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Special article

[Translated article] Patient-reported outcome measures for assessing atopic dermatitis in clinical practice

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ABSTRACT

Atopic dermatitis is a chronic skin condition that affects up to 20% of children and 10% of adults worldwide. Due to the high burden of dermatological signs and symptoms, atopic dermatitis has a significant impact on the quality of life of patients and their families. In the absence of objective measures to accurately assess severity and symptom burden, patient-reported outcome measures are essential to monitor the impact and progression of the disease, as well as the efficacy of treatments. Although there are currently no standardised guidelines for their use in clinical practice, there are some initiatives, such as the Harmonise Outcome Measures for Eczema and *Vivir con Dermatitis Atópica*, that can provide guidance. As healthcare systems move toward value-based healthcare models, patient-reported measures are becoming increasingly important for incorporating the patient perspective and improving the quality of healthcare services. The use of these measures can help monitor disease activity and guide treatment decisions. This article discusses the impact of atopic dermatitis and describes the patient-reported outcome measures commonly used in atopic dermatitis and the recommendations of the initiatives that have selected a core set of measures to best assess atopic dermatitis in clinical practice. Considering the recommendations of these initiatives and based on our experience in clinical practice, we propose the use of the Dermatology Life Quality Index to assess the impact of the disease on quality of life, the Patient-Oriented Eczema Measure to assess symptom severity, and the Numerical Rating Scale or the Visual Analogue Scale to measure itch intensity. To systematise the administration of these measures and to integrate them into hospital information systems and medical records, we emphasise the importance of telemedicine platforms that allow the electronic administration of these instruments.

Medidas de resultados comunicados por el paciente para evaluar la dermatitis atópica

Palabras clave:
Dermatitis atópica
Calidad de vida
Medidas de resultados comunicados por los pacientes
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RESUMEN

La dermatitis atópica es una enfermedad cutánea crónica que afecta hasta al 20% de los niños y al 10% de los adultos en todo el mundo. Debido a su elevada carga de signos y síntomas dermatológicos, tiene un impacto significativo en la calidad de vida de los pacientes que la sufren y sus familias. A falta de medidas objetivas para evaluar con precisión la gravedad y la carga sintomática, las medidas de resultados comunicados por los pacientes (*patient-reported outcome measures*) son esenciales para valorar el impacto y la progresión de la enfermedad, así como la eficacia de los tratamientos. Aunque actualmente no existen pautas estandarizadas sobre su uso en la práctica clínica, disponemos de algunas iniciativas, como la

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Iniciativa HOME
HOME-CP
Iniciativa ViDA
Iniciativa Naveta

Armonización de medidas de resultados para el eccema (*Harmonise Outcome Measures for Eczema)* y Vivir con Dermatitis Atópica, que pueden orientarnos. Conforme los sistemas sanitarios evolucionan hacia modelos de atención sanitaria basada en el valour, las medidas comunicadas por los pacientes son cada vez más importantes para incorporar la perspectiva del paciente y mejorar la calidad de los servicios sanitarios. El uso de estas medidas puede ayudar a monitorizar la actividad de la enfermedad y orientar las decisiones terapéuticas. En este artículo se analiza el impacto de la dermatitis atópica y se describen las medidas de resultados comunicados por los pacientes que suelen usarse en la dermatitis atópica y las recomendaciones de las iniciativas que han seleccionado un conjunto básico de medidas para evaluar de manera idónea la enfermedad en la práctica clínica. Teniendo en cuenta las recomendaciones en las que coinciden estas iniciativas y basándonos en nuestra experiencia en la práctica clínica, proponemos utilizar el *Dermatology Life Quality Index* para valorar el impacto de la enfermedad en la calidad de vida, la *Patient-Oriented Eczema Measure* para evaluar la gravedad de los síntomas y una escala para evaluar la intensidad de prurito, la *Numerical Rating Scale* o la Escala Visual Analógica. Para sistematizar la administración de estas medidas e integrarlas en los sistemas de información hospitalaria y las historias clínicas, destacamos la importancia de las plataformas de telemedicina que permiten la administración electrónica de estos instrumentos.

