

CLEFT-Q[©]

A Guide for Researchers and Clinicians

USER'S GUIDE
VERSION 1.0
JULY 2018

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 McMaster University. Copyright © 2017 of McMaster University. All Rights Reserved.

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.

Printing History: July 2018 Version 1.0

Licensing: The CLEFT-Q[©] is intellectual property of Drs Anne Klassen and Karen Wong. The CLEFT-Q[©] is owned by McMaster University (Hamilton, Canada) and the Hospital for Sick Children (Toronto, Canada). Users must sign a Licensing Agreement. The CLEFT-Q[©] 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 Dr Anne Klassen, aklass@mcmaster.ca

Copying: Copying or altering any parts of the CLEFT-Q[©] is not permitted.

Table of Contents	PAGE
1. What is the CLEFT-Q©?	3
2. How was the CLEFT-Q© Developed?	3
3. CLEFT-Q© Scales	3
4. Administration of the CLEFT-Q©	6
5. Response Options for CLEFT-Q© Scales	6
6. Scoring the CLEFT-Q©	6
7. Translations of the CLEFT-Q©	6
8. Conditions of Use of the CLEFT-Q©	6
9. Frequently Asked Questions	7
10. Acknowledgements	8
11. CLEFT-Q© Publications	9

1. What is the CLEFT-Q©?

The CLEFT-Q© is a rigorously developed patient-reported outcome (PRO) measure that can be used internationally to collect and compare evidence-based outcomes data from patients aged 8 to 29 years with cleft lip and/or palate (CL/P).

2. How was the CLEFT-Q© Developed?

Figure 1 shows the multiphase mixed methods approach we used to develop the CLEFT-Q©. Content for the CLEFT-Q© was developed from interviews with 138 patients from Canada, England, India, Kenya, the Philippines and USA. The findings from the interviews were used to develop a conceptual framework comprised of the following 3 domains: appearance, health-related quality of life and facial function. Cognitive interviews with 69 patients from Canada, India, Ireland, Philippines, the Netherlands and USA, and feedback from 44 international CL/P experts provided input used to refine the scales and to establish their content validity. To facilitate the involvement of multiple non-English speaking countries, the scales were translated and culturally adapted into Dutch, Hindi, Spanish, Swedish and Turkish following ISPOR international guidelines. Field-test data were collected from 2434 patients with CL/P at 30 hospitals in 12 countries. We used a modern psychometric approach called Rasch measurement theory (RMT) analysis to refine the scales and to examine reliability and validity. Analysis led to the refinement of an eating/drinking checklist and 12 scales Table 1). Normative CLEFT-Q© values were computed for age, gender and cleft type.

