

Generic PROMs menu Advice

Advice from the Linnean working group on PROMs and PREMs

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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 \(htx-h2020.eu\)](#)



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1 INTRODUCTION

The Linnean initiative aims to support patients and healthcare professionals in obtaining outcome information to make better, well-informed choices about patient treatment. This requires good and practical outcome measurement instruments that provide insight into treatment results, both clinical and patient-experienced outcomes. Patient experience outcomes are measured using tools called Person/Patient-Reported Outcome Measures (PROMs). These are important tools to map (changes in) aspects of perceived health and quality of life in a standardised manner.

To support the use of PROMs in the consulting room and to standardise the outcome measurements in health care some more, the PROMs and PREMs working group of the Linnean Initiative developed the Linnean ‘menu’ of generic PROMs. **The Linnean menu** contains a list of outcomes that are relevant to many patients with different conditions (Person/Patient-Reported Outcomes, PROs). For each of these results - PROs - some outcome measurement instruments - generic PROMs - are offered.

1.1 WHO IS THIS MENU FOR?

The Linnean menu is intended as a selection tool for anyone involved in choosing PROs and PROMs for use in health care. The menu is suitable for people who start using PROMs, but also for people who already work with PROMs, to evaluate what is already being done and how it can possibly be made more efficient.

For more PROMs not mentioned in this menu, see the **PROM-overview**, which is made available in the user-friendly web-application helping users to select PROMs: the **PROM-select app**. The **PROM-links** tool provides links to useful websites.



1.2 PURPOSE OF THE LINNEAN MENU

The purpose of the menu is to accelerate, facilitate and standardise the use of PROMs in the consulting room.

The purpose of using PROMs in the consulting room is to support the discussion between patient and healthcare professional. A good discussion does not always require outcome measurement instruments, and outcome measurement instruments do not replace the discussion with the patient. However, PROMs can be used to map relevant PROs in different domains in a structured way, in preparation for, for example, joint decision-making and evaluation of the effects of disease and treatments. It is important to use patient experiences (holistic approach) alongside clinical information.

In addition to a good discussion, the use of PROMs in the consulting room also provides input for improvement information and selection information.

The purpose of the menu is also to promote the standardisation of outcome measurements, to simplify the introduction and interpretation of outcome measurements and to facilitate the exchange of data between healthcare professionals.

1.3 HOW TO USE THE LINNEAN MENU

The Linnean menu is a supplement to (and not a replacement of) the **PROM toolbox**, consisting of the **PROM-guide**, **the literature review on the use of PROMs** and the **PROM-cycle**.

The menu aligns to steps 2 and 3 of the **PROM-cycle** (Figure 1, promtoolbox.zorginzicht.nl), the process of selecting PROs and PROMs.

The menu is advisory in nature. The purpose is to help people to select PROs and PROMs, not to make something mandatory. No PROs or PROMs are prescribed that should be measured or used in all patients, because no PRO is relevant to all patients and no PROM is proven as valid and reliable for all patients. The final choice for PROs and PROMs for a particular patient group



or patient treatment pathway should be made jointly in consultation with all healthcare professionals and patients involved.

The Linnean menu provides some generic PROMs, which can be used to measure PROs that are relevant to many patients. These generic PROMs can be supplemented, if necessary, with relevant disease-specific PROMs that are relevant to a specific group of patients. Generic PROMs can also be supplemented with individualised PROMs (e.g. Goal Attainment Scaling or the patient specific symptoms list) where desired. Finally, a general question, ‘what would you like to work on?’ could be added to support the discussion in the consulting room.

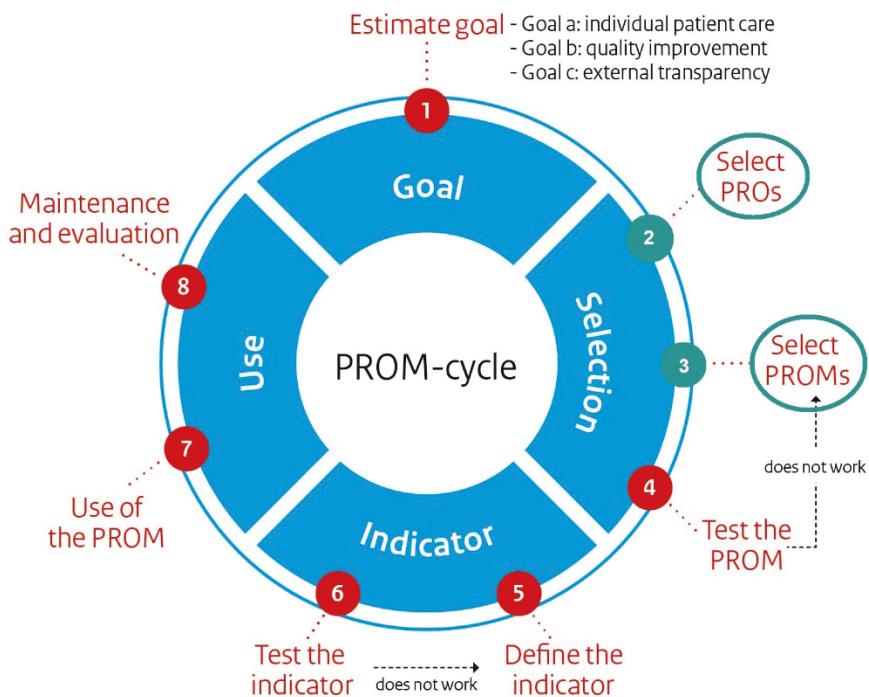


Figure 1. This advice focuses on steps 2 and 3 of the **PROM-cycle**

2 PRINCIPLES OF THE LINNEAN MENU GENERIC PROMs

“Generic, unless...”

