CAPT Conference:
Decisional Balance Session

Going Beyond Effectiveness and Cost-Effectiveness: How Can we Identify and Incorporate Other Important Factors for Healthcare Decision-Making?

April 19, 2011

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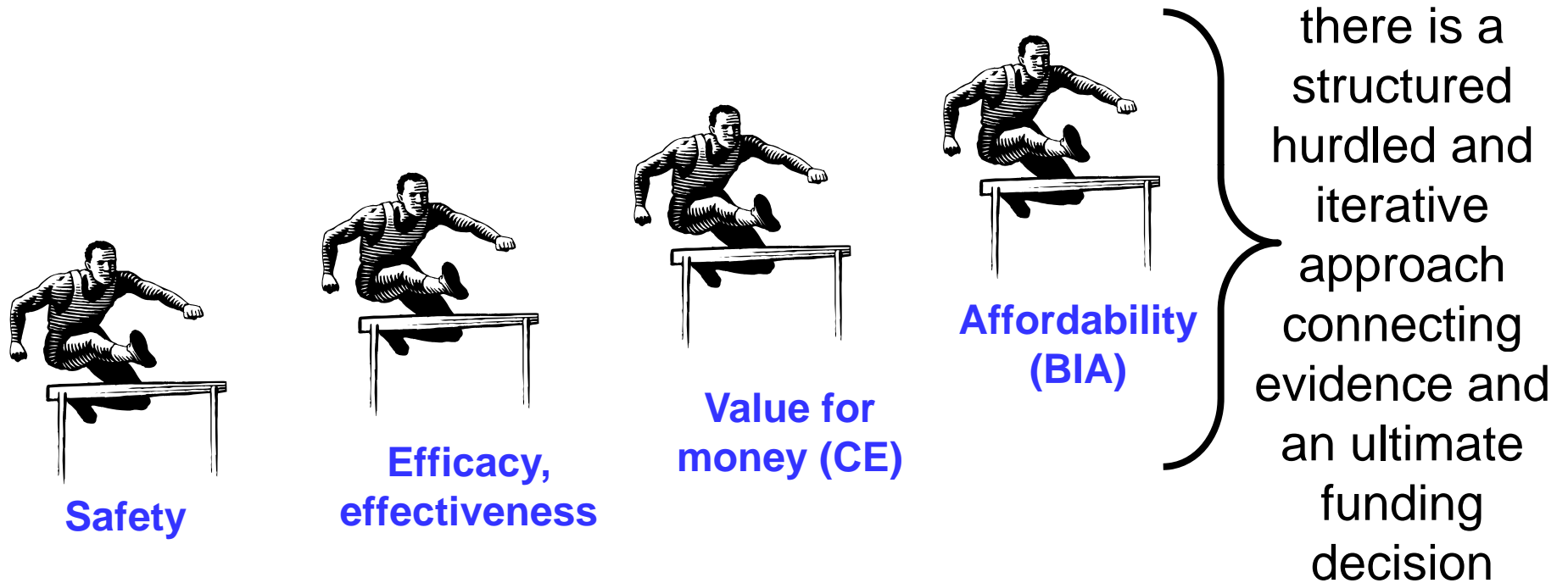PATH Research Institute, St Joseph's Healthcare Hamilton

Traditional Decision Making Criteria

➢ Often talk about 'traditional' D-M criteria

➢ Reality, hard to define 'traditional' D-M in Canada

➢ Varies across jurisdictions, across technologies (e.g. drugs, devices, procedures), D-M level (national, provincial, local authority, hospital), time

➢ For the most part, D-M for drugs & non-drug technologies have been based on four criteria:

- Safety
- Efficacy, effectiveness
- Cost-effectiveness
- Budgetary impact/affordability

Often a Staged Iterative Process

Safety

Efficacy, effectiveness

Value for money (CE)

Affordability (BIA)

Certainly not perfect, but there is a structured hurdled and iterative approach connecting evidence and an ultimate funding decision

Weight of any criteria depends on the cumulative information gained as we clear each hurdle (**weights revisited**)

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Handling of Other Important Factors?

Safety

Efficacy, effectiveness

Value for money (CE)

Affordability (BIA)

Other factors of value to D-M (ethical issues, social values, feasibility of implementation, unmet needs, legal issues, …)

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Re-Thinking of Other Considerations

How can we fit these factors in and how will this change our hurdled iterative re-weighting D-M process

