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

Bioethicist, Toronto Central CCAC and University of Toronto Joint Centre for Bioethics
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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
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.
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.
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.”
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


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.
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

1. **Vignette Preparation**
   - Identify Stakeholders
   - Up to 4 Weeks
   - Using the approved PE stakeholder categories seek input on determining the appropriate outcomes to be assessed for effectiveness

2. **Review Period**
   - 16 Weeks
   - Medical Advisory Secretariat
   - Clinical Experts
   - Opinion Leaders
   - Industry
   - Systematic Analyses prepared by MAS for presentation to OHTAC

3. **Recommendation Development Period**
   - 14 Days
   - OHTAC Medical Advisory Secretariat
   - Draft review and draft recommendation: Approved by OHTAC through electronic circulation

4. **Draft Analysis and Recommendations Consultation Period**
   - 21 Days
   - Public and Professional Stakeholders
   - Seek public & professional input by applying agreed upon engagement processes

5. **Public Input Evaluation Period**
   - 12 Days
   - Medical Advisory Secretariat
   - Review engagement output and determine if draft recommendation needs to return to OHTAC

6. **Post Recommendation Period**
   - Open Ended
   - Knowledge Transfer Strategies
   - Publication of OHTAC recommendations in various forms – Web, Academic Journals, E-Bulletin
   - Recommendation open to appeal for 60 days

Evidence-Based Process
Objective

A consumer-stakeholder consultation was undertaken to:


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

- I might not need to go to the lab to get a blood test: 12
- I may not need the help of others: 12
- It only requires a drop of blood: 12
- My INR may be better controlled: 11
- My medication may be better controlled: 11
- I may receive my results quicker: 11
- I may be tested more frequently: 10
- I might not need to visit my doctor to get a blood test: 10
- I may adjust my own medication: 6
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)
“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

Participants responding 'Strongly Agree/Agree'

- ...I may have difficulty using the device
- ...my INR might not be monitored by the lab
- ...I might have to be responsible for checking my own INR
- ...I might have to interpret my INR
- ...I may not feel comfortable adjusting my own medication
- ...my International INR might not be monitored by my doctor
- ...I may not feel comfortable using the device
- ...I may still need the help of others
- ...I might not understand how to use 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

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>STAGE IN HTA PROCESS</th>
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<tbody>
<tr>
<td>Colorectal cancer screening</td>
<td>Late: Draft analysis &amp; recommendation</td>
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<tr>
<td>Percutaneous aortic valve replacement</td>
<td>Early: Scoping, defining review questions &amp; outcome measures</td>
</tr>
<tr>
<td>Breast cancer screening for average and high risk women</td>
<td>Late: Draft analysis and recommendation</td>
</tr>
<tr>
<td>Gene expression profiling (Oncotype DX test)</td>
<td>Early: Scoping, defining review questions &amp; outcome measures</td>
</tr>
<tr>
<td>Serologic testing for Celiac disease</td>
<td>Late: Draft analysis &amp; recommendation</td>
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## The Project (in brief)

### Data Collection

<table>
<thead>
<tr>
<th>DATA COLLECTED</th>
<th>SOURCE</th>
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<tbody>
<tr>
<td>Values elicited during facilitated discussions (general and technology-</td>
<td>Pre- and post-meeting questionnaires; qualitative analysis of meeting</td>
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<tr>
<td>specific discussions)</td>
<td>transcripts</td>
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<tr>
<td>Assessments of procedural elements and impacts on HTA decision making</td>
<td>Post-meeting questionnaires; meeting observation notes; exit interviews</td>
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Eliciting ethical and social values in health technology assessment: A participatory approach

Yvonne Bombard a, *, Julia Abelson b, Dorina Simeonov b, Francois-Pierre Gauvin c

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b Centre for Health Economics and Policy Analysis, Department of Clinical Epidemiology and Biostatistics, McMaster University, Canada
c National Collaborating Centre for Healthy Public Policy, Institut national de santé publique du Québec, Canada

VALUES ELICITATION FINDINGS
Convergence Toward Core Values

Discussions

- ‘Universal Access’
- ‘Choice of Options’
- ‘Quality Care’

Equity

Choice

Quality

Distribution of Health Care

Patient Autonomy

Doctor-Patient Relationship

Questions
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
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

