The International Dermatology Outcome Measures Group: Formation of patient-centered outcome measures in dermatology

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As quality standards are increasingly in demand throughout medicine, dermatology needs to establish outcome measures to quantify the effectiveness of treatments and providers. The International Dermatology Outcome Measures Group was established to address this need. Beginning with psoriasis, the group aims to create a tool considerate of patients and providers using the input of all relevant stakeholders in assessment of disease severity and response to treatment. Herein, we delineate the procedures through which consensus is being reached and the future directions of the project. (J Am Acad Dermatol 2015;72:345-8.)

Key words: body surface area; Delphi exercises; Dermatology Life Quality Index; disease severity; International Dermatology Outcome Measures; National Psoriasis Foundation; Outcome Measures in Rheumatology; patient-centered outcome measures; Physician Global Assessment; psoriasis; Psoriasis Area and Severity Index; psoriatic arthritis; quality of life.

The International Dermatology Outcome Measures (IDEOM) initiative was established to address the need for standardized, patient-centered clinical outcome measures to assess disease course and response to treatments, and ultimately to improve patient outcomes and access to high-quality

Abbreviations used:

IDEOM:	International Dermatology Outcome Measures
OMERACT:	Outcome Measures in Rheumatology
PASI:	Psoriasis Area and Severity Index

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Funding sources: None.

Disclosure: Dr Gottlieb maintains current consulting/advisory board agreements with Amgen Inc, Astellas, Centocor (Janssen), Celgene Corp, Bristol Meyers Squibb Co, Beiersdorf Inc, Abbott Labs (Abbvie), TEVA, Actelion, UCB, Novo Nordisk, Novartis, Dermipsor Ltd, Incyte, Pfizer, Canfite, Eli Lilly, Coronado, Vertex, Karyopharm, CSL Behring Biotherapies for Life, Glaxo Smith Kline, Xenoport, Catabasis, and Sanofi Aventis. Dr Armstrong served as a consultant and was investigator for Abbvie, Amgen Inc, Janssen, Eli Lilly, Pfizer, and Merck. Dr Abernethy served on the advisory board of Abbvie and as speaker for Pfizer receiving honoraria and is an employee for National Psoriasis Foundation receiving salary. Dr Duffin served on the advisory board and was consultant and investigator for Amgen Inc, Janssen, Eli Lilly, and Pfizer; served as consultant and investigator for VBL Therapeutics receiving honoraria and salary; was investigator for Abbvie receiving salary; and served as consultant for Bristol Myers Squibb Co receiving honoraria. Dr Garg served on the advisory board of Eli Lilly, Amgen Inc, Abbvie, Genentech, and Pfizer receiving honoraria. Dr Merola served on the advisory board and was investigator for Amgen Inc; was on the advisory board on Eli Lilly and Novartis; was an investigator for Pfizer and Biogen; was speaker for Abbvie; and had an "other" relationship with Abbvie and Biogen receiving honoraria. Ms Maccarone is the founder of Associazione per la Difesa degli Psoriasici—Italian Association for Psoriasis receiving no compensation. Dr Christensen receives no compensation from industry. Tufts Medical Center received research/educational grants from Centocor (Janssen), Amgen Inc. Abbott Labs (Abbvie), Novartis, Celgene, Pfizer, Eli Lilly, Coronado, Levia, and Merck. Ms Levin and Dr Bhushan have no conflicts of interest to declare.

Accepted for publication November 3, 2014.

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Published online December 6, 2014.
0190-9622/$36.00