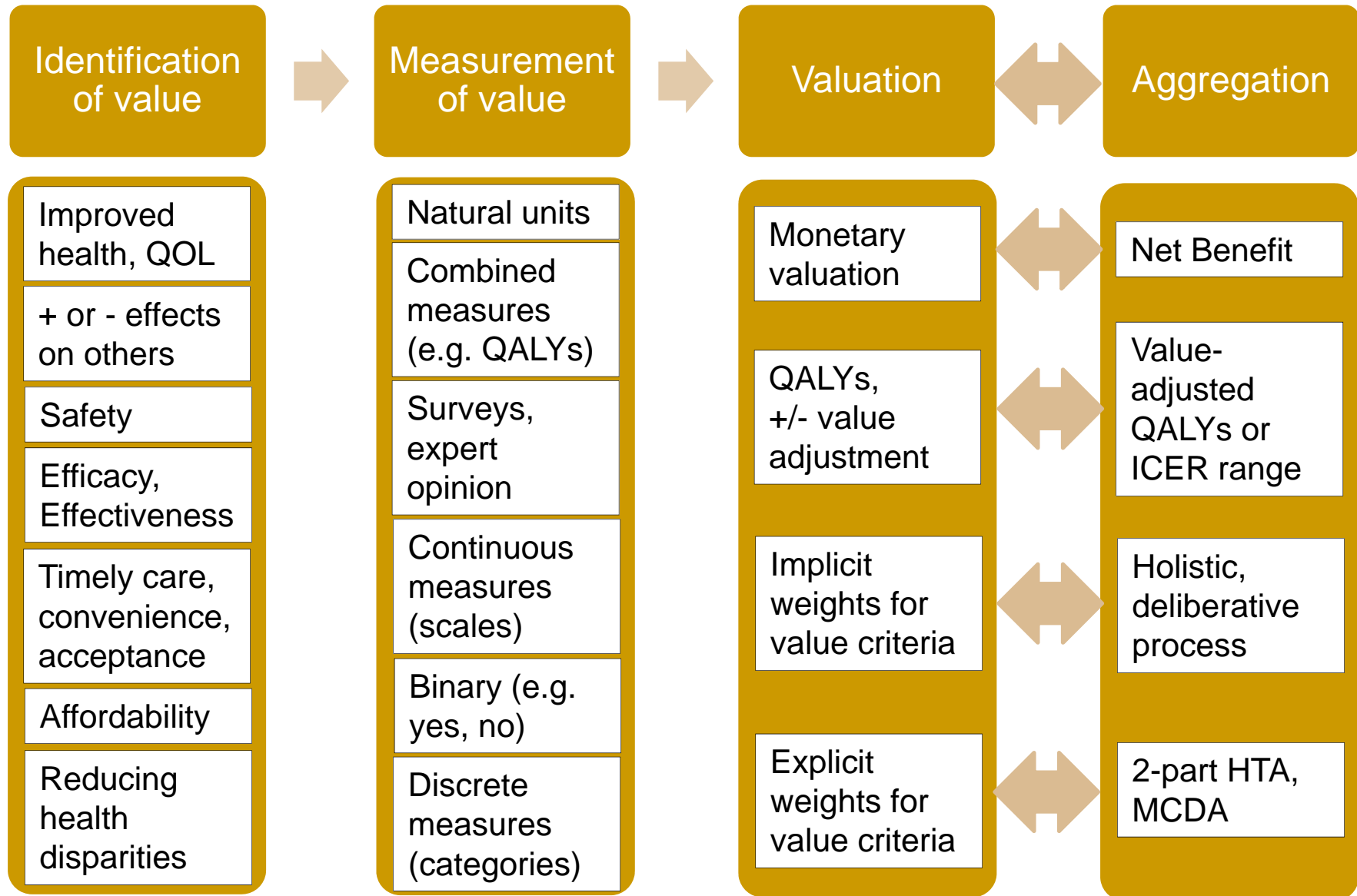**Safety**

Efficacy, effectiveness

Value for money (CE)

Affordability (BIA)

Other factors of value to D-M (ethical issues, social values, feasibility of implementation, unmet needs, legal issues, …)

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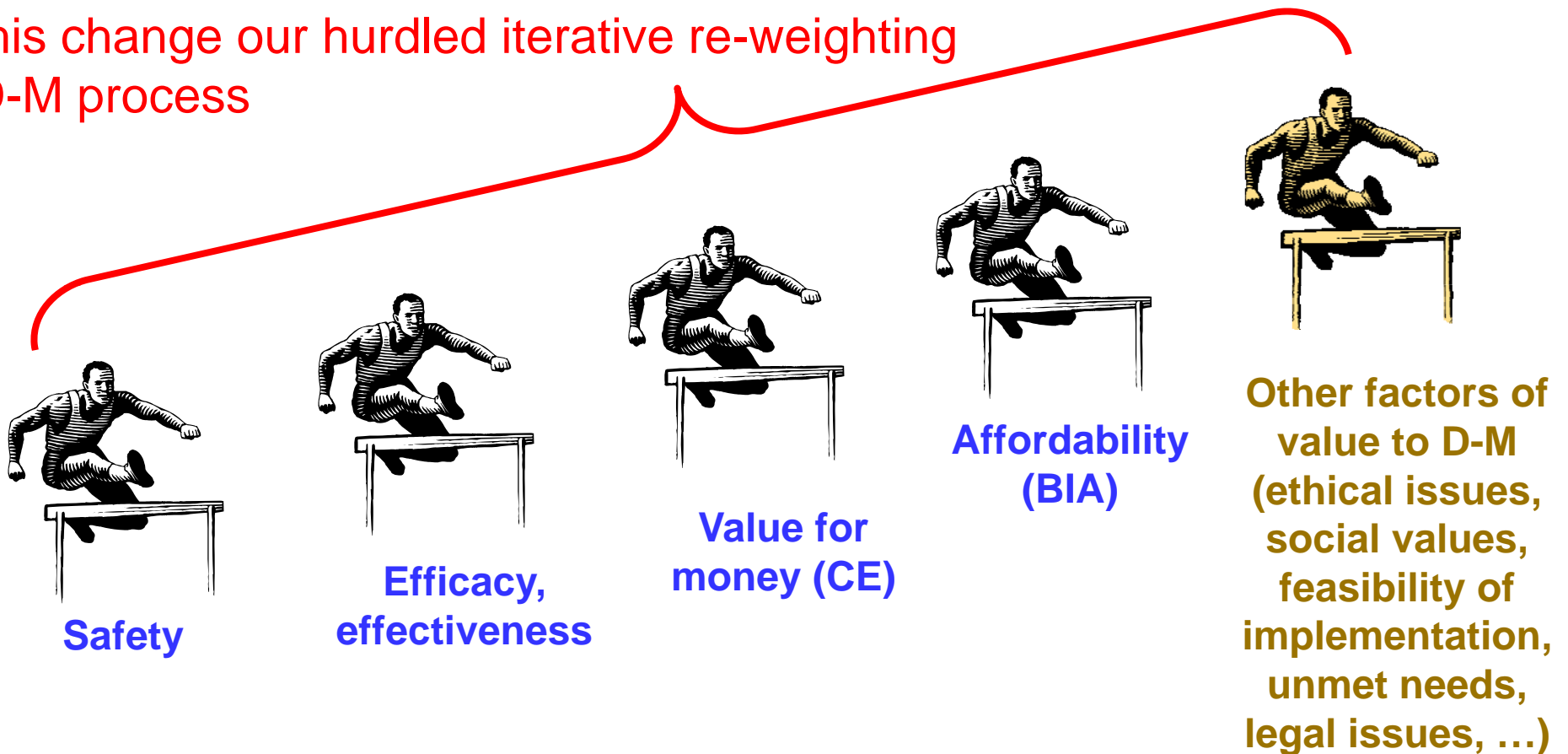
How to Incorporate Other D-M Criteria?