The use of PROMs in health care poses several challenges.

1. There are many PROMs available to measure a particular Patient-Reported Outcome (PRO) such as pain, fatigue and cognition. The existing PROMs vary in content and quality (measurement properties) and for many PROMs, knowledge about relevant measurement properties is lacking. It is therefore difficult to determine which PROM is best for a particular target group;
2. The various questionnaires have different scores that the practitioner finds difficult to interpret in the consulting room, because they all work differently;
3. Patients are increasingly having multiple disorders. It is a major burden for patients if they have to fill in a different PROM for each condition. Patients also often find it difficult to attribute their symptoms to one particular disease (see box);
4. The burden on healthcare professionals is high when they have to decide for each patient separately which PROMs the patient has to fill out;
5. Some patients have conditions for which no disease-specific PROMs are available, and sometimes patients do not have a definitive diagnosis.

As an example, how does a patient with hip osteoarthritis fill in the following question: Do you feel depressed because of your osteoarthritis?

What if they suffer from depression, which is not caused by the osteoarthritis?

Do they reply with “no”?

Moreover, is questioning the patient about depression relevant for a hip replacement?



If we want to make value-driven care a success in Europe, we need to make it as easy as possible for patients and healthcare professionals. One of the solutions is to use as many generic PROMs as possible that measure the health of the patient as a whole, regardless of the condition(s) that a patient has.

By using generic PROMs as much as possible, we aim to minimise the burden and practical applicability for patients (in particular patients with multiple conditions) and healthcare professionals, to prevent the proliferation of questionnaires, and to make the interpretation of outcomes as comparable as possible.

The guiding principles of the Linnean menu:

- This menu takes the individual as the starting point. It focuses on the patient at the heart of the health care, and the outcomes can be used in the healthcare process, not just for quality evaluations;
- The guiding principle is to measure how patients feel and function in daily life, with or without one or more disorders;
- The menu takes the PROs as a starting point for selecting subscales or individual items from instruments that can measure these PROs. This will provide a separate score for each PRO;
- Generic PROMs do not always replace disease-specific PROMs. Generic PROMs provide an overarching picture of the impact of a particular condition on the daily functioning of the patient. There is also room for disease-specific PROMs for outcomes that are only relevant to a particular disease, such as itching, hearing, etc. See Annex 6 on differences between generic and disease-specific PROMs;
- Measure only things that are relevant to the patient and that can be linked back. In this way, the patient receives information about their disease activity/condition;
- Only measure as often as is really necessary for the patient and at the time that is relevant for the patient;
- Consider using licence-free instruments over licensed instruments;

The Linnean menu

- Consider new methods of taking questionnaires such as Computer Adaptive Tests (CATs) that are more patient-friendly (shorter) and more accurate in assessing patient health;
- By using the menu, we hope to promote uniformity by using generic PROMs for PROs that are relevant for multiple patients.

Where possible, modern PROMs are included in **the Linnean menu**; these can be used as CATs because with this method, patients need to answer fewer questions to get reliable scores.

The menu contains 13 PROs that are often relevant. These PROs, outcomes of health care related to the patient's perceived health, are:

- **Pain**
- **Daily activities**
- **Cognition**
- **Social roles**
- **Perceived quality of life**
- * **Fatigue**
- * **Problem-solving**
- * **Depression**
- * **Sexual functioning**
- * **Sleep problems**
- * **Social activities**
- * **Anxiety**
- * **Perceived health**

This list of PROs has been compiled based on expertise and experiences of members of the working group and on an inventory of all PROs and PROMs from 24 available ICHOM sets. This showed an enormous overlap in PROs and great heterogeneity in terminology.

For more PROs not mentioned here, see the **PROM-overview**, which is made available in the user-friendly web-application helping users to select PROMs: the **PROM-select app**.



3 CLUSTERING OF PROs

The PROs in **the Linnean menu** are divided into different levels of measurement: symptoms, functional status, perceived health and perceived quality of life; see Figure 2. This classification is based on various conceptual models such as the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization, the Wilson & Cleary model, and the conceptual model of the Patient-Reported Outcomes Measurement Information System (PROMIS®).

