Acne-specific Quality of Life Questionnaire (Acne-QoL) Manual & Interpretation Guide

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Contents

Development of the Acne-QoL

I.   Background and History

The Acne-specific Quality of Life questionnaire (Acne-QoL) is a health-related quality of life instrument developed for use in clinical trials to assess the impact of therapy on quality of life among persons 13-35 years of age with facial acne.

Conceptual Framework

Acne is a common condition affecting nearly 100% of young adults. It appears to be more prevalent in men than in women.   Physiologically, acne is a common inflammatory pilosebaceous disease consisting of a mixture of open and closed comedones (blackheads and whiteheads), papules, pustules and nodules of varying number and size[1]. A complex interplay between hormones, follicular keratinization, sebum and bacteria determines the severity of acne. Acne typically begins at puberty when the increase in androgens causes an increase in size and activity of the pilosebaceous glands, and incidence peaks at about 18 years. The condition is often improved in the summer with exposure to sun. In severe cases, irreversible scarring may occur.

Much of the literature on acne is devoted to assessment of acne in terms of lesion counts or grading classifications as well as measuring response to medical intervention using global improvement rated by the dermatologist and patient. Although global questions can detect change from initiation of treatment, it is not usually possible to see changes in certain aspects of a patient's quality of life.   A good portion of the literature therefore, is devoted to the psychological aspects of acne, in terms of increased anxiety and possibly depression, social withdrawal or isolation, and lack of self-confidence[2-17].   Several reports show a lack of correlation between physician global evaluation and patient assessment of condition and change in condition. This lack of correlation suggests that there may be certain aspects of the disease which are important to the patient but are not captured by general measures. In addition, these aspects may be what prompt patients to seek care and undertake treatment. In most cases, however, non-standardized unvalidated scales were used to assess the social and psychological attributes of patients, and in cases where standardized scales were used, the scales were typically developed for evaluating psychiatric patients instead of acne patients. Disease-specific measures have greater power of detecting important differences by focusing on aspects most affected by the disease, and of greater importance to the patient.

A few recent efforts to quantify the impact of facial acne on health-related quality of life have resulted in several acne-specific instruments such as the Acne Disability Index (ADI)[10], Cardiff Acne Disability Index[18], and Dermatology-specific Quality of Life (DSQL)[19] instrument. The DSQL in particular was developed for use within clinical trials of facial acne patients, however the responsiveness of the instrument at the time of this writing was not known.

Since acne can have profound effects on patients' lives, and since improvements in health-related quality of life after receiving different therapeutic interventions with different efficacy and side

effect profiles may vary, an effort was undertaken to develop an instrument suitable for use in clinical trials of therapeutic interventions for acne.

II. Selection and Origin of Items

The strategy used to develop the questionnaire involved four phases, item generation, item reduction, piloting and assessment of measurement characteristics. The development of the instrument has been described in detail elsewhere and is summarized below[20].

Phase I: Item Generation

The objective of the item generation phase was to identify aspects of health-related quality of life (HRQL) that were affected by acne according to individual subjects. Items were generated through a review of the acne literature, discussion with clinical experts who treat acne patients, and detailed, unstructured one-on-one interviews by a well-trained interviewer with subjects judged to be articulate about their experience(s) with facial acne. Criteria for recruitment of the twenty-five interviewees with acne aged 13-35 years included a willingness to state aspects of their lives affected by acne, and recruitment was achieved through advertisement. Although a population-based random sample was not practical, effort was made to ensure that a broad spectrum of patients were included in terms of facial acne severity, age, gender and educational level. Interviews were audio-taped and subsequently transcribed to ensure that important items were not overlooked. The items identified from the three sources (literature review, discussion with clinical experts and interviews with acne patients) were compiled and used to construct an initial self-administered importance ranking questionnaire designed to be widely inclusive for use in the item reduction phase.

