

Development of a Conceptual Framework for a Patient-Reported Impact of Dermatological Diseases (PRIDD) Measure: A Qualitative Concept Elicitation Study

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Existing patient-reported outcome measures cannot comprehensively capture the full impact of living with a dermatological condition. The aim of this study was to develop a conceptual framework on which to build a new Patient-Reported Impact of Dermatological Diseases (PRIDD) measure. Adults (≥ 18 years of age) living with a dermatological condition, worldwide and/or representatives from a patient organization recruited via a global patient organization network, were invited to an individual or group interview. Data were analyzed thematically. Sixty-five people from 29 countries, representing 29 dermatological conditions, participated. Key themes were: (i) impacts at the individual, organizational and societal levels; (ii) impacts were point-in-time and cumulative; and (iii) impact is a multifaceted construct, with two subthemes (iiia) common impacts and (iiib) psychological and social impacts are most significant. The conceptual framework shows that impact is a multifaceted concept presenting across physical, psychological, social, financial, daily functioning and healthcare, and provides the basis for co-constructing the PRIDD with patients.

Key words: patient-reported outcome measure; skin disease; psychological distress; qualitative research; quality of life; life change events.

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Dermatological conditions cause substantial pain, disfigurement, disability, and stigma, with consequent psychological, social, and financial impact (1, 2). Addressing this impact on patients' lives is important in dermatology, where often no cure exists and therefore treatment focuses on improving quality of life. The full impact of dermatological conditions on patients is underestimated, because most assessments are based on data derived from conceptually and methodologically limited patient-reported outcome measures (PROMs).

Our earlier systematic review (3) of dermatology-specific PROMs (which are used across dermatological

SIGNIFICANCE

Dermatological conditions can affect all areas of a patient's life. Our earlier review of existing measures of this impact found that none were able to capture the full impact. The current study drew upon substantial patient input to develop a new model of impact to inform the new Patient-Reported Impact of Dermatological Diseases measure. Sixty-five people with a variety of dermatological conditions from around the world were interviewed to determine what impacts were shared across conditions. Impact was found to be complex, affecting physical, psychological, social, financial, and daily functioning, and involving healthcare. These findings provide the basis for developing Patient-Reported Impact of Dermatological Diseases.

conditions) revealed that the existing measures, including the widely-used Dermatology Life Quality Index (DLQI) and Skindex, could not be recommended for use according to the gold-standard consensus-based standards for the selection of health measurement instruments (COSMIN) criteria (4), primarily due to insufficient patient input during development. Thus existing PROMs may not fully capture aspects of impact that are important to patients. The review (3) concluded that there is a need to develop a new dermatology-specific measure in close collaboration with patients, which can comprehensively capture the impact of dermatological conditions on a patient's life.

The current paper reports the first step (concept elicitation) in the development of the new Patient-Reported Impact of Dermatological Diseases (PRIDD) measure. PRIDD is designed to measure the impact of living with dermatological conditions on the lives of all adults with a dermatological condition worldwide, in research and clinical practice.

Concept elicitation is completed to develop a conceptual framework of core concepts in relation to the impact of dermatological conditions in collaboration with the target population (5, 6). There is no agreed conceptual framework for 'impact' within dermatological conditions. Without this, the dermatology community (including clinicians, researchers, and core outcome set groups) and regulatory agencies (e.g. the US Food and

Drug Administration) cannot comprehensively judge whether a measure of impact adequately includes the relevant concepts (7). People living with dermatological conditions are uniquely placed to judge impact.

The aim of this concept elicitation study was to develop a conceptual framework of the impact of dermatological conditions.

MATERIALS AND METHODS

Design

This was a qualitative descriptive interview study, using four group interviews and 28 individual interviews. The study was tested against the latest COSMIN guidance on the development of PROMs (8–10). Ethical approval was obtained from Cardiff University School of Healthcare Sciences Ethics Committee (SREC:637). All participants read the participant information sheet and informed consent was given before their commencement in the study.

Participants

To explore the impact of dermatological conditions with the target population of PRIDD (Table I), adults (aged ≥ 18 years) worldwide, proficient in English, and who lived with a dermatological condition or were a representative of a dermatology patient organization, were recruited via the International Alliance of Dermatology Patient Organizations' (GlobalSkin) global membership network.

Purposive sampling helped to achieve maximum variation according to dermatological condition, country of residence, sex, and age. Recruitment ceased when both the key sample characteristics were obtained and analysis resulted in no new or relevant information (full details of data saturation evaluation are given in Appendix S1) (11).

Materials

A semi-structured topic guide was developed for the focus groups (Appendix S2) and individual interviews (Appendix S3). It was based on: (i) extant literature, (ii) Wilson and Cleary's conceptual model of health-related quality of life (HRQoL) (12), and (iii) the Common-Sense Self-Regulatory Model (CS-SRM) (13). Wilson and Cleary's model of HRQoL combines biomedical and social science paradigms and includes five major domains (biological, symptoms, function, general health perception and overall HRQoL) and illustrates how these are interrelated. The HRQoL model was used here to inform the level of measurement of PRIDD, which, in turn, suggests that the micro, meso and macro levels should be considered and outlines domains that sit on the causal pathway to impact and therefore should be considered during development. The CS-SRM is a widely used theoretical framework that captures emotional, cognitive, and coping responses to health and illness.

Table I. Definition and elaboration of the Patient-Reported Impact of Dermatological Diseases (PRIDD) target construct, population, and purpose

PRIDD definition	
Construct of interest	The impact of dermatological conditions on patients' lives.
Target population	Adults (≥ 18 years) living with a dermatological condition, worldwide.
Purpose	'Discriminative' to distinguish people according to the amount of impact their dermatological condition has had on their lives (29).

