

## SESSION 5 –PUBLIC ENGAGEMENT & HEALTH SYSTEM DECISION MAKING

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# Presenter Disclosure

- **Session Name:** Public Engagement and Health System Decision Making
- **Presenters:** Frank Wagner (moderator), Yvonne Bombard, Julia Abelson, Meredith Vanstone
- **Relationships with commercial interests:**
  - Not Applicable

# Disclosure of Commercial Support

- This session has received no commercial support

# Mitigating Potential Bias

- Not applicable

# Session Objectives

1. Learn about the public engagement activities of the Ontario Health Technology Advisory Committee (OHTAC) and develop an understanding of OHTAC's ongoing efforts to engage the public.
2. Learn about how OHTAC incorporates qualitative research and societal and ethical values in its recommendations.

# HQO/OHTAC AND PUBLIC ENGAGEMENT

## Setting the Context

**Frank Wagner, MA, MHSc**

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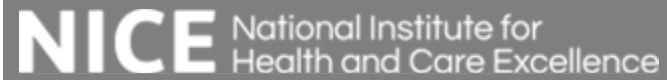
**Assistant Professor**, Department of Family and Community Medicine

# OHTAC and the Public Engagement Subcommittee

- February 2005 recommendation by 360 degree External Reviewer that “*OHTAC should review the various options for increasing the involvement of the general public in its decision-making process*” (Recommendation #6)
- Concern that there should be greater public input into the evidence based analysis process and increased transparency
- Existing website and MASinfo sheets were not seen as sufficiently proactive for encouraging public input



# OHTAC and the Public Engagement Subcommittee



✿ Driven by public **reaction to NICE guidance regarding Alzheimer drug** where caregivers challenged the chosen patient outcomes for assessing effectiveness of technologies—

i.e. need to find out **what matters most to patients and their caregivers when determining effectiveness**





# OHTAC and the Public Engagement Subcommittee

✿ In 2007, **OHTAC** had its first appeal of a recommendation, and wanted to test if **earlier public and provider consultation** could avoid future appeals on the grounds of misinterpretation of evidence

✿ Establishment of Ontario Local Health Integration Networks **(LHINS)** with **extensive mandate to consult the public** about needs for local services



# Transparent Drug System for Patients Act, 2006

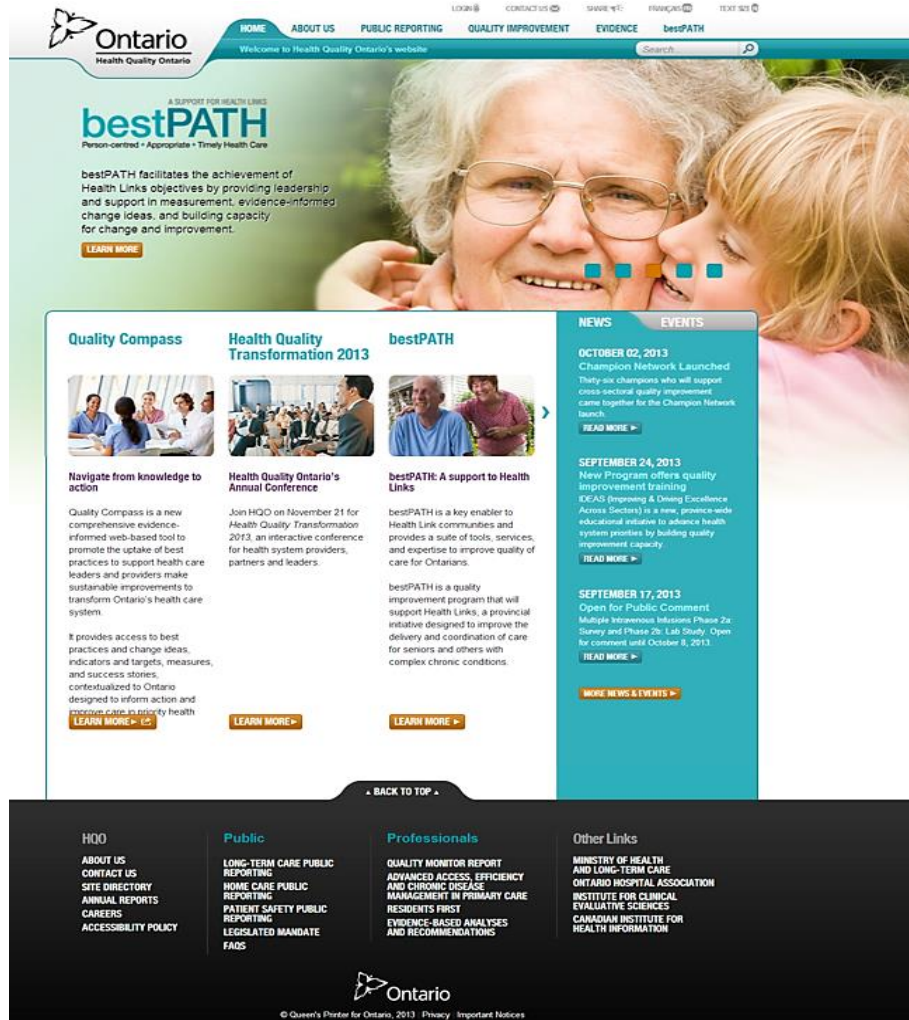
- ✿ Also, in 2006, Ontario passed the *Transparent Drug System for Patients Act*.
- ✿ Section 5.1 of this bill amends the *Ontario Drug Benefit Act*, setting out 5 principles, of which #2 is most significant:
  1. The public drug system aims to meet the needs of Ontarians, as patients, consumers and taxpayers.
  2. The public drug system aims to involve consumers and patients in a meaningful way.
  3. The public drug system aims to operate transparently to the extent possible for all persons with an interest in the system, including, without being limited to, patients, health care practitioners, consumers, manufacturers, wholesalers, and pharmacies.
  4. The public drug system aims to consistently achieve value-for-money and ensure the best use of resources at every level of the system.
  5. Funding decisions for drugs are to be made on the best clinical and economic evidence available, and will be openly communicated in as timely a manner as possible.

# Transparent Drug System for Patients Act, 2006

## Citizen's Council

- ✿ The Ontario Drug Benefit Act was amended by adding the following section in regard to a **Citizens' Council**
  - ✿ *The Minister shall establish a Citizens' Council whose duty shall be to ensure the involvement of patients in the development of pharmaceutical and health policy (new s. 1.5)*
- ✿ This is the only mention of the Citizens' Council in the legislation, keeping in mind Principle 2: **"The public drug system aims to involve consumers and patients in a meaningful way."**

# Evolution of Public Engagement and OHTAC



Objectives for the OHTAC Public Engagement Sub Committee were **informed by Michael Drummond's report of Feb 2005:**

*Determining Policies For Health Technologies In Ontario - A Process Review And Evaluation*

Final Report of the OHTAC Public Engagement Subcommittee (September 7, 2007) established a **strategic framework and made 11 recommendations.**

One of the key recommendations was that **OHTAC seek public engagement through it's website and through circulation of it's recommendations**

# Evolution of Public Engagement and OHTAC

- ✿ Naomi Aronson, Michael Drummond, and Stuart MacLeod, March 2008 *External Process Review and Evaluation of the Evidence-Based Health Technology Analysis Program in Ontario*, **recommended that OHTAC should adopt the (11) recommendations** of its Public Engagement Sub-Committee regarding involvement of the general public in its activities.
- ✿ One of **OHTAC's Key Activities in its Terms of Reference** 2008 stated:
  - ✿ Create and implement mechanisms to involve the general public in OHTAC decision-making and invite public engagement in reaching recommendations on evidence-based analysis.



