The Family Dermatology Life Quality Index: measuring the secondary impact of skin disease

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Conflicts of interest
A.Y.F. is joint copyright owner of the Dermatology Life Quality Index (DLQI) and Family Dermatology Life Quality Index (FDLQI). A.Y.F.’s department gains some income from the use of the DLQI. A.Y.F. gives paid consultancy advice to several pharmaceutical companies but this study has not involved any pharmaceutical company and has not received any external funding. M.K.A.B. is a joint copyright owner of the FDLQI.

This study was conducted at the University Hospital of Wales, Cardiff, U.K.

Summary

Background Skin diseases are known to have a major impact on the lives of patients and their families. Many instruments are available to measure the health-related quality of life (HRQoL) of patients but no measure has been developed so far to quantify the secondary impact on family members of the patients.

Objectives To develop and validate a dermatology-specific instrument to measure the adverse impact on the HRQoL of family members of patients with skin disease.

Methods Detailed semi-structured interviews were conducted with family members of patients to identify different aspects of HRQoL affected. An initial draft version of the questionnaire based on the main topic areas was pilot tested to assess the face and content validity. A 10-item questionnaire, the Family Dermatology Life Quality Index (FDLQI), was finalized after modifications to the draft questionnaire based on feedback from families and dermatology professionals and on item reduction. Psychometric evaluation was conducted on a new cohort of family members (n = 132) who completed the FDLQI and the patients (n = 109) who completed the Dermatology Life Quality Index (DLQI).

Results Fifty-nine different aspects of family members’ HRQoL were identified from the analysis of the interviews, which were categorized into main topic areas. Factor analysis of 10 items of the final questionnaire revealed two factors and together these explained 60% of the common variance. The FDLQI demonstrated high internal consistency (Cronbach’s α = 0.88) and test–retest (intraclass correlation coefficient = 0.94) reliabilities. The responsiveness of the instrument to change was shown by significant change in the family members’ FDLQI scores in cases where patients’ clinical condition either improved or worsened. Construct validity was assessed by testing a number of a priori hypotheses. A strong correlation was seen between the family members’ FDLQI scores and patients’ DLQI scores (r = 0.69), a significantly higher FDLQI score was seen for inflammatory skin diseases compared with noninflammatory diseases/isolated lesions (P < 0.0001), and there was a positive relationship between the family members’ FDLQI scores and patients’ disease severity (r = 0.49).

Conclusions The FDLQI is simple and practical and seems to have the potential to be used as an additional outcome measure in clinical practice and evaluation research.

Skin disease can have a major impact on patients’ lives and a number of patient-completed instruments have been described to measure this impact. Quality of life (QoL) of individuals is closely related to the QoL of those around them such as partners and in some situations the QoL of a partner may be more impaired than the patient. Family caregivers may experience a major impact on their lives such as physical and mental exhaustion, social disruption, marital problems and financial implications. Efforts to improve the QoL of individuals should therefore also address the QoL of the families or caregivers. The concept of Family QoL has been described as being a situation where ‘the family needs are met...
and family members enjoy their life together as a family and have the chance to do things that are important to them’. Family QoL is considered to be an important outcome of services and policies, and should be analysed independently and additionally to the QoL of the patient. In some specialities, for example paediatrics, the QoL of the family is regarded as a part of the patient’s health. However, in dermatology, the awareness of the importance of this impact of disease on a patient’s family is relatively recent.

Because the lives of some people with skin disorders are severely disrupted and because family members are involved in caregiving, it would be expected that families’ lives would also be affected. The families of children with eczema have lower QoL than families of healthy children and taking care of a child with moderate to severe atopic eczema has been shown to be more stressful than caring for a child with insulin-dependent diabetes mellitus. Family QoL is related to the severity of eczema and can actually improve following specialist clinical care. The impact of a patient’s skin disease on family members has been studied in only a small number of dermatological conditions with most attention focused on atopic eczema.

Disease-specific instruments to measure the secondary impact of skin disease on the family have been described for atopic eczema. Although disease-specific instruments are good for tapping specific aspects of a certain disease, they do not allow generalizability. However, a generic instrument is useful not only for comparisons across different dermatoses and monitoring interventions, but also in meta-analysis research. In the same way that dermatology-specific measures such as the Dermatology Life Quality Index (DLQI) or Skin-dex can be used across a wide range of skin diseases, there is a need for a generic dermatology-specific instrument that could be used to measure the secondary impact on health-related QoL (HRQoL) of families across different skin diseases. If it was possible to quantify this secondary impact of skin disease, the awareness of the secondary impact would be enhanced, encouraging a clinical focus on addressing these problems. The existence of such a tool would allow its use as an appropriate outcome measure in clinical and health service research.