Phase II: Item Reduction

The item reduction phase assessed frequency and patient-perceived importance of HRQL items generated in the previous phase. Subjects with facial acne (n=165) were recruited from several sources: (1) subjects visiting a dermatologist for their acne, (2) subjects responding to advertisements from a large work site in Pennsylvania, and (3) subjects who responded to public announcements from a local community college. The latter two sources were included to reduce the potential referral or health care seeking behavior bias which might be present when only including patients in dermatology clinics. Because acne is a prevalent condition for which subjects often do not seek care, this approach was believed to promote better representativeness given the impracticability of recruiting a population-based random sample. Interested individuals were asked if they would be willing to complete a questionnaire on how acne affected certain aspects of their quality of life. Eligible subjects were 13-39 years of age with facial acne. Each item identified in the item generation phase was listed in a self-administered questionnaire, which asked subjects to recall their experiences with acne, identify the items that they felt negatively affected their quality of life and to rate their importance on a 5-point scale from "not very important" to "extremely important." Frequency was then defined as the proportion of patients identifying a certain item as being affected by acne, and mean importance was obtained by averaging participant 5-point ratings of importance. Each item was ranked

for its overall importance, determined by multiplying the proportion of subjects who identified the item as important in impairing their quality of life (frequency) by the mean importance score of the item. In addition, principal component factor analysis with varimax rotation was performed in order to categorize items into interpretable subsets and to establish meaningful domains. To avoid relying solely on such analysis for domain composition, the investigators scrutinized the items comprising each domain for relevance to the domain construct. Little difference was found between factor analysis results and composition of domains according to the investigator opinions prior to item reduction, supporting the statistical and clinical meaningfulness of the domains.

Phase III: Piloting

The pilot-testing phase was conducted to determine if the questions and the instructions on the questionnaire were easy to understand and answer. Subjects (13-41 years of age) with facial acne and varying levels of education and acne severity were recruited. Initially, nine participants completed the questionnaire and were then interviewed to determine the following: (1) does each question measure what it is intended to measure? (2) are questions answered correctly? (3) are the response categories exhaustive enough? (4) is each question clear, simple and easy to understand? (5) are the instructions clear, concise and easy to understand? (6) does the subject feel that the questionnaire asks appropriate questions on how acne affects their HRQL (i.e., have good face validity)? The questionnaire was then modified based on comments from the participants. The modified questionnaire was then administered to another group of eight subjects with acne to assure that no further difficulties existed in completing the questionnaire.

In all phases, subjects were required to have facial acne, but were otherwise in good health. Participants were not necessarily currently under the care of a dermatologist. Potential subjects were excluded if they had a history of drug or alcohol abuse or had poor understanding of English. Written informed consent was obtained from all subjects before their participation in any phase of the study. For subjects under the age of 18 years, written permission to participate in the study was obtained from the subjects' parent and/or legal guardian. Except for those recruited from the major work site, all subjects received a small reimbursement for their travel costs. Acne severity of the participants in each phase was assessed by a dermatologist or raters trained by a dermatologist according to the 1991 American Academy of Dermatology (AAD) Consensus Panel recommendations[21].

Phase IV: Assessment of Measurement Characteristics[23]

Male and female subjects (13-35 years) falling into one of two categories were recruited as they presented for routine care of their facial acne at a central Pennsylvania teaching university dermatology clinic. The first category was comprised of patients with acne presenting for standard treatment other than isotretinoin (Accutane®) who had not received topical treatment within 2 weeks or systemic treatment for acne within one month prior to the baseline visit and who met the following criteria for acne: <= 3 nodules, at least 15 inflammatory lesions, and at least mild by the AAD classification.

The second category of participants were patients with acne who were to be prescribed isotretinoin for the first time.

An Institutional Review Board approved the study protocol and informed consent form. Upon entering the study, eligible participants were asked to complete the acne-specific quality of life questionnaire (Acne-QoL). One week later, the participants returned to the clinic for global photography to be used for reference at the end of the study in assessing improvement, lesion counts using a facial template as described by Lucky et al[22], and patient- and dermatologist-rated acne severity ratings, along with a second administration of the Acne-QoL instrument. Patient perceptions of acne severity were completed using a 5-point scale (minimal, mild, moderate, severe, very severe) and the AAD classification (mild, moderate, severe) was used for physician assessments. Patients were instructed at this time to begin taking medications prescribed one week earlier. All study medications were recorded on the case report forms. Participants returned at weeks 12 and 16 for lesion counting, acne severity assessments, therapy efficacy assessments and to complete the Acne-QoL.

Final testing of the questionnaire in two randomized, double-blind, placebo-controlled clinical trials was performed and is summarized in Fehnel et al[24].

