PROM-cycle

Eight steps to select and implement PROMs for healthcare settings

Authors Dutch version

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The **PROM-cycle** describes eight steps to select and implement Person/Patient Reported Outcome Measures (PROMs) for healthcare settings. Each step provides existing guidelines and tools to support this selection and implementation process. Examples are given for clarification. The **PROM-cycle** is part of the **PROM toolbox**.

The **PROM toolbox** consists of the **PROM-guide,** step 3 accompanied by **the literature review on the use of PROMs,** and **the PROM-cycle**[4]. of which step 2 and 3 are supplemented with generic PROMs in **the Linnean menu.** The **PROM-links** tool provides links to useful websites.

The making of the PROM-overview & PROM-select app describes the development of the Excel database containing Patient-Reported Outcome Measures (PROMs) recently used in the EU and made available in this user-friendly web-application helping users to select PROMs: **The PROM-select app. The making of the PROM-overview & PROM-select app** describes their development.

Contents

1. What is the PROM-cycle?

Selecting and implementing a PROM consists of 4 phases and 8 steps. The **PROM-cycle** shows the customary order of these steps in a cyclic approach. Each step refers to existing guidelines and tools and, if applicable, refers to examples from practice and insights into methodology. In daily practice, a more flexible attitude is sometimes needed whereby steps can be omitted or taken in a different order. The **PROM-cycle** is part of the **PROM toolbox** that includes the **PROM-guide** and the **PROM-cycle**.

Estimate goal - Goal a: individual patient care
- Goal b: quality improvement
- Goal c: external transparency

Select PROs

Select PROMs

does not work

Test the PROM

Define the indicator

Test the indicator *does not work*

Use of the PROM

Maintenance and evaluation

Goal — Selection — Indicator — Use
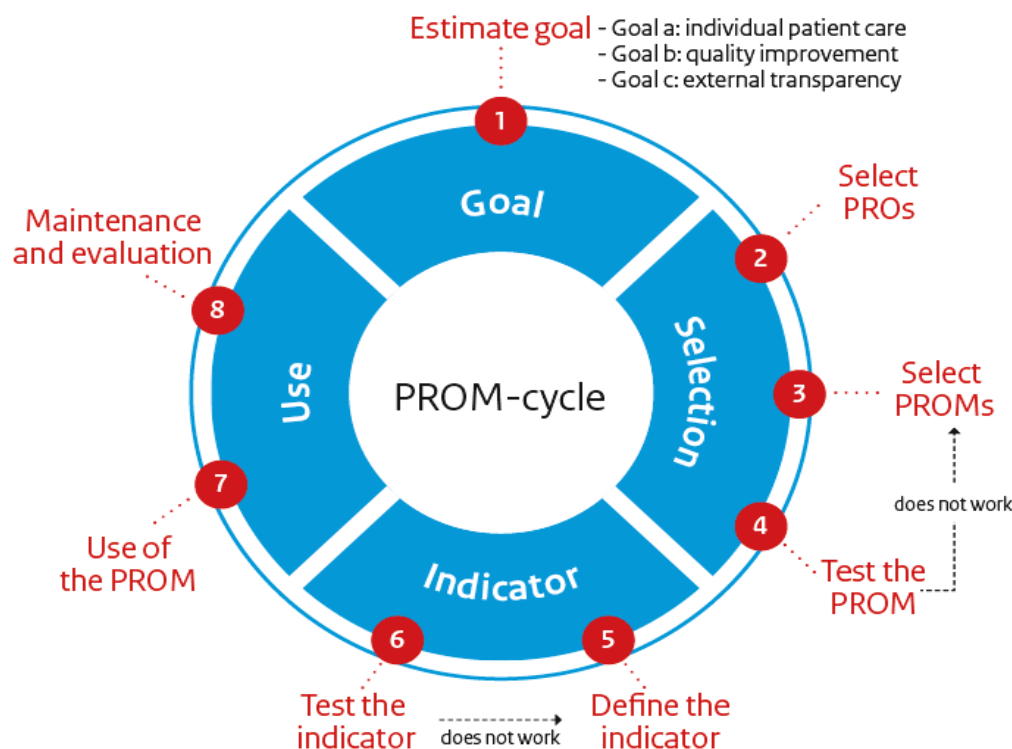
PROM-cycle

How to use the PROM-cycle?
The **PROM-cycle** allows you to navigate to the 4 phases and 8 steps. We would advise you to read all the steps first; this way you can take into account the whole cycle during each step.

Focus of the PROM-cycle
The **PROM-cycle** focuses on selecting and implementing a PROM to gain insight into the health of an individual patient. This information can be used for and by the patient during consultation hours or for quality registrations that generate information for internal and/or external quality purposes. To reduce the administrative burden of registration as much as possible we aim to select PROMs that can be used for both individual patient care and quality of care. That way there will only be one source of data collection instead of multiple data collections. However, this is not easy to achieve, since goals often have different demands regarding the outcomes to be measured (PROs), measurement characteristics and usability of the PROMs. The **PROM-cycle** has a supportive role in making these choices.
This **PROM-cycle** has not been developed for scientific research, in which a PROM is used to measure an outcome on the self-perceived health of a patient. The reason for this is that requirements for reliability of data collection are usually higher in research with measurements conducted for a limited time period in a controlled setting with fewer participants involved. Even so, the cycle can be useful in scientific research.

Background: what is a PROM?

Patients are increasingly asked how they experience their health for the purposes of health care measurements. The outcome of their health experience is called a PRO (Patient-Reported Outcome). PROs refer to such symptoms as pain and anxiety, physical or mental health, or how the patient functions at work, during sports or when performing household tasks. These aspects of health are often grouped under the label 'quality of life'. A PRO is measured by asking the patient one or more a questions,

resulting in single-item of multiple item questionnaires. Such a questionnaires is called a PROM (Patient-Reported Outcome Measure).

In the selection and implementation process of PROMs, various parties collaborate, such as patient representatives, healthcare professionals and health insurers. This can be a complicated and lengthy process. Several steps need to be taken and decisions need to be made. The **PROM-cycle** can be of help in this.

Goals of the PROM-cycle

- Informing all stakeholders (such as patient representatives, healthcare professionals, health insurers and researchers) on which steps to take to select and implement PROMs.
- Creating more awareness with all stakeholders on important decisional moments and possible dilemmas.
- Supporting all stakeholders by offering them an overview of existing tools and guidelines.

Glossary

PRO
Patient-reported outcome. A patient reported aspect of health condition (e.g. health status or functioning). Often combined under the label 'quality of life'.

PROM
Patient-reported outcome measure. A questionnaire to measure PRO(s) as perceived by the patient obtained by directly asking the patient (or carer) to self-report. A PROM can be specifically developed to measure the outcomes of a certain disease (disease-specific) or it can be generally applicable, irrespective of the disease (generic).

Indicator
An indicator may identify possible differences in the quality of care by comparing healthcare settings or providers over a certain time period. Outcomes of PROMs can be converted to an indicator.

Implementation
Systematic introduction of changes with the goal of these changes becoming a structural part of care and performance.

PREM
Patient-reported experience measure. A questionnaire measuring how the patient experiences health-care, for example on the topic of communicating with the care professional.

2. Explanation of the phases

Phase 1: Goal
The first phase in selecting and implementing a PROM is determining and recording the goal, the target group and the setting. These issues will be very influential in guiding the successive phases.

Accordingly, agreement on these issues at the beginning of the process can be of great value at a later stage when choices have to be made.

Phase 2: Selection
This phase determines what exactly will be measured (PRO, step 2) and how it will be measured (PROM, step 3). Subsequently the best PROMs will be tested in practice (step 4).