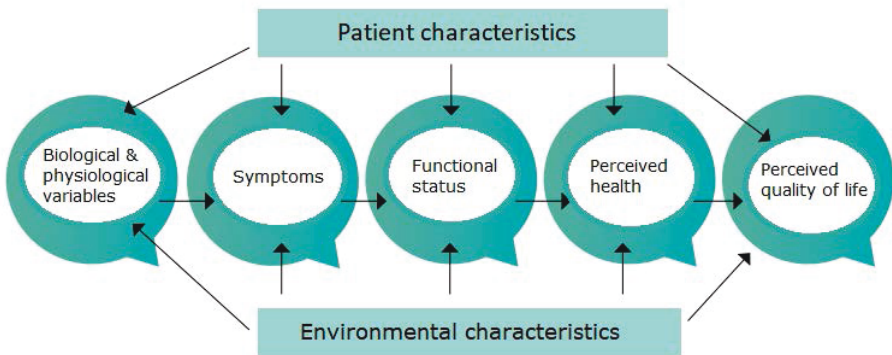


Figure 2: Clusters of PROs

The classification in levels is somewhat causal: a disease manifests itself in pathophysiological manifestations. These can lead to symptoms such as pain, fatigue, or anxiety. These symptoms can lead to limitations in daily functioning (physically, mentally).

These limitations can then lead to a reduced perceived health and quality of life. However, the impact of disease on symptoms, functional status, perceived health and quality of life is different for each patient and is influenced by personal factors (e.g. coping) and environmental factors (e.g. social support). That is why patients with the same illness can experience an entirely different quality of life; sometimes, patients can have a very good quality of life despite a severe illness. The causality can also sometimes swing the other way; for example, limitations in functioning can also affect symptoms. Due to this complexity, it is often recommended to measure PROs at different levels.

Within the symptoms and functional status levels, a distinction is made between physical, mental and social aspects. Table 1 provides an example of a clustering within symptoms and physical functioning.

Symptoms	
Physical functions / symptoms	Pain
	Fatigue
	Sleep problems

Table 1. Example of generic PROs within the symptom/physical function levels

Generic PROMs can very often be used, regardless of a particular disease, especially at the level of functional status (restrictions that someone experiences in daily life), perceived health and perceived quality of life. At the level of symptoms, a number of PROs can be distinguished that are relevant to many patients, such as pain, anxiety, fatigue (Table 1). However, there are also many symptoms that are disease-specific, such as itching or hearing problems, and these must therefore be measured with disease-specific PROMs.

4 RELEVANT PROMS

The menu has been chosen for a limited set of generic PROMs that have good measurement properties and are widely used. Rather than recommending whole questionnaires, each PRO was looked at to see which subscale (or item) of an existing PROM could be used to measure this PRO. Therefore, the starting point is the PRO – what you want to measure. Subscales from PROMs can be used separately.



The core instruments are the Short Forms and Computer Adaptive Tests (CATs) from the PROMIS measurement system and the subscales of the SF-36/ RAND-36.

The SF-36/RAND36 subscales, not the SF-12, have been chosen because the SF-12 only offers two subscales that measure global physical and mental health; so the SF-12 subscales do not measure the individual PROs as defined in the menu. The items of the EQ-5D have been added for use in economic evaluations. However, the EQ-5D is primarily intended to allow health conditions to be valued by a general public (utilities) from a social perspective, and not as a PROM for use in the consulting room.

For cancer patients, subscales of the EORTC QLQ-C30 have been added. For children, subscales of the PedsQL are included and for the elderly, subscales and items from the Topics-MDS have been added.

For measuring perceived health and quality of life, some summary questions are included. These concepts can often be measured well with just one question (a type of report mark), whereby the patient weighs all the factors that determine their perceived health or quality of life.

Relevant PROMs per target group

If the target group are Children, the PROMIS and PedsQL are relevant. When the target group consists of adults the PROMIS and SF-36 are relevant, the EQ-5D for Economic evaluations and in case of cancer EORTC QLQ-30 is relevant. In Elderly the PROMIS (-PF_{GR}), SF-36 and TOPICS-MDS are relevant.

The menu (Annexes 1-3) also provides information on the number of questions that make up the questionnaire, whether the instrument is free of charge and whether it is possible to use the questionnaire as a CAT.

Annex 4 contains a brief description of the instruments and links to relevant websites for more information.

Annex 5 describes the process by which the PROMs and PREMs working group arrived at this menu. In addition, annex 6 shows arguments for a generic or disease-specific PROM.



5 STRENGTHS AND WEAKNESSES OF THE MENU

The Linnean menu of generic PROMs was created based on existing conceptual models from the literature, a systematic extraction of all the PROs from 24 ICHOM sets and expert experience. The menu is open to feedback from the target audience and specific relevant stakeholders, and the feedback from various individuals and organisations, such as ISOQOL-NL, the PROM platform, LUMC, UMCG, ZN, DICA, and Netherlands Patient Federation is already processed. The feedback was related to the clarification of the menu's purpose and target group, the relationship between generic and disease-specific lists, comments on specific tools, translation of scores and the limitations of the menu.

The menu is primarily designed for use in the consulting room. Most of these PROMs may also be used for research or at an aggregate level for benchmark purposes. However, the menu is not without restrictions:

- Domain-specific PROMs are lacking. In addition to generic PROMs, there are several good PROMs that measure one or more PROs, such as the HADS or PHQ9 for measuring depression, the USER questionnaire for measuring mobility and participation, the Fatigue Severity Scale for measuring fatigue. These PROMs are not included because time and resources were lacking to find out which PROMs are best used.
- It is not clear what the best PROMs are. There are insufficient studies and systematic reviews available that demonstrate the best generic PROMs. The PROMs in this menu have been used often or are promising, but we are not sure if they are the PROMs with the best measurement characteristics. More research is required to establish this.
- The included PROMs may be less suitable for people with lower health skills and reduced literacy. No good PROMs are currently available for these target groups.

