



EAR-Q©

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 in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of McMaster University. Copyright©2020 McMaster University and The Hospital for Sick Children. All Rights Reserved.

Printing History: November 2021

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 EAR-Q patient-reported outcome measure was authored by Drs Anne Klassen and Karen Wong. The copyright to the work is owned by McMaster University (Hamilton, Canada) and The Hospital for Sick Children (Toronto, Canada). Users must sign a Licensing Agreement. The EAR-Q can be used free of charge in 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 the McMaster Industry Liaison Office at McMaster University, email: milo@mcmaster.ca.

Table of Contents

1. What is the EAR-Q?	2
2. How was the EAR-Q Developed and Validated?	2
3. EAR-Q Scales	7
4. Administration of the EAR-Q	8
5. Scoring the EAR-Q	8
6. Conditions of Use	9
7. Frequently Asked Questions	10
8. Acknowledgements	11
9. Publications	12

1. What is the EAR-Q?

The EAR-Q is a rigorously developed patient-reported outcome (PRO) measure that can be used to collect and compare evidence-based outcomes data from patients aged 8 to 29 years with any type of ear condition. The EAR-Q includes two ear-specific scales and scales measuring health-related quality of life (HRQOL) that were field-tested in the FACE-Q® | Craniofacial field-test study. These scales measure the appearance of the ears (e.g., size, shape, photos) and adverse effects following treatment (e.g., itchy, painful, numb). There are also 3 single items that ask about how ear scars look and feel and how hearing aids look.

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

The EAR-Q represents a new generation of PRO instruments developed using a modern psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PRO measure are each 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, EAR-Q scales can be used with individual patients to inform clinical care.

We followed internationally recommended guidelines for PRO measure development to create the EAR-Q. Figure 1 shows the multiphase mixed methods approach used by our team [1]. The content for the ear-specific scales was developed from qualitative interviews with 25 patients aged 8 to 21 years with microtia (n=14), prominent ears (n=9), or another ear condition (n=2), and refined with patient and expert input [2]. The EAR-Q was then translated into multiple languages in preparation for field-testing [3]. Data collection took place as part of the FACE-Q Craniofacial field-test study that involved 863 participants: 607 with microtia, 145 with prominent ears, and 111 with another ear condition [4]. Sample characteristics are shown in Table 1. The sample provided 960 assessments for the Appearance scale and 137 assessments for the Adverse Effects scale. RMT analyses for these scales provided evidence of reliability and validity. Data fit the Rasch model for both the Appearance ($\chi^2(80) = 90.9, p=0.19$) and Adverse Effects ($\chi^2(20) = 24.5, p=0.22$) scales. All items in each scale had ordered thresholds and good item fit. There was no evidence of Differential Item Function for the Appearance scale by age, gender, language, and type of ear condition. Reliability was high for the Appearance scale, with Person Separation Index (PSI) and Cronbach's alpha values with and without extremes >0.92 . Reliability for the Adverse Effects scale was adequate (i.e., PSI and Cronbach alpha values >0.71).

In addition to the ear-specific scales, three HRQOL scales developed as part of the CLEFT-Q© [1, 5-9] were shown to have content validity for use in patients aged 8 to 29 years

with a broad range of craniofacial conditions [10]. The qualitative sample included 84 participants of whom 9 had microtia and 9 had prominent ears. In RMT analysis, three of the HRQOL scales (Psychological, Social, School) evidenced reliability and validity in a combined sample of 4743 children and young adults with cleft and noncleft craniofacial conditions [12]. The large international sample included 860 participants with an ear condition, including 604 participants with microtia, 145 with prominent ears, and 111 with another ear condition. The 860 participants provided a total of 957 assessments that were included in the RMT analysis (3 participants who completed the ear-specific scales did not complete the HRQOL scales).

In addition to the three HRQOL scales, a new scale measuring Appearance-Related Distress was developed and refined as part of the FACE-Q Craniofacial module [10-11]. This scale evidenced strong psychometric properties in the field-test sample of 1495 participants with craniofacial conditions. The field-test sample included 222 participants who had an ear condition, including 98 participants with microtia, 37 with prominent ears, and 87 with another ear condition [13]. The sample of 222 participants provided one assessment each in the RMT analysis. The four HRQOL scales can be used alongside the two ear-specific scales to measure outcomes for patients aged 8 to 29 years with ear conditions. More information about the HRQOL scales is available in the CLEFT-Q and FACE-Q Craniofacial User's Guides. Figure 2 shows the EAR-Q conceptual framework.

