



FACE-Q[®] | HEAD & NECK 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: November 2017
January 2023

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 | Head & Neck 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 | Head & Neck 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 Head & Neck Cancer?	2
2. How was the FACE-Q Developed and Validated?	2
3. FACE-Q Head & Neck Cancer Scales	6
4. Administration of the FACE-Q Head & Neck Cancer	8
5. Scoring the FACE-Q Head & Neck Cancer	8
6. Conditions of Use	10
7. Frequently Asked Questions	12
8. Publications Related to FACE-Q Development and Validation	13

1. What is the FACE-Q | Head & Neck Cancer?

The FACE-Q Head & Neck Cancer is a patient-reported outcome measure (PROM) that can be used to evaluate healthcare experience and outcomes of treatment for head and neck cancer from the patient's perspective. The FACE-Q can be used to measure outcomes that matter to patients with any type of head and neck cancer.

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, the FACE-Q conceptual framework was developed from extensive qualitative research with 26 patients with head and neck cancer, close examination of the research literature, and engagement of a panel of clinical experts. A range of cancers and oncologic surgery were represented in the sample. The analysis led to the development of a conceptual framework that included the following domains: 1) altered facial function and the psychosocial impact; 2) altered facial appearance and the psychosocial impact; and 3) modifiers, such as cancer worry. Qualitative interviews were used to develop and refine a set of 14 draft scales that measure aspects of the conceptual framework important to people with head and neck cancer (Figure 2).

In phase 2, the FACE-Q was field-tested at Memorial Sloan Kettering Cancer Center (USA). A sample of 219 patients were recruited. A subset of 38 participants completed the module twice and providing test-retest data. The sample included patients who had or were planning to undergo surgery for cancer of the head and neck region. All facial tumor sites and pathologic subtypes were included to ensure the FACE-Q would be broadly applicable. Sample characteristics are shown in Table 1.

The RMT analysis provided evidence of validity and reliability of 14 scales. For reliability, Person Separation Index values were > 0.75 for all scales; Cronbach alpha values were > 0.87 for all scales; and intraclass correlation coefficients for the test-retest data ranged from 0.86–0.96. The scales performed well in a clinically predictable way, demonstrating functional and psychosocial differences across disease sites and with adjuvant therapy.

Overall this FACE-Q module was found to be clinically relevant and scientifically sound and provides a means to measure outcomes in research and clinical practice.

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.)

