Objectives, Budgets, Thresholds, and Opportunity Costs—A Health Economics Approach: An ISPOR Special Task Force Report

Abstract

The fourth paper of our Special Task Force (STF) report focuses on a health plan or payer's technology adoption or reimbursement decision, given the array of technologies, based on their different values and costs. We discuss the role of budgets, thresholds, opportunity costs, and affordability in making decisions. First we discuss the use of budgets and thresholds in private and public health plans, their interdependence and connection to opportunity cost. Essentially, each payer should adopt a decision rule about what is good value for money given their budget; consistent use of a cost-per-QALY threshold will assure the maximum health gain for the budget. In the US, different public and private insurance programs could use different thresholds, reflecting the differing generosity of their budgets and implying different levels of access to technologies. In addition, different insurance plans could consider different additional elements to the QALY metric discussed elsewhere in our STF report. We then define affordability and discuss approaches to deal with it, including consideration of disinvestment and related adjustment costs, the impact of delaying new technologies, and comparative cost-effectiveness of technologies. Over time, the availability of new technologies may increase the amount that populations want to spend on health care. We then discuss potential modifiers to thresholds, including uncertainty about the evidence used in the decision-making process. This paper concludes by discussing the application of these concepts in the context of the pluralistic US health care system, as well as the "excess burden" of tax-financed public programs vs. private programs.

4.1 Introduction

Previous sections considered the elements of value at the individual and population level. In this section, we focus on a health plan or payer's technology adoption or reimbursement decision, given the array of technologies, with their different values and costs. Assuming a payer or population perspective, what are the objectives and constraints? We follow the Second Panel in recommending the cost-per-QALY gained (i.e., cost-effectiveness (CEA)) as the central measure for most of these decisions [1]. Our main focus here is on the use of thresholds, opportunity costs, and budgets in constraints in relation to decisions about technology adoption and reimbursement. We briefly discuss the incorporation of a broader range of elements of value, particularly those related to equity, and this is then discussed more extensively in Section 5 [2].

In Section 2, we noted that two microeconomic approaches—welfare economics and extra-welfarism—can each be used to justify a cost-per-QALY threshold for the inclusion of new technologies in the benefit package [3]. In a welfare-economics approach, the "budget" for each health plan is determined through market interactions of the buyers and sellers of health care insurance policies. The buyers seek to maximize their utility allocating their resources (including any subsidies) between insurance to cover health care in the event of illness and to protect against catastrophic financial or health loss, and other, non-health goods. In a typical extra-welfarist approach, the size of the health budget of a public payer is determined through a political process in which taxpayers allocate funds to health versus other services. Public payer health budgets tend to be fixed in the short run and the primary aim is to maximize population health gain, subject to other modifiers, such as equity considerations. In both private and public insurance contexts, the choices have opportunity costs—some in the short run and some in the long run—and short term decision making should take into account the longer term options and constraints.

In this section, we discuss the general application of these principles. However, as this Task Force is focusing on US value frameworks, we say more in Sections 4.5 and 4.6 about specific implementation in the US healthcare system, which is a pluralistic system with (a) some public programs that are expected to operate within fixed annual budgets and (b) many private plans that, to varying degrees, view their annual premium revenue as a target annual budget. Hence, although implementation in the US health care system raises some specific issues, there will be some commonality in implementation with single-payer public health insurance systems such as the UK and Canada where budgets are fixed.

Applying CEA for health sector decision making requires a decision rule. The most commonly recommended approach is for the decision maker to adopt an explicit or implicit "threshold" of cost-effectiveness representing the maximum level of cost-effectiveness deemed acceptable for technology adoption and reimbursement within a given plan. The rationale for this approach is that consistent use of a threshold assures that health gain is maximized for the covered population, given the payer's budget. For example, in England NICE has a threshold of £20,000 per QALY gained, with a range up to £30,000, but also up to £50,000 in the case of 'end-of-life' treatments. As discussed above, health sector decision making typically considers more than just cost-per-QALY. In this section we discuss the role of budgets, thresholds, opportunity costs, and affordability in making decisions. Section 4.2 discusses the role of budgets and thresholds in private and public health plans, their interdependence and connection to opportunity cost. Section 4.3 defines affordability and discusses approaches to deal with it. Section 4.4 discusses potential modifiers to thresholds, including uncertainty about the evidence used in the decision-making process. Section 4.5 discusses application of these concepts in the context of the pluralistic US health care system, and Section 4.6 discusses "excess burden" (extra implicit costs) of tax-financed public programs vs. private programs. The next section of the report, Section 5, discusses how a larger set of value elements might be weighted and aggregated into a more comprehensive, augmented CEA and how these elements could be considered as part of a structured deliberation, for example, using a form of MCDA.

