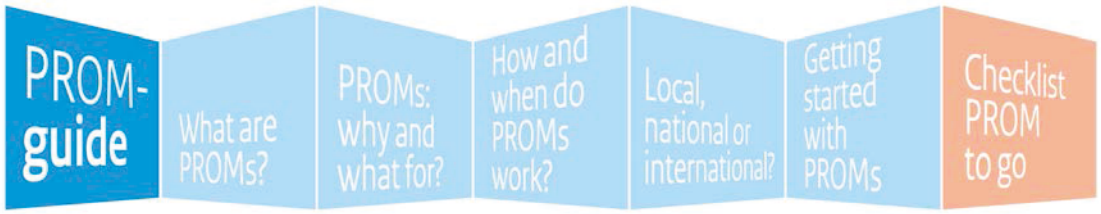
Zorginstituut Nederland

Next Generation Health Technology Assessment

PROM-guide



Orientation and preparation for measuring patient-reported outcomes with Patient/Person-Reported Outcome Measures

Authors of the Dutch version 2018 *Over de PROM-wijzer | Zorginzicht* Dutch ***PROM-guide***
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The **PROM-guide** is part of the **PROM toolbox** and deals with orientation and preparation for measuring patient-reported outcomes (PROs) with Patient-Reported Outcome Measures (PROMs). Step 3 of the **PROM-guide** is accompanied by **the literature review on the use of PROMs**.

Next to this **PROM-guide**, the **PROM toolbox** also contains a **PROM-cycle** for the selection and application of PROMs in healthcare. Step 2 and 3 of the **PROM-cycle** are supplemented with generic PROMs in **the Linnean menu.** The **PROM-links** tool provides links to useful websites.

The **PROM-overview** is an Excel database containing Person/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.

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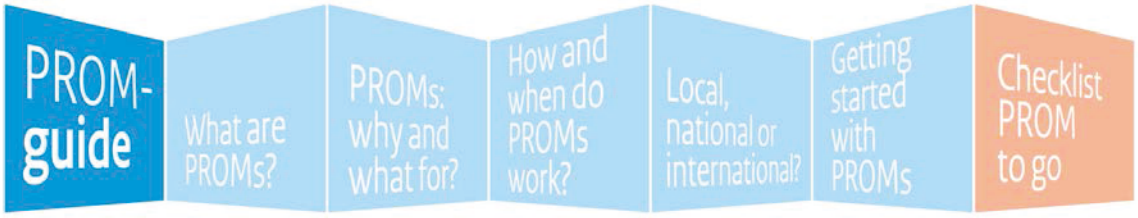
PROM toolbox: PROM-toolbox: PROM-wijzer en PROM-cyclus | Zorginzicht
HTx project: www.htx-h2020.eu; **PROM toolbox:** HTx Project | Publications (htx-h2020.eu)

PROM-guide

Explanation

NOTE: This PROM-guide is integrated with the PROM-cycle in the PROM toolbox.

The PROM-guide is part of the PROM toolbox and deals with orientation and preparation for the use of PROMs. After orientation and preparation for measuring PROs with PROMs using the PROM-guide, the PROM-cycle may be used, which is intended for the selection and application of PROMs in healthcare.



The PROM-guide consists of five 'Steps' and a checklist. Each Step deals with a specific subject that is important in PROMs. In addition to brief explanations and clarifications, choices and dilemmas are discussed, accompanied by examples. You can study the Steps chronologically (1 to 5), but you can also go directly to a specific topic. Step 1 explains what PROMs are. Step 2 is about why PROMs are used and what they are used for, and Step 3 is about how and when PROMs work. Step 4 discusses the scope of initiatives to have PROMs measured (local, national or international). Step 5 describes how PROMs are started. Finally, you can use a checklist to check whether you have thought of all the relevant issues and to estimate how useful or meaningful it is to use PROMs. We chose orange for the checklist and guide, because you can skip reading parts which you already know and read what you want to learn.

Who is the PROM-guide intended for?

This guide is intended for health care providers, professional or industry organizations, scientific associations, policymakers and patient organisations who want to get started with PROMs.

Talk to each other

Talk to relevant parties and stakeholders about choices and dilemmas. Make a list of relevant parties for your project and discuss the checklist with them. This preparation provides every one with insights into the preconditions for a successful and useful implementation of PROMs. The process and the possible result will be clarified. The most important thing when applying PROMs is that there is a benefit to the patient. That is why you should always involve patients and patient organisations in the preparations and later phases: from choosing and applying to optimising and evaluating PROMs.

Who designed the PROM-guide?

This PROM-guide was revised by Elise H. Quik, but was initially designed in Dutch by Nivel and IQ healthcare, in collaboration with the VSOP - Patient Alliance for Rare and Genetic Diseases and the Netherlands Patients Federation. Commissioned by the National Health Care Institute.

The selection and composition of the Steps was a joint effort. The content and texts are based on a literature study, interviews with key figures and project leaders of PROM projects, and on input from many PROM experts. For more information about the creation of the PROM-guide, see:

Accountability.

What is not included in the PROM-guide?

This guide does not contain the details and nuances expected by PROMs experts. For example, what exactly is involved in selecting a PROM? These details are not necessary to make an initial assessment of the usefulness of PROMs. For parties who want to continue with PROMs after an initial exploration, the **PROM-cycle** provides much more information.

Accountability

The development of the **PROM-guide** consisted of the following steps:

1 Literature study into the ways in which PROMs are used internationally, and into whether and how PROMs contribute to the quality of care and quality of life. This study looked specifically into the degree of evidence, working principles/mechanisms and contextual factors.

2 Interviews with initiators and key figures/project leaders of various PROM projects in the Netherlands. To gain insight into various success/failure factors, important preconditions and common views and obstacles.

3 Consultation with experts during two meetings with the experts and the interviewed key figures/project leaders of PROM projects (from step 2).

a. The first meeting (7 December 2017) looked at the target group, scope and possible forms of the **PROM-guide**. b. The second meeting (8 February 2018) looked at what the most crucial elements and subjects of the **PROM-guide** should be, from a basic point of view. In addition, the experts were consulted for the revision and final version of the **PROM-guide**.

4 The design process of the **PROM-guide**, consisting of organising and integrating the insights from steps 1 to 3, exploring different forms of the **PROM-guide**, supplementing insights with essential knowledge from various guides and tools (such as the **PROM-cycle**), and developing the final design.

The **PROM-guide** was made available in English by the National Health Care Institute and reviewed by; i.e. Marloes Zuidgeest, Dolf de Boer, and the h2020 EU HTx project stakeholders among which EURORDIS. Elise Quik made the necessary changes and additions. The National Health Care Institute will update the **PROM toolbox** annually.

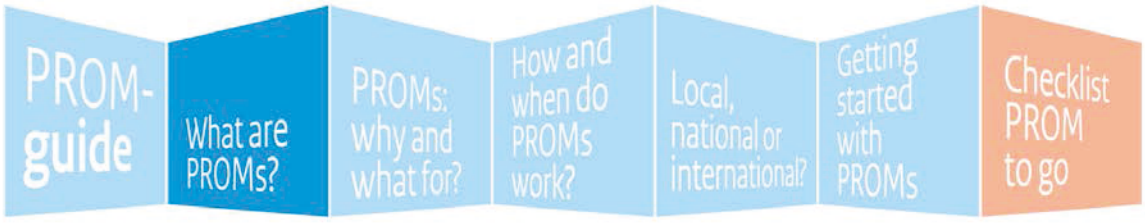
All this has resulted in a **PROM-guide** with the key considerations and points of attention for getting started with PROMs. This **PROM-guide** can be used by various parties in the health care sector for an initial exploration and orientation on PROMs. If parties want to take it further, they can then use the **PROM-cycle** and involve specific expertise for more information about PROMs.

See also

PROM toolbox: **PROM-guide**, **the literature review on the use of PROMs**, **PROM-cycle**, **the Linnean menu**, **The PROM-select app** and PROM glossary

Contents

1 What are PROMs?



For a good understanding of PROMs, the following information is about what PROMs are and what these questionnaires are about, with associated dilemmas and choices, and practical examples.

What are Person/Patient-Reported Outcomes (PROs) and PROMs? Which applications are there? Which types are there? What are the dilemmas?

1.1 Background

PROs and PROMs

PROs deal with aspects of health that cannot be observed 'objectively' and can therefore only be measured by asking the patient, for example, symptoms and complaints such as pain or anxiety, and work, sport or housekeeping performance. Such aspects of health are often grouped together under the heading of quality of life. See **PROM-cycle** for more examples and categories of PROs.

By answering questions, a patient gives their own opinion about their health and quality of life. If patients are unable to complete a questionnaire themselves (such as children or people with severe cognitive impairments or limitations), their relatives can do so on their behalf (as a proxy). This way, PROMs can provide insight into the effects of treatments or care (the yield or 'value' of care) from the perspective of patients or their relatives.

PROs and PROMs are characterized by the fact that they deal with aspects of perceived health that:

- are important for patients;
- supplement and have additional value for the outcomes that can be determined in other ways, such as through observations, clinical assessments or tests (e.g. pulmonary function or walking speed);
- can be asked of patients or their relatives.

Applications of PROMs

In health care, PROMs are used to map out a person's health (issues): before, during and after a treatment, or during a specific care path. The health care provider and the patient can use the outcomes to jointly set goals, make joint decisions about treatment, monitor progress and evaluate whether the treatment goal has been achieved. In addition, another application of PROMs is on the rise, namely the measuring of quality of care and making it transparent. Health care providers can use the results of the PROMs to compare their outcomes to those of their colleagues. This can be used as the basis for quality improvement. Patients can use the outcomes to choose a particular health care provider. Health insurers can use the outcomes for their purchasing policy. Step 2 and the **PROM-cycle** elaborate on the different goals for the use of PROMs.

Types of PROMs

A PROM may be generic, disease-specific, population-specific, dimension-specific, summary items e.g. UK General Lifestyle Survey questions about accidents or utility measures

Generic means applicable for everyone, with or without (one or more) disorders. Specific means applicable for patients with a certain condition or problem.