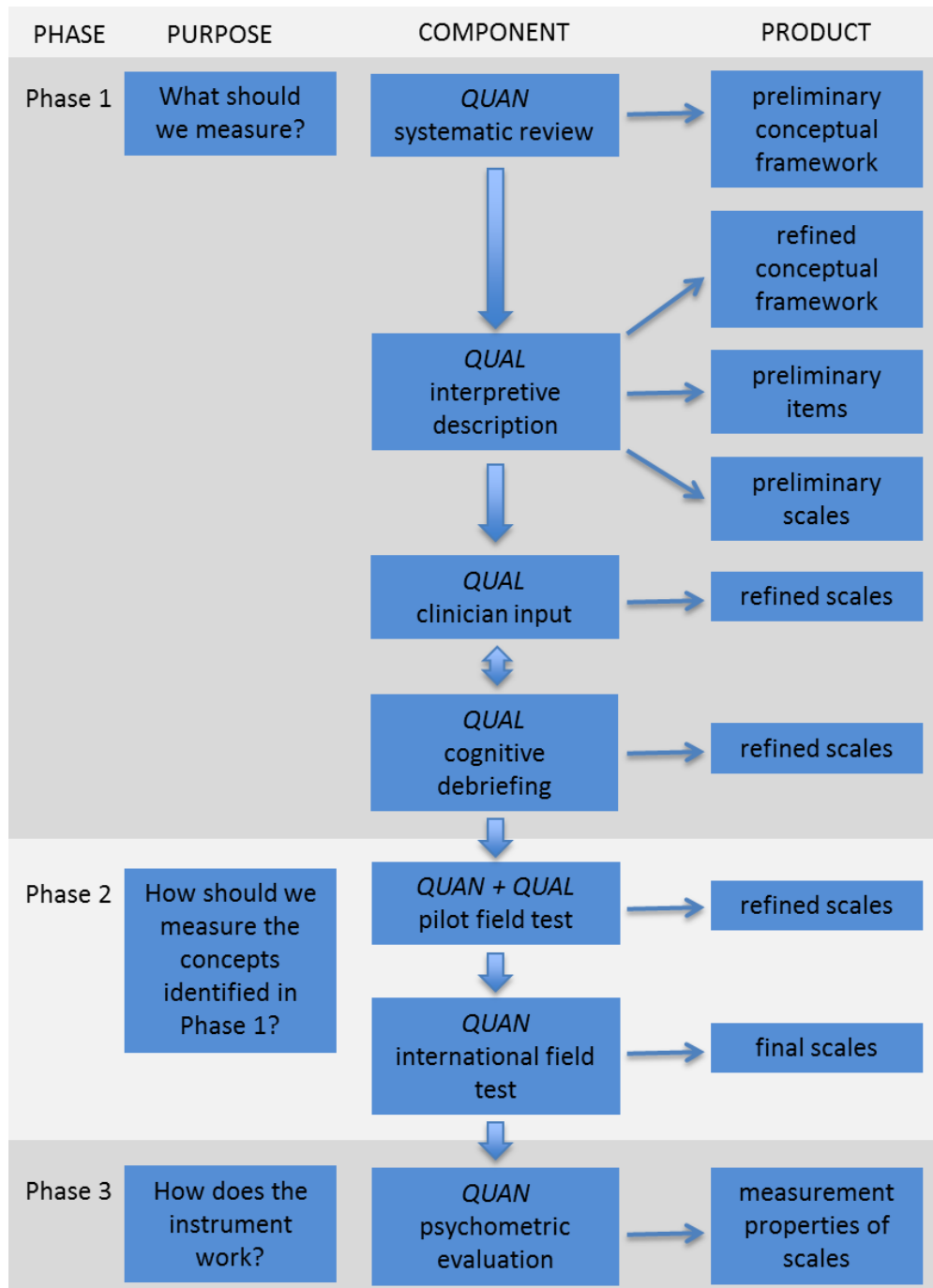
3. CLEFT-Q© Scales

Table 1: CLEFT-Q© scales, including the number of items, appropriate ages and cleft type, recall period for completing and grade reading level. Below Figure 1 is a brief description of each scale.

Name of scale	Items	Age	Cleft type	Recall period	FK grade
Face	9	8 to 29	All diagnoses	now	0.7 (0-3.6)
Nose	12	8 to 29	All diagnoses	now	0.8 (0-2.5)
Nostrils	6	8 to 29	All diagnoses	now	1.2 (0.5-2.4)
Teeth	8	8 to 29	All diagnoses	now	0.6 (0-2.4)
Jaws	7	12 to 29	All diagnoses	now	0.3 (0-0.6)
Lips	9	8 to 29	All diagnoses	now	0.1 (0-0.6)
Cleft lip scar	7	8 to 29	CLP, CLA, CL	now	0.3 (0– 0.8)
Psychological function	10	8 to 29	All diagnoses	past week	2.2 (0.5-5.2)
School function	10	8 to 18	All diagnoses	past week	1.9 (0.5-3.7)
Social function	10	8 to 29	All diagnoses	past week	1.8 (0-3.7)
Speech distress	10	8 to 29	CLP, CP, CLA	past week	2.5 (0.5-3.7)
Speech function	12	8 to 29	CLP, CP, CLA	past week	2.9 (0-4.9)
Eating and drinking	9	8 to 29	All diagnoses	past week	1.2 (0-3.9)