This paper describes the development and evaluation of an instrument to quantify the impact of a patient’s skin disease on family members—the Family Dermatology Life Quality Index (FDLQI). The aim was to construct and validate a generic dermatology-specific tool for the family members of patients, applicable to a wide range of skin diseases, which should be simple and user-friendly for clinical use and could serve as an additional outcome measure in evaluation research or clinical trials.

Materials and methods

This open prospective study was approved by the South East Wales Local Research Ethics Committee and completed in a number of stages. Written informed consent was given by participants at all stages.

Study sample

The main study participants were the immediate family members accompanying patients attending the dermatology outpatient clinic of the University Hospital of Wales, Cardiff. Inclusion criteria for the family members were age above 18 years, ability to understand and read the English language, having a close relationship with the patient and living in the same household. Family members were excluded if they or the patients had any other significant illness or disability that impaired their quality of life, in order to avoid confusion of that impact with dermatology-related HRQoL.

Interviews and item generation

Detailed semi-structured interviews were conducted with 50 family members or partners of patients with different skin diseases. Participants were encouraged to describe all the ways that their lives had been affected by living with a patient with skin disease. Enquiries were then made into those aspects of the family member’s QoL that were not mentioned by the participant but were considered important by the interviewer, using a checklist of possible HRQoL domains. From the content analysis of interview transcripts, 59 aspects of family members’ affected HRQoL were identified. These were categorized into main topic areas by a consensus of the investigators (Fig. 1). A preliminary draft questionnaire based on the main topic areas of family members’ HRQoL was formulated which contained 19 items, each given a four-point response and score format, i.e. not at all/not relevant = 0, a little = 1, quite a lot = 2 and very much = 3. All questions asked about the QoL impact over the last 1 month.

Pilot test

The purpose of the pilot test was to test the content and face validity of the draft questionnaire and to select appropriate items for the final questionnaire. A new cohort of 20 subjects who were immediate family members of patients attending the dermatology clinic was recruited. Each participant was given the draft questionnaire to complete and then asked to comment on the clarity, understandability and relevance of individual items and also to identify those aspects of family impact that were not covered in the questionnaire. At the same time, opinion was sought from 14 dermatology staff members regarding the practicality and face validity of the questionnaire.

Finalization of the questionnaire

The final selection of the items was based on the results of the pilot test and initial statistical analysis of the responses to assess the internal consistency of the items. Some of the items were rewritten or revised and some were amalgamated to enhance relevance and practicality and reduce ambiguity. The criteria adopted for item removal was that either the specific
item was endorsed by very few respondents or had low item–
total correlation (< 0.20). Because our aim was to develop
an instrument that would be both evaluative and potentially
sensitive to change, the items that were scored high by the
majority of the subjects were retained for the final question-
naire.

The present version of the questionnaire (the FDLQI) is
self-administered, contains 10 items (see Appendix) and can
be completed in 2–3 min. Each question inquires about the
family member’s perception of a certain specific impact on
his/her HRQoL over the last 1 month, a time consistent with
the episodic nature of many dermatological conditions, and is
scored on a four-point scale (0–3). The scores of individual
items are summed to generate a total scale score with a range
of 0–30; higher total FDLQI scores indicate greater impair-
ment of the family member’s HRQoL.

Psychometric evaluation of the Family Dermatology Life
Quality Index

The technical properties of the FDLQI were assessed on a new
cohort of family members and patients with various skin con-
ditions. Eligible family members/partners were given a copy
of the FDLQI to complete while the patients (only those older
than 16 years) were requested to complete the DLQI. The
DLQI is a self-administered questionnaire and consists of 10
questions, each scored on a four-point scale. Scores are added
to yield a total score; higher scores mean greater impairment
of patient’s HRQoL. A global question (GQ) was included at
the end of both the FDLQI and DLQI which asked the
respondent about his/her subjective assessment of the patient’s
disease severity over the last month on a 0–10 visual analogue
scale; 0 indicating ‘clear’ skin and 10 ‘worst possible’. The
medical record of the patient was used to ascertain the clinical
diagnosis. Enrolled participants were also given an envelope
containing the FDLQI with the GQ to self-assess disease sever-
ity, to complete after 1 week and return by post, but only if
they thought that the patient’s skin condition had remained
stable during this period. A subset of subjects was approached
3–6 months later at one of their routine follow-up visits by
one of the investigators (M.K.A.B.) and asked whether the
patients’ skin condition had changed (improved or deterior-
ated) since the last administration of the questionnaire. If it
had, the family members/partners were given the FDLQI with
the GQ about the patient’s disease severity to complete again.
At each stage questionnaires with more than one missing item
were excluded from analysis.

