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World Workshop on Oral Medicine VIII: Development of a core outcome set for oral lichen planus: The patient perspective

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Objective. This study aimed to explore the lived experience of patients with oral lichen planus (OLP) and investigate what treatment-related outcomes are the most important to them and should be included in a core outcome set (COS) for OLP.

Study Design. A qualitative study involving focus group work with 10 participants was conducted. Interviews with each focus group were held twice: session 1 explored the lived experience of patients with OLP, and session 2 allowed patients to review a summary of the outcome domains used in the OLP literature to date. The discussions were recorded, transcribed verbatim, and analyzed using framework analysis.

Results. In session 1, 4 themes and 8 sub-themes emerged from the data analysis. An additional outcome, 'knowledge of family and friends,' was suggested in session 2.

Conclusions. We have gained valuable insight into the lived experience of patients with OLP via this qualitative study. To our knowledge, this study is the first to explore the patient perspective on what should be measured in clinical trials on OLP, highlighting an important additional suggested outcome. This additional outcome will be voted upon in a consensus process to determine a minimum COS for OLP. (Oral Surg Oral Med Oral Pathol Oral Radiol 2023;000:1−11)

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Oral lichen planus (OLP) is an immune-mediated inflammatory condition that affects nearly 1% of the global population.[1] Although the exact etiology remains unknown, the condition likely represents a common reaction pattern in response to extrinsic antigens, altered self-antigens, or superantigens.[2] The most aggressive forms of OLP may cause pain, burning sensation, and discomfort, negatively impacting the patient's quality of life.[3] Currently, no cure is available, and any therapy's primary goal is to alleviate patients' symptoms.

To establish evidence-based protocols for the management of OLP, meta-analyses of sufficiently homogenous clinical trials regarding participants, interventions, and outcomes are required. However, there is a wide variety and lack of standardization in clinician- and patient-reported outcomes among studies of treating OLP.[4,5] Developing a core outcome set (COS), a standardized set of outcomes that should be measured and reported, as a minimum, in all clinical trials of a specific condition,[6] would contribute to solving this issue. The World Workshop on Oral Medicine (WWOM) Outcomes Initiative for the Direction of Research (WONDER Project) was created to develop a COS for OLP using an established methodology by the Core Outcome Measures in Effectiveness Trials (COMET) initiative.[6]

The development of a COS is a multistage process that requires the participation of different stakeholders, including clinicians, researchers, and patients.[6] The first stage in developing a COS is the identification of the outcomes used in previous interventional studies. This stage was achieved through a systematic review of interventional studies on OLP and oral lichenoid reactions published between 2001 and 2022.[7] The second stage in determining a COS for OLP requires using focus groups of patients with OLP that allow for synergistic discussions between individuals with different disease experiences to ultimately agree on the essential outcome measures to be included in future studies.[8] This incorporation of the patient perspective in COS development is of vital importance.[6] Patients with OLP often live with long-term symptoms, and as such, their input on what should be measured and recorded cannot be overlooked. For instance, in developing COS for rheumatoid arthritis, Kirwan et al.[9] highlighted the importance of including the previously overlooked outcome, fatigue, which was proposed via patient input.[9] Presently, no standardized methodology is identified for generating the patient perspective in developing a COS, but it is hoped that further guidance will come.[10]

Thus, as the second stage of the WONDER project to develop a COS for OLP, this study aimed to explore the lived experience of patients with OLP. The focus group discussions emphasized treatments that were used and outcomes of care. The treatment-related outcomes of greatest importance to these patients were also discussed.

MATERIALS AND METHODS

A qualitative study incorporating focus groups of patients with OLP was conducted. The reporting of the study follows guidance from the Standard for Reporting Qualitative Research (SRQR).[11] Interviews with each focus group were held twice: session 1 explored the lived experience of patients with OLP, and session 2 allowed patients to review a summary of the outcome domains used in the OLP literature to date. From the patient's perspective, a discussion ensued regarding the importance of the various outcome domains found in the literature and which outcome domains of importance to patients were absent from the list presented.

Ethical considerations

This study received ethical approval from the Clinical Research Ethics Committee of Cork Teaching Hospitals (ECM 3 [rrr] 01/06/2021). Those willing to participate were given the study information leaflet and a consent form, which they completed, signed, and returned before any research procedures were initiated.

