The making of the

PROM-overview & PROM-select app

enabling users to select Patient-Reported Outcome Measures

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The making of the PROM-overview & PROM-select app is part of the **PROM toolbox** and describes the development of the Excel database containing Patient-Reported Outcome Measures (PROMs) used in the EU and in general and in the field of Head and Neck Cancer, Diabetes Mellitus, Multiple Sclerosis, MyeloDysplastic Syndrome and (Long lasting) COVID. This **PROM-overview** is also made available in a user-friendly web-application enabling users to select PROMs: **The PROM-select app.**

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PROM toolbox: PROM toolbox (summary in English) | Zorginzicht
HTx project: www.htx-h2020.eu; **PROM toolbox:** HTx Project | Publications (htx-h2020.eu)

Content

Background

HTx:
Next Generation Health Technology Assessment to support patient centred, societally oriented, real-time decision-making on access to and reimbursement for health technologies throughout Europe

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 overall objective of HTx is to create a framework for next generation Health Technology Assessment (HTA) that supports patient-centred, societally oriented, real-time decision-making for integrated healthcare throughout Europe.
The chosen health technology for diagnosis or treatment should be appropriate for the patient as a person with his/ her individual values, needs and preferences. Therefore, in order to make healthcare provision more patient/centred, it is important to take these preferences and values into account when appraising health technologies and in clinical decision-making. 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). So, PROMs use patients as the source of information. 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 choose PROMs that are fit-for-purpose. The methodological, statistical and practical issues that PROM users need to take into account, are described comprehensively e.g. by Cella et al. (2012, [1]) and by the International Society for Quality of Life Research (ISOQOL, 2018, [2]). Widely used PROMs need to be assessed against these methodological, statistical and practical criteria in order to provide a user-friendly overview for HTA institutes and researchers of how these PROMs perform on aspects such as relevance to patients, measurement of errors, response percentages in various patient groups, case mix factors that need be taken into account, experiences with use for different purposes (clinical outcomes research, performance measurement, routine clinical practice) etc. For the compilation of the PROMs overview, co-operation with the Patient-Reported Indicators Survey (PaRIS) initiative of the OECD will be sought. One of the aims of the PaRIS initiative is to support countries to adopt validated, standardised, internationally-comparable patient-reported indicators. Currently the focus is on hip and knee replacements, breast cancer care, and mental health care. According to the OECD, selected PROMs should be relevant to patients, and acceptable to both physicians and patients. PROMs selection should be “based on strict criteria, which includes taking patients’ priorities into account using focus groups. Instruments should meet methodological requirements of cognitive testing and psychometric properties of validity, reliability and international comparability.” The PROMs overview that will be prepared in HTx can contribute to this line of work within the OECD. Patient-centricity in clinical decision-making implies that clinicians should discuss health technology options and their possible outcomes, and actively engage patients in decisions about their care. Such shared decision-making (SDM) requires that clinicians provide understandable information and involve patients in making a treatment decision on which both parties agree.

Patient-reported outcomes (PRO)

Patient-reported outcomes (PROs) also called instruments are measurable outcomes from the patient’s perspective, including symptoms, quality of life, wellbeing and functional status. PROs deal with aspects of health that cannot be observed ‘objectively’ and can therefore only be measured by asking the patient,

such as perceived health, mobility, pain, depression, anxiety, daily activities, perceived quality of life, fatigue, cognition, social roles, sport performance, housekeeping, work performance, problem-solving, physical function, sexual function, sleep problems and social activities. Such aspects of health are often grouped together under the heading of quality of life. They rely on the idea that patients are the best judge of their own health state and wellbeing and can be defined as follows:

> *A PRO is directly reported by the patient without interpretation of the patient's response by a clinician or anyone else and pertains to the patient's health, quality of life, or functional status associated with health care or treatment.*[3]

Patient are asked to give their own opinion about their health, wellbeing and quality of life by filling in standardised, validated questionnaires. If patients are unable to complete a questionnaire themselves (such as children or people with severe cognitive impairments or limitations), their relatives, then called a proxy, can do so on their behalf. For more information please see the **PROM-guide**.

What are Patient Reported Outcome Measures (PROMs)?

Patient Reported Outcome Measures (PROMs) are tools, most often a questionnaire or scale, for measuring the patient's perspective on the outcomes of their own treatment and care.
PROMs are intended to collect additional information about aspects of health and outcomes of care, in addition to clinical data, such as observations, clinical assessments or objective tests and deal with aspects of perceived health that are important for patients. 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.
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 patient together with the health care provider can use the outcomes to jointly set goals, make joint decisions about treatment, monitor progress and evaluate whether the treatment goal has been achieved.

PROMs have long been included in clinical trials to assess the health outcomes of interventions such as surgeries, but are increasingly used to monitor outcomes of individual care. In addition, another application of PROMs is on the rise, namely the measuring of quality of care and making it transparent. Patients can use the outcomes to choose a particular health care provider and health insurers can use the outcomes for their purchasing policy. Health care providers can compare the results of the PROMs to those of their colleagues, laying the basis for quality improvement.
In addition, another application of PROMs is measuring of quality of care and making it transparent. Health care providers use the results of the PROMs to compare their outcomes to those of their colleagues 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 of the **PROM-guide** and the **PROM-cycle** elaborate on the different goals for the use of PROMs.

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

Multi-attribute utility measures are short health questionnaires designed to generate a single index value for the health state being measured, which may be used to derive Quality-Adjusted Life Years (QALYs). Well-known examples of a utility measures are the EuroQol 5 Dimensions (EQ-5D), Health Utility Index 3 (HUI3), the Short Form-6 Dimensions (SF-6D) 15D, and Quality of Well-Being (QWB) questionnaires. They are often used in health technology assessment (HTA). For the EuroQol 5 Dimensions (EQ-5D), see **the Linnean menu**.

Generic means applicable for most patients, with or without (one or more) disorders and measure single aspects of health (e.g. pain) or cover multiple dimensions of health status. These multi-dimensional

questionnaires generally focus on and assess outcomes in relation to overall health such as include items on physical functioning, role functioning, psychological symptoms and pain and are general quality of life questionnaires. Often used generic PROM are the Short Form Health Survey (SF-36[4] and SF-12), see **the Linnean menu**.

A generic PROM and utility measures may be used for comparison of outcomes across conditions, for example cost-effectiveness analysis to estimate relative benefits and of different treatments/health technologies. 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. 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.

Specific means applicable for patients with a certain condition or problem and their advantage is sensitivity and specificity. Specific PROMs can only be completed by those with the disease, condition, population or dimension concerned.

Disease-specific PROMs focus on and assess outcomes that are specific to a certain disease or clinical condition, such as symptoms assessment scales (pain rating scale), functioning measures (Oxford hip and knee osteoarthritis index for osteoarthritis) and health-related quality of life measures (EORTC-QLQ-C30 for cancer, see **the Linnean menu**). They provide far more detailed information about a patient's experience of symptoms than generic instruments and can be complementary to a generic PROM.
Generic and disease-specific PROMs used together may provide complementary information and can be used to measure improvements over time.

Condition-specific PROMs have questions that directly relate to specific health conditions and their associated treatments and do not focus on a particular disease. For example, some PROMs enable patients to report the severity of the symptoms or apply to mental health problems.

Population-specific PROMs apply to specific service sectors or part of the population. For example, some PROMs have been designed to be used with children or with a population segment such as the elderly. For instance, for children, the Patient-Reported Outcomes Measurement Information System (PROMIS®[5]) and subscales of the PedsQL and for the elderly, subscales and items from the Topics-MDS and the PROMIS (-PFGR) may be used, see **the Linnean menu**.

An example of domain/dimension-specific PROM is the Hospital Anxiety and Depression Scale (HADS) or Patient Health Questionnaire (PHQ)-9 for measuring depression and the Fatigue Severity Scale for measuring fatigue.

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 are less suitable for monitoring, quality improvement, but are great for discussions with health care providers. Examples of an individualised PROM is the Patient Generated Index.

In addition, the Patient Reported Outcomes Measurement Information System (PROMIS®[5, 6]) has been developed as a generic and dynamic system that is a computer system that uses adaptive testing. Its Global Health-10 scale has been developed using modern psychometric methods (e.g. item response theory) next to classical test theory, making them suitable for computerised adaptive testing (CAT)[5] increasing feasibility. 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 conceptual framework for PROMIS is based on the World Health Organisation's physical, mental and social framework. Five initial sub-domains: physical functioning, fatigue, pain, emotional distress, and social role participation are measured.[6] The aim of PROMIS is to make intelligent, computer-guided PROMs available for use in all patient groups. Patients may interact dynamically with the PROMIS item banks via a computerised adaptive testing system that creates tests that are tailored to their own health status but still psychometrically valid and reliable. Static versions (e.g. paper and pencil) are also available. For more information visit Home (healthmeasures.net).

International health outcome standard measurement sets

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 standard sets.

PROMs are being used to optimize value-based healthcare. The International Consortium for Health Outcomes Measurement (ICHOM) is an international consortium for outcome measurements in medical care and develops PROMs standard measurement datasets for measuring outcomes in specific disorders. Also supporting their implementation for international comparison together with patient representatives, physicians and registry leaders. They developed more than 20 health outcome standard measurement sets for diseases, populations[7], conditions (e.g. chronic disease management, dementia, incontinence conditions, mental health, assessment and monitoring of the elderly and asthma) and for particular situations (e.g. assessment and monitoring in primary and community care). These collections of PROMs may contain for instance both generic and disease or condition-specific measures. Each Standard Set contains and measures health outcomes that matter the most to patients. ICHOM assembles international expert groups to assess relevant PROMs for each disease/condition for value based health care and health outcomes evaluation. They actively promote value-based health care as well as international outcomes benchmarking using standard measurement sets to assess health outcomes data. Numerous international health sector agencies are currently collaborating with the ICHOM initiatives. This has increased the interest in the use of PROMs in health outcomes evaluation internationally and is particularly evident in countries such as the US, UK, Sweden and the Netherlands.

Patient-Reported Outcomes Measurement Information System (PROMIS®)

The Patient-Reported Outcomes Measurement Information System (PROMIS) also focuses on PROMs for a number of chronic conditions.