Well-known examples of a generic PROM is the Short Form Health Survey (SF-36) and Utility measure the EuroQol 5 dimensions (EQ-5D). These are general quality of life questionnaires. In addition, the Patient Reported Outcomes Measurement Information System (PROMIS) has been developed as a generic and dynamic system (see 4.1).

Another distinction is made between standardized PROMs, questionnaires consisting of a fixed set of questions, and individualized PROMs: questionnaires where patients can describe individual problems. These questionnaires provide excellent information for discussions with health care providers, but are less suitable for monitoring, quality improvement and transparency. Examples of such PROMs are Goal Attainment Scaling, or Patient-Specific Symptoms.

PROMs and clinical outcomes

PROMs are intended to collect additional information about aspects of health and outcomes of care, in addition to clinical data. It is well known that clinical parameters do not always accurately reflect how a patient really feels or how they are doing in daily life. Clinical outcomes say little about what the patient experiences as the effect of care.

PROMs and PREMs

PROMs and Patient Reported Experience Measures (PREMs) seem the same, but they are different instruments. PROMs measure the perceived health and quality of life of patients and are often collected with repeated measurements in order to see the progress over time. PREMs are questionnaires that focus on the care process and how patients experience the care received. They are usually only measured afterwards. PREMs are, for example, about experiences with information provision, communication and treatment (dealing with care providers) or about general satisfaction with the care, measured with ratings or recommendation questions (such as the Net Promoter Score, NPS).
PREMs and PROMs can be combined, but this is not always the case, as they are different instruments. PREMs are included in **the Linnean menu**, but not included in this **PROM-guide**.

1.2 Dilemmas and options

Different views and definitions of PROMs

There is a lot of confusion about PROs and PROMs, about what exactly they are and what you can do with them. It is also not always clear how measuring health outcomes (PROMs) differs from measuring experiences with the care process (PREMs). Therefore, use a clear definition for PROMs (see 1.1) and distinguish this explicitly from PREMs and clinical outcomes.

Large variety and multiplicity of PROMs

It seems there is a 'proliferation' of PROMs, because there are increasingly more questionnaires and initiatives. There are already many PROMs available, but new questionnaires are still being developed (about different health outcomes, for various conditions). This requires an orientation on existing PROM initiatives and decision-making. Which questionnaires are already being used and developed? If you are going to work with PROMs, you need to check out the already available PROMs and how you can use these. Consult the **PROM toolbox** and see 4.3 for a list of PROM initiatives.

Alignment of PROM initiatives

If there are several PROM initiatives, each initiative often has its own questionnaire, question method and software package. This leads to fragmentation, with a greater chance of unwanted overlap when questioning the same patients. That is why it is important to coordinate PROM measurements of comparable initiatives (with the same target group). For example, by making national agreements, limiting the number of questionnaires (through standardization or harmonization), by jointly measuring, making agreements on ICT and secure data exchange, and making the results usable by multiple health care providers or parties. For instance, the personal health environment (with patient data) and the health care providers' information systems can uniformly and securely communicate with each other via Health Information Exchanges; a personal health app or a website with the secure exchange of health data between care users and care providers such as MedMij.

Patients receive multiple questionnaires

There are also often several PROM initiatives, from different departments within hospitals. For example, patients are often asked about pain, quality of life, daily functioning and fatigue by different departments when they have a number of conditions at the same time (multimorbidity). Some departments also have several PROM projects. Completing questionnaires repeatedly is an unnecessary burden on patients. It may also be at the expense of the responses. That is why it is important to provide a good list of existing initiatives and PROM measurements within a hospital and check whether they can be combined.

"They all ask about pain, they all ask about quality of life, they all ask about daily functioning, fatigue. These are areas you want to know about for almost every disease."

"The patient is categorized in the pain group, but he also had knee surgery. Therefore, he is asked the same questions twice... The questioning of the patient really requires coordination."

Which questionnaire is the most appropriate?

Choosing a PROM is difficult, because:

- Which questionnaire from the wide range is the most relevant and appropriate for the patient group?
- How do you know if a PROM is appropriate for a certain purpose within a certain setting?
- Should it be a disease-specific or a generic questionnaire?
- What is the subject of the PROM and which measurement properties are important?

These are all questions that come up when selecting the PROM. Go through the PROM-cycle (see figure 1) to find answers to these questions.

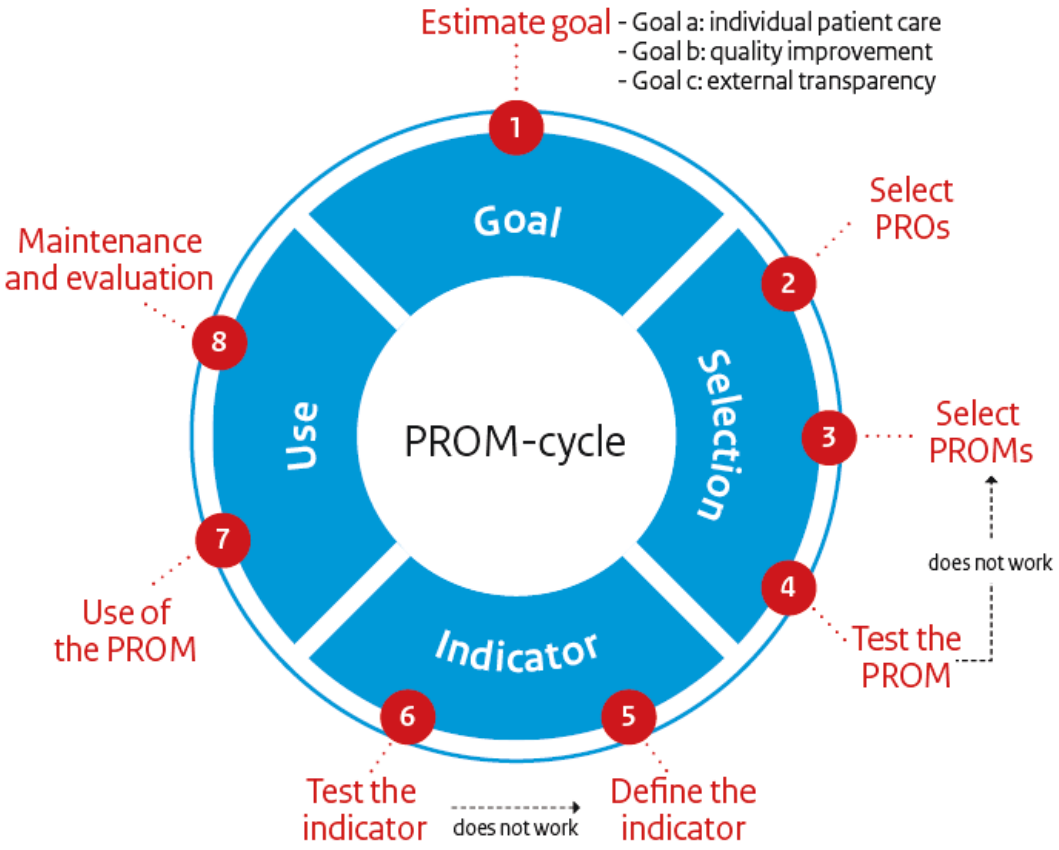
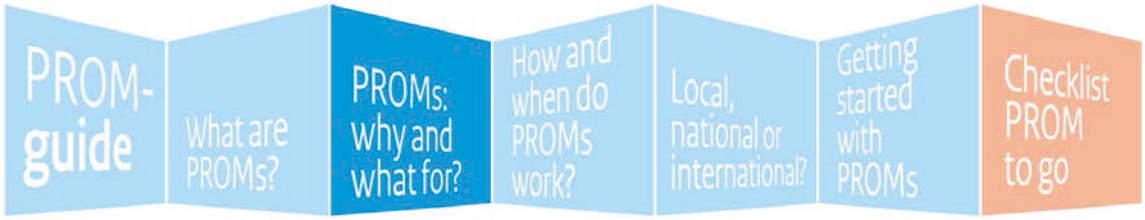


Figure 1. The PROM-cycle

2 PROMs: why and what for?



The following background information about the emergence, goals and applications of PROMs, and about the target groups and users of PROMs, aims to explain why and what for PROMs are used. These are complemented by relevant dilemmas, options and practical examples.

The background of PROMs, different goals and applications, and some examples of different applications.

2.1 Background

Why use PROMs?

PROMs were initially used since the 1970's mainly for scientific research. In recent years, the use of PROMs in healthcare has increased significantly. This has to do with developments in healthcare and changing views on health and care.

The biomedical model with 'hard' clinical parameters (e.g. mortality and morbidity) has increasingly given way to a bio-psychosocial model that puts the psychosocial aspects, perceived health and quality of life of patients first. As a result, healthcare is shifting from purely medical treatment to patient preparation and support, aimed at participation in work, family, sports and leisure.

Patient-centered and (cost)effective care has become of greater importance with the recent emergence of value-based health care (VBHC). Increasing attention is being paid to the value of patient care and what the patient considers important. These developments prompt a growing interest in PROMs, because they measure health outcomes and quality of life and can thus provide insight into the (added) value of care for patients.

Patient-centricity in appraising health technologies

In order to increase the value of healthcare, the effectiveness of interventions should be assessed by analysing or comparing outcomes that matter most to patients. Patient Reported Outcome Measures (PROMs) have been developed to capture outcomes from the perspective of patients, including outcomes that can only be reported by patients themselves (e.g. pain or fatigue). The source of information of PROMs are patients. However, that does not necessarily mean that PROMs measure outcomes that are relevant for patients. Clinicians, patient organizations and researchers need better guidance about how to develop and select generic and/or more specific outcome measures that are relevant to patients. In addition, guidance is needed to help clinicians, patients and researchers to choose PROMs that are fit-for purpose.

Goals and applications

PROMS are used for a variety of purposes, with the overarching goal of making a positive contribution to the health and quality of life of patients and to the quality of care. The use of PROMs is aimed at promoting or maintaining health or quality of life, and at improving or guaranteeing the quality of care.