Introduction

Atopic dermatitis (AD) or atopic eczema is a chronic inflammatory skin condition characterised by eczematous lesions and intense itching.[1] It is estimated to affect up to 20% of children and 10% of adults worldwide, and can have a major impact on the quality of life (QoL) of those affected.[2,3] It is often associated with sleep disorders, and the prevalence of anxiety, stigmatisation, depression, and suicidal ideation is higher in patients with AD than in those without the condition.[1,4]

The precise aetiology of AD has not yet been elucidated, but some triggering factors have been identified. These include the interaction between genetic and environmental factors, immune dysregulation, and alterations of the skin barrier and microbiome.[5,6] Standard treatment involves topical anti-inflammatory drugs (corticosteroids or calcineurin inhibitors), oral antihistamines, elimination of exacerbating factors (such as stress or excessive bathing), and skin hydration.[6,7] Severe cases may require phototherapy or systemic treatment with conventional immunosuppressants (e.g., cyclosporine) or biologics (e.g., dupilumab or tralokinumab). Recently, Janus Kinase inhibitors have also become a treatment option (e.g., abrocitinib, upadacitinib, or baricitinib).[6,7] Disease management requires a multidisciplinary approach that addresses psychosocial aspects and monitors the condition and treatment through outcome questionnaires.[8]

Currently, no biomarkers are available to accurately reflect the clinical manifestations and severity of AD, nor are there objective measures to assess its symptom burden.[9] Symptoms such as pruritus and pain can only be assessed subjectively by patients. Therefore, a comprehensive approach to AD should include the use of patient-reported outcome measures (PROMs). These tools help healthcare professionals to accurately assess the severity and impact of symptoms, psychological aspects, and the stigma associated with having a visible skin condition.[9–11] The use of PROMs can help monitor AD activity and guide therapeutic decisions.[12]

In 2006, Porter and Teisberg proposed a new paradigm of value-based healthcare, which has led to increasing recognition of the importance of assessing patient-reported outcomes (PROs).[13,14] The Food and Drug Administration defines a PRO as “any report of a patient's health status provided directly by the patient, without a physician or anyone else interpreting the patient's response”.[15] Porter defines value in healthcare as relevant patient outcomes divided by the costs per patient of achieving those outcomes.[14] Using PROs to better evaluate patients is part of the trend toward value-based healthcare, which focuses on achieving the best health outcomes at the lowest cost.[13,14]

PROs are measured using PROMS, which are questionnaires completed by patients. They assess variables such as functional status, health-related QoL, symptoms and disease burden, health-related behaviour, and psychological distress.[16] Assessment typically uses disease-specific PROMs to measure symptom severity in combination with generic PROMs to assess QoL.[16]

Patient-reported experience measures (PREMs) are used to complement PROMs by assessing relevant aspects of the quality of care processes as perceived by patients.[17] PREMs typically measure patients' experiences of care, treatment, and support received with the aim of improving the quality of services. Scores are largely independent of perceived health.

PROMs provide complementary information to the clinical outcomes assessed by healthcare professionals, both in clinical trials and in routine practice.[18] They also help these professionals, regulators, and healthcare system administrators to understand the impact of disease from the perspective and experience of patients in their daily lives.[18]

Although many PROMs assess various aspects affected by AD, there are currently no standardised guidelines on which measures should be used in clinical practice.[10–12] As a result, several initiatives have emerged to harmonise and promote the use of PROMs by selecting a core set of measures.[8,12,19] For example, in 2014, the Harmonising Outcome Measures for Eczema (HOME) statement was published to assess clinical signs of atopic eczema in clinical trials.[19] Recently, the HOME Clinical Practice (HOME-CP) initiative has provided recommendations on appropriate PROMs for the management of AD in clinical practice.[12] In Spain, the Vivir con Dermatitis Atópica (ViDA) initiative has been developed to identify and address unmet needs in the care of patients with moderate to severe AD. Among other strategies, it proposes prioritising the use of certain PROMs at different levels of care.[8,20]

This special article analyses the impact of AD, and describes PROMs commonly used for the condition, as well as those recommended by initiatives for its accurate assessment. Based on these initiatives and the authors' experience, recommendations are provided to promote and facilitate the implementation of PROMs in clinical practice for managing AD.

Methods

The information presented in this article is based on an analysis conducted by a team of hospital pharmacists with expertise in the management of patients with chronic diseases (including AD) and in the administration of PROMs in hospital pharmacy outpatient clinics. The team also included dermatologists with experience in the use of PROMs to assess patients with AD in clinical practice. The authors were guided on the use of PROMs in clinical practice by the expert committee of the Naveta initiative.[21–23] This body comprises physicians, psychologists, hospital pharmacists, e-Health technology experts, and members of the BiblioPRO initiative (a database of Spanish-language PRO questionnaires). The aim of this initiative is to select standard PROM sets for different chronic diseases, including AD.

