

# Exploring, describing, and mapping the constitutive elements of patient-reported outcomes (PROs) used in clinical practice

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## Background

*The functionality and purpose of patient-reported outcomes (PROs) have evolved as a result of their digitalisation and extended application in clinical practice. The diffusion of PROs on various organisational levels in different sectors and disease areas has further shaped their usage and construction. Thus, this paper identifies the main elements consti-*

tuting a PRO in the context of clinical practice. The aim is to create a concept map (PRO Elements) grounded in the extant literature, translating, combining, and mediating different interpretations of PRO among stakeholders, to enhance users' understanding and use of PROs with a particular focus on patient participation.

## Methods

The study is based on a systematic document analysis—a sub-study of an extensive scoping review (PubMed, Embase, CINAHL, Scopus) of PROs and patient participation in clinical practice.

## Results

The mapping of PRO reveals that, in clinical practice, a combination of eight main elements constitutes a PRO— validated questionnaire(s), developers, content, measures, mediation, respondents, data, and outcomes – forming the concept map called PRO Elements.

## Conclusion

The article provides an interdisciplinary mapping, presentation, and discussion of PROs' constitutive elements, with an emphasis on patient participation. The holistic conceptualisation map illustrates various types of PROs that may prompt stakeholders to engage in discourse on the development, implementation, and evaluation of PROs.

*Keywords:* Concept map, PRO Elements, patient-reported outcome (PRO), patient-reported outcome measure (PROM), education, communication, digitalisation, interdisciplinarity, clinical practice, patient participation.

# Background

The use of patient-reported outcomes (PROs) is expanding across different sectors, organisational levels, and disease areas in Denmark and increasingly in clinical practice, resulting in a wide range of applications, triggered especially by the increased digitalisation of PROs [1–3]. A digital transformation of PROs that makes it relevant to explore, describe and map the constitutive elements of PROs when integrated in clinical practice, which is the aim of this study. One way of using PROs as part of clinical practice is exemplified in the following fictive story:

*Prior to a consultation at the outpatient clinic, Susan, who suffers from a chronic condition, receives a validated PRO questionnaire in her digital mailbox asking her to answer questions concerning her social and physical functionality, well-being, symptoms, and health-related quality of life (HRQoL). The questionnaire was developed by healthcare professionals (HCPs), patients, and other experts working in collaboration to ensure that generic and disease-specific measures integrated into the PRO questionnaire are meaningful and relevant to Susan. In her home environment, Susan completes the questionnaire on her tablet, transmitting PRO data digitally that provides the HCPs at the outpatient clinic a broad, instant, and timely overview of Susan's self-perceived health status. In subsequent patient-HCP consultations, Susan's perspective of her current health condition is integrated through the use of PRO data, affording the HCPs a more authentic understanding of Susan's condition. Additionally, PRO data enable Susan and her healthcare practitioner to follow disease progression and the outcomes of former treatment interventions, and they form the basis for their discussions of future treatments on a systematic and informed basis, potentially enhancing decision-making and patient management. Consequently, with the completion of PRO questionnaires and the use of PRO data, Susan may feel more knowledgeable and empowered, enabling enhanced self-management and, thus, more appropriate handling of her chronic condition.*

The story is included to highlight functionalities, purposes and patient-oriented expectations linked to the use of PRO on the individual level in clinical practice, particularly in the case of a patient suffering from a chronic condition [3-5]. In addition, the story underscores some essential elements constituting a PRO that are embedded in the concept map presented in this paper. The fictive story is an example of how PROs ideally can provide utility and value in clinical practice; however, the development, implementation, and adoption of PROs are typically affected by contextual factors, which means that the use of PROs might result in different types of outcomes. Accordingly, awareness regarding clinician attitudes, technological infrastructures, workflows, culture, and available resources is required when using PROs in clinical practice [6]. Hence, the importance of exploring the elements constituting a PRO as it links to how PROs are developed, implemented, and applied in clinical practice.

In 2009, the U.S. Food and Drug Administration (FDA) published their guidance on PRO measures, which included the now standard definition: 'A PRO is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else' [7], an interpretation of PRO that is linked to the instrument's use in drug

testing or scientific purposes as part of clinical trials. In the report, the FDA describes how to develop and evaluate PRO instruments, provides guidance on PRO instrument validity and reliability, and suggests how to conduct clinical trials and data analysis. It is further noted that the use of PRO measures is advisable when testing new drugs, which must be done in a systematic manner according to specific scientific criteria [7]. However, due to PROs' digitalisation and their increasing application in clinical practice, new contextual features warrant further considerations, which will be discussed in this paper.

According to researchers in the field, PRO data may improve decision-making and communication in clinical practice, enhance treatment and patient management, elicit the patient's perspective, provide HCPs with a better understanding of the patient's symptoms and disease situation, allow real-time patient assessment, screening, and monitoring, enable performance evaluations of providers and quality assurance, and function as a baseline score when appraising the health status and quality of life (QoL) of a population [8–11].

In the Danish context, the application of PRO data is expected to improve patient pathways and patient–HCP consultations and improve the patient experience [2]. Further highlighted are PROs' economic potential and their empowerment and participatory potential to increase chronic patients' self-management [1, 12], features that rest largely on the digitalisation of the instruments [3].

Accordingly, digitalisation and patient participation are central aspects of current healthcare policies and national PRO initiatives [2, 13]. Therefore, it is reasonable to consider PROs as focal tools in the healthcare sector in which expenditures historically increase incrementally and where current challenges concern demographics (increasing numbers of elderly citizens and patients with chronic conditions, relatively fewer labour-active citizens), technology (development of new technologies and medicine, digitalisation of healthcare), and cultural issues (increasing demands from users/patients and tailored/individualised healthcare solutions) [14]. Developments that explain the political focus on improved population health, quality healthcare, and an economically efficient system—the main topics in the so-called 'triple aim' [15]. Therefore, wider use of PROs may help mitigate current healthcare issues, since PROs' functionality aligns with the 'triple aim' goals [16]. In this context, the 'digitalisation' of PROs does not merely refer to 'the conversion from analogue to digital' [17, p. 15], but to 'the process of using digital technology and the impact it has' [17, p. 15] and/or to digital transformation which concerns 'new ways of doing things that generate new sources of value'

[17, p. 15]. Moreover, the digitalization of PRO means that the instrument can be perceived as a technology, which is reasonable considering Don Ihde's definition, which emphasises that a technology needs to consist of a concrete component, be used in some sort of human praxis and connect humans through various relations [18], criteria that reflect characteristics of PROs used in clinical practice [5].

