1. TITLE

"PRO Reuma Initiative": collecting patient-reported outcomes using touchscreen technology

2. INTRODUCTION

In recent years, there has been an increased concern on placing patients at the center of healthcare system.

According to US Food and Drug Administration (FDA), a Patient-Reported Outcome (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"[1]. PROs can be measured by self-completed questionnaires that reflect a range of health-concepts such as pain, physical functioning, global assessment of disease activity, emotional impact of the disease or even perception towards the treatment given. These data cannot be captured by objective clinical measures or biochemical markers – they can only be obtained accurately from the patient. In daily clinical practice, PROs provide a means to facilitate and optimize patient-clinician communication and may have even a role in decision-making[2,3]. In addition to its usefulness in the clinical milieu, PROs have also been recognized as an important tool in research area[4], playing a central part in measuring the effectiveness and risks of pharmaceutical and non-pharmaceutical interventions, alongside other traditional measures. The inclusion of PROs as endpoints in clinical trials[5] is an evidence of the importance of the patient perspective, which provides a more holistic interpretation and comprehensive assessment of benefits of healthcare interventions.

PROs have become a pivotal part of the evaluation of patients with rheumatic diseases and are now commonly used in rheumatology practice settings[6]. In Portugal, Rheumatic Diseases Portuguese Register (Reuma.pt) includes distinct PRO measures, such as visual analogue scales of pain, HAQ, EQ5D, SF36, FACIT, among others. Data are usually collected during the patient's visit within the physician's office. Patients are asked to read and answer the questions all by themselves or, alternatively, to verbally answer the questions made by the clinician. In some cases, if possible, patients can fill in the questionnaires at home between office visits, entering their own data in the registry.

There are, however, some barriers to a more widespread adoption of PROs in routine rheumatology care, such as the impact on clinical workflow and the time consumption for both patients and healthcare professionals. The "PRO Reuma Initiative" is a national project promoted by the Portuguese Society of Rheumatology, designed to overcome these challenges

and to increase data collection of PROs in Reuma.pt. In this initiative, touchscreen devices (tablets or kiosks) will be provided and strategically installed in the waiting room or in the hospital outpatient department of different centers, so that patients can easily complete the questionnaires through the patient-portal while waiting for the visit and/or treatment.

Our hypothesis is that this new electronic system will hopefully increase patient acceptability and participation on PRO questionnaires, allowing a more efficient collection of these data.

3. OBJECTIVES

Primary objective

a) To compare response rates to PRO questionnaires before and after the implementation of "PRO Reuma Initiative".

Secondary Objectives

a) To determine differences in responses of PROs collected by different methods: when questionnaires are self-completed without any interference from the clinician (using electronic devices in the waiting room/outpatient department or at home) or when the questions are asked directly by the clinician (in his office).

b) To examine the demographic characteristics of patients who responded the questionnaires using each method.

4. METHODS

Study Design:

This is a multicenter, prospective, observational study, using data from Rheumatic Diseases Portuguese Register (Reuma.pt).

Population:

Inclusion criteria: all patients from centers participating in the "PRO Reuma Initiative", registered in Reuma.pt. At the moment, these centers include: Hospital de Egas Moniz, Hospital de Faro, Hospital de Santa Maria, Hospital Garcia da Orta, Instituto Português de Reumatologia, Centro Hospitalar Cova da Beira, Centro Hospitalar e Universitário de Coimbra, Hospital de Aveiro, Centro Hospitalar de Vila Nova de Gaia, Hospital de São João, Unidade

Local de Saúde do Alto Minho. We pretend to include all rheumatology national centers in the near future.

Variables

The following variables will be collected from the Reuma.pt database:

- Demographic characteristics (age, gender, ethnicity, educational level)
- Diagnosis of rheumatic disease
- Disease duration
- Patient Reported Outcomes, measured by different instruments according to the diagnosis (table 1) *

Table 1. Patient Reported Outcomes available in Reuma.pt for each diagnosis.

