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ABSTRACT

Objective: Major guidelines regarding the application of cost-effectiveness analysis (CEA) have recommended the common and widespread use of the “societal perspective” for purposes of consistency and comparability. The objective of this Task Force subgroup report (one of six reports from the International Society for Pharmacoeconomics and Outcomes Research [ISPOR] Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis [Drug Cost Task Force (DCTF)]) was to review the definition of this perspective, assess its specific application in measuring drug costs, identify any limitations in theory or practice, and make recommendations regarding potential improvements.

Methods: Key articles, books, and reports in the methodological literature were reviewed, summarized, and integrated into a draft review and report. This draft report was posted for review and comment by ISPOR membership. Numerous comments and suggestions were received, and the report was revised in response to them.

Results: The societal perspective can be defined by three conditions: 1) the inclusion of time costs, 2) the use of opportunity costs, and 3) the use of community preferences. In practice, very few, if any, published CEA have met all of these conditions, though many claim to have taken a societal perspective. Branded drug costs have typically used acquisition cost rather than the much lower social opportunity costs that would reflect only short-run manufacturing and distribution costs. This practice is understandable, pragmatic, and useful to current decision-makers. Nevertheless, this use of CEA focuses on static rather than dynamic efficacy and overlooks the related incentives for innovation.

Conclusions: Our key recommendation is that current CEA practice acknowledge and embrace this limitation by adopting a new standard for the reference case as one of a “limited societal” or “health systems” perspective, using acquisition drug prices while including indirect costs and community preferences. The field of pharmacoeconomics also needs to acknowledge the limitations of this perspective when it comes to important questions of research and development costs, and incentives for innovation.

Keywords: drug costs, dynamic efficiency, social costs, societal perspective.

Background to the Task Force

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (Drug Cost Task Force [DCTF]) was recommended by the ISPOR Health Science Policy Council on December 13, 2004 and approved by the ISPOR Board of Directors on May 15, 2005. Because how drug costs should be measured for cost-effectiveness analyses (CEAs) depends on the perspective, five Task Force subgroups were created to develop drug costs standards from the societal, managed care, US government, industry, and international perspectives. This report is part II: societal perspective (one of six reports from the DCTF). The other reports (part I: issues and recommendations; part III: a managed care perspective; part IV: US government perspective; part V: industry perspective; and part VI: international perspective) are also published in this issue of Value in Health. The DCTF subgroup met to develop core assumptions and an outline before preparing a draft report. The Task Force subgroups held open forums and/or group leader breakfast meetings at the ISPOR Annual International Meetings and European Congresses. The draft report was circulated to 174 Task Force primary reviewers (who were self-identified from a broad range of perspectives). After this review, a new draft was prepared and made accessible for broader review by all ISPOR members. Comments for these reports by Task Force primary reviewers and ISPOR membership are posted at the ISPOR Web site. All opinions reflect those of the authors and not necessarily their affiliations.

Introduction

In addressing its mission, the ISPOR Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis chose to address this complex issue by considering the question from multiple perspectives. Historically, in the field of pharmacoeconomics, the “societal perspective” has frequently been recommended, and some would consider it the most important perspective to be applied. Our subgroup was charged with exploring the issues of measuring drug costs from this perspective, which is probably more complicated than has been recognized. We issued a draft report in 2008, and benefited from comments received from DCTF members as well as the broader ISPOR membership.

Over 10 years have elapsed since the US Public Health Service Panel on Cost-Effectiveness in Health and Medicine (PCEHM) issued its definitive recommendations on state of the art in CEA [1]. 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...
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The definition of this societal perspective in subsequent literature. Perhaps the clearest definition still comes from the PCEHM volume itself [p. 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 conditions, 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 for drugs as well as other inputs. Assuming that market prices reflect opportunity costs may be a reasonable assumption for many resources (such as physician visits or hospital stays). Nevertheless, 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 10 years knows that the pharmaceutical prices used in the vast majority of CEAs are either based on average wholesale prices (AWPs) in the United States 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 overestimate 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?
- What is the role of CEA from a societal perspective?
- If the field of pharmacoeconomics aims 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 a “true societal perspective,” briefly, as meeting three key conditions:

1. Productivity gains and losses (i.e., indirect or time costs) are included.
2. Costs of drugs and other inputs are measured by opportunity costs.
3. Community preferences are used to estimate the utility of health states.

Because our focus here is on costs, we will consider only the first two conditions. And we do not address the important discussion about inconsistencies in the societal perspective due to the omission of unrelated medical or to utilities reflecting lost income [2].

The major point here is that given that the branded drug prices under patent protection generally greatly exceed the short-run social opportunity costs, the “true societal perspective” has seldom been applied and is of limited relevance. We recommend for a new approach to the reference case analysis, which would explicitly use what could be called a “limited societal” or perhaps “health system” perspective, in contrast to the true societal perspective or the widely used payer perspective.

We first explore the origins of the term “societal perspective,” then examine its role as a normative—as opposed to a positive or behavioral—approach to economic analysis. Next, we discuss three related concepts in turn: the economics of monopoly pricing, a short-run versus long-run perspective on drug research and development (R&D), and innovation as global rather than local public good. Finally, we provide a list of concrete and specific recommendations for a way forward.

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.

