

Is Value Based Pricing the Answer to the Economic Problem?

If not, what is it the answer for?

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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?

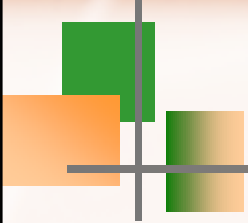
Answers based on criteria of ...

- ❖ 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 Underlying Premise of the Economic Problem

❖ “ ‘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)*

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



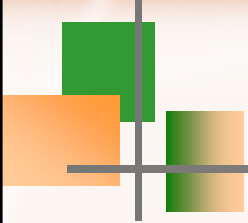
The “economic problem” finally recognized in the US

- ❖ “ High health care expenditures and the growing number of people without health insurance set the US apart from other industrialized countries. The US spends twice per capita what other major industrialized countries spend on health care but is the only one who fails to provide near-universal health insurance coverage. We also fail to achieve health outcome as good, or value for health, as what is achieved in other countries” (Davis, NEJM;2008).
- ❖ Hence cost control is an important goal (but not the only one) of Obama’s health care reform (Fuchs, NEJM:2008, Marmor et al, Annals;2009, Orszag and Emanuel, NEJM;2010).
- ❖ The US has to deal with the “inconvenient truth” about the US health care system.




Suggested solutions

- ❖ Adoption of cost-effectiveness analysis (CEA) is suggested as a way to curtail spending and enhance value. Following England National Institute for Health and Clinical Excellence (NICE) or the Canadian approach.
- ❖ Risk –sharing & value based pricing & value based scheme are advocated as the methods which pharma and medical device companies can obtain HTA approval to finance their products from limited budgets.



“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)



CEA: The “Garden of Eden approach”

- ❖ The Underlying premise of CEA – “For every given level of resources available, society (or the decision maker), wishes to maximize the total aggregate health benefit conferred” (Weinstein and Stason, NEJM;1977) .
- ❖ 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*)



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
- ❖ Ubel et al (2003) – US \$50,000; US \$100,000; US \$265,000
- ❖ Kanis and Jonsson (2002) – US \$60,000 for developed countries
- ❖ 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.



“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 intrinsic 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?
- ❖ *"However beautiful is the strategy, you should occasionally look at the results" (Sir Winston Churchill)*



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, once approved by Minister, are mandatory (Was changed recently)



NICE Results?!

- ❖ Failed to demonstrate increased efficiency
- ❖ Resulted in unplanned increase expenditures

- ❖ “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)*



ICER =
Information Created to Evade Reality



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.



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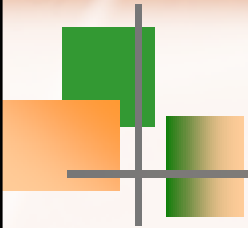
Pursuing Efficiency: Back to the Future

- ❖ 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 al (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
- ❖ Step 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”



Value Based Pricing (VBP)

- ❖ Establishing the value of a drug requires an assessment of whether the additional health expected to be gained from its use exceeds the health forgone from other drugs/interventions that will have to be displaced by its additional costs (The concept of opportunity costs).
- ❖ This means that for a health care system that wants to say maximize the health of the population from the available resources, VBP means that drugs will be approved for use only at prices that ensures that their expected health benefits exceeds the health displaced.
- ❖ But this is not what is suggested!



VBP (Cont)

- ❖ Like CEA, the debate about VBP is focused on the value of the new drug/device as compared with the best available intervention to deal with the same indication.
- ❖ While this might be appealing to clinicians (e.g., the “effectiveness approach”), it is not consistent with the “efficiency question” and thus cannot provide a solution to the economic problem.
- ❖ In other words (i.e., in Fuchs “words”) it can be called another Garden of Eden Approach if advocated as an answer to the economic problem.
- ❖ So what is the answer to?



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

A. Maynard