A pilot trial of integrating the Patient-Reported Outcome Measurement Information System (PROMIS®) into rheumatology care

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Abstract

Objective

Utilising Patient-Reported Outcomes Measurement Information System (PROMIS®) questionnaires can enhance clinical care by measuring longitudinal changes in symptom severity as reported by the patient. The aim of this pilot study was to assess the feasibility and impact of incorporating PROMIS® questionnaires at the point-of-care in rheumatology practice.

Methods

Patients with rheumatic diseases and decrements in ≥1 PROMIS® domain (pain intensity, physical function, or sleep disturbance) were stratified by their concerning domain, then randomised to either receive an interpretation of their PROMIS® scores prior to their rheumatology appointment (Arm 1) or to usual care (Arm 2) (ClinicalTrials.gov ID: NCT05026853). The primary outcome was the documentation of PROMIS® scores in the electronic medical record (EMR). Secondary outcomes include recommendations made by physicians based on PROMIS® scores, patient-provider communication, and change in the most concerning PROMIS® domain score from baseline to 12 weeks.

Results

110 patients were enrolled. 55 were randomised to receive report cards (Arm 1), of which 46 received the report card, and 55 received usual care (Arm 2). Documentation of PROMIS® scores in the EMR was 50% higher in Arm 1 (12.7% in Arm 2, $p<0.0001$). More recommendations were made based on PROMIS® scores for Arm 1 patients. There was no significant difference in post-visit PROMIS® score improvement between Arm 1 and Arm 2.

Conclusion

Providing PROMIS® report cards to patients and healthcare providers increased score documentation in the EMR. Increased recommendations made based on PROMIS® scores in Arm 1 suggest that having a score interpretation might help direct medical decision-making.

Key words

quality of life, outcome assessment, arthritis, fibromyalgia, scleroderma and related disorders

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Received on April 15, 2024; accepted in revised form on August 24, 2024.

Competing interests: J. Lee is supported by the NIH/NIA (R03 AG067975 and K23 AG082727). D. Khanna is a consultant/advisor to AbbVie Inc., AstraZeneca, Amgen, Boehringer Ingelheim International GmbH, Bristol Myers Squibb, Janssen Global Services, LLC, Merck Pharma, Mitsubishi Tanabe Pharma, Zura Bio; and has received grant/research support from Amgen, Bristol Myers Squibb, Pfizer Inc. The other authors have declared no competing interests

Introduction

Rheumatic diseases (RD) are a leading cause of disability in the United States (US) with approximately 1 in 4 adults having an RD diagnosis (1). RD-related disability impacts an individuals' physical, mental, and emotional well-being (2). Patient-reported outcomes (PROs) are any reports of the status of a patient's health condition that comes directly from the patient, and they are used to measure various domains pertinent to RD. PROs can supplement clinical decision making by aiding assessment and management of conditions. There is increased enthusiasm within the rheumatology research community to integrate PRO measures with clinical assessments (3, 4).

In 2004, a cooperative group of the National Institutes of Health developed the Patient-Reported Outcomes Measurement Information System (PROMIS®) as a tool to measure Health Related Quality of Life (HRQoL) (5). PROMIS® utilises item response theory (IRT) in each domain, providing reliable instruments that can be administered as short forms and computerised adaptive tests (6). Scores are calculated as T-scores or scores on a scale depending on the domain. Whether a higher or lower score is preferable depends on the domain.

PROMIS® surveys are available to integrate into electronic medical records (EMRs) like Epic® (7). PROMIS® has been utilised in the general population and with different chronic diseases, including RDs. Much work in this field has focused on performance in observational studies and clinical trials where an improvement in underlying RD has led to improvement in PROMIS® scores (8, 9). Our team's previous work defined the relevant PROMIS® domains and identified meaningful cut-points for these domains in patients with RD using input from patients and physicians (9).

Our pilot trial aimed to assess the impact of incorporating PROMIS® questionnaires at point-of-care (POC) in a single academic centre rheumatology practice. From this, we aim to promote the review and discussion of PROs between patients and healthcare providers (HCPs).