The CS-SRM was used as the primary model to understand how patients responded to their dermatological conditions, the impact it has had on their lives, along with the drivers of impact. Use of the CS-SRM within the level of measurement required by the conceptual model of HRQoL ensured that intra- and inter-personal and contextual factors were adequately addressed. The aim was not to test these existing theories, but to draw on relevant aspects of both to situate the study findings within the existing body of knowledge. Key topics in the guides included: domains of impact; drivers of impact; and the interaction between impacts and other variables, such as age, sex, ethnicity, socioeconomic status, and proximity to specialist medical advice. The guide was continually adapted based on initial analysis of completed interviews to reflect new topics or themes that needed further probing.

Procedure

There were two stages of data collection (Fig. 1). The first stage consisted of 4 concurrent group interviews (session 1) followed by a plenary respondent validation exercise (session 2). The second stage was a series of 28 individual interviews. The group discussions enabled us to confirm with participants in real-time whether the concepts discussed were common across conditions rather than specific to a particular condition or individual. The decision to conduct further interviews individually and online was a pragmatic response to the travel and social distancing restrictions imposed by the COVID-19 pandemic. These individual interviews had the benefit of providing a private setting to further probe potentially sensitive topics. Audio data were recorded, transcribed verbatim, and anonymized.

The group interviews (session 1) and respondent validation exercise (session 2) were conducted during GlobalSkin's patient organization conference in Milan, Italy, in June 2019. They were scheduled to immediately precede the World Congress of Dermatology, in order to benefit from the rare opportunity to convene a group of dermatology patient organization representatives in attendance from around the world.

All facilitators (authors RP, RH, NTS, and EC) were trained in group facilitation by CB, a chartered health psychologist, and were experienced in qualitative health research. Twelve vignettes (short stories; Appendix S4) were created to structure, prompt, and broaden discussions around topics. They were based on real patient stories from clinical practice or patient organization websites. Each vignette highlighted different impacts of dermatological diseases and was written to represent people of different ages, sexes, ethnicities, cultures, and dermatological conditions.

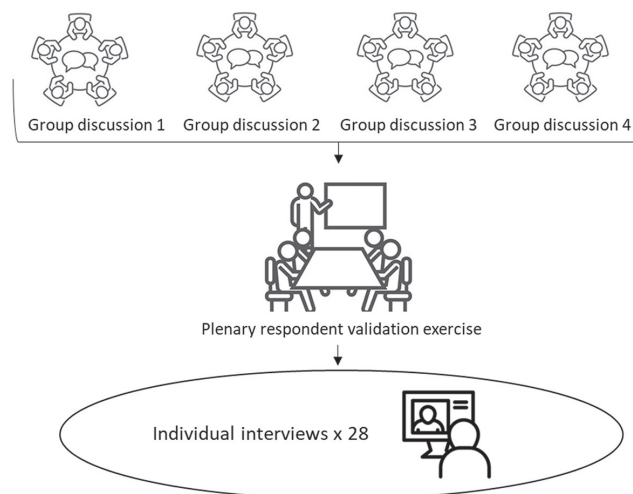


Fig. 1. Data collection procedure.

A plenary respondent validation exercise (session 2) determined the relevance and comprehensiveness of the constructs identified during each group discussion. Group facilitators used flipcharts to present preliminary findings in real-time, organized into categories and themes. Participants were asked to add information they felt was absent from each category and note relevant information that did not fit within any of the existing categories on a flipchart titled 'missing'. Facilitators asked participants whether the words listed were understood and if they should be used to label the concept. Participants voted, using sticky notes, for the three categories they felt were most important to the impact of dermatological conditions.

Next, 28 individual interviews were conducted by authors RP and RH from April to June 2020 using video-conferencing software.

Analysis

All transcripts were inserted into the NVivo 12 data software package (QSR 1999–2018; QSR, Massachusetts, USA). Data collection and analysis were interrelated and concurrent, meaning that analysis began after the first interview to incorporate emergent themes into subsequent interviews.

A framework analysis was conducted following Gale et al. (14), using the conceptual model of HRQoL and the CS-SRM as a theoretical lens. This combined inductive-deductive approach allowed for exploration of known and novel issues related to impact.

A minimum of two researchers were involved in each stage of the analysis. Following transcription and familiarization, the facilitators coded the data. Coders met to compare coding, resolve discrepancies, and construct a coding framework that was consistent with the theoretical frameworks. Code groups were refined based on incoming data and further discussion between researchers. The process was repeated until no new codes were generated. The final framework consisted of 273 defined codes that were clustered into categories.

Two researchers (RP and RH) systematically applied the final analytical framework to all transcripts in NVivo 12. Themes were derived from the codes. A matrix was generated for each theme in Microsoft Excel by abstracting, summarizing, and charting supporting data. Each matrix was reviewed and thematically analyzed; key themes were named and defined, and relationships between themes were reported.

RESULTS

A total of 65 people (Table II) from 29 countries (Table III) participated in the study.