To understand PROs' substance, capabilities, and potential impact on clinical practice, a more holistic approach capturing the most essential elements constituting a PRO is required. This study aims to identify the elements currently constituting a PRO and to create a map applicable and modifiable for use in different clinical practices. Rather than explaining what a PRO is, the paper aims to identify, describe, and discuss its elements and illustrate formats that might emerge in practice. The study is grounded in extant literature that focuses on patient participation and digitally mediated PROs and was conducted to complement existing approaches and offer a comprehensive and interdisciplinary understanding of a PRO. The resulting concept map is also meant to improve dialogue and collaboration among HCPs and stakeholders, ensure a stronger link between theory and practice, and serve educational purposes.

## Methods

The articles comprising this study were originally identified using a scoping review to explore the connection between PRO and patient participation [6]. The document analysis herein eliciting the main elements constituting a PRO is categorised as a sub-study in relation to the prior scoping review, a meaningful and viable analytical approach, considering the extent of the primary study and the limited body of literature covering the subject field [6]. Accordingly, the scope of the sub-study is to map and combine the elements that constitute a PRO. The included literature derives from the following databases: PubMed, Embase, CINAHL, and Scopus. In the main study, the applied search strings combined 'patient-reported outcome' with 'patient recognition,' 'patient empowerment,' 'patient participation,' and similar concepts. Articles regarding children, traditional RCT studies in which PRO acted as a secondary endpoint, measure validation, and PRO as part of primary care were excluded. The included articles contain knowledge on electronic PROs (ePROs) and the content, functionality and purpose of PROs.

Initially, 6,895 articles were included, reduced to 4,343 articles after the removal of duplicates, which were then screened by reading the abstracts, resulting in the identification and full-text reading of 256 articles. Further information detailing the original search process can be found in the review article, in which the entire search process is elucidated [6].

In the present sub-study, relevant articles were identified among the preliminary 256; articles pertaining to the elements constituting a PRO were included. Hence, in the inclusion process, three questions were asked: a) Does the article provide knowledge on what constitutes a PRO? b) Does the article provide additional knowledge on what constitutes a PRO compared to other included articles? and c) Does the article explain what constitutes a PRO better or more comprehensively than other included articles? Articles were included if the first answer and either of the other two were yes.

The included articles were analysed systematically and categorised thematically, adhering to Braun and Clarke's (2006) guidelines on thematic analyses [19]. Initially, in the main study, themes were identified in accordance with Braun and Clarke's characterisation of an 'inductive approach,' meaning that themes are substantially independent of the original research question, that themes emerged consecutively through the inquiry, and that the process is therefore basically data-driven [19]. An approach that explains and legitimizes the shift in focus when analysing the empirical data, where the main study concerns the association between PRO and patient participation, while the sub-study regards the elements constituting a PRO. Although the coding process in the present sub-study was initiated without a pre-existing coding frame, the epistemological lens was centred on patient participation, and the elements constituting a PRO in clinical practice delimited the scope. Nevertheless, a reasonably open approach allowed the findings and themes to be identified exploratively.

In practice, the analyses of the documents were conducted in four steps. First, the 256 articles were read and relevant information concerning ePROs and the content, functionality and purpose of PROs were extracted, resulting in a document of 304 pages. Second, the empirical data contained in the document of 304 pages, was scrutinized and divided into different documents to construct overall analytical categories based on the empirical data. In this process, relevant empirical data concerning the elements constituting a PRO was identified and assembled in a single 'content-document'. The third step was a detailed analysis of the tentative themes comprising the 'content-document', specifically, the empirical data

were thematically divided into different categories, marked by various colours; a process that helped identify the main elements constituting a PRO in clinical practice. The fourth and last step was the arrangement of the eight basic elements, leading to the creation of the concept map *PRO Elements* (see Figure 1). The included categories were the ones that appeared most frequently and/or were deemed to significantly influence the shaping of a PRO in clinical practice. The initial three steps of the process were handled by the main author while all the authors contributed to the creation of the map, the fourth step.

## Results

Following a systematic outline, this section identifies and describes chronologically the elements that constitute a PRO. At the end of the section, the elements are merged into the concept map titled *PRO Elements*.

### Overview of documents

As explained in the method section, the analysis took place in four steps. In this process, the 256 articles selected for document analysis were thoroughly read, assessed, and roughly sorted as to their substantial link to the subject field, which yielded the 'content-document' based on insights from the 61 articles shown in Table 1. Hence, these 61 articles were included as they explain various aspects of what constitutes a PRO in clinical practice. Based on the analysis described above the following eight main elements were identified and combined to create the concept map (see Figure 1):

- Validated questionnaires
- Developers
- Content
- Measure
- Mediation
- Respondent
- Data
- Outcomes

As the study was explorative and inductive, there were no pre-established categories; categories were created from analysing the material. Supplemental material, not identified through the original search process, was added if deemed to be key

documents in a PRO context and is included to enhance the analysis of the identified elements. The majority of these additional sources were included since the authors were familiar with them and aware of their relevance prior to the study; other sources were included during the study process as the authors recognized how they facilitated the description of PROs in clinical practice.

Table 1 provides an overview of the included documents divided into reference number, authors, year of publication, country of authors' institutional affiliation, method(s), disease area, document type and contribution to the map. Table 1, is sorted according to how each included article contributes to the map and is thematically ordered in the same manner as the *PRO Elements*, starting with *Validated questionnaires* and ending with *Outcomes*.



Table 1. Overview of the documents included in the analysis.

