



FACE-Q[®] | SKIN CANCER

A User's Guide for Researchers and Clinicians

Information in this document is subject to change without notice. Complying with all applicable copyright laws is the responsibility of the user. No part of this document may be reproduced or transmitted on any form or by any means, electronic or mechanical, for any purpose, without the express written permission of Memorial Sloan Kettering Cancer Center. Copyright©2016 Memorial Sloan Kettering Cancer Center. All Rights Reserved.

Printing History: October 2017
May 2022

Trademarks: FACE-Q[®] is a registered trademark. Other products and company names mentioned herein may be the trademarks of their respective owners. While every precaution has been taken in the preparation of this User's Guide, the publisher assumes no responsibility for errors or omissions, or for damages resulting from the use of information contained herein.

Licensing: The FACE-Q | Skin Cancer patient-reported outcome measure was authored by Drs Anne Klassen, Andrea Pusic, and Stefan Cano. The copyright to the work is owned by Memorial Sloan Kettering Cancer Center (New York City, USA). Users must sign a Licensing Agreement. The FACE-Q | Skin Cancer can be used free of charge for non-profit purposes (e.g., clinicians, researchers and students). For-profit users (e.g., pharmaceutical companies) are required to pay a licensing fee. For more information, contact: qportfolioteam@gmail.com

Table of Contents

1. What is the FACE-Q Skin Cancer?	2
2. How was the FACE-Q Developed and Validated?	2
3. FACE-Q Skin Cancer Scales	6
4. Administration of the FACE-Q Skin Cancer	7
5. Scoring the FACE-Q Skin Cancer	7
6. Conditions of Use	8
7. Frequently Asked Questions	9
8. Publications Related to FACE-Q Development and Validation	12

1. What is the FACE-Q | Skin Cancer?

The FACE-Q is a patient-reported outcome measure (PROM) that can be used to evaluate healthcare experience and outcomes after facial skin cancer procedures from the patient's perspective. The FACE-Q Skin Cancer can be used to measure outcomes that matter to patients having any type of facial skin cancer surgery.

2. How was the FACE-Q Developed and Validated?

The FACE-Q represents a new generation of PROMs developed using a modern psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PROM are designed to measure and score a unidimensional construct. In scale development, data that meet the requirement of the Rasch model provide interval-level measurement. When a scale has high content validity and is targeted to measure a concept as experienced by a sample, accurate tracking of clinical change can be achieved. In addition to their use in research studies, FACE-Q scales can be used with individual patients to inform clinical care.

Figure 1 shows the multiphase mixed methods approach used by our team to develop PROMs. We followed internationally recommended guidelines for PROM development to ensure that FACE-Q meets requirements of regulatory bodies.

In phase 1, qualitative interviews were conducted with 15 patients who had different types of facial skin cancer. The interviews were used to elicit concepts important to patients. We identified five major themes on the impact of skin cancer surgery: appearance-related concerns; psychological (e.g., fear of new cancers or recurrence); social (e.g., impact on social activities and interaction); physical (e.g., pain and swelling) concerns, and satisfaction with the experience of care (e.g., satisfaction with information). The qualitative data were used to form a set of scales that were refined through cognitive interviews with patients and input from experts.

In phase 2, the FACE-Q was field-tested at Memorial Sloan Kettering Cancer Center (USA) between July 2014 and July 2015. A sample of 209 patients were recruited and provided 326 assessments. The sample ranged in age from 25 to 92 years (mean=64) and included 113 females and 96 males. Participants had the following types of skin cancer: basal cell carcinoma (N=143), squamous cell carcinoma (N=40), melanoma (N=25), or other skin cancer (N=1).

RMT analysis provided evidence of reliability and validity of five FACE-Q Skin Cancer scales. These scales measure appearance (of face and scars), health-related quality of life (appearance-related distress, cancer worry), and satisfaction with information. Figure 2 shows the FACE-Q Skin Cancer conceptual framework. All items had ordered thresholds and good psychometric fit. Reliability was high (person separation index and Cronbach's alpha ≥ 0.90) and scales measuring similar constructs were correlated. In

addition, the Cancer Worry scale was shown to measure responsiveness in a subset of 63 participants who completed the scale before and after surgery.

The item set for two FACE-Q scales did not work together statistically (i.e., the item set did not map out a clinical hierarchy for the concept of interest), and instead formed checklists. These checklists measure sun protection behavior and adverse effects of treatment. The checklists can provide clinically important information, such as monitoring for post-operative adverse effects.