Overarching themes

Three themes were derived: (i) impact at the individual, organizational, and societal levels; (ii) impact on life can be both point-in-time and cumulative; and (iii) impact is a multifaceted construct. The final theme further di-

Table II. Participant characteristics for the group and individual interviews

	Group interviews n (%)	Individual interviews n (%)	Total n (%)
Total	35 (55.6)	28 (44.4)	63 (100)
Age			
18–24 years	1 (2.8)	2 (7.4)	3 (4.7)
25–34 years	6 (16.7)	6 (22.2)	12 (19)
35–44 years	6 (16.7)	6 (22.2)	12 (19)
45–54 years	9 (25)	6 (22.2)	15 (23.8)
55–64 years	11 (30.6)	5 (18.5)	16 (25.4)
>65 years	3 (8.3)	2 (7.4)	5 (7.9)
Sex			
Male	3 (8.1)	18 (64.3)	21 (32.3)
Female	34 (91.9)	10 (35.7)	44 (67.7)
Dermatological condition			
Acne	0	2 (7.1)	2 (3.1)
Alopecia	2 (5.4)	5 (17.9)	7 (10.8)
Atopic dermatitis	5 (13.5)	6 (21.4)	11 (16.9)
Psoriasis	5 (13.5)	9 (32.1)	14 (21.5)
Vitiligo	0 (0)	6 (21.4)	6 (9.2)
Other*	25 (67.6)	0	25 (38.5)
Duration			
<1 years	0	1 (3.6)	1 (1.5)
1–5 years	5 (13.5)	3 (10.7)	8 (12.3)
6–10 years	0	4 (14.3)	4 (6.2)
11–15 years	0	2 (7.1)	3 (4.6)
16–20 years	1 (16.2)	7 (25)	8 (12.3)
>20 years	11 (29.7)	11 (39.3)	22 (33.8)

*Autoimmune blistering diseases ($n=1$), congenital melanocytic naevus ($n=2$), cutaneous lymphoma ($n=1$), cutis marmorata telangiectatica congenita ($n=1$), dermatomyositis ($n=1$), epidermolysis bullosa ($n=5$), erythropoietic protoporphyria ($n=1$), genital lichen planus ($n=1$), Gorlin syndrome ($n=1$), hidradenitis suppurativa ($n=1$), hyperhidrosis ($n=1$), ichthyosis ($n=2$), lichen sclerosis ($n=2$), pemphigus and pemphigoid diseases ($n=1$), porphyria ($n=1$), port wine birthmark ($n=1$), xeroderma pigmentosum ($n=3$).

vided into two subthemes: (a) common impacts and (b) psychological and social impacts are most significant.

Theme 1: impact at the individual, organizational, and societal levels. Dermatological conditions impact across 3 interacting levels: individual, organizational (i.e. healthcare services, employers, financial services), and societal (Fig. 2). Social and cultural factors influence how participants experienced, and organizations and society interact with, the condition. This reflects different experiences across regions, each with its own cultural norms and values, which can influence healthcare service provision and equity of access.

Theme 2: impact can be both point-in-time and cumulative. Point-in-time impacts (e.g. pain and itch) were discrete and time-restricted, though often recurrent. Conversely, cumulative impacts were identified that affected the life trajectory; for example:

"I think, if I don't have this [...] disease [...] I might still be working [...] not do the early retired thing." (PID 19) Psoriasis, China

Table III. Geographical location of participants

Continent	Focus groups n (%)	Individual interviews n (%)	Total n (%)	Countries represented
Africa	3 (8.1)	8 (28.6)	11 (16.9)	Nigeria, Kenya, South Africa, Zimbabwe
Asia	2 (5.4)	11 (39.3)	13 (20)	China, Hong Kong, Indonesia, Israel, Pakistan, Philippines, Singapore
Europe	17 (45.9)	1 (3.6)	18 (27.7)	Austria, Belgium, Denmark, France, Germany, Italy, The Netherlands, Slovenia, Spain, UK
North America	13 (35.1)	4 (14.3)	17 (26.1)	Canada, Cuba, Mexico, USA
Oceania	1 (2.7)	3 (10.7)	4 (6.5)	Australia, New Zealand
South America	1 (2.7)	1 (3.6)	2 (3)	Argentina, Colombia

Distinguishing between the two forms of impacts was not always helpful, as minor point-in-time impacts often accumulated to contribute to a significant overall impact; for example, the toll of daily treatment regimens.

Theme 3: impact is a multifaceted construct. Impact was individual, but with commonalities across participants. Participants reported that many aspects of their lives had been adversely affected:

"It just impacts every part of your life; financially, socially, psychosocially, mentally just, just, it's just way beyond the, the condition and then you have the condition." (Focus group 2)

It was found that these shared impacts could be grouped into six distinct domains, informed by the conceptual model of HRQoL:

- physical
- psychological
- social
- financial
- daily life and responsibilities
- impact of healthcare.

Theme 3a: Common impacts

There were impacts common across dermatological conditions.

"To hear it over and over no matter what conditions on a piece of paper [...] that the emotions behind it are the same, it's just really powerful." (Focus group 2)

The volume and breadth of these common impacts are significant. Hence, a summary of the common impacts for each of the domains identified is provided.

Physical. All dermatological conditions had physical consequences for patients, although the nature and degree of these varied within and between conditions. Most conditions resulted in noticeable changes in appearance, including differences in pigmentation, dry skin, or bald patches:

"I think the visibility of skin conditions [...] there are some, few which are not visible but most of them are really visible, so you always have to deal with people staring, people giving wonderful comments, having great advice, and stuff like that, so I think this is one of the things for everyday life, in public is a big, big problem." (Focus group 1)

Participants explained how visible changes in appearance affected their personal identity, challenged their ability to perform preferred gender roles (e.g. femininity), and resulted in distress or discomfort and problems with social interactions:

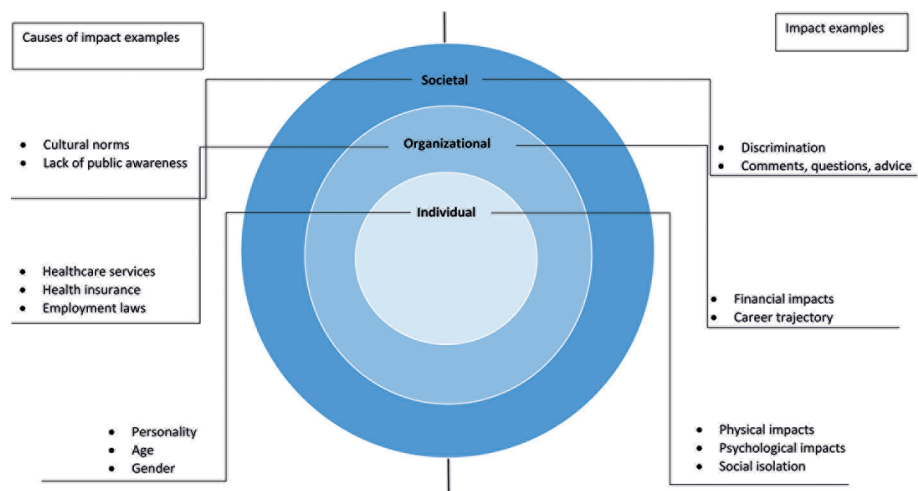


Fig. 2. Dermatological conditions impact at the individual, organizational, and societal levels.

