Unrelated future costs and unrelated future benefits: Reflections on NICE Guidance to the Methods of Technology Appraisal

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Abstract

In this editorial, we consider the vexing issue of "unrelated future costs" (for example, the costs of caring for people with dementia or kidney failure after preventing their deaths from a heart attack). The National Institute of Health and Care Excellence (NICE) guidance is *not* to take such costs into account in technology appraisals. However, standard appraisal practice involves modelling the benefits of those unrelated technologies. We argue that there is a sound principled reason for including both the costs and benefits of unrelated care. Changing this practice would have material consequences for decisions about reimbursing particular technologies and we urge future research to understand this better.

1. Introduction

Health economic evaluation has progressed enormously in the last 20 years, and is now embedded in decision making in several jurisdictions when evaluating medical technologies (Drummond et al., 2015). However, one unresolved issue has been that of so-called "unrelated future costs" (UFC), succinctly captured in the *NICE Guide to the Methods of Technology Appraisal* (NICE, 2013) which includes the following recommendation:

"5.5.7 Costs related to the condition of interest and incurred in additional years of life gained as a result of treatment should be included in the reference-case analysis. *Costs that are considered to be unrelated to the condition or technology of interest should be excluded*." (authors' italics)

NICE gives no reasoning, and the reader may surmise that the recommendation in italics is not contentious. However, this is not the case (Garber and Phelps, 1997; Meltzer, 1997; Nyman, 2004; van Baal et al., 2007; Lee, 2008; Feenstra et al., 2008). The debate was summarised by Meltzer in a recent contribution that predated the NICE guidance (Meltzer, 2012). Published objections to the routine inclusion of UFC are that to do so:

- Involves making assumptions about future care decisions
- Is practically difficult
- Is not material to decision making.

Even more recently, Van Baal and colleagues (2016) have challenged these arguments. Van Baal et al. (2016) approach the question of whether to include UFC by formulating and conducting a technical analysis of a two period constrained optimisation model which captures the essential elements of the NICE decision framework. From that, they conclude that ignoring UFC leads to

suboptimal decision rules. The current editorial is complementary to that of van Baal et al. (2016), in that we take a more qualitative, principles-first approach to analysis, which leads us to a similar destination, albeit by a different route. In particular, we consider the three arguments above under the headings of *Principles*, *Practicalities*, and *Implications for patients and the population at large* respectively.

2. Principles

Drummond et al. (2015) define economic evaluation as "the comparative analysis of alternative courses of action in terms of both their costs and consequences" (p4). It is generally recognised that how these costs and consequences are defined flow from the notion of *perspective*: for example, from the societal perspective, the value of carer time should be monetised and included in analysis, whereas from the perspective of the public purse, the value of carer time should not be included in the analysis.

For the purposes of this discussion we assume the following.

- That the remit of the healthcare system is to maximise health subject to budget constraints on health and social care spending, suggesting the appropriate perspective is the health and social care budget. While this frame already incorporates contestable assumptions, it is the default frame for most health economic analysis in many jurisdictions and underlies the perspective of NICE's current reference case.
- Within this remit, in the words of the UK's overarching guidance on economic appraisal (HM Treasury, 2003), "The relevant costs and benefits to government and society of all options should be valued… In this context, relevant costs and benefits are those that can be affected by the decision at hand" (p. 19). Thus, the test for including or excluding a cost or benefit depends on whether it flows from the commitment which we are being asked to make at the moment of decision.

