Patient prioritisation of impact items to develop the patient-reported impact of dermatological diseases (PRIDD) measure: European Delphi data

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C. Janus | N. Courtier | R. M. Hewitt | C. Bundy | M. Augustin

Abstract

Background: The Global Research on the Impact of Dermatological Diseases (GRIDD) project is developing a patient-reported measure of the impact of dermatological disease on the patient's life called Patient Reported Impact of Dermatological Diseases (PRIDD). We developed a list of 263 potential impact items through a global qualitative interview study with 68 patients. We next conducted a Delphi study to seek consensus on which of these items to prioritize for inclusion in PRIDD. This study aims to explore patterns in demographic (e.g. country) and clinical variables (e.g. disease group) across the impacts ranked as most important to European dermatology patients.

Methods: We conducted a modified, two rounds Delphi study, testing the outcomes from the previous qualitative interview study. Adults (≥18 years) living with a dermatological disease were recruited through the International Alliance of Dermatology Patient Organizations’ (GlobalSkin) membership network. The survey consisted of a demographic questionnaire and 263 impact items and was available in six languages. Quantitative data were collected using ranking scales and analysed against a priori consensus criteria. Qualitative data were collected using free-text responses and a Framework Analysis was conducted. European data were obtained, and descriptive statistics, including multiple subgroup analyses, were performed.

Results: Out of 1154 participants, 441 Europeans representing 46 dermatological disease from 25 countries participated. The results produced a list of the top 20 impacts reported by European patients, with psychological impacts accounting for the greatest proportion.

Conclusion: This study identified what patients consider to be the most important issues impacting their lives as a result of their dermatological disease. The data support previous evidence that patients experience profound psychological impacts and require psychological support. The findings can inform research, clinical practice and policy by indicating research questions and initiatives that are of most benefit to patients.
INTRODUCTION
Nearly half of all European adults have at least one skin disease. This high prevalence carries significant impact on quality of life: There is robust and growing literature on the substantial physical, psychological and social burden for patients and their families. Despite this, dermatological diseases are often treated superficially, referred to as 'just a rash', and consequently are overlooked in the global health debate. Open Access funding enabled and organized by Projekt DEAL.

The burden of dermatological diseases was systematically underestimated in the Global Burden of Disease (GBD) studies because only symptoms that affect the skin (itch, disfigurement) were considered. The GBD did not account for the often systematic nature and broader psychological and social aspects including depression, anxiety, stigma and social isolation in its burden metric.

Evidence suggests that isolated use of clinical indicators, without the patient perspective, can underestimate the impact of a disease on the patient and overestimate the effectiveness of interventions. The European Academy of Dermatology and Venereology (EADV) burden of skin disease team recently performed the largest epidemiological population-based study of dermatological diseases in Europe, but reported that little is known about the impact of dermatological disease on quality of life, stigmatisation and access to care in Europe. Two large-scale European studies observed that psychological comorbidities and distressing symptoms of body dysmorphic disorder were significantly more frequently associated with dermatological diseases compared to healthy skin controls. While the prevalence of dermatological diseases and their economic burden is important, to identify patient need and optimize best patient care and planning in health policy, knowledge of their impact on patients is essential.

Patient-reported outcome measures (PROMs) provide ‘patient-centred’ data which may capture the impact of the disease and its treatment on the patient’s life. However, our systematic review of the existing dermatology-specific (i.e. used across diseases) PROMs found that none can be recommended for use when evaluated against the gold-standard consensus-based standards for the selection of health measurement instruments (COSMIN) criteria. Other systematic reviews of existing quality of life PROMs in the context of psoriasis, eczema and acne have found a similar lack of adequate dermatology-specific PROMs. The most common reason for poor quality assessment revealed by our review was the lack of patient input during their development.

Based on the results of the review, we are developing the new Patient-Reported Impact of Dermatological Diseases (PRIDD) measure with patients taking a leading role globally. PRIDD is designed to measure the whole person impact of living with a dermatological disease and is for use with all adults living with any dermatological disease.

As the first step in new measure development, we collected data via a global qualitative interview study to develop a conceptual framework of impact. We identified 263 areas of impact that cut across diseases and global regions. This work formed, to our knowledge, the basis for the first conceptual framework of the impact of dermatological diseases on patients’ lives. The framework depicts impact as a complex, multifaceted construct presenting across six domains: physical impacts, psychological impacts, social impacts, financial impacts, daily life and responsibilities impacts and impacts of healthcare.