1) Net benefit (monetary value on everything)

2) Value-adjusted QALYs (QALY+ approaches)

3) Holistic, deliberative process (several factors/ criteria with no explicit weighting)

4) Two-part health technology appraisal

   • ICER + Comprehensive Benefits of Value (CBV)

5) Multi-criteria decision analysis (explicit weighting of factors/criteria and calculation of score)

Approaches: Similarities & Differences

Identification of value	Measurement of value	Valuation	Aggregation
Improved health, QOL	Natural units	Monetary valuation	Net Benefit
+ or - effects on others	Combined measures (e.g. QALYs)	QALYs, +/- value adjustment	Value-adjusted QALYs or ICER range
Safety	Surveys, expert opinion		
Efficacy, Effectiveness	Continuous measures (scales)	Implicit weights for value criteria	Holistic, deliberative process
Timely care, convenience, acceptance	Binary (e.g. yes, no)		
Affordability	Discrete measures (categories)	Explicit weights for value criteria	2-part HTA, MCDA
Reducing health disparities			

Net Benefit Approach

➢ Identify and measure all relevant D-M criteria and place a monetary value on each (+ and -)

- Calculate Net Benefit and if NB > 0; then technology is considered 'socially desirable'

➢ Advantage: all relevant D-M criteria considered, better grounding in economic theory?

➢ Disadvantages: feasibility # WTP measurements (CV/EV), huge adding-up issues, validity of responses?

- Still need to consider affordability (not all technologies with NB > 0 can be funded, not a D-M 'rule')
- NB 'threshold' (affordability & opportunity cost)

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Value Adjusted QALYs, QALY+

- 2 main approaches
  - Adjust the QALY - value adjusted QALY (e.g. more weight to end of life QALYs or certain diseases)
  - D-M threshold range (e.g. £20K-£30K / QALY) reflecting value (higher threshold for end of life or certain diseases)

- Advantage: implementable on existing D-M hurdled and iterative processes (e.g. process used by NICE)

- Disadvantage: value adjusted approach requires D-M criteria of value to be directly linked to QALY
  - Therefore, not all relevant D-M criteria can be included (e.g. size population, unmet need, innovation)

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Example of ICER Threshold Range
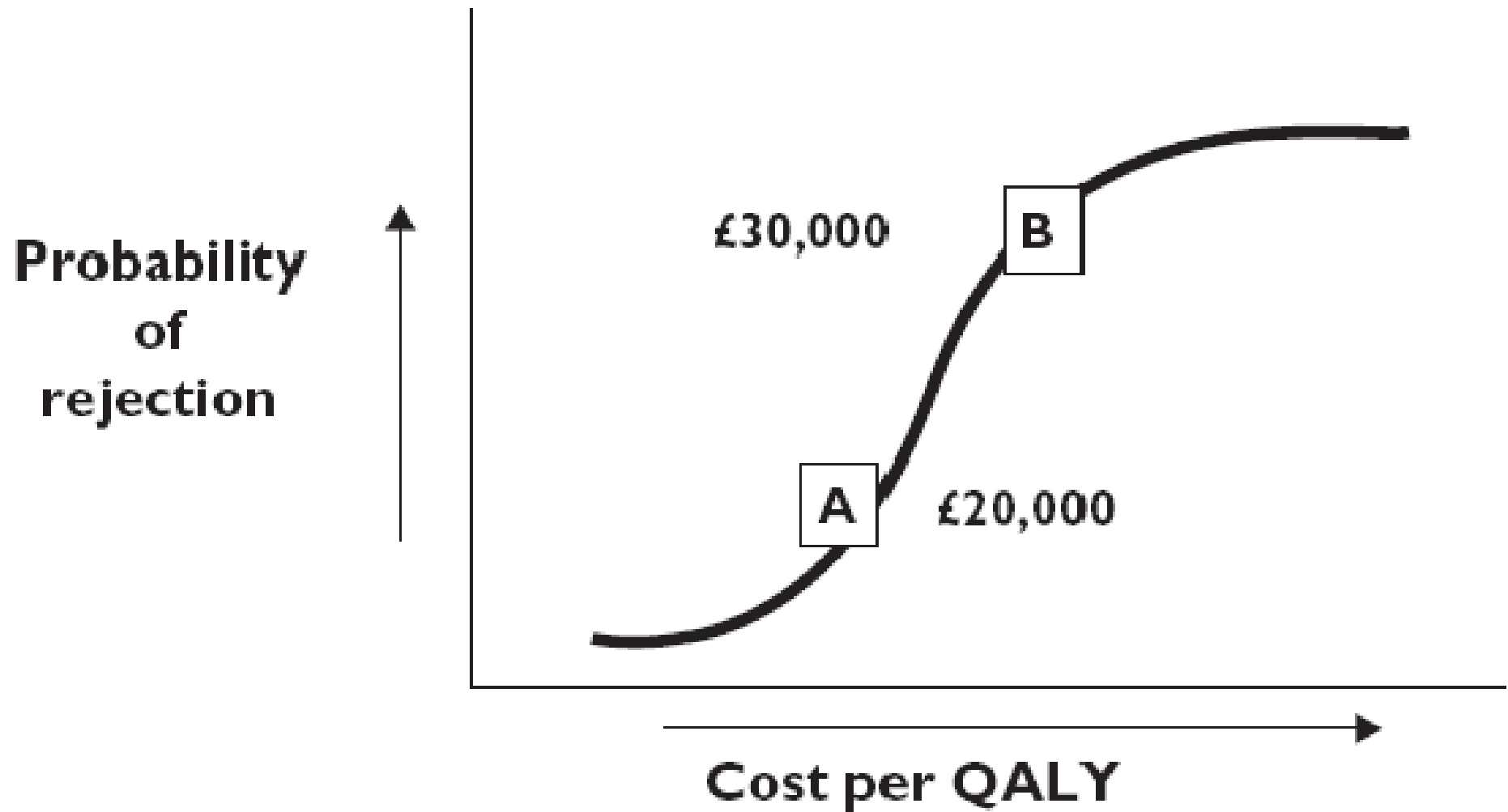
Holistic, Deliberative Process

➢ Identify and measure all relevant D-M criteria (no explicit weights assigned to each criterion)

➢ Considers all criteria and evidence/information all together (holistically) and make a recommendation

➢ Advantage: all D-M criteria of importance can be considered, can accommodate hurdled iterative process?