Figure 1: Multiphase mixed methods approach taken by our team to develop PRO measures (Reprinted from Riff KW, Tsangaris E, Goodacre T, et al. International multiphase mixed methods study protocol to develop a cross-cultural patient-reported outcome instrument for children and young adults with cleft lip and/or palate. *BMJ Open*. 2017;7(1):015467.)

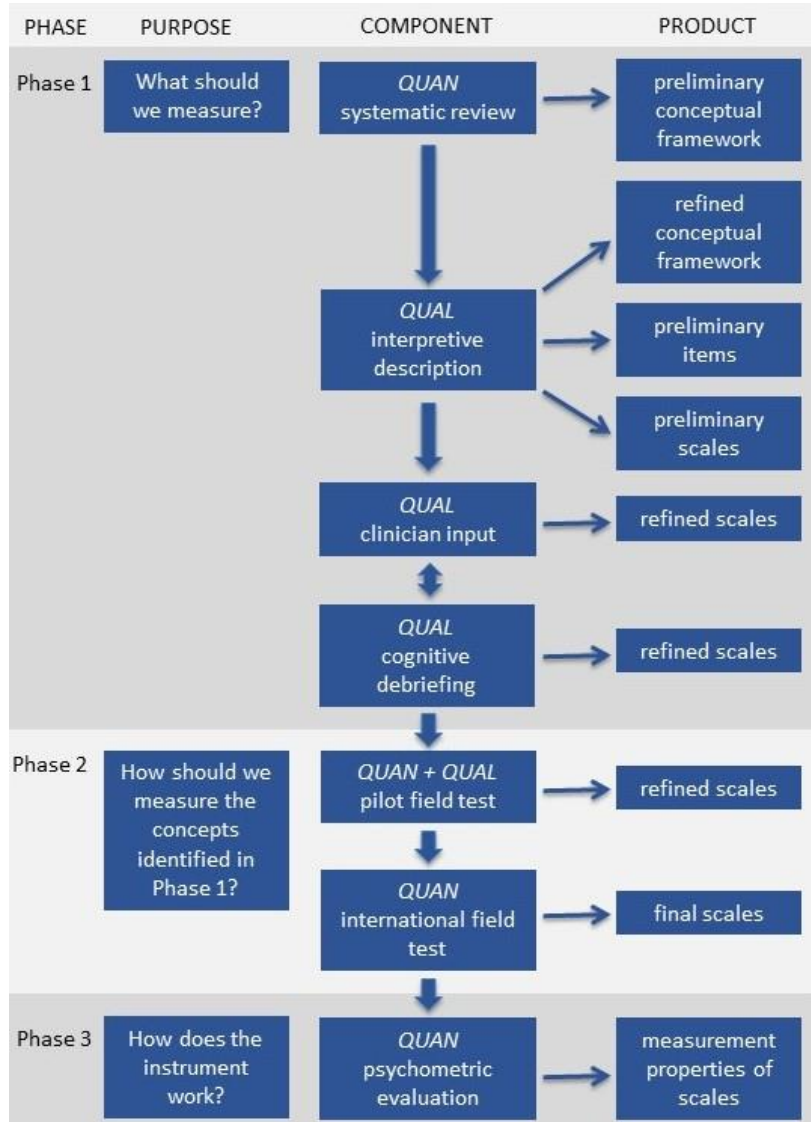
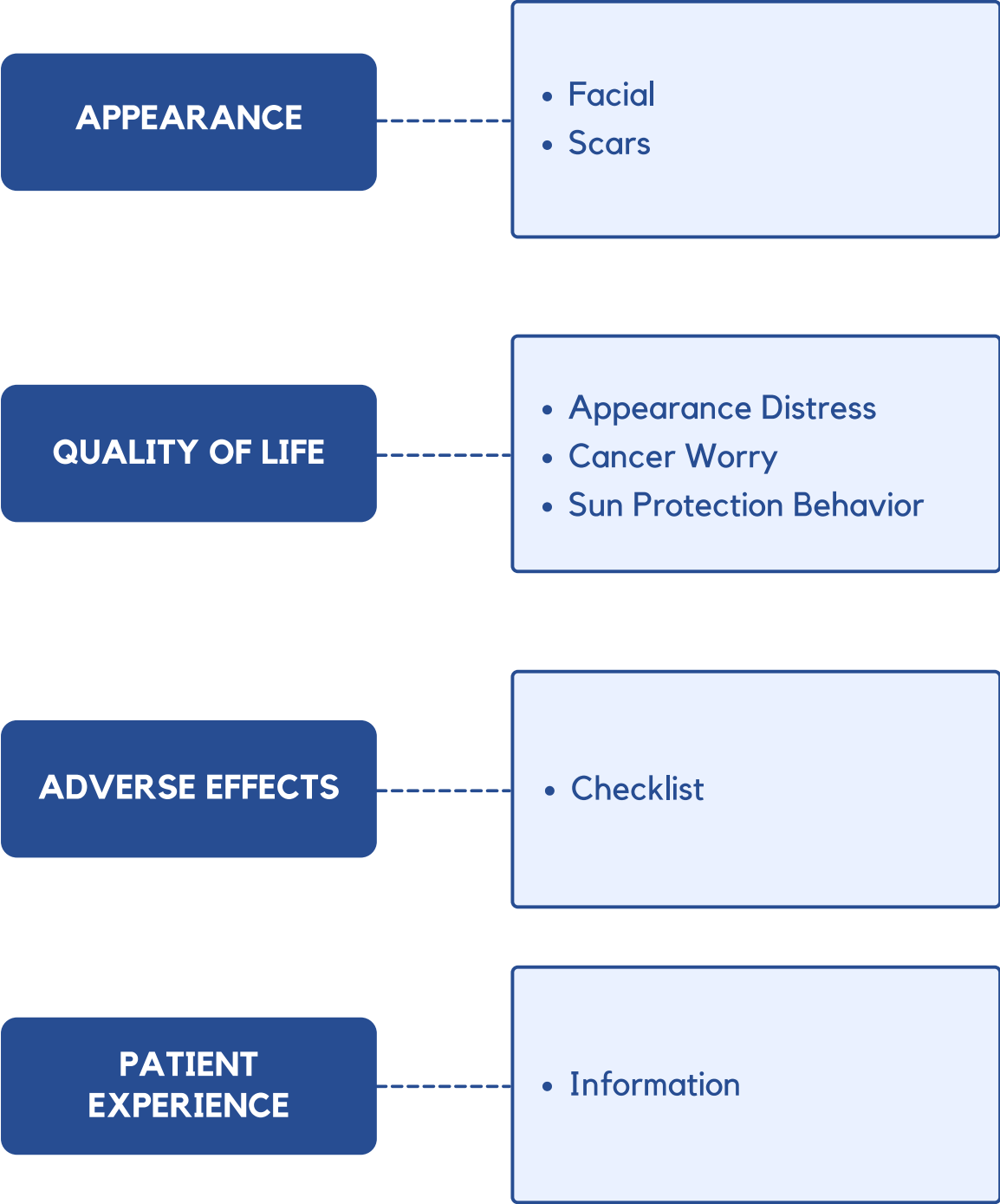