Steps 2 and 3 can be carried out in quite an extensive and systematic way, as they have been described in this document. In practice, however, this is not always necessary. In addition, there is not always enough resources or time available to do so. For example, when there is not much time and a certain PROM is rather well suited for the target group and meets the requirements, then a systematic literature search for relevant PROMs is perhaps not necessary.

Phase 3: Indicator
In this phase the PROM will be converted to an indicator, allowing an easier interpretation of the outcomes measured. The interpretation of this particular phase strongly depends on the goal chosen, the target group and the setting as defined in Step 1.

Phase 4: Use
In this phase, the PROM is put into practice and the indicator will be used. The PROM, the indicator and the goal will be evaluated periodically and if necessary, adapted and tested again. The cycle can be repeated.
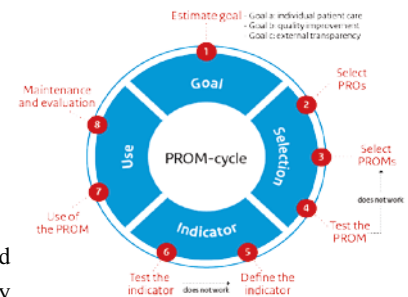
Step 1: Determining the goal

Key point
Determining why, for whom and in which setting the PROM will be used.

Description
Goal/objective, target group and setting of the PROM influence the interpretation of the following steps. So, before you decide 'what' you would like to measure (PROs; step 2) and 'how' you would like to measure (PROMs; step 3), it is important to consider 'why, for whom and in which setting' (step 1) you would like to measure.

Goal
Carrying out a PROM can serve various goals/objectives:

Goal a - Understanding of **the individual patient**: the care professional and the patient use the out-comes of an individual patient's measurement to gain a better understanding of the patient's performance or health. Moreover, the outcomes of the measurement are used when diagnosing, when choosing a treatment or helping in the communication between care professional and patient.

Goal b – Understanding of **internal quality**: the PROM is measured in a group of patients from a care institution, a number of care institutions or nationally, while the outcomes of the measurement are used to make the quality of care transparent, to be able to compare between care professionals/care institutions and to make improvements. The information gathered will not be made public for patients or care insurers.

Goal c – Understanding of **external quality**: the PROM is measured nationally and the outcomes are made public, in order to allow patients to compare healthcare organisations. That way they can opt for a particular healthcare organisation. Care insurers can use these outcomes to contract healthcare organisations. Regulatory bodies can also use the outcomes.

PROMS can also be used in scientific research to map the results of interventions from the perspective of the patient (many PROMS have originally been developed with this goal in mind). The toolbox can serve as an aid for this goal, even though it was not developed for this purpose.

Multiple goals simultaneously
Using multiple PROMS for the different goals may ask a lot of patients and care professionals, and administrative burden should be as low as possible. For that reason, our aim is an integrated use of PROMs, to gain an understanding of the individual patient, as well as of internal quality and external quality. This is however not easy to achieve, since every goal sets different requirements of the PRO's concerned, the measurement characteristics and the handling of the PROMs, as well as of the extent of involvement of the healthcare professional. If you intend to use a PROM for multiple goals, there is a possibility that these will be conflicting, thus providing dilemma's during the process. It is therefore good to consider, together with the stakeholders, which goal is most important.

Target group and setting
After the decision about the reason for the measurement, you will need to limit the study population, so you will have to decide upon the target group, and in which setting the measurements will be carried out. For that, you can take into account the disease and the age of the target group, as well as the type of care the target group will receive from the various care professionals.
To be able to make these choices, you will need to have good insight in the care process. For example, an older target group will ask for different requirements from the PROM than a younger target group. For the latter group it is also possible that the parents of the patient will fill in the PROM. You will have to consider carefully in what way you would eventually like to use and present the outcomes of the PROMS.

Key point
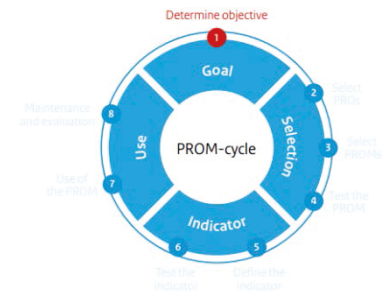
The set goal, the target group and the setting are therefore leading in the interpretation of the subsequent steps of the **PROM-cycle**.

Appendix 1 of this document provides a table to assist in clarifying and determining your goal, the target group and the setting, plus its influence on selecting and implementing PROMs
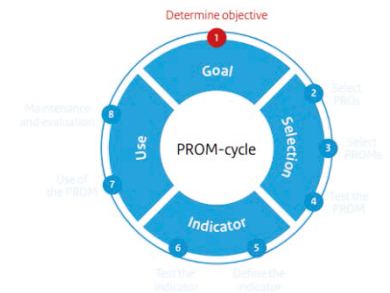
Aligning with existing PROMs to prevent administrative burden

Administrative burden of healthcare professionals and patients should be minimized. For that reason, we advise mapping which PROMs have already been measured in your target group. This will allow you to consider these and align with currently used PROMs. For mapping the use of existing PROMs, please contact your target group's patient organisation or contact your professional association. PROMs are also increasingly used in national quality registries. When a patient receives treatment in a multi- disciplinary setting, it is preferable that he will be able to fill in the same PROM across various disciplines.

Relevant tools

• ISOQOL user's guide to implementing patient-reported outcomes assessment in practice (pdf, 380 kB): The International Society for Quality of Life research is aimed at encouraging the use of patient reported outcome measures. This guideline describes the options for implementing PROMs and providing feedback on them. Pages 4 to 10 provide options for both the goal and the target group.

Step 2: Selecting PROs

Key point
Determining what will be measured.

Description

When selecting PROs it will be decided which aspects of health or functioning, such as pain, anxiety, physical health, or quality of life, are important and will need to be measured through a PROM.

Patients (and patient organisations) play an important role here, since the patient perspective is very important in this. Other relevant parties will also be involved, depending on the goal of the PROM. To gain insight into internal quality (**goal b**) the input of care professionals is also essential. Should the results be used for purchasing care by health insurers (**goal c**), then the input of health insurers is obviously important. Therefore, the relevant stakeholders need to be involved in the selection of PROs, and they need to be aware of the goal of the PROM.

Choosing the final set of PROs consists of the following parts:

## Step 2a: Determine which PROs you would like to study

Health is a rather broad concept that can be measured in various fields. Various models and classifications have been developed to this effect to provide more clarity. Appendix 1 gives you a number of models. Table 1 provides you with an example of an overview of levels that can be measured. Another, inter- national model is the International Classification of Functioning, Disability and Health (ICF). After having studied the various models you will be able to decide on which level, you want to start measuring and which themes can be of relevance.

Table 1: Levels used for measurements and examples of PROs

Levels	Examples of PROs
Symptoms	Pain
	Fatigue
	Sleeping problems
	Illness-specific symptoms Cognition
	Depression Anxiety
Functional status	Performing daily activities
	Solving problems
	Performing social activities (sport, hobbies)
	Performing social roles (work, family, relatives)
Self-perceived health	Self-perceived health
Quality of life	Self-perceived quality of life

Step 2b: Identify relevant PROs

By using (a combination of) various methods you can make a complete list of relevant PROs. A first step in this will be to do a literature search for existing knowledge on relevant PROs in your target group, your goal and the context. For this, you can use additional sources for PROs and PROMs and for literature search. A next step consists of holding interviews or focus groups to find out, which PROs are really considered important by your target group. The relevant PROs you have found in this way can be classified in one of the models of step 2a.
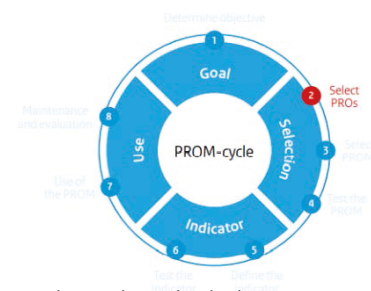
The following appendixes can be found at the end of this document to assist you in the process:

- Appendix 2: Additional interviews and focus groups
- Appendix 3: Additional sources for PROs and PROMs
- Appendix 4: Additional literature search
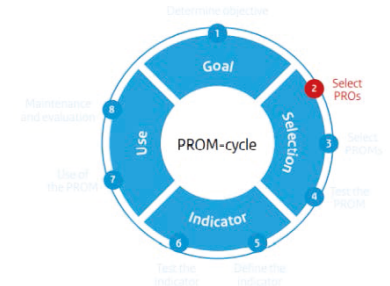
Contact an expert if necessary to help you with the literature search or the interviews/focus groups.