Ref no.	Authors	Year of publication	Country of authors' institutional affiliation	Method(s)	Disease area	Document type	Contribution to the concept map
7	FDA	2009	US	Development guidelines	Across diseases	Report	Validated questionnaire, Respondents,
20	Basch et al.	2015	US	Expert panel, Environmental scan	Across diseases	Research paper	Validated questionnaire
21	Mokkink et al.	2011	NL/CA/ES/US	Delphi, Expert Panel	Across diseases	Research paper	Validated questionnaire
22	Øvretveit et al.	2017	SE/US/DK/IL	Workshop and clinician perspectives	Across diseases	Research paper	Validated questionnaire, Respondents
23	Fleischmann & Vaughan	2018	AU		Osteopathy	Commentary	Validated questionnaire
24	Patrick et al.	2011	US/SE	Development guidelines	Across diseases	Research paper	Validated questionnaire
25	Patrick et al.	2011	US/SE	Development guidelines	Across diseases	Research paper	Validated questionnaire
26	Noonan et al.	2017	CA/US	Workshop	Across diseases	Research paper	Validated questionnaire
27	Ishaque et al.	2016	AU	Systematic literature review	Across diseases	Research paper	Validated questionnaire, Respondents
28	Black	2013	UK		Across diseases	Commentary	Validated questionnaire, Data
29	Appleby et al.	2016	UK		Across diseases	Book	Validated questionnaire
30	Mejdahl et al.	2018	DK	Semi-structured interviews with clinicians	Epilepsy	Research paper	Validated questionnaire
31	Mejdahl et al.	2016	DK	Participant observation, Semi-structured interviews with patients	Renal Medicine	Research paper	Validated questionnaire
32	Greenhalgh et al.	2013	UK	Audio recordings of consultations	Oncology	Research paper	Validated questionnaire
33	Hughes et al.	2012	US	Review, expert interviews	Across diseases	Research paper	Validated questionnaire
34	Moss & Havrilesky	2018	US	Literature review	Gynecology	Research paper	Validated questionnaire, Content, Mediation
35	Nielsen et al.	2020	DK	Scoping review	Across diseases	Research paper	Validated questionnaire
36	Halyard	2011	US	Literature review	Oncology	Research paper	Validated questionnaire
37	Zimlichman	2015	IL	Case studies	Across diseases	Book chapter	Validated questionnaire, Developers
38	Tevis et al.	2018	US	Literature review	Oncology	Research paper	Validated questionnaire
39	Kjær et al.	2018	DK	Evaluation	Human immunodeficiency virus	Research paper	Validated questionnaire
40	Leblanc et al.	2017	US	Literature review	Oncology	Research paper	Validated questionnaire, Mediation
41	Nelson et al.	2012	US/SE	Case studies	Across diseases	Report	Validated questionnaire
42	Boyce et al.	2017	IE/UK	Systematic literature review	Across diseases	Research paper	Validated questionnaire
43	Rieckmann et al.	2015	DE/IT/RU/FI/UK/CZ/NL/FR/CA/CH/ES/BE	Expert panel, Literature review	Multiple Sclerosis	Research paper	Validated questionnaire, Outcomes
44	Wang & Bellows	2018	US		Across diseases	Book chapter	Validated questionnaire, Outcomes
45	Rose & Bezjak	2009	DE/CA	Workshop	Across diseases	Research paper	Validated questionnaire

46	Ysraelit et al.	2018	AR	Cross-sectional study	Multiple Sclerosis	Research paper	Developers
47	Stanizewska et al.	2012	UK		Across diseases	Commentary	Developers, Outcomes
48	Chang et al.	2014	AU	Literature review	Chronic Heart Failure	Research paper	Developers
49	Cannella et al.	2018	IT/AT	Literature review	Hematology/Oncology	Research paper	Developers
50	Haywood et al.	2017	UK/NL/BE	Development guidelines	Across diseases	Book chapter	Developers
51	Wiering et al.	2017	NL	Literature review	Across diseases	Research paper	Developers, Measures
52	McHorney	1999	US	Literature review	Across diseases	Research paper	Developers, Mediation, Outcomes
1	ViBIS	2016	DK	Expert panel, literature review	Across diseases	Report	Content, Respondents, Measures, Mediation
9	Meadows	2011	UK		Across diseases	Commentary	Content, Measures
53	Lipscomb et al.	2007	US	Literature review	Cancer	Research paper	Content, Measures
54	Glouberman	2011	CA		Across diseases	Commentary	Content
55	Velikova et al.	2004	UK	Prospective randomised controlled study	Oncology	Research paper	Content
56	Bingham III et al.	2017	CA/US	Workshop	Across diseases	Research paper	Content
57	Huebner et al.	2014	DE/BE	Expert panel, Literature review	Oncology	Research paper	Respondents
58	Dean et al.	2017	UK	Literature review	Ophthalmology	Research paper	Respondents
59	Snyder et al.	2012	US/NL/UK	Literature review	Across diseases	Research paper	Respondents
60	Marquis et al.	2006	US/FR/CA		Across diseases	Commentary	Measures
61	Palfreyman	2011	UK		Across diseases	Commentary	Measures
62	Gensheimer et al.	2018	US		Across diseases	Commentary	Measures
63	Smith & Weldring	2013	UK		Across diseases	Commentary	Measures
64	Costal et al.	2017	UK/ES	PRO questionnaires, interviews with clinicians	Clinical genetics	Research paper	Measures
3	Eriksen et al.	2020	DK	Scoping review	Across diseases	Research paper	Mediation
65	Wu et al.	2016	US	Interviews with clinicians and patients	Oncology	Research paper	Mediation
66	Alonso et al.	2013	ES/US/DE/NL/UK/CA/SE/IT/FR/CN		Across diseases	Commentary	Mediation
10	Deshpande et al.	2011	IN		Across diseases	Commentary	Mediation
11	Greenhalgh	2009	UK	Theory-driven description of PRO	Across diseases	Research paper	Data
67	Jayadevappa & Chhatre	2011	US	Literature review	Across diseases	Research paper	Data
68	Bowyer & Royse	2018	AU		Clinical Anaesthesiology	Commentary	Outcomes
69	Hewlett	2003	UK	Literature review	Arthritis	Research paper	Outcomes
70	Haywood et al.	2006	UK	Systematic review	Across diseases	Research paper	Outcomes
71	Lavallee et al.	2016	US		Across diseases	Commentary	Outcomes
72	Chang	2007	US		Across diseases	Commentary	Outcomes
73	MedCom	2019	DK	Survey, interviews	General Practice	Report	Outcomes
8	Black et al.	2016	UK/US/CA/ES		Across diseases	Commentary	Outcomes

The number of countries represented (20), papers applying across diseases (39), and literature reviews (20) and commentaries (15) are noteworthy. Most authors have institutional affiliations in the US (26) or the UK (18), but affiliations in 20 countries indicate that the literature used to construct the concept map has an international character; hence, it is reasonable to assume that *PRO Elements* have relevance across national healthcare settings. Considering the aim of the study, it is interesting that material applicable across disease areas comprises a substantial part of the total. That this kind of paper was identified and used is probably no coincidence, since what they have in common is a more general and/or comprehensive approach to PROs. In other words, the document analysis is mostly based on articles that describe PROs' substance, functionality, and purpose in more general terms.

