

**Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: A  
Report of the ISPOR Drug Cost Task Force – Part II: A Societal Perspective**

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## 1. Introduction

Over ten years have elapsed since the U.S. Public Health Service Panel on Cost-Effectiveness in Health and Medicine (PCEHM) issued its definitive recommendations on the state-of-the-art in cost-effectiveness analysis (CEA). To improve comparability and consistency, they recommended that all studies include, at a minimum, a “reference case” analysis that follows a set of uniform principles and methods. Core to this reference case is the adoption of a “societal perspective.” It is not as easy as one might think to find a concise definition of this societal perspective in subsequent literature. Perhaps the clearest definition still comes from the PCEHM volume itself (page 61):

“...the comprehensive societal viewpoint has important methodological ramifications. It means that all costs and all effects should be incorporated no matter who pays the costs or who receives the effects. . . . It means that all types of resources of value to society should be included; thus, patient’s time costs (lost work time, lost leisure time) are counted . . . . It means that opportunity costs are the appropriate method of valuation . . . , and it means that the general public is the appropriate source of preferences for health outcomes . . . .”

In practice, very few, if any, CEAs published since the report have met all of these standards, though many claim to have taken a societal perspective. Generally, claiming to take a societal perspective has meant that some attempt has been made to account for indirect costs related to productivity losses. Very few studies have attempted to estimate true opportunity costs of resources, using instead market prices. Assuming that market prices reflect opportunity costs is a reasonable assumption for many resources (such as physician visits or hospital stays). However, when it comes to measuring the opportunity cost of patented drugs, the difference between price and true opportunity cost may be the greatest among all of the factors typically included in a CEA.

Any reader of the empirical literature of the past ten years knows that the pharmaceutical prices used in the vast majority of CEAs are either average wholesale prices (AWPs) in the U.S., or government-negotiated prices in Europe. The former are not only imperfect measures of actual prices paid (e.g., ignoring discounts and rebates), but may also greatly social opportunity costs because of the implicit inclusion of producer surplus created through patent-protected monopoly pricing. The latter may or may not bear any relationship to true opportunity costs.

This raises three questions that we discuss below:

- How is the “society” in “societal” defined? Conceptually? Nationally? Globally?
- What is the role of CEA from a societal perspective?
- If the field of pharmacoeconomics is going to take the reference case recommendation for a “societal” perspective seriously, how should this be implemented?

For purposes of this discussion, we adopt the PCEHM definition of societal perspective, briefly, meeting three key conditions:

1. Productivity gains and losses (i.e., indirect or time costs) are included.

2. Costs are measured by opportunity costs.
3. Community preferences are used for the utility of health states.

Since our focus here is on costs, we will consider only the first two of these.

## **2. Origins and Use of the Term “Societal Perspective”**

To our knowledge, no one has yet prepared a history of the term and concept of “societal perspective.” Indeed, it may well have arisen in the fields of health technology assessment, outcomes research, and/or pharmacoeconomics, and its use may be largely confined to these fields.

Skimming several old, classic texts on cost-benefit analysis does not yield any matches to this term. In classical economics and public finance, and especially in environmental economics, the distinction is between “private” and “social” costs and benefits.

One might hypothesize that “societal” is a variant of term “social” that was coined in economic evaluations of health technologies. Perhaps the issue arose because it was clear that one had a choice of conducting evaluations from the payer or government perspectives, especially if they are not one and the same. Or perhaps given the high proportion of interdisciplinary social science research in the health services field, use of the term “social” is too ambiguous. A full search and history of the term would be interesting, but is beyond the scope of this review.

It is also interesting, however, that the term is not always used consistently or pervasively in textbooks. A search of the medical literature turns up few methodological discussions of this issue. The ISPOR Book of Terms does not have a distinct entry about “perspective” or a definition of the societal perspective: lost productivity is mentioned as an indirect cost (p. 5); opportunity cost is defined (p.52-3); and “aggregate societal comparison of welfare” is mentioned under welfare economics. Even the well-known Drummond et al. (2005) standard reference methods handbook does not define or discuss the societal perspective. On page 9, they say that: “Analytic viewpoints may include any or all of . . . the community or societal viewpoint(s).” On page 18, their Analyst C says one should take “a broad societal perspective.” They later go on to say:

“In short, we believe that economic evaluations in health care should, where feasible, consider the societal viewpoint, although on occasions analytical difficulties will preclude full measurement and valuation of all costs and consequences in monetary terms.” (p. 87)

It is interesting that they more frequently use the word “viewpoint” rather than “perspective,” and nowhere do they specifically discuss estimating the opportunity cost of drugs rather than using market prices.