Step 2c: Prioritise and select the best PROs

The next step is to determine, together with the relevant stakeholders, which PROs are the most essential ones and which ones you will finally select. Important in this respect is that:

- **There should be consensus between the relevant stakeholders** on the choice of PROs. Stakeholders are, at any rate, patients (or patient organisations) and healthcare professionals (or their professional bodies). If the PRO will be used to gain insight into external quality (goal c), then health insurers are also a relevant stakeholder.
- **The PROs should fit the goal chosen**. The PRO should be affected by the treatment, especially when its goal is to monitor the progress made in the individual patient's treatment (**goal a**). If the goal is to improve internal quality (**goal b**), then the PRO should also be affected by the way in which care has been provided. That way care professionals will be able to see the result of their efforts reflected in better outcomes. The latter is also important when publishing outcomes for external quality (**goal c**); since the PRO may identify differences in scores between providers, reflecting potential differences is quality of care.

Appendix 5 at the end of this document provides additional systematic consensus methods.

Relevant tools

- National Quality Forum Methodological issues in the selection, administration and use of patient- reported outcomes in performance measurement in health care settings (pdf, 459 kB): provides an overview of issues with PROs and PROMs to gain insight into the individual patient (goal a). Chapter 2 of this report describes the pros and cons of the various types of PROs.
- Step 2 and 3 are supplemented with generic PROMs in **the Linnean menu.**
  The Linnean Initiative developed **The Linnean menu** of generic PROMs. The menu is advisory in nature and contains a list of outcomes that are relevant to many patients with different conditions (PROs). For each of these PROs some outcome measurement instruments (generic PROMs) are offered in order to help people to select PROs and PROMs and support the use of PROMs in the consulting room and in health care.

Step 3: Selecting PROMs

Key point

Determining how the measurement will be carried out. In this step, existing questionnaires (PROMs) will be checked and evaluated on their validity, reliability and applicability.
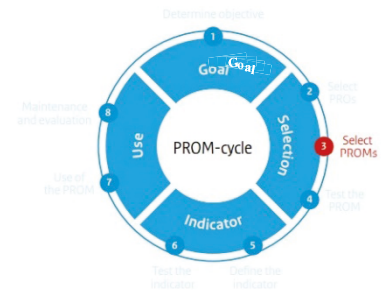
Description

A subsequent step after selecting the PROs can be to look for questionnaires (PROMs) that will measure these outcomes. We would like to avoid healthcare professionals and patients being burdened by administering the PROMs. For that reason, we advise you to map which PROMs have already been measured in your target group. This will allow you to consider these and align with currently used PROMs.

Moreover, when a patient receives treatment in a multidisciplinary setting, it is preferable that he will be able to fill in the same PROM across the various disciplines. We advise you to consider using a PROM that has already been measured, in order to avoid burdening the patient and the healthcare professionals, even though the PROM might not be completely suited to your goal and your preferences.

This step 3 consists of the following:

Step 3a: Determine the requirements for the PROM

Together with the project team and, if necessary, the relevant stakeholders, determine the requirements for the PROM. The goal, the target group and the context are leading in this. The following items are important here:

• Type of measurement instrument, such as generic or disease-specific.
• How the questionnaire is administered, for example a paper questionnaire or a (telephone) interview, via the computer or tablet, or with the help of a relative.
• Clinimetric characteristics, such as validity and reliability. Step 3d will address this item in more detail.
• Applicability and acceptation of the PROM by the various relevant stakeholders. Step 3e will address this item in more detail.

Step 3b: Make an inventory of all existing PROMs

For every PRO we recommend identifying all existing PROMs relating to this PRO. The reason for that is that a PROM that is currently used does not necessarily have to be the best PROM to suit your goal, your target group and your context. Your best option would therefore be a systematic literature search. Apart from searching the scientific literature, you can also search databases containing PROMs. Below you will find a number of examples of databases that can be of use to you: Eprovide: www.proqolid.org, Rehabilitation Measures Database: https://www.sralab.org/rehabilitation-measures and https://database.cosmin.nl/.

For more databases containing PROMs please use the 'additional sources for PROs and PROMs listed at the end of this document:

• Appendix 3: Additional sources for PROs and PROMs
• Appendix 4: Additional literature search

Contact an expert if necessary to help you with the literature search.

To help you getting started we compiled recently used PROMs with useful information in the **PROM-overview** and made available via a user-friendly web application: **The PROM-select app.**

Step 3c: Make a preselection based on content

Study the content of the PROMs and estimate whether this will measure your PROs. If you want to measure the quality of life of a patient suffering from a particular disease, then you can make an initial judgement to see whether the questions addressed by the PROM do indeed measure this aspect. This is called face validity. Step 3d will provide more information on validity. The PROMs resulting from this preselection will be evaluated in more detail in the following steps.

Step 3d: Determine the clinimetric characteristics of the PROMs selected

The PROMs will be studied in more detail and the clinimetric characteristics that are deemed important for the goal, the target group and the context will be evaluated. Validity and reliability are the two most important clinimetric characteristics. They have often, though not always, been studied in scientific research.

The COSMIN risk of bias checklist can be of help when evaluating research articles on the measuring characteristics of PROMs.

When you start testing the PROM (step 4), you can determine the characteristics that have not been studied yet in general or not yet for your target group.
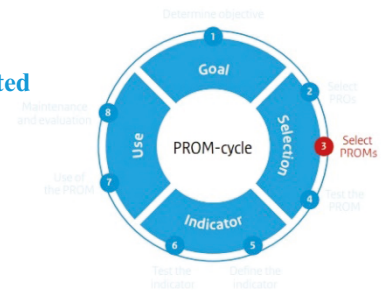
Validity: a good validity means that the PROM measures that what it is supposed to measure. For example, a PROM that is supposed to measure depression but in fact, predominantly measures anxiety does not have a high validity. There are many kinds of validity and ways to measure them. In step 3c, you have already made a preselection through face validity. In addition, scientific literature may help you further to assess the content validity, structural validity, construct validity, criterion validity, responsiveness and cross-cultural validity.

Reliability: a good reliability means that the PROM is accurate, reproducible, and consistent in estimating the same outcomes in the same circumstances. Therefore, a PROM measuring depression and providing large differences in outcomes in two successive measurements, while the patient still feels the same level of depression, is not reliable.

Step 3e: Determine the applicability, interpretability and acceptance level of the selected PROMs

With this step, you will judge the characteristics that are important when implementing the PROM with the goal, the target group and the context. These are applicability, interpretability and acceptance level.

Applicability: how convenient is the use of the PROM for the patient and the healthcare professional? A good applicability means that the PROM is easy to read and not very burdensome for the patient, while at the same time easy for the care professional to handle and interpret. A low level of applicability can be acceptable if the benefit of the PROM is high. This also includes a number of practical issues, such as costs for usage and availability in the correct language.

Interpretability: how meaningful is the outcome of a PROM? When a PROM is constructed in such a way that it can be properly interpreted, it will be clear whether a score of for example 37 is either high or low, and whether a change of 3.5 points is relevant. The so-called 'minimal important change' and the 'smallest detectable change' are an indication of the interpretability of a PROM.

