Critical Review of Generic and Dermatology-Specific Health-Related Quality of Life Instruments

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The measurement of health-related quality of life (HRQOL) is increasingly important in patients with skin diseases. Despite the availability of a variety of instruments and new psychometric techniques, there is no consensus as to which HRQOL instruments are to be preferred in dermatology. The objective of this review is to evaluate the generic HRQOL measures (i.e., health profiles) that have been used in dermatology (Short-Form-36 (SF-36) and -12, NHP, SIP, World Health Organization Quality of Life (WHOQOL)-100 and -BREF) and all dermatology-specific HRQOL measures (Dermatology Life Questionnaire Index, Skindex-29, -16, and -17, Dermatology Quality of Life Scales, and Dermatology-Specific Quality of Life). Criteria for evaluation were adapted from existing guidelines and included conceptual and measurement model, reliability, validity, responsiveness, item functioning, meaning of scores, administrative burden, respondent burden, the availability of alternative forms, and of cultural and language adaptations. Furthermore, an overview of skin diseases in which the included HRQOL tools have been used is presented. Although the selection of the appropriate HRQOL instrument remains a trade-off between various psychometric properties and research objectives, for now, we recommend the combination of SF-36 and Skindex-29 as the instruments of choice in dermatology. Promising new instruments for future research are the WHOQOL and the Skindex-17.

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Abbreviations: DLQI, Dermatology Life Questionnaire Index; DQOLS, Dermatology Quality of Life Scales; DSQL, Dermatology-Specific Quality of Life; HRQOL, health-related QOL; IRT, item response theory; MCID, minimal clinically important difference; NHP, Nottingham Health Profile; SF-36, Short-Form-36; SIP, Sickness Impact Profile; WHOQOL, World Health Organization Quality of Life

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INTRODUCTION

The World Health Organization (WHO) defined quality of life (QOL) as ''the individuals' perception of their position in life, in the context of the cultural and value systems in which they live and in relation to their goals, expectations, standards and concerns''. QOL is multidimensional and is determined by health and multiple non-medical aspects such as socio-economic status, marital status, professional career, personality, happiness, ambition, expectations, and religious experience. In medicine, QOL assessments focus on health-related (HR)QOL because of its focus. HRQOL measures include the physical, psychological, and social health domains both in a subjective and objective manner (e.g., work impairment is relatively objective measure of the social domain compared to personal relations; Testa and Simonson, 1996; Muldoon *et al.*, 1998). Especially in chronic non-life-threatening diseases such as skin diseases, HRQOL has become increasingly important in the assessment of disease severity, the evaluation of interventions, and allocation of resources.

In dermatology, HRQOL can be assessed with generic instruments (i.e., applicable in a broad range of conditions allowing for comparisons between diseases), dermatology-specific instruments (i.e., applicable in all skin diseases and allowing for comparisons between skin diseases) and condition-specific instruments (i.e., use is restricted to a specific skin disease and only comparisons between patient groups with the same skin condition are possible). More specific HRQOL tools are clinically sensible, often have a good conceptual validity, and may be more responsive than generic instruments (Wiebe *et al.*, 2003). Most of the generic instruments have been developed for use in conjunction with condition-specific instruments. Among the generic HRQOL measures, there is a distinction between health profiles and preference-based measures. Health profiles assess different domains of HRQOL resulting in scores for each of these domains (some health profiles also provide a composite score). The preference-based tools provide a single score (i.e., a health index), usually between 0 and 1, that is based on empirically measured preference weights (Coons *et al.*, 2000). Preference-based measures are especially designed for use in health economics.

The objective of this review is to grade several psychometric characteristics of the most commonly used generic health profiles and dermatology-specific HRQOL instruments to provide an overview of the advantages and limitations of each of these tools. It may assist researchers to choose the most appropriate HRQOL instruments for their studies and to

identify important research questions in the field of dermatology and HRQOL measurement.

DISCUSSION

Instrument of choice

Making an informed decision about the choice of a HRQOL measure or combination of measures is a trade-off between the pros and cons of the available instruments (preferable tested in dermatology patients), the objective of the study and the disease under investigation. Table 1 enables researchers in dermatological HRQOL research to make an evidence-based choice for selecting an appropriate measure with the best properties in consideration of its application. Of the psychometric properties, conceptual validity of an HRQOL instrument is crucial in every study design, reliability in particular in cross-sectional studies and responsiveness in clinical trials. For most applications, the Short-Form-36 (SF-36) is the reference measure and the WHOQOL is promising generic (HR)QOL measure (Table 2). Of the dermatology-specific HRQOL tools, the Skindex-29 is the most optimal available instrument, but it is challenged by its brief versions such as the Skindex-17. Adding a generic to a dermatology-specific health profile is generally recommended and is especially indicated if there is a need to compare HRQOL across diseases like in burden of disease studies, measure individuals' health status in generic terms, and in situations where the skin disease has a substantial generic HRQOL impact beyond the disease-specific impact. In health economic analyses such as cost-effectiveness analyses, the EQ-5D is the measure of choice (EuroQoL group, 1990; Brooks, 1996; www.euroqol.org) and the SF-6D may be a promising alternative (Brazier *et al.*, 1998, 2002).

We have tried to minimize bias in the grading of the HRQOL instruments by using widely accepted criteria and reaching consensus by three HRQOL experts. We acknowledge that apart from quality, the quantity of available studies is likely to affect the grading of the included instruments. This implies that newer instruments are likely to be graded lower on several criteria than older instruments and that very commonly used measure may score better or worse (SF-36 and Dermatology Life Questionnaire Index (DLQI), respectively) than those less commonly used. An overall quality score, as is often done in systematic reviews, was not given because it assumes that the contribution of the different measurement properties to the overall quality is known and that these properties are equally important.

