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**Quality of Life Measurement in Acne. Position Paper of the European Academy of Dermatology and Venereology (EADV) Task Forces on Quality of Life and Patient Oriented Outcomes (QoL and PO) and Acne, Rosacea and Hidradenitis Suppurativa (ARHS)**

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PV Chernyshov<sup>1</sup>, CC Zouboulis<sup>2</sup>, L Tomas-Aragones<sup>3</sup>, G Jemec<sup>4</sup>, L Manolache<sup>5</sup>, T Tzellos<sup>6</sup>, F Sampogna<sup>7</sup>, AWM Evers<sup>8</sup>, C Dessinioti<sup>9</sup>, SE Marron<sup>10</sup>, V Bettoli<sup>11</sup>, O van Cranenburgh<sup>12</sup>, A Svensson<sup>13</sup>, A Liakou<sup>14</sup>, F Poot<sup>15</sup>, J Szepietowski<sup>16</sup>, MS Salek<sup>17</sup>, AY Finlay<sup>18</sup>

<sup>1</sup> Department of Dermatology and Venereology, National Medical University, Kiev, Ukraine

<sup>2</sup> Departments of Dermatology, Venereology, Allergology and Immunology, Dessau Medical Center, Theodore Fontane Medical University of Brandenburg, Dessau, Germany

<sup>3</sup> Department of Psychology, University of Zaragoza; Aragon Health Sciences Institute (IACS), Zaragoza, Spain

<sup>4</sup> Department of Dermatology, Zealand University Hospital, Roskilde, Denmark

<sup>5</sup> Dermatology, Dali Medical, Bucharest, Romania

<sup>6</sup> Department of Dermatology, Faculty of Health Sciences, University Hospital of North Norway, Troms, Norway

<sup>7</sup> Clinical Epidemiology Unit, Istituto Dermopatico dell'Immacolata (IDI)-IRCCS FLMM, Rome, Italy

<sup>8</sup> Health, Medical, and Neuropsychology unit, Leiden University, Leiden, The Netherlands

<sup>9</sup> Department of Dermatology, Andreas Syggros Hospital, Athens, Greece

<sup>10</sup> Department of Dermatology, Royo Villanova Hospital, Aragon Health Sciences Institute (IACS), Zaragoza, Spain

<sup>11</sup> Department of Medical Sciences, Section of Dermatology, University of Ferrara, Ferrara, Italy

<sup>12</sup> Department of Medical Psychology, Academic Medical Center, Amsterdam, The Netherlands

<sup>13</sup> Department of Dermatology and Venereology, Skane University Hospital, Malmö, Sweden

<sup>14</sup> 2nd Department of Dermatology and Venereology, National and Kapodistrian University of Athens Medical School, “Attikon” General University Hospital, Athens, Greece

<sup>15</sup> ULB-Erasme Hospital, Department of Dermatology, Brussels, Belgium

<sup>16</sup> Department of Dermatology, Wroclaw Medical University, Wroclaw, Poland

<sup>17</sup> Department of Pharmacy, Pharmacology and Postgraduate Medicine, School of Life & Medical Sciences, University of Hertfordshire, Hatfield, UK

<sup>18</sup> Department of Dermatology and Wound Healing, Division of Infection and Immunity, School of Medicine, Cardiff University, Cardiff, UK. ORCID 0000-0003-2143-1646

Address for correspondence:

Pavel Chernyshov, Department of Dermatology and Venereology, National Medical University, Bulvar Shevchenko, 13, 01601 Kiev, Ukraine.

Tel./ Fax: +38 044 2348660

E-mail: [chernyshovpavel@ukr.net](mailto:chernyshovpavel@ukr.net)

**Key words:**

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### ***Conflict of interest***

The department of CCZ has received compensation from Galderma Laboratories for participation in clinical studies. AYF is joint copyright owner of the DLQI, CDLQI, CADI and ADI. Cardiff University and AYF receive royalties.