# Excellent Care for All Act, 2010

- ✿ Section 12 (4) (1) (c) (1) of the *Excellent Care for All Act* specifies that HQO shall
  - ✿ seek the advice of the public in relation to the matters referred to in sub clause (1) (c) (ii).





# OHTAC Needs Public Engagement

- ✿ Decision Determinants Subcommittee produced a document originally published in June 2009 and revised September 2010
  - ✿ The Ontario Health Technology Advisory Committee (**OHTAC**) **Decision-Making Process for the Development of Evidence-Based Recommendations**
  - ✿ **Public engagement may help to contextualize** the criteria that are part of the decision determinants for example:
    - ✿ Consistency with expected societal and ethical values
    - ✿ Value for money
- ✿ Social Values and Ethics Subcommittee of OHTAC
  - ✿ **Articulate the basic values** that should guide all EDS assessments and OHTAC deliberations
  - ✿ **Develop methods** for identifying and addressing HTA topic-specific ethics and values issues

# Public Engagement Subcommittee

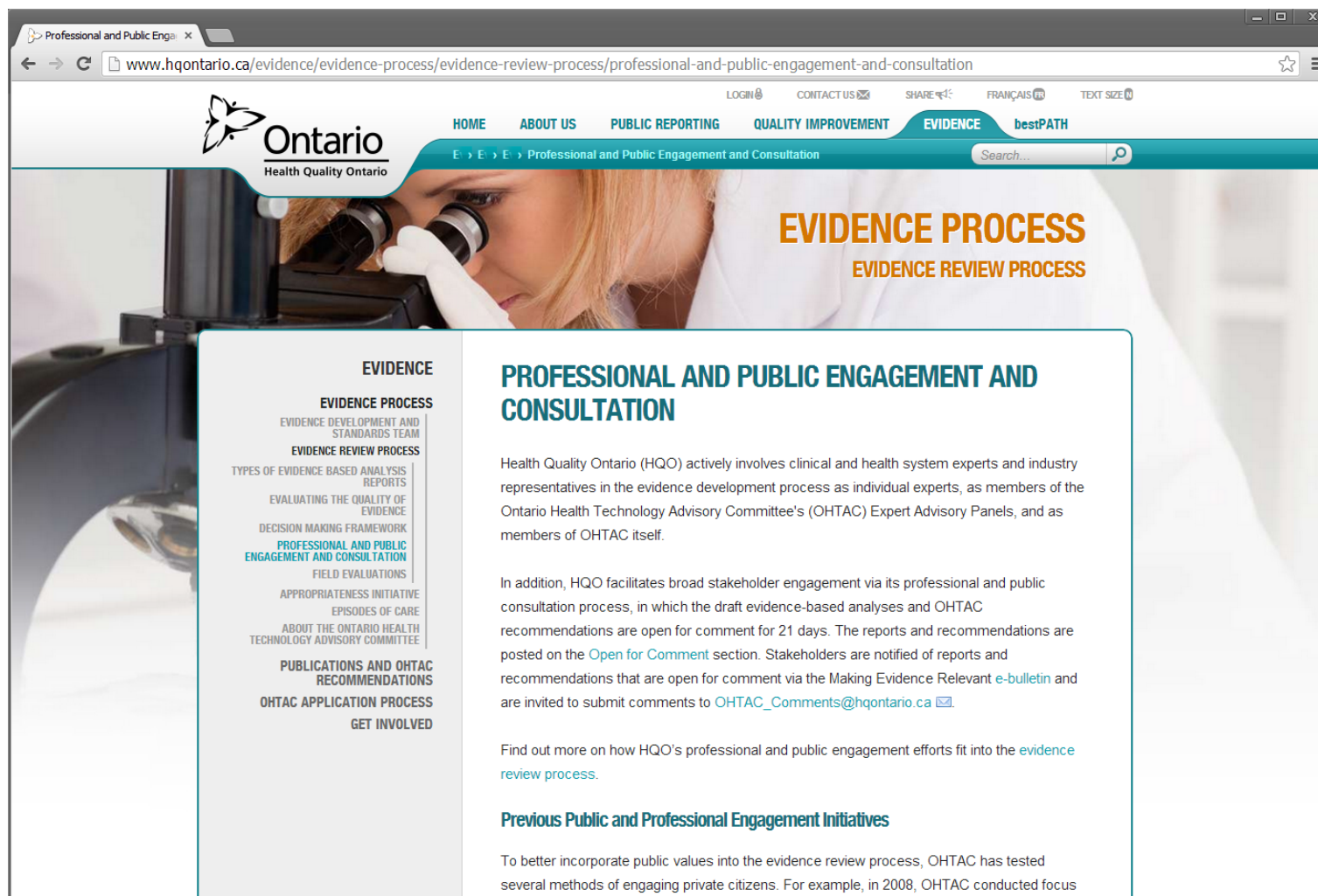
## Achievements by 2011

- ✿ Identification of stakeholders in final documents
- ✿ 21-day public consultation process established and public input included in formation of final OHTAC recommendations
- ✿ Consideration of public input in decision to return to OHTAC with a revised recommendation
- ✿ Web page for Public Engagement
- ✿ Communication vehicles beyond web postings



# Public Engagement Subcommittee

## Achievements by 2011



# Session Outline

- ✿ Two cases of public engagement:
  - ✿ Public Engagement Pilot Study on Point-of-care International Normalized Ratio Monitoring Devices
  - ✿ The Citizens' Reference Panel on Health Technologies (CRPHT)
- ✿ Including Patient Voices: Qualitative Research
- ✿ New Directions and the OHTAC Public Engagement Subcommittee