Validated questionnaire: *Psychometric validation, contextual adaptation*

A PRO consists of validated questionnaires and items. Other forms of questionnaires may collect patient-reported data, but to be considered a PRO, the questionnaires need to be psychometrically valid instruments [7, 20, 21], a mandatory methodological prerequisite if PROs are to play a role in clinical practice [22, 23]. Specifically, PRO instruments' internal consistency, content validity, criterion validity, construct validity, cross-cultural validity and responsiveness need to be ensured through systematic approaches and testing [21, 24, 25]. Validated PRO measures (PROMs) produce standardised information on patients' experiences and health status [26], which is an important feature, as it distinguishes PROMs from traditional outcome measures and healthcare data collected non-systematically [27]. A rigorous methodological approach means that PROMs' reliability is comparable to traditional clinical measures, such as blood pressure, survival, and morbidity data [28]. Furthermore, standardised PRO measures and data enable comparisons and benchmarking of healthcare interventions, the creation of useful aggregated population data, and preventive healthcare initiatives for the general population [29].

When PROs are applied in clinical practice, contextual adaptation is also required; otherwise, contradictions may occur if standardised PROs do not align with contextual preferences, workflow, and professional needs and attitudes [30]. Thus, studies on the application of PROs in clinical practice have disclosed several challenges underscoring the importance of acknowledging and investigating contextual matters when assessing PROs as part of clinical practice. Studies indicate

that barriers concern clinicians' ability to use and interpret PROs [31-34]; patients' non-use of PROs [35]; clinicians' attitudes and expectations pertaining to PROs' clinical value [30, 36]; stakeholders feeling of ownership [23, 30, 36-40]; synergy with clinical workflows [30, 36, 38, 41, 42], PROs alignment with the culture in the healthcare system [22, 42, 43]; the technical infrastructures, support systems and the administration of PROs [26, 44, 45] and lack of time and resources [30, 34, 38]. Consequently, PROs might not be used by clinicians or applied in an incorrect manner [32]. Hence, examples of why contextual adaptation and validation are necessary.

Developers of a PRO: *Patients, clinicians, others*

This element concerns the development of PROs, which involves two activities: a) the development of a new PRO instrument from scratch and b) the selection and combining of validated questionnaires into a new type of PRO questionnaire. Traditionally, PROs' development was dominated by HCPs due to their primary research interests—assessment of healthcare interventions and drug testing. However, discrepant views between patients and HCPs regarding health outcomes [46, 47] and a change in purpose and functionality as PROs have become more common in clinical practice suggest that inputs from a multitude of stakeholders in the development process are required if PROs are to be useful, meaningful, and aligned with the needs of the users [37, 48]. Therefore, it is advised that HCPs' expertise should be complemented by patient experiences and management perspectives in this phase [49, 50]. Patients themselves, in particular, are central users of PROs, since the existence of PRO data relies on patients' active engagement and because PRO questionnaires and data is meant to reflect the patient's perspective; therefore, genuine inclusion of patients in the development process is strongly recommended [51]. The category 'Other stakeholders' refers to—software developers, statisticians, researchers, organisers, and managers at various levels (state, regional, and municipal) as well as patient associations and experts in related fields (psychologists, physiotherapists, etc.). Although several PRO questionnaires exist, the selection of instruments is not necessarily an easy task; the number of questionnaires can be a challenge, and trade-offs between preferred content and the potential patient burden must be taken into account [52].

Content of a PRO: *Functioning, mental and physical health status, symptoms, HRQoL*

The report PROGRAM PRO, published by the Danish Knowledge Centre for User Involvement (ViBIS), is based on inputs from 29 Danish experts in the field [1]; therefore, this interpretation of what constitutes the content of a PRO is integrated into this paper and the constructed concept map. This report states that: 'PRO data (Patient Reported Outcome data) are data regarding the patient's health condition, including physical and mental health, symptoms, health-related quality of life, and functioning. PRO data are reported directly by the patient' [1]. Thus, the four themes labelled 'content' in Figure 1. follow these ViBIS guidelines and interpretation. Functioning, symptoms, and mental and physical health status are closely related, as these instruments reveal how patients are affected physically, psychologically, and socially by certain impairments linked to their condition and to what degree they are able to engage in specific activities [9]. The fourth category, HRQoL, makes the content of PROs unique: first, they originate partly from and largely consist of HRQoL data; second, HRQoL is a subjective appraisal of patients' health status and well-being, which distinguishes PRO data from traditional clinical data [34, 53]; and last but not least, increasing numbers of patients with chronic illnesses mean that HRQoL issues have become increasingly important in today's healthcare systems [54, 55]. The content of a PRO questionnaire may vary substantially since it is closely related to its intended functionality and disease area; hence, the purpose of a PRO questionnaire should be clarified during the development process to ensure its alignment with relevant content outcomes [24,25,56].

#### PRO Respondents: *Patients, assistance, proxies*

As emphasised in the FDA definition presented above and in subsequent guidelines, PRO answers come directly from the patient [1, 7]. Thus, PRO questionnaires can elicit the patients' unaffected perspectives on their disease situation, a key reason why PROs hold such promising potential as part of clinical practice [57, 58].