"Vitiligo gave me a lot of stress, mentally and emotionally, and it also give me decline in self-confidence because you can't meet the people who used to know you, you don't know what to tell them. Also, the stigmatization, social stigmatization, that people staring, people running away from you, whenever they saw you." (PID 3) Vitiligo, Kenya

Covering symptoms (e.g. wearing wigs and long clothing) helped patients to feel like they fitted in with others.

Physical discomfort (pain, soreness, and itch) was almost ubiquitous. Other physical impacts were less common or disease-specific. While sleep disturbance was sometimes attributed to psychological factors, such as stress and rumination, it was mainly caused by physical discomfort. Participants reported being unable to fall asleep because of pain and itch, and regularly waking during the night to scratch. This was a double-edged sword because sleep was viewed, by some, as the only respite from their condition. Sleep disturbances could also adversely affect the sleep routine of other people present in their room, such as a bed partner or roommates, and, in turn, their relationships.

"With a lot of patients, they say [...] take away my itch, I don't mind dying early if I can live without the itch and the pain." (Focus group 1)

"So, it's of course, it's very hard for people to sleep with you because you are, most of the night you are like this scratching, and this is like it hurts really bad. I'm more or less okay now but it was as this, so they cannot sleep, so not only my, my, my boyfriend it was very hard for him to sleep but also when I was a student my roommates didn't want to sleep with me because they couldn't, sleep. Of course, intimacy is the problem because not only the look, it hurts, it itches, you don't want to be touched." (Focus group 2)

"Depression because when it's hurting you it's bad, you don't want to, like you're thinking about this all the time because it's hurting you all the time. I was like just in peace, let's say, when I was sleeping." (PID 28) Acne, Israel

Co-morbid long-term conditions were reported as well. Dermatological conditions could also impact general health through choice of coping strategies (e.g. engaging in or avoiding exercise, alcohol, and sociali-

zing) and treatment consequences (e.g. liver and kidney dysfunction, hypertension, infertility, heart disease, pain throughout the body, immunity to antibiotics, cancer). Concerns about starting a family were widespread. Many worried that they would pass their condition on to their children and feared judgement by others. Some chose not to have children as a result:

"You then go down that whole rabbit hole of okay, you know, here's my relationship, should I have children? If I pass this on what's the responsibility, then I'm responsible for bringing a child into the world with this condition that I am also struggling [with]." (Focus group 2)

Psychological. Participants reported a constant battle against the condition itself, its visibility, the lack of awareness surrounding it, as well as the poor quality and availability of health and social care. Despite feeling like they were fighting a losing battle, they continued to battle to avoid further suffering:

RES11: "Battling with people who don't understand and then you're battling with the authorities to get what you need."
RES10: "Yes, it's one big battle in all aspects." RES2: "It's a constant battle, it's the 24 h, the 365 days a year, it's like that all the time." (Focus group 3)

Dermatological conditions inherently challenged personal autonomy, reduced patients' sense of control, and restricted choices. The avoidance of triggers was a major source of choice restriction across the sample, particularly for people with atopic dermatitis (AD) who often had allergies. To avoid triggers, individuals would restrict the clothes they wore, food and drink consumed, bedding and products used, and places they travelled. Trigger avoidance had social consequences, as individuals faced peer pressure and social exclusion when they could not participate in social or cultural activities.

"It's just one extra thing that, that you've kind of gotten no choice or control over [...] You know, I can't wake up one morning and go oh I've got my hair back, you know, it's not like a you know, a broken arm or something you're gonna heal from." (PID 33) Alopecia, USA

Lack of control was exacerbated for those who had conditions with a relapse-and-remitting course and variable, or unpredictable, symptoms.

"No control over it getting worse, no control about it getting better and regrowth [...] you have no control. No control." (Focus group 4)

The increased "mental load" that came with managing the condition and its impacts was reported as tiring or draining. Many said their condition preoccupied them and prevented them from having 'mind space' (Focus group 2), or the mental break they needed. For some, this resulted in hypervigilance or constant planning ahead. Mental load was further increased by feeling the need to hide the condition. This involved constantly checking the visibility of symptoms and planning strategies to hide, if necessary.

"It makes me very uncomfortable, emotionally and you feel, you feel tired of it because I'm conscious of everything." (PID 26) AD, Kenya

Distress (anxiety and depression) was common. Some people reported all-consuming, widespread appearance-related concerns and anticipatory worry about social situations, as well as pressure to complete treatment regimens. Seeing the condition deteriorate or realizing treatment was ineffective was disheartening and frustrating for participants. Low mood and depression were extreme in some participants, with some having contemplated suicide because of their condition.