CLP = cleft lip and/or palate; CLA = cleft lip and alveolus; CL = cleft lip only; CP = cleft palate only; All diagnoses = CL, CLP, CLA, CP; FK = Flesch-Kincaid grade reading level

Figure 1: The multiphase mixed methods approach for developing the CLEFT-Q (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 (CLEFT-Q). *BMJ Open*. 2017;7(1):015467.)



APPEARANCE SCALES

Face: This 9-item scale measures facial appearance with items that ask about how the face looks in a variety of circumstances (e.g., in photos, from the side). Other items cover the shape of the face and how the face looks up close.

Nose: This 12-item scale measures nose appearance, with items that ask about the size, shape and length of the nose, as well as how the patient's nose looks in photos, from the side and when smiling.

Nostrils: This 6-item scale measures nostril appearance, with items that ask about the size, shape and width of the nostrils, in addition to questions about how the patient's nostrils look when they smile and in photos.

Teeth: This 8-item scale measures teeth appearance, with items that ask about the size, straightness and proximity of the patient's teeth. The scale also asks questions about how the teeth look when smiling and how they meet when biting.

Jaws: This 7-item scale measures the appearance of jaws, with items that ask about the shape and size of the jaws, in addition to items about how the jaws look from the side and when the mouth is closed.

Lips: This 9-item scale measures the appearance of lips, with items concerning the shape, size and fullness of the lips. Other items ask about how the lips look while smiling, when the mouth is closed and up close.

Cleft Lip Scar: This 7-item scale measures the appearance of the cleft scar, with items that ask about the shape, width, color and size of the scar. In addition, items ask about how the scar looks when smiling, in photos and in the mirror.

FACIAL FUNCTION SCALES/CHECKLIST

Speech Function: This 12-item scale measures a patient's speech, with items that ask about trouble speaking out loud, being understood and avoidance.

Eating and Drinking: This 9-item checklist measures problems with eating and drinking. Items ask about food or liquid nasal regurgitation, avoidance of certain foods, having to eat slowly and difficulty biting certain foods.

HEALTH-RELATED QUALITY OF LIFE SCALES

Psychological: This 10-item scale measures psychosocial well-being, with items that ask about self-esteem, body image and self-confidence.

School Life: This 10-item scale measures social functioning at school, with items that ask about participation, safety, fitting in and liking school.

Social Life: This 10-item scale measures social life, with items that ask about friends (having fun with them, feeling accepted by them), feeling confident in social settings and how the respondent feels when other people look at their face.

Speech Distress: This 10-item scale measures how a patient feels about speaking, with items that ask about nervousness, frustration, teasing, embarrassment and ability to be understood.

4. Administration of the CLEFT-Q©

The CLEFT-Q© is designed to be completed by patients aged 8 to 29 years. It is important to note that patients do not need to complete all of the available CLEFT-Q© scales in any given study or clinical encounter. Each scale is designed to function independently. Patients can thus be asked to complete a subset of scales relevant to their situation. Brief instructions are provided at the start of each scale. The CLEFT-Q© was field-tested using online data collection, i.e., Research Electronic Data Capture System (REDCap), as well as paper-and-pencil.

5. Response Options for the CLEFT-Q© Scales

Each CLEFT-Q© scale provides 3 or 4 response options. Appearance scales use the following response options: 1 (Not at all), 2 (A little), 3 (Quite a bit), 4 (Very much). The speech function and speech distress scales use the following response options: 1 (Always), 2 (Sometimes), 3 (Never). All other scales use the following response options: 1 (Never), 2 (Sometimes), 3 (Often), 4 (Always).