The implementation of PROs and PROMs is outside the scope of this menu. It is argued that the use of PROMs should always include the engagement of the patient.



6 Funding statement

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.

The HTx project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 825162.



Annex 1. Common PROs and PROMs – adult target group

Outcome measurement instruments						
Levels	Relevant PROs	PROMIS	RAND / SF-36	Domain-specific instruments	EQ-5D (economic evaluations)	EORTC QLQ-C30 **
Symptoms						
Physical functions/ symptoms	Pain	Limitations due to pain	subscale Pain	VAS/NRS pain	Pain/symptoms	subscale Pain
		Reactions to pain				
		Pain intensity				
	Fatigue	Fatigue	subscale Vitality			Subscale Fatigue
	Sleep problems	Sleep disorders				Item 11: Have you had trouble sleeping?
		Problems due to sleep disorders				
Mental functions/ symptoms	Cognition	Cognitive functioning				subscale Cognitive functioning
	Depression	Depression	subscale Mental health		Mood	
	Anxiety	Anxiety				



Outcome measurement instruments						
Levels	Relevant PROs	PROMIS	RAND / SF-36	Domain-specific instruments	EQ-5D (economic evaluations)	EORTC QLQ-C30 **
Functional status						
Physical activities / Physical functioning	Performing daily activities	Physical functioning, Mobility, Upper extremity	subscale Physical functioning		Daily activities	subscale Physical functioning
					Mobility	
					Self-care	
Mental activities / Mental functioning	Problem-solving					subscale Emotional functioning
Social functioning	Performing social activities (sports, hobbies)	Ability to participate in social roles and activities, Satisfaction with social roles and activities	subscale Social functioning			subscale Social functioning
Participation	Performing social roles (work, family, relatives)		subscale Physical Role functioning			subscale Role functioning
			Subscale Emotional Role functioning			
	Sexual functioning	Overall satisfaction with sex life *				

Outcome measurement instruments						
Levels	Relevant PROs	PROMIS	RAND / SF-36	Domain-specific instruments	EQ-5D (economic evaluations)	EORTC QLQ-C30 **
Perceived health						
	Perceived health	Global01: Overall, how would you rate your health?	GHP1: Overall, how would you rate your health?			Item 29: How would you rate your general health over the past week?
Quality of life						
	Perceived quality of life	Global02: Overall, how would you rate your quality of life?				Item 30: How would you rate your general quality of life over the past week?

* Not yet translated into Dutch

** Cancer-specific, 3 items on nausea and vomiting and 6 items on cancer-specific symptoms are not included here

PROMIS	number of items	costs	applicable as CAT
Limitations due to pain	4-40	Short Forms free, CATs €0.12 - €0.24 per CAT for software use	yes
Reactions to pain	4-39		yes
Pain intensity	1		no
Fatigue	4-95		yes
Sleep disorders	4-27		yes
Problems due to sleep disorders	4-16		yes
Cognitive functioning	4-32		not yet because only the 8-item Short Form has been translated
Depression	4-28		yes
Anxiety	4-29		yes
Physical functioning	4-165		yes
Physical functioning – Mobility	4-15		yes
Physical functioning - Upper extremity	7-46		yes
Ability to participate in social roles and activities	4-35		yes
Satisfaction about social roles and activities	4-44		yes
General satisfaction about sex life	7		no
Global01: Overall, how would you rate your health?	1		no
Global02: Overall, how would you rate your quality of life?	1		no

RAND / SF-36	number of items	costs	applicable as CAT
subscale Pain	2	RAND-36 free, SF-36 (newer version) not free, free for non-commercial purposes	no
subscale Vitality	4		no
subscale Mental health	5		no
subscale Physical functioning	10		no
subscale Social functioning	2		no
subscale Physical Role functioning	4		no
subscale Emotional Role functioning	3		no

GHP1: Overall, how would you rate your health?	1		no
VAS/NRS	number of items	costs	applicable as CAT
VAS/NRS pain	1		no

EQ-5D	number of items	costs	applicable as CAT
Pain/symptoms	1		no
Mood	1		no
Daily activities	1		no
Mobility	1		no
Self-care	1		no

EORTC QLQ-C30 - cancer specific	number of items	costs	applicable as CAT
Subscale Pain	2		no
Subscale Fatigue	3		no
Item 11: Have you had trouble sleeping?	1		no
Subscale Cognitive functioning	2		no
Subscale Physical functioning	5		no
Subscale Emotional functioning	4		no
Subscale Role functioning	2		no
Subscale Social functioning	2		no
Subscale general health / quality of life	2		no

Annex 2. Common PROs and PROMs – child target group

Outcome measurement instruments			
Levels	Relevant PROs	PROMIS	PedsQL
Symptoms			
Physical functions / symptoms	Pain	Limitations due to pain	
	Fatigue	Fatigue	
	Sleep problems	Sleep disorders	
		Problems due to sleep disorders	
Mental functions / symptoms	Cognition	Cognitive functioning	
	Depression	Depression symptoms	
	Anxiety	Anxiety	
Functional status			
Physical activities / Physical functioning	Performing daily activities	Physical activity - Mobility, Physical activity - Upper extremity	subscale Physical functioning
Mental activities / Mental functioning	Problem-solving		subscale Emotional functioning
Social functioning	Performing social activities (sports, hobbies)		subscale Social functioning
Participation	Performing social roles (work, family, relatives)	Relationships with fellow sufferers, Relationships with family	subscale Educational functioning

Outcome measurement instruments			
Levels	Relevant PROs	PROMIS	PedsQL
Perceived health			
	Perceived health	Global01r1: Overall, how would you rate your health?	
Quality of life			
	Perceived quality of life	Global02r1: Overall, how would you rate your quality of life?	

