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Developing a Values Based Framework for Decision Making in Health Technology Assessment

MURRAY KRAHN

CADTH LECTURE SERIES

MARCH 12, 2015

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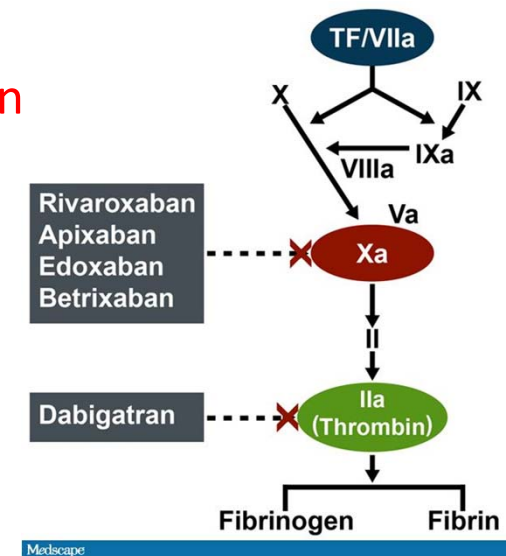
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Acknowledgement....

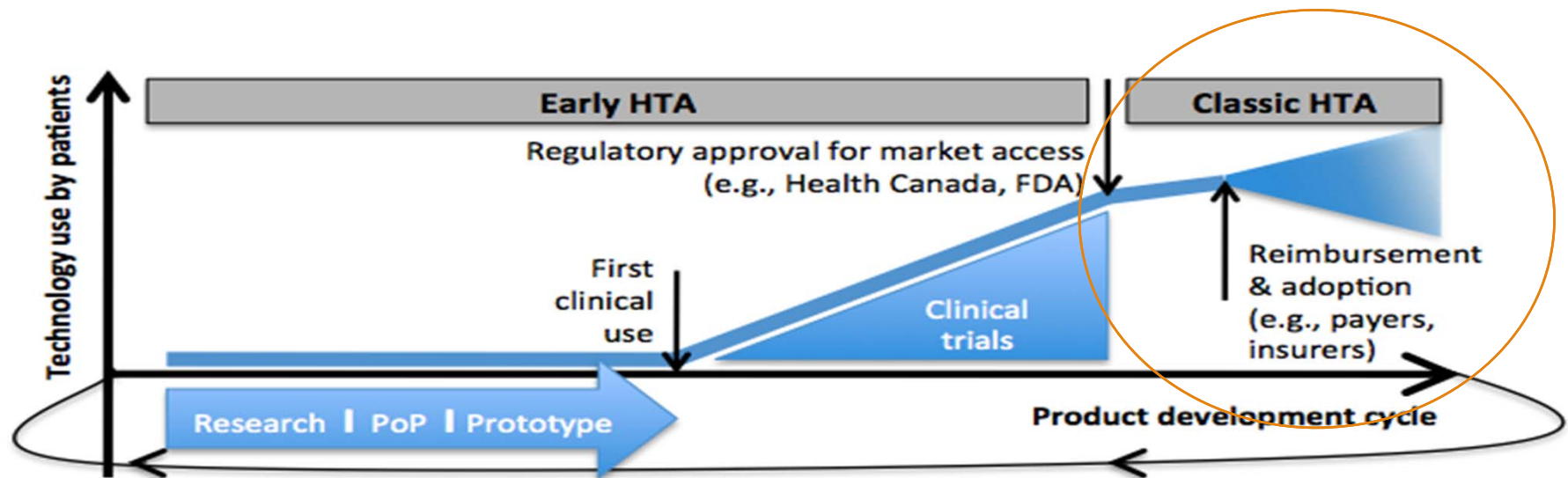
Mita Giacomini/ Fiona Miller	Ron Goeree	Ahmed Bayoumi
Frank Wagner	Tony Culyer*	Holger Schuneman
Shawn Winsor	Mike Paulden*	Ba' Pham
Juliani Yi	Gabrielle van de Velde	
Health Quality Ontario- Stephen Petersen, Anna Sampson, Laura Park-Wyllie, Nancy Sikich, Sahba Eftekhary * resigned		

One technology, many decisions...

- should **I** take dabigatran for atrial fibrillation – **individual decision**
- should **patients take...**- **clinical practice guideline**
- should dabigatran be **licensed** – **regulatory decision**
- should dabigatran be **listed**- **purchasing decision**
- should dabigatran be **de-listed**- **disinvestment**



DECISION POINTS IN TECHNOLOGY ADOPTION



What is the key principle in decision making around health (technology)?



Use of best evidence?

Evidence

- 1) Systematic reviews and meta-analyses
 - 2) Randomised controlled trials with definitive results
 - 3) Randomised controlled trials with non-definitive results
 - 4) Cohort studies
 - 5) Case-control studies
 - 6) Cross sectional surveys
 - 7) Case reports
- (Pettigrew and Roberts 2003, 527).



Use of best evidence?

Evidence

- 1) Systematic reviews and meta-analyses
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 - 4) Cohort studies
 - 5) Case-control studies
 - 6) Cross sectional surveys
 - 7) Case reports
- (Pettigrew and Roberts 2003, 527).

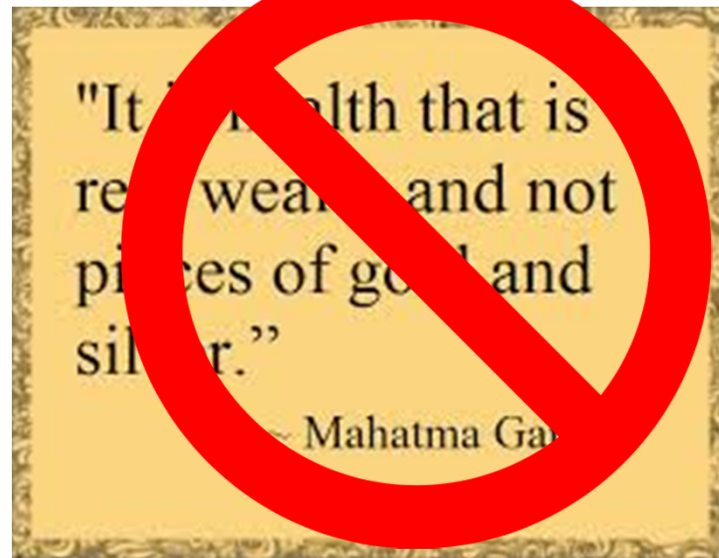


Maximizing health

"It is health that is
real wealth and not
pieces of gold and
silver."

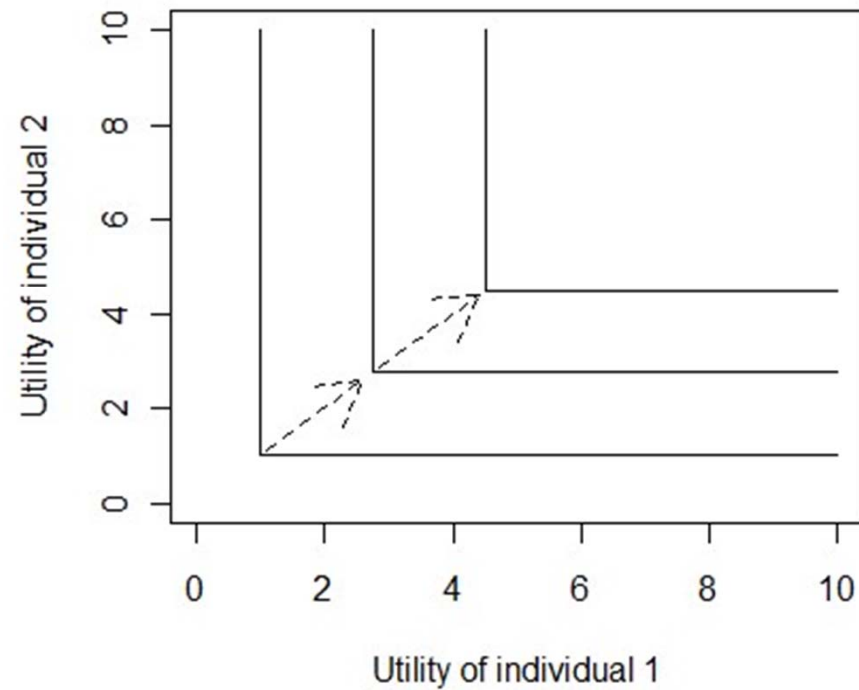
~ Mahatma Gandhi

Maximizing health



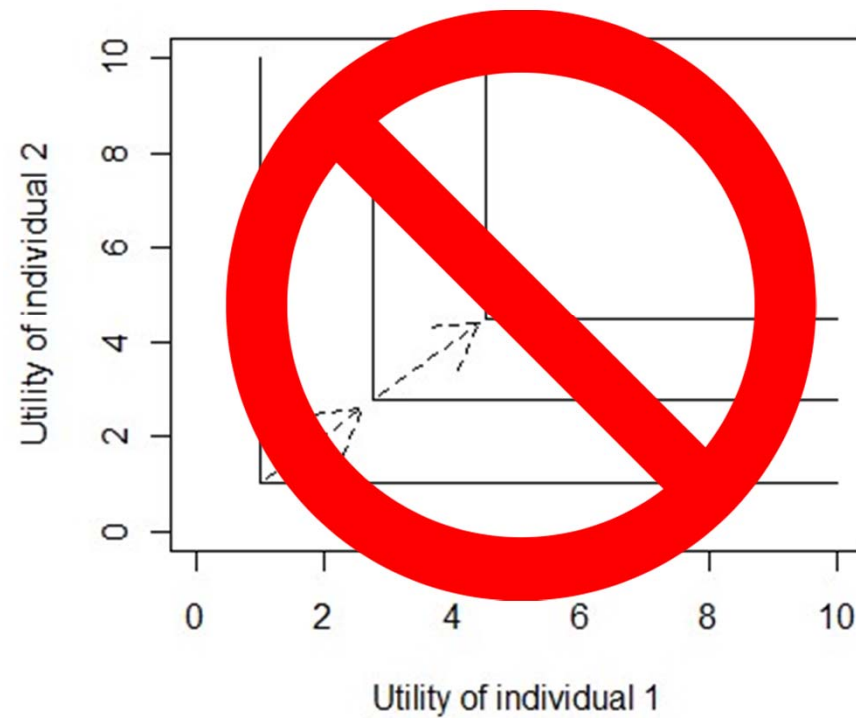
Maximizing social welfare?

Rawlsian Social Welfare

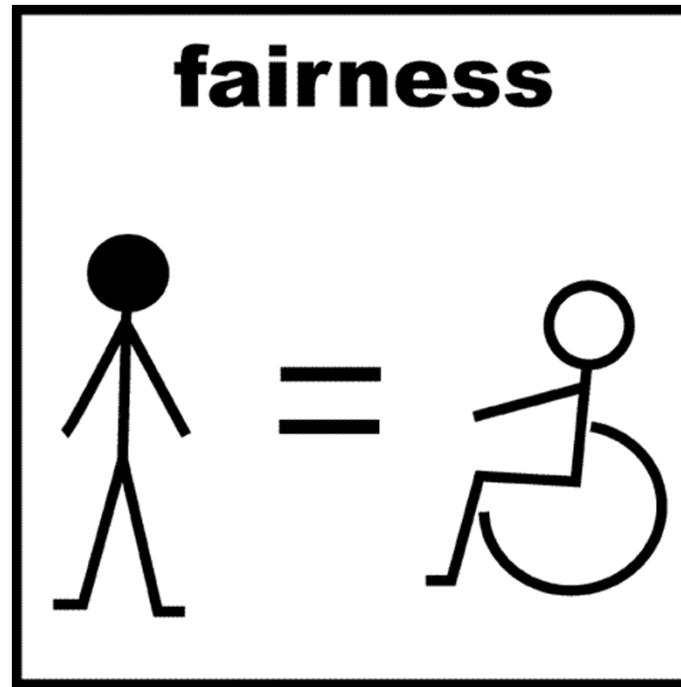


Maximizing social welfare?

