Interpreting Patient-Reported Outcome Measures: Narrative and the “Fusion of Horizons”

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Abstract

Patient-reported outcome measures (PROMs) are valued in healthcare evaluation for bringing patient perspectives forward, and enabling patient-centered care. The range of evidence permitted by PROMs to measure patients’ quality of life narrowly denies subjective experience. This neglect is rooted in the epistemic assumptions that ground PROMs, and the tension between the standardization (the task of measurement) and the individual and unique circumstances of patients. To counter the resulting methodological shortcomings, this article proposes a hermeutical approach and interpretive phenomenology instead of generic qualitative research methods.

1. Introduction

Questionnaires are a common method in healthcare and clinical research for measuring medical outcomes via patient self-reported data. As a result, there is a plethora of questionnaires and rating forms developed to measure a range of concepts such as health-related quality of life and health status, which can be broadly categorized as patient-reported outcome measures (or PROMs). As per the United States Food and Drug Administration (FDA), a PROM 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 (FDA 2009).

Despite the popularity of PROMs, there is a lack of a theoretical/epistemic underpinning in their development and application (Mcclimans 2010a). Moreover, Jae Yung Kwon, Sally Thorne, and Richard Sawatzky (2019) have argued that as PROMs increasingly become key outcome indicators in healthcare, there has been growing concern about the potential negative consequences that could result when interpretations are being made to inform clinical and policy decisions as a consequence of this lack of theoretical underpinning.

Health as a concept has changed significantly over the decades, notably with the shift from the biomedical model to the biopsychological model developed by George L. Engel and colleagues (Engel 1977; Schwartz and Rapkin 2004; Kaplan 1990; Anderson 1998).
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The biopsychological approach places the individual at the center of care, with a greater focus on the psychological, relational and social aspects of the individual that are able to influence one’s quality of life (Migliorini, Cardinali, and Rania 2019).

However, according to Leah McClimans,

the PROM’s popularity is undoubtedly due to a larger initiative to provide patient-centred care, but if they are to do this job, then these measures must faithfully provide patients with a voice. Thus it is important that patients are treated as individuals who create and follow different life plans and that these measures treat patients as self-determining agents. (2010b, 67)

In this article I argue that the application of PROMs results in a narrow conception of evidence of the patient’s quality of life and health status by the overriding of the subjectivity of individual experiences, beliefs and judgments as a result of the logical-positivist epistemological underpinning their development.¹

2. A Brief History of the Questionnaire
The questionnaire was invented by the Statistical Society of London in 1838 (Council of the Statistical Society of London 1838; Gault 1907), the design being attributed to Francis Galton. It was Arthur Lyon Bowley, however, who made the most significant methodological breakthrough—in social surveys as we know them today—in terms of the precise questions to be asked and definitions of the unit under investigation (Bowley 1915; Marsh 1970).

The distinctive feature of the research of Galton and Bowley is that it was scientific in spirit and method, in that their method of investigation was linked to the fixed-format standardized questionnaire (Jones 1941).

Indeed, the motto of the Statistical Society of London was aliis exterendum—let others use the facts to inform their value positions while we get on with the job—with the basis of the foundation of the society being that members would agree that “the first and most essential rule of its conduct is to exclude all opinions” (Marsh 1970, 294), a position considered the “common and fundamental epistemological flaw of a survey.”

3. The Emergence of Patient-Reported Outcome Measures
Initially known, generically, as performance measures or health status measures, PROMs were first used in cancer trials (Karnofsky and Burchenal 1949), then as “quality of life measures,” and then relabelled in the early 2000s as “patient-reported outcome measures” or PROMs (McClimans 2010a). The emergence of PROMs and their use over the past three decades or so has been extensive. For example (i) the FDA of the United States’ publication “Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims” (FDA 2009); (ii) the publication of the King’s Fund’s Getting the Most out of PROMs: Putting Health Outcomes at the Heart of NHS Decision-Making (Devlin and Appleby 2010); (iii) the creation of the European

¹ McClimans (2019) argues that quality of life/PROMs serve healthcare as vehicles for patient-centered care and this has important consequences for how we theorize these and to this end, quality of life/PROMs need to be patient directed and inclusive.
Organisation for Research and Treatment of Cancer (EORTC) Academic Fund in 2005 to support noncommercial clinical trials; (iv) the National Health Service (NHS) in the United Kingdom’s pilot study of generic instruments in primary care (Weenink, Braspenning, and Wensing 2014); (v) the development of the Euroqol (EQ-5D) (Rabin and De Charro 2001); and (vii) the development of the 36-item Short Form Survey (SF-36)—and subsequent spin-offs—developed as part of the Medical Outcomes Study (MOS) in the United States (Ware and Sherbourne 1992).