The PCEHM discussion in relation to this may still be the most insightful and comprehensive, where Luce et al. discuss “R&D costs and other first copy costs.” They say:

“Strictly speaking, R&D costs should be included if the decision addresses whether to provide the intervention at all. That is, if the intervention is not already in existence, the appropriate long-term perspective includes the expected R&D, production, distribution, and provision costs.” (p. 195)

But if it is already developed and in use, they would recommend the exclusion of R&D costs. And they recognize that:

“In the case of pharmaceuticals, the marginal costs of production and distribution of a drug are often significantly less than the market price, especially during the period of patent protection. . . .” (p. 195)

In the end they make a pragmatic argument that it would be very costly to estimate this, that drug classes need to “break even,” and that prevailing transaction prices (e.g., average wholesale price) are a “serviceable way to value consumption of drugs.” (p. 195)

### **3. An Economic Perspective on the “Societal Perspective”**

There are clearly two strains of thinking about the fundamental basis in economic theory for the types of CEAs done in pharmacoeconomics: 1) motivation from welfare economics and utilitarianism {Garber and Phelps((1997), McGuire (2001)], and 2) the extra-welfarist approach. The difference between the two is elusive, but according to the ISPOR Book of Terms, it is that the latter maximizes health gain while the former attempts to maximize welfare more broadly construed.

Another distinction that may be helpful in this context is between positive and normative economics. Positive economics is descriptive and aims to explain, predict, and understand, whereas normative economics is prescriptive and aims to determine what should be done.

It seems clear that the societal perspective is clearly a normative one. However, one can reasonably ask: does anyone take this perspective in practice? For example, even a national-level payer like NICE in the UK claims to primarily take a payer perspective. A market-oriented economist might well argue that a well-functioning free market would approximate the outcome of the societal perspective. Then what is the social value of doing these analyses? At least, two arguments come to mind. First, from the perspective of a system like the UK, one might argue that decision-makers should at least understand how far their payer-oriented decisions might depart from a social optimum. Second, the health marketplace in the U.S.—and indeed in most national markets—is so rife with pricing distortions due to taxes, insurance subsidies, occupational cartels etc., an outside standard is needed to think about public policy reforms.

But what use is an analysis from a societal perspective in such a distorted system? The answer could be it gives clinical and public policy decision-makers a standard that attempts to abstract from these distortions, by measuring opportunity costs. Thus, as the “right way to do things”, clinical guidelines, for example, can create independent pressure as a practice standard, social norm, or even legal norm that can counter-balance the incentives for payers, physicians, and patients to pursue their own narrow ends in a distorted marketplace.

The preceding discussion does not apply only to drug utilization or to drug prices: all factors of production including physician and hospital care are affected by the distortions

inherent in this “second-best” world. For our purposes here, however, we focus on the difference between drug prices and long-term marginal social cost.

#### 4. Drug Cost from a Societal Perspective

Following the PCEHM, it is clear that the estimate of drug cost in the reference case societal perspective should not be based on price or acquisition cost, but instead, should be based only on the marginal cost of producing and distributing the drug. There are two arguments for this position. The first is based on the classic observation from microeconomic theory that producer surplus, the cumulative difference between price and marginal cost, is a gain for society, not a loss [Landsberg (1989), McCloskey (1985)]. The second is based on the recommendation that transfer payments be excluded from societal cost estimates of health-related interventions.

##### *Producer Surplus – A Gain in Societal Welfare*

Figure 1 illustrates an example of the gains from trade that are attained in a market where the equilibrium price exceeds the marginal societal cost (MSC) of production and distribution. (For simplicity, this figure assumes a constant MSC and ignores the impact of taxes). One would expect this price-to-MSC relationship to apply to patent-protected pharmaceuticals, regardless of whether the manufacturer is acting as a monopolist or is competing in the context of a differentiated products oligopoly.

The triangular region at the top of Figure 1 represents “Consumer Surplus” (CS), which can be thought of as the cumulative difference between the value of the product to each consumer and the price that the consumer must pay to acquire it. Given that we are assuming a societal perspective, consumer surplus in this case represents the cumulative difference between the marginal societal benefit (MSB) of the product and its equilibrium price (which we assume equals the total acquisition cost, net of discounts and rebates). Note that for pharmaceuticals, MSB is the sum of all marginal benefits enjoyed by all affected parties, such as the patient, his/her family, and his/her employer.