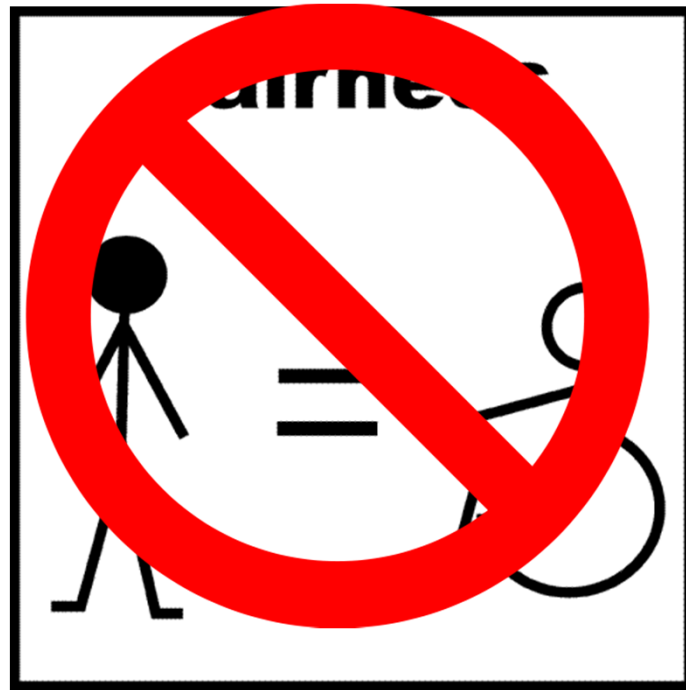
Rawlsian Social Welfare



Fairness?



Fairness?



Hypothesis....

The key principle is not....

- to implement best evidence
- to maximize health subject to resource constraints
- to maximize welfare of Canadians
- make decisions fairly



Alice laughed. 'There's no use trying,' she said: 'one can't believe impossible things.'

'I daresay you haven't had much practice,' said the Queen. 'When I was your age, I always did it for half-an-hour a day.'

Why, sometimes I've believed as many as six impossible things before breakfast."



...faith is the substance of things hoped for, the evidence of things not seen.

Epistle to the Hebrews 11:1



Outline

Review of the original Decision Determinants framework

Health Values of Canadians

Three Paradigms in Health Technology Assessment

Methods for Revision

The revised framework

Recommendations



Ontario Health Technology Advisory Committee [OHTAC]

- Consultation with 29 hospital CEOs in 2003 -
- Strong consensus to create a single portal for uptake and diffusion of non-drug health technologies



EVIDENCE PROCESS

EVIDENCE

EVIDENCE PROCESS

[EVIDENCE DEVELOPMENT AND STANDARDS TEAM](#)

[EVIDENCE REVIEW PROCESS](#)

[APPROPRIATENESS INITIATIVE](#)

[CHOOSING WISELY](#)

[EPISODES OF CARE](#)

[ABOUT THE ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE](#)

[MEMBERSHIP](#)

[TERMS OF REFERENCE](#)

ABOUT THE ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE

The Ontario Health Technology Advisory Committee (OHTAC), a standing advisory subcommittee of the Health Quality Ontario (HQO) Board, makes recommendations about the uptake, diffusion, distribution, or removal of health interventions in Ontario. OHTAC's recommendations are based on a careful review of results from the HQO analyses through the lens of its decision determinants framework. The framework considers the overall clinical

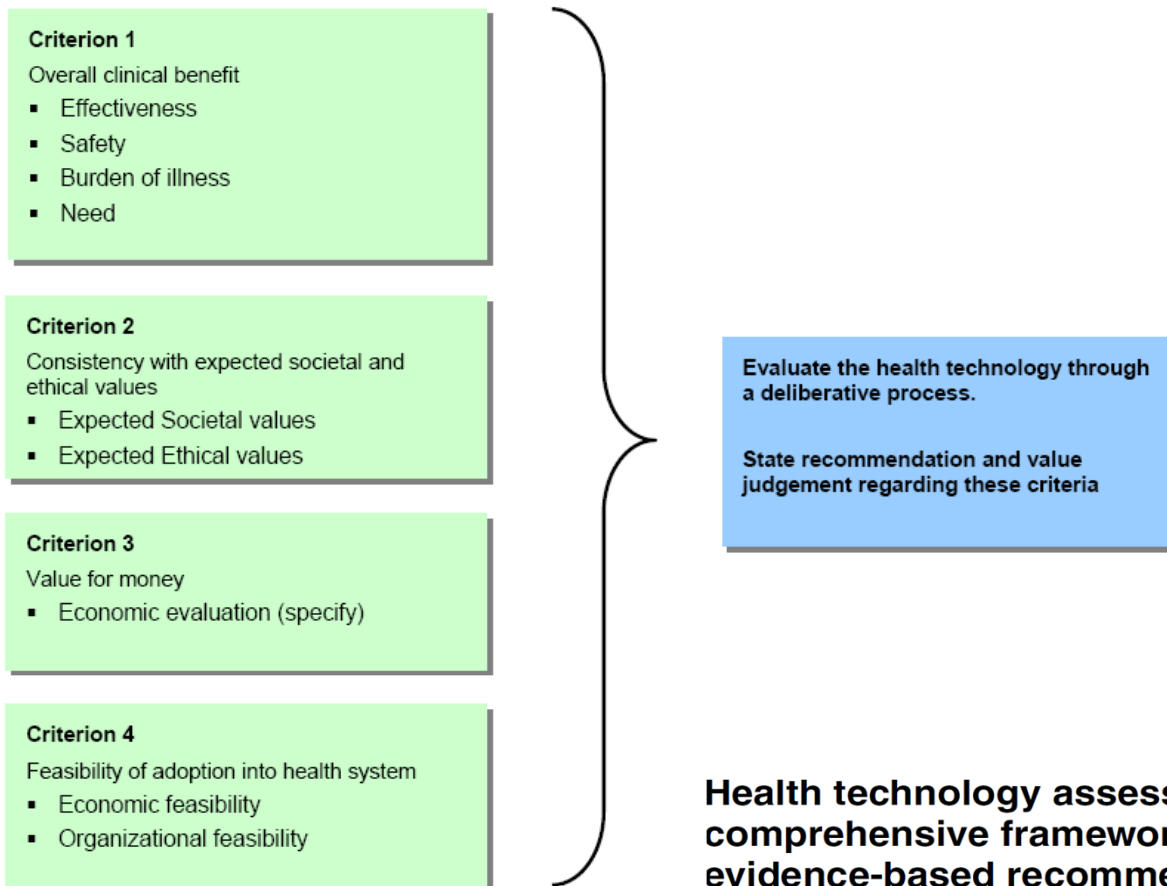


Figure 1: OHTAC decision making model

Elements of Decision Frameworks

Attributes

- E.g. Health gain
- E.g. Value for money

Decision rules for combining attributes

- E.g. If high quality RCT, then “high quality” evidence
- E.g. Attribute weights in MCDA

Process-

- Who are the decision makers
- How are data presented, who formulates recommendations
- Transparency, appeals

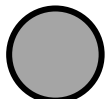
The original DD framework

Four decision domains:

“Dots”



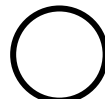
High



Moderate



Moderate
Uncertainty



Uncertain

Main Criteria	Sub-Criteria	Definitions and considerations
Overall clinical benefit	Effectiveness	<ul style="list-style-type: none"> The potential health impact of the technology compared to the available alternatives. Should be measured in terms of relevant patient outcomes including mortality, morbidity, and quality of life of persons using the technology. The magnitude and direction (increase/decrease) of the technology's effect should be considered when evaluating its potential health impact.
	Safety	<ul style="list-style-type: none"> The frequency and severity of adverse effects specific to the new technology compared to the available alternatives.
	Burden of illness	<ul style="list-style-type: none"> The burden of illness on society of the target condition to which the technology is applied as evidenced by the incidence, prevalence, or other measure of disease burden on the population.
	Need	<ul style="list-style-type: none"> The need for the technology compared to the availability of an effective alternative technology to manage the target condition. Need may be great if no other alternatives are available for the target condition.
Consistency with expected societal and ethical values	Expected societal values	<ul style="list-style-type: none"> Broadly shared values in society that bear on the appropriate use and impact of the technology.
	Expected ethical values	<ul style="list-style-type: none"> The potential ethical issues inherent in using or not using the technology. Relevant ethical issues should be listed.
Value for money	Economic evaluations	<ul style="list-style-type: none"> A measure of the net cost or efficiency of the health technology compared to available alternatives. OHTAC does not use a value for money threshold. Can be assessed by the appropriate economic evaluation including incremental cost effectiveness analysis, incremental cost-utility analysis, net monetary health benefit, acceptability curves, cost-consequence analysis.
	Economic feasibility	<ul style="list-style-type: none"> The net budget impact of the new health technology derived by determining all relevant costs and savings in the health care system. The default perspective for the budget impact analyses will be that of the funder of the health system. OHTAC may request alternative perspectives if they would better inform the decision-making process.
Feasibility of adoption	Organizational feasibility	<ul style="list-style-type: none"> 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).

