Adaptation of the Self-Report SF-36v2® and SF-12v2® to Proxy-Reported Outcome Measures

KD Jacobs, PhD[1], Jamie Pomeranz, PhD[2], and Michelle (White) Carty, PhD[1]

[1]QualityMetric Incorporated, LLC, Johnston, Rhode Island, United States
[2]University of Florida College of Public Health & Health Professions, Gainesville, Florida, United States

BACKGROUND

- Patient-centered health outcomes, such as those related to disease experience and health-related quality of life (HRQoL), are best captured from the patient's perspective. However, in some instances, patients may not be able to reliably self-report (e.g., cognitive impairment, high symptom burden, clinical deterioration, young children)
- A proxy-reported outcome (ProxRO) measure gathers information related to the patient experience, such as disease symptoms or HRQoL, from someone other than the patient
  - Administering a patient reported outcome (PRO) measure to a proxy reporter on behalf of the patient can risk validity of collected data, as items can be interpreted differently between proxy respondents
  - ProxRO measures typically capture data from one of two perspectives (**Figure 1**) which can impact how the data is interpreted[1]

Figure 1. ProxRO Measure Perspective Types[1]

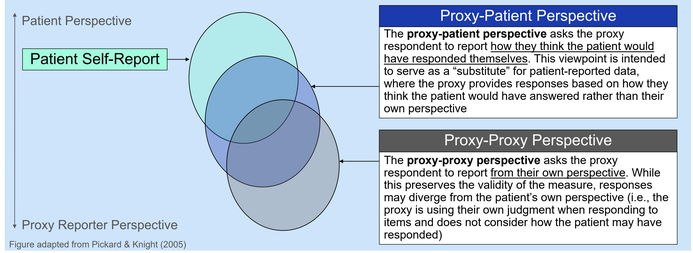


Figure adapted from Pickard & Knight (2005)

- The person responding, termed the proxy reporter, should be someone who knows the patient well enough to respond of their behalf
  - Proxy reporters are most often family members, but can also be healthcare providers involved in the patient's care, formal caregivers, as well as other types of informal caregivers
- The SF-36v2® and SF-12v2® Health Surveys[2] are frequently used general HRQoL PRO measures in clinical trials
  - The SF-36v2 (36 items) and SF-12v2 (12 items) measure 8 domains of physical and mental functioning and well-being; scores on all domains are used to calculate summary measures for overall physical and mental health[3]
  - Historically, many studies have administered these surveys to proxy reporters using either the self-report version as-is or creating study-by-study adaptations of the measures

OBJECTIVES

- Identify best practices for modifying existing PROs to ProxRO measures described within the literature
- Adapt the SF-36v2 and the SF-12v2 into ProxRO measures

METHODS

- A literature review was conducted in PubMed, Google Scholar, and ePROVIDE PROQOLID™ database to identify articles that used ProxRO measures to assess HRQoL, functional health, and/or wellbeing (**Table 1**)

Table 1. ProxRO Measure Perspective Types

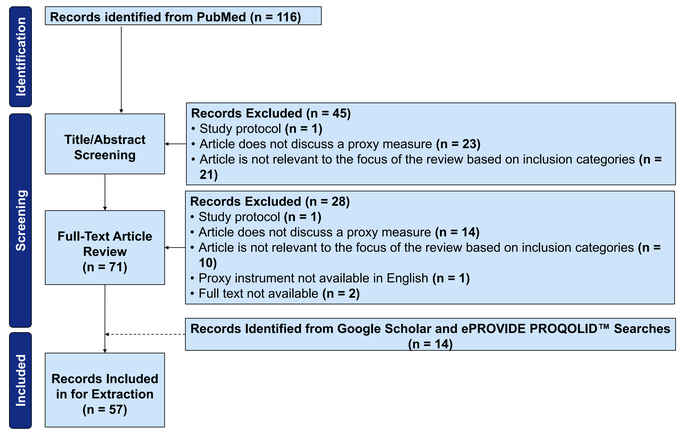
Content Area	PubMed Search String Terms
Proxy Report	"proxy-report*"[Ti] OR "proxies"[Ti]
HRQoL/Wellbeing	"quality of life"[TiAb] OR "QoL"[TiAb] OR "QL"[TiAb] OR "health related quality of life"[TiAb] OR "HRQoL"[TiAb] OR "HRQL"[TiAb] OR "well-being"[TiAb] OR "wellbeing"[TiAb] OR "health status"[TiAb] OR "outcome*"[TiAb] OR "function*"[TiAb]
Measure/Instrument	"assessment*"[TiAb] OR "questionnaire*"[TiAb] OR "instrument*"[TiAb] OR "measure*"[TiAb]
Search Filters	English [Language] AND 10 Years [Publication Date] AND "Humans" [Species]

  - All records were identified against selection criteria. Articles were excluded during full-text review if they did not contain information pertinent to proxy form development
  - Literature descriptions of modifications to wording, instructions, and specifications for study eligibility related to the proxy-patient relationship were evaluated
- Instruments were modified based on literature findings. They were evaluated by three key opinion leaders, revised, and a final consensus review was conducted

RESULTS

- The search of the PubMed database, conducted on August 24, 2022, yielded 116 articles. Following the article screening and review, 57 articles were included for extraction (**Figure 2**)

Figure 2. Literature Review PRISMA Chart



- Most relevant articles were focused on the evaluation of psychometric properties of ProxRO measures (21 papers, 36.8%) and/or the concordance between patients and proxy reporters (19 papers, 33.3%) (**Table 2**)

