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Weighting must wait: incorporating equity concerns into cost effectiveness analysis may take longer than expected.

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Abstract

Current practice in economic evaluation is to assign equal social value to a unit of health improvement ("a QALY is a QALY is a QALY"). Alternative views of equity are typically considered separately to efficiency. One proposal seeks to integrate these two sets of societal concerns by attaching equity weights to QALYs. To date, research in pursuit of this goal has focussed on candidate equity criteria and methods for estimating such weights. It has implicitly been assumed that should legitimate, valid, and reliable equity weights become available, it would be a straightforward task to incorporate them into as a separate simple calculation after estimating cost per unweighted QALY. This paper suggests that in many situations these simple approaches to incorporating equity weights will not appropriately reflect the preferences on which the weights are based and therefore equity weights must be incorporated directly into the cost effectiveness analysis. In addition, to these technical issues, there are a number of practical challenges that arise from the movement from implicit to explicit consideration of equity. Equity weights should be incorporated in economic evaluation, but not until these challenges have been appropriately addressed.

1. Introduction

Against a backdrop of rising healthcare costs, decision makers the world over increasingly consider issues relating to the economic efficiency of alternative uses of limited healthcare budgets. The last two decades in particular have seen a shift away from decision making which traditionally considered only issues relating to safety and efficacy, to processes which also incorporate consideration of cost effectiveness. As the role of economic evaluation in decision making has become more prominent, there have been parallel developments in the methods for conducting such studies (Drummond and McGuire, 2001).

One field in particular that has witnessed substantial methodological development is that of the measurement and valuation of health outcomes. This, in turn, has resulted in measures such as the Quality Adjusted Life Year (QALY) establishing a dominant position as the outcome measure for economic evaluations in many jurisdictions. However, whilst the use of QALYs in cost effectiveness analysis (CEA) is compatible with the aim of maximising health benefits, this is unlikely to be the sole goal either of health care decision makers (Drummond and McGuire, 2001; PHARMAC; NICE, 2007) or of the populations they serve (Schwappach, 2002; Dolan *et al.*, 2005). The implicit equity approach embodied in CEA is to assign equal value to each unit of health gain, irrespective of the characteristics of the recipients, how the benefit is generated, or the reason an intervention is required in the first place ("a QALY is a QALY"). This approach has long been questioned (see Dolan *et al.*, 2006 for a review), yet no formal framework exists which would permit alternative approaches to equity to be incorporated. In the absence of a formal approach, decision

makers must rely on implicit trade-offs between competing equity and efficiency criteria, or may even consider certain equity criteria as rights which trump all consequential issues, including cost effectiveness. In the former case, the criteria by which decisions are reached cannot be entirely transparent and there is a strong risk of inconsistency across decisions; in the latter case, opportunity cost is not considered and therefore economic evaluation becomes redundant.

An alternative approach to this implicit incorporation of equity has been proposed whereby societal preferences across different equity criteria would be used to construct values for adjusting QALYs. These so called "equity weights" would be used to generate estimates of cost per equity adjusted QALY and decisions based on this figure and willingness to pay per "super" QALY (Wagstaff, 1994; Williams, 1997; Nord et al., 1999; Dolan and Olsen, 1999; Dolan and Tsuchiya, 2006). A larger proportion of the information relevant to decision makers would be brought inside the analytical framework of cost effectiveness by the development of this maximand (Dowie, 1998).

It is worth noting that there may also be efficiency based reasons for proposing that some characteristics attract a greater weight than others. For example, it could be argued that the desire to allocate greater weight to parents rather than non parents is motivated by efficiency rather than equity concerns. Disaggregating these motives, particularly in relation to age weights, may be an important task. The discussion below refers to equity weights but the same considerations will apply to efficiency weights as well. The equity weighted QALY approach may be appealing to some but has not been considered viable to date due to uncertainties about relevant equity characteristics, insufficient data and a lack of agreement on methods with which to estimate the required weights. However, beneath these concerns, it has been implicitly assumed that should legitimate, valid and reliable weights become available, it would be relatively straightforward to incorporate those weights into CEA.

This paper argues that in order to avoid misrepresenting the preferences over health outcomes and equity that the use of QALYs in conjunction with equity weights is intended to reflect, more complex methods will often be required. The appropriate application of equity weights is challenging and remaining technical, methodological and evidential challenges require consideration before equity weights can be explicitly incorporated into health care decision making. Candidate equity characteristics may include age, gender, severity of the untreated condition and accountability for ill health, and we will use some of these in our hypothetical examples in this paper. However, it is not our objective to argue for (or against) any of these characteristics per se in this paper.