Acceptance level: to what extent do patients and care professionals support the PROM? When for example a PROM has been in use for a long time, it is possible that a broad support base has been developed for it and implementation and use of this particular PROM will therefore be relatively easy.

Step 3f: Selecting the PROM best suited

Based on the information obtained from steps 3d and 3e, you will be able to opt for the PROM that is best suited to the chosen goal. If there is no PROM available that meets all the criteria, you can select, based on the goal, the target group and the context, which criteria are the most important. It is important to involve all relevant stakeholders in this process. This can be done through a systematic consensus method.

Appendix 5 at the end of this document provides additional systematic consensus methods Contact if necessary an expert to help you with the systematic consensus method.

Step 3g: Choose the follow-up phase

You will choose a follow-up phase depending on the PROMs you have found as well as the characteristics found. Three types of follow-up phases are possible:

- **Testing**: The selected PROM seems to be suitable for measuring PROs without needing to be adapted, and will therefore be tested in practice (step 4).
- **Further development**: The selected PROM seems suitable, but does need to be adapted (further developed) prior to being tested in practice.
- There can be various reasons as to why an existing PROM is not yet suited for the goal of a measurement. Some frequently occurring reasons are:
  - The PROM does not measure all the PROs selected.
  - The PROM has not been tested with the target group concerned.
  - The PROM has not been translated into the language of the country concerned.
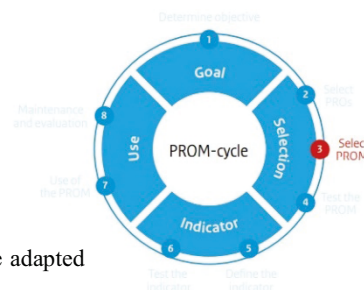
The necessity to further develop a PROM depends on the nature and the extent of the information that is missing about the characteristics of a PROM or the deficiencies in this. In addition, the budget and the time available often play a role in this. The relevant stakeholders need to jointly decide whether further development is needed. Ideally, experts in the field of further developing or evaluating questionnaires support stakeholders in this process.

Development: There is not a single PROM available that could be suited to measure PROs after a possible adaptation. Therefore, a completely new PROM will need to be developed. The development of a new questionnaire is complex, requiring specific scientific expertise that can be found at universities and research institutes.

After a PROM has been (further) developed, it can be tested in step 4 and the cycle can be concluded. The exact interpretation of the (further) development of a PROM is outside the scope of the cycle. Below, you will find some links to relevant tools for (further) development.

Relevant tools

- National Quality Forum Methodological issues in the selection, administration and use of patient- reported outcomes in performance measurement in health care settings (pdf, 459 kB): provides an overview of issues with PROs and PROMs to gain insight into the individual patient (goal a). Chapter 3 describes the pros and cons of the various ways of carrying out a PRO. Chapter 4 of this report describes the selection of PROMs through various characteristics.
- ISOQOL user's guide to implementing patient-reported outcomes assessment in practice (pdf, 380 kB): the International Society for Quality of Life research is an organisation aimed at encouraging the use of patient reported outcome measures. This guide (and its companion guide) describes the options for applying PROMs and providing feedback on outcomes measured with PROMs. Pages 11 to 13 of this guide list the pros and cons of the various types of PROMs.
- Step 2 and 3 are supplemented with generic PROMs in **the Linnean menu.**
  The Linnean Initiative developed **The Linnean menu** of generic PROMs. The menu is advisory in nature and contains a list of outcomes that are relevant to many patients with different conditions (PROs). For each of these PROs some outcome measurement instruments (generic PROMs) are offered in order to help people to select PROs and PROMs and support the use of PROMs in the consulting room and in health care.

Tools for the (further) development of PROMs

- Book Measurement in medicine: this book describes the process of the development and validation of a PROM.
- Book Health| measurement scales: this book describes the development and validation of a questionnaire.

Step 4: Testing a PROM

Key point

In this step, the PROM selected will be tested in practice, in order to evaluate whether it is actually suited to the goal, the target group and the setting.

Description

Interpreting this step depends on the goal. If the goal of the PROM is implementation in individual care by the healthcare professional and the patient (**goal a**), then it would seem obvious to set up a project in order to evaluate this implementation. If the goal is to be able to compare healthcare professionals or healthcare organisations for internal quality improvements (**goal b**), then the focus should be on testing the possibility of measuring differences. If the goal of the PROM is to develop indicators and to publish these for better insight into the external quality (**goal c**), then the focus should be on measuring the differences and their interpretation for patients and health insurers (see also steps 5 and 6 Defining and testing the indicator).

You will need to check whether the validity, reliability and applicability that you have found are still valid for your target group and still meet your requirements. For that, you will need to collect the test results of the PROM as well as the experiences of the patient and the healthcare professional. Examples of questions you can ask them are: Is this PROM indeed applicable for the patient and the healthcare professional? Do the response categories match the experience of the patient?

This testing phase can also be used to test the (further) developed PROM and to pilot-test the feasibility of implementing a PROM. It can actually prove to be quite a challenge to ensure that the PROM will be used in practice, even in a test setting (see step 7: Implementing a PROM).
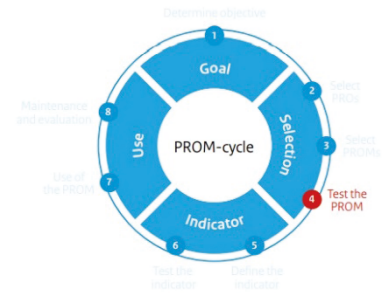
Step 5: Defining the indicator

Key point
This step describes the development of an indicator that will give meaning to the outcomes of the PROM.

Description
An indicator can be calculated from the outcomes of the PROM that will give meaning to those outcomes. An example of a PROM is a scale measuring the extent of pain in the leg after an operation on herniated discs. You will need to be clear on the target group and the setting in order to determine the indicator. An example of the way in which an indicator can be formulated is: what is the average pain experienced by adults in the affected leg 6 weeks after the herniated disc operation, on a numeric ratingscale from 0-10, whereby 0 means no pain and 10 means maximum pain?

The indicator is often compared to a standard value: this helps in their interpretation. Without such a standard value it is hard to define whether for example a score 12 on a PROM for the domain anxiety (on a scale of 0-15) is actually a good, moderate or bad score for a patient, care professional or care institution.

Summing up: a PROM is a questionnaire that provides a (domain) score for an individual patient, such as score 12 (from 0-15) on the domain anxiety. An indicator gives meaning to outcomes of groups of patients, such as the percentage of patients scoring 10 or higher on anxiety.

An indicator with a standard gives an indication for the quality of care, which means that possible differences in quality can be shown. Care institutions can use an internal indicator to improve their quality (**goal b**). Regarding external quality (**goal c**), patients can use the external indicator to decide on a care institution, while health insurers can use it to sign contracts with care institutions.
Regarding individual patient care (**goal a**) a standard value can be used to decide on the treatment: what are the outcomes expected by the patient based on the outcomes of other patients? When a certain treatment has been decided upon, the outcomes of the individual patient can be compared to the standard value.

Since formulating an indicator hugely influences the interpretation of the outcomes of the PROM, this should always be done together with all relevant stakeholders.

A good, valid and reliable PROM is the best basis for a good indicator. For an external indicator belonging to goal c, higher requirements have been formulated regarding the extent to which the outcomes of the various care institutions can be compared ('comparability') and the extent to which the indicator shows the differences between the care institutions ('ability to differentiate').

Please note: there can be all sorts of reasons for possible differences in outcomes between care institutions based on the indicator. Therefore, its interpretation is of major importance to be able to evaluate quality of care in using the indicator. In the case of indicators, it is most often not a matter of an absolute statement on quality of care being good or not good; it is merely an indication to further study the quality.