### **Abstract**

Acne causes profound negative psychological and social effects on the quality of life (QoL) of patients. The European Dermatology Forum S3-Guideline for the Treatment of Acne recommended adopting a QoL measure as an integral part of acne management. Because of constantly growing interest in Health-related QoL assessment in acne and because of the high impact of acne on patients' lives, the European Academy of Dermatology and Venereology Task Forces on QoL and Patient Oriented Outcomes and Acne, Rosacea and Hidradenitis Suppurativa has documented the QoL instruments that have been used in acne patients, with information on validation, purposes of their usage, description of common limitations and mistakes in their usage and overall recommendations.

### **Introduction**

Acne is common dermatologic diagnosis accounting for 22–32% of dermatology patients and is one of the most common reasons for visiting a physician (1.1%)<sup>1</sup> with an estimated prevalence of 650 million people affected.<sup>2</sup> A systematic analysis for the Global Burden of Disease study indicated that acne was the 8th most prevalent disease globally in 2010.<sup>3</sup> Acne is considered a chronic disease owing to its prolonged course, pattern of recurrence and relapse, and manifestations such as acute outbreaks or slow onset. Moreover, the disease causes profound negative psychological and social effects on the quality of life (QoL) of patients.<sup>4</sup> Most people

experience acne during adolescence, with >95% of teenage boys and 85% of teenage girls affected.<sup>5</sup> Of these young people, 20-40% have moderate-to-severe acne and as many as 50% continue to suffer from acne in adulthood. Familial predisposition and especially acne in the mother are significantly associated with a more severe course.<sup>5</sup> Acne patients are managed primarily by dermatologists (93%) but also by general practitioners (6.3%) and pediatricians (0.6%).<sup>6</sup> In 2004, the direct annual costs in the USA had climbed to over 2.2 billion US dollars.<sup>7</sup>

Patients with clinical acne require medical therapy, either because of the severity or duration of their disease. Recent scientific advances have contributed to a better understanding of the pathogenesis of acne and to optimizing the therapeutic approach.<sup>8-12</sup> Health-Related QoL (HRQoL) assessment in patients with acne are recommended by several national guidelines.<sup>13</sup> The European Dermatology Forum S3-Guideline for the Treatment of Acne recommended adopting a QoL measure as an integral part of acne management.<sup>14</sup>

HRQoL assessment in acne patients is often used in clinical trials as an outcome measure but there are also many reasons to measure HRQoL in clinical practice.<sup>15</sup> To facilitate the integration of thinking about QoL into routine clinical practice the new word “QUIMP”, meaning quality of life impairment, was recently proposed.<sup>16</sup>

Because of growing interest in the assessment of HRQoL in acne and the major impact of acne on patients' lives, the European Academy of Dermatology and Venereology (EADV) Task Forces (TFs) on QoL and Patient Oriented Outcomes (POO) and Acne, Rosacea and Hidradenitis Suppurativa (ARHS) have documented the QoL instruments that have been used in acne patients, with information on validation, purposes of their usage, description of common limitations and mistakes in their usage and overall recommendations of the TFs.

This information should assist dermatologists and researchers in choosing appropriate QoL instruments, avoid common mistakes and facilitate the use of validated QoL instruments in their research and clinical work.

## **Methods**

Members of the EADV TFs on QoL and POO and ARHS were invited to participate. A literature search was performed using the PubMed database, which was searched from 1980 to November 2016 using the key words combination: “acne” and “quality of life”. All publications written in English or that had English abstracts were considered. All those who volunteered were allocated a section of the identified articles to review.

Exclusion criteria:

- Review articles, guidelines, protocols
- Studies without HRQoL assessment
- Measurement of HRQoL in conditions other than acne
- Studies where HRQoL was measured in patients with conditions other than acne but some of whom may also have acne
- Studies where HRQoL was studied in acne and other diseases but results on acne were not presented and/or discussed separately
- Studies on post-acne scars and post-acne hyperpigmentation

All publications were independently assessed by two co-authors. The assessments were compared and discrepancies discussed and resolved. The remaining publications were analyzed in detail and the QoL instruments used in acne were listed. Additional PubMed searches were carried out for “acne” and the name of each of the measures from this list.

## **Results**

13 members of the EADV Task Forces took part in the literature review. Figure 1 shows the literature search procedure. Validated HRQoL instruments that were used in acne studies are described in Table 1. Figure 2 shows how frequently these instruments were used.

