

## Comparative Effectiveness Research: Get to Know the Term

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In this issue of *Cutis*<sup>®</sup>, Sadick and Sorhaindo<sup>1</sup> compare the effectiveness of trichloroacetic acid 100% peels with cryosurgery in the treatment of disseminated facial molluscum contagiosum in patients with human immunodeficiency virus, which differs from previous reports of therapy for this difficult condition. Instead of reporting the efficacy of a single treatment, the authors compared the effectiveness of 2 treatments.<sup>1</sup> This commentary is not meant to discuss the relative merit of these particular treatments but rather to discuss the coming of age of comparative effectiveness research.

Dermatologists frequently decry the anecdotal nature of the data on which we often have to base therapeutic decisions. As we strive for better controlled trials demonstrating the effectiveness of therapeutic agents, we should remain mindful that the next step is data on comparative effectiveness. Comparative effectiveness research provides data on the relative benefits, cost, and risks of medical interventions relative to the available alternatives, and will be a major focus of efforts to improve the delivery of healthcare in the United States.

The US Food and Drug Administration requires clinical trials that demonstrate the safety or efficacy of new drugs and medical devices. Traditionally, these trials have focused on efficacy relative to a placebo, but increasingly, agents will be compared to a standard therapy. Some countries, including Australia, Canada, and Germany, require economic assessments of medications and medical therapies before they are reimbursed.<sup>2</sup> We can expect to see an increasing demand for demonstration of effectiveness compared with existing, alternative, and less expensive therapies. Drugs are only part of the story, as most healthcare spending relates to surgical procedures rather than pharmaceuticals or devices. As dermatologists, we perform a tremendous number of procedures on our patients, and there will be

increasing pressure to demonstrate the comparative effectiveness of these surgical procedures.

The pressure comes from many sources, not the least of which are the executive branch and US Congress. The United States spends much more per capita on healthcare than other developed nations, but critics of our healthcare system are quick to point to a lack of data demonstrating that this spending corresponds with better health outcomes. For better or worse, reform of our existing healthcare system will be a major focus of the new administration, and the future of medicine in the United States will depend on how we respond to this challenge. Dermatologists will face increasing demands to demonstrate the cost-effectiveness of our services. Our future depends on data that demonstrate our superior skills in the diagnosis and treatment of skin disease and the cost savings that result.

A white paper from Senate Finance Committee Chairman Max Baucus on healthcare reform states that “[r]eforming the health care system is essential to restoring America’s overall economy and the financial security of our working families.”<sup>3</sup> There have been calls to replace the current fee-for-service system of payment with one “that encourages and rewards innovation in the efficient delivery of quality care.”<sup>4</sup> Whether we like it or not, healthcare funding as we know it is being challenged. Data on comparative effectiveness will play an increasing role in any discussion of healthcare finance, and specialties unprepared to present data will suffer.

Chairmen of both the Senate Finance and the Senate Budget Committees have cited the need for comparative effectiveness research and proposed a national institute to compare the effectiveness of medical treatments.<sup>5</sup> This function could ultimately reside in a separate institute, within the Agency for Healthcare Research and Quality (AHRQ) or the Institute of Medicine, or it may be divided between different organizations. We are already witnessing efforts to establish a national agenda of comparative effectiveness research priorities, and the American Recovery and Reinvestment Act included \$1.1 billion in funding for comparative effectiveness

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research, including \$300 million in grants to be administered by the AHRQ, \$400 million by the National Institutes of Health, and \$400 million to be allocated at the discretion of the secretary of Health and Human Services.<sup>6,7</sup>

In a statement before the Subcommittee on Health of the US House of Representatives Committee on Ways and Means, Carolyn M. Clancy, MD, director of the AHRQ, noted that advances in “biomedical research have resulted in many new diagnostic and therapeutic options.”<sup>8</sup> The result is that clinicians have to choose among an expanding array of choices for treating disease. The goal of comparative effectiveness research is to provide information to patients, clinicians, purchasers, and policy makers upon which they can make informed healthcare decisions. Health information technology will be increasingly used to make information on comparative effectiveness available in the form of decision support tools. Much of the emphasis will focus on chronic illnesses, such as hypertension, heart failure, and diabetes mellitus, but dermatology will not be left on the sidelines.

Cancer remains a national healthcare research priority and comparative effectiveness research in this area is likely to be funded. Diagnostic errors are now being recognized as a major and underappreciated threat to patient safety.<sup>9</sup> As the experts in the diagnosis of skin disorders, the increasing focus on diagnostic errors provides us an opportunity to demonstrate the value of our skills. While our role in preventing diagnostic errors is most apparent for the diagnosis of cutaneous malignancies, including melanoma, the timely diagnosis of inflammatory skin diseases also is critical for efficient and cost-effective care.

There are countless opportunities for research that will demonstrate the value and cost-effectiveness of care rendered by dermatologists. The challenge is to produce the data. Data are particularly important for smaller specialties such as dermatology because there will be an increasing focus on funding for primary care and systems of care. Our patients cannot afford to be left behind and we should act as their proponents.

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