However, although a patient's unaffected response is preferable, this is not always obtainable, as some patients are not able to complete questionnaires by themselves, due to cognitive challenges, low health literacy, or simply being too ill [22, 59]. Therefore, in clinical practice, two additional scenarios are likely. First, a PRO questionnaire can be completed by the patient with the assistance of and in collaboration with an HCP or a family member. Second, in the case of patients unable to participate, the questionnaire might be completed entirely by a proxy

[59]. Therefore, initial consideration of the type of users/patients and their ability to engage in PRO completion is recommended.

PRO measures (PROMs): *Generic, disease-specific, domain-specific, preference-based*

PRO measures are typically categorised as generic, disease-specific, domain-specific, or preference-based [1, 60]. While the first three are constructed according to psychometric standards, the fourth is related to the science of economic evaluation in healthcare [53, 60]. These measures may be unidimensional or multidimensional, indicating how many aspects of a phenomenon they are intended to capture [1, 53, 61].

Generic PROMs enable the measurement of health-related quality of life (HRQoL) across illnesses and conditions [1, 61], and are used to make comparisons and generalisations across patient groups and populations [9, 62]. Disease-specific PROMs have a different scope, focussing on particular issues linked to a given disease or health condition [1, 60, 61], and contain questions concerning HRQoL in a particular patient group [9]. Disease-specific PROMs complement generic PROMs by adding more detailed and specific data [61]. They enable the assessment of specific symptoms' connection to specific conditions [63]. Domain-specific PROMs are used to assess a single aspect of patients' HRQoL (e.g., anxiety, pain, etc.). The application of such measures is useful when a more comprehensive understanding of a particular aspect of a condition is sought [1, 61].

Preference-based PROMs are interdependent questions used to calculate an overall score of the patient's health. Scores obtained estimate the strength of patients' preferences for different health outcomes [53, 60, 61]. When using PROMs in this manner, questions theoretically have equal importance to patients, but this may not always be the case [61]. In practice, generic, disease-specific, and domain-specific PROMs are typically combined into different types of PRO questionnaires, a construction that brings forth a more nuanced picture of the patient's experience [64], whereas preference-based PROMs are mainly used for cost-effectiveness analyses of interventions [53].

PRO Mediation: *Digital, paper-based*

The digitalisation of PROs has expanded their functionalities [3]; however, in this section, the focus is on how the digitalisation of PROs has influenced the distribution and completion of the questionnaires. Most commonly, PRO data are collected via self-reporting surveys but are also obtainable through interviews or by

combining these methods [1, 10], paper-based and digitally mediated. However, PRO questionnaires are increasingly mediated electronically, and the transition from paper-based to digitally mediated PROs and their integration into clinical workflow is now feasible [40, 65, 66]. Such digitalisation has opened new forms of patient access and distribution; for example, it has paved the way for an initiative named Patient-Reported Outcome Measurement Information System (PROMIS), where the objective is to ensure access to validated and digitalized PROs that are applicable in clinical research and practice [34, 66].

#### PRO as data: *Individual PRO, population PRO*

In general, PRO data consist of two types: individual PRO data and population PRO data [11]. Individual PRO data is generated when a citizen completes a PRO questionnaire once or repeatedly over a period. Thus, individual PRO data relate to an individual's continuous disease progression; that is, the individual's disease progression can be assessed and monitored over time. The use of individual PRO data may facilitate shared decision-making and improve patient-provider dialogue. The data can also be used for screening or monitoring patients to improve decision-making and communication among members of multidisciplinary healthcare teams as well as between HCPs and patients [11]. Hence, individual PROs align well with a patient-centred healthcare approach that, *respects and responds to the individual patient's preferences, needs and values and ensures that clinical decision incorporates patients' values*" [67, p. 15].

Population PRO data cover the characteristics of a specific patient population, which can then act as baseline data for comparing an individual's PRO answers, an approach typically used as a decision-making tool for surgery or another beneficial intervention [11]. Thus, aggregated PRO data may enhance healthcare interventions, decision-making in clinical practice, and patient outcomes, while also allowing assessment of provider performance [11, 28].

Therefore, the application of PRO data is a great example of the PRO's purpose needing to be determined initially in the development process. Of interest is either the patient's perspective of their disease situation or the probability of certain outcomes from a healthcare intervention. Both types of PRO data are useful in clinical practice as well as in aggregate [11].

#### PRO as outcomes: *Subjective outcome, objective outcome*

PROs generate either subjective or objective outcomes [68]. Initially, PRO questionnaires were used in research designed to elicit patients' perspectives on healthcare interventions and the effect of drugs, which are relevant because studies have shown discrepancies between patients' and HCPs' perceptions of a patient's health status [47, 69]. Therefore, PRO questionnaires are useful by enabling the inclusion of patients' subjective outcomes as part of clinical practice. In other words, PRO questionnaires are meant to elucidate patients' perceptions of their disease situations [8, 44, 52], ultimately providing HCPs with a more holistic view of the patient's health, facilitating better diagnoses and patient management [43, 70–72]. However, in practice, the assessment of a patient's health status also relies on objective outcomes, such as blood pressure or blood sugar levels, and for that reason, such outcomes are sometimes integrated into PRO questionnaires [73]. Therefore, although PRO data was originally developed to complement traditional clinical data by adding patients' subjective outcomes into the equation, the actual integration of objective outcomes means that PRO questionnaires at times act as a hybrid generating both types of outcomes [73].



PRO Elements: An overview of the elements constituting a PRO in clinical practice