Pärna et al<sup>38</sup> used the RAND-36 instrument: this has identical content to the SF-36 but has a slightly different scoring system. Acne patients were included in the creation and initial validation of the 11-item Turkish quality of life (TQL) instrument<sup>199</sup>. The Children's Life Quality Index (CLQI), a 12-item generic proxy instrument has been used to compare children with skin disease with children with other chronic diseases<sup>176</sup>. Two German instruments were also used to assess HRQoL in acne patients<sup>98,200</sup>.

Truchuelo et al<sup>201</sup> reported the use of the 9-item Social Quality-of-Life (SOQOL) scale, citing Krejci-Manwaring et al.<sup>89</sup>. However Krejci-Manwaring et al<sup>89</sup> do not give information on the 9-item instrument. Nair and Nair appear to have combined the DLQI and CADI under the title Total Acne Quality of Life (TAQOL)<sup>202</sup>. Five “study-specific” untitled questionnaires with QoL elements were also used in acne patients<sup>203-207</sup>.

There are several reports of acne studies in which QoL instruments were used outside their validated age limits. For example, Skindex-29, an instrument for adults, was used in children from 12 years old<sup>79</sup> and the DLQI, designed for use in those over 16 years old, was used in children aged 15<sup>22,37</sup>, 14<sup>42,55</sup>, 13<sup>48</sup> and 12 years old<sup>25</sup>.

The titles of some QoL instruments have been inaccurately presented.<sup>45, 159</sup> Some authors did not provide references for the QoL instruments that they used<sup>79,160</sup>.

Most of the publications identified were clinical trials, epidemiologic studies and studies on creation and/or validation of QoL instruments. However, there were also publications on educational work in acne patients<sup>39,51,181</sup>, compliance and adherence to treatment<sup>25,83,142</sup>, correlation of QoL with acne severity measures<sup>26,74</sup>, psychological problems<sup>23,38,41,45,47,54,65,94,99,120,175,190,200</sup>, gender differences<sup>28, 102</sup>, racial differences<sup>140</sup>, comparison of generic and

disease-specific QoL instruments<sup>34,61</sup>, and comparison of QoL impairment in patients with acne and other diseases<sup>35,47, 60, 78, 85,169, 176</sup>.

### Clinical trials

The different interventions assessed, for which the greatest number of studies have been identified, were those concerning isotretinoin<sup>18, 19, 22, 40, 41, 52, 54, 106, 136, 170,171, 185, 188</sup> and benzoyl peroxide<sup>76, 77, 79, 117, 133, 135, 152, 157, 162, 179</sup>.

### Epidemiologic studies

A study from France showed that quimp in women with acne, assessed by the DLQI, was significantly different from women without acne.<sup>62</sup> Another French study reported that patients' daily lives were affected in nearly half of acne patients (48%).<sup>103</sup> A study from Iraq found significant association between age and QoL impairment in 510 acne patients.<sup>111</sup> Acne influenced QoL “moderately” to “very much”, in 51.8% of patients in a study from Iran.<sup>31</sup> On the other hand, 478 Serbian pupils with self-reported acne reported low HRQoL impairment.<sup>112</sup>

### Educational work in acne patients

Mean DLQI<sup>39,51</sup> and CADI<sup>39</sup> scores improved after 12 weeks of text messages<sup>39</sup> and multiple-choice questions.<sup>51</sup> Internet-based acne education using automated counseling was not superior to standard-website education in improving acne severity and QoL<sup>181</sup>.

### Compliance and adherence to treatment

In patients with acne, being female, married, employed and not paying for prescriptions were characteristics associated with increased medication adherence and better HRQoL<sup>25</sup>. Young females with high Skindex-29 scale scores and males with low Skindex scores are especially prone to non-adherence.<sup>83</sup> Better adherence was related to lower Skindex-29 scale scores at the end of their study<sup>83</sup>. Zaghoul et al. found significant negative correlation between DLQI scores



and medication adherence<sup>25</sup>. Tan et al. reported that adherence increases with greater levels of impact on acne-specific QoL assessed by the Acne-QoL questionnaire<sup>142</sup>