We conducted literature searches in PubMed/MEDLINE to find original and review articles. In addition, we conducted grey literature searches in the PROQOLID database, BiblioPRO, conference websites, Google Scholar, and Google.

The search strategy focused on 3 subtopics related to AD: the impact of the condition, published recommendations on the use of PROMs in AD, and the characteristics of PROMs used in AD. The terms “atopic dermatitis”, “atopic eczema”, and “dermatitis atópica” were combined with terms such as “quality of life”, “impact”, “burden”, “productivity”, “sleep”, “sexuality”, “depression”, “stigma”, “PROM”, “recommendations”, “recomendaciones”, “clinical practice”, “HOME initiative”, “HOME-CP initiative”, and “iniciativa ViDA”. Based on the literature search, we identified the most frequently used PROMs, as well as those recommended by the HOME, ViDA, and Naveta initiatives. These PROMs were grouped into the following categories: QoL, severity of AD, pruritus, sleep disorders, anxiety and depression, long-term disease control, and satisfaction with treatment. The selected PROMs were further examined to determine their main characteristics: domains measured, target population, type of instrument (generic or specific), number of items, scoring, and interpretation. A descriptive summary of these characteristics was made with some observations on the use and recommendations of each PROM.

Results

Impact on QoL and the financial burden of AD

AD significantly affects the QoL of patients and their families.[24] This is due to its high burden of dermatological symptoms and signs, early onset, chronicity, and psychosocial impact.[1,4,25] Symptoms of AD include itching, scaling, dryness, pain, fatigue, sleep disorders, depression, anxiety, and low self-esteem.[25–27] Many studies have evaluated the impact of AD on patients' daily lives and their findings include the following:

- The majority of patients with moderate to severe AD experience daily itching.[28,29]
- More than 60% of patients experience skin pain, which manifests as aching, burning, or discomfort.[6]
- Patients with AD are at increased risk of skin and systemic infections, especially *Staphylococcus aureus*.[30]
- Sleep disorders occur in 47%–87% of children and 33%–90% of adults.[31]
- Patients with moderate to severe AD score lower on mental and physical health-related QoL questionnaires than patients with diabetes or heart disease.[25]
- More than one-third of children with AD experience low self-esteem.[26]
- Many patients with AD report issues in their social lives due to the stigma associated with the skin lesions caused by the condition.[32]
- More than 80% of patients with AD report that it interferes with their sexual lives, and about 40% of patients with severe AD report that it affects their libido.[33]
- Adult AD is associated with an increased risk of depression, anxiety, and suicidal ideation and behaviour.[10,18]

According to the results of the Global Burden of Disease Study (1999–2017), AD has a higher burden of morbidity, measured in disability-adjusted life years, than any other dermatological disease.[4] The economic burden includes both direct treatment costs and indirect costs such as the lost productivity of patients or their families. According to results from the 2013 US National Health and Wellness Survey, healthcare resource use is significantly higher in patients with AD than in patients without the condition. A previous study found that the average annual cost per patient was $10 000 higher than that of non-AD controls.[2] A European study of more than 1000 patients with moderate to severe AD found that about a quarter of them reported missing more than 6 days of work per year because of the condition.[27] A Dutch study found that the average annual cost of lost productivity was €10 040 in patients with moderate to severe AD.[24] A study conducted in Spain with 6186 participants found that the average direct and indirect healthcare costs for patients with AD were €1504 per year, with severe forms reaching €3686 per year.[5] In short, AD places a significant burden on healthcare systems in terms of resource use and expenditure, especially in its more severe forms.

PROMs to assess atopic dermatitis

Over recent decades, a number of patient tools have been developed to assess the problems caused by AD symptoms, including itching, pain, fatigue, and activity limitations, as well as the impact of AD on physical, psychological, and social health.[9,10] PROMs and QoL measures are increasingly being used to assess AD symptoms, both in clinical trials and in everyday practice.[9–11] Currently, there are no standard guidelines for selecting PROMs for use in clinical practice, nor for determining when and how they should be administered. However, several initiatives, such as HOME and VIDA, have provided recommendations and selected core sets of measures for AD.[8,19,34] Before discussing the specific recommendations of these initiatives, we review the domains most commonly assessed in AD and some of the PROMs frequently used in both clinical trials and in the clinical management and follow-up of patients with AD. Table 1 summarises these PROMs, grouped by category according to the aspects most commonly affected by AD, with a brief description of the characteristics of each instrument. Some of these measures are generic, others are for use in a variety of dermatological conditions, and some are specific to AD.[11]