ICEUR: Incremental Cost-Effectiveness Utility Ratio (ICEUR); QALY: Quality of Life Years gained (QALY); LYG: Life Years Gained

Principles

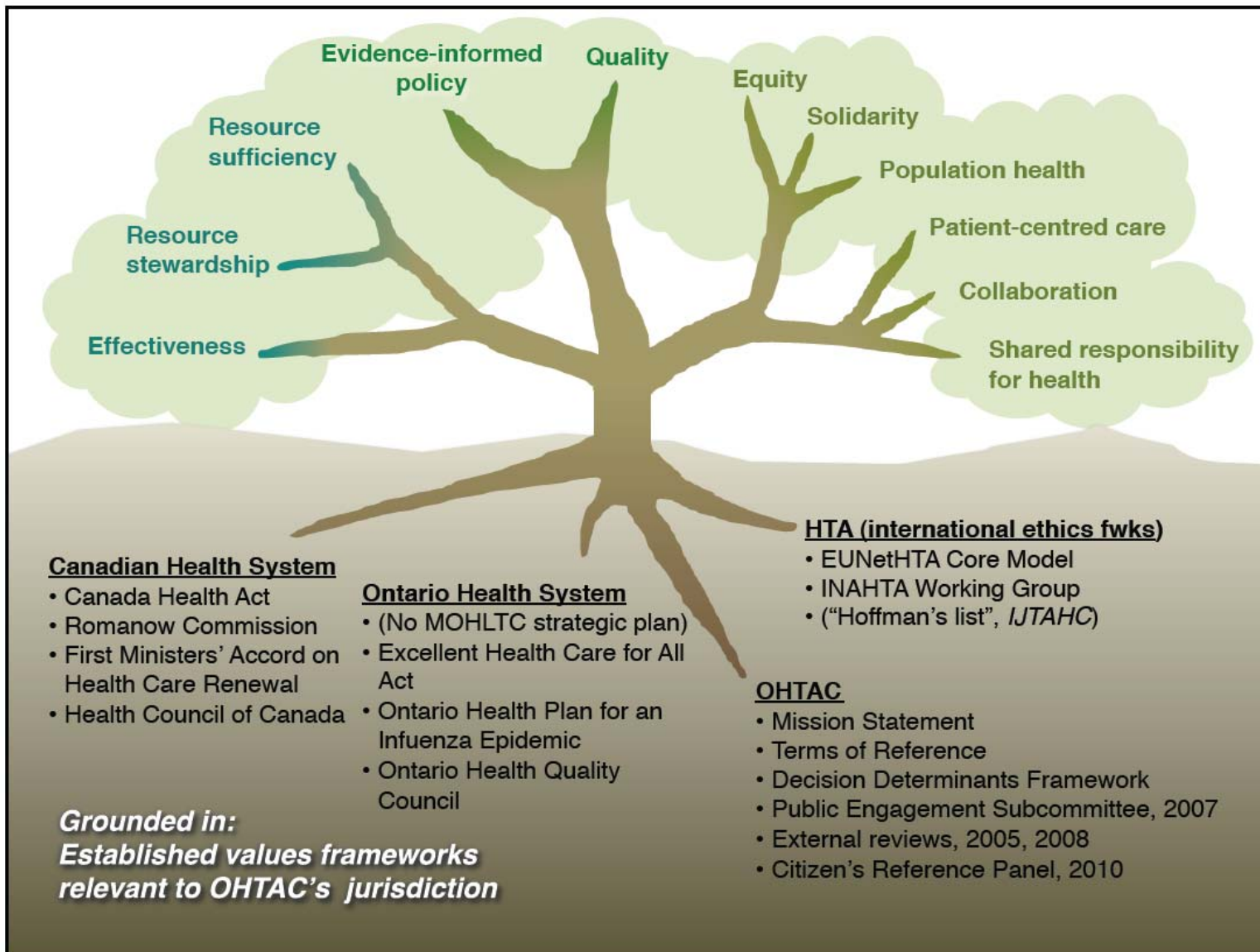
1. Continuity

2. Congruent with OHTAC's mandate

- Mainly scientific appraisal
- Implementation / feasibility to be considered

3. Values based framework

4. Three paradigms





Social and ethical values subcommittee (Giacomini et. Al.)

Objective:

- To articulate the basic values that should underlie evidence assessment and OHTAC deliberations

-Consensus values apparent in the health care system

-Values represented in HTA process

-Values represented in HTA methods

Defining the values

Pragmatic, as opposed to academic

-derived from source documents

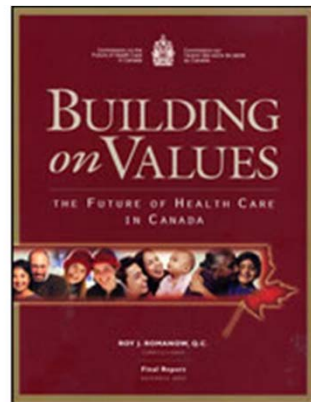
To be used for:

-helping to understand the foundation of the entire HTA process

-bringing a “values” perspective to the process

- -vignette stage (flagging issues)
- -gathering and interpreting information
- -deliberation- recommendation stage

Where value statements come from



Canadian health system values (Canada Health Act, Romanow Commission etc)

Ontario health system values (Excellent Health Care for All Act, OHQC)

HTA values

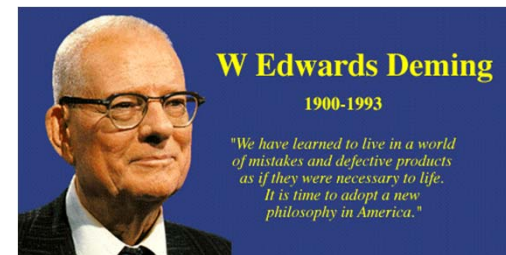
- -cross-national (e.g. EUNEHTA core model), “Hoffman’s List”
- OHTAC (Mission statement, terms of reference)

Quality

Quality refers to the excellence of things- not only the achievement of what is good, but also continual striving for improvement



Quality applies to each of the values in this framework, especially as they are translated into goals for policy



Evidence informed policy

Policy making should be informed by rigorous and relevant data

Where possible, research knowledge should be consulted to answer questions of fact



Effectiveness

Health care should be effective in producing health and well-being

Well-being includes physical and mental dimensions



Resource stewardship

Responsible stewardship of resources means ensuring their sustainability over time, and preventing their unnecessary waste

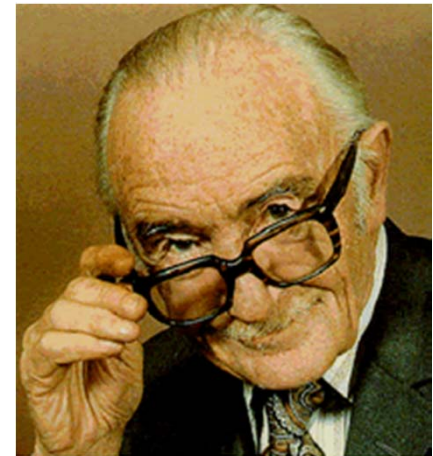
Value for money should be understood and pursued



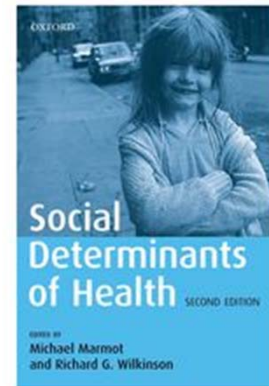
Resource sufficiency

Policies should be supported by adequate resources for their implementation and success

Responsibility for sufficient funding is shared among the public (who fund governments) and governments (who fund providers and services)



Equity



Access to health care should be universal among Canadians and based on individual need

Individuals should not face discrimination based on:

ability to pay, wealth, geographic location, origin, gender, or age

Solidarity

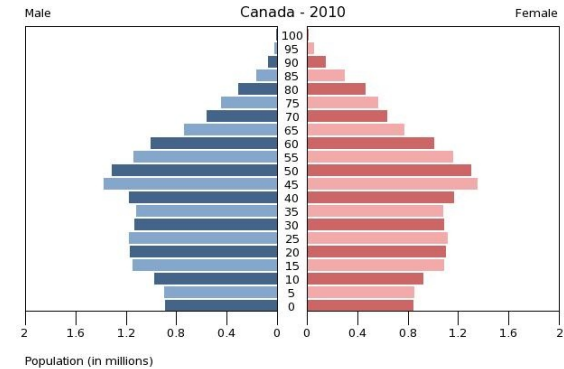
The principle of solidarity recognizes the importance of relationships and interdependence for individual and societal flourishing

Solidarity entails sustaining strong, trusting, and compassionate relationships in the health system: patients and providers, citizens and government.

Solidarity also implies that conflicts of interest and externalities should be transparent and addressed



Population health



The health system should serve the health of the population as well as the health of individuals

Policy makers should consider implications of decisions for population health, prevention, and protection of the public from harm.

Patient centered care

Processes of care, and patient experiences matter, in addition to health outcomes

Health care services should be responsive to patients' needs, values, and preferences

The dignity, rights, liberty, autonomy, and privacy of patients must be respected throughout the health care process



Collaboration

Health care is complex. Success depends on constructive collaboration between many providers, agencies, organizations, professionals, patients, and caregivers.

Health technologies should be analyzed in context, including attention to both their integral components and how they integrate with other aspects of health care



Shared responsibility for health

The health system holds partial responsibility for individual and population health

Consider not only personal, but also social determinants of health



The Values, as a Set

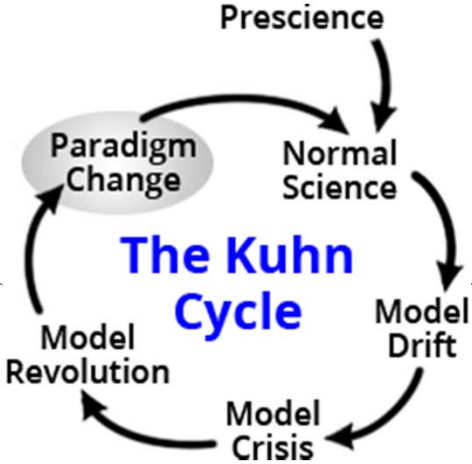
All Values matter

No particular value trumps another

Conflict depends upon context



Three Paradigms in
Health Technology Assessment:



What is a (scientific) paradigm?

“an entire constellation of beliefs, values and techniques.....shared by the members of a given community”

[Kuhn, T S; The Structure of Scientific Revolutions, 2nd Ed., Univ. of Chicago Press, Chicago & London, 1970, p.175]



Scientific Paradigm

what is to be observed and scrutinized,

the kind of questions that are supposed to be asked and probed for answers in relation to this subject,

how these questions are to be structured,

how the results of scientific investigations should be interpreted.

Kuhn, T S; The Structure of Scientific Revolutions, 1970, p.175

Scientific Paradigm

Intellectual construct(s)

- Values, beliefs, techniques

Social construct

- Set of ideas represented in social institutions
 - Societies, journals, public institutions



Evidence Based Medicine

PARADIGM -1

CLINIMETRICS, CLINICAL EPIDEMIOLOGY, OUTCOMES/
HEALTH SERVICES RESEARCH, KNOWLEDGE TRANSLATION



Evidence Based Medicine

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.

Sackett D. BMJ 1996;312:71-72
Evidence based medicine: what it is,
and what it is not.



To Improve the Evidence of Medicine: the 18th Century British Origins of a Critical Approach

Trohler 2001. Journal of the Royal Society of Medicine

- “The intellectual basis was essentially the emergence of a climate of `rational empiricism', a general emphasis on observation rather than theory, and also the profusion of medical societies allowing these views to be propagated. “

EBM...ideas about evidence...

Method

Context-free

Efficacy Diagnosis
Effectiveness Prognosis

Context-sensitive

ethics
economics

Colloquial

values
politics

Relevance

EBM...techniques



EBM...ideas
about how to
apply evidence



values

evidence

costs?



Patron saints...

Alvan Feinstein



Archie Cochrane



David Sackett



Journals...



Institutions...



CADTH



Economic evaluation

PARADIGM 2- COST EFFECTIVENESS ANALYSIS,
PHARMACOECONOMICS, HEALTH ECONOMICS, CLINICAL DECISION
ANALYSIS, PREFERENCE/UTILITY ASSESSMENTS, CONSUMER
DECISION SUPPORT



Definition

comparative analysis of alternative courses of action in terms of both their costs and consequences“.

(Drummond et. Al. Methods for the Economic Evaluation of Health Care Programmes)



Economic evaluation...ideas about evidence...