Figure 1: The multiphase mixed methods approach our team follows to develop a PRO measure. (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.)

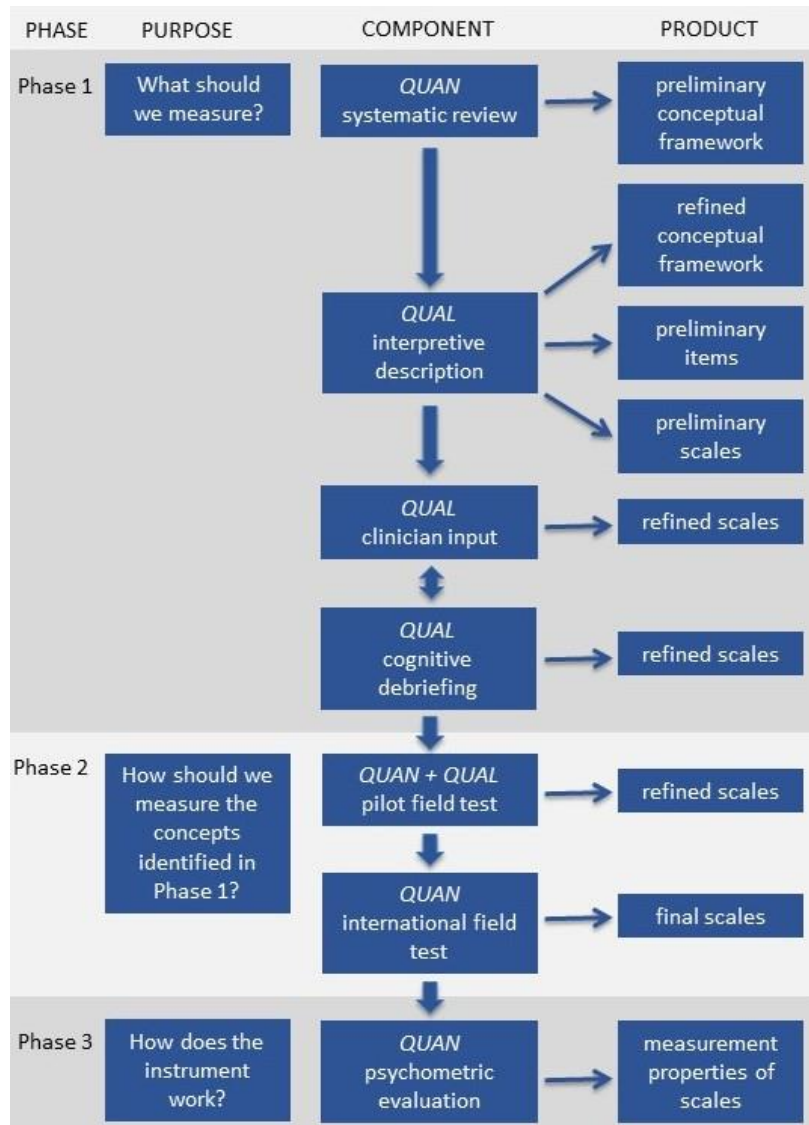


Figure 2: EAR-Q Conceptual Framework

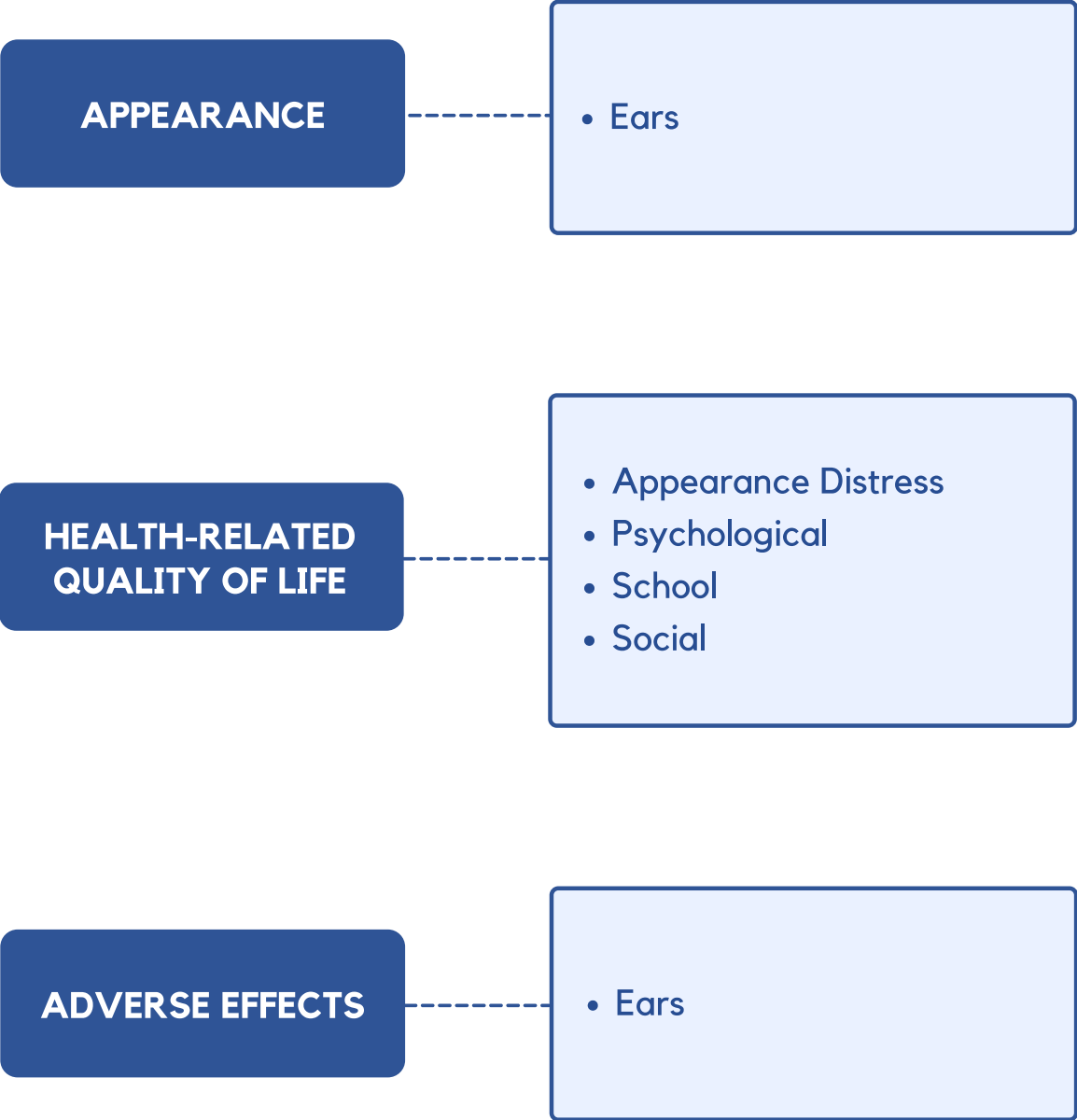


Table 1: Characteristics for the 863 participants who completed the EAR-Q

		N	%
Country	China	361	41.8
	Canada	220	25.5
	UK	175	20.3
	USA	35	4.1
	Spain	28	3.2
	Brazil	20	2.3
	Ireland	14	1.6
	Australia	8	0.9
	Missing	2	0.2
Language	English	452	52.4
	Chinese	361	41.8
	Other	50	5.8
Age in Years	8 to 9	132	15.3
	10 to 11	204	23.6
	12 to 13	186	21.6
	14 to 15	139	16.1
	16 to 29	202	23.4
Gender	Male	495	57.4
	Female	367	42.5
	Other	1	0.1
Ear Condition	Microtia	607	70.3
	Prominent	145	16.8
	Other	111	12.9
Number of Assessments	One	863	89.9
	Two or more	97	10.1
Treatment History	Need surgery	400	41.7
	Had surgery	370	38.5
	Need and had surgery	108	11.3
	Neither had or need	81	8.4
	Missing	1	0.1

NOTE: In the full field-test sample from FACE-Q Craniofacial, the total number of patients with an ear condition was 869 (609 microtia, 149 prominent ears, and 111 other). Of these, 6 participants with ear conditions (2 microtia, 4 prominent ears) were excluded from the EAR-Q publication that reported on 863 participants with ear conditions (607 microtia, 145 prominent ears, and 111 other) because they did not complete the ear-specific scales. Furthermore, 137 participants had a different craniofacial condition as their main condition.