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 for longer term and wider or EU application. 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 in The Netherlands.
Important international developments and PROM initiatives in which the EU is involved are those of Organisation for Economic Cooperation and Development (OECD), International Consortium for Health Outcomes Management (ICHOM) and PROMIS.
The HTx project is involved in the work of the OECD. In 2017, the 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 general objective of the PaRIS initiative is to develop, pilot and implement new patient-reported indicators of health system performance, specifically patient-reported outcome measures (PROMs). PaRIS is developing instruments, definitions and data collection strategies to enable international benchmarks for patient-reported indicators of health system performance. 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. In this programme, the OECD cooperates with ICHOM to collect, analyse and publish outcomes reported by patients for international comparisons. The working group for hip and knee replacements has created a first international database that includes pre- and post-scores on quality of life, using the EQ-5D and condition-specific instruments such as the Hip dysfunction and Osteoarthritis Outcome Score (HOOS), Oxford hip scores (for hips) and Knee dysfunction, Osteoarthritis Outcome Score (KOOS) and Oxford knee scores (for knees). The OECD has collected PROM data with a range of stakeholders and experts, including patients and clinicians, of initiatives in e.g. national in England, Netherlands, Sweden and regional in Switzerland (Geneva), Finland (Coxa hospital) and in Italy (Galeazzi Institute) Charité Universitätsmedizin Berlin, Germany, Erasmus Medical Center, Rotterdam, Netherlands, Capio St Göran Breast Unit, Södersjukhuset Bröstcentrum and Karolinska Univ.sjukhuset Bröst Endokrin och Sarkom, Stockholm, Sweden, Universitätspital Basel, Basel, Switzerland, Manchester University Hospitals NHS Foundation Trust, Manchester, UK.

The Boston Consulting Group, was the first to introduce competitive strategy to the business world and one of the founding organizations of International Consortium for Health Outcomes Management (ICHOM). ICHOM is developing a new paradigm focused on health outcomes that matter most to patients. Their approach is built on a solid framework developed in the US at Harvard Business School by Professors Michael E. Porter and Elizabeth O. Teisberg in 2006, (book: Redefining Health Care) which outlines the argument for using health outcomes data to redefine the nature of competition in health care. Their new definition of success transforms health care by quality of care improvement, reducing costs and publishing health outcomes data, patients can choose the physicians and treatments that best suit them. The mission is to unlock the potential of value-based healthcare by defining global ICHOM Standard Sets of outcome measures that matter most to patients and driving adoption and reporting of these measures worldwide to create better value for all.[8]
ICHOM Standard Set are developed by international (so including the EU) Working Groups of leading clinicians, outcomes researchers, registries leaders, and patient advocates and include the components patient-centered outcomes, case-mix variables, data sources, time points and validated instruments that are used to measure the outcomes and case-mix variables including PROMs. PROMs are thoroughly researched and then selected based on the criteria coverage of outcome domains of importance, psychometric quality[9], feasibility/burden of assessment, financial/licensing requirements, established in the field/locations in use/translations.

The International Society for Quality of Life Research (ISOQOL) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) provide training, conferences and guidelines on PROMs use and mechanisms for data collection. ISOQOL has developed a User's Guide for Implementing Patient-Reported Outcomes Assessment in Clinical Practice, which is available under GUIDES in their Resource Center | ISOQOL.

The European Observatory of the World Health Organisation (WHO) reports health indicators for Europe.[10] Most PROM data is collected in the Netherlands and the UK. In addition, the WHO was involved in the development of a leading generic PROM used internationally mainly in population health research: the 26 item short version WHOQOL-BREF.[11] The original WHOQOL-100 quality of life assessment was developed by the WHOQOL Group with 15 international field centres, simultaneously, in order to develop a quality of life assessment applicable across cultures.

The ISPOR established a task Using real-world data for coverage and payment decisions. See Garrison LP Jr, Neumann PJ, Erickson P, Marshall D and Mullins CD (2007) Using real-world data for coverage and payment decisions: The ISPOR Real-World Data Task Force report. Value in Health. Vol. 10, No.5, pp.326-35.

Examples of PROM initiatives in the Europe in the field of the HTx case studies are:
Case Study 1 Head and Neck Cancer (HNC): European Head & Neck Society - Home (ehns.org)
Case Study 2 Diabetes Mellitus (DM): https://connect.ichom.org/standard-sets/diabetes/
Case Study 3 Multiple Sclerosis (MS): The Patient Reported Outcomes Initiative for Multiple Sclerosis: https://www.charcotms.org/initiatives/proms
Case Study 4 MyeloDysplastic Syndrome (MDS): Patient Reported Outcomes 5 | MDS Foundation (mds-foundation.org)
And **COVID**: COVID-19 – ICHOM Connect

The Netherlands

There are 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 hospital 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 may be combined.

In Europe, the Netherlands appears to be the most prominent in the inclusion of PROMs in national registry collections as well as in clinical practice/hospitals. The Netherlands is driving international collaboration around outcome measurement through organisations such as the OECD, ICHOM and World Economic Forum. The Minister of Public Health has started a project to use the work of ICHOM in the Netherlands. (ICHOM in the Netherlands).
Since 2009, the Dutch Institute for Clinical Auditing (DICA) is building national outcomes registries in the Netherlands[12] Nineteen Clinical clinician-led and payer-funded (including Ministry of Health and industry groups registries were developed collecting PRO data. The Dutch Institute for Clinical Reporting (DICA) is funded by the Dutch Association of Insurance Companies and facilitates payers, providers and clinicians in the development of and collaboration on the collection, analysis and benchmarking of outcomes data. DICA uses value-based payments adopted ICHOM outcome standard sets (e.g. low back pain and prostate cancer) into most of its clinical registries[12]. Providers risk losing reimbursement for the data collection if they fail to measure these outcomes. Some examples of registries including PROM data are the National Quality Registry for Parkinson's disease[13].

For PROM use in The Netherlands also see the Guideline for conducting economic evaluations in healthcare | Publication | Dutch Health Care Institute (ZiN) they briefly mentioned in the ICECAP for care. Furthermore, see in particular the Annex in which is stated: 'The standard analysis: the EQ-5D-5L It has already been described above that preference is given to a validated generic quality of life questionnaire that links valuations to health conditions through time trade-off or standard gamble. These ratings should be given by a representative stitch test of the general population of the Netherlands. There

are currently two questionnaires in the Netherlands that meet these requirements: EQ-5D-3L and the EQ-5D-5L. The latter is a further developed version of the earlier EQ-5D-3L, and has 5 answer levels per question instead of 3 as in the 'old' EQ-5D-3L. This further development has taken place to improve the sensitivity of the instrument. In addition, the valuation has improved through time trade-off. The questionnaire is being developed by an international, non-commercial group of researchers, with a strong Dutch share. EQ-5D-3L is the most widely used questionnaire in economic evaluations worldwide and is methodologically the most researched questionnaire. The use of the questionnaire is free for non-commercial health economic research after registration on www.euroqol.org. Of other internationally used generic QALY questionnaires such as the SF-6D, HUI 3, 15D, QWB and the AQoL-8D, there are currently no published ratings from the Dutch public. All this makes the guideline mention the EQ-5D-5L as a standard analysis for measuring health-related quality of life.'

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 including PROMs from national quality registrations. Dutch Health Care Institute (ZiN) and the Dutch Ministry of Health, Welfare and Sport (VWS) work together on this with patient organisations, providers of decision aids, providers of medical education, specialist medical care umbrella organisations (hospitals, doctors, nurses), the Linnean initiative, health insurers, Dutch organisation for health research and development (ZonMw), International consortia (such as ICHOM or PROMIS), hospitals and clinics, hospital alliances (e.g. Santeon, Samen Beslissen), Dutch Healthcare Authority (NZa), Health Insurers Netherlands (ZN), quality registry administrators, current initiatives (incl. MedMij, Registratie aan de Bron, VIPP, Zorgladder) and healthcare providers are all working together on the four developments:
1. More insight into outcomes
2. More shared decision-making
3. Organisation and funding of care is focused more on outcomes
4. Better access to relevant and up-to-date outcomes information.

Dutch Health Care Institute (ZiN) started the Program Value based healthcare 'Programma Uitkomstgerichte zorg' :

- Dutch Health Care Institute (ZiN): Value based healthcare 'Uitkomstgerichte zorg' Home | uitkomstgerichtezorg
- *https://platformuitkomstgerichtezorg.nl/home/default.aspx*
- Dutch Health Care Institute (ZiN): Shared decision making 'Samen beslissen' file (patientenfederatie.nl)

KLIK Quality of Life in Clinical Practice

KLIK is a method to give a clear overview of how patients (children and their parents/caretakers and (young) adults) are doing who are being or have been treated in a hospital. On the KLIK website you can fill out questionnaires about your daily life. The answers are converted into a clear KLIK PROfile. One of the practitioners will discuss the KLIK PROfile with you.

All available groups within KLIK are: (Auto)immune diseases, Adult medical psychology, Asthma, Brain tumour (after)care, CF, Change, CHIL, Chronic kidney diseases, Cleft lip, CMN, Coagulation diseases, Congenital hand and arm disorders, Cranio, Dermatology, Diabetes, Dialysis/Pheresis, Ear & Hearing, EB, Eating disorders, Endocrinology, Epilepsy, FARAO, Follow Me Intensive Care Children, FUDOR, Galactosemia, Gastroenterology, Genderdysforie, General paediatric, heart abnormalities, Heavy menstrual bleeding, Hereditary anaemia, HIPPO, Home parenteral nutrition, IBD (Crohn's and Colitis), IMID, Immunology, Kidney transplantation, Child dentistry, LEARNS, LEEF, Lysosomal storage disease, Marfan, Meningitis, Muscle centre, N=You, Neonatology, neurologic learning disorders, Noonan, Oncology, Ophthalmology, PANDA, Paediatric surgery, Phenylketonuria, PIE=M, POCOS, Psych0social department, Rheumatology, Spherocytosis, Sickle-cell, Skeletal dysplasia, Social paediatrics BKZ, Spina bifida, Therapy resistant constipation, ToP program, Vascular malformations, Virus and Your Coach Next Door. See KLIK (hetklikt.nu).

For individual patient care examples of effects in the consulting room or for self-management are:

- 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.

And for 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.

And for 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.

The Netherlands Institute for Health Services Research (NIVEL) concerns applied and applicable multidisciplinary health services research in order to advising health policy. NIVEL collaborated on the **PROM-guide** and the **PROM-cycle** and is conducting a number of research projects related to PROMs.

The Linnean initiative aim is to accelerate the use of outcome measures in healthcare and to join forces to this end. Several workgroups have developed components, including the application of PROMs and **the Linnean menu**.

The EMGO Institute of Health and Care Research now called EMGO+ the Institute for Research in Extramural Medicine VUmc was involved with the development of Consensus-based Standards for the selection of Health Measurement Instruments (COSMIN).[14]

United Kingdom

Academic groups in the UK are using PROMs in quality improvement applications and clinical effectiveness research and provide research support to the NHS PROMs initiative. This may include providing advice about the selection of PROMs.
The NHS England PROMs initiative makes use of both generic and disease-specific measures. The EQ-5D has been used as a measure of health gain by the NHS in the UK[15] and UK values for the EQ-5D-5L have been developed by the Office of Health Economics.[16,17,18] Raising the number of levels in the EQ-5D from 3 to 5, the differences between EQ-5D-5L states proved to be more subtle[19]. NHS providers in England also collect outcomes data using PROMs in four areas of elective surgery: hip and knee replacement, groin hernia repair, and varicose vein surgery.[20] Patients are administered a disease-specific

PROM (Oxford Hip Score, Oxford Knee Score, or Aberdeen Varicose Vein Score) and a generic PROM (EQ-5D index and EQ-Visual Analogue Scale) before and after their procedure.