We next conducted a global Delphi study to seek consensus on which of the 263 items to prioritize for inclusion in PRIDD. To the best of our knowledge, no data on the impact of dermatological diseases on European patients are available. While there was global consensus across World Health Organization (WHO) regions on the items to prioritize for PRIDD, the ranking of these items in terms of importance differed across regions. We aimed to rank the impacts on European dermatology patients and explore patterns in demographic (e.g. country) and clinical variables (e.g. disease group).

PATIENTS AND METHOD
Design
We conducted a Delphi study consisting of two rounds. The methods have previously been described elsewhere. European data were obtained. Ethical approval was received from Cardiff University School of Healthcare Sciences Ethics Committee (SREC:637). Informed consent was obtained from all participants.

Participants
We recruited 1154 adults (≥18 years) living with a dermatological disease through the International Alliance of Dermatology Patient Organizations’ (GlobalSkin) unique global membership network. Clinicians and patient proxies, such as family members or carers, were excluded because (a) evidence of content validity must come from the target population and (b) to maintain patient-centredness in the item reduction process. For subgroup analyses, patients were classified into ‘rare’ and ‘non-rare’ diseases according to the frequency of the disease. The classification was based on the European Union (EU) program for rare diseases which defines diseases with a prevalence of less than 5 per 10,000 persons in the population as rare (Supplementary Material S1).

Materials
The study was conducted using an online platform developed by information technologists with expertise in Delphi surveys.
In lieu of an idea generation round, the survey was developed based on the outcomes from the qualitative interview study. The survey consisted of a demographic’s questionnaire and 263 impact items. Participants rated the importance of the items using a 5-point Likert-type scale with the responses: ‘not at all’ (O), ‘somewhat’, ‘moderately’, ‘quite a lot’, and ‘very much’. Qualitative data were collected using free-text responses that allowed participants to provide feedback and identify any relevant missing concepts.

The survey was translated from English into German, Spanish, French, Arabic and Chinese. Professional translators employed back-translation methods to ensure cross-cultural construct equivalence.

Procedure

In the first round (December 2020–February 2021), participants completed the demographics questionnaire, ranked the items and could provide additional feedback. The results of this round were briefly summarized in reports to participants on the online platform at the start of Round 2. In the second round (May–June 2021), they rated the importance of the items using the same scale as Round 1 in the refined item pool of 27. The procedure of item reduction and creating the list of items for inclusion in PRIDD is described elsewhere.

For both rounds, participants were given at least 4 weeks to respond. A reminder email was sent 2 weeks after the initial invitation email. Only participants who had participated in Round 1 were invited to participate in Round 2.

Before launch, both Delphi surveys were pilot tested with public and patient involvement with at least one native speaker for each of the survey languages for quality review.

Data analysis

To inform the EADV burden of disease policy supplement, data from European participants were extracted. Quantitative data were ranked in importance and analysed with SPSS version 27 (IBM). Descriptive statistics, including multiple subgroup analyses, were performed to investigate patterns of impact related to demographic, country and clinical variables (e.g. condition type). Qualitative data were managed using the NVivo 12 (Alfasoft GmbH) qualitative data software package. A framework analysis was conducted on the free-text responses following an inductive–deductive approach using our conceptual framework of impact.

RESULTS

A total of 1154 people participated. Of whom, 441 Europeans participated in Round 1 and 194 (43.9%) in Round 2. Table 1 details the European participant characteristics for both rounds. A total of 46 dermatological diseases (Table 2) and 25 countries (Table 3) were represented. The dermatology diseases number refers to the primary disease reported; 56 (12.7%) patients had multiple dermatological diseases.

Item-specific descriptive

The top 20 most important impacts of dermatological diseases for European patients are presented in Table 4. The psychological impact domain accounted for almost half of the top 20 impacts overall (Figure 1). For the full list of all items of Round 1 and 2 see Supplementary Material S1.

Impact domains by demographic variables

The greatest impact domain across age groups (Figure 2), with the highest proportion in 30- to 39-year-old participants was psychological. Physical impact, ranked second, was most pronounced in 60- to 90-year-old participants.

The psychological impact domain accounted for the largest proportion of the top 20 impacts for both genders (Figure 3), with a higher proportion for female (55%) than for male participants (45%). Male participants (35%) showed higher proportion for physical impact than female participants (25%).

The psychological impact domain was also greatest across all four European regions (Figure 4).