Three steps are distinguished when defining an indicator:

### Step 5a: Determine which outcome precisely will be measured
The outcome can be determined when the target group is known, which PROM will be used and when. An example of a precise outcome is the average pain on a scale of 0-10 for adults 6 weeks after an operation on a herniated disc.
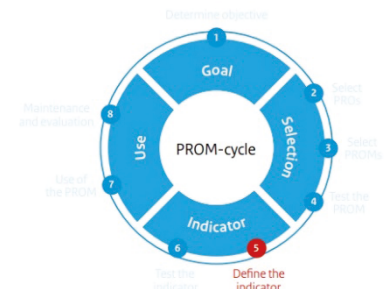
Step 5b: Describe the way in which the outcomes should be measured, so that they can be compared

In order to compare the outcomes, you will need to focus on three aspects:

• Standardization of data collection: data should be collected in a comparable way. This means that it is important that procedures for data collection and analysis have been formulated in a clear and unambiguous way.

• Population comparability: the results reflect the true differences in the quality of the care delivered and not the population differences between care institutions. For example, some care institutions only treat elderly patients. Patients attending the various care institutions would then need to be comparable.

• Alternatively, statistical case-mix correction could be carried out for the differences in patient characteristics that can be of influence on the outcomes. A patient's age, gender or education should be added to the data collection in order to correct for those characteristics. Another solution would be to define subgroups: this is also called stratification.

• Validity of sample and response: patients who will be measured should be representative for all patients attending the various care institutions.
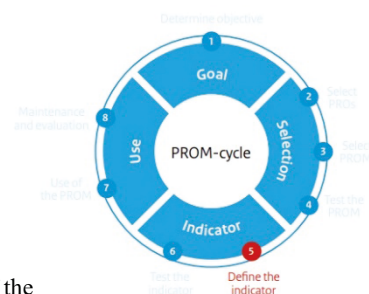
Step 5c: Define the draft indicator

At this point you will have a clear description of how, with whom and when measurements will take place. An example: the score on a certain PROM for pain in adults in their affected leg 6 weeks after an operation on a herniated disc.

The next step is to determine a standard that indicates good or bad quality. When for example you decide that a pain score of 5 or higher is more than can be expected, the standard should be fixed at 4. Several sources can form the basis for this standard:

• The standard is a result of scientific studies.
• Experts determine the quality desired and with that the standard.
• The standard is determined by the average or another cut-off point from the values already measured.

In many cases, an absolute standard has not (yet) been defined in advance. In that case, the relative differences in outcomes between care institutions can be studied. An example would be to consider care institutions that score (a lot) higher or lower than the average score of all care institutions together. Such deviations from the average can be an indication for higher or lower quality.

An indicator is often expressed as a percentage. The denominator most often describes the target group that will be discussed. The numerator describes the number of correct or desired actions in the target group. Returning to the example of the pain score, we have the number of persons in the target group with a pain score of 4 or lower, divided by the total number of persons in the target group. A high number of this percentage will be an indicator of how well the hospital meets the standard. Example: The target group consists of 100 persons. In hospital A 20 persons have a pain score of 4 or lower (indicator = 20%), while in hospital B 50 persons have a pain score of 4 or lower (indicator = 50%). Therefore, hospital B is more successful in meeting the standard compared to hospital A.

When defining the indicator, you should also determine on which level the indicator would be calculated: on the level of the healthcare organisation, the department, or a specific site of the healthcare organisation. Important aspects to take into consideration here are on which level quality differences can be expected and on which level the outcomes can be implemented.

The ability to differentiate is the extent to which the indicator points at differences. This affects the amount of information and the usefulness of the outcomes that the indicator provides. The ability to differentiate can be tested in step 6.

Contact an expert if necessary to help you with the indicators.

Relevant tools

- Book Improving patient care. The implementation of change in clinical practice: this book by Grol et al. describes the process of implementation for quality improvement. One of the chapters deals with the role of indicators in healthcare.
- Research article 'Framework and indicator testing protocol for developing and piloting quality indicators for the UK Quality and Outcomes Framework': this article by Campbell et al. describes a framework for developing and testing indicators.
- Scientific article 'Clinical indicators: development and applications': this article by Wollersheim et al. describes the standards a good indicator should meet and it contains steps to develop and implement indicators.
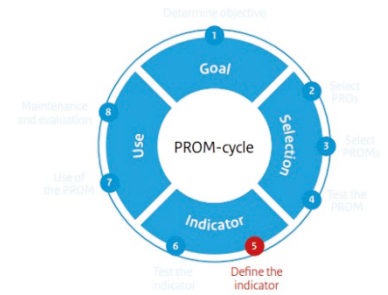
Step 6: Testing the indicator

Key point
With this step, the indicator will be tested in practice and it will be determined whether the indicator meets the requirements that were defined beforehand. Based on this testing phase the indicator will be further specified and a definitive version will be made.

Description
When testing the indicator, you will need to study in a small setting whether the requirements that were defined beforehand on the aspects of comparability and ability to differentiate are correct and feasible. That means that you have to check whether the outcomes of the care professionals can be compared in a reliable way and whether the differences found are relevant.

To determine relevant differences in outcomes you will first have to study whether differences between care professionals are actually present, or were caused by coincidence. This is done by statistic testing (statistical significance). You will need to carry out sufficient measurements to be able to do this. As a rule of thumb, at least 30 patients in each care institution will need to have been measured to be able to test a difference, whereby 30 institutions will have to participate in the measurements.

Even if any statistically significant differences have been found, that does not mean that those differences are also relevant. When many measurements have been carried out, even a minor difference can be statistically significant, but possibly not relevant for the quality aspect. Yet, there is not much known about when differences between care professionals are relevant, thus indicative of their quality. Testing the indicator in practice is therefore important to gain knowledge: based on that knowledge you will be able to make a definitive version of the indicator. Based on the tests in practice, the indicator can be further specified and turned into a definitive version. An example would be to define a standard based on the relevant differences found in the practice test.

When the test shows that the indicator does not meet the requirements, you can consider either redefining it (step 5), selecting a different PROM (step 3), further developing a PROM or developing a new PROM (step 3).

Relevant tools
• Research article 'Framework and indicator testing protocol for developing and piloting quality indicators for the UK Quality and Outcomes Framework': this article by Campbell et al. describes a framework for developing and testing indicators.
• Research article 'Clinical indicators: development and applications': this article by Wollersheim et al. describes the standards a good indicator should meet and it contains steps to develop and implement indicators.
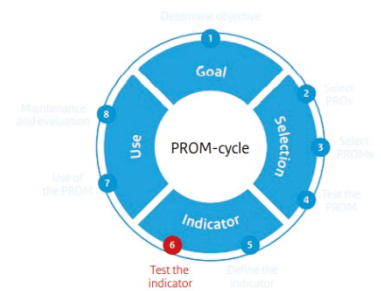
Step 7: Implementing the PROM

Key point
With this step, the selected and further developed PROM and indicator will be put into practice.

Description
After the testing phase, the PROM can actually be implemented in daily practice. In this step, the health insurer will use the indicator for the following goals: quality improvement, decisions by patients, and/or health purchases. If the indicator has been developed with the aim of gaining insight into external quality, it will be necessary in this step to publicise the outcomes of the PROM (anonymously) and to disclose the scores on the indicator in various ways (websites, articles, policy documents, incorporation into decision aids for patients, etc.).

Implementation
Arranging for PROMS to be systematically measured and implemented in daily practice can be rather complicated. You often come across practical, organisational, cultural and contextual barriers. By using the test in step 4, you have already practised implementing the PROM in practice. You can use this experience when you will eventually implement the PROM. Generally speaking, it is useful when the measuring process is not too burdensome and the stakeholders are supportive of it. Moreover, each context differs, which is why the implementation strategy needs to be tailored to your specific situation. For that, you will need to make an inventory of the factors that will be a barrier or a facilitator to the implementation process, regarding the care professional, the patient, the organisation, the culture, as well as legislation. You can then design the strategy that will have an effect on the factors that are relevant in your situation. Examples of implementation strategies are educational meetings, educational material, feedback on the implementation of PROMs, adaptations in the organisation and encouragement by a leading figure.