4.2 The Relationship among Budget Constraints, Thresholds, and Opportunity Costs

The approach for determining the budget and threshold for a given year (or whatever the decision period) depends on the context. The most straightforward case is a jurisdiction operating its health care system efficiently with a firm budget constraint on one or more parts of the health system that is fixed in the short run. In this context, the most appropriate short-run approach to defining the threshold is the opportunity cost of displacing existing covered technologies, since if a technology with a cost-per-QALY gained higher than the threshold were to be adopted, there would be a net loss in total health within the budget period [4]. In the longer run, evidence on individuals' willingness to pay for improved health would be relevant, to inform the discussion of whether the budget for health care should be changed over time. In this context, the forgone benefit of cutting back on non-health goods and services is the opportunity cost of increasing the budget for health or raising the threshold. Important to note is that the threshold, the budget, and the measure of health gain cannot be set independently of one another.

If novel elements of value are added to the QALY measure of health gain, with no change in the budget, the threshold would need to be reduced because the average measured benefit of technologies would increase. Although it might seem that using such an expanded QALY measure of health gain would argue for increasing the health budget, because certain indirect benefits of health technologies have been recognized, it is important to consider whether some of these types

of attributes also apply to non-health spending. Investing in housing and education, for example, can create option value and can bring additional value to risk-averse people. Consideration of other attributes to augment the health QALY measure may require expanding the measure of the opportunity cost of health spending. The impact on consumer or taxpayer preferences about health budgets is uncertain *a priori.* There may also be a dynamic aspect to consider. If the budget and/or the threshold is expected to change significantly over time, then some account needs to be taken of the long-term cost-effectiveness of a technology to ensure health and related benefits are maximized over time. Furthermore, over time, as incomes rise, and/or technological change occurs in health care, and/or non-health opportunity sets change, consumers' willingness to pay for health and related benefits, and consequently the size of health budgets and threshold levels will change, as discussed below.

In a US private market context where private plans (both employer-sponsored and not) compete by offering different levels of coverage, more generous coverage implies a higher threshold and a higher premium and budget. Thus the threshold could be a convenient summary of coverage generosity that could be informative for consumers seeking to choose between plans. In this private market context, enrollees' willingness to pay (WTP) premiums would reflect the WTP for health gain (and other health-related attributes) and define the payer's budget for the year. In theory, market sorting would result in consumers (or employees) enrolling into plans that best match their preferences and WTP for health. In practice, such sorting may be imperfect due to adverse selection risk, fixed costs of operating plans, and social preferences (e.g., as mandated or imposed by Federal or State government) for some minimum level of coverage for all.

For public plans, the budget may be fixed in the short run but in the longer can be changed by Congress. The threshold could be a way of eliciting taxpayers' WTP for different levels of tax funding or health care budgets that enable different levels of coverage generosity. As noted earlier, in the short run (within a budget period), the threshold could reflect the value (i.e., opportunity cost) of the marginal technology displaced if a new technology were to be adopted in the context of a fixed budget: this is, in technical terms, the "shadow price" of the relevant budget constraint in the jurisdiction concerned. It is a measure of the health gain forgone if an established technology is displaced. In the longer run, use of either a WTP or an opportunity-cost approach should yield the same threshold if the system has been implemented to perfectly match population preferences, income, and other determinants of taxpayer/beneficiaries' WTP for health within this public program. An expansion of the set of available technologies may change the opportunity cost in the short run, as discussed below in Section 4.3 on Affordability.