Further research

The increasing importance of HRQOL in clinical practice (i.e., included in reimbursement criteria of the biologicals for psoriasis), clinical trials (i.e., important end points), and resource allocation (i.e., cross-sectional, comparative, and pharmacoeconomic studies) warrants the use of state-of-the-art generic and specific instruments. This increased importance of HRQOL measures emphasizes the need for more methodological studies about HRQOL in dermatology. A prospective, international comparative study of several generic instruments (including at least the SF-36, WHOQOL, and EQ-5D) may show where and to what extent the most optimal generic HRQOL instrument fail to assess pivotal dermatology-specific HRQOL information, which should be obtained by a more specific tool. Because each of the existing dermatology-specific instruments has conceptual limitations and/or suboptimal or unknown psychometric properties an existing instrument such as the Skindex (or its short versions) should be studied and refined or a tool should be developed *ex novo*. It may also be worthwhile to obtain preferences of the possible health states of this dermatology-specific HRQOL by the general population so that it can be used to calculate quality-adjusted life years.

Although it is a dilemma how to judge, select, and incorporate new insights and techniques in current HRQOL research, item response theory (IRT) models are now considered standard in the psychometric community, especially in the evaluation of instruments' structure (graded ''A''; Table 3; McHorney, 1997). In contrast to the generic tools, relatively few studies have used IRT in existing dermatology-specific HRQOL instruments (Mazzotti *et al.*, 2005; Nijsten *et al.*, 2006a, b, 2007), but it has been used in the development of a psoriasis and atopic dermatitis-specific HRQOL instrument (McKenna *et al.*, 2003; Whalley *et al.*, 2004). Because HRQOL instruments are used in populations that vary in demographically, cultural background, and/or disease characteristics, it is pivotal that responses to items and scales should not be affected by these external factors, except for the differences the tool intends to measure (i.e., HRQOL impairment; Angoff, 1993; McHorney and Fleishman, 2006). However, little evidence exists about the item bias across important variables such as gender, age, cultural background, diagnosis, and clinical disease severity of the dermatology-specific instruments, except for the Skindex-17 (Nijsten *et al.*, 2006a, b, 2007). It would also be very interesting to explore further the effect of comorbidity on patients' skin-related QOL (Unaeze *et al.*, 2006; Chen *et al.*, in press).

Conclusion

For now, the SF-36 and the Skindex are the HRQOL instruments of choice and promising ''runnerup'' measures are the WHOQOL and the Skindex-17. However, additional methodological studies are needed to compare and improve our understanding of these instruments in a heterogeneous population to reach a consensus of HRQOL measurement in dermatology.

MATERIALS AND METHODS

Multiple tools were identified based on several recent reviews on generic and/or dermatology-specific HRQOL instruments (Finlay, 1997; Ashcroft *et al.*, 1998; Coons *et al.*, 2000; Halioua *et al.*, 2000; De Korte *et al.*, 2002; Bennett *et al.*, 2003; Haywood *et al.*, 2005; Nemeth, 2006). We consulted existing reviews and we systematically searched Pubmed for publications of the instruments' characteristics by entering the ''MeSH'' terms ''Quality of Life'', ''Dermatology'', and ''Skin'' in combination with the full and the abbreviated name of each of the identified instruments. Also, reference lists of all papers obtained were hand searched to identify

Table 1. Global evaluation of generic and dermatology-specific HRQOL instruments

	Generic HRQOL instruments				Dermatology-specific HRQOL instruments					
	Health profiles									
Characteristics	**SF-36**	**NHP**	**SIP**	**WHOQOL**	**DLQI**	**Skindex-29**	**Skindex-16**	**Skindex-17**	**DSQL**	**DQOLS**
Validity										
Conceptual	A	B	B	A	B	A	A	A	B	A
Construct	A	A	A	A	A	A	A	A	B	B
Convergent	A	A	A	A	A	A	A	A	B	C
Interpretability										
Norms	A	B	C	B	C	C	C	C	C	C
2Categorization	B	C	C	C	A	B	C	B	C	C
MCID	A	C	C	C	B	C	C	C	C	C
Dermatology patients										
Development	A	C	C	B	B	A	A	A	C	B
Testing	—	—	—	—	A	A	B	C	C	B
Measurement model	B	B	B	A	B	A	A	A	C	A
Reliability										
Internal consistency	A	B	A	B	A	A	A	A	A	A
Retest reliability	A[1]	A	A	A	B[2]	A[2]	B[2]	C[2]	C[2]	B[2]
Structure	B[3]	B	C	A	C	B	B	A	B	B
Responsiveness	A	B	B	A	A	A	A	C	B	C
Item bias	A	B	C	B	C	B	C	A	C	C
Cultural issues										
Translations	A	B	B	A	B	B	C	B	C	C
Cultural equivalence	A	B	C	A	C	C	C	B	C	C
Respondent burden	B	A	C	C	A	B	A	A	B	B
Administrative burden	A	A	C	A	A	A	A	A	B	A
Alternative forms	A	B	B	B	C	C	C	C	C	C

DLQI, Dermatology Life Questionnaire Index; DSQL, Dermatology-Specific Quality of Life; DQOLS, Dermatology Quality of Life Scales; HRQOL, health-related quality of life; MCID, minimal clinically important difference; NHP, Nottingham Health Profile; SF-36, Short-Form-36; SIP, Sickness Impact Profile; WHOQOL, World Health Organization Quality of Life. — not applicable.
[1]Most authors report an good retest reliability (Coons *et al.* (2000); Haywood *et al.* (2005)), but this is debated by some authors (Hunt and McKenna (1993); Gompertz *et al.* (1992)).
[2]Retest reliability expressed as correlation coefficients, which were all good to excellent, but not as κ coefficients.
[3]Item response theory models only confirmed the unidimensionality of the physical functioning scale but not of other scales and components.

additional studies of interest. Generic HRQOL measures were included if they were designed to assess health profiles and used in one or more dermatological studies. All dermatology-specific HRQOL instruments were included, except those instruments that were developed with the intention to be used only in specific countries such as Germany, French, and Turkey (Grob *et al.*, 1999; Schafer *et al.*, 2001; Gurel *et al.*, 2005). HRQOL measures that focused on only one specific skin condition were not included in this review.

