Measuring Outcomes in Clinical Practice: Don’t Get Mad. Get Data!

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DISCLOSURE OF RELEVANT RELATIONSHIPS WITH INDUSTRY

Current Consulting/Advisory Board Agreements/or Speakers Bureau:

Janssen Inc.; Celgene Corp., Bristol Myers Squibb Co., Abbvie, UCB, Novartis, Incyte, Lilly, Reddy Labs, Valeant, Dermira, Allergan, Sun Pharmaceutical Industries, Xbiotech, Leo, Avotres

Research/Educational Grants:

Incyte, Xbiotech, UCB (pending), Novartis (pending)
“If dermatologists don’t participate in a meaningful collection of real-world data, then other entities, government and insurance providers, for example, will set for us unsubstantiated and invalidated standards of care”
If you are not at the table, you are on the menu.
IDEOM: Mission

• “To establish patient-centered measurements to enhance research and treatment for those with dermatologic disease”

• Perspectives of patients, health economists, payers, non-profits, physicians and regulatory agencies are included from the onset

• IDEOM’s goal is to establish validated and standardized outcome measures that satisfy the needs of all stakeholders and can be applied to clinical research and clinical practice

• A 501C3 non profit organization
Selected Deliverables To Date

• **Domains for Psoriasis for Clinical Trials Selected**

• **Collaboration with and obtained funding support for HISTORIC, an international consortium of HCPs and patients, provided domains for Hidradenitis Suppurativa clinical trials.**

• **Published results of a Stakeholders meeting with payers to get their perspective on unmet issues.**
Selected Deliverables to Date Continued

- Working with acne outcome group (ACORN) to establish global measures for clinical practice
- Helped NAAF in their development of a PRO for AA
- Multi-year direct involvement with the FDA’s Dermatology Division at IDEOM meetings
- Initiated a continuing collaboration with the AAD and patients to establish HCP-and Patient Provided- global measures for clinical practice
  - Alice B. Gottlieb, MD, PhD, Nicole Salame, BA, April W. Armstrong, MD, MPH, Joseph F. Merola, MD, MMSc, Sylvia Parra, MD, Junko Takeshita, MD, PhD, MSCE Suephy C. Chen, MD, MS John Latella, BS, MS, Marta Van Beek, MD, MPH. A Provider Global Assessment Quality Measure for Clinical Practice for Inflammatory Skin Disorders JAAD, https://doi.org/10.1016/j.jaad.2018.09.017.
Psoriasis Domains for Clinical Trials

Skin Manifestations
- Primary (BSA/erythema/induration/scale)
- Location of Skin Lesions
  - Palmar-Plantar Psoriasis
  - Scalp Psoriasis

Investigator Global
Psoriasis and Psoriatic Arthritis
Symptoms

Patient Global
Treatment Satisfaction
Health Related Quality of Life

Skin Manifestations
- Nail Psoriasis
- Inverse Psoriasis
- Genital Psoriasis
- Guttate Psoriasis
- Secondary Manifestations

PsA signs
Economic Impact
- Direct cost
- Indirect cost
Work Productivity/Participation
Cardiovascular disease
Two active workgroups working on psoriasis core outcomes

- **Psoriatic Arthritis Symptoms**
  - Delphi process completed. PSAID 9 and 12 chosen
  - PSAID part of CORRONA data collection and psoriasis clinical trials

- **Treatment Satisfaction**
  - Systematic review in preparation
  - Validation of a new instrument is about to begin
HS workgroup working on outcome measures for core domains:

• The final set includes five domains, voted critical by both HCPs and patients:
  • pain
  • physical signs
  • HS-specific quality of life
  • progression of course
  • global assessment
What Payers Need from Outcome Measures

- Universally accepted, published outcome measures, useful in clinical practice, and mandated to perform in published guidelines issued by major professional societies
- Clinically meaningful outcome measures (i.e., not enough to be better than placebo)
- Outcomes which can be used to justify cost given the benefit/risk aspects of a drug
- Outcomes which can measure how the overall cost of care decreases by the treatment intervention
  - e.g., Reduce incidence of PSA or cardiovascular morbidity/mortality
- Outcomes which measure effects on patient productivity
- Outcomes which, when applied universally, reduce variability in practice, thus making costs more predictable
- Would like to see a measure which “would look like a diagnostic test” so that a solid connection between using the outcome measure and making a therapeutic decision can be made
  - Treat to Target is an example
- EMRs are obstacles currently

A Provider Global Assessment Quality Measure for Clinical Practice for Inflammatory Skin Disorders: Results of a Meeting Held February 3, 2018 in NYC

On Behalf of The International Dermatology Outcome Measures and the American Academy of Dermatology

Alice B. Gottlieb, MD, PhD Nicole Salame, BA April W. Armstrong, MD, MPH Joseph F. Merola, MD, MMSc Sylvia Parra, MD Junko Takeshita, MD, PhD, MSCE Suephy C. Chen, MD, MS John Latella, BS, MS Marta Van Beek, MD, MPH. JAAD, 2018, https://doi.org/10.1016/j.jaad.2018.09.017.
Why did we meet?

• Dermatologists need to prove the value of care they provide to patients with skin diseases. Healthcare economists define value as quality of outcomes divided by cost of care.

• Current quality measures for inflammatory skin diseases have limited validity (do they measure what they are supposed to?) and feasibility (are they practical?).

• In the absence of robust quality measures, cost becomes the major determinant of quality. Also, it is impossible to treat to a target if the target is unknown.

