

Comparative Cost Effectiveness Modeling: Why the Pharmaceutical and Medical-Surgical Device Industries Are Embracing the Coming Market Evolution

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ABSTRACT:

For more than 30 years, the discipline of health economics has assisted healthcare stakeholders in making informed evaluations of treatment alternatives. Health economics research quantifies the “value” of therapeutic options through examination of both clinical benefit and costs over an appropriate episode of care, thus framing the clinical benefit in economic terms.¹ The related fields of comparative effectiveness and now more recently Comparative Cost Effectiveness (CCE) evaluations seek to achieve overall healthcare cost reduction through choosing products with the highest total “value.” The methodology for measurement of “value” in both fields is evolving; however, it is clear that both Comparative Cost Effectiveness and “monetized” reporting of outcomes will significantly impact the way in which pharmaceutical and medical-surgical products are marketed and sold.

This paper examines several key factors leading to the market’s rapidly accelerating embrace of Comparative Cost Effectiveness, and makes specific recommendations to pharmaceutical and medical-surgical manufacturers regarding the examination of both clinical and economic consequences of their products. These clinical and economic data are more critical than ever before to the effective commercialization and sale of products to medical facility purchasers, healthcare providers, and payers.

By taking an informed, proactive approach to the evolving market trend regarding Comparative Cost Effectiveness, research, and value analytics modeling, pharmaceutical and medical-surgical manufacturers will help sustain ongoing success in the marketplace. Manufacturers and marketing teams that fail to recognize the importance of evaluating and objectively delivering both clinical and CCE economic data regarding their products will find themselves at a significant competitive disadvantage.

¹Bonk R.J. *Pharmacoeconomics in Perspective*. New York: Pharmaceutical Products Press; 1999:5.

CCE AND COMPARATIVE EFFECTIVENESS RESEARCH: DEFINITIONS AND MARKET IMPACT

Comparative cost effectiveness refers to a methodology that hospitals employ to manage their costs while providing high-quality care. CCE offers an opportunity to compare the long-term consideration of total costs and overall value associated with using two or more technologies or products.²

Comparative effectiveness research (CER) refers to analyses that rely on careful selection of outcomes measures for meaningful comparison of alternative therapies.³ It usually involves taking two or more therapies for the same condition or two or more manufacturers for the same product and evaluating whether, in what manner, and/or for what patient populations one is better than the other.⁴ But CER typically does not consider cost—only CCE does this.

The United Kingdom, Australia, New Zealand, Finland, and numerous other countries currently employ CER to evaluate pharmaceutical, biotechnology, and medical-surgical products.

Comparative Effectiveness in the United States

In the United States, the Agency for Healthcare Research and Quality (AHRQ) was established in 2003 to conduct evaluations on comparative effectiveness of products and services. More recently, the U.S. Senate's Comparative Effectiveness Research Act of 2008 authorized the establishment of a nonprofit quasi-government corporation called the Patient-Centered Outcomes Research Institute (PCORI). The aim of PCORI is to conduct patient-centric CER in the field of medicine and to work with medical experts and stakeholders to prioritize interventions and services to be studied.⁵ It is currently proposed that CER will be conducted by public and private organizations approved by the Institute. The Obama administration's economic stimulus package allocated \$1.1 billion to advance this initiative, aimed in part at comparing alternative treatments for the same disease. Considerable discussion has erupted around whether product costs should be included with clinical outcomes in the comparative effectiveness evaluations (ie., Comparative Cost Effectiveness). This remains an ongoing debate, though many health economists contend that CER in the absence of the dimension of cost is a "toothless tiger."