It is sometimes suggested that the health budget and/or threshold be set in some relation to the GDP per capita in the jurisdiction concerned, reflecting the evidence that richer countries typically devote more of their wealth to health care, or reflecting an aspiration of the amount that countries should spend on health care [5]. This GDP-based approach may be a useful rough guideline for broad comparisons across countries. However, actual decisions in individual countries reflect citizens' WTP for health for themselves and others, which depends on many factors besides income, including tastes, politics, and the efficiency of tax-financed spending.

In a setting where health budgets can be easily increased, the approach for determining the threshold is more complex, especially in situations where there is considerable patient copayment with no stop-loss on patient cost-sharing and where payers may stipulate limits on coverage for certain services. In theory, information on enrollees'/taxpayers' WTP is relevant since one option when considering whether or not to adopt a technology would be to consider immediately increasing the budget for health care, by raising insurance premiums and/or patient copayments. An opportunity cost of adopting a new technology still exists, but instead of falling in the health care

sector, it would fall on other private consumption or on non-health public services or on future generations through public budget deficits, depending on how the funds to pay for the new technology are ultimately raised. Such a context is potentially problematic if the interests of those parties who end up bearing at least part of the cost are ignored in the decision making with regard to setting (or ignoring) thresholds and spending constraints, as occurs if budgets are poorly defined.

4.3 Affordability

Whether we are examining (i) individuals' budget constraints for purchasing treatments or third-party insurance, or (ii) third-party (whether private, social, or tax-based) insurers' budget constraints, plan members in practice choose to place a rough limit or budget on their spending on medical care during a given year. This reflects their preferences for medical care vs. other non-health goods and services, which may of course change as the range of health and non-health technologies changes over time. The budget is expressed in the premiums they are willing to pay for private insurance or the taxes they are willing to pay for public or social insurance in a given year. The budget may in part depend on the ability or cost to the individual or third-party payer of borrowing across time periods and, in the case of public payers, any intergenerational implications of unfunded liabilities.

As discussed in 4.2, in theory the payer's healthcare budget, WTP threshold, and services reimbursed are simultaneously determined and are adjusted over time, as changes occur in consumer incomes, in health technologies, and in non-health consumption opportunities. Most new value-creating medical technologies can be accommodated by the displacement of older, inferior technologies and/or by growth of health budgets with income. However, some new services may meet the cost-effectiveness threshold but have a sufficiently large budget impact that they raise issues of affordability.

Formally, we define "affordability" as being relevant if paying for all patients potentially eligible for a new treatment would force either an overrun of the payer's planned budget or displacement of other treatments regarded as being cost-effective. (This discussion thus does not address cases where "affordability" is primarily a strategic argument in negotiations between payers and providers over price.) Such "unaffordability" is most likely to occur if a new drug or drug class is highly effective such that it can justify a relatively high value-based price and also affects a large patient population. Recently, affordability has, for example, been a concern for drugs to treat hepatitis C. It has also be raised as a potential concern for cardiovascular disease or Alzheimer's disease, and could also be a concern if a large number of high-priced orphan drugs came to market in quick succession, as could occur given the current pipeline of compounds with orphan status targeting cancer.

If the payer's budget is fixed in the short run, being spent efficiently, and, by assumption, cannot accommodate all existing services and the new service meets the current threshold, then in principle the threshold should be adjusted: this is sometimes called an "infra-marginal adjustment." This would call for elimination of those treatments that are no longer cost-effective at the new, lower threshold. (Of course, if lower prices can be negotiated with suppliers of these services, this would mitigate the need for quantity adjustments.) However, an important consideration may be the adjustment costs of disinvesting and switching resources into new uses, which could include changing protocols, withdrawing services, or switching patients to alternative regimens, which may entail budget, time, and health adjustment costs.

The optimal short-run adjustment would thus weigh the benefits and costs, including adjustment costs, of either discontinuing some existing treatments or deferring the treatment of some patients with the new drug. In practice, such budget challenges can often be handled at the margin by

stratifying patients eligible for the new drug, focusing immediate treatment on those at significant risk of disease progression, while deferring treatment of those at early stages and at low risk of disease progression in the short run. Such delay in treating diseases that progress slowly may incur minimal health loss or adjustment costs, compared to the alternative of discontinuing other, existing treatments that meet the cost-effectiveness threshold but whose treatment interruption would incur significant adjustment costs. Delay in treating early-stage patients with the new technology also allows time for the entry of alternative, competing technologies, which may offer additional benefits and/or compete on price (as occurred recently with new hepatitis C medicines). In the long run, new technologies that meet cost-effectiveness thresholds are optimally absorbed by some combination of: expansion of budgets if necessary (but note that some "curative" technologies that create budget pressure in the short run, such as hepatitis C treatment, may reduce long term expenditures); possible threshold adjustment; and/or discontinuance of existing treatments that are rendered less cost-effective by the launch of superior new technologies.