In order to burden patients and healthcare professionals as little as possible, and to increase the chances of a successful implementation, try to integrate the PROM into existing processes as much as possible. For that, you will need to study the care process from the perspective of both the healthcare professional and the patient. This determines whether you will implement the PROM digitally or via paper, how the outcomes will be processed (automatically or manually), when the patient will fill in the PROM (for example when he is at home, in the waiting room or in the consultation room), when the care professional will study the outcomes and in what way these will be given as feedback to the patient.

When implementing a PROM and processing the outcomes please take into account privacy regulations and protection of personal data.

Contact an expert in the field of implementation if necessary.

Relevant tools implementation
- Book Improving patient care. The implementation of change in clinical practice: this book by Grol et al. describes the process of implementation for quality improvement.
- ISOQOL user's guide to implementing patient-reported outcomes assessment in practice (pdf, 380 kB): the International Society for Quality of Life research is an organisation aimed at encouraging the use of patient reported outcome measures. This guide describes the options for carrying out PROMs and providing feedback on them. Pages 14 to 36 of this guide list the pros and cons of the various ways of implementing PROMS.
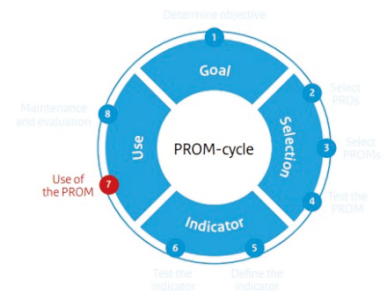
Step 8: Maintenance and evaluation

Key point

With this step, the PROM and/or the outcome indicator will be evaluated and if necessary, the **PROM-cycle** will be (partly) run through again, to optimise measurement.

Description

To ensure long-term maintenance and evaluation, structural financing is often needed, which is some-times difficult to realise.

The regular use of a PROM can lead to new insights, asking for an adjustment of the indicator. Within this evaluation, it is important to answer the following questions:

• Do the PROs opted for still serve the purpose of the goal?
• Does the PROM meet the requirements of measuring the desired outcome?
• Has the PROM been measured sufficiently and is the routing for the data collection still correct?
• Does the outcome indicator still meet the requirements of comparability of measurements and of theability to differentiate between care professionals?

When the goal has not been achieved or the goal itself has been changed, you can easily gothrough some of the steps in the cycle again to achieve your ultimate goal.

When a PROM has been implemented, to gain insight into internal quality (**goal b**) or external quality(**goal c**), our hope is that after a period of quality improvement all care professionals or care institutions will have a higher score. That could however point at a PROM's decreased ability to differentiate. In that case, you need to reconsider whether this PROM is still serving its purpose or that it has become irrelevant and should therefore not be used any longer.
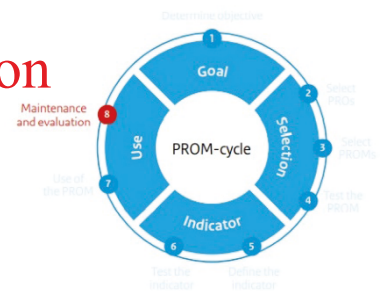
Appendix 1: Table for the goal, the target group and the setting

The following table can assist you in clarifying and determining your goal, the target group and the setting, plus its influence on selecting and implementing PROMs.

To do	Explanation	Tick the box / write down what applies to your project	What do you have to take into account when going through the PROM-cycle?
Determine goal(s)	The goal(s) you would like to achieve by using the outcomes of the PROMs. *Example: The treating physician discusses the measurement with the patient in relation to previous measurements, the nurse screens all patients and will act when a certain cut-off point has been reached, there is a need for national comparative information, etc.*	- individual patient - internal quality - external quality	How to take into account the goal(s)?
Determine the target group	The people filling in the questionnaire. *Example: children for which the parents will have to fill in the questionnaire, people with disabilities who need assistance with filling in, elderly people who are not handy with computers, etc.*	Description of the target group:	How to take into account the target group?
Determine the setting	The care institution and the care professionals involved in the PROM measurement *Example: at home prior to the appointment, in the waiting room, during the appointment, during the recording. The information will be used by 1 treating physician, by 3 specialists, by all nurses on the ward, etc.*	Where and when will the PROM be measured? Which healthcare professional(s) will be using the outcomes of the PROM?	How to take into account the setting?

Appendix 2: Additional sources for PROs and PROMs

Many sources can help you in finding PROs and PROMs, apart from a systematic search in the scientific literature. Below you will find a number of sources to be used:

PROs
- An ICF Core Set has been developed for a number of disorders. This set provides an overview of the relevant PROs for a particular disorder. Here you will find an example that describes the development of an ICF Core Set for depression.
- The COMET initiative is a database containing articles on the development and implementation of Core outcome sets for scientific research. These sets can also be of interest for the care practice.

PROs and PROMs
- The International Consortium for Health Outcomes Measurement (ICHOM) develops PROM sets for worldwide implementation. Standard sets of PROs and PROMs have already been developed for a number of disorders.

PROMs
- The website of ePROVIDE contains a database with PROMs.
- www.healthmeasures.net offers a database of PROMs.
- The European League Against Rheumatism (EULAR) has a database containing relevant PROMs for a number of musculoskeletal disorders.
- The European organisation for research and treatment of cancer (EORTC) mentions a few frequently implemented PROMs for cancer patients.
- The Consensus-based standards for the selection of health measurement instruments (COSMIN) database contains research articles describing literature studies into PROMs.
- https://database.cosmin.nl/ can be used to search for scientific articles concerning PROMs.

You can also contact experts or visit websites of relevant patient organisations or professional associations. If you are looking for relevant PROs for a particular disorder, you can also look for frequently implemented PROMs for that disorder.

Sometimes there is not much time and/or resources to check if a certain PROM is rather well suited for the target group and meets the requirements. Then a systematic literature search for relevant PROMs may take too much time. In order to help you save time, we made an overview of PROMs, their relevant scientific literature and other sources were you may find relevant information about those PROMs. The **PROM-overview** is an Excel database containing Patient-Reported Outcome Measures (PROMs) recently used in the EU in i.e. in the fields of our HTx case studies: Head and Neck Cancer, Diabetes Mellitus, Multiple Sclerosis, MyeloDysplastic Syndrome, (Long lasting) COVID and in general. The **PROM-overview** is made available in a user-friendly web-application helping users to select PROMs: the **PROM-select app.** When using this **PROM-select app** you may choose your selected PRO and relevant health problem/disorder or patient group/population. When selected a PRO and health problem you'll get a list of relevant PROMs. When clicking on a PROM, you will find an overview of relevant information about the PROM and links to more information. We also included relevant scientific articles and links to other scientific literature.

Appendix 3: Additional literature search

A literature search is a method for collecting existing knowledge on your subject. In your case, this will probably entail a search for PROs and PROMs to serve your goal, target group and setting. Various sources will provide you with this knowledge, such as research articles, books, papers, dissertations and archive material. You will often search and select the information in a systematic way, thereby guaranteeing that you will be able to answer your research question. A literature search can be carried out either in a very extensive and exhaustive way or in a quick and pragmatic way, depending on the time and resources available and the importance of being as exhaustive as possible.

- A typology of reviews: an analysis of 14 review types and associated methodologies: this research article describes the background of literature searches as well as 14 different types. It contains a description of every type of literature search, while the pros and cons are summed up and an example is given.
- Guide for undertaking reviews in healthcare: this guide in English is aimed at people who have yet no experience in literature searches and provides a full description of which steps to take in systematic literature searches.