Based on the identified themes detailed in the results section, the concept map

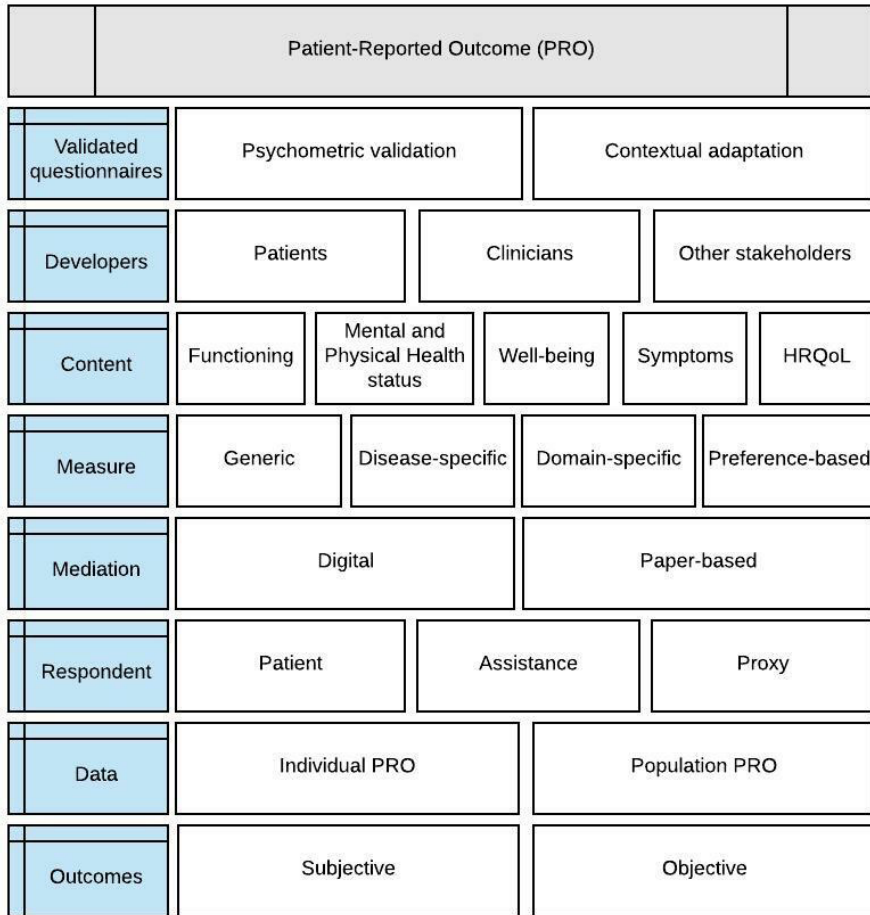


Figure 1. PRO Elements: the basic elements constituting a Patient-Reported Outcome (PRO) in clinical practice.

Figure 1 visualises that a PRO consists of *validated questionnaires* (validation occurring pre- or post-development, psychometrically, and contextual adaptation) created by a heterogenic group of *developers* (emphasising patient participation) with specific *content* based on certain types of *measures*, *mediated* in different ways (recommending digital solutions), completed by various *respondents* (typically pa-

tients), and producing particular types of *data* and *outcomes* (on individual and population levels, typical subjective).

In other words, the concept map explains how different factors shape a PRO, underscoring its embedded interdisciplinarity, to assist relevant stakeholders in comprehending, conceptualising, visualising, and discussing PROs, enhancing their use in a healthcare context. The elements identified are not necessarily mutually exclusive; on the contrary, they are combinable in a variety of ways. What matters is that stakeholders consider whether the customisation of the eight basic elements (the light blue categories in Fig. 1) is tailored to the intended use of a specific PRO. The light blue rows refer to the main elements constituting a PRO, and the white boxes are their operationalisations in more detail.

*PRO Elements* serves three purposes: First, to provide an interdisciplinary overview of the basic elements forming a PRO that might improve the understanding of newcomers, more experienced users, and other stakeholders as to what constitutes a PRO in clinical practice. Thus, it is an educational and informative tool. Second, the concept map may function as a reflection, customisation, and decision-making tool in the initial phase of designing a PRO questionnaire. The visualisation and organisation of a PRO's potential elements allow stakeholders to discuss and identify the appropriate type of PRO from a common point of view, potentially enabling more effective and targeted development, implementation, and evaluation of PROs. How a PRO takes shape depends on a number of things, among which context, purpose, and intended functionality are likely the decisive factors [5]. Third, the concept map may facilitate constructive dialogues across organisational levels, disciplines, and professions, due to its interdisciplinary and holistic presentation of common forms and perceptions of PRO, a useful feature, considering how the digitalisation of PROs has expanded their functionality and purpose [3, 4]. Hence, based on this variety in PROs functionality and purposes it is reasonable to assume that the use of *PRO Elements* in practice depends on the purpose of the PRO at hand. The holistic nature of the map is symbolized by the eight constituting elements, which provides a more comprehensive picture of a PRO in clinical practice [74], whereas the interdisciplinary aspect refers to the fact that the map is based on perspectives stemming from different disciplines [75]. On the one hand, *PRO Elements* reflects the flexibility in the design and use of PROs, which is quite extensive. On the other, the reductionist character of the concept map reflects that there are limits to what constitutes a PRO and likely also what might be achieved through the application of PROs in clinical practice—a

focal point, considering the many expectations and purposes attached to the diffusion and application of PROs [3, 4].

## Discussion

The elements contained in *PRO Elements* are identified and described in the results section. In this section, the elements and related topics are discussed and reflectively critiqued.

### *Are PROs validated questionnaires?*

Although PRO measures are subject to strict psychometric requirements, universal application demands caution, since PROs' functionality is also shaped by contextual conditions [20, 25]. Thus, validating a PRO questionnaire to be implemented in a new setting is recommended, which is often a costly and complex process, making it a continuous challenge. However, if this is not done systematically, discrepancies between PROs' perceived and actual functionality may result, an increasingly important issue as PRO applications continue to expand. Hence, as 'validity is a process rather than an endpoint' [76, p. 723], continuous PRO evaluation is demanded. However, even when PROs are psychometric validated citizens' perceptions and interpretations of the questions answered may still vary; hence, awareness regarding these types of discrepancies is necessary when using PROs in clinical practice [77]. Moreover, at this point, the validity of a PRO instrument merely refers to its psychometric properties, which is sufficient when used for drug testing or scientific purposes, but when integrated into clinical practice, contextual adaptation and situational validity inquiries and measures are warranted, an area that needs further attention considering how the functionalities and purposes of PROs have expanded [3, 4]. When assessing the situated utility of digital PROs in clinical practice, one option is to make use of health technology assessment models where contextual and interrelational matters are scrutinized through a mix of methods [75, 78]. Studies show that adaptation of PRO might be improved by education of users, implementation of support systems [26, 34, 42, 45, 49, 62, 79, 80] evidence on PROs clinical value [36] and appropriate technical infrastructures [26].