For each criterion, the selected HRQOL instruments were graded simply from A (excellent track record), C (substantial inadequacy or not reported), and B somewhere in between. The evaluation criteria included conceptual and measurement model, reliability, validity, responsiveness, item bias, meaning of scores, administrative burden, respondent burden, and the availability of alternative forms, and of cultural and language adaptations (Table 3). This set of criteria was adapted from the Medical Outcomes Trust (Lohr *et al.*, 1996; Andresen, 2000). The criteria on validation in dermatology patients, interpretability of scores and test–retest reliability were added (Guyatt *et al.*, 2002; Terwee *et al.*, 2007). The grading of the HRQOL measures was performed by TN, MLEB, and JB until consensus was reached. If uncertainty remained about the appropriate grading, we selected the most favorable option. Because of a limited number of psychometric evaluations of generic HRQOL instruments in dermatology patients, the presented grades were based on other (diseased) populations. Because psychometric properties depend on the population studied, we discussed the psychometric properties of each measure reported in dermatology patients separately.

Generic HRQOL instruments (health profiles)

Medical Outcome Study Short Form. The SF-36 is a health survey questionnaire designed for use in epidemiological and clinical research and practice by American social scientists working

Table 2. Short global evaluations of the HRQOL instruments

HROQL instrument	Short global evaluation
SF-36	Although its structure and retest reliability may be somewhat controversial, the SF-36 is the most studied and validated HRQOL instrument available and behaves well in a broad range of clinical conditions. The SF-36 is considered the reference instrument by most researchers.
SIP	This is a long tool of 136 items and is not an optimal instrument in dermatology because of its focus on disability, which is likely to result in skewed response distributions and unresponsiveness to change.
NHP	The binary item responses of NHP make it an easy to administer HRQOL instrument but this may affect the instruments' response distribution and responsiveness. Additional research of NHP behavior in dermatology patients is warranted.
WHOQOL	This is promising new instrument to assess overall QOL and is truly cross culturally equivalent. Additional research is needed and supposedly ongoing to test the long and short version of the WHOQOL tool, in and outside dermatology.
DLQI	This instrument was the first and is the most widely used dermatology-specific HRQOL instrument, but has several major limitations such as focus on disability, response distribution, and dimensionality and item bias.
Skindex	The Skindex-29 is a valid, reliable and responsive instrument. For now, we recommend its use, but its current scales did not fit the Rasch model (questioning its structure) and the meaning of the scores is not well documented. Of the reduced versions, the Skindex-16 is likely to have similar (dis)advantages and the Skindex-17 is promising because it fitted both the classical test and item response theory, but additional validation studies are needed.
DQOLS	The development of this tool has been suboptimal with regard to item creation and selection. Some of the psychometric techniques used are unusual.
DSQL	The initial item creation and selection has been suboptimal. Validation was restricted to acne and/or contact dermatitis patients. The items responses are heterogeneous and summing of the overall score is inappropriate.

DLQI, Dermatology Life Questionnaire Index; DSQL, Dermatology-Specific Quality of Life; DQOLS, Dermatology Quality of Life Scales; HRQOL, health-related quality of life; NHP, Nottingham Health Profile; SF-36, Short-Form-36; SIP, Sickness Impact Profile; WHOQOL, World Health Organization Quality of Life.

for a health insurance survey (Brazier *et al.*, 1992; Ware and Sherbourne, 1992; Ware *et al.*, 1993; Stewart *et al.*, 1988; www.sf-36.org). The items represent professionals' assumptions about issues relevant to health status and relate to the previous 4 weeks, except the item about general health (last year). An ''acute version'' of the SF-36 makes use of a reference period for HRQOL of ''last week''. The items are assigned to eight scales each aggregating 2–10 items, except a single item on perceived change in health (Table 4). The SF-36 is the only instrument assessing a notion of positive health (''full of life''), which may make it a sensitive instrument in the better ranges of HRQOL. Factor analysis of the SF-36 showed a two-factor model with physical and mental component (abbreviated to PCS and MCS, respectively) with separate summary scores (Ware *et al.*, 1993; Essink-Bot *et al.*, 1997). IRT models demonstrated the unidimensionality of the physical functioning scale (Haley *et al.*, 1994; van der Heijden *et al.*, 2003), but not of the other scales. The SF-36 scored well for most of the other psychometric features reviewed (Tables 1 and 2), except that half the scales suffer from suboptimal response distributions (i.e., floor effect in very sick patients and some ceiling effect in general population) The test–retest reliability was below 0.70 for three scales (Brazier *et al.*, 1992; Gompertz *et al.*, 1992; Hunt and McKenna, 1993; McHorney *et al.*, 1994). It takes about 7–10 minutes to complete the questionnaire and multiple administration modes are available (www.sf-36.org). The SF-36 is available in more than 50 different languages and has been tested extensively for cultural equivalence (Anderson *et al.*, 1996; Wagner *et al.*, 1998; www.sf-36.org). Norms have been calculated for the general US population and representative samples of the United Kingdom and other European countries. Although it has been assumed that the minimal clinically important difference (MCID) of the SF-36 scales was about 3–5 points (Stewart *et al.*, 1989), the MCID may vary more between scales and diseases (Wyrwich *et al.*, 2005) and the exact MCID of the eight scales in dermatology patients is unknown.

The SF-36 has been widely used in dermatology with different objectives. For instance, it has been used as a reference HRQOL measurement in validation studies of dermatology-specific instruments such as the DLQI and Skindex (Chren *et al.*, 1997a; Abeni *et al.*, 2002; Lewis and Finlay, 2004). The SF-36 has also been used in cross-sectional studies (Table 5), epidemiological surveys (Bingefors *et al.*, 2002), and in clinical psoriasis trails (Reich *et al.*, 2006; Shikiar *et al.*, 2006). A systematic review of the HRQOL tools in psoriasis concluded that the SF-36 is the generic instrument of choice (De Korte *et al.*, 2002). The PCS and to a much lesser extent the MCS of the SF-36 correlated well with the DLQI (Wallenhammar *et al.*, 2004; Sampogna *et al.*, 2004a; Shikiar *et al.*, 2006). Several psychometric properties of the SF-36 have been studied in detail using data from an adalimumab trial in psoriasis patients (Shikiar *et al.*, 2006). The bodily pain and social functioning scales correlated well with the DLQI, EQ-5D, and clinical end points, and these scales were most responsive to change after psoriasis treatment. The MCID estimations in psoriasis patients of the PCS and MCS of the SF-36 varied between 0.5–3.9 and 1.8–6.61 points, respectively. In contrast to the DLQI, the SF-36 detected gender differences in patients with hand eczema (Wallenhammar *et al.*, 2004). Internal consistency of the SF-36 has not been reported in patients with skin diseases.