# **CASE 1**

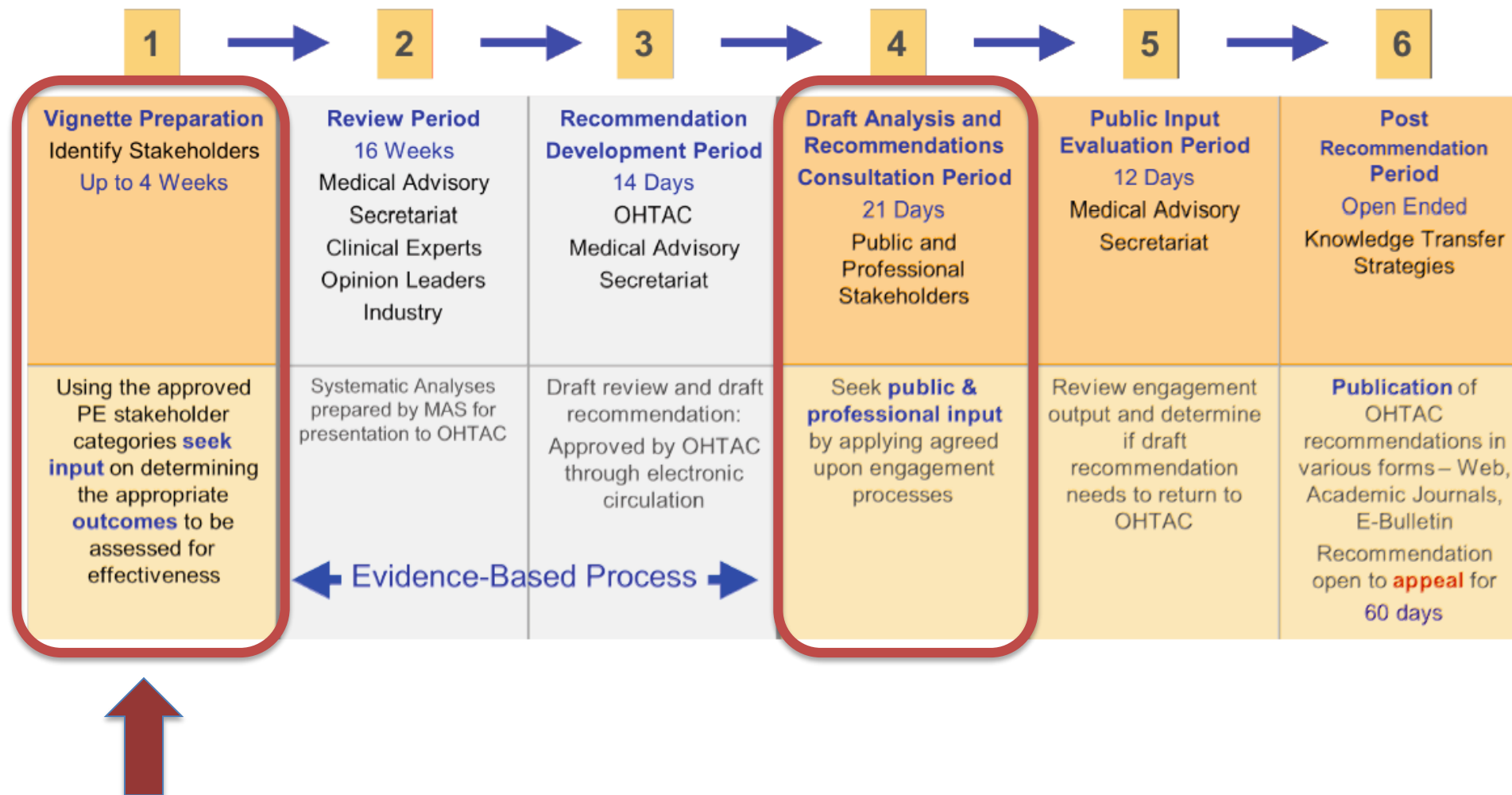
## **Public Engagement Pilot Study on Point-of-care International Normalized Ratio Monitoring Devices**

**Yvonne Bombard, PhD**

**Scientist**, Li Ka Shing Knowledge Institute, St. Michael's Hospital

**Assistant Professor**, Institute of Health Policy, Management and Evaluation, University of Toronto

# Evidence-Based Analysis & Consultation Processes



# Objective

A consumer-stakeholder consultation was undertaken to:

1. Gather *input on the research question* framing an evidence-based analysis on Point-of-Care International Normalized Ratio *(INR) Monitoring Systems for Patients on Oral Anticoagulation Therapy*.
2. Ensure that the research questions incorporated *patient-centred outcomes*.

# Methods

## In-person focus group, Nov 2008

✿ Patients and caregivers (TGH thrombosis clinic)

✿ N=12; 56 years of age (range: 30-69, SD: 13.9)

✿ 8 women; 8 university educated; 6 employed; 6 live in city centre

## Discussion guide:

✿ Have we *incorporated important outcomes* in our research question?

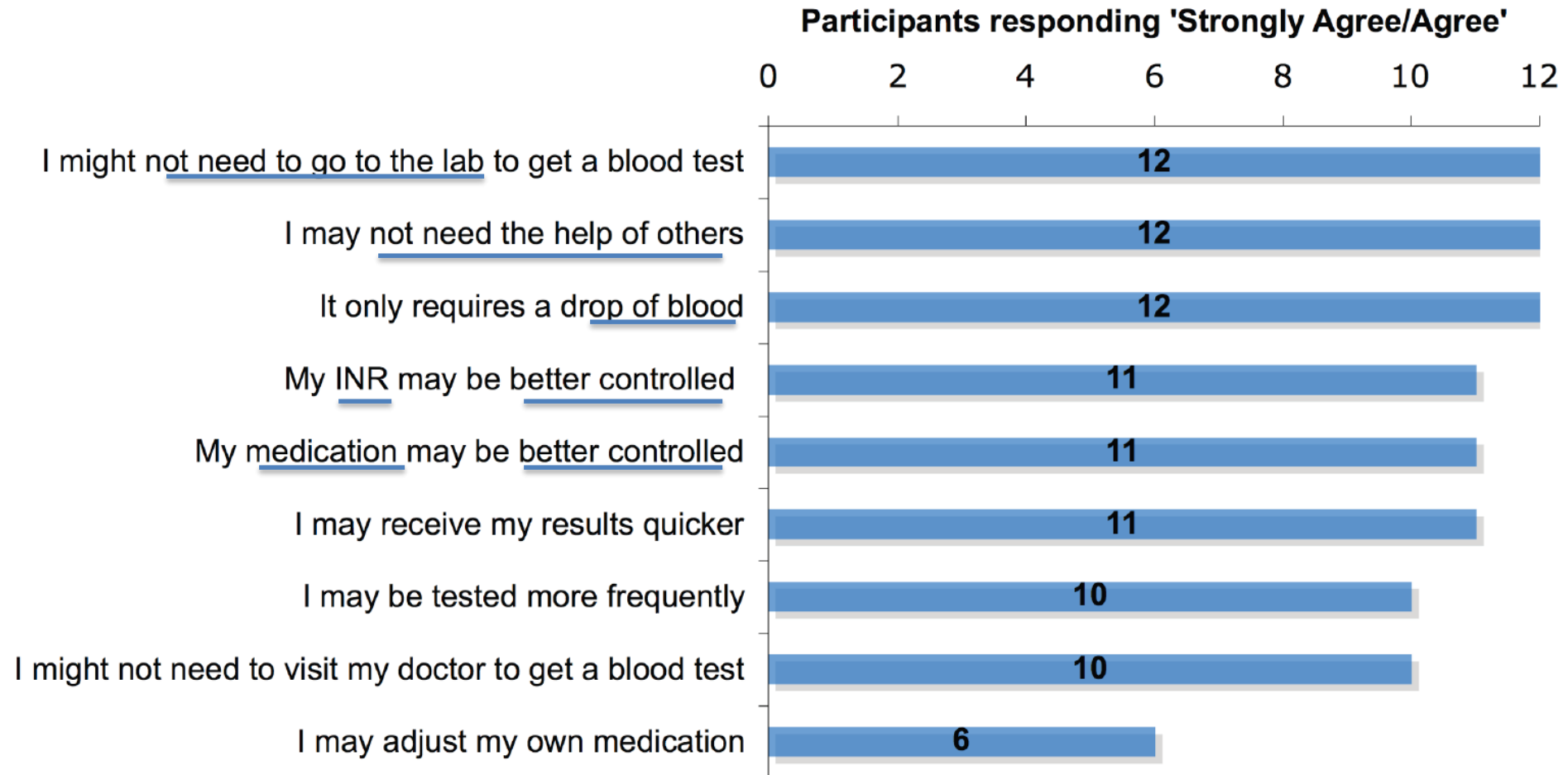
✿ How might POC INR Monitoring Devices *help manage your condition*?

✿ How might POC INR Monitoring Devices *impact your quality of life, family/caregiver*?

✿ Are there *factors that might concern you* about POC Monitoring Devices for INR Testing?

