Curr Derm Rep (2015) 4:15–19
DOI 10.1007/s13671-014-0096-8

EPIDEMIOLOGY (JI SILVERBERG, SECTION EDITOR)

Patient-Centered Outcomes in Dermatology

Tyler S. Okland · April W. Armstrong

Abstract Health outcomes can be captured and reported from a number of perspectives, and the patient's perspective is central to successful healthcare delivery and optimizing health outcomes. A patient-centered approach is important in dermatology. We discussed the meaning and application of "patient centeredness," "patient-centered outcome measures (PCOM), " and "patient-reported outcomes (PROs)" in dermatology. We highlighted the important roles that organizations such as the Patient-Centered Outcomes Research Institute (PCORI) and the International Dermatology Outcome Measures (IDEOM) play in advancing patient centeredness in skin diseases. We examined classic patient-reported outcome measures such as the Dermatology Life Quality Index (DLQI) and the Skindex. We also explored patient-centered outcomes in dermatologic surgery. With the development of patient-centered outcome measures, patients are able to express how their skin disease affects their lives in a systematic and valid fashion. These responses are highly valuable in guiding clinical decision-making and improving all aspects of patients' well-being.

Keywords Patient centered · Dermatology · Patient-Centered Outcomes Research Institute · International Dermatology Outcome Measures · Dermatology Life Quality Index · Skindex

This article is part of the Topical Collection on *Epidemiology*

T. S. Okland · A. W. Armstrong (✉)
Department of Dermatology, Colorado Health Outcomes Program (COHO), School of Medicine, University of Colorado Denver,
12801 East 17th Avenue, Mail Stop 8127, Aurora, CO 80045, USA
e-mail: aprilarmstrong@post.harvard.edu

A. W. Armstrong
e-mail: april.armstrong@ucdenver.edu

Introduction

Health outcomes can be captured and reported from a number of perspectives. Investigators or clinicians have traditionally used outcome measures to capture and quantify patient responses. Efforts in comparative effectiveness research in the past decade enabled the development of patient-centered outcome measures (PCOMs), which evaluates outcomes that patients deem to be most valuable. Specifically, PCOMs are defined as outcome measures that integrate decision-making needs, preferences, and symptoms patients consider most important to their disease process [1, 2, 3•]. PCOMs allow patients to understand what will happen if they choose a treatment and what adverse and beneficial outcomes exist and provide information guided by the preferences of patients treated before them.

In dermatological practice, PCOMs remain relatively underdeveloped. This lack of development of validated PCOM makes evaluation of patient progress difficult. The construction of patient-centric instruments that measure clinically relevant outcomes will be highly valuable to patients, clinicians, and researchers in various dermatological diseases. To achieve this goal, the International Dermatology Outcome Measures (IDEOM) consortium was established in 2013, with the goal of developing standardized dermatological outcome measures for a variety of skin diseases [6]. IDEOM includes patients as well as providers in the instrument development process, in an effort to learn what is most important to measure from the perspective of those living with skin conditions. In this article, we discuss the progress of patient-centered outcome measures in the field of dermatology.

Patient Centeredness and Patient-Reported Outcomes

The terms "patient centeredness," "patient-centered outcome measures," and "patient-reported outcomes (PROs)" share common concepts. To distinguish among these terms, *patient centeredness* is the principle that patient preferences are highly valued in all aspects of health care. PCOM are instruments that integrate decision-making needs, preferences, and symptoms patients consider most important to their disease process [5]. While PCOM usually seeks responses from patients, infrequently they can also seek response from other individuals. Finally, PROs are responses provided by patients regarding their experience with particular aspects of the diseases [8]. In most instances, PCOM are used to obtain PROs.

One example of PCOM in dermatology is the Dermatology Life Quality Index (DLQI), which is a questionnaire developed from adult patients with a variety of skin diseases [6]. The questionnaire seeks to address how skin diseases impact the patients' lives including psychological, social, and work aspects [7].