Because affordability can cause significant adjustment and other costs, some payers estimate the expected budget impact of a new technology, along with its value, as part of the coverage decision process. Estimating and planning for budget impact can be prudent and can facilitate some of the adjustments to minimize disruptions mentioned above, such as staging the adoption of a new technology with a large potential budget impact. However, we do not recommend considering budget impact as an integral part of value assessment itself or structuring/requiring an automatic discount linked to budget impact, or introducing an inverse relationship between value and budget impact. Even if the potential level of investment requires considering an infra-marginal adjustment of the threshold, such an adjustment in the threshold should be considered separately, not as an integral part of value assessment. Although it might seem logical that a lower threshold should be used for drugs to treat very large populations, such an inverse relationship between threshold (and implicitly, reimbursed price) and target population would make sense only if WTP thresholds were designed mainly to pay for R&D and R&D costs were invariant across drugs. However, in general we have argued that thresholds should reflect value and WTP of consumers, not costs to producers. Whether producers can develop drugs that meet payer and consumer WTP thresholds is a matter for them. This argues against structuring an inverse relation between thresholds and budget impact.

4.4 Potential Threshold and Decision Modifiers

Even in cases where decision makers operate with an explicit threshold, a deliberative process (see Section 5) is typically followed, in which other modifying factors may be applied [2]. Many of these factors mirror the elements of value discussed in Section 3 [6]. The objective is not to maximize health alone, but to consider other health-related elements of value and to consider who might be getting the health gain. For example, as mentioned above, NICE operates with an end-of-life criterion, whereby the expert committee can increase the value of the QALYs gained, hence raising the effective threshold for adoption of the technology to £50,000 per QALY in order to reflect society's view that, in some circumstances, health gain at the end of life is worth more to individuals than at other points in their lives [7]. The Scottish Medicines Consortium identifies several 'modifiers' that may justify accepting a higher cost per QALY gained [8]. These include, but are not limited to, evidence of a substantial improvement in life expectancy or quality of life (reflecting possible 'step-change' innovations), evidence that the medicine can be targeted at a sub-group of patients that may derive specific or extra benefit (possibly reflecting severity of disease), absence of other therapeutic options of proven benefit (e.g., at end of life), or possible bridging to another definitive therapy (possibly reflecting 'real option value' and 'value of hope').

Evidentiary Uncertainty as a Modifier

When assessing a new medical technology, decision makers struggle with uncertainty and with how much evidence to collect. Evidence collection costs money and takes time, during which a medicine may not be given to patients, some of whom could benefit, while others may avoid risks. Thus, in general, additional evidence should only be sought as part of a value assessment if the expected benefit of evidence collection, in terms of the value of reduced uncertainty, exceeds the costs.

It is important to separate whether decision makers are concerned about uncertainty because: (i) it means the health system may adopt a technology that turns out to be poor value for money on average, or alternatively, not adopt one that looked to be poor value for money but actually provided a lot of benefit at a cost-effective price; or (ii) there is real risk to health, that some patients may have been harmed by being treated. These are both valid but have different implications for value assessment. In relation to achieving value for money, we might expect decision makers to be risk neutral, and look for a positive expected net benefit over cost, taking account of the threshold. In relation to uncertainty about the incremental health effect (including any downside risks to health from adverse events), however, decision makers may then be expected to be risk-averse on behalf of patients. Hence, the common use of a p-value of 0.05 for evidence of expected positive health effect, rather than a much higher p-value of 0.5 which is implicit in our assumption of risk neutrality in payer assessment of value for money. Thus, payers (and HTA bodies operating as their agents) typically use a two-stage approach, using one hurdle for evidence of clinical benefit and another for evidence of value for money.