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1Phases 2-3 refer to evidence-based processes where public input is not sought; Phase 6 is not applicable
2Technologies for which the panel’s input raised awareness about ethical and social values at early and later HTA stages
3Technologies 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

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Sub-Criteria</th>
<th>Sub-Criteria Definitions</th>
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<tbody>
<tr>
<td>Overall Clinical Benefit</td>
<td>Effectiveness</td>
<td>The potential health benefit of the new technology compared to the available alternatives, measured in terms of relevant patient outcomes such as mortality, morbidity, quality of life. Magnitude and duration of effect should be considered.</td>
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<tr>
<td></td>
<td>Safety</td>
<td>Frequency and severity of adverse effects associate with the new technology compared to the available alternatives.</td>
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<tr>
<td></td>
<td>Burden of illness</td>
<td>Incidence, prevalence or other measure of disease burden on the population.</td>
</tr>
<tr>
<td></td>
<td>Need</td>
<td>Availability of an effective alternative to the technology. Is there an available and effective alternative?</td>
</tr>
<tr>
<td>Consistency with Expected Societal and Ethical Values</td>
<td>Societal Values</td>
<td>The potential ethical issues inherent in using or not using the technology. Relevant ethical issues should be listed.</td>
</tr>
<tr>
<td></td>
<td>Ethical Values</td>
<td>The potential ethical issues inherent in using or not using the technology. Relevant ethical issues should be listed.</td>
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<tr>
<td></td>
<td>Value for Money</td>
<td>Economic Evaluations</td>
</tr>
<tr>
<td></td>
<td>Feasibility of Adoption into Health Systems</td>
<td>Economic Feasibility</td>
</tr>
<tr>
<td></td>
<td>Organization Feasibility</td>
<td>The ease with which the health technology can be adopted will be evaluated by looking at the health system enablers and barriers to diffusion within the health system infrastructure (operational, capital, human resources, legislative and regulatory)</td>
</tr>
</tbody>
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- [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)
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

- Social values
- Ethical implications
- Identify new issues
- Respond to a particular query

- Does this technology challenge patient autonomy?
- What are patient concerns about this technology?
- What barriers do patients face to medication adherence?
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

For example:
Technological imperatives, Industrial interests, etc.

For example:
Diagnostics Imaging techs
Noninvasive techs
Embodied techs

For example:
Diagnostic Imaging

For example:
"Cardiac Diagnostic Imaging for the Diagnosis of Coronary Artery Disease"

For example:
CAD CAD Risk

For example:
Cardiac diseases

For example:
Risk constructs, Medicalization, etc.

Challenge: Finding the Research

Synthesizing the Research

Photo credit: Rupert McElvie, *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

1. **SCOPING**
   - HQO drafts brief overview of intervention
   - OHTAC determines which interventions proceed to a full review

2. **EVIDENCE-BASED ANALYSIS**
   - HQO reviews evidence in consultation with:
     - Clinical experts
     - Expert panels
     - Scientific partners
     - Industry
     - Government

3. **DRAFT OHTAC RECOMMENDATIONS**
   - OHTAC drafts recommendations based on evidence-based review

4. **PROFESSIONAL AND PUBLIC CONSULTATION**
   - Draft review and recommendations are posted on the HQO/OHTAC website for public and professional comment

5. **ASSESSMENT OF COMMENTS**
   - HQO reviews public and professional comment feedback
   - OHTAC modifies recommendations as required

6. **POST REVIEW AND RECOMMENDATION**
   - HQO evidence-based review and OHTAC recommendations published on website and announced in e-bulletin

7. **FIELD EVALUATION**
   - OHTAC may request a field evaluation to assess effectiveness and cost-effectiveness of an intervention in the Ontario context

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Seek public input to formulate the research question and inform appropriate outcomes to be assessed for effectiveness.

Share patient perspectives and experiences regarding the technology under review.

Public perspectives would inform the EBA through meta-qualitative analysis. Frame OHTAC recommendations so that they are relevant to and take into account patients and their families.

Consider, analyze, and respond to public feedback from reports and recommendations issued by EDS and OHTAC respectively.

Members of the public and other stakeholders that submit comments may be asked for further clarification or to work with OHTAC/EDS to propose revisions to the reports or recommendations.

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?