HTx partner Jamie Elvidge from NICE:

NICE has a very strong preference for EQ-5D. If EQ-5D data are not available, the next preference is to use an algorithm to map an alternative PROM onto the EQ-5D. Other PROMs are usually only considered when it is demonstrated that the EQ-5D is not suitable (e.g. missing crucial dimensions of health, or in children). In these circumstances we have seen alternative PROMs like SF-36 and HUI-3.

Ireland

Academic groups in Ireland are using PROMs in quality improvement applications and clinical effectiveness research and provide research support to the NHS PROMs initiative. This may include providing advice about the selection of PROMs.

Sweden

In Sweden the use of PROMs is linked with national disease-specific quality registries and include a generic measure such as the EQ-5D and/or the SF-36 or disease-specific PROM in their collection. The EQ-5D has been used as a measure of health gain by Swedish registries[21] and has been preferred since 2013, as it is less prone to ceiling effects and there are Time Trade Off values for the health states derived from the EQ-5D-5L.[22] Sweden provides comprehensive quality registries. There are more than 100 registries, benchmarking treatment costs and outcomes for a broad range of diseases and conditions, including dementia and mental health conditions (see Swedish Quality Registry website, Appendix 2d). In 2012-13, some included a generic or disease-specific PROM in their collection.[23] Uptake of PROMs such as a generic measure such as the EQ-5D or the SF-36 has been rapid in the intervening years, because Swedish registries are certified according to the quality and comprehensiveness and registries certified at Level 2 (of 3 levels with 1 being the highest rating) must incorporate PROMs.[21]

The Swedish Rheumatology Quality Registry developed a clinical decision support tool (a dashboard) to allow the patient and provider to work together to optimise health according to what matters to the patient. Data is exported to the national registry, facilitating collaboration and leveraging data use for improving patient population health.

The program for hip and knee replacement in Stockholm (Ortho Choice, 2009) resulted in reductions in complication rates, length of stay and costs, while functional outcomes remained constant.[24]
SVEUS is a research collaboration between key stakeholders to develop models for value-based health care (VBHC) by seven Swedish regions with support from the Ministry of Social Affairs, including involvement of more than 50 organizations. Their value-based monitoring of healthcare and reimbursement systems may include PROMs for measuring e.g. mental health and physical function. Several value-based bundled payment schemes are in use in Sweden. Initiatives being tested in Sweden are: diabetes, obstetrics, obesity - bariatric surgery, osteoarthritis, spine surgery, stroke, osteoporosis and breast cancer.[25] More information in Swedish only can be found via www.sveus.se.

The Swedish Association of Local Authorities and Regions/Swedish National Board of Health and Welfare wrote the report: 'Quality and Efficiency in Swedish Health Care Regional Comparisons'[26]. The report is largely based on indicators of survival, processes of care, and health outcome-related

indicators. An example of the inclusion of PROMs in national quality and efficiency reporting is the health problem stroke where PROs concerning functional skills e.g. activities of daily living, rehabilitation and patient satisfaction were collected.

In a pilot study of antibiotic use for cystic fibrosis using patient-reported data including PROMs collected through a mobile telephone application to investigate the conditions for patients to have access to information about dispensation of their antibiotics at pharmacies, which can also be shared among care providers and reported to registers. The patients can share this information with their various health care providers and/or a register and may be used to evaluate the patient's state of health when the patient meets with his/her care provider and for follow-up of a patient group for e.g. care utilisation and treatment effects. Thereby increasing data quality and confidence in PROMs.

https://www.tlv.se/download/18.56badf381759794f6036e4fc/1605190417351/follow_up_of_cancer_pharmaceuticals_and%20other_pharmaceuticals_via_alternative_data_sources.pdf

The interim report is available in Swedish here:

https://www.tlv.se/download/18.1fc7385174b9d2fac779938/1601535284499/pilotstudie3_battre_uppfoljning_av_antibiotikaanvaandning_vid_cystisk_fibros.pdf

Finland

Like many EU states the health system of Finland faces the challenges of escalating costs, eroding access, an ageing population and expanding inequalities[27]. Finland realizes that in healthcare increased focus on value is required, which implies the routine collection and monitoring of health outcomes including PROMs[27, 28].

Denmark

A European Observatory WHO reports that there is no systematic use of PROMs in the Danish health system although they are used in some clinical databases and scientific studies[29]. WestChronic is a Danish generic integrated PROM system largely used to support clinical decision making. The Danish registry collection is using the ICHOM low back pain standard outcome measurement set[30].

Belgium

At the policy level, sciensano's Health Survey (formerly WIV) already uses PROMs. In this way, the government gets a picture of how citizens assess their health and their experiences with Belgian healthcare, and can adjust its policy accordingly. PROMs could also play an important role in certain reimbursement decisions of the INAMI/RIZIV, e.g. to decide whether a promising new medicine is eligible for reimbursement at an early stage. Until now, however, relatively few questionnaires have been administered to the patients involved, except for clinical trials.
As part of the reform of hospital funding, a 'pay-for-performance' financing for a number of voluntarily participating hospitals was launched from 1 July 2018. This means that in order to receive (part of their) funding, hospitals must achieve certain quality results (e.g. antibiotic use).
There are no uniform PROMs used, because language version of the PROM may differ per citizen, which makes it complicated.
For information about the European Organisation for Research and Treatment of Cancer (EORTC) based in Brussels, please visit https://www.eortc.org/.

Hungary

Method:

- rapid literature review on Google/Google Scholar on articles written in Hungarian, with a combination of the following search terms: ([name of the disease in latin] OR [name of the disease in Hungarian] AND (quality of life OR questionnaire)
- asking clinicians within the broader network of our colleagues who 1) have been working with PROMs in the past 2) are working in different hospitals throughout the country with either of the four indications from the HTx case studies

Results:

- All the listed PROMs are available in Hungarian and have been used either in clinical studies and/or clinical practice.
- No data available on Hungarian patients' preferences regarding these PROMs.

Table 1 PROM overview: PROMs used in Hungary

Multiple sclerosis	**In studies:** MSQOL-54, SF-36, Support Dimension Scale – SDS, Shortened Stockholm Marital Stress Scale, Exoanded Disability Status Scale, Fatigue Severity Scale, Hamilton Depression Rating Scale, Voice Handicap Index (source: lit)
	In clinical practice: Expanded Disability Status Scale, Multiple Sclerosis Functional Composite (MSFC) (source: lit), MS Neuropsychological Screening Questionnaire (MSNQ), Modified Fatigue Impact Scale (MFIS) (source: clinicians from 5 of the 30 MS centers in Hungary answered)
Head and neck cancer	**In studies:** EORTC H&N 35 (Source: literature) Those quality of life PROMs are used which were developed by the sponsor (Source: clinicians)
	In clinical practice: No PROMs used in clinical practice (Source: clinicians)
Type 2 diabetes	**In studies:** EQ-5D, Illness Intrusiveness Rating Scale, SWLS-H, HADS, DTSQs, ADDQOL-19 (Source: literature) EQ-5D, Nottingham Health Profile DTSQs and DTSQc (Diabetes Treatment Satisfaction Questionnaire, status/ change versions) (Source: PROMs expert colleagues)
	In the HTx case study: Swedish National Diabetes Register (NDR)'s diabetes-specific questionnaire (source: University of Pécs)
	In clinical practice: no data
Myelodysplastic syndrome	**In studies:** no data
	In clinical practice: No PROMs used in clinical practice (Source: clinicians)
Generic tools	**In studies:** HRQoL: EQ-5D, SF-36, Nottingham Health Profile Depression PRO questonnaire: Hospital Anxiety and Depression Scale Medication adherence questionnaire: MMAS-4, MMAS-8 Health Literacy: European Health Literacy Survey Smoking PRO: Heaviness of Smoking Index (Source: PROMs expert colleague)
	In clinical practice: no data

France

In France, the Mapi Research Trust is a non-profit organisation facilitating access to information about patient-centred outcomes, promoting the use of scientific approaches in this field and encouraging exchanges between academics, pharmaceutical companies and international organisations around the world (e.g. ISOQOL, ISPOR, IQOLA, Cochrane Collaboration and ERIQA). Mapi hosts databases including one specifically for PROM instruments; the Mapi Research Trust Patient Reported Outcomes Quality of Life Instrument Database (PROQOLID), concerns with translation and adaptation of instruments to enable cross-cultural research, webinars about particular PROM issues and provides a newsletter and. PROQOLID is a tool for obtaining summary information about PROMs and a subscriber domain with more extensive information to assist in the selection of PROMs for research and practice.

Bulgaria

The NCPR (National council on prices and reimbursement) is an institution which takes the decision for prices, reimbursement and performs HTA evaluation of new INNs or indications. Regarding the diseases of interest most often is used EQ5D, and if the companies provide information on any specific disease related QoL instrument it is considered by the NCPR.

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.

Why are PROMs used?

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-centred 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.

How do PROMs work?

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.

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).

Which PROM is the most appropriate?

Steps to select PROMs

First check out our **PROM-guide** for more basic information on PRO's and PROM's. We provide an overview of the eight steps (divided into four phases) that should be completed in the selection and implementation of PROMs in healthcare. These phases and steps described in detail in the **PROM-cycle** are:

Goal
1. *For which goal(s) do you want to use PROMs?* *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.

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.

