LIMB-Q KIDS

A User's Guide for Researchers and Clinicians

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1. What is the LIMB-Q Kids?

The LIMB-Q Kids is a rigorously developed patient-reported outcome measure (PROM) that can be used internationally to collect and compare evidence-based outcomes data from patients aged 8-18 years with lower limb differences. Lower limb differences (LLDs) can result from congenital conditions or are acquired from trauma, infection, tumors, or other medical conditions. LLDs mainly include leg length discrepancy, lower limb deficiency, and associated angular and rotational deformities. The LIMB-Q Kids is composed of 9 independently functioning scales. The use of a modular approach means that only the scales most relevant to a specific research objective or clinical patient population need to be administered.

2. How was the LIMB-Q Kids Developed and Validated?

The LIMB-Q Kids 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 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 the target sample, accurate tracking of clinical change can be achieved. In addition to their use in research studies, LIMB-Q Kids scales can be used with individual patients to monitor their progress over time and inform clinical care.

LIMB-Q Kids was developed as there was no rigorously developed and internationally applicable PROM for children with LLDs as identified in our systematic review (1). We followed internationally recommended guidelines for PROM development to create the LIMB-Q Kids (2). Figure 1 shows the multiphase mixed-methods approach we used to develop LIMB-Q Kids.

The qualitative phase involved 79 interviews with patients (N=39) aged 8-18 with a diagnosis of LLD and with their parents (N=40) from Canada, Ethiopia, India, and the USA (3) (Table 1). The findings from the interviews were used to develop a conceptual framework comprised of 5 main themes: appearance, physical health, psychological health, school, and social health, with other factors such as coping, emotional support, and instrumental support being identified as mediating factors. Cognitive debriefing interviews were conducted with 17 patients (Table 2) from sites in Australia, Canada, and the USA. Additionally, 23 experts including orthopaedic surgeons, nurses, physiotherapists, and prosthetists from Australia, Canada, Ethiopia, India, UK, and the USA provided input used to refine the scales and establish their content validity (4).

To facilitate the involvement of non-English speaking countries, the scales were initially translated and culturally adapted into German, Danish, and Hindi following ISPOR (The Professional Society for Health Economics and Outcomes Research) guidelines (5–7).

The quantitative phase involved the collection of data from 800 patients with lower limb differences from 16 sites in 7 countries (8). Table 3 shows the sample characteristics. The final conceptual framework and set of scales is shown in Figure 2.

Table 1: Characteristics of participants in the qualitative study

	Canada - 1	Canada - 2	USA	India	Ethiopia	Total
Interviews (parent and patient)	16	10	21	20	12	79
Interviews (patients)	7	5	11	10	6	39
Congenital Lower Limb Deformity	6	5	11	7	5	34
Acquired Lower Limb Deformity	1	0	0	3	1	5
Average Age (in years for patients)	13.7	11	12.3	13.7	13	12.9
Age Range (in years for patients)	11 to 18	8 to 18	9 to 16	11 to 18	10 to 17	8 to 18
Gender						
Female	2	2	7	2	2	15
Male	5	3	4	8	4	24
Interview in English						
Yes	16	0	21	0	0	37
No	0	10	0	20	12	42

Note: Table 1 reproduced from Chhina H, Klassen AF, Kopec JA, Oliffe J, Iobst C, Dahan-Oliel N, Aggarwal A, Nunn T, Cooper AP. What matters to children with lower limb deformities: an international qualitative study guiding the development of a new patient-reported outcome measure. J Patient Rep Outcomes. 2021 Apr 1;5(1):30. doi: 10.1186/s41687-021-00299-w. PMID: 33792793; PMCID: PMC8017030.

