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ABSTRACT

Objectives: The industry perspective on drug costs should be framed by the need for decision-makers to use actual and relevant costs, and to inform real-world decisions regarding medication selection and use. The objective of this report is to provide guidance and recommendations on how manufacturers should approach the use of drug costs.

Methods: The Task Force was appointed with the advice and consent of the ISPOR Board of Directors. Members were experienced developers or users of drug cost information working in academia and industry, and came from several countries. Following the core assumptions developed and outlined by the Task Force, a draft report was prepared. Comments were solicited on the outline and several draft reports both from a core group of external reviewers and more broadly from the ISPOR membership of ISPOR via the ISPOR Web site.

Results: The industry should always strive for: 1) a focus on drug value and not just cost; 2) credibility—that is correct and consistent costs; 3) transparency—by disclosing the prices and costs, and ensuring that they reflect the actual cost of the drug whenever possible; and 4) providing actionable results that help customers comprehend the value offered by a drug therapy and to use products more efficiently and effectively.

Conclusions: Understanding and accounting for all costs and consequences of the use of a medical treatment is in the best interests of all parties involved in the prescribing, consuming, reimbursement, selling, and manufacturing of bio/pharmaceuticals. Transparency, consistency, and clear communication of costs and value are essential for appropriate decision-making and should be important goals for all parties.

Keywords: cost study, drug cost, industry, pharmacoeconomic.

Background to the Task Force

The ISPOR Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (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) depend on the perspectives, five Task Force subgroups were created to develop drug costs standards from the societal, managed care, US government, industry, and international perspective. This report is Part V: an industry perspective (one of six reports from this ISPOR Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (DCTF). The other reports (Part I: issues and recommendations; Part II: a societal perspective; Part III: managed care; Part IV: US government perspective; and Part VI: international perspective) are also published in this issue of Value in Health (Volume 13, Issue 1). This DCTF subgroup met to develop core assumptions and an outline before preparing a draft report. The Task Force subgroups held open forums and group leader breakfast meetings at the Annual ISPOR 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 published at the ISPOR website. All opinions reflect those of the authors and not necessarily their affiliations.

Introduction

The objective of this report is to provide guidance and recommendations on how manufacturers should approach the use of drug costs. This task force report is part of a series of Good Research Practices for estimating drug costs for pharmacoeconomic and outcomes research studies. The reader is referred to “Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: Issues and Recommendations: A Report of the ISPOR Drug Cost Task Force—Part I” for more details on the Task Force, its goals, and objectives. This document reflects the authors’ own experiences developing drug costs for use in CEA models and publications but is not intended as a comprehensive review of the literature.

Task Force Process

The ISPOR Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (DCTF) was approved in 2005 by the ISPOR Board of Directors. The Chair of the Industry Subgroup, Jack M. Mycka, was appointed by the Task Force Chairs, Joel Hay and Jim Smeeding. All Subgroups members were selected by the Subgroup Chairs from interested ISPOR members.

The Task Force held teleconferences and used electronic mail to develop core assumptions and an outline before preparing a draft report. The Chair participated in face-to-face meetings held at two ISPOR international meetings. Initial recommendations
were presented at an open forum in May 2007. A draft report was circulated among the Task Force leadership group for comments. This draft report was then sent to the Drug Cost Standards Reviewer Group in August 2008 for a 1-month review period and was made accessible for broader review by all ISPOR members in October 2008. Several teleconferences of the Task Force leadership group were held to discuss the comments received and to incorporate feedback and make revisions. A final open forum was held in May 2009 to address comments received on report drafts. This final version reflects input from all of these sources of comment.

Often, those examining the pharmaceutical and biotech industry confuse the concepts of “value,” “price,” and “cost,” using the terms interchangeably or assuming there is a direct relationship among them. The price may or may not fully reflect the economic value of the product or the actual cost of acquiring and using it because, in general, medicines offer economic value that is considerably higher than the prices that are charged for them. Even within the industry, these terms are often confused because of varying academic and practical views. In this article, we will attempt to align the theoretical view of “where costs should go” and the practical application of “making it happen.” This alignment is essential as marketers build “value frames” that can be used to discuss the merits of their products and to support the drug selection and use decision-making process.

For purposes of clarity, we offer the following definitions:

- The **price** of a medicine is the monetary exchange component of a business transaction.
- The **cost** of using a medicine includes the acquisition cost, the costs of ancillary and associated products and procedures, and the humanistic and societal costs that may be incurred with the use of the medicine.
- The **value** of the medicine is the net of the clinical, economic, and humanistic effects of the use of the medicine.

In different types of research, drug cost has different meanings. For example, a budget impact analysis is obviously different from a CEA, and they require different approaches to the consideration of items like copayments. In CEAs, copays can be ignored, but, depending on perspective, they may play an important role in a budget impact analysis.

From an industry perspective, ensuring that cost goes beyond acquisition cost to the drug’s value is what matters most. This somewhat lofty goal needs to be balanced with the need to provide relevant and clear information that can be used in decision-making processes by manufacturers/marketers; payers; physicians; patients; pharmacists; society in general; and all others involved in prescribing, consuming, and paying for pharmaceutical, biotech, and associated products.

Below we address both the theoretical goal and the short-term practical goals that we believe the industry should pursue. We have illustrated these statements with a few relevant examples and recommendations.

**Value versus Cost Focus**

Studies should focus on the total value provided by the drug (economic, humanistic, and operational value) and not just the cost of the drug. Whether researchers look at the value of a therapy or treatment regimen, the goal of a study that has a meaningful impact on clinical decisions is more easily achievable. The actions affected should be the clinical development and pricing decisions of the manufacturer/marketer as well as those of customers once a product is marketed after approval.