2. Challenges to incorporating equity weights into cost effectiveness analyses

In considering the importance of some of the potential challenges to using equity weights, it is important to recognise that the aim is to reflect public preferences over the distribution of health outcomes. "Equity" in this approach operates at the same level as QALY maximisation, that is, in making decisions between and within broad groups of patients and not at the individual patient level. Two general types of

concerns to using equity weights are identified in relation to the aim of improving decision making at this level. First, there are technical challenges to accurately reflecting preferences over efficiency and equity. Second, moving away from a decision making framework in which equity is considered in terms that are not commensurable with those used to express efficiency, to an approach in which equity is implicit to the analysis gives rise to a number of potentially problematic issues.

2.1 Simple incorporation of equity weights into CEA

There are two straightforward approaches to incorporating equity weights alongside cost per QALY calculations. In both cases, this occurs as a separate stage to the calculation of the costs and un-weighted QALYs for the interventions under considerations.

The first approach adjusts the number of additional QALYs generated by an intervention according to the relevant equity weight and compares this to the standard willingness to pay threshold. For example, an intervention generating 5 additional QALYs in a patient group for whom an equity weight of 1.5 was considered applicable would generate 7.5 equity weighted QALYs. Provided the additional cost was no more than £150,000 then this would be considered a cost effective intervention, assuming a threshold of £20,000 (£150,000 / 7.5QALYs).

The alternative approach adjusts the willingness to pay threshold used to determine whether an intervention is cost effective. Since the threshold incremental cost effectiveness ratio (ICER) is the inverse of the marginal health gain per unit of expenditure of the displaced intervention, this approach in effect downgrades the QALYs for the displaced group based on the equity weight applicable to the recipients of the new intervention. For example, imagine an intervention which generates 5 additional QALYs at an additional cost of £125,000. The ICER of £25,000 would be judged against an equity weighted threshold value. If the usual threshold of £20,000 were adjusted to take into account the equity weight of 1.5, this results in an equity weighted threshold of £30,000 and the new intervention would be considered cost effective. Implicitly, the QALYs generated by those that bear the opportunity cost have been factored down by the equity weight.

Whilst these two approaches are mathematically equivalent, the second approach of adjusting the threshold highlights an apparent inconsistency. The QALYs generated in one group of patients are adjusted not according to the characteristics of the patients that receive those health benefits, but according to the characteristics of a different patient group. This issue is discussed in more detail below.

2.2 Technical challenges

In many situations, the time horizon over which cost and benefit differences between treatment options accrue is long term. Therefore, for many interventions for chronic conditions, it is appropriate to use decision models to make what can be life long estimates. However, it is also likely that relevant equity characteristics will change over time for the patients considered in these models. Of the likely candidate criteria for equity weights, this is most obvious in relation to age but is also important to other characteristics. For example, characteristics such as individual responsibility for ill health may take a complex pattern over time depending on whether or not patients continue with the health damaging behaviour beyond disease onset or where risk

taking behaviour is related to life stage characteristics such as having children. In these situations, where not only do the patient characteristics attracting equity weights and the size of these weights change over the relevant time frame of the model, but they also may have an impact on clinical effectiveness, the application of a constant equity weight (as implied by adjusting either the final QALYs generated and thereby the final ICER, or the threshold willingness to pay) will not be appropriate. The calculation of cost effectiveness will need to recognise that over time, as patients progress through a model, they may attract differing weights.

Whilst this raises the need to incorporate equity weights directly into the modelling process, it also raises an important issue regarding the status and interpretation of age based weights. Attaching different weights according to patient age as they progress through a model is assumed to reflect the preferences of the general population from whom equity weights will be elicited, but this is only the case if these weights reflect true preferences for age rather than a cohort effect. For example, it has been suggested that equity weights could reflect preferences towards the current very elderly cohort due to the payment of national insurance contributions over a lifetime and the implicit contracts with the state that many thought this entailed (Johnson and Falkingham, 1992). This may not be considered relevant to younger cohorts when they reach the same age given that the link between contributions and entitlements is no longer explicit. The precise way in which changing equity weights should be used to reflect changing patient age within models will require a detailed understanding of the reasons why such preferences exist in order to appropriately reflect those preferences.