Table 2: Demographics and clinical characteristics of patients participating in cognitive debriefing interviews in the content validity study, n (%)

Demographic and Clinic	Number (%)	
Country	Australia	5 (29.4)
	Canada	11 (64.7)
	USA	1 (5.9)
Sex	Male	10 (58.8)
	Female	7 (41.2)
Age (years)	8–10	4 (23.5)
	11–13	6 (35.3)
	14–18	7 (41.2)
	Average (range)	13 (8 to 17)
Type of Deformity	Fibular hemimelia	6 (35.3)
	Amputation	4 (23.5)
	Hemi-hypertrophy	2 (11.8)
	Ollier's disease	1 (5.9)
	Spondylocostal dysostosis and scoliosis	1 (5.9)
	Posteromedial tibial bowing and leg length discrepancy	1 (5.9)
	Congenital short femur	1 (5.9)
	Leg length discrepancy and dysplastic lateral femoral condyle	1 (5.9)

Note: Table 2 reproduced from Chhina H, Klassen A, Bade D, Kopec J, Cooper AP. Establishing content validity of LIMB-Q Kids: A new patient-reported outcome measure for lower limb deformities. Qual Life Res. 2022;31(9):2805-2818. PMID: 35471486.

Figure 1: The multiphase mixed methods protocol for developing the LIMB-Q Kids (Reproduced with permission from Wong Riff KWY, 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:e015467.)