III. Summary of Concepts and Measures

As discussed above, the Acne-QoL questionnaire contains questions organized into four domains which address the impact of facial acne on health-related quality of life. These are Self Perception, Role-social, Role-emotional and Acne Symptoms. The items included within each domain are those which facial acne sufferers consider important[20], which can distinguish between acne severity groups and were responsive to changes in acne severity over time following treatment[23] in an uncontrolled study. For all domain scores, the responses to items comprising the domain are summed, and no weighting scheme is used. Table 1 presents the four domains and the items which comprise each domain with the corresponding Acne-QoL question numbers .

Self Perception

The Self Perceptions domain of the Acne-QoL is comprised of 5 questions. In each question, the respondent is asked the extent to which their facial acne has affected a particular area of their self perception over the past week. Items such as feeling self-conscious, feeling unattractive, dissatisfaction with self appearance are included in the domain. The response options are on a 0-6 scale (extremely, very much, quite a bit, a good bit, somewhat, a little bit, not at all). The range of possible scores is 0 to 30.

Role-social

The Role-social domain of the Acne-QoL is comprised of 4 questions which attempt to assess the impact of facial acne on a respondent's intersocial relationships. For example, questions related to going out in public, meeting new people, and socializing

are included. The response options are on 0-6 scale (extremely, very much, quite a bit, a good bit, somewhat, a little bit, not at all).   The range of possible scores is 0 to 24.

Role-emotional

The Role-emotional domain is focused on the emotional effect or impact of facial acne. The domain includes questions about the respondent's annoyance at having to spend time cleaning and treating their face, their worry or concern that medications were working fast enough, the bothersomeness of needing to always have cover-up available, etc. The response options are on a 0-6 scale exactly as the same as that for the Self Perceptions and Role-social domains, ranging from "extremely" to "not at all". The range of possible scores is 0-30.

Acne Symptoms

The final domain of the Acne-QoL is aimed at assessing the physical symptoms experienced by facial acne sufferers, which acne patients rated as frequent and important. The response options for this domain are on a 0-6 scale (extensive, a whole lot, a lot, a moderate amount, some, very few, none) and differs from the above domains for several of the questions . Five questions comprise the Acne Symptoms domain covering symptoms such as the number of bumps on the face, the extent of scabbing from the acne, and the level of worry associated with scarring from the acne. Possible domain scores range from 0 to 30.

Table 1: Content Areas of Acne-QoL Domains

Self Perception		Role-emotional	
1	Feel unattractive	5	Spending time treating face
3	Feel self-concious	9	Need to have meds or cover-up available
10	Self-confidence affected	8	Meds won't clear face fast enough
2	Feel embarrassed	7	Not looking your best
6	Dissatisfied with self appearance	4	Feel upset
Role-Social		Acne Symptoms	
12	Going out in public	15	Bumps on face
11	Meeting new people	16	Bumps full of pus
14	Interacting with opposite sex (or same sex if gay) a problem	17	Scabbing from acne
13	Socializing with people a problem	18	Concerned with scarring
		19	Oily skin

**IV.	Application of the Acne-QoL**

The Acne-QoL instrument was developed to characterize the impact of facial acne on mild, moderate and severe facial acne sufferers between the ages of 13 and 35. It was developed for use in clinical trials of experimental medications for the treatment of facial acne. Although the instrument was shown to be responsive to 'usual care' treatment over a 16-week time period, the performance of the questionnaire within a randomized controlled clinical trial has not yet been assessed. Modifications to the instrument may be necessary based on analyseis of controlled clinical trial data.

**V.	Administration of the Acne-QoL**

The Acne-QoL was developed as a self-administered questionnaire. The completion of the instrument should take about 10 minutes, and no longer than 15 minutes. Because the survey instrument is intended to assess the impact of facial acne on mild, moderate and severe acne sufferers, dermatologist office-based distribution of the instrument is appropriate. The reliability and validity of oral administration by face-to-face or telephone interview has not been assessed. Note that the instrument was developed in both males and females within the age range of 13-35; therefore, it is unknown how applicable some of the questions may be to patients outside this age range.

It is required that each respondent be capable of reading and understanding English. If a respondent does not read English, he or she will be unable to participate in completing the questionnaire. If a participant has difficulty reading the instrument due to visual limitations, offer a large-type version of the Acne-QoL.

In a clinic or dermatology office setting, the Acne-QoL should be administered prior to meeting the physician. If other questionnaires are to be administered at the same time, the Acne-QoL should be completed first so that answers to other questionnaires do not influence the responses to the Acne-QoL.