"It's a full-time job to mentally always think [...] I have to keep some space for my body to recover [...] so it's constantly thinking about things all the time, that other people don't think about." (Focus group 2)

"With hyperhidrosis, we get so many emails from patients who are just crying for help saying they're considering suicide." (Focus group 4)

Social. Many participants believed that awareness of dermatological conditions, although increased over time, was still lacking at the individual, organizational, and societal levels. Some lacked awareness and understanding of their own conditions, such as their long-term and cyclical nature:

"What caused it, why did it happen, you know. Is there going to be a cure? You know when is it going to get to the point where I can't cover the tracks anymore or do I [...] when do I get to the point where I have to make a decision of whether to shave it off or not? [...] So, the worry, the actual part that's always in the back of your mind is the present and the future, where it's going to lead to, or what it's going to lead to." (PID 17) Alopecia, USA

Lack of awareness and understanding of dermatological conditions across societies profoundly impacted patients' psychological and social well-being. Public attitudes towards appearance negatively impacted patients' self-esteem, and increased anxiety and fear of other people's thoughts and behavior towards them:

"I'm stressed because not a lot of people know about this disease [...] I'm stressed, because the way people treat me [...] when I socialize with them, they often question because they don't have the knowledge." (PID 29) Psoriasis, Indonesia

Negative comments, questions, and assumptions from others were almost ubiquitous, causing additional pressure when in public spaces and more distress:

"It is quite annoying you know that every time, every new people they will ask oh why your skin like this [...] Then have to explain how it is not infectious, don't worry about it, something like that blah-blah-blah. Literally every time." (PID 8) Psoriasis, China

"Having to give an explanation leaves me low." (PID 29) Psoriasis, Indonesia

Pre-conceived ideas about dermatological diseases being dirty, contagious, or a curse increased stigma and led to the social exclusion of individuals. Experiences of discrimination and bullying in the workplace, schools, and public places, particularly swimming pools, were common occurrences and shared across most participants.

Stigma was seen to fuel avoidance coping; for example, social withdrawal, which exacerbated low mood and further increased social isolation.

"As a community [...] we are raised up to has its own culture and beliefs, so you find it difficult to, to, to mingle with other people cos you will find some of the people in your community has that mentality that maybe it's a curse [...] So it gives you problem to cope with people and explain to people what is happening [...]" (PID 3) Vitiligo, Kenya

"I say social relationship is not easy to build, because other people do not understand your skin condition, what is your skin problem, they think, most of them misunderstood it is contagious [...] some people say is it because you go to some dirty place, not good hygiene, or even have, have, sexually transmitted disease from someone else [...] they misunderstood the, the situation and I have to explain to them, that it is my, err, the skin problem is, err, inherited from my parents [...] so understanding of psoriasis is not very deep actually. Yeah, but when I say, tell them it is, err, similar to or eczema, they, they understand more." (PID 7) Psoriasis, China

Greater awareness in general was regarded as important for helping patients and others in society to accept these conditions and understand their impact.

"I've started to accept it. I think it's impact on my, on my life, becomes the negative part becomes smaller [...] I started to treasure my, my life and also treasure my relationship with those, with those close to me, and, and I don't want to spend time with unnecessary things [...]. A person with normal skin is a very, very lucky. So even nowadays, what, one day, with, with normal skin and a very, normal life, is, is, is worth to be appreciated." (PID 10) Psoriasis, China

Financial. Significant economic pressures were reported and were perceived to not be appreciated by those without dermatological conditions.

"It's illness for rich people." (PID 23)

"You wouldn't think that defaulting on a credit card would have anything in the world to do with a, with a skin condition." (Focus group 2)

The costs associated with dermatological conditions reduced financial resources and, in turn, personal choice. High medical costs prevented individuals from saving money needed for important and expensive purchases, for example:

"Consequences is I cannot buy a bigger house. [...] normally I can do my saving for investment or improve my life but now I need to use my savings to buy medicines or doctor consultations [...] it takes a very big proportion of my savings every year I would say. Yes, it's quite a big burden for me." (PID 8) Psoriasis, China

The extent and impact of costs varied by country of residence and, in turn, whether medical costs were covered by the healthcare system and/or health insurance.

"The first one was really dealing with the disease and when I finally got that under control then it took me another ten years to deal with the financial impact of it [...] almost filing for bankruptcy [...] it was like are you kidding me. Like I just came through, I almost died, I, I managed to get through this and now I have to deal with the, the financial like, how much more do you want, need, and, and being ashamed because, and not wanting to ask people for help because I felt like I didn't want anybody to feel sorry for me, or that I couldn't do it, or that I couldn't manage it, or anyone in my employer to think that I was not capable." (Focus group 2)

People from countries without medical care that was free at the point of delivery were under particular financial

pressure. These people often relied on health insurance provided by their workplace. This put them in a double bind, where their job may not suit or worsen their condition, but they could not receive healthcare without it.

"It's the fear. I needed my health insurance. I needed my job. I couldn't be seen as being unable to do my job because of my condition, that was, this in the mid-90s, so I could have easily been fired [...] the pressure of having to pretend and to do what you're doing in order to make sure that I could financially deal." (Focus group 2)

The expense of treatments in some countries contributed to health inequalities. Some people chose to forgo or limit their treatments to offset the expense. But by not taking the therapeutic dose, they threatened their disease control. Others felt there was no choice but to pay for expensive treatments.

"You don't think about the expense too much because there's no choice, you will get the medication either way." (PID 23) Psoriasis, Israel

"The right treatment is really important [...] but the biologic treatment is not free, it's very expensive, err, it takes [...] equivalent to thirty per cent of my salary at least [...] it works but it cannot have an effect for too long, only one or two years is the most I can afford." (PID 7) Psoriasis, China

Daily life and responsibilities. The impact on people's daily routines dictated their everyday choices and the time spent on meaningful activities (e.g. work, school, hobbies, and holidays). Many patients had to alter the structure of their day to manage their condition. For instance, those with photosensitive conditions, such as vitiligo and erythropoietic protoporphyria, often completed outdoor activities in the early morning or evening to avoid sun exposure. This was challenging, indeed impossible for those who worked outdoors. This led to reduced independence and contributed to a loss of autonomy and experiences of social isolation.