### Correlation of QoL with acne severity measures

In the majority of studies that addressed the issue, HRQoL correlated with acne severity.<sup>89, 177, 187</sup> Hanisah et al. found that only students with severe acne, assessed with the global acne grading system (GAGS), had high CADI scores<sup>123</sup>. There was a positive correlation between overall scores on the Echelle de Cotation des Lésions d'Acné (ECLA) scale and CADI scales before and after treatment in one study<sup>115</sup> but no correlation in another study<sup>102</sup>. Some studies found no correlation between the impairment of QoL and the severity of acne.<sup>26, 110, 118</sup> The report of a case-control study in university students stated that even though the AQOL and DLQI scores were significantly higher in acne patients compared to controls, the level of impairment of QoL was not associated with the severity of acne.<sup>26</sup> In addition, there was no correlation between CADI scores and GAGS in an acne study of female patients<sup>118</sup>.

### Psychological problems

A high impairment of dermatologic QoL seems to be associated with an increased risk of having an anxiety disorder<sup>65</sup>. Anger was significantly related to both global QoL and skin-related QoL in the study by Rapp et al.<sup>94</sup> Bowe et al. showed that Body Image Disturbance Questionnaire scores correlated with Skindex-16 scores<sup>92</sup>. Significant correlation was found between Beck's depression inventory and APSEA<sup>188</sup>.

### Gender differences

In a population study of 1531 school pupils from Greece, the HRQoL of girls and boys were equally affected in those with acne<sup>177</sup>. Similarly, no difference was reported in other studies.<sup>27, 110</sup> In contrast, in several studies females were reported to experience a greater impact

on QoL than males<sup>28,107,111,146, 187</sup>. However in a study carried out in Egypt, the mean DLQI scores of male patients with acne were higher than those of female patients.<sup>55</sup>

### Racial and ethnic differences

Gorelick et al. explored the impact of racial background on the perceived HRQoL impact of acne<sup>141</sup>, categorising subjects into “White”, “Black”, “Hispanic” and “Asian”. “White” and “Black” subjects reported less negative impact of acne on QoL than “Hispanic” and “Asian/other subjects” measured by the Acne-QoL. “Black” subjects reported significantly less negative impact in the self-perception domain compared with “Asian/other subjects”. By racial/ethnic group, social functioning was less negatively impacted by acne in “White” and “Black” subjects than in “Asian/other subjects”. There were no statistically significant differences in either the role-emotional or acne symptoms domains among racial/ethnic groups.<sup>141</sup> Callender et al. did not find significant differences in HRQoL between white/Caucasian and non-white/Caucasian women with acne.<sup>140</sup>

### Comparison of generic and disease-specific QoL instruments

Significant correlation in an acne population was reported between all domains of the SF-36 and the DLQI scores.<sup>34</sup> The dermatology-specific instrument, the DLQI, was demonstrated to be more responsive to change compared to the two generic measures, the SF-36 and EQ-5D.<sup>61</sup>

### Comparison of QoL impairment in patients with acne and other diseases

Patients with acne experienced functioning and emotional effects from their skin disease comparable with those experienced by patients with psoriasis, but had fewer symptoms.<sup>85</sup>

Patients with severe acne reported levels of social, psychological and emotional problems that were as great as those reported by patients with chronic disabling asthma, epilepsy, diabetes, back pain or arthritis.<sup>60</sup> In the study from Brazil, patients with acne had the fourth highest quimp,

surpassed only by psoriasis, vitiligo and atopic dermatitis.<sup>29</sup> In children psoriasis and atopic dermatitis caused the greatest impairment of QoL, followed by urticaria and acne.<sup>176</sup>

## **Discussion**

In all studies reviewed, the measures used detected impairment of QoL caused by acne. Acne, especially when severe, may have an impact on the life of patients comparable to that caused by other dermatologic diseases, such as psoriasis, vitiligo, atopic dermatitis and urticaria,<sup>29, 85, 176</sup> and non-dermatologic diseases, such as asthma, epilepsy, diabetes, back pain and arthritis<sup>60</sup>. In the study by Sampogna et al<sup>208</sup>, the only skin diseases that had a greater psychosocial impact than acne were hyperhidrosis, hirsutism, ectoparasitic infections and bullous diseases.