PROMs are primarily intended as a measuring instrument for determining, evaluating and monitoring health or quality of life. The information can be used on two levels: on an individual level (in individual patient care) or on an aggregated (group) level (for quality improvement, transparency and research).

In general, PROMs can be used for four purposes (and related sub-targets):

1. Individual patient care:

- Screening, medical history and diagnostics (making a diagnosis and care allocation or referrals);
- Identifying topics of conversation;
- Joint decision-making (jointly deciding on treatment options and plan);
- Support for self-management (e.g., remote self-monitoring);
- Monitoring health and quality of life during treatment;
- Evaluation of the treatment outcome.

2. Internal quality information/improvement:

- Feedback of results to health care providers (via feedback/mirror reporting);
- Benchmarking: comparing teams, departments and health care providers;
- Identifying best practices;
- Control and management information for quality improvement.

3. External quality information and transparency:

- Public information about care outcomes and quality of care (e.g. to help patients choose a health care provider);
- Accountability information for supervision and policy (for inspectorates, health care authorities, policymakers)
- Healthcare purchasing information (for health insurers, for selective purchasing on costs and quality)

4. Science and policy research:

- Increasing the knowledge about the course of diseases and disorders;
- gathering scientific evidence for the effectiveness of treatments and interventions;
- Prognostic information (to support treatment choices);
- developing and evaluating guidelines and standards of care;
- monitoring and evaluating policy (for example with research into practice variation);
- National and international benchmarking of performance and outcomes of health care providers and care systems.

Target groups and users

Patients and health care providers are seen as the primary target groups and users of PROMs. Other parties that use the information from PROMs are:

- patient organizations
- professional and trade associations and scientific associations
- Health care organizations (hospitals, clinics, care groups, practices, etc.)
- health insurers
- policymakers and regulators (government)
- scientists and researchers

Below are examples of PROM uses and applications for primary users:

Users	Purpose
Patients	○ **Treatment or health care provider selection** (based on public information about treatment options and quality) ○ **Insight into health and outcomes** (result of the treatment)
Patients and health care providers	**Individual care and use in the physician's consulting room** ○ Screening or diagnostics ○ Identifying problems (in time) ○ Supporting and improving conversation and communication ○ Joint decision-making: weighing treatment options and choosing an appropriate treatment (based on prognostic information about 'patients like me') ○ Monitoring: evaluating health and treatment effects over time ○ Evaluating treatment and care (and, if necessary, adjusting the treatment plan) ○ Supporting patient self-management
Health care providers	**Quality improvement, transparency and accountability** ○ Gaining insight into outcomes and improvement opportunities within an organization, department or team ○ (More) efficiently assigning care or referring patients ○ Supplying (more) appropriate care ○ Comparing health care providers (organizations/departments/teams) for insight into variation and improvement opportunities ○ Accountability for performance and quality delivered

2.2 Dilemmas and choices

How do you choose goals?

Parties often have different and multiple goals in mind. The goals of PROMs are sometimes revised or broadened over time due to continually advancing insights. The question is always: how do you jointly choose a goal of PROMs? For example, there may be conflicting demands between the application of PROMs in practice versus external goals or scientific research.

Patient organizations put the interests of the patient first and find it crucial that these are continuously promoted and monitored, but the needs and requirements of patients do not always match the desired applications and goals of other parties. That is why it is important to discuss the common goals with all parties involved and stakeholders.

"They are an incredibly interesting tool for a university hospital to conduct a lot of research. But that is not what they are intended for."

When choosing or putting together PROM questionnaires, it is also important to have a good understanding of the goals and the target group. They must align with the PROs and PROMs. The response and results largely depend on how well the questionnaires fit the purpose and target group. The **PROM-cycle** (step 3) provides guidance for the selecting of PROM.

"And make sure you know which domains are important for that patient, to ensure a good target for your PROMs. […] We want this and that for that specific target group. And then you find the matching PROMs. Not: we have PROMs and that gives us an insight into the patient's functioning, for instance."

It is therefore important that the goal, the target group and the characteristics of the PROM be aligned. For example: for comparisons over time (monitoring) or between groups, organizations, countries, etc. (benchmarking) two specific measurement characteristics are of great importance, namely: it must be sensitive enough to measure changes (responsiveness) and suitable to measure differences between units or groups (distinctiveness). Consequently, the selection of the PROM is essential, as is the period over which the measurements are taken. In addition, it is essential for benchmarking that there are sufficient respondents per analysis unit (for example per health care provider) to make meaningful comparisons. See the PROM-cycle for more information on selecting a PROM.

One or more goals?

The PROM is often used for multiple ends (for individual patient care as well as for internal and external quality information), and on several levels (local, regional, national or international).
For example: when PROMs are started locally in the consulting room, people often want to take into account that the results are to be compared on an aggregated and national level for benchmarking and quality improvement at a later time. This is not easy, because each goal sets different requirements for the questionnaire, data collection, measuring moments, data and analyses. When used in the consulting room, for example, it is important to link measuring moments to consultations. For benchmarking purposes, it is important that these measurement moments be standardized, to enable a good comparison.
Experience shows that it is important to choose one primary goal or primary application of PROMs, and to take this as a basis for the design of the PROM path. You can consider other uses when setting up the PROM. However, you can also decide to scale up to other goals at a later stage.

Affordability of many PROM initiatives

Health care organizations are faced with an increasing number of PROM processes that all together cost a lot of money and time. These PROM initiatives often involve high preparation and implementation costs. Another issue is the dominant position of a limited number of software and electronic patient/medical records suppliers.
Experts in the field are therefore concerned about the costs of IT in the implementation of PROMs.

> *"Every hospital has its own special module, right? So you can't say: you link up once and you connect all hospitals. Every time, you have to deliver customized solutions. And that is not so much a problem just for us, but for anyone who wants to link an application to such a system. And of course, those companies have a fairly dominant position. (...)*
> *That is the major concern: that it will now become a revenue model for some parties."*

That is why it is important that health care organizations, before starting with PROMs, first thoroughly check whether it is useful and feasible to use PROMs (see also: 5.2 and the Checklist). On the other hand, it is likely that the cost precedes the benefit. The outcomes relevant to patients, measured with PROMs, are the benchmark for making good decisions about value-driven and efficient care.

2.3 Examples

Interviews with PROM project leaders yielded a number of good examples and quotes about the increasing interest in PROMs and various applications.

Increasing interest in PROMs:

- Kidney diseases (Dutch Kidney Patient Association):

> *"The first transplants took place in the mid-1960s. Survival was the most important thing and quality of life came second. Major steps have been taken since 2000 [....]. So, at first, the parameters were very medically indicated and the challenge or question became: what does dialysis add to the quality of life?*

- Orthopaedics (Sint Maartenskliniek):

> *"The orthopaedic paradigm is actually very biomedical. [...] Thoracic surgeons are of course very focused on the thorax. But the introduction of the pain management programme 'RealHealth' has also made them think differently. It has added a bio-psychosocial layer of thinking."*

(The interviewee indicated that this development contributed to the use of PROMs.)

Applications in individual patient care:

- Selective allocation of care for chronic low back pain (Sint Maartenskliniek):

> *"The pressure at the outpatient clinic has been increasing enormously. For many of these people, there is no actual solution. Because the treatments are not effective enough, patients keep coming back with the same issues. And that is what the decision tool is all about: to get the right patient to the right physician on time".*

(About the Nijmegen Decision Tool for Chronic Low Back Pain (NDT-CLBP); decision models for triage based on PROMs.)

- Crohn's disease and atopic eczema: In these chronic episodic conditions (with a variable and unpredictable course), PROMs are used to monitor and act on flare-ups or exacerbations, and to support self-management.

> "The cause is actually the clinical picture. *If you have a chronic bowel disease, you are not always sick. There are times when you are very well and there are times when you are very poorly. If you are really well, you can't really see any point in going to the doctor, and you ask yourself 'What am I doing here?' and the doctor will sort of feel the same*."

(About the reason for monitoring patients with PROMs, instead of standard follow-up consultations.)

- Oncological disorders/KLIK project: PROMs help to monitor patients and their symptoms and to identify whether and when extra help is needed. PROMs can therefore act as a conversation starter in the consulting room.

Applications for quality improvement:

- National PROMs databases for Parkinson's, intermittent claudication, and kidney diseases (kidney dialysis): PROMs are used to improve quality and reduce variation between health care providers, and sometimes to generate more attention for quality of life.

> *"And what you can start to see is that in five years' time, people in one hospital will deteriorate less rapidly than in another hospital, for instance."*

Applications for research/science:

- Rare disorders, such as Turner's syndrome: PROMs are used to gain more insight into the range of symptoms and how the health care can be better matched to the patient's symptoms.

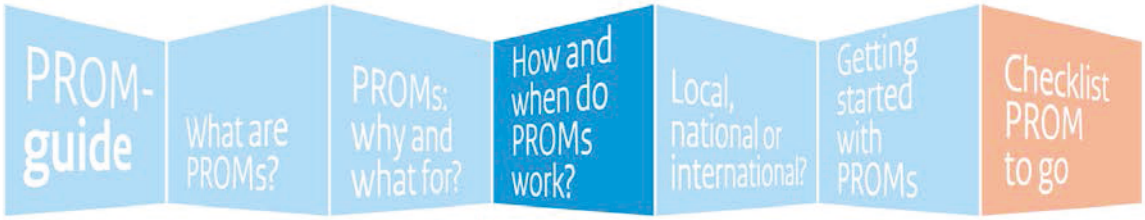
> "PROMs enable you to find out what is going on in this rare patient population. *You might have an idea, but no actual numbers. For instance, we have found out that a lot of issues are stress-related. And 50% or 60% of patients are obese and fatigued. The numbers that we have collected in the past years are now helping us to match our care to this data.*"

- Activity/effectiveness of biologicals (e.g., Crohn's disease and atopic eczema): PROMs are used to provide evidence for these products that are made from proteins of living organisms and that are used as anti-inflammatory agents in specific pathologies such as rheumatism, Crohn's disease, psoriasis and eczema.