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>European participant characteristics of Delphi Rounds 1 and 2.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>313 (71.0)</td>
</tr>
<tr>
<td>Male</td>
<td>123 (27.9)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (0.11)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>M = 46.69 (SD = 15.12, range 18–80)</td>
</tr>
<tr>
<td>18–29</td>
<td>77 (17.5)</td>
</tr>
<tr>
<td>30–39</td>
<td>72 (16.3)</td>
</tr>
<tr>
<td>40–49</td>
<td>89 (20.2)</td>
</tr>
<tr>
<td>50–59</td>
<td>108 (24.5)</td>
</tr>
<tr>
<td>60–69</td>
<td>69 (15.6)</td>
</tr>
<tr>
<td>70–79</td>
<td>25 (5.7)</td>
</tr>
<tr>
<td>80–89</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Member of patient organisation</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>
**Impact domains by clinical variables**

For common (defined as ‘non-rare’) dermatological diseases, the psychological impact (50%) again accounted for the greatest proportion of the top 20, while for rare dermatological diseases, psychological impact (35%) and physical impact (35%) were of equal importance (Figure 5). The daily life and responsibility impact domain had a slightly higher proportion for patients living with rare diseases (20%) than for patients with common diseases (10%).

For patients living with one and more than one dermatological disease, psychological impact made up the largest proportion of top impacts (Figure 6).

**Subgroup analysis**

Mann–Whitney U tests were used to identify differences across the items between gender and clinical types (common vs. non-rare dermatological diseases; File S2). Statistical differences were found for 67 (88%) items for gender and 25 (33%) items for common versus non-rare diseases, respectively.

**Qualitative feedback**

Overall, 116 (26.3%) participants contributed at least one free-text comment. Two key themes were discerned: (1) the nature of dermatological diseases and (2) inadequate healthcare. These mainly supported or clarified the conceptual framework of impact.

**Theme 1: The nature of dermatological diseases**

Physical discomfort is a common and significant impact of dermatological diseases.

‘Pain when riding a bike, sitting and having sex’. Patient with Psoriasis, Germany

‘My skin marks a lot, so I have to adapt my clothes to avoid bruising (bra stays, belts, boots, etc.). When I had a big flare-up, I had pain everywhere, especially in my joints. I had difficulty moving.’ Patient with pemphigus superficial, France.

The variability of symptoms and their physical and psychological consequences were highlighted:

‘The answers to the questions would vary greatly depending on the season. Now, in the winter months, the disease of the skin is worse, and thus also the experienced impairments and the mental mood than, for example, in the summer months.’ Patient with psoriasis, Germany.

**Theme 2: Inadequate healthcare**

Many participants felt that the care they received for their dermatological disease was non-existent or inadequate. Being unable to access care, lack of integrated, whole-person

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**TABLE 2** Dermatological diseases represented.

<table>
<thead>
<tr>
<th>Dermatological disease</th>
<th>Round 1, n (%)</th>
<th>Round 2, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atopic dermatitis</td>
<td>121 (27.4)</td>
<td>43 (22.2)</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>99 (22.4)</td>
<td>54 (27.8)</td>
</tr>
<tr>
<td>Pityriasis rubra pilaris</td>
<td>40 (9.1)</td>
<td>21 (10.8)</td>
</tr>
<tr>
<td>Vitiligo</td>
<td>32 (7.3)</td>
<td>14 (7.2)</td>
</tr>
<tr>
<td>Lichen sclerosis</td>
<td>32 (7.5)</td>
<td>9 (4.6)</td>
</tr>
<tr>
<td>Alopecia areata</td>
<td>21 (4.8)</td>
<td>7 (3.6)</td>
</tr>
<tr>
<td>Hidradenitis suppurativa</td>
<td>13 (2.9)</td>
<td>5 (2.6)</td>
</tr>
<tr>
<td>Acne</td>
<td>10 (2.3)</td>
<td>6 (3.6)</td>
</tr>
<tr>
<td>Other</td>
<td>34 (16.8)*</td>
<td>24 (40.2)</td>
</tr>
</tbody>
</table>

*Actinic keratosis (solar keratosis), albinism, alopecia totalis, alopecia universalis, androgenetic alopecia, angioedema, autoimmune skin diseases, basal cell carcinoma, bullous pemphigoid, cutis laxa, dermatitis herpetiformis, dyshidrotic eczema, ectodermal dysplasia, erythroproctitis protoporphyria, frontal fibrosing alopecia, generalized pustular psoriasis, herpes simplex types 1 and 2 infection, hyperhidrosis, ichthyoses, keratoses pilaris, lichen planus, lupus erythematosus, malignant melanoma, melanocytic naevus, mucous membrane pemphigoid (cicatrichal pemphigoid), pemphigus foliaceus, pemphigus superficial, pemphigus vulgaris, pityriasis lichenoides et varioliformis acuta, pyoderma gangrenosum, rosacea, scalp folliculitis, Sjögren syndrome, skin allergy, tinea pedis, urticaria, psoriasis arthritis.