Method

Context-free

Efficacy Diagnosis
Effectiveness Prognosis

Context-sensitive

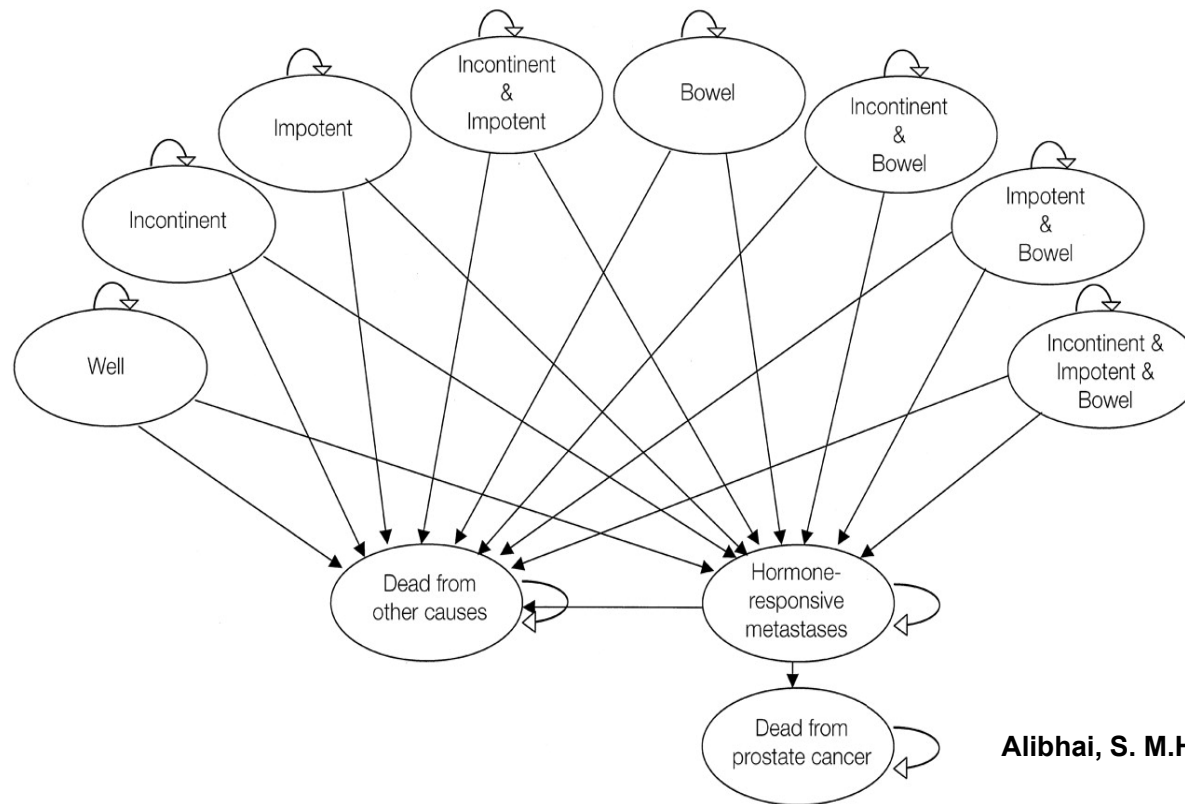
ethics
economic

Colloquial

values
politics

Relevance

Economic evaluation...techniques



Alibhai, S. M.H. et al. J Clin Oncol; 21:3318-3327 2003

Patron saints...



Milt Weinstein



Michael Drummond



George Torrance



Journals...



Institutions...



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Bioethics/ Social Science

PARADIGM 3- ACCOUNTABILITY FOR
REASONABLENESS, ETHICS OF RESOURCE ALLOCATION,
“ELSI”, PATIENT/ CITIZEN ENGAGEMENT, PATIENT
EXPERIENCES

Definition- A4R

- Framework for priority setting that has 4 components
 - Publicity- (transparency)
 - Relevance- (reasons that are relevant and adequate)
 - Appeals
 - Enforcement

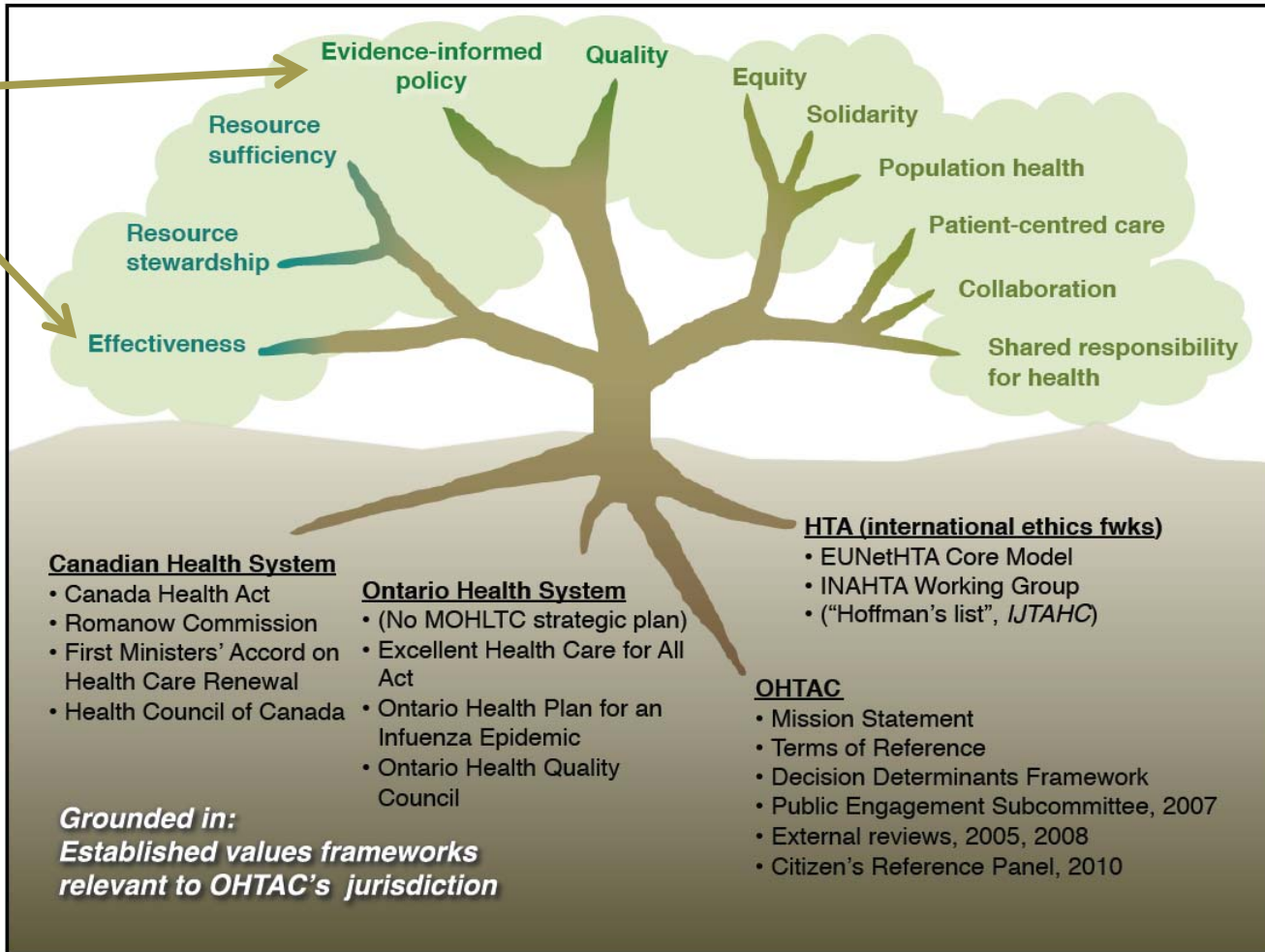
Hasman and Holm-
Accountability for Reasonableness.
Opening the black box of process
Health Care Analysis 2005

In the absence of consensus on principles, a fair process allows us to agree on what is legitimate and fair. Key elements of fair process will involve transparency about the grounds for decisions; appeals to rationales that all can accept as relevant to meeting health needs fairly; and procedures for revising decisions in light of challenges to them.⁸ Together these elements assure "accountability for reasonableness."

