International Dermatology Outcome Measures Initiative as Applied to Psoriatic Disease Outcomes: An Update

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ABSTRACT. Previous publications have described the International Dermatology Outcome Measures (IDEOM) group, comprising patients, physicians, health economists, participating pharmaceutical industry partners, payers, and regulatory agencies. The goal of IDEOM is to create patient-centered, validated measures of dermatologic disease progression and treatment efficacy for use in both clinical trials and clinical practice. We provide an update of IDEOM activities as of our 2015 IDEOM meeting in Washington, DC, USA. (J Rheumatol 2016;43:959–60; doi:10.3899/jrheum.160114)

Key Indexing Terms:
PSORIASIS IDEOM OMERACT OUTCOME MEASURES

The International Dermatology Outcome Measures (IDEOM) initiative was established to address the need for standardized, patient-centered clinical outcome measures that satisfy the needs of all (patients, healthcare providers, payers, and regulators). The goal of these outcome measures is to assess disease course and response to treatments, ultimately improving patient outcomes and access to high-quality care. Previous publications have outlined the founding goals and objectives of IDEOM at some length[1,2,3].

Although the development of a core set of domains to be measured in studies will initially target interventional clinical trials, with an ever-increasing emphasis on performance and quality metrics, many of these same domains will be recommended for use in the clinic and in longterm clinical registries. The IDEOM group has used a Delphi consensus process to define and meet the needs of a broad group of stakeholders in developing a novel set of core measures. Working groups have been formed to focus on psoriasis and to evaluate hidradenitis suppurativa, with ultimate interest in multiple areas of dermatologic disease.

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The first IDEOM meeting occurred in 2013 in Boston, Massachusetts, USA, where participants conducted a literature review and generated items for review through a preliminary Delphi round[2]. Further expansion and refinement of candidate items for domains/subdomains were reviewed at an IDEOM meeting held in Toronto later in 2013, which led to a Delphi exercise on 21 proposed domains, the first results of which were presented at an international meeting in Rome, in April 2014. A revision of the conceptual model was prepared for the next rounds of Delphi consensus.

The fourth IDEOM meeting, held in Washington, DC, USA, in February 2015, comprised a group that included physicians (dermatologists); regulators [representation from the US Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS)]; nonprofit organizations, e.g., American Academy of Dermatology (AAD) and Advancing Innovation in Dermatology; experts in patient-centered outcomes [from the Patient-Centered Outcomes Research Institute (PCORI)]; experts at the forefront of quality metrics and outcomes [representatives from the National Quality Forum, Agency for Healthcare Research and Quality (AHRQ), and PCORI]; industry partners; health economists; and most importantly, patients. In total, 62 participants represented the following groups: patients (n = 7), physicians (n = 14), payers (n = 1), industry partners including health economists (n = 2), regulators (n = 8), nonprofit organizations (n = 11), and others (n = 19).

The Washington meeting was organized into a needs assessment review followed by a working meeting around the Delphi process, initially to be specifically focused on psoriasis domains in clinical trials and to include a later, more comprehensive assessment of domains for registries and clinical practice.

The review and assessment of needs/gaps in psoriasis

disease state outcomes began with a presentation from each relevant group.

William Ju, MD, Advancing Innovation in Dermatology. Dr. Ju reviewed the potential influence of IDEOM as it relates to drug development and innovation. Investment in new therapies and their development will be substantially enabled (a) with validated primary endpoints that create a path to registration, and (b) with outcome measures that demonstrate value to patients, providers, and payers.

Sophia Autrey, MPH, of CMS. Autrey presented Physician Quality Reporting System measures selection and the process of submission of measures for evaluation by CMS.

Kendall Marcus, MD, FDA Director of the Division of Dermatology and Dental Products. Dr. Marcus discussed the interests and needs of the FDA around psoriasis outcome measures. She reported that all clinical psoriasis trials should expect to continue using the Physician Global Assessment (primary outcome of clear/almost clear and a 2-point improvement on preferred 5-point scale), as well as the 75% improvement in the Psoriasis Area and Severity Index (PASI75) as a co-primary endpoint. Dr. Marcus discussed a recent emphasis on validated patient-reported outcomes to more accurately assess the patient's experience and the labeling that reflects that experience.

James Taylor, MD, Chair, Committee on Patient Safety and Quality of the AAD. Dr. Taylor discussed the need for outcome measures in clinical practice, focusing on the AAD's DataDerm, a clinical database to provide dermatologists with benchmark reports, access to clinically relevant data, quality measurement, and information to improve patient care.

Elise Berliner, PhD, AHRQ. Berliner reviewed patient involvement in research and outcome measure development, emphasizing the need for large amounts of high quality data to evaluate and compare outcomes.

Jean Slutsky, PA, of PCORI, reviewed the research goals and grant funding criteria that PCORI applies to facilitate patient-centered research initiatives.

Aligned with FDA interests in secondary exploratory outcome measures, the IDEOM group is planning its next steps, including development of relevant and novel outcome measures focused on functional impairment, social functioning, and identifying events for which a complex interplay between individual disease and treatment may exist.

To summarize the Delphi process to date, an initial list of over 193 psoriasis-relevant items was generated at the first meeting in Boston. This was followed by distillation exercises, and Delphi questionnaire rounds with the goal of identifying core domains whose response to treatment must be measured in every clinical trial. Using the products of this work, IDEOM is actively developing a framework with which to approach psoriasis clinical trials and eventually apply standards in the measurement of disease in clinical practice and real-world registries. An 18-question revised Delphi survey is currently circulating among stakeholders.

At our next IDEOM meeting in March 2016, in Washington, agenda items will include presentation of the results of the round 1 Delphi, results of a payers roundtable (in collaboration with the US National Psoriasis Foundation), and updates from key participants including Dr. Marcus of the FDA. A new IDEOM working group focused on the development of outcome measures in hidradenitis suppurativa will also report its findings at the 2016 event.

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