## Questionnaire (pre-tested)

# Motivations to use the Device



# Physical & Psychological Impacts

- ✿ *“They had intravenous stuck in whatever place they could get in that **would work** and then they’d come to this arm, which is very poor for allowing them to get blood. At six o’clock every morning, **I’d be begging and I’d be squinting saying: ‘Please! No!’**” (62 y.o. Female, INR testing: 2 yrs)*
- ✿ *“**The stress is phenomenal. It just ruins your life...** the stress alone does.” (60 y.o. Female, INR testing: 15 yrs)*



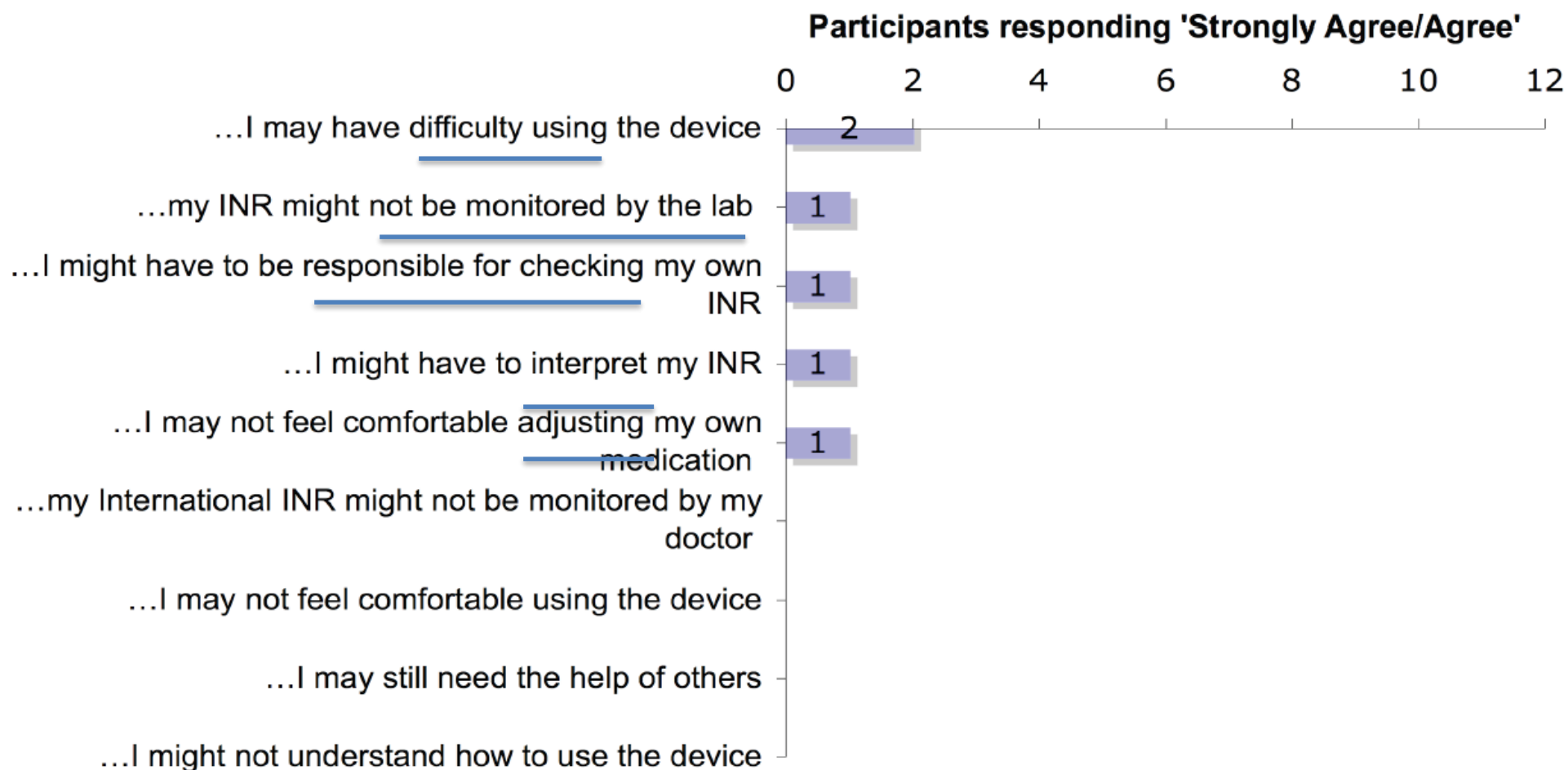
# Limited Access to Testing Facilities

- ✿ *“It’s been a **life saver** to just, you know, realize that it’s ten o’clock at night and that I can get **a reading on the spot**” (33 y.o. Male, INR testing: 1 yr)*
- ✿ *“For me, it’s life and death, **it’s not a convenience issue**” (60 y.o. Female, INR testing: 2 yrs)*

# Control and Empowerment

✿ *“I didn’t know any better. I was told that Warfarin was a little pill you took every day and had your blood tested every month or so. That was what I expected and that’s how much respect I gave to a drug like Warfarin... **Now you’ve got your monitor, you know what Warfarin mismanagement can do to you. All the red flags are up – I gotta know what I’m doing here. I wanna find out everything.**” (69 y.o. Female, INR testing: 4 yrs)*

# Concerns with the Device



# Conclusions

- ✿ Pilot initiative identified themes warranting further exploration and possible inclusion in the research question:
  - ✿ Does POC INR testing reduce pain and discomfort, stress and complications compared to standard lab-based testing;
- ✿ This pilot initiative became one of the main decision determinants in favor of OHTAC's recommendation to fund the technology.

## CASE 2

# Incorporating Social Values into the HTA Process: The Citizens' Reference Panel on Health Technologies (CRPHT)

**Julia Abelson, PhD**

**Professor**, Centre for Health Economics and Policy Analysis,  
Department of Clinical Epidemiology & Biostatistics, McMaster University

# The Citizens' Reference Panel on Health Technologies

**Objective 1:** To establish a process for Ontario citizens to inform OHTAC deliberations and evidence-based recommendations regarding the use of health of technologies in the Ontario health system;

**Objective 2:** To experiment with a particular method for engaging the public in the HQO/OHTAC process which has been used in other health system contexts.

# The Project (in brief)

## Recruitment



- ✿ 14-member panel recruited in 2008:
  - ✿ 3500 Ontario residents mailed invitation letter, information sheet and postage paid response form
  - ✿ 165 expressions of interest received
  - ✿ Blinded selection of panelists; stratified by LHIN region, age and sex



# The Project (in brief)

## Structure & Process

- ✿ Met over 5 Saturdays between February 2009 and June 2010
- ✿ Pre-circulated reading material and discussion questions
- ✿ Structured, facilitated deliberation
- ✿ Values elicitation process for 5 health technologies at various stages of review (early & late)





# The Project (in brief)

## Technologies Reviewed

TOPIC	STAGE IN HTA PROCESS
Colorectal cancer screening	Late: Draft analysis & recommendation
Percutaneous aortic valve replacement	Early: Scoping, defining review questions & outcome measures
Breast cancer screening for average and high risk women	Late: Draft analysis and recommendation
Gene expression profiling ( <b>Oncotype DX test</b> )	Early: Scoping, defining review questions & outcome measures
Serologic testing for Celiac disease	Late: Draft analysis & recommendation