PRO	RA	SpA	PsA	JIA	SSc	SLE	SjS	EA	AIS	Vasc	OA	Others
PGA (VAS)	X	X	X	X		X	X	X	X			X
Pain (VAS)	X			X				X	X			X
Nocturnal back pain (VAS)		X	X					X				
Total back pain (VAS)		X	X					X				
EQ-5D	X	X	X		X	X	X	X	X	X	X	X
HADS	X	X	X	X	X	X	X	X	X	X	X	X
SF36	X	X	X	X	X	X	X	X	X	X	X	X
FACIT	X	X	X	X	X	X	X	X	X	X	X	X
HAQ	X		X	X	X	X	X	X	X		X	X
CHAQ				X					X			X
SHAQ					X							
PsAQoL			X									
ASQoL		X										
BASDAI		X	X					X				X
BASFI		X	X									
UCLA SCTC GIT					X							
ESSPRI							X					
ESS							X					

PROFAD-SSI							X					
KOOS											X	
FIHOA											X	
HOOS											X	

RA, rheumatoid arthritis; SpA, spondyloarthritis; PsA, psoriatic arthritis; JIA, juvenile idiopathic arthritis; SSc, systemic sclerosis; SLE, systemic lupus erythematosus; SjS, Sjögren syndrome; EA, early arthritis; AIS, autoinflammatory syndrome; Vasc, vasculitis; OA, osteoarthritis.

- Participating center
- Portal through which the data was inserted in Reuma.pt (patient-portal or clinician-portal). Data entered through patient-portal presumes that patients inserted their own data, using electronic devices in the waiting room, outpatient department or at home. Data entered through clinician-portal presumes that the physician asked and manually entered the patient's responses.

*At the last visit before implementation of "PRO Reuma Initiative" and at 6 and 12 months after implementation.

Statistical Analysis

Statistical Package for Social Science (SPSS) version 23 will be used for analysis of data.

Categorical variables will be displayed as frequencies and percentages. Continuous variables will be presented as mean and standard deviation; or in case of skewed distribution as median and interquartile range.

Response rates before and after implementation of "PRO Reuma Initiative" will be compared using chi-square test or the Fisher's exact test when appropriate. T-test or Mann-Whitney U test will be used to compare PRO scores between patients who entered their own data and those patients whom data was inserted by the clinician. A *p* value of less than 0.05 indicates statistical significance. We will take into account potential confounders, such as the educational level, the type of joint involvement, extra-articular manifestations, the degree of disease activity or current therapies.

Expected size sample:

At the end of 2017, there were 18105 patients registered in Reuma.pt. All of them are potentially eligible for this study.

EXPECTED RESULTS AND LIMITATIONS:

We expect to confirm that the integration of new electronic devices in rheumatology services will increase PRO data collection in Reuma.pt and improve standard clinical care.

The main limitation regards the possibility of missing data, particularly on control variables. An effort will be done to collect and introduce missing data in Reuma.pt.

CALENDAR OF TASKS:

	June 2018	June 2019	January 2020
Data collection	✓		
Data analysis		✓	
Final report/ Abstracts submission • **CPR 2020** • **EULAR 2020**			✓

PROPONENT: Agna Neto - Rheumatology Department, Hospital Egas Moniz

RESEARCH TEAM: Agna Neto, Ana Filipa Mourão, Nathalie Madeira, Ricardo Figueira, Jaime Cunha Branco e Luís Cunha Miranda.

FUNDING AND CONFLICTS OF INTEREST

"PRO Reuma Initiave" is funded by Novartis. There are no conflicts of interest to declare.

REFERENCES:

1. U.S Department of Health and Human Services Food and Drug Administration Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. U.S. FDA, Clinical/Medical. 2009
2. Nelson EC, Eftimovska E et al. Patient reported outcome measures in practice. BMJ. 2015 Feb 10;350:g7818.
3. Fautrel B, Alten R et al. Call for action: how to improve use of patient-reported outcomes to guide clinical decision making in rheumatoid arthritis. Rheumatol Int. 2018 Jun;38(6):935-947.
4. Deshpande PR, Rajan S et al. Patient-reported outcomes: A new era in clinical research. Perspect Clin Res. 2011 Oct;2(4):137-44.

5. Gossec L[1], Dougados M[2], Dixon W. Patient-reported outcomes as end points in clinical trials in rheumatoid arthritis. RMD Open. 2015 Apr 2;1(1):e000019.
6. Van Tuyl LH, Boers M. Patient-reported outcomes in core domain sets for rheumatic diseases. Nat Rev Rheumatol. 2015 Dec;11(12):705-12.