

# Report on “Burden of Skin Disease” Workshop

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Abrar A. Qureshi,\* Irwin Freedberg,† Lowell Goldsmith,‡ and Alan Moshell§

\*Channing Laboratory, Department of Dermatology, Brigham & Women’s Hospital, Harvard Medical School, Boston, Massachusetts; †Department of Dermatology, New York University, New York, New York; ‡Departments of Dermatology and Epidemiology, University of North Carolina Chapel Hill, North Carolina; §Skin Diseases Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, Bethesda, Maryland, USA

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### Workshop Discussion and Focus

A wide range of professionals and representatives from lay support groups met to address the “Burden of Skin Disease” in a meeting hosted by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in September 2002. Proceedings from the meeting were transcribed and are summarized herein. Recommendations were developed addressing the burden of skin disease in the United States and will be the basis of an initiative to encourage additional research and development related to this important issue.

The burden of skin disease represents more than just the economic burden and may not be measured by classic morbidity or mortality data. Rather, it represents the overall influence of skin disease on patients (including quality of life issues), their families and society (Barendregt *et al*, 1997; Murray and Lopez, 1997; Lopez and Murray, 1998). There is a relative (almost absolute) lack of data for most of these burdens and, more importantly, a deficiency of valid instruments to measure them at this time.

**Traditional measurements of the burden of skin disease** There is no single number or quantitative estimate, mathematical equation, or ratio that can summarize the burden of skin disease precisely or intuitively. The two main issues are:

1. How is skin disease defined?
2. How do we define the burden of skin disease?

Although the skin is a well-defined organ, it can be primarily or secondarily involved in a number of systemic conditions. Hence, the definition of skin disease remains ambiguous. Additionally, there is no consensus on terminology for coding skin disease. Definitions for skin disease will enhance an acceptable taxonomy system.

To approach a precise definition of skin disease, there must first be agreement on the names for skin disease. Currently the Dermatology Lexicon Project sponsored by NIAMS and the Carl J. Herzog Foundation is focusing on this problem and will have recommendations available soon. Another prerequisite is consensus among dermatology investigators and other professionals on methods for

analyzing data on clinical outcomes. Let us consider a study of mortality resulting from melanoma as an example. Data are obtained from the National Death Index (NDI). The data for NDI come from death certificates on which physicians document a cause of death. If the patient died because of a massive stroke in turn caused by melanoma metastases, then the cause of death could be documented as melanoma or stroke (Freedman *et al*, 2002). If it were the latter, deaths resulting from melanoma would be missed. Despite these limitations on the manner in which causes of mortality are classified and defined, mortality at least is a reliable clinical outcome because it is an all or nothing phenomenon (Severi *et al*, 2000; Geller *et al*, 2002). Nevertheless, few skin diseases are a direct cause of mortality.

Similarly, “incidence” is an important measure, usually expressed as an age-adjusted rate of the number of new cases of a particular disease or condition per a unit of time. Incidence rates have been presented in several ways, for example, in relation to geographic location or body site (Mathers *et al*, 2002). For malignancies, the SEER registries maintained by the National Cancer Institute since the 1970s are an important resource that provide data on the incidence of melanoma (Shaw *et al*, 1977). The drawback from a burden of skin disease perspective is that SEER does not include information on nonmelanoma skin cancer.

The “prevalence” of skin disease is another example of a frequently used point estimate. Prevalence takes into account a specific period of time over which new cases developed. It provides a more accurate and representative estimate of disease burden for chronic conditions. For example, prevalence of melanoma may underestimate the burden of this potentially life-threatening malignancy if patients with melanoma die soon after being diagnosed. On the other hand, incidence of psoriasis, that is, new cases of psoriasis per year, may underestimate the burden of this chronic inflammatory condition that is better captured by prevalence.

