

CLEFT-Q[©]

A Guide for Researchers and Clinicians

USER'S GUIDE
VERSION 1.0
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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, Philippines and USA, the findings of which were used to develop a conceptual framework comprised of 3 domains as follows: 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 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 (see Table 1). Normative CLEFT-Q© values were computed for age, gender and cleft type.

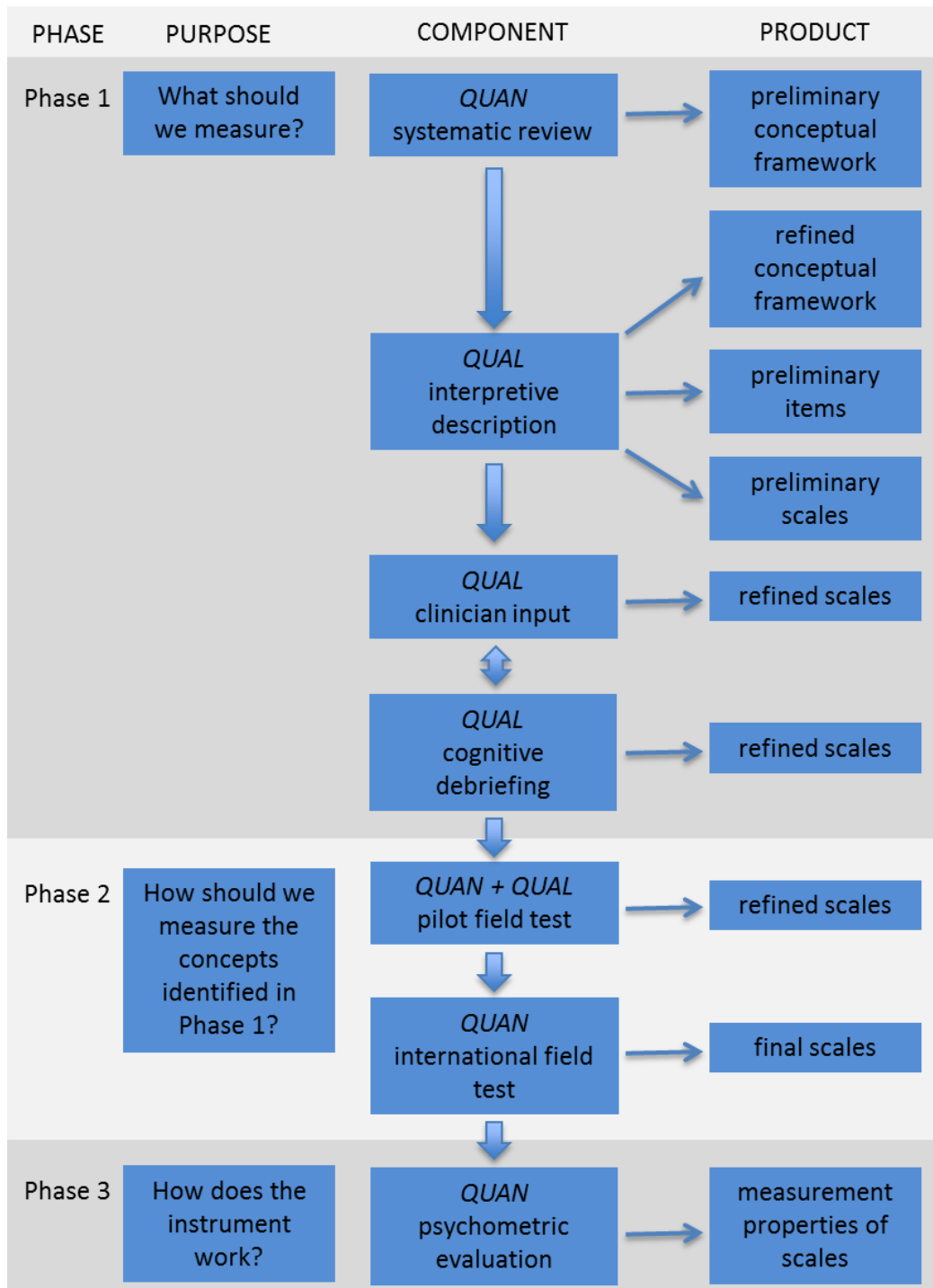
3. CLEFT-Q© Scales

The table below shows the CLEFT-Q© scales, including number of items, 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 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 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 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 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 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 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 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 scale measures a patient's speech, with items that ask about trouble speaking out loud, being understood and avoidance.

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

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

Social Life: This 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 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 in our study of multiple non-English speaking countries, 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©

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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.

Nonprofit users can access the ACNE-Q using the following link: <https://mcmaster.flintbox.com/>

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

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

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9. Frequently Asked Questions

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

Yes, you must sign a licence 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 were 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 the scales?

Patients can be asked to complete some or all 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 or add or change any items or response options of the CLEFT-Q©?

You cannot delete or 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 our website and with our team first to make sure there is not already 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 he/she would like to administer the scales.

Is there an electronic version I can use?

A template file of the CLEFT-Q© for administration via the Research Electronic Data Capture (REDCap) portal is available. Please contact the authors for more information.

Does it cost money to use the CLEFT-Q©?

Use of CLEFT-Q© scales is free to 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 K W Y, Tsangaris E, Goodacre T E E, 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 K W Y W, 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.
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