Every literature search goes more or less along the same lines:

1. Formulate the research question

As a first step formulate the research question as specifically as possible and check whether a literature search has already been carried out on your research question. The latter you can check by visiting the following databases that focus on literature searches:

- Cochrane Library
- Campbell Library
- EPPI-Centre
- PROSPERO
- PubMed (use the filter Systematic reviews, Meta-Analyses)
- PsycINFO (use methodology limits Systematic reviews, Meta Analyses)
- EMBASE (use limit EBM-Systematic Reviews)

Example

For the example given below the search was for PROMs for children with orthopaedic problems. The goal of this literature search was: *find out whether a usable and suitable PROM is available to check and evaluate the effect of a treatment for the most frequently asked questions for help in children with orthopaedic problems.* No previous literature search had been carried out on this topic yet.

2. Choose the databases you want to search

The next step is to select which databases to search. Below you will find a number of databases containing research literature:

- Medline (articles in the area of biomedical science)
- PubMed (publicly accessible version of Medline, which is the most often consulted database for medical articles)
- PsycINFO (articles in the area of psychology)
- EMBASE (articles in the area of pharmaceutical topics as well as European literature, here you will find an overview of the differences between PubMed, Medline and EMBASE)
- CINAHL (articles in the area of nursing, healthcare and paramedic specialisations)
- Web of Science (articles from all areas of science)
- PiCarta
- COSMIN (contains a database with systematic literature searches into PROMs)

Apart from systematically searching the scientific literature, you can also find a lot of information on PROs and PROMs in the so-called grey literature and in the PROM databases. You can find these in the *Additional sources for PROs and PROMs*, which you can find in the **PROM toolbox**.

Example

We started our project of finding a PROM for children with orthopaedic problems with a survey to list the most frequently occurring requests for help. We found that these types of request mostly dealt with the development of the fine and gross motor skills, orthopaedic problems and asymmetry.

The project team did a systematic literature search for PROMs that fitted the requests for help mentioned above. The following databases were used for that: CINAHL, Cochrane, EMBASE, MEDLINE, PEDro, PsychINFO, PubMed and Web of Science.

3. Collect search terms and formulate a search strategy

The next step in doing a systematic literature search is collecting search terms and formulating a search strategy. You can draw up a list of search terms of each subject you are doing a search on, such as 'anxiety', 'dementia', and 'PROM'.

It is useful at this point to search for a number of articles containing possibly relevant search terms. You can find these articles by going through their titles, abstracts or key words. You can also test your search strategies by checking whether they will come up with all the example articles.

There is a validated PubMed filter for clinimetrical characteristics of PROMs as well as a PubMed filter for PROMs that can be used.

It is often not easy to find a balance between a search strategy that is as complete as possible, and at the same time comes up with a number of articles that are actually manageable. This really depends on the amount of time available and the importance of finding all the relevant articles. By using filters on for example publication date, language or type of article you can limit the number of results.

Example

For our search strategy for PROMs for children with orthopaedic problems, we searched on three subjects: orthopaedic, child and self-report. We then excluded other elements using the term NOT. The partially given search strategy you will find below was used with the database Web of Science and resulted in 2157 articles.

Search term	Search terms
Orthopaedic	(TS=Musculoskeletal system* AND TS=Musculoskeletal pain*) OR (TS=Musculoskeletal system* AND TS=Pain*) OR (TS=Musculoskeletal disease* AND TS=Upper extremit*) OR (TS=Musculoskele- tal disease* AND TS=Lower extremit*) …
Child	TS=(Child*) OR TS=(High School*) OR TS=(Infant*) OR TS=(Kids*) OR TS=(Kindergarten*) OR TS=(- Middle School*) OR TS=(Minors*) OR TS=(Minor person*) OR TS=(Neonat*) OR TS=(Newborn*) OR TS=(Nursery School*) …
Self Report	(TS=(Patient reported outcome*)) OR (TS=("Patient reported outcome measure*")) OR (TS=(MH "Visual Analog Scaling")) OR (TS=("visual analog scale")) OR (TS=("Age & stages")) OR (TS=("Subjective account")) OR (TS=(MH "Self Assessment")) …
NOT	TS=(Mental*) OR TS=(Psychiatric*) OR TS=(Psychologic*) OR TS=(Emotional*) OR TS=(Sexual*) OR TS=(Abuse*) OR TS=(Suicid*) OR TS=(Anorex*) OR TS=(Cerebral Pals*) OR TS=(Neurol*) OR TS=(E-lectro*) OR TS=(Nasal*) OR TS=(Facial*) …

4. Enter the search strategy and select relevant articles

When the search strategy for your systematic literature search is ready, you enter the search and select the relevant articles. You then have to export the articles to a programme that allows you to manage them, such as Endnote, Mendeley, Zotero, Covidence or EPPI reviewer. When you have collected literature from various sources, we advise you to remove the articles that have been doubly included. Prior to selecting the relevant articles, you will have to formulate clear inclusion criteria to select the articles that have to be included. Sometimes a number of researchers, to prevent mistakes, carries out this selection process. The selection process can be carried out in various rounds: first, a selection is made based on title and abstract, and second on full text. You can also search through the articles for references to other relevant articles. This process is called snowballing.

Example

The project team searching for PROMs for children with orthopaedic problems found 7016 articles, out of which 673 were eventually selected.

5. Analyse the articles found

The next step is to analyse the selected articles and to collect the data you are searching for, in this case probably PROs or PROMs. You will then probably also be interested in the clinimetrical characteristics of the PROMs, wishing to collect those as well.

At this stage, you will be able to choose the quality of the articles. The COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments) has developed a checklist to review studies that researched the characteristics of a PROM.

For the data extraction, we advise you to draw up a form that will list all the information of each article you would like to collect. You can carry out the data extraction with several researchers working independently on this.

Example

The project group filtered 150 possibly suitable PROMs out of the 673 included articles, thereby extracting the aspect of manageability as well as the clinimetrical characteristics. 37 possibly suitable PROMs remained, after exclusion of 9 PROMs that were not filled in by children or their 11 parents, 79 that were not specifically aimed at children, and 25 that were not focused on orthopaedic problems or quality of life. These 37 were then presented to relevant parties in a systematic consensus meeting in order to make a selection.

We also included relevant scientific articles and links to other scientific literature in the **PROM-overview**, which is made available in the user-friendly web-application helping users to select PROMs: **The PROM-select app**

Appendix 4: Additional interviews and focus groups

Interviews and focus groups are a good way of identifying relevant PROs, because these can help you find out what is important to a person with a particular condition. The goal of this qualitative research is often to explain and find out about symptoms. The advantage here is that you are able to delve deeper into someone's motivations, feelings or preferences. With qualitative research, the text of an interview or a focus group is analysed. Quantitative research is the opposite of qualitative research: the focus there is on data, such as blood pressure, number of days in the hospital or PROM score.

Interviews and focus groups are the research methods most frequently used in qualitative research. The table below gives a succinct description of both methods, which can be carried out face to face or by telephone, although face-to-face is preferable. Both methods can also be audio taped and typed out, after which the text can be analysed.

A number of tools provide information on both these methods.
• Article Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups: article by Tong et al., 2007.

