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# Experts Perception of Patient-Reported Outcomes (PROs) in a Danish Context

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## Abstract

This paper elucidates the understanding of Patient-Reported Outcomes (PROs) among experts in a Danish context. PROs are currently implemented on a regional and national level in Denmark (DK); even though, their purpose and functionality seem unclear.

Methodologically the study is based on seven semi-structured interviews with core PRO-experts.

PRO was identified as: data on an individual/population level; an active/passive functionality; contextual dependent; quality improvements; Value-Based Healthcare; patient-centred care; part of clinical practice; technology and as an economic tool.

An analysis of the discrepancies among PRO-experts reveals that their perceptions are associated with their experiences and/or organizational positions.

## Keywords

Patient-reported outcome, PRO, PROM, HRQoL, PRO-experts.

## 1 INTRODUCTION

In 2015, PRO was for the first time part of the annual economic agreement between the Ministry of Finance, The Local Government Denmark and Danish Regions (1). Thus, this document marks the introduction of Patient-Reported Outcomes (PROs) on a national level within the Danish healthcare sector. Formerly, PROs have been developed on a regional level and as bottom-up projects, initiated by enthusiastic healthcare professionals. Therefore, PROs background and integration into the Danish healthcare system is influenced and shaped by different stakeholders. Hence, it is interesting to elicit how PRO is perceived among experts who have worked with PRO in different ways and on different organisational levels. Especially, considering that the current perception of PRO among these experts likely indicate the direction of the future PRO-development may take within the Danish healthcare sector.

A common understanding of PRO originates from the American Food and Drug Administrations (FDA) coining (2009): 'Any report of the status of patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else' (2). A broad interpretation as 'any report' allows several different interpretations and applications of PRO. However, the Danish expert group who authored 'Program PRO' (2016), agreed on a more specific definition of PRO: 'Data concerning the patient's health condition such as physical and mental health, symptoms, health-related quality of life and functional ability reported directly by the patients themselves' (3). Thus, PRO was no longer merely 'any report', but a specific type of data. A focal point in the majority of PRO-definitions is that the answers come directly from the patient, as this feature is what makes PRO-data so valuable in current healthcare.

Since PRO in Denmark has evolved bottom-up as well as top-down, potential conceptual discrepancies are

important to elicit; potentially, ensuring correct and meaningful application of PROs in the future. Therefore, the following research question is examined in this study:

RQ: What perspectives on PRO can be identified among Danish PRO-experts, located at a regional and national level?

Moreover, the results presented in this paper is an initial step regarding the creation of a theoretical PRO-framework, which is done, firstly, to develop a more accurate nomenclature and a common PRO-language in a Danish context and, secondly, to contribute to current research and literature concerning PROs theoretical foundation. An endeavour inspired by Joanna Greenhalgh's encouragement to apply a theory-driven approach when applying PRO in clinical practice (4). Hence, a stronger theoretical understanding of PRO in a Danish context might improve the application, implementation and evaluation of PRO in practice.

## 2 METHOD

The unit of analysis for this study comprises of seven semi-structured interviews with core Danish PRO-experts. Data was collected, by the first author, between the 23<sup>rd</sup> of October 2018 and the 30<sup>th</sup> of January 2019.

The informants have been included due to their engagement in and influence on PRO activities in Denmark. Thus, the informants operate on a national or a regional level; have clinical and/or political experience with PRO and work as either developer, implementer, coordinator and/or theoretical contributor. Hence, they arguably have a thorough practical understanding of PRO.

The identification and sampling of experts are based on two sources. Firstly, a broader PRO-engagement in a Danish

context is quite recent meaning that the amount of relevant PRO-literature produced in DK is limited. Thus, reading of the most pertinent reports and articles regarding PRO in DK and identification of experts was relatively manageable. Secondly, through fieldwork, e.g. participation in national workshops concerning the development of new PRO-questionnaires and as part of regular meetings among implementers on a regional level, further knowledge regarding PRO-stakeholders and experts was acquired. Hence, the fieldwork enabled informal meetings with several of the experts, which may have paved the way for the interviews included in this article. Therefore, inclusion and identification of informants were based on knowledge stemming from literature and fieldwork pertaining to PRO.

Work experience	Informant						
	A	B	C	D	E	F	G
National level	x	x				x	
Regional level			x	x	X		x
Clinical experience		x		x	X		
Political level	x	x	x			x	
Developer	x			x			
Implementer				x	x		X
Coordinator	x		x		x		X
Theoretical input		x		x		x	

**Table 1** Main characteristics and experiences of the informants.

All informants have given informed consent and allowed citation by name. However, due to ethical considerations aligned with recommendations made by Kvale and Brinkmann (2015)(5), the informants' identities are kept anonymous. This is done as PRO is embedded in a political context, where they are key actors, which means that their statements might have personal consequences.