In the context of the value-for-money assessment, the issue of a price adjustment for uncertainty arises. Any price adjustment for uncertainty in a value assessment should meet the requirement that, in the absence of the price adjustment, the expected benefit of evidence collection (in terms of the value of reduced uncertainty) must exceed the costs. Thus, if uncertainty cannot be reduced at an acceptable cost, it becomes irrelevant to value-for-money decision making. If uncertainty can be reduced by further evidence collection or simply the passage of time, then the decision maker could require evidence collection or make the price contingent on the actual outcomes observed over time. The appropriate decision will depend on the institutional context and on costs of administering such contingent contracts [9].

We note that there may be separate issues of uncertainty about the budget constraint, optimal threshold, and/or opportunity cost estimate that should be used in decision making. So we have, in principle, uncertainty about our estimate of the incremental effectiveness and value of the technology *and* uncertainty around our estimate of our value for money or budget hurdle. This second issue has begun to be discussed in the literature, but we do not pursue it here [10-12].

4.5 Application in the US

In this section, we further elaborate on how these concepts might be applied in the US which is a pluralistic health care system with multiple private and public health plans. Different health plans could choose different thresholds, reflecting the differing WTP of their enrollees and, to the extent that the plan benefits from tax-financing, the WTP of taxpayers. Payers—both private and public—are thus agents for their enrollees or taxpayers. In making coverage decisions, a payer perspective is used, which reflects the average preferences of their enrollees/taxpayers. The individual patient perspective becomes relevant for patients and their doctors when making choices between covered technologies or treatment options.

Private sector employer-sponsored plans. These plans can in theory freely choose their threshold WTP and implied premium cost as elements of competitive plan design. The threshold and premium in theory depend on the WTP for health (relative to other goods) of their employees. But the fact

that workforce composition can change over time (and sometimes is purposely changed by owners by altering the type of benefits) makes these relationships difficult to measure in practice. However, because the open-ended tax subsidy means that part of cost of choosing a more generous threshold is shifted to taxpayers, either a cap on the tax exclusion or a tax on insured health expenditures that exceed some threshold is appropriate.

In the treatment decisions of individual patients, plan administrators, and providers should take into account individual patient preferences among alternative technologies that meet the collectively-determined threshold. If a patient wants a technology that does not meet the plan threshold, it would not be reimbursed. He or she could pay wholly out of pocket—but is unlikely to do so unless the patient's WTP is greater than the threshold. A variation of this would be for the threshold value to be paid for by the plan with the balance required to be paid for by the patient, i.e., "balance billing."

Medicaid and other fully tax-subsidized programs. We assume that such programs are funded by Federal and State taxpayers out of altruistic and equity concerns of taxpayers for program recipients. Taxpayer equity concerns may also include a Rawlsian approach as to what provision for the most disadvantaged people (in terms of both health needs and income) they would want to have provided. If so, program budgets reflect taxpayers' WTP for such programs and to pay higher taxes for better health outcomes for people on low incomes or otherwise disadvantaged in access to health care. Thresholds are defined by opportunity cost of resource use within the program. In treatment decisions of individual patients, their preferences among approved treatment options should be taken into account.

***Medicare*.** Medicare is a hybrid that is financed largely by current taxpayers, with some contributions from current beneficiaries (current payments for Parts B and D and past contributions to Part A), and some shifting of unfunded liabilities to undefined future taxpayers. In theory, the budget and threshold should reflect some average of the WTP of taxpayers and beneficiaries. In treatment decisions of individual patients, the patient's preferences between technologies that meet the threshold should be taken into account.