Patient-Centered Outcomes Research Institute

In 2010, the Patient Protection and Affordable Care Act was signed into law. Alongside this legislation was the formation of the Patient-Centered Outcomes Research Institute (PCORI) [4]. According to Section 6301 of the Act, PCORI's function is "to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence [8]." The institute has been charged with building on the well-established comparative effectiveness research (CER) investments of both the National Institute of Health and the Agency for Healthcare Research and Quality. CER has been defined by the Institute of Medicine as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care" [12].

PCORI was so named by its Board of Governors in an effort to emphasize a patient-centered perspective to their research approach. As an example, in the institute's first funding announcement, they requested proposals for methods to better integrate patient perspectives. More than 800 responses were received, and the NIH as well as 48 volunteer patients and providers reviewed these responses. In addition, the extent of patient engagement was used as a criterion for proposal selection [9].

Between 2010 and September of 2013, PCORI invested \$316.1 million for 192 studies towards five priorities: assessment of prevention, diagnosis, and treatment options; improving healthcare systems; communication and dissemination research; addressing disparities; and accelerating patient-centered outcomes research and methodological research [14]. More recently, PCORI invested \$100 million to launch the National Patient-Centered Clinical Research Network, PCORnet. PCORnet is a national research infrastructure comprised of 11 clinical data research networks (CDRNs) and 18 patient-powered research networks (PPRNs). Each CDRN is responsible for building large patient cohorts with longitudinal electronic data and to develop policies for standardizing the data. Each PPRN is made up of patients, providers, and family members connected by a common condition [10]. Resonating with the goals of PCORI, the National Psoriasis Foundation has established a PPRN to advance research that is important to psoriasis patients.

International Dermatology Outcome Measures Initiative

In 2013, a group of clinicians, researchers, patients, and other stakeholders interested in developing and validating outcomes in dermatology formed the IDEOM consortium. This organization was launched to address the lack of standardized outcomes in dermatology. The mission of the IDEOM is to establish patient-centered measurements to enhance research and treatment for those with dermatologic disease [11••]. Patients are an integral part of the IDEOM process, where they participate in each step of outcomes measures developing, validation, and evaluation.

The IDEOM initiative originally developed from concepts that born out of the Outcome Measures in Rheumatology (OMERACT) process, which has produced many of the core outcome measures currently used in rheumatology. The OMERACT process identifies the attributes most central to a disease process by soliciting feedback from expert providers and patients [12–14]. These attributes are then prioritized by a multi-stakeholder voting process to confirm core outcomes.

In 2013, patients and clinicians presented dermatological outcome measure gaps to the 35 IDEOM members. Following the meeting, a questionnaire was distributed to 155 psoriasis stakeholders. Since then, the IDEOM group has convened three international meetings to distill outcomes most important to the various stakeholders in psoriasis.

Patient-Centered Outcomes in Dermatology

Dermatology Life Quality Index

A classic example of a patient-reported outcome measurement in dermatology is the DLQI [6]. The DLQI was developed in 1994 and was the first dermatology-specific health-related quality of life instrument. It is a 10-query questionnaire covering symptoms, feelings, and how a patient's dermatological disease affects their work, social, and personal lives. Each question presents with the same set of answers, which may be marked by a tick box: "not at all," "a little," "a lot," or "very much." The questions are then scored and summed, yielding a range of 0 (no impairment to quality of life) to 30 (maximum impairment) [15].

The DLQI was developed from the experiences of over 120 adult patients with dermatological conditions. The authors, Finlay and Khan, also interviewed patients to ensure the DLQI was composed of questions that addressed the many ways psoriasis can affect quality of life. The DLQI is now a widely used health-related quality of life measurement in dermatology [16•].

A study by Lewis et al. found that the DLQI has high specificity when compared to a normal population, confirmed in seven studies [15]. Four studies demonstrated repeatability of the DLQI score, and five studies found that the DLQI has a Cronbach's alpha coefficient of 0.83 to 0.93. the DLQI was also relatively sensitive to change; however, the questionnaire cannot be administered in frequencies less than 7 days.