Historically, the pharmaceutical, biotechnology, and medical-surgical device industries have relied on clinical outcomes and physician preference as the primary means to advance the

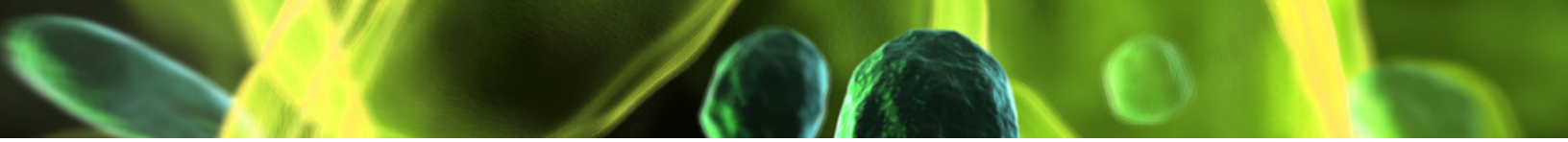
marketing and sales strategies of their products and brands. Furthermore, manufacturers often have been reluctant to conduct head-to-head comparative effectiveness studies of their products versus alternative treatments, especially when conducting such studies was unnecessary to gain product approval.⁶ Today, however, CCE initiatives are beginning to affect the pharmaceutical and medical-surgical industry in new and profound ways, forcing brand teams to rethink its strategic approaches to product commercialization and marketing.

At the same time, there is also a shift occurring in the marketplace as drug sales are moving away from the consumer/pharmacy retail market and to the institutional/facility market where the device industry has lived for years.⁷ As a result, industry are being seriously challenged today to devise objective methodologies to address the increasing head-to-head comparative effectiveness requirements among an evolving institutional product acquisition audience. As noted by Lawton R. Burns, PhD, MBA, Professor of Health Care Management and Chair, Health Care Management Department, Wharton Center for Health Economics:

"From 1990 to 2003, retail sales have dropped from 88% to 73% of the total market. Whether they are biologics, institutional drugs, or drugs that have to be infused, this means that more sales will be going into the institutional setting, where purchasers are trying to get hospitals and physicians to collaborate and figure out how to balance the money and technology flows.... This is the threat facing the device and pharmaceutical companies."⁸

There is...a highly significant opportunity for pharmaceutical and medical-surgical manufacturers of higher-priced products who embrace the Comparative Cost Effectiveness process.

The medical-surgical industry, on the other hand, has historically relied heavily upon technological innovation and a high degree of surgeon preference to drive product uptake and sales. As a result, the prospect of Comparative Cost Effectiveness has the industry somewhat uncomfortable with this pending market change—especially when it comes to the inclusion of head-to-head cost and/or cost-effectiveness comparisons.



However, there is in fact a very significant opportunity for pharmaceutical and medical-surgical manufacturers of higher-priced and higher-value products who embrace the CCE and analytics process. As more product sales shift from the retail to the institutional setting, the vast majority of hospital and medical facility purchasing teams are seeking a true Comparative Cost Effectiveness approach to product acquisition. Manufacturers who provide objective, third-party designed and validated cost and/or cost-effectiveness data will give their customers the information needed to make effective purchasing decisions. Moreover, these manufacturers will stay ahead of mandated AHRQ product evaluations in the coming years over which they may have little or no influence.

EMBRACING CHANGE

Hospitals and Integrated Delivery Networks in general are moving toward Comparative Cost Effectiveness because they have found that the two approaches they've used in the past for product acquisition—(1) high-cost product purchasing driven by physicians; and then (2) low-cost product purchasing driven by finance—have both failed as methods of improving bottom-line facility performance and improved clinical outcomes.

Higher-quality and higher-priced products may result in lower costs over time, but today much more than merely a clinical “inference” about a product’s economic value in a publication is needed to support such claims among purchasers.

Initially, facilities took the guidance of their doctors and surgeons, buying whatever new and costly items physicians wanted. This purchasing approach resulted in poor bottom-line performance. In response, facilities went to the opposite extreme, purchasing the least expensive products available, with a markedly lower regard for physician preference and product innovation. Soon, however, they discovered that this approach also failed to lead to bottom-line improvements, because of the cascade of hidden costs that may be associated downstream with the use of low-price/lower-value products.

Today, in order to find the middle position—that is, the balance point of true *product value*—hospitals need to determine the way costs are incurred over an *entire episode* of patient care and whether and how these costs can be attributed to specific products. The measurement of costs associated with a product over an entire episode of care is a very different and much more complete analytic process than simply examining supply costs of clinical efficacy alone. Higher-quality and higher-priced products may result in lower costs over time, but today much more than merely a clinical “inference” about a product’s economic value in a publication is needed to support such claims among purchasers. Most facilities are not set up to gather the cost and outcomes data necessary to determine these value-based, comparative end points, and manufacturers up until now have either not wanted to provide such data, were simply unable to do so, or both.