In contrast to mortality, incidence, and prevalence measures, the concept of “years of potential life lost” is computed in a number of different ways. One government agency may count years of life lost by estimating how much an individual’s life expectancy is reduced by an illness. Another

government agency may compute the number of years of life lost as an individual's years until mortality up to the age of 65 y (those formally being the productive years of life). This can result in very different answers for relative ranking of diseases by years of potential life lost.

There is a trade-off between making an attempt to summarize facts into a single number versus retaining their richness and information content. The results of the global burden of disease, as assessed initially by the World Bank, indicated that the burden of skin disease was relatively unimportant in all countries, regardless of income level. Approximately 1/10th of 1% of overall "burden" is attributable to melanoma, and approximately 1/10th of 1% of burden is due to other skin diseases. There has been widespread criticism of such an analysis among both economists and physicians and the face validity (whether the data makes sense at first glance) and content validity (whether the data address the question being asked) of the data have been questioned.

In this context, the Onchocerciasis Control Program (OCP) dramatically illustrates how the burden of skin disease is often underestimated (Benton *et al*, 2002). The OCP is a collaborative program implemented in 11 West African countries, initiated by the World Bank in collaboration with the World Health Organization. A complication of the disease onchocerciasis is "River Blindness," and the original concern was that loss of vision in a worker dependent on daily wages in a developing country would lead to major economic consequences. The economic impact is due to both the disability for the patient and the large areas of fertile land lying unused because of the risk of infection in endemic areas. After about 25 y of a sustained effort and careful economic analysis of benefits versus costs, one of the striking findings that emerged from the analysis was that although blindness was indeed important to patients, a major concern of the people who had been in the endemic region was the cutaneous complications of onchocerciasis including both severe itching and the long-term social consequences, because women who had been seriously affected could not marry because of skin-related problems. Thus, the cutaneous complications were substantially more important than the visual consequences in the lives of the people affected by the disease and to the beneficiaries of the control programs.

The message is that a single number or estimate cannot capture the true burden of skin disease. The challenges are to make sure that the goals of the measurement are clear, that the tools being used to gather data are reliable and valid for the population being studied, and that improvements are constantly being made to extend the analyses. Nomenclature for skin disease needs to be agreed upon and adopted as a standard. Once a standard is established, health services research can be conducted using standardized codes for disease categories, generating more reliable estimates for incidence or prevalence. These numbers or estimates can then be incorporated into matrices that will allow for priority setting exercises in terms of health policy development.

**Novel concepts of burden of skin disease and its impact on society** Public and congressional interest in the burden of disease stems from the trade-off between health burden

(impact of illness on functional status of the individual and society) and cost burden (impact of illness on economic status of individual and society) (Atherly *et al*, 2000; Brown *et al*, 2000). Funding of research efforts can have an impact in this trade-off, by allowing interpretation of findings and informed priority setting (Freedberg *et al*, 1999). Both the health burden and the cost burden are important to consider when planning such research efforts. Rising costs with little additional benefit are detrimental to the health-care delivery system. The purpose of measuring the overall burden of skin disease is to eventually focus on serious dermatologic conditions that have been previously:

1. Considered merely cosmetic in nature and hence allocated less research funding; or
2. Deemed less of a burden compared to a noncutaneous disease and hence also provided less attention at the policy level.

The burden of skin disease, or of any disease, must be a multidimensional concept, including the adverse impact of skin disease on economic factors, on length of life, and on various dimensions or domains of health, including physical health, psychological health, and social functioning. It includes impairments or pain, and it includes health perceptions of well-being, concern, or worry. How does disease impact society? How many and who are affected? What happens to their disease and the prognosis of their disease? What happens to them as individuals and how is their lifestyle affected? Can we measure the resulting job changes or losses, for example, and burden on society or on an individual as a result of losing that worker or that job? How much does it all cost?

A reliable and valid summary measure(s) of health and disease is needed. A theoretical ratio or mathematical comparison between "good" health on one end of the spectrum and "bad" health at the other extreme would constitute a single estimate of the burden of disease. The limitations of trying to define the concept of "burden of disease" have been discussed and such endeavors may not fully capture the essence of this concept, factually or philosophically (Gold and Muennig, 2002).

