Information Created to Evade Reality (ICER)

Things We Should Not Look To For Answers

Amiram Gafni, Ph.D.

Professor

Centre for Health Economics and Policy Analysis

Department of Clinical Epidemiology and Biostatistics

McMaster University

Hamilton, Ontario, Canada

Difficult questions and difficult answers …

- ❖ which services to provide?

- ❖ how much to provide?

- ❖ at what stage in the disease process to provide it?
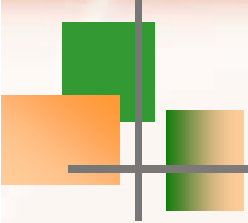
- ❖ to whom it should be provided?

Answers based on criteria of …

- ❖ effectiveness
- ❖ efficiency

Effectiveness

- Does a procedure, service or program do more good than harm to those clients to whom it is offered?

- This concept deals only with the evaluation of benefits and risks to clients of an intervention when compared with other interventions to deal with the *same indication*

- The resource implications of choosing treatment A or B (or no treatment) are not considered in an effectiveness type analysis

"Some fear that evidence based medicine will be hijacked by purchasers and managers to cut the costs of health care. This would not only be a misuse of evidence based medicine, but suggests a fundamental misunderstanding of its financial consequences. Doctors practicing evidence based medicine will identify and apply the most efficacious interventions to maximize the quality and quantity of life for individual patients; this may raise rather than lower the cost of their care."

(Sackett et al, BMJ, 1996)

"Health economics as a discipline does not exist independently of economics as a discipline."

A.J. Culyer, 1981

When the discipline of economics is being chosen as the *mode of thinking* for resource allocation in health, the principles of the discipline must be followed
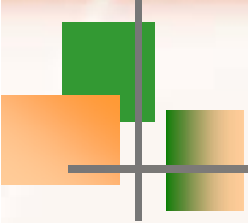
Note that I refer to a *discipline* not a *profession*

Efficiency

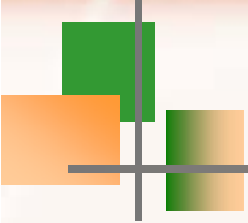The concept of (economic) efficiency stems from the realization that:

❖ Resources available to provide health care to given populations are limited (i.e., *scarcity*)

❖ Health care systems whose objective is to maximize say the health of the population, for any given level of available resources, are forced into making treatment *choices*

❖ By choosing to use resources in one particular way, other opportunities for using those resources are foregone (the concept of *opportunity costs*)

❖ Efficient allocation of resources is achieved by ensuring that the *value* of what is being produced by using available resources in one particular way is greater than the *value* of what's being produced by alternative uses the same resources

Efficiency *(cont'd.)*

Unlike effectiveness type analysis in efficiency analysis

- ❖ Resource implication of choosing treatment A or B play a major role

- ❖ The efficiency of an intervention is determined relative to all other potential uses of the same resources (i.e., the analysis is not restricted to a given indication)

- ❖ In deciding what to do with available resources, we are also deciding what not to do with them. Hence, the efficiency of a particular service is 'context specific' and cannot be determined by information on the costs and effectiveness of the service in isolation

- ❖ In efficiency analyses patients constitute only one group of beneficiaries. Other groups may include potential patients, individuals who are at no risk to develop the disease.

"The basic economic problem is how to allocate scarce resources so as to best satisfy human wants. This may be contrasted with the romantic point of view that fails to recognize scarcity of resources and … is misled into confusing the real world with the Garden of Eden"

V. Fuchs (1974)

Economic Evaluation

- Economic evaluation involves 'ensuring that the value of what is gained from an activity outweighs the value of what has to be sacrificed' *(Williams, 1983)*.

- Cost-effectiveness analysis (CEA) is the most commonly used form of economic evaluation.

