Ethical Objections Against Including Life-Extension Costs in Cost-Effectiveness Analysis: A Consistent Approach

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Abstract One of the major ethical concerns regarding cost-effectiveness analysis in health care has been the inclusion of life-extension costs (“it is cheaper to let people die”). For this reason, many analysts have opted to rule out life-extension costs from the analysis. However, surprisingly little has been written in the health economics literature regarding this ethical concern and the resulting practice. The purpose of this work was to present a framework and potential solution for ethical objections against life-extension costs. This work found three levels of ethical concern: (i) with respect to all life-extension costs (disease-related and -unrelated); (ii) with respect to disease-unrelated costs only; and (iii) regarding disease-unrelated costs plus disease-related costs not influenced by the intervention. Excluding all life-extension costs for ethical reasons would require—for reasons of consistency—a simultaneous exclusion of savings from reducing morbidity. At the other extreme, excluding only disease-unrelated life-extension costs for ethical reasons would require—again for reasons of consistency—the exclusion of health gains due to treatment of unrelated diseases. Therefore, addressing ethical concerns regarding the inclusion of life-extension costs necessitates fundamental changes in the calculation of cost effectiveness.

Key Points for Decision Makers

One of the major ethical concerns regarding cost-effectiveness analysis in health care has been the inclusion of life-extension costs (“it is cheaper to let people die”).

Yet, for consistency reasons, addressing ethical concerns regarding health-related life-extension costs requires a more comprehensive approach than a simple exclusion of these costs.

Our analysis shows that some health benefits need to be removed from the calculation of the cost-effectiveness ratio.

1 Introduction

Life-extension costs can be economically relevant and may substantially alter the cost effectiveness of health interventions, particularly when they increase length of life more than quality of life [1, 2]. Examples where life-extension costs are relevant are given in patients with heart failure [3] or dialysis treatment.

Life-extension costs have been a source of debate for many years [2, 4–14]. Many authors have argued to exclude them. For example, Russell [14] did not consider life-extension costs “relevant to deciding whether the program is a good investment” because they are “indirect consequences of the health gains from a program”. On the other hand, Drummond [4] argued in favor of including life-extension costs “if the quality or quantity of life years gained as a result of treatments given in later life are

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included in the denominator of the cost-effectiveness model". Similar to Drummond, Nyman [11] argued that "it would be appropriate to include the average annual costs of (non-related) medical care as an additional cost for each year of survival" if a patient benefits not only from the treatment to be evaluated but also from other treatments that result in a gain of life extension and/or quality of life. This argument is based on standard welfare economic theory, which suggests that every consumer transaction entails both costs and utility gains resulting in a net effect [15].

Some debate has been sparked over the inclusion of consumption costs in added life-years. As shown in the example of hypertension treatment, these costs can have a significant influence on cost effectiveness [16]. According to Nyman [11], consumption costs should be excluded in added life-years because none of the existing direct or indirect utility measures explicitly recognizes variations in consumption or foregone leisure. However, others commented that consumption and foregone leisure are implicitly included in estimates of health gains [6, 13]. In line with Nyman [11], Liljas [17] argued that consumption costs should be excluded because quality-adjusted life-years (QALYs) are unlikely to be consistent with a utility function also including consumption and leisure. He suggested instructing individuals not to include consumption and foregone leisure in their QALY assessments.

Apart from the above discussion around consumption costs in added life-years, there has been an ethical controversy around health-related costs in added life-years (related or unrelated to the disease or intervention in question). It has been coined with the phrase "it is (...) cheaper to let people get sick" [18] or die. The phrase is used in a cynical way, i.e. to reduce the inclusion of life-extension costs to absurdity. That is, those who use the phrase would like to stress that it is actually worth extending life. Anecdotal evidence suggests that many analysts have opted to rule out life-extension costs from the analysis due to the underlying ethical objection. However, surprisingly little has been written in the health economics literature regarding this ethical concern and the resulting practice.

Given that a consensus for including/excluding some or all health-related life-extension costs has not yet been reached, guidelines for the conduct of cost-effectiveness analysis (CEA) of health interventions either do not address life-extension costs explicitly or take a middle position. For example, the German Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) considers in the base case only those life-extension costs related to the intervention in question. In contrast, unrelated health care expenditures are excluded from the base case and considered in a sensitivity analysis [19].

Where guidelines do not address health-related life-extension costs explicitly, the exclusion/inclusion of life-extension costs is left to the discretion of the analyst. For instance, a recent review of cost-effectiveness modeling analyses of screen-and-treat strategies for osteoporosis prevention revealed that 25 % of analyses published from 2006 to 2011 accounted for all life-extension costs, while 75 % did not [20]. Note that apart from an ethical objection to include all health-related life-extension costs, this practice may also result from limited data availability and technical difficulties in calculating total life-extension costs.