The DLQI, a dermatology-specific instrument, and the acne-specific instruments CADI and Acne-QoL were used much more frequently than the generic SF-36 questionnaire. The dermatology-specific instruments CDLQI and Skindex-29 were also both used more than 10 times. This may reflect a higher interest amongst investigators in assessing dermatology- and acne-specific aspects of HRQoL impairment. Currently in routine clinical practice HRQoL assessment is still infrequent despite there being many potential benefits from such use.<sup>15</sup>

The dermatology-specific questionnaire the DLQI showed greater response sensitivity following successful treatment than the generic SF-36 and EQ-5D instruments.<sup>61</sup> Appropriate response is especially important in clinical trials, the commonest reported context for QoL measurement in acne patients. The instruments most used in clinical trials are the DLQI and CADI.

The impairment of QoL in patients with acne has been reported in epidemiologic studies in various countries.<sup>31,62,103,110,111,177</sup> The impact on QoL correlates with acne severity in some but not all studies, underlying the need for the effective and timely management of acne even for patients with less severe acne.<sup>62,103,177</sup>

The major impact of acne on HRQoL documented in the reviewed studies emphasizes the need for educational programs for acne patients about living with and treating acne.<sup>39,51</sup> At the moment an educational approach is much less developed than in atopic dermatitis or psoriasis. The creation and critical evaluation of high quality educational programs should be given priority by organizations that focus on acne, researchers and clinicians. QoL assessment may be used in this context as an outcome measure and source of additional information from patients. Prediction of compliance and adherence to treatment in acne patients is another potential aspect of the use of HRQoL instruments. However, current evidence suggests that this is not an easy task.<sup>25, 83, 142</sup> Probably, when starting a new treatment, those patients with the most highly impaired HRQoL generally adhere better to the therapy. From a longer-term perspective, those patients whose acne improved the most showed improvement in their HRQoL and had superior adherence to therapy.

Impaired QoL is also often associated with significant psychological problems in acne patients.<sup>65,92,94,188</sup> Gender differences may also play a role. Although acne affects female and male adolescents in about the same proportion, a higher impact on QoL in females compared to males has been shown in several studies.<sup>28,107,111,146,187</sup> No gender difference was found in other studies<sup>27,110, 177</sup> There is only one report<sup>55</sup> of male patients having a greater impact of acne on their QoL, probably influenced by local regional peculiarities. It may be that racial and ethnic differences in QoL assessment by acne patients<sup>141</sup> are also based on difference in cultural attitudes.

As different studies examine different age ranges of subjects and use different HRQoL questionnaires, there is little standardization of results, emphasising the need for the development of agreed core outcome measures for use across all studies.

During this review, many examples were identified of inappropriate use or reporting of QoL measurement in acne. These included use of “study-specific” unvalidated questionnaires that

included elements of QoL, inaccurate presentation of titles of QoL instruments, absence of information on instruments and use of QoL instruments out of their validated age limits. Similar problems were also reported concerning QoL measurement in patients with atopic dermatitis.<sup>209</sup> Such activity reduces the scientific value of published results and may discredit HRQoL assessment. There is a need for educated input when researchers plan studies that include HRQoL assessment and a need for editors to set clear standards for the reporting of HRQoL data. On the basis of this literature review and expert opinion our Task Forces recommend the DLQI, CDLQI and Skindex-29 as dermatology-specific, CADI and Acne-QoL as acne-specific and SF-36 as generic instruments for the assessment of HRQoL in acne. Experience of the use in acne of other instruments presented in this paper is too limited. The brevity of the DLQI, CDLQI and CADI and Acne-QoL makes these instruments suitable for use in routine clinical practice. Acne-specific instruments may assess HRQoL in both children and young adults.<sup>210</sup> It is acknowledged that some of the recommended measures may not have ideal validation characteristics.

The recommendations of the Task Forces are given in Figures 3 and 4.

Table 1. Details of HRQoL instruments that were used in articles reviewed

Figure 1. Literature search procedure

Figure 2. Number of studies in which each HRQoL instrument was used

Figure 3. Task Forces recommendations for use of HRQoL measures in acne

Figure 4. Flow chart to assist selection of appropriate HRQoL instrument

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