Addressing this novel and complex concept of "burden of skin disease" forces us to address a number questions simultaneously:

1. What are the elements that comprise the burden of skin disease?
2. What is the impact of these elements on public health and daily living?
3. What are current data collection instruments and can they be improved?
4. What kind of data collection instruments will be needed to facilitate the collection of future data, and what data will we need in the future?

The burden of cost of care is a recently developed but well accepted and validated metric (O'Brien and Briggs, 2002). Nevertheless, other factors that contribute to the overall well-being of patients with skin disease, such as personal and family issues, education, relationships, quality of life, and societal and social functioning, have not been

the focus so far. It is the purpose of this report to bring to the attention of policy makers and researchers, several areas of potential research in skin disease that require more rigorous study.

**Available quality of life and other measurement instruments** There are two overall approaches to assessing health-related quality of life. One involves global measures that integrate all aspects of quality of life such as social, mental, and physical well-being and provide a single number as an estimate. A disadvantage of this method is that a score of 0.60 gives little information about the ways in which a respondent's quality of life might be affected; an individual who is very physically impaired may have an identical score to one who is mentally impaired. The other method uses evaluation-oriented approaches. This method produces multiple scores for various subscales or domains, for example, a score for mental health, another for physical health, or body image or anxiety.

The patient's perspective of the burden of skin diseases is critical; because skin diseases rarely affect survival but often alter appearance and affect function (Kurwa and Finlay, 1995), they can affect patients' lives in complex ways, especially in emotional and functional domains. Patients' estimates of quality of life often correlate poorly with clinicians' estimates of the severity of a disease.

Health-related quality-of-life measures can also be classified as general or disease-specific (Table I) (Harlow *et al*, 2000; Levine and Ganz, 2002). Skin disease is not a single condition, but symptoms may be common to a number of conditions. Therefore, a general instrument can generate responses from any patient with a skin condition, whereas disease-specific quality-of-life measures are best suited for evaluating a patient's experience of a particular disease (Dijkers, 2003; Wiebe *et al*, 2003). Although not particularly sensitive to skin-specific domains, general quality-of-life measures have the advantage of providing estimates that can be compared across multiple diseases in the same specialty or in primary care or to compare dermatologic with nondermatologic diseases (examples include the medical outcomes short form (SF-36) and the sickness impact profile (SIP)). In addition to looking at health-related quality of life, economic burden (O'Hagan and Stevens, 2002) and—importantly—patient satisfaction can also be measured. The goal is to use a measure that can access the areas of most interest to the researcher and one that will be sensitive to change.

*Skin-specific quality-of-life indices* Examples of two commonly used skin-specific quality of life indices are the dermatology quality-of-life index (DLQI) (Finlay and Khan, 1994; Finlay, 1998) and Skindex. The DLQI (described in more detail elsewhere in this issue of the journal) was developed in the United Kingdom and has 10 items that address a variety of quality of life aspects. A single score is generated, varying from 0 to 30 (30 being the poorest quality of life). Skindex, developed on the United States, is available in a longer (29-item) and shorter (16-item) version. Responses to Skindex are reported as subscale scores for symptoms, emotions, and functioning. Skindex scores vary from 1 to 100 (100 being poorest quality of life).

Some additional examples of disease-specific quality of life measures in dermatology are the Psoriasis Disability Index, the Acne and Eczema Disability Index, the Acne Specific Questionnaire and other acne indices (Lasek and Chren, 1998) and Scalpdex (Chen *et al*, 2002). Ongoing work on evaluating patient preferences (utilities), emphasizing the patients' roles in their own health care, are related to but distinct from quality of life measures and have been demonstrated to be feasible in dermatology patients.

