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Debate

Beyond the threshold

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The question of how to determine coverage in a national health insurance system involves issues of both principle and practice. What are these benefits that we are trying to achieve? Is it the maximisation of population health, assuring a right to health care, or maximising individual life potentials? In any of these are we able calculate the effectiveness of interventions or our marginal social willingness to pay with sufficient rigour to give us confidence in the wisdom of our decisions? Last, given vested interests how do we resolve the practical and political issues of covering new interventions in place of those that are covered now?

Culyer approaches these questions with an elegantly illustrated lesson in the analytics of priority setting, and a clear focussed approach to decision making. The general theme is that weighing up the opportunities foregone in any funding decision, whatever the objective, is always subject to considerable error but a guide to decision making that is open and honest will improve health.

He illustrates this lesson using the classic approach popularised by Weinstein and Stason (1977). This parable imagines a world in which the community has decided how much public money to spend on health improvement. The public funding agency then has to decide on what particular health interventions are covered by the insurance system. In this simple world, where the decision makers have access to complete information on the benefits and costs of all current and future perfectly divisible linear health programmes, ranking the programmes by total benefit per dollar and then running down the list until we run out of money will achieve the goal of maximising a unidimensional health gain [e.g. quality-adjusted life-years (QALYs)]. This is what Weinstein describes as a shopping spree and in Culyer this becomes a trip to the bookshop for a new book and a reorganisation of the older ones on the shelf at home. Culyer gives us a particularly clear exposition, not least because it unusually concentrates on the marginal gain per dollar. It starts with the idea that the health gain per dollar for the last funded programme reveals the health gains foregone from not spending that last dollar, as

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well as the social willingness to pay for a unit of health gain. Limited resources for health care, a desire to maximise aggregate health, and the constraint of existing technology together determine what is covered. It is the novelty of focussing on the incremental benefit per dollar rather than the usual incremental cost per QALY that makes this paper so valuable, as it illustrates very clearly the nature of the opportunity cost involved in making coverage decisions. Culyer acknowledges that we may not always dedicate the right amount of resources to health or discrete health portfolios (drugs, prevention, cancer). Some currently insured interventions have a lower benefit per dollar spent than the explicit or implied thresholds routinely used. It seems quite likely therefore that there is a gap between the opportunity cost of new technologies and our maximum willingness to pay for them (Eckermann and Pekarsky, 2014). This is even more likely to be the case when the resource requirements of the new programme far exceed the size of the existing programme (Gafni and Birch, 2003). In practice, we may end up with second best choices, but by and large the process of comparing new interventions with their opportunity, however, approximate, will improve outcomes. Culyer is correct that many of the real world complexities in this kind of incremental decision making can be accommodated if we are more nuanced in our approach. Assumptions that underlie the conventional interpretation of incremental cost-effectiveness ratios, such as independence between interventions and divisibility with proportional returns to scale, can often be relaxed without abandoning the simple, basic paradigm. This might mean looking at different levels and targets of coverage, considering different scales of operation in different sub-groups of the population (Weinstein, 2012), and ensuring that the incremental benefit from new interventions is meaningful in size. We can also go beyond a single objective by making some adjustments for fairness considerations.

Nevertheless, there is still the potential that deciding on coverage by comparing new interventions with existing inefficient ones will raise the cost of health care. Culyer argues that a simple rule of taking on new services that are more cost-effective than some existing ones will still move us in the right direction over time. Of course this is only true if less cost-effective interventions are the ones replaced rather than simply those that are the easiest to remove. A number of authors have claimed that explicit rationing using health technology assessment is implicated in the enormous growth of health expenditure in the last 30 years. They claim that incremental decisions allocate more resources to the health budget when specific unmet needs are exposed by the coverage process and we fail to remove inefficient interventions (Ham and Coulter, 2001; Gafni and Birch, 2006; Harris *et al.*, 2015).

In practice, we do not find many instances of systematic removal of programmes from public funding even on the grounds of a lack of efficacy or evidence of harm let alone on the grounds of efficiency. This may lead us to question the second best results of incremental evaluation and adoption (Haas *et al.*, 2012). In some cases, there will be a natural attrition of older technologies, but the maintenance of high

prices and high opportunity costs might mean that we need to do more to provide incentives to ration effectively.