The Notion of Value Differs by Audience

The definition of value is quite different among the various audiences manufacturers must interface with while selling their products. Payers, facility P&T committees, supply chain management and healthcare providers all have differing views of value. Consequently, each stakeholder has to be considered as a separate customer group with a distinctly different economic need—with differing data and analytical output requirements—to make sound management decisions.

For example, facilities typically define value as both *cost-effectiveness as well as budgetary impact*, but they are also interested in *patient outcomes*. Healthcare providers are interested in these endpoints as well, but are also interested in *revenue generation*, as are facilities. Thus, the design of highly rigorous predictive CCE economic models which allow comparative data to be reviewed by key stakeholders and customer segments, must be customized for each audience.

The coordination of product-specific economic data gathering—followed by rigorous, statistically validated evidence synthesis and analysis—may sound daunting to marketing teams looking at CCE for the first time. The process, however, is straightforward and precisely aligned with the notion of *segmented market messaging* to distinct stakeholders, a theme basic to all strategic marketing. Once the “value creation” process is grasped and the economic and clinical needs of each customer segment in the product acquisition value chain are identified, Comparative Cost Effectiveness initiatives can be viewed as the huge opportunity that it is.

Table 1. Differing Views of Product “Value”

Cost Effectiveness: The synthesis of multiple data sources comparing the benefits and harms of different interventions and strategies (drugs, devices, testing, etc.) to prevent, diagnose, treat and monitor health conditions in “real world” settings; typically does NOT include the dimension of cost in its analysis.

Comparative Cost Effectiveness (CCE): Adds the comparative dimension of total cost over a clearly defined episode of patient care, and examines clinical outcomes inclusive of the economic impact of side effects and AEs. CCE considers total healthcare resource consumption (medical utilization, time, HR, supplies) and not only simple acquisition cost or clinical differences between products to assess the total comparative value associated with a given improvement or decrement in clinical outcomes between comparative drugs, devices, or technologies.

Budgetary Impact: The bottom-line financial impact, over an appropriate period of time, associated with use of a particular product. For example, hospitals may want to understand the impact on their overall expenditures—not just pharmacy-specific—if they replace one drug with another.

HEALTH ECONOMICS IS A STRATEGIC DISCIPLINE

As a starting point, pharmaceutical and medical-surgical marketing and brand teams want to know how best to approach creating value analyses for their products. A key first step is to segment their “value messaging” to the various audiences and stakeholders with whom they interface.

Institutional purchasing managers need comparative cost and effectiveness data, specific to their facility or facility type, to make good product acquisition decisions.

Understanding CCE Value Analysis Models

The segmentation of value messaging to different audiences can be accomplished within a single model; however, it must incorporate the various perspectives of its audiences. Thus, a model comparing the costs and consequences of one drug or medical-surgical device versus another can often have the same basic “structure,” but the costs and consequences it captures and analyzes within that structure will vary by audience. Those different perspectives, whether addressed in a single model or via multiple models, enable stakeholders to compare “apples to apples” outputs to determine a given product’s value. Today, institutional purchasing managers

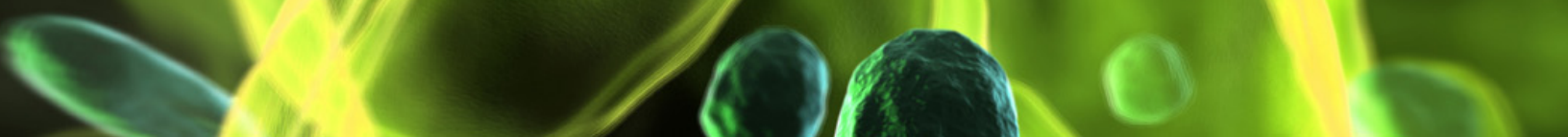
need comparative cost and effectiveness data, specific to their facility or facility type, to make good product acquisition decisions. Similarly, payers are increasingly pressured to evaluate cost-effectiveness data before granting preferred status to new pharmaceutical products or giving favorable coverage decisions for medical devices.