Research team and reflexivity

The research team consisted of 2 researchers (R.N.R. and H.B.) with experience in qualitative interviewing and data analysis. The lead researcher (R.N.R.) was responsible for recruiting participants, whereas both researchers conducted the focus groups and data analysis. A debriefing meeting was held after each focus group to encourage reflexivity.[12]

Participants and sampling strategy

Participants older than 18 years with a diagnosis of biopsy-proven OLP who attended the Oral Medicine unit of Cork University Dental School and Hospital were asked by the research team if they were willing to participate in the study. Participants needed to speak and understand the English language and be willing to participate in a group discussion to be considered for the study. There were no other inclusion or exclusion criteria. Table I displays the demographic characteristics of the participants.

Statement of Clinical Relevance

As the second step in developing a core outcome set for oral lichen planus, this qualitative study identified the treatment-related outcomes important to patients with this condition to be measured in future trials.

Table I. Demographics of focus groups for patients with oral lichen planus.

Focus group	*Age*	*Sex*	*Role*	*Time since diagnosis (months)*	*Current medication*
Focus group 1 Patient 1	75	Female	Retired	79	Topical corticosteroid
Focus group 1 Patient 2	68	Female	Retired	74	Topical corticosteroid
Focus group 1 Patient 3	54	Male	IT consultant	144	Topical corticosteroid
Focus group 1 Patient 4	57	Male	Customs officer	33	Hydroxychloroquine
Focus group 1 Patient 5	62	Female	Retired	26	Hydroxychloroquine
Focus group 2 Patient 1	71	Female	Retired	42	Topical corticosteroid
Focus group 2 Patient 2	77	Female	Retired	46	Topical corticosteroid
Focus group 2 Patient 3	58	Male	Teacher	18	Topical corticosteroid
Focus group 2 Patient 4	60	Male	Works in retail	36	Hydroxychloroquine
Focus group 2 Patient 5	76	Female	Retired	120	Hydroxychloroquine

The sampling strategy was directed to include participants who had OLP of varying severity, with some patients managed with topical therapy only and others using systemic medications to manage their symptoms. Time since diagnosis was also considered when recruiting participants to include those recently diagnosed and other longstanding patients of the host Oral Medicine Unit.

A total of 20 patients were contacted by telephone between March and April 2022. Two face-to-face focus groups with a total of 10 participants were held. Each focus group lasted between 40 and 50 minutes. Data analysis was an iterative process, with the initial focus group recording being transcribed and analyzed before the second focus group was held. Recruitment ceased once data saturation was achieved. Data saturation was defined as the moment at which the data collected had sufficient breadth and depth that it was adequate to answer our research questions, and no new themes emerged from the data analysis.[13] Because data saturation was achieved after 2 focus groups, the remaining 10 patients recruited to the study were not required to participate.

Data collection and analysis

A topic guide was developed by the research team, with minor edits of the topic guide following feedback from participants in the initial focus group (Figure 1). The topic guide allowed a similar scope of areas to be covered in both focus groups. However, the facilitator ensured that conversations flowed between participants with minimal intervention.[14] The focus group methodology allowed group interactions, ensuring participants had the opportunity to share lived experiences and collectively explore outcomes of OLP treatment that were significant to the group.[15] The focus group discussions were audio recorded and transcribed verbatim.

An interpretive methodology was used to identify themes of the lived experience of the patients, keeping in mind the conceptual framework of Locker's Model of Oral Health.[16,17] The transcripts were analyzed on a line-by-line basis independently by 2 researchers (R.N.R. and H.B.). The transcripts were coded as a means of defining the data that was to be analyzed. This data analysis was done manually using Microsoft Word (Microsoft, Inc, Redmond, MA, USA). The coding process involved identifying text passages that exemplify a descriptive idea and linking them under a single idea or code. This process allowed the transcripts to be categorized and facilitated the identification of key themes.

The research group generated a summary of the outcomes used in the literature after a rigorous systematic review (cross-reference paper 1). A lay explanation of the outcomes was presented to the patients for discussion (Figure 2). Patients were provided with the opportunity to suggest additional outcomes not previously identified.

RESULTS

Session 1 - Lived experience

Four themes and 8 sub-themes emerged from the data analysis. Table II outlines the themes, subthemes, and descriptors.

Theme 1—Living with OLP: Symptoms and function. Different descriptions were provided for the symptoms experienced with OLP, including soreness, pain, rawness, funny feeling, burning, and piercing. Others spoke about the severity of these symptoms.