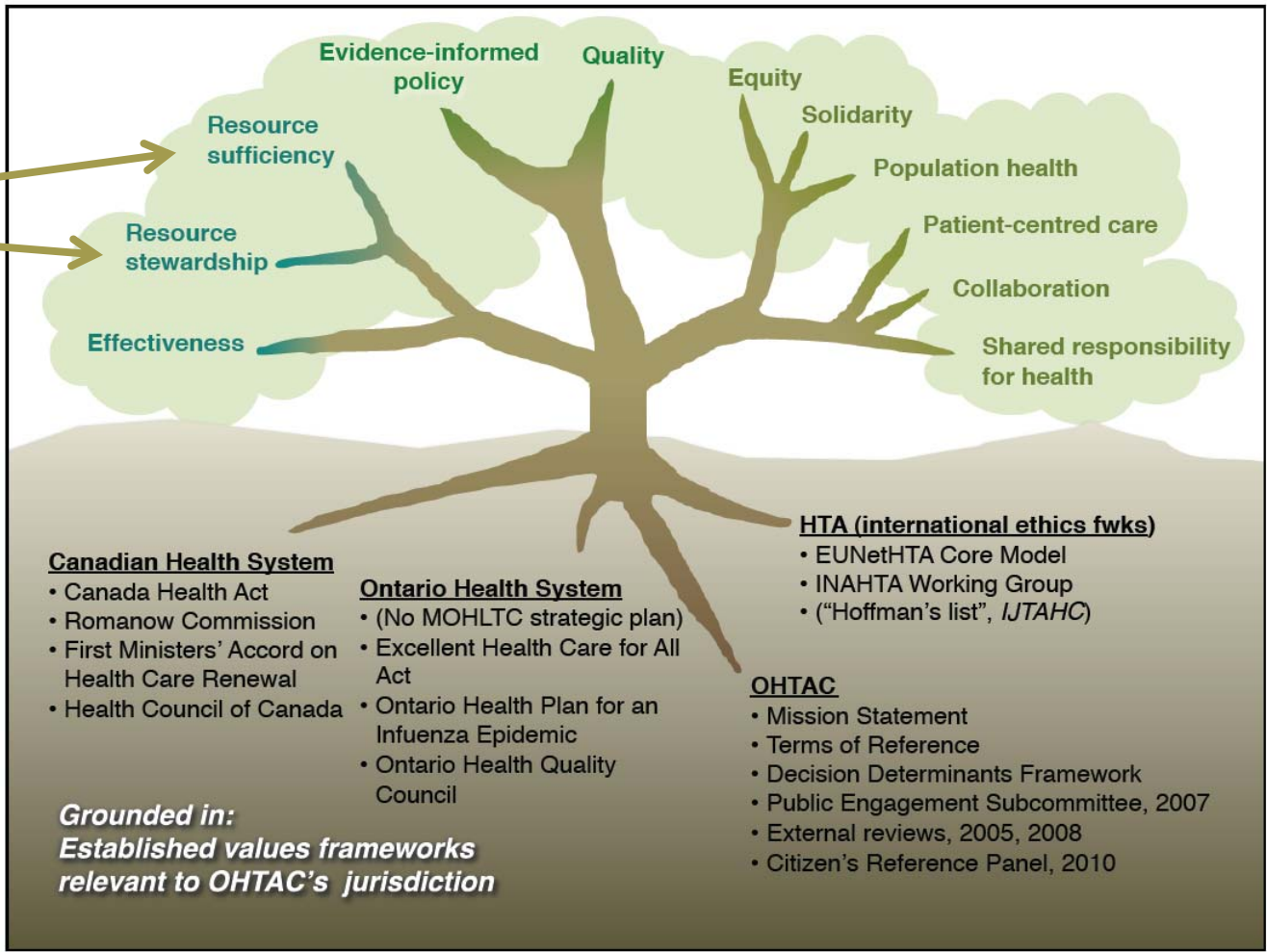
Daniels *BMJ* 2000;321:1300-1301

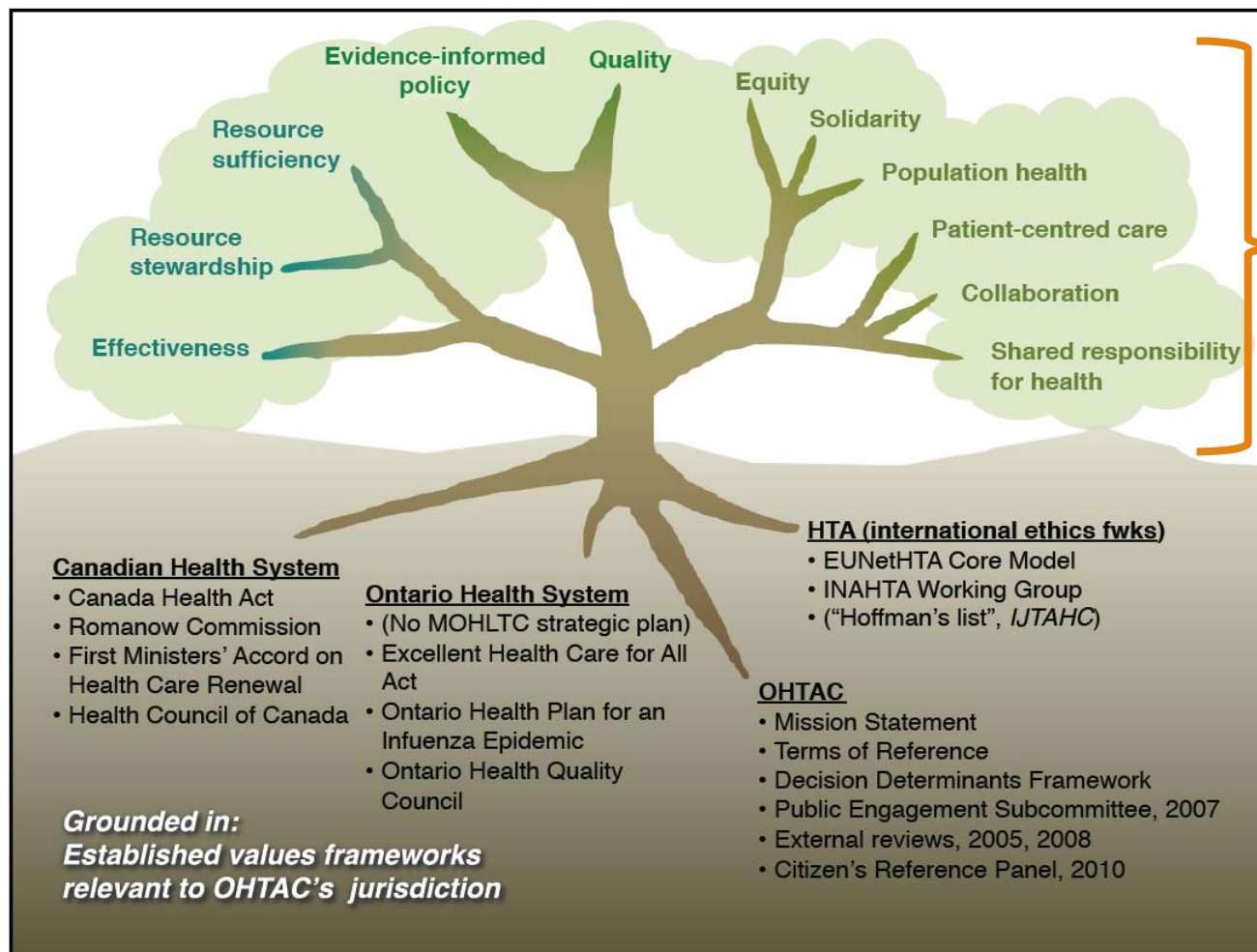


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2





Implications...

The primary goal of the health system is not....

- to maximize welfare of Ontarians
 - to implement best evidence
 - to maximize health subject to resource constraints
 - make decisions fairly
- 

Developing a Values Based Decision Framework-

METHODS- 1

Presentations

- Pan Canadian Oncology Drug Review (Fields)
- Committee to Evaluate Drugs (Grill)
- GRADE (Schuneman)
- Multicriteria DA (Goetgebhur, Diaby)
- Paradigms (Krahn)
- Values (Giacomini)



Methods-2

systematic review of decision attributes



Criteria	Terms
Efficacy- Potential benefit of the intervention (mortality, morbidity, PRO)	Health benefit, potential health gain in terms of <i>mortality</i> (saving life, life expectancy gains, average life-year benefit per patient, prolongation of disease-free survival); <i>morbidity</i> (health benefit, enhanced health outcome, relative advantage, incremental health gain); <i>patient-reported outcomes</i> (quality of life, number of QALYs gained per patient, disability adjusted life years, relative value to patient). Overall gain in quality of care. Health benefits relative to current standard therapy.
Safety of the intervention	Side (adverse) effects, unintended consequences, safety and tolerability, risks, risk management, harm, risk of event, risk of toxicity compared with standard therapy.
External impact of intervention	Impact on patient's family, possible harms to others, infectious disease involved, population effect (positive or negative), public health interest, social impact, social benefit, prevention of ill health, prevention.
Need (clinical)	Treatment alternatives, comparative intervention limitations (unmet needs), availability of alternative treatments, availability of effective alternative treatments, availability of preventative measures, clinical need, emergencies and need.
Disease determinants	Factors responsible for the persistence of the burden.
Disease burden-clinical	Prevalence of disease, incidence of disease, number of patients, severity of disease, impact of disease/condition on quality of life, number of potential beneficiaries, indirect beneficiaries,
Quality of evidence (re: effectiveness research)	Availability of evidence, strength of evidence, consistency of findings, quality of data, choice of end points, validity of data, certainty, precision of effect, selection of studies, proof, scientific evidence, time of assessment in technology development, therapy mechanism of action.
Relevance of evidence/generalizability/ effectiveness in real practice	Relevance of evidence, representativeness of patients (studies vs. real world), representativeness of technology user (e.g. skill of surgeon or health care practitioner in studies vs. real world), representativeness of context (e.g. acute vs long term care; country differences), response rate, patient compliance, level of generalization, effectiveness in real practice, evidence of effectiveness.

Disease burden-cost	Cost to treat disease, cost to prevent disease, national cost of the disease/condition to the health care system.
Opportunity costs	Opportunity costs to the population.
Efficiency / value for money for patient.	Maximizing impact on health for a given level of resource compared to available alternatives for this patient group (e.g. cost-effectiveness, cost-utility, cost per QALY, cost-effectiveness utility curves, cost consequence analysis.). Could include comparisons of interventions with different objectives (e.g. psycho-therapy vs. pain meds).
Quality of evidence (re: efficiency & cost estimates)	Uncertainty in QALYs, possible benefit/harms not included in the QALY (i.e. non-health benefits, social benefits)
Cost per patient.	Cost per patient, unit cost.
Financial/budget impact-costs of intervention	Budget impact, affordability, operating and start-up costs, national medical costs per year, financial impact on government.
Financial impact-savings of intervention	Cost-savings, national savings in terms of costs of absences per year, savings in terms of medical costs.
Costs (benefits) of externalities	Costs of externalities such as: impact on patient's family, possible harms to others, infectious disease involved, population effect (positive or negative), public health interest, social impact, social benefit, prevention of ill health, prevention.



Criteria	Terms
Human dignity	Human integrity and dignity, basic human rights, meets patient's basic needs.
Patient autonomy and patient preference	Patient autonomy, patient preference. (e.g., patient-centred healthcare? Is there patient & public involvement?)
Equity, fairness and justice	Equity, fairness, health equity, equality, distributive justice, formal justice, procedural justice, social justice, addressing health status inequalities at population level, geographical equity, equity of access, timeliness of access.
Utility	Utility, utilitarianism.
Solidarity	Solidarity, collectivism, cohesion.
Cultural aspects	Cultural and religious convictions.



Methods- 3 Deliberation

Deliberation refers to a type of discussion in which there is a careful weighing of reasons for and against some proposition. (16, 17) The DD Subcommittee took the approach that collective problem-solving is the critical element of deliberation in which individuals from different academic backgrounds and experiences are given the opportunity to listen, understand and potentially persuade and that this process can ultimately lead to more reasoned and informed decisions. (16-20) The value of discussing issues

Values Based Decision Framework



1. CONTEXTUAL FACTORS

Origin of/reason for the request	<i>Who requested the review? What was their rationale? What is their responsibility/mandate?</i>
Incidence/prevalence	<i>What is the burden of disease?</i>
Availability of comparable alternatives	<i>List the available technologies (including drugs), devices, and interventions that are considered alternatives.</i>
Decisions by other jurisdictions	<i>What have other jurisdictions (provinces, countries) done with respect to the technology, device, or intervention being studied?</i>
Stakeholders and potential conflicts of interest	<i>Who are the key stakeholders, and what conflicts of interest might be at play with respect to the technology, device, or intervention being studied?</i>
Types of analyses conducted	<i>Options: Evidence-Based Analysis, Rapid Review, Expert Consultation, other (please describe).</i>
Affiliation of author(s)	<i>Examples: Health Quality Ontario, PATH Research Institute, THETA Collaborative</i>

Benefits and Harms

Ahmed Bayoumi



2. Primary appraisal criteria

BENEFITS AND HARMS

					Rank	
Benefits and Harms	Benefit	Magnitude	<i>Insert measures of effectiveness. For example, relative risk reduction, or odds ratio</i>			
		Certainty	<i>Insert measures of certainty. For example, confidence intervals (for random error) or GRADE assessment (for risk of bias).</i>			
	Harm	Magnitude	<i>Insert measures of harm. For example, relative risk or odds ratio for adverse event.</i>			
		Certainty	<i>Insert measures of certainty. For example, confidence intervals (for random error) or GRADE assessment (for risk of bias).</i>			
	Patient perspective	Strongly for/against or not a determinant	<i>Patient inputs on how patients perceive the net benefits and harms.</i>			
	SUMMARY	Takes into account both the magnitude and certainty of benefits and harms, and the ways in which patients perceive these benefits and harms, to produce the likelihood that this technology/ intervention will produce net benefit or harm.	<i>Highly likely to produce net benefit</i>	<i>Moderately likely to produce net benefit</i>	<i>Uncertain benefit/ harm</i>	<i>Moderately likely to produce net harm</i>

Certainty vs. Magnitude

Table 2. Incidence of Pressure Ulcers Overall According to Risk Group Stratification and Allocation to Repositioning Interval

Group	All Participants	2 Hours	3 Hours	4 Hours	P-Value, Wilcoxon (for Ordered Categories)
	Participants with Ulcers/All Participants, n/N (%)				
All participants	19/942 (2.0)	8/321 (2.5)	2/326 (0.6)	9/295 (3.0)	.68
Moderate risk	13/617 (2.1)	6/210 (2.9)	0/209 (0.0)	7/198 (3.5)	.68
High risk	6/325 (1.8)	2/111 (1.8)	2/117 (1.7)	2/97 (2.1)	.90
Moderate vs high risk					.79