Further studies about measurement properties of DLQI have revealed that the instrument performs differently in different dermatological conditions. Twiss et al. used Rasch analysis to test the measurement properties of DLQI and analyzed patients with psoriasis or atopic dermatitis (AD) (n=146 for each, n=292 total) [17]. The study found that the DLQI exhibited differential item functioning specifically for item 7 (impact of skin condition on working or studying) on the questionnaire. AD patients were more likely to affirm this item than psoriasis patients, regardless of disease severity. This shows that a dermatology-specific but not disease-specific instrument can result in different scoring patterns across different dermatological diseases. Additionally, the study found that the instrument measures populations differently depending on their age and gender. For example, a young man from America may produce a different DLQI score than an older woman from the UK, even if their clinical cases were identical [16•]. Lastly, the authors found the DLQI had an insufficient number of items at the mild end of the scale, indicating that the instrument may not be as sensitive for individuals with mild diseases. Overall, DLQI is a pioneer instrument that is one of the most widely used PCOMs in dermatology.

Skindex

Skindex-29 and Skindex-16 are generic, skin-specific quality of life instruments that were developed after introduction of DLQI. Developed in 1996, the first Skindex was a 61-item prototype, was reproducible and valid, and displayed a high degree of internal consistency and reliability with a Cronbach's alpha value of 0.76–0.86 across all eight scales of the instrument [18]. However, the Skindex-61 took a great deal of time to complete, was not sufficiently sensitive to change, and discriminated unsatisfactorily among patients with different degrees of quality of life impairment. Therefore, suboptimally performing and redundant items were removed from Skindex-61 and new items that better address the discriminative and evaluative performance were added to create Skindex-29.

In Skindex, the effects of skin disease on quality of life may be divided into three domains: symptoms, emotions, and functioning. Skindex-29 is represented by 7 items in the symptoms domain, 10 items in the emotional domain, and 12 items in the functioning domain. Items on the questionnaire pertain to the frequency of an outcome (never, rarely, sometimes, often, all the time) and are graded on a scale of 0 (never affected) to 100 (experiencing constantly). The result is a shortened, 29-item questionnaire scored in three discrete scales based on the three domains [19].

Most recently, Skindex-16 was designed. The goal was to make a version of Skindex that would retain accuracy and responsiveness, but would contain itself to a single page. Additionally, the designers wanted to measure how much a particular outcome disturbed patients, rather than simply how often. New items were also composed in response to underrepresented outcomes patients complained of frequently in qualitative reports. In a study by Chren et al., Skindex-16 was completed by 541 patients waiting for dermatology appointments, and scale scores were reproducible after 72 h (r= 0.88–0.90) and were internally reliable (Cronbach's alpha= 0.86–0.93) [20].

In an observational, prospective study by Fernandez-Penas et al., 379 patients with mild to severe psoriasis completed the Skindex-29, 144 patients completed the DLQI, 135 patients completed the Psoriasis Disability Index (PDI), and 100 answered the Short Form 36 (SF-36) [21]. The study showed that the majority of subscales for the DLQI, the PDI, and the SF-36 had substantial floor effect, indicating these measures would have poor sensitivity responsiveness in mild to severe psoriasis. The study did not find the floor or ceiling effects in the Skindex-29. The authors concluded that the Skindex-29 had better sensitivity to clinical severity than the other instruments and further that the Skindex-29 measured most of the domains the other instruments investigated as well.

Pre- and Postoperative Patient Preferences in Dermatologic Surgery

Not many studies have evaluated patient preference among those undergoing dermatological surgery. Sharon et al. investigated patient-centered outcome measures surrounding pre- and postoperative Moh's microsurgery [22, 23]. The same 97 patients were included in both studies, and these patients were given online surveys to complete. The primary outcome of interest for the preoperative study was patient preferences for separate versus same-day preoperative surgical consultation. The primary outcome of interest for the postoperative study was patient perception of the importance of postsurgical follow-up visit interval. Patient demographics, self-perceived attractiveness level, education level, and past medical history were obtained a priori.