6. Scoring the CLEFT-Q©

There is no overall or total CLEFT-Q© score, only scores for each independent scale. Each CLEFT-Q© scale is transformed into scores that range from 0-100. The scores are computed from the responses to the items by adding them together and converting the raw score to a scale from 0 to 100. Higher scores reflect a better outcome. If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Tables available from the authors to convert the raw summed scale score into a score from 0 (worst) to 100 (best).

7. Translations of the CLEFT-Q©

To facilitate the involvement of multiple non-English speaking countries in our study, the CLEFT-Q© was translated and linguistically validated into Catalan, Dutch, Hindi, Spanish (Columbia, Chile, Spain), Swedish and Turkish following international guidelines. The CLEFT-Q© should only be completed by patients using a version available to them in a language they can read and complete independently. If you are interested in translating the CLEFT-Q© for use in another language, it is important to follow internationally recommended guidelines. Please note that the developers of the CLEFT-Q© own the copyright of all translations of the CLEFT-Q©. Please contact us for more information.

8. Conditions of Use of the CLEFT-Q©

McMaster University holds the copyright privileges of the CLEFT-Q© and all of its translations (past, on-going 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©2017 McMaster University, Hamilton, Canada and The Hospital for Sick Children, Toronto Canada. All rights reserved."

Use of the CLEFT-Q© questionnaire requires completion of a User's Agreement. The use of the CLEFT-Q© in non-profit academic research and in clinical care is free of charge. The use of the CLEFT-Q© by 'for-profit' organizations is subject to a licensing fee.

Non-profit users can access the CLEFT-Q using the following link:

<https://research.mcmaster.ca/industry-and-investors/technologies-available-for-licensing/questionnaire-request-form/>

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

Licensing Assistant
McMaster Industry Liaison Office (MILO)
McMaster Innovation Park, Suite 305
175 Longwood Rd S, Hamilton ON L8P 0A1
W: milo.mcmaster.ca
E: milo@mcmaster.ca
905-525-9150 ext. 22176

For questions regarding study design and optimal use of CLEFT-Q© scales contact:

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

or

Karen Wong Riff, MD PhD
Hospital for Sick Children
Toronto, Ontario
Canada
karenw.wong@sickkids.ca

9. Frequently Asked Questions

Do I need to sign a license to use the CLEFT-Q©?

Yes, you must sign a licencing agreement for any use of the questionnaires, whether it is commercial or academic. The questionnaires are protected by copyright and are the exclusive property of McMaster University.

Which CLEFT-Q© scales are in the ICHOM cleft standard set?

Nine CLEFT-Q© scales are included in the ICHOM cleft standard set: face, jaw, teeth, eating and drinking, psychological, social, school, speech distress and speech function. For more information, see: <http://www.ichom.org/medical-conditions/cleft-lip-palate/>

Do I have to use all of the scales?

Patients can be asked to complete some or all of the CLEFT-Q© scales. It is not necessary for a patient to complete all of the scales as there is no overall or total CLEFT-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, add or change any items or response options of the CLEFT-Q©?

You cannot delete, add or change the wording of any items or response options of the CLEFT-Q©. Any modification to the content of the CLEFT-Q© is not acceptable. There are three main reasons why deleting or adding items is not allowed. The first is that deleting or adding items would nullify the psychometric properties of CLEFT-Q© scales. The second reason is that by deleting or adding items, it would then not be possible to score the CLEFT-Q© and you would not be able to compare findings with those of other CLEFT-Q© studies. Finally, adding or deleting items is prohibited under copyright laws.

Can I translate CLEFT-Q© scales into a new language?

Yes, you can translate the CLEFT-Q© into different languages. Check with the licensing assistant at McMaster (milo@mcmaster.ca) 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 sign a licensing agreement. Please note that the developers of the CLEFT-Q© own the copyright of all translation of the CLEFT-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 CLEFT-Q©?