> *"A biological is a rather expensive product that therefore needs to be used effectively. The patient association [VMCE] wants to help ensure that the product is used properly (...) If you prescribe it, you must use a method to see how the product works. "*

(PROMs can play a role in this, according to the interviewee.)

3 How and when do PROMs work?



In order to know what the potential benefit and effect of PROMs are, information about the demonstrated effects, mechanisms of action, and important context factors for PROMs discussed below. This includes information about relevant dilemmas, options and practical examples.

What are the effects of PROMs? How do they work? What dilemmas are there in this area, and what examples are there?

3.1 Background

Effects of PROMs

Scientific literature shows that PROMs mainly have a positive effect on the care process. Examples of this are:

- better communication between physician and patient;
- better conversations in the consulting room (e.g. by discussing symptoms or problems);
- better screening or detection of health issues and psychosocial problems;
- less or a more efficient uptake of care;
- greater patient satisfaction about the care delivery.

The positive effect of the use of PROMs on health outcomes has not yet been very clearly demonstrated in scientific literature. Some effects are reported, such as:

- Less pain;
- better symptom control;
- changes in patient behaviour or self-management.

Nevertheless, such indications are relatively scarce and sometimes contradictory. The effects of PROMs on patient health outcomes have also been measured less often.

Research into the effects on quality improvement and the performance of health care providers and health care systems through the use of PROMs and increased transparency about health outcomes is sparse. The applications of PROMs for these purposes are still being developed. PROMs add the patient perspective to traditional outcomes such as mortality and morbidity. However, for the most part, it remains to be seen whether and how PROMs contribute to improving the quality of care and the health or quality of life of patients (see 3.2).

How do PROMs work? Lack of scientific evidence

Parties that start working with PROMs would be wise to clarify how they want the PROMs to contribute to the quality of care and quality of life. We provide an overview of the 'mechanisms of action' or expectations about 'how it works' described in **the literature review on the use of PROMs**: Current knowledge and scientific evidence for the use of Patient-Reported Outcome Measures (See downloads).

The literature review on the use of PROMs contains ways in which PROMs can contribute to:

- better individual patient care;
- internal quality improvement;
- quality improvement through external quality information (accountability or transparency).

Individual care	Internal quality	External quality
Patient can discuss problems (conversation)	Feedback on performance stimulates quality improvement	Wanting to be as good as or better than colleagues (improving through competition)
Patient uses PROM information for self-management	Feedback on performance influences the behaviour of health care providers	Collaborating in quality improvement (by learning from each other)
The health care provider reviews the completed PROM and discusses it with the patient	Intrinsic motivation of health care providers to improve	Maintain or increase market share
Due to the PROMS feedback, the health care provider takes action (together with the patient)	Wanting to be as good as or better than colleagues (improving through competition)	Protecting or improving the reputation of professionals or organisations
Health care providers discuss the PROMs feedback and action is taken	Collaborating on quality improvement (by sharing information and good examples and by learning from each other)	Increasing income (financial incentives or sanctions from health insurers)
		Being accountable to stakeholders for the quality delivered

Context

The literature study also shows that various contextual factors play a role in the operation of PROMs. We present these factors schematically, subdivided into individual patient care and quality improvement/transparency. The latter factors roughly relate to three things:

- data credibility (including completeness, representativeness and adequate case-mix correction);
- possibilities for action (including direct feedback and feedback of results);
- incentives or sanctions (including financial incentives, setting standards and voluntary or mandatory participation).

Individual care	Internal and external quality (quality improvement and transparency)		
Patient care	Data credibility	Options for 'action'	Incentives or sanctions
Structure and format of the PROM questionnaire	Suitability of PROM data for measuring quality	Direct (online) feedback from PROM data	Financial incentives or sanctions (data as a quality indicator or as a settlement instrument)
Clear presentation and interpretability of the PROM data	Adequate case mix correction	Clear presentation and interpretability of the PROM data	Standard setting or not
Feasibility of completing the PROM and embedding it in the care process	Meaningful measurement moments	The extent to which health care providers see opportunities for quality improvement within their 'span of control' (problem identification + task perception)	Mandatory or voluntary measurement of PROMs
Relationship between health care professional and patient (PROM reinforces or detracts from this)	Completeness and representativeness of data (collection) (including clinical outcomes)	Focus on outliers or general quality improvement	Media coverage
Job description of physicians and nurses	Level of analysis (institution versus health care provider)	Quality improvement support	
Financial incentives or sanctions	Trust in the initiator and in the organisation that processes, analyses and provides feedback on PROM data	Resources and support for quality improvement (knowledge and expertise, capacity, money, feedback tools/dashboards, etc.)	
The extent to which PROMs are used for multiple purposes	Involvement and support of physicians	Attention to 'easy aspects/improvements' versus things that are difficult to change	
Involvement of physicians		Degree of variation between health care providers or other providers (little variation, little reason for improvement)	

3.2 Dilemmas and options

Lack of scientific evidence

Although there are many ideas about how PROMs can be used for various purposes, so far it has been mainly the effects on the health care process that have been demonstrated. There is little scientific evidence for the effects of PROMs on quality improvement and transparency. This lack of evidence is largely due to the many methodological limitations and heterogeneity of the studies performed. In addition, many (local) PROM initiatives have not been structurally evaluated through scientific research. Moreover, the application of PROMs often relates to chronic or progressive disorders,

where hardly any effect can be expected in terms of health improvement (and preservation of quality of life is the main goal). More standardized studies on the effects of PROMs are needed to demonstrate the effects and benefits of PROMs for various purposes.

Financial incentives

There is some evidence of the impact of financial incentives on the use of PROMs. The danger of excessive pay-for-performance (P4P) incentives is that individual patient care may be disadvantaged. Financial incentives can, for example, have unwanted side effects, such as data manipulation, tunnel vision (only improving what is measured), threshold effects (only achieving the threshold value or minimum standard), and the avoidance of sick patients (risk selection). These unwanted side effects of financial incentives can damage the quality of the data. Thus, harm the application of the data for joint decision-making (making decisions together with the patient).

When applying financial incentives, it is important to combine and integrate different outcomes (e.g. clinical indicators and patient-reported outcomes). This means that the reward is based on an overall picture and not on a single outcome. Rather, incentives or reward systems are used to stimulate a culture of continuous learning and improvement, based on feedback on the outcomes of care.

In Europe, the first explorations are taking place for selective care procurement based on patient-reported outcomes in specialist medical care (for example: hip and knee osteoarthritis). Health insurers find it especially important that PROMs are used to measure outcomes of care from the patient perspective. Insurers also look at the variation and any standard scores or reference values that emerge from the national measurements. They will discuss this with the hospitals and clinics.

3.3 Examples

Below you can read some examples of the benefit of PROMs in practice (from interviews).

Individual patient care

Examples of effects in the consulting room or for self-management:

- Use of PROMs in the consulting room for the KLIK project (AMC/EKZ) and Turner syndrome (Erasmus MC): better conversations and consultations, in which more psychological and social problems and symptoms are discussed, and care that is more appropriate.
- Use of PROMs for self-management at MijnIBDcoach (CCUVN): more effective care because the number of consultations and hospital admissions decreased and patients received direct or remote care at the right times.

Internal quality improvement

- Embedding PROMs measurements in the quality policy of ClaudicatioNet and ParkinsonNet: PROMs are used in the quality system of these networks to visualize mutual variation and to improve quality using this method.
- Embedding PROMs measurements in the quality policy of ClaudicatioNet and ParkinsonNet: PROMs are used in the quality system of these networks to visualize mutual variation and to improve quality using this method.

External quality (accountability and transparency)

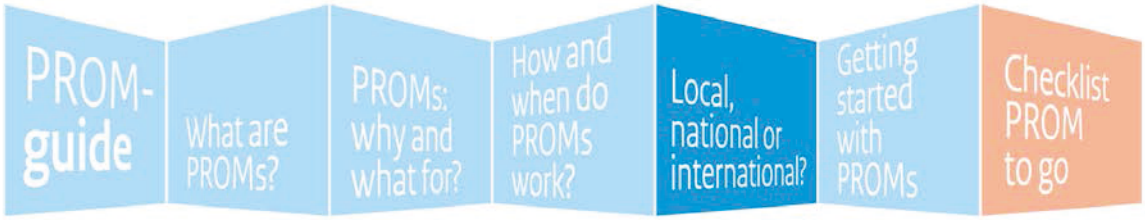
- Annual publication of the “MaartensFacts” by the St. Maartenskliniek: transparency for patients, referrers and health insurers about the care provided and the results of the provided care.

Downloads

The literature review on the use of PROMs:
Current knowledge and scientific evidence for the use of Patient-Reported Outcome Measures

This Step 3 is accompanied by **The literature review on the use of PROMs**: Current knowledge and scientific evidence for the use of Patient-Reported Outcome Measures; an overview of the 'mechanisms of action' or expectations about 'how it works'.

4 Starting locally or connecting to national or international initiatives?



For more insight into the application possibilities of PROMs, at different levels, here is information about local, national and international initiatives. This includes information about relevant dilemmas, options and practical examples.

4.1 Background

PROMs in Europe and the link with International initiatives

In recent years, various PROM initiatives have been launched at local, regional and national levels in Europe. Some care organisations have pioneered a local and pragmatic approach with enthusiasm and conviction. They actively reinvented the wheel themselves, in order to subsequently make the project suitable – in the longer term – for wider or national application. There are also already many national initiatives of umbrella organisations, professional groups or patient associations that local parties can join. The nature and scope of initiatives vary enormously per condition, target group and setting.

See Dutch quality registrations for examples of Dutch quality registrations with PROMs. Participation in these registrations is in some cases mandatory if there is a tripartite agreement and support for this from patient organisations, health care and other providers, professional organisations and health care insurers.
The national programme, 'Outcome-based Healthcare 2018-2022' is used for the registration and processing of data. This can be used by patients to share their outcomes with professionals. Physicians and patients will jointly use the data from national quality registrations. PROMs are an important part of this programme.
The so-called Linnean initiative was recently started in the Netherlands. The aim is to accelerate the use of outcome measures in healthcare and to join forces to this end. Several workgroups have been started to develop components, including the application of PROMs.