PROMIS	number of items	costs	applicable as CAT
Limitations due to pain	4-20	Short Forms free, CATs €0.12 - €0.24 per CAT for software use	yes
Fatigue	4-25		yes
Sleep disorders	4-7		yes
Problems due to sleep disorders	4-6		yes
Cognitive functioning	4-43		yes
Depression symptoms	4-14		yes
Anxiety	4-15		yes
Physical functioning - Mobility	4-24		yes
Physical functioning - Upper extremity	4-34		yes
Relationships with fellow sufferers	4-15		yes
Relationships with family	4-47		yes
Global01r1: Overall, how would you rate your health?	1		no
Global02r1: Overall, how would you rate your quality of life?	4-44		no

PedsQL	number of items	costs	applicable as CAT
Physical functioning	8	"not free for large organisations or for research and evaluation"	no
Emotional functioning	5		no
Social functioning	5		no
Educational functioning	5		no



Annex 3. Common PRO and PROMs – elderly target group

The PROs and PROMs from the adult menu can also be applied for the elderly. The PROMs below are intended as a supplement.

Outcome measurement instruments			
Levels	Relevant PROs	PROMIS	TOPICS-MDS*
Symptoms			
Physical functions / symptoms	Pain		Pain/symptoms (EQ5D)
	Fatigue		
	Sleep problems		
Mental functions / symptoms	Cognition		
	Depression		Mood (EQ5D)
			subscale Mental Health from RAND-36
	Anxiety		

Functional status			
Physical activities / Physical functioning	Performing daily activities	PROMIS-PF _{GR} activity - Upper extremity	Daily activities (EQ5D)
			Mobility (EQ5D)
			Self-care (EQ5D)
			Customised version of the Katz Index of Independence in Basic Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL) and a question about mobility

Outcome measurement instruments			
Levels	Relevant PROs	PROMIS	TOPICS-MDS*
Functional status			
Mental activities / Mental functioning	Problem-solving		
Social functioning	Performing social activities (sports, hobbies)		1 item from RAND-36
Participation	Performing social roles (work, family, relatives)		
	Sexual functioning		
Perceived health			
	Perceived health		On a scale of 0 to 10: How is your health in general?
Quality of life			
	Perceived quality of life		On a scale of 0 to 10: how satisfied are you with your life?

* Questions about oral health and the use of health care are not included here

PROMIS	number of items	costs	applicable as CAT
PROMIS-PFGR (short form)	25		no



TOPICS-MDS	number of items	costs	applicable as CAT
Pain/symptoms (EQ5D)	1	free for non-commercial purposes	no
Mood (EQ5D)	1		no
subscale Mental Health from RAND-36	5		no
Daily activities (EQ5D)	1		no
Mobility (EQ5D)	1		no
Self-care (EQ5D)	1		no
Customised version of the Katz Index of Independence in Basic Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL) and a question about mobility	10		no
1 item from RAND-36	1		no
On a scale of 0 to 10: How is your health in general?	1		no
On a scale of 0 to 10: how satisfied are you with your life?	1		no

Annex 4. Additional information about the selected PROMs

PROMIS®

The ‘Patient-Reported Outcomes Measurement Information System’ (PROMIS®) is a valid and reliable measurement system that enables the highly efficient measurement of patient-reported health outcomes and well-being in adults and children, with or without one or more (chronic) conditions. The unique thing about PROMIS is that it uses item banks. An item bank is a large set of questions (items), all of which measure the same outcome, for example physical function. The questions (items) in an item bank are ranked on their degree of ‘difficulty’ using modern psychometric methods (Item Response Theory (IRT)) (e.g. the question ‘Can you get in and out of bed?’ is easier than the question ‘Can you run 5 km?’). Once this order of items is established, subsets of items can be used as short form and the item bank can be used as a Computer Adaptive Test (CAT). With a CAT, the computer selects the next (more difficult or easier) question based on the patient's answer after a starter question. This gives the patient more relevant questions (if the patient, for example, indicates that they are having trouble walking a little bit, they are not asked if they can run) and the smart way of measuring means that patients only have to fill in 3-7 questions for a reliable score.

The PROMIS short forms and CATs are validated in diverse patient populations in a number of countries.

There are standard short forms available in different lengths (usually between 4 and 8 questions) that cover the entire range of the scale. It is also possible to create a short form (custom short form), for example a short form with mostly easy questions about physical functioning has been developed for geriatric rehabilitation patients.