An example of a broader approach is the New Zealand government. PHARMAC in New Zealand has a fixed budget for community pharmaceuticals and assesses new drugs for inclusion on the national subsidised formulary using cost-effectiveness. They appear to have maintained that fixed budget for over 20 years using a more nuanced set of strategies than simply exclusion of interventions that fall below the benefit per dollar threshold. They negotiate bundles of products from a company where the older drugs might see a price reduction to allow newer ones (PHARMAC, 2015). Another example of relaxing the constraints of the simple model of decision making is to acknowledge that the threshold price or marginal opportunity cost of interventions may not be constant with the size of the intervention. Take, for example, the 2015 decision to reimburse new medications for Hepatitis C in Australia (Sofosbuvir, Ledipasvir, Daclatasvir and Ribavirin). The budget cost over five years is forecast to be $1 billion or almost 2% of the annual federal government pharmaceutical budget (Australian Government, 2015a, 2015b). With such a large budget share, it seems likely that the health gains foregone per dollar spent at the margin would be greater than a typical new drug. The pragmatic response of the Australian Pharmaceutical Benefits Advisory Committee (PBAC) has been to suggest a lower acceptable cost per QALY for such drugs:

> "As in the consideration of all medicines with a potential high financial impact, there is a significant opportunity cost to the health care system, such as the access to future cost-effective medicines. The PBAC considered that the acceptable ICER/QALY for Hepatitis C treatment should be at the low end of the range previously accepted for these other population preventative interventions because of the extraordinarily large opportunity cost associated with the treatment of Chronic Hepatitis C" (Australian Government, 2015a, 2015b).

The paradigm of health maximisation is not without its critics. For example, a number of surveys of the public by Richardson in Australia and Abellan-Perpiñán and Pinto Prades in Spain, and Ubel among jurists in the United States claim to find little support for the notion of opportunity cost in health care allocation decisions. Richardson in summarising this small literature claims that respondents did not want to maximise lives saved but rather to allocate some health to each of the groups, including groups where the (opportunity) cost exceeded benefits (Richardson and McKie, 2007). Two issues here are that we cannot be sure that the context of the surveys is equivalent to real decision making and second that a popular poll is not necessarily the best way to make ethical judgements. Nor is it clear exactly what maximand if any should replace health. Ranking solely on the basis of effectiveness or need is unlikely to result in socially acceptable decisions where the budget is constrained. On the other hand, if the issue is that for some groups health is inherently more valuable than others then a weighting scheme

could be used either directly in the calculation of QALYs or as a further constraint in the decision process. In fact, the empirical evidence from some jurisdictions suggests that this is what decision makers do in practice. In most jurisdictions severity of illness is an implicit and occasionally explicit modifier of the influence of cost-effectiveness on decisions to fund new interventions. Explicit consideration of life-extending treatment at the end of life by National Institute for Health and Care Excellence (NICE) in England and Wales is an example of that. Less explicit in the Australian context of drug reimbursement decision makers consider not only cost per QALY but also whether the severity of the condition is life threatening and the drug last line (Harris *et al*., 2008). In the Australian drug reimbursement system if the condition is both life threatening and there is no alternative effective treatment the increased likelihood of funding is equivalent to a $A46,000 fall in the cost per QALY; if the cost to the government exceeds $A10 million the equivalent threshold is $30,000 higher (Harris *et al*., 2015). Of course there is nothing inherent in these decisions to say that the thresholds are the correct ones, but they do illustrate that decisions can be made that allow for varying opportunity cost by size of the effect on the budget and the type of patient group. The question might be how we can ensure that the choices made represent true social values. While evidence alone cannot make social choices, Culyer believes in the value of transparent scientific evidence as part of the process in advancing towards our social objectives. In this he echoes the view of Claxton *et al*. (2008: 253) in relation to value-based pricing when they say:

> "It is not so much price 'negotiation' that is required but scientific deliberations between an assessment authority, the manufacturer, and other stakeholders concerning what the available evidence implies for estimates of cost effectiveness, price, and guidance. Any disputes will necessarily turn on explicit scientific questions that can ultimately be resolved through further investigation and a suitable appeal process" (Claxton *et al*., 2008: 253).