Important international developments and PROM initiatives in which Europe is involved are those of ICHOM, OECD and PROMIS.

The International Consortium for Health Outcomes Measurement (ICHOM) is an international consortium for outcome measurements in medical care. ICHOM develops standard sets for measuring outcomes in specific disorders. PROMs occupy a prominent place within the ICHOM sets. The Minister of Public Health has started a project to use the work of ICHOM in the Netherlands. (ICHOM in the Netherlands).

In 2017, the Organisation for Economic Cooperation and Development (OECD) started preparations for the so-called Patient-Reported Indicator Survey (PaRIS). The aim of the PaRIS programme is to measure experiences and health outcomes of care and to make them internationally comparable. The programme consists of two parts. In the first part of the programme, the OECD stimulates the use and application of existing PROMs in national measurements; these also enable international comparisons.

The second part of the programme deals with the development of an international gauge for measuring health outcomes and experiences of patients with one or more chronic conditions who receive primary health care. Representatives participate in the initiative through the steering group and the various working groups. In this programme, the OECD cooperates with ICHOM to collect, analyse and publish outcomes reported by patients for international comparisons.

The aim of the Patient-Reported Outcomes Measurement Information System (PROMIS®, see the glossary) is to make intelligent, computer-guided PROMs available for use in all patient groups.

4.2 Dilemmas and choices

Starting locally or connecting to national or international initiatives?

Many health care organisations struggle with the question: should I start a local PROM project myself, or join national or international PROMs initiatives?

This issue has significant consequences for:

- the goals for which PROMs can be used;
- the method (e.g., whether and how the question fits in with the care process);
- what kind of data is collected;
- using which PROM;
- what kind of results this produces.

Each approach has advantages and disadvantages. Sometimes there is nothing to choose, because for some patient groups there are no national or international initiatives to join.
The great advantage of a local initiative is that initiators can make use of locally available motivation and energy. They can adapt PROMs to the local situation as closely as possible. That way you can take steps and make decisions much faster than with national or international initiatives. However, there are also significant drawbacks to a local approach:

1. You cannot make use of the opportunities and advantages that national or international initiatives offer, e.g., studying practical variations, and benchmarking or comparing scores between health care providers or countries. Goals that depend on the ability to benchmark cannot be easily achieved with a local approach.
2. Local initiatives usually have limited resources (capacity, money) and can therefore invest less in development, testing, etc. National and international initiatives can often call in more expertise and often have more resources.
3. If a local initiative later wants to join a national or international initiative, there is a great risk that the local initiatives will still have to adapt because different national or international choices or conditions apply.
4. If local initiatives want to link up with international initiatives later on, this can lead to a break in method or trend, making comparison with previous measurements problematic. This problem also applies if questionnaires are revised over time (see quote below).

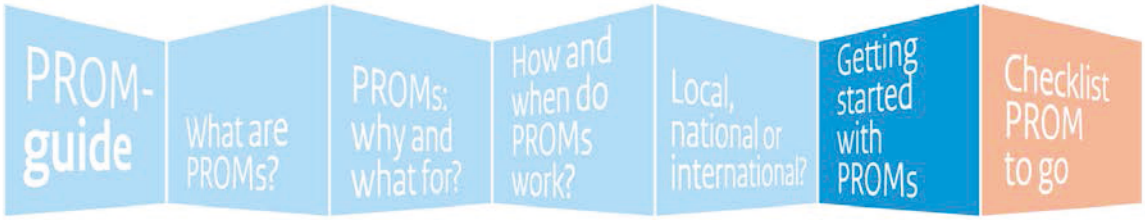
"Sometimes you have to conclude that a questionnaire keeps developing, and at other times that a different list is actually needed. But if you adjust it, you lose the comparison with last year. This means a break in the trend."

Local initiatives are therefore wise to align themselves as far as possible to what is happening on a national or international level. If there is not much available for a specific target group nationally or internationally, local initiatives can develop their own approach. In that case, it is wise to stay in contact with national umbrella or branch organisations and other (local) initiatives. This is to harmonise as much as possible, because as soon as PROMs are used for comparisons (between departments, locations, regions or countries), the harmonisation or standardisation of questionnaires and measurements is necessary. For international initiatives, this can be done, for example, by ensuring that a PROM project is 'ICHOM compatible' (see 4.1).

4.3 Examples

PROM initiatives in the Europe:
Case Study 1: European Head & Neck Society - Home (ehns.org)
Case Study 2: https://connect.ichom.org/standard-sets/diabetes/
Case Study 3: The Patient Reported Outcomes Initiative for Multiple Sclerosis: https://www.charcot-ms.org/initiatives/proms
Case Study 4: Patient Reported Outcomes 5 | MDS Foundation (mds-foundation.org)

5 Getting started with PROMs



Before you start, it is important to create a good plan for the implementation of PROMs. It is also important to know which follow-up steps, preconditions, potential dilemmas and examples there are.

Starting up a PROM project: step-by-step plan, preconditions, dilemmas (including in terms of response, interpretation and feedback). When is it useful to start with PROMs?

5.1 Background

Set-up and design of a PROM project

Many practical lessons are about the set-up and design of PROM projects. The reason that this is so important and at the same time so difficult is due, among other things, to the fact that implementing PROMs is often an unpredictable process. This means that it is vital to make good preparations, and keep in mind and anticipate any developments during the implementation. A good project structure and involvement of different areas of expertise are essential.

When setting up a PROM project, a good project or consultation structure is needed first. This requires the composition of a project group (or steering committee and working group) and a guidance committee (or advisory or sounding board group). All relevant parties must be involved and represented, with the necessary expertise (substantive, methodological and IT technical expertise). Consider the representation of customers and subsidy providers, patient, healthcare, industry and professional organizations, scientific associations, health care providers (physicians, nurses, etc.), health insurers, policy makers, IT experts, researchers, methodologists and PROM experts.

Good project management is also needed, with clear planning and division of roles, tasks and responsibilities for the project participants. During the application of PROMs, it is also important for it to be clear at all times who the coordinator or the central point of contact within an organisation is.

The preparation or design phase of a PROM project is an essential phase, for which an appropriate approach must be devised.
The main points are:

- Clarifying and choosing the goal (see also 2.1);
- Selecting appropriate outcomes (PROs) and questionnaires (PROMs, see **The PROM-select app**);
- Finding the best application from PROMs for a specific goal or patient group and health care setting (with the **PROM-cycle**).

This requires customisation and takes a lot of time and thought. Sometimes this even means a reorganisation of the care process. A PROM project is not something you can ‘do on the side’.

Steps to select and apply PROMs

We provide an overview of the eight steps (divided into four phases) that must be completed in the selection and implementation of PROMs. These phases and steps are described in detail in the **PROM-cycle**. A good project plan for the implementation of PROMs contains these eight steps. Alternatively, at least, provides a justification for the absence of one or more of these steps.

Phase:	Step:	Description	Check (v)
Goal	**1. Estimate goal**	*Estimate why, with whom and in what setting the PROM is used.*	☐
Selection	**2. Selecting PROs**	*Determine what will be measured (which PRO).*	☐
	3. Selecting PROMs	*Determine how to measure (with which PROMs).*	☐
	4. Testing PROM	*Testing of selected PROM in practice, evaluate its suitability for purpose, target group and setting.*	☐
Indicator	**5. Defining the indicator**	Developing an indicator that gives meaning to the PROM results.	☐
	6. Testing the indicator	Testing the indicator in practice to determine if the indicator meets pre-defined requirements.	☐
Use	**7. Implementing the PROM**	Putting the selected or developed PROM into practice.	☐
	8. Maintenance and evaluation	Evaluation and possible optimisation of the PROM and/or outcome indicator.	☐

Preconditions for PROMs

For the application of PROMs, it is important to be aware of and put in place the following types of preconditions:

- Patient involvement ('by and for patients') and the central role of patient (organisations).
- Attitudes and support, such as vision, enthusiasm and confidence in the use of PROMs.
- Practical matters, such as sufficient time, expertise and available resources, the infrastructure, and the connection to the work process in which PROMs are used.
- Methodological aspects, such as measurement properties and the user-friendliness of PROMs.
- Other matters that affect the actual use and impact of PROMs, such as feedback, interpretation and transparency of results.

Make sure the patient benefits and involve patient and patient organisations

The most important thing when applying PROMs is that they benefit the patient. This must be paramount in everything. That is why you should always involve patient and client organisations in the preparations and later phases: from choosing and applying to optimising and evaluating PROMs. Take advantage of the experience and expertise that patient organisations have built up around PROMs and listen to their needs. This will make the introduction of PROMs efficient and will ensure better alignment with national initiatives and regional developments. The principle is to measure and address only those issues that are relevant to the patients. Please refer to the Patient Participation Guide for PROMs of the Netherlands Patient Federation (see also the **PROM-cycle**).

It only makes sense to ask for information from patients when they can experience that the information is actually being used. This increases the chance that they will want to complete a questionnaire later on and provides better responses. Depending on the purpose, PROMs provide the patient with insight into their own situation, sometimes compared to similar patients. This information can help you make better-informed choices about your own life and healthcare with the health care provider. In addition, PROM information can be useful to determine, in consultation, which care adds the most value. Alternatively, to continuously improve and monitor healthcare together in a way that matters to the patient.

Attitudes and support for the use of PROMs

This deals mainly with the vision and culture of an organisation, the enthusiasm of directors and employees, and confidence in the method and the information it provides. Think of directors' long-term vision for more patient-focused and value-driven care, quality improvement, a culture of continuous learning and improvement that requires systematic feedback about patient experiences and health outcomes, and the will to be a pioneer and to find out and try things for yourself.

Attitudes and the support for PROMs can be improved by giving professionals insight into the arguments for the use of PROMs and by involving them at an early stage in the planning and implementation. Providing targeted feedback on PROM data and sharing success stories can further increase support among health care providers. Organisations or departments also need ambassadors or pioneers, in other words health care providers that stimulate and promote the use of PROMs. Furthermore, nurses and paramedical care providers play an important role, because they are often the ones discussing the PROMs and are involved in the measurement process.