Focus group 1 patient 4 (FG1Pt4) *'The pain, no, the rawness, in both cheeks was unbearable.'*

FG2Pt1 *'I was very bad at the time. I couldn't even swallow water (because) my palate was so raw. It was that dramatic! It has made me cry.'*

FG2Pt5 *'When I get it on my tongue, it gets so bad that I get a sharp, piercing pain from my tongue out to my ear.'*

FG2Pt2 *'I get the same. I get an ulcer on my tongue then I would get the sharp, shooting, piercing pain out to my ear. It is like a knife.'*

FG2Pt3 *'You know it feels like you burn your mouth. The slightest thing makes it feel like a piercing, and*

- Personal history and knowledge about OLP
    - What do you understand about your condition?
    - Number of years/months living with OLP
- Characteristics of the disease
    - How often do you have a flare-up of your OLP?
- Experience of living with OLP
    - How has OLP impacted on:
        - Quality of life – activity limitations – Have you had problems while eating, drinking, or speaking?
        - Mood: have you stopped doing things due to the emotional burden of OLP? Have you worried? Do you think that your mood has any influence on your pain?
        - Family and social interactions – has anything changed regarding social interactions? Have you stopped making plans with your friends or family? Have you stopped going out for meals?
        - Productivity – Have you had to take time off work?
- Treatment of OLP
    - What treatments have you had?
    - Satisfaction with treatment
        - Was it successful?
        - What do you understand about success of treatment?
- Treatment outcomes
    - When you think about your symptoms of OLP
        - What do you consider to be the most important treatment outcome?
    - When you think about your treatment,
        - Did you consider the side effects/adverse effects before choosing a treatment?
- If you had to think about a list of the most important treatment outcomes, what would they be?

Fig. 1. Final topic guide used in focus groups.

that's it; you have it for a few days and can't really use your mouth.

FG2Pt1 *'When I was very bad . . . it would make me physically sick.'*

Many participants spoke about the impact of the clinical manifestations and the symptoms on their oral function. A limitation in the ability to speak, eat, and drink was frequently discussed.

FG1Pt2 *'I couldn't eat or talk. It was like having razor blades in my mouth.'*

FG2Pt3 *'You can't form the words sometimes. It is just too much of a physical effort.'*

FG2Pt2 *'If my tongue is really sore, then it stops you from talking—you just don't want to talk.*'

FG1Pt3 *'I find if it flares up, talking is a problem. It happens on my tongue, so getting the words out is practically impossible. You would rather not say anything. Better to keep your mouth shut.'*

FG1Pt4 *'Did you find you were much slower with eating? Everyone would be finished at the dinner table.*

Please rate **how important** you think these outcomes are to record in a trial looking at treatments for oral lichen planus.

1–3 Not important at all (should not be included)
4–6 Perhaps of some importance
7–9 Very important (definitely should be included)

Please circle the most appropriate importance rate for each statement

How much of your mouth has oral lichen planus

1 2 3 4 5 6 7 8 9

The type of oral lichen planus

1 2 3 4 5 6 7 8 9

The size of ulcers in your mouth from oral lichen planus

1 2 3 4 5 6 7 8 9

The size of (dimensions of) the red areas in your mouth

1 2 3 4 5 6 7 8 9

How red the areas are in your mouth

1 2 3 4 5 6 7 8 9

The number of ulcers or red areas in the mouth

1 2 3 4 5 6 7 8 9

How severe the lichen planus is in your mouth

1 2 3 4 5 6 7 8 9

Change in severity in response to treatment

1 2 3 4 5 6 7 8 9

The amount of time it takes for your mouth to improve when you use treatments

1 2 3 4 5 6 7 8 9

Fig. 2. Lay language presentation of the outcomes from the literature.