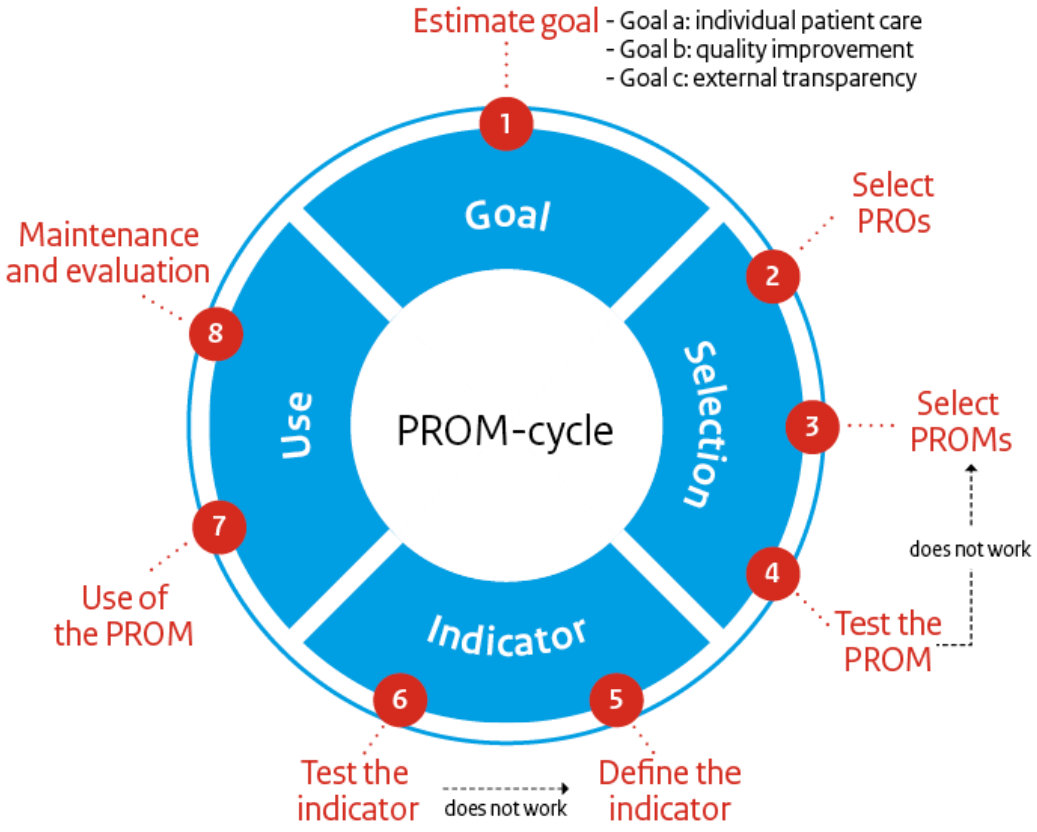


Figure 1. The PROM-cycle

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 (micro level):
- Screening, medical history and diagnostics;
- 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 (meso level):
- Feedback of results to healthcare 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 (meso/macro level):
- Public information about care outcomes and quality of care;

• Accountability information for supervision and policy;
• Healthcare purchasing information.

4. Science and policy research (macro level):
• 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;
• National and international benchmarking of performance and outcomes of healthcare providers and care systems.

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.

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

PROM selection

This phase of the **PROM-cycle** determines what exactly will be measured (PRO, step 2) and how it will be measured (PROM, step 3). Subsequently the best PROMs will be tested in practice (step 4). Steps 2 and 3 can be carried out in quite an extensive and systematic way, as they have been described in the **PROM-cycle**. In practice, however, this is not always necessary. In addition, there is not always enough resources or time available to do so. For example, when there is not much time and a certain PROM is rather well suited for the target group and meets the requirements, then a systematic literature search for relevant PROMs is perhaps not necessary.

When selecting PROs it will be decided which aspects of health or functioning, such as pain, anxiety, physical health, or quality of life, are important and will need to be measured through a PROM. The next step is to determine, together with all relevant stakeholders, which PROs are the most essential ones and which ones you will finally select. There should be consensus between the relevant stakeholders on the choice of PROs and PROs should fit the goal chosen.

According to a position statement released by the Mayo Clinic to educate community hospital stakeholders about the merits of collecting and reporting PROs, a good PROM is:

- simple (i.e. it can be read by a 12 year old)
- brief – not more than 12-15 minutes to complete
- developed with input from patients
- reliable, valid and responsive to change
- easily scored and interpreted [31].

Another relevant tool that may provide help is the National Quality Forum Methodological issues in the selection, administration and use of patient- reported outcomes in performance measurement in health care settings (pdf, 459 kB). It provides an overview of issues with PROs and PROMs to gain insight into the individual patient (goal a). Chapter 2 of this report describes the pros and cons of the various types of PROs.

A subsequent step after selecting the PROs can be to look for questionnaires (PROMs) that will measure these outcomes. We would like to avoid healthcare professionals and patients being burdened by administering the PROMs. For that reason, we advise you to use the user-friendly **PROM-select app**!

Levels of PROMs

PROMs are used for three levels: micro level for enhancing clinician-patient interactions using individual-level data, meso level for comparing the effects of different treatments and for understanding the factors that influence outcomes variation among healthcare providers and macro level for population surveillance and informing policy.

Three more reasons to use PROMs:

- *Patients are the best judges of and can be most accurate in describing the impact of their treatment on their own symptoms, pain, function and quality of life.*
- *PROMs can be used in clinical settings to valuable support shared decision making and patient-centred care.*
- *Systematically collected across providers (e.g. via clinical registries), PROMs generate valuable data on treatment effectiveness, adverse events and variations in healthcare delivery and outcomes to inform efforts to improve safety and quality.*

Target groups and users
Patients and health care providers are seen as the primary target groups and users of PROMs. Other parties that may 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.*

Economic evaluation

PROMs are important input into comparative effectiveness research. Next to clinical indicators they provide the 'value' of a given health intervention to patients. 'Value' in value based healthcare is defined as outcomes measured relative to costs. Lower costs are not always a sign of efficiency as long as they are linked with equal or even better health outcomes when the standard is compared to the new technology.

Quality Adjusted Life Years (QALYs)
Multi-attribute utility measures may be used is for the calculation of the Quality Adjusted Life Year (QALY), which is used in determining cost-effectiveness of health technologies such as treatment

pathways or interventions. The health state of a person or group is measured in a way that the benefits of treatment, in terms of length of life, are adjusted to reflect the quality of life and integrates side effects other than mortality. A QALY is equal to one year of life in perfect health and provide guidance for choosing between treatments for a condition and across conditions to inform overall health resource allocation decisions.
Interventions can have an effect on longevity and/or quality of life. In economic evaluations, both are important and can be used to justify the costs. The relevance of the effects on longevity and quality of life in relation to costs should be demonstrated by means of a 'cost-utility analysis' (CUA). The 'utilities' of the CUA are operationalized by 'quality of life adjusted life years', or 'Quality Adjusted Life Years': QALYs.

Correction factors of quality of life
In the context of measuring QALYs, should be determined by validated generic quality of life questionnaires completed by patients. The outcome measures of these questionnaires are health conditions defined in terms of health-related quality of life. The validated questionnaires link a quality of life correction to the health conditions. This correction factor is called a weighting, valuation or utility. These 'appreciations for quality of life' must consist of a weighting of the quality of life versus time of life. The evaluations for the health conditions of the patients must be based on the preferences of the general population, so that the analyses can be carried out from the social perspective.

When calculating QALYs a value is placed on different states of health by using a generic health-related quality of life index such as the EQ-5D.
In the Netherlands, guidelines are provided for performing economic evaluations in healthcare: https://www.zorginstituutnederland.nl/publicaties/publicatie/2016/02/29/richtlijn-voor-het-uitvoeren-van-economische-evaluaties-in-de-gezondheidszorg
It states that the standard analysis is done with the EQ-5D-5L, since preference is given to a validated generic quality of life questionnaire that links valuations to health conditions through time trade-off or standard gamble. These ratings should be given by a representatives of the general population of the Netherlands. There are currently two questionnaires in the Netherlands that meet these requirements: EQ-5D-3L and the EQ-5D-5L. The latter is a further developed version of the earlier EQ-5D-3L, and has 5 answer levels per question instead of 3 as in the 'old' EQ-5D-3L. This further development has taken place to improve the sensitivity of the instrument, because there were concerns about the sensitivity of the EQ-5D-3L measure both across conditions and in such a broad application as the evaluation of national health system performance. In addition, the valuation has improved through time trade-off. The questionnaire is being developed by an international, non-commercial group of researchers, with a strong Dutch share. EQ-5D-3L is the most widely used questionnaire in economic evaluations worldwide and is methodologically the most researched questionnaire. The use of the questionnaire is free for non-commercial health economic research after registration on www.euroqol.org. Of other internationally used generic QALY questionnaires such as the SF-6D, HUI 3, 15D, QWB and the AQoL-8D, there are currently no published ratings from the Dutch public. All this makes the guideline mention the EQ-5D-5L as a golden standard analysis for measuring health-related quality of life [32].

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’).
It is important to use valid, reliable and appropriate instruments when selecting PROMs. The dimensions should be considered when selecting instruments and measures for outcome evaluation. Reliability refers to consistency of measurement, e.g. internal consistency and test/retest reliability. Validity concerns the question: does the instrument measure what it claims to measure? There are different types of validity; content, construct, criterion, concurrent, convergent, discriminant etc.

Discriminant validity: is the instrument able to discriminate well between groups? Sensitivity concerns: can the instrument detect change in health status over time?

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, but also, for example, the response, user-friendliness or length of the questionnaires.
In addition, the usability of data and results.
The key feasibility factors:

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

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.

HTx: where does this work fit in our IHTAM model?

This work was undertaken as part of the HTx project. HTx has delivered a novel framework to support innovation in HTA methods: 'Guidance for the Innovation of Health Technology Assessment Methods – the IHTAM framework'; Jiu et al. (2020; full paper submitted 2021, not yet published). The IHTAM framework provides a systematic way for HTA stakeholders to innovate methods, by following 3 phases:

1. Identification: Learn from past experiences and existing methods, imagine a better approach, and identify the needs of stakeholders to reach it.
2. Development: Dedicate resources to designing new methods or processes to address the identified needs, and subject them to pilot testing.
3. Implementation: Establish a plan to implement the novel methods, apply them to real-world practice, evaluate their performance and transfer to other settings.

To date, IHTAM has not been tested in the context of a real-world case study.

This PROM-overview report presents the identification, development and implementation phase (IHTAM).

The first **identification** phase started by searching for past experiences and existing methods, imagine a better approach and identify needs of the stakeholders and users. We found existing methods:

- 'meetinstrumenten in de zorg'
- Mapi trust eprovide
- Sralab
- MSsociety
- ICHOM
- OECD
- ISPOR
- ISOQOL
- Etc.

Those are all very helpful, but we wanted a user-friendly web application enabling the user to select PROMS in general and for our 4 case studies: Head and Neck Cancer (HNC), Diabetes Mellitus (DM), Multiple Sclerosis (MS) and MyeloDysplastisch Syndrome (MDS). We also thought that an overview of PROMs in the field of (Long lasting -) COVID would be helpful, since there are no aids for that yet too and that it would be very relevant right now. No such web application exist in and for the EU to our knowledge and we concluded that indeed there is a need for novel methods and we will proceed to the second phase of IHTAM: "**development**".

After many conversations with (HTx) stakeholders, Dutch **PROM-guide/PROM-cycle** developers, clinicians, ICHOM/Vintura members, OECD (PaRIS) members, policy makers, (Eastern-)EU patient organisation members, patients, academics, researchers, health economists, decision makers, colleagues within ZiN and IT specialists we compiled a PROM variable wish list. In the next stage 2 **development**, we inventoried all relevant variables of PROMs from the conversations and tried to include them as much as possible within our time frame in our Excel datasheet: **PROM-overview**. Literature as well as the internet was searched for relevant PROMs in the fields of our case studies and COVID. We collected many variables per PROM and then piloted the **PROM-overview** Excel datasheet with relevant parties and even added more variables/columns that would be addressing the needs of possible users, which were collected, may be collected now if possible or in the future.

