



INTERNATIONAL DERMATOLOGY OUTCOME MEASURES

## PRESIDENT'S UPDATES

**Alice Bendix Gottlieb MD, PhD**

**Board of Directors**

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Since the last IDEOM newsletter, IDEOM met with representatives from the AAD's quality, database and outcomes committees and are co-developing outcome measures for clinical practice across multiple dermatologic disorders. For health care providers, a single physician's global assessment (PGA) tool to measure treatment outcomes for psoriasis, atopic dermatitis and acne has been selected. In October, this same group will meet with patients with psoriasis, atopic dermatitis and acne to choose a Patient Reported Outcome (PRO) tool for patients to use in clinic to assess treatment response.

In May, the IDEOM annual meeting was held in Washington DC and was a huge success. Dr. Kendall Marcus, the Head of the Dermatology Division at the FDA, spoke to us on how the FDA picks PROs. The psoriasis group focused on the treatment satisfaction and psoriatic arthritis symptoms outcome measurement tools. The hidradenitis suppurativa workgroup met and reported on their progress, to be further discussed by Dr. Garg later on in this newsletter. The ACORN acne workgroup presented their outcomes research to date. A lively discussion was held around the use of PGAs in acne. We look forward to another exciting annual meeting in 2019. We presented our work at multiple meetings including the AAD's annual meeting, the International Investigative Dermatology meeting, and the International Federation of Psoriasis Associations. I have listed our peer reviewed publications for the year to date below:

### **Papers on Outcome Measures published by IDEOM members this year:**

1. Thorlacius L, Garg A, Ingram JR, Villumsen B, Theut Riis P, Gottlieb AB, Merola JF, Dellavalle R, Ardon C, Baba R, Bechara FG, Cohen AD, Daham N, Davis M, Emtestam L, Fernandez-Penas P, Filippelli M, Gibbons A, Grant T, Guilbault S, Gulliver S, Harris C, Harvent C, Houston K, Kirby JS, Matusiak L, Mehdizadeh A, Mojica T, Okun M, Orgill D, Pallack L, Parks-Miller A, Prens E, Randel S, Rogers C, Rosen CF, Choon SE, van der Zee HH, Christensen R, Jemec GBE. Towards global consensus on core outcomes for Hidradenitis Suppurativa research: An update from the HISTORIC consensus meetings I and II. *Br J Dermatol.* 2018;178(3):715-721.
2. Thorlacius L, Ingram JR, Garg A, Villumsen B, Esmann S, Kirby JS, Gottlieb AB, Merola JF, Dellavalle R, Christensen R, Jemec GBE. Protocol for the development of a core domain set for hidradenitis suppurativa trial outcomes. *BMJ Open*

- 2017;7(2):e014733\
3. Joseph F. Merola, David A. Amato, Kyoungah See, Russel Burge, Craig Mallinckrodt, Clement K Ojeh, Alice Gottlieb. Evaluation of sPGAxBSA as an outcome measure and treatment target for clinical practice. *J. Invest. Dermatol.* *J Invest Dermatol.* 2018 Mar 22. pii: S0022-202X(18)31741-X. doi: 10.1016/j.jid.2018.01.041. [Epub ahead of print]
  4. Callis Duffin K, Merola JF, Christensen R, Latella J, Garg A, Gottlieb AB, Armstrong AW. Identifying a Core Domain Set to Assess Psoriasis in Clinical Trials:A Combined Delphi Consensus Survey from the International Dermatology Outcome Measures Initiative, *JAMA Dermatology*, Published online June 6, 2018. doi:10.1001/jamadermatol.2018.1165
  5. Gottlieb AB, Merola JF, Chen r, Levi E, Callis Duffin K: Assessing clinical response and defining minimal disease activity in plaque psoriasis with the Physician Global Assessment and body surface area (PGA x BSA) composite tool: An analysis of apremilast phase 3 ESTEEM data. *JAAD* 77: 1178-1180, 2017.
  6. Gottlieb AB, Kirby B, Ryan C, Naegeli AN, Burge R, Bleakman AP, Anatchkova MD, Yosipovitch G. The development of a patient-reported measure for assessment of genital psoriasis symptoms: The genital psoriasis symptoms scales (GPSS). *Dermatology and Therapy* published online. <https://doi.org/10.1007/s13555-017-0213-2>, 2017
  7. Gottlieb AB, Kirby B, Ryan C, Naegeli AN, Burge R, Bleakman AP, Anatchkova MD, Cather J: The development of the genital psoriasis sexual frequency questionnaire (GenPs-SFQ) to assess the impact of genital psoriasis on sexual health. *Dermatology and Therapy*, published online. <https://doi.org/10.1007/s13555-017-0212-3>, 2017