This condition can significantly affect various aspects of patients' lives due to the constant itching and its visible symptoms (e.g., redness, scaling, bleeding from scratching).[10] QoL is one of the 4 main outcome domains that the HOME initiative suggests should be measured and reported in all clinical trials.[19] Together with pruritus, QoL is the most commonly assessed domain in Spanish observational studies and clinical trials on AD.[10,11] Generic PROMs for QoL include the European Quality of Life-5 Dimensions (EQ-5D) questionnaire, which was developed in 1990 by the EuroQol group.[35] Its most recent version assesses 5 dimensions of health with 5 levels of severity for each dimension, and includes a Visual Analogue Scale (VAS) for the overall assessment of health status.[36] It is the most widely used measure

Table 1
Characteristics of the most commonly used PROMs to assess atopic dermatitis.

Measure	Type of instrument	Age of target population	No. of items	Domains measured	Scoring and interpretation	Comments
Quality of life						
EQ-5D[22,35–37]	Generic	Adults and adolescents	5 + VAS	Mobility, self-care, daily activities, pain/discomfort, anxiety/depression	11 111 (best)–55 555 (worst) Supplemented by the VAS score (included below)	Recommended by NICE for the technology appraisal process selected by the Naveta initiative
SF-36[38,39]	Generic	Adults	36	Physical function, role (physical), bodily pain, general health, social functioning, vitality, role (emotions), and mental health	0–100 Higher scores indicate better general health	One of the most widely used questionnaires for generic health assessments
DLQI[8,22,39–42]	Specific to dermatology	>16 years	10	Symptoms, feelings, daily activities, leisure, work/school, personal relationships, treatment	0–30 Higher scores indicate greater QoL impairment	Recommended by the HOME, ViDA, and Naveta initiatives
CDLQI[8,39,40,42]	Specific to dermatology	Children aged 4–16 years	10	Physical symptoms (itching, loss of sleep) and psychosocial aspects (friendships, bullying, school)	0–30 Higher scores indicate greater QoL impairment	Recommended by HOME and ViDA
IDLQI[39,40,42]	Specific to dermatology	<4 years	10	Physical symptoms (itching, loss of sleep), emotions, play, meals, bathing	0–30 Higher scores indicate greater QoL impairment	Recommended by the HOME initiative, completed by parents
Skindex-29[43,44]	Specific to dermatology	Adults	29	Intensity of symptoms, psychosocial functioning, and emotional state	0–100 Higher scores indicate better general health	One of the most-used PROMs to assess QoL in AD clinical trials
QoLIAD[22,45]	Specific to AD	>16 years	25	Needs affected by AD related to physical, mental, emotional, and psychosocial aspects	0–25 Higher scores indicate greater QoL impairment	Recommended by the Naveta initiative
Severity of AD						
POEM[8,10,12,22,42,46]	Specific to AD	Adults and children	7	Frequency of AD symptoms (dryness, itching, scaling, flaking, sleep disorders, bleeding, and oozing/suppuration)	0–28 Higher scores indicate greater severity of AD symptoms	Recommended by the HOME, HOME-CP, ViDA, and Naveta initiatives
PO-SCORAD[12,47]	Specific to AD	Adults and children	9	Affected area and intensity of AD symptoms, itching, and sleep disorders	0–103 Higher scores indicate greater severity of AD	Recommended by HOME-CP
Intensity of pruritus/sleep disorders						
Peak Pruritus NRS at 24 h[12,22,42,48]	Specific to pruritus	Adults	1	Intensity of pruritus	0–10 Higher scores indicate greater intensity of pruritus	Recommended by HOME, HOME-CP, and Naveta
VAS[8]	Generic	Adults	1	Intensity of pruritus Sleep disorders	0–10 Higher scores indicate greater intensity of pruritus or sleep disorders	Recommended by ViDA
NRS[8]	Generic	Adults	1	Intensity of pruritus Sleep disorders	0–10 Higher scores indicate greater intensity of pruritus or sleep disorders	Recommended by ViDA
Multidimensional impact of pruritus						
5-D Itch Scale[22,49]	Specific to pruritus	Adults and children	5	5 dimensions of pruritus: degree, duration, course, impact on QoL, and distribution	5–25 Higher scores indicate greater severity of pruritus	Recommended by Naveta
Anxiety and depression						
HADS[8,28]	Generic	Adults	7 + 7	Anxiety and depression	0–21 Scores ≥8 indicate states of anxiety or depression Higher scores indicate greater severity	Recommended by ViDA
Long-term disease management						
RECAP[12,42,50]	Specific to pruritus	All ages	7	Overall perception of eczema, itchiness, sleep, day-to-day activities, feelings	0–28 Higher scores indicate worse AD management	Recommended by HOME and HOME-CP
ADCT[12,42,51]	Specific to pruritus	≥12 years	6	AD symptoms and impact on life and functioning (e.g., itchiness, sleep, daily activities, mood, and emotions)	0–24 Scores ≥7 indicate poor control of AD Higher scores indicate worse AD management	Recommended by HOME and HOME-CP
Satisfaction with treatment						
TSQM[52,53]	Generic	Adults	14	Satisfaction with medication: effectiveness, side effects, convenience, and overall satisfaction	0–100 Higher scores indicate a higher degree of satisfaction	
SIAQ[54]	Generic	Adults	8 + 23	Pre-injection module (feelings about injections, self-confidence, and satisfaction) + post-injection module (ease of use, pain and skin reactions, feelings about injections, self-confidence, self-image, satisfaction)	Each item is scored on a 1–10 scale Higher scores indicate a better self-injection experience	