*Nontraditional measures of burden of skin disease* Qualitative research can also provide rich data about the burden of skin disease, particularly data that permit us to understand the complexities of this burden. For example, 10,000 e-mail messages were analyzed from 225 adults in an Internet support group for patients with eczema (presented by S. Diamond, San Francisco, CA). The results documented a broad range of quality-of-life effects including frequent incidents of shunning and outright discrimination, generalized anxiety, and pessimism regarding all intimate relationships. There were also specific fears of rejection and being considered unacceptable. The disease had an influence on family planning choices; the decision to bear children was affected by concerns about a possible child developing atopic dermatitis.

These results amplify typical results from quantitative studies of quality of life of specific diseases (Liakopoulou *et al*, 1997; Williamson *et al*, 2000): The physical, social, and emotional consequences of skin diseases are myriad and substantial. A quality-of-life study was performed on alopecia areata patients from 1994 through 1997 and a disease-specific questionnaire was validated. Approximately 740 questionnaires were distributed, 200 subjects responded, and the majority of the respondents were women (presented by Dr W. Bergfeld, Cleveland, OH). Body image, distortion, worry, patient expectations, poor attitude toward the present treatment, and discomfort about a diagnosis were found to be the major associations. Clinical depression was seen in all age groups. Disease-specific instruments can be used in further studies involving patients with alopecia areata.

An innovative example of a data collection vehicle that is not on paper or performed by an interview focused on a group of asthma patients who had been provided with video cameras. The videotapes they produced of their lives with asthma were used by multidisciplinary teams of physicians and psychologists to learn what that particular individual finds problematic in their life while living with this chronic illness.

From the perspective of the National Psoriasis Foundation (presented by T. Rolstad, National Psoriasis Foundation), the spectrum of burden of psoriasis again involves multiple quality-of-life domains including physical limitations from the disease, external limitations imposed on the individual by others, and emotional and psychosocial limitations. The physical limitations are experienced certainly most, but not exclusively, by people with moderate to severe psoriasis, which is about 1.5 million people in the United States. Severe itching, skin pain, swelling, and sleep deprivation are commonly experienced symptoms that cause significant quality-of-life problems. Plaques on the hands or feet, although they may not cover much of the body surface area, can prevent people from being able to

**Table I. A brief list of available health-related quality-of-life (HR-QOL) instruments**

<b>Instrument</b>	<b>Reference</b>	<b>Salient features</b>	<b>Dermatology-specific issues</b>
Generic instruments			
EuroQoL (EQ-5D)	Brooks <i>et al</i> (1996)	Simple instrument to administer 5 health dimensions addressed on a three-category response scale Principal question is a 20-cm vertical Visual Analog Scale	Typically used in cost-utility evaluation
Nottingham Health of Profile (NHP)	Hunt <i>et al</i> (1981)	More focused on feelings and emotions rather than behavior change (as in SIP)  38 items, 6 health dimensions No single summary index	Main focus is on genetics and immunology of psoriasis
Patient Generated Index (PGI)	Ruta <i>et al</i> (1994)	Based on patient nominated aspects of life that are then scored according to severity PGI scores items on a 0–10 scale SEIQoL scores items on a vertical Visual Analog Scale	Can be used as general QOL measures
Schedule for Evaluation of Individual Quality of Life (SEIQoL)	Hickey <i>et al</i> (1996)		
Short Form-36 (SF-36)	McHorney <i>et al</i> (1993)	Widely used generic HR-QOL instrument Items chosen from larger dimension-specific instruments used in Rand Medical Outcomes Study 36 items, 8 health dimensions One global question about overall health	Can be used as a general QOL measure
Sickness Impact Profile (SIP)	Bergner <i>et al</i> (1981)	Developed in the 1970s Measures illness-related dysfunction 136 statements, 12 health dimensions Interviewer- or self-administered Can be used as a general QOL measure	
Disease-specific instruments			
Dermatology Quality of Life Index (DLQI) <sup>a</sup>	Finlay and Khan (1994)	Skin disease-specific 10 items, 6 health dimensions	Has been evaluated in various skin diseases
European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30	Aaronson <i>et al</i> (1993)	Cancer-specific 30 items, 5 functional scales, 3 symptom scales Global health-status-QOL scale and single items assessing cancer-related symptoms such as insomnia, constipation, etc.	May have some use in skin cancer research
Functional Assessment of Cancer Therapy (FACT)	Cella <i>et al</i> (1993)	Disease-specific instrument FACT-G is the core instrument, part of the Functional Assessment of Chronic Illness Therapy (FACIT) 29 items, 5 health dimensions	May have some use in skin cancer research
Pediatric Asthma Quality of Life Questionnaire (PAQLQ)	Juniper <i>et al</i> (1996)	Targeted to children aged 7–17 y with asthma 23 items, 3 health dimensions One global question Interviewer-administered version preferred	
Rotterdam Symptom Checklist (RSCL)	Smets <i>et al</i> (1996)	Cancer focused 30 items on 4-point scales, a question about activity level, a global question with seven categories	May have some use in skin cancer research
Skindex <sup>a</sup>	Chren <i>et al</i> (1996)	Skin disease-specific 29 or 16 items; 3 scales Self-administered	Has been evaluated in various skin diseases

