An Update on The IDEOM (International Dermatology Outcome Measures) Initiative to Restructure Current Psoriasis Outcome Assessment Measures to a Globally Uniform Set of Patient-Centric Outcome Measures for Use in Clinical Trials and Clinical Practice

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ABSTRACT
The International Dermatology Outcome Measures (IDEOM) group was created with the goal of establishing improved, as well as patient-centered, outcome measures. The effort involves the worldwide participation of those involved in the treatment of psoriasis, including dermatologists, rheumatologists, pharmaceutical and device company medical officers, payors, regulatory officers, patient advocacy groups including the National Psoriasis Foundation, and patients themselves. This review will outline the work done to date, the methodology utilized, and future planned action, including a worldwide search for patient representatives to this endeavor.

INTRODUCTION
The IDEOM (International Dermatology Outcome Measures) group was created with the goal of establishing improved, as well as patient-centered, outcome measures (identified results produced by an exposure or intervention) for various dermatological conditions.¹² In order to gain international regulatory and payer acceptance, these new outcome measures must meet the approvals not only of the researchers and pharmaceutical industry but also from treating physicians, payers, patients, patient advocates, and more. Global participation is necessary.

The need for patient-centered studies is becoming recognized throughout medicine. The Wall Street Journal recently published an article discussing the new trends toward greater patient involvement in evaluation and formation of clinical trials. Investigators working on new prostate cancer medications are modifying evaluation of drug efficacy to include the effects on patient lifestyle and function, stressing outcome measures not traditionally measured. Patients are helping design trials to monitor diabetes in children at the University of Wisconsin and epilepsy drugs in children at Emory University.³ The Patient-Centered Outcomes Research Institute (PCORI) is a nonprofit group that allows for funding of comparative effectiveness research. Its goal is to improve the quality and relevance of available information to help patients, physicians, insurers, and others make informed health decisions. By funding research that addresses the questions and concerns most relevant to patients, the methods used to conduct studies can be improved.⁴ The goals of IDEOM are part of a larger need for this modification of traditional clinical research.

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The first undertaking for IDEOM has been for psoriasis. The initial meeting occurred in Boston in 2013 and was attended by dermatologists, rheumatologists, pharmaceutical and industry representatives, payers, patients, and regulatory agencies. Since then, IDEOM has met in Toronto in 2013 and in Rome in 2014. IDEOM has been organized into a 401c3 with support from industry, The Group for Research & Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), and the National Psoriasis Foundation (NPF), a psoriasis patient advocacy group.

In 2012, pSOAR (psoriasis outcome assessments), with a similar plan of action, was started through DermatoEpidemiology Expert Resource Group (DermEpiERG) of the American Academy of Dermatology (AAD) and Ameriderm DermatoEpidemiology Network (ADEN). An overlapping international group of dermatologists, patient advocacy groups, pharmaceutical and device industry, regulatory agents, CROs, IRBs, and others was assembled at the AAD 2013 in Miami Beach by James A. Solomon, M.D., Ph.D., and Murad Alam, M.D. April Armstrong, M.D., M.P.H., a member of both groups, initiated the efforts to join with IDEOM to create a single combined effort, starting with the Toronto 2013 IDEOM meeting.

**METHODOLOGY**

As noted in previous articles in the Psoriasis Forum, the methodology used by IDEOM is modeled after the OMERACT (Outcome Measures in Rheumatoid Arthritis Clinical Trials) precedent for improvement of outcome measurement in rheumatoid arthritis in 1992. Similarly, IDEOM’s aim is to define outcome measures in dermatological diseases, starting with psoriasis.

Psoriasis has multiple components. It classically presents with skin and nail manifestations. However, there also is psoriatic joint disease. The disorder is associated with metabolic syndrome, an increased cardiovascular morbidity and mortality, depression, and self-destructive behavior such as smoking and alcohol. The complex manifestations of this disease necessitate outcome measurements that encompass all these aspects.