ADCT, Atopic Dermatitis Control Tool; CDLQI, Children's Dermatology Life Quality Index; QoL, quality of life; AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; NRS, Numerical Rating Scale; EQ-5D, European Quality of Life-5 Dimensions; VAS, Visual Analogue Scale; HADS, Hospital Anxiety and Depression Scale; IDQoL, Infants' Dermatitis Quality of Life Index; NICE, National Institute for Health and Care Excellence; POEM, Patient-oriented eczema measure; PO-SCORAD, Patient-Oriented Scoring of Atopic Dermatitis index; PROM, Patient-reported outcome measures; QoLIAD, Quality of Life Index for Atopic Dermatitis; RECAP, the Recap of Atopic Eczema instrument; SF-36, Short Form-36 Health Survey; SIAQ, Self-Injection Assessment Questionnaire; TSQM, Treatment Satisfaction Questionnaire for Medication.

of adult QoL worldwide and is recommended by the UK's National Institute for Health and Care Excellence for use in the technology appraisal process.[36,37] It was also selected by the Naveta initiative for the core set proposed for AD.[22] The Short Form-36 Health Survey is another generic PROM to assess QoL.[38,39] It is widely used to determine the impact of various dermatological conditions, including AD, on QoL in both cross-sectional studies and clinical trials.[39]

The Dermatology Life Quality Index (DLQI) is frequently used in clinical trials to assess the impact on the QoL of adults with dermatological conditions.[40,41,55] It is the most widely used questionnaire for AD-related QoL in observational studies in Spain and in clinical studies worldwide.[10,11] It is recommended by the HOME, ViDA, and Naveta initiatives.[8,22,42] There are versions of the questionnaire for children aged 4–16 years and for children less than 4 years. They can be completed by children with the help of parents or caregivers, or directly by parents or caregivers.[43] Skindex is another dermatology-specific questionnaire commonly used in clinical trials to assess QoL in AD and is available in 16-, 17-, and 29-item versions.[43,44] A study comparing Skindex-29 and the DLQI found that the DLQI better reflects activity-related aspects of QoL, whereas Skindex-29 better captures the emotional impact of the condition, based on the opinions of patients with AD and psoriasis.[56]

The Quality of Life Index for Atopic Dermatitis (QoLIAD) is an AD-specific PROM.[45] It is based on a model in which patients' QoL is determined by their ability to meet their needs.[57] Therefore, unlike other QoL questionnaires, it assesses which needs are affected by the condition, rather than which abilities or functions are impaired.[45,57] The Naveta scientific committee has recommended it for the assessment of AD.[22]

Another AD-specific PROM is the Patient-Oriented Eczema Measure (POEM), which measures the severity of AD symptoms and assesses the weekly frequency of symptoms.[46] It is recommended by various international bodies, expert reviews, and by the HOME, HOME-CP, ViDA, and Naveta initiatives, and is widely used in clinical practice and clinical trials.[8,10–12,22,42] The Patient-Oriented Scoring of Atopic Dermatitis (PO-SCORAD) index is another tool specifically designed to assess the symptoms of AD, with a special focus on their intensity.[47] It is recommended for clinical use by the HOME initiative.[12]