Finally, the validity and reliability of the collected data are essential for acceptance. This is partly determined by the accuracy of the data, sensible measurement timings, an adequate correction for patient or population characteristics (case mix) when comparing health care providers, and the reliability of the organisation providing the PROM feedback.

Practical matters

These include infrastructure, technology applications, and work routines that use PROMs. Think of embedding PROMs in the care process and electronic patient record (EPR), dashboards, or patient portals for clear feedback and presentation of results to health care providers and patients, and mobile technology (measurements using apps and smartphones). All of this is, of course, accompanied by the necessary expertise and IT support, agreements on data exchange and sufficient budget to achieve these things.

Connecting PROM measurements to the work process, the care points and disease course is essential for the use of PROMs in clinical practice. This could lead to a reorganisation of the logistics or the outpatient clinic consultation hours. Embedding in the EPR is also an important condition, as it facilitates the response, routine data collection, and easy assessment of the effectiveness of treatments. For example, any administrative burden on PROMs in the workplace will be kept to a minimum, which greatly improves the use of PROMs. Reducing administrative burdens is an important issue in healthcare, so try to set up the process as efficiently as possible.

Methodological aspects

It is important that PROMs data are properly collected, analysed and fed back. This requires a good balance between the required measurement characteristics (validity, reliability, responsiveness) and the applicability or ease of use of PROMs, for the target group and users, with a suitable approach (‘user centred design’).

User-friendliness for patients means that questionnaires are understandable, clear and not too laborious: not too long, not too intrusive or emotionally moving, and not asked too often (or at the wrong time). Patients with visual, mental or cognitive limitations, diminished health skills or literacy problems should also be able to fill out the questionnaires (or be offered help).

Other preconditions

Feedback and transparency are important conditions for the effective use of outcome information and the impact of PROMs on individual care delivery and quality improvement. This requires that the results of measurements are effectively and understandably linked back to the target groups and users, and made public if possible. In addition, the linking of outcomes to other data, such as clinical data or process indicators, can improve the interpretation of PROMs. The results can be interpreted in a meaningful way and it is easier to link the experienced quality and quality improvement. To further study and better understand the workings and usefulness of the PROMs, more time and scientific research are needed.

5.2 Dilemmas and options

How feasible is the use of PROMs?

Various factors play a role in the question of whether the application of PROMs is feasible. These are not only the necessary preconditions (see 5.1), but also, for example, the response, user-friendliness or length of the questionnaires. In addition, the usability of data and results.

We will discuss a number of key feasibility factors:

- the length of the questionnaires;
- the response;
- the interpretation and feedback of data.

Length of the questionnaires

The length of a questionnaire also determines the (time) burden and usefulness for the target group. The final questionnaire is often very long, especially if questionnaires are combined, or if generic and specific PROMs are used at the same time. This may be at the expense of the response, although it is difficult to estimate beforehand. You should always consider what is right for the target group, and what the options are for keeping the questionnaire as short as possible. See also PROMIS, the **PROM-cycle** and Tool review and optimisation of patient experience questionnaires.

> *"So that's the big concerns that those questionnaires will be so long that you're going to get a non-response anyway."*

> *"We had a number of Parkinson patients tested and one was ready within 20 minutes and the other took over an hour. […] We had a test panel (…) and at some point, we just assumed: well, if it is about half an hour on average, it will be good.*
> *But that was guesswork, and we would have liked to have had a little more help in that."*

Response

The response plays a major role in the power and usefulness of the collected data. The response determines representativeness and reliability. In general, it is the more educated, literate and most healthy patients who fill out the PROMs. Vulnerable target groups are hardly reached. There is also a general trend of declining responses to questionnaires and patient experience research.

A low response is certainly a problem in national or temporary projects that are not primarily intended for consultations in the consulting room, but for benchmarking and quality improvement, for example. When patients receive a PROM questionnaire to complete at home, either digitally or otherwise, physicians or nurses often forget to motivate patients to participate and the response is often lower.

> *"The neurologist must ask for consent, which is often forgotten. They really haven't embedded the whole process of asking people if they want to participate and fill out the PROMs. That's a real stumbling block."*

> *"The final output is completely determined by that one nurse, or that consulting assistant at the clinic. They must ensure that the patient is motivated, that the response is high, that the questionnaire is handed in."*

There may be a lot of variation in the responses to national initiatives for comparing outcomes between hospitals. As a result, some hospitals have little use for the collected data in their own practice.

> *"You can see that there is a big difference in response level: there are centres that have a response score higher than 50% and centres with a 10% response."*

> *"We have 1,500 of these patients per year, so if 5% fill out the PROMs that means 75 patients. At a hospital-wide level, that's not really enough. 'Ah', the [national body] says, 'that's not bad at all because we have enough data to use on a national level'. But for us as a hospital, for 5%, do you want to apply this in the consulting room? Because it is only 5% of the patients that we treat. So, logistically, this is not a real option during a consultation."*

One negative result of a low response is that people are less willing to invest in the measurements and necessary facilities, such as IT systems and links, although linking and embedding in the EPR makes data collection, feedback and use in the consultation room easier. These are the conditions for getting more responses. Therefore, you must find ways to increase the response, such as:

- make sure the patient benefits; that is a motivating factor. For example, by providing direct feedback and using it in the consulting room, or by supplying feedback through a patient portal;
- ensure that consent to the use of data is given and that patient privacy is guaranteed;
- Make PROMs part of the care process and make them meaningful;
- allow health care providers, such as nurses, who in practice often act as carers, to motivate patients to complete questionnaires;
- use an automated invitation process to ensure that each patient is invited consistently to complete the PROM questionnaire;
- ensure the embedding of PROMs in the EPR and relevant IT systems and networks;
- ensure that the care provider or organisation benefits from it, for example by using data for the learning and improvement cycle or PDCA cycle (plan-do-check-act);
- provide feedback to all relevant patients, organisations, and care providers about what can be learned from the PROM measurements and how.

Interpretation and feedback of data

Interpreting PROM information requires:

- standards
- reference values from a group of similar patients
- context information (clinical data)

In this context, 'clinically relevant differences' are often mentioned. PROMs are therefore often tagged with a MID (minimal important difference) or MCID (minimal clinical important difference), which indicates the minimum difference required for there to be better health or quality of life.

"That was also the difficult thing in looking for those PROMs: it was just very difficult to get the information: what is a good indicator that really says something about the quality of care."

In addition, the use of PROM information in patient care (in the consulting room, for online feedback via patient portals, or for various tools for selection or self-management) requires:

- individual patient scores, with any averages and standard or target values for the patient group (tailored to comparable patients)
- above all, a clear visual representation of the scores

For the latter, refer to the Guidelines for the presentation of quality information to consumers. Most patients want to see something visual (a line chart, bars or smileys), preferably in colour, not just scores or text. Whether to reference standard data or not is a point of discussion, especially in case of children and progressive disorders or cancer.

"At some point, the feedback was given in a certain format and we said it needs to be much more visual."

"At first, we also returned the standard data to the patient. However, we work with children so that was not desirable. The children got the idea that they were less than the others, and that wasn't a positive development, to say the least. So we took that information out. So they can see their own development, but not the standard against which that is measured."

Quality improvement requires mirror information, with own scores and reference data or 'benchmarks' in the form of averages across the aggregated data at a departmental or organizational level. Preferably, it should include standard or target values and context information to properly interpret the data. Context data includes characteristics of the patient population, for example. This information is also necessary to correct for differences in background characteristics (case mix) in comparative analysis. In addition, to better understand the results, it may be necessary to link PROM data to other data, such as clinical or process indicators, health care consumption, and costs. This makes it even clearer which changes can be made to improve quality.

When would it make sense to get started with PROMs?

When determining whether it makes sense to launch a PROM initiative, it is crucial that a PROM fits the purpose, the target group and the setting. To do this, go through the PROM-cycle. The usefulness and feasibility of PROMs also depend on a large number of factors, such as:

- Potential for improvement in healthcare: the greater the potential for improvement (opportunities for quality improvement or more effective healthcare), the more meaningful PROMs will be;
- treatment options and choices in healthcare: the more treatment options and choices there are, the more meaningful PROMs can be to deliver and evaluate customised and appropriate care;
- variation in health and outcomes: the greater the variation in health and outcomes of care, the more meaningful the use of PROMs will be;
- psychosocial factors: the greater the role and influence of psychosocial factors in diseases and disorders or health problems, the more meaningful the use of PROMs will be;
- evidence for PROMs: the more evidence there is for the added value and operation of PROMs, the more meaningful they become;
- support for the use of PROMs: the greater the support and willingness of relevant parties and stakeholders to use PROMs, the more meaningful the use of PROMs will be;
- involvement of health care providers and patients: the greater their involvement, the more meaningful the use of PROMs will be;
- the importance and usefulness for patients: the more patients consider the use of PROMs important and the more it benefits them (e.g. in the discussion with health care providers and for self-management), the more meaningful the use of PROMs will be;
- feasibility and attainability of PROM measurements: the more user-friendly (easier to fill in) PROMs are and the less (administrative) burden health care providers and patients experience, the more meaningful the use of PROMs will be. Connection to the care process is also a requirement;
- other opportunities or alternatives to PROMs: the fewer other possibilities there are for finding or determining health outcomes (e.g. pain and fatigue that cannot be demonstrated with clinical parameters or functional tests), the more meaningful PROMs will be;
- funding and capacity for the implementation of PROMs: the more budget and work force available for the implementation of PROMs, the more meaningful the use of PROMs will be.

Because extensive measurements and registrations are usually costly, national PROM measurements and registrations mainly look at the volume, practical variation and improvement potential. Nevertheless, even on a smaller scale, insufficient insight into the disease course can already be sufficient reason to use PROMs in the consulting room. You can use the Checklist to determine if it makes sense to get started with PROMs.

When and how to start using PROMs?