The nub of the issue here is that a commitment to introduce a new technology may introduce a flow of future needs for healthcare which it may not be possible politically or indeed ethically to deny. However, clearly, when we make decisions about technologies, we do not know what decisions will be made about future care – indeed, we may not even know what the care options will be; for example, if we save the life of a 30 year old in 2015, who knows what the cost of preventing or treating her dementia in 2065 will be? All we can observe is the current costs of care and the historic benefits of having provided care. Two possible responses to this uncertainty are: to take a *narrow scope of decision,* taking the view that in funding current care, we are not making any commitments about future healthcare treatment; or to take a *broad scope of decision,* recognising

that we are retaining the option to provide future care and to make some definite plausible (though potentially incorrect) modelling assumptions about what future treatment might be (e.g. we assume that the said 30 year-old will experience similar dementia care in 2065 to that which an 80 year old would receive in 2015).

We highlight this in Figure 1 which shows four options for the handling of unrelated costs and benefits which flow from future decisions.

Figure 1 about here

Standard practice in economic evaluation (Briggs et al., 2006) often involves using life-tables from clinical trials, observational studies, or population studies to estimate future benefits. Lifetables describe all-cause mortality and so reflect the health benefits which flow from decisions to prevent or treat all health conditions. Accounting for living longer, but excluding UFC, is represented by quadrant 2 of Figure 1 where the benefits of treating other conditions on mortality is included, but where UFC are excluded. Such practice contradicts the light of Treasury Green Book advice, which recommends considering both costs and benefits. Moreover, it is hard to see why the scenario represented in quadrant 2 should be any more acceptable in principle than the scenario of quadrant 3, which also involves the inconsistent treatment of costs and benefits (this time including UFC but excluding the benefits).

3. Practicalities

The analysis of Section 2 suggests that there are two ways to make current practice consistent:

a. Include the costs of future decisions about healthcare (bringing practice from quadrant 2 to quadrant 1)
b. Exclude the benefits of future decisions about healthcare (bringing practice from quadrant 2 to quadrant 4)

We appraise these options from the point of view of practicality. Health economists have developed several methods to include the costs of future decisions about healthcare (Kruse et al, 2012, Manns et al, 2003; Meltzer et al, 2000; van Baal et al, 2011). What these methods have in common is that they implicitly assume that decisions about future healthcare will be in line with the current standard of care. This has the advantage of being consistent with the use of survival tables to model benefits, which implicitly assume the current standard of care (in the sense that the current standard of care is embedded in historical experience reflected in the survival tables).

Of course, life expectancy tends to increase over time, the cost of a given treatment tends to fall over time, and as costly new treatments become available, the future costs of the future standard of care

may differ from the current costs of the current standard of care. Hence, one means to develop these methods is to try to project forward the experienced cost and benefit trajectory rather than to model the costs and benefits of future healthcare decisions based on the current standard of care. Overall, then, we consider option a. (to include the costs of future decisions) to be a feasible option, while recognising the scope for further development of methods in this area.

What of the practicality of Option b. (to exclude the benefits of future decisions)? In some settings, e.g., when offering a life-extending operation to patients with end stage renal disease, where the future decision may include continuing dialysis or not, excluding the life-prolonging benefits of dialysis would mean assuming zero residual life expectancy, and so it may be possible and relevant to generate estimates for quadrant 4. In other settings, however, it is challenging to define the untreated natural history of disease. Even if the untreated natural history of the disease is observed, for example in countries where there is little access to medical care, the data from such countries tends to be poor and people are subject to other hazards (infectious disease, poor sanitation, conflict) which makes it hard, if not impossible, to generalise to richer countries. Thus, option b. seems less practical in general and perhaps impossible in many settings.

Following the analysis of this section, we conclude that from a practical point of view, including the costs of future decisions about healthcare is the most promising way to make practice consistent.

4. Implications for patients and the population at large

Taking into account UFC may or may not change recommendations. In particular, in the case of interventions which do not materially affect survival (such as alleviating transitory conditions), the resulting change in costs of future healthcare provision are negligible and may be ignored. However, in cases in which gains from improving health are small compared to gains in survival, the impact may be substantial (Meltzer, 2007). Thus, changing practice may change the cost effectiveness ordering of interventions and the funding mix recommended by analysis with regard to subpopulations and conditions. For example, treatments for older populations with more co-morbidities than younger populations may be relatively disadvantaged by accounting for UFC. The reasoning is that, in general, the unrelated conditions these groups experience in gained life years occur sooner following treatment (and therefore would be discounted less) than they would for younger patients. Treatments for conditions which would otherwise lead to quick and relatively inexpensive deaths (such as pancreatic cancer) may likewise be disadvantaged.