Factor analysis

For an instrument to be able to use a summed total score, it is
necessary to demonstrate that the instrument shows either
strict or essential unidimensionality. Strict unidimensionality
indicates the presence of a single common factor whereas
essential unidimensionality shows the presence of a reasonably
dominant common factor along with other secondary minor
factors. Exploratory factor analysis was performed on the 10
items to identify the factor structure underlying the FDLQI
items and to determine whether expected essential unidimen-
sionality was present to support the use of a total FDLQI score.
Because we expected that the factors would be interrelated,
we used the oblique rotation produced by the Oblimin
method followed by Kaiser normalization.

Reliability

The FDLQI was evaluated in terms of internal consistency
and test–retest reliability. Internal consistency was assessed by
means of Cronbach’s alpha (\(\alpha\)) coefficient, which expresses
the degree of consistency of the items. It has been suggested
that \(\alpha\) should be above 0.70 and not more than 0.90. \(\alpha\) coefficient values below 0.70 are regarded as indicative of

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individual items not adequately contributing to overall scale score, while a very high \( \alpha \) coefficient shows that items are measuring a common latent trait with a high level of item redundancy. Reproducibility (test–retest reliability) examines the stability of the scale on repeat measurement. It was determined by means of the intraclass correlation coefficient (ICC) using a one-way random effects parallel model. \(^{35} \) To ensure that only stable individuals were included for test–retest, only those questionnaires (returned within 1–2 weeks) were analysed in which the GQ rating about the disease severity had not changed by more than one point on the 0–10 scale.

Responsiveness to change

A subset of participants (family members) who confirmed that patients’ skin condition had changed completed the FDLQI (and GQ) 3–6 months later. To assess the sensitivity of the FDLQI to change, the difference in the scores on the two occasions was calculated as well as the difference in the disease severity GQ score. Based on the difference in the GQ (disease severity) score, subjects were divided into two groups: ‘improved’ (in whom the GQ score decreased) and ‘worsened’ (in whom the GQ score increased). The paired sample t-test was used to assess the within-group difference and the Mann–Whitney \( U \)-test was used to interpret the difference in FDLQI scores between improved and worsened groups. The Spearman’s rank correlation coefficient was used to determine the correlation between the change in FDLQI score and the change in the disease severity score.

Validity

We assessed the construct validity of the instrument by testing a number of a priori hypotheses.

Firstly, we hypothesized that there would be a moderate to high correlation between the HRQoL of the patient and the family. To assess this we compared the FDLQI scores of the family members with the DLQI scores of the patients (only those \( \geq 16 \) years of age) using Spearman’s rank correlation; here we expected to find strongly positive correlation.

Secondly, we hypothesized that family members of patients with inflammatory skin diseases would have greater impairment of their HRQoL when compared with the family members of patients with noninflammatory diseases or isolated lesions. To test this we divided the participants into two disease category groups: inflammatory (family members of patients suffering from inflammatory skin diseases, e.g. acne, eczema, psoriasis) and noninflammatory (family members with patients having noninflammatory diseases or isolated benign, premalignant or malignant lesions, e.g. naevi, viral warts, basal cell carcinoma (BCC), solar keratoses). Then we compared the FDLQI scores between the two disease categories using the Mann–Whitney \( U \)-test. Within-group analysis was also carried out to examine the relationship between different diseases and the family impact (e.g. psoriasis, eczema, acne).

Thirdly, we hypothesized that family impact would be related to the patient’s disease severity. \(^{36} \) Here we tested the correlation between FDLQI scores and the patient’s disease severity score (GQ), as rated by the family members using Spearman’s correlation coefficient.

All the statistical analysis was carried out on SPSS version 12.0 computer software (SPSS Inc., Chicago, IL, U.S.A.).