Use of CLEFT-Q© scales is free for non-profit users, including the use by hospitals implementing the ICHOM standard set. For-profit users should contact McMaster University to sign a license (milo@mcmaster.ca).

10. Acknowledgements

Development of the CLEFT-Q© has involved the collaboration of countless health care professionals and researchers around the world who recruited 2434 patients with CL/P. We are truly grateful for their dedication and help with our research. The CLEFT-Q© study has been generously funded by the following grants:

Phase I: Qualitative

Wong KW (PI), Klassen A, Forrest C. CLEFT-Q: Development of a Patient-Reported Outcome Measure for Cleft Lip and Palate. Canadian Society of Plastic Surgeons; Outcomes/Clinical study Research Grant. (2012, Jul – 2013, Jun)

Wong KW (PI), Klassen A, Forrest C. CLEFT-Q: Development of a Patient-Reported Outcome Measure for Cleft Lip and Palate. Physician Services Incorporated Foundation (PSI) Resident Grant. (2010, Jul – 2011 Jun)

Phase II and Phase III: International Field-test and Psychometric Statistical Study

Klassen A (PI), Wong K, Forrest C, Pusic A. An International Study to Develop a Patient-Reported Outcome Instrument for Cleft-Lip and/or Palate Patients: The CLEFT-Q. Canadian Institutes of Health Research. (2013, Jul – 2018, Aug)

11. CLEFT-Q© Publications

1. Klassen AF, Riff KWW, Longmire NM, Albert A, Allen GC, Aydin MA, Baker SB, Cano SJ, Chan AJ, Courtemanche DJ, Dreise MM, Goldstein JA, Goodacre TEE, Harman KE, Munill M, Mahony AO, Aguilera MP, Peterson P, Pusic AL, Slator R, Stiernman M, Tsangaris E, Tholpady SS, Vargas F, Forrest CR. Psychometric Findings and Normative Values for the CLEFT-Q based on 2,434 Children and Young Adult Patients with Cleft Lip and/or Palate from 12 Countries. *CMAJ* 2018. 2018 Apr 16;190(15):E455-62.
2. Wong Riff KWW, Tsangaris E, Goodacre TEE, Forrest CR, Lawson J, Pusic AL, Klassen AF. What Matters to Patients with Cleft Lip and/or Palate: An International Qualitative Study Informing the Development of the CLEFT-Q. *Cleft Palate Craniofac J*. 2018 Mar;55(3):442-50.
3. Tsangaris E, Riff KWW, Vargas F, Aguilera MP, Alarcón MM, Cazalla AA, Thabane L, Thoma A, Klassen AF. Translation and cultural adaptation of the CLEFT-Q for use in Colombia, Chile and Spain. *Health Qual Life Outcomes*. 2017 Nov 28;15(1):228.
4. Tsangaris E, Wong Riff KWW, Goodacre T, Forrest CR, Dreise M, Sykes J, de Chalain T, Harman K, O'Mahony A, Pusic AL, Thabane L, Thoma A, Klassen AF. Establishing content validity of the CLEFT-Q: A new patient-reported outcome measure for cleft lip and/or palate. *Plast Reconstr Surg Glob Open*. 2017 Apr 25;5(4):1305.
5. Wong Riff KW, Tsangaris E, Goodacre T, Forrest CR, Pusic AL, Cano SJ, Klassen AF. 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 (CLEFT-Q). *BMJ Open*. 2017 Jan 11;7(1):e015467.
6. Wong KW, Forrest CR, Goodacre TE, Klassen AF. Measuring outcomes in craniofacial and pediatric plastic surgery. *Clin Plast Surg*. 2013 Apr;40(2):305-12.
7. Klassen A, Tsangaris E, Forrest CR, Wong KW, Pusic AL, Cano SJ, Syed I, Dua M, Kainth S, Johnson J, Goodacre T. Quality of life of children treated for cleft-lip and/or palate: a systematic review. *J Plast Reconstr Aesthet Surg*. 2012 May;65(5):547-557.