International DErmatology Outcomes Measures

Modeled after OMERACT: Outcomes Measures in Rheumatology

1992 original intent: obtain agreement on the minimum number of outcome measures to be included in all rheumatoid arthritis clinical trials. Global organization, applied rigorous methodologies to determine core measures in all areas of rheumatology.
• Recognized that most effectiveness trials evaluate whether an intervention is effective and safe

• Choice of measures to reflect benefit and harm

• In most areas:
  • choices not standardized
  • heterogeneity between trials
  • potential for bias (selective outcome reporting)
  • choice of measures less relevant to users (e.g. PASI75)
Rigorous methodology to gain consensus, for a disease state:

WHAT to measure (CORE DOMAINS)
HOW to measure (CORE MEASUREMENT SET)
In WHICH setting (trial, longitudinal study, clinical practice)
OMERACT Filter

**Truth:** Does the outcome tool measure what it is supposed to in an unbiased and relevant manner?

**Discrimination:** Does the outcome measure discriminate between situations? e.g., measures changes with treatment, comparison with active or placebo control

Reliability and sensitivity to change are important

**Feasibility:** Is this a practical measure? Factors include time, money, etc.
Important: choice of additional Domains, Depending on study question

Research: additional Domains of interest

one Domain from each of 4 CORE AREAS:
Pathophysiologic manifestations
Life Impact
Death
Resource Use
Psoriatic Arthritis Core set

**CORE:**
- Peripheral joint activity
- Skin activity
- Patient global
- Pain
- Physical Function
- Health Related Quality of Life

**Areas of interest:**
- Dactylitis
- Enthesitis
- Spinal
- Fatigue
- Radiology
- Acute phase reactants

**Research:**
- MRI
- CT
- Ultrasound
- Tissue analysis
- Participation

OMERACT working groups

Large Vessel Vasculitis
Low Back Pain
Myositis Osteoporosis
Polymyelgia Rheumatica Psoriatic Arthritis
Remission in RA
Systemic Lupus Erythematosus Systemic Sclerosis
Vasculitis
• **501c3**

• **Current psoriasis working group and board of directors:**
  - Alice Gottlieb MD, PhD
  - Kristina Callis Duffin MD, MS
  - April Armstrong MD, MPH
  - Amit Garg MD
  - Joe Merola MD, MMSc

• **Patient members of working group:**
  - Courtney Schneider
  - Ellen Clements

• **NPF Volunteers assisting with IDEOM efforts:** Leah North, Leah Howard

• **OMERACT advisors:** Maarten Boers, Philip Mease, Dafna Gladman, Robin Christensen
IDEOM’s Inaugural Meeting:
Boston, MA January 2013

100 attendees, representation from many stakeholder groups:
Dermatologists
Rheumatologists
OMERACT Advisors (Philip Mease, Maarten Boers)
National Psoriasis Foundation
GRAPPA
Patients
Industry
American Academy of Dermatology

Missing: payers/CMS, FDA
LITERATURE REVIEW and GENERATION of CANDIDATE DOMAINS/SUBDOMAINS

DEVELOP CONCEPTUAL MODEL of DOMAINS/SUBDOMAINS

CONSENSUS PROCESS (DELPHI): to determine the CORE DOMAIN SET

DETERMINATION OF Core Outcome Measurement Set FOR CLINICAL TRIALS

1st IDEOM Meeting, Boston, MA January 2013:
- Literature Review, generation of items
Post meeting:
- Preliminary Delphi to generate items

2nd IDEOM Meeting, Toronto, Ontario, Canada, July 2013:
- Further expansion and refinement of candidate items for domains/subdomains
Post meeting:
- Delphi on 21 proposed domains

3rd IDEOM Meeting, Rome, Italy April 2014
- Presentation of first Delphi results
Post meeting:
- Revision of conceptual model to prepare for new Delphi

4th IDEOM Meeting, Washington, DC February 2014
- Presentation and vote on Core Domain Set
- Initiate determination of Core Measurement Set for psoriasis clinical trials
Example: what a Psoriasis Core Domain set might look like when finished – after rounds of Delphi

One Domain from each of 4 CORE AREAS:
- Pathophysiologic manifestations:
  - Skin activity
  - Nail activity
  - Musculoskeletal activity
  - Investigator global
- Life Impact:
  - Psoriasis symptoms
  - Patient global
  - HRQOL
- Death

additional Domains, Depending on study question:
- Resource Use
- Scalp activity
- Inverse activity
- Palmar-plantar activity

Research: additional Domains of interest:
- Comorbidities
- Participation
- Tissue analysis
EXAMPLE: Potential psoriasis core set

DOMAINT: INSTRUMENT
Skin activity: PASI?
Nail activity: NAPSI?
Investigator global: PGA? PGA x BSA?
Patient global: VAS?
Psoriatic arthritis: ?
Psoriasis symptoms: PSI? PSD?
HRQOL: DLQI

Apply OMERACT Filter:
TRUTH
DISCRIMINATION
FEASIBILITY

CONSENSUS on WHICH MEASURES

If doesn’t meet criteria
DEVELOPMENT of NEW MEASURE
IDEOM short and long term objectives

Establish Core Domains
psoriasis clinical trials

Establish Core Measurement sets for psoriasis

Apply IDEOM methodology to other settings and skin conditions

Psoriasis clinical practice
Psoriasis registries

Hidradenitis suppurativa, lupus, pemiphigus, acne, others

For second layer and research agenda, establish working groups to develop or guide development of new measures