http://dx.doi.org/10.1016/j.jaad.2014.11.002

dermatologic care[1]; this goal is represented in the mission statement, "Establish patient-centered measurements to enhance research and treatment for those with dermatologic disease."[1] It is IDEOM's practice that the perspectives of patients, health economists, and payers are represented along with those of physicians and regulatory agencies in outcome measures for dermatologic disease. Alice B. Gottlieb, MD, PhD, first proposed the group's formation in recognition of a lack of comprehensive outcome measures that satisfy the needs of all stakeholders and that can be used in clinical practice. IDEOM's goal is to establish validated and standardized outcome measures that can be applied both in clinical trials and clinical practice. Unlike the evaluation of blood pressure or diabetes, for example, quantifying the severity of psoriasis in clinical records is not straightforward. As a result, we lack adequate tools to compare the quality of care for psoriasis among clinical practices, thus cost becomes the default measure to compare dermatologists. Payers limit access to dermatologists who provide the full spectrum of psoriasis care based on higher cost and not quality of care. This manifests as higher copays for physicians caring for the sickest patients; access is thus limited by economic disincentives. US payers are increasingly demanding disease-specific outcome measures generated by both patients and physicians that can be easily used in the clinical setting. Most of the measures in existence do nt fully address patients' concerns. Some are not practical for use in clinic whereas others are overly reductive in their simplicity. IDEOM has included patients and physicians from its beginnings to develop clinically meaningful end points reflective of measures primary to patients, including how a patient feels, functions, and performs activities of daily living.

At the inaugural IDEOM meeting in January 2013, in Boston, MA, 35 members selected psoriasis as the prototype disease given its burden on patients, the relative absence of patient input for existing measures, and the significant advancement in therapy over the past 2 decades. Patients with psoriasis are frequently undertreated; 1 National Psoriasis Foundation survey found that up to 50% of patients with severe psoriasis are treated exclusively with topical medications.[2] Participants agreed that current outcome measures lack truth, discrimination, and feasibility. Psoriasis Area and Severity Index (PASI), for example, is not efficiently applied to the clinical setting because of cumbersome calculations and a lengthy process; this demonstrates lack of feasibility.[3] Moreover, it is not sensitive to change in patients with low body surface

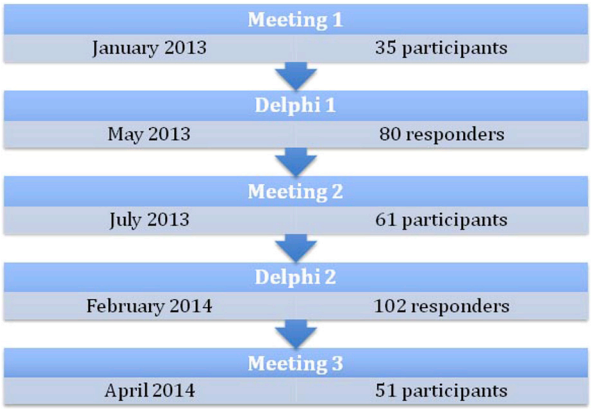

Fig 1. Flowsheet delineating the Delphi process.

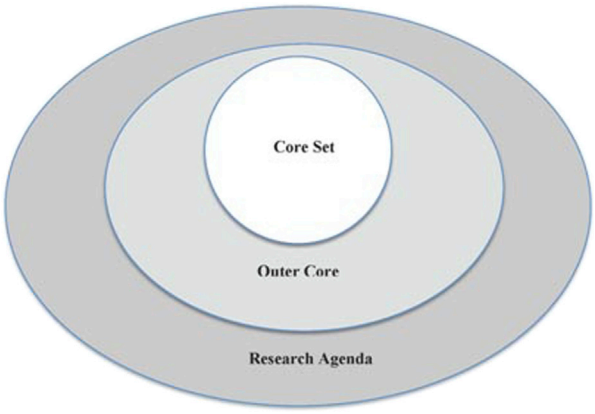

Fig 2. Onion model. Core set: $P_{combined} \geq .70$ AND a lower limit of the 95% confidence interval ≥ 0.50, outer core: either patients or health care providers report $P \geq .70$, research agenda: $P_{combined} \geq .50$. $P_{combined}$ is the proportion of votes for an item being important across both patients and health care providers. ($P \geq .70$ was adopted from the Outcome Measures in Rheumatology model. Modified with permission from Mease et al.[13])

area and it does not accurately represent disease impact on nonskin integument, such as nails: limitations in its truth and discrimination.[4] The PASI scale is not on a normal distribution curve and the upper end is infrequently used.[5] Although the PASI has good intraobserver variability, it lacks significant interobserver variability.[6] It also lacks a patient-reported portion, it does not measure quality of life, and it fails to account for the impact of involvement of cosmetically or functionally sensitive areas. Nevertheless, PASI remains the most common outcome measure in use, and has in fact increased in prevalence from use in 30.6% of studies in 1977 through 2000 to 57.7% in 2001 through 2006.[7] Physician Global Assessment is also problematic, with various numerical scales coexisting and no