Besides the question of whether it makes sense to start with PROMs, there are important questions: when and how do you start using PROMs? In practice, we see that many parties are enthusiastic about it at the start, gradually learning what is needed and adjusting the project where necessary (as an iterative process). This is where the desire to be a pioneer, or to invent and develop the process, is a major success factor for the realisation of a PROM project.

"Each project must follow its own process."

"Well, I think that what gave us wings initially, later turned out to be a barrier?. We invented something, we were very innovative, but to get that innovation actually implemented at the hospital... I think we should have paid much more attention to that in the beginning. But if you had done that, it might not have got off the ground at all, that's the other side of the coin."

However, there is also a need for guidelines to determine the right approach or the 'business case' and for the continuation, embedding or scaling up of the use of PROMs. This PROM-guide and various other guidelines and resources offer the necessary tools (see Zorginzicht.nl).

Time investment

Researching and implementing PROMs is a long-term process. It calls for considerable time investment and perseverance, especially if adjustments to the care process are needed (see below). Therefore, you should take into account that it takes at least one to two years for a PROM to be selected and actually applied.

> *"We developed MijnIBDcoach during our spare time, as did the physicians also. We are also located far apart, so we're asking a lot from the physicians. It all has to be done in their spare time. The same goes for us as a patient association."*

How to connect to the care process?

In places where PROMs are intended for use in individual patient care, the integration of PROMs into the care process (connection to work flow and care moments) is essential. This requires customization of IT and logistics, and all kinds of choices about who is doing what at what time. That is why the practical application of PROMs requires sufficient preparation time. Sometimes a reorganisation of the care process or the work processes is also required (see also 5.3).

> *"We first put the care path we worked with on paper, and documented the bottlenecks. Then we determined which questionnaires are important for this patient group, and how to better organise the care path. I think it took us over nine months to a year to really get this properly mapped out and adjusted."*

How do you ensure the implementation of PROMs?

When applying PROMs, there must be constant attention to evaluating, maintaining and, where necessary, adjusting the goals and questionnaires. For example, in the long term, the PROMs can be applied on a wider scale, to other target groups or hospitals, or scaled up to national level. In the long term, it is also likely that a substantive renewal or adjustment of a PROM questionnaire will be necessary. Clues for this are documented in the **PROM-cycle** and Tool for evaluating and optimising patient experience questionnaires.

5.3 Examples

Practical views on the meaningfulness of PROMs

The interviews about PROM projects contain several statements about when PROMs are meaningful.

> *"If there is no large group to be analysed thoroughly, it will be very difficult to reach reliable conclusions. You need volume to make it meaningful."*

> *"For use in the consulting room, you don't have to perform complete registration, but it can give the patient insight. There's a choice there."*

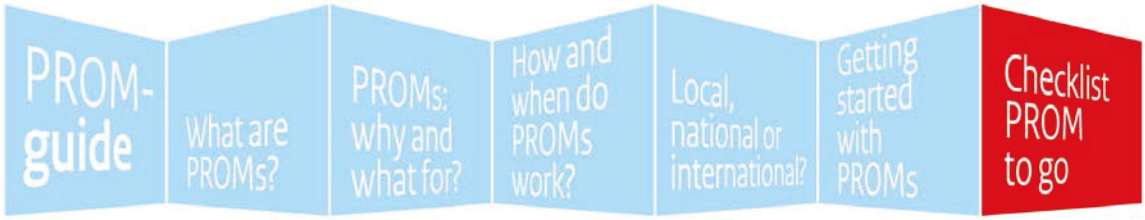
Connection to the care process (work flow, care moments)

Examples of care providers or projects where logistic processes have been adapted to use PROMs to get the right patient to the right practitioner in time are the Sint Maartenskliniek, KLIK, MijnIBDcoach, Turner, and Claudicatio Intermittens.

> *"At MijnIBDcoach, […] you need to adjust your care process and you never do that for one patient. So you need at least 50 patients to change your care. As a hospital, you have to be open to this. You need nurses who are trained to do so. So it requires quite a lot of adjustment in a hospital."*

> *"But we're going to look in detail for each group how this fits into their clinical work flow, because I think that's where the greatest barriers occur."*

6 Checklist: PROM to go?



Before starting with PROMs, it is important to ensure that you have considered all relevant issues. This checklist provides an overview of the relevant questions and necessary preconditions. You can also assess whether the use of PROMs is meaningful.

6.1 Checklist before getting started with PROMs

The checklist below will help you to ensure that there is sufficient clarity about PROMs in advance, and that the necessary preconditions are in place. As long as the answers and conditions are not yet available ('No, not at all' or 'A little'), it is advisable to continue discussions with the relevant partners and to create the necessary preconditions. Sometimes it is not feasible to answer questions in advance with 'For the most part' or 'Yes, completely'. In these cases, it is important that the parties realise this. They can consider this as a point of attention and still go ahead working with PROMs, filling in any gaps later.

Please complete this checklist before continuing with the **PROM-cycle**. You can use the questions and considerations in 6.2 to explore the checklist further.

Checklist: have the questions been answered and preconditions realised?

Questions:	To what extent have the questions below been answered?	No, not at all	A little	For the most part	Yes, completely
Goal, target group and users of PROMs	*The goal(s) of the PROMs is specified?*	☐	☐	☐	☐
	The primary target is chosen and described?	☐	☐	☐	☐
	The patient group is clearly defined and described?	☐	☐	☐	☐
	Is there an overview of all relevant parties/users?	☐	☐	☐	☐
	The goals of all users are specified?	☐	☐	☐	☐
Function, effects and suitability of PROMs	*Are the assumptions or expectations about the operation of PROMs clearly defined?*	☐	☐	☐	☐
	Is there evidence/justification for the use of PROMs for this purpose, for this target group and/or in this setting? (from scientific research and/or practical experience)	☐	☐	☐	☐
	Are the intended effects of PROM(s) defined?	☐	☐	☐	☐
	Are alternatives considered and is it clear why PROMs are really needed?	☐	☐	☐	☐
Support, involvement and alignment with national and international PROM initiatives	*Is there coordination with patients and patient organisations?*	☐	☐	☐	☐
	Is there support from all parties for the use of PROMs?	☐	☐	☐	☐
	Is it clearly defined how the parties are involved?	☐	☐	☐	☐
	Is the application consistent with national and international developments and PROM initiatives?	☐	☐	☐	☐
Application and performance of PROM measurements	*Is it defined at what level (local, regional, national or international) PROMs are applied?*				
	Is it clear how many patients and departments/locations/organisations are measured?	☐	☐	☐	☐
	Is it clearly described how the measurements will take place?				
	Is it clearly described how the feedback about the results will take place?	☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
Preconditions:	**To what extent are the preconditions present/realised?**	**No, not at all**	**A little**	**For the most part**	**Yes, completely**

Attitudes and support within the organisation	*Do patients benefit sufficiently from the PROMs? ('By and for patients'?)*				
	Vision and leadership: the organisation wants to be a pioneer or participate in national or international PROM initiatives				
	Confidence in the use of PROMs (including reliable initiator and method)				
	Ambassadors/pioneers within the organisation (contact points/motivators in the workplace)				
	Coaching/supervision, feedback and sharing of success stories				
Practical, methodical and other issues	*Sufficient time (long time horizon) and realistic planning for implementation of PROMs*				
	Budget and capacity (hours/compensation for deployment of health care providers/employees)				
	Expertise for PROMs (e.g. methodologists and trained staff)				
	IT support, dashboards and mobile technology				
	Connection of PROMs to the care process (measurements/feedback linked to care moments)				
	Embedding PROMs in the EPR (for measurements)				
	Can the information be easily linked back to patients and health care providers?				

6.2 Questions and considerations for the use of PROMs

The following is an overview of questions that are important when considering the use of PROMs. The more these questions have been answered, the better the starting point for a meaningful use of PROMs. These questions must be answered to get a clear picture of:

- why and for whom PROMs are important;
- whether there is sufficient evidence of the performance and added value of PROMs;
- what should be taken into account in the application of PROMs.

Use the space behind each question to describe the answers.

Subject:	Question:	Answers/descriptions:
Goal, target group and users of PROMs	***For which goal(s) do you want to use PROMs?*** • *What is the primary goal of your PROMs initiative?* • *Are there any other goals?* ***What is the target audience?*** • What is the patient population for the PROMs? ***Who are the users?*** • *Which parties will use the PROM data?* • *And what for? (goal per party/user group)*	
Function, effects and suitability of PROMs	***How can PROMs help to achieve the goal?*** • *What are the hypotheses or expectations about 'how it works'?* • *Are these hypotheses/assumptions appropriate for the goal and target group?* ***Are PROMs effective?*** • *Is there evidence/justification that PROMs are effective for this goal, for this target group and/or in this setting?* • *Is this evidence based on research or practice?* • *What are the expected effects of PROMs?* • *How do they benefit the patients? ('By and for patients'?)* ***Have alternatives to PROMs been considered?*** • *Why are alternatives unsuitable or inadequate?*	

Subject:	Question:	Answers/descriptions:
Support, involvement and alignment with national and international PROM initiatives	***Is there support from or involvement and alignment with other initiatives?*** • *Is there coordination with patients and patient organisations?* • *Do the parties agree on the goal, application and possible value (usefulness) of PROMs?* • *How are or will the parties/users be involved?* • *Is there an alignment with national and international developments and PROM initiatives?*	
Application and performance of PROM measurements	***At what level and on what scale are PROMs applied?*** • *At local, regional, national or international level?* • *For how many patients and at how many departments/locations/organisations?* ***How are measurements performed?*** • *Through digital (online) or paper questionnaires?* • *Are data collected via the EPR or using separate software?* ***How are the results linked back?*** • *Online (EPR, dashboard, or patient portal) or on paper?* • *Presentation mode: line/bar graph, colours, smileys, etc.?* • *With or without standard scores and/or averages for the target group?*	
Preconditions: practical, methodical and other matters	***Which preconditions should be taken into account in the application of PROMs?*** • *Does the use of PROMs provide enough benefits for the patient?* • *What about attitude/support within the organisation?* • *What practical matters need to be regulated? (e.g. time, budget, expertise and support)* • *What methodical matters are important? (e.g. linking to care process, embedding in EPR)* • *What other matters are important?*	