Interviews conducted were qualitative and semi-structured, which allowed for a nuanced understanding of each informant's perception of PRO. An approach which was chosen, since it provides room for flexibility, openness and exploration during an interview (6). Moreover, as the informants were considered experts and it was their perspective on PRO, which was the subject field, the interview design had to be flexible to ensure that the initial interview guide did not exclude valuable understandings and reflections regarding PRO.

All interviews have been transcribed and thematically analysed based on acknowledged guidelines and recommendations made by Braun and Clarke (2006)(7). Hence, interview data were analysed through an inductive thematic analysis, meaning that informants understanding of PRO in this article is based on patterns elicited in the empirical data. However, since knowledge obtained during an interview is socially constructed, and as findings in the interview data are based on interpretations, the social context and the preunderstanding of the main author are important factors. Factors, which were taking into consideration during the interviews through the application of a flexible interview design; subsequently, ensuring that the informants', and not the interviewers, perceptions were prioritized during the conversations.

All the interviews were conducted in Danish, and quotes have been translated. In this process, interpretations prioritize the original meaning of a statement above exact verbatim reproduction.

### 3 RESULTS

#### 3.1 Population PRO and Individual PRO

When explaining what PRO is and how it is used, some of the informants refers to individual PROs and population PROs. Used on a population level PROs are accumulated data designed for scientific purposes, while applied on an individual level, PROs are targeted clinical practice and patient-provider consultations (informant C and D). A dichotomy explained by informant C: '...PRO as part of the individual process, where one, e.g. selects or complete some questionnaires, which then are used in collaboration with the physician, e.g. during a consultation to figure out, how is it going? What works for you? What does not work for you? Which kind of experiences you had lately regarding effects or side-effects etc., used as a dialogue tool and on the other side of the continuum is where one collects and accumulate PRO-data as part of quality development' (informant C). Hence, the functionality and purpose of individual PROs and population PROs are different. Furthermore, informant D points out that individual PROs integration into clinical practice obliges healthcare professionals to use them. An accentuation he makes as PRO in clinical practice stands in contrast to how aggregated PRO-data and similar data, obtained through questionnaires, formerly has been used, or rather, not used by clinicians (informant D).

#### 3.2 Active PRO and Passive PRO

The group of 29 experts who authored 'Program PRO' (3), also looked into the PRO-terminology. As a result, the conceptions 'active PRO' and 'passive PRO' emerged (informant B). Informant B explains that passive PRO has been part of the Danish healthcare sector for several years; however, primarily as a post-treatment instrument to assess patients health status, as a means to collect data for the clinical quality databases used for research purposes. A functionality, which explains the rigorous scientific requirements traditionally attached to PRO-measures (informant B).

Thus, the new 'active use of PRO' is different (informant B): '...'Active PRO' means that one applies it in a way, where the patient is asked to report [data] regarding his/her health status physically, mentally, etc. by the use of a PRO tool; hence, a questionnaire one completes, which then forms the starting point of the consultation with a healthcare professional...' (informant B). Since 'active' PROs has a different purpose than 'passive' PRO, informant B underscores that methodological requirements ought to be less restrictive (informant B): '...I actually believe that PRO should be seen as much as a communication tool as a measurement, but it is true that there is a dimension of PRO, where PRO-data is used for research purposes, which is fine, then you can optimize your tool, which allows you to measure...' (informant B). Hence, PRO instruments should be shaped according to their specific purpose; consequently, the PROs used for research need to be validated tools (informant B).

### 3.3 PROs contextual dependency

Informant G explains that PROs utility depends on the particular disease area: ‘...diabetes is a bit more complex in relation to PRO, exactly due to all the measurements, there are quite some examinations and so on, which needs to be conducted; thus, PRO-data can not to the same extent, stand-alone, as the case is for epilepsy..’ (informant G). Hence, in the area of diabetes, PRO-data acts as a supplement, whereas in the case of epilepsy, it is acknowledged as a primary data source in clinical practice (informant G). As a result, informant G foresees that PRO-data probably has a greater clinical effect in areas where clinical decision-making is less reliant on other types of data sources (informant G). Furthermore, informant G explains how PROs used as a tool for visitation support have no effect in relation to chemotherapy; whereas, patients ability to register symptoms and side-effects has a huge effect as it enables physicians to adjust treatment accordingly (informant G). Hence, the use of PRO in clinical practice ought to be considered in relation to its contextual purpose (informant A, G).