<sup>a</sup>Skin-disease-specific instruments.

hold their children, work at a computer, or care for their homes. Treatment may require clinic visits three or four times a week, particularly for patients undergoing phototherapy. In addition, self-care can take 1 h or more per day for many people including bathing and application of topical ointments, treatments, and moisturizers. External limitations that are faced by people with psoriasis and many other skin diseases include discrimination. Because of inappropriate questions of contagion, patients are asked not to work in food service or customer service positions or maybe prevented from taking advantage of recreational opportunities, such as participating in health clubs, swimming pools, or school sports.

All clinicians caring for patients with skin diseases can attest to the fact that the effects of dermatologic disease on patients are not captured by traditional measures (Gilbody *et al*, 2002). Repeat testing may provide more reliable data compared to a single evaluation. Hence, the emphasis on the richness of the information obtained from quality-of-life measurements (Chren *et al*, 1997) and, in this report, the guarded skepticism about summary measures.

**Available databases and data sets** There are a number of databases that have been generated either by purposeful disease surveillance mechanisms (e.g., National Health and Nutrition Examination Surveys) or as a by-product of the health-care delivery system (e.g., billing and coding data from the Centers for Medicare and Medicaid Services). A few examples of national, population-based databases and privately maintained, disease-specific databases are summarized in Table II. The list is by no means complete but serves as an introduction to a variety of databases available for researchers.

Databases can be classified into four broad categories. *Administrative databases* contain data that are collected for administrative purposes, such as billing or scheduling. Although administrative databases are created for a nonresearch purpose, a great deal of information relevant to burden of disease can be gleaned from them. *Patient record databases* are compilations of information that are meant to aid in patient care. The trend over the past few years to create electronic medical records has allowed such databases to be created. *Registries* can be incredibly helpful to researchers in the health services arena since these databases contain already identified or diagnosed individuals of interest. *Cross-sectional surveys* can yield a wealth of information that is usually of high quality, as it is typically collected for research purposes.

Databases do have limitations because of the manner in which data compilation is performed and the initial purpose of data collection. Consistency and completeness of data are important. Whether it is the economic burden and cost of managing illness or the health-related aspects of burden in terms of premature mortality and disability, data are not always collected with research hypotheses in mind. Bearing in mind some of these limitations, databases can be used to obtain answers to research hypotheses of interest.

## Workshop Recommendations

**Novel approaches to defining and evaluating the burden of skin disease** It is clear from existing evidence that more

work is needed in the patient-oriented research arena. Creative approaches are needed to measure how much of an impact skin disease can have on an individual or a community. There is a natural tendency to use techniques and strategies that have been created and validated in other fields, which is reasonable as long as the overall approach is also relevant to measurable outcomes in skin disease. Nevertheless, this dilemma of burden of skin disease measurement also creates a unique opportunity for groundbreaking work in the development of measures specific to dermatology. There are even fewer measurements looking at the burden of skin disease in children, and this should be kept in mind when designing new studies.