All respondents should be encouraged to answer each question. If the respondent asks for clarification of a particular item, read the question to the subject verbatim. If the respondent still asks for clarification, explain to him/her that he/she should use his/her own interpretation of the question. If necessary, guide the participant to answer each question with the response which most closely corresponds to his/her feelings. (See Instructions for Using the Acne-QoL in Appendix B)

**VI.	Scoring the Acne-QoL**

Standardization

As with all scored questionnaires, it is important that the administration and scoring of the Acne-QoL be as standardized as possible across all participants. The administration guidelines and scoring rules presented in this manual are meant to help ensure the reliability and validity of scores reported above and in future studies using the Acne-

QoL. The standardization also enables researchers to make meaningful comparisons across studies, where appropriate.

General Scoring Information

The scoring of the Acne-QoL should proceed in the following manner: 1) code each response. Responses are numbered starting with '0' in ascending order (ie. extremely=0, very much=1, quite a bit=2, a good bit=3, somewhat=4, a little bit=5, not at all=6); Please note that coding begins on the left with 0, and that 'not at all' is actually coded as a 6; this coding scheme was adopted so that higher scores for each domain in Acne-QoL reflect increased health related quality of life, ie. less negative self perception, social, emotional and symptomatic effects associated with acne. 2) check for missing data and code missing values as indicated below; 4) calculate overall domain scores for each domain by summing the coded responses to each question in the domain; 5) perform scoring checks.

Missing Values

Every effort should be made to reduce missing data in the questionnaire, and the questionnaire should be reviewed for completeness while the patient is present in order to allow obtaining responses to questions which may have been inadvertently skipped.

Within each domain, a minimum number of responses is required in order to score the domain. At least 3 items must be answered within each domain in order to calculate the domain scores. If the minimum number of items have been answered but 1-2 questions have missing responses, calculate the mean value within the domain for the answered items and replace missing values with the mean value. This assumes that responses to the missing questions would have been similar (on average) to the responses for the non-missing items, by simply using a weight to adjust the sum of the non-missing items for the missing items. Using substitution of the mean is a straightforward way to accomplish this. If fewer than the minimum number of items have been answered, the domain score should not be calculated.

Calculation of Domain Scores

Calculation of the domain scores is accomplished by simply summing all item responses within each domain (after replacing missing values). Domain weights are not necessary because each item contributes the same amount of information to the domain scores.

Scoring Checks

After coding the questionnaires, entering the data and computing domain scores, scoring checks should be conducted. Routine range checking, correlation analysis of items within domains and manual calculation of domain scores on a sample of the respondents is suggested. Any errors in scoring could be a result of incorrect statistical programs, errors at data entry or improper coding of data, among others. The user is responsible for ensuring that the data collected using the Acne-QoL is valid and accurate.

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Appendix A
Acne-specific Quality of Life Questionnaire (Acne-QoL)

Date: _____

Acne-Specific Quality of Life Questionnaire (Acne-QoL)

ID Number:

(Please check one box for each question)

1.	In the past WEEK, how unattractive did you feel because of your facial acne?

extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
☐	☐	☐	☐	☐	☐	☐

2.	In the past WEEK, how embarrassed did you feel because of your facial acne?

extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
☐	☐	☐	☐	☐	☐	☐

3.	In the past WEEK, how self-conscious (uneasy about oneself) did you feel about your facial acne?

extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
☐	☐	☐	☐	☐	☐	☐

4.	In the past WEEK, how upset were you about having facial acne?

extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
☐	☐	☐	☐	☐	☐	☐

5.	In the past WEEK, how annoyed did you feel at having to spend time every day cleaning and treating your face because of your facial acne?

extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
☐	☐	☐	☐	☐	☐	☐

6.	In the past WEEK, how dissatisfied with your self-appearance did you feel because of your facial acne?

extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
☐	☐	☐	☐	☐	☐	☐

7.	In the past WEEK, how concerned or worried were you about not looking your best because of your facial acne?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

8.	In the past WEEK, how concerned or worried were you that your acne medication/products were working fast enough in clearing up the acne on your face?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

9.	In the past WEEK, how bothered did you feel about the need to always have medication or cover-up available for the acne on your face?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

10.	In the past WEEK, how much was your self-confidence (sure of yourself) negatively affected because of your facial acne?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