There is a general presumption that a more open decision-making process that includes involvement of all of those affected by the decisions will improve rationing outcomes. Culyer subscribes to this in part with his belief that making the best scientific information available on the opportunity cost of programmes will improve decision making for the benefit of the community. There are arguments in favour of an open process such as fairness in decision making but it is not obvious that this results in better outcomes beyond inducing some kind of consistency through accountability. For example, bargaining behind closed doors, informed by the evidence on value for money, may well result in lower prices (Harris *et al*., 2015; PHARMAC, 2015). Openness and transparency are efficient features in contracts where risk is shared between parties and full information between negotiating parties on the costs and benefits of the contract are important for bargaining on price and coverage decisions. However, it is not the case that complete openness to everyone is necessarily socially beneficial. If transparency

leads to a commercial disadvantage and that reduces the gains available to all then it may be socially harmful. I have already mentioned the example of PHARMAC for the way in which it negotiates prices and coverage within a fixed budget without full disclosure of the multiple deals struck with individual companies as a means of mitigating social risk. Other jurisdictions behave similarly with respect to high-cost drugs There is an argument for full transparency in information on the costs and benefits of programmes in jurisdictions where there is a danger of corruption or industry capture of public funders. There are ways around this with strong audit but in some jurisdictions with less strict governance this might be ineffective and shining the bright light of open access to evidence on comparative costs, effectiveness and cost-effectiveness might well be necessary for priority setting.

As Culyer rightly says, the rules of cost-effectiveness decision making are only a guide. There is no suggestion that we slavishly fund only those interventions that fall below a cost-effectiveness threshold. To do so would be to deny both the existence of other objectives beyond health maximisation, the incompleteness of the evidence base and the lumpy and non-linear nature of health production. In practice, this might mean extending our considerations to the effectiveness of intervention compared with doing nothing, how total cost impacts on the availability of other interventions, and how targeted contracts can achieve more cost-effective health care.

References

Australian Government (2015a), 'Public summary document: sofosbuvir'. http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2015-03/Files/sofosbuvir-psd-march-2015.pdf [21 December 2015].

Australian Government (2015b), 'Turnbull Government invests over $1B to cure Hep C'. https://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-ley154.htm?OpenDocument&yr=2015&mth=12 [21 December 2015].

Claxton, K., A. Briggs, M. J. Buxton, A. J. Culyer, C. McCabe, S. Walker and M. J. Sculpher (2008), 'Value based pricing for NHS drugs: an opportunity not to be missed?', *BMJ*, **336**(7638): 251–254.

Eckermann, S. and B. Pekarsky (2014), 'Can the real opportunity cost stand up: displaced services, the straw man outside the room', *Pharmacoeconomics*, **32**(4): 319–325.

Gafni, A. and S. Birch (2003), 'NICE methodological guidelines and decision making in the national health service in England and Wales', *Pharmacoeconomics*, **21**(3): 149–157.

Gafni, A. and S. Birch (2006), 'Incremental cost-effectiveness ratios (ICERs): the silence of the lambda', *Social Science & Medicine*, **62**(9): 2091–2100.

Haas, M., J. Hall, R. Viney and G. Gallego (2012), 'Breaking up is hard to do: why disinvestment in medical technology is harder than investment', *Australian Health Review*, **36**(2): 148–152.

Ham, C. and A. Coulter (2001), 'Explicit and implicit rationing: taking responsibility and avoiding blame for health care choices', *Health Services Research & Policy*, **6**(3): 163–169.

Harris, A., J. Li and K. Yong (2015), 'What can we expect from value-based funding of medicines? A retrospective study', *Pharmacoeconomics*, 1–10, doi:10.1007/s40273-015-0354-z.

Harris, A. H., S. R. Hill, G. Chin, J. J. Ling and E. Walkom (2008), 'The role of value for money in public insurance coverage decisions for drugs in Australia: a retrospective analysis 1994-2004', *Medical Decision Making*, **28**: 713–722.

PHARMAC (2015), 'Fact sheet #5: medicines and medical devices contract negotiation', New Zealand: New Zealand Government.

Richardson, J. and J. McKie (2007), 'Economic evaluation of services for a National Health Scheme: the case for a fairness-based framework', *Journal of Health Economics*, **26**(4): 785–799.

Weinstein, M. C. (2012), 'Decision Rules for Incremental Cost-Effectiveness Analysis', in A. M. Jones (ed.), *The Elgar Companion to Health Economics*, 2nd edn, Cheltenham: Edward Elgar Publishing, Inc., 505–514.

Weinstein, M. C. and W. B. Stason (1977), 'Foundations of cost-effectiveness analysis for health and medical practices', *New England Journal of Medicine*, **296**(13): 716–721.