Change in taste

1 2 3 4 5 6 7 8 9

Burning

1 2 3 4 5 6 7 8 9

Itching

1 2 3 4 5 6 7 8 9

Pain

1 2 3 4 5 6 7 8 9

Irritation

1 2 3 4 5 6 7 8 9

Intensity of symptoms

1 2 3 4 5 6 7 8 9

Soreness

1 2 3 4 5 6 7 8 9

Dry mouth

1 2 3 4 5 6 7 8 9

Side effects of treatment

1 2 3 4 5 6 7 8 9

Getting thrush from treatment

1 2 3 4 5 6 7 8 9

Complications of treatment found of blood tests

1 2 3 4 5 6 7 8 9

Record of how toxic the drug is

1 2 3 4 5 6 7 8 9

Fig. 2. Continued

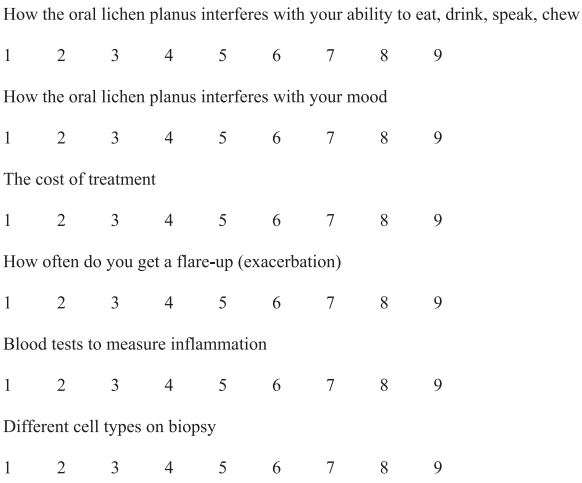


Fig. 2. Continued

They would be all saying, 'you are still eating.' I would be like, 'ya, I'm really slow'—it was embarrassing.'

An extensive list of foods and drinks that exacerbate symptoms was discussed.

FG1Pt4 *'When I have a bad flare-up, even fruit drives it mad.'*

FG1Pt3 *'Ya, same. I can eat bananas but can't even look at a grapefruit.'*

FG1Pt2 *'You realize what food is really acidic. I had to avoid spicy (foods) too and chocolate.'*

FG1Pt5 *'I avoid food with crusts. They kill the lichen (planus). No toast, or brown bread or bread rolls.'*

FG1Pt3 *'And wine. Red wine—it gets very bad and brings it on straight away.'*

FG2Pt1 *'I can't touch ice-cream. Anything that is too cold is terrible. Or too hot too. Temperature is a real problem... I would never drink anything cold out of a fridge. Coffee and tea are lukewarm.'*

FG2Pt5 *'It really limits your intake of food.'*

Theme 2—Social impact: Disability, worry for the future, and isolation.. The risk of malignant change in OLP was foremost in the minds of many participants. Others referenced extraoral manifestations and a concern about how many other sites would become involved.

FG1Pt3 *'When I got the diagnosis, I got a load of documentation, and it all mentioned about the cancer risk. . .and it was looking into the future that you would worry.'*

FG1Pt2 *'I was told about the risks attached to it; that was my worry. That's what frightened me . . . I was very sad at the start for a few years about it.'*

FG2Pt5 *'I just worry about the cancer. It is in my head all the time.'*

FG2Pt4 *'Ya, it is always on my mind. I try to put it to the back of my mind, but it is always there.'*

FG1Pt5 *'I was worried about the risks as well. . .I'm also worried 'cos along with my mouth; I got it on my scalp and on my body. My mouth came first, and then all the rest came together. When will it stop!'*

The degree of discomfort from OLP contributed to patients isolating themselves and withdrawing from social events.

FG2Pt2 *'When it's bad, I'm having to set alarms to remember to use the medications. I can't go out. I have to be back by a certain time. If you are going to really treat it, you are going to have to stay at home for the few days.'*

FG2Pt3 *'When it's bad, I lock myself in the bathroom for hours at a time to hide away from people. . . . . It just makes you want to run away from society.'*

FG2Pt1 *'You just can't go out when it's bad. You just can't.'*

FG2Pt2 *'It all gets too much for me. Much too much. Life is very difficult with it (OLP).'*

FG2Pt4 *'I just didn't want to go out to work. It is very tiring. It takes more effort and energy to function when it is bad.'*

FG2Pt5 *'Lockdown (COVID-19 restrictions) has made it easier because I didn't have to see people or meet people or talk to people. I didn't have to worry about going to a restaurant.'*

Theme 3—Treatments and outcomes of care. Participants discussed the merits and risks of the various treatment options used to manage OLP. Based on their experience of the different treatments, they then considered the outcomes of the care they thought important.

Table II. Themes, subthemes, and descriptors.