In addition, it is unlikely that any group of patients will be homogenous with respect to the equity characteristics of relevance, including those that change over the appropriate time horizon. Thus, within a patient group, some patients' health gains will be valued more highly than others for equity reasons, even when the size of the health gain is the same. In this situation, two approaches are feasible. The first is to define patient subgroups according to equity characteristics as well as the more traditionally accepted subgroups defined in terms of characteristics that affect clinical outcomes or cost. The second is to estimate the true equity weighted ICER for a patient group that is a weighted average of the patients it contains. The two approaches may lead to very different conclusions and challenges. The first approach gives rise to the possibility of decision makers being faced with an ordering of treatment options by group that may conflict with the ordering of health benefits (or even the costs) derived by those groups. This will occur where characteristics which attract equity weights are negatively correlated with effectiveness and the former outweigh the latter. This may give rise to significant challenges for decision makers. Yet the second approach which would obscure such decisions, in fact entails the inconsistency of being prepared to use the valuations of the general population in one element of the decision (the incorporation of the equity weights) yet ignores them at the subsequent stage. This inconsistency would penalise certain groups: either those for whom the proposed treatment is cost effective but are denied because the decision groups them with other "worse" patient groups, or those who bear the opportunity cost of positive decisions that give treatment to those in whom the intervention is only cost effective because they have been grouped with a "better" equity group. The incorporation of equity weights at the analytical stage of the decision making process requires they are considered legitimate (in terms of acceptability of differentiating

between patients in terms of the particular characteristics and in terms of the robustness of the estimates). A consistent approach would also apply these weights at the decision making stage.

The simplistic approaches to incorporating equity weights will be sufficient when the patients under consideration are homogenous with respect to these equity characteristics. Whilst it is rarely the case that interventions are relevant only to patients of a particular age, we must also consider the degree to which equity weights themselves distinguish groups in order to determine how frequently a simplistic approach will be sufficient in practice. Where equity weights are quite 'lumpy', for example, in the case of age, only distinguishing between children, adults and the elderly, then the simplistic approaches may be appropriate more frequently. However, this may be expected to diminish over time as the evidence base on which equity weights are founded is developed.

This task may be further complicated by the fact that equity preferences are likely to exist over several characteristics. The appropriate weight to be applied to any individual patient or group of patients will not solely be a function of their status in each equity domain but will be determined by the interaction between these domains. To estimate the form of the equity weight function requires an evidence base that does not currently exist. Without knowing whether applying numerous equity weights should be done in multiplicative, additive or another form risks introducing a bias that may be no more defensible than the use of un-weighted QALYs that the weights were intended to replace. Indeed, there is currently no agreement as to the equity domains

that that should be considered legitimate: a task that clearly must precede the challenge of identifying the appropriate functional form for multiple characteristics.

2.3 Implicit versus explicit equity positions

Moves towards the explicit incorporation of equity weights into cost effectiveness analysis must recognise that current practice is not free of equity implications and, to avoid the risk of double counting, their impact must be factored out.

For example, in the hypothetical case where equity weights for social class attach greater importance to health gains generated by those in the lower compared to the higher classes, it would be important to factor out any difference in health gain due to differential life expectancy. For a life saving intervention, current practice would not estimate ICERs for subgroups defined by class even though these could differ substantially: life expectancy at birth is approximately 7 years more for professionals compared to unskilled manual workers in the United Kingdom (Office for National Statistics, 2008). At the margin, the implicit equity approach embodied in current practice could lead to therapies being provided to populations in whom they are not cost effective, and not provided in populations in whom they are cost effective. If explicit equity weights are to be incorporated into cost effectiveness analyses these implicit weights ought first to be removed, that is, the health course with and without the experimental treatment and the costs incurred in all states within the health course should all be equity sub-group specific. Only then should explicit equity weights be introduced in order to avoid double counting.

Current practice would need to be amended where any of the characteristics which attract equity weights are also related to any factor that influences either expected benefits or costs. Examples are life expectancy, compliance with treatment and vulnerability to complications. Whilst this has implications for the generation of data which could inform these equity weighted subgroup estimates, there may also be other unintended consequences. Compared to current approaches that do not distinguish such groups, the estimation of equity based subgroups might actually disadvantage those in the groups equity weights are intended to favour. This will occur where the true estimates of effectiveness (lower life expectancy for lower social classes in the above example) are not offset by the additional equity weighting of those benefits.