There are two mutually exclusive, but not collectively exhaustive, categories of disease burden measurement that the workshop participants felt should be addressed in future research endeavors:

1. Cost-effectiveness studies, including issues of direct costs, and productivity losses associated with the disease (Emery and Schneiderman, 1989); and
2. Quality-of-life measures, including the social and emotional impact of disease.

Using these approaches, data need to be collected in the United States in large population studies. One option is to collect disease-specific data using disease-specific instruments, capturing the consequences and impact of a specific condition. This option has the capacity to track progress in the treatment or prevention of that condition. Another option is to collect disease-specific data using generic instruments that yield quantitative information that can be compared to similar data from other disease-specific analyses. Such comparisons can potentially be used to inform a larger priority-setting exercise at a health-policy level. One can make the argument that these two methods of data collection are not alternatives and, in fact, are complimentary.

Another approach would be to employ a combination of measures, with the data-gathering vehicle composed of multiple modules. Core modules would collect data that are common to all areas of skin disease and disease-specific modules would ask questions about a specific disease type. A global skin disease quality-of-life instrument that is not disease-specific could be matched with other disease-specific instruments as chosen by individual investigators.

The combination of factors that affect quality of life can be collectively referred to as the compounded burden of disease. The variables that are of particular significance to an individual, as well as the comprehensive burden, may be immeasurable using standardized instruments. If the goal is to have an impact on patient care, additional qualitative tools must be used. As in the psychometric assessment arena, such new measures or instruments that serve as data collection vehicles will take some time to develop, test, and validate.

How can one best quantitatively measure a qualitative problem such like quality of life? First, a comprehensive hypothesis or a conceptual framework for the effects of skin disease on patients' quality of life must be developed. Second, questions or items that address all aspects of the

Table II. A list of available databases

Database	Agency/organization	Web site	Salient features	Dermatology-specific issues
BLS (Bureau of program Labor Statistics)	U.S. Department of Labor	<a href="http://www.bls.gov/">http://www.bls.gov/</a>	Fact-finding agency in labor economics and statistics.  Several programs including "Prices and living conditions" and "Employment and unemployment." About 160,000 workers surveyed annually.	Injuries, illness and Fatalities (IF) relevant to occupational dermatoses.
Coalition of Patient Advocates for Skin Disease Research	National Institute of Arthritis and Musculoskeletal and Skin Diseases and American Academy of Dermatology	<a href="http://www.aad.org/patientadvocacy.html">http://www.aad.org/patientadvocacy.html</a>	Registry of about 2500 subjects.  Data on costs available, e.g., cost of dental work in a patient with ectodermal dysplasia.	Mixed population of skin diseases.
GPRD (General Practice Research Database) <sup>a</sup>	Medicines and Healthcare Products Regulatory Agency (MHRA)	<a href="http://www.gprd.com/">http://www.gprd.com/</a>	Approximately 35 million years of data, 3 million patients since 1987, approximately 5% of the UK population. Computer medical records database.	Skin-disease specific data available in diagnosis and treatment.
Marfans syndrome and related disorders genotype consortium	National Marfans Foundation	<a href="http://www.marfan.org/">http://www.marfan.org/</a>	Interest in Fibrillin-1 International collection of genetic mutations found in fibrillin-1 gene.	Phenotype-genotype correlations.
Medicare, Medicaid, Current Beneficiary Survey	CMS (Centers for Medicare and Medicaid Services)	<a href="http://cms.hhs.gov/">http://cms.hhs.gov/</a>	<i>Medicare:</i> Mainly claims data, some clinical data. All beneficiary data deidentified. Since 1991, 33 million active enrollees, 70 million in entire database. <i>Medicaid:</i> More recent, since 1999. 25 states contribute data, hence not national. <i>Medicare Current Beneficiary Survey:</i> Face-to-face interviews with beneficiaries Prescription drug information	Skin-disease specific data available.
NAMCS (National Ambulatory Medical Care Survey)	NCHS (National Center for Health Statistics) at the Centers for Disease Control and Prevention	<a href="http://www.cdc.gov/nchs/about/major/ahcd/ahcd1.htm">http://www.cdc.gov/nchs/about/major/ahcd/ahcd1.htm</a>	Annually, 3000 physicians randomly selected.  Nonfederally employed. 30 patient visits per physician recorded over 1 wk 1973–1981, 1985, and annually since 1991.	Dermatologists interviewed as well.
NDI (National Death Index)	NCHS (National Center for Health Statistics) at the Centers for Disease Control and Prevention	<a href="http://www.cdc.gov/nchs/r&amp;d/ndi/ndi.htm">http://www.cdc.gov/nchs/r&amp;d/ndi/ndi.htm</a>	Centralized index of death records  Solely for statistical use. Records since 1979.  1-y lag time for records to appear on index.	Deaths from skin cancer-related causes recorded.