CEA: The "Garden of Eden Approach"

❖ " 'Would you tell me please, which way I ought to go from here?' asked Alice. 'That depends a good deal on where you want to go.' said the Cat. 'I do not much care where.' said Alice. 'Then it does not matter which way you go.' said the Cat". *(From Alice in Wonderland by Lewis Carroll)*

❖ The underlying premise of the CEA approach: For every given level of resources available, society (or the decision maker), wishes to maximize the total aggregate health benefit conferred.

❖ Scarcity, and the need to make tough choices, reflect the nature of the problem facing decision makers in the health care system.

The use of QALY (quality-adjusted life years) as a measure of outcome

- ❖ QALYs - duration of time weighted by a health status preference score, discounted

- ❖ "The policy objective underlying the QALY literature is the maximization of the community's health. An individual's "health" is measured in terms of QALYs and the community's health is measured as the sum of QALYs"

A. Wagstaff, JHE, 1991

The Analytical Tool of CEA

❖ The Incremental Cost-Effectiveness Ratio (ICER)

❖ Represents the difference in costs between the two programs compared, divided by the difference in outcomes (e.g. LYS, QALYs)

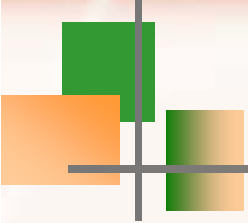# The Use of ICER to determine resource allocation in health

The decision rules:

(I) The league table approach:

The decision maker is only concerned with the relative value of the ICER and programs are adopted in a descending order of cost-effectiveness until all available resources are exhausted.

(II) The threshold approach:

The decision maker focuses on the absolute value of the ICER, if the program's CE ratio is lower than the threshold value, it should be adopted.

Example: Incremental Costs and Effects of 4 New Drugs

Drug	Health Gain(QALY)	Cost (m$)	ICER ($/QALY)
A	250	10	40,000
B	300	16	53,300
C	70	4	57,100
D	80	10	125,000

Budget $20 M

Are Current Decision Rules Helpful?

❖ Under certain assumptions the ICER can be used to identify interventions associated with an efficient use of resources *(Weinstein and Zeckhauser, 1973)*

-- Perfect divisibility (production, consumption)
-- Constant returns to scale

❖ Unrealistic assumptions *(Birch and Gafni 1992, 1993)*

❖ Under these assumptions:

1. Maximizing health benefits produced from available resources will occur under either of the decision rules (i.e. league table and threshold value approaches)

Are Current Decision Rules Helpful? (*Cont'd.*)

2. The threshold ICER is equal to the ICER of the last program selected and represents the opportunity cost of the marginal health care resources

3. The threshold ICER is a function of the budget

4. The costs and effects of all programs (including the last program selected for funding) are subject to uncertainty. As a result, the threshold ICER is stochastic too.

5. As new programs are funded and others replaced, the identification of the last program funded changes, implying that the threshold value changes.

The "Arbitrary Threshold" Approach

❖ Because information on the ICER of all programs is incomplete, the comprehensive league table required to determine the threshold value cannot be produced

❖ The value of the threshold ICER cannot be determined from the information available to the decision maker

❖ However this has not prevented researchers and others to identify the cost-effectiveness of new programs based on some "preferred" or assumed value of the threshold

"The Silence of the Lambda"

❖ Laupacis et al (1992) – Can $20,000

❖ NICE (   ) 30,000 BP (assumed)

❖ NICE (2004) < 20,000 BP; > 30,000 BP

❖ Rawlins and Culyer (2004) < 5000 – 15,000 BP; > 15,000 –25,000 BP

❖ No attempt is made to justify the different threshold values and to explain how the application of the threshold will lead to the maximization of health benefits from available resources.

❖ Claxton et al (2006) note that "It is not the social valuation that is relevant ... but the shadow price of the budget constraint"

"The Silence of the Lambda" *(Cont'd.)*

❖ Williams (2004) acknowledges that there is no practical way to determine the threshold and suggests "a bit of common sense".