"For coming here, I needed to, my boyfriend come with me because for me drive the car is impossible because I have the sun in my direction and the hands start to burn." (Focus group 1)

Adherence to treatment regimens interfered with people's daily routines and required compensation, such as sacrificing sleep duration. People with conditions that caused skin flaking and bleeding, or that required topical treatments, spent extra time on daily chores, such as cleaning and doing laundry. Even with less arduous treatments, participants described the cumulative impact of having to plan and complete regimens every day.

"[I] remember once we did a campaign on psoriasis, the people with psoriasis had to wake up an hour before the rest of them, 1 h before just for psoriasis, imagine for epidermolysis". (Focus group 3)

Career choices were constrained by the perceived limitations of dermatological conditions and by people's level of confidence in applying for jobs and participating in certain work activities.

"Now because of this disease, maybe I have to consider some job that would be, no need to go on a trip, I mean no need for travelling, that would be better for me." (PID 19) Psoriasis, China

The time that people spent attending hospital appointments affected the time available to work, with some employers being intolerant. Some participants opted for early retirement, while others were persuaded or forced to leave. People in the sample reported workplace discrimination and being refused jobs, which prevented them from moving up their career ladder:

"I remember that I tried to change my job once [...] I was about to face the job interview. But before I had to fill out papers you know, one of the requirements was not having any visible marks on the skin [...] So then, I didn't go to the interview because I realized that that job was not for me [...] Even when I had all the qualities you know, the qualifications to do the job." (PID 48) Vitiligo, Cuba

Physical symptoms and fatigue made it difficult for some participants to perform caregiving or childcare duties. Although sometimes participants prioritized caring for their children at the expense of following their treatment routines, which was difficult when the child also had a dermatological condition:

"When I was suffering and [my daughter] was suffering it was crazy because I was always taking care of her first. [...] That's the instinct of a mother and I [...] would bathe her and put her clothes and maybe the bandages, I would put her to sleep, then I would fall asleep. [...] I wouldn't have the energy to take care of myself too." (PID 22) AD, Israel

Impact of healthcare. Lack of medical awareness affected the quality of dermatological care provided. Not everyone had access to specialist care, particularly those in low-income countries and rural areas. People with access to dermatology services reported that some specialists lacked expertise in dermatological conditions and awareness of their wider impacts, evidenced by stories of inaccurate and delayed diagnoses. Nevertheless, participants were hopeful that more dermatology research would increase medical awareness and improve condition management and service provision in the long term.

I met five doctors, and the last doctor, confirmed that I have the psoriasis (PID 29) Psoriasis, Indonesia

Diagnosis is almost impossible and where it's available it's very exorbitant. (Focus group 1)

Only a minority of participants expressed satisfaction with their healthcare. These people usually received whole-person care or effective medication. Dissatisfaction was partly due to factors beyond their individual healthcare, such as the perceived lack of evidence-based and effective treatments available for their condition. Factors relevant to their individual care included inaccurate or delayed diagnosis, poor clinician communication, and a disintegrated, biomedical approach to condition management.

Some people with dermatological conditions were prescribed medication by their clinician and independently conducted research into more effective medications and other strategies to improve their condition. Others had not been prescribed any medication, typically because they had not been able to access a clinician with sufficient expertise or because no adequate treatments

existed. Participants variously reported researching and trialling medications, psychological therapies and holistic/natural remedies.

Many participants felt that clinicians preferred to manage dermatological conditions with medication alone and did not consider or provide information on other important environmental and lifestyle factors. This led some to be cynical of clinicians who they saw as predominantly motivated by profit.

I'd like to raise the issue of doctors recommending medication as ... they make patients feel like it's the only solution, probably because that contributes to the patients giving them their paycheque, but I think from what I've been studying, I think there's another whole lot of information that, I don't know if it's been deliberately hidden ... or doctors don't know genuinely. (PID 11) AD, Kenya

In Africa, and I believe in many parts of the world ... the doctors ... just tell you to not take this, use this cream come back after a week or two weeks. If it doesn't work in three or four days come back. They won't tell you that it's because of such fabric in your house, or what you're wearing. (PID 12) AD, Kenya

As a result, individuals felt let down and spent considerable time and effort using a trial-and-error approach to self-management. Some found that the information they found through the internet led to better disease control than that provided by clinicians.

Different doctors were giving you different advice ... you don't know which one to follow, and ... after series of times, I work out my own, own ways to, to treat, to deal with my diet. (PID 10) Psoriasis, China

More advanced treatments could relieve some pressure, as they were usually more effective, less time-consuming and required less planning. Biological medications emerged as a key example, although some patients found self-injecting to be traumatic.

Now with biologics, you forget about everything, it's just once every two weeks and forget about anything else and it works. So forget about all the other things. (PID 5) Psoriasis, Cuba

Although conducting research could improve disease control and encourage participants to engage in healthy lifestyle behaviors, it could also be a source of misinformation and anxiety, inducing a fear of comorbidities and treatment consequences. By far the most common mode of research was the internet/Google, although patients also obtained information by attending conferences, joining patient organizations, subscribing to newsletters and magazines, reading books and joining forums or other forms of peer-to-peer information sharing.

Theme 3b: Psychological and social impacts are most significant. While the physical impact of dermatological conditions was important and could be profound, the general consensus was that the psychological and social impacts were the most significant and often underappreciated:

"And even if, if epidermolysis bullosa was cured tomorrow that will always be in your head. We seem to think of a lot of the physical strain that it does, the skin conditions on people, but we forget that mentally it'll never leave, and I think there's very little that people do for that. There's not a magic pill that you

can take and you're going to forget. I think that the mental implications involved into a skin, it's not just physical, it's very mental as well [...] So, there's an internal scar, that doesn't go away." (Focus group 2)

This assertion was strengthened in the voting in the plenary session, where the psychological and social categories obtained the most votes (Fig. 3).