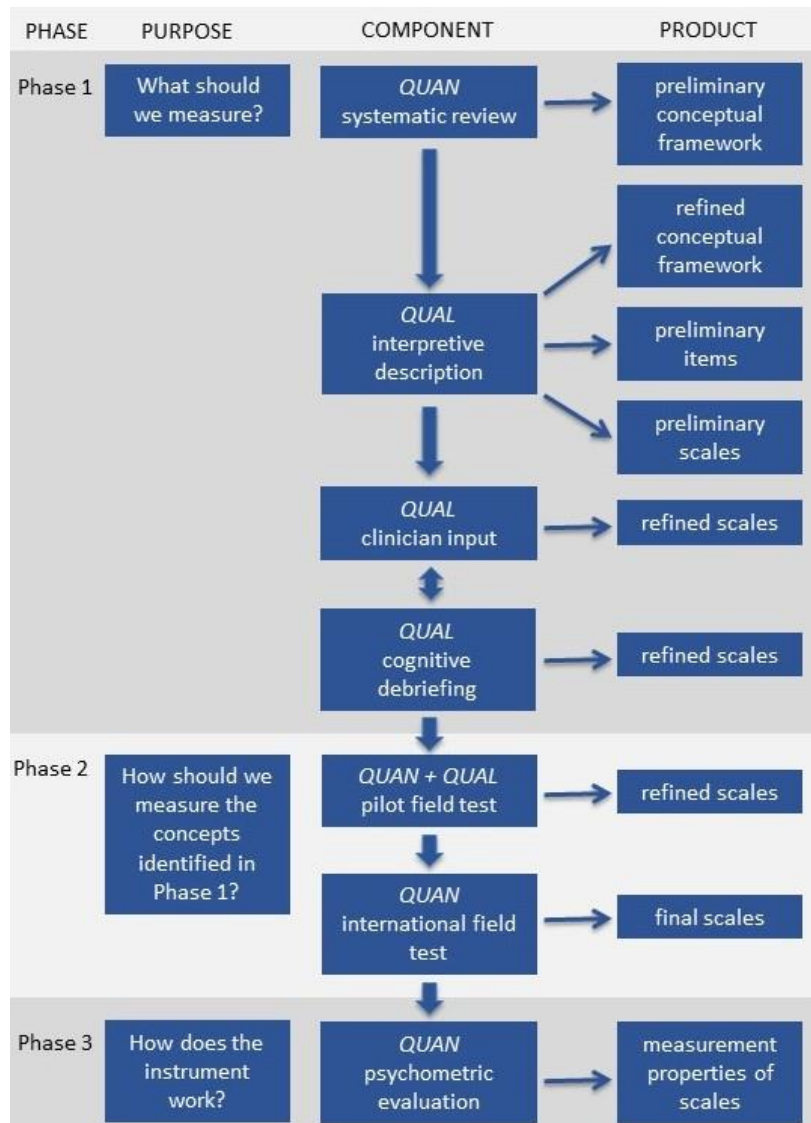


Figure 2: FACE-Q Head & Neck Cancer conceptual framework



Table 1: Characteristics (Number, %) of field-test participants

		N	%
Age in years	21-30	5	2
	31-45	5	2
	46-60	70	32
	>60	139	64
Gender	Female	75	34
	Male	144	66
Racial/Ethnic Groups	White	190	87
	Black/African American	11	5
	Asian or Pacific Islander	11	5
	South Asian or East Indian	3	1
	Other/Unknown	4	2
Surgical Treatment	Mandibulectomy	49	22
	Maxillectomy	23	11
	Glossectomy/Floor of Mouth	42	19
	Laryngectomy/Pharyngectomy	22	10
	Skin/Soft Tissue/Parotidectomy	83	38

3. FACE-Q | Head & Neck Cancer Scales

Table 2 shows the FACE-Q scales, including the number of items, response options, time frame, and Flesch-Kincaid (FK) grade reading level. Below the table is a brief description of each scale.

Table 2: Description of FACE-Q | Head & Neck Cancer scales

Name of Scale	Items	Response Options	Recall	FK
Facial Appearance				
Appearance	10	agree → disagree	past week	2.2
Facial Function				
Eating and Drinking	8	not at all → a lot bothered	past week	1.9
Oral Competence	5	not at all → a lot bothered	past week	0.0
Salivation	8	not at all → a lot bothered	past week	1.9
Smiling	7	not at all → a lot bothered	past week	2.1
Speaking	7	not at all → a lot bothered	past week	5.6
Swallowing	8	not at all → a lot bothered	past week	2.3
HRQOL				
Appearance Distress	6	agree → disagree	past week	3.2
Eating Distress	7	none of the time → all of the time	past week	4.5
Drooling Distress	6	none of the time → all of the time	past week	5.0
Smiling Distress	5	none of the time → all of the time	past week	3.1
Speaking Distress	7	none of the time → all of the time	past week	4.9
Cancer Worry	8	none of the time → all of the time	past week	5.7
Experience of Care				
Satisfaction with Information	10	dissatisfied → satisfied	n/a	7.0

FACIAL APPEARANCE

Appearance: This 10-item scale measures the appearance of the entire face with items that ask about facial proportion and size, as well as if the face looks unattractive, uneven, or abnormal.

FACIAL FUNCTION

Eating and Drinking: This 8-item scale measures the ability to eat and drink, with items that ask about chewing, drinking, tasting, as well as the effort and time required to perform these activities.

Oral competence: This 5-item scale measures the ability to close the mouth and lips, with items that ask about drooling, food and liquid spilling out of the mouth, as well as needing to wipe the mouth or face when eating.

Salivation: This 8-item scale measures problems with saliva, with items that ask about having a dry mouth, needing to drink liquids frequently, as well as having trouble eating and speaking due to a dry mouth.