Themes	*Subthemes (Based on Locker Model of Oral Health)*
Theme 1 – Living with oral lichen planus: Symptoms and function	- Functional limitation/Disability both psychological and physical with limitation in ability to eat, drink (dietary restrictions), and speak - Discomfort and pain with discussion on symptoms
Theme 2 – Social impact: Disability, worry for the future and isolation	- Disability both psychological and social with limitation of social circle - Disability both psychological and social with worry for the future and concerns about potential malignant transformation
Theme 3 – Treatments and outcomes of care	- Discomfort and pain with discussion on discomfort associated with some treatments used - Function limitation due to time taken for relief of symptoms
Theme 4 – Knowledge and understanding of health care practitioners, family, and friends	- Disability both psychological and social due to lack of support from family and friends and poor understanding from some health care providers - Function limitation due to difficulty maintaining social interactions during periods of exacerbation

FG1Pt2 *'I'm on the (corticosteroid) mouthwash, and I use it every 6 to 8 weeks; it definitely helps. It could take 2 weeks for it to really work, though. That's too long! It's not as sore as it used to be.'*

FG2Pt2 *'The (corticosteroids) mouthwash is a problem for me. It works, but it causes pain when I use it. It brings tears to my eyes. Then it helps after about 5 days.'*

FG1Pt5 'I used the mouthwash first and then the (corticosteroid) cream with cotton wool rolls. Nothing works for me. I'm on a tablet (hydroxychloroquine) now, and it is great.'

FG1Pt4 'I'm on that (hydroxychloroquine) too, and it is brilliant. I have no flare-ups.'

FG2Pt2 *'When I use the (corticosteroid) mouthwash, I can feel it calming and healing.'*

FG2Pt3 *'It gets less and less sore when I use the (corticosteroid) mouthwash, and when you wake up, the soreness is just gone.'*

They went on then to consider what care outcomes they considered important based on their experience of the different treatments.

FG2Pt1 *'I just want it not to be sore anymore.'*

FG2Pt5 *'All I want is to get rid of the soreness and get back to function.'*

FG1Pt5 *'I never think of the side effects of what I take; I just need to take it to get some relief.'*

FG1Pt3 *'When I use mouthwash or something else, I just want to feel at ease interacting with the people around me after I use it.'*

Theme 4—Knowledge and understanding of health care practitioners, family, and friends.. Participants discussed their initial presentation and highlighted their frustrations with the limited knowledge of health care practitioners regarding OLP.

FG1Pt5 *'I went to the GP, and she didn't know anything about it. She just gave me, um, like, drops that I could use for my mouth. When that didn't clear, I phoned her after a number of days, and she said no, you'll be fine, that'll settle down.'*

FG2Pt1 *'In the pharmacy, they gave me a mouthwash one day. My tongue just sizzled with it. It was awful. I thought I would end up in the hospital. I thought they'd know better.'*

FG1Pt2 *'I went to the chemist thinking it was an ulcer or something, and it never cleared. Then I ended up going to the GP who sent me to an ENT specialist, who did a biopsy, and who didn't know what it was either.'*

FG1Pt5 *'The GP needs to be aware of it. My GP didn't know anything about it, and I just got drops and told it would settle down.'*

There was frustration with the lack of understanding and awareness of family and friends.

FG2Pt5 *'People just don't understand. They think you have a little mouth ulcer—get over it!'*

FG2Pt1 *'They just don't want to know after a while.'*

FG1Pt4 *'Not a lot of people know about it, so a bit of publicity is needed.'*

FG1Pt1 *'You never hear about it. It would be great if there was something on the TV.'*

Reference was made to the impact of exacerbations of OLP on interactions with family and friends.

FG1Pt1 *'It bothers the rest of the people in the house too. It upsets everyone else too, when you have a flare-up.'*

FG1Pt3 *'It would change your mood, well that's what I was told so by my wife! I have had it for 12 years, as it started after my mother died. I thought I am more used to it now, but my wife still tells me it affects my mood.'*

Session 2—Review of outcomes from the literature

Most participants agreed that all the outcomes generated in the literature were of some relevance with variable importance.

FG2Pt3 *'Everything seems to be covered, but only some are of importance.'*

FG2Pt5 *'Ya, everything seems to be covered, but I wouldn't want to be asked or checked for all of these things if I was doing a study (clinical trial). That's too much.'*

Due to OLP's impact on personal and professional interactions, others thought that additional outcomes focused on these interpersonal interactions should be considered.