The SF-12 was developed from the SF-36 for use in large surveys and longitudinal studies and includes seven items PCS items and five MCS items with 2–6 response options (Ware *et al.*, 1995, 1996).

Table 3. Important characteristics of HRQOL instruments[1]

Characteristics	Definitions	Grades and criteria		
Validity Conceptual[2] Construct[3] Convergent[3]	Does the tool measure what it is supposed to measure? Are the relevant domains captured? Does tool confirm hypothesized difference (e.g., diagnosis, clinical disease severity, others) Does the tool relate to other tools measuring the same construct?	A1: well balanced objective and subjective domains B1: more focused on objective or subjective domains C1: missing important HRQOL domains.	A2: >75% of results are in accordance with specific hypotheses B2: <75 of results are in accordance with specific hypotheses C2: no information.	A3: correlation >0.70 B3: correlation <0.70 C3: no information
Interpretability Norms Categorization MCID[4]	Are there standard comparative data from the general population and/or dermatology patients published and/or available? Are there categories of the obtained score available? Has the minimal change that is relevant to patients been reported?	A1: general and dermatology patients B1: general or dermatology patients C1: general nor dermatology patients	A2: using anchor or banding techniques B2: using distribution based techniques C2: not reported	A3: MCID is known in heterogeneous sample B3: MCID is known in limited sample C3: not reported
Dermatology patients For generic tools Testing For dermatology-specific tools Development Testing	Has the instrument been validated in dermatology patients? Have patients with a variety skin diseases been involved in the development of the tool? Has the tool been used in a variety skin diseases?[5]	A1: yes, tested for validation, reliability and responsiveness B1: yes, tested for validation, reliability and/or responsiveness C1: not at all A2–3: large B2–3: moderate C2–3: little		
Floor and ceiling effects (measurement model)	Does the tool capture the detail and breadth of real differences among persons? (i.e., does the tool or its scales show 'floor' or 'ceiling' effects of >20%?)	A: no problems B: some problems C: substantial problems		
Reliability[3,6] Internal consistency Retest-reliability	Does the tool provide a consistent answer? The extents to which items in a (sub)scale are intercorrelated, thus measuring the same construct (Cronbach's α)? Does a repeated administration of the tool within a reasonable period result in a similar outcome?	A1: 0.95>Cronbach's α>0.70 B1: Cronbach's α< 0.7 or >0.95 C1: Cronbach's α not reported		A2: κ or ICC >0.7 B2: κ or ICC <0.7 or correlation coefficients >0.7 C2: κ or ICC not reported or correlation coefficient <0.7
Structure	Have the domains and/or summary score of the tool been confirmed?	A: item response theory B: Factor analysis C: no factor analysis or item response theory.		
Responsiveness	Is the tool sensitive to detect changes over time or due to therapy using patient centered and/or clinical criteria?	A: strong B: moderate or conflicting evidence C: absent, weak, or solely based on statistical evidence		
Item bias	Do the items of the tool function similar across external factors such as age, gender and diagnosis?	A: strong B: moderate or conflicting evidence C: absent or weak		
Cultural issues Translations Cultural equivalence	Has the tool been translated using guidelines? Has the tool been analyzed in a cultural equivalence study?	A1: always B1: sometimes C1: never, not reported		A2: always B2: sometimes C2: never
Respondent burden	Is the length and content acceptable to the patients?	A: brief (<15 min) B: long or problems of acceptability C: long and problems of acceptability		

Table 3 continued on follow page

Table 3. continued

Characteristics	Definitions	Grades and criteria
Administrative burden	How easy is the tool to administer, score and interpret (i.e., is specialized training or special software required)?	A: simple B: moderate C: complex
Alternative forms	Is the tool available and tested for alternate forms of administration such as interviews in person or telephone, self-administration or computer-assisted interviews.	A: strong evidence B: moderate or conflicting evidence C: absent or weak evidence

HRQOL, health-related quality of life; ICC, intraclass correlation coefficient.
[1]Adjusted from Lohr *et al.* (1996); Andresen (2000) and Terwee *et al.* (2007).
[2]Objective and subjective domains are described by Muldoon *et al.* (1998).
[3]Criteria of construct validity and reliability were based on description by Terwee *et al.* (2007).
[4]MCID, minimal clinically important difference (i.e., the minimal difference, which is measured and is relevant to a patient and is not due to intrinsic variance of the instrument).
[5]Refer to Table 2.
[6]Reliability is concerned with the temporal stability of instrument scores (test-retest) and internal consistency, which is estimated by Cronbach's α, evaluates the relationship between all items (of a scale) and their ability to measure a single underlying domain. Test–retest reliability assess score consistency over two points in time assuming no change in health status and may provide a more rigorous of reliability due to the different sources of variance. Test–retest reliability should best be expressed in a κ coefficient or ICC. Spearman's correlation coefficients are less optimal for retest reliability. No distinction was made for comparisons at group or person level.

Table 4. Generic and dermatology-specific HRQOL instruments including their health domains

Generic HRQOL instruments (health profiles)	**SF-36**[1]	**NPH**	**SIP**	**WHOQOL**
	Physical functioning Role limitations due to physical problem Bodily pain General health Vitality Social functioning Role limitations due to emotions Mental health Health transition	Energy level Emotional reactions Physical mobility Pain Social isolation Sleep	*Physical dimension* Ambulation Mobility Body care and movement *Psychosocial dimension* Communication Alertness behavior Emotional behavior Social interaction *Independent categories* Sleep and rest Eating Work Home management Recreation and pastimes	Physical Psychological Level of independence[2] Social relationships Environment Spirituality[2]
Dermatology-specific HRQOL instruments	**DLQI** Symptoms Daily activities Leisure Work/school Personal relationships Treatment	**Skindex**[3] Emotions Functioning Symptoms	**DQOLS** *Psychosocial* Embarrassment Despair Irritableness Distress *Activities* Everyday Summer Social Sexual Symptoms	**DSQL** Physical symptoms Daily activities Social activities Work/school experiences Self-perception SF-36 vitality subscale SF-36 mental subscale

DLQI, Dermatology Life Questionnaire Index; DQOLS, Dermatology Quality of Life Scales; DSQL, Dermatology-Specific Quality of Life; HRQOL, health-related quality of life; NHP, Nottingham Health Profile; SF-36, Short-Form-36; SIP, Sickness Impact Profile; WHOQOL, World Health Organization Quality of Life.
[1]SF-36 includes eight scales and has a physical and mental component. The SF-12 includes the later two components.
[2]Conceptually, the WHOQOL has six domains but two could not be confirmed by factor analysis.
[3]The Skindex-29 and-16 have three domains but the psychosocial scale of the Skindex-17 combines emotions and functioning resulting in two domains.