If one includes the costs and benefits of future unrelated care when assessing a proposed new intervention, then logically they should also be included in when assessing health opportunity costs. Empirical estimates of a cost–effectiveness threshold that reflects health opportunity costs attempt

to capture the health effects of changes in current expenditure (Claxton et al., 2015a). However, changes in mortality and survival will also lead to changes in the costs of the system in the future. Given estimates of the costs of unrelated care at older ages and estimates of where health opportunity costs are likely to fall (by disease area, age and gender) (Claxton et al., 2015b), it should be possible to assess the implications of such changes in survival and mortality for the threshold.

5. The way forward

The issue of unrelated future costs (UFC) has been an unresolved issue in economic evaluation for several years. We appreciate and acknowledge that there is uncertainty about future treatment and its associated costs. Indeed, in many situations it may be appropriate to perform scenario analyses to investigate how treatment regimes (and associated life trajectories) may evolve. However, this does not constitute a rationale for excluding UFC, while at the same time including unrelated future benefits, in an economic evaluation. In our view, those responsible for technology appraisal should include the costs of future healthcare decisions in analyses where they may make a material difference to results.

Being given permission to include UFC should be a source of relief to analysts. Including "related" but excluding "unrelated" future costs requires analysts to make judgements about whether particular costs are related or unrelated. Such judgements may involve deep scientific and conceptual questions - as one of our anonymous reviewers asked, "Do we really know enough about a disease like rheumatoid arthritis, for example, or a childhood autoimmune disorder, to judge which cancers, cardiovascular, mental or musculoskeletal disorders are entirely unconnected?"

Areas of research also include:

- What is the effect of including UFC on the mix of funded interventions for a representative jurisdiction, taking into account both changes in the priority ordering of interventions and changes in the cost effectiveness threshold? For some conditions and technologies the impact could be substantial: for example, relatively inexpensive blood pressure lowering therapies now widely available may make people live longer only to develop dementia which in the UK has been associated with costs of care substantially greater than those of cancer or stroke (Luengo-Fernandez et al, 2012).
- What challenges exist in developing costing models to capture UFC? A simple way to model such costs is to use age-specific per capita health expenditures but more nuanced and realistic models exist. For example, PAID (van Baal et al., 2011) models costs for the Dutch population as depending on both age and time to death. Developing and validating models the drivers of

lifetime healthcare costs for multiple countries using local large scale linked data sources, building on work such as that of Seshamani and Gray (2004) and Georghiou et al (2012), seems an urgent research priority.

We believe that answering these questions will help analysts perform more robust and defensible analyses. Of course the policy question – of what to fund - remains with decision makers. However, healthcare systems worldwide will face increasing fiscal and demographic stresses in years ahead. When decision makers are faced with choices which may exacerbate these pressures, the responsibility lies with the analytic community to provide an accurate accounting of costs and benefits and make the consequences of these choices clear.

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Conflict of interest

The authors declare no conflicts of interest.

Originality

This work is original with the authors and no part has been previously published.

Ethics

The paper is conceptual in nature and raises no ethical issues.

	Include estimates of the *costs* of future decisions to prevent or treat unrelated condition	*Exclude* estimates of the *costs* of future decisions to prevent or treat unrelated condition
Include estimates of the *benefits* of future decisions to prevent or treat unrelated condition	1	2
Exclude estimates of the *benefits* of future decisions to prevent or treat unrelated condition	3	4

Figure 1. Options for inclusion/ exclusion of costs/ benefits