Results

Development of the questionnaire

Of the 51 family members recruited for interviews, one was later found to have a significant heart problem and was excluded. The demographic characteristics of the remaining 50 participants are shown in Table 1. The mean age of the family members was 48.1 (range 24–82) years; 19 were male and 31 were female. Most of them were either one of the parents (44%) or spouses/partners (44%) of the patients. The patients (mean age = 35.7 years; range 5 months–84 years) suffered from one of the 21 skin diseases shown in Table 1. Interview analysis identified 59 different aspects of family members’ life quality which were adversely affected by the patients’ skin diseases. These were grouped into main topic areas (Fig. 1). A detailed description of these initial interviews is presented elsewhere. \(^{37} \)

The most frequently described aspects were psychological distress (98%), burden of care (54%), social life (48%), holidays (46%) and housework (42%). The two least frequently mentioned aspects of life were the effect on sex life and the

<table>
<thead>
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<th>Characteristics</th>
<th>%</th>
<th>Diagnoses</th>
</tr>
</thead>
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<td>Sex</td>
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<td>Acne</td>
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<td></td>
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<tr>
<td>Ichthyosis</td>
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<td></td>
</tr>
<tr>
<td>Married</td>
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<tr>
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<td>24</td>
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</tr>
<tr>
<td>Divorced/widowed</td>
<td>10</td>
<td>Basal cell carcinoma</td>
</tr>
<tr>
<td>Malignant melanoma</td>
<td>4</td>
<td></td>
</tr>
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<td>Keratoacanthoma</td>
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</tr>
<tr>
<td>Solar keratosis</td>
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<td></td>
</tr>
<tr>
<td>Alopecia areata</td>
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<td></td>
</tr>
<tr>
<td>Angiodema</td>
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<td></td>
</tr>
<tr>
<td>Pemphigus</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Vitiligo</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Haemangiomma</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Lichen sclerosis</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Urticaria</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Incontinentia pigmenti</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Mycosis fungoides</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Dental sinus</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Table 1 Sociodemographic characteristics of subjects (n = 50) in the interview stage

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role of religious faith in coping with the patients’ illness (included here due to its major significance in some cultures and mentioned by some subjects during the interviews); each of these were described by only 8% of the participants. There was no statistically significant difference between the male and female participants in the frequency of any of the HRQoL aspects.

The present 10-item version of the FDLQI questionnaire was finalized after meticulous reviewing of the feedback from the family members of the patients and dermatology experts during the pilot test and initial psychometric testing of the 19 items. Items were removed if either the item–total correlation was < 0.28 or if it was endorsed by very few respondents.28

Evaluation of the questionnaire

Of the 141 family members/partners approached, five declined to participate for personal reasons. Two more were later dropped from analysis after finding from their medical records that they had other significant health issues not mentioned at the time of recruitment. Responses of two subjects were eliminated due to incomplete answers. The final psychometric analysis was carried out on data from 132 family members (of patients with 45 different skin conditions) who completed the FDLQI and 109 of their related patients (only those ≥16 years of age) who completed the DLQI. The sociodemographic characteristics of study participants are shown in Table 2 and the dermatological characteristics in Table 3. There was no statistically significant difference in the age of male and female participants [family members (P = 0.10), patients (P = 0.24)].

Family Dermatology Life Quality Index score distribution

Scores for the overall scale (0–30) ranged from 0 to 26, median = 7.0; mean = 8.02 and SD = 6.36, indicating the ability of the instrument to detect subject variability on a continuum of QoL impact (Table 4). There were no ceiling effects (i.e. maximum score of 30 not reached) and a minimum of floor effects with only 7.6% subjects scoring 0.

Using the mean score for individual items (range 0–3), the most highly scoring items were the emotional impact (1.39), burden of care (0.95), effect on the physical well-being of the family member (0.86), extra household expenditure (0.82) and problems due to people’s reaction to the patients’ skin appearance (0.80) (Fig. 2). Using the percentage (out of 132) responding positively (combining a little, quite a lot and very much), the most commonly reported QoL aspects were emotional aspect (79.5%), burden of care (60%), impact on physical well-being (53.1%) and extra household expenditure (53%). Although for each of the 10 items the female mean score was marginally higher than the male mean score, there was neither a statistically significant difference in the total FDLQI scores (M = 7.24, F = 8.43, P = 0.31) nor in the individual item scores (P = 0.08–0.91) between male and female subjects. However, there was a significant difference in the FDLQI scores (P < 0.001) of family members of patients 12 years of age or younger (mean FDLQI score = 12.4, SD = 6.6, n = 16) compared with those with family members older than 12 years (mean FDLQI score = 7.4, SD = 6.1, n = 116).