There are multiple scoring systems to evaluate the severity of a psoriasis disease state, including the Physician Area and Severity Index (PASI), Physician’s Global Assessment (PGA), and Body Surface Area (BSA). The PASI is the most widely accepted outcome measure and considered the gold standard in clinical trials. Nonetheless, the PASI scoring fails to account well for improvements greater than 90% and fails to distinguish involvement that interferes with activity of daily living and/or emotional well-being. In addition, it does not take into consideration other facets of psoriatic disease, such as nail involvement, quality of life, and associated comorbidities. The Dermatology Life and Quality Index (DLQI) evaluates the extent to which psoriasis affects quality of life, well-being, and daily physical function. Other scoring systems evaluate different aspects of psoriasis. They each have their own pitfalls. No outcome measure scoring system addresses economic impact. None of these assessments fully addresses patient-oriented outcome assessments, which can be used uniformly throughout the world. A psoriasis outcome assessment measure that addresses severity, quality of life, and economic impact and other patient-identified essential criteria is needed.

The most recent meeting of IDEOM took place in July 2014 in Rome. It was determined that the primary obstacle to optimal psoriasis care was access. Often, psoriasis treatment is viewed as a cosmetic problem by payers and regulators and thus not equal in significance to problems such as rheumatologic disorders, for example. Current outcome measures are contributing to this by not taking into account all aspects of psoriatic disease as they affect the patient from the patient’s perspective. In addition, current measures may not be helpful in distinguishing which drugs add extra value. Consequently, payers are making decisions on physician and drug quality based on standards that do not assess either patient severity or disease-specific outcomes.

The convening parties discussed these issues and reached consensus via the Delphi survey process, an iterative process serving to prioritize core set and domains most pertinent. This allows for elimination of interpersonal problems, efficient use of time, diversity of ideals, and accuracy of solutions and predictions. In this way, outcome measures can address the needs of all stakeholders. Outcomes are ranked in increasing importance and subsequently stratified into classes.
RESULTS
The first Delphi questionnaire completed by 138 psoriasis experts and 17 patients in Boston resulted in a list of five preliminary core sets and domains for psoriatic disease: namely, Pathophysiology; Quality of Life/Psychosocial; Economics; Psoriatic Arthritis; and Death. In addition, 21 element groups were identified for discussion in the second Delphi. In the first part of Delphi 2, there were 102 responders representing 8 countries and consisting of 79 health care providers, 12 patients, 8 pharmaceutical scientists, 1 researcher, 1 payer, and 1 professional associate. Part two of Delphi 2 was conducted in Rome at the IDEOM meeting, was attended by 80 people including the NPF, 55 providers and researchers, and 14 patients. The need for sensitive and reliable measures to capture disease severity, in a manner feasible for use in both clinical trials and practice, was expressed. Participants agreed that psoriatic arthritis assessment was a requisite in outcome measures, though seldom addressed in psoriasis trials. The three highest scoring domains were: Psoriasis morphology; Location and area; and Psoriatic arthritis. For the third round of Delphi analysis, teams of dermatology and patient experts have grouped psoriasis aspects into six core areas: Pathophysiological manifestations; Adverse events; Life impact; Death; Resource use/economic Impact; and Contextual factors.

GOALS
IDEOM has adopted the goal to reach out globally to patients and patient groups to increase patient input, ultimately resulting in a ratio of 1:1 patient to provider/other stakeholder participants. The 2015 meeting will take place in Washington, D.C. Through collaboration at these IDEOM meetings, dermatologists can equip themselves with new means to confront the multi-focal entity that is psoriasis, and eventually apply this method to other skin diseases. This effort will require international participation from patients, dermatologists, rheumatologists, payers, patient advocacy groups, and many others. The development of standardized outcome measures is the basis through which effective patient-centered care can be achieved.

Currently, in conjunction with NPF and GRAPPA, IDEOM is seeking patient representatives from around the globe who can represent not only themselves but also other patients with psoriasis. Patients as well as patient groups interested in being part of the process should contact Dr. Solomon at drjsolomon@ameridermresearch.com.

REFERENCES