However, the historical development of PROMs situates them at the vertex of two very different trends in medicine: patient-centered care and standardization, leading to an obvious tension between the need for a measure, which pulls in the direction of standardization, and the recognition of patient perspectives, which pulls in the direction of the individual (McClimans 2021).

4. The Philosophical Basis of the Patient-Reported Outcome Measure

The discussion is now less on what PROMs are, but on what they do to capture the patient’s experiences (McClimans 2010a). However, the use of PROMs and associated methods cannot be divorced from theory as PROMs are operating within a set of theoretical assumptions about the world.

Based on the nomothetic approach (Allport 1937), positivism is the epistemological philosophy underpinning outcome measurement (Harvey 2012–20; Romm 2013). Inherent in this approach to research is the view that it is possible to measure behavior independent of context, social phenomena are “things” that can be viewed objectively, and researchers can take a “scientific” perspective when observing social behavior (Hughes 1980; Travers 2001). It is in this context that the critics of the research process of translating concepts into empirical indicators that are observable, recordable and measurable in some objective way have bitten the deepest (Marsh 1970).

A different representation of reality is the idiographic assessment, which addresses some of the concerns raised by critics of the positivist/nomothetic approach in the measurement of patient-reported outcomes (Allport 1937; Hughes and Sharrock 1997). In contrast to the nomothetic approach, idiographic assessment allows respondents—based on predefined content—to nominate the areas of their life that are most important to good quality of life (O’Boyle et al. 1993). However, the idiographic approach has its critics. As pointed out by Mark Ashworth, Maria Kordowicz, and Peter Schofield (2012), the content presented is not directly related to the individual’s own story but is generally based on a thematic analysis—reductionism—which accordingly is predetermined. Furthermore, McClimans (2021) argues that the idiographic approach is not culture free, but the respondents’ answers are bound within a social and cultural context.

5. Questions and Answers

In the broadest of terms, PROMs consist of a series of questions designed to obtain information on subject matter that the researcher understands imperfectly—for example,

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2 The nomothetic approach involves establishing laws or generalizations that apply to all people.
3 Idiographic assessment is the measurement of variables and functional relations that have been individually selected, or derived from assessment stimuli or contexts that have been individually tailored, to maximize their relevance for the particular individual (Haynes, Mumma, and Pinson 2009).
health-related quality of life or perceived health status, as this information cannot be easily obtained (in contrast to, for example, the measurement of blood pressure). However, obtaining this information by asking questions about quality of life or health status does not lead to understanding and interpreting meaning. For the researcher investigating complex phenomena, the hermeneutical task is to go beyond the receiving of information to understanding and interpreting the patient’s response to the question(s) (Gadamer 2003). PROMs solicit answers to questions about quality of life and health status, but understanding is more than grasping the patient’s responses; it is integrating those responses into a meaningful whole (Zimmermann 2015). According to Jens Zimmermann “meaningful knowledge and communication requires more than mere information exchange and cannot be mastered by mere technique” (2015, 10).

According to Hans-Georg Gadamer (2003), we ask questions when we have a poor or imperfect understanding of something. In such cases, Gadamer classes these questions as genuine. A genuine question is one that stems from curiosity, is open and is value free or judgment free. Not only do such questions request information, but they also provide an opportunity for a greater understanding of the subject matter (McClimans 2010a). Gadamer contrasts questions with “apparent questions,” which are not open. As McClimans describes: “Apparent questions are not equally open to reinterpretation since, for Gadamer, we can claim to know an answer only when we understand it as the answer to a particular question—a question whose meaning is not in doubt” (2010a, 227).

However, most PROMs resulting from their positivist epistemic underpinning are standardized and therefore the questions and their respective meaning have been predetermined. Consequently, when we come to assess the patient’s self-report of their health status or quality of life we are claiming to know something of the subject matter. Our assessment of the person’s quality of life or health status is based on criteria determined in advance; that is, the PROMs score range upon which the respondent’s assessment is classified—for example, from poor to excellent: “Thus the questions and their respective meanings are determined in advance. Such questions function as apparent questions and thereby suggest that our subject matter is already understood” (McClimans 2010a, 228).