Smiling: This 7-item scale measures problems with smiling, with items that ask about the ability to smile and to move the mouth when smiling.

Speaking: This 7-item scale measures problems with speaking, with items that ask about difficulty making certain sounds, saying certain letters or words, and having difficulty being understood.

Swallowing: This 8-item scale measures problems with swallowing, with items that ask about choking, coughing, food getting stuck in the throat, and problem swallowing liquids.

HEALTH-RELATED QUALITY OF LIFE

Appearance Distress: This 6-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.

Eating Distress: This 7-item scale measures how eating problems may affect the respondent by asking them to indicate how often they do not enjoy eating meals, feel self-conscious when eating, or avoid eating in public.

Drooling Distress: This 6-item scale measures how drooling affects the respondent by asking them to indicate how often they feel frustrated, embarrassed, or avoid social situations.

Smiling Distress: This 5-item scale measures how problems with smiling affect the respondent by asking them to indicate how often they feel self-conscious, embarrassed, or avoid smiling.

Speaking Distress: This 7-item scale measures how problems with speaking affect the respondent by asking them to indicate how often they feel socially isolated, embarrassed, or avoid public speaking.

Cancer Worry: This 8-item scale measures cancer worry. Respondents are asked to indicate how often they worry the cancer may come back, they will die from cancer, and how much the cancer interferes with their daily activities.

EXPERIENCE OF CARE

Satisfaction with Information: This 10-item scale measures satisfaction with information from the medical team and includes items concerning the surgical process, potential complications, and recovery.

4. Administration of the FACE-Q | Head & Neck Cancer

The FACE-Q was designed to be completed by patients by themselves. Each scale 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.

FACE-Q scales were 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 | Head & Neck Cancer

There is no overall or total FACE-Q score. Instead, the FACE-Q is composed of independently functioning scales 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. For example, if there is a 10-item scale and someone has not responded to all the items, but has responded to ≥ 5 items, all other items for that person can be imputed with a within-person mean (rounded to the nearest integer), and a

summed score can be calculated. Alternatively, for a 10-item scale, if someone has responded to ≤ 4 items, the summed score for this person cannot be computed and is classified as missing data. Importantly, the Conversion Tables are only valid with complete data (i.e., when a person has $\geq 50\%$ completed responses). 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 to 100. The conversion, which linearizes the scores, is based on the findings from the Rasch analysis.

Higher scores for FACE-Q scales reflect a better outcome with the exception of the Cancer Worry scale. For the Cancer Worry scale, higher scores indicate more cancer worry. To ensure that higher scores for all other scales represent a better outcome, the raw data need to be scored as shown in the box below. The Conversion Tables for changing raw scores into 0 to 100 scores are available after a licensing agreement is signed.

RAW SCORES FOR SCALE ITEMS

For the scales that measure how much you have been bothered, the raw data needs to be scored as follows: “A lot bothered” = 1; “A little bothered” = 2; “Not at all” = 3. This includes the following scales: Eating and Drinking, Oral Competence, Salivation, Smiling, Speaking, and Swallowing.

For measuring agree/disagree, the raw data needs to be scored as follows: “Definitely agree” = 1; “Somewhat agree” = 2; “Somewhat disagree” = 3; “Definitely disagree” = 4. This includes the following scale: Appearance Distress.

One exception is Appearance, which needs to be scored as follows: “Definitely agree” = 1; “Somewhat agree” = 2; “Somewhat disagree” = 3; “Definitely disagree” = 3.

For scales that measure amount of time, the raw data needs to be scored as follows: “All of the time” = 1; “Some of the time” = 2; “None of the time” = 3. This includes the following scales: Eating Distress, Drooling Distress, and Smiling Distress.

One exception is Speaking Distress, which needs to be scored as follows: “All of the time” = 1; “A lot of the time” = 2; “Some of the time” = 3; “A little of the time” = 4; “None of the time” = 5.

Another exception is Cancer Worry, which needs to be scored as follows: “None of the time” = 1; “A little of the time” = 2; “Some of the time” = 3; “All of the time” = 4.