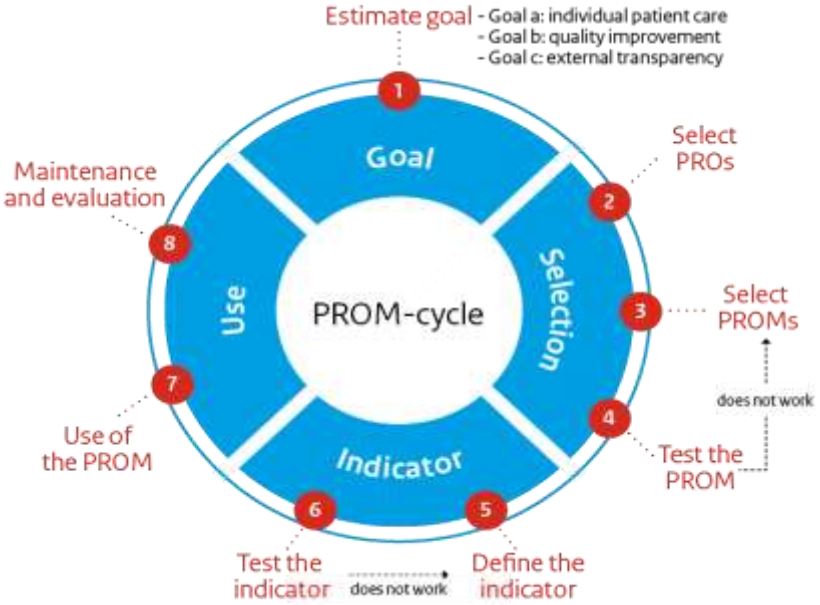
To **implement** our **PROM-overview** data, a web application was built to **implement** the novel methods, apply them to real-world practice, evaluate their performance and transfer to other settings. This user-friendly web application will enable users to select PROMs by choosing between different patient reported health outcomes in combination with health problem/disease/patient population. Then a list of PROMs will be optional to choose from and when clicking on a PROM in the list, properties available in the PROM-overview Excel sheet will be given in a user-friendly way. This web application will function as a user-friendly interface between user and **PROM-overview** Excel sheet(s), making the data even patient friendly next to clinician, researcher/other user-friendly.

The **PROM-overview** is an Excel database containing Patient-Reported Outcome Measures (PROMs) recently used in the EU in i.e. in the fields of our HTx case studies: Head and Neck Cancer, Diabetes Mellitus, Multiple Sclerosis, MyeloDysplastic Syndrome, (Long lasting) COVID and in general. The **PROM-overview** is made available via a user-friendly web-application helping users to select PROMs: **The PROM-select app.**

The PROM-overview & the PROM-select app

We are aware that sometimes there is not much time and/or resources to check if a certain PROM is rather well suited for the target group and meets the requirements. Then a systematic literature search for relevant PROMs may take too much time. In order to help you save time, we made an overview of PROMs, their relevant scientific literature and other sources were you may find relevant information about those PROMs. The **PROM-overview** is an Excel database containing Patient-Reported Outcome Measures (PROMs) recently used in the EU in i.e. in the fields of our HTx case studies: Head and Neck Cancer, Diabetes Mellitus, Multiple Sclerosis, MyeloDysplastic Syndrome, (Long lasting) COVID and in general. This **PROM-overview** is made available in this user-friendly web-application helping users to select PROMs: this **PROM-select app.**

So, first check out our **PROM-guide** for more basic information on PRO's and PROM's. Next, we provide an overview of the eight steps (divided into four phases) that should be completed in the selection and implementation of PROMs in healthcare. These phases and steps described in detail in the **PROM-cycle**:



Then, using this **PROM-select app** you may choose your selected PRO and relevant health problem or patient group/population. When selected a PRO and health problem you'll get a list of relevant PROMs. When clicking on a PROM, you will find an overview of relevant information about the PROM and links to more information.

You may select:

What Patient Reported Outcome do you want to measure?

1health-related quality of life, health, QoL
2 physical functioning/activity, mobility
3pain discomfort
4depression emotional distress/wellbeing anxiety, worry, fear
5work productivity ADL self-management self-efficacy, self-care, daily living
6fatigue energy vitality sleep dyspnoea
7social role participation/performance, social support/relationships, social health behavioural functioning
8 cognitive/psychological/brain function mental health
9 health literacy, attitudes, knowledge of disease
10 satisfaction, well-being
11 perception, vision hearing speech
12 sexual function
13 spiritual function
14 incontinence, bladder dysfunction gastrointestinal dysfunction, Nutrition/feeding, swallowing, dry mouth
15 recovery rehabilitation

What is your health problem and/or patient group?

0=generic
1=(Head and Neck) Cancer
2=Diabetes
3=MS
4=MDS
5=(long)COVID
6=mental health
7= surgery
8=chronic disease
9=lifelong disorder
10=other

If you are interested in more information about PROMs and how the **PROM-overview** and **PROM-select app** came to be, then you can read more about it in this report: **the making of the PROM-overview & PROM-select app.**

PROM toolbox

The **PROM toolbox** can be found at HTx Project | Publications (htx-h2020.eu) and PROM toolbox (summary in English) | Zorginzicht

The PROM toolbox holds the following tools:

- **The PROM-guide**
- **The literature review on the use of PROMs**
- **The PROM-cycle**
- **The Linnean menu**
- **The PROM-links**
- **The making of the PROM-overview & PROM-select app**
- **The PROM-overview**
- **The PROM-select app**
- **The PROM-select app usability test report**
- **The PROM toolbox presentation (HTx Expert Forum meeting 25-11-2021)**

The **PROM toolbox** consists of the **PROM-guide,** step 3 accompanied by **The literature review on the use of PROMs,** and **the PROM-cycle**[4]. of which step 2 and 3 are supplemented with generic PROMs in **the Linnean menu.** The **PROM-links** tool provides links to useful websites. In addition, the **PROM-overview** is an Excel database containing PROMs accompanied by relevant information made available via a user-friendly web-application helping users to select PROMs: **The PROM-select app**.

The **PROM-guide** deals with orientation and preparation for the use of PROMs. Step 3 is about how and when PROMs work and 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'.
The assessment framework **the PROM-cycle**[4] is about the selection and application of PROMs in healthcare. **The Linnean menu** is a supplement to **the PROM-cycle**[4] and aligns to steps 2 and 3, the process of selecting PROs and PROMs.
The **PROM-links** tool provides links to useful websites.

The making of the PROM-overview & PROM-select app describes the development of the Excel database containing Person-Reported Outcome Measures (PROMs) recently used in the EU in i.e. in the fields of our HTx case studies: Head and Neck Cancer, Diabetes Mellitus, Multiple Sclerosis, MyeloDysplastic Syndrome, (Long lasting) COVID and in general. The **PROM-overview** is made available via a user-friendly web-application helping users to select PROMs: **The PROM-select app: https://www.prom-select.eu.**

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. The literature review contains ways in which PROMs can contribute to better individual patient care, internal quality improvement and quality improvement through external quality information (accountability or transparency).

Research has shown that patients are not consistently involved in the process of developing PROMs. Moreover, many PROMs have already been developed and put into practice in HTA and value-based healthcare initiatives, such as the International Consortium for Health Outcome Measurement (ICHOM)[7]. Patient organisations and researchers therefore need better guidance on how to select outcome measures that are relevant to patients and fit-for-purpose.
We started by constructing a framework for assessing PROMs, derived from the guidance provided by Cella et al., 2012[5], the International Society for Quality of Life Research (ISOQOL)[2] and other relevant publications.
The PROM-cycle is part of the PROM toolbox and deals with the selection and application of PROMs in healthcare. In terms of sequencing, the PROM-cycle therefore comes after the PROM-guide, which is intended for the orientation and preparation for the use of PROMs The PROM-cycle was the initial framework and was discussed with relevant partners in ZiN, OECD/PaRIS, ICHOM, the Linnean initiative, Sandra Beurskens of "meetinstrumenten in de zorg", KEMTA of the MUMC, KLIK/VUmc and stakeholders within the HTx project. It was tested for a subset of generic PROMs and the report was added to the PROM toolbox: the Linnean menu. The Linnean menu is a supplement to the PROM toolbox, and aligns to steps 2 and 3 of the PROM-cycle (promtoolbox.zorginzicht.nl); the process of selecting PROs and PROMs.

In Europe, VBHC in health policy may provide new opportunities for SDM, especially by using PROMs in routine medical encounters (The use of PROMs and shared decision-making in medical encounters with patients: An opportunity to deliver value-based health care to patients (nih.gov)).
The PROM-cycle can also linked to the topic of shared-decision-making. The use of PROMs in shared decision-making (SDM) is an opportunity to deliver value-based health care (VBHC) to patients. The PROM-cycle aids in choosing PROMs to monitor changes in individual PROs over time and PROMs to make treatment decisions. The final use of PROMs might stimulate option, team, choice, and decision talks between the patient and clinician.
The PROM-guide as well as the PROM-cycle aids in educating health care staff in PROMs used in SDM by following the steps in the PROM-cycle within a team. Placing attention to choosing better outcomes for patients and selecting the best fitting PROMs may prevent overtreatment and avoid misdiagnosis. One thing that has to be kept in mind is that PROMs delivered electronically need a solid IT platform, which facilitates a user-friendly PROM ensuring feasibility. In addition, a nice dashboard may stimulate the patient to keep filling in the PROMs scores and may aid the patient in discussing the outcomes with the clinicians.

The reviewed PROM-cycle led to a final version of this assessment framework, which was then used to assess frequently used PROMs resulting in the PROM-overview Excel file and a web application enabling users to select and search PROMs.

PROM-Overview

The basis for the selection of PROMs was the scoping review on patient involvement in PROM development, conducted by Wiering et al., 2017[33]. This selection of 193 PROMs was complemented with PROMs in ICHOM-sets and PROMs that are relevant for the case studies in WP1 and in addition (long lasting) COVID.

ZIN started by constructing a framework for the assessment of PROMs, derived from the guidance provided by Cella et al, 2012[5] and other relevant publications (see **PROM-overview**). This initial framework was discussed with e.g. ZiN (OWIZ, value based healthcare), OECD/PaRIS, ICHOM, the Linnean initiative, Sandra Beurskens of "meetinstrumenten in de zorg", KEMTA of the MUMC, KLIK/VUmc, many others and relevant partners in the HTx project and tested for a subset of PROMs (the Linnean menu). This resulted in a final version of the assessment framework: the **PROM-cycle**.