# The Project (in brief)

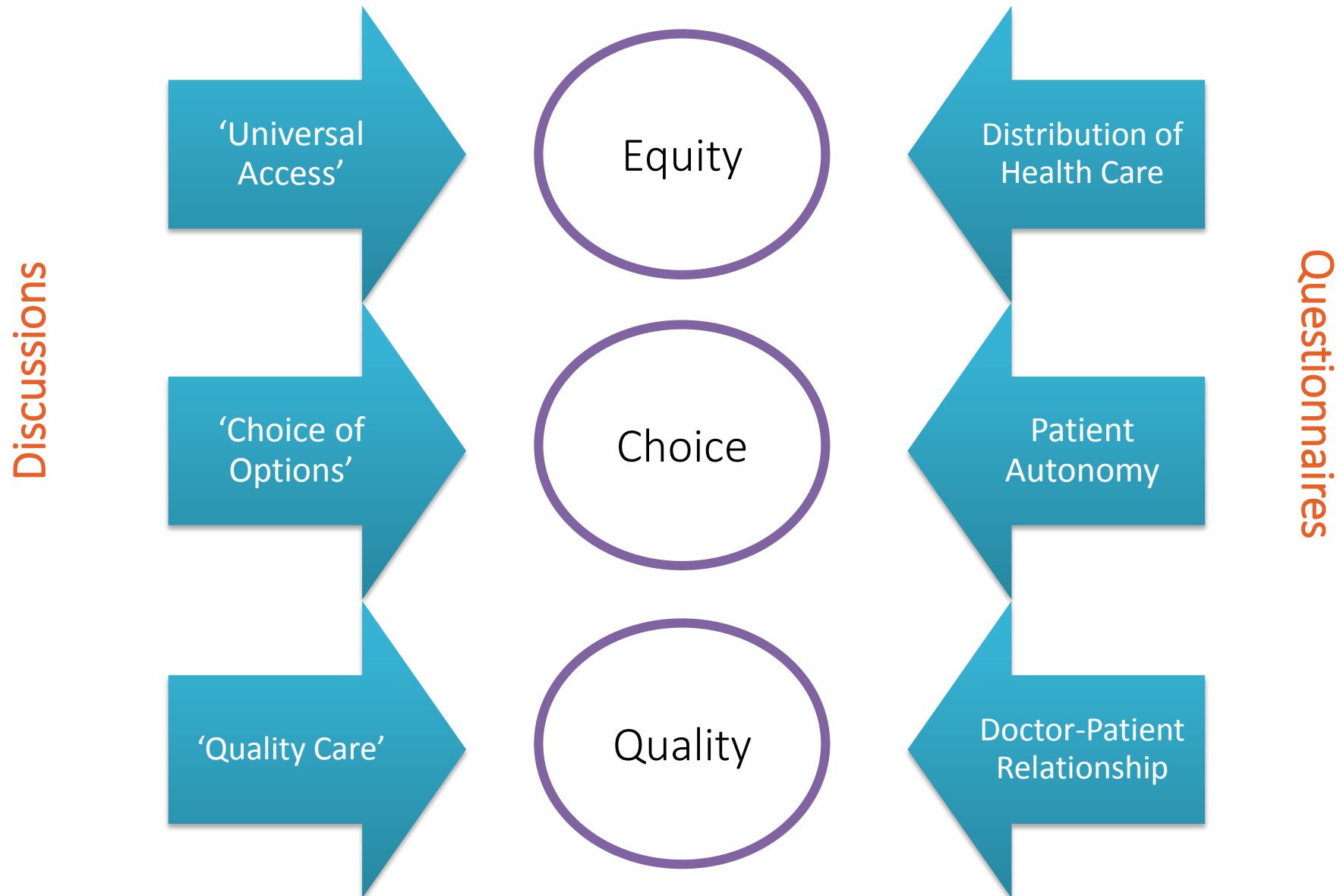
## Data Collection

DATA COLLECTED	SOURCE
Values elicited during facilitated discussions (general and technology-specific discussions)	Pre- and post-meeting questionnaires; qualitative analysis of meeting transcripts
Assessments of procedural elements and impacts on HTA decision making	Post-meeting questionnaires; meeting observation notes; exit interviews with panel members and MAS-OHTAC personnel



# VALUES ELICITATION FINDINGS

# Convergence Toward Core Values



# Equity

 Increasing disparity in access to health care, challenging the principle of universality:

*“I think that the Ontario government has to ensure that the technology is going to be used by everybody, not just the middle class who may be better off, have a doctor, or have the wisdom or education to read about or look into it. That’s the obligation.”*

*Ken*

# Choice

- ✿ Is there real choice in population screening program? Will there be repercussions if I decline to participate in screening or use a particular modality?

*“That choice piece is, of course, it’s a bit of a fine line or a double-edged sword, so to speak... If it’s population-based [screening]... Do we really have a choice to take that test? And if we do, who do we run into conflict with? Do we run into conflict with our doctor? Our pharmacist? The whole health network? So do we really have choices? So that’s the ethical question, is: are we in potential conflict with that very person, or people or system, that we’re dependent upon for our health?”*

*Paula*

# Quality Care




- ✿ Founded on mutual trust between provider & patient; facilitated by providing information, options and collaborating on decision, and hindered by unequal access to care providers.
- ✿ Desire for full information about all screening modalities:

*“Everybody’s going to be looking at it a little differently...The fifty-fifty [detection rate of FOBT], it almost seems like a waste. You need to get that [rate] a little higher of course, but it’s not a waste again, the negative of the colonoscopy and the perforation, that is obviously a risk and that’s where having choice and the person at the doctor level or a person at the population-based program or what have you making that decision as [to whether] the person should do it. The doctor should have the knowledge and make sure that he presents that information to make a choice. “*

*Frank*

# Conclusions

## 'Core' values:

-  Seen as broad **overarching categories** to guide consideration of societal & ethical issues in HTA
-  Should be **complemented & informed** by ethics expertise & evidence review of specific HT
-  Require **further research** with broader range of HTs & in other jurisdictions and contexts