6.3 When is the use of PROMs meaningful?

The answer to this question depends mainly on the intended goal, the target group (patient characteristics) and setting (environmental factors), and whether a PROM fits in with this (see **PROM toolbox**). Below are a number of determining factors for making a global assessment of the meaningfulness of starting with a PROM. The more answers that apply on the right, the more meaningful the use of PROMs is likely to be. The more answers that apply on the right, the more meaningful the use of PROMs is likely to be.

less meaningful	< < < PROMS meaningful? > > >	more meaningful
Minor (patient does not consider PROMs to be so important and/or benefits little from	**Importance and usefulness of PROMs for the patient?** (e.g. for self-monitoring and discussions with the health care provider)	**Major** (patient considers PROMs to be important and benefits a lot from them)
Few opportunities for improvement in healthcare	**Potential for improvement in care?** (opportunities for quality improvement / more effective care)	**Many opportunities for improvement** in healthcare
Few options / choices in healthcare, little customisation required	**Treatment options / choices in healthcare?** (need for customisation)	**Many options / choices in healthcare,** a lot of customisation required
Little variety / few differences in health and quality of life	**Variation/differences in health (outcomes)?** (for specific diseases/conditions or population)	**Much variation/many differences in health and quality of life**
Little influence from psychosocial factors (play no/hardly any role)	**Role/influence of psychosocial factors?** (for disease course and disease burden)	**Much influence from psychosocial factors** (play substantial role)
No or hardly any evidence for effect/performance of PROMs	**Proven added value and performance of PROMs?** (to achieve a specific goal)	**Strong evidence** for effect/performance of PROMs
Few parties want to use PROMs	**Support of relevant parties/ Stakeholders for PROMs?**	**Many parties** want to use PROMs
Minor (health care providers/patients are not or hardly involved and motivated)	**Involvement of health care providers and patients?** (role conceptions and motivation)	**Major** (health care providers and patients are very involved and motivated)
Low (e.g. long questionnaire, no embedding in care process/EPR)	**Feasibility/attainability of PROM measurements?** (e.g. user-friendly questionnaires and alignment with care process)	**High** (e.g. short questionnaire, good care process/EPR embedding)
Many suitable alternatives	**Other options/alternatives for PROMs?** (e.g. clinical parameters, function test or interview model)	**No alternative**
Not available	**Funding and capacity for the implementation of PROMs?** (budget and manpower)	**Available**

PROM-guide Glossary

Glossary of terms commonly used in the **PROM toolbox**.

Implementation
Planned implementation of changes with the aim of ensuring that they are given a structural place in the course of action.

Indicator
An indication of any differences in quality of care. Results of PROMs can be converted into an indicator.

Item bank
A set of questions that all measure the same concept (e.g. depression, fatigue, pain, emotional support, etc.). These questions can be used to measure physical, mental and social aspects of health and well-being.

PREM
Patient-reported experience measure. A questionnaire that measures how the patient experiences healthcare, for instance how the patient communicates with the health care provider.

PRO
Patient-reported outcome. A patient-reported aspect of perceived health. PROs reflect the patient's opinion and assessment of their health.

PROM
Patient-reported outcome measure. A questionnaire that measures PROs and that allows the patient (or their next of kin) to assess their health status.

PROM-guide
Orientation and preparation for measuring patient-reported outcomes with Patient-Reported Outcome Measures

PROM-cycle
Selection and application of Patient-Reported Outcomes and Measures

PROMIS®
Patient-reported outcomes measurement information system. This is a computer system that uses adaptive testing. This will guide respondents through a set of PROM questions in a faster and smarter way. The aim is to obtain precise measurements of the most relevant PROs with as few questions as possible. Based on the answer to a question (can you get in and out of bed?), the computer determines the next question (is it easy or difficult for you to run 5 km?) PROMIS consists of a dynamic system of item banks and was originally developed in the United States.

The Linnean menu
A supplement to the **PROM toolbox** and aligns to steps 2 and 3 of the **PROM-cycle**.

The literature review on the use of PROMs Current knowledge and scientific evidence for the use of Patient-Reported Outcome Measures
An overview of the 'mechanisms of action' or expectations about 'how it works' (step 3 **PROM-guide**).

See also

- **PROM toolbox**
- HTx Project | Publications (htx-h2020.eu)
- Ontwikkelen | Zorginzicht
- PROM toolbox Dutch homepage
- PROM-guide Dutch homepage
- PROM-cycle Dutch homepage
- **PROM-cycle** Homepage
- PROMs - patiëntgerapporteerde uitkomsten - Linnean
- Linnean-producten - Linnean
- PROM-overview
- **The PROM-select app**

Appendix 1 Authors of the Dutch PROM-guide (PROM-wijzer)

Authors and PROM experts

A project group of authors developed the Dutch PROM-guide:

- Mattanja Triemstra (Nivel)
- Irene van de Glind (IQ healthcare, Radboudumc)
- Philip van der Wees (IQ healthcare, Radboudumc)
- Rinie Lammers (Netherlands Patient Federation)
- Ildikó Vajda (VSOP - Patient Alliance for Rare and Genetic Diseases)
- Nanne Bos (Nivel)
- Dolf de Boer (Nivel)

In addition, many experts were involved in the development of the Dutch PROM-guide.

Consulted experts

The Dutch PROM-guide was created with the cooperation and input of many experts.
During two meetings (on 7 December 2017 and 8 February 2018), knowledge was shared and the principles and content of the Dutch PROM-guide were discussed. In addition, experts and PROM project leaders participated in an interview about their experiences with PROMs in practice (as examples for the Dutch PROM-guide). Subsequently, experts were asked to provide input for the Dutch PROM-guide during several consultation rounds (via email). The following persons have contributed Dutch PROM-guide to the creation of the Dutch PROM-guide:

Name	Position(s)	Organisation(s)
Bernd Arents	Former chairman / volunteer Medical Affairs & Care	Association for People with Constitutional Eczema (VMCE)
Carla Bakker	Staff member master Vitality and Ageing	Leiden University Medical Centre
Hans Bart	Managing Director	Dutch Kidney Patient Association (NVN)
Dorien van Benthem	Project leader	Dutch Federation of Cancer Patient Organisations
Michael van den Berg	Policy analyst	Amsterdam UMC, Location AMC, dept. Public Health / Organisation for Economic Cooperation and Development
Sandra Beurskens	Endowed professor and lecturer	Zuyd University of Applied Sciences
Sandra Boots	Process coordinator	ParkinsonNet
Jozé Braspenning	Senior university lecturer	IQ healthcare
Floortje Diephuis	Project leader	MediQuest
Simone van Dulmen	Researcher	IQ healthcare / Radboudumc
Simone Klappers	Researcher / Quality agency	Rijnstate
Caitlin Graupner	Physician Researcher	Maastricht UMC+
Mirthe Groothuis	Project leader Patient Feedback & Clinical Audit	Dutch Institute for Clinical Auditing
Lotte Haverman	Health care psychologist / post-doctorate research officer	Amsterdam UMC, Location AMC - Emma Children's Hospital
Rosella Hermens	Researcher	IQ healthcare / Radboudumc
Miranda van Hooff	Researcher / Clinical epidemiologist	Sint Maartenskliniek / Radboudumc - Orthopaedics
Danielle van der Horst	Policy officer	Dutch Association for Crohn's Disease and Colitis Ulcerosa
Henk Jan Idema	Staff Advisor Quality	University Medical Centre Groningen
Barbara van Leiden	Policy advisor programme quality	Association of 10 Dutch Health Insurers
Tineke Markus	Managing Director	Sananet Care BV MijnIBDCoach
Hedy van Oers	Psychologist / researcher	Amsterdam UMC, Location AMC - Emma Children's Hospital

The exchange, pooling and promotion of scientific knowledge and their use in the daily practice of patient reported outcomes was done during four organised public meetings held every year. Topics that were discussed during these meetings were:
The relationship between the goal and the selection of a 'patient-reported outcome' (PRO)
Selecting and testing of appropriate PROMs
Implementing a PROM
Developing a care or improvement plan using a PROM
Evaluating and maintaining (the use of) PROMs

Participants

The participants were:
Patient organisations: Netherlands Patient Federation, VSOP - Patient Alliance for Rare and Genetic Diseases, Dutch Association of Renal Patients
Health care providers: FMS, V&VN, NVZ, NFU, ZKN, UMCG, Rijnstate
Health insurers: ZN
Knowledge institutes: Radboudumc, LUMC, VUmc, MUMC, ErasmusMC, UMCU, AMC, UvT, ISO QOL, NIVEL, RIVM, Equalis, Hersenletsel, Acute Care Network Brabant
Quality registrations: DICA, LROI, DHNA, LNAZ, Parkinsonnet, Meetbaar Beter
Policy makers: Ministry of Health, Welfare and Sport, National Health Care Institute
A president, secretary and core group were selected from the participants; this team prepared the meetings.

President

Dr. Philip van der Wees, Radboudumc;
Rinie Lammers, Netherlands Patient Federation
Secretary
Dr. Jozé Braspenning, Radboudumc

Core group

Sjors van Aalst, NVZ;
Prof. Sandra Beurskens, Maastricht University;
Dr. Carla Bakker, LUMC;
Dr. Dolf de Boer, NIVEL;
Dr. Jacqueline Hartgerink, DICA;
Henk Jan Idema, UMCG;
Ildikó Vajda, STZ;
Dr. Marloes Zuidgeest, National Health Care Institute ZIN

In December 2020 the PROM-wijzer was translated by The National Health Care Institute to the English **PROM-guide** as part of the h2020 HTx project task 4.3.1: 'Increasing patient-centricity in decision-making'. This document was translated in order to accompany **PROM-cycle** in the **PROM toolbox**. Elise H. Quik checked and edited the translated version. 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 in the next version.

Contact

The National Health Care Institute commissioned this **PROM-guide**.
If you have any questions, comments or feedback about this **PROM-guide**, please contact EQuik@zinl.nl or HTX@zinl.nl.

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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