

New Appointments at RCRI

RCRI is pleased to announce the appointment of Monica Schultz as Director of Health Economics and Outcomes Research and Barbara Duerr as Clinical Project Director. Monica brings over 14 years of reimbursement and clinical services management experience to RCRI and has held significant roles in a number of medical technology companies and third party payor/providers in the Twin Cities including Blue Cross Blue Shield of Minnesota, St Jude Medical Inc., and Guidant Inc. Barbara has spent the last eight years working for the pharmaceutical division of 3M on clinical studies in the pulmonary and dermatology areas. Her clinical experience includes managing and monitoring phase II and III studies to support NDAs, as well as studies to support marketing. She also has experience supporting regulatory submissions.

For further information, contact John Lambert, Director of Marketing at 952-746-8080 x 250 or email jlambert@rcri-inc.com or info@rcri-inc.com.

Primer in Health Economics

On January 30, 1989, the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) published proposed cost-effectiveness criteria for Medicare coverage of new technology. Medical device companies, via the Health Industry Manufacturers Association (now AdvaMed), vehemently opposed the criteria due to methodological reasons and other concerns. Although the proposed criteria were withdrawn eight years later, demand for cost-effectiveness analyses have only increased. One can surmise that ever-rising health care costs will continue to increase demand for these analyses from both insurers and providers.

Since the publication of the proposed Medicare coverage criteria, cost-effectiveness methodologies have become more standardized, thanks to the efforts of groups such as the Panel on Cost-Effectiveness Analysis in Health and Medicine. The Panel's recommendations offer useful guidelines for the conduct of cost-effectiveness studies.

This is the first in a series of articles that will address the basics of cost-effectiveness analysis. The intent of these articles is not to provide comprehensive guidelines, but rather to offer a starting point for medical device companies to embark upon this very important, yet often neglected, type of analysis. This article pertains to the perspective of analysis data collection. Future articles will introduce commonly used statistical terms and methods.

Please note that although the term "therapy" is used throughout these articles, cost-effectiveness studies provide invaluable information for not only therapies, but also diagnostic tests.

Cost-effectiveness analysis attempts to determine the costs required to produce an additional unit of a desired outcome relative to a competing alternative (e.g., hospitalization avoided, life saved, bleeding life-threatening event avoided, etc.) Cost-effectiveness analysis evolves from decision analysis, in which several treatment options are identified and possible outcomes for each treatment alternative are assigned probabilities. By comparing the chances of each outcome occurring, physicians are better able to make decisions regarding therapeutic options. Ideally, to collect cost and probability data, a cost-effectiveness trial can be conducted, or cost-effectiveness endpoints can be attached to an ongoing trial. However, provided the data are available, many cost-effectiveness studies can be completed via literature review and good detective work. Most, if not all, medical device companies can embark on a cost-effectiveness analysis by thoughtful consideration to several questions.

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What is the scope of the intervention?

Cost-effectiveness analysis requires careful definition of the cascade of care and resulting outcomes for all therapies of interest. “Therapies of interest” include *both* the product which you produce and current competing therapies. After therapies are identified, all expected adverse events and favorable outcomes for each therapy should be identified. In addition, the investigator should explicitly state the time period that the cost-effectiveness study will address. This is most often dictated by the amount of follow-up time for patients in the current literature. Although future probabilities can be projected, the uncertainty surrounding those estimates can be problematic and should be addressed carefully.

Who is your audience: (hospital, payer, society), or all three?

Each perspective requires slightly different inputs and therefore can produce different results. For example, a hospital may only be interested in the costs associated with a particular length of stay. A payer’s perspective widens, encompassing not only the services provided during a particular episode but also other services that may or may not result *after* the patient is provided with initial therapy. A societal perspective widens still further, looking at how much caretaking that person requires by family members, how soon the person can return to work, etc. Ideally, a cost-effectiveness study will take a *societal* viewpoint, because it encompasses all parties of interest. Separate reports can then be provided to interested parties utilizing data of most interest to them.