Methods

Study overview

We performed a pilot clinical trial (ClinicalTrials.gov ID: NCT05026853) to assess if a PROMIS® report card (Fig. 1) will increase the documentation of PROs in the EMR, facilitate patient-physician communication, and improve patient self-reported health status. The trial is designated as pilot as the trial assessed the feasibility of incorporating PROMIS® score in clinics and to have data for the proposed outcome measures to design an appropriately powered trial. PROMIS® item banks for physical function, pain intensity, and sleep disturbance for patients with RD (9, 10). These were administered using the short form that was incorporated as part of the Epic® EMR. This study was approved by the Institutional Review Board at the University of Michigan (HUM00149448) on 21 August 2018.

Study design and population

Michigan Medicine rheumatology healthcare providers (HCPs) were approached to participate. Twenty HCPs (rheumatologists and allied health professionals) were approached at a clinic site and eight HCPs consented and participated. Eligible patients were at least 18 years of age, able to read and write English, diagnosed with any RD seen in rheumatology clinics, and had access to the internet and patient portal. No RD was excluded in this trial.

The study period was from October 2021 to May 2023. A list of patients under the care of the participating HCPs was generated from Epic® at least one month ahead of their office appointment. A recruitment email or text was sent to the patients approximately 3 weeks before their appointment with information about the trial, consent, and an optional demographics survey. Responses were populated using REDCap electronic data capture. After consenting to enroll in the study, patients were asked to complete PROMIS® surveys in their patient portal. If PROMIS® surveys were not completed, patients were sent up to 3 reminders.

Eligible patients needed ≥1 concerning score in the 3 PROMIS® domains: pain (score ≥5 on 0–10 scale), physical func-

Guide for interpreting PROMIS® scores

	PROMIS® pain intensity	PROMIS® physical function	PROMIS® sleep disturbance
Higher score means...	More pain	Better physical function	Worse sleep
Discuss options for addressing symptoms when...	Score ≥ 5	Score ≤ 40	Score ≥ 60

Domain	Interpretation
Pain intensity	A higher score denotes more pain intensity. A score of greater than or equal to 5 is suggestive of moderate-to-severe pain. Consider evaluating the cause(s) of the ongoing pain and management of pain (including pharmacologic and non-pharmacologic management and appropriate referral).
Physical function	The mean score for the US general population is 50. A higher score denotes a better physical function. A score of less than or equal to 40 is suggestive of moderate-to-severe limitation in physical function. Consider optimizing therapy (such as PT or change in medication) or reevaluation at follow up visit.
Sleep disturbance	The mean score for the US general population is 50. A higher score denotes worse sleep disturbance. A score of greater than or equal to 60 is suggestive of moderate-to-severe impact in their sleep quality. Consider optimizing therapy (such as referral to sleep medicine), counseling about sleep hygiene, or reevaluation at follow up visit.

Patient name: [PATIENT'S LAST NAME, PATIENT'S FIRST NAME]
MRN: [PATIENT'S MRN]
Upcoming appointment at: [MONTH DATE, YEAR, TIME]

PROMIS® domains	Appointments	
	[mm/dd/yy]	[mm/dd/yy]
Pain intensity	3.0	2.0
Physical function	40.0*	48.0
Sleep disturbance	53.0	49.0
*Starred scores are in the concerning zone [red highlight section on the graph]—consider discussing symptoms and options for addressing symptoms with the patient.		