Figure 2: FACE-Q Skin Cancer conceptual framework



3. FACE-Q | Skin Cancer Scales

Table 1 shows the FACE-Q scales and checklists, including number of items, response options, recall period, and Flesch-Kincaid (FK) grade reading level. Below the table is a brief description of the content of each scale.

Table 1: Description of FACE-Q | Skin Cancer scales and checklists

Name of Scale/Checklist	Items	Response Options	Recall	FK
Appearance				
Facial	9	dissatisfied → satisfied	past week	0.0
Scars	8	extremely bothered → not at all	past week	1.4
Quality of Life				
Cancer Worry	10	disagree → agree	past week	6.1
Appearance-related Distress	8	disagree → agree	past week	3.2
Sun Protection Behavior	5	never → always	n/a	3.3
Adverse Effects				
Checklist	10	not at all → extremely bothered	past week	9.9
Patient Experience				
Information: Appearance	6	dissatisfied → satisfied	n/a	0.6

APPEARANCE

Satisfaction with Facial Appearance: This 9-item scale measures the appearance of the entire face with items that ask about symmetry and shape, as well as how the face looks in photos, in the mirror, and up close.

Appraisal of Scars: This 8-item scale measures the appearance of scars with items that ask about features such as color, length, and location.

QUALITY OF LIFE

Cancer Worry: This 10-item scale measures cancer worry. Respondents are asked to indicate how often they worry about the skin cancer recurring, spreading to other parts of the body, and how much worrying about skin cancer interferes with their relationships.