However, apparent questions do not permit meaningful access to the person’s reality of their quality of life or health status. Knowledge of a person’s PROM score alone will not help the researcher’s understanding of the meaning of such a score (Zimmermann 2015). For this, we need hermeneutical insight.

Hermeneutics is about understanding the meaning of a communication or life situation.4 It is also concerned with the analysis of the conditions for understanding. For Gadamer, this understanding is achieved by asking a narrative text or its analogue genuine questions about its subject matter. How does a genuine dialogue uncover the meaning of a text or text analogue? It does so by revealing the text as something from which we can learn (McClimans 2010a). I return to this issue in more detail in section 8. Next, I discuss further limitations of PROMs resulting from the positivist epistemic underpinning of their development and use.

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4 The term hermeneutics comes from the Greek (hermeneuein—to utter to explain, to translate). It focuses on the interpretation of meaning—notably Hans-Georg Gadamer’s theoretical account.
6. Limitations to the Standardized Patient-Reported Outcome Measure

To be sure, completion of a questionnaire is a social and contextually orientated activity. Indeed, the importance of context in the understanding of survey questions and how words become meaningful against a shared context have been discussed by Herbert H. Clark and Michael F. Schober (1992; see also McClimans 2010a). However, McClimans points out that simply understanding the contextual setting implied by a statement is not enough to clarify its meaning; the context should also give us insight into the purpose or aim of someone uttering a sentence (McClimans 2010a).

However, within the context of standardization the respondent is unable to make such utterances or negotiate an “illness narrative” (Montague 2012). As a result, the assumption can be made that the standard PROM limits the individual’s ability to fully express what it is that constitutes a good quality of life or health status (Carr and Higginson 2001).

McClimans (2021) points to two requirements of patient centeredness in the context of the quality of PROMs; namely, being patient-directed and inclusive. Furthermore, she argues that PROMs must reflect a variety of perspectives as to what constitutes a good quality of life or health status and recognize the individual nature of quality of life.

Dan Brock (1993) defines a number of components of a good quality of life, which he terms “primary functions.” These functions are seen as being centrally important activities which, when missing from one’s life, significantly limit one’s choices or opportunities in creating and pursuing different life plans—a loss of self-determination—and, as a consequence, one’s quality of life. According to Brock, primary functions are signified by the measure’s different dimensions; with the questions of the dimensions assessing the impact of disease or illness on an individual’s subjective experience (Brock 1993; McClimans 2021).

The built-in assumption of the standardized PROM is that the predetermined primary functions or dimensions are equally valuable for everyone and that negative responses on any one dimension limits an activity, consequently leading to the inability to fulfill the goal of self-determination. But do we need to accept that a good quality of life or health status always requires certain prerequisites (McClimans 2010b)? That being the case, it can be argued that with their predetermined primary functions, standardized measures fail to attend to the variable conditions in which different choices are considered valuable in achieving a good quality of life. I discuss this specific issue below in the context of living with diabetes and quality of life.

7. Diabetes and Patient-Reported Outcome Measures

Diabetes is a chronic disorder of the endocrine system, resulting in an absolute or relative inability to reproduce insulin for the regulation of blood glucose. Despite being a serious condition, living a healthy lifestyle and adopting effective management strategies, the person with diabetes can generally live a long, healthy life. However, a person with diabetes will need to carry out daily and regular self-care behavior, and deal with fears and worries about both potential acute and chronic complications, such as severe hypoglycemia, coma, blindness, kidney and heart disease, sexual problems in men, and premature death. As a consequence, living with diabetes can be a challenge. For some, this results in lost life opportunities and behavioral and emotional dysfunction, leading to reduced self-determination and hence quality of life and health status.
There has been much research and much has been written on the impact of living with diabetes on the person’s quality of life (Meadows et al. 1996; Meadows, Abrams, and Sandbaek 2000; Kim, Park, and Yoo 2015; Trikkalinou, Papazafiropoulou, and Melidonis 2017). The Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID) has 109 diabetes-specific standardized measures, including health-related quality of life, psychological distress, and behavior (Pinotti 2016). The Diabetes Distress Scale (DDS) comprises four primary functions, including emotional burden, physician-related distress, regimen-related distress, and interpersonal distress (Polonsky et al. 2005). The Diabetes Quality of Life (DQOL) measure covers six functions/dimensions, including satisfaction, impact, worry, diabetes-related worry, and social and vocational worry (Jacobson, De Groot, and Samson 1994). The Problem Areas in Diabetes Scale (PAID) has a primary function of emotional adjustment (Welch, Jacobson, and Polonsky 1997) while the Diabetes Health Profile (DHP-1 and DHP-18) has three primary functions: psychological distress, barriers to activity, and eating restraint (Meadows et al. 1996; Meadows, Abrams, and Sandbaek 2000).