COSMIN Database of systematic reviews of outcome measurement instruments, PubMed, Google, Google scholar, Bing were searched for reviews and publications describing the development of PROMs, and their methodological and statistical properties, recent articles and HTA related articles.

In addition, a literature search focussed on selecting examples of different forms of use of the selected PROMs was performed.

Because of the expected large amount of publications in which the selected PROMs are used, the searches were limited to recent years and preferably use of PROMs within the EU countries.

In the following phase, the relevant links to the selected publications was pasted in the **PROM-overview**. Articles were selected by using the assessment framework: the **PROM-cycle**. In addition, the assessment framework the **PROM-cycle** was used as the basis for the description of the characteristics of the selected PROMs.

This resulted in a final version of the assessment framework the **PROM-cycle**, the **PROM-overview** Excel file and a web-based PROMS interface enabling users to select PROMs. This web application **PROM-select app** will be maintained and updated annually by ZIN during this HTx project. Depending on the demand for this service, ZIN is willing to maintain and update the application also after the end of our HTx project.

Search strategy

The HTx project task 4.3.1 incorporated an environment scan and a literature review. A search of the academic literature, web-based searching for grey literature (i.e., reports, policy documents and other relevant material) from EU countries was performed. PubMed and the COSMIN Database of systematic reviews of outcome measurement instruments were searched for publications describing the development of the selected PROMs, their methodological and statistical properties, forms of use and usage within HTA. The link to the article of the original author mentioned by Wiering et al., 2017[33] was provided in the **PROM-overview** Excel file. In addition, links to original or preferably in EU validation articles for the PROMs used in the ICHOM standard sets were sought and added to the **PROM-overview** Excel file and a link that in PubMed gives you all articles this article is cited by. Furthermore, a link to an article discussing the properties was searched for and added to the **PROM-overview** Excel file preferably with affiliations in the EU. Moreover, an article concerning the forms of use or when not found a recent article preferably with affiliations in the EU was searched and added. After consulting potential users and HTx stakeholders a column was added to the **PROM-overview** Excel file filled in with a link to a mapping study on an utility measure or when not available with an link to an article concerning another HTA decision making topic preferably with affiliations in the EU.

To ensure that the **PROM-overview** Excel file stays up-to-date a search string searching the latest articles concerning the PROM in PubMed was added and a link that displays all articles that cited the original article.

If the PROM was found available online as for instance a ePROM or as web application, the link is added too.

The assessment framework was used as the basis for the description of the characteristics of the selected PROMs. In Excel one row is destined for one PROM. In the columns the characteristics of the selected PROMs were added as much as possible. The characteristics of the selected PROMs searched for using Google chrome with Google search and Microsoft Egde using Bing. In addition, the COSMIN Database of systematic reviews of outcome measurement instruments, https://database.cosmin.nl/, was used.

In addition, the literature search was focussed on selecting examples of different forms of use of the selected PROMs. Because of the expected large amount of publications in which the selected PROMs are used, this search was limited, e.g. to recent years and to use of PROMs within the EU countries.

Different sources from the academic and from the grey literature were included in this review, also see the **PROM-overview** column sources for this.
The search strategy covered both academic literature (i.e. published, peer-reviewed journal articles) and grey literature (i.e. reports, policy documents and relevant materials obtained from a variety of sources, including websites of for instance government departments, patient organisations, agencies and other organisations). Contact information on relevant websites was used to ask for more information, for instance, patient organisations of several EU countries, ICHOM and the OECD were emailed. Different strategies were used to search for the two types of literature.

In PubMed, references of searched articles were found and the cited by and similar articles functions were used; snowball searching (pursuing references of references and tracking citations forward in time) and searching by checking other articles by the original PROM developers/authors was performed. Title scans were conducted to identify relevant material and abstracts were checked. For instance, 'Patient-Reported Outcome Measures' was googled and in combination with the case study fields Head and Neck Cancer (HNC), Diabetes Mellitus (DM), Multiple Sclerosis (MS), MyeloDysplastisch Syndrome (MDS) and COVID.

The following databases and websites were searched:

- https://database.cosmin.nl/
- www.eprovide.mapi-trust.org
- https://www.sralab.org/
- https://www.nationalmssociety.org/
- https://www.mssociety.org.uk/
- https://www.msif.org/
- https://b-s-h.org.uk/guidelines/guidelines/guidelines-for-the-diagnosis-and-evaluation-of-prognosis-of-adult-myelodysplastic-syndromes/
- www.physio-pedia.com
- www.facit.org
- https://qportfolio.org/
- https://euroqol.org/
- https://www.eortc.org/
- www.apta.org
- https://www.apta.org/patient-care/evidence-based-practice-resources/

- www.neuropt.org
- https://connect.ichom.org/standard-sets/
- www.commonfund.nih.gov
- Oxford University PROM database http://phi.uhce.ox.ac.uk/perl/phig/phidb_search.pl
- CAMbase: http://cambase.dmz.uni-wh.de/CiXbase/camdb/index_en.html
- IN-CAM Outcomes database http://www.incamresearch.ca/node/153
- Examples of PROMs | Patient Reported Outcomes
- Dashboard Kwaliteit van leven en gezondheid | Tableau Public
- https://meetinstrumentenzorg.nl/
- and many other websites

Scope of the search

The search strategy focused on material relating to the relevant PROMs. Academic and grey literature searching covered the original article and newest (latest November 2021) literature. The following PROMs were considered for inclusion:

- used in the EU and/or translated for EU countries.
- Used in the field of Head and Neck Cancer (HNC), Diabetes Mellitus (DM), Multiple Sclerosis (MS), MyeloDysplastisch Syndrome (MDS), and COVID.

Next to that, the library department within ZIN searched for PROMs used in HTA; health policy and decision making, CEA's and REA's. The outcome of this search can be found in appendix 1 coming soon

Grey literature: search results

To capture non-academic literature related to the use of PROMs in policy and practice, a grey literature search was undertaken for European countries.

The main search term was 'Patient-Reported Outcome Measures' entered into Google. PROM, PRO, Patient Reported Outcome Measure, Quality of Life, instrument and questionnaire were search terms too, also in combination with Head and Neck Cancer (HNC), Diabetes Mellitus (DM), Multiple Sclerosis (MS) and MyeloDysplastisch Syndrome (MDS), COVID. Internet page entries were excluded if they were commercial companies; did not relate to a EU country with the exception of some USA websites. Journal articles relating to PROMs were included from the grey literature search. Supplementary searches were undertaken where necessary. For example, links available on one site could lead to information on an additional site. Health department websites for were also searched.

Selection of appropriate outcome measures

PROMs of Wiering et al.[33] were added to the **PROM-overview** Excel datasheet. Next PROMs used by ICHOM in the standard sets were added. Furthermore, PROMs in the field of our HTx case studies were searched and added. In addition, PROMs used in case of (long lasting) COVID were searched and added.

Information needed to fill in the columns was sought The columns were:

- Source PROMs
- PROM

- HTx Casestudy (0=generic; 1=(HN)C, 2=Diabetes, 3=MS, 4=MDS, 5=(long)COVID 6=mental health, 7= surgery, 8=chronic disease, 9=lifelong disorder, 10=other)
- Outcome(s)
- Dimensions/Domain(s)
- Outcome/domain 1health-related quality of life, health, QoL 2 physical functioning/activity, mobility, recovery 3pain discomfort 4depression emotional distress/wellbeing anxiety, worry 5work productivity ADL self-management self-efficacy, self-care, daily living 6fatigue energy vitality 7social role participation/performance, social support/relationships, social health behavioural functioning 8 cognitive/psychological/brain function mental health 9 health literacy, attitudes, knowledge of disease 10 satisfaction, well-being 11 perception, vision hearing 12 sexual function 13 spiritual function 14 incontinence
- Specific (1) or generic (2) or semi-generic (3) PROM (4) utility
- Health problem(s)
- Availability for free / Meetinstrumentenzorg
- Mapi-trust ePROVIDE
- Sralab.org/ apta.org/ physio-pedia
- link to questionnaire
- original/validation article
- original article cyted by in Pubmed
- Properties
- Forms of use/recent article
- mapping to Utility scores (EQ5D/HUI /CHU9D etc.) reference values/HTA
- Zoekstring pubmed: PROM, properties, validity, etc. (caroline Terwee) https://pubmed.ncbi.nlm.nih.gov/?term==REGEL&sort=pubdate
- ePROM/webapp
- items
- time (min)
- levels
- type/soort
- Method of administration (electronic/paper)
- Available languages
- Hungarian
- Polish
- Slovanisch/Czech
- Country (developed in)
- HTx Casestudy (0=generic; 6=other)
- Specific (1) or generic (2) or semi-generic (3) PROM (4) utility
- Health outcome measured as outcome of surgery (1), cancer (2), chronic disease (3), mental health(4), other (5), lifelong disorder (6)
- Author Wiering
- PubYear
- Patients
- Patient involvement in establishing which outcome to measure (No=0; Yes=1; Limited=2)
- Patient involvement, by use of focus groups, in item development
- Patient involvement, by use of interviews, in item development
- Patient involvement in item development using other methods
- Items (partly) derived from other PROMs or other non-patient sources
- Cognitive interviews Patient involvement in testing for comprehensibility

- Establishing the comprehensibility of the PROM by other means than cognitive interviews, but with the use of patients
- Establishing the comprehensibility of the PROM without patient input
- Patient involvement
- The number of development phases with patient involvement
- Goal PROM: gespreksinstrument, uitkomstmaat RCT's, utiliteit
- Crosswalk
- Used in HTA decision making/REA/CEA
- Costs
- definitie concept
- extra info

PROM-select app

A new column was added with PRO options to choose from in the web-application. The following categories were created based on the outcomes and dimensions of the PROMs:

- *health-related quality of life, health, QoL*
- *physical functioning/activity, mobility*
- *pain discomfort*
- *depression emotional distress/wellbeing anxiety, worry, fear*
- *work productivity ADL self-management self-efficacy, self-care, daily living*
- *fatigue energy vitality sleep dyspnoea*
- *social role participation/performance, social support/relationships, social health/functioning*
- *cognitive/psychological/brain function mental health*
- *health literacy, attitudes, knowledge of disease*
- *satisfaction, well-being*
- *perception, vision hearing speech*
- *sexual function*
- *spiritual function*
- *incontinence, bladder dysfunction gastrointestinal dysfunction, Nutrition/feeding, swallowing, dry mouth*
- *recovery rehabilitation*

When a category was used less than 10 times, the category was placed under the other most matching category.

Then, another column was formed to help the selection process of selecting health problems:

What is your health problem and/or patient group?