Appearance-related distress: This 8-item scale measures how facial appearance affects the respondent by asking them to indicate how much they agree/disagree with feeling depressed, anxious, or unhappy when others look at them.

Sun Protection Behavior: This 5-item checklist assesses sun protection behavior. When spending time outdoors, the respondent indicates how often sunscreen, a hat, or clothing is used.

ADVERSE EFFECTS

Checklist: This 10-item checklist asks about problems the respondent may be experiencing due to their recent skin cancer treatment, such as pain, numbness, itching, or swelling.

PATIENT EXPERIENCE

Satisfaction with Information: Appearance: This 6-item scale measures satisfaction with information provided by the medical team with items concerning how the respondent's appearance would change and how scars would change overtime.

4. Administration of the FACE-Q | Skin Cancer

The FACE-Q was designed to be completed by patients by themselves. Each scale/checklist takes only a few minutes to complete. Each scale is independently functioning, which means that only scales relevant to the particular research or clinical situation need be completed. Brief instructions are provided at the start of each scale/checklist. The FACE-Q was field-tested using paper-and-pencil as the form of data collection. You may use the paper-and-pencil format or create an online version for ease of administration in non-profit academic research (e.g., REDCap) and in clinical care (e.g., hospital EMR such as Epic). If you plan to have an ePRO company capture and manage FACE-Q data collection, the ePRO company may need a license. If you have had FACE-Q scales converted into an electronic format and require an e-conversion review and certificate, please email qportfolioteam@gmail.com.

5. Scoring the FACE-Q | Skin Cancer

There is no overall or total FACE-Q score. Instead, FACE-Q is composed of independently functioning scales and checklists that are scored separately.

To score a scale, the raw scores for the set of items in a scale are added together to produce a total raw score. If missing data is less than 50% of the scale's items, the within-person mean for the completed items can be imputed for the missing items prior to computing a total raw score. As necessary, the imputed raw score for each item should be rounded to an integer. Then the items can be summed to produce a total

scale raw score. Once a total raw score for the scale is computed, the Conversion Table can be used to convert the raw score into a score that ranges from 0 (worst) to 100 (best). The conversion, which linearizes the scores, is based on the findings from the Rasch analysis. Higher scores for the scales measuring appearance (Face Overall, Scars) and the Information scale reflect a better outcome whereas higher scores on Cancer Worry and Appearance-Related Distress indicate more cancer worry and appearance-related distress. The Conversion Tables for changing raw scores into 0 to 100 scores are available after a license agreement is signed.

To score a checklist, the raw scores for the items in a checklist can be used to identify problems experienced by a patient or a sample. Checklists do not have Rasch Conversion Tables because the set of items did not work together statistically (i.e., the item set did not map out a clinical hierarchy for the concept of interest). Even though there are no Conversion Tables based on Rasch analysis for the 2 checklists, they can provide clinically important information, such as monitoring for post-operative complications.

6. Conditions of Use

Memorial Sloan Kettering Cancer Center holds the copyright of the FACE-Q | Skin Cancer and all of its translations (past, ongoing, and future). To avoid any copyright infringement, a copyright notice shall be included on the original questionnaire and all of its derivatives (including, but not limited to translations) as follows: “Copyright©2016 Memorial Sloan Kettering Cancer Center, New York, USA. All rights reserved.”

Use of the FACE-Q requires completion of a licensing agreement. The use of the FACE-Q in non-profit academic research and in clinical care is free of charge. The use of the FACE-Q by “for-profit” organizations (e.g., pharmaceutical companies, contract research organizations, ePRO companies) is subject to a licensing fee. Non-profit users can access the FACE-Q using the following link:

<https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=WTNMDPJRC7>

For questions regarding fees to be paid by ‘for-profit’ organizations, please contact:

Licensing Manager

Office of Technology Development

Memorial Sloan Kettering Cancer Center

633 3rd Ave, 4th Floor, New York, NY 10016

gotdtrm@mskcc.org

PLEASE NOTE

When you sign a FACE-Q license, you agree to the following terms:

- You will not modify, adapt, or create another derivative work from the FACE-Q
- You will not sell, sublicense, rent, loan, or transfer the FACE-Q to anyone
- You will not reproduce any FACE-Q scales in publications or other materials
- You will not translate the FACE-Q without permission from our team

For questions regarding study design and optimal use of FACE-Q | Skin Cancer scales, contact:

Erica Lee, MD
Memorial Sloan Kettering Cancer Center
New York, NY
USA
lee@mskcc.org

or

Andrea Pusic, MD, MHS, FACS, FRCSC
Brigham and Women's Hospital
75 Francis St.
Boston, MA 02115
apusic@bwh.harvard.edu

7. Frequently Asked Questions

Do I have to use all of the FACE-Q | Skin Cancer?