Table #. Expected Benefit

		<i>Magnitude</i>		
		High	Medium	Low
<i>Certainty</i>	High	A	B	C
	Medium	B	B	C
	Low	C	C	C

Table #. Expected Harm

		<i>Magnitude</i>		
		High	Medium	Low
<i>Certainty</i>	High	A	B	C
	Medium	A	B	B
	Low	A	A	B

		<i>Expected benefit</i>		
		A	B	C
<i>Expected harms</i>	A	3	4	4
	B	2	3	3
	C	1	2	3

Patients' perspectives

The new DD framework proposes that such information be provided directly by patients or their representatives. Patient input is solicited in a similar way at CDEC, pCODR, and CED. The committee recognized that soliciting a wide and representative spectrum of patients' views may be difficult for logistical reasons and because some patient groups are supported by groups with a strong financial incentive in the decision or other conflicts of interest. Nevertheless, the committee felt that such input would be valuable and mechanisms for soliciting such input should be coordinated with the Patient Engagement subcommittee. In

Patient engagement in evidence review: Who and How

2 EVIDENCE-BASED ANALYSIS (may include expert panel input & qualitative meta synthesis)

Groups	Mechanism	Tools
<ul style="list-style-type: none">• Patient organizations	<ul style="list-style-type: none">• Consultation	<ul style="list-style-type: none">* Invited submissions
<ul style="list-style-type: none">• Patients	<ul style="list-style-type: none">• Consultation • Participation	<ul style="list-style-type: none">* Surveys* Social media analysis* Qualitative research/synthesis * Committee representation (e.g., expert panel)

2. Primary Appraisal Criteria- Economics

Ron Goeree



2. Primary appraisal criteria

ECONOMICS

✓	Check mark ("✓") indicates formal analysis completed. X mark ("X") indicates no formal analysis completed.							
Economics	Type of analysis							
	Value for money	Cost effectiveness	CE Threshold	<i>Highly likely to be CE (80%-100%)</i>	<i>Moderately likely to be CE (60%-79%)</i>	<i>Uncertain CE (40%-59%)</i>	<i>Moderately likely to not be CE (20%-39%)</i>	<i>Highly likely to not be CE (0%-19%)</i>
			\$50K/QALY					
			\$100K/QALY					
	Adequacy	Downgrade Consideration	<i>Adequate</i>			<i>Not adequate</i>		
		Appropriateness of cost and outcome measures Comprehensiveness of cost and outcome valuation/ aggregation						
	SUMMARY	Taking account of both the probability of cost effectiveness, and the adequacy of the measures used, select the overall likelihood that this technolog(ies)/ intervention is cost effective.	CE Threshold	<i>Highly likely to be CE (80%-100%)</i>	<i>Moderately likely to be CE (60%-79%)</i>	<i>Uncertain CE (40%-59%)</i>	<i>Moderately likely to not be CE (20%-39%)</i>	<i>Highly likely to not be CE (0%-19%)</i>
			\$50K/QALY					
			\$100K/QALY					

Figure 4. Example scatterplot used to express parameter uncertainty in a probabilistic model

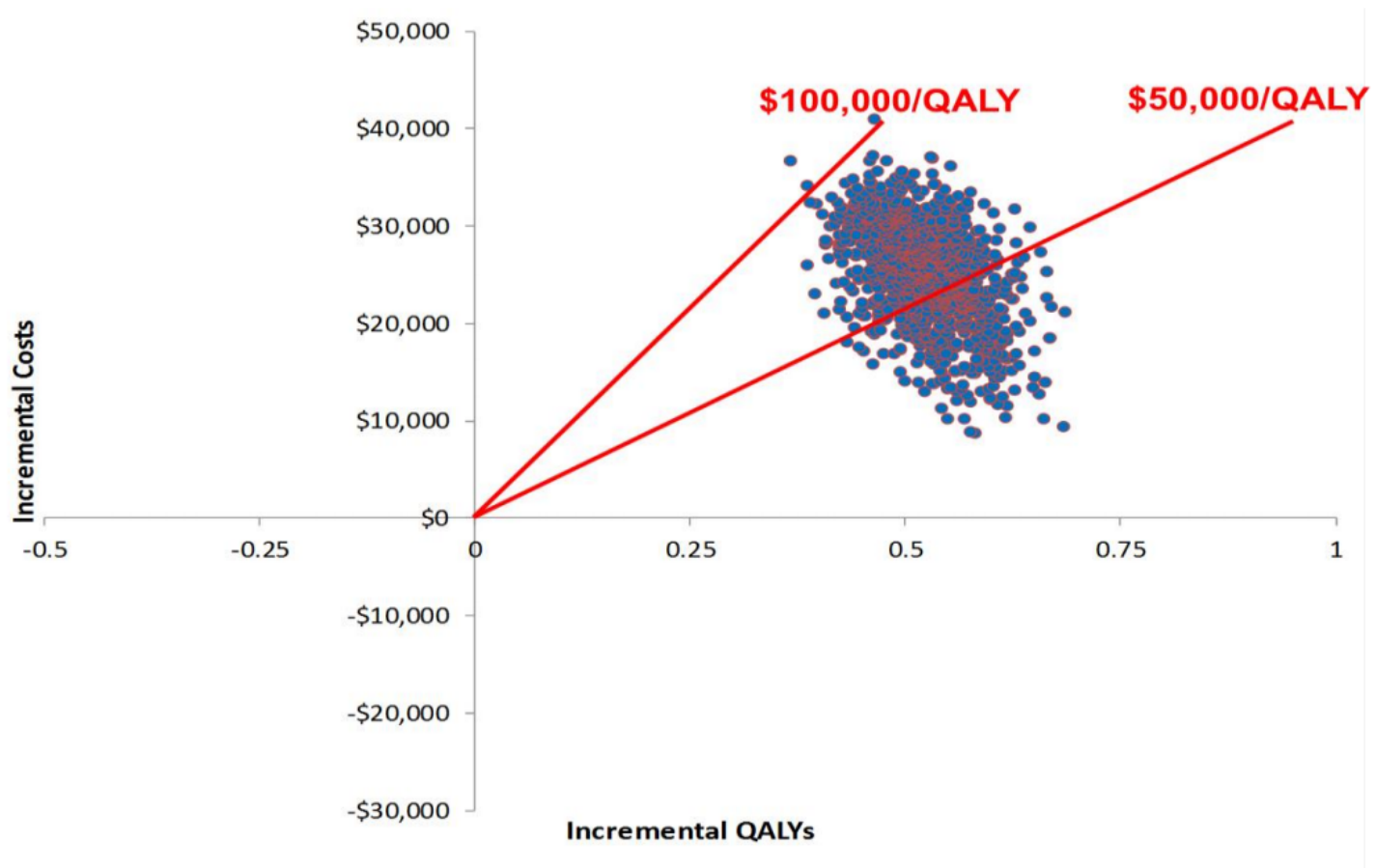
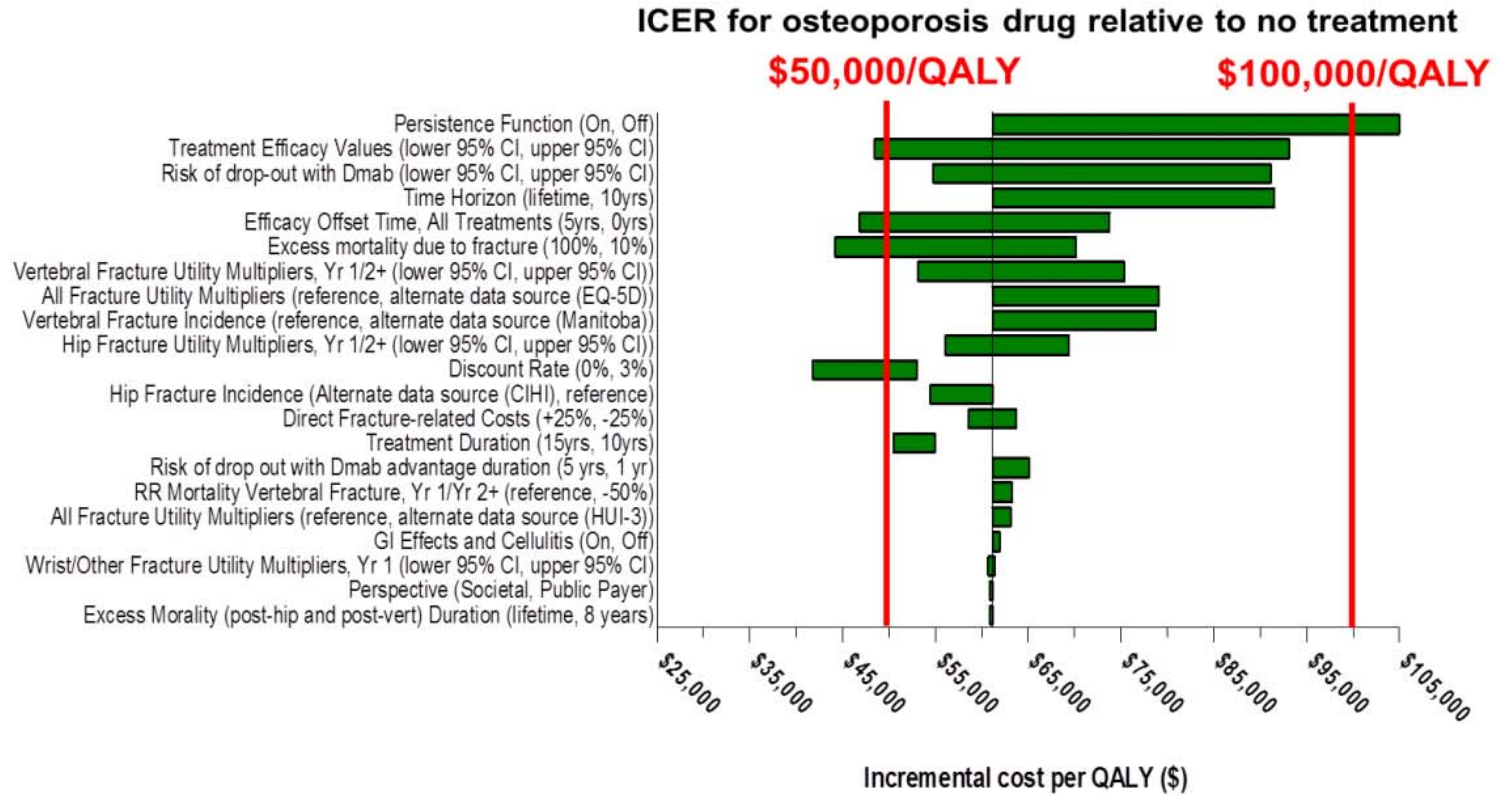


Figure 3. Example tornado diagram used to express uncertainty in a deterministic economic model



LIFE-SAVING TREATMENTS AND DISABILITIES

Are All QALYs Created Equal?

