

A Guide for Researchers and Clinicians

USER'S GUIDE VERSION 1.0 AUGUST 2017

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1. What is the BODY-Q©?

The BODY-Q© is a rigorously developed patient-reported outcome (PRO) measure designed to evaluate outcomes for patients who are obese and undergo weight loss through diet, exercise and/or bariatric surgery/medicine, and body contouring patients (following massive weight loss for cosmetic reasons).

The BODY-Q© also has a Chest Module that can be used to measure the appearance of the chest in gynaecomastia, massive weight loss and gender affirming chest surgery.

2. How was the BODY-Q© Developed?

Figure 1 shows the multiphase mixed methods approach used by our team to develop PRO measures. We followed internationally recommended guidelines for PRO measure development to ensure that the BODY-Q© meets requirements of regulatory bodies.

In Phase 1, a literature review and 63 patient interviews were used to create the BODY-Q conceptual framework and a set of scales that measure concepts that matter to weight loss and body contouring patients. The scales were further refined through 22 patient interviews and input from 9 clinical experts. In phase 2, the scales evidenced reliability, validity, and responsiveness in an international (Canada, USA and UK) sample of 403 pre- and post-weight loss and 331 pre- and post-body contouring surgery patients.

The BODY-Q© represents a new generation 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 (no total score). 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.

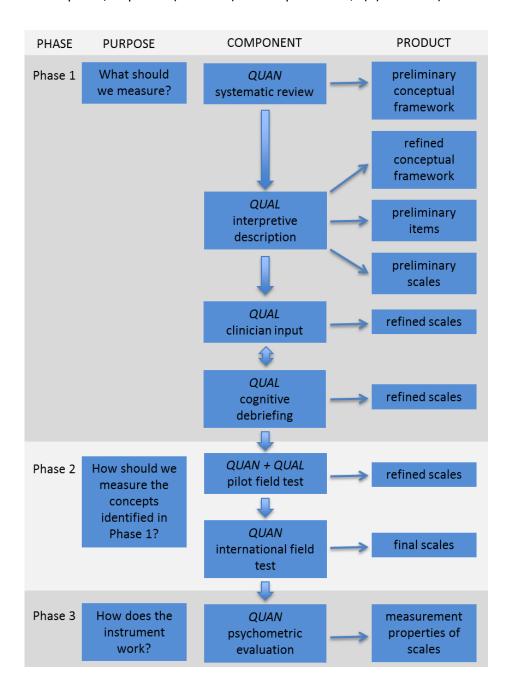
The BODY-Q© (see Table 1) is composed of a series of independently functioning scales that measure three domains (appearance, HRQL, and experience of healthcare). In addition, there is an obesity-specific symptom checklist.

The original BODY-Q© field-test publication included 18 scales and the obesity-specific symptom checklist. More recently, the BODY-Q© has added a Chest Module (chest and nipples scales). These scales were field-tested in 689 participants aged 16 years and older from Canada, USA, Denmark, and the Netherlands (i.e., 174 gynaecomastia, 224 weight loss, 291 trans men having gender confirming surgery).

A new scale to measure the appearance of stretch marks has also been developed and field-tested in an international sample that included 630 participants who provided 774 assessments.

We are currently field-testing a new scale to measure the appearance of cellulite. We are also developing scales to measure additional concerns of patients undergoing weight loss via bariatric surgery and weight management programs. Contact us for more details.

Figure 1: The multiphase mixed methods approach our team follows 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 (CLEFT-Q). BMJ Open. 2017;7(1):015467.)



3. BODY-Q© Scales

Table 1: BODY-Q© scales including the number of items, response options, time frame and grade reading level. Below the table is a brief description of each scale.