The Peak Pruritus NRS is designed to measure the maximum daily intensity of pruritus and is recommended by HOME and Naveta.[12,22,42,48] Two other unidimensional tools are the VAS and the NRS.[8] The latter 2 scales are generic and can also be used to assess sleep disturbance due to pruritus. They are recommended by the ViDA initiative.[8] The 5-D Itch Scale is a multidimensional instrument that measures the long-term evolution of pruritus and is also included in the Naveta core AD PROMs.[22,49] It can be completed in less than 5 min and is easily scored.[9]

The Hospital Anxiety and Depression Scale (HADS) is one of the most widely used tools to assess the psychological impact of the condition.[28] Patients with AD are at increased risk of depression, anxiety, and even suicidal ideation, especially in severe cases. The ViDA initiative therefore recommends the use of this PROM.[8,10,18]

Long-term management of AD is another domain that should be measured in clinical practice, as it is considered a key outcome by all parties involved in clinical trials: patients, caregivers, healthcare professionals, and researchers.[12,42] The HOME initiative recommends the AD-specific Atopic Dermatitis Control Tool (ADCT) and the Recap of Atopic Eczema (RECAP) instrument.[12,50,51]

In value-based healthcare models that prioritise patient preferences, it is also important to measure patient satisfaction with treatment.[52] These instruments may serve to predict adherence to treatment.[52] Two questionnaires can be used for this purpose: the Treatment Satisfaction Questionnaire for Medication assesses treatment satisfaction in patients with chronic diseases,[52,53] while the Self-Injection Assessment Questionnaire can be used for treatments requiring self-injection, such as dupilumab.[7,54]

The HOME initiative

The HOME initiative was founded in 2010 with the primary aim of standardising outcome measures by agreeing on a core set of outcomes to be included in all AD clinical trials so that data from these trials can be compared and evidence aggregated.[19,42] Another objective is to provide a list of suitable instruments to measure health domains in clinical practice.[42] Since its foundation, HOME has held annual or biannual consensus meetings that have established a set of domains that should be assessed and the core outcome measures that should be reported in all AD clinical trials.[42,58] The 4 core domains that should be assessed are clinical signs, patient-reported symptoms, QoL, and long-term disease management.[42,58] Table 2 shows the recommended instruments for these domains.

More recently, the HOME-CP initiative was established to agree on a set of clinical practice measurement tools to support the management and follow-up of patients with AD and to facilitate real-world research.[12,34] This is not an obligatory minimum core set of instruments, but rather an array of PROMs that can be selected according to the needs of patients, clinicians, and health systems.[12] There is no theoretical limit to the number of instruments that should be used or to the number of instruments for each domain.[12,34]

The HOME-CP consensus meetings established symptoms and long-term disease control as priority domains for assessment in clinical practice, although future meetings are planned in which other domains of interest may be established.[12] The POEM and PO-SCORAD instruments were selected from the PROMs for measuring symptoms. Two instruments were recommended by consensus to measure itch intensity at 24 h and 1 week: the Peak Pruritus 24-h NRS, measuring peak itch; and the PROMIS Itch Questionnaire 1-week NRSs, measuring average and peak itch.[12,59] The RECAP instrument and ADCT were recommended for the long-term control of AD, which is in line with the recommendations made for clinical trials.[12]

The HOME-CP initiative encourages physicians and patients to use at least one of the recommended instruments in clinical practice as a valuable complement to the anamnesis and physical examination.[34] Regarding the timing of administering PROMS, HOME recommends that these tools be used between visits to provide a clear picture of disease control and symptom burden, or while patients are waiting in the consultation room to provide the healthcare professionals with information for assessing the patients.[34] The initiative also recommends the use of electronic questionnaires or mobile applications that can be embedded in medical records, allowing patients to

Table 2
Core set of outcome measures recommended by the HOME initiative for clinical trials in atopic dermatitis.