The purpose of this paper was to present a framework and potential solution for ethical objections against the inclusion of health-related life-extension costs. While the purpose of this paper was not to defend or attack the abovementioned reasons for excluding some or all life-extension costs, we would like to point out an inconsistency that occurs when some or all life-extension costs are excluded.

From a utilitarian viewpoint, consideration of life-extension costs is ethically justified as it fully acknowledges the limitation of resources (utilitarians aim at maximizing total utility of citizens given scarce resources [21]). Therefore, in the following, we will use the term 'ethical' only with regard to non-utilitarian theories. Furthermore, we will use the terms 'life-extension costs' and 'future costs' interchangeably. Finally, we will only discuss health-related future costs and ignore future costs related to consumption and leisure foregone. Health-related future costs may be related or unrelated to the disease or intervention in question.

2 Levels of Ethical Concern

At the most extreme level, the ethical objection against life-extension costs concerns all life-extension costs (disease-related and -unrelated). This is perhaps the most common ethical viewpoint among non-experts in the field and has been coined with the phrase "it is (...) cheaper to let people get sick" [18] or die. Note that for a purely life-extending intervention (i.e. the intervention does not improve quality of life and yields a health gain based on life extension alone), a 'penalty' not only results from the presence of life-extension costs but also from the absence of a morbidity reduction. For such an intervention we use the term 'double penalty' in the following.

A less extreme viewpoint is to exclude disease-unrelated costs only. This is perhaps the most popular approach in CEAs today. The underlying ethical principle is to avoid holding an intervention responsible for consequences which are not under its control.

An in-between position is taken by the non-federal US Panel on Cost-Effectiveness in Health and Medicine [22]. The US panel suggests excluding disease-related costs not influenced by the intervention (i.e. the level of care not necessarily part of the target intervention). Suppose, for example, a CEA evaluating the provision of anti-diabetics to reduce the risk of cardiovascular events in diabetic patients. In this case, disease-unrelated costs such as dementia or low back pain should be excluded. However, “age-specific background costs of coronary heart disease—that is the level of disease that would occur among people who are not candidates for intervention—are also unrelated to the intervention and should also be excluded”. Ignoring this would mean that life-prolonging interventions are “encumbered with all future costs of heart disease even though they target only for excess risk” [22].

3 Creating Methodological Consistency

It seems uncontroversial and consistent to exclude unrelated health care expenditures in added life-years when related health expenditures are excluded for ethical reasons (when there is a concern against all life-extension costs or against disease-related costs not influenced by the intervention). Also, it seems uncontroversial to exclude consumption costs in added life-years when related and unrelated health care costs are excluded.

Now, consider the case where all life-extension costs (disease-related and -unrelated health care costs) are to be excluded for ethical reasons (the first case mentioned in the previous section). Furthermore, consider a purely life-extending intervention, which yields a health gain based on life extension alone (i.e. the intervention does not improve quality of life). For this type of intervention, the ‘penalty’ resulting from the cost burden of life extension is removed. Still, as a purely life-extending intervention does not result in a cost offset, it cannot save costs. Therefore, a ‘penalty’ for extending life without avoiding morbidity (improving quality of life) remains. The ‘double penalty’ for pure life extension is thus reduced to a ‘single penalty’. In lay terms, it would still be cheaper to let people die.

To avoid the phenomenon of a single or double penalty, all downstream health care costs would need to be excluded. This way, the intervention that only affects a person’s morbidity level would lose its inherent cost advantage over the intervention that only prolongs life. Still, without further adjustment this approach actually leads to a comparative disadvantage of measures that only reduce morbidity (without affecting mortality). The reason is that the health gain caused by a life-prolonging intervention indirectly includes the health gain from unrelated interventions that are provided during added life-years. In contrast, the

health gain caused by a quality-of-life-improving intervention is clearly attributable to the intervention itself. Therefore, the health gain caused by a life-prolonging intervention should exclude the health gain from unrelated interventions. There are unrelated interventions though which lead to immediate or near-immediate death in their absence, e.g. dialysis treatment in patients with end-stage renal disease. In the absence of such unrelated interventions, the health gain caused by an additional intervention would then also be zero or close to zero. To avoid such anomalies, we propose determining the health gain in hypothetical members of the general population who do not receive additional health care. To this end, we apply the relative treatment benefit to the baseline risk of these hypothetical members.