➢ Disadvantages:
- Lack of transparency/consistency, potential for bias (e.g. focus on memorable or scientific evidence)
- Cost and time of obtaining broader range of evidence
- When considered all together, is the hurdled iterative process lost? Weights re-adjusted?

Example: Holistic/Deliberative Process

Decision Determinants Guidance Document

The Ontario Health Technology Advisory Committee (OHTAC) Decision-Making Process for the Development of Evidence-Based Recommendations

Revised September 2010

Ontario

Medical Advisory Secretariat
Ministry of Health and Long-Term Care

www.health.gov.on.ca/english/providers/program/mas/pub/guide_decision.pdf

Moving from Traditional 4 to 9 Criteria

Criterion 1

Overall clinical benefit
- Effectiveness
- Safety
- Burden of illness
- Need

Criterion 2

Consistency with expected societal and ethical values
- Expected Societal values
- Expected Ethical values

Criterion 3

Value for money
- Economic evaluation (specify)

Criterion 4

Feasibility of adoption into health system
- Economic feasibility
- Organizational feasibility
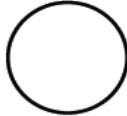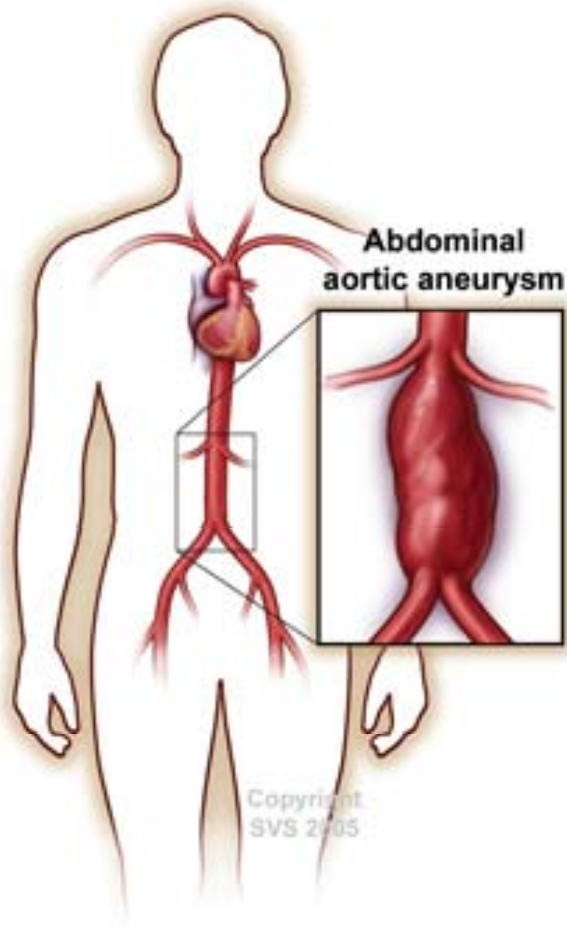
Evaluate the health technology through a deliberative process.

State recommendation and value judgement regarding these criteria

www.health.gov.on.ca/english/providers/program/mas/pub/guide_decision.pdf

OHTAC's DD Rating System

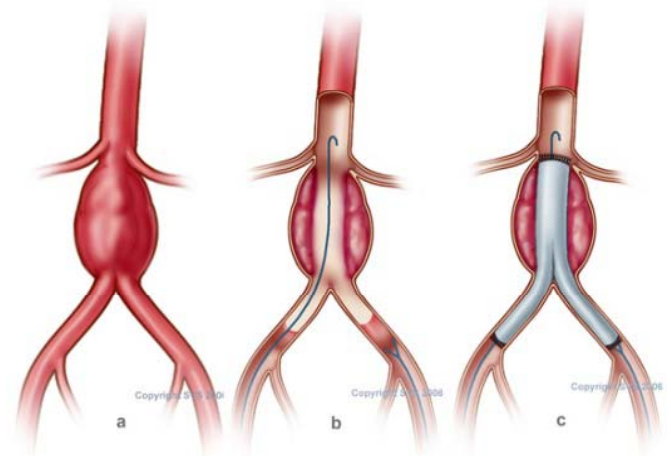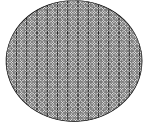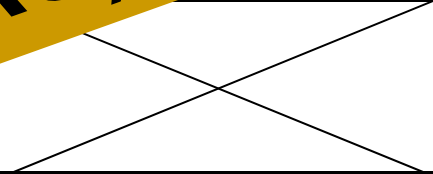| Symbol	Meaning
●	High/Large
●	Moderate/Medium
○	Low/Small
(dashed circle)	Uncertainty in the evidence as reflected by quality of evidence or assessment of quality of evidence
?	Unknown

EVAR vs OSR for AAA (Low Risk pts)

