

Patient-reported outcome measure (PROM) and Patient-reported experience measure (PREM) in home respiratory therapies: oxygentherapy, CPAP treatment, mechanical ventilation and aerosoltherapy

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Introduction

Home respiratory therapies (HRT) are treatments aimed at pathologies, generally chronic, that have a significant impact on the biopsychosocial aspects of the patient's life. Currently, there are no psychometrically validated PREMs and PROMs reported by the patient to assess the impact of the treatments themselves (of long duration) on quality of life (QoL). The reason is that standardized measures of QoL are focused on a specific disease. However, it is possible to develop them based on the fact that each of the therapies covers a wide spectrum of pathologies that manifest with a common main symptom: dyspnea in the case of oxygentherapy, somnolence in the case of CPAP, blood gas normalization (PaCO₂) in mechanical ventilation and respiratory insufficiency in aerosoltherapy. Air Liquide Healthcare has been developing Value Based programs for 3 years, and although it has included outcomes in its measures, the development of PROMs and PREMs for each one of the therapies to be measured systematically is seen as a necessary step.

Method

There is currently no outcome-set for HRTs. The project responsables studied the presentation modality used, and followed the model proposed for identifying outcomes in each one of the therapies. The process followed 2 steps:

1) Identification of PRO using a consensus technique with patients, caregivers, specialist doctors and therapists. It was based on items that were collected from questionnaires related to prevalent pathologies treated with HRT and that are used in clinical practice. Those responsible were a scientific committee made up of 1 pulmonologist, 1 sociologist, and HRT specialists (psychologist, pharmacist, nurse and physiotherapist) from Air Liquide Healthcare. The phases of this study were: 1) Review of the literature to identify potential outcomes in the different HRTs; 2) Based on the results of the literature review and their clinical experience, the scientific committee prepared a list of potential outcomes. 3) 12 semi-structured interviews were conducted with patients (4 for oxygentherapy, 4 for CPAP, 2 for mechanical ventilation and 2 for aerosoltherapy) and 4 interviews with caregivers (2 for aerosoltherapy and 2 for mechanical ventilation). 4) Two nominal groups were organized with patients and with health specialists (17 pulmonologists) to whom the lists of potential outcomes were presented. The objective was to establish the most valuable outcomes (consensus > 75% of the participants agree). 5) The inclusion or not of those outcomes that did not reach consensus between the nominal groups and the semi-structured interviews was determined. The dimensions related to outcomes were: Empowerment, relationships and processes, changes in habits, adherence and satisfaction.

Psychometric validation of PROM and PREM questionnaires in each of the therapies; This consisted of an exploratory factor analysis (EFA) and a confirmatory factor analysis (CFA). 1) Permission was requested from the Human Research Ethics Committee of the Rey Juan Carlos University and the Ethics and Clinical Research Committee of the La Princesa University Hospital (Madrid). 2) The questionnaire was passed to a total of 177 patients with oxygen therapy, 251 with CPAP, 141 with mechanical ventilation and 81 with aerosol therapy. 3) An EFA and an FCA were carried out using SPSS v26 and MPLUS 8.2.

Results

For the step 1, the results were: - 17 PRO and 17 PRE items for oxygentherapy; 31 PRO and 17 PRE items for aerosoltherapy; - 18 PRO and 17 PRE items for CPAP; 14 PRO and 17 PRE items for mechanical ventilation.

A first PREMs and PROMs set related to HRT has been developed, with good reliability indices, both in the exploratory (Cronbach's alpha) and in the confirmatory (CRI) (see tables 1 and 2). In conclusion, these are questionnaires with a scale of 5 Likert points, which the patient can quickly complete with excellent scores for acceptability, reliability and validity in psychometric tests.

	PROM	PROM Oxygentherapy	PROM CPAP	PROM Mechanical Ventilation	PROM Aerosoltherapy
Cronbach's alpha		.899	.807	.786	.899
CRI		.969	.865	.796	.939
Factors (CRI)		-Empowerment (CRI = .905) -Changes in relations and processes (CRI = .761) -Change in Habits (CRI=.878)	- Changes in habits(CRI = .827) - Adherence (CRI = .802) - Satisfaction (CRI = .845)	- Empowerment (CRI = .829) - Changes in habits(CRI = .713) - Adherence + Changes in processes (CRI=.710)	- Changes in habits(CRI = .948) - Adherence (CRI = .877) - Satisfaction (CRI = .918)
Global Adjustment	Chi-Square	(311) 482.792; p<.0001	(87) 160.250; p<.001	(32) 65.236; p=.0005	(227) 353.170; p<.001
	RMSEA	.079 [.064-.093]	.058 [.044-.072]	.086 [.056-.116]	.083 [.066-.099]
	CFI	.933	.963	.946	.948
	TLI	.927	.955	.924	.942
	SRMR	.064	.061	.066	.098

	PREM	PREM Oxygentherapy	PREM CPAP	PREM Mechanical Ventilation	PREM Aerosoltherapy
Cronbach's alpha		.642	.807	.575	.609
CRI		.770	.865	.827	.728
Factors (CRI)		-Empowerment – Adherence (CRI = .829) -Relationships and processes - Habits - Satisfaction (CRI = .752)	- Empowerment (CRI = .929) - Relationships and processes - Habits - Satisfaction (CRI = .890) - Adherence (CRI = .927)	- Empowerment (CRI = .571) - Relationships and processes - Satisfaction (CRI = .605) - Adherence- Changes in habits(CRI = .714)	Empowerment (CRI = .728)
Global Adjustment	Chi-Square	(12) 15.692; p<.266	(87) 223.005; p<.001	(32) 61.200; p=.0014	(5) 6.648; p=.2482
	RMSEA	.034 [.000-.086]	.080 [.067,.093]	.081 [.050-.112]	.064 [.000-.178]
	CFI	.999	.968	.954	.990
	TLI	.999	.962	.936	.981
	SRMR	.049	.056	.081	0.047

Conclusions

A first PREMs and PROMs set related to HRT has been developed, with good reliability indices, both in the exploratory (Cronbach's alpha) and in the confirmatory (CRI) (see tables 1 and 2). In conclusion, these are questionnaires with a scale of 5 Likert points, which the patient can quickly complete with excellent scores for acceptability, reliability and validity in psychometric tests.