In the preoperative study, 67 % of the patients reported they preferred same-day preoperative consult, and 33 % favored a prior consult day with the surgeon. After adjustment for other covariates, the remaining significant variables included education level, prior surgical complications, and preoperative size. In particular, patients with a high school degree or less were less likely to prefer same-day preoperative consult than a patient with a postgraduate degree (odds ration (OR)=0.10, 95 % confidence interval (CI)=0.016–0.66, p=0.02). Likewise, patients with a college degree were less likely to favor same-day preoperative consult than those with postgraduate degrees (OR=0.66, 95 % CI=0.13–3.33, p=0.61). The study also demonstrated that those patients who had experienced surgical complications beforehand were less likely to prefer same-day preoperative consultation (OR=0.017, 95 % CI= 0.0015–0.19, p=0.001). In addition, multivariate analysis determined that for each 1 cm^2 increase in defect size, patients were 22 times more likely to favor same-day preoperative consult.

In the postoperative study, 88.7 % of patients considered follow-up important, and only 11.3 % of patients said follow-up was unimportant. Although none of the covariates remained significant after multivariate analysis, both a lower self-perceived level of attraction as well as a greater number of prior skin cancers were associated with reporting follow-up as unimportant.

Conclusion

Healthcare is becoming increasingly more patient-centered. This patient-centered approach is especially important in dermatology, a field where a physician's assessment of clinical severity does not always correlate with patient-reported scores. With the development of patient-centered outcome measures, patients are able to express how their skin disease affects the various aspects of their lives in a systematic and valid fashion. It is important that clinicians and researchers use that data to guide clinical decision-making and improve all aspects of patients' well-being.

Compliance with Ethics Guidelines

Conflict of Interest TS Okland declares no conflicts of interest.

AW Armstrong serves as investigator and/or consultant to AbbVie, Amgen, Janssen, Merck, Lily, Celgene, Novartis, UCB, Pfizer, and Modernizing Medicine.

Human and Animal Rights and Informed Consent All studies by AW Armstrong involving animal and/or human subjects were performed after approval by the appropriate institutional review boards. When required, written informed consent was obtained from all participants.

References

Papers of particular interest, published recently, have been highlighted as:
- • Of importance
- •• Of major importance