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## PATIENT'S PERSPECTIVE

**John J. Latella**  
**Board of Directors**  
**Patient Research Partner**



The IDEOM Annual Meeting held in Washington D.C. in early May has stirred efforts to dedicate a section of the IDEOM Website ([dermoutcomes.org](http://dermoutcomes.org)) to patient concerns and information. In this manner everyone is kept up to date on the latest information shared at the Patient's Pre-Meeting held the evening prior to the conference. Dermatologic disease groups represented in IDEOM were in attendance, as was North American, Europe and African representation with either patients or patient organizations.

From the May meeting Nicole Salame, Lourdes Perez Chada and Bente Villumsen provided a wealth of written information on the subjects we discussed Saturday at the conference in language that was easily understood. Additionally, Nicole and Lourdes created a 'Glossary of Terms' with definitions that helped to an even greater degree to understand what was presented for psoriatic disease patients. Bente also provided a wonderful glossary for HS patients. All of this information can be found on the Patient's Page on the IDEOM Website. If you have suggestions for additional input, feel free to contact me or Amanda Pacia.

John J. Latella  
IDEOM Board of Directors  
Patient Research Partner

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## PSORIASIS UPDATE

**April W. Armstrong, MD, MPH**  
**and Kristina Callis Duffin, MD, MS**

## Board of Directors IDEOM Workgroup Leads for PsO



During the 2017 IDEOM meeting in Washington, D.C., the Psoriasis Workgroup had ratified the Core Domain Set to be measured in all psoriasis clinical trials. International consensus on these core domains was reached through an iterative Delphi process among all stakeholders, including providers, regulators, payers, and patients.

Since the 2017 meeting, the Psoriasis Workgroup has made significant progress towards the identification of a Core Measurement Set, which is comprised of valid and feasible measures of the Core Domain Set. Through systematic review of the literature and use of COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology, the Psoriasis Workgroup has identified and evaluated the performance of treatment satisfaction, investigator global, patient global, and pediatric psoriasis instruments.



At this year's IDEOM meeting in Washington, D.C. (May 2018), the Psoriasis Workgroup convened to present and discuss the workgroup's progress towards the identification of a Core Measurement Set. Stakeholders included 15 dermatologists, 2 rheumatologist-dermatologists, 16 industry partners, 10 patients and patient-association representatives, 1 non-profit dermatology organization, and 2 research fellows. The geographic representation of attending stakeholders spanned the continents of Asia, Africa, Europe, North America, and South America. The workgroup met over two concurrent sessions with the goal of presenting the identified instruments, discussing the appraisal of their measurement properties, and voting on their use in the Core Measurement Set.

During the first plenary session, the workgroup presented and discussed results from the analysis of the measurement properties of identified treatment satisfaction, investigator global, and patient global instruments used in psoriasis. A treatment satisfaction instrument in development was also presented, and stakeholders voted on features of the instrument. Results from the critical appraisal of the performance of identified treatment satisfaction instruments have been published. Results for the investigator and patient global instruments will be presented in future publications.

During the second plenary session, the workgroup presented and discussed identified outcome measures used in pediatric psoriasis. Published results from the analysis of the measurement properties of these measures were also presented. Stakeholders then voted on the feasibility of each of the measures. In addition, stakeholders voted on the validity of the highest performing instrument, the Children's Dermatology Life Quality Index (CDLQI), for use in the pediatric psoriasis population.

Following the IDEOM meeting, the Psoriasis Workgroup will continue efforts towards the identification of a Core Measurement Set. Systematic review of the literature and critical appraisal of the performance of identified instruments will inform this process. Future efforts will be published and presented at the upcoming IDEOM meeting in May 2019.