**TABLE 3** Geographical spread of European participants according to UN regions.

<table>
<thead>
<tr>
<th>European regions</th>
<th>Countries presented</th>
<th>Round 1, n (%)</th>
<th>Round 2, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northern Europe</td>
<td>Denmark, Finland, Ireland, Norway, Sweden, United Kingdom</td>
<td>134 (30.4)</td>
<td>55 (28.4)</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>Czech Republic, Poland</td>
<td>3 (0.7)</td>
<td>3 (1.5)</td>
</tr>
<tr>
<td>Southern Europe</td>
<td>Croatia, Italy, North Macedonia, Portugal, Serbia, Slovenia, Spain</td>
<td>92 (20.9)</td>
<td>30 (15.5)</td>
</tr>
<tr>
<td>Western Europe</td>
<td>Austria, Belgium, France, Germany, Lichtenstein, Netherlands, Switzerland</td>
<td>209 (47.4)</td>
<td>106 (54.6)</td>
</tr>
<tr>
<td>Other</td>
<td>Turkey, Israel, Kyrgyzstan</td>
<td>3 (0.7)</td>
<td>-</td>
</tr>
</tbody>
</table>
care and poor clinician communication and information provision were key issues.

‘Appointments only after many months 3/4 year waiting time for first appointment. This considerably delays diagnosis and therapy initiation. Care close to home not possible due to rejection by rheumatologists. There is no cooperation with other specialties. E.g., ophthalmologists, dermatologists, orthopaedists, gynaecologists, general practitioners, urologists. Either too little knowledge or unwillingness to deal with the disease/patient. Orthopaedic surgeons only look at arthrosis, psoriasis arthritis doesn’t interest them. Rheumatologist the other way round. Dermatologist doesn’t even look at skin...
properly and only prescribes the standard remedies. If they don’t help, he just shrugs. No one is interested in genital psoriasis. Neither the rheumatologist, dermatologist nor gynaecologist. You simply fall by the wayside and spend a lot of time researching on the internet. You have to talk about other treatment options yourself. You have to initiate the possibility of rehabilitation yourself.’ Patient with psoriasis, Germany.

It emerged that, though important, the ‘impact of healthcare’ domain had a causal rather than a reflective relationship with impact and was, therefore, removed from the conceptual framework.

**DISCUSSION**

Previous work to determine the burden of dermatological diseases in Europe have focused on prevalence; little is known about the impact on quality of life. To our knowledge, this is the first study to establish consensus on the absolute and relative impacts of dermatological diseases on European patients’ lives. The results generated a list of top 20 impacts of dermatological disease as ranked by patients, representing the key issues faced by patients.

These data validated and refined the conceptual framework of impact generated during the development of PRIDD. Participants’ free-text responses and ranking of items encompassed the biopsychosocial nature of their
diseases and no new impacts or impact domains were suggested. This indicates that the conceptual framework provides a comprehensive understanding of impact and can be used to judge whether measures of impact adequately reflect the relevant concepts. The items prioritized by patients here show some overlap with items in existing dermatology-specific PROMs, indicating some concordance between patients and scientists. Nevertheless, unlike PRIDD, none of these existing PROMs capture all of the impacts that patients considered most important in one single measure.

Psychological impacts accounted for the largest proportion of the top 20 impacts. This held across demographic (age, gender, European regions) and clinical groups (disease group). This finding demonstrates that focusing solely on physical symptoms is unlikely to reduce the burden of dermatological diseases; it is essential to support patients with the psychological impact of their disease too. Indeed, patients consistently report that the psychological aspects are a major component of their disease—more so than the physical symptoms for many. The European Delphi data show that 25.8% have thought about or attempted to take their life. In the UK, 98.0% of dermatology patients report that their disease affects their emotional and psychological well-being, with 5.0% having suicidal thoughts linked to their disease, yet only 18.0% have received some form of psychological support. In the dermatology consultation, psychological support can be implemented as a strategy to prevent suicidality.