• Through collaboration and a modified Delphi process, the International Dermatology Outcome Measures (IDEOM) group and American Academy of Dermatology (AAD) aimed to reach consensus on a valid and feasible provider-assessed global disease severity outcome measure to be incorporated into a quality measure for inflammatory dermatoses.
Methodologies Used:

• To help make informed decisions during the Delphi process, a review of the literature was performed, and data were reviewed on current provider-assessed global disease severity outcome measures.

• Following literature review, 36 members of IDEOM and the AAD participated in the modified Delphi process to reach consensus on features of the outcome measure. At the start, 23 inflammatory skin diseases were suggested by those present to be put in the Delphi process.

• Because of the controversy regarding access, confidentiality, and security of integrated patient-reported data into the electronic medical record, a provider-assessed, as opposed to a patient-assessed, metric was chosen.

• The roles of the 36 members are shown on the next slide:
### Demographics of Collaborators (n=36)

<table>
<thead>
<tr>
<th>Category</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatologists</td>
<td>18 (50)</td>
</tr>
<tr>
<td>Rheumatologists or rheumatologists/dermatologists</td>
<td>6 (17)</td>
</tr>
<tr>
<td>Pediatric dermatologists</td>
<td>3 (8)</td>
</tr>
<tr>
<td>Outcome measures experts</td>
<td>7 (19)</td>
</tr>
<tr>
<td>Patient</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Research Fellow</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>
Initial List of Diseases for Global PGA

• Acne
• Atopic Dermatitis
• Psoriasis
• Cutaneous Lupus
• Hidradenitis Suppurativa
• Rosacea
• Seborrheic Dermatitis
• Urticaria
• Vitiligo
• Alopecia Areata
• Dermatitis (drug eruptions, contact dermatitis, nummular dermatitis)
• Actinic Keratosis
What were the top 3 diseases chosen?
Consensus was achieved when ≥90% (“overwhelming consensus”) of collaborators voted “strongly agree” or “somewhat agree” on an item. Psoriasis, atopic dermatitis, and acne achieved overwhelming consensus for inflammatory dermatoses that could be measured in a global disease severity outcome measure.

<table>
<thead>
<tr>
<th>Response, n (%)</th>
<th>Inflammatory Skin Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Psoriasis</td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>28 (80)</td>
</tr>
<tr>
<td>Somewhat Agree</td>
<td>6 (17)</td>
</tr>
<tr>
<td>Neutral</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Somewhat Disagree</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Total</td>
<td>35 (100)</td>
</tr>
</tbody>
</table>
## Selection of a Global Assessment Tool

<table>
<thead>
<tr>
<th>Response, n (%)</th>
<th>Global Assessment Scale-Type</th>
<th>5-point ordinal scale (0-4)(^a) without descriptors</th>
<th>5-point ordinal scale (0-4)(^a) with descriptors</th>
<th>10-point Numeric Rating Scale (NRS)</th>
<th>Dichotomous (aka yes or no) assessment of achieving clear/almost clear versus not</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly Agree</td>
<td>16 (49)</td>
<td>15 (46)</td>
<td>5 (15)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Agree</td>
<td>9 (27)</td>
<td>6 (18)</td>
<td>2 (6)</td>
<td>2 (6)</td>
<td></td>
</tr>
<tr>
<td>Neutral</td>
<td>1 (3)</td>
<td>4 (12)</td>
<td>4 (12)</td>
<td>4 (11)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Disagree</td>
<td>5 (15)</td>
<td>7 (21)</td>
<td>12 (37)</td>
<td>8 (23)</td>
<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>2 (6)</td>
<td>1 (3)</td>
<td>10 (30)</td>
<td>21 (60)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>33 (100)</td>
<td>33 (100)</td>
<td>33 (100)</td>
<td>35 (100)</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) without descriptors
Summary of IDEOM’s Annual Meeting in May 2018, Delphi on Outcome Measures for Clinical Practice

• Consensus on wanting both a Provider- and a Patient-Reported Outcome measure for every patient encounter

• Consensus on payers basing treatment payment based upon both a Provider- and a Patient-Reported Outcome measure

• Treat to target strategies should be based upon maximizing both a Provider- and Patient-Reported Outcome Measure
Developing a Global Patient Reported Outcome Measure for Clinical Practice: October 13, 2018
Summary of Global PRO Outcome Measure for Clinical Practice IDEOM/AAD Collaboration

• 10 adult patients each with acne, psoriasis and atopic dermatitis and selected HCPs met in Chicago in October, 2018. Process education, literature review and voting process was similar to that used for the HCP meeting.

Results of Meeting’s Activities:
• Most patients thought the use of a PRO was to initiate a conversation with the HCP not to determine treatment choice
• Combination of a Patient PGA and Skindex mini (3 question PRO) was liked
• No consensus on single set of measurement times for PRO administration; appeared to be disease specific
What’s next?

• We will approach the AAD to accept a MIPS process measure which asks: “Did you measure the outcome of your treatment?”.

• We will continue to work on validating simple and EMR-friendly measurement tools that can be used by community dermatologists and their patients to quantitate outcomes of their treatments.
  • Validate our 3-disease PGA against the individual, disease-specific PGAs
Regulatory Approval and Publications are Just the Beginning:

The true finish line is when the patient gets to the right doctor and the right treatment and their disease has minimal to no impact on their quality of life.
Don’t Get Mad: Get Data!