Models should always be built using the best evidence and the most rigorous analytical and data synthesis methods possible. Well-constructed CCE Models, however, don’t have to be complicated to use, however—and indeed shouldn’t be challenging to the user, no matter how complex. Additionally, they must be fully transparent and completely intelligible to the non-expert stakeholder/user.

Predictive CCE Models that are necessarily more complex—for whatever reason—can always be built with a simple user interface or “dashboard.” Furthermore, no matter how complex the “engine” of the model, its assumptions and methods must be explained and available in plain language that is understandable to its presenter and its audience.

WHERE TO START?

To begin, the following recommendations can help guide pharmaceutical and medical-surgical marketing and brand teams in taking the initial steps to obtaining true value analyses, incorporating both costs and outcomes, for their products.



1 Start collecting data early: As early as possible within the clinical development process, work with clinical colleagues to build economic end points and/or additional health outcomes into prospective clinical trials to begin amassing the data that is key to supporting the product’s value propositions in the marketplace. This is a good beginning, as it allows preliminary CCE Models to be developed based on data rather than supposition. Ultimately, these pre-market data can and should be supplanted by post-market “actual use” data—clinical and economic data collected from physicians in real-world patient environments.

2 Work with what you have as a starting point: Even if a manufacturer has only very early data or evidence—be it a retrospective review of a payer database, a review of clinical patient charts, or a review of a hospital database—these findings can be extrapolated into a real-world model to provide meaningful product data, even if long-term definitive comparative outcomes are not yet available. In this regard, a wide array of data, or evidence, can be leveraged in a model, each with differing levels of credibility (Figure 1).

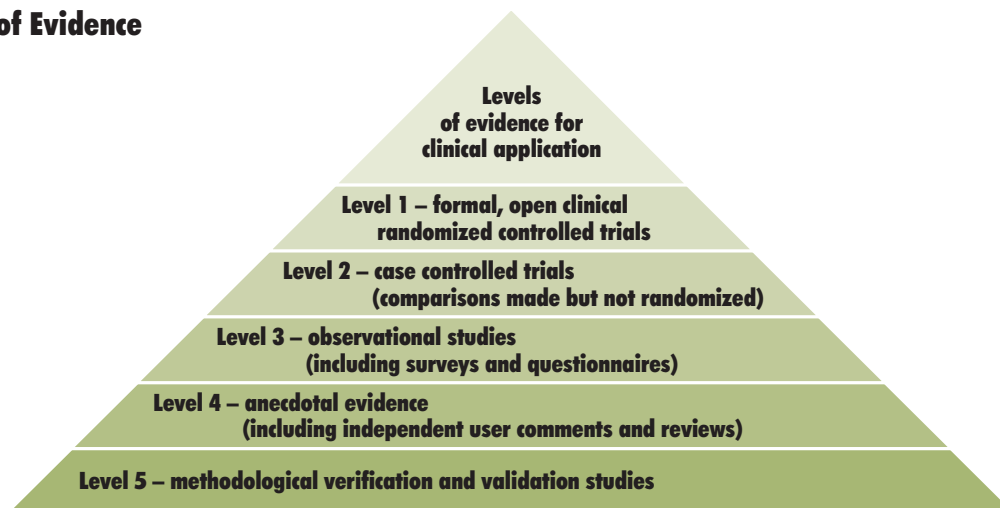
For example, models can be designed to examine what would happen if longer-term costs increased and/or if clinical effectiveness isn’t as good in actual practice as clinical efficacy in protocol-driven product trials. A well-designed CCE Model will allow exploration of changes in these and many other variables across “sensitivity ranges,” pointing to a wide array of “what if” scenarios that can be useful in projecting the true value of the product in actual use.

3 The economic modeling effort can be approached in stages: Retrospective data, or even early clinical data, can be used in CCE Models as a credible first step to gain a foothold with facilities, payers, and physicians as additional data-gathering efforts are ongoing. Stakeholders are receptive to credible economic product findings that are “in-process,” but that nevertheless clearly point to a product’s value as more conclusive research continues.