# ASSESSING THE IMPACTS OF CITIZEN DELIBERATIONS ON THE HEALTH TECHNOLOGY PROCESS

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**Sarah Boesveld**

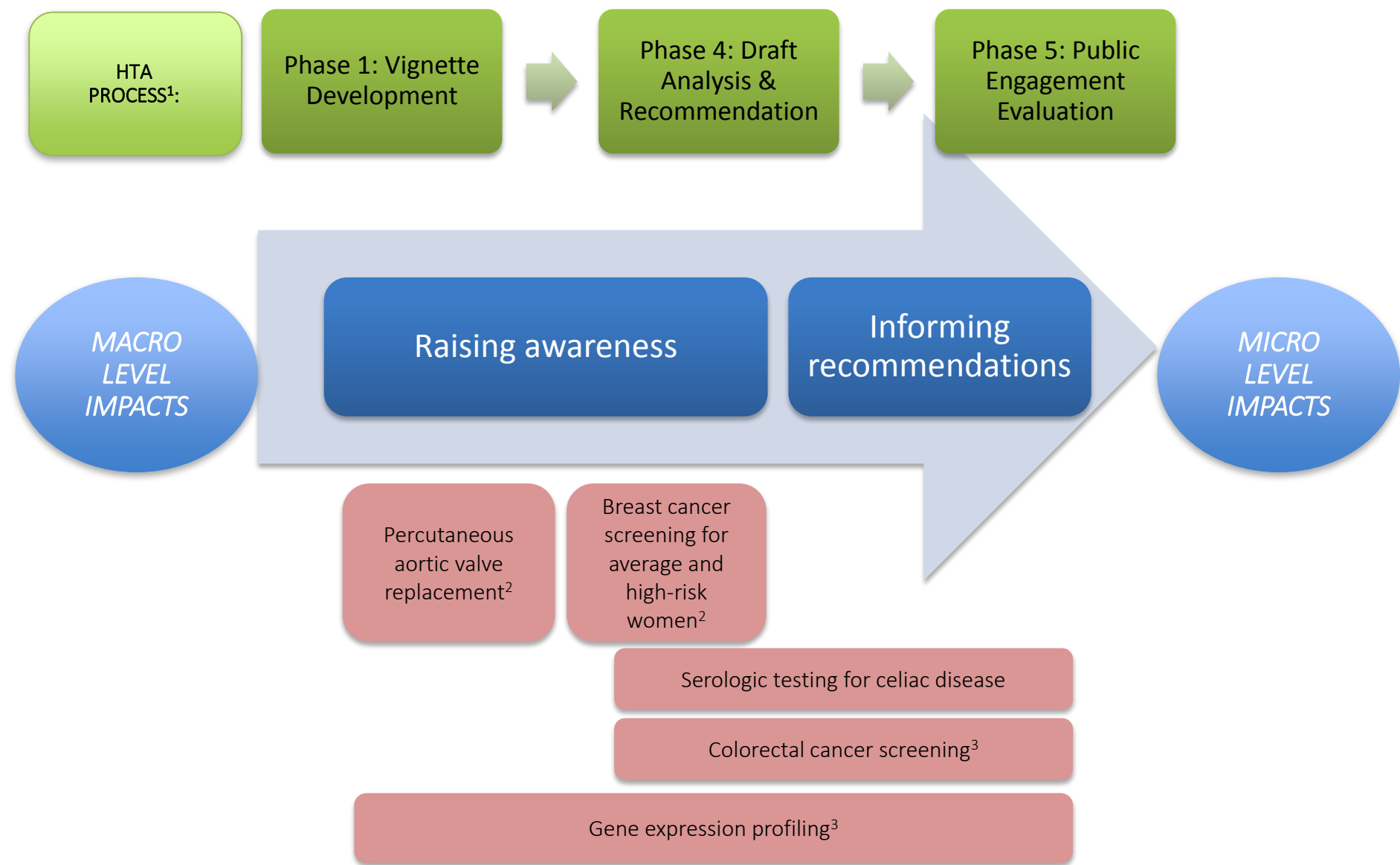
*Centre for Health Economics and Policy Analysis, McMaster University, Hamilton, Ontario, Canada*

## Impact Findings

# Defining Impact

- ✿ Whether and how the input obtained from the citizens' panel was **considered** by OHTAC
  - ✿ e.g., reports, presentations and discussions of panel findings at OHTAC meetings
- ✿ Whether and how the panel input **influenced** OHTAC deliberations and the decisions arising from them
  - ✿ e.g., actions arising from discussions (incorporation of panel input into HTA reports)

Figure 1: Conceptual Framework of Citizens’ Reference Panel Impacts



<sup>1</sup>Phases 2-3 refer to evidence-based processes where public input is not sought; Phase 6 is not applicable

<sup>2</sup>Technologies for which the panel’s input raised awareness about ethical and social values at early and later HTA stages

<sup>3</sup>Technologies for which the panel’s input raised awareness about values & informed HTA recommendations at early and later HTA stages

# Example: OHTAC response to panel input on colorectal cancer screening

## Panel input:

- 🌸 concerns about the lack of choice in the wording of the draft recommendation (FOBT as “only modality that should be used”)

## OHTAC response:

- 🌸 revised language (softer tone)
- 🌸 more explanation for the recommendation
- 🌸 new language (emphasis on informed consent in discussing screening modalities)
- 🌸 new section on “Ethical and Societal Perspectives” (emphasis on choice)

# Panel member reflections

*I don't really know how much we may have influenced OHTAC to this point . . . I would like to think that we made a contribution. Whether we have? I would say yes, we did – we did get some wording in a recommendation changed.*

(Panel member)

*To me, it didn't matter how much we were getting through at this point in time. To me it was about setting up a process that was replicable . . .*

(Panel member)

# OHTAC member reflections

*[It] provided a **reference point** as we attempted to identify and evaluate the importance of issues emerging from the information we were gleaning from [other sources] . . . [the] **material helped strengthen the process and contributed to a level of confidence** as we commented on societal and ethical values relevant to the OHTAC initiative.*

(OHTAC member)

# Conclusions

- ✿ Citizens' panels provide a traceable source of social values input (early and late HTA stages; for different types of HTs)
- ✿ Use in conjunction with other more routinized PE methods (purpose should drive method)
- ✿ Panel impacts are facilitated through:
  - ✿ **opportunities for direct exchange** (citizens and experts)
  - ✿ **'report back' and accountability** mechanisms
  - ✿ **institutionalized commitment to public engagement** within the organization

# Including Patient and Public Voices by Synthesizing Published Qualitative Research

**Meredith Vanstone, PhD**

**Assistant Professor**, Centre for Health Economics and Policy Analysis,  
Department of Clinical Epidemiology & Biostatistics, McMaster University



# Including Patient/Public Voices by Looking at Qualitative Research

- ✿ Additional approach to including citizen voices: looking for relevant patient/public opinions that have already been published in qualitative research.
  - ✿ Can include a much broader array of opinions
  - ✿ May facilitate the inclusion of hard-to-reach individuals (socially marginalized, disabled, very ill)

# Why Look at Qualitative Research?

- ✿ Large body of qualitative research in the social science addressing issues relevant to patient-centered care:
  - ✿ Experiences of illness/health care
  - ✿ Lay understandings of health and illness
  - ✿ Preferences for health care
  - ✿ Patient-defined aspects of process or outcomes of care
  - ✿ Unmet needs
- ✿ Empirical and theoretical research can also draw attention to potential social and ethical issues.
  - ✿ Perspectives or interests not yet included in evaluation
  - ✿ Groups that may benefit or be disadvantaged by an intervention
  - ✿ Public opinions about controversial issues

# How does this fit with OHTAC's approach?

## Decision Determinants

Criteria	Sub-Criteria	Sub-Criteria Definitions
Overall Clinical Benefit	Effectiveness	The <u>potential health impact</u> of the new technology compared to the available alternatives, measured in terms of <u>relevant patient outcomes</u> such as mortality, morbidity, quality of life. Magnitude and direction of effect should be considered.
	Safety	<u>Frequency</u> and <u>severity</u> of adverse effects associate with the new technology compared to the available alternatives.
	Burden of Illness	Incidence, prevalence or other measure of <u>disease burden on the population</u>
	Need	<u>Availability of an effective alternative</u> to the technology. Is there an available and effective alternative?
Consistency with Expected Societal and Ethical Values	Societal Values	<u>Broadly shared values in society</u> which bear on the appropriate use and impact of the technology.
	Ethical Values	The potential ethical issues inherent in using or not using the technology. <u>Relevant ethical</u> issues should be listed.
Value for Money	Economic Evaluations	A measure of the <u>net cost</u> or efficiency of the health technology <u>compared to available alternatives</u> .
Feasibility of Adoption into Health Systems	Economic Feasibility	The <u>net budget</u> impact of the new health technology derived by determining all relevant costs and savings to the health care system
	Organizational Feasibility	The <u>ease</u> with which the health technology can be adopted will be evaluated by looking at the health system <u>enablers</u> and <u>barriers</u> to diffusion within the health system infrastructure (operational, capital, human resources, legislative and regulatory)