One may think that such an outcome is unacceptable and that the introduction of equity weights should always advantage the vulnerable group. However, the dilemma arises because current practice masks the fact that benefits are inflated in a way that becomes difficult to defend once explicit weights are derived.

Finally, it must be recognised that economic evaluation is founded on the principle of opportunity cost and care must be taken if equity weights are to be applied only to the denominator in cost per QALY analyses. In the case of decision making within a limited health care budget, the additional costs associated with any intervention represent foregone health benefits by other patients. If no explicit consideration is given to the equity characteristics of patients that bear the opportunity cost then the implied assumption is that these foregone benefits are equity neutral, that is they are

assigned a unitary weight. Whilst it may be difficult to predict where the opportunity cost will fall, and this will differ according to the decision making environment and the technologies in question, it should not automatically be assumed that the losers will be equity neutral. It has been suggested that the opportunity cost tends to fall on patient groups that lack a high profile with the general public or enjoy powerful clinical support, even where these are within the same specialty (Barrett et al., 2006) – precisely the groups of patients that are likely to attract strong equity weights.

In fact, equity weights must be neutral across the population to which the health care budget is applied. Therefore, the incorporation of weights into decision analysis must be prepared to apply weights which downgrade the health benefits in some populations as well as upgrade them in others. If analyses routinely apply weights of one or greater to the populations that are the subject of decisions based on economic evaluations, then the implication is not that the populations that bear the opportunity cost are equity neutral but that they are in fact equity negative. The question for analysts and decision makers in every analysis should be "which" weight to apply, which is determined both by the recipients of the intervention under consideration and those likely to bear the opportunity cost, not whether a weight should be applied at all.

3. Conclusions

In this paper we have attempted to describe why the incorporation of equity weights into cost effectiveness analysis will often be more complicated than has previously been considered. The simplistic approaches of either adjusting the willingness to pay threshold or the final ICER will be liable to misrepresentations of public preferences. Approaches which factor equity weights directly into the estimation of costs and

benefits should therefore be favoured. We recognise that this may impose a further degree of complication to an area that has seen rapid ratcheting up of analytical techniques over the past decade (for example by increasingly complex model types and analysis of uncertainty). Indeed, there may be an increasingly frequent need for more complex individual sampling models to truly represent equity weights because of the need to incorporate patient history. This in turn may conflict with other techniques such as the ability to perform probabilistic sensitivity analysis. Thus, the move to the incorporation of equity weights into decision making may have broader methodological research implications.

This is not to argue that we should avoid taking explicit account of society's preferences over equity. We broadly agree with the arguments by Cookson and Williams (2000) for transparency in decision making processes. The development of decision making processes is dynamic. At any point in time, there are arguments in a decision problem that cannot be adequately captured in the analytical processes that inform decision making. This may be due to lack of evidence or the absence of an adequate analytical technique. It is part of the decision maker's role to take account of these arguments as well as the analytical evidence that does exist in order to arrive at a decision. Over time, in the interests of transparency and consistency, decision making processes should aspire to increase the proportion of arguments in the decision problem that are addressed analytically and reduce the degree to which the decision is determined in the 'black box' of the decision maker's head. It is important to understand that acknowledging that some important issues in a decision cannot be addressed analytically is not an argument for reverting to simplistic cost consequence type analyses.

There are therefore clear challenges yet to be addressed by different groups. At the political level, there must be direction given as to which of the potential equity characteristics may be considered legitimate, with the potential for health care resources to be directed differentially between these groups. At the methodological level, there remains the challenge of estimating reliable weights and the appropriate functional form for combining them together. For cost effectiveness analysts and the recipients of those analyses there will be challenges in incorporating weights in a manner that respects societal preferences over efficiency and equity and in recognising the appropriate weights to apply to different groups.

To conclude, whilst the aim of incorporating equity weights into cost effectiveness analyses should be pursued, it must be recognised that this will not be straightforward. There has been some expectation that the most difficult stage in this endeavour is in establishing legitimate, valid and reliable weights, and that once these are available it would be a relatively simple calculation to apply them to the analyses. This paper has pointed out that there are further remaining challenges on the way. Equity weights should be incorporated in economic evaluation, but not until these challenges have been appropriately addressed.

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