F1Pt3 *'Effects on family and friends. That should be asked. They would have to avoid me when the flare-up was bad.'*

F1Pt2 *'I used to find work awkward. You take the mouthwash 3 times a day, and you would have to sneak off somewhere. Hope the phone doesn't ring.'*

F1Pt5 *'You literally have to hide away because you don't want to talk to anyone.'*

DISCUSSION

Using a COS for future OLP research investigations will enable outcomes to be pooled across studies to allow meta-analyses of data and translate to higher-quality evidence-based interventions. The involvement of patients in COS development is an essential aspect that ensures the lived experience of a condition is considered.[18] In the first stage of developing a COS for OLP, a systematic review of interventional studies on OLP identified 422 outcome measures, grouped into 69 final outcomes (cross-reference paper 1). However, relying solely on identifying outcomes through literature searches may lead to overlooking important patient outcomes. This study describes the second stage in developing a COS for OLP, which was undertaken to identify outcomes that were considered important from the patient's perspective.

This stage of considering the patient's perspective is not unique to the patient population with OLP and has been previously demonstrated in the medical literature. In a study evaluating treatment outcomes of importance to patients with depression and their clinicians, the authors found that symptom reduction was considered most important by clinicians. In contrast, patients prioritized return to social function and interpersonal relationships as of greater importance.[19] A qualitative study of patients with heart failure highlighted this disparity in patient and clinician opinions on what is considered important in the context of the treatment provided.[20] From a medical context, readmission rates and mortality were considered important care outcomes. In contrast, from the patient's perspective, reduction in symptoms, restoration of function, and health-related quality of life were deemed of greater value.[20] Despite the significant impact of the OLP on the daily lives of patients,[21,22] few studies have incorporated patient-reported outcomes (PROs) into their study design.

The PROs constitute an essential part of measuring health outcomes, and they can be defined as "any information on the state of the patient's health condition reported directly by the patient without the interference or interpretation of the clinician and other health professionals."[23] With the help of the PROs, patients can describe their symptoms, their perception of well-being, and how their condition interferes with their daily activities.[24] This focus group study allowed us to explore the lived experience among patients with OLP, its interference with daily activities, and its mental and social impact. It facilitated discussion regarding treatment modalities used and what the patients considered as 'success' in the context of the management of OLP. In this study, a new outcome not previously identified in the systematic review, namely "knowledge and understanding of family and friends," was included in the list of outcomes.

In a previous systematic review of patient-reported outcomes measures (PROMs) in oral mucosal lesions, including OLP, a significant heterogeneity in the PROMs used in research studies was identified. Pain assessment using the visual analog scale (VAS) was the most widely used of the 33 PROMs reported in the OLP studies.[25] In this qualitative study, the participants used multiple descriptive terms to convey their experiences, using analogies or metaphors, making their oral soreness more visual and visceral to the listener. The participants emphasized the impact of their condition on their families and social life. Our results agreed with those obtained from previous qualitative studies. The burden of OLP on patients' daily lives has been explored using qualitative methods to a limited extent in the literature to date. These studies demonstrate that OLP is associated with the disease's physical impact, including oral discomfort and difficulty in eating, oral hygiene care, and speech, as well as negative psychological consequences due to its chronicity, unpredictable clinical behavior, and potential for malignant transformation.[26–28] Of these studies, 1 conducted a qualitative study using focus patient groups with patients limited to OLP and emphasized the symptoms

and triggers for exacerbations of symptoms.[26] The authors included patients from Ireland and the USA, and they defined 7 items that represented trigger factors contributing to the soreness of patients with OLP: brushing teeth, eating food, drinking liquids, smiling, breathing through the mouth, talking, and touching.[26]

The main limitation of this study is that patients were enrolled from only a single site in Cork, Ireland. There was also no diversity regarding ethnicity. Because the patient's perception of the disease may vary depending on cultural and social factors, involving patients with OLP from different backgrounds and geographic locations would have been desirable.

The outcomes and domains identified in these first 2 stages will be used in the third stage of COS development. During this stage, the combined list of outcome domains will be submitted to a consensus process via a face-to-face meeting with global experts (clinicians, researchers, and representatives of patient support groups), followed by an additional round of patient voting. This final stage will allow discussion and consensus on the outcomes that should be included in the final COS.

CONCLUSION

We gained valuable insight into the lived experience of patients with OLP via this qualitative study. This study is the first to explore the patient perspective on what should be measured in clinical trials of OLP, highlighting an important additional suggested outcome. This additional outcome will be voted upon in the consensus process to determine which outcome domains should be included in the COS.

DECLARATION OF COMPETING INTEREST

None.

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