Note that even with this adjustment we cannot avoid the fact that for a life-extending intervention it would still be cheaper to let people die. We only ensure that for quality-of-life-improving interventions it would also be cheaper to leave people without treatment. From a resource allocation viewpoint with the goal to maximize health or utility, both types of intervention would then have equal priority status.

Hence, a consistent approach of dealing with the ethical concern regarding all life-extension costs is to exclude not only all downstream costs from the analysis but also health gains from unrelated interventions. That is, interventions are only compared in terms of their ratio of intervention costs to intervention-related health gains (option A in Table 1). Intervention-related costs would not only include the direct costs of intervention but also the cost of treating side effects as well as the costs of related services such as counseling, monitoring, and testing. Clearly, if the unrelated component is excluded from the health gain but not from the costs, the incremental cost-effectiveness ratio (ICER) increases. Therefore, compared with the approach where all health care costs and health gains are included, the proposed accommodation of the ethical concern regarding life-extension costs may actually increase the ICER. Importantly, however, the ICER of a quality-of-life-improving intervention always increases with this adjustment. This holds because not only downstream savings are excluded but also unrelated health gains.

To illustrate the approach, consider the example of a 60-year-old man with myocardial infarction who receives a bypass which, compared with no intervention, increases his life expectancy by 15 years (20 years vs. 5 years). Furthermore, this patient develops depression not related to the bypass after 7 years and receives treatment which restores his health completely (Fig. 1). To determine the costs and related health gain of the bypass we would need to exclude all costs beyond year 5 plus the benefits of depression treatment, i.e. consider the disease course without treatment.

Table 1 Different approaches of calculating incremental cost-effectiveness ratios

Option	Components included/excluded	Incremental cost-effectiveness ratio
A	Inclusion of intervention costs and intervention-related health effects, exclusion of all other costs and health gains	$\frac{\Delta C_i}{\Delta E_{ir}}$
B	Inclusion of costs and health effects due to intervention and related diseases, exclusion of disease-unrelated costs and health effects	$\frac{\Delta C_i + \Delta C_{dr}}{\Delta E_{ir} + \Delta E_{dr}}$
C	Inclusion of costs and health effects due to intervention and related diseases, exclusion of disease-related background costs and health effects as well as disease-unrelated costs and health effects	$\frac{\Delta C_i + \Delta C_{dr} - \Delta C_{drb}}{\Delta E_{ir}}$

C_i costs of intervention, C_{dr} disease-related costs (including disease-related background costs), C_{drb} disease-related background costs
 E_{ir} intervention-related health effects, E_{dr} disease-related health effects (including disease-related background health effects)

At the other extreme, excluding only disease-unrelated life-extension costs for ethical reasons requires an adjustment of health gains to be included in the ICER. The health gain would then need to exclude the portion explainable by disease-unrelated interventions but would still retain a portion attributable to the treatment of related diseases which is unrelated to the intervention itself [23]. The underlying consistency principle is that excluding certain treatment costs requires a simultaneous exclusion of treatment benefits related to these costs. Savings from avoiding disease would still be included because they are related to the intervention. With regard to the above case example, we would exclude the costs and health gains of depression treatment and retain all other costs and health gains (option B in Fig. 1).

In-between is the exclusion of disease-unrelated costs plus disease-related costs not influenced by the intervention (background costs). The exclusion of all costs unrelated to the intervention then requires—for reasons of consistency—the exclusion of health gains unrelated to the intervention. Again, savings from avoiding disease would still be included because they are related by the

intervention. With regard to the above case example, we would not only exclude the costs and health gains of depression treatment but also costs and health gains of treatments for myocardial infarction other than the bypass (option C in Fig. 1). Therefore, fewer QALYs are gained than in the case where only health gains from depression treatment are excluded (i.e. disease-unrelated health gains). This explains the difference between the *solid* and *dotted* graphs in Fig. 1. In contrast to option A, we would retain any savings from providing the bypass.

4 Feasibility

The main implementation problem of the three approaches described above is the availability of data to make a correct distinction between life-years gained resulting from related and unrelated care (where related/unrelated may refer to an intervention or disease, depending on the level of ethical concern). Health gains attributable to unrelated interventions inside and outside the health care system need to be eliminated from the calculation of health gains. This requires information on how long and at what quality of life people would live without unrelated interventions inside and outside the health care system [23]. As stated above, in order to avoid anomalies, we propose determining health gains in the general population and not among individuals with the disease in question. Recently, a few studies have been published that might provide some insight into this issue. For example, evidence from coronary heart disease (CHD) suggests that medical treatments have contributed to approximately one-third to one-half of the decrease in CHD deaths [24–27]. This evidence may be used when calculating health gains from treatment of other diseases. For example, consider the case where a drug cures cancer and the person goes on living. This person will benefit from treatments that are available for CHD. Without such treatments the person would live for a shorter period. How much shorter? This depends on the shape of