**Total value.** Discussions of value in health care are often limited to narrow considerations of the direct costs of an intervention and do not consider incorporating the broader aspects of value listed below.

**Economic value.** The economic value of a treatment is the net economic effect of its use, relative to alternative interventions, considering all costs associated with the treatments and their consequences. Although there are standard methods for the measurement of economic value, often this measurement is limited to price, drug acquisition cost, or some other narrow measure, without consideration for broader economic effects.

**Humanistic value.** The humanistic value of a treatment is the net effect of its use on the ability of a patient to perform and enjoy the activities of daily living, relative to the effect of alternative interventions. This type of value is commonly referred to as “Quality of Life” and can be captured and reflected in a variety of instruments. This value, however, can often be manifested in individuals other than patients (e.g., caregivers, providers), and these aspects of the humanistic value of a treatment must also be considered.

**Operational value.** The operational value of a treatment is the net effect on the physical aspects of providing care relative to alternative interventions. Factors such as ease or difficulty of use, administration, acquisition, compliance, and recognition of effects have an impact on care that is seldom measured but must be considered when the total value of a treatment is evaluated. Attempts to quantify some of these factors have been made, and their presence must be acknowledged in some manner, even without quantification.

A focus on total value often does not match the narrow budget focus of decision-makers. This mismatch can be attributed to a difference between who bears the various cost components and who enjoys the various value components. This is apparent in different types of health economics studies. For instance, with a budget impact model, all affected parties should be considered, including patients, whose budget constraints might affect actual utilization and other parties’ budgets through mechanisms such as copayments. Similarly, various parties may experience different aspects of the value of a drug in areas like productivity gains and losses. This reality should be recognized and acknowledged by making the differences apparent and as easily separated as possible. Nevertheless, this does NOT relieve all parties from the responsibility of examining the overall value of medications in use and avoiding needless confusion related to the cost (or other) data used.

**Credibility**

The use of prices should be both correct and consistent. Too often, simple discrepancies in the price used (or not disclosed) undermine the overall credibility of a study or model. We will leave a discussion of the methodological differences among costs, prices, and charges to a separate part of this effort. We believe, however, that studies should not be conducted simply to support a predetermined position; instead, studies should focus on the relevance of the data presented to the customers likely to use it.

An example of the need for reality-based scenarios can be seen in how a model’s assumptions need to change based upon its time horizon. For instance, if a 25-year model is prepared, it should reflect the expected market realities of price changes, if any, during the patent-protected period and the impact of generic entry and its related price erosion.
Of course, this introduces additional variables such as the amount of any price changes (increases and/or decreases), the date that generics become available, and the prices of those generics. From the opposite view, changes such as inflating prices of competing products where there is no basis for the increase should be avoided because they are methodologically inappropriate, obscure the usefulness of the model, and directly undermine its credibility.

**Pricing Transparency**

Because drug cost is almost always a key factor in these studies, the prices used should be disclosed and should reflect the actual cost of the drug whenever possible. To achieve a true comparison, drug prices used in studies must reflect different dosing regimens and use patterns in the real world rather than simply relying on the respective product package inserts. This same principle applies across countries and payment systems, and the basis for these key factors should always be disclosed. A practical and reasonable first step would be to ensure that an explicit statement defining the perspective and scope of the costs cited is included. This will enable users to easily identify the basis used and to assess the comparability and adaptability of the information to their own situation.

An example in this area is the inclusion (or exclusion) of value added tax (VAT) in European drug price analyses. VAT could have a significant impact on the results and their comparability, especially when it is very high (~23%) and the comparator is placebo or conservative care, where prices, let alone VAT, may not exist. This same issue needs to be accounted for if these studies are conducted and/or applied outside of the EU where tax systems (as well as distributions and pharmacy margins) can be significantly different.

A US-based example in this area is the evolution from average wholesale price toward wholesale acquisition cost or ex-factory price and beyond to average sales price (ASP) and average manufacturer price. For instance, although ASP is an average, it more accurately reflects actual costs after discounts and rebates, and it is readily and consistently available for many drugs. Using the same price level across products and disclosing which price level is used is a simple first step toward transparency.

Transparency as to the price used and its relevance to particular payers (government, commercial, patients, etc.) is critical to meaningful evaluation. The drug costs used should reflect actual amounts wherever possible, and care must be taken to disclose the costs used so that comparisons can be made. Accurate comparison becomes especially difficult when costs are examined on a multinational basis where prices are different and reflect the impact of different payment systems and economic realities, such as various margin and VAT differences.

**Actionable Results**

By focusing on value and ensuring the credibility and transparency of costs used, researchers will ensure that the results of studies and models will be more valuable to all decision-makers (including the manufacturer/marketer). The results from such studies will help customers to comprehend the value offered by a drug therapy and to use products more efficiently and effectively.

This goal of actionable results should be achievable. Optimally, pricing, research, and modeling will all support decision-making outside of siloed perspectives while also recognizing their existence. Meaningful and transparent data will promote clear communication and keep all decision-makers from hiding inside their respective silos.

Understanding and accounting for all costs and consequences of the use of a medical treatment is in the best interests of all parties involved in the prescribing, consuming, reimbursement, selling, and manufacturing of bio/pharmaceuticals. This concept is especially important because the use of models and other decision support mechanisms is growing in acceptance, and these models must be fully populated. Transparency, consistency, and clear communication of costs and value are essential for appropriate decision making and should be important goals for all parties.

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