Reviewing 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 customary 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 pharmacoeconomics textbooks. Our search of the medical literature found few methodological discussions of this issue. Indeed, the ISPOR Book of Terms [3] 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 (pp. 52–3); and “aggregate societal comparison of welfare” is mentioned under welfare economics. Even the well-known Drummond et al. [4] standard reference methods handbook does not define or explicitly define 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 that 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) [4].

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) [5].

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) [5].

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., AWP) are a “serviceable way to value consumption of drugs” (p. 195). In practice, analysts have followed this recommendation, thereby departing from the strict definition of the societal perspective.

Why Use a “Societal Perspective”?: Normative Economics as Market Correction

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 [6,7], and 2) the extra-welfarist approach [8]. The difference between the two is elusive, but according to the ISPOR Book of Terms, it is that the latter maximizes health gain whereas the former attempts to maximize welfare that is more broadly construed.

Another distinction that may be helpful in this context is between positive and normative economics. Positive—or behavioral—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 a normative one. Nevertheless, one can reasonably ask: Does anyone take this perspective in practice? For example, even a national-level payer like the National Health Service 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? Two related 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 United States—and indeed, in most national markets—is so rife with pricing distortions due to taxes, insurance subsidies, occupational cartels, etc.; that an outside standard is needed to think about public policy decisions and reforms.

But what use is an analysis from a societal perspective in such a distorted system? The answer could be it gives both clinical and public policy decision-makers a standard that attempts to abstract from these distortions, by measuring opportunity costs. Thus, by defining 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 counterbalance 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.

Monopoly Drug Pricing 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 [9,10]. 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, CS 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 MSC of producing and distributing it. The total gains from trade—the overall increase in societal welfare from the production, distribution, and 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).

[Image of Figure 1: Gains from trade (ignoring taxes). CS, consumer surplus; PS, producer surplus.]
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). Nevertheless, 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. Nevertheless, this argument may be less clear and/or less convincing for noneconomists. 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 et al. [5] wrote in the PCEHM volume on doing CEAs 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 redistributional 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. 138-40) [5].

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 [11].

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 lead 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 are 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 a “true” societal perspective is being adopted within an economic evaluation, these transfers should not be included as costs.

Mansley and Abbott [12] have, for example, illustrated how one could estimate this short-run marginal cost for drugs and have argued that the MSC is on the order of 40% to 60% of total acquisition cost. Thus, from a “true” societal perspective, the vast majority of CEAs to date have likely overestimated the costs and cost-effectiveness ratios of new drugs.

Societal Perspective and the Long Term: Static versus Dynamic Efficiency

The preceding discussion raises the question of how to handle the supra-normal profits that accompany the most successful patented drugs. Philipson and Jena [13] argue, for example, that drug manufacturers of acquired immune deficiency syndrome (AIDS) drugs have been able to capture as producer surplus only a small share (5%) of the total surplus created by their innovative products. Because 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,” that is, considering as well 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 would one not 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 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 United States had a well-functioning, market-based health insurance system (e.g., Enthoven’s [14] managed competition or the voucher system of Emanuel and Fuchs [15]). In other words, suppose everyone was covered by insurance and the health-care markets worked efficiently. Payers operating from the payer perspective would then provide good signals to companies on what drugs are really worth to their plan members. Why would anyone need to do analysis from a “societal perspective?” Is it not 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 community norm 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—for the utilization decision—would ignore them. Nevertheless, 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 society through biomedical innovation.

Although it is beyond the scope of the discussion here, a question thus 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 that 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 [16], Hay [17], 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.

### National versus Global Societal Perspective

In general, information—including knowledge about how drugs work in the body—can be a global public good. All citizens of the world can potentially benefit from pharmaceutical innovation. Throughout this discussion, we have not specifically stated whether “society” refers to the entire world, or to an individual country that includes the citizens 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 transfers 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 health care.

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 and dynamic efficiency. 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 aggregate (global) willingness to pay for biomedical innovation. This would cut down on free riding because of the public good nature of information, and with more knowledge generated, we would all be better off [18].

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 desirable to reform local country pricing and reimbursement systems to reward value and innovation more consistently and transparently.

### 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 as applied to branded drugs. Yet, it also raises substantial questions and issues about the 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. Alternatively, given that the “societal perspective” and the “payer perspective” are relatively widely used, it might be better to refocus the term “health system perspective” for this use. 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 there could be an explicit supplemental discussion or qualitative caveat for those who want to emphasize that point. Reimbursement policies relying on static CEA estimates will need to consider their long-term implications, both locally and globally.

In support of this, we recommend that the full ISPOR Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (DCTF) 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 because of 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 two of three conditions required for this perspective, viz., including indirect costs and using community preferences. Or it may be easier and clearer to redefine this as a “health system perspective,” in contrast to the payer perspective or a true societal perspective.
3. Insist that analysts not claim that they are taking a true societal perspective when they are not.
4. Suggest that analysts note that using some fraction (e.g., 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, but that a limited societal or a health systems perspective is more relevant and useful for current decision-makers.
5. Distinguish between positive (or “behavioral”) CEAs—that explain or predict behavior—and normative CEAs—that prescribe decisions that would support a specified objective.

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 versus dynamic efficiency.

9. Emphasize that drug prices for patented products are, in effect, rewards and incentives for innovation.

10. Begin discussion and design of value-based reimbursement systems.

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References


