Group Concept Mapping to Understand the Patient Perspective and Burden of Psoriasis

Colby Evans,[1] Louise Humphrey,[2] Corey Pelletier,[3] Stacie Hudgens[4]

[1]Evans Dermatology, Austin, TX, US; [2]Clinical Outcomes Solutions, Folkestone, Kent, UK; [3]Celgene Corporation, Summit, NJ, US; [4]Clinical Outcomes Solutions, Tucson, AZ, US

INTRODUCTION

- Psoriasis is one of the most prevalent autoimmune diseases in the United States and impacts up to 2% of the nation's population.[1]
- It is a chronic, symptomatic condition that goes through cycles of week- to month-long flares. Some common symptoms of psoriasis are skin redness, burning, itching, and joint stiffness.[2]
- Psoriasis can present at any age, but has been observed to have a bimodal onset across populations, peaking at 15–20 and 55–60 years of age.[1]
- Caucasians have the highest prevalence of psoriasis in the United States at an estimated 3.6%, followed by African Americans (1.9%,) Hispanics (1.6%,) and others (1.4%).[3]
- Topical corticosteroids are the traditional and most widely used psoriasis therapy in the US, ranging from over-the-counter 1% hydrocortisone to more potent Class 1 corticosteroids.[4]
  - Additional treatments are phototherapy, systemic retinoids, methotrexate, cyclosporine, apremilast, and newer biological agents.[5]
- The symptoms and treatment of psoriasis have a significant negative impact on patient-reported quality of life (QoL).
  - A survey by the National Psoriasis Foundation showed that nearly 75% of patients believed psoriasis had a moderate to large negative impact on their QoL, with alterations in their daily activities.[5]
- There are a number of clinical outcome assessments that have been used to measure QoL in psoriasis patients ranging from psoriasis-specific measures (Psoriasis Index of Quality of Life, Psoriasis Disability Index), to skin-specific measures (Questionnaire on Experience with Skin Complaints, Dermatology Life Quality Index) to generic measures (Short Form-36, EuroQol 5D, Work Productivity Assessment Index).[5]
- With a high prevalence and large burden of disease, there is interest to explore and understand patient priorities and unmet needs for the treatment of psoriasis.
  - This initiative will engage patients, clinicians, and payers to develop research questions and execute prospective research activities with the aim of generating evidence to support identified areas of unmet need in psoriasis.
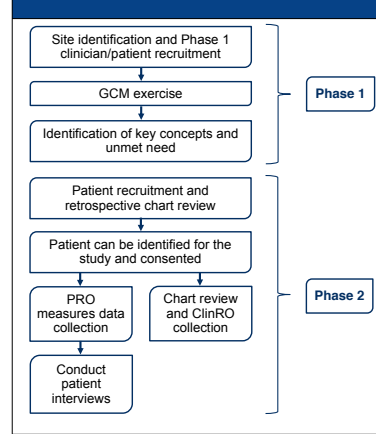
OBJECTIVE

- To collect quantitative and qualitative insights into patients' experiences with psoriasis that identify the most important and relevant outcomes for psoriasis patients and identify populations of psoriasis patients who may benefit from new treatment options.
- Group concept mapping (GCM) will be used to develop research questions based on data gathered from patient and clinician participants. Guided by these GCM results, data from multiple sources will be collected and triangulated:
  - Patient-reported outcomes (PRO) data;
  - Clinical chart data and clinician-reported outcomes data;
  - Qualitative data generated from interviews with psoriasis patients.

METHODS

Study Design

- The study consists of two phases (**Figure 1**):
  1. A GCM exercise involving psoriasis patients and clinician participants to identify key concepts and areas of unmet need in the psoriasis patient population.
  2. A cross-sectional, non-interventional, mixed-methods study to more thoroughly explore the identified concepts through the administration of surveys and qualitative interviews to psoriasis patients.

Figure 1. Study Schematic

ClinRO = clinician reported outcome; **GCM** = group concept mapping; **PRO** = patient reported outcome

Recruitment

- Up to 10 sites will be recruited in the United States (US) to identify 120 patients with psoriasis to participate in either the GCM exercise or observational study.
- Additionally, 10 clinicians will be recruited for the GCM exercise.

