaks
Study population	Varied by study
Relevant exposure	Swimming exposure to fresh water with water quality measured by *E. coli* concentrations
Primary outcome	Focus on GI illness

Relevant review methods	Meta-analysis of studies investigating: • association between GI illness and exposure to water quality indicator *E. coli* in fresh water • association between GI illness and exposure to *E. coli* above or below EPA guideline threshold in fresh water
Results & Limitations	
Relevant results of review	• High *E. coli* levels in fresh water (ranging from 187-204 cfu/100 mL) were significantly associated with GI illness (RR=1.78; 95% CI: 1.45-2.20), whereas low *E. coli* levels (ranging from 45-170 cfu/100 mL) were not (RR=1.22; 95% CI: 0.99-1.51). • In fresh water, *E. coli* was a more reliable and consistent predictor of GI illness than other bacterial indicators. *E. coli* levels above EPA threshold (126 cfu/100mL) with a median density of 187 cfu/100 mL were significantly associated with GI illness (RR=1.81; 95% CI: 1.47-2.22), whereas levels below with a median density of 60 cfu/100 mL were not significantly associated with illness (RR=1.20; 95% CI: 0.97-1.48).
Comments/limitations	• Only five studies included in meta-analyses of studies of *E. coli* levels in fresh water beaches. • Heterogeneity of studies in terms of study population and control group (i.e. non-swimming versus swimming control group). This was accounted for by using conservative random effects model in analyses. • Evidence for possible publication bias found (borderline).

Items reviewed	Guideline #1 of 2: Guidelines for Canadian Recreational Water Quality, third edition
General Information & Quality Rating	
Author(s), Date, Country	Health Canada, 2012, Canada
Quality rating	• Moderate (using AGREE II tool by two independent reviewers) • Guideline recommended for use with modifications
Focus & Objectives	• Provide guidance on management of untreated recreational waters, including approaches to water quality hazard assessment, monitoring and implementation of preventive/corrective actions. • Establish guideline values for specific parameters used to monitor recreational water quality including bacteriological indicators of fecal contamination, cyanobacteria and their toxins, and values for physical and aesthetic objectives. • Provide related technical and scientific information on water quality parameters and hazards of importance for Canadian recreational waters. • Relevant section: Subsection 4.1.1 (Fresh waters: *Escherichia coli*) of Section 4.1 (Indicator organisms for primary contact recreation) of Part II: Guideline Technical Documentation Note: The remainder of this table focuses on the *E. coli* guideline in fresh water and its scientific rationale.
Target audience	Authorities and decision-makers (i.e. province/territories/local public health) responsible for recreational water management
Target population	General population
Exposure of interest	Primary contact exposure to fresh water defined as the whole body or face and trunk frequently immersed or face frequently wetted by spray, and some water likely swallowed (through activities such as swimming, surfing, waterskiing). Water quality measured using *E. coli* as an indicator of fecal contamination.
Primary outcome	Gastrointestinal illness
Types of evidence used to inform guideline	• Results of literature review • Risk management decisions based on assessment of possible health risks and potential benefits (e.g. health and enjoyment) for recreational water use. • Feedback from external peer-review by four international experts • Stakeholder/public consultation feedback
E. coli **guideline in fresh water** (cfu=colony forming units)	• Geometric mean (minimum of 5 samples) $\leq$ 200 cfu/100 mL • Single sample maximum concentration $\leq$ 400 cfu/100 mL (based on 1986 U.S. EPA water quality criteria with acceptable GI illness risk level of 0.99%)

Details on methodology of literature review	
Number of included primary studies/reviews	23 new studies/reviews overall since last update of Health Canada guideline (1992) (two relevant studies including a prospective cohort study and a randomized trial)
Search period	1989-2008
Literature search sources	PubMed, published texts, and grey literature (epidemiological investigation reports, disease surveillance reports and guideline documentation from other government and multinational organizations)
Inclusion/exclusion criteria	Inclusion/exclusion of articles determined by internal discussion among Federal-provincial-territorial working group. No formal criteria developed. Studies of "high quality" as determined by the working group were included in the review based on the following considerations: • addressed temporal and spatial variation in indicator organism concentrations • related water quality to bathers at time of exposure • clear definitions of exposure • uniformity between exposed and unexposed groups • clear, recognized definitions of illness • appropriate sample size, response method and response rate • accounted for non-water-related causes of illness in analysis
Settings of primary studies/reviews	U.S., Germany, the Netherlands
Comments/limitations	• *E. coli* guideline value has not changed since last guideline in 1992. The results of the literature review indicated insufficient evidence to suggest revision of existing guideline. • There were no systematic criteria for inclusion of studies nor systematic assessment of study quality. Although there was no structured critical appraisal tool used, studies of high quality were included based on certain considerations.

