

**OK, so EBM is not enough.
What next then?**

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Dodgy theory – incoherent practice!

Context – what interventions (technologies) 'ought' to go into the publicly insured basket?

- What are the criteria?
- Who are the people?
- What is the process?

The criteria

Essentially (but complicatedly) two:

- Cochrane adapted: only interventions that 'work' in that they are more likely to advance health than interventions not in the basket (and by more per unit of resource) – Evidence-Informed Decision Making (EIDM)
- Only interventions that are 'equitably' provided in that they do not promote a greater inequality in the population distribution of health than if they were not in the basket and, once in, if they were not appropriately distributed

Nailing the criteria further

- 'working' is equivalent to cost-effectiveness (not mere effectiveness, let alone efficacy), the foregoing criterion implies that opportunity costs are to be minimised
- 'equity' is equivalent to treating people sufficiently *unequally* to make lifetime health experiences more similar
- 'health' is both the maximand and the distribuendum

Personal bias

- Those were my personal prejudices
- Not everyone shares them
- So let's dig deeper ...

'Working' and evidence

- Evidence – any factual matter that gives one a reason for believing or suspecting something to be empirically true
- Types of evidence:
 - **Type I:** scientific evidence on efficacy (and, sometimes, effectiveness; less frequently, relevant relative effectiveness)
 - **Type II:** scientific evidence on cost-effectiveness, implementation feasibility, time scale, organizational capacity, service impact
 - **Type III:** colloquial evidence about resources, expert and professional opinion, political judgment, values, habits and traditions, lobbyists
 - **Type IV:** colloquial evidence and opinion gleaned from the media, personal contacts and other sources

The ingredients of decisions

- Perspective (whose 'welfare' matters) (social value judgments)
- Whether 'welfares' are preference-based, preference-informed or unrelated to client preferences (svj's)
- How the 'welfares' ought to be measured and discounted (svj's)
- Evidence (four kinds)
- Trading-off when 'welfares' clash (svj's)
- Evaluating evidence - scientific quality judgments, relevance, completeness (efficacy vs effectiveness, end points, sub groups, outcomes, comparators), accuracy and precision, ambiguity, dealing with scientific controversy
- Equity – who gains, who loses, how much, how gains and losses are to be weighted (svj's)
- Implementability, service impact, professional (etc.) acceptability, political acceptability (some svj's)
- Appraising and allowing for uncertainty and risk (some svj's)
- Narrowing the options and making a decision

Horse and rabbit pie

- Values are at least as omnipresent as evidence
- Evidence is often (even usually) either absent or highly imperfect
- Judgment has to play a huge role (both svj's and other kinds of judgment)
- When evidence is the rabbit, it may be a misdirection of effort to concentrate on breeding the ideal type of rabbit for pie-making; perhaps we ought to focus more on the horse

Some significant implications

- EIDM ain't as easy as it looked at first
- Algorithmic approaches will not do (alone)
- Process will need to be transparent if it is to inspire confidence
- Process will need to be multi^m (multi-disciplinary, multi-professional, multi-stakeholder, multi-regional, multi-cultural, ...)
- Non-health experts will have key roles
- Deciders will need to learn to engage with one another

The challenges

- How to determine the decision rule
- How to eliminate type IV evidence altogether
- How to combine different types of evidence (clinical and economic)
- How to embody risk assessment
- What meaning to attach to 'equity'
- How to choose an ICER 'threshold'
- How to choose the participants
- How to train the deciders
- How to attach a Humean 'ought' to the evidence (it being impossible to infer any 'ought' merely from 'evidence')

Help!

Is there any theory out there to help?

- 'Accountability for reasonableness' seems incomplete, distant from the issues and hard to apply in specific instances
- Ethics and political philosophy rarely engage with the nitty-gritties and tend to focus on 'hard cases'
- *Economists* tend to have their own particularist agendas (some corrupted by commercial interests); *economics* is firmly rooted in a form of utilitarianism that not all accept (including some economists!)
- Epidemiologists also have their own particularist agendas (and some are also corrupted) and are largely free of explicit (normative) theory
- Ad hocery rules?

Back to basics

- What are the criteria?
- Who are the people?
- What is the process?

- Some tentative first steps ...

The criteria – an agenda

- Maximand and distribuendum?
- Welfarism or extra-welfarism?
 - ‘Welfare’ or ‘health’
 - Social value judgments (who counts? What (else than ‘health’) counts? What discount rate? What threshold? What of uncertainty?)
- Equity
 - Cutting through the ad hocery, confusion in search of *das Konkret*

The people – an agenda

Who participates as a:

- Decider
- Evidence provider
- Expert witness ('knowledge' and 'understanding' skills)
- Commentator
- Consultee
- Manager of the processes in which the above are entailed?

The process – an agenda

Are some processes for making decisions about the 'basket' better than others?

- What does 'better' mean
- How is it assessed?
- What's the evidence?

What ought we to do about the process of deciding?

- the decision rule needs to be clear and clearly understood (whether or not participants have participated in determining what it is)
- decision makers need access to people with skills in thinking about key attributes – e.g. skills in synthesizing literatures with different qualities (such as qualitative and quantitative studies, and evidence lying at different points on a Cochrane type hierarchy of evidence), skills at picking apart ethical issues, skills in thinking about uncertainty, ways of limiting its disadvantages and helpful rules of thumb

What ought we to do about the process of participating?

- Identify those who ought to be participants in:
 - Deciding
 - Providing evidence
 - Being expert
 - Consulting
 - Commentating
- Enable each participant in the decision making process at least to comprehend the language of the others at the minimal level required to detect bunk and interrogate witnesses and one another

What ought we to do about social value judgments?

- it's usually worth discovering what values are actually held by relevant stakeholders (preference-informed vs preference-based)
- identify the relevant stakeholder groups who may gain or lose in particular cases and provide an analysis of the gains and losses by group (this may also suggest where the most resistance to change is likely to be)
- ensure that the idea of equity is 'distanced' from the self-interest of any participating group
- determine whether the equity issues are horizontal, vertical or a mixture of both

Envoie!

- So many questions - too few answers
- Someone, somewhere, needs to start a networked program of research to sort this mess out!