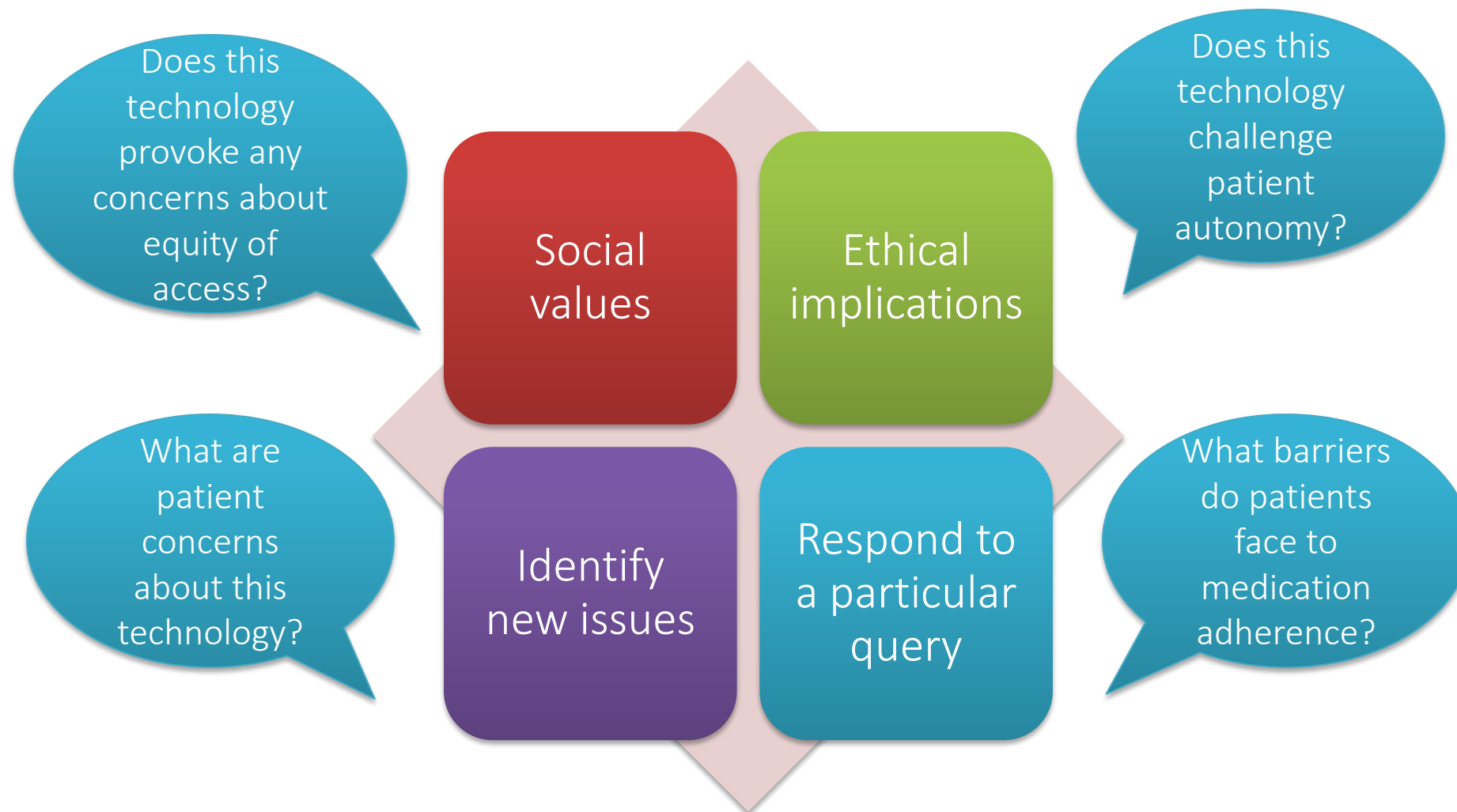
- [http://www.health.gov.on.ca/english/providers/program/ohtac/decision\\_frame.html](http://www.health.gov.on.ca/english/providers/program/ohtac/decision_frame.html)
- Johnson, A. P., N. J. Sikich, et al. (2009). "Health technology assessment: A comprehensive framework for evidence-based recommendations in Ontario." International Journal of Technology Assessment in Health Care 25(2): 141–150

# Our Approach

## Systematic Review & Qualitative Synthesis

- ✿ Work with organization to identify research question
- ✿ Conduct a systematic review of the literature to identify all relevant empirical qualitative research publications
- ✿ Extract all relevant findings or results from those relevant research publications
- ✿ Findings are our data, which we categorize, re-group, categorize again to form a new interpretation or synthesis.
- ✿ Goal of analysis:
  - ✿ Should reflect the range of findings while retaining the original meaning of the authors
  - ✿ A new, integrative interpretation should be produced by comparing and contrasting findings across studies.
- ✿ Methodology: Qualitative meta-synthesis (Sandelowski and colleagues)