11.	In the past WEEK, how concerned or worried were you about meeting new people because of your facial acne?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

12.	In the past WEEK, how concerned or worried were you about going out in public because of your facial acne?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

13.	In the past WEEK, how much was socializing with people a problem for you because of your facial acne?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

14.	In the past WEEK, how much was interacting with the opposite sex (or same sex if gay or lesbian) a problem for you because of your facial acne?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

15.	In the past WEEK, how many bumps did you have on your face?						
	Extensive	A whole lot	A lot	A moderate amount	Some	Very Few	None
	☐	☐	☐	☐	☐	☐	☐

16.	In the past WEEK, how many bumps full of pus did you have on your face?						
	Extensive	A whole lot	A lot	A moderate amount	Some	Very Few	None
	☐	☐	☐	☐	☐	☐	☐

17.	In the past WEEK, how much scabbing from your facial acne did you have?						
	Extensive	A whole lot	A lot	A moderate amount	Some	Very Few	None
	☐	☐	☐	☐	☐	☐	☐

18.	In the past WEEK, how concerned or worried were you about scarring from your facial acne?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

19.	In the past WEEK, how oily was your facial skin?						
	extremely	very much	quite a bit	a good bit	somewhat	a little bit	not at all
	☐	☐	☐	☐	☐	☐	☐

Appendix B
Instructions for Using the Acne-QoL Questionnaire

Administration of Acne-QoL

The purpose of this questionnaire is to record the patient's feelings and opinions concerning the effects of acne on health-related quality of life. ***Please review these guidelines carefully and adhere to them during the study.***

The Acne-QoL is self-administered (i.e., the patient is able to complete the questionnaire without assistance). Since validation of the Acne-QoL was done assuming the questionnaire is self-administered, the questionnaire has not been validated for oral administration by an interviewer. The questionnaire should take approximately 10 minutes or less to complete. Review the questionnaire and the patient instructions with the patient to ensure that there is no misunderstanding about how the questionnaire should be completed.

If possible, the patient should complete the questionnaire in a quiet and private setting (in the absence of family or friends). If possible, have the patient work at a table or desk.

<u>Required Instructions to Patient</u>

1) Emphasize that we are interested in **the patient's own opinions** about the questions on the questionnaire, not the opinions of his or her doctor, nurse, family or friends. Inform the patient that there are no right or wrong answers.

2) Tell the patient to read the instructions before completing the questionnaire. **Ask the patient to read the questions carefully because in some questions, the response options differ.**

3) Make sure that the patient understands that the questions refer to experiences during the time period specified in the questions (*in the past week*).

4) Tell the patient the questionnaire must be completed with a black ballpoint pen.

5) Emphasize that the patient must answer **all** of the questions.

6) Tell the patient that if he or she is not sure how to answer or does not understand the question, to read the question again carefully and answer based upon his or her best understanding of the question.

7) The patient must write his or her initials and date next to any changes made to answers on the questionnaire.

8) Tell the patient that all answers will remain confidential.

9) Emphasize the importance of collecting this information about the patient's health-related quality of life. The results may help in the development of treatments that improve the health-related quality of life for acne patients in the future.

When the patient returns the questionnaire to the study site, a study coordinator should review the questionnaire for completeness and to make sure the answers make sense (i.e., the answers go in the appropriate directions). If any confusion remains, the study coordinator should write a

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brief explanation in the margin of the questionnaire, or attach a note to the questionnaire, explaining why the confusion exists. Do not question the patient about his/her reasons for selecting an answer. However, if a patient completely omitted response to a question(s), the study coordinator should ask the patient to complete that question or those questions prior to the patient leaving the clinic.

Responding to Patient Questions:

Explain the instructions or the specific procedures for the questionnaire in a manner that the patient understands.

If the patient asks the meaning of a specific word, you may define that word. If the patient asks the meaning of a question, **DO NOT** explain or paraphrase the question. However, you may read the question aloud exactly as it is printed. If the patient continues to have difficulty understanding the question or how to answer, explain that you are not permitted to give any further help. Instruct the patient to place an 'X' in the box that best answers the question according to his or her best understanding of the question.

If the patient indicates he/she does not know how to answer a question because it does not apply, tell the patient to place an 'X' in the box that best answers the question according to his or her best understanding of the question. If the patient says that he or she cannot, or will not, answer a question, tell him or her that it can be left blank (after encouraging him or her to try to answer).