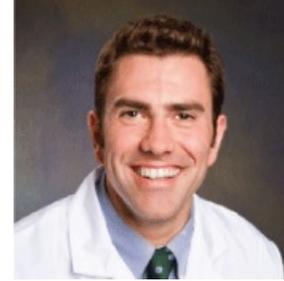
### Psoriasis Workgroup Publications, 2017-2018:

Identifying a Core Domain Set to Assess Psoriasis in Clinical Trials: A Combined Delphi Consensus Survey from the International Dermatology Outcome Measures Initiative  
JAMA Dermatology, in press  
Callis Duffin K, Merola JF, Christensen R, Latella J, Garg A, Gottlieb AB, Armstrong AW

Are Your Patients Satisfied? A Systematic Review of Treatment Satisfaction in Psoriasis  
Dermatology, in press  
Salame N, Perez-Chada LM, Singh S, Callis Duffin K, Garg A, Gottlieb AB, Latella J, Merola JF, Armstrong AW

Patient-Reported Outcome Measures for Pediatric Psoriasis: A Systematic Review and Critical Appraisal from International Dermatology Outcome Measures (IDEOM)  
Dermatology, in press  
Salame N, Torres J, Sandhu J, Callis Duffin K, Garg A, Gottlieb AB, Latella J, Merola JF, Armstrong AW

## Board of Directors IDEOM Workgroup Lead for PsA



The IDEOM Psoriasis Workgroup has included Psoriatic Arthritis (PsA) Symptoms in the core domain set to be measured in all psoriasis clinical trials. Psoriatic Arthritis is a progressive, inflammatory condition frequently associated with psoriasis that can lead to irreversible joint damage and impairment of quality of life. Despite this, PsA is rarely assessed in psoriasis clinical trials. Furthermore, the cases of PsA among patients with psoriasis are not well defined in this setting.

The PsA Workgroup has conducted an international, multidisciplinary and multi-stakeholder on-line Delphi survey to achieve consensus on whether patients enrolling in a psoriasis clinical trial should first be screened for PsA and then with which measure their PsA symptoms should be assessed. The results showed that 90% of participants agreed that all patients enrolling in a psoriasis trial should be screened for PsA. Regarding the measurement set for “PsA Symptoms”, the Psoriatic Arthritis Impact of Disease 9 (PsAID9) was selected as the most appropriate measure, while the Routine Assessment Patient Index Data 3 (RAPID3) could be an acceptable alternative to PsAID9.

The Delphi results were presented at the 2018 IDEOM Annual Meeting, Washington D.C., with audience polling. Among respondents (N=40), 77% agreed that there is no need for a second Delphi round to determine whether patients should be screened in psoriasis clinical trials before measuring “PsA Symptoms”; 76% agreed that there is no need for a second round to establish that PsAID9 is the best instrument to measure PsA Symptoms, and that RAPID3 is an acceptable alternative; 86% preferred the PSAID9 over RAPID3 to measure PsA symptoms in psoriasis clinical trials. This will be followed by a workshop at the GRAPPA 2018 annual meetings to review discussion points as well as any need for a second Delphi round.

Efforts of the PsA Workgroup were recently presented at the at the American Academy of Dermatology (AAD) meeting (San Diego, 2018), the Society for International Investigative Dermatology (IID) meeting (Orlando, 2018) and the 5th World Psoriasis and Psoriatic Arthritis conference (Stockholm, 2018).

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## HIDRADENITIS SUPPURATIVA UPDATE

### Amit Garg, MD

#### Board of Directors

#### IDEOM Workgroup Lead for HS



HISTORIC (the Hidradenitis Suppurativa cORE outcomes set International Collaboration) is an international scientific collaboration among IDEOM, the Cochrane Skin Group-Core Outcome Set Initiative (CSG-COUSIN), and Zealand University Hospital, Roskilde. HISTORIC’s goal is the development of a Core Outcome Set (COS) suitable for HS interventional clinical trials, regardless of treatment setting or mode of administration. This goal will be accomplished in two phases:

- Phase 1: Achieve Consensus on Core Domain Set (completed)
- Phase 2: Develop a Core Measurement Set (in progress)

With over 100 stakeholders, including roughly equal representations of patients and experts from 19 different countries across 4 continents, HISTORIC has made significant progress towards this goal.

In Phase I of COS development, consensus was reached on a set of *core domains* to be measured in interventional trials. This phase was initiated in 2016 with the generation of 60 items deemed by stakeholders as relevant for measurement in HS clinical trials. Item generation was accomplished by combining data from a systematic review of the literature, qualitative patient interviews, and expert panel

survey, and a subsequent Delphi process which included five electronic rounds and three in-person meetings in Vienna (September 2016), New York City (October 2016), and Copenhagen (February 2017). The core domain set was presented and ratified at the annual IDEOM meeting in Washington, D.C., in May, 2017.