| Name of scale | Items | Response options | Recall period | FK grade | |
|---|-------|--------------------------------|---------------|----------|--|
| Appearance scales | | | | | |
| Abdomen | 7 | dissatisfied/ satisfied | past week | 3.1 | |
| Arms | 7 | dissatisfied/ satisfied | past week | 1.4 | |
| Back | 4 | dissatisfied/ satisfied | past week | 0 | |
| Body | 10 | dissatisfied/ satisfied | past week | 2.1 | |
| Buttocks | 5 | dissatisfied/ satisfied | past week | 1.2 | |
| Chest | 10 | dissatisfied/ satisfied | past week | 2.7 | |
| Nipples | 5 | dissatisfied/ satisfied | past week | 0.9 | |
| Hips & outer thighs | 5 | dissatisfied/ satisfied | past week | 1.2 | |
| Inner thighs | 4 | dissatisfied/ satisfied | past week | 0.6 | |
| Excess skin | 7 | not at all/ extremely bothered | past week | 3.2 | |
| Scars | 10 | not at all/ extremely bothered | past week | 1.2 | |
| Stretch marks | 10 | not at all/ extremely bothered | past week | 1.4 | |
| Cellulite* | 15 | not at all/ extremely bothered | past week | 4.5 | |
| Health-related quality of life scales/checklist | | | | | |
| Appearance-related | 8 | agree/ disagree | n/a | 2.7 | |
| psychosocial distress | | | | | |
| Body image | 7 | agree/ disagree | past week | 2.5 | |
| Expectations | 8 | agree/ disagree | n/a | 1.5 | |
| Physical | 7 | all the time/never | past week | 2.7 | |
| Psychological | 10 | agree/ disagree | past week | 3.5 | |
| Sexual | 5 | agree/ disagree | n/a | 5.3 | |
| Social | 10 | agree/ disagree | past week | 3.7 | |
| Obesity symptoms | 10 | all the time/never | past week | 2.8 | |
| Patient experience scales | | | | | |
| Doctor | 10 | agree/ disagree | n/a | 4.2 | |
| Information | 10 | dissatisfied/ satisfied | n/a | 5.0 | |
| Medical team | 10 | agree/ disagree | n/a | 3.6 | |
| Office staff | 10 | agree/ disagree | n/a | 3.9 | |

FK = Flesch-Kincaid grade reading level. *Field-test version

APPEARANCE SCALES

Satisfaction with abdomen: This 7-item scale measures satisfaction with the appearance of the abdomen. Items ask about abdomen shape and size, how clothes fit, as well as how the abdomen looks from the side, in a swimsuit and when naked.

Satisfaction with upper arms: This 7-item scale measures satisfaction with the appearance of the upper arms. Items ask about upper arm size, shape, skin, as well as how the upper arms look when lifted and when not covered.

Satisfaction with back: This 4-item scale measures satisfaction with the appearance of the back. Items ask about the back in terms of how toned and smooth the back looks, as well as how the back looks from different angles and when naked.

Satisfaction with body: This 10-item scale measures satisfaction with the appearance of the body. Items ask about the body in terms of size, shape, how clothes fit, as well as how the body looks from the side, behind, in a swimsuit and when unclothed.

Satisfaction with buttocks: This 5-item scale measures satisfaction with the appearance of the buttocks. Items ask about the size, shape and skin, as well as how the buttocks look from the side.

Satisfaction with chest: This 10-item scale measures satisfaction with the appearance of the chest. Items ask about how masculine the chest looks, how the chest looks in a snug T-shirt and how the chest looks in the mirror without a shirt on.

Satisfaction with nipples: This 5-item scale is a companion to the chest scale. Items ask about satisfaction with the appearance of the nipples including their size, shape and how much they show through a snug T-shirt.

Satisfaction with hips and outer thighs: This 5-item scale measures satisfaction with the appearance of the hips and outer thighs. Items ask about size, shape and skin, as well as how the hips and outer thighs look from behind.

Satisfaction with inner thighs: This 4-item scale measures satisfaction with the appearance of the inner thighs. Items ask how smooth and toned the inner thighs are, as well as how the skin looks and how the inner thighs look when naked.

Appraisal of excess skin: This 7-item scale measures being bothered by the appearance of excess skin. Items ask about the amount of skin, how it hangs, having to dress in a way to hide the skin, and how the skin looks when naked.

Appraisal of scars: This 10-item scale measures being bothered by the appearance of body contouring scars. Items ask about being bothered by the width, location, length and colour of the scars, as well as how noticeable they are and people seeing them.

Appraisal of stretch marks: This 10-item scale measures being bothered by the appearance of stretch marks. Items ask about being bothered by how wide they are, their length, their location, as well as how noticeable they are and how they look up close.

Appraisal of cellulite: This 15-item scale measures being bothered by the appearance of cellulite. Items ask about being bothered by the amount of cellulite, where it is located on the body, how noticeable it is in tight-fitting clothes, as well as how it looks up close.

HEALTH-RELATED QUALITY OF LIFE

Appearance-related psychosocial distress: This 8-item scale measures appearance-related distress using a range of emotional responses to appearance, e.g., feeling anxious, stressed and unhappy.

Body image: This 7-item scale measures body image. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree with being proud of their body, happy with their body, positive towards their body, etc.

Expectations: This 8-item scale measures how someone expects their appearance and life will change after a cosmetic procedure.