The diversity in the dimensions represented in these measures is not surprising, considering the lack of an explicit theory guiding PROM development in general (McClimans 2019). Moreover, not only is the assumption that the primary functions are valuable for everyone, but they are also assumed to act as a threshold below which quality of life worsens. For instance, consider the PAID, which comprises 20 items—for example, “Feeling scared when you think about living with diabetes”—and scores of 40 or more indicate severe diabetes-related distress, warranting further exploration (Polonsky et al. 2005). Here, the implicit assumption is that a set of predetermined valuable choices—for example, to go on holiday—or functions need to be maximized, resulting in a low score to envisage a distress-free, good life for someone with diabetes. Moreover, as argued above, these predetermined primary dimensions may not necessarily represent the most important determinants of the patient’s quality of life. A further example illustrates this point.

The diabetes Quality of Life Questionnaire (QoL-Q) has been developed to assess quality of life for adults with Type 1 diabetes undergoing complex interventions, including transplantation (Speight et al. 2010). The scale comprises 23 items—for example, “I can go out or socialise as I would like e.g. cinema, concerts, eat or drink with friends, go to busy or crowded places,” “I can have the holidays I would like e.g. accommodation, location, travelling,” and “I can be as physically active as I would like e.g. walking, gardening, shopping, sports.” Items are rated on a five-point scale ranging from “Strongly disagree” to “Strongly agree.”

Clearly, each of these statements of the QoL-Q may provide valuable choices/opportunities for some to meet the goal of self-determination and thus a good quality of life. However, the issue is the relevance of these choices to the person with diabetes. Even with positive responses to the available choices, the opportunities may not be the most important determinants of quality of life for a particular individual. For example, going on holiday may not be a valuable opportunity for a good quality of life; it may be more important to them to deal with reduced opportunities due to fears of hypoglycemia.

Asking respondents to answer questions on their quality of life and health status when those questions have been predetermined and based on what researchers and clinicians think is important will not necessarily be relevant or important to the respondent. For example, in response to being asked to answer the DDS item, “I feel angry, scared and/or depressed when I think about living with diabetes” (Polonsky et al. 2005), the patient’s...
response was: “I skipped over it because I never feel angry. I never feel scared. I might occasionally feel a bit depressed...I probably looked at angry and scared and thought no to feel like that.” When asked about the DDS in general, the patient’s response was: “The first thing I’m thinking about is that it’s immediately setting a negative frame, which doesn’t reflect my experience.” Another patient’s’s response to the DDS item, “Feeling that diabetes is taking up too much of my mental and physical energy,” was:

It’s very difficult because I don’t know. Because all the physical things that are wrong with me. I don’t put them down to diabetes. I put them down to the cancer, the heart attack. You know, I mean, I’ve got that many serious things wrong with me, but I don’t think the diabetes is as serious as the others.

When respondents attempt to understand the questions in these measures, we can see how they relate the questions to themselves, and how they use these questions to articulate their own questions. This shows that respondents understand these questions in these measures in different ways.

We need to acknowledge these differences in respondents’ understanding of the questions and the limitations of accessing the patient narrative or story because of the empirical epistemic underpinning of PROMs and use this knowledge to create better measures. One way is an ongoing infusion of qualitative work in our quantitative measures (Riessman 1993; Mishler 1995; McClimans 2010a).

8. Where Next?
If we are to continue depending on patients’ self-reports in order to guide healthcare practices, there is a need to continue to develop and improve methods to ensure the data collected is of the highest quality, central to the lives of people, and providing new insights into their quality of life and health status, through an understanding of which functions are representative of or embody the individual’s quality of life.