Themes and their implications for Patient-Reported Impact of Dermatological Diseases (PRIDD)

The themes presented above inform the content and structure of PRIDD. We found that personal and contextual factors operating at the individual (e.g. beliefs about distress and behavior), organizational (e.g. impact of healthcare services) and societal levels (e.g. lack of public awareness) influence the experience and degree of the impact of dermatological conditions. Our theoretical model of impact (Fig. 4) illustrates the relationship between themes and concepts as well as modifiers, thereby providing context and aiding greater understanding of impact.

Table IV summarizes the implications of each overarching theme on measuring the impact of dermatological conditions. Fig. 5, based on the common impacts this study identified (Theme 3a), depicts the conceptual framework of the impact of dermatological conditions.

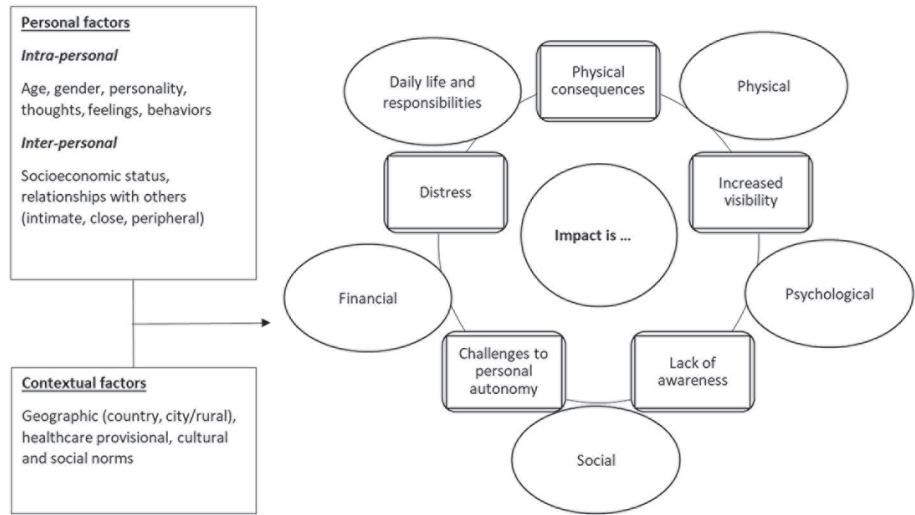


Fig. 4. Theoretical model of the impact of dermatological conditions.

DISCUSSION

The concept of 'impact of dermatological conditions' encompasses physical, psychological, social, financial, and

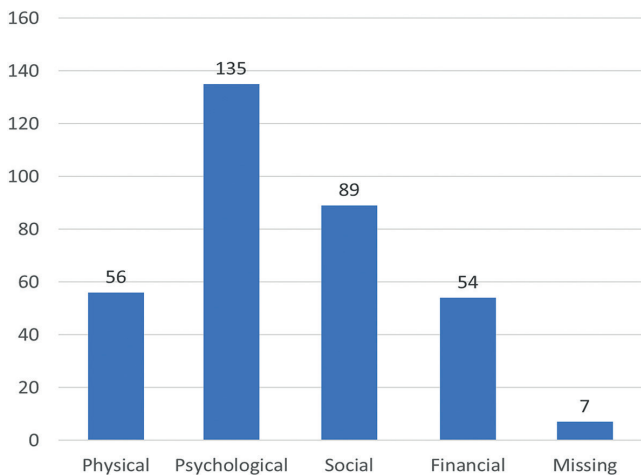


Fig. 3. Number of votes by plenary session attendees regarding the perceived importance of each impact category.

daily functioning and involves healthcare. Many experiences were common across dermatological conditions, indicating that a dermatology-specific measure is appropriate. Data from this study resulted in the development of a conceptual framework (Fig. 5) to underpin a measure of the impact of living with a dermatological condition. The degree of patient input in this study meets the gold-standard COSMIN criteria (Appendix S5) (6, 10).

Research into the impact of dermatological conditions on patients' lives is limited and is often unidimensional, focused on a single condition, and/or narrowly focused on a specific impact category. This study consolidates and extends existing knowledge. We present here two novel findings of the impact of dermatological conditions that were previously hidden: (i) many people with dermatological conditions report employment discrimination; and (ii) many are hesitant to have children.

Implications for Patient-Reported Impact of Dermatological Diseases (PRIDD)

Multiple aspects of impact have not previously been captured using a single measurement instrument, and previous measures have focused on point-in-time impacts (3). This study supports the concepts of Cumulative Life Course Impairment (15) and the Major Life-Changing Decision Profile (16) in dermatology by unifying distinct point-in-time and cumulative impacts to attain a comprehensive understanding of the overall impact of living with a dermatological condition.

The current results provide a working definition of impact and inform how it should be measured (Figs 4 and 5). The finding that participants primarily assess the impact of their condition in terms of their psychological, social and daily functioning, rather than physical functioning or symptoms, supports the need to assess the impact of these conditions more widely, and by extension the need for PRIDD.