Physical function: This 7-item scale asks respondents to indicate how often they experience problems with various physical activities, including getting up from a bed, standing for long periods of time, doing moderate exercise, etc.

Psychological function: This 10-item scale measures psychological function. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree with feeling happy, confident, in control of his/her life, etc.

Sexual function: This 5-item scale measures sexual function. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree with being satisfied with their sex life, being comfortable with the lights on during sex, feeling sexually attractive when undressed, etc.

Social function: This 10-item scale measures social function. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree with feeling accepted by people, feeling that they make a good first impression, feeling confident in a group situation, etc.

Obesity symptoms: This 10-item checklist asks how often someone experienced a set of obesity-specific symptoms, including feeling tired during the day, back pain, shortness of breath with mild exercise, excess perspiration, etc.

EXPERIENCE OF CARE

Satisfaction with doctor: This 10-item scale measures a patient's experience of care in terms of how they were treated by the doctor. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree that the doctor treated them with respect, made them feel comfortable, spent enough time with them, etc.

Satisfaction with information: This 10-item scale measures the patient's experience of care in terms of satisfaction with the information they received from their medical team. Items are positive in both content and phrasing and ask respondents to indicate how satisfied they are with information they received about activities to avoid during recovery, options for how the surgery could be done, the kinds of complications that could happen, etc.

Satisfaction with medical team: This 10-item scale measures a patient's experience of care in terms of how they were treated by members of the medical team. Items are positive in both content and phrasing and ask respondents to indicate how much they agree/disagree that the medical team treated them with respect, were easy to talk to, worked together as a team, etc.

Satisfaction with office staff: This 10-item scale measures the patient experience of care in terms of how they were treated by members of the office staff. Items are positive in both content and phrasing

and ask respondents to indicate how much they agree/disagree that the office staff treated them with respect, were attentive to their needs, welcomed them at the front desk, etc.

4. Administration of the BODY-Q©

It is important to note that patients do not need to complete all of the available BODY-Q© scales in any given study or clinical encounter. Each scale is designed to function independently and takes only a few minutes to complete. Brief instructions are provided at the start of each scale.

The BODY-Q© was field-tested using two modes of data collection as follows: paper-and-pencil (N=339, 46 percent) and online (N=394, 54 percent). The online data were collected using Research Electronic Data Capture System (REDCap).

5. Scoring the BODY-Q©

There is <u>no overall or total</u> BODY-Q© score; only scores for each independent scale. All BODY-Q© scales are transformed into scores that range from 0-100. The scores are computed by adding the response items together and then converting the raw sum scale score to a score 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).

6. Conditions of Use of the BODY-Q©

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Use of the BODY-Q© questionnaire requires completion of a user's agreement. The use of the BODY-Q© and its modules in non-profit academic research and in clinical care is <u>free of charge</u>. The use of the BODY-Q© by 'for-profit' organizations is subject to a licensing fee.

Non-profit users can access the BODY-Q using the following link: https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=NRKX3HPT9J

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

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7. Frequently Asked Questions

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

Yes, you must sign a licensing 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 the universities where they were developed.

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

Use of BODYQ© scales is free for non-profit users. For-profit users need to pay a licensing fee through Memorial Sloan Kettering Cancer Centres (see conditions of use above).

Do I have to use all of the BODY-Q© scales?

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

You cannot make any changes to the wording of any items or response options of the BODY-Q©. 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 the BODY-Q© scales. The second reason is that by deleting or adding items, it would then not be possible to score the BODY-Q© and you would not be able to compare findings with those of other BODY-Q© studies. Finally, adding or deleting items is prohibited under copyright laws.

Can I translate the BODY-Q© into a new language?

Yes, you can translate the BODY-Q© into different languages. Check our table of translations available in REDCap (https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=NRKX3HPT9J) 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 prior to translating the BODY-Q©. Please note that the developers of the BODY-Q© own the copyright of all translation of the BODY-Q©. For a helpful publication showing the rigorous translation of the BODY-Q© into Danish, see Poulsen et al. 2017.

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.

8. Acknowledgements

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Qualitative Phase: Pusic A, Cano S, Klassen A. Development and validation of a new patient-reported outcome measure for body contouring patients. National Endowment for Plastic Surgery, Sept 2009 – Oct 2010.

Quantitative Phase: Klassen, A, Cano S, Pusic A, Taylor V, Thoma A. Developing a patient-reported outcome measure for bariatric and body contouring surgery patients: The BODY-Q©. Canadian Institutes of Health Research, 2012 Oct – Mar 2016.

9. BODY-Q© Publications

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