Abbas Tashakkori and Charles Teddlie (2003) propose that pragmatism is the most appropriate epistemology for mixed methods—for example, by enabling respondents to provide a narrative text to supplement their selected responses to the PROM. In so doing, one is acknowledging the tension between the demands of standardization and the importance of patient individuality.

Returning to philosophical hermeneutics, discussed above, hermeneutics provides a useful approach in the analysis of narrative. For Gadamer, the understanding or interpretation is achieved by asking questions about its subject matter from the narrative text, artifacts, and analogies (Gadamer 2003; Regan 2012). Here, the dialectical processes that occur during interpretation are emphasized to provide—in the case of PROMs—insights into how users interpret and use standardized questions about health and quality of life (Kwon, Thorne, and Sawatzky 2019). For Gadamer (2003), interpretation is essentially dialogic: the representation of an ongoing conversation.

Gadamer talks of a “horizon” as a way to conceptualize understanding as the totality of all that can be realized or thought by a person at a given time and culture (Gadamer 2003; Clark 2008). As Gadamer puts it, a horizon is “the range of vision that includes everything that can be seen from a particular vantage point” (2003, 306). To acquire a horizon, one has to learn to look beyond what is close at hand in order to see it better (Gadamer 2003). The process of understanding is a “fusion of horizons” leading to a new understanding or horizon (Clark 2008). One can see that the fusion of horizons can be a metaphor for what happens between the patient and researcher in the understanding of the narrative—each
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has their own pre-understandings and preconceptions (circles of understanding). As the researcher goes around their circle of understanding, interpretation of the patient’s narrative is updated (Gadamer 2003; Clark 2008). Acknowledgment of these two circles of understanding goes far beyond so-called patient-centered medicine by enabling the patient’s self-expression and allowing them to tell their own story (Launer 2002, 2003).

The researcher’s horizons may change during the encounter as a result of their changed understanding of the patient’s horizon. Jeff Clark describes this as “gaining wisdom from our patients” (Clark 2008, 59). During an encounter, we are constantly breaking apart our understanding, comparing it to another view or new experience and then putting it back together to produce a new understanding or horizon. During this process we apply our pre-understanding, involve our prejudices, and make use of our fore-conceptions, language and imagination. All the time we remain open to meaning. (Clark 2008, 59)

We listen to the individual’s story and help them to add a little more; we do not simply wipe out their story and write a new one (Clark 2008, 59).

9. Methodological Considerations
What distinguishes hermeneutics from the “generic” form of qualitative research used by the FDA and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines (Rothman et al. 2009)? Julie Frechette et al. (2020) provide a comprehensive overview of the key distinguishing features of interpretive phenomenological research and generic qualitative research. I briefly draw on their work to illustrate three of the key distinguishing features of hermeneutics and generic qualitative research for PROM development.

9.1 Researcher Stance
The stance of the PROM developer is most likely to be reflexive and naturalistic, so as to ensure content validity of the specific constructs and to obtain respondent input into the meaning of the questions in order to develop questions with a standardized meaning (McClimans 2010a). In contrast, the focus of the hermeneutic researcher is the unique understanding of being (the lived experiences of the participant) and the view that new understandings are created through the bridging of the researcher’s and participant’s significant horizons (Frechettee et al. 2020).

9.2 Research Objectives
For the hermeneutic researcher, the orientation is towards an exploration of the lived experience, with the acknowledgment that the social context is embedded within the individual’s being. The divergence between the hermeneutic and the generic qualitative approaches can be summed up in the reductionism of the generic qualitative content to develop a framework of standardized PROM items and domains (Cheng and Clark 2017).

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5 Gadamer conceptualizes the hermeneutic circle as an iterative process through which a new understanding of a whole reality is developed by means of exploring the detail of existence. Gadamer views understanding as linguistically mediated, through conversations with others, in which reality is explored and an agreement is reached that represents a new understanding (Malpas 2018).
The development of a robust and meaningful PROM requires combining both inductive and deductive research processes. Establishing content validity through qualitative methods is the first and critical step to ensure the items of a new PROM have meaning and relevance to the population of interest.