Caregivers can estimate the severity of patient’s disease accurately.36,38 The family members’ assessment of the patients’ disease severity (GQ) score ranged from 0 to 10, with a mean of 5.1 (SD = 2.8). The patients’ own assessment of their disease severity (GQ) mean score was 5.3 (SD = 2.8). There was a high correlation between the family members’ and patients’ subjective assessment of the patients’ disease severity (r = 0.69, Pearson’s rank correlation coefficient, P = 0.01).

Factor analysis

Factor analysis of the data (from 132 participants) was performed using principal component analysis followed by oblique rotation with Kaiser normalization.32 Based on the guidelines suggested by Gorsuch,31 i.e. 5–10 cases for each item, the sample size of our study (n = 132 for a scale of 10 items) was considered adequate for factor analysis. Two

<table>
<thead>
<tr>
<th>Total number of family members (n)</th>
<th>132</th>
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<tbody>
<tr>
<td>Males</td>
<td>45</td>
</tr>
<tr>
<td>Females</td>
<td>87</td>
</tr>
<tr>
<td>Mean age of family members (years)</td>
<td>49.2</td>
</tr>
<tr>
<td>Relation with patient (%)</td>
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<tr>
<td>Parents</td>
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<tr>
<td>Spouses/partners</td>
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<tr>
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<tr>
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<tr>
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<tr>
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<tr>
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<td>Residence (%)</td>
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<tr>
<td>Rural</td>
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<td>Educational status (%)</td>
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<td>Secondary</td>
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<td>Mean age of patients (years)</td>
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main factors were identified by retaining those factors with eigenvalues > 1; the first factor had an eigenvalue of 4.78 and accounted for about 12% of the variance (Table 5). The two factors together accounted for 60% of the common variance, which is higher than the minimum recommended (i.e. 50%) for a stable factor solution. The two extracted factors were significantly interrelated ($r = 0.48$), confirming that our approach of using oblique rotation was appropriate. Reckase has suggested that unidimensionality can be assessed through the eigenvalues of factors. A scale is considered to exhibit unidimensionality if there is one dominant factor. Another method to conclude unidimensionality is to calculate the ratio of the first and second factor eigenvalues. If the ratio is higher than a critical value, such as four, as suggested by some psychometricians, the scale is unidimensional. Figure 3 shows the scree plot that demonstrates the eigenvalues against each factor. As can be seen, from the first factor onwards the line is almost flat meaning that it is only the first factor that accounts for most

<table>
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<th>Component</th>
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<td>2</td>
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<td>7</td>
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<tr>
<td>9</td>
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<table>
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<th>%a</th>
<th>Group 2</th>
<th>%b</th>
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<td>Naevi</td>
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</tr>
<tr>
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<td>Solar keratosis</td>
<td>5</td>
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<tr>
<td>Acne</td>
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<td>Basal cell carcinoma</td>
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<td>Viral wart</td>
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<td>Haemangiomata</td>
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<td>Morphea</td>
<td>1</td>
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<td>1</td>
<td>Bowen disease</td>
<td>1</td>
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<tr>
<td>Erythema nodosum</td>
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<td>Squamous cell carcinoma</td>
<td>0</td>
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<td>11</td>
<td>Total</td>
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<table>
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<th>Overall FDLQI score</th>
<th>n</th>
<th>Mean score</th>
<th>SD</th>
<th>Range</th>
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<td>8</td>
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<tr>
<td>FDLQI—inflammatory</td>
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<td>0.30</td>
<td>1</td>
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<tr>
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<td>4</td>
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<td>0.47</td>
<td>0</td>
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<td>0.51</td>
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<td>0–26</td>
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<td>0.67</td>
<td>3</td>
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<tr>
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<td>0.89</td>
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<td>0–20</td>
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<tr>
<td>Psoriasis</td>
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<td>1.67</td>
<td>3</td>
<td>0–16</td>
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<td>Naevi</td>
<td>7</td>
<td>1.10</td>
<td>0</td>
<td>0–8</td>
</tr>
<tr>
<td>Basal cell carcinoma</td>
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<td>1.10</td>
<td>1</td>
<td>0–4</td>
</tr>
<tr>
<td>Solar keratosis</td>
<td>7</td>
<td>1.10</td>
<td>0</td>
<td>0–2</td>
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</table>

Table 3 Dermatological characteristics of patients in the validation stage

Table 4 Family Dermatology Life Quality Index (FDLQI) score distribution in various family member groups and main dermatoses