1. Frez ML, Asawanonda P, Gunasekara C, Koh C, Loo S, Oon HH, et al. Recommendations for a patient-centered approach to the assessment and treatment of scalp psoriasis: a consensus statement from the Asia Scalp Psoriasis Study Group. J Dermatol Treat. 2014;25(1):38–45.
2. Chambers CJ, Parsi KK, Schupp C, Armstrong AW. Patient-centered online management of psoriasis: a randomized controlled equivalency trial. J Am Acad Dermatol. 2012;66(6):948–53.
3.• Parsi K, Chambers CJ, Armstrong AW. Cost-effectiveness analysis of a patient-centered care model for management of psoriasis. J Am Acad Dermatol. 2012;66(4):563–70. *This paper represents the progression of patient-centered outcomes research. In it, the economics of a patient-centered care model for psoriasis management are evaluated, providing data guide pragmatic future models.*
4. Selby JV, Lipstein SH. PCORI at 3 years—progress, lessons, and plans. N Engl J Med. 2014;370(7):592–5.
5. Methodological standards and patient-centeredness in comparative effectiveness research: the PCORI perspective. JAMA. 2012;307(15):1636–40.
6. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)—a simple practical measure for routine clinical use. Clin Exp Dermatol. 1994;19(3):210–6.
7. Finlay AY, Basra MK, Piguet V, Salek MS. Dermatology life quality index (DLQI): a paradigm shift to patient-centered outcomes. J Investig Dermatol. 2012;132(10):2464–5.
8. Clancy C, Collins FS. Patient-Centered Outcomes Research Institute: the intersection of science and health care. Sci Transl Med. 2010;2(37):37cm18.
9. Selby JV, Beal AC, Frank L. The Patient-Centered Outcomes Research Institute (PCORI) national priorities for research and initial research agenda. JAMA. 2012;307(15):1583–4.
10. Fleurence RL, Curtis LH, Califf RM, Platt R, Selby JV, Brown JS. Launching PCORnet, a national patient-centered clinical research network. J Am Med Inform Assoc. 2014;21(4):578–82.
11.•• Gottlieb AB, Armstrong AW, Christensen R, Garg A, Duffin KC, Boehncke WH, et al. The International Dermatology Outcome Measures initiative as applied to psoriatic disease outcomes: a report from the GRAPPA 2013 meeting. J Rheumatol. 2014;41(6):1227–9. *The GRAPPA 2013 represents the first, large-scale commitment by the dermatology community to explore and advance patient-centered outcomes research. This meeting also reviewed the efficacy of standing patient-centered outcomes and established routes for growth.*
12. Boers M, Tugwell P. OMERACT conference questionnaire results. OMERACT Committee. J Rheumatol. 1993;20(3):552–4.
13. Fried BJ, Boers M, Baker PR. A method for achieving consensus on rheumatoid arthritis outcome measures: the OMERACT conference process. J Rheumatol. 1993;20(3):548–51.
14. Tugwell P, Boers M. Developing consensus on preliminary core efficacy endpoints for rheumatoid arthritis clinical trials. OMERACT Committee. J Rheumatol. 1993;20(3):555–6.

15. Lewis V, Finlay AY. 10 years experience of the Dermatology Life Quality Index (DLQI). J Investig Dermatol Symp Proc. 2004;9(2):169–80.

16.• Nijsten T. Dermatology life quality index: time to move forward. J Investig Dermatol. 2012;132(1):11–3. *This paper evaluates the Dermatology Life Quality Index, one of the most widely used patient-centered outcome measures in dermatology. The paper comments on the strength of the index, as well as potential shortcomings that must be addressed in future outcome measures.*

17. Twiss J, Meads DM, Preston EP, Crawford SR, McKenna SP. Can we rely on the Dermatology Life Quality Index as a measure of the impact of psoriasis or atopic dermatitis? J Investig Dermatol. 2012;132(1):76–84.

18. Chren MM, Lasek RJ, Quinn LM, Mostow EN, Zyzanski SJ. Skindex, a quality-of-life measure for patients with skin disease: reliability, validity, and responsiveness. J Investig Dermatol. 1996;107(5):707–13.

19. Chren MM. The Skindex instruments to measure the effects of skin disease on quality of life. Dermatol Clin. 2012;30(2):231–6. *xiii*.

20. Chren MM, Lasek RJ, Sahay AP, Sands LP. Measurement properties of Skindex-16: a brief quality-of-life measure for patients with skin diseases. J Cutan Med Surg. 2001;5(2):105–10.

21. Fernandez-Penas P, Jones-Caballero M, Espallardo O, Garcia-Diez A. Comparison of Skindex-29, Dermatology Life Quality Index, Psoriasis Disability Index and Medical Outcome Study Short Form 36 in patients with mild to severe psoriasis. Br J Dermatol. 2012;166(4):884–7.

22. Sharon VR, Armstrong AW, Jim On SC, Ibrahimi OA, Eisen DB. Separate- versus same-day preoperative consultation in dermatologic surgery: a patient-centered investigation in an academic practice. Dermatol Surg. 2013;39(2):240–7.

23. Sharon VR, Armstrong AW, Jim-On S, Ibrahimi OA, Eisen DB. Postoperative preferences in cutaneous surgery: a patient-centered investigation from an academic dermatologic surgery practice. Dermatol Surg. 2013;39(5):773–8.