9.3 Data Analysis
The data yielded by qualitative research is mainly unstructured and text-based, usually transcripts and diary notes. The analysis of qualitative data is a process of systematically searching and arranging the interview transcripts, observation notes, or other non-textual materials that the researcher accumulates to increase the understanding of the phenomenon. The purpose of this analysis within PROM development is, as discussed above, to ensure the measure has content validity and to develop a framework of PROM items and domains (Cheng and Clark 2017). Juxtaposed to this process is the hermeneutical approach to data analysis based upon the concept of the “hermeneutic circle” (Gadamer 2003). Here, the researcher is moving in and out of the detail of the transcripts in an iterative manner (the hermeneutic circle) asking the following questions: “How is the phenomenon being expressed in this encounter? What is the meaning for the interviewee and the researcher about this element in relation to the studied phenomenon and why? ‘What do I now know or see that I did not expect or understand before I began...?’” (Benner 1994, 101)” (Frechette et al. 2020, 10).

With origins in the deep understanding of being, interpretive phenomenology methodology calls for data analysis that moves beyond description to interpretation, as well as allowing for the pointed definition of research questions and objectives and an in-depth exploration of the lived experience (Frechette et al. 2020).

I have summarized three of the key distinguishing features of hermeneutics and generic qualitative research detailed by Frechette et al. (2020). The main methodological contribution of their article is the detailed articulation of how research methods can be developed in coherence with the interpretive phenomenological tradition. Their central thesis is the exploration of lived experience, with the acknowledgment that the social context is embedded within an individual’s being, in contrast to the reductionism of the qualitative content in PROM development.

10. Discussion
The historical development of PROMs situates them at the vertex of two very different trends in medicine: patient-centered care and standardization, leading to an obvious tension between the need for a measure, which pulls in the direction of standardization, and the recognition of patient perspectives, which pulls in the direction of the individual (McClimans 2019). An illustration of this was presented in the above examples where respondents attempted to understand the questions in these measures as they relate it to themselves—they use these questions to articulate their own questions within the context of their own lived experiences.

Although in this article I have focused my attention on what I consider the limitations of the nomothetic approach to the development and application of PROMs, of course the implementation of any new approach in getting a better understanding of the patient’s perspective in the context of patient-reported outcomes will require changes in how they are administered and how respondents attempt to understand the questions in these measures. Moreover, creating a more inclusive and individual perspective will have
consequences on the modeling of patient outcomes, validity, and their interpretability (McClimans 2019). However, as McClimans points out:

If quality of life research is meant to provide an outlet for the patients’ perspective, so that it might be more sensitive to their needs and so they might have more control over the health care services provided to them; if a good quality life [or health status] is part of a self-determining life, then we might do well to consider such modifications. (McClimans 2010b, 76)

Qualitative studies have been used in studies during the development of PROMs, together with published guidelines by the FDA and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (FDA 2009; Rothman et al. 2009). Yet, Bianca Wiering, Dolf de Boer, and Diana Delnoij (2017) found that while developers agreed that patient involvement is necessary, a lack of resources was a stumbling block, resulting in developers relying on guidelines, personal experience, or practical considerations for choosing a qualitative method.

The logic of my argument here, however, differs from the general call for more qualitative research during the development of PROMs. In this article I have proposed a mixed-method approach to gaining greater insight into individual experiences. In doing so, I have argued that hermeneutics presents a unique way to enable an in-depth understanding of the lived experience of the individual when used in tandem with the quantitative data obtained during the application of a PROM. With interpretive phenomenology—and, more specifically, hermeneutics—the focus is on interpretation of meaning of lived experience through the back-and-forth movement of the hermeneutic circle, thus providing the researcher with elements of reflection of his/her being-in-the-world, their horizons of significance and reflexivity (Frechette et al. 2020). The researcher cannot be detached from his/her own presuppositions and should not pretend otherwise (Hammersley 2000; Mouton and Marais 1990).

While I propose an epistemology anchored in an existential understanding of Dasein and their existentialia, such as put forward in this article, should be an integral part in the assessment of quality of life and health status, it needs to be recognized that there are limitations to the methodology. Primarily, quantitative PROMs allow for large sample sizes compared to the approach proposed here and in this context qualitative studies are more likely to be less efficient. Nevertheless, the limitations of the nomothetic approach to PROM assessment need to be taken into account in our use of quantitative measures. These include notably the lack of an interpretive stance, the inability of the respondent to provide their own narrative, and the expectation built into standardized PROMs that respondents will understand the questions and answers consistently and uniformly.

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