- *Generic*
- *(Head and Neck) Cancer*
- *Diabetes*
- *Multiple Sclerosis*
- *MyeloDysplastic Syndrome*
- *(long lasting) COVID*
- *mental health*
- *surgery*
- *chronic disease*
- *lifelong disorder*
- *other*

Then, using this **PROM-select app** you may choose your selected PRO and relevant health problem or patient group/population. When selected a PRO and health problem you'll get a list of relevant PROMs. When clicking on a PROM, you will find an overview of relevant information about the PROM and links to more information.

This and the info mentioned on the PROM toolbox homepage was used to develop **the PROM-select app** homepage:

https://www.prom-select.eu

Review and changes

When the web application was developed several changes were made in the PROM-overview and PROM-select homepage text.

All links that were pasted as hyperlinks in the cells in the Excel file had to be replaced by the link texts for them to work in the web application. For example PROM select app (prom-select.eu) had to be changed to https://www.prom-select.eu/.

After a first review of the created **the PROM-select app**, several changes were made.

Dissemination and implementation

The department communication of ZIN handled building a the website:
https://www.zorginzicht.nl/ondersteuning/prom-toolbox-summary-in-english

And uploading all PROM-toolbox documents to that website and the PROM toolbox document was used to create the PROM toolbox homepage. Special thanks for that goes to Léon van den Haak of the department communication.

Since that website was not fit for launching a user-friendly web application, another solution was sought in collaboration with Diana Delnoij, the head of my department Dirk Deelstra, our information management and IT department. Finally our IT department: Business applications & IT Services and supplier wooltown helped us developing the PROM select web application with special thanks to Jeroen Tetteroo for arranging and managing everything and Abel Schooleman for supplying the web application.

To increase the visibility of **the PROM-select app,** a link on a well visited website providing information on PROMs provided in Dutch by Dutch universities was provided. Since **the PROM-select app** contains many links to this website that contains very relevant information on PROMs and the website was tested to be very easy to translate to other languages by using google translate and therefore available to any user in the EU, decided was to sponsor this website. By sponsoring this website: https://meetinstrumentenzorg.nl/sponsors/ were able to add a link to **the PROM-select app.** For this a figure was designed to link to the hyperlink: https://www.prom-select.eu/. For example, see:

In addition, we added this to the HTx website. Then the text was not so clear, so another one was made

Usability testing of the PROM select app

The PROM-select app was tested for usability also called user-friendliness as defined in the HTx project proposal, which states that the deliverable is a user-friendly web application enabling users to select PROMs. For a web application to be user-friendly, usability testing is necessary. Usability Testing also known as User Experience Testing helps to enhance the user experience of an application or website. Usability testing is the practice of testing how easy and user-friendly a web application is to use. A set of decision makers, health care professionals, researchers, IT specialists, patients, and HTx partners, all potential end-users, used the web application to expose usability defects. This testing was performed during the initial design phase and also gave more visibility on the expectations of the users. It was s a great way to discover how easy **the PROM-select app** is to use from the user's perspective and to collect user feedback for improving the design and functionality.

To aid in the usability testing of **the PROM-select app**, we gave the user an email with the task to

- open **the PROM-select app** and to
- select a PRO and health problem and then
- select a PROM.
- Try to find more information of a PROM selected by clicking on it.
- In addition we provide a short introduction and a questionnaire, please fill in:

The Patient Reported Outcome Measure-select app

The **PROM toolbox** consists of the **PROM-guide,** step 3 accompanied by **The literature review on the use of PROMs,** and **the PROM-cycle** of which step 2 and 3 are supplemented with generic PROMs in **the Linnean menu.** The **PROM-links** tool provides links to useful websites. In addition, the **PROM-overview** is an Excel database containing PROMs accompanied by relevant information made available via a user-friendly web-application helping users to select PROMs: **The PROM-select app**. **The making of the PROM-overview & PROM-select app** is a report describing their development.

The **PROM-overview** contains Person/Patient-Reported Outcome Measures (PROMs) recently used in the EU in i.e. in the fields of our HTx case studies: Head and Neck Cancer, Diabetes Mellitus, Multiple Sclerosis, MyeloDysplastic Syndrome, (Long lasting) COVID and in general. The **PROM-overview** is made available in a user-friendly web-application helping users to select PROMs: **The PROM-select app: https://www.prom-select.eu.**

Then, using **this PROM-select app** you may choose your selected PRO you want to measure and relevant health problem or patient group/population. When selected a PRO and health problem you will get a list of relevant PROMs. When clicking on a PROM, you will find an overview of relevant information about the PROM and links to more information.

What Patient Reported Outcome do you want to measure?

- health-related quality of life, health, QoL
- physical functioning/activity, mobility
- pain discomfort
- depression emotional distress/wellbeing anxiety, worry, fear
- work productivity ADL self-management self-efficacy, self-care, daily living
- fatigue energy vitality sleep dyspnoea
- social role participation/performance, social support/relationships, social health/functioning
- cognitive/psychological/brain function mental health
- health literacy, attitudes, knowledge of disease
- satisfaction, well-being
- perception, vision hearing speech
- sexual function
- spiritual function
- incontinence, bladder/gastrointestinal dysfunction, Nutrition/feeding, swallowing, dry mouth
- recovery rehabilitation

What is your health problem and/or patient group?

- Generic
- (Head and Neck) Cancer
- Diabetes
- Multiple Sclerosis
- MyeloDysplastic Syndrome
- (long lasting) COVID
- mental health
- surgery
- chronic disease
- lifelong disorder
- other

Usability test/User-friendliness check of the PROM-select app

https://www.prom-select.eu

What kind of device did you use? If possible, test the app on more than one device.

- Laptop
- IPad
- IPhone
- Mobile (android)
- Other, namely ... … … …

What kind of web browser did you use?

- Mozilla Firefox
- Google Chrome
- Microsoft Edge
- Internet Explorer
- Other, namely … … … …

Does **the PROM-select app** look appealing to you? Yes / no

If no, please state what not: … … … ...

Is the content correct without any spelling or grammatical errors? Yes / no

If no, please state the errors: … … … ...

Did you find **the PROM-select app** easy to navigate? Yes / no

If no, please state why not: … … … ...

Could you find the button to **the PROM-select app**? Yes / no

If no, please state why not: … … … ...

Could you select a Patient/Person Reported Outcome (PRO)? Yes / no

If no, please state why not: … … … ...

Could you select a PRO measure (PROM)? Yes / no

If no, please state why not: … … … ...

Did you find any broken links and/or images? Yes / no

If yes, please state the errors: … … … ...

Did you get an error message? Yes / no

If yes, please state error message: … … … ...

Other remarks: … … … …

Thank you very much for completing this! Please email to: EQuik@zinl.nl

We emailed this request and document to all HTx partners/members, decision makers, health care professionals, researchers, IT specialists, and patients.

Report and changes

When the web application was developed several changes were made in the PROM-overview and PROM-select homepage and PROM select app. See the Usability PROM-select EU report for changes made: https://www.zorginzicht.nl/binaries/content/assets/zorginzicht/algemeen-ondersteuning/usability-report-patient-reported-outcome-measure-select-app.pdf

What kind of device did you use? If possible, test the app on more than one device.

- **Laptop**
- **IPad**
- **IPhone**
- **Mobile (android)**
- Other, namely ... … … …

What kind of web browser did you use?

- **Mozilla Firefox**
- **Google Chrome**
- **Microsoft Edge**
- **Internet Explorer**
- Other, namely … … … …

Does **the PROM-select app** look appealing to you? **Yes** / no

If no, please state what not: … … … ...

Is the content correct without any spelling or grammatical errors? **Yes** / no

If no, please state the errors: … … … ...

Did you find **the PROM-select app** easy to navigate? **Yes** / no

If no, please state why not: … … … ...

Could you find the button to **the PROM-select app**? **Yes** / no

If no, please state why not: … … … ...

Could you select a Patient/Person Reported Outcome (PRO)? **Yes** / no

If no, please state why not: … … … ...

Could you select a PRO measure (PROM)? **Yes** / no

If no, please state why not: … … … ...

Did you find any broken links and/or images? Yes / **no**

If yes, please state the errors: … … … ...

Did you get an error message? Yes / **no**

If yes, please state error message: … … … ...

The most frequent answers of 27 filled in questionnaires were mark in bold in the questionnaire above. So the select app is found to be user-friendly.

Other remarks, some of them were resolved see statement in blue, were:

Link function when clicking on the HTx logo was missing, expected was to go home when clicking on the HTx logo.
As a reaction to this remark the logo was changed to meet the expectation and got a home function when users click on it.

Too much color is used, which may seem a bit unprofessional.
Many others liked the use of colour for the different tools, so we decided to keep the colours for the different tools.

Search function is missing.
Since all PROMs are listed in alphabetical order, we did not see a necessity for adding a search function.

When searched on the internet, no hits appear…
The link of the PROM-select app will be placed on a well visited similar Dutch website: https://meetinstrumentenzorg.nl/sponsors/. And on the HTx website: https://www.htx-h2020.eu/publications/ improving the visibility. A special figure was made for this:

Some things were written in Dutch.
The newest PROM-overview Excel file was checked for Dutch and all was translated to English. In addition, a spelling check was performed in English United Kingdom.

As a small contribution, I would propose to put the sentence "Choose 1 or more Patient Reported Outcome(s) and/or 1 or more health problem(s) from the items below" before the selector buttons and leave only the "No selection made" part in the "Search results" box. I think it would make it more intuitive.

I don't see PROMs only a menu that stays open when selected a PRO.
The menu now closes when chosen an option in the menu. It is still possible to choose more than one option, but now you see PROMs related to your selection when a option is selected.

It is a bit confusing that when you select a PRO the menu disappears and you need to press the button again if you want to select another PRO. If possible, it would be more usable to keep the menu to allow selecting several PROs in one click.
Other users found it to be confusing for the menu to stay open and not seeing any PROMs then. That is why we changed it to this way. It is still possible to choose more than one option.

In several cases, such as the WHO 5 the WHO (Five) Wellbeing Index scale, Available languages, it is written "Danish for Denmark English for the UK"; I don't fully understand why it is important to indicate the country
PROMs are being validated per country.

I suggest to include available language in all cases, at least indicate if it is available in English, for example in "PROMIS Pain Interference Patient-reported Outcomes Measurement Information System (PROMIS)", available languages does not appear. In this way the information contained will be more uniform.
We choose to only display variables that were filled in in the Excel sheet. In this case, PROMIS, the info (languages) can be found using the link to the PROMIS website: https://www.healthmeasures.net/explore-measurement-systems/promis.

One suggestion: since the same categories are not shown for the all the PROs, I suggest to use different background colors (light colors) to visually identify faster the section that you are looking for (e.g. link to source, or to other scientific works).
Others already stated we used to much colour, so we won't use more colour. People need to read it, and they probably will when looking for specific info; the info will pop out.

When clicking on the to select app button an message: 'fetching data' appeared in 4 cases.
A security header blocked the data, this is now resolved via fine tuning.