Abdominal aortic aneurysm

Abdominal aortic aneurysm

Graft being sewn into place

EVAR

OSR

AAA
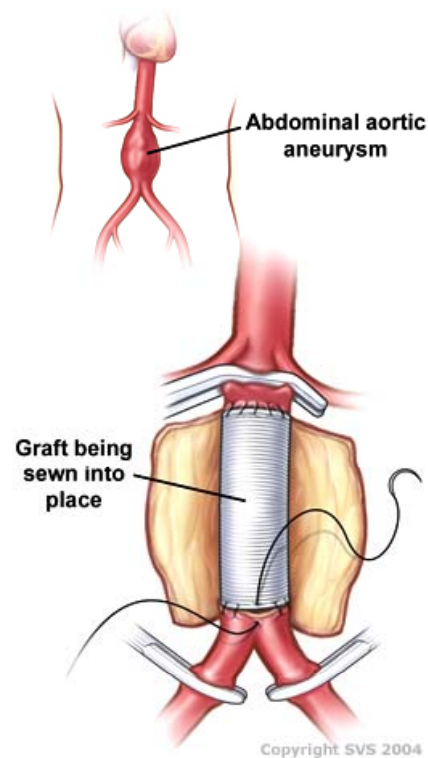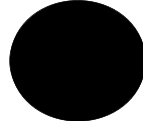
OHTAC Holistic Deliberative Process

Criterion Groupings		OSR
Overall clinical benefit		⬤ (gray)
Consistency and ethical		?
Value for		✕
Feasibility of the health system	⬤ (gray dashed)	⬤ (black)

Funding expansion into low risk patients: "cannot be supported from a health system perspective" (OHTAC)

www.health.gov.on.ca/english/providers/program/ohtac/tech/
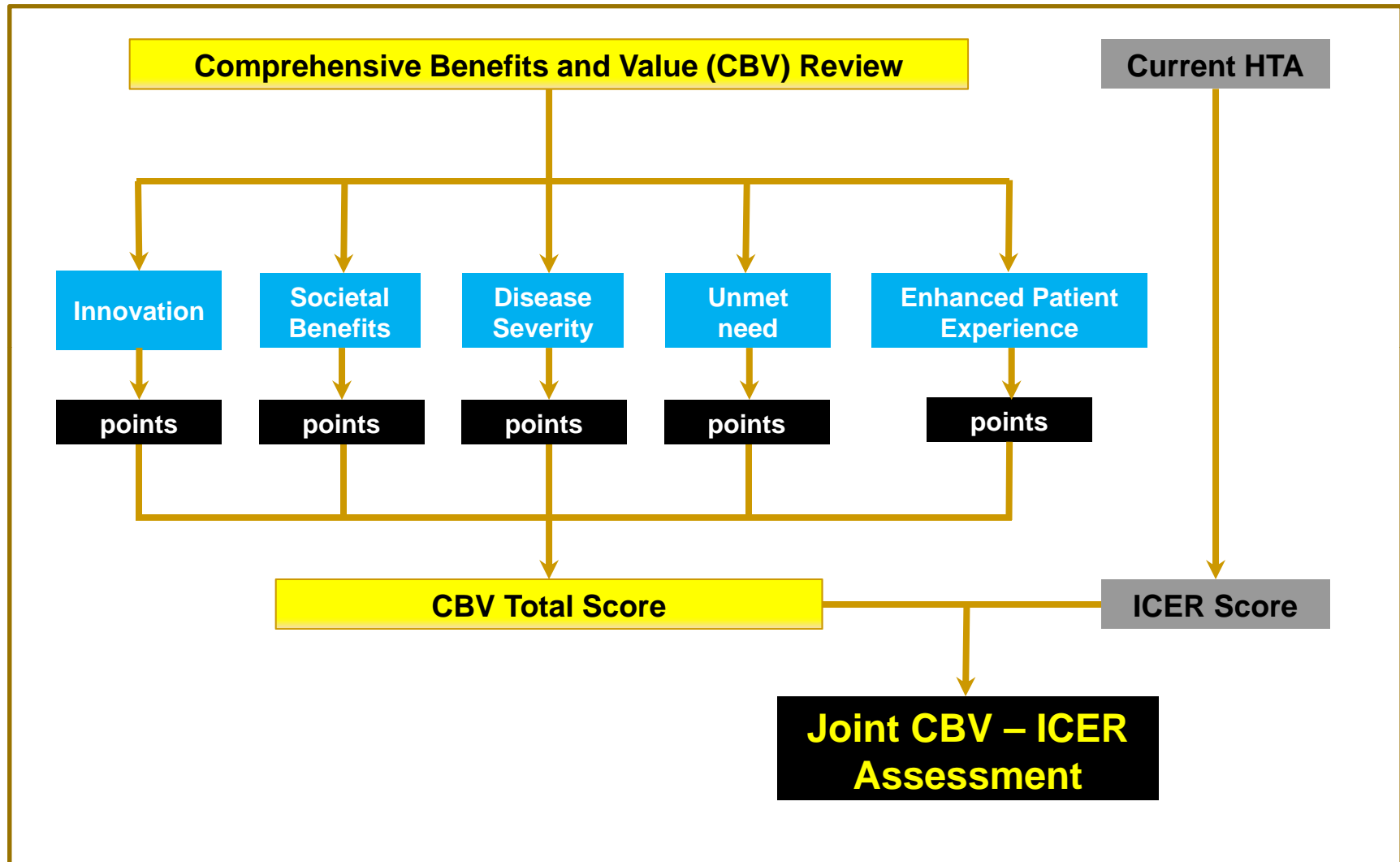recommend/rec_evar_20100113.pdf

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Two-Part Health Technology Appraisal

➢ Variation on full MCDA approach

➢ Proposal for 2 weighted score calculations:

- ICER score based on traditional CEA

- CBV score based on other criteria not included in QALY

- Joint ICER-CBV score calculated for prioritization

➢ Advantage: can be combined (add-on) with existing D-M processes (e.g. ICER)

➢ Disadvantages: 2 sets of scores?, multiple weights?

- Cost and time of obtaining broader range of evidence

- Static weights – can one priority score (big hurdle) replace hurdled iterative re-weighting process?