A major impediment in the European health care model is the predominantly biomedical approach and consequent lack of psychological services, causing inadequate care for patients. Most dermatologists recognize that people with dermatological diseases benefit from psychological support and the creation of the European Society for Dermatology...
and Psychiatry and the EADV Psychodermatology Taskforce over recent years demonstrates that the field is acknowledging the complex relationship between the biological, psychological, and social aspects of dermatological diseases. However, psychological services remain limited by availability due to financial constraints or lack of expertise and confidence among providers.\(^{35,34}\) Instead, healthcare in Europe has largely focused on symptom management.\(^{36}\)

Our top three impacts identified were physical, although this domain accounted for only the second greatest proportion of the top 20 impacts overall. Physical symptoms and impairments are highly prevalent in people living with dermatological diseases.\(^{3}\) Three physical impacts were consistently ranked as important across demographic and clinical groups: skin sensitivity, skin quality and pain. These impacts of physical impairment are known to be present in many patients (e.g. acne, alopecia areata and psoriasis).\(^{37–39}\) However, skin sensitivity, changes in skin appearance, pain or itching go far beyond the skin surface involving psychological factors and emotional distress.\(^{39,40}\) We argue that a biopsychosocial approach is needed to ensure appropriate management of patients’ symptoms.\(^{41,42}\)

**Strengths and weaknesses**

This Delphi study maximized quality and quantity of patient involvement, unlike many other PROM development studies.\(^{17}\) The descriptive data allowed us to develop an understanding of what European patients considered the most important issues impacting their lives as a result of their dermatological disease and to identify demographic and disease trends.

The survey was conducted online and anonymized, providing access to the useful aspects of group decision-making (e.g. seeking expert input without geographical or time constraints), while limiting the less useful features (e.g. conformity to prevailing opinion). This enabled the recruitment of a large sample of dermatology patients to prioritize the impact items. A particular strength of the survey is that it was translated from the original English into several other languages—German, Spanish, French, Arabic and Chinese—using standard cross-cultural translation procedures (i.e. forward and backward translation) to ensure construct equivalence. Although some languages were missing, particularly those from Eastern Europe, the diversity of languages increased the validity and robustness of the data. While plausibility checks indicate that patients were proficient in the survey language used, we were not able to verify that all participants completed the measure in their native language, which may affect the validity of the results.

In total, 414 European dermatology patients participated, well above a typical Delphi sample size of 11–30 members.\(^{43,44}\) Overall, there was an acceptable split across age groups, gender and an array of disease type (i.e. common, rare, inflammatory, autoimmune, etc.) for survey research. Despite this, there was evidence that the sample was not fully representative of the European population with dermatological diseases. Only three patients from Eastern European countries participated and some diseases were over- or under-represented in relation to their prevalence.

Finally, as participants were recruited through GlobalSkin, a global alliance of patient organisations focused on research, advocacy and support, these results may not represent the experiences of people who are not in contact with patient organisations. However, our findings show that half of the participants (46.9%) did not belong to a patient organisation.

**Implications for clinical**

The findings highlight that the psychological impact is of high importance to patients. Specialist psychological
support should be available and integrated into the wider care of patients with dermatological diseases. An evidence-based training package already exists to allow clinicians to address the basic psychological needs of patients in the dermatology consultation. The list of top impacts identified here indicates the areas on which such training could focus.

Implications for research

Research priority setting initiatives have been conducted for acne, alopecia, eczema, hidradenitis suppurativa, psoriasis, and vitiligo, but none have been conducted for the European dermatological population as a whole. Our findings are broadly consistent with the existing priority setting findings in that the top 20 priorities across all diseases recognize the need for research on psychological interventions and lifestyle factors as well as traditional biomedical aspects such as pharmacological interventions. In the absence of priority setting data for European dermatology patients, our Delphi data helps us to understand what European patients consider to be the most important impacts of their diseases and in developing corresponding research questions and initiatives.

CONCLUSIONS

This study has identified what patients from Europe consider to be the most important issues impacting their lives. The data support previous evidence that patients experience profound psychological impacts and require psychological support. To identify patient needs and optimize the best possible patient care and planning in health policy, knowledge of their impact on patients is essential. In the next steps of measurement development, PRIDD has been pilot tested and is in the psychometric testing phase. The final measure aims to gather comprehensive impact data globally which will include patients from Europe. The findings of this study can inform research, clinical practice and policy by informing research questions and initiatives that are of most benefit to patients.

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CONFLICT OF INTEREST STATEMENT

The authors report no conflicts of interest in this work.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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REFERENCES


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