Now in Phase II of COS development, HISTORIC aims to establish a set of *core measures* for the core domains identified in Phase I. This phase has begun with formation of workgroups for each of the domains that are charged with evaluating existing measures in HS. The workgroups have met once at the annual IDEOM meeting in May, 2018, and will reconvene in Toronto adjacent to the 3rd annual Symposium on Hidradenitis Suppurativa Advances in October, 2018.

#### **HISTORIC Publications to date:**

1. Thorlacius L, Ingram JR, Villumsen B, Esmann S, Kirby JS, Gottlieb AB, Merola JF, Dellavalle R, Nielsen SM, Christensen R, Garg A and Jemec GBE, on behalf of the Hidradenitis Suppurativa cORE outcomes set International Collaboration (HISTORIC). A Core Domain Set For Hidradenitis Suppurativa Trial Outcomes: An International Delphi Process. *Br J Dermatol*. 2018 Apr 14. doi: 10.1111/bjd.16672
2. Thorlacius L, Garg A, Ingram JR, Villumsen B, Theut Riis P, Gottlieb AB, Merola JF, Dellavalle R, Ardon C, Baba R, Bechara FG, Cohen AD, Daham N, Davis M, Emtestam L, Fernandez-Penas P, Filippelli M, Gibbons A, Grant T, Guilbault S, Gulliver S, Harris C, Harvent C, Houston K, Kirby JS, Matusiak L, Mehdizadeh A, Mojica T, Okun M, Orgill D, Pallack L, Parks-Miller A, Prens E, Randel S, Rogers C, Rosen CF, Choon SE, van der Zee HH, Christensen R, Jemec GBE. Towards global consensus on core outcomes for Hidradenitis Suppurativa research: An update from the HISTORIC consensus meetings I and II. *Br J Dermatol*. 2018;178(3):715-721.
3. Thorlacius L, Ingram JR, Garg A, Villumsen B, Esmann S, Kirby JS, Gottlieb AB, Merola JF, Dellavalle R, Christensen R, Jemec GBE. Protocol for the development of a core domain set for hidradenitis suppurativa trial outcomes. *BMJ Open* 2017;7(2):e014733.

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## **ACNE UPDATE**

### **Diane Thiboutot, MD**

#### **IDEOM Workgroup Lead for Acne**



At the IDEOM annual meeting, the ACORN attendees comprised the acne workgroup and participants consisted of a patient representative, an internist, medical student, 10 dermatologists (2 of whom were industry partners, and 2 represented the AAD). The geographic breakdown of the dermatologists in the acne workgroup included USA (5), and 1 each from Canada, Switzerland, Mexico, Italy, and Israel. There were 3 breakout sessions of the workgroup and one session for voting by the larger IDEOM group.

The goal of the workgroup meeting was to begin to secure consensus on subdomains to measure within Signs and Symptoms and who will assess each in clinical trials. A second objective was to discuss the role of global assessment and satisfaction with treatment a data to track in clinical practice as part of the AAD's quality initiative.

Workgroup discussions focused on the Signs and Symptoms domain regarding challenges associated with assessment of global acne severity including ambiguity in text descriptors in global assessment scales, the assumptions that severity of comedones tracks with severity of inflammatory lesions, questions regarding the relative contribution of comedones to perception of global disease severity. Plans were made to study the relative contribution of comedones to global acne severity using existing photographic and lesion count datasets with assessments of data by both patients and healthcare providers. Other domains discussed included Satisfaction with Appearance and Health-Related Quality of Life.

A series of questions were developed for voting within the larger IDEOM group (n=50) with the following results.

For clinical trials

- 84% felt that a patient global assessment of acne should be included in every clinical trial.

For clinical practice,

- 94% of participants felt that a patient and provider global acne assessment should be conducted at each visit and
- 73% felt global assessment should be based on a 5-point scale (Clear to Severe).
- 92% felt that patient satisfaction with treatment should be captured at every visit.

The next steps for the ACORN group are to continue to appraise existing outcome measures for suitability to measure the core outcomes and to secure consensus on:

- Additional subdomains to measure within Signs and Symptoms and determine who will assess each;
- How many core outcome measures are needed;
- Whether novel approaches are required to assess long term control of acne and
- The most important domains constructs or impacts of acne to include in a PROM or HRQoL or other.