Fig. 1 Gain in QALYs as a result of life extension, with a subsequent decrease in quality of life due to an unrelated disease in the intervention group. QALYs quality-adjusted life-years. ----- life extending intervention including the gain in QALYs from an intervention unrelated to the disease in question. — life extending intervention excluding the gain in QALYs from an intervention unrelated to the disease in question (option B). life extending intervention excluding the gain in QALYs unrelated to the intervention in question (option A and C)

the survival curve. For example, for an exponential survival function the reduction in length of time is directly proportional to the increase in mortality if such treatments were not available [28]. Assuming that CHD mortality increased by 31 % in the absence of such treatments [25] and that medical treatments for other diseases make the same degree of contribution to overall survival, the related health gain would only be 69 % (100–31 %) of the actual health gain. While this example considers the contribution of unrelated care to gains in life expectancy, the contribution of unrelated care to quality of life also needs to be considered.

Calculation of related health gains is complicated by the presence of interrelationships between chronic conditions. For example, a study showed that the impact of selected chronic conditions on health-related quality of life was not additive but superadditive [29]. This implies that when determining related health gains for the treatment of a given disease and excluding unrelated health gains from the treatment of other conditions, related health gains may be smaller than suggested by condition-specific data.

We would like to note that a complete cost analysis, which includes unrelated costs and would be required when ignoring the ethical concerns mentioned, may also suffer from a separation problem. It lies in separating expenditures related to the disease or intervention from age-specific general health care expenditures in order to determine unrelated costs; otherwise double counting of related expenditures would occur. Yet, in an incremental analysis, some of the double-counted costs cancel out between comparators. In fact, double counting of costs may only lead to a small error because it is confined to the life-extension period.

5 Discussion

As stated, this paper took ethical concerns with regard to health-related life-extension costs as given. That is, the purpose of this paper was not to question these ethical concerns. Instead, we accepted those concerns and searched for a consistent way of accommodating them. For ethical concerns regarding the inclusion of unrelated costs we relied on a consistency principle published by van Baal et al. [23]. Yet, our consistency principle based on one of the most critical ethical concerns against CEA, the inclusion of life-extension costs in total, is original. Our proposal is to avoid a remaining ‘single penalty’ of life-prolonging interventions by excluding all downstream costs from the numerator as well as related health gains from the denominator of the ICER. From a utilitarian standpoint, this approach is not justified as it does not maximize health.

One may also object that the suggested consistency approach with the resulting (partial) elimination of costs and health gains denies the existence of scarce resources and cannot be described as a constrained optimization problem. Yet, this is not the case. For example, excluding downstream costs in order to remove a penalty for life-extending interventions does not mean that downstream costs are ignored. The reason is that these costs are intervention costs in unrelated areas. The same holds for unrelated health gains. At the same time, removing the penalty for life-extending interventions is equivalent to the situation where health gains from life-extending measures receive an additional weight compared to quality-of-life-improving interventions. Therefore, the approach suggested in the paper could still be accommodated within the scope of a constrained optimization problem considering all available resources plus the resulting (weighted) health gains.

For the other two ethical objections the situation is similar. Excluded disease-unrelated life-extension costs as well as disease-related background costs are not ignored but still considered when evaluating other interventions. The weight for life-extending measures then depends on how the ratio of excluded costs to excluded health gains compares with the ratio of retained costs to retained health gains. If the ratio is larger than one, related health gains from life-extension measures receive an additional weight, otherwise their weight is reduced. Again, using this weighting, we can still describe the allocation problem as a constrained optimization problem considering all available resources plus the resulting (weighted) health gains.

Clearly, with this (non-utilitarian) approach, availability of data to separate related from unrelated health gains becomes an issue and would require knowledge on the length and quality of life of patients without unrelated medical care during gained life-years [23]. While recently some data have been published and provide guidance on this issue [24–27], the separation of health gains will still be subject to large uncertainty. Yet, this may not be a reason to discard separation and instead one may incorporate uncertainty around separation into the model. A similar challenge of quantifying uncertainties was described with regard to future technologies [30] but this did not keep the authors from arguing in favor of the inclusion of future advances in CEA. In any case, a growing body of research will improve the availability of data both for the calculation of unrelated health gains and costs.

In summary, addressing ethical concerns regarding health-related life-extension costs requires a more comprehensive approach than a simple exclusion of some or all life-extension costs. Our analysis shows that some health benefits need to be removed from the calculation of the ICER. While our approach requires more information

about how health gains are divided between related and unrelated diseases/interventions, it requires less information on costs.

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