The short forms can be administered on paper or by computer, tablet, or phone and are free of charge. A link with the Dutch-Flemish Assessment Centre is required for the use of CAT. Various systems, such as KLIK (www.hetklinkt.nu) include such a link. PROMIS CATs are also available in Epic. There are costs involved in the use of CATs.



The use of short forms and CATs can be combined. Scores of short forms and CATs that measure the same outcome (e.g. depression) are expressed on the same scale and are directly comparable.

Relevant websites:

- www.healthmeasures.net/promis
- www.dutchflemishpromis.nl

SF-36/RAND-36

One of the most commonly used questionnaires to measure perceived health is the SF-36. This questionnaire consists of 8 subscales with 36 questions in total, which measure the following aspects of health: physical functioning, physical and mental functioning, social functioning, mental functioning, vitality, pain, and perceived health. The 8 subscales can also be used separately. The questionnaire has been validated in diverse patient populations in various countries.

A licence is required to use the SF-36; the use also includes fees. The use of the RAND-36 is free, but it is an older version.

Relevant websites:

- <https://www.meetinstrumentenzorg.nl/Home/SearchPost?meetinstrument=4169>
- https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form.html
- <https://www.optum.com/solutions/life-sciences/answer-research/patient-insights/sf-health-surveys/sf-36v2-health-survey.html>
- <https://meetinstrumentenzorg.blob.core.windows.net/documents/Instrument47/RAND-36%20SF-36%20form.pdf>

Scores from SF-36 and PROMIS can be converted into the other for the following scales:

PROMIS	SF-36
Limitations due to pain	Pain
Anxiety	Mental health
Depression	Mental health
Fatigue	Vitality
Physical functioning	Physical functioning

See: <http://www.prosetastone.org/measures/SF-36/Pages/default.aspx>

EQ-5D

The EuroQol 5D (EQ-5D-5L) is a standardised PROM consisting of 5 questions that measure five outcomes: mobility, self-care, daily activities, pain/discomfort and anxiety/depression.

The questionnaire is intended for economic evaluations, to determine a valuation (utility) of a health status.

The 5 questions are each scored on a 5-point scale (1-5). By placing these numbers in succession, a 5-digit index is created that represents a health profile (e.g. 12343). Each profile includes a certain rating, a number between 0 and 1, where 0 is death and 1 represents the best state of health imaginable. These valuations are determined by a sample from the general populations. The valuations are not really PROs, because only the patient provides the answers to the 5 questions; the patient does not do the valuation. The 5 questions can be used as 5 separate PROMs. Since this is just 1 question with only 5 answer options, these PROMs are not very reliable and are not responsive to changes. We therefore recommend that the EQ-5D be used, not as a PROM but only as a valuation tool in economic evaluations.

Relevant websites:

- <https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/>



EORTC QLQ-C30

The European Organization for Research and Treatment for Cancer Quality of Life Questionnaire (EORTC QLQ-C30) is a disease-specific measuring instrument developed for use in patients with, or who have been cured of, cancer. The questionnaire consists of 9 subscales that can also be used as separate PROMs. The subscales are divided into 5 functional categories {physical functioning (PF: items 1-5); role functioning (RF: items 6 and 7); emotional functioning (EF: items 20-25); social functioning (SF: items 26 and 27)}; three symptom scales {fatigue (items 10, 12, 18), nausea and vomiting (items 14 and 15) and pain (items 9 and 19)} and an overall quality of life category (QoL: 2 items 29 and 30). In addition, there are some individual questions regarding symptoms (items 8, 11, 13, 16, 17 and 28).

The generic C30 version can be extended to a tumour-specific measuring instrument, for example for lung cancer (EORTC QLQ-C30-LC13).

Relevant websites:

- https://meetinstrumentenzorg.blob.core.windows.net/test-documents/Instrument333/453_1_N.pdf
- <https://qol.eortc.org/questionnaire/eortc-qlq-c30/>

PEDSQL

The Paediatric Quality of Life Inventory (PedsQL) is a questionnaire designed to measure health-related quality of life in children and their parents or carers in four areas: physical, emotional, social and educational functioning. Initially, the PedsQL was developed with and for children with cancer and their parents or carers. Over the years, several disease-specific modules have been added. The target group is children from 2 to 18 years of age.

Both self-reporting and parental versions are available. Self-reporting for children: ages 5 to 7, ages 8 to 12 and ages 13 to 18. Versions for the parents of children: 2 to 4 years, 5 to 7 years, 8 to 12 years and 13 to 18 years.



The Linnean menu

The PedsQL is not freely available; permission from the developer is required for use. Use can be requested via a form: Pedsql.org/PedsQL-Core-UserAgreement.doc.

Relevant websites:

- <https://www.meetinstrumentenzorg.nl/HomeSearchPost?meetinstrument=4170>
- <https://www.pedsql.org/>
- <https://eprovide.mapi-trust.org/instrumentspediatric-quality-of-life-inventory>

TOPICS-MDS

The Older Persons and informal Caregivers Survey Minimum Dataset (TOPICS-MDS) consists of separate questions from validated questionnaires about the physical and mental health, quality of life and care use of the elderly and informal caregivers. The questions are partly composed of the SF-36 and EQ-5D. TOPICS-MDS is a project funded by ZonMw (Memorabel) that collects and centralises data to enable reuse of the research data.