Evidence and Scoring of Levels

Comprehensive Benefits and Value (CBV) Review

Current HTA

Innovation	Societal Benefits	Disease Severity	Unmet need	Enhanced Patient Experience
points	points	points	points	points

CBV Total Score

ICER Score

Joint CBV – ICER Assessment

www.nice.org.uk/media/CF1/62/KennedyStudyWSAMGENandPHE.pdf

Tomas Philipson, University of Chicago, Precision Health Economics

Multi-Criteria Decision Analysis (MCDA)

➤ Calculate an overall prioritization score (values)
- Identify all relevant D-M (value) criteria
- Define levels (scoring) for evidence around each criteria
- Collect evidence (scientific, colloquial, surveys, opinions)
- Obtain weights for each criteria
- Calculate total score – Σ (criteria weights x level scores)

➤ Advantage: all relevant D-M criteria considered, transparency, consistency, predictability - prioritization

➤ Disadvantages: varied criteria/levels definitions and process (need consistency, rigor - EVIDEM)

- Cost and time of obtaining broader range of evidence
- Static weights – can one priority score (big hurdle) replace hurdled iterative re-weighting process?

MCDA Example - EVIDEM

| Evidence and Value: Impact on DEcisionMaking |

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Events & News

▶ Updated decision criteria tool v.2.1 now available

▶ ISPOR Baltimore 2011, Int'l survey on decision criteria - Poster session 23 May

▶ CAPT Ottawa 2011 (PDF: 83 Kb), Join us at a plenary session 19 April 2011

▶ CADTH Vancouver 2011, Panel session on multicriteria 4 April 2011, 1:30 pm

▶ CADTH, Ottawa 7 December 2010, Invited Presentation

▶ The EVIDEM Collaboration was awarded a CIHR grant to support its activities

The EVIDEM Collaboration is a non-profit organization run by an international **Board of Directors** established in 2009 to: "Promote public health through transparent and efficient healthcare decisionmaking via systematic assessment and dissemination of the evidence for and value of healthcare interventions".

Towards this goal, the Collaboration makes publicly available, under a Creative Commons license, a decisionmaking framework and tools/instruments and is developing a Collaborative registry for the use of all healthcare stakeholders globally.

The tool

The EVIDEM Framework
(beta-testing version)

A practical decisionmaking framework bridging health technology assessment (HTA), multicriteria decision analysis (MCDA), ethics and values to:

- consider all aspects of decision*
- support consistent deliberative process
- provide synthesized relevant evidence
- share decisions transparently

- Instruments and processes to help synthesize evidence and consider all aspects of decision freely available under a Creative Commons license

* The framework is based on a comprehensive set of standard *criteria of decision* that goes beyond cost-effectiveness by including, for example, disease severity, unmet needs and ethics.

MCDA in Daily Life (PDF: 586 Kb)

The product

The EVIDEM Collaborative Registry
(under development)

An open access registry under a Creative Commons license to provide open access to synthesized evidence for healthcare interventions to all stakeholders

- See open access prototypes

www.evidem.org/

Computer-Based Example

Most Weight on Clinical Eff

NICE Appraisal of New Technology

Scores

New technology	0.866
Comparator	0.132

Weightings

p Clinical effective	p CE @ £20K/QALY	Acceptability (pt & doc)	Terminality (end of life)	Orphan/no Alt Rescue drug	Other Equity	Clinical Priority	Feasibility /Impact	Innovation	Wider Societal Considerations
0.910	0.010	0.010	0.010	0.010	0.010	0.010	0.010	0.010	0.010

Ratings

	p Clinical effective	p CE @ £20K/QALY	Acceptability (pt & doc)	Terminality (end of life)	Orphan/no Alt Rescue drug	Other Equity	Clinical Priority	Feasibility /Impact	Innovation	Wider Societal Considerations
New technolo...	0.900	0.200	1.000	1.000	0.000	0.000	0.800	0.300	0.900	0.500
Comparator	0.100	0.800	0.500	0.980	0.000	0.000	0.800	0.500	0.000	0.500

More Weight Other Criteria

NICE Appraisal of New Technology

Scores

	Value
New technology	0.617
Comparator	0.595

Weightings

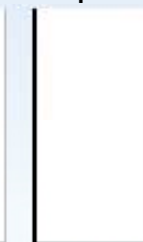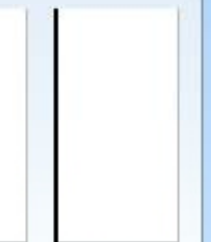|	p Clinical effective	p CE @ £20K/QALY	Acceptability (pt & doc)	Terminality (end of life)	Orphan/no Alt Rescue drug	Other Equity	Clinical Priority	Feasibility /Impact	Innovation	Wider Societal Considerations
	0.016	0.350	0.103	0.125	0.016	0.016	0.153	0.016	0.188	0.016

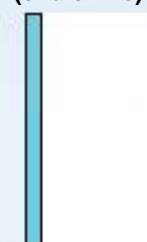### Ratings

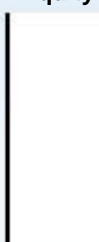|	p Clinical effective	p CE @ £20K/QALY	Acceptability (pt & doc)	Terminality (end of life)	Orphan/no Alt Rescue drug	Other Equity	Clinical Priority	Feasibility /Impact	Innovation	Wider Societal Considerations
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Comparator	0.100	0.800	0.500	0.980	0.000	0.000	0.800	0.500	0.000	0.500

Most Weight on CE

NICE Appraisal of New Technology

Scores

New technology	0.308
Comparator	0.685

Weightings

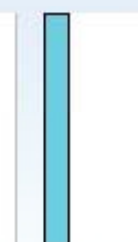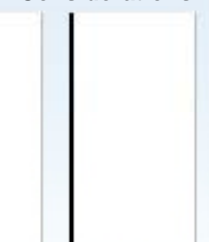|	p Clinical effective	p CE @ £20K/QALY	Acceptability (pt & doc)	Terminality (end of life)	Orphan/no Alt Rescue drug	Other Equity	Clinical Priority	Feasibility /Impact	Innovation	Wider Societal Considerations
	0.030	0.730	0.030	0.030	0.030	0.030	0.030	0.030	0.030	0.030