Table IV. Themes and their implications for Patient-Reported Impact of Dermatological Diseases (PRIDD)

Theme	Measure
Impact at the individual, organisational and societal levels	As a patient-reported measure, PRIDD must focus on the impacts acting at the individual level, in the context of the organisational and societal levels.
Impact can be both point-in-time and cumulative	To comprehensively capture the impact of dermatological conditions, PRIDD must include items that reflect both point-in-time and cumulative impacts.
Impact is a multifaceted construct	<p>A range of subscales are required to measure impact:</p> <ul style="list-style-type: none"> • physical impacts • psychological impacts • social impacts • financial impacts • impacts on daily life and responsibilities • impact of healthcare <p>The final domain appeared to influence rather than reflect impact, so it may not be suitable to include in the conceptual framework. This need to be tested further.</p> <p>As a dermatology-specific measure, PRIDD should consist of concepts common across conditions. The common impacts identified will form the basis of the items of each subscale.</p>

While some items could be viewed as causal, namely those of the 'healthcare impacts' domain, overall our conceptual framework is consistent with a reflective measurement model as each of the items reflect impact. A reflective model, unlike a formative model, has the advantages of the acceptability of missing items and the presence of well-developed measurement theories, such as item response theory, to develop and evaluate PRIDD (17). Although there is uncertainty regarding the relationship between the 'healthcare impacts' domain and impact, this domain has been included in the conceptual model to be further tested with patients in the next phase of the research.

Strengths and limitations

This study met the highest standards for concept elicitation studies outlined by COSMIN (Appendix S5) (6, 10). The study achieved high levels of patient engagement by recruiting through the unique global membership network of IADPO. The diverse study sample represented both inflammatory and non-inflammatory dermatological conditions (common, uncommon, rare) across the six populated continents. This strengthens the content validity of PRIDD for global use across dermatological

conditions. The participants were patient organization members and therefore may not represent the experiences or views of non-members. Data were collected using a mixture of in-person groups and online individual interviews. The resultant methodological and data triangulation provided rich and robust data to support study conclusions.

Implications for clinical practice

The WHO recognizes that health inequalities can affect quality of life (18) and promotes person-centered healthcare (19). This concept emphasizes the need for fair access to healthcare for the right patient at the right time. We found accessibility and quality of dermatological care varied according to geographical location (i.e. country, city, rural) and socioeconomic status. Inadequate healthcare was an important determinant of impact. Resource allocation to dermatology that reflects the burden of dermatological conditions could help to improve the provision and accessibility of dermatological care and reduce patient burden.

In line with the CS-SRM, the current findings indicate that a range of disease-related thoughts (e.g. genetic cause), emotions (e.g. shame), and behaviors (e.g. avoidance coping) characterize people's experiences of living with dermatological conditions. Illness beliefs are known to influence individuals' cognitions, emotions, and coping behaviors, influence physiological outcomes (20) and predict outcomes for a range of long-term conditions (13). Beliefs about psoriasis are better predictors of outcomes than disease severity (21–23) and are closely linked with medication adherence (24). Illness beliefs are amenable to change and therefore represent modifiable determinants of impact. They are partly shaped by the information provided by healthcare professionals as well as from other, arguably less reliable, sources (25). It is clear, therefore, that clinicians can influence the impact of dermatological conditions, beyond diagnosis, assessment, and treatment.

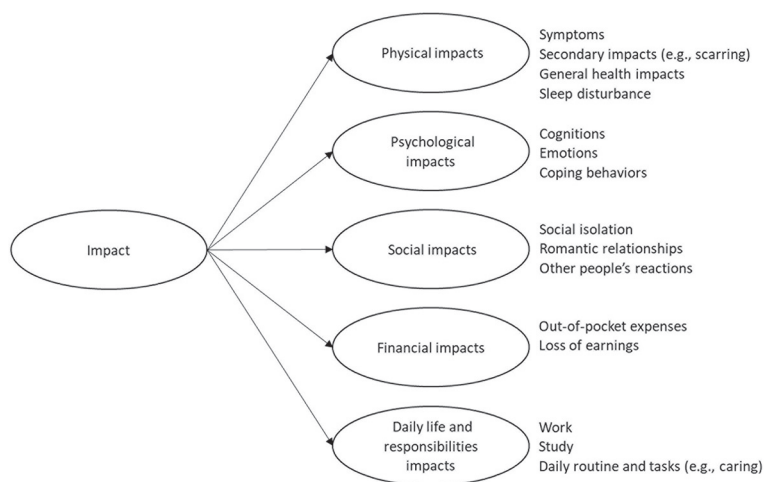


Fig. 5. Conceptual framework of the impact of dermatological conditions with example concepts.

However, as the current study indicates, clinicians first need to broaden their awareness and understanding of the impact of dermatological conditions.

Good communication skills are crucial to dermatology research and practice. This population are known to understate the impact of their condition unless encouraged otherwise (26), and so this study employed skilled interviewers to elicit a rich dataset on how dermatological conditions affect patients. Patient-centered research based on good communication skills provides a good platform for clinicians to understand their patients and enhance their consultations.

Finally, participants in this study recognized the value of psychological support in the management of their condition. However, many were not able to access this support as it was not integrated with their routine care and was too expensive to access privately. This is particularly concerning, given that our participants reported experiencing anxiety, depression, and suicidality. Evidence-based training exists to allow clinicians to address basic psychological needs of patients in the dermatology consultation (27, 28). In addition, specialist psychological support should be available and integrated with the wider care of patients with dermatological conditions.

Implications for research

The approach taken in the current study provides a model for the development of other patient-perspective speciality-specific measures. To maintain the high level of content validity achieved in this study, future work should consult a wider group of people with dermatological conditions to validate the impacts identified here, check whether any relevant impacts are missing, and identify which items to prioritize for inclusion in PRIDD.

Conclusion

This study adhered to a gold-standard methodological approach in developing the new measure called PRIDD. The findings reinforce and broaden our understanding of dermatological conditions as complex long-term conditions that have impacts beyond the skin. We have developed the first conceptual framework of the impact of dermatological conditions on patients' lives to be tested through participatory (consensus-seeking methods) and statistical methods (psychometric testing).

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