Relevant websites:

- <https://www.meetinstrumentenzorg.nl/Home/SearchPost?meetinstrument=4166>
- <https://topics-mds.eu/>
- <https://topics-mds.eu/wp-content/uploads/2018/08/TOPICS-MDS-achtergrond-informatie-ronde-5.pdf>
- <https://topics-mds.eu/wp-content/uploads/2017/10/TOPICS-MDS2017-zorgvrager-baseline.pdf>
- <https://topics-mds.eu/wp-content/uploads/2014/09/TOPICS-Data-Brief-Introduction-June-2014-Dutch.pdf>

Annex 5. Menu development

In April 2018, the PROMs and PREMs working group started a discussion at the St. Antonius Hospital in Nieuwegein on the importance of PROMs and the desire to speed up the use of these outcome measures with the Linnean initiative. During the meeting, the use of PROMs and the influence of different goals on the choice of PROs and PROMs were discussed. Three objectives were formulated:

- Individual feedback from the completed questionnaires ensures that outcomes can be used in the consulting room. The results of the large patient group are distributed. This supports the collaboration between the patient and the healthcare provider in order to make a well-informed choice together.
- Providing feedback about the outcomes to healthcare professionals to learn and improve (improvement information)
- Using outcome information to identify quality of care for patients who want to select a healthcare provider (selection information).

There was much talk about whether international outcome sets (such as the one by the International Consortium of Outcome Measurement, ICHOM) should be leading. However, the ICHOM sets are perceived as far too detailed for use in the consulting room. The questionnaires are too long, so the response is low. It was therefore decided not to copy the ICHOM sets directly but to use them as inspiration, for example to answer the following questions: What are recurring outcomes?

Moreover, which outcome measurement instruments do we want to link to this?

In June, the working group discussed various conceptual models that could serve as a frame for selecting relevant PROs and PROMs, such as the International Classification of Functioning, Disability and Health (ICF) scheme of the World Health Organization, the Wilson & Cleary model, and the PROMIS conceptual model. These models are based on different levels of measurement, of symptoms, functional status, and perceived health to perceived quality of life. The discussions showed that a session was needed to determine the relevant PROs for each level. This was done during the next meeting at the Netherlands Patient Federation.



The experiences of participants in the Linnean initiative with the use of generic PROMs were also applied. It was also discussed whether the usage goals of the relevant PROs differ. The conclusion was that the same PROs are relevant for various uses.

In November 2018, it was determined that consensus is needed about what we mean by a PRO(M), domain, item, disease-specific and generic PROM. This led to the following table of definitions, see Table B5.1.

Domain, concept, construct	Health-related outcome, for example: pain
PRO	Outcomes of care that relate to the patient's health and that the patient reports without the intervention of a healthcare provider, for example: impact of pain, intensity of pain
PROM	Instrument (questionnaire) used to measure this PRO, for example: VAS, NRS, multi-item questionnaire
Item	A question within a questionnaire
Disease-specific PROM	A PROM specifically developed for one specific patient group. Disease-specific PROMs usually ask about symptoms or limitations as a result of a particular condition
Generic PROM	A PROM that is universally applicable to patients with different conditions. Generic PROMs ask about perceived symptoms or limitations in general

Table B5.1: Speaking the same language

Barriers to the use of PROMs in the consulting room were also discussed, Table B5.2. For example, how do we increase compliance where it is low? It was considered desirable to make questionnaires shorter and more comprehensible. Here, we must also take into account people with low health literacy. It was concluded that research is needed to develop PROMs for patients with reduced literacy. The inventory ultimately led to a research agenda, supplemented with feedback from the entire Linnean initiative and relevant organisations such as ISOQOL-NL and the PROM platform.

Length	ICT feedback EMR with registration system
Moment	Implementation – Support
Level	Not-invented-here syndrome
Skills: ICT	Culture - Change
Time and money	Motivation to implement
Lack of standards, storage and exchange	Language, reduced literacy, computer illiteracy, cognitive problems
Cost of instruments	Response
Privacy & laws and regulations	Feedback to the patient
Data usage and ownership 3rd parties	Outcome measurement instruments
Taboo	Data shareability
Relevance to healthcare professional and patient	Interpretation, display
Maintenance & development of PROMs	Measuring during the chain
Multimorbidity	Indicators

Table B5.2: inventory of barriers

A first draft menu was created and distributed to the working group members for feedback. The first draft menu was based on expertise and experiences of members of the working group and on an inventory of all PROs and PROMs from 24 available ICHOM sets. This showed an enormous overlap in PROs, but a large variety of terminology, definitions and recommended PROMs. In February 2019, the draft menu was discussed in the working group. The working group discussed the option of a more binding instrument. However, the group decided not to recommend disease-specific PROs or PROMs,



because no PRO is relevant to all patients and no PROM is proven as valid and reliable for all patients. It was therefore decided to offer only preferred instrument per PRO.

Initially, the menu includes only generic PROMs that cover multiple PROs such as PROMIS and SF-36. It was suggested to add generic PROMs that only cover one PRO, such as a generic PROM for anxiety or depression. However, after an initial attempt to make an inventory of these PROMs, it was decided not to do so because it was not possible to select the best PROMs per PRO with limited resources and to make an informed choice for the recommendation of such PROMs. The menu has therefore been limited to generic PROMs covering several PROs.