Another gain in societal welfare generated by the purchase and utilization of this medicine is reflected in the rectangular region at the bottom of the figure. This represents “Producer Surplus” (PS), which can be thought of as the cumulative difference between the equilibrium price of the product (i.e., sales revenue per unit), and the marginal societal cost (MSC) of producing and distributing it. The total gains from trade--the overall increase in societal welfare from the production, distribution, & consumption of this product--are equal to the cumulative difference between the product’s MSB and MSC. This is simply the sum of consumer and producer surplus (CS+PS).

These gains from trade apply to pharmaceuticals just as they do to other products. Yet, for some reason, the concept of producer surplus and the gain it represents for society are largely ignored when pharmaceutical interventions are evaluated. We say that because there is little, if any, differentiation made between the price or acquisition cost of a medicine and its marginal cost of production and distribution. Typically, the per unit cost of a pharmaceutical to society is assumed to be greater than or equal to its equilibrium price (i.e., final acquisition cost, net of discounts and rebates). However, that equilibrium price would not be expected to equal marginal cost in markets for patented pharmaceuticals. Hence, when a societal economic evaluation is done using price or

acquisition cost rather than marginal cost, that analysis is implicitly assuming that producer surplus is a loss to society--a notion that is inconsistent with conventional microeconomic theory.

### *Excluding Transfer Payments from Societal Economic Evaluations*

For economists, the fact that producer surplus is a gain for society may be a relatively straightforward argument for why price or acquisition cost is not a good estimate of the marginal cost of a drug to society. However, this argument may be less clear and/or less convincing for non-economists. For that reason, we present a second argument based on the exclusion of transfer payments in economic evaluations done from the societal perspective.

As others have pointed out, transfer payments should not be included as a cost in a societal economic evaluation. Consider what Luce, Manning, Siegel, and Lipscomb wrote in the PCEHM volume on doing cost-effectiveness analyses of health interventions:

“Income transfers, involving the redistribution of money, are not real costs to society and should not be included in the cost-effectiveness ratio. The exchange of money per se does not necessarily indicate that resources have been consumed. ....We do encourage analysts to track and report transfers when they are significant, because redistributive effects of interventions are often of concern to the audience of a CEA. When describing transfer costs, it is important to emphasize that they should not be added to the real societal resource costs in the analysis.” (pp.183-40)

This quote is consistent with our reasoning, as well as the well-accepted third postulate for applied welfare economics proposed by Harberger in his classic 1971 essay on the subject:

“When evaluating the net benefits or costs of a given action (project, program, or policy), the costs and benefits accruing to each member of the relevant group (e.g., nation) should normally be added without regard to the individual(s) to whom they accrue.”

Nevertheless, when it comes to the evaluation of pharmaceuticals, many analysts fail to recognize that much of the “cost” of medicines reflects transfers among different members of society.

As alluded to in the Luce et al. quote above, keeping track of the distributional effects of these transfers may be useful, insofar as they are important to the users of the economic evaluation. For example, some may argue that the additional profits ensuing from patent protection leads to inequities across industries, as transfers are made from companies with relatively low profit margins to companies with relatively high profit margins. Others, however, might argue that the relatively high transfers to pharmaceutical companies during the patent protection period is necessary to induce investment in a high-risk enterprise involving the discovery and development of new medicines (which ultimately become available cheaply once the patent runs out). Regardless, when the societal perspective is being adopted within an economic evaluation, these transfers should not be included as costs.

Mansley and Abbott (2005) have, for example, illustrated how one could estimate this short-run marginal cost for drugs and have argued that the marginal societal cost is on the order of 40-60% of total acquisition cost. Thus, the vast majority of CEAs to date have mostly likely overestimated the costs and cost-effectiveness ratios of new drugs.

## **5. Long-Term vs. Short-Term Societal Perspective**

The preceding discussion raises the question of how to handle the supra-normal profits that accompany the most successful patented drugs. Philipson and Jena (2006) argue, for example, that drug manufacturers of AIDS drugs have been able to capture as producer surplus only a small share (5%) of the total surplus created by their innovative products. Since we would assume that investment will be a function of these rewards, it is clear that this innovation reward system, based on patents to create intellectual property and on reimbursement only roughly commensurate with health value-added, could have a profound impact on the level of global R&D and ultimately innovation.

For a given product on the market, the sunk costs of R&D have been borne, and the societal perspective is therefore short-term, and a CEA from a societal perspective should use the short-run marginal costs. But Philipson and Jena would argue that this is really looking only at “static efficiency” and not “dynamic efficiency”, considering the cost and returns to R&D.