For the scale that measures satisfaction, the raw data needs to be scored as follows: “Very dissatisfied” = 1; “Somewhat dissatisfied” = 2; “Somewhat satisfied” = 3; “Very satisfied” = 4. This includes the following scale: Information.

6. Conditions of Use

Memorial Sloan Kettering Cancer Center holds the copyright of the FACE-Q 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 | Head & Neck Cancer using the following link:
<https://qteam.mcmaster.ca/surveys/?s=9X73E834MCH4LPY3>

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 Head & Neck Cancer scales, please contact either:

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

Evan Matros, MD, MMSc
Memorial Sloan Kettering Cancer Center
1275 York Avenue
New York, NY 10065
matrose@mskcc.org

or
Jennifer Cracchiolo, MD
Memorial Sloan Kettering Cancer Center
1275 York Avenue
New York, NY 10065
cracchij@mskcc.org

or
Anne Klassen, DPhil (Oxon)
McMaster University
Hamilton, Ontario
Canada
aklass@mcmaster.ca

7. Frequently Asked Questions

Do I have to use all of the FACE-Q | Head & Neck Cancer scales?

Each scale functions independently, therefore patients can be asked to complete some or all of the FACE-Q scales. It is not necessary for a patient to complete all of the scales as there is no overall or total FACE-Q score. A researcher or clinician may therefore select a subset of scales 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 | Head & Neck 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 | Head & Neck 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 3 below.

Can I translate FACE-Q | Head & Neck 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 scales?

A researcher or clinician can decide the time points they would like to administer the scales.

Does it cost money to use the FACE-Q?

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).

8. Publications Related to FACE-Q Development and Validation

1. Cracchiolo JR, Klassen AF, Young Afat D, Albornoz CR, Cano SJ, Patel S, Pusic AL, Matros E. Leveraging patient-reported outcomes data to inform oncology clinical decision making: Introducing the FACE-Q Head and Neck Cancer module. *Cancer*. 2019 Mar 15;125(6):863-872. doi: 10.1002/cncr.31900.
2. Albornoz CR, Pusic AL, Reavey P, Scott AM, Klassen AF, Cano SJ, Cordeiro PG, Matros E. Measuring health-related quality of life outcomes in head and neck reconstruction. *Clin Plast Surg*. 2013;40(2):341-9. doi: 10.1016/j.cps.2012.10.008.
3. Pusic A, Liu JC, Chen CM, Cano S, Davidge K, Klassen A, Branski R, Patel S, Kraus D, Corderio P. A systematic review of patient-reported outcome measures in head and neck cancer surgery. *Otolaryngol Head Neck Surg*. 2007;136(4):525-35. doi: 10.1016/j.otohns.2006.12.006.

Table 3: Shortened items for FACE-Q scales to use in a publication

APPEARANCE	saliva	APPEARANCE DISTRESS	SPEAKING DISTRESS
too big	fluids	depressed	isolated
sunken	water	insecure	insecure
disfigured	dry	anxious	limits social
shape not normal	SMILING	unhappy	embarrassed
unattractive	unable	not normal	frustrated
disproportionate	grimace	self-conscious	avoid social
damaged	emotions	EATING DISTRESS	repeat
abnormal	move	embarrassed family	CANCER WORRY
uneven	crooked	avoid public	come back
different	asymmetric	not enjoy	about
EAT/DRINKING	problem	embarrassed public	may die
soft foods	SPEAKING	self-conscious	fighting for life
cup	face-to-face	cannot eat	interferes relationships
falling out	understand	difficult	interferes activities
taste	sounds	DROOLING DISTRESS	preoccupied
wide	letters	avoid social	enjoying life
effort	phone	worry	INFORMATION
time	words	insecure	how done
hard foods	repeat myself	frustrated	questions
ORAL COMPETENCE	SWALLOWING	embarrassed	extent surgery
lips not close	choke liquids	self-conscious	complications
drools	liquids	SMILING DISTRESS	healing
food spills	cough drink	limits social	pain
liquid spills	cough eat	avoid	worst scenario
wipe	choke solids	embarrassed	all you needed
SALIVATION	stuck	insecure	changes appearance
speaking	concentrate	self-conscious	changes function
dry eat	solids		
trouble eating			
dry speak			