Participant Selection Criteria

Patient Inclusion Criteria

- Aged ≥ 18 years;
- Able to read, comprehend, and complete questionnaires and interview in English;
- Has access to an internet-connected computer/ tablet/ smart-phone;
- Has clinician-confirmed diagnosis of current moderate-severe psoriasis as judged by clinician in the case report form; and
- Able to read, comprehend, and sign informed consent.

Patient Exclusion Criteria

- Has a mental or physical condition that would prevent completion of questionnaires or participation in interviews;
- Is currently enrolled in any other psoriasis interventional study or quality of life (QOL) study (registry studies and post-marketing safety studies are permitted); or
- Has a documented history in the past 12 months of alcohol or other substance abuse.

Clinician Inclusion Criteria

- Is currently practicing as a prescribing dermatologist;
- Has a significant number of patients treated in their clinical practice with psoriasis; and
- Is fluent in US English and able to read, comprehend, and sign an informed consent form for participation.

Clinician Exclusion Criteria

- Is on the FDA debarment list; or
- Is unwilling or unable to comply with requirements of the study.

Background Information and Chart Review

- For psoriasis patients, clinicians complete chart data relating to the patient's disease and treatment history.
- Clinicians will provide information regarding their work and experience with psoriasis patients (**Table 1**).

Table 1. Schedule of Assessments

Assessment	Study Enrollment	GCM	Observational Study
Informed consent	X		
CRF/Clinician information form	X		
Eligibility screening	X		
Patient GCM exercise		X	
Clinician GCM exercise		X	
Patient surveys			X
Qualitative patient interviews			X

CRF = case report form; **GCM** = group concept mapping

Group Concept Mapping Exercise

- Psoriasis patients (N = 20) and clinicians (N = 10) who agree to participate in the GCM exercise will be sent a link to the GlobalMAX platform, where they will participate in concept generation, sorting, and rating activities (**Figure 2; Table 2**).
- The responses will be used to generate a qualitative representation of unmet treatment needs in psoriasis.
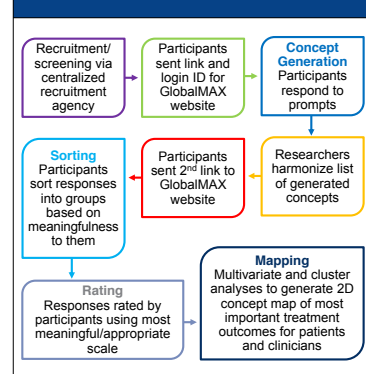
Figure 2. Process for Conducting GCM Study

Table 2. GCM Prompts

Population	Prompt
Psoriasis patients	• An ideal treatment to manage the symptoms of my psoriasis should …
Clinicians	• An ideal treatment to manage the symptoms of psoriasis should …

Implementation of GCM Results

- Upon completion of the GCM exercise, the research team will interpret the GCM results and identify key research interests for the psoriasis population. Analysis and interpretation will guide selection of PRO measures and the development of qualitative interview topics, which will be employed in the second phase of the study.

Psoriasis Patient Survey

- The remaining psoriasis patients (N = 100) will be surveyed for the PRO measures directly aligned with the research questions and concepts elicited in the GCM exercise.

Psoriasis Patient Interviews

- Twenty psoriasis patients who completed the survey will be scheduled for a qualitative telephone interview with a trained interviewer.
- Interview content will be guided by the research questions and concepts elicited in the GCM exercise, but is expected to entail:
  - Burden of illness in terms of symptoms, impact experience, functional status, cost of care, and QoL;
  - Unmet clinical needs in terms of treatment options; Impression of treatment satisfaction.

Analyses

- The results of the GCM exercise will be developed into a visual representation of the burden and unmet needs of psoriasis patients and will be used to develop and select research questions, survey instruments, and interview guides for the observational study.
- Clinical data and clinician-reported data will be considered against the patient reported QoL, symptom, and treatment satisfaction data to measure and characterize the unmet needs and burden of psoriasis from the GCM exercise and to identify populations of psoriasis patients who may benefit from new psoriasis treatments.

RESULTS

- This study is currently in progress.

CONCLUSIONS

- This ongoing study uses a novel methodology to characterize the burden of psoriasis from the patient and clinician perspectives.

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DISCLOSURES

- Colby Evans is a consultant/speaker for Celgene and Abbvie; and speaker for Novartis.
- Louise Humphrey and Stacie Hudgens have nothing to disclose.
- Corey Pelletier is a Celgene employee.