Domains	Instruments
Clinical signs reported by the practitioner	EASI
Patient-reported symptoms	POEM and Peak Pruritus NRS
Long-term disease management	RECAP or ADCT
Quality of life	DLQI (adults), CDLQi (children), IDQoL (infants)

ADCT, Atopic Dermatitis Control Tool; CDLQI, Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; EASI, Eczema Area Severity Index; IDQOL, Infants' Dermatitis Quality of Life Index; NRS, POEM, Patient Oriented Eczema Measure; RECAP, the Recap of Atopic Eczema instrument. Source: Williams et al.[42]

complete them from anywhere. This can save time and encourage the regular use of PROMs.[12]

The ViDA initiative

The VIDA initiative was created in 2021 with the aim of identifying and prioritising the unmet needs of patients with AD to improve their QoL.[8,20] The first phase included more than 150 professionals and patients and identified 10 challenges or unmet needs to be prioritised for patients with moderate to severe AD.[8,20] The second phase focused on proposing strategies that could improve the comprehensive approach to these patients. It established 3 main lines of action: professional training and patient education, improving coordination between professionals, and the use of PROMs and PREMs in clinical practice.[8] These measures were proposed to improve aspects related to the detection of the condition and its clinical management.

In addition, the initiative identified barriers to implementing these strategies in clinical practice in Spain.[8] Some of the identified barriers included the need for data integration (a requirement for making the data available to staff in patients' medical records), lack of time, the large number of PREMs and PROMs, and the lack of standardised processes.[8]

To encourage the systematic use of PROMs in clinical practice, the VIDA initiative proposes limiting the number of measures to those that assess pruritus, sleep disorders, and emotional issues, which are the most common effects of moderate to severe AD.[8] Table 3 shows the recommended PROMs for assessing these domains. It should be noted that the main PREM is the assessment of patient satisfaction.[8]

These PROMs, together with an as yet unspecified adherence detection tool, should facilitate the clinical follow-up of patients and provide useful information for future healthcare appointments. They should be administered across various levels of care, including primary care, paediatrics, dermatology, nursing, and hospital pharmacy.[8]

The Naveta initiative

Naveta is a community open to healthcare professionals focused on promoting value-based healthcare protocols and evaluating the impact of their use. It is associated with the telematic administration of PROM and PREM modules for various diseases, including AD.[21,22] Its technological infrastructure is supported by a software platform specialised in telemedicine projects. The Naveta initiative was founded in 2020 and, via this platform, currently monitors more than 3000 patients with chronic immune-mediated diseases, cancer, and other diseases in 20 hospitals across Spain. Its infrastructure allows for the automation and, consequently, the streamlining of care processes as well as establishing a direct telematic channel with patients to monitor them, resolve questions, provide education about their condition and treatment, promote healthy habits, and so on.

Table 3
PROMs proposed by the ViDA initiative for systematic use in clinical practice.

Most-affected aspects	Instruments
Pruritus and sleep	VAS/NRS
Quality of life	DLQI (adults), CDLQI (children)
Symptom severity	POEM
Anxiety and depression	HADS

CDLQI, Dermatology Life Quality Index; DLQI, Children's Dermatology Life Quality Index; NRS, Numerical Rating Scale; VAS, Visual Analogue Scale; HADS, Hospital Anxiety and Depression Scale; POEM, Patient Oriented Eczema Measure; PROMs, Patient Reported Outcome Measures. Source: Cohen et al.[8]

Table 4
Core set of PROMs recommended by the Naveta initiative to assess atopic dermatitis.

Domains	Instruments
Quality of life	DLQI, QoLIAD
Intensity of pruritus	Peak Pruritus NRS
Multidimensional impact of pruritus	5-D Itch Scale
Symptom severity	POEM

DLQI, Dermatology Life Quality Index; NRS, POEM, Patient Oriented Eczema Measure; PROMs, Patient-reported outcome measures; QoLIAD, Quality of Life Index for Atopic Dermatitis. Source: Naveta Health.[22]

A multidisciplinary committee of experts selects a set of PROMs for a comprehensive approach to each condition, based on the latest scientific evidence.[22] Table 4 shows the basic set of PROMs selected for AD. Although Naveta, like other initiatives, recommends the DLQI to assess QoL, it combines it with QoLIAD to assess the patient needs affected by the condition. Like HOME, Naveta recommends the Peak Pruritus NRS to evaluate itching intensity, and the 5-D Itch Scale for its multidimensional impact. It is also in line with the other 2 initiatives in recommending POEM to measure disease severity.

If patients' responses to the QoLIAD questionnaire are suggestive of emotional issues, the HADS questionnaire is subsequently administered to assess anxiety and depression.