Table 5. The different skin conditions in which the HRQOL instruments have been used

HRQOL instruments	Used in following skin conditions
SF-36	Acne[1], atopic, contact and occupational dermatitis[2–5], herpes zoster[6], ichthyosis[7], lupus erythematosus[8], neurofibromatosis[9], (non)melanoma skin cancer[1,10,11], port wine stains[12], psoriasis[2,13], sensitive skin[1,14], Sezary syndrome[15], systemic sclerosis[16], toxic epidermal necrolysis[17], ulcers[1,18], varicose veins[19]
SIP	Atopic dermatitis[20], basal cell carcinoma[21], Ehlers–Danlos syndrome[22], psoriasis[13]
NHP	chronic (pressure) urticaria[23,24], eczema[25], ichtyosis[26], leg ulcers[27], lymphedema[28], psoriasis[13]
WHOQOL-100	Melasma[2,29], psoriasis[30], sarcoidosis[31]
DLQI	acne (ectopica)[35], actinic keratosis[35], alopecia[35], atopic dermatitis[35], basal cell carcinoma[35], Behcet's disease[35], bullous pemphigoid[35], contact dermatitis[35], Darier's disease[35], discoid lupus erythematosus[35], dystrophic epidermolysis bullosa[35], erythropoietic protoporphyria[36], Haily-Haily disease[35], hirsutism[35], HIV lipodystrophy[37], hyperhidrosis[35], ichtyosis[7], leg ulcers[35], lichen planus[35], lymphoedema[35], melasma[35], nevi[35], nonmelanoma skin cancer[11], prurigo[35], pityriasis rosea[35], pruritis[35], psoriasis[13,35], radiation dermatitis[38], rosacea[35], scabies[35], seborrheic dermatitis[35], seborrheic warts[35], tinea[35], warts[35].
Skindex-29	Acne[39,40], actinic keratosis[39], alopecia[39,41], atopic dermatitis[42], benign growths[39], cutaneous T-cell lymphoma[43], fungal disease[39], hand dermatitis[44], Haily–Haily disease[45], HIV-related dermatoses[46], hyperhidrosis[47], leg ulcers[48], nail disease[39], neurofibromatosis-1[49], nevi[50], onychomycosis[50], psoriasis[13], rosacea[39], scalp dermatitis[51], skin cancer[39], ulcer[39], viral disease[39], vitiligo[39]
Skindex-16	Acne[52], actinic keratosis[53], atopic and contact dermatitis[54,55], benign tumors[53], chronic venous insufficiency[56], dermatomyositis[57], facial blemishes[58], seborrheic dermatitis[53], nonmelanoma skin cancer[59], melasma[60], warts[53]
Skindex-17	Acne[61], alopecia areata[61], nevi[61], psoriasis[61], seborrheic dermatitis[61], vitiligo[61]
DSQL	Acne[62], contact dermatitis[62]
DQOLS	Acne[64], eczema[64], psoriasis[65], urticaria[66]

DLQI, Dermatology Life Questionnaire Index; DQOLS, Dermatology Quality of Life Scales; DSQL, Dermatology-Specific Quality of Life; HRQOL, health-related quality of life; NHP, Nottingham Health Profile; SF-36, Short-Form-36; SIP, Sickness Impact Profile; WHOQOL, World Health Organization Quality of Life.
[1]Also, used SF-12.
[2]Used WHOQOL-BREF.
References: (1) Klassen *et al.* (2000); (2) Lundberg *et al.* (2000); (3) Thomson *et al.* (2002); (4) Wallenhammar *et al.* (2004); (5) Hutchings *et al.* (2001); (6) Chidiac *et al.* (2001); (7) Ganemo *et al.* (2004); (8) Ferraz *et al.* (2006); (9) Wolkenstein *et al.* (2001); (10) Trask and Griffith (2004); (11) Rhee *et al.* (2003); (12) Schiffner *et al.* (2002); (13) de Korte *et al.* (2002); (14) Misery *et al.* (2005); (15) Bouwhuis *et al.* (2003); (16) Cossutta *et al.* (2002); (17) Haber *et al.* (2005); (18) Iglesias *et al.* (2005); (19) Chetter *et al.* (2006); (20) Salek *et al.* (1993); (21) Blackford *et al.* (1996); (22) Berglund and Nordstrom (2001); (23) Berrino *et al.* (2006); (24) O'Donnell *et al.* (1997); (25) Whalley *et al.* (2004); (26) Ganemo *et al.* (2004); (27) Lindholm *et al.* (1993); (28) Sitzia and Sobrido (1997); (29) Cestari *et al.* (2006); (30) Skevington *et al.* (2006); (31) Guryleva (2003); (32) Kernick *et al.* (2000); (33) Shikiar *et al.* (2006); (34) Weiss *et al.* (2005); (35) Lewis and Finlay (2004); (36) Holme *et al.* (2006); (37) Blanch *et al.* (2004); (38) Wells *et al.* (2004); (39) Sampogna *et al.* (2004b); (40) Lasek and Chren (1998); (41) Fischer *et al.* (2001); (42) Augustin *et al.* (2004); (43) Demierre *et al.* (2005); (44) Fowler *et al.* (2006); (45) Gisondi *et al.* (2005); (46) Mirmirani *et al.* (2002); (47) Weber *et al.* (2005); (48) Hareendran *et al.* (2005); (49) Page *et al.* (2006); (50) Zghal *et al.* (2003); (51) Chen *et al.* (2002); (52) Hayashi *et al.* (2005); (53) Chren *et al.* (2001); (54) Higaki *et al.* (2004); (55) Kadyk *et al.* (2003); (56) Duque *et al.* (2005); (57) Hundley *et al.* (2006); (58) Balkrishnan *et al.* (2006); (59) O'Reilly *et al.* (2006); (60) Balkrishnan *et al.* (2003); (61) Nijsten *et al.* (2006b); (62) Anderson and Rajagopalan (1998); (63) Anderson and Rajagopalan (1997); (64) Morgan *et al.* (1997); (65) Feldman *et al.* (2004); (66) O'Donnell *et al.* (1997).