What components of the analysis should be collected?

At the very least both *probabilities of events* and *costs* should be collected.

Probabilities

Probabilities are most often obtained from a clinical trial and/or published research literature. A probability of occurrence must be assigned for each outcome identified in the “cascade of care.” The reader of your analysis will want to know the chance of occurrence for every favorable outcome and every adverse event identified. The credibility of probabilities selected will depend upon their source. Probabilities stated in well-designed trials are more credible than those obtained from small observational studies or anecdotal data. Statistical methods can provide options for working with uncertainty inherent in estimates obtained from less rigorous studies. However, choose the best sources you can. Methods for literature review, criteria for literature selection, and the final sources themselves should be clearly stated.

Costs

The term “costs,” though used frequently, is misleading. Dollar amounts collected for health care related costs are most often either hospital *charges* or average insurance *payments*, though some hospitals may agree to provide actual costs. Select which cost measure you will collect – charges, payments, or actual medical costs – and try to remain consistent for all therapies being compared across the entire cascade of care identified. Three types of costs may be estimated dependent on the perspective taken:

Health Care Costs (“direct costs”)

These costs include dollars spent for both delivery of the therapy and the cost associated with short-term complications.

Future Health Care Costs

These include those costs related to the long-term consequences of the treatment. Examples of these include life-long medication required, supportive medical care, etc.

Non-health care related (“indirect”) costs

These types of estimates can only be obtained in a clinical study, where patients and families self-report the variables of interest. Examples of non-health care related costs include time for the patient to access therapy, time lost from work, and caregiver time (even if unpaid). Unpaid caregiver time and time lost from work can be estimated by multiplying estimated time by an average hourly wage from a national source such as the Bureau of Labor Statistics.

If you would like additional information or have questions regarding cost-effectiveness analysis, please contact Monica Schultz at mschultz@rcri-inc.com or call 952-746-8080 x 253

The next installment of this series will include a discussion of optional components in a cost-effectiveness analysis: quality adjusted life years

Winning at Venture Capital

Raising the capital needed to establish and grow a company is one of the major barriers to success for health care inventors and entrepreneurs. Why is raising venture capital so extremely difficult and what are the key issues to consider? Much of the problem appears to be associated with a lack of understanding of what is available, how to approach the various investment sources and what to expect during the due diligence process. A company should ensure that its financing objectives are complementary to those of a potential investor *prior to* approaching the fund. Each investment group develops its own preferences with respect to the size of investment, stage of the investment, potential for participating within an investment syndicate, and desire to function as the lead investor. It is therefore important for a company to consider its positioning before approaching the venture fund, especially with respect to whether or not the company fits the fund’s mandate. It is important to realize that acquiring the funding should be only a small part of the picture (though it is difficult to truly understand this before obtaining financing). Ideally, far more focus should be placed on the long-term business relationship with the venture partner.

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Winning at Venture Capital

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Entrepreneurs should realise the nature of this long-term relationship, and perform appropriate due diligence of their own. Although each venture fund's investment mandate and due diligence process are likely to vary, the primary issues common to most venture capitalists are: management; useful and patentable technology; large and accessible markets; and exit strategy.

Management - The strength of the management team is the critical factor. Venture capitalists look for experience and a demonstrable understanding of what is required in developing and articulating a corporate vision and strategy. They will assess the ability of the management team to execute the strategy, and while recognising that the team may not be complete, will be eager to gain an understanding of how the full team will be developed.

Useful and Patentable Technology - Investors look for world-class technology capable of providing the company with a competitive advantage and the potential to become an industry or market leader.