4.6 The Excess Burden of Tax-Financed Public Spending

When taxpayers provide much of the funding for a public insurance program that pays for a new technology, the full societal opportunity cost of raising that funding should ideally be taken into account, along with any benefits of using the public rather than the private sector. To date, conventional CEA of new medical technologies has not addressed this issue raised in public finance economics. One generally accepted conclusion from public finance is that all tax bases except for lump sum taxes generate "excess burden", which is also called "deadweight loss" (DWL). Excess burden refers to the distortion that arises as an individual is discouraged from an efficient activity that would also increase his or her share of the tax base. Thus, a worker may be discouraged from working additional hours or switching to a better paid but higher productivity job, an investor may be discouraged from a profitable investment, and everyone is encouraged to hire more tax accountants. The reason why behavior is changed is because it is behavior that would otherwise increase the person's share of the tax base and hence of taxes. The assumption is that, even if the person attaches a very high value to the public activity that would be financed with the taxes, unless the person controls a very large share of the base he or she would ordinarily think that the amount of the public good in question would be unchanged by an individual decision. Rather than increase one's share of the taxes to finance some praiseworthy public activity but with no appreciable change in the amount of that activity, the person may decide to forgo the efficient choice. If all taxpayers try to reduce their shares at the expense of others, all cut back and all lose.

The size of the excess burden depends on the elasticity of response of the taxed activity to a tax. It is higher for tax bases that are more easily altered (like investment in or purchase of specific commodities like sugary drinks). Empirical estimates of the burden as a percentage of funds collected range from 20 to 60% (but are almost never negligible [13]. There have been some calculations made of the excess burden of financing medical care in the US, along with the conjecture that smaller programs will be chosen if the tax base has higher elasticity (like the income tax compared to the payroll tax) [14].

Assuming a significant excess burden of taxes to fund health care, in theory we may need to consider whether the threshold for public spending should be adjusted upward to reflect excess burden. However, such an adjustment is not appropriate if there are different but offsetting distortions in providing private insurance, as discussed next.

The usual assumption is that there is no excess burden for privately financed care, though if an employer imposed more of the cost of a group insurance benefit on workers as their earnings rose there would be a distortion compared to a situation where each worker's wage is reduced by a lump sum amount to finance the employer premium share. The employee's explicit premium share is rarely tied to wages (although occasionally it is) so any excess burden from this source would be rare.

However, because employer plans reflect collective choices and each employer can only offer a limited number of plans (due to tax, fixed costs and adverse selection concerns), the employer plan(s) on offer to individual employees may diverge significantly from each employee's preferred plan. This divergence between their cost (in terms of forgone wages plus employee premium contribution) and their perceived value of the plan acts like a "tax" on purchasing employer-sponsored private insurance that should in theory be considered, analogous to the excess burden on public insurance. On the other hand, to the extent that the collective choice of employer plans operates to reduce adverse selection risk, this is a mitigating factor.

Further, in the case of publicly funded programs like Medicare and Medicaid, it could be argued that these were established as public programs specifically because taxpayers wanted to provide health care for the elderly and poor, and deemed that such coverage could be provided more cheaply and equitably by the government than by the private sector (due to adverse selection in private provision and free riding in voluntary financing of such programs). If so, they may rationally not view the taxes paid to support these programs as a DWL. Even if each taxpayer thinks their own contribution is negligibly small, everyone knows that free riding would undermine voluntary altruism, and that overcoming this effect is a benefit of using the tax system.

These considerations suggest at a minimum that different taxpayers may have different views of the DWL and the value of paying taxes to fund public health programs. Similarly, employees may have different views of the value to them of paying for employer-sponsored private insurance. Given the many unknowns, on balance at this stage, it is unclear what adjustments for distortions, if any, are appropriate for setting thresholds for public or for private insurance.

4.7 Conclusion

We have several clear recommendations based on the discussion in this section. Each payer should adopt a decision rule about what is good value for money given their budget. Consistent use of a cost-per-QALY threshold will assure the maximum health gain for the budget. In the US, different public and private insurance programs could use different thresholds, reflecting the differing

generosity of their budgets and implying different levels of access to technologies. In addition, different insurance plans could consider different additional elements to the QALY metric discussed above and in Section 5. Issues related to the affordability of healthcare technology are most efficiently addressed by considering both (a) the adjustment costs of reducing spending on, or replacing, existing technologies, (b) the impact of delaying or staging implementation of new technologies, and (c) the cost-effectiveness ratios of new and existing technologies. Over time, the availability of new technologies may increase the amount that populations want to spend on health care. Fundamentally, budgets and thresholds must continually be brought into alignment. Thus, as payers consider adding coverage of new technologies or new elements to the measure of benefits, implications for budgets and/or thresholds must simultaneously be considered in order to bring opportunity costs, thresholds, and health expenditures into alignment.

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