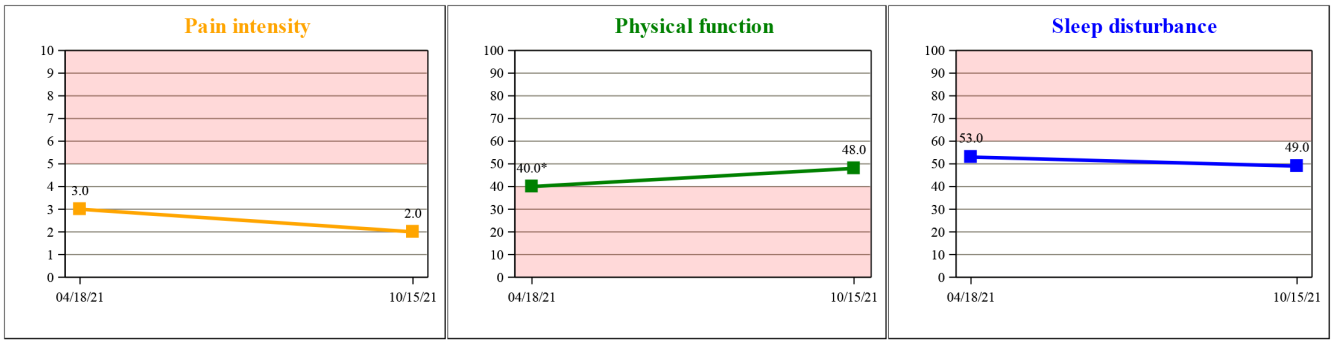

Fig. 1. Scorecard example for patients and health care providers.
The first table in this interpretation provides an explanation of concerning score cut-offs. The second table provides details on how to interpret scores. The third table provides the patient's most recent PROMIS® scores.

tion (T-score ≤40, ≥1 standard deviation worse than the US general population), or sleep disturbance (T-score ≥60, ≥1 standard deviation worse than the US general population). These cut-points were considered clinically meaningful based on our previous work (9). Eligible patients were stratified into their concerning PROMIS® domain. Patients with ≥1 concerning score were stratified into the domain they ranked most impactful on their screening survey. We used a permuted block randomisation scheme stratified by the most concerning PRO domain to determine which arm the patient would enter with equal probability in both arms.

Arm 1 patients received a report card, as did their HCP the day before their appointment. The report card included a PROMIS® score interpretation, scores from their last 3 rheumatology appointments at which they completed the scores, and a graphical, longitudinal representation of these scores (Fig. 1). Arm 2 patients did not receive a report card, nor did their HCP, and they attended their appointment as usual. Patients in both arms received an Interpersonal Processes of Care (IPC) survey 2 weeks after their appointment. The IPC assesses patient satisfaction with their physician clinic visit and measures 7 subscales: hurried communication, elicited concerns/responses, explained results/medications, patient-

centered decision making, compassion, discrimination, and disrespectful office staff (11). Patients repeated PROMIS® surveys at the 12-week time point to determine changes in PROMIS® scores. Recruitment was active for 18 months. There was no sample size calculation for this study due to lack of published data for estimating appropriate sample size. Participants included were of a convenience sample.

Data, such as any medication or dosage changes, recommendations made (including referrals), and labs ordered, was manually extracted from the HCPs' EMR note. Study team members searched for any indication in the EMR note of PROMIS® scores being the source of recommendations. PROMIS® scores were easily auto populated by HCPs in the EMR note through the use of a phrase. The data was extracted from the assessment/plan of the EMR note. Recommendations made based on PROMIS® scores were defined as those in which the physician directly stated in the EMR note that the recommendations were made based on PROMIS® scores.

Primary and secondary outcomes

Choice of primary and secondary outcomes was influenced by the work of Greenhalgh *et al*. who theorised the lack of impact of PROs in the provider's clinical decision-making (12). We postulated that providing the PROMIS® scores to patients and HCPs at the POC will give patients an opportunity to discuss their concerning symptoms with their HCPs and be actively involved in decisions about medications and treatments. The first step in improving patient outcomes is documenting these scores in the EMR and capturing associated recommendations to improve the health. The primary outcome measure was the percentage of appointments at which PROMIS® scores were documented in the EMR note by the participating HCP. Secondary outcome measures included: the percentage of appointments at which a recommendation related to the PROMIS® score was documented in the EMR note by the participating HCP, patient-provider communication as analysed by the IPC survey and change in the most concerning PROMIS® domain score from baseline to 12 weeks. We also analysed types of recommendations made based on the PROMIS® scores and the change in all PROMIS® scores from baseline to 12 weeks between Arm 1 and Arm 2.