QALYS AND AGEISM: PHILOSOPHICAL
THEORIES AND AGE WEIGHTING

AKI TSUCHIYA*
Centre for Health Economics, University of York, York, UK

**Cost-utility analysis:
Use QALYs only with great caution**

Maurice McGregor

COMMENTARY

Transferability of economic
evaluations: approaches and
factors to consider when using
results from one geographic
area for another

Ron Goeree^{a,b}, Natasha Burke^{a,b}, Daria O'Reilly^{a,b},
Andrea Manca^c, Gord Blackhouse^{a,b} and Jean-Eric
Tarride^{a,b}

3. Patient Centered Care

Fiona Miller

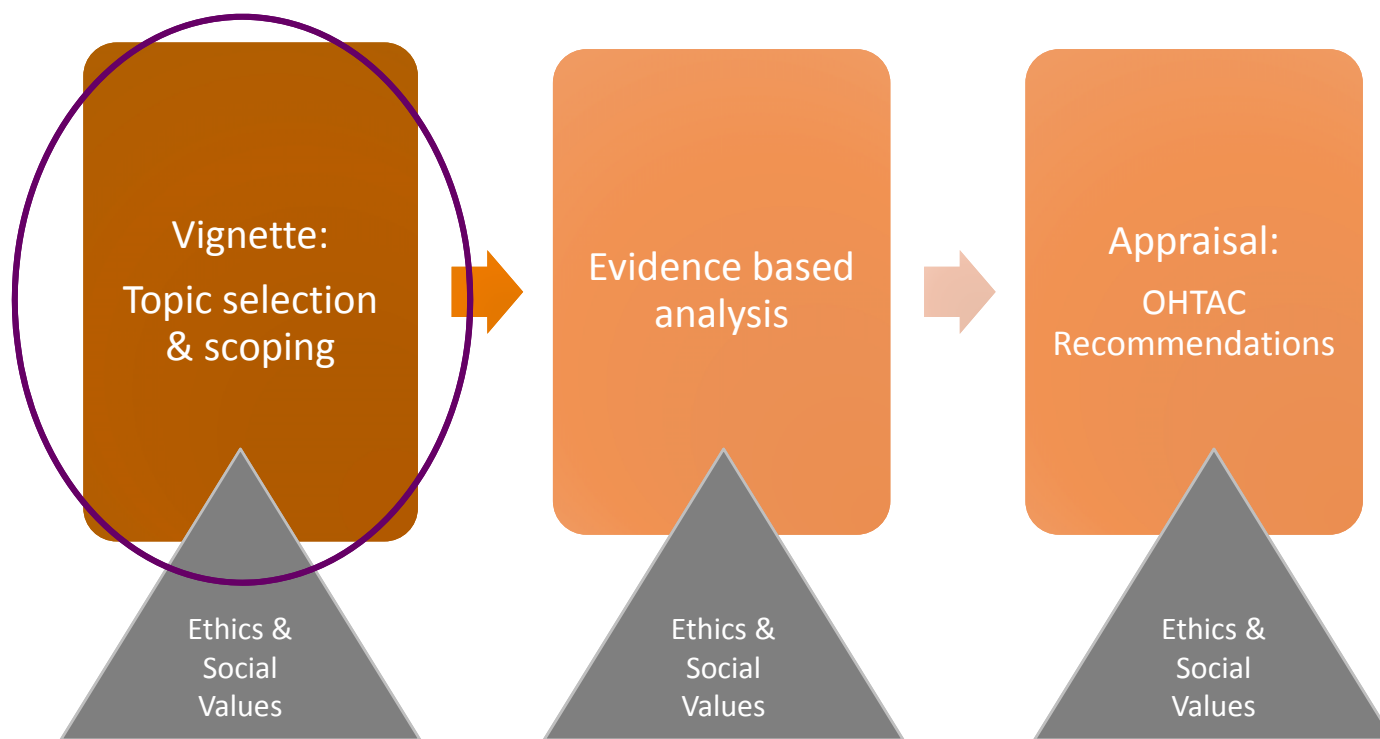


3. Primary appraisal criteria

PATIENT CENTRED CARE

✓	Check mark ("✓") indicates formal analysis completed. X mark ("X") indicates no formal analysis completed.						
Patient-Centred Care	Patients: Values & Preferences	Aligned with patient values & preferences	<i>Do patients have specific values, preferences or needs related to the condition, treatment or life impact that are relevant to this assessment? (NB. Values and preferences of family, informal caregivers or the public to be considered, as appropriate)</i>				
		Consistent with commitments to autonomy, privacy, confidentiality	<i>Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy or confidentiality that are relevant to this assessment?</i>				
	Populations: Equity & Coordinated Care	Enhances equity in access or outcomes	<i>Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved (or not worsened) that are relevant to this assessment?</i>				
		Coordinates care	<i>Are there challenges in the coordination of care for patients that might be improved (or not worsened) that are relevant to this assessment?</i>				
	SUMMARY	Taking account of these considerations, select the degree to which the evidence supports the use of the technology(ies)/ intervention.	Strongly supports	Somewhat supports	Neutral/ Unknown	Does not support	Strongly discourages

The stages of an HTA



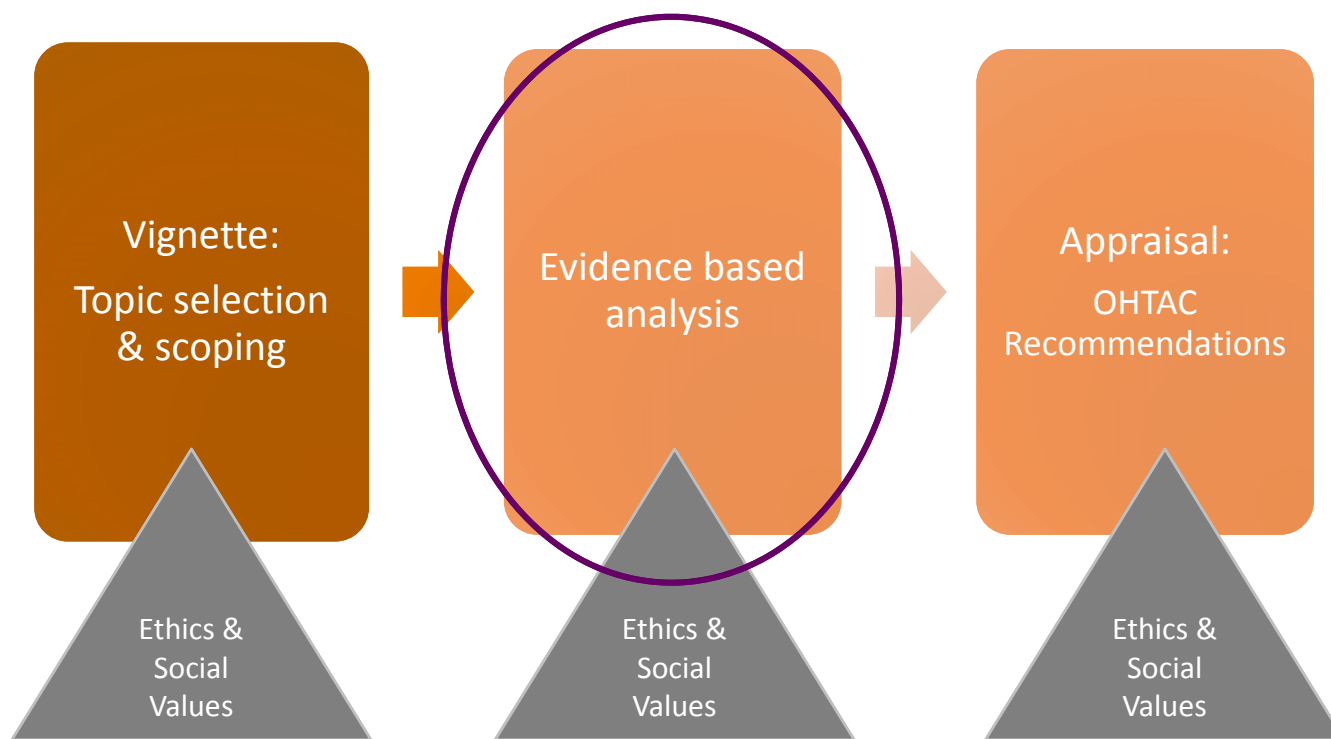
OHTAC prioritization guide – Current approach to E&SV

Domain	Criteria	Ranking			Unknown	RANK
		A	B	C		
Social values considerations	Potential to impact on social values	Significant social values issues	Some social values issues	No remarkable impact on social values	Unknown	

OHTAC prioritization guide – V2

Domain	Criteria	Ranking			Unknown	RANK
		A	B	C		
Patient-centred care	Patient & public values	<i>Consistent with patient values & preferences</i>	<i>Limited impact related to patient values/preferences</i>	<i>Contrary to patient values and preferences</i>		
	Equitable & integrated care systems	<i>Has the potential to improve the delivery of equitable and integrated care</i>	<i>Limited impact on the delivery of equitable and integrated care</i>	<i>May worsen the delivery of equitable and integrated care</i>		

The stages of an HTA



'Triggering' evidence-based E&SV analysis

All mega-analyses (multi-technology appraisals) should be accompanied by an evidence-based E&SV analysis

- Conducted by experts in evidence-based E&SV analysis
- Supported by expert committee struck for each mega-analysis
- Other HTAs (i.e., single technology appraisals) **may** require a full evidence-based E&SV analysis, under certain circumstances (see **checklist**, over)

Shawn Winsor



Checklist- Patient Centered Care

Where treatments or outcomes are sensitive to patient preferences, values or needs

Where the patient population is vulnerable or marginalized

- For example, ill children, individuals with impaired cognitive capacity, institutionalized persons, etc.
- Marginalized by unfair or unjust health differences

Where the technology is proposed for use in healthy populations

- Population screening; prophylactic interventions

Where the technology is 'disruptive' of existing services or systems

- Changing health care delivery and disease management processes
- Changing job prospects for health care providers
- Requiring new capital equipment and infrastructure

Where the technology challenges legal or ethical commitments to patient autonomy, privacy or confidentiality

Use of checklist

Who uses checklist

- Clinical epidemiologists, clinical or patient experts, as appropriate

When is checklist used

- At scoping stage for every technology
- May also be helpful at other stages, especially at early stages of clinical EBA, when new issues are being identified

What checklist leads to

- Consultation with experts in E&SV to consider/conduct evidence-based E&SV analysis

Evidence-based E&SV analysis: Recommended approach

Recommendation

- Evidence-based E&SV analysis should involve a systematic review of research evidence
- And, where appropriate, primary data collection or public engagement