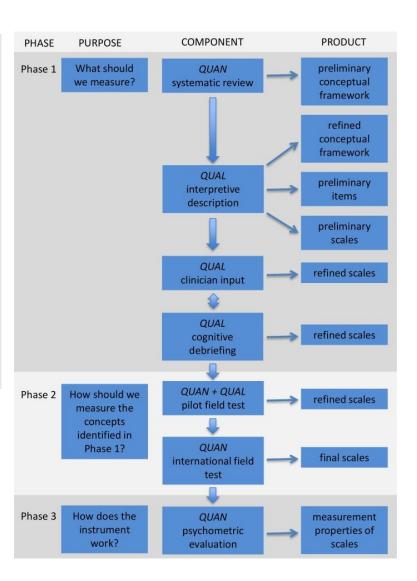


Figure 2: LIMB-Q Kids conceptual framework

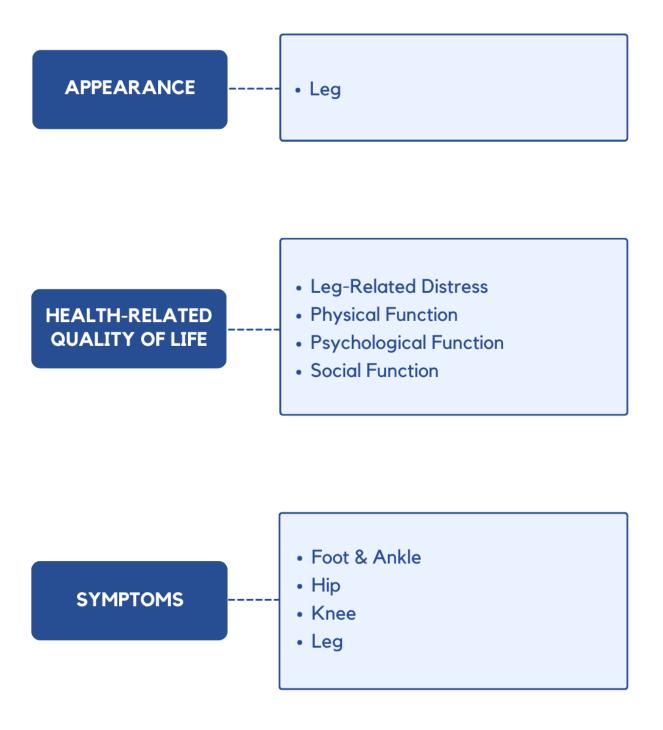


Table 3: Characteristics (Number, %) of field-test participants

		N (800)	%
Age (years)	8 to 11	249	31.1
	12 to 14	276	34.5
	15 to 19	247	30.9
	20 to 25	24	3.0
Gender	Girl/Woman	361	45.4
	Boy/Man	433	54.4
	Other/ Not sure/ Prefer not to answer	2	0.3
Attend school	Yes	742	93.5
Country	Australia	37	4.6
	Canada	187	23.4
	Denmark	52	6.5
	England	209	26.1
	Germany	54	6.8
	India	50	6.3
	Scotland	37	4.6
	USA	174	21.8
LLRS AIM index score	Normal	128	16.0
	Minimal complexity	528	66.0
	Moderate complexity	115	14.4
	High/Substantial complexity	29	3.6
Diagnosis*	Leg Length Discrepancy	348	43.5
	Genu Valgus	145	18.1
	Fibular Hemimelia	99	12.4
	Skeletal Dysplasia	56	7.0
	Hemi-hypertrophy	45	5.6
	Congenital Femoral Deficiency	44	5.5
	Genu Varum	32	4.0
	Blount's disease	29	3.6
	Idiopathic Leg Length Discrepancy	20	2.5
	Posteromedial Tibial Bowing	19	2.4
	Leg Length Discrepancy secondary to Perthes	17	2.1
	Leg Length Discrepancy secondary to Clubfoot	16	2.0
	Osteogenesis Imperfecta	14	1.8
	Congenital Pseudarthrosis of Tibia	10	1.3
	Patellar Instability	10	1.3
	Tibial Hemimelia	9	1.1
	Amputations (Due to trauma, infection, or other diagnosis)	6	0.8
	Post Traumatic Deformity	6	0.8
	Genu Recurvatum	5	0.6
	Perthes	4	0.5
	Hemi-atrophy	3	0.4
	Osteofibrous Dysplasia	3	0.4
	Trauma	3	0.4
	Achondroplasia	2	0.3
	Arthrogryposis	2	0.3
	Fibrous Dysplasia	2	0.3
	Growth Arrest	2	0.3
	Hereditary Multiple Exostosis	2	0.3

Leg Length Discrepancy Secondary to Developmental Dysplasia Hip	2	0.3
Neurofibromatosis Type 1	2	0.3
Spina Bifida	2	0.3
Other	48	6.0

^{*}More than 1 can be reported

Note: Table 3 reproduced Chhina H, Rae C, Podeszwa D, Fernandes J, Johnson L, Vogt B, Rölfing J, Kerrigan A, Ranade A, Messner J, Belthur M, Esparza M, Wright J, Bade D, McMahon S, Iobst C, Sabharwal S, Abouassaly M, Cooper A, Klassen A. Psychometric Findings for LIMB-Q Kids Based on an International Study of 800 Children and Adolescents with Lower Limb Differences. J Patient Rep Outcomes. Accepted April 2025.

3. LIMB-Q Kids Scales

Table 4 shows the LIMB-Q Kids scales including number of items, the population included in the Rasch Measurement Theory analysis, response options, recall period, and scoring. Of note, the patients in the field test included patients with a wide range of diagnoses causing lower limb differences. Below the table is a brief description of the content of each scale.

Table 4: Description of LIMB-Q Kids scales

Scale	Items	Response options	Recall	Scoring
Appearance				
Leg Appearance	10	Not at all, A little bit, Quite a bit, Very much	Now	0-100
Health-Related Qua	lity of Lif	e		
Leg-Related Distress	11	Always, Sometimes, Never	Past week	0-100
Physical Function	11	I CANNOT do this, I have TROUBLE doing this, I CAN do this	Past week	0-100
Psychological Function	9	Never, Sometimes, Often, Always	Past week	0-100
Social Function	10	Never, Sometimes, Often, Always	Past week	0-100
Symptoms				
Foot & Ankle	10	Always, Sometimes, Never	Past week	0-100
Hip	10	Always, Sometimes, Never	Past week	0-100
Knee	9	Always, Sometimes, Never	Past week	0-100
Leg	8	Always, Sometimes, Never	Past week	0-100

APPEARANCE

Leg: This 10-item scale measures how much (not at all, a little bit, quite a bit, very much) the participant likes the look of their leg. Items ask about the appearance of the leg in terms of length, size, and impact of clothing, as well as in comparison to other people's legs. Items also ask about the appearance of the foot and knee.

Scar: This is a stand-alone item which measures how much (not at all, a little bit, quite a bit, very much) the participant likes how the scar(s) on their leg looks. Thus, the patient's response is taken as the score for this item. If you would like to measure scars in more detail, the SCAR-Q is a patient-reported outcome measure that can be used to evaluate scars for anyone aged 8 years and older. See: https://qportfolio.org/scar-q/

HEALTH-RELATED QUALITY OF LIFE

Leg-related Distress: This 11-item scale measures how often (always, sometimes, never) the participant feels distress due to their leg. Items ask about avoiding going out or wearing shorts or skirts, getting upset, feeling unhappy, disliking how the leg looks, and worry.

Physical Function: This 11-item scale measures a patient's ability (cannot do, have trouble, can do) to perform different physical functions. Items ask about the ability to walk, get up from floor, jump, climb, play sports, and run.