3. EAR-Q Scales

Table 2 shows the EAR-Q scales, including the number of items, the age of participants included in the validation study, response options, recall period, scoring, and Flesch-Kincaid (FK) grade reading level. Below the table is a brief description of the content of each scale and the three single items designed to evaluate outcomes of surgery.

Table 2: Description of EAR-Q scales and single items

Name	Items	Age	Response options	Recall	Scoring	FK
Appearance						
Ears	10	8-29	not at all → very much	now	0-100	1.3
Ear Scars	2	8-29	not at all → very much	now	single item	0
Hearing Aid	1	8-29	not at all → very much	now	single item	1.0
Health-Related Quality of Life						
Appearance Distress	8	8-29	always → never	1 week	0-100	3.2
Psychological	10	8-29	always → never	1 week	0-100	2.2
School	10	8-18	always → never	1 week	0-100	1.9
Social	10	8-29	always → never	1 week	0-100	1.8
Adverse Effects						
Ears	10	8-29	a lot → not at all	1 week	0-100	2.0

APPEARANCE

Ears: This 10-item scale measures how much (not at all, a little bit, quite a bit, very much) someone likes how their ears look. Items ask about ears in terms of their shape and size, as well as how they look in photos, from the side, and when they wear a hat.

Ear Scars: These single items ask about how much (not at all, a little bit, quite a bit, very much) someone likes how their ear scars look and feel.

Hearing Aid: This single item measures how much (not at all, a little bit, quite a bit, very much) someone likes how they look when they wear a hearing aid.

HEALTH-RELATED QUALITY OF LIFE

Appearance Distress: This 8-item scale measures psychosocial distress caused by appearance in terms of frequency (always, sometimes, never) and the past week. Items ask about social issues (going out, meeting people, covering up) and psychological issues (feeling unhappy or self-conscious about appearance).

Psychological: This 10-item scale measures psychological function in terms of frequency (never, sometimes, often, always) and the past week. Items are positively worded and ask about self-esteem (e.g., I like myself), body image (e.g., I feel good about how I look), and confidence.

School: This 10-item scale measures social function at school in terms of frequency (never, sometimes, often, always) and the past week. Items are positively worded and ask about seeing friends at school, feeling safe (not bullied), fitting in, and liking school.

Social: This 10-item scale measures social function in terms of frequency (never, sometimes, often, always) and the past week. Items are positively worded and ask about having fun with friends, feeling accepted by friends, fitting in, and feeling the same as other people.

ADVERSE EFFECTS

Ears: This 10-item scale measures how ears feel after surgery. Items ask (not at all, a little, a lot) whether the ears in the past week hurt, felt itchy, were puffy or swollen, felt numb, or were tingly.

4. Administration of the EAR-Q

The EAR-Q is designed to be completed by patients aged 8 to 29 years on their own (self-report). Each scale is independently functioning, which means that only scales relevant to the clinical situation or research question need be completed. Brief instructions and the timeframe for reporting are provided at the start of each scale. The EAR-Q was field-tested using two modes of data collection, i.e., online data collection using Research Electronic Data Capture System (REDCap) and paper-and-pencil. 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 EAR-Q data collection, the ePRO company may need a license. If you have had EAR-Q scales converted into an electronic format and require an e-conversion review and certificate, please email qportfolioteam@gmail.com.

5. Scoring the EAR-Q

There is no overall or total EAR-Q score. Instead, the EAR-Q is composed of independently functioning scales and single items.