### 3.4 PRO as quality improvement

PRO as a tool to enhance quality within healthcare was one of the perceptions shared by a majority of the informants. Both by one of the authors behind ‘Program PRO’, which is the white paper, that lay down the tracks for PROs dissemination on a national level in DK: ‘...as we started [the ‘Program PRO’-initiative], is this something one can use? Is it a type of patient data that one can use to improve quality?’ (informant F). And by informant C, who is positioned on a regional level, where PROs are supposed to be part of clinical quality databases (informant C): ‘...PRO-data is being accumulated to make us smarter when patients report data concerning their quality of life or self-perceived health, etc. it might indicate that some treatments should be changed, classical quality improvements...’ (informant C). Similarly, PRO is also perceived as supplemental data in relation to benchmarking and knowledge-sharing across healthcare departments; however, a functionality which does require standardized PRO tools (informant F). Thus, this use of PRO-data enables measurement of quality seen from a patient perspective; subsequently, complementing traditional experience and satisfaction data (informant C).

### 3.5 PRO as Value-Based Healthcare

Three of the informants mentions how PRO might be used as part of Value-Based Healthcare. Informant C explains how departments and hospitals used to be evaluated in relation to their respective effectiveness, productivity and activity. Hence, an increase in the number of surgical operations within a department resulted in more funding. However, it was a problematic system as too many of the patients ended up having side-effects, eventually making it a less effective system (Informant C). Thus, Value-Based Healthcare is currently a new and attractive approach: ‘...if we somehow can identify what brings value to the patient, this is value, and then divide it with its costs...’ (informant C). An approach which is inspired by Michael E. Porter, who according to informant C, invented the original Value-Based Healthcare model (informant C). Informant C explains how this approach is currently worked on, which

stands in contrast to Informant B and F who acknowledge it as a future possibility but consider it a secondary application of PRO-data (informant B, F): ‘...at some point people talked about Value-Based Healthcare; however, the system is not ready to attach economy, to economically punish some actors, we perceive it [PROs functionality] through a quality and learning perspective...’ (informant F).

### 3.6 PRO as patient-centred care

Another understanding of PRO that surfaced was as patient-centred care, where PRO is used as a tool to facilitate patient involvement, patient empowerment and improved self-management. According to informant E the use of PRO resembles patient-centred care, since the patient perspective functions as a baseline for the patient-clinician consultations (informant E). ‘...you need to elicit the individual patient and the individual patient pathway since you need to meet the patient where he is...’ (informant E). Therefore, PRO-data potentially enables patient involvement during the patient-clinician consultations, as PRO-data systematically ensures that the patient perspective becomes an integrated part of the conversation (informant F). A focal feature since patient participation is a central purpose when applying PROs in clinical practice (Informant B), and as informant E points out: ‘...to me, it is really important what the patients think, but the patient can’t have an [informed] opinion without proper knowledge...’ (informant E). Moreover, as patients are able to show up informatively prepared for consultations, they potentially feel more empowered and able to engage in conversations with a healthcare professional (informant A). Another perspective accentuated by informant A concerns PROs ability to affect patient’s self-management: ‘...there are definitely some patients who say that it [PRO] provides them with an opportunity to manage their own disease, actually quite a lot of them mention this...’ (informant A). This self-management manifests when patients use PRO as a learning tool. Thus, PRO-data might increase patients knowledge regarding their respective condition; potentially, enhancing their self-management (informant A, E).

### 3.7 PRO in clinical practice

Three other descriptions of PRO are linked to its use in clinical practice, as a tool for enhanced treatment, improved decision-making and as a means to strengthen the patient-clinician dialogue: ‘...well, PRO is a way for the patients to completely subjectively communicate with the clinician about how they actually are doing...’ (informant G). Hence, patients’ subjective assessment of their current health status is, via PRO-data, given a central position during consultations (informant B). Consequently, it provides the patient with an opportunity to articulate and confront the healthcare professional with subjects, which otherwise might be skipped (informant A). The physicians might also benefit from PRO as part of the patient-clinician dialogue since it enables physicians to construct more systematic anamneses (informant B). Moreover, the use of individual PRO-data might provide clinicians with valuable information, potentially used to improve decision-making and treatment (informant G). Especially, within surgery, the use of aggregated PRO-data, where a patient’s profile pre-operation is compared to data stemming from a similar

population; PRO might facilitate patient-tailored solutions and shared decision-making (informant A, C).

### 3.8 PRO as Technology

PRO is also perceived as a tool for visitation support, increased productivity and monitoring, which are functionalities emanating from PROs digitalization.