### *Who are the key developers?*

While it may appear obvious and unnecessary to point out, patients are central to sound PRO development [5, 50]. PRO questionnaires and data are supposed to mirror patients' perspectives on their disease or health situation. In addition, PROs' long-term sustainability relies on patients' continuous engagement and willingness to complete PRO questionnaires; ultimately, PRO data are meant to enhance patients' participation and self-management. Moreover, the expanding functionality of PROs, due to their digitalisation and integration into clinical practice, encourages the development of processes that actively engage all potential users [5]. Unfortunately, in some cases, PRO questionnaires are still being developed solely by HCPs [51], which is justifiable when a PRO instrument is part of research or drug testing but problematic when it is supposed to be a routine part of clinical practice. Furthermore, when patients are key actors involved in the development process, the following questions require attention: How should patients be involved? How do we ensure a representative patient segment or sample? Are we targeting all patients or only specific patient groups? Taking such considerations into account may prevent biased design solutions useable only by 'People Like Us' and the exclusion of the most vulnerable patient groups, the 'Disconnected, Disengaged and Disempowered' who may be most in need of medical attention [81]. Another issue pertains to patients' actual influence during the development process—how to avoid tokenism and ensure that patient voices have a real impact. Even though, sufficient and effective patient involvement during the development process is not a simple task it is critical if PRO instruments are to persist as a valuable part of clinical practice and provide high-quality data [5].

Guidelines on how to ensure patient participation during the development of PRO instruments have been introduced by Haywood et al. [50]. According to this approach, high face and content validity can be achieved by including the patients throughout the entire development process. This continuous participation is ensured by a) making patient representatives members of the advisory group, which provides feedback to the developers throughout the development process; b) the inclusion of patients in the expert reference group who are consulted at key stages during the development process and c) creating a core research team that consists of both researchers and patients patient; ensuring, that patient engagement is part of the daily research activities [50].

#### *PRO content and measures*

When discussing the content of a PRO questionnaire, the distinction between QoL and HRQoL is central. The World Health Organization (WHO) defines QoL as

'individuals' perception of their position in life in the context of the culture and value systems in which they live in relation to their goals, expectations, standards, and concerns' [82]. Thus, QoL is a situational and relational concept affected by cultural, societal, and individual characteristics—a broad term compared to HRQoL, which 'incorporates the physical, psychological, and social functioning that are affected by the disease or treatment as well as existential aspects of QoL that relate to psychological well-being' [83]. Therefore, HRQoL has a relatively narrow scope compared to QoL. The former measures are those integrated into PRO instruments. However, some researchers dispute the division between QoL and HRQoL, since in practice, it can be difficult to identify whether the generative mechanisms affecting patients' health status stem from elements pertaining to QoL or to HRQoL [84].

Moreover, cultural factors are known to generate inequities in healthcare [84], requiring awareness regarding the current lack of cultural-related measures in PRO instruments. However, if cultural measures are systematically applied, awareness concerning the already known issues pertaining to clinicians' lack of use and challenges when interpreting PRO scores are required [31-34]. Then again, it should be considered whether instruments providing a more holistic and culturally embedded reflection of the patient's disease situation might prevent non-use of PROs by patients [5, 35]. Aligned with this reasoning, one might also argue that measures reflecting citizens' spiritual and religious position in life are focal subjects that should be considered when deciding the content of a PRO [72]. On the one hand, HRQoL instruments may not be broad enough in scope, questioning the content validity of some instruments, since PROs' functionality and purpose have expanded [3, 4]. On the other hand, too extensive a questionnaire may result in increased patient burden, potentially lowering response rates. There are no easy solutions to this matter but approaches such as computer adaptive testing (CAT) that increase the flexibility and amount of content in questionnaires may offer viable solutions [72].

#### *Who are the respondents?*

According to the most prominent PRO definitions, PRO questionnaires are completed exclusively by the patient [7]. However, as explained above, in some cases, the assistance of proxies is necessary to ensure that a PRO questionnaire is completed at all. Although methodologically and from a research perspective, this is a problem, as it affects the validity of the PRO data, if proxies are not allowed to

complete the PRO questionnaires, it seems reasonable to assume that response rates may decline, affecting the quality of the data, and certain patient groups, likely the most vulnerable [5]. Therefore, if the use of PRO questionnaires is to be mandatory, considerations regarding the inclusion of proxies are warranted. For this reason, proxies are explicitly included in *PRO Elements* as ‘eligible’ respondents. However, to enhance the validity of PRO data, transparency—identifying the actual respondent, whether patient, assistant, or proxy—may be a feature to consider in current and future PRO questionnaires. The magnitude of the challenge regarding proxy assistance and knowledge of the type of patient groups affected is still relatively unclear; however, what we do know is that the exclusion of certain patient groups remains a challenge [86]. Thus, future research needs to examine in more detail how different patient groups experience the use of PRO questionnaires and data to identify potential barriers and solutions and disclose the types of patients that are being excluded to allow the healthcare system to implement countermeasures.

#### *PROs’ digital mediation*

The digital mediation of PRO questionnaires influences the potential location of completion. Accordingly, ePROs can be completed either at home [73], increasing the time window for completion [87] or at a relevant healthcare clinic, where assistance may be available if needed. When ePROs are accessible via mobile phones, patients’ locations of completion become extremely flexible [88]. As already mentioned, the digitalisation of PROs enables the use of CAT, which is a feature based on item response theory. Essentially, during the completion process, CAT tailors the PRO questionnaire consecutively according to individual responses, thereby presenting patients with more meaningful questions that lower patient burden and increase relevance [51, 89, 90].

Conversion from paper-based PRO questionnaires to ePROs also means that patient data become instantly accessible and collected systematically, positively affecting both the management and the validity of data, thereby enhancing its potential use in clinical trials and clinical practice [36, 65, 86, 91]. Digitalisation has also paved the way for the routine use of PRO in clinical practice and improved decision-making due to the accessibility of real-time PRO data [36, 78, 92, 93]. Furthermore, ePROs allow graphical presentations of data and may improve patient–HCP communication in consultations [36, 92, 93]. Another often highlighted characteristic pertains to ePROs’ monitoring feature, which enables HCPs to track

patients' disease progression, such as symptoms and treatment effects over time. Thus, ePROs may facilitate improved patient management [36, 87]. Such a tool, when accessible to patients, provides an opportunity to self-monitor one's disease situation [61, 93], facilitating improved patient participation and self-management [91, 94] as well as ensuring more efficient use of resources [72, 95].

