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The Contribution of Health Services Research to Improved Dermatologic Care

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Abstract

To translate scientific discovery into improved health, we must study health care itself: ie, how people access health care, costs or other barriers to the provision of good care, and what happens to patients as a result of this care. Health services research (HSR) is the interdisciplinary field that studies health care and its effects. This paper reviews different types of HSR and highlights some dermatologic examples that have resulted in improved health care systems or have helped us understand access to existing systems. The paper also addresses some of the political and systematic challenges for health services research overall, and for individual investigators and program leaders.

We like to think that “You get what you pay for” but the platitude does not apply to health. For example, despite spending more than any country in the world on basic research and on medical care, the US overall has relatively poor health by most metrics (Davis *et al.*, 2010). To figure out why, we need health services research. To translate scientific discovery into improved health, we must study health care: ie, how people access health care, costs or other barriers to the provision of good care, and what happens to patients as a result of this care (AHRQ, 2002).

In this paper I will define health services research, and will describe some of the reasons why it has not fully spearheaded the translation of science into health. I will highlight some examples from dermatology that have resulted in improved health care systems or have helped us understand access to existing systems. I will also point out some of the challenges to the field in the next decade, and will suggest some potential solutions.

What is Health Services Research?

Health services research (HSR) is an interdisciplinary field that studies health care itself, and its effects. The methods of HSR are those of the social sciences, including epidemiology, biostatistics, economics, sociology, anthropology, and psychology, but the focus of HSR studies is different; for HSR, the goal is, most simply, to assess the provision and quality of health care.

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The continuum of clinical research is depicted in the Figure. In so-called T1 Translational Research, basic biomedical research at the bench, focused largely on molecular medicine, is translated into potentially efficacious therapies to treat disease at the bedside, in patients. The cornerstone of this efficacy research is the clinical trial (which is discussed in another paper). In T2 Translational Research, efficacious therapies may be demonstrated to be effective in the population of patients with a condition. Archie Cochrane, a premier clinical epidemiologist of the last century, referred to the research questions in efficacy research as “Can this work?” and in effectiveness research as “Does this work?” (Haynes, 1999). The health services researcher focuses farther along the continuum, and asks “Is this working to improve health overall?” Subsets of HSR include, for example, outcomes research (in which the effects of a condition or treatment on a patient or society are precisely measured) and implementation research (which studies the adoption of research findings into routine healthcare). The overall goal, however, is to learn how health care can best and most efficiently improve health.



HSR studies themselves can be basic or applied (Vargas *et al.*, 2004). For example, the development of outcomes measures or risk adjustment methods provides tools that can then be used for measuring and comparing care in highly rigorous ways. Similarly, health services researchers often develop and use advanced statistical methods to analyze complex clinical data about care and its provision. Applied HSR, on the other hand, can seem almost activist in its outlook, since it often addresses or informs pressing questions that have significant policy implications. For example, why is there disparity in melanoma stage at diagnosis among patients of different races (Hu *et al.*, 2009)? Why are there unexplained variations in care for skin conditions seen in different practice settings (Chren *et al.*, 2004)? How often do medical errors and adverse events occur in dermatologic practice, and how can they be reduced (Gawkrödger, 2011)? Addressing these types of questions requires the multidisciplinary resources of health services research.

Health Services Research and Politics

At first glance, it seems as if research that is highly practical, that provides the basis for determining the quality and value of a nation's investment in health research and healthcare, should be politically and popularly non-controversial. In fact, the National Institute for Health and Clinical Excellence (NICE) was established in 1999 by the National Health Service in the UK, to provide evidence-based recommendations about strategies to improve health (<http://www.nice.org.uk/>).

But in the US, research on the quality of health care has not been a national priority, a situation that has been consistent for decades. In fact, over the last 30 years, the ratio of

American dollars spent on basic biomedical research (through the National Institutes of Health) to those spent on HSR [through the agencies designated for this purpose, currently the Agency for Healthcare Research and Quality (AHRQ)] has typically been around 100:1 (Gray *et al.*, 2003). Why should this be? Basic research has several important ‘marketing’ advantages. For example, it often focuses on the pathogenesis of serious diseases, which are universally understood as threatening to Congress and voters. The big-ticket items for HSR, on the other hand, are often highly prevalent, chronic conditions that may not be widely regarded as serious. Also, basic research itself is economically advantageous both to academic medical centers and the for-profit companies that produce drugs and other patient care devices. The findings of HSR, on the other hand, may conflict with vested interests if, for example, a newer technology were found to be less cost-effective than a cheaper, older alternative. Also, there may be few or weak incentives to implement the results of comparative effectiveness research in a complex, often profit-driven market such as that in the US. The effects of changing American politics on HSR funding have been reviewed, including the history of powerful lobbies confronting Congress when they objected to the findings of HSR studies (Gray *et al.*, 2003).