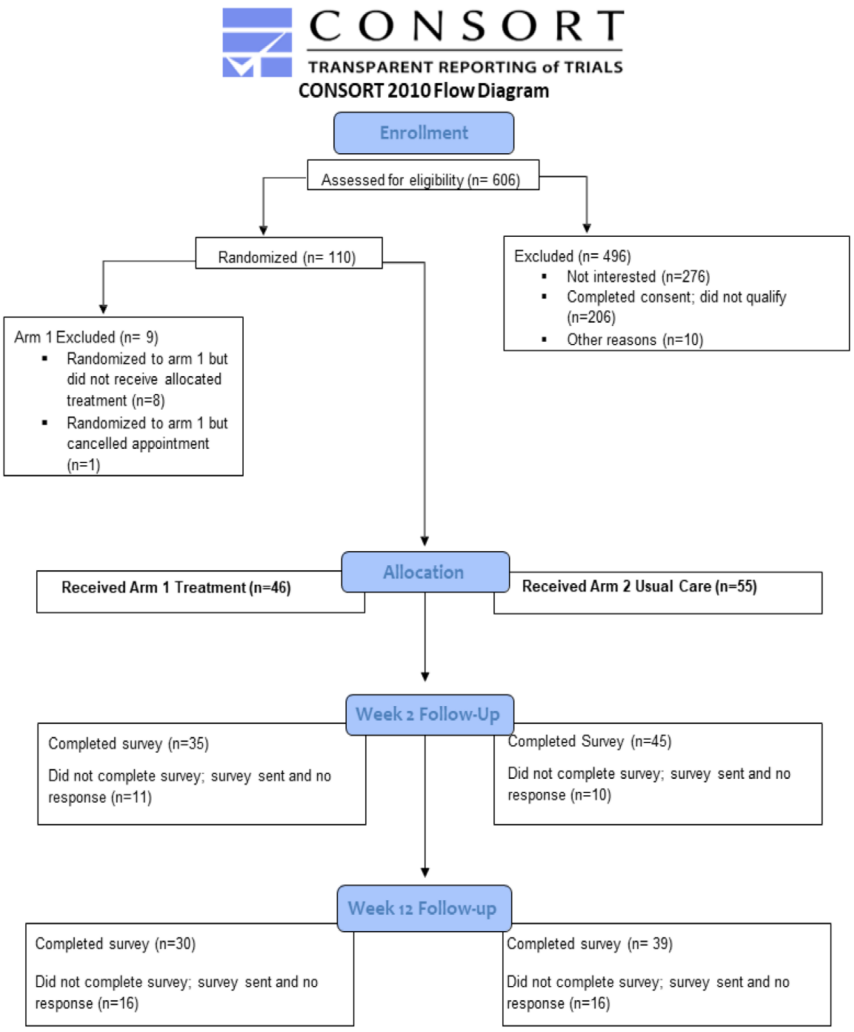

Fig. 2. Consort diagram for patients in the trial.

Statistical analyses

Demographic and baseline characteristics, primary, secondary, and survey outcome measures were summarised by the treatment arm. The scaled score of 0–10 for the pain intensity PROMIS® domain and T-scores for the physical function and sleep disturbance domains were calculated at baseline and 12 week follow-up. Median with 1st and 3rd quartiles were reported for numeric IPC survey data; mean and standard deviation were reported for other numeric variables. Count and percentage were reported for categorical variables. T-test was performed for numeric outcome measures that followed a normal distribution, and the Wilcoxon rank sum test was performed for numeric outcome measures that did not follow a normal distribution. A Wald chi-square test was performed for categorical outcome measures. Normality of the data visually was determined using histograms and QQ plots, no formal statistical testing was performed to assess this.

Results

Figure 2 summarises the patients assessed for this trial (CONSORT diagram). 606 patients responded to recruitment surveys and were assessed for eligibility. Of these, 496 were excluded from participation and 110 patients were randomised into either Arm 1 treatment (n=55) or Arm 2 usual care

Table I. Baseline characteristics of patients.
Arm 1 patients received PROMIS® report cards prior to their rheumatology appointment. Arm 2 received usual care.