Table 5 Factor analysis: components and their eigenvalues with % of variance explained by each component
of the variance and each successive factor accounts for smaller and smaller amounts of the total variance. It has also been suggested that unidimensionality may hold if at least 20% of the variance is accounted for by the first factor. The variance explained by the first factor in our principal component analysis, which was about 48%, again supports the assumption of a dominant single underlying dimension. These results support the justification for using a single total FDLQI score. Items were then identified that loaded on each of the two components with standard regression coefficients of more than 0.50 (Table 6). Factors were labelled as Psychosocial impact, which loaded six items (emotional impact, physical well-being, impact on relationships, peoples’ reaction, social life and leisure activities) and Physical impact, which loaded four items (burden of care, additional housework, effect on job/study and extra household expenditure). The assignment of a particular item to a component was based on higher loading of the items of the scale contribute to the total score. The value of \( \alpha \) was more than the minimum of 0.70 required for a panel of items such as the FDLQI to be considered a scale, showing further that the individual items were contributing adequately to the overall scale score. All item-to-total score correlations were significant at \( P < 0.001 \).

Of the 64 (47.7%) respondents who returned the second set of completed questionnaires 1–2 weeks after the first administration, 13 were eliminated because the patients’ disease severity score self-assessed by the family member had changed by more than one point from the initial score. One more questionnaire was excluded due to incomplete responses. Final reproducibility (test–retest reliability) assessment was based on data from 50 respondents (37.8%) in whom the clinical severity of patients’ disease had not changed (assessed by maximum change in GQ score of one point). Test–retest reliability of the scale assessed by ICC, was 0.94, reflecting the scale’s ability to show reproducible results in stable subjects. For individual items the value of ICC ranged between 0.70 and 0.87 indicating substantial agreement between the two scores.

**Responsiveness to change**

Responsiveness of the scale to change was assessed on 27 family members 3–6 months after initial FDLQI administration at the routine follow-up visit of the patient. Only those subjects who reported that the patient’s skin condition was improved or worsened compared with the first administration were given the questionnaire to complete. Of these responses, only data from subjects in whom the subjects’ self-assessed disease severity (GQ score) was changed by two or more points were analysed (n = 27).

In those subjects who confirmed that the patients’ condition had improved (n = 17), the mean FDLQI score decreased from 11.4 to 4.8 (mean change = -6.6, SD = 3.3, Fig. 4a), which was highly significant (\( P < 0.0001 \)); the corresponding decrease in global rating of disease severity (GQ score) was from 6.9 to 3.9 (mean change = -3.0, SD = 1.3). In subjects who reported that the patients’ skin condition had worsened...
Validity

Construct validity of the FDLQI was assessed by testing the a priori hypotheses. There was strong correlation between the families’ FDLQI scores and patients’ DLQI scores ($r = 0.69$, Spearman’s rank correlation, $P = 0.01$) assessed in 109 paired subjects and patients (aged 16 years of age) (Fig. 5). The overall mean DLQI score was 8.12, $SD = 7.3$, range $= 0–29$, $n = 109$. This reflects that the overall level of impairment of the HRQoL of the family member is related to that of the patient.

The mean FDLQI score for the inflammatory group (mean $= 10.0$, $n = 90$) was much higher than for the non-inflammatory/isolated lesion group (mean $= 3.8$, $n = 42$, $P < 0.0001$) using the Mann–Whitney U-test. The difference was also significant across all the individual FDLQI items (Fig. 2) except for peoples’ reactions ($P = 0.1$). This result suggests that the magnitude and nature of the family impact differed between the two clinical groups and most of the items of the FDLQI were able to discriminate between the two clinical groups. Within-group analysis for two disease categories showed that the FDLQI scores were able to discriminate between different dermatoses (Table 4). The family impact within the inflammatory group was seen to differ ($P = 0.001$) between psoriasis (mean $= 6.7$, $SD = 2.9$, $n = 20$), eczema (mean $= 13.1$, $SD = 5.9$, $n = 20$) and acne (mean $= 8.9$, $SD = 5.6$, $n = 20$). Similarly for the noninflammatory/isolated lesions group, the FDLQI scores were clearly low as expected, e.g. benign naevi (mean $= 3.1$, $SD = 3.1$, $n = 7$), BCC (mean $= 1.6$, $SD = 1.7$, $n = 5$) and solar keratosis (mean $= 1.1$, $SD = 0.9$, $n = 7$).