# Types of Questions We Can Answer

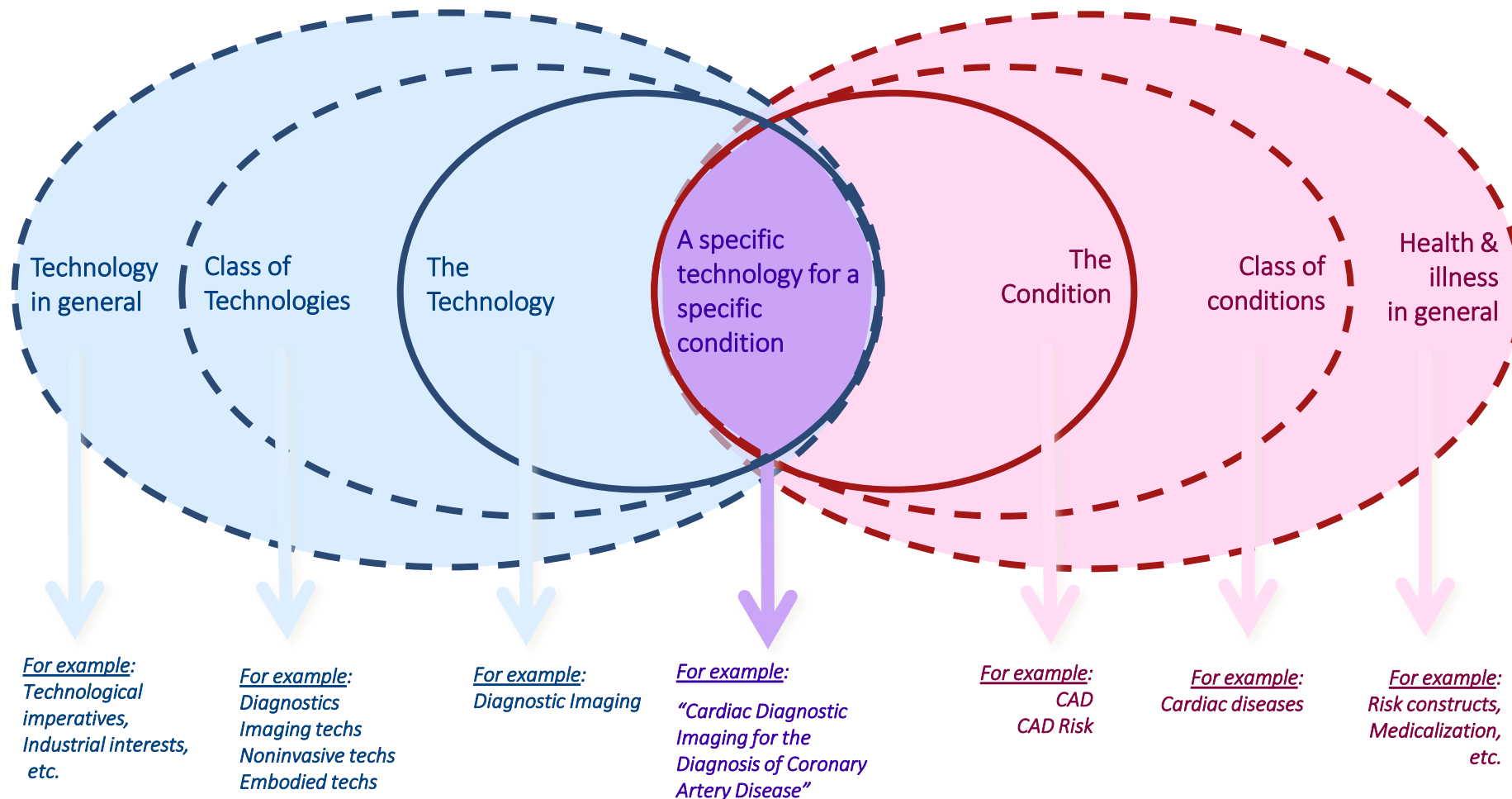


# Challenges to this Approach

- ✿ Researchers are not conducting the research with HTA context in mind- requires adaptation of findings.
- ✿ Most research conducted outside of Canada: must consider applicability to our own health care context
- ✿ Tendency to identify and describe problems, requires translation to positive values, goals for service provision
- ✿ We don't get to ask the questions, so sometimes must extrapolate information to apply it, sometimes must look more broadly at an issue to find relevant.

# Challenge:

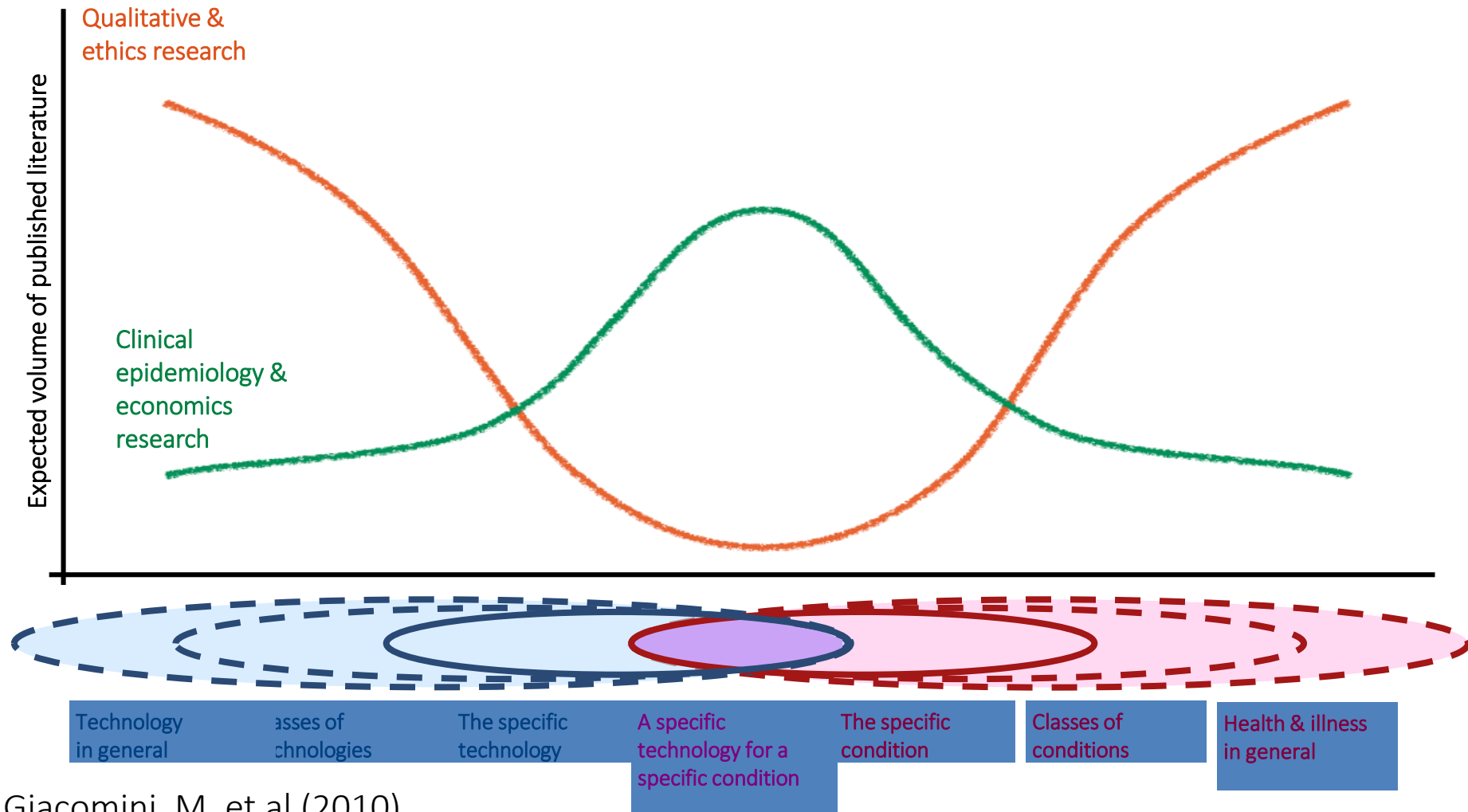
## Defining the Topic



Giacomini, M. et al (2010)

# Challenge:

## Finding the Research



Giacomini, M. et al (2010)



# Synthesizing the Research



Photo credit: Rupert Mckelvie, *Missing Pieces*

# Conclusions

- ✿ Useful way to gather a lot of information in a relatively short time
- ✿ Can address broad topics, identify issues, or answer specific questions
- ✿ Dependent on what has been published

**HQO/OHTAC PUBLIC ENGAGEMENT  
SUBCOMMITTEE**  
**The Journey Continues...**

Frank Wagner, MA, MHSc

# OHTAC HTA/Public Engagement Process Overview



# The “So What?!” Slides

- ✿ How previous work (e.g., POC INR study and CRPHT) has influenced decision making
  - ✿ Public engagement forms a critical part of developing research questions and gaining societal/stakeholders’ perspectives.
  - ✿ It offers crucial insights on the physical, psychological and social impacts associated with the current standard of care, which may have otherwise not been incorporated into the HTA process.



# The “So What?!” Slides

- ✿ Challenges in doing empirical work in an organization like Health Quality Ontario
  - ✿ PE within HTA agencies presents numerous implementation challenges, particularly in ensuring that the PE is timely and relevant to the overall HTA.
    - ✿ Arms-length approach to recruitment is ideal but may be unfeasible in existing timelines.
  - ✿ Evaluation of the PE strategy on the HTA process & final recommendation is critical to examine the role of PE in the decision-making process.



**Thank You**





# Remaining Questions

- ✿ How are public engagement findings and qualitative data integrated into HTA and decision-making?
- ✿ How to ensure these inputs are incorporated in a timely fashion?
- ✿ Are these activities conducted in HTA agencies or at arms-length?