Moreover, digital mediation also refers to cases in which algorithms are integrated into a digitally mediated PRO. Hence, PROs may also function as part of a triage system based on algorithms [69]. Basically, patients complete digitally mediated PRO questionnaires, and then, based on their answers, they are divided into three health status groups—green, yellow, and red. Then, based on their status, some are allowed to skip HCP–patient consultation, while others require a consultation promptly [39, 90, 96]. This might facilitate a more proper allocation of resources and HCPs' time [79] and thereby enhance the economics of healthcare [72, 95]. The digitalisation of PROs also allows algorithms to differentiate patients' PRO answers into categories to facilitate the interpretation of PRO scores during the consultation [41]. Consequently, the digital mediation of PROs substantially affects its potential and application as part of clinical practice.

#### *The value of PRO data*

Over the past 10–20 years, the use of PRO data in clinical trials and clinical practice has increased. Although PROs were traditionally used for research and drug testing as secondary endpoints, the use of PROs as primary endpoints and as part of broader clinical practice is now gaining wider support [38, 40, 63].

A PRO is not a single abstract entity but rather a construction consisting of different elements, as visualised in *PRO Elements*. Stakeholders must ensure that the application and interpretation of PRO data are aligned with their inherent functionalities. For example, if an individual's disease situation or progression is the focus, then individual PRO data and subjective outcomes are preferable because the two jointly reflect the patient's perspective of their disease situation over time. Likewise, healthcare interventions based on population PRO data afford reasonable predictions of likely individual outcomes based on aggregated data. Therefore, the choice of PRO data depends on the intended functionality purpose [3, 4].

Another issue relevant to the value of PRO data is whether they are meaningful and useful to stakeholders [33, 97]. Thus, it is essential that PRO data be readable, interpretable, and actionable [33, 40, 98]. The optimisation of graphical formats when accessing PRO data is essential [99], and using appropriate guidelines when



educating HCPs and patients is needed to avoid improper applications and undesirable outcomes [ 31, 32, 45, 100]. Furthermore, considering the resources it takes to develop and implement PRO questionnaires, the value of PRO data, from an economic point of view, is only realised if PRO data are actually being used in clinical practice [101]. From an ethical standpoint, it would also be wrong not to use PRO data after patients were asked to spend time completing the questionnaires [101]; patients themselves have noted that they expect HCPs to use and refer to their PRO data during consultations [65].

### *Study limitations*

First, this study is based primarily on scientific literature extracted from four databases; the identification and interpretation of the elements constituting a PRO are therefore limited. To achieve a broader understanding of PRO, inputs stemming from alternative sources are needed. Second, the search terms the identification of articles is based on are relatively narrow as they concern patient participation, empowerment and recognition limiting the boundaries of the analysis and the concept map. Hence, an inquiry with a broader scope through the inclusion of other relevant search terms might provide additional knowledge regarding the elements constituting a PRO in clinical practice. Third, the first author single-handedly conducted the first part of the analysis, which increases the risk of bias. Hence, even though, all the authors have contributed to the interpretation of the results and creation of the map, earlier involvement of peers would potentially have nuanced and improved the analysis. Fourth, the concept map's educational functionality has already been tested, as it was disseminated by the first author at the DASYS-documentation conference of 2020 [102], hosted and attended by primarily HCPs, thus serving as a test of its face validity. In general, the participants were curious and recognised the value of the map. What was striking was that those approaching after the presentation were HCPs who had experience using PRO in clinical practice. They noted that the map offered a useful overview and pointed out that former uncertainties concerning PRO were addressed by the concept map. In other words, the holistic and interdisciplinary interpretation of what constitutes a PRO was in line with experienced users' perceptions, suggesting that the map has value to both newcomers and experienced users. Nonetheless, the concept map still needs to be tested and validated in the contexts of development, implementation, application, and evaluation to see how and whether it provides value in clinical practice. Fifth, a weakness of the map is the reductionist illu-



stration of the PRO it promotes. Hence, the map is expandable both horizontally and vertically, as additional information would explain in more detail what constitutes a PRO. In that sense, the map's strength—a simple overview of a PRO in clinical practice—may also be seen as a limitation.

## Conclusion

The digitalisation of PROs and their integration into clinical practice has expanded their functionalities and opened new opportunities. Such development increases the complexity of developing, applying, implementing, and evaluating PROs, making it even more important to identify and comprehend their elements. This study found eight basic elements: validated questionnaires, developers, content, measures, mediation, respondents, data, and outcomes. In conjunction, these elements and their subcategories form the interdisciplinary concept map *PRO Elements*, a concept map providing a holistic and multidiscipline conceptualisation of PROs that illustrates how different types of PROs exist within clinical practice and enables users to identify exact types of PROs in more detail. Additionally, the link between PRO in theory and PRO in clinical practice is strengthened, potentially enabling newcomers, experienced users, and a wider variety of stakeholders to engage in PRO-related work and discussions from a common point of view. *PRO Elements* facilitates discourse and collaboration across sectors, disciplines, and professions on pertinent issues concerning the development, application, implementation, and evaluation of a PRO. Consequently, careful and transparent considerations prompted by *PRO Elements* may improve the quality of PRO instruments and lead to realising the inherent potential of digitally mediated PRO questionnaires and data to enhance patient-centred healthcare and patient participation.

### List of abbreviations

HCP	Healthcare professional
HRQoL	Health-related quality of life
PRO	Patient-reported outcome
PROM	Patient-reported outcome measures
QoL	Quality of life

## **Declarations**

*Ethical approval and consent to participate*

Not applicable.

*Consent for publication*

Not applicable

*Availability of data and materials*

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

*Conflicts of interest*

The authors declare that they have no competing interests.

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*Authors' contributions*

JE conducted the literature review, mapped the elements and analysed the data. PB and AB supervised, reviewed the article, and contributed to the interpretation of results and creation of the map. All authors have read and approved the final version of the manuscript.

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