Discussion

AD is a chronic skin condition that can have a significant impact on those affected.[2] Eczematous lesions, severe pruritus, pain, sleep disturbances, and other symptoms and signs associated with the condition, especially when severe, can significantly impact the QoL of patients and their families, as well as place considerable economic stress on healthcare systems.[1,5,24,27] Currently, there are no objective measures to accurately assess the severity and symptom burden of AD.[8] PROMs are therefore an essential adjunct to anamnesis and physical examination to assess the impact and course of the condition and the effectiveness of treatment.[8,34]

The perspectives of patients and their families are becoming increasingly relevant as the value-based healthcare paradigm continues to take hold in healthcare systems.[12,25] PROMs and PREMs enable us to learn about patients' perceptions of their condition and treatment, as well as their experience of the care they receive.[27,28] The systematic use of PROMs for patients with AD in clinical practice can support shared decision-making on the therapeutic approach based on objectives quantified by these measures.[12] In addition, the data obtained in this way can be used for real-world comparative effectiveness studies.[34]

Although the use of PROMs is well established in AD clinical trials, their use in clinical practice remains limited.[10,11,34,42] Barriers include lack of time and the absence of standardised guidelines or recommendations on the most appropriate instruments for AD.[8,12,34] Various PROMs can be used for AD in clinical practice, but so far, no single PROM can capture all aspects of the condition.[11] The current strategy is to use a core set of instruments, selecting the most appropriate ones to measure the aspects that have the greatest impact on patients' QoL.[8,12,42]

This special article aims to raise awareness of the PROMs commonly used in AD and to highlight the recommendations of initiatives that have focused on selecting the most appropriate instruments for assessing AD in clinical practice, based on evidence and consensus processes. We have described the international HOME and HOME-CP initiatives, the Spanish ViDA initiative, and the Naveta initiative, which focus on the telematic administration of PROMs.[8,12,22,42] These initiatives prioritise the assessment of domains such as QoL, pruritus, sleep disorders, long-term disease control, and psychological impact.[12,42] They recommend limiting the number of PROMs to a core set of tools so that health professionals can incorporate them into their practice without increasing their workload.[8,12] Taking into account the recommendations of the HOME, HOME-CP, ViDA, and Naveta initiatives, and based on our own experience in clinical practice, we propose a core set of PROMs for AD that includes at least the following instruments: the DLQI or QoLIAD, to assess the impact of AD on patients' QoL; POEM, to evaluate the severity of disease symptoms; the NRS or VAS to determine the intensity of pruritus; and HADS to assess emotional wellbeing.[8,12,33,42]

The growing interest in incorporating PROMs into the assessment of AD is evident from the numerous studies and reviews assessing the usefulness of various PROMs across different disease domains and their integration into clinical trials.[10,11] Further studies are needed to encourage the implementation of PROMs in the care of patients with AD by demonstrating that their use in clinical practice can improve patient outcomes, as has already been shown in diseases such as cancer.[60] Studies are also needed to provide guidance on the optimal frequency and timing of administration of these instruments in routine clinical practice.[12]

We believe that pharmaceutical practice for patients with AD in hospital pharmacy outpatient clinics can and should be an integral part of the multidisciplinary approach. In addition, the implementation of the CMO (Capacity–Motivation–Opportunity) model and subsequent patient stratification should help to achieve the therapeutic objectives for this group of patients.[61]

Integration into hospital IT systems is a significant and imminent challenge, and telemedicine platforms capable of administering PROMs will be essential. The use of digital questionnaires that patients can complete at any time from a personal device (e.g., smartphone, tablet, or computer) simplifies their administration and encourages the systematic use of these instruments. Finally, it is critical that telemedicine platforms used to administer PROMs enable the data collected to be incorporated into patients' medical records, so that this information can be accessed by healthcare professionals at any time.[8] We believe that this type of practice will facilitate the incorporation and widespread use of these valuable tools in medical consultations and our daily routines.

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Gabriel Mercadal-Orfila: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Carlos Seguí-Solanes:** Conceptualization, Supervision, Writing – original draft, Writing – review & editing. **Nuria Rudi-Sola:** Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. **Maria Eugenia Escriva-Sancho:** Conceptualization, Supervision, Writing – original draft, Writing – review & editing. **Rosa Taberner-Ferrer:** Conceptualization, Supervision, Writing – original draft, Writing – review & editing.

Declaration of competing interest

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