NHANES (National Health and Nutrition Examination Survey)	NCHS (National Health Statistics) at the Centers for Disease Control and Prevention	<a href="http://www.cdc.gov/nchs/nhanes.htm">http://www.cdc.gov/nchs/nhanes.htm</a>	Since 1970s.  Physical examination component in Mobile Examination Center (MEC). US population-based home interview. Health and nutrition information.	Dermatology digital imaging component in NHANES III.
NHIS (National Health Interview Survey)	NCHS (National Health Statistics) at the Centers for Disease Control and Prevention	<a href="http://www.cdc.gov/nchs/nhis.htm">http://www.cdc.gov/nchs/nhis.htm</a>	Approx. 38,500 households screened in 2002 (107,000 individuals). Health status and resource utilization. Self-reported data. Targeted for inclusion of minorities.	A few questions targeting dermatitis, in the workplace.
NPTB (National Psoriasis Tissue Bank)	National Psoriasis Foundation	<a href="http://www.psoriasis.org/">http://www.psoriasis.org/</a>	Approx. 50,000 members.  Tissue bank set up since 1994.	Main focus is on genetics and immunology of psoriasis.
National Registry for Ichthyosis and Related Disorders	University of Washington and National Institutes of Health	<a href="http://depts.washington.edu/ichreg/ichthyosis.registry/">http://depts.washington.edu/ichreg/ichthyosis.registry/</a>	Approx. 800 subjects partially enrolled.  Approx. 500 subjects fully enrolled. Subjects self-enrolled. Health-related quality-of-life data can be evaluated for approx. 500 subjects.	Covers the following disorders: inherited ichthyosis, erythrodermatitis, Darier's disease, Hailey-Hailey, palmar-plantar keratoderma, pachyonychia congenita, extensive epidermal nevi.
SEER (Surveillance, Epidemiology and End Results)	National Cancer Institute	<a href="http://www.seer.cancer.gov/">http://www.seer.cancer.gov/</a>	Program ongoing since 1978. At present 11 population-based cancer registries and three supplemental registries.  Covers 14% of US population. More than 3 million cancers included to date.	Melanoma included. Nonmelanoma cancers not included.
Veteran Data and Information and NSV (National Survey of Veterans)	Department of Veterans Affairs	<a href="http://www.va.gov/voletdata/">http://www.va.gov/voletdata/</a>	Census 2000 data. Expenditure data, 1999. Medical workload data by station, 1999. NSV with 20,048 interviews.	

<sup>a</sup>Based in London, UK.

hypothesized framework must be composed or borrowed from other instruments that may test similar issues. Third, the instrument must be pilot tested with patient responses to determine the reliability, validity, and sensitivity to change of the instrument. Finally, the instrument must be modified based on the pilot data obtained before being used for data collection.