Although the SF-12 explained more than 90% of the SF-36 variance and validation studies including factor analysis confirmed its structure and good psychometric characteristics (Jenkinson and Layte, 1997), it is considered a less valid, reliable, and responsive instrument compared to the SF-36 (Haywood *et al.*, 2005). In heart failure patients, the MCID of the SF-12 PCS and MCS was 1.3 and 2.3 points, respectively (Bennett *et al.*, 2003). The SF-12 has been tested for cultural equivalence across nine countries (Gandek *et al.*, 1998). It takes less than 5 minutes to administer the single page SF-12, which can be scanned, and alternative forms such as computer administration exist. The SF-12 has been used in a French general population survey to assess the impact of sensitive skin (Misery *et al.*, 2005), a comparative study of HRQOL instruments in patients with venous leg ulcers (Iglesias *et al.*, 2005) and in the validation of a utility questionnaire in patients with skin cancers (Littenberg *et al.*, 2003). No psychometric evaluation of this tool has been reported in dermatology patients.

Sickness impact profile. The Sickness Impact Profile (SIP) was one of the first self-reported health measures published in 1976 and revised in 1981 (Bergner *et al.*, 1981). The SIP focuses on the objectively measurable impact of illness on daily activities and behaviors and much less on the mental aspects of diseases. It contains 136 items divided over 12 scales (Table 4). Apart from five independent scales, these scales can be grouped into a physical (four scales) and psychosocial domain (three scales). The SIP does not include a pain scale. The construct validity of the SIP judged by factor analysis has not been documented (De Bruin *et al.*, 1992). The SIP asks a respondent to tick only the items that are applicable to him on a given day. This speeds up the administration, but complicates the interpretation of missing items (i.e., was the activity not applicable on a given day or is the item mistakenly missed?) The items are weighted based on the level of dysfunction the item represents. The scores obtained (range 0–100) can be calculated per scale, domain, and as an overall score (most often used), but their interpretability is not well

documented. However, of the 136 items that sum up to the overall score, only 82 items fitted an extended Rasch model suggesting that an overall score is not appropriate (Lindeboom *et al.*, 2004). The SIP has been reported as a valid and reliable tool (de Bruin *et al.*, 1992; Coons *et al.*, 2000) with some important limitations (Tables 1 and 2). The SIP works best in patient groups with moderate to high disability associated with mobility impairment (e.g., psoriasis patients with arthritis). The SIP suffers from ceiling effects in general population samples, suggesting that it is insensitive to change in these circumstances and does not discriminate well among relatively healthy individuals (Andresen and Meyers, 2000). Twenty-three items showed significant item bias across age, gender, and diagnosis (Lindeboom *et al.*, 2004). Depending on the patients' health, it takes about 30 minutes to complete the SIP and it can be self-administered. The SIP has been translated into several languages using varying methods that seem to function well, but cross-cultural equivalence studies are lacking (Anderson *et al.*, 1996).

The SIP has been used in psoriasis research (Table 5) to assess the effect of cyclosporin, in and outpatient dithranol and calcipotriol therapy (Wall *et al.*, 1998; de Korte *et al.*, 2002; Prins *et al.*, 2005). Despite its insensitivity in patients with low levels of impairment and its focus on disability, the SIP has been used to assess the impact of basal-cell carcinoma (Blackford *et al.*, 1996). No psychometric evaluation of the SIP has been reported in dermatology, except in a small validation study of the Psoriasis Disability Index (Finlay *et al.*, 1990).

Nottingham Health Profile. The Nottingham Health Profile (NHP) was developed as a survey tool to reflect the lay perception of health status in the United Kingdom (Hunt *et al.*, 1986; McEwen and McKenna, 1996). The NHP assesses subjective health with binary responses (''yes/no'') to 38 items in six sections (Table 4). The social domain is underrepresented in the NHP, but it includes sleep (Essink-Bot *et al.*, 1997). The NHP results can be analyzed by summing the number of positive responses in a dimension or weighting items to calculate a dimension score (range 0–100). A factor analysis yielded two higher order factors confirming the two domains of the NHP (Essink-Bot *et al.*, 1997), but this structure could not been confirmed by Rasch analysis (Prieto *et al.*, 1998). Only a few reliability studies of the NHP have been performed and suggested a good test–retest reliability and a moderate Cronbach's α of about 0.7 (Coons *et al.*, 2000). The simple NHP scoring format has the advantage that missing values are low and it can be completed swiftly (5–10 minutes). However, if individuals score ''yes'' (i.e., the problem is present) and they get worse they cannot express this deterioration. Indeed, the NHP has been reported to be not very sensitive to minor levels of impairment and change over time (Table 2). For example, 26% of patients with acne or psoriasis who visited an UK outpatient university hospital clinic scored optimal on all NHP categories (Morgan *et al.*, 1997). Limited normative data of the general population are available (Erdman *et al.*, 1993). The NHP is intended for self-administration, but can also be administered by an interviewer. In a review about cultural equivalence, the authors conclude that there is preliminary evidence that the basic properties of multiple NHP versions, which have been unauthorized and untested, have been retained (Anderson *et al.*, 1996).

The NHP has been used in validation studies of patients with eczema and psoriasis and correlated poorly with the DLQI ($r < 0.32$), but the ''emotional reactions'' and ''mobility'' domains were more responsive than some of the DLQI domains (Badia *et al.*, 1999). It has been used to test the convergent validity of the Dermatology-Specific Quality of Life (DSQL; Morgan *et al.*, 1997). Several cross-sectional studies have used the NHP to assess HRQOL in dermatological patients (Table 5), but no studies have been published that included its reliability, factor analysis, responsiveness and item functioning.