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## In the News



### Alice Gottlieb honored with the 2018 National Psoriasis Foundation "Excellence in Leadership Award"

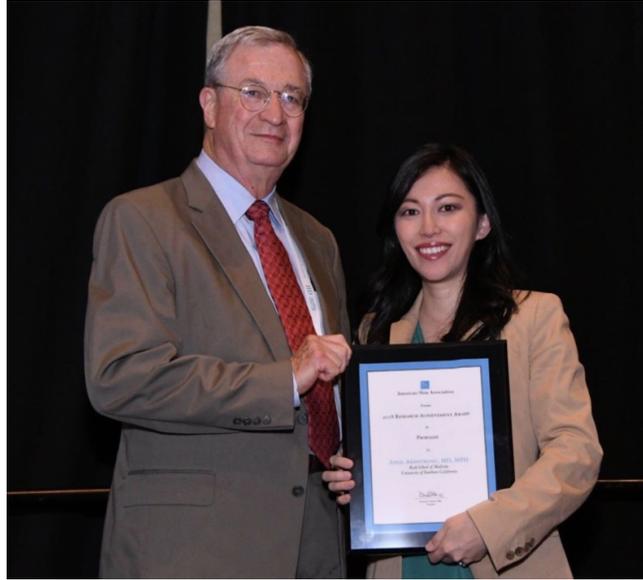
**President Alice Gottlieb received the 2018 "Excellence in Leadership Award" from the National Psoriasis Foundation for her work in psoriasis and psoriatic arthritis; June 7, 2018, NY, NY**

**Dr. Alice Gottlieb** is an internationally recognized expert and leader in the field of psoriasis, psoriatic arthritis and related disorders. She is currently Professor of Dermatology at New York Medical College. From 2006 to 2016, Dr. Gottlieb was Chair of Dermatology and Dermatologist-in-Chief at the Tufts Medical Center and Tufts University School of Medicine. She is the former Professor of Medicine and Founding Director of the Psoriasis Center of Excellence at University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School. Dr. Gottlieb is triple-boarded in dermatology, rheumatology and internal medicine, one of only a handful of doctors in the U.S. certified in all three specialties. She obtained her M.D. from Cornell Medical School and her Ph.D. in immunology from the Rockefeller University.

Dr. Gottlieb was elected to the Board of Directors of the American Academy of Dermatology from 2011-2015 and is the founder and President of the Board of the International Dermatology Outcome Measures group. She is also active as a councilor of the International Psoriasis Council, member of the Executive and Steering Committees of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis, the National Psoriasis Foundation Medical Board, and co-Editor-in-Chief of

Her research has provided new understanding of the pathogenesis of psoriasis and provided the foundation for biologic drug development in psoriasis and psoriatic arthritis. She has authored over 300 publications and presented her research at more than 200 conferences across the globe. She has also presented for NPF patient and provider education events. Dr. Gottlieb has received numerous awards for mentoring and teaching, including the 2016 National Psoriasis Foundation's Outstanding Educator in Psoriatic Disease Award.

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### **April Armstrong honored with the 2018 Research Achievement Award in Psoriasis from the American Skin Association**

Dr. April Armstrong received the 2018 Research Achievement Award in Psoriasis from the American Skin Association. She was honored at the 2018 International Investigative Dermatology meeting in Orlando Florida this year. Dr. Armstrong's research in psoriasis focuses on (1) investigating epidemiology of psoriasis comorbidities, (2) identifying treatment patterns, treatment goals, and economic burden of psoriasis, and (3) increasing patient access using innovative, technology-enabled healthcare delivery methods. Currently, Dr. Armstrong is Associate Dean and Professor and Dermatology at the University of Southern California.

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### **Thank You Nicole Salame**

**IDEOM thanks Nicole Salame**, for her dedication and work with IDEOM over the past year as IDEOM's Research Fellow. Nicole is in her last year of medical school and will be applying to residency this year! We wish Nicole all the best and hope to see her involved with IDEOM in the future.



Lourdes Perez Chada will act as the official IDEOM Research Fellow over the next year. Lourdes has already been very active with the PsA Workgroup and we are very pleased to have her assist with the important work we are doing.

### **IDEOM Welcomes Lourdes Perez-Chada as Research Fellow**

Dr. Perez-Chada is a dermatologist dedicated to improving the care and quality of life of patients with psoriatic disease. She

trained as a dermatologist in Buenos Aires, Argentina and graduated from the Master of Medical Sciences in Clinical Investigation at Harvard Medical School. Her research focuses on outcome measures and under-detected comorbidities in psoriasis, with special interest in sleep disturbance. In addition to her role as the IDEOM Research Fellow, Dr. Perez Chada holds the position of Psoriasis and Psoriatic Arthritis Clinical Research Fellow at the Brigham and Women's Hospital.



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