A precedent for the type of overall measures proposed may have already been set. In 2001, the National Cancer Institute (NCI) undertook a major initiative to help establish a core set of health-related quality-of-life cancer measures. The goal was to improve comparability and to maximize the usefulness of data collected. Thirty-five scientific experts were assembled as the Cancer Outcomes Measurement Working Group to assess the state of outcomes measurement in cancer and identify priorities for future research and practice. This group serves not as an advisory body or a consensus panel, but provides input to define a core set of outcome measures for health-related quality of life. In addition, the group will eventually evaluate ways to measure economic burden and patient satisfaction as well as the continuum of care (Deffenbaugh, 1994). The latter ranges from screening and prevention treatment to survivorship and end-of-life issues. The group will also evaluate various applications including patient and clinician decision-making algorithms, clinical trials, observational studies, and population monitoring, as well as reimbursement and policy decisions.

As a variety of different measures are developed and used to quantify various aspects of the burden of skin disease, involvement of patient groups is pivotal to demonstrate their confidence and trust for the research endeavors to patients. The Coalition of Patient Advocates for Skin Disease Research has an important view of future research endeavors. Their intent is to examine the burden of skin manifestations that relate to systemic involvement, age, sex, disease severity, and psychosocial effects, with the assumption that evaluating quality-of-life issues for an individual in the context of the family and the community would yield results more representative of the problem. Because accurate measurement and integrated assessment is needed, partnerships between patient groups and surveillance entities, like government, academia, or industry, can encourage patient participation and compliance.

**Data collection and warehousing needs** As noted, there are unique challenges even in defining the term "skin disease." The definition is quite broad: Thermal burns, eczema, and skin infections are all classified as skin disease. Decubitus ulcers are also skin disease, but may not be managed by dermatologists, and melanoma is primarily considered an oncologic disease rather than a skin problem. An even bigger challenge is that certain conditions are not considered a disease per se, such as skin aging, striae, and male pattern baldness. Also important to consider is the perspective of society versus the perspective of the family or an individual, all of whom view the burden of skin disease from a different angle.

Before large databases are planned, there needs to be consensus on a nominative system for skin disease categories to aid in coding. As previously noted, the

Lexicon Project will report its recommendations in the near future. Multicenter initiatives that include investigators from many disciplines are then needed to plan for creation of large-scale prospective databases that are assembled at the point of care, prospectively over time. Population-based measures and studies will help measure the impact of disease on the individual patient over a relatively short interval, but a large sample size can help provide an assessment about the state of the population.

It is important to realize that a registry is a kind of database that allows investigators to perform prospective studies on patients who have been identified with a particular disease. In the classic sense, a registry is just a list of names that enables other people to perform the prospective studies, validate different instruments, use the tissue samples that were obtained decades before, and evaluate what happens to the patient after therapy.

A database or registry that is set up to measure burden of skin disease in the United States will be faced with an ethical dilemma. Should it be focused on a population-wide approach to data collection or should it be focused on a subset of the population that is at "high risk" for development of the skin disease of interest. Ethical issues arise if a large proportion of individuals who are equally high risk are neglected if the mechanism to identify those at high risk is inaccurate and unreliable. Investigators assembling databases of this nature will be in the best position to resolve this issue.

Costs for assembling a comprehensive database can be extremely high. If databases are assembled for research purposes, significant amounts of grant funding and participation of multiple centers or at least one large center is necessary. If the research hypotheses target problems that are relatively common in the source population, a relatively small database may suffice. Nevertheless, when disease trends are largely unknown, very large data sources with very large numbers of people are needed if any conclusions are to be drawn (Taylor, 2001). Once a database is available, a range of study designs can be applied depending on the nature of the research question, including cohort, nested case-control, case-cohort, case-control, and cross-sectional studies.

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Address correspondence to: Alan Moshell, MD, Skin Diseases Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892-4872. Email: moshella@mail.nih.gov

For more information, see Dynamic Assessment of Patient-Reported Chronic Disease Outcomes (<http://grants.nih.gov/grants/guide/rfa-Files/RFA-RM-04-011.html>)

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