WHOQOL. In 1998, the WHOQOL-100, which was designed prospectively in 15 health centers worldwide, was published (WHOQOL Group, 1994, 1998a). From an initial pool of 1,800 questions and a pilot study of 236 items, 100 items (plus four global items) were selected using strict quantative and qualitative criteria. The items refer to the prior 2 weeks and use a five-point response scale. Conceptually, 24 ''facets'' with each four items and four general questions (total is 100 items) were grouped in six domains (Table 4), but factor analyses retained only four domains (WHOQOL Group, 1998a). The WHOQOL assess overall QOL and not just HRQOL: it includes domains such as ''environment'' and ''spirituality''. More than half of the variance of the 24 facets was explained by ''positive feelings'' suggesting that this is an important predictor of an individuals overall QOL (Skevington, 1999). Although there is a WHOQOL Rasch Project Scientific Committee, no Rasch analysis has yet been published. In populations from the UK and USA, the WHOQOL demonstrated to have good discriminant validity, reliability (Cronbach's α values and intraclass correlation coefficients > 0.80) and responsiveness (Table 1; Skevington, 1999; Bonomi *et al.*, 2000). The convergent validity of the WHOQOL was not optimal because it did not consistently correlate with SF-36 as expected (Bonomi *et al.*, 2000). The interpretability of the obtained scores is not documented, except one study reporting normative data for the general Danish population (Noerholm *et al.*, 2004). The burden for the respondent is substantial given the high number of items, but the administrative burden for the researcher is relatively low given the ease of the scoring algorithm. Each of the over 40 translations has been performed in accordance with a strict protocol. Remarkably, none of the initial ''national'' questions had to be included in the final WHOQOL-100, which makes it a truly cross-cultural instrument.

The WHOQOL-100 has been extensively investigated in psoriasis patients treated in an Ingram regimen outpatient program (Skevington *et al.*, 2006). Apart from the social and environment, all domains were significantly more affected among psoriasis patients compared to healthy individuals. More severe disease correlated negatively with physical health and level of independence but not with the other QOL domains. Convergent validity was generally supported by modest to good correlations with the SF-36. All items showed a Cronbach's α of 0.95 and for most domains it was > 0.80. The Ingram regimen improved four of six domains suggesting an adequate responsiveness.

In 1998, a short form of the WHOQOL-100 instrument (i.e., WHOQOL-BREF) was developed for brief QOL assessments in epidemiological surveys and/or clinical trials (WHOQOL Group, 1998b; http://www.who.int/substance_abuse/research_tools/whoqolbref/en/). Conceptually, the WHOQOL work group

decided that at least one item of each of the 24 facets should remain in the short version. In a large group of patients from 18 different countries, 26 items were selected based on four criteria including variance explained, confirmatory factor analyses, and discriminate validity. The four domains of the original and brief version correlated well, showed good to excellent internal consistency, and good retest reliability. Each of the four domains of the WHOQOL-BREF fitted a two-parameter IRT model but did not fit the Rasch model suggesting that domains scores are more appropriate than a composite score (Noerholm *et al.*, 2004). The WHOQOL-BREF has been used in patients with (cutaneous) sarcoidosis and in the validation of a melasma-specific HRQOL tool (Table 5). It has not been psychometrically tested in dermatology patients.

Dermatology-specific HRQOL instruments

DLQI. The DLQI was the first dermatology-specific tool to assess skin-related QOL. It was designed as ''a simple practical measure for routine clinical practice'' (Finlay and Khan, 1994; http://www.dermatology.org.uk/). This instrument was developed in UK patients visiting a university clinic and focused on patients' functioning in their daily activities and does not fully capture emotions and mental health (Badia *et al.*, 1999; De Korte *et al.*, 2002). This suggests that the DLQI may lack conceptual validity in patients with minor dermatological conditions or in diseases primarily affecting mental health such as vitiligo and alopecia. The measure has 10 items rated on a four-point scale. However, the response format has been dichotomized because of numeric instability in patients with hand eczema (Wallenhammar *et al.*, 2004) and patients were unable to differentiate between response categories for most items (Nijsten *et al.*, 2006a, 2007). A composite score can be calculated (range 0–30). In psoriasis patients, a confirmatory factor analysis showed a clear second-order factor structure suggesting the underlying unidimensionality of the DLQI, but this could not be confirmed by several Rasch analyses (McKenna *et al.*, 2004; Mazzotti *et al.*, 2005; Nijsten *et al.*, 2006a, 2007). On the basis of face validity the developers of the DLQI suggested that six health domains (Table 4) were assessed, but subsequent factor analyses did not confirm this assumption (Kent and Al-Abadie, 1996; Wallenhammar *et al.*, 2004; Mazzotti *et al.*, 2005). The internal consistency is good to excellent. For test–retest reliability, high Spearman's correlation coefficients were reported (Table 1; Lewis and Finlay, 2004). Correlations between DLQI and other HRQOL measures were high and in the expected direction, except that the DLQI correlated less with mental and emotional aspects. The DLQI has been proven to be responsive to change, but may not be very sensitive to detect small impairments because of substantial ceiling effect. Items 1 and 2 account for most of the DLQI's variability (Morgan *et al.*, 1997; Badia *et al.*, 1999; Shikiar *et al.*, 2006). Five categories of the DLQI scores have been proposed (Hongbo *et al.*, 2005). The MCID of the DLQI varied between 3 and 6 points in patients with chronic urticaria and psoriasis (Shikiar *et al.*, 2005, 2006). A large proportion of the items behaved significantly different across gender and age (Nijsten *et al.*, 2006a, 2007). No information is available whether the items of the DLQI function comparable in patients with different skin diseases. It takes less than 5 minutes to complete. Different administration forms are available including an illustrated, family and children's version (http://www.dermatology.org.uk). Multiple translations have been used, but little documentation is published on the translation process, except for the more recent ones. A recent cultural equivalence study in psoriasis patients suggest that the scoring of all items were affected by nationality (Nijsten *et al.*, 2007). By now, the DLQI is the most commonly used HRQOL instruments in dermatology and is used in most HRQOL studies in patients with skin diseases (Table 5; Lewis and Finlay, 2004).