Could not open the *.pdf by the Arm Function in MS Questionnaire.
The link is changed to the website stating the link to the *.pdf and is now functioning.

Hyperlinks by some PROMs, such as the Aberdeen PROMS, link to PROM search in Pubmed is not functional. See example:

These links; PROM search in Pubmed, were formed using the text in column D, In some cells the sign ';' caused the link did not function correctly. All cells in column D were checked for ';' and this was replaced by a space. In addition, all cells were checked for more text than only the name of the PROM and all additional text was removed (ctrl+X) and replaced (ctrl+V) in column AD to prevent other errors.

This surely looks good and interesting, especially I like the app! However, I find this webpage https://www.prom-select.eu/ a little confusing. To me the main result is the app, but the text is mainly about other things such as PROM-guide and toolbox. Moreover, from this webpage it is difficult to find link for the app, it does have links to several other places though. Link could be provided already in the title of the page. I would reorganize the text so that it first introduces the app, and then explains that inorder to use the app you need to check PROM-toolbox and guide.
We changed the text on the webpage to:

Patient Reported Outcome Measure-select app

A patient-reported outcome (**PRO**) is a patient-reported aspect of perceived health. PROs reflect the patient's opinion and self-assessment of their health. A Patient-Reported Outcome Measure (**PROM**) is a questionnaire that measures PROs and that allows the patient to assess their own health status. PROMs have been developed to capture outcomes from the perspective of patients, including outcomes that can only be reported by patients themselves, or their next of kin, such as pain, quality of life or fatigue.

Using this PROM-select app, you may choose your selected PRO and relevant health problem or patient group/population. When selected a PRO and health problem you will get a list of relevant PROMs. When clicking on a PROM, you will find an overview of relevant information about the PROM and links to more information.

The PROM toolbox consists of the PROM-guide, step 3 accompanied by the literature review on the use of PROMs, and the PROM-cycle of which step 2 and 3 are supplemented with generic PROMs in the Linnean menu. In addition, the PROM-overview is an Excel database containing PROMs accompanied by relevant information made available via a user-friendly web-application helping users to select PROMs: this PROM-select app.

First, the PROM-guide deals with orientation and preparation for measuring PROs with PROMs. Step 3 is about how and when PROMs work and is accompanied by the literature review on the use of PROMs: Current knowledge and scientific evidence for the use of PROMs; an overview of the 'mechanisms of action' or expectations about 'how it works'. Next to this guide, the PROM toolbox contains a framework for the assessment of PROMs: the PROM-cycle. The PROM-cycle is intended for the selection and application of PROMs in healthcare. For an example of the use of the PROM-cycle, see the the Linnean menu where a popular subset of PROMs, such as the EuroQol 5 Dimensions (EQ-5D), Short Form Health Survey (SF-36 and SF-12) and the Patient-Reported Outcomes Measurement Information System (PROMIS®) was tested.

The PROM-overview is an Excel database containing Patient-Reported Outcome Measures (PROMs) recently used in the EU in i.e. in the fields of our HTx case studies: Head and Neck Cancer, Diabetes Mellitus, Multiple Sclerosis, MyeloDysplastic Syndrome, (Long lasting) COVID and in general. The PROM-overview is made available in this user-friendly web-application helping users to select PROMs: this PROM-select app.

So, first check out our PROM-guide for more basic information on PRO's and PROM's. Next, we provide an overview of the eight steps (divided into four phases) that should be completed in the selection and implementation of PROMs in healthcare. These phases and steps described in detail in the cycle:

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PROM-links

PROM toolbox

PROM Toolbox | Article Framework | PROM-Guide | PROM-Review | PROM-Cycle | PROM-Menu

PROM Toolbox | PROM-wijzer | PROM-Cyclus | KIZ NL | PROMS Spreek-kamer | Linnean NL

The PROM-overview

PROM-Overvi | PROM-Select

Literature

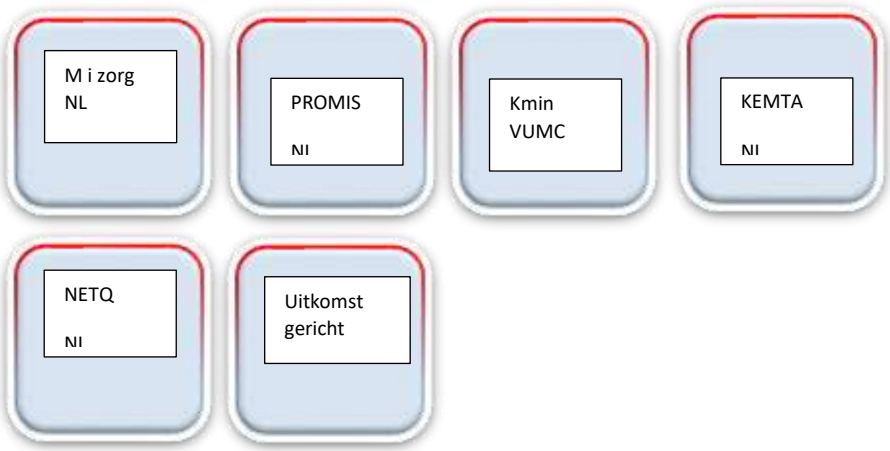
PROMS Cella'12 | PROMS Wiering'16 | COSMIN S. Reviews | Cochrane library

International PROM-websites

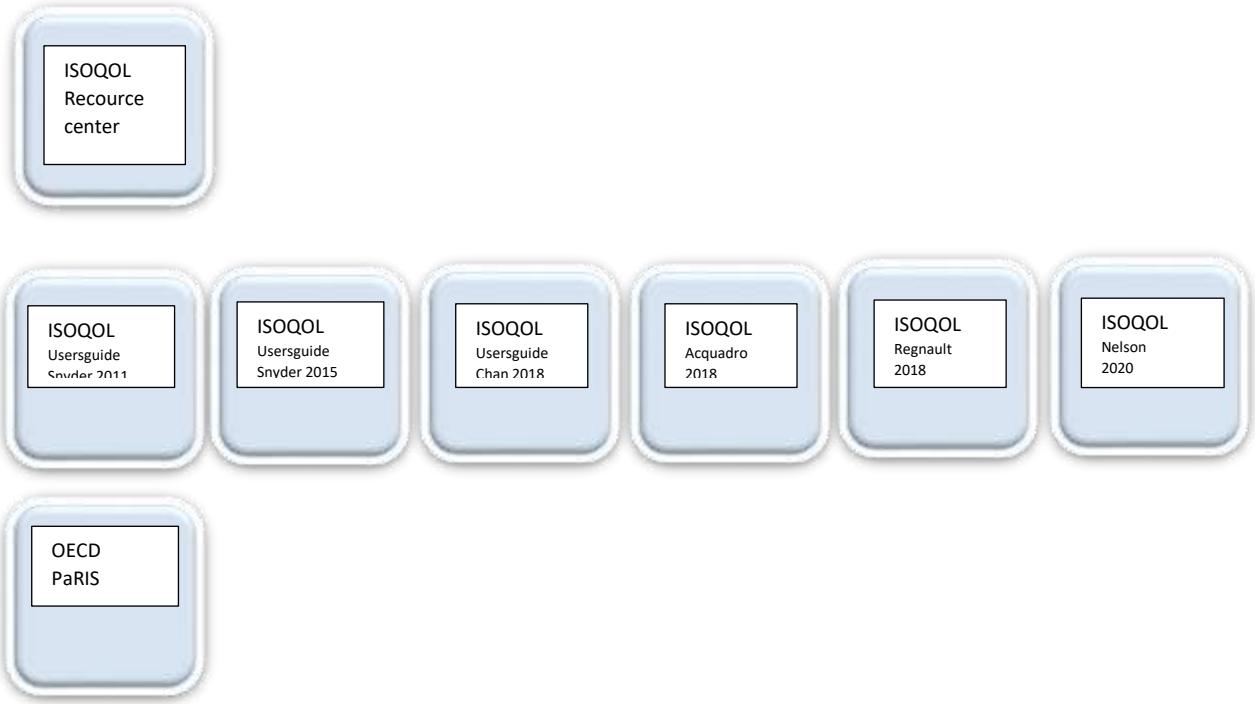
ICHOM | COSMIN COMET | PROMIS | PROMIS NIH | PRO-QOLID

Psych Tools | EBSCO | ROM | SRAlab | PROM Sources

Dutch PROM-websites



Other PROM-tools



USA

HTx H2020

Next Generation Health Technology Assessment to support patient-centred, societally oriented, real-time decision-making on access to and reimbursement for health technologies throughout Europe.

HTx

Case study 1 Head and Neck cancer

EORTC

Case study 2 Diabetes Mellitus

The PROMs that we are considering in this case study are either diabetes specific and generic ones.

Concerning the RWD that we will access in this case study, the available PROMS are SF36 and - EuroQol- EQ-5D.

Reviews

Scoping Review 2020

Income Review 2020

Review Gibbons

Used by CS2

They recommend:

ADDQoL

DQoL

DHP

Str.Sys. Review Nano '20

This review recommends:

WHO-5

PHQ-9

PAID

Case study 3 Multiple Sclerosis

Case study 4 MyeloDysplastic Syndrome

Please find below a paper that came out of our MDS-RIGHT project, describing PROMS for low-risk MDS patients. This is relevant to case study 4.

In our dataset, we have EQ-5D and survival.

Review

Used by CS4: EQ-5D

Other useful links

Eenvoudig vragenlijsten & ePROs uitvragen voor medisch onderzoek | Open HealthHub

Prism | Institute for Health Informatics (umn.edu)

Patient Reported Outcome Measures (PROMs) – National Council for Osteopathic Research (ncor.org.uk)

Electronic Patient Reported Outcomes Collection | Buddy Healthcare

Data collection App for Patient-reported Outcomes | PROMs, ePRO (teamscopeapp.com)

Patient Reported Outcome Measures (cms.gov)

Patient-Reported Outcome Measures (PROMs) — The Clinician

Hip knee: Patient-reported outcome measures (PROMs) | CIHI

Werken aan zorgkwaliteit met PROMs.pdf (netqhealthcare.nl)

JMIR Research Protocols - The Smartphone App haMSter for Tracking Patient-Reported Outcomes in People With Multiple Sclerosis: Protocol for a Pilot Study

https://meetinstrumentenzorg.nl/wp-content/themes/v4-meetinstrumenten/bronnen/bronnen-meetinstr-april-2021-engels.pdf

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HTx consortium map on the HTx site

- Idea: colored dots per CS data available in HTx and when you click on them show PROMs available in the data.
- Idea: Per country, when you click on the country show PROMs translated/validated for that country/language.

Appendix 1 Outcomes library search PROMs in CEA


211005-HTA CAE specifieke proms [pros


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