Drug prices in a world with time-limited patents represent not just costs but also rewards to innovation. If one is taking a “societal perspective,” why wouldn’t one want to consider the implications for the resources devoted to R&D?

It is reasonable to expect that in market systems as well as with centralized government purchasing, payers and patients are going to take prices as given and try to optimize health or welfare given their budgets. A CEA publication presenting a reference case analysis from a proper societal perspective is going to be of limited utility to them. Indeed, an “improper” one using AWP may be of more relevance to most payers. A properly done reference case will only come into play if it influences clinical guidelines or standards of care, and thereby forces payers to consider that factor in their decision-making.

Imagine that the US had a well-functioning, market-based health insurance system (e.g., Enthoven’s (1978) managed competition or the voucher system of Emanuel-Fuchs (2005)). In other words, suppose everyone were covered by insurance and the health care markets really worked. Payers operating from the payer perspective would then provide good signals to companies on what drugs are really worth. Why would anyone need to do analysis from a “societal perspective”? Isn’t it only done because we think it can be used to correct some market failure? But what would be the failure? Some might argue that the patent system creates that failure.

Thus, the reference case societal perspective might also be seen as corrective to the welfare loss associated with monopoly pricing. By forcing a standard that is not based on market price, coverage decisions would provide access to more patients. This could push quantity consumed higher toward to the competitive equilibrium level. It would, however, mean more profits.

Should analysts taking a societal perspective have to deal with the question of dynamic (i.e., long-term) efficiency? For example, given that the sunk costs of R&D have been borne, it seems that the correct societal analysis would ignore them. However, for a situation in which the central government is deciding coverage and price (e.g., as in Australia), it would seem that the government should give some thought to the incentives for R&D and long-term implications for the future improvement in health of the members of the society through biomedical innovation.

Although it is beyond the scope of the discussion here, a question arises about the usefulness of the societal perspective in a system with the severe “distortions” to drug prices from the patent and insurance systems. These distortions ultimately affect the size and shape of aggregate investment and innovation in pharmaceuticals.

Perhaps raised by the issue of AIDS drugs in Africa and Brazil, increasing globalization has made it clear than drug R&D has long-term implications for the health and well-being of all citizens of the world. We have to question whether the current patent system produces the optimal amount of global R&D. Kremer (1998), Hay (2006), and others have discussed the option of patent buy-out or prizes based on value delivered as an alternative mechanism to promote greater dynamic efficiency.

## **6. National vs. Global Societal Perspective.**

Throughout this discussion, we have not specifically stated whether “society” refers to the entire world, or to an individual country that includes the patients of interest and all of the parties involved in the manufacture and distribution of the drug. Consider an alternative situation where, for example, the manufacturer of the drug is outside of one’s definition of “society” (e.g., outside of the country of interest): then, the consideration of producer surplus and transfer payments becomes much more complex.

For example, consider a situation where “society” is defined to be Country X, and an analyst is evaluating the cost-effectiveness of a medicine that is used in Country X but produced in Country Y. In this case, the transfers referred to above may be small. Although some tax revenues may still go to governments in Country X and some transfer payments may go to international investors living in Country X, the bulk of the transfer payments are likely to go to Country Y, which is considered outside of the “society” of interest. Note that this issue forces one to consider more carefully what they mean by “societal perspective,” something that is not altogether clear in published guidelines for economic evaluations in healthcare.

The opportunity costs of other inputs and drugs, productivity impacts, and patient preferences will vary across countries, so it is clear that CEAs done from a national societal perspective would yield different recommendations in different countries.

A global societal perspective would seem to make more sense when one is considering the costs of R&D. One reason that a global long-term societal perspective might be ideal for R&D, is that—with price discrimination (i.e., differential pricing) across countries—we would be better able to capture the global willingness to pay for biomedical innovation. This would cut down on free-riding due to the public good nature of information, and with more knowledge generated, we would all be better off.

For example, a global patent buy-out or prize system might seem to make some sense in this context; however, given the effort that has gone into expanding “free trade” and the patent system under the World Trade Organization, it seems unlikely that global prizes (except for neglected diseases) are anywhere in the offing. Nonetheless, it may be desirable to reform local country pricing and reimbursement systems to reward value and innovation more consistently and transparently.