Method	Description	Preparation	More information
Interviews	Individual talks Allows an in-depth conversation on motivations, wishes and perceptions of individual participants, although it can be rather a lot of work to have many interviews. Suited for the discussion of sensitive topics that people rather not discuss in a group.	Set up an interview guide with themes or questions that need to be addressed. You will have to use this guide during all the interviews.	
Focus groups	Group talks with 4-12 participants (either a homogeneous group (the same type of participants) or a heterogeneous group (various types of participants). Allows for interaction between participants and for brain-storming. Participants have the opportunity to challenge each other. Although it can be complicated to plan a meeting where all participants can be present, one or two of such meetings will give you a good idea of the various view-points. There is however, a risk that dominating participants will overshadow the less dominating ones, resulting in the latter's opinions not being heard as much.	Develop a script that needs to be used in all focus groups. This script will help you to address all the topics and to keep track of the time. We advise you to appoint a moderator as well as someone who will observe and someone who will take notes. The chairperson plays an important role in guarding the group process. To prepare for this he/she can do the following: - Indicate purpose and method at the start of each group talk - Give participants at the start of the talk some time to reflect on the purpose - Create a safe atmosphere and adhere to the rules for feedback - Make sure that all participants are heard; explicitly address those who have not said anything (yet) and ask for their opinion; cut short dominant speakers in a friendly way.	Article Qualitative Research: Introducing focus groups by Kitzinger et al., 1995.

Appendix 5: Additional systematic consensus methods

A systematic consensus method can be useful when looking for common ground or similarities in the opinions of relevant stakeholders. The goal is to formulate a joint opinion, while trying to prevent this resulting in winners and losers of the decision made. To prevent the decision-making process becoming dominated by one or more participants, as sometimes happens in a normal meeting, the following methods have been developed.

Consensus methods are often characterised as follows:
- They are often anonymous, to prevent dominating participants to be too overly present. You can imagine that participants will (subconsciously) value the opinion of a respected authority on a certain subject higher than the opinion of an unknown person. Alternatively, that a rather dominant participant will express his opinions more often than a more amenable participant will.
- They often consist of several iterative rounds, allowing participants to adjust their opinions and in doing so come to an agreement with each other.
- •All (anonymous) results will be shared with the participants, allowing for the full width of the various opinions to become visible.

Reaching consensus between the relevant stakeholders is very important for a successful implementation of these and subsequent steps in a **PROM-cycle**. Most notably regarding the actual implementation (step 7) it is essential that all parties support the PRO and PROM decided upon. When the PROM is presented to the Registry of the (Dutch) National Health Care Institute (step 7), it is actually compulsory for all relevant stakeholders to support it.

The table at the end of this document lists the most well known methods used to reach consensus. You will find a short description of what each method entails, when it can be used and where you will be able to find more information on that particular method.

A number of tools are available that give an overview of several systematic consensus methods. Here you will find a list of them:
- Consensus development methods and their use in clinical guideline development: even though this report is aimed at reaching consensus on the content of guidelines, it will also give you an overview of the Delphi method, the Nominal Group Technique (NGT) as well as the Consensus Development Conference method. The report also provides a lot of background information.
- Methods of Formal Consensus in Classification/Diagnostic Criteria and Guideline Development: This article describes the techniques of the Delphi method, the NGT, the Rand-UCLA Appropriateness Method (RAM), and the Consensus development conference method, including pros, cons and examples for each method.
- Consensus methods: Review of original methods and their main alternatives used in public health: This article describes the techniques of the Delphi method, the NGT, the RAM and the Consensus development conference method.
- Qualitative Research: Consensus methods for medical and health services research: this article describes the techniques of the Delphi method and the NGT, and discusses their methodological challenges.

Method	Description	When to use	More information
Delphi method	One or more rounds in which each participant is asked for their opinion, which is then returned as anonymous feedback to the other participants. Firstly, statements are formulated. This can be done through input from experts, scientific literature, or an initial round among the participants. Secondly, the participants will voice their opinions on all statements. These opinions will subsequently be put together and sent to the participants. They will then be able to see the opinions of their fellow participants, allowing them to adjust their own opinions accordingly. With each round the various opinions will become more converged, until a decision can be made. Participants will not be able to see each other face to face. The advantage of this setup is that the input of both dominant and participants that are more amenable will be equal. Another advantage is that the Delphi procedure is quick and cheap, as the procedure can be carried out via the Internet. It can however be complicated to reach consensus when the participants are not able to talk to each other directly.	When you have a very large group of participants, making it difficult to organise a face to face meeting. When you cannot organise meetings for budgetary or planning reasons.	The Delphi Technique: Making Sense Of Consensus Qualitative Research: Consensus methods for medical and health services research
Nominal Group Technique (NGT)	A face to face meeting with stakeholders in which the participants will firstly brainstorm individually on paper, secondly share all their ideas with each other one by one, thirdly discuss the ideas put forward, and fourthly all vote (anonymously) for the idea that in their eyes is the best one. The NGT can also be carried out in two meetings, whereby during the second meeting the results of the voting round will be discussed, after which participants will vote anew. The advantage of this technique is that all participants will be heard and they will be encouraged to bring forward all their ideas. Disadvantages are the fact that only one subject can be discussed per meeting, that the meetings are very structured and that there is not much room for spontaneity. Moreover, planning these meetings can take up a lot of time.	When it is important to generate new ideas and to prioritise them.	Nominal Group Technique Gaining Consensus Among Stakeholders Through the Nominal Group Technique
RAND –UCLA appropriateness method (RAM)	This is an extension of the Delphi method with face to face meetings. A literature search will be the start of it, the results of which will be discussed in an expert panel. Statements will follow from these discussions, and these will be reviewed anonymously by the participants. The results will be subsequently discussed in a face to face meeting, where consensus will be reached. The advantage is that the participants are jointly able to reach consensus during the meetings. It is however possible that dominant participants will have had a disproportionately large influence on the conclusion. A good moderator is very important in this. Moreover, it can take up a lot of time to plan the two meetings.	When both the anonymous aspect of the Delphi rounds and the face to face reaching of consensus is important, and when there is sufficient time available for this procedure.	The RAND/UCLA Appropriateness Method User's Manual
Consensus development conference	A one or two day conference where a group of experts will collect scientific evidence and present it to a jury, with a live audience. The jury and the audience will have the opportunity to address questions to the experts. The jury will then withdraw, so as to form an opinion. Afterwards, the jury will present the decision to the audience. The advantage of this method is that a large audience will be able to take part in the decision making process, which will create a lot of support. But it is also possible that the jury comes to a decision which is not supported by a part of the audience, because with this method the audience lacks the time to reach consensus of opinion. Another disadvantage is that planning such a conference takes up a lot of time.	When it is important that, apart from a selected group of experts, a certain type of audience is also allowed to provide input.	Format and Conduct of Consensus Development Conferences: Multination Comparison Consensus Development Conferences: Overview and FAQ

Appendix 6: Authors

Authors Dutch version

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The **PROM-cycle** has been developed in cooperation with the Expertise Network Patient Reported Outcomes. The expertise network advised us on the form and content of the project, provided feedback on (earlier) versions of the **PROM toolbox** and contributed to the practice test.

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Printable version of the website www.zorginzicht.nl/kennisbank/paginas/PROM-toolbox.aspx

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In December 2020 the PROM tools were translated by The National Health Care Institute to the English PROM-tools as part of the h2020 HTx project task 4.3.1: 'Increasing patient-centricity in decision-making'. This document were translated in order to accompany this then updated version of the **PROM-cycle** in the **PROM toolbox**. Elise H. Quik checked and edited the translated versions. Then in March 2021 the English version was send around to the original authors Dolf de Boer, Philip van der Wees, Marloes Zuidgeest, and the HTx project stakeholders/consortium. Any feedback is welcome and will be integrated into the next versions.

Contact

The National Health Care Institute (Zorginstituut Nederland), The Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra) and the 2021 version by the EU H2020 HTx project including the National Health Care Institute (Zorginstituut Nederland), commissioned the development of the **PROM-cycle**.

HTx is a Horizon 2020 project supported by the European Union lasting for 5 years from January 2019. The main aim of HTx is to create a framework for the Next Generation Health Technology Assessment (HTA) to support patient-centered, societally oriented, real-time decision-making on access to and reimbursement for health technologies throughout Europe.

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If you have any questions, remarks or feedback concerning the **PROM toolbox**, please contact EQuik@zinl.nl or HTx@zinl.nl.