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, for each missing item, insert the mean of the completed items prior to computing the total raw score. The total raw score for the scale is then converted to 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 EAR-Q scales reflect a better outcome. The Conversion Tables for changing raw scores into 0 to 100 scores are available after a licensing agreement is signed.

EAR-Q has 3 stand-alone (i.e., single) items. These items ask about how ear scars look and feel and how hearing aids look. To score single items, the raw score can be used to provide descriptive information about the patient or sample. There is no Conversion Table for the single items.

6. Conditions of Use

McMaster University and The Hospital for Sick Children hold the copyright of the EAR-Q and all of its translations (past, on-going, and future). To avoid any copyright infringement, the following copyright notice shall be included on the questionnaire and all of its derivatives (including, but not limited to translations): “Copyright©2020 McMaster University, Hamilton, Canada and The Hospital for Sick Children, Toronto, Canada. All rights reserved.”

Use of the EAR-Q questionnaire requires completion of a licensing agreement. The use of the EAR-Q in non-profit academic research and in clinical care is free of charge. The use of the EAR-Q by “for-profit” organizations (e.g., pharmaceutical companies, contract research organizations, ePRO companies) is subject to a licensing fee.

To obtain a license to use the EAR-Q, use the following link:

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

For questions regarding an EAR-Q license, please contact:

Licensing Assistant
McMaster Industry Liaison Office (MILO)
McMaster Innovation Park, Suite 305
175 Longwood Rd S, Hamilton ON L8P 0A1
milo@mcmaster.ca

PLEASE NOTE

When you sign an EAR-Q license, you agree to the following terms:

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

For questions regarding study design and optimal use of EAR-Q scales, please contact either:

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

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

7. Frequently Asked Questions

Do I have to use all the scales?

Each scale functions independently; therefore, patients can be asked to complete one or more scale. It is not necessary for a patient to complete all of the scales as there is no overall or total EAR-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 use any full items of the EAR-Q in my publication?

According to the licensing agreement, you cannot reproduce the content of EAR-Q scales verbatim in a publication. However, it is possible to show shortened versions of items. The short forms of items for the two ear-specific scales and HRQOL scales that can be used in a publication are shown in Table 3 below and in the psychometric publications for the EAR-Q, CLEFT-Q, and FACE-Q Craniofacial [4, 9, 13].

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

APPEARANCE	ADVERSE EFFECTS	APPEARANCE DISTRESS	PSYCHOLOGICAL	SCHOOL	SOCIAL
far away	blood	going out	happy with life	seeing friends	friends accept
shape	tingly	mirror	enjoy life	teachers	fun friends
size	active	cover up	feel happy	accepted	people listen
wet hair	bruised	meet people	feel okay	liked	treat same
top part	discolored	unhappy	believe in self	happy	like being with
photos	puffy	dislike	proud of self	nice to me	confident out
profile	numb	people stare	like self	listen to me	fit in
hat on	sleep	self-conscious	feel confident	safe	make friends
up close	itchy		feel great	make friends	same others
other people	sensitive		good look	join activities	people look

Can I delete or add or change any items or response options of the EAR-Q?

You cannot delete or add or change the wording of any items or response options of the EAR-Q. Any modification to the content of the EAR-Q is prohibited under copyright laws. Also, making any changes to EAR-Q scales would invalidate their psychometric properties.

Can I translate the EAR-Q into a new language?

Yes, with permission, you can translate the EAR-Q into different languages. Before starting a translation, check our translations 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 EAR-Q own the copyright of all translations of the EAR-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 EAR-Q?

Use of EAR-Q scales is free for non-profit users, including use by hospitals. For-profit users should contact McMaster University for information about fees: milo@mcmaster.ca.

8. Acknowledgements

Development of the EAR-Q has involved hundreds of children and young adults with ear conditions, along with the collaboration of numerous health care professionals and researchers around the world. We are truly grateful for their dedication and help with our research. The scales that form the EAR-Q have been generously funded by the following grants:

Phase I: Qualitative

Klassen A, Wong K, Forrest C, Davidge K, Borschell G, Zuker R, Giglia L, Pusic A. Development of the FACE-Q Kids PRO Instrument. The Plastic Surgery Foundation, May 2015 – April 2016.