The FDLQI scores and disease severity of the patient (GQ score), as assessed by the family member, were moderately correlated ($r = 0.49$, $P = 0.01$, $n = 132$, Spearman’s rank correlation) in the postulated direction confirming the hypothesis that family impact of skin disease is positively associated with the disease severity of the patient.

Discussion

The impact of many skin diseases is not limited to the patient but may extend to the rest of the family.44 Family members play a central role in the care of such patients, especially those with inflammatory skin disease, and so family impact data are potentially important components of the measurement of the overall burden of skin disease. In dermatology, measurement of this ‘secondary impact’ of skin diseases on the patients’ family members has largely been ignored except for atopic dermatitis. Families may not get the level of psychosocial support that they need, further affecting medical and economic outcomes.
This paper describes the development and initial validation of an instrument which is specific for the family members/partners of patients with a wide range of skin diseases. The evaluation of the FDLQI was conducted to meet the basic criteria\textsuperscript{28,45} necessary for an instrument to be scientifically valid and hence used with confidence.

The FDLQI measures family impact over the previous 1 month, a duration consistent with the episodic nature of many skin diseases\textsuperscript{3} and a reasonable period to attain stability after a change in therapy.\textsuperscript{6} The results of exploratory factor analysis support the assumption of unidimensionality and hence justify summing individual scale items to yield an overall scale score. The score ranged from 0 to 26, reflecting the measure’s sensitivity to variation in the family impact. To be sensitive to absence or presence of QoL impairment, QoL instrument scale scores should not have large floor or ceiling effects.\textsuperscript{46} A scale having a ceiling effect of more than 20% suggests that items with a higher range of impact measurement are needed to differentiate moderate cases from severe. In the same way, a floor effect of more than 20% is considered to be insensitive to important lower levels of impact on QoL.\textsuperscript{46} In this context, the FDLQI, having a minimal floor effect (7-6%) and no ceiling effect, would be expected to perform well in studies measuring change. The FDLQI demonstrates content validity on the grounds that its item content was based on the most frequently raised issues\textsuperscript{47} described by the patients’ families, confirmed during the pilot testing as well as by the consensus of experts in dermatology.

The reliability of the scale was clearly demonstrated; internal consistency and test–retest reliability were reasonably adequate with Cronbach’s $\alpha$ of 0.88 and ICC of 0.94. When an instrument is required for monitoring individuals or in clinical trials, an internal consistency reliability of Cronbach’s $\alpha$ in excess of 0.85 is needed.\textsuperscript{48} A high ICC value indicates that the scale was reproducible in stable subjects. Although our sample for responsiveness was not large, we were able to show sensitivity of the scale to change in subjects’ HRQoL with respect to change in clinical severity of patients’ skin disease. The FDLQI has demonstrated evidence of validity based on successfully testing the a priori hypotheses about its construct. We were able to demonstrate that a family’s HRQoL was not only related to the patient’s HRQoL, but it was also related to the clinical severity of the patient’s disease in the expected direction and as shown by others.\textsuperscript{17} In fact, one study of the family impact of atopic eczema\textsuperscript{16} demonstrated that the caregiver’s assessment of severity of the child’s eczema was the strongest predictor of the secondary family impact. The known group validity of the FDLQI was also demonstrated by its ability to differentiate between groups on the basis of the nature of skin disease as predicted, i.e. the inflammatory skin disease group having significantly higher score than the non-inflammatory/isolated lesions group. One of our findings was that eczema causes more impairment of family’s HRQoL than psoriasis ($P < 0.0001$); this complements the previous finding that HRQoL of eczema patients is more affected than that of psoriasis patients.\textsuperscript{5,29} This possibly reflects the relatively younger and more family-dependent age of onset in eczema patients as well as the more itchy nature of eczema than psoriasis.

There are several limitations of our study. There was a relatively small sample size and recruitment of convenience samples, which implies that scores and prevalence estimates could be applied only to those who participated in the study. Further studies in different settings and different populations should be carried out to confirm our findings on family impact. Although the preliminary analysis has provided some evidence of the probable unidimensionality of the instrument, we feel more work, as suggested by Mazzotti et al.,\textsuperscript{59} is required to confirm this issue. Further evidence needs to be collected of the responsiveness of the instrument to clinical change, for example before and after hospital admission or other major intervention. There will also be a need to define the meaning of FDLQI scores\textsuperscript{50} as well as the minimal important difference for overall FDLQI score. The establishment of validity is an ongoing process and there is no gold standard against which QoL instruments can be validated.\textsuperscript{51} Measuring other aspects of validity, such as convergent and divergent validity, by comparing FDLQI scores with other generic family-oriented QoL scales would increase our confidence in the use of the instrument and further strengthen its potential usefulness in clinical practice and observational research.