The draft menu was then submitted for feedback to all the members of the working group, the board of ISOQOL-NL and the PROM platform.

The final **the Linnean menu** was created based on the feedback received.

In December 2020 **the Linnean menu** was translated by The National Health Care Institute to English 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 the **PROM-guide**, the **literature review on the use of PROMs** and **PROM-cycle** in the **PROM toolbox**. Elise H. Quik checked and edited the translation, the figures and tables. Then in March 2021, the English version was send around to the original authors Marloes Zuidgeest, Caroline B. Terwee, Harald E. Vonkeman and the HTx project stakeholders/consortium. Any feedback will be integrated in the next version.



Annex 6. Generic PROMS versus disease-specific PROMs: when to use, when not to use?

Over the past 30 years, researchers and healthcare professionals have mainly used disease-specific PROMs, sometimes supplemented by generic PROMs, because disease-specific PROMs contain more relevant questions for patients with a specific condition and were better able to measure changes than generic PROMs.

However, the increase in the number of patients with multiple disorders led to a new interest in generic PROMs. Research shows that the relevant PROs for patients with different conditions are often the same. Patients want a better quality of life, want to be able to perform their daily activities, participate in their social roles and activities, and have no pain, fatigue, sleep problems, or anxious and depressed feelings. It also appears that patients with multiple disorders often cannot properly attribute their symptoms to one particular condition.

The interest in generic PROMs was also increased by the availability of modern generic PROMs that use Computer Adaptive Testing (CAT). With CAT, the computer selects one question at a time from a large set of questions (an item bank) based on the answers already given. For example, if a patient indicates that they are having trouble walking, no questions will be asked about running. This gives patients questions that are (more) relevant and allows a reliable score to be obtained with a few questions. Modern PROMs, such as the Patient-Reported Outcomes Measurement Information System (PROMIS) instruments, are often as responsive as disease-specific PROMs.

These changes have altered the arguments for the use of generic versus disease-specific PROMs. Table B6.1 summarises the arguments for generic and disease-specific PROMs, taking into account the changed patients and the availability of modern PROMs.



Table B6.1 Arguments for generic and disease-specific PROMs

Arguments for generic PROMs	Arguments for disease-specific PROMs
<p>Burden on healthcare professionals</p> <p>It is difficult for healthcare professionals to think about which PROM to use for each patient. PROMs differ in content, scoring methods, scales and interpretations, all of which must be kept apart and must be known.</p> <p>Burden for patients</p> <p>It is annoying for patients to have to fill in different, often long questionnaires when they visit different caregivers.</p>	
<p>Multimorbidity</p> <p>More and more patients have more than one condition. It is confusing and burdensome for these patients to have to fill in multiple PROMs.</p>	
<p>No diagnosis</p> <p>There are patients who do not (yet) have a diagnosis or where the diagnosis changes over time. In those cases, it is unclear which PROM should be filled in and switching from one PROM to another makes the scores incomparable over time.</p>	
<p>Overlap in relevant domains</p> <p>There is a lot of overlap in domains that are measured with disease-specific questionnaires, in particular in the field of daily functioning and quality of life, e.g. physical functioning, pain, depression, fatigue, participation. These domains appear to be important to all patients.</p>	<p>Relevant domains</p> <p>Disease-specific PROMs contain domains (subscales) that are most relevant to patients with a specific disease. Certain outcomes are truly disease-specific, especially at a symptom level. This requires disease-specific questions (and questionnaires).</p>

<p>Relevant questions</p> <p>Modern analyses (Item Response Theory: IRT) can be used to develop item banks consisting of a large set of questions that contain relevant questions for all patients. Items from item banks can be applied as short form or as a Computer Adaptive Test (CAT).</p>	<p>Relevant questions</p> <p>Disease-specific PROMs contain questions within certain domains (items in subscales) that are most relevant to patients with a specific disease.</p>
<p>Responsiveness</p> <p>Modern PROMs (applied as CAT) seem as responsive as disease-specific instruments because they select patient-relevant questions from an item bank and can therefore measure more accurately.</p>	<p>Responsiveness</p> <p>Traditional generic PROMs (e.g. SF-36, EQ-5D) are less responsive than disease-specific PROMs and are less suitable for measuring the effects of treatment.</p>
<p>Costs</p> <p>There are sometimes (licence) costs associated with questionnaires.</p>	<p>Costs</p> <p>There are costs associated with the CATs. Computers are also needed. Short forms are free, but they are less responsive than CATs.</p>
<p>Comparable scores</p> <p>Generic PROMs allow direct comparison of scores between patients (and patient groups).</p>	<p>Comparable scores</p> <p>Disease-specific PROMs can directly compare disease-specific scores between patients, patient groups and subgroups.</p>
<p>One measurement scale</p> <p>Modern analyses (IRT) allow the scoring of generic and disease-specific PROMs on the same measurement scale (common metric), making scores comparable.</p>	<p>One measurement scale</p> <p>Modern analyses (IRT) can be used to convert the scores of disease-specific PROMs into a generic measurement scale (common metric), making scores comparable.</p>

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