US funding for effectiveness research—a type of health services research-- received a boost when President Obama funded the American Recovery and Reinvestment Act in 2009, which committed \$1.1 billion to fund Comparative Effectiveness Research. The impetus for this funding was not only to infuse funds into the ailing economy but also to begin to address the monumental American increase in health care spending. In announcing the funding, the President coincidentally asked a fundamental and complex health services research question, “*If there's a blue pill and a red pill, and the blue pill is half the price of the red pill and works just as well, why not pay half price for the thing that's going to make you well?*” (CBS News, 2009). Studies to compare effectiveness and to understand barriers to adoption of cost-effective therapies are a cornerstone of HSR. (After the announcement, the Institute of Medicine sought broad input about which conditions should receive the most funding, and 2606 nominations were received from 1758 persons; of 100 initial priority topics, four were related to Dermatology: psoriasis, acne vulgaris, leg ulcers, and psoriatic arthritis). Despite the infusion of these funds, however, funding for health services research in the US remains dramatically lower than funding for biomedical research through the NIH (the President's requested FY 2012 budget for the National Institutes of Health was \$32 billion).

Examples of Health Services Research in Dermatology

Basic Health Services Research: Development of Research Measures

Diagnostic and Outcomes Measures—Fundamental to studying health care is the ability to measure disease and its effects accurately, which is relatively straightforward if the effect is straightforward to define and assess (mortality or abnormal laboratory values, for example). More challenging, however, is the typical situation in Dermatology in which the clinical course of disease is a changing rash, patients live with their conditions rather than die from them, and laboratory values-- if they are altered at all-- do not capture the severity of disease and effects of care on patients' lives.

Much basic HSR in Dermatology has focused on the development and testing of accurate tools to measure complex health states or outcomes such as the diagnosis of disease (Dominguez *et al.*, 2009) or skin-related quality of life (Chren *et al.*, 1997; Finlay and Khan, 1994). The example of clinical severity measures for atopic dermatitis (AD) illustrates the necessary focused and incremental approach. Dermatologic health services researchers studied available measurement tools and concluded that of the twenty published outcomes measures for AD, only four had adequate measurement properties such as reliability and validity (Schmitt *et al.*, 2007). The same investigators developed an international standardization for core outcomes measures for AD and identified the key domains that should be included in any outcomes tool (Schmitt *et al.*, 2011; Schmitt and Williams, 2010). This background work is essential to the development of an accurate measure of clinical severity in AD.

Risk Adjustment Methods—A notable example of risk adjustment methods applied to a skin condition is the staging system for melanoma, recently updated in 2009 (Balch *et al.*, 2009). The system was developed with an evidence-based approach, using a large international database that contained information from nearly 40,000 patients. The current version also illustrates the continuous improvement in risk adjustment strategies that are possible as more data are accumulated and analyzed, and as variables not previously in the staging system are identified and included.

Prediction tools—Quantitative models that predict clinical outcomes can also identify variables to include in clinical prediction models to be used both by researchers and by clinicians or patients to understand individual prognoses and improve outcomes. For example, the staging system for melanoma cited above has been used as a basis for a web-based tool that will predict an individual patient's survival prognosis (Gershenwald *et al.*, 2010). A predictive tool for healing of leg ulcers has been developed and tested (Kurd *et al.*, 2009), and another instrument estimated the risk of developing melanoma, to assist in the identification of high risk groups for screening (Fears *et al.*, 2006).

Applied Health Services Research

Outcomes Research—A premier example of the systematic examination of the effects of health care on patients and society is the 25 year-old Psoralen plus ultraviolet A (PUVA) follow-up study. This multicenter cohort study carefully followed over 1300 patients with psoriasis who were treated with PUVA, and documented many outcomes of the treatment, including clinical course (Nijsten *et al.*, 2007), quality of life (McKenna and Stern, 1997), adverse events (Stern *et al.*, 1980), cost (Stern *et al.*, 1981), and risks of cancer (Stern, 1990; Stern *et al.*, 1997; Stern and Vakeva, 1997), cardiovascular disease, and death (Stern and Huibregtse, 2011). Outcomes studies that enroll patients based on diagnosis rather than treatment type permit comparative effectiveness research among different treatments. For instance, the Nonmelanoma Skin Cancer (NMSC) Cohort Study enrolled over 1500 patients with NMSC at the time of diagnosis; both patient-reported and long-term clinical outcomes after treatment have been examined (Asgari *et al.*, 2009; Chren *et al.*, 2007; Chren *et al.*, 2011).

Behavioral Research—Broadly, behavioral research is the collection of systematic information about human behavior and, in the case of health services research, how it affects health. Patients' health-related behaviors are important to their risks of developing some skin diseases, and their responses to treatments. Dermatologic health services investigators have studied important aspects of skin health behavior, including the use of sun safety and risk behaviors (Hillhouse *et al.*, 2010), and patient self-care (Robinson *et al.*, 2008). In addition, interesting studies on adherence have informed strategies to increase the likelihood that prescribed treatments will be adopted by patients (Chisolm *et al.*, 2010).