Phase II: International Field-Test

Klassen A, Wong K, Forrest C, Pusic A. An International Study to Develop a Patient-Reported Outcome Instrument for Conditions Associated with a Facial Difference: FACE-Q Kids, Canadian Institutes of Health Research (FRN 148779), July 2016 – June 2018.

9. Publications

1. 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.
2. Klassen AF, Longmire NM, Bulstrode NW, Fisher DM, Kasrai L, O'Hara J, Panchapakesan V, Pusic AL, Stewart K, Tsangaris E, Ziolkowski N, Wong Riff K WY. Development of a New Patient-reported Outcome Measure for Ear Conditions: The EAR-Q. *Plast Reconstr Surg Global Open*. 2018 Aug 7;6(8):e1842.
3. Tsangaris E, Wong Riff K WY, Bergenguer B, Bulstrode NW, Celerier C, Cugno S, Fanous A, Mazed A, Marchac A, Stotland M, Klassen AF. Translation and cultural adaptation of the EAR-Q into Arabic, Chinese, French and Spanish for use in an international field-test study. *European J Plast Surg*. 2019; 43:159-164.
4. Klassen AF, Rae C, Bulstrode NW, Berenguer B, Cui C, Fisher DM, Kasrai L, Li Yiyuan, Lloyd M, Panchapakesan V, Pusic A, Reinsch J, Frank R, Stewart K, Todd A, Tsangaris E, Wang Y, Wong Riff K WY, Zhang R, An international study to develop the EAR-Q patient-reported outcome measure for children and young adults with ear conditions. *J Plast Reconstr Aesthet Surg*. 2021 Feb 5:S1748-6815(21)00057-7.
5. Wong Riff K WY, 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.
6. Tsangaris E, Wong Riff K WY, 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.
7. Tsangaris E, Wong-Riff K, Forrest C, Dreise M, Steirnman M, Kaur MN, Piplani B, Aydin A, Naser G, Kharashgah M, Stotland MA, Thabane L, Thoma A, Klassen AF. Translation and cultural adaptation of the CLEFT-Q into Arabic, Dutch, Hindi, Swedish, and Turkish. *Eur J Plast Surg*. 2018 August;41(5):1-10.
8. Tsangaris E, Riff K WY 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.
9. Klassen AF, Riff K W W, 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 Apr 16;190(15):E455-62.
10. Longmire NM, Wong Riff K WY, Bhoomika P, O'Hara J, Goodacre TEE, Forrest C, Klassen AF.

Development of a new module of the FACE-Q for children and young adults with diverse conditions associated with visible and/or functional facial differences. *Facial Plast Surg.* 2017 Oct;33(5):499-508.

11. Kamran R, Longmire NM, Rae C, Riff KQW, Forrest CR, O'Hara J, Bulstrode N, Klassen AF. Concepts Important to Patients With Facial Differences: A Qualitative Study Informing a New Module of the FACE-Q for Children and Young Adults. *Cleft Palate Craniofac J.* 2021 Aug;58(8):1020-1031.
12. Klassen AF, Rae C, Wong Riff KW, Bulstrode N, Denadai R, Goldstein J, Hol ML, Murray DJ, Bracken S, Courtemanche DJ, O'Hara J, Butler D, Tassi A, Malic CC, Ganske IM, Phua YS, Marucci DD, Johnson D, Swan MC, Breuning EE, Goodacre TE, Pusic AL, Cano S. FACE-Q Craniofacial Module: Part 1 validation of CLEFT-Q scales for use in children and young adults with facial conditions. *J Plast Reconstr Aesthet Surg.* 2021 Jun 10:S1748-6815(21)00292-8.
13. Klassen AF, Rae C, Riff W, Denadai R, Murray DJ, Bracken S, Courtemanche DJ, Bulstrode N, O'Hara J, Butler D, Goldstein J, Tassi A, Hol ML, Johnson D, Ganske IM, Kölby L, Benitez S, Breuning EE, Malic CC, Allen GC, Pusic AL, Cano S. FACE-Q craniofacial module: Part 2 Psychometric properties of newly developed scales for children and young adults with facial conditions. *J Plast Reconstr Aesthet Surg.* 2021 Mar 25:S1748-6815(21)00098-X.