Table 2. Literature Review Study Characteristics

Study Characteristics (n = 57)	n (%)
Sample Age Group	
Children	33 (57.9)
Adults*	24 (42.1)
Study Type	
Psychometric Validation	21 (36.8)
Proxy-Patient Concordance	19 (33.3)
Application of ProxRO to Assess Health Outcomes	10 (17.4)
Content Validation	5 (8.8)
Review Article	2 (3.5)
Specificity of Study Measure(s)	
General Quality of Life	28 (49.1)
Disease-Specific	26 (45.6)
General Quality of Life and Disease-Specific	3 (5.3)

*Includes studies with both adults and children

- Studies investigating health outcomes in adult samples (24 papers, 42.1%) primarily used condition-specific measures (19 papers, 79.2%) (**Table 3**)
  - ProxRO measures were used in a variety of disease areas, including dementia/Alzheimer's disease, intellectual disability, late-stage cancer, epilepsy, and stroke
  - The only non-disease-specific ProxRO measure was a health utility measure; the EQ-5D (Proxy Version)

Table 3. Literature Review Adult Sample Study Characteristics

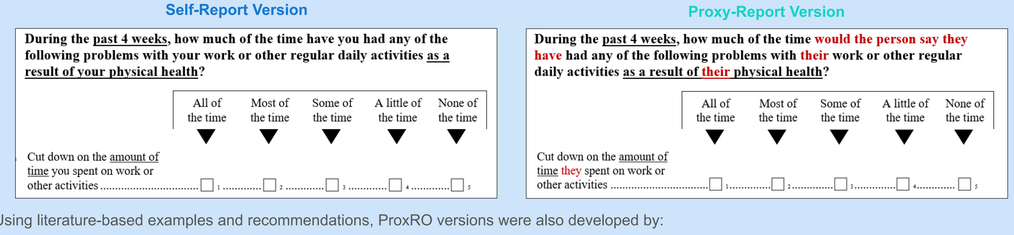
Study Characteristics — Adult Sample (n = 24)	n (%)
Study Type	
Psychometric Validation	10 (41.7)
Proxy-Patient Concordance	5 (20.8)
Application of ProxRO to Assess Health Outcomes	5 (20.8)
Content Validation	3 (12.5)
Review Article	1 (4.2)
Specificity of Study Measure(s)	
General Quality of Life	5 (20.8)
Disease-Specific	18 (75.0)
General Quality of Life and Disease-Specific	1 (4.2)

- Results suggested that proxy-form adaptations will likely need to go beyond simple rewording, and clear instructions will be required[4]
- ProxRO versions of the SF-36v2 and SF-12v2 were developed to capture the proxy-patient perspective (**Table 4; Figure 3**)

Table 4. Terminology Adaptations from Self-Report to Proxy-Report

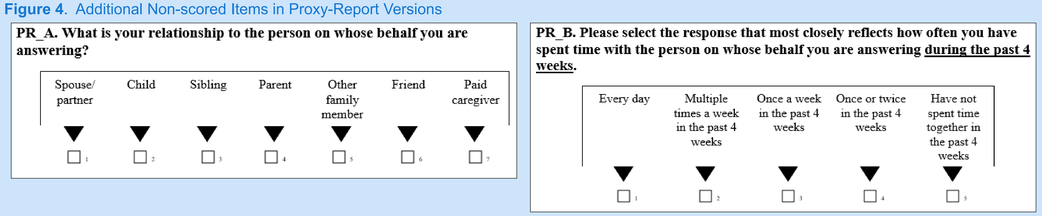
Survey Component	Self-Report	Proxy-Report
Heading	Your Health and Well-Being	Health and Well-Being To be completed on behalf of another person
Survey Instructions	"mark the box that best describes your answer"	"select the one response that best describes how the person would answer"
Reference to Patient	"You"	"Another Person" and "The Person"
Pronouns	N/A ("Your")	"They" or "Their" or "Them"

Figure 3. Example of Item Adaptation from Self-Report to Proxy-Report



Using literature-based examples and recommendations, ProxRO versions were also developed by:
- Altering instructions and item wording to prompt proxy reporters to respond how they think the patient would answer
- Adding two optional non-scored items to gather information on the relationship between the proxy-reporter and the patient. These items can be modified by survey administrations to match study-specific goals (**Figure 4**)

Figure 4. Additional Non-scored Items in Proxy-Report Versions



SUMMARY & CONCLUSIONS

- While ProxRO measures are not preferred when capturing data related to the patient experience, using such measures can prevent the exclusion of data from patients who are unable to self-report
  - ProxRO measures have potential applications when patients are unable to recall their experiences and in longitudinal studies when clinical deterioration is expected (e.g., late-stage cancer or dementia)
- ProxRO measures providing clear instructions and item wording can mitigate potential variability in interpretation by proxy reporters
  - Because the SF-36v2 and the SF-12v2 are so widely used in health research studies, there are broad benefits to patients, caregivers, and the research community in having standard proxy versions available
- While the study was limited by a paucity of literature in best practices for modifying existing PROs to ProxROs, this was mitigated by key opinion leader input
- The SF-36v2 and SF-12v2 ProxRO measure versions were finalized for two recall periods (standard and acute) in three modes of administration (paper, handheld, and tablet). Future research is necessary to assess the content and psychometric validity of the SF-36v2 and SF-12v2 ProxRO adaptations

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