Implementation Research—Some health interventions, such as an occupational sun safety program (Mayer *et al.*, 2009), are implemented into the community with variable success. Many effective interventions have yet to be implemented into health care more broadly, however. The reasons for this 'roadblock' are complex, and are the focus of many types of HSR, including behavioral research, cost-effectiveness research, and studies of health disparities and access. In many cases, fundamental knowledge must be directly acquired in the field about the reasons underlying the failure of effective strategies to be implemented (Hajjaj *et al.*, 2010). For example, barriers to the adoption of sun protection policies in schools have been identified (Geller *et al.*, 2008).

Needs Assessment—Too often, health care interventions are introduced and broadly used in the community before adequate evaluations have been performed of need (Hay and Fuller, 2011), efficacy, effectiveness, and ability to improve health care and health. National dermatologic health care needs are typically not rigorously determined, but a premier example is "Skin conditions in the UK: a Health Care Needs Assessment," which was updated in 2009 (Schofield JK, 2009); this research on needs and effectiveness can be directly used to inform health care planning.

Technology Assessment—The use of teledermatology is increasing rapidly, but this technology is also being assessed in rigorous ways by dermatologic health services researchers who have not only examined its diagnostic accuracy but have synthesized what is known about its usefulness and cost (Warshaw *et al.*, 2011).

Research on Access to Care—The reasons for health inequities are complex (Suaia and Dellavalle, 2009), and may be related to lack of access to health care. In the US, access to dermatologic care is likely uneven, although the effects on dermatologic health have not been well-studied. Patient socioeconomic barriers or limited health literacy may lead to poor access (Wich *et al.*, 2011).(Hernandez *et al.*, 2011); obstacles related to health care reimbursement may also be important (Resneck *et al.*, 2006).

Research on Work Force—Because of the importance of adequate access to care and the expense of training physicians, determining the optimal number of dermatologists has significant implications for achieving the best health care. Studies of this issue have highlighted persistent unmet demand over time (Kimball and Resneck, 2008) and substantial skin care provided by non-dermatologists (Armstrong *et al.*, 2009).

Cost and Cost Effectiveness Analyses—The application of health economic methodologies to the analysis of dermatologic health care had expanded greatly in the last two decades. We now have estimates of the overall cost of care for many common skin conditions such as atopic dermatitis (Ellis *et al.*, 2002) and melanoma (Seidler *et al.*, 2010). Cost effectiveness studies require not only accurate determination of monetary expenditures, but also a measurement of treatment effectiveness. For example, cost effectiveness analyses have been conducted of common therapies for warts (Thomas *et al.*, 2006) and nonmelanoma skin cancer (Essers *et al.*, 2006). Effectiveness of therapy can be based on, highly specific outcomes, or more general effects of the therapy and treated condition on patients' survival and quality of life, using a standard metric called utilities. A catalog of dermatologic utilities has been developed (Chen *et al.*, 2004), which can be used both for future cost-effectiveness analyses, and for further refinements of the methodology itself.

Challenges to Health Services Research in Dermatology

To understand how best to translate scientific discovery into improved dermatologic health, our specialty shares many of the challenges faced by health services researchers overall (Vargas *et al.*, 2004). First, there are too few qualified dermatologic health services investigators. As is the case for the vast majority of medical research, the necessary research skills in the multidisciplinary methodologies of HSR most often require focused and intensive post-doctoral research training, which may be a disincentive to potential researchers. Most HSR is conducted in academic medical centers, and requires a specialized environment with easy access to expertise in the social sciences and biostatistics, as well as to computers, specialized software, and the research infrastructure needed to store, manage, and analyze data directly collected from patients, or from databases. But tools alone are not enough; the research setting must also provide a supportive and collaborative environment that encourages collaboration across the research spectrum (Figure), and that values patient-based research equally with bench research. Collaboration with the generalist specialties such as general internal medicine and geriatrics, which have long track records in HSR, can enhance and enrich the environment for dermatologist investigators. Mentoring in HSR is as important for career development as it is in basic biomedical research; a useful model is that of a 'mentoring team' in which a few senior experts highly committed to a mentee's advancement each provide different aspects necessary for mentoring, such as scientific mentoring, and academic /career mentoring. A supportive and committed department Chair is the centerpiece of making the environment 'work' for a health services researcher. Finally, of course, in the US, substantial increases in research funding through the NIH and AHRQ will be necessary before we can study dermatologic health care adequately.

Conclusion

Health services research in dermatology is growing dramatically. Twenty years ago the Society for Investigative Dermatology (SID) received very few research abstracts in patient-based research, and even fewer that studied the care of skin diseases. Now the SID receives many abstracts in HSR, enough to support a robust concurrent session at the annual meeting. Similarly, over most of the last seventy-five years, the *Journal* only uncommonly published studies about health care. Now it more regularly features cutting-edge papers that report

results of many types of HSR studies in dermatology. We need HSR to answer pressing questions about our health and our investment in health care, and as a specialty we are beginning to participate in the response.

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