A very common understanding of PRO, mentioned by almost all the informants, pertains to its functionality as part of a visitation system. Basically, it is a triage system where patients, based on their PRO-answers, are categorized as either 'green', 'yellow' or 'red', a sorting which is handled by preprogrammed algorithms. Thus, patients are automatically divided into two groups, based on their present health status: a) those who need to show up for consultation at the outpatient clinic and b) those who are allowed to skip consultation, as it is assessed to be unnecessary (8). According to informant D, the visitation system is required within the Danish healthcare sector since patients are hospitalized for a shorter duration of time, while the number of outpatient consultations simultaneously have arisen (informant D). Moreover, it is an application of PRO, which apparently is acceptable to patients (informant D, E): '...and a lot of consultations, when the patient comes in, then it turns out, that right now the patient does actually not have any problems..you ask those 2-3 questions until you figure out that this is completely irrelevant, and the patient also finds it irrelevant..' (informant D) Furthermore, the visitation support system allows patients to skip their travel back and forth to the hospital; hence, it is particularly useful in settings where the physical distance between hospital and patients are an issue (Informant D, G). A functionality, which is attractive for and therefore demanded at the management level: '...there have been a huge demand from the top management, there has been a demand from hospital management and department management...but particular, the demand from top management has been related to the reduction of [patient] appearances...' (informant G).

Hence, PROs has an ability to increase the productivity and efficiency of the outpatient clinics (informant D). Thus, by using epilepsy as a case, informant D explains how patients now are able to get timely appointments at the outpatient clinic, which after the implementation of the triage system has resulted in increased productivity. However, as he points out, this change does not reflect that the number of patients consulted by a healthcare professional has risen. The increase in productivity actually indicates that some patients, due to the visitation system, are allowed to skip outpatient consultations; subsequently, creating extra timeslots for more critical patient cases (informant D).

Another dimension relating to PROs technological and digital mediation materialize when PRO-data is utilized as a monitoring tool (informant A, C), thus: '...when PRO is used by chronic patients, it becomes [a tool for] continuous real-time monitoring...' (informant C). Subsequently, enabling preventive care as symptoms over time are continuously monitored, assessed and managed (informant A, B). Additionally a feature which provides the patients with an option to self-monitor; hence, an opportunity to follow and manage their own disease progression assisted through the use of PRO-data (informant B).

Furthermore, the digitalization of PRO enables the data to be used as a coordination tool; potentially, resulting in improved patient pathways (information F): '...patient pathways are actually one of the things we have considered, whether it [PRO] could be used as a mutual tool applied across sectors somehow...' (informant F). A functionality, which might bring great benefits to the entire healthcare system, but as informant F underscores, successful coordination facilitated by PROs requires an improved technological infrastructure and a more homogeneous culture within the healthcare sector (informant F).

### 3.9 PRO as economic efficiency

Besides an increase in productivity, the management level, also perceived PRO as a tool, with economic efficiency potential: '...the top-level management did not expect that it would actually cost more resources, there was definitely an expectation that the implementation of PRO would lead to efficiency improvements, that is for sure...' (informant G). Hence, there seems to be a discrepancy between the expected economic gains and the actual result in practice (informant G). However, according to informant A and D, the implementation of PRO is not meant to be a money-saving exercise (informant A, D): '...first and foremost, this is not a money-saving exercise, and this did not start as a money-saving exercise...' (informant D). Therefore, a more accurate description of PROs economic characteristics is as a tool used for reallocation of resources (informant D). Thus, in practice PRO is a redistribution tool used to allocate resources more effectively, ensuring that the neediest patients have the highest priority regarding access to consultations with healthcare professionals (informant A).

## 4 DISCUSSION

To sum up, several different understandings of PRO rife in a Danish context. Thus, perceptions regarding PRO on an individual versus population level; active versus passive PRO; PROs contextual dependency; PRO as quality improvements; PRO as Value-Based Healthcare; PRO as patient-centred care; PRO in clinical practice; PRO as technology and PRO as economic efficiency, were among the themes informants elaborated upon.

When scrutinizing how informants perceive PRO compared to their respective organizational position, functionality and experience with PRO, a few noteworthy patterns appear. What primarily distinguish the informants acting on a regional level compared to those on a national level, is their heavy emphasize on PRO as a visitation tool, whereas, informants on a national level accentuate the potential advantage pertaining to patient-centred care and PROs benefits in clinical practice.