❖ He argues that in the UK there are 18,000 BP worth of real resources per citizen to provide for all needs (e.g. food, shelter, transportation)

❖ He suggests adopting this figure as the threshold value because "it is clear that we could do that at the margin for a few people without imposing great hardships on the bulk of the population, but we could not do it for many"

❖ He acknowledges that this threshold value is "just my opinion" and does not attempt to show how the use of this threshold will be compatible with maximizing health gains from available resources

"The Silence of the Lambda" *(Cont'd.)*

❖ A positive ICER means that the resources used by the current intervention are not sufficient to cover the costs of the new intervention for the same number of patients

❖ Therefore, to address the decision maker's questions, we need to consider the total additional cost and consequences of the new intervention in its proposed use, and to compare this with the outcomes produced by the range of other interventions that would have to be forgone to fund the new intervention ("opportunity costs")

"The Silence of the Lambda" *(Cont'd.)*

❖ But total costs are not part of the ICER calculations

❖ Instead, a value judgment is made about whether an ICER represents a "good buy" (i.e. the biggest bang for the buck)

❖ But this assumes the availability of an unconstrained stream of additional resources at a constant marginal opportunity cost *(Birch and Gafni, 1993; Gafni and Birch 1993; Sendi and Briggs, 2001)*

❖ "..make a judgement about the intrisic worth of a QALY and adjust the budget accordingly..." *(Williams, 2004)*

"The Silence of the Lambda" *(Cont'd.)*

❖ Some *(eg. Rawlins and Culyer, 2004, CADTH, 2006),* have argued that CEA is not about affordability, it is about value for money" (which they call "efficiency")

❖ As Williams (2004) notes, if affordability could be separated from efficiency there would be no need for a threshold.

❖ But matters of efficiency cannot be separated from matters of affordability *(Birch and Gafni, 1992, 1993)*

❖ Because money represents only command over resources, value for money is determined in relation to what it can purchase. Hence whether a particular intervention represents 'value for money' is determined by what is forgone in order to 'afford it' (i.e. opportunity cost).

Inclusion of Drugs in Provincial Drug Benefit Program: The Case of Ontario

- Drug Quality and Therapeutics Committee of the Ontario Ministry of Health and Long Term Care

- The committee reviews submission by pharmaceutical manufacturers who wish to have their drugs included in the provincial formulary of the drug benefit program for Ontario residents over the age of 65 years and those on social assistance (ODB)

- Laupacis, CMAJ, 2002; 166: 44-47

- "...resources for health care are limited, it seems sensible to me that cost-effectiveness is the main criterion used to determine which drugs are reimbursed from the public purse".

- "...the Therapeutics Committee makes reasonable decisions in what are often very difficult circumstances".

Observation

❖ Despite the use of CE information, "In 1999/2000 the total expenditures by the Ministry of Health and Long-Term Care on drugs was $1.6 billion, and the annual rate of increase during the previous 3 years was 10.6%, 9.9% and 10.1%. In 2000/01 the increase in expenditures was 15%.

❖ ". . . This serves to remind us that most cost-effective drugs are not cost saving and that their use in a substantial portion of the population entails a large cost. I am not arguing that these drugs are not good value for money . . . but it is wrong to think that the use of these drugs will save money"

❖ "The size of the Ontario Drug Benefit Program budget, and it's recent rapid increase illustrates the fact that total costs are important. Indeed, they are so important that the Ministry of Health and the Premier of Ontario have suggested that the province should re-examine whether it can continue to afford the Ontario Drug Benefits Program as it currently exists".

Observation *(Cont'd.)*

❖   So, how did 'reasonable decisions' lead to uncontrolled growth in expenditures?

❖   Is there evidence that this growth in expenditures led to any increase in total health improvements?

NICE and Decision Making in the NHS

- ❖ National Institute for Clinical Excellence (NICE)

- ❖ Commission appraisals:
  - -- Clinical and cost effectiveness of technologies
  - -- Wider implications of technologies for NHS

- ❖ Recommendations of NICE, are (were) mandatory

NICE results?