Items reviewed	Guideline #2 of 2: Recreational Water Quality Criteria
General Information & Quality Rating	
Author(s), Date, Country	U.S. Environmental Protection Agency, 2012, U.S.
Quality rating	• Moderate (using AGREE II tool by two independent reviewers) • Guideline recommended for use with modifications Note: The AGREE II tool was not entirely suitable for appraising this guideline due to the nature of the evidence used to inform the guideline (i.e. primary studies conducted by the EPA). Not all sections of tool were applicable. For the Rigour of Development domain (except items 13 and 14) and Clarity of Presentation domain, only the methodology and recommendations relevant to the *E. coli* guideline were appraised.
Focus & Objectives	• Recommend recreational water quality criteria (RWQC) for the protection of primary contact recreation in both coastal and non-coastal waters, based on all available information relating to the effects of fecal contamination on human health • Describe how scientific findings were used to develop RWQC • Provide information for states that prefer to adopt water quality criteria that differ from RWQC • Main relevant section: Section 3.2.4 Developing *Enterococci* measured by culture criteria and comparable values for culturable *E. coli* and *Enterococcus* spp. measured by qPCR Note: The remainder of the table focuses on the *E. coli* guideline for fresh water.
Target audience	States responsible for developing or implementing recreational water quality criteria
Target population	General population
Exposure of interest	Primary contact exposure to fresh water (i.e. swimming, bathing, surfing, or similar water contact activities) with *E. coli* used as water quality indicator.
Primary outcome	Gastrointestinal (GI) illness
***E. coli* guidelines in fresh water** (cfu= colony-forming units)	• Geometric mean (within 30-day interval) $\leq$ 126 cfu/100 mL • Statistical threshold value (STV) $\leq$ 410 cfu/100 mL (based on an estimated GI illness[a] rate of 36 per 1000 bathers; equivalent to 8 per 1000 bathers using 1986 definition[b]) OR • Geometric mean (within 30-day interval) $\leq$ 100 cfu/100 mL • STV $\leq$ 320 cfu/100 mL (based on an estimated GI illness[a] rate of 32 per 1000 bathers; equivalent to 7 per 1000 bathers using 1986 definition[b])

	No greater than 10% of samples should exceed STV within the same 30-day interval.
Details on methodology	
Types of evidence used	1986 EPA Recreational Water Quality Criteria 2007 Expert Scientific Workshop (convening of national and international experts to determine research needs for developing/revising recreational water quality criteria) - EPA's National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) studies - External peer review feedback - Stakeholder consultation feedback
Included primary studies	Relevant NEEAR studies described in the guideline and in these publications: Wade et al. (2008). High sensitivity of children to swimming-associated gastrointestinal illness-results using a rapid assay of recreational water quality. *Epidemiology,* 19(3): 375-383. Wade et al. (2010). Rapidly measured indicators of recreational water quality and swimming-associated illness at marine beaches: a prospective cohort study. *Environmental Health,* 9: 66.
Settings of primary studies	Temperate fresh water settings (the U.S. Great Lake beaches), temperate marine water settings (Alabama, Rhode Island, Mississippi)
Types of research included	Prospective cohort study
Search period	N/A
Literature search sources	N/A
Inclusion/exclusion criteria	N/A
Comments/limitations	- Guideline value for *E. coli* has not changed since 1986 criteria except for different definition of GI illness. - GI Illness rates in marine and fresh water beaches derived from NEEAR studies. *E. coli* threshold was not directly re-validated through the NEEAR studies. - The quality of NEEAR studies has not been appraised. - The NEEAR studies ensured that children were overrepresented in the study sample. However, the studies provided inconclusive evidence that children (age 10 years and under) exhibited a significantly different illness response than the rest of the population. - Guideline is protective in both coastal (e.g. Great Lakes) and non-coastal (e.g. inland waters) water bodies. - Guideline is protective regardless of source of fecal contamination (human/non-human), because there was insufficient evidence to distinguish health risks from human vs. non-human sources at a national level.

a GI illness defined in EPA's 2012 guideline as any of the following within 10-12 days after swimming: a) diarrhea (three or more loose stools in a 24 hour period), b) vomiting, or c) nausea or stomach ache and impact on daily activity.
b GI illness defined in EPA's 1986 Recreational Water Quality Criteria as: one or more symptoms within 8-10 days of swimming including vomiting, diarrhea with fever or disabling condition (remained at home, remained in bed or sought medical advice because of symptoms), or stomach ache or nausea accompanied by fever. Estimated translation factor between the 1986 and 2012 GI illness definitions is 4.5.