Each scale and checklist functions independently, therefore patients can be asked to complete some or all of the FACE-Q. It is not necessary for a patient to complete all of the scales and checklists as there is no overall or total FACE-Q score. A researcher or clinician may therefore select a subset depending on the particular purpose of the study or use.

Can I delete or add or change any items or response options of the FACE-Q | Skin Cancer?

You cannot delete or add or change the wording of any items or response options of FACE-Q. Any modification to the content of the FACE-Q is prohibited under copyright

laws. Also, making any changes to FACE-Q scales would invalidate their psychometric properties.

Can I reproduce FACE-Q | Skin Cancer in a publication or other public document (e.g., PhD thesis)?

According to the licensing agreement, you cannot reproduce the content of FACE-Q verbatim in a publication. However, it is possible to show shortened versions of items. The short forms of items that can be used in a publication are shown in Table 2 below.

Can I translate FACE-Q | Skin Cancer into a new language?

Yes, with permission, you can translate the FACE-Q into different languages. Before starting a translation, check our translation list on www.qportfolio.org to see if there is a translation in the language you need. If there is not a translation in the language you need, you will need to obtain permission from our team, sign a translation licensing agreement, and receive information on the method you need to follow. Email us at qportfolioteam@gmail.com for more information. Please note that the developers of the FACE-Q own the copyright of all translations of the FACE-Q.

Are there specific time points when patients complete the FACE-Q | Skin Cancer?

A researcher or clinician can decide the time points they would like to administer the FACE-Q.

Does it cost money to use the FACE-Q | Skin Cancer?

Use of FACE-Q is free for non-profit users, including use by hospitals. For-profit users need to pay a licensing fee through Memorial Sloan Kettering Cancer Centre (see conditions of use above).

Table 2: Shortened items for FACE-Q scales/checklists to use in a publication

FACIAL APPEARANCE	come back	scar change
shape	anxious	scar fade
contour	may spread	scar look
symmetric	become more serious	help with scarring
even	interferes with activities	SUN PROTECTION BEHAVIOR
both sides match	worry every day	careful
smooth	keeps from enjoying life	sunscreen
photos	may die	shady areas
mirror	interferes with relationships	hat
up close	APPEARANCE DISTRESS	clothing
SCARS	self-conscious	ADVERSE EFFECTS
color	insecure	pain
looking crooked	unhappy	discomfort
wide	anxious	sensitivity
noticeable in photos	stressed	numbness
length	embarrassed	tingling
thick	depressed	tightness
noticeable	avoid family and friends	itchiness
location	INFORMATION: APPEARANCE	swelling
CANCER WORRY	appearance change	bruising
worry	healed	facial movements

8. Publications Related to FACE-Q Development and Validation

1. Cowen EA, Veldhuizen IJ, Klassen AF, Cano SJ, Dusza SW, Nehal KS, Pusic AL, Lee EH. Sun protection behaviour checklist for targeted counselling in skin cancer patients. *Australas J Dermatol*. 2022 Apr 23. doi: 10.1111/ajd.13845.
2. Vaidya TS, Nehal KS, Rossi AM, Lee EH. Patient-reported adverse effects after facial skin cancer surgery: long-term data to inform counseling and expectations. *J Am Acad Dermatol*. 2019 Dec; 81(6):1423-1425.
3. Lee EH, Klassen AF, Cano SJ, Pusic AL. FACE-Q Skin Cancer Module for measuring patient-reported outcomes following facial skin cancer surgery. *Br J Dermatol*. 2018 Jul;179(1):88-94.
4. Lee EH, Klassen AF, Lawson JL, Cano SJ, Scott AM, Pusic AL. Patient experiences and outcomes following facial skin cancer surgery: A qualitative study. *Australas J Dermatol*. 2016 Aug;57(3):e100-4.
5. Lee EH, Klassen AF, Nehal KS, Cano SJ, Waters J, Pusic AL. A systematic review of patient-reported outcome instruments of nonmelanoma skin cancer in the dermatologic population. *J Am Acad Dermatol*. 2013 Aug;69(2):e59-67.