4 Conduct comparative product evaluations yourself: As stated earlier, there is concern among some manufacturers that the AHRQ will tag their products for comparative evaluation. Don’t wait. Industry should actively conduct rigorous comparative evaluations both before market entry and on a continuing basis. This is a large-scale opportunity to be embraced.

5 Engage a health economics firm: Let our team of experts show you how comparative product data can be collected and incorporated into appropriate analyses to help objectively drive your product or brand. Take a leadership position that demonstrates your product’s value with validated comparative analytics. Taking this approach will eliminate the concern that AHRQ / PCORI will conduct a study of your product over which your company has no control. Such an approach can significantly help to advance and enforce your product’s sales and position in the marketplace.

Figure 1. Levels of Evidence



Source: <http://www.2aida.org/aida/graphics/pyramid-evidence.gif>



SUMMARY

Given the accelerating shift toward comparative effectiveness research, Comparative Cost Effectiveness, and value-based purchasing initiatives, pharmaceutical and medical-surgical marketing and brand teams should adopt and strategically employ the use of Comparative Cost Effectiveness information in the commercialization of their products. A proactive approach to this emerging market direction is essential. Gaining a deeper understanding of health economics, Comparative Cost Effectiveness, predictive modeling and the current state of marketing and regulatory issues impacting the industry as a whole is of critical importance. Doing so can lead to the development of powerful, brand- and product-specific CCE Models and analyses for industry to define and articulate the value proposition of its products to hospital purchasers and acquisition teams, payers, physicians, and other stakeholders in the product-acquisition value chain.

²Burns LR, Wharton School Colleagues. *The Health Care Value Chain*. San Francisco, CA: Jossey-Bass; 2002:269.

³Bonk RJ. *Pharmacoeconomics in Perspective*. New York: Pharmaceutical Products Press; 1999:36.

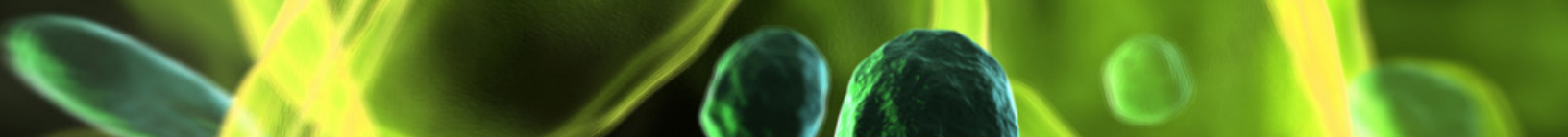
⁴Burns LR. Value-based purchasing: Impact on pharma. *American Health & Drug Benefits*. January 2009;2(suppl 1):34S.

⁵Shah NR. Evidence standards in the era of comparative effectiveness. *American Health & Drug Benefits*. January 2009;2(suppl 1):46S.

⁶Burns LR. Value-based purchasing: Impact on pharma. *American Health & Drug Benefits*. January 2009;2(suppl 1):34S.

⁷Burns LR. Value-based purchasing: Impact on pharma. *American Health & Drug Benefits*. January 2009;2(suppl 1):33S.

⁸Ibid.



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Josh Feldstein leverages 25 years of pharmaceutical, medical device, and biotech experience working with U.S. and global Fortune 500 multinational, middle-market, and early-phase companies. He has designed and managed hundreds of initiatives in Comparative Cost Effectiveness, health economics, medical education, medical communications, and scientific publishing across 30 therapeutic categories for a wide range of clients, from Fortune 100 to early-stage companies. A published medical book author, Mr. Feldstein has written and edited textbook chapters, peer review journal manuscripts, scientific content healthcare trade magazine articles, and audio and video CD/DVDs. He has coordinated extensive qualitative and quantitative health economic research; has presented lectures and professional education in Comparative Cost Effectiveness for organizations including the AHRMM, HIGPA, DIA, and SMI; has designed CCE predictive models for hospitals and the pharmaceutical and medical-surgical industry; and has served as an editor for pharmacoeconomic journal manuscripts for industry.