Psychological Function: This 9-item scale measures psychological function in terms of frequency (never, sometimes, often, always) and in the past week. Items are positively worded and ask about feeling happy, proud, and confident.

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

SYMPTOMS

Foot & Ankle: This 10-item scale measures symptoms related to foot and ankle in terms of frequency (always, sometimes, never) and in the past week. Items ask about the ankle or foot hurting, feeling wobbly, walking, standing, and running.

Hip: This 10-item scale measures symptoms related to the hip in terms of frequency (always, sometimes, never) and in the past week. The items ask about the hip hurting, feeling weak, making a sound, sitting, walking, and running.

Knee: This 9-item scale measures symptoms related to the knee in terms of frequency (always, sometimes, never) and in the past week. Items ask about the knee hurting when it's stuck, resting, straightening, or bending, and about swelling and weakness.

Leg: This 8-item scale measures symptoms related to the knee in terms of frequency (always, sometimes, never) and in the past week. Items ask about the leg hurting when sleeping, touching it, resting, running, and standing.

Reference Images

Anatomical reference images are intended to support participant's understanding and improve response accuracy by providing visual context for anatomical locations.

Please note that these images were not included in the Danish, German and English version used for the field test study. Hindi version used for the field test study included these reference images.

These images have now been incorporated in all versions of LIMB-Q Kids based on the positive feedback obtained during the cognitive debriefing interviews conducted for Arabic, Dutch, Hebrew, Hindi and Portuguese translation process.

4. Administration of the LIMB-Q Kids

The LIMB-Q Kids is designed to be completed by patients on their own (self-report). Each scale is independently functioning, which means that only scales relevant to the clinical situation or research question need to be completed. Patients can thus be asked to complete a subset of scales relevant to their situation. Brief instructions and the time frame for reporting are provided at the start of each scale. The LIMB-Q Kids was field-tested using online data collection, i.e., Research Electronic Data Capture System (REDCap) as well as 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 or Cerner). If you plan to have an ePRO company capture and manage LIMB-Q Kids data collection, the ePRO company may need a license. If you have had or plan to have an ePRO company convert LIMB-Q Kids scales into an electronic format, e-conversion review, and certification is required. Please email hchhina@cw.bc.ca for more information.

PLEASE NOTE

Once you have received the data dictionary for REDCap, please keep the following in mind:

- Do not upload these excel files to the REDCap library
- Do not share the REDCap data dictionary with anyone who has not signed the license agreement for using LIMB-Q Kids

5. Scoring the LIMB-Q Kids

There is no overall or total LIMB-Q Kids score. Instead, the LIMB-Q Kids is composed of independently functioning scales (see Table 4). Higher scores on a scale reflect a better outcome.

To score a scale, the raw scores for the set of items in a scale are added together to produce a total raw score. The choice of how to handle missing data, such as whether or not to impute the mean when there is missing data, is ultimately up to the end user of LIMB-Q Kids. Our suggestion follows the most popular method for scoring when there is missing data, which is to impute a missing value by the mean response to completed items if more than 50% of items are answered. This method is recommended in the scoring manuals of numerous widely used PROMs, such as the SF-36 generic questionnaire used extensively in research for decades (9,10). As such, LIMB-Q Kids scores can be computed if missing data is less than 50% of the scale's items. In this approach, 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.

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 LIMB-Q Kids 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.

Below is an example of how to compute a scale score using the LIMB-Q Kids Leg Symptoms scale. First, you compute the <u>sum score</u> by adding the raw scores for items 1 - 8. In the example below, the sum score = 19. Second, you will find the sum score for the Leg

Symptoms Conversion Table, which is shown below. The sum score of 19 is then converted to 66.