Category	Overall n=101	Arm 1 n=46	Arm 2 n=55
Age in year, mean (SD)	54.0 (14.5)	52.5 (14.9)	55.2 (14.3)
Female, n (%)	78 (77.2%)	39 (84.8%)	39 (70.9%)
Race, n (%)			
Caucasian/White, not Hispanic	82 (81.2%)	36 (78.3%)	46 (83.6%)
Type of rheumatic disease(s), n (%)			
Rheumatoid arthritis	40 (39.6%)	20 (43.5%)	20 (36.4%)
Fibromyalgia	26 (25.7%)	14 (30.4%)	12 (21.8%)
Osteoarthritis	25 (24.8%)	15 (32.6%)	10 (18.2%)
Seronegative spondylarthritis	23 (22.8%)	9 (19.5%)	14 (25.5%)
Sjögren's syndrome	15 (14.9%)	5 (10.9%)	10 (18.2%)
Scleroderma/systemic sclerosis	13 (12.9%)	8 (17.4%)	5 (9.1%)
Systemic lupus erythematosus	11 (10.9%)	5 (10.9%)	6 (10.9%)
Gout	7 (6.9%)	3 (6.5%)	4 (7.3%)
Polymyalgia rheumatica/vasculitis	4 (4.0%)	1 (2.2%)	3 (5.4%)
Other rheumatic conditions	25 (24.8%)	16 (34.8%)	9 (16.4%)
PROMIS® scores, mean (SD)			
Pain intensity^{-}	5.3 (1.9)	5.2 (1.8)	5.5 (2.1)
Physical function^{+}	37.9 (6.6)	38.2 (7.0)	37.7 (6.3)
Sleep disturbance^{-}	57.6 (8.4)	58.2 (7.4)	57.1 (9.2)

Some patients advocated >1 diagnosis.
$^{+}$ indicates higher score is better; $^{-}$ indicates lower score is better; SD: standard deviation.

Table II. Primary and secondary outcome measures in the trial.
Arm 1 patients received PROMIS® report cards prior to their rheumatology appointment. Arm 2 received usual care.

	Overall n=101	Arm 1 n=46	Arm 2 n=55	*p*-value
Primary outcome measures				
PROMIS® scores documented in EMR	30 (29.7%)	23 (50.0%)	7 (12.7%)	**<0.001**
Secondary outcome measures				
Overall recommendations	79 (78.2%)	38 (82.6%)	41 (74.5%)	0.328
Recommendations related to PROMIS® scores documented in EMR by HCP	23 (22.8%)	17 (37.0%)	6 (10.9%)	**0.002**
Difference in PROMIS® scores 12 weeks after appointment, mean (SD)				
Pain Intensity, n=69	-0.2 (2.2)	-0.1 (2.0)	-0.2 (2.4)	0.893
Physical function, n=67	0.0 (5.1)	-0.3 (3.2)	0.2 (6.1)	0.688
Sleep disturbance, n=67	-0.9 (7.0)	-0.6 (6.7)	-1.0 (7.3)	0.803
Difference in most concerning PROMIS® score 12 weeks after appointment, mean (SD)				
Pain intensity^{-}, n=21	-1.0 (2.4)	-1.1 (2.5)	-0.9 (2.4)	0.571
Physical function^{+}, n=33	0.5 (4.1)	-0.5 (2.6)	1.1 (4.8)	0.228
Sleep disturbance^{-}, n=14	-3.0 (6.3)	-2.8 (6.6)	-3.3 (6.4)	1.000

$^{+}$ indicates higher score is better; $^{-}$ indicates lower score is better; SD: standard deviation,

(n=55). Of the 55 patients randomised to Arm 1, 46 received the allocated treatment (report card); 8 patients did not receive the allocated treatment due to technical issues with the programme generating the report card, and 1 patient cancelled their rheumatology appointment. Of those in Arm 2, 55 received their usual care. Table I summarises the baseline characteristics of these patients. The average age was 53.5 years, majority were women, and the mean physical function, sleep disturbances, and pain intensity scores at baseline were 37.9, 57.6, 5.3, respectively.