❖ *Costs of NICE recommendations:*

Taylor (2002): First 10 recommendations to introduce 250 million; Estimated expenditures 150 million BP

Mayor (2002): The costs of implementing recommendations exceeded 575 million BP in the first 2.5 years

Gold and Bryan (2007): NICE decisions led to an unplanned increase in NHS expenditure of 836 million pounds in 2005

"However beautiful the strategy, you should occasionally look at the results"   (Winston Churchill)

NICE results?

Effect on population health:

Cookson et al (2001) suggest that this has resulted in inappropriate allocation of resources by "…diverting funding away from more cost-effective services that lack politically powerful advocates" and "… by cutting (or by diluting, delaying, deterring, or deflecting) other services".

"Patients with Alzheimer's disease might receive Donepezil (a drug recommended by NICE) but perhaps be worse off because they lose some of their nursing and social care" (Smith 2001)

Barrett et al (2006) argue that by recommending the adoption of Herceptin as treatment for breast cancer without suggesting what treatments to cut, NICE 'creates more problems than solutions'.

NICE results?   *(Cont'd.)*

❖   Failed to demonstrate increased efficiency

❖   "NICE has effectively become an advocacy mechanism by which lobbies and specialists and their supporters in the pharmaceutical industry extract more public money from the NHS. Instead of challenging the pharmaceutical industry to show value for money, NICE has become their golden goose" *(Cookson et al, 2001)*

❖"Has the involvement of economic evaluation in NICE's decision-making done more good than harm? **I believe so**" (Drummond, 2007)

Australia

❖ An ICER threshold approach was introduced for decision-making for the pharmaceutical benefit program in the early 1990s as a means of controlling cost escalation and promoting efficient use of program resources

❖ Costs of the program were observed to increase by over 14% per annum over the first 10 years of using the approach (Zinn, 2002)

❖ The effect of these increased expenditures on drugs for the overall increases in health gains among Australian residents remain unknown

Information Created to Evade Reality

❖ Despite these fatal limitations of the ICER threshold approach as a solution to the constrained maximization problem, considerable research attention has been given to dealing with issue of:

   - Uncertainty (i.e. CE acceptability curves, NHB)

   - Sample size requirements

   - Determination of the value of additional information (i.e. EVPI, EVSI)

All based on the ICER and the threshold ICER approach

❖ Hence, all these approaches offer no help to decision-makers faced with choices between different ways of allocating resources.

Example: Incremental Costs and Effects of 4 New Programs

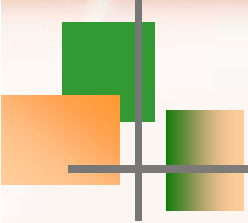| Program	Health Gain(QALY)	Cost (m$)	ICER ($/QALY)
A	250	10	40,000
B	300	16	53,300
C	70	4	57,100
D	80	10	125,000

Budget $20 M

Pursuing Efficiency: Back to the Future

❖ Existing approaches to constrained maximization, such as IP, solve the decision maker problem without the need to subscribe to unrealistic assumptions.

❖ "..it is unlikely that a given league table will contain all the relevant comparisons of programmes...to enable a budget to be allocated. To approach this in a more formal sense would also require mathematical programming techniques" *(Drummond, Torrance, Mason, 1993)*

❖ "The only universal approach to ranking under constraint is through the use of mathematical programming techniques" *(Drummond, 1980)*

❖ Chen and Bush (1976) provided a framework for maximizing health output subject to political and administrative constraints using mathematical programming techniques.

Pursuing Efficiency: Back to the Future *(Cont'd.)*

❖ Torrance et all (1972) identified the use of mathematical programming model to solve the decision maker's problem

❖ These methods can help decision makers to allocate health care resources efficiently under circumstances of fixed, shrinking or increasing budgets.

❖ Although the data requirement for these methods may be substantial, they reflect the complexity of the question being addressed.