		Always	Sometimes	Never
1.	My leg hurts when I sleep.	1	2	3
2.	My leg hurts when I touch it.	1	2	(3)
3.	My leg hurts when I rest or relax.	1	2	3
4.	My leg feels weak (eg, shaky).	1	2	3
5.	My leg hurts when I run.	1	2	3
6.	My leg gets tired when I walk.	1	2	3
7.	My leg hurts when I stand for a long time.	1	2	3
8.	My leg gets tired when I run.	1	2	3

LIMB-Q KIDS[™] – LEG SYMPTOMS: CONVERSION TABLE

SUM SCORE	EQUIVALENT RASCH TRANSFORMED SCORE (0-100)
8	0
9	5
10	15
11	24
12	31
13	37
14	42
15	47
16	51
17	56
18	61
19	(66)
20	71
21	76
22	83
23	90
24	100

6. Conditions of Use

The University of British Columbia and McMaster University hold the copyright of the LIMB-Q Kids and all of its translations (past, on-going, and future). To avoid any copyright infringement, please ensure that the copyright notice of LIMB-Q Kids is included in the questionnaire. If you are unsure of the copyright notice for LIMB-Q Kids, our website lists the copyright and trademark notice: https://qportfolio.org/copyright-information/.

Use of the LIMB-Q Kids requires completion of a licensing agreement. The use of the LIMB-Q Kids in non-profit academic research and in clinical care is <u>free of charge</u>. The use of the

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https://research.mcmaster.ca/industry-investors/technologies-available-for-licensing/request-for-license/

For questions regarding a LIMB-Q Kids license, please contact:

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McMaster Innovation Park, Suite 305
175 Longwood Rd S, Hamilton ON L8P 0A1
milo@mcmaster.ca

PLEASE NOTE

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

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

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

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aklass@mcmaster.ca

7. Frequently Asked Questions

Do I have to use all of the LIMB-Q Kids scales?

Each scale functions independently; therefore, patients can be asked to complete one or all of the LIMB-Q Kids scales. It is not necessary for a patient to complete all of the scales as there is no overall or total LIMB-Q Kids 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 LIMB-Q Kids?

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

Can I reproduce LIMB-Q Kids scales in a publication or other public document (e.g., PhD thesis)?

According to the licensing agreement, you cannot reproduce the content of LIMB-Q Kids scales 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 5 below.

Can I translate LIMB-Q Kids scales into a new language?

Yes, with permission, you can translate the LIMB-Q Kids 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 no translation in the language you need, you need to obtain permission from our team, sign a translation licensing agreement, and receive information on the methods you need to follow. Email us at milo@mcmaster.ca for more information. Please note that the developers of the LIMB-Q Kids own the copyright of all translations of the LIMB-Q Kids.

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 LIMB-Q Kids?

Use of LIMB-Q Kids scales is free for non-profit users. For-profit users should contact McMaster University for information about fees (milo@mcmaster.ca).

8. Acknowledgements

Development of LIMB-Q Kids has involved more than 800 patients with a diagnosis of lower limb differences, 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 LIMB-Q Kids study has been generously funded by the following grants:

Phase I: Qualitative

Chhina H, Cooper A. Development and validation of a Patient Reported Outcome Instrument for Children with Lower Limb Deformities. UBC Orthopaedics Research Excellence Fund, 2015 – 2017.

Chhina H, Klassen A, Cooper A. Development of a Patient Reported Quality of Life Questionnaire for Children with Lower Limb Deformities. Canadian Orthopaedic Research Legacy Grant, 2017 – 2019.

Phase II and Phase III: Field-Test and Psychometric Study

Chhina H, Klassen A, Cooper A. International Field Test and Translation and Cultural adaptation of LIMB-Q Kids: A new patient reported outcome measure for participants with lower limb deformities. Canadian Orthopaedic Research Legacy Grant, 2022 – 2024.

Chhina H, Klassen A, Cooper A. International study to field-test a new patient-reported outcome measure for participants with lower limb differences. Canadian Institutes of Health Research (GR026260), 2023.

Additional Note

Investigators Dr. Anthony Cooper and Dr. Harpreet Chhina are part of the Limb Reconstruction Research program which was partially funded by the BC Children's Hospital Foundation during the LIMB-Q Kids development.

Table 5: Shortened items for LIMB-Q Kids scales to use in a publication

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9. Publications Related to LIMB-Q Kids Development and Validation

- 1. Chhina H, Klassen A, Kopec JA CA. Development of a patient-reported outcome instrument to measure quality of life of children with lower limb deformities: preliminary results. Qual Life Res. 2016;25(138).
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- 10. Ware JE, Kosinski M, Keller SD. SF-36 physical and mental health summary scales: a user's manual. 2nd ed. Boston, MA: The Health Institute; 1995.