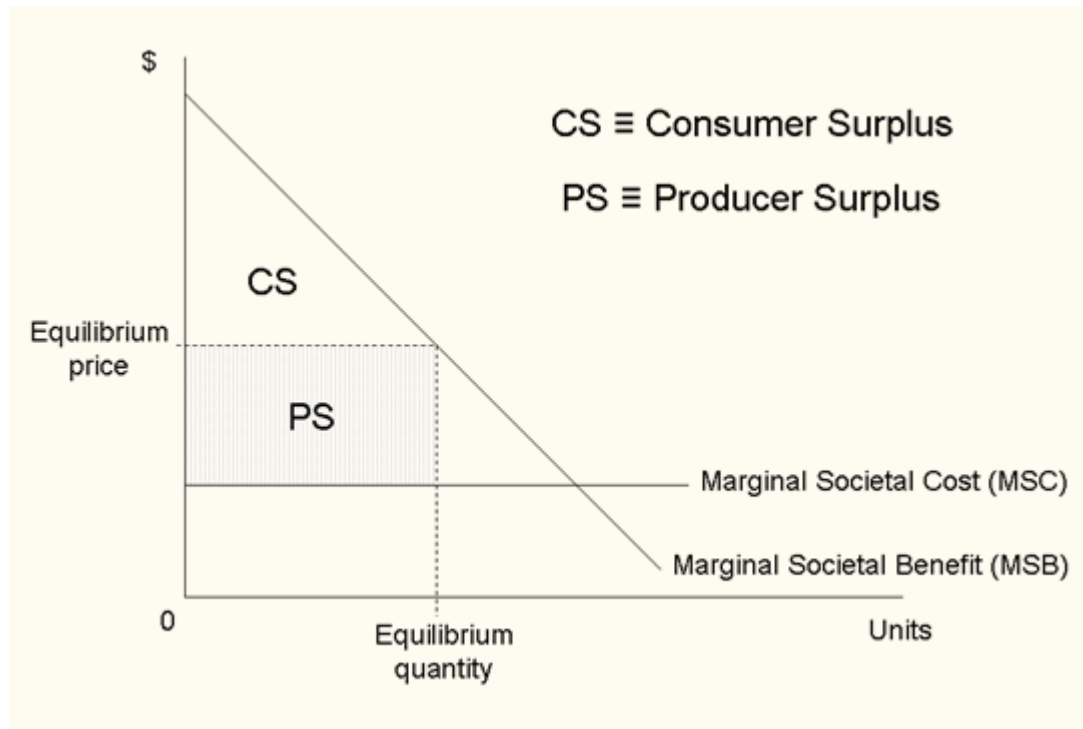
## **7. Conclusion and Recommendations Regarding a Societal Perspective.**

This discussion has attempted to clarify the appropriate definition and use of the concept of the “societal” perspective in health technology assessment and cost-effectiveness evaluation. Yet, it also raises substantial questions and issues about current practice, as it is clear that the term is widely misunderstood and misused. Furthermore, the current practice of focusing on static efficiency and not considering dynamic efficiency allows decision-makers to ignore the reality that their short-term decisions have long-term consequences for biomedical R&D, especially from a global perspective.

Given the rampant distortions inherent in the second-best world of health care insurance and delivery existing to a large degree in probably all countries, it may make more sense to clarify and redefine the reference case to embrace a different practice. Indeed, it might make more sense to define and introduce new terminology such as a “restricted” or “limited” societal perspective or an “expanded” payer perspective to align current practice with the guidelines in our field. Namely, this perspective would encompass what is simply the payer perspective plus indirect costs while using community preferences for utilities. True opportunity costs would not be used in the reference case, but could be an explicit supplemental discussion for those who want to emphasize that point.

In support of this, we recommend that the full ISPOR Drug Cost Task Force consider the following potential points in developing its recommendations:

1. Raise awareness that few published CEAs produce a reference case with a truly societal perspective, particularly due to an overestimate of drug cost.
2. Consider proposing that the reference case embrace a new concept of a “restricted” or “limited” societal perspective, defined as meeting the following two of three conditions required for this perspective, viz., including indirect costs and using community preferences.
3. Insist that analysts not claim that they are taking a societal perspective when they are not.
4. Suggest that analysts note that using 40%-60% of net acquisition drug cost (i.e., cost net of discounts and rebates) would be an appropriate proxy for opportunity cost for a societal CEA for marketed products.
5. Distinguish between positive (or “behavioral”) vs. normative CEAs.
6. Emphasize that the payer perspective is a valid normative approach: i.e., advising payers on what they should do.
7. Encourage greater discussion within ISPOR of the role of pricing and reimbursement and the incentives for R&D.
8. Highlight the issue of static vs. dynamic efficiency.
9. Emphasize that prices are rewards.
10. Begin discussion and design of value-based reimbursement systems.



**Figure 1. Gains from Trade (ignoring taxes).**

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