The informants understanding of PROs functionality on a population level aligns with the UK tradition exemplified here by researchers like, e.g. Appleby et al. (2015)(9) and Greenhalgh (2009)(10). Thus, Appleby et al. analyse and discuss how PRO, among other things, functions as a tool for qualitative improvements on both a clinical and management level, and how PRO might be used to increase productivity and measure cost-effectiveness (9). Themes also mentioned by the experts mirroring their impact on Danish healthcare. Value-Based Healthcare, which is

related to the perceptions qualitative improvements were also mentioned; however, this approach was by the informant directly linked to the American economy professor Michael E. Porter's thoughts on this subject, presented in the article 'What is Value in Healthcare?'(11), where he emphasizes the inclusion of patients values in healthcare, which resembles some of the informants' reflections regarding this subject.

Greenhalgh's description of the difference between 'Group PRO data' and 'Individual PRO' is quite similar to how the informants divide PRO-data into an individual level used in clinical practice and a population level where accumulated data is used for research and preventive healthcare (10).

Some of the perceptions also stem from conceptualizations of PRO inherent in a Danish context. For example, 'Active' versus 'passive' PRO was coined in 'Program PRO'(3), the white-paper, which contained guidelines regarding the development and implementation of PRO.

A third division, which is related to the others, was PROs aimed for research versus PROs targeted clinical practice. Thus, these dichotomies descriptions of PRO all bring relevant insights to the table, making them essential parts of a future theoretical PRO-framework. Understandings of PRO pertaining to the clinical level and patient-centred care are closely linked to how PROs functionality is presented by the national PRO-secretariat, where PRO is presented as a patient-oriented tool (12).

Despite divergent interpretations of PROs, it seems quite clear that PROs digitalization is pivotal regarding its current functionality. Hence, both the visitation system and PROs patient-centred aspects are dependent on proper technological infrastructures.

As this study is as a first step in constructing a theoretical framework, some reflections concerning general patterns in data are appropriate. There seem to be at least five different dichotomies in play: PRO on an individual level versus PRO on a population level; active PRO versus passive PRO; PRO used for research and preventive healthcare versus PRO used in clinical practice; Standardized PROs versus contextual adapted PROs; PROs increasing economic efficiency/productivity and patient-oriented PROs improving patients healthcare. However, the identified dichotomies are arguably intertwined; thus, through analytical scrutinization of PROs perceived functionality, two main categories emerge. One focusing on the 'system-level', where PROs functionality revolves around improvements of the healthcare system, economically and qualitatively and another category, pertaining to the 'patient-level', where the patient's health situation is focal; thus, PRO-data can support patients both during consultations and in managing their disease from at home.

Since the results in this article are based on seven interviews, findings are not statistically representative. However, the informants interviewed possess in-depth knowledge regarding PRO, and they are key actors regarding the development, implementation and application of PROs in a Danish context. Hence, the experts' understandings contain a unique qualitative value at this stage as PROs functionality and distribution is increasing in DK. Nonetheless, additional perceptions and

experiences concerning PRO among different stakeholders, e.g. among managers, politicians and patients and on other levels like, e.g., in municipalities and in General Practice. Furthermore, perceptions of PRO as part of surveys might also be of value in the future as the common Dane becomes increasingly familiar with PROs.

## 5 CONCLUSION

This study shows how perceptions of PRO among experts in a Danish context are numerous and varying. Thus, PRO is understood as: data on an individual and population level; a tool used actively and passively; a contextual dependent tool; a tool to improve quality in healthcare; measurement of Value-Based Healthcare; patient-centred care; a tool in clinical practice to enhance dialog, treatment and decision-making; a technology, where particular the visitation system was emphasized and as an economic tool. Viewpoints and perceptions of PRO were associated with the informants' PRO experience and their organizational position. Hence, regional actors heavily emphasized PROs visitation functionality, whereas national actors focused mainly on PRO as a patient-centred tool. Furthermore, some understandings of PRO can be associated with PROs application in the UK. e.g. PRO as a tool used for quality improvements, as individual/population data and a way to increase productivity and economic efficiency. While the experts accentuating PROs capabilities in clinical practice and in relation to patient-centre care aligns closely with the official understanding of PRO in a Danish context.

This study was a first step in the development of a theoretical PRO-framework, intended to improve the understanding and conceptualization of PRO. Next step is an analysis of the perception of PRO within the academic literature. Therefore, findings in this article and results from an ongoing systematic search and review are the pillars the future theoretical framework are build upon. As a result, conceptual and theoretical insights might enable improved and appropriate application, implementation and evaluation of PRO in the future.

Nevertheless, changes are already occurring within healthcare, as, it seems evident that the traditional one-size-fits-all approach slowly is being replaced by functionalities inherent in PRO, partly enabled by PROs digitalization.

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