Ratings

	p Clinical effective	p CE @ £20K/QALY	Acceptability (pt & doc)	Terminality (end of life)	Orphan/no Alt Rescue drug	Other Equity	Clinical Priority	Feasibility /Impact	Innovation	Wider Societal Considerations
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Comparator	0.100	0.800	0.500	0.980	0.000	0.000	0.800	0.500	0.000	0.500

Some Issues With Expanding Criteria

➤ Identification

- Selection of criteria

➤ Measurement

- Evidence and scoring of levels

➤ Valuation

- Weighting for criteria

Identification of Criteria

➢ Criteria should reflect goals/objectives of D-M body
- Easier to define and identify criteria with a smaller body (e.g. hospital, local health authority)
- Broader you go, ⬆ D-Mer, opinion diversity, ⬇ operationalize
- ⬆ likely use committee as agent (with ?? D-M representation)
- Committee composition/leadership important to ensure process represents D-M goals (avoid bias/COI from KOLs)

➢ Identify set of universal criteria (one size fits all)?
- Broader you go, ⬆ complexity in finding universal criteria set
- Constant across interventions (e.g. public health programs, health educational programs, screening programs, Dx, Tx)?
- Constant over time? (e.g. new government, new priorities), how often do we have to re-visit the criteria?
- Number criteria? (broader application ⬆ criteria?)

Evidence and Scoring of Levels

➢ Where to find evidence?

- Decades of experience in searching for, abstracting and synthesizing scientific evidence (esp. safety, effectiveness) (e.g. meta-analysis, network m-a, indirect comparisons,..)

- Good practices/guidelines for economic evaluation/HTA

- Where (search strategy) do we find evidence for other criteria (health disparities, patient acceptance, unmet needs,…)?

- Literature, surveys, expert opinion, qualitative reviews,…

- How much evidence? how broad a search or survey? how to synthesize? how to combine scientific and colloquial evidence or combine quantitative and qualitative evidence?

➢ Levels scoring (all different)

- Symbols, continuous (0-100), discrete (0,1,2,3)?

- Discrimination & responsiveness properties

EVAR Expansion to Low Risk Patients

	Endovascular Repair	Open Surgical Repair
Consistency with Expected Social Values	● *	?
Consistency with Expected Ethical Values	?	?
Consistency with Expected Ethical and Societal Values fit	●	?

➢ Based largely on assumption that patients prefer less invasive procedure

www.health.gov.on.ca/english/providers/program/ohtac/tech/
recommend/rec_evar_20100113.pdf

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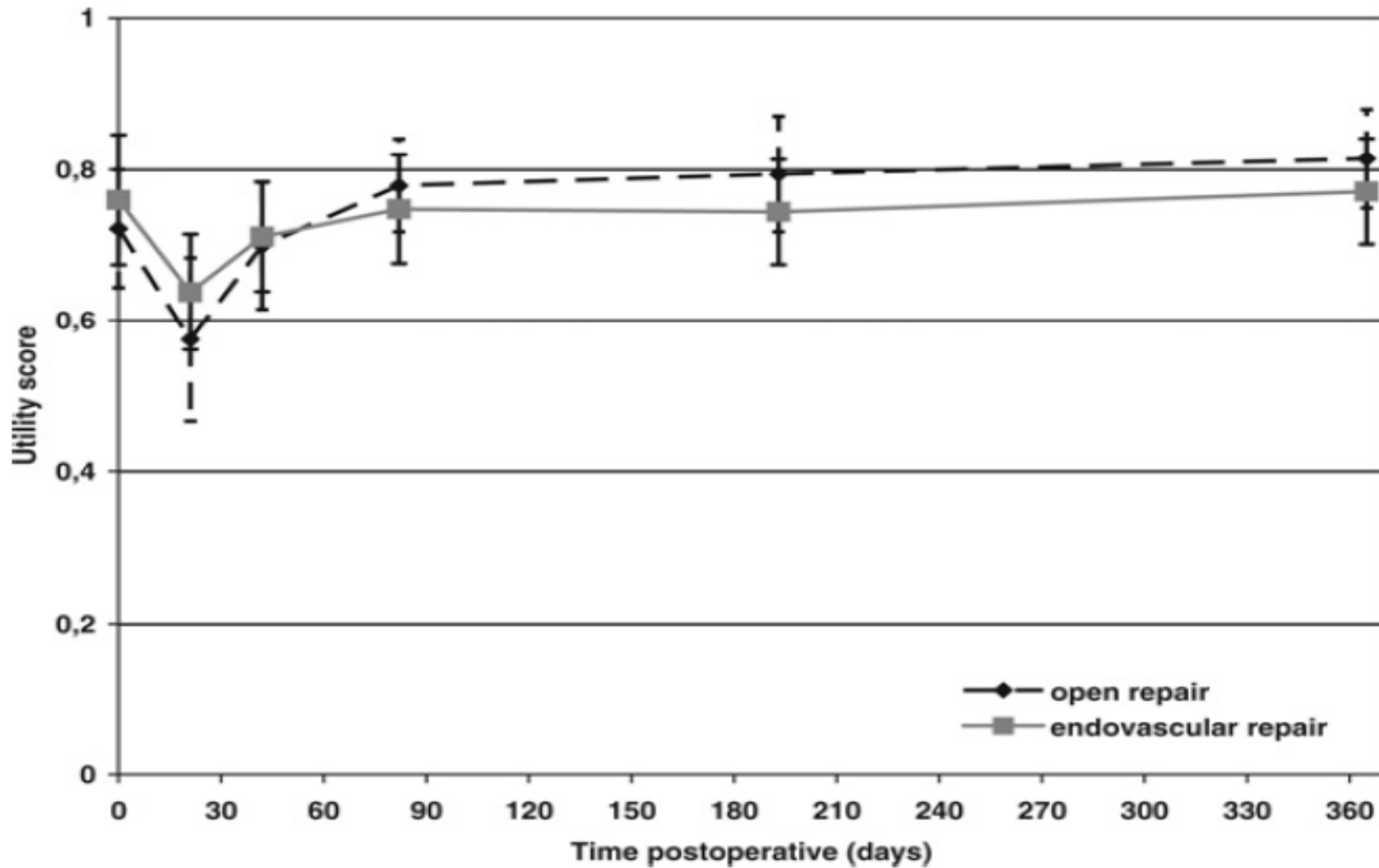RESEARCH INSTITUTE