Large and Accessible Markets - Venture capitalists wish to see that the company's products address unmet needs in large markets that are readily accessible. They are not generally enamoured of strategies developed on dominating niches, however well defined

Exit - Investors need to understand when and how they may expect to realise their gains. It is helpful for the company to demonstrate how it plans to reach the point of cash self-sufficiency and, following that, how liquidity will be created for shareholders. The usual exits for investors are through mergers and acquisition and initial public offerings (IPOs).

Where Do Marketing and Strategic Planning Fit? - At a very high level, securing financing is simply the challenge of appropriately positioning the company against the investor's criteria. Marketing and strategic planning touch on each of the primary issues of concern to venture capitalists.

Management - Early stage companies typically do not have a complete executive team, and hence do not have the depth of talent needed for critical functions such as reimbursement, business development or regulatory. Sophisticated investors will not expect a complete team to be in place, but will need to see a rationale of when and how the team will be grown. The management team can expect to be assessed for the purpose of gauging their understanding of the process of bringing a product to market. The dynamics of financial markets are such that venture-backed start-ups are expected to grow quickly. This requires undertaking as much of the development process (market assessment, R&D, and manufacturing process development) as concurrently as possible while outsourcing those tasks not readily available within the core team.

Technology - Since the risk profile is such that venture capitalists require the potential for dramatic returns on investment, positioning of the technology is critical. Many investors wish to see a 'platform technology' – one that is capable of generating multiple products. A critical distinction in the minds of many investors is whether a given opportunity represents a single product or many. Since creating a competitive advantage is often based on a technology, it is important to demonstrate that the products are markedly superior and deliver significant, unique benefits to the end-user.

Markets - The key here is demonstrating that the company's products address unmet needs in large, accessible markets. A demonstrated understanding of the marketplace and customer, supported by quantitative data, accurate segmentation, reflection of current market dynamics, and competitive analysis will go far in convincing investors of the attractiveness of the opportunity.

Growth strategies - It is important for early stage companies to give consideration to the type of strategy they will employ in growing the company. At a high level, strategies may be organised into two categories:

- operational – a strategy is operational if the company exists in a stable environment and is creating a competitive advantage through executing more efficiently than its competitors.
- transformational – a strategy may be considered transformational if the company is operating in a dynamic environment and intends to create an advantage by employing new technologies, business models and processes.

Most early stage technology-based companies should be focused on creating successful transformational strategies. A company in a dynamic environment with a transformational strategy will need to overcome serious challenges from customers, channels and competitors. Executives with marketing and business development backgrounds have much to offer here, since they are often better able to develop insight into the evolution of an industry and can rapidly identify market-based opportunities. Each of the two types of strategy requires different skills to execute. In early stage companies, where management resources are stretched thin, it can be nearly impossible to locate both skill sets in the same place. Therefore, once a company has oriented itself towards a particular type of strategy, it is extremely difficult to transition to the other skill set. This is why it is important to ensure that the strategy is aligned with the company's ability to execute. Ultimately, the winning strategy is the best one that the company is able to implement. A common mistake for managers of early stage companies is to negate the relationship between strategy and execution. This can lead to failure to formally articulate a 'Plan B' – a strategy that, while more modest in scope, is within their capability to execute. Technology-based companies often operate in an environment where information may be incomplete, yet rapid decisions must be made in establishing market and product development priorities. It is essential for early stage companies approaching venture funding to understand the unmet needs of customers, the regulatory environment, the ability to obtain reimbursement, the competitive situation, the impact of new technology, the industry and the competitive advantages of rivals. Specialist outsourcing can be the solution to many of the primary issues facing early stage health care companies. *For more information contact John Lambert at 952-746-8080 x 250 or email jlambert@rcri-inc.com*

RCRI

From Concept to Market

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Be sure to visit RCRI at:

Euro PCR, Paris, May 25 - 28

RAPS West Coast Conference, Santa Clara, May 25 - 26

MN Venture Capital Conference, Minneapolis, June 7 - 8

Med Edge International, Minneapolis, June 23 - 25

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Contact Information

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