"To every complex question, there is a simple answer … and it is wrong."   *H.L. Menken*

"Reality is horrendously complicated…the more complex the reality is, the more dangerous it is to rely on intuitive short-cuts rather than careful analysis"   *Williams A (2004)*

A Second Best Solution

Modify the objective from one of *optimization* to one of *unambiguous improvement*

* Step 1: Use a proper, unambiguous, measure of outcome

* Sept 2: - Find programs that can be cancelled to make dollars (resources) available to operate the new program

  - Candidate programs (for cancellation) are those where the total benefits foregone is less than the total benefit gained

* Step 3: How to find such programs?

  e.g.; use the strategy of "clean your own house first"

Efficiency and Equity

❖ Equity is an important consideration in health care decisions although it is often left implicit

❖ Equity and efficiency are not separable

❖ Efficiency involves maximization of an objective function that, by definition, already incorporate equity considerations, subject to a constraint

❖ "The policy objective underlying the QALY literature is the maximization of the community's health. An individual's health is measured in terms of QALYs and the community's health is measured as the sum of QALYs" *(Wagstaff, 1991)*

Efficiency and Equity *(Cont'd.)*

❖ "A QALY is a QALY regardless of who gains it and who loses it"

❖ One may not like the equity position incorporated in the optimization problem (e.g. where all health gains are weighted equally irrespective of who receives them).

❖ In this case one can incorporate the preferred equity position into the objective function (e.g. to 'favour' outcomes accruing to one particular individual or social group) or incorporate it as an additional constraint (e.g. to ensure equal availability of services irrespective of outcome).

Efficiency and Equity *(Cont'd.)*

❖ By incorporating the equity considerations into the underlying model of constrained maximization we ensure:

(1) Transparency of the equity considerations used
(2) Explicit and systematic consideration of the opportunity costs of pursuing these considerations

❖ 'If the nature and implication of ... equity principles are to be clarified in a policy-relevant way, it is necessary to quantify what might otherwise merely remain vaguely appealing but ambiguous slogans. Only with some quantification will it be possible to convert them into criteria that can be applied in a consistent manner, and with a reasonable change of checking on performance (i.e. holding people accountable)" *(Williams and Cookson, 2000)*

Equity in action: Riluzole

- New drug for treatment of Motor Neurone Disease

- *NICE* appraisal:
  Estimated ICER 34,000 - 43,000 BP / QALY
  NICE 'threshold' (past decisions) 30,000 BP/QALY
  Recommendation to introduce Riluzole

- Rationale: Special considerations
  Severity of condition   incorporated in QALY
  Short lifespan   incorporated in QALY
  Patient preferences   societal preferences

NICE and End of Life Drugs

- NICE responded to political pressure by amending the simple threshold approach.

- NICE considers the weight needed to be assigned to the QALYs in this patient group in order for the ICER of the drug to satisfy the NICE thresholds

- The adoption of the intervention is than based on a *judgment* whether this weight is warranted i.e., whether considerations of equity warrant the benefits to these patients being considered of such greater value to society than the same benefit quantity to other patients.

NICE and E of L Drugs (cont.)

- This *post hoc* judgment involves no considerations of opportunity costs. Instead, an intervention that according to NICE's own criteria, represents an inefficient use of NHS resources, is to be adopted and the resources to fund the intervention are to be found from somewhere else irrespective of any opportunity cost considerations.

- In other words, those making the equity judgments are not operating within the constrained resources of the decision-maker's problem further reinforcing the 'blank cheque' basis of NICE recommendations.

Changing the Problem to Fit the Solution

❖ Baltussen et al (2003) acknowledge that comparisons of interventions based on ICER values cannot provide solution to context specific decisions

❖ They argue, however, that "CEA can be most useful with more modest goals"

❖ However, they do not explain what these more modest goals are or whether these goals are compatible with the problem of constrained maximization facing the decision making process that CEA is intended to inform.

❖ Sculpher et al (2004) argue that "for this research to be relevant to policy, it needs to be seen less as economic evaluation and more as evaluation"

❖ But if decision makers are faced with the problem of constrained maximization, how is a departure from economic principles and the concept of opportunity cost "relevant to policy"? !

**"Health economists,
while seeking to colonize the clinical mind,
may have lost their disciplinary head"**

A. Maynard