Skindex. The Skindex-29 was designed to measure HRQOL in different populations and to detect changes in time Chren *et al.*, 1996, 1997a, b). Its development study included patients from US private practices and a Veteran hospital. The first Skindex consisted of 61 items, but a refinement study resulted in the Skindex-29. The Skindex-29 has 30 items of which 29 items (except item 18) are assigned to three scales with separate scores (Table 4). This structure has been confirmed in several factor analyses (Chren *et al.*, 1997b; Abeni *et al.*, 2002; Augustin *et al.*, 2004). Although a composite score is sometimes calculated, it has not formerly been studied, has no face validity and did not fit the Rasch model (Nijsten *et al.*, 2006b). The questions ask about frequency respondents experience the assessed impact on their life on a five-point response scale. Distribution-based analyses suggested that there are four to five categories for the three Skindex-29 scales *(Nijsten et al., submitted)*. The Skindex-29 scored well for most criteria, except interpretability of scores, structure, and item bias (Table 1). Several items show item bias across gender, age, disease severity, and diagnosis (Nijsten *et al.*, 2006b). Completion requires about 10 minutes. In The Netherlands, a computerized version is available. The Skindex-29 has been translated from US English into Dutch, German, Spanish, Italian using a standard protocol, but about half the items of the 29 show differential item functioning across culture (Nijsten *et al.*, 2007). The development studies of the Skindex-29 and the validation studies of the German, Italian, and Spanish translations were performed in large, heterogeneous patient populations (Chren *et al.*, 1996; Jones-Caballero *et al.*, 2000; Abeni *et al.*, 2002; Augustin *et al.*, 2004). The Skindex-29 has been predominantly used in independent cross-sectional studies in a variety of skin conditions (Table 5) but not in (industry sponsored) clinical trials. Nevertheless, in a review about the HRQOL instruments in psoriasis, this tool was considered the measure of choice (de Korte *et al.*, 2002). The Skindex-29 has been used to test the validity of other (disease-specific) HRQOL instrument such as the Scalpdex (Chen *et al.*, 2002), pictorial presentation of illness measure in vitiligo (Rumpf *et al.*, 2004) and Skindex-17.

Two brief versions of the Skindex-29 exist. First, the Skindex-16 included items of the Skindex-29 that were not mentioned in qualitative responses to open-ended questions and/or more than half the participants responded ''never'' were deleted (Chren *et al.*, 2001). The three original scales of the Skindex-29 were respected. In addition to reducing the number of items, the Skindex-16 assesses degree of ''bother'' and not ''frequency'' and some items were refined or collapsed. In the development study of the Skindex-16 its three scales showed good to excellent internal consistency, good content, and construct validity and were responsive (Table 2). These psychometric characteristics were confirmed in a validation study of a Japanese version of the Skindex-16 and in atopic dermatitis (Higaki *et al.*, 2002, 2004). Since it was published in 2001, the Skindex-16

has been used in several skin conditions (Table 5) and in the validation of melasma-specific HRQOL instrument (Balkrishnan *et al.*, 2003).

Second, the Skindex-17 is a Rasch reduced version of the Skindex-29 (Nijsten *et al.*, 2006b). It has a psychosocial and a symptom scale. The five-point scoring system was re-grouped into three categories and demonstrated logical response order for all but one item. More than 85% of the variance of the three Skindex-29 scales was captured by the two scales of the Skindex-17 suggesting that little information was lost. No item bias was detected across gender, age, disease severity, and six diagnoses. Classical psychometric properties such as response distribution and internal consistency of the two subscales of the Skindex-17 were adequate (Table 2). The majority of the items of the psychosocial but not of the symptom scale were cultural equivalent (Nijsten *et al.*, 2007). A validation study of the Skindex-17 in psoriasis patients from other European countries confirmed its good psychometric properties (Nijsten *et al.*, 2007). So far, the Skindex-17 has only been studied and tested using existing data from the Skindex-29.

Dermatology Quality of Life Scales. Fifty outpatients from an UK university dermatology department were asked ''to write down all the ways your skin condition affects you'' by the subheadings feelings and personal relationships, daily and social activities and symptoms (Morgan *et al.*, 1997). Subsequently, the developers created the Dermatology Quality of Life Scales (DQOLS) yielding 17 psychosocial, 12 physical items, and 12 symptom items. A five-point response scale was used assessing patients' current experience. The three domains have separate scores ranging between 0 and 100. The questionnaire was validated in a different sample of 118 patients attending a hospital outpatient clinic (more than half had inflammatory skin diseases). Explanatory factor analysis showed four subscales of the psychosocial and activities scales (Table 4). The internal consistency was excellent for the psychosocial and activities scales (0.92 and 0.83, respectively) and the retest reliability was tested in 50 UV-treated patients (Table 1 and 2). Some of the techniques in the psychometric evaluation of the DQOLS were unusual such as the use of different patient samples, a Bland Altman plot (Bland and Altman, 1986; Gompertz *et al.*, 1992) to estimate retest reliability and the comparison between Dermatology-Specific Quality of Life (DSQL) and NHP scores to assess ''sensitivity''. Several hypotheses were tested to assess DQOLS construct validity and its' face validity was considered good using the DLQI as reference. It takes 5–10 minutes to complete this instrument. Except for a cross-sectional study in patients with chronic urticaria and in a clinical trial of alefacept in psoriasis (Table 5), the use of this instrument has not been reported in dermatological studies.

DSQL. In 1997, US researchers published the DSQL (Anderson and Rajagopalan, 1997). In total 52 items were included, which were derived from the SF-36, the literature, clinical experience, and a focus group of seven acne patients. Of the 52 items, eight were global questions scored on a 0–10 scale assessing intensity or satisfaction and the remaining items on a five-point ordinal scale assessing frequency. All items asked about the ''last month'' and grouped into seven scales (Table 4). A summary score was obtained by simply adding all raw scores. A pilot study to assess item behavior was restricted to acne patients and the final report includes patients with contact dermatitis as well. In the DSQL development study, the psychometric properties were reasonable and included construct validity, internal consistency, and factor analysis and, in acne patients, it was responsive (Table 1 and 2)(Anderson and Rajagopalan, 1998). The DSQL is self-administered and takes less than 15 minutes to complete. Except in subsequent acne and contact dermatitis studies by the developers of the DSQL (Table 5), this tool has not been used nor tested in other dermatological populations.

CONFLICT OF INTEREST

The authors state no conflict of interest.

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