The International Dermatology Outcome Measures Initiative as Applied to Psoriatic Disease Outcomes: A Report from the GRAPPA 2013 Meeting

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ABSTRACT. In the United States, access to care is the number one issue facing our patients with dermatological conditions. In part, this is because we do not have outcome measures that are useful in clinical practice and available in databases where payers and governmental agencies can compare the performance of physicians and treatments. There is a growing recognition that insufficient attention has been paid to the outcomes measured in clinical trials and subsequently in clinical practice. The International Dermatology Outcome Measures group includes all willing stakeholders: patients, physicians, payers, and pharmaceutical scientists. As reported herein, the group's goal is to develop outcome measures in dermatology that address the needs of all involved. (J Rheumatol 2014;41:1227–9; doi:10.3899/jrheum.140176)

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Dermatologists need validated outcome measures for dermatologic diseases that are useful not only in clinical trials but also to payers, patients, and healthcare providers in the community. In the United States, payers judge the quality of dermatologists and their treatment choices based upon data collected from claims databases and not upon data using disease-specific outcome measures. The lack of validated, standardized outcome measures for most dermatologic diseases contributes to the difficulty in assessing value of treatments supporting third-party payment for appropriate dermatologic care.

In the past, decisions on treatment choice were made by physicians. In the United States, payers increasingly dictate what provider and which treatments a patient can access. Payers often stratify physicians based upon their cost efficiency (physician tiering). Too often, tiering makes dermatologists who assume the challenges of treatment-resistant and severe patients appear less cost-effective compared to their peers who deal with milder disease or choose not to offer the full repertoire of treatments. Current physician-tiering initiatives do not assess either case mix (patient severity) or disease-specific outcomes when making decisions regarding cost effectiveness and quality of healthcare providers. The unintended result is that physicians taking care of the most complicated and sick patients are often tiered as being the least cost-efficient[1,2].

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Most primary care physicians receive limited training about dermatology during residency and therefore have inadequate knowledge about the serious aspects of dermatologic diseases. For example, too often, diseases such as psoriasis are viewed by payers and regulators as largely cosmetic problems and not equal in severity to the rheumatologic disorders. In part, this is due to skin disease outcome measures that do not include all aspects of psoriatic or other multisystem diseases in which skin is the major organ involved.

Current outcome measures may lack truth, discrimination, and feasibility[3]. For example, the Psoriasis Area and Severity Score[4,5], accepted as one of the major outcome measures for psoriasis, exhibits multiple failures: It is not practical to use in the clinical setting (feasibility); it is not responsive to change at lower body surface areas; and it does not include all skin involvement, e.g., nails (truth and discrimination).

Rheumatologists initiated the OMERACT process (Outcome Measures in Rheumatology) during the explosion of new biologic treatments developed for rheumatoid arthritis (RA) in the 1990s[3]. Many of the rheumatologic outcome measures we now take for granted were developed through the OMERACT process and are now used as core outcome measures in clinical trials in rheumatology[6].

The OMERACT process gathers all the relevant groups and is interactive and data-driven. Objectives of the OMERACT process include determination of the core domains that constitute a disease and that should be measured in clinical trials, as well as development and validation of outcome measures. All, including expert clinicians and patients, participate in nominal group exercises and focus groups to determine candidate domains, followed by Delphi exercises and a voting process to prioritize domains and confirm a core set to be measured. The first disease studied by OMERACT was RA, but the process has also developed outcome measures for numerous other rheumatologic conditions including psoriatic arthritis, vasculitis, gout, osteoarthritis, and fibromyalgia.

In January 2013, the first meeting of the International Dermatology Outcome Measures (IDEOM) group was held in Boston, Massachusetts, USA. IDEOM members (n = 35) chose to study outcome measures for psoriasis first, given the large number of clinical trials in this area. The group started with a very small budget and with significant help from the US National Psoriasis Foundation (NPF). International attendees included dermatologists interested in psoriasis, acne, and cutaneous systemic lupus erythematosus (SLE) outcomes; OMERACT mentors; pharmaceutical industry health economists; payer representatives; patients; and expert members of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), NPF, and the American Academy of Dermatology (AAD). Introductions to the OMERACT process were made, and analytic techniques and current outcome measures for psoriasis were reviewed. Patient, payer, and physician representatives presented outcome measure needs from their particular perspectives. As a result of this meeting, a preliminary list of items and domains for psoriatic disease was generated, broadly including pathophysiology, quality of life/psychosocial, economics, psoriatic arthritis, and death.

Following the inaugural IDEOM meeting, a preliminary Delphi questionnaire was distributed in May 2013 in a global Internet survey to 155 participants (138 psoriasis experts including dermatologists, rheumatologists, payers, regulators, and industry partners; and 17 patients with psoriasis). The objective of this first Delphi exercise was to identify items for further evaluation as outcome measures for psoriatic disease from the various perspectives of patients with psoriasis, healthcare providers, and others. The initial survey items were generated from the Boston meeting in January 2013 and from additional input. The Delphi questionnaire comprised 193 items, and all participants were asked to evaluate each item as "very important," "maybe important," and "not important." Multiple reminders were sent prior to closing response to the questionnaire.

Eighty participants completed the questionnaire. Data analysis was adapted from the OMERACT process based on the "onion model," where an item was to be included in the core set, outer core, or research agenda, if it met a set of determined criteria[7]. These criteria accounted for the total number of respondents, distribution of the responses, and participant perspectives. Of the 193 items on the questionnaire, 40 items were entered into the preliminary core set, 28 into the preliminary outer core set, and 58 into the preliminary research agenda category. Initial data analysis showed that 67 items would have been eliminated from further evaluation based on statistical criteria alone.

The above results were then presented for discussion at the second meeting of IDEOM in July 2013 in Toronto, Ontario, Canada. The 61 attendees included physicians, patients, and pharmaceutical company representatives. The overall goal was to determine which items that would have been eliminated based on statistical criteria alone should remain on the item list while still minimizing the total number of items. The participants voted on item inclusion, provided justification for their choices, and were asked to provide feedback on item wording as well as suggesting new items for the list. When a new item was suggested, participants voted on whether to add that item; ultimately, several new items will be added to the original set. Between the Toronto meeting and the meeting in Rome, Italy, in April 2014, a second Delphi international survey will have been circulated to a larger number of patients and dermatologists.

In addition to addressing outcome measures for psoriatic disease, the Toronto meeting included progress reports on cutaneous SLE outcome measures, presented by Dr. Victoria Werth (University of Pennsylvania, Philadelphia,

Pennsylvania, USA), and on outcome research initiatives, presented by Drs. Murad Alam (Northwestern Memorial Hospital, Chicago, Illinois, USA, representing the AAD) and Matthias Augustin (University Clinics of Hamburg, Germany, representing the European initiatives). In breakout sessions, IDEOM members chose the following mission statement: "Establish patient-centered measurements to enhance research and treatment for those with dermatologic diseases." Plans for the second Delphi analysis were further refined and an expanded invitee list for IDEOM's work was generated. Results of breakout group activities were reported to all attendees.

It is the goal of IDEOM to apply the OMERACT process to dermatologic diseases in order to develop validated and standardized outcome measures useful in both academic and community practice. Analogous to how OMERACT started with RA, IDEOM has chosen to start with psoriasis outcome measures and then apply its methodology to other dermatologic disease. The ultimate goal is to develop outcome measures that reflect the true effect of disease so that our patients can receive the right therapy from the right provider.

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