Ontario EVAR Study
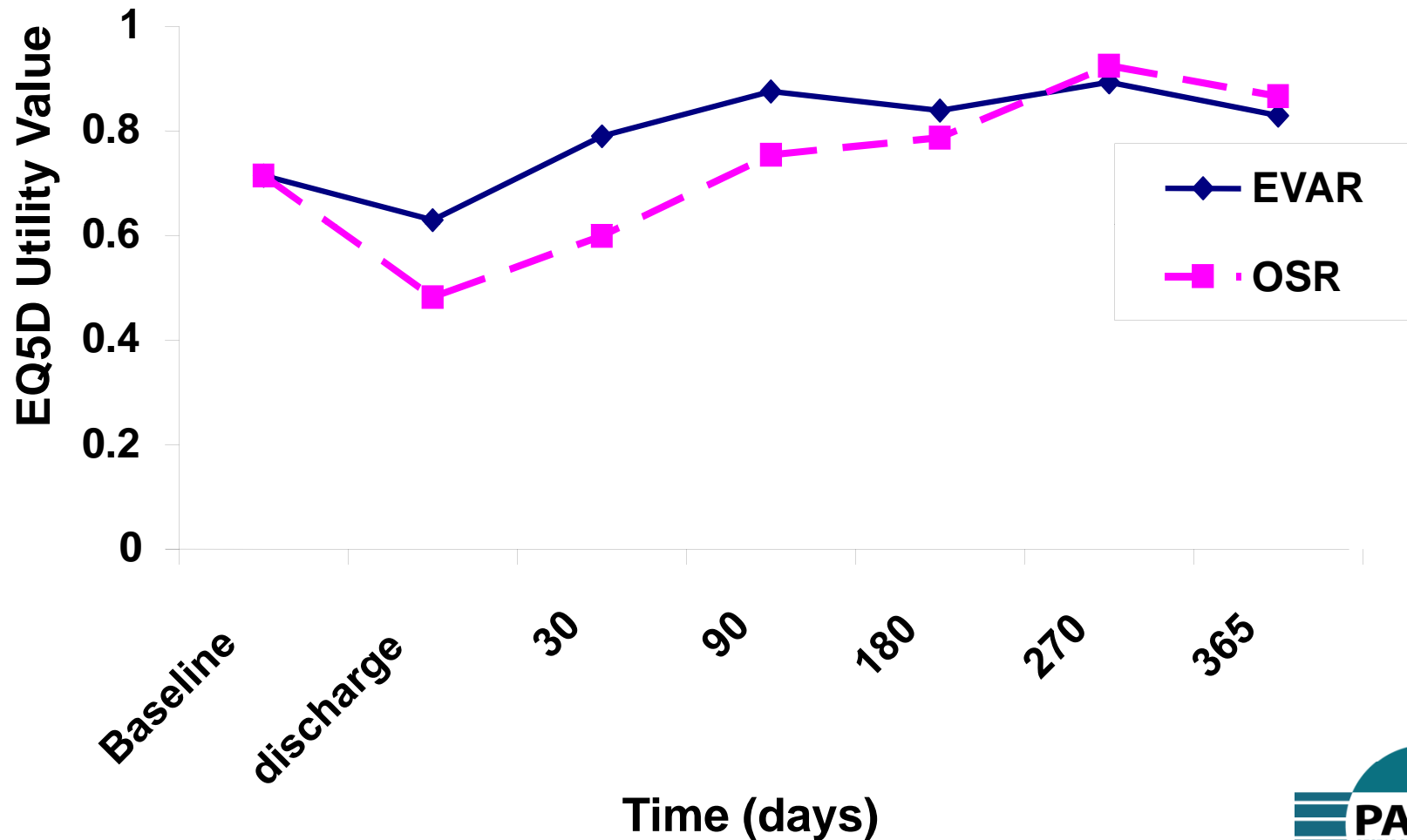
Tarride, *J Vasc Surg*, 2008

DREAM EVAR Study

Prinssen, *J Vasc Surg*, 2007

Valuation (Weighting for Criteria)

➢ Who should derive the weights (D-M, committee as agent)?

➢ How are weights derived? Process?

➢ Bias/influence? (e.g. intermediate outcome)

➢ Validity, are respondents used to thinking about weights? (using up the scale)

➢ How to address iterative re-weighting process?

➢ Constant across interventions, over time?

➢ Is the frequently used linear additive model ok?

• Are criteria mutually preference independent?

Research Agenda: Expanding Criteria

➢ Bring more scientific rigor, comprehensiveness, consistency, validity to process of defining criteria and levels, in finding and combining/synthesizing evidence/information, weights for criteria

- Extensive review and synthesis of existing criteria, levels, definitions, approaches in healthcare (completeness, operational, mutual independence, redundancy)
- Consensus meetings, develop guidelines / good practices

➢ Which criteria for which D-M body/level? (goals)

➢ D-M input and perspectives (need their values)

- Not those of special interest groups, KOLs, academics
- D-M champions are critical to validity of process

Final Comments

➢ Good reasons for considering and formally incorporating other criteria into D-M process

- Great for transparency, consistency & prioritization based on values (criteria) and evidence/information

➢ How can approaches which expand criteria list address traditional iterative re-weighting process?

- How to use priority scores for actual funding decisions?
- Are some criteria (value-for-money, BIA) 'trump cards' and should they be removed from prioritization criteria?

➢ Remember that expanding the list of D-M criteria is not the panacea for basic opportunity costs

- Health care versus other sector expenditures
- Drugs versus other health care expenditures

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