One motivation for this study has been a wish to heighten awareness of a very major consequence of skin disease, which up to now has been largely ignored. If a concept cannot be measured it attracts little scientific attention; by proposing for the first time a method applicable to all skin diseases to score the secondary impact of skin disease on life quality of family members, it is hoped that attention will be focused on this important aspect of clinical dermatology.

The ability to identify and score this secondary impact may encourage the development of new strategies to alleviate this impact and will allow the assessment of such strategies. The FDLQI could potentially be used as an additional outcome measure for health service research and clinical trials. A speciality-specific measure, such as the FDLQI, may complement generic health status measures in addressing issues concerning health services funding and the distribution of resources between specialities.\textsuperscript{52}

There was very high acceptance of and interest in the FDLQI by respondents. Many commented on the great impact caused to them by their family members’ skin disease and often mentioned that this burden had never before been acknowledged by health service providers. This very strong feedback has encouraged us to consider that these concepts do need to be understood, measured and acted upon.

In conclusion, the FDLQI was developed to meet the need for a comprehensive yet simple and practical instrument for general clinical use and as an additional outcome measure in dermatology for research and clinical trials. It is easy to complete and score and seems reliable, valid and responsive to improvement or deterioration in HRQoL.
Acknowledgments

We wish to thank the dermatology patients, their family members and dermatology staff for their help with this study. In particular we wish to thank Sister Anne Thomas for advice on ethical issues and Mrs Susan Williams for her help.

References


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The Family Dermatology Life Quality Index, M.K.A. Basra et al. 537

Appendix: the Family Dermatology Life Quality Index (FDLQI)

Name: ................................................ FDLQI Score  ................................................
Relationship with patient: .............................................
Patient’s diagnosis (if known): ............................................. Date: .............................................

- The questions relate to the impact of your relative/partner’s skin disease on your quality of life over the last month.
- Please read the questions carefully and tick one box for each.

1. Over the last month how much emotional distress have you experienced due to your relative/partner’s skin disease (e.g. worry, depression, embarrassment, frustration)?
   Not at all/Not relevant □ A little □ A lot □ Very much □

2. Over the last month how much has your relative/partner’s skin disease affected your physical well-being (e.g. tiredness, exhaustion, contribution to poor health, sleep/rest disturbance)?
   Not at all/Not relevant □ A little □ Quite a lot □ Very much □

3. Over the last month how much has your relative/partner’s skin disease affected your personal relationships with him/her or with other people?
   Not at all/Not relevant □ A little □ Quite a lot □ Very much □

4. Over the last month how much have you been having problems with other peoples’ reactions due to your relative/partner’s skin disease (e.g. bullying, staring, need to explain to others about his/her skin problem)?
   Not at all/Not relevant □ A little □ Quite a lot □ Very much □

5. Over the last month how much has your relative/partner’s skin disease affected your social life (e.g. going out, visiting or inviting people, attending social gatherings)?
   Not at all/Not relevant □ A little □ Quite a lot □ Very much □

6. Over the last month how much has your relative/partner’s skin disease affected your recreation/leisure activities (e.g. holidays, personal hobbies, gym, sports, swimming, watching TV)?
   Not at all/Not relevant □ A little □ Quite a lot □ Very much □

7. Over the last month how much time have you spent on looking after your relative/partner (e.g. putting on creams, giving medicines or looking after their skin)?
   Not at all/Not relevant □ A little □ Quite a lot □ Very much □

8. Over the last month how much extra housework have you had to do because of your relative/partner’s skin disease (e.g. cleaning, vacuuming, washing, cooking)?
   Not at all/Not relevant □ A little □ Quite a lot □ Very much □

9. Over the last month how much has your relative/partner’s skin disease affected your job/study (e.g. need to take time off, not able to work, decrease in the number of hours worked, having problems with people at work)?
   Not at all/Not relevant □ A little □ Quite a lot □ Very much □

10. Over the last month how much has your relative/partner’s skin disease increased your routine household expenditure (e.g. travel costs, buying special products, creams, cosmetics)?
    Not at all/Not relevant □ A little □ Quite a lot □ Very much □

Thank you for completing the questionnaire.

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