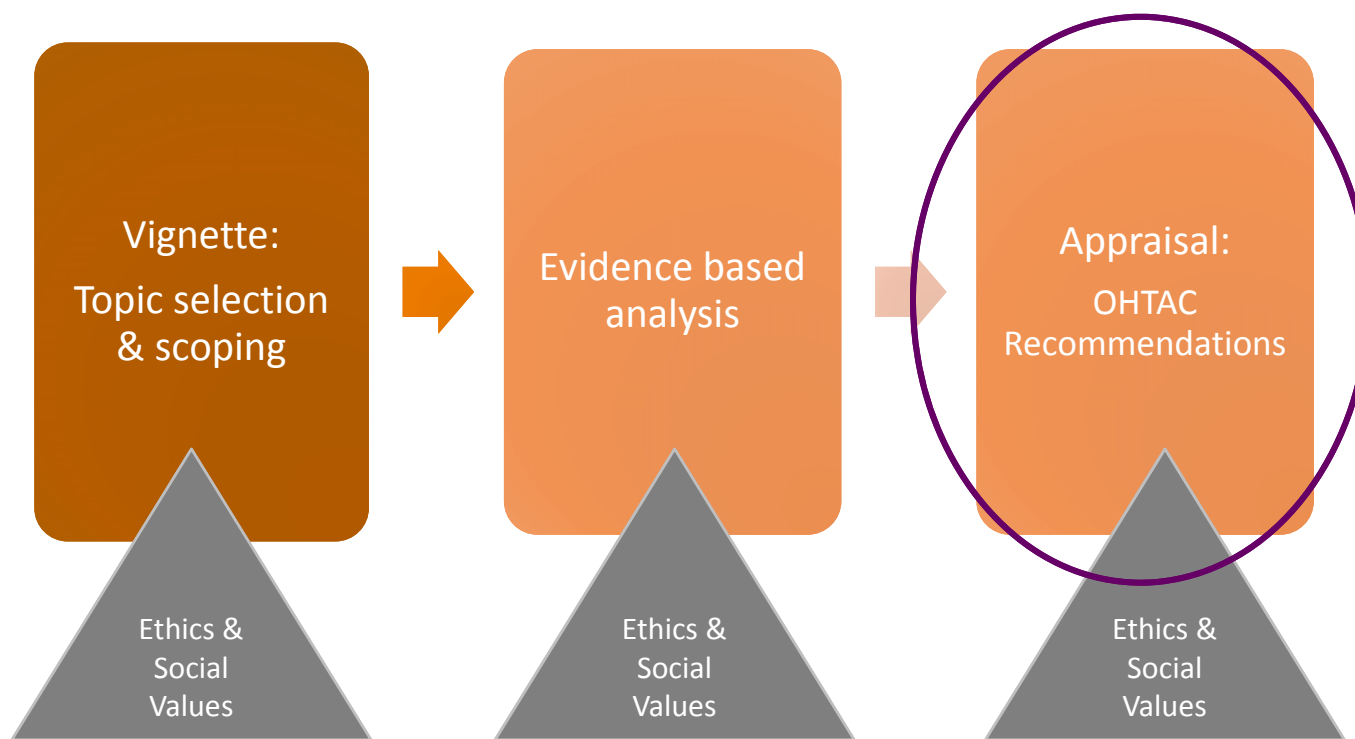
Rationale

- Encourages a consistent evidence-based approach to all relevant decision criteria
- Consistent with recommendations of PE subcommittee
 - PE subcommittee focused on engagement approaches
 - DD subcommittee has focused on evidence-based approaches

Suggested methodology

- **Scoping** review
- Addressing multiple domains of interest to E&SV analysis - drawing on 3 non traditional approaches to research synthesis
 - **Qualitative research** – To illuminate patient (and other stakeholder) values, preferences and experiences; also social and cultural beliefs, perceptions of treatments and outcomes, implementation-relevant considerations
 - **Health equity** – To identify “differences in health outcomes that are avoidable, unfair and unjust.”
 - **Health ethics** – To identify the moral issues arising in technologies, technology appraisal, or technology use

The stages of an HTA



3. Primary appraisal criteria

PATIENT CENTRED CARE

✓	Check mark ("✓") indicates formal analysis completed. X mark ("X") indicates no formal analysis completed.					
Patient-Centred Care	Patients: Values & Preferences	Aligned with patient values & preferences	<i>Do patients have specific values, preferences or needs related to the condition, treatment or life impact that are relevant to this assessment? (NB. Values and preferences of family, informal caregivers or the public to be considered, as appropriate)</i>			
		Consistent with commitments to autonomy, privacy, confidentiality	<i>Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy or confidentiality that are relevant to this assessment?</i>			
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		Coordinates care	<i>Are there challenges in the coordination of care for patients that might be improved (or not worsened) that are relevant to this assessment?</i>			
	SUMMARY	Taking account of these considerations, select the degree to which the evidence supports the use of the technology(ies)/ intervention.	Strongly supports	Somewhat supports	Neutral/ Unknown	Does not support

4. Primary Appraisal Criteria

HEALTH SYSTEM FEASIBILITY

Cost considerations	<i>What are the relevant cost considerations associated with implementing this technology/intervention (e.g., budget impact)?</i>
Organizational implications	<i>What are the relevant non-cost implications (e.g., logistical, human resources) associated with implementing this technology/intervention?</i>

Global Recommendations

1. We recommend that the Decision Determinants framework be considered to include both the attributes relevant to decision making, and the process of decision making. We recommend that that the key attributes relevant to decision making be considered to be: i) Contextual factors; ii) Primary appraisal criteria; and iii) Feasibility/ implementation criteria.

Global Recommendations

2. The DD Subcommittee recommends that OHTAC provisionally adopt the revised DD framework and that HQO allow for a period approximately 12 months of formal pilot testing, evaluation, and validation with other HTA organizations. In addition, the subcommittee recommends that a detailed workbook be developed to guide analysts in the consistent completion of each aspect of the DD tool

Global Recommendations

4. We do not recommend a quantitative scoring algorithm be used in the appraisal process at this time. Nor do we recommend that a minimum threshold be achieved in any or all domains. We recommend that the process of integration of the key decision attributes should be accomplished through deliberation and consensus.

2. Primary appraisal criteria

BENEFITS AND HARMS

					Rank		
Benefits and Harms	Benefit	Magnitude	<i>Insert measures of effectiveness. For example, gain in quality-adjusted life year (QALY), relative risk reduction, or odds ratio</i>				
		Certainty	<i>Insert measures of certainty that the benefit is true. For example, confidence intervals (for random/systematic error) or GRADE assessment (for risk of bias).</i>				
	Harm	Magnitude	<i>Insert measures of harm. For example, relative risk or odds ratio for adverse event.</i>				
		Certainty	<i>Insert measures of certainty that the harm is true. For example, confidence intervals (for random/systematic error) or GRADE assessment (for risk of bias).</i>				
	Patient perspective	Strongly for/against or not a determinant	<i>Patient inputs on how patients perceive the net benefits and harms.</i>				
	SUMMARY	Takes into account both the magnitude and certainty of benefits and harms, and the ways in which patients perceive these benefits and harms, to produce the likelihood that this technology/ intervention will produce net benefit or harm.		<i>Highly likely to produce net benefit</i>	<i>Moderately likely to produce net benefit</i>	<i>Uncertain benefit/ harm</i>	<i>Moderately likely to produce net harm</i>

Benefits and Harms

5. The DD Subcommittee recommends that HQO support (directly, or through EDS human resources) empirical research to determine an appropriately develop and refine this algorithm and scoring rubric for the Benefits and Harms domain.

Table #. Expected Benefit

		<i>Magnitude</i>		
		High	Medium	Low
<i>Certainty</i>	High	A	B	C
	Medium	B	B	C
	Low	C	C	C

Table #. Expected Harm

		<i>Magnitude</i>		
		High	Medium	Low
<i>Certainty</i>	High	A	B	C
	Medium	A	B	B
	Low	A	A	B

*Expected
harms*

	<i>Expected benefit</i>		
	A	B	C
A	3	4	4
B	2	3	3
C	1	2	3

Recommendations Related to Economics

9. The subcommittee recommends that OHTAC support (directly or indirectly through grant applications) empirical work on developing cost effectiveness threshold values in Ontario.
10. Given the complexity of interpreting uncertainty and adequacy in economic models, the working group recommends that a detailed workbook for health economists be developed, and formal training provided to health economists in applying results of economic evaluations to the decision framework.

Methods for the Estimation of the NICE Cost Effectiveness Threshold

Revised Report Following Referees Comments

Karl Claxton,^{1,2} Steve Martin,² Marta Soares,¹ Nigel Rice,¹ Eldon Spackman,¹ Sebastian Hinde,¹
Nancy Devlin,³ Peter C Smith,⁴ Mark Sculpher¹

2 Study methods

2.1 The aim was to develop methods to estimate the NICE cost-effectiveness threshold making use of routinely available data. Objectives were:

- i. Informed by relevant literature, to provide a conceptual framework to define the threshold and the basis of its estimation.
- ii. Using programme budgeting data for the English NHS, to estimate the relationship between changes in overall NHS expenditure and changes in mortality.
- iii. Extend the measure of benefit in the threshold to QALYs by estimating the quality of life (QoL) associated with additional years of life and the direct impact of health services on QoL.
- iv. Present the best estimate of the cost effectiveness threshold for policy purposes.

3 Central or 'best' estimate of the threshold

3.1 The most relevant threshold is estimated using the latest available data (2008 expenditure, 2008-10 mortality). The central or 'best' threshold is estimated to be £18,317 per QALY.

Recommendations Related to Ethics and Social Values

15. We recommend that OHTAC revise the “Prioritization Guide for Applications from the Health System” to ensure that decisions about whether to conduct an HTA appropriately reflect ethics and social values considerations.
16. We recommend that an evidence-based ethics and social values analysis be completed for all mega-analyses (multiple-technology appraisals). Mega analyses consider a network of interventions and/or technologies and thus provide an opportunity to integrate ethics and social values commitments related to patient centred care for patients and populations.

Recommendations Related to Ethics and Social Values

17. We recommend that decisions on whether to conduct an evidence-based ethics and social values analysis for other HTAs conducted by OHTAC (single technology appraisals, rapid reviews) be informed by the checklist developed by the working group. This checklist does not identify a specific 'trigger' for an ethics and social values analysis; instead, it identifies issues to consider in deciding whether an evidence-based ethics and social values analysis might be advisable. Consultation with relevant experts or OHTAC deliberation may be needed to guide these decisions.

Recommendations Related to Ethics and Social Values

18. We recommend that evidence-based ethics and social values analysis at OHTAC involve a comprehensive and rigorous review of the relevant research evidence.
 - Through the test case, the working group has identified approaches to the synthesis of non-traditional research evidence that are relevant to this recommendation. We would suggest that the research synthesis strategy used by members of working group for the MRgHIFU test case continue to be used, so that it may be further assessed and modified, as appropriate.
 - *NB.* Expertise with appropriate methods will be required to complete such reviews. This could be developed by the Evidence Development and Standards Division or contracted out to groups with the requisite expertise.

Process

22. In keeping with the recommendations of PE committee, we recommend that representatives from OHTAC, HQO Evidence Development and Standards,, and the DD committee, work together to improve key aspects of the **process** of technology appraisal.
- Transparency with respect to the process of selection of technologies for evaluation.
 - Adequate time for consideration of each aspect of a technology in the OHTAC deliberative process.
 - Standardization of the **process** of crafting OHTAC recommendations. Draft recommendations to be developed jointly by several individuals. These may include analysts involved in evidence, economics, and values assessment, and other representatives of EDS and OHTC.
 - Standardization of the **form** of OHTAC recommendations. We recommend that consistent language be used in recommendations (e.g. “Should be implemented”, “May be implemented”, “Should not be implemented”).

Summary

- making decisions about health technology is ultimately about values...
- making decisions based on values requires consideration of both process and decision criteria
- no single method, perspective, or intellectual tradition is adequate to operationalize the full range of relevant values in decision making

Final ruminations.....

1. How is this different from what we currently do?
2. How is this different from other decision frameworks?
3. Is there a theoretical basis for this approach?

Thanks!!

Mita Giacomini/ Fiona Miller	Ron Goeree	Ahmed Bayoumi
Frank Wagner	Tony Culyer*	Holger Schuneman
Shawn Winsor	Mike Paulden*	Ba' Pham
Juliani Yi	Gabrielle van de Velde	
Celine Cressman		
HQO- Stephen Petersen, Anna Sampson, Laura Park-Wyllie, Nancy Sikich, Sahba Eftekhary, Nik Goyert THETA- Ann Sylvia Brooker		
* resigned		

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