Table II summarises the primary and secondary outcome measures. The proportion of documented PROs in the EMR was significantly higher in Arm 1 (50%) than in Arm 2 (12.7%), $p<0.0001$. There was no difference in the overall percentage of appointments at which recommendations were made. However, in Arm 1, there was a statistically significant increase in recommendations made based on the PROMIS® scores at 37% *versus* recommendations based on PROMIS® scores in Arm 2 at 10.9%. There were no significant differences in patient-provider communication as measured by the IPC and percentage of patients who received a medication change, recommendations, or new labs ordered between Arm 1 and Arm 2 (Table III and online Supplementary Table S1).

There was improvement in scores of the pain intensity and sleep disturbance PROMIS® domains 12 weeks after their rheumatology appointment, but this was not a significant difference. There was no overall change in the physical function domain score 12 weeks after their appointment, though there was a slight, non-significant improvement in physical function score for Arm 1 patients. We compared the PROMIS® scores for the 3 most common RDs-rheumatoid arthritis, fibromyalgia, and osteoarthritis. The average baseline scores and changed scores for the total PROMIS® scores and most concerning scores were similar between the 3 groups (Table IV).

Discussion

Our pilot trial showed that integrating PROMIS® scores during POC increased PRO score documentation in the EMR and recommendations based on scores. This did not result in improved PRO scores at week 12 or patient-physician communication. Our findings are consistent with results from previous studies integrating PROMIS® measures into clinical practice (8).

Similar to the study on PROMIS® Integration in Rheumatoid Arthritis (RA) patients (13), our results indicate PROMIS® integration might influence treatment decisions. In the study made by Greene *et al*., 119 RA patients selected one of five PROMIS® domains as the most impactful. This was entered into the patient's EMR with a summary report of PROMIS® scores. The study demonstrated improvement in CDAI

Table III. Recommendations made at in person clinic appointments.

Characteristic Statistic or category	Overall n=101	Arm 1 n=46	Arm 2 n=55	*p*-value
Medication change or dosage increase, n (%), n=101				
Yes	56 (55.4%)	24 (52.2%)	32 (58.2%)	0.545
No	45 (44.6%)	22 (47.8%)	23 (41.8%)	
Referral or recommendations, n (%), n=101				
Yes	27 (26.7%)	13 (28.3%)	14 (25.5%)	0.751
No	74 (73.3%)	33 (71.7%)	41 (74.5%)	
Labs ordered, n (%), n=101				
Yes	16 (15.8%)	6 (13.0%)	10 (18.2%)	0.481
No	85 (84.2%)	40 (87.0%)	45 (81.8%)	

Arm 1 patients received PROMIS® report cards prior to their rheumatology appointment. Arm 2 received usual care.

Table IV. Primary and secondary outcome measures by disease subtype.

Characteristic Statistic or category	Overall n=101	Rheumatoid arthritis n=40	Fibromyalgia n=26	Osteoarthritis n=25
Pain Score at randomisation, mean (SD)	5.3 (1.9)	5.9 (2.0)	5.7 (1.4)	5.5 (1.8)
Physical Function Score at randomisation, mean (SD)	37.9 (6.6)	36.3 (5.7)	35.1 (4.2)	36.4 (7.2)
Sleep Score at randomisation, mean (SD)	57.6 (8.4)	59.1 (7.3)	57.9 (6.1)	57.0 (6.8)
Endpoint				
Primary outcome measure				
PROMIS® scores documented in EMR	30 (29.7%)	13 (32.5%)	10 (38.5%)	10 (40.0%)
Secondary outcome measures				
Difference in PROMIS® scores 12 weeks after appointment, mean (SD)				
Pain intensity⁻	-0.2 (2.2) n=69	0.1 (2.0) n=28	0.3 (1.3) n=16	0.6 (1.9) n=18
Physical function⁺	0.0 (5.1) n=67	-0.0 (3.1) n=27	0.1 (2.6) n=16	-0.8 (4.3) n=17
Sleep disturbance⁻	-0.9 (7.0) n=67	-0.3 (7.0) n=27	-2.1 (5.6) n=16	-1.2 (6.1) n=17
Difference in most concerning PROMIS® score 12 weeks after appointment, mean (SD)				
Pain intensity	-1.0 (2.4) n=21	-0.2 (1.9) n=10	0.3 (1.0) n=8	0.0 (1.6) n=4
Physical function⁺	0.5 (4.1) n=33	-0.2 (2.6) n=15	0.1 (1.3) n=6	-1.3 (5.0) n=10
Sleep disturbance⁻	-3.0 (6.3) n=14	-2.0 (11.4) n=3	-3.9 (4.0) n=2	-4.3 (5.8) n=4

⁺ indicates higher score is better; ⁻ indicates lower score is better; SD: standard deviation.

score one year after baseline which correlated with PROMIS® score improvement (13). Our investigation of the documentation of PROMIS® scores in the EMR, as well as referrals or recommendations based on PROMIS®scores was novel to this study, warranting further studies into the influence on PROMIS® score interpretations on medical decision making.

There are complexities to the application of PROs in clinical practice (14). PRO implementation could have various effects: influencing patient health behaviours, detecting unrecognised problems, supporting discussions of PROs between patients and HCPs, and aiding HCPs in monitoring patients' health. These factors contribute to the intermediate processes that occur before we can see improvement in the distal outcome of patient health status or quality of life. Our results demonstrating an improvement in documentation of PRO scores in the EMR is a positive proximal outcome. This is a necessary step to reach the distal outcome of improving patients' outcomes.

Our study has several strengths. We started our iterative process a decade ago by determining the PROMIS® domains that are important to patients with RDs, calculating the meaningful cut points, and incorporating PROMIS®scores in the EMR (15). Second, we focused on patients with at least one concerning score as we postulated that this would be meaningful to both patients and physicians and would lead to a recommendation (such as change in therapy or referral).

There were some limitations to this study. As expected in a pilot trial, there were some technical issues with generating the report cards initially, causing lost potential data. Since the surveys patients completed were online, this increased our patients lost to follow-up despite reminders to complete the surveys, increasing the attrition bias. We assessed whether any recommendations were made at the time of the patient's rheumatology appointment, and whether recommendations were made based on PROMIS® scores. Some recommendations may have been made based on PROMIS® scores, even if those scores were not reported in the EMR note. Recommendations may have also been made without the HCPs directly stating the scores were the reason. The recommendations could have been based on the overall assessment of the patient where PROMIS® scores could have been factored but were not the sole influencers on the decision to make a recommendation. Consequently, the percentage of recommendations made based on PROMIS® scores could be higher than is reported in the data. In the future, this could be resolved by sending providers a short post-appointment survey asking this. The participants were also a self-selected group of patients which were limited to those that speak English and were comfortable utilising technology to complete the consent and surveys that were delivered via email or text.

This study contained a large number of different RDs, as our goal was to assess the feasibility of PROMIS® report

card in general rheumatology practice. Future research should be conducted to better understand the effectiveness of integrating PROMIS® scores into rheumatology care based on specific RD diagnosis. As an example, in a study assessing PRO incorporation in patients with systemic lupus erythematosus (SLE), the results indicated a gap between patient and clinician disease concerns (16). Clinicians were more concerned with preventing organ failure, while patients were more concerned with managing symptoms.

Utilisation of PRO score interpretations in clinics may improve the PROMIS® score documentation by HCPs in the patients' EMR. Further research is needed on how this influences patient health status. Perhaps 12 weeks post-appointment is not enough time to see an improvement in patients' health status. In the realm of longitudinal care as with RDs, PRO completion by patients and interpretation by the HCPs is a conditioning process that can influence patient and provider behaviour. A future study with a longer duration of follow-up will provide more data points on PROs and PRO-influenced HCP decision making to understand the impact on health. We found no differences in the IPC domains; both groups had high scores in patient-physician communication, as seen in a previous trial (17).

Incorporation of the PROMIS® scores at rheumatology POC can allow for HCPs to better monitor the impact of each PROMIS® domain on patients' lives longitudinally. Tabular and graphical displays of longitudinal PROMIS® scores are readily available for HCP use in EMR notes at Michigan Medicine. By educating providers on the availability of this tool and clinical interpretation of these scores, we may be able to improve utilisation and documentation of PROMIS® scores, as well as medical decision-making based on PROs.

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