

Does patient-reported outcome measures use at new foot and ankle patient clinic visits improve patient activation, experience, and satisfaction?

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Abstract

Background: Patient-reported outcome measures (PROMs) can help predict clinical outcomes and improve shared clinical decision-making discussions. There remains a paucity of research assessing how the use of PROMs may drive improved patient experience and patient activation.

Methods: New foot and ankle patients completed PROMIS physical function (PF), pain interference (PI), and depression assessments. Patients were then randomized to viewing and discussing their PROMIS scores with their surgeon or not. Following the clinic visit, patients completed a series of Clinician & Group Survey—Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) questions and the Patient Activation Measure (PAM). Responses to the CG-CAHPS questions and PAM were compared between the 2 groups and after clustering on surgeon. Potential interaction effects by social deprivation were also explored.

Results: After enrolling patients but removing those lost to follow-up or with missing data, 97 and 116 patients remained in the intervention control cohorts, respectively. No difference was found in CG-CAHPS responses nor PAM scores between the 2 groups (P > .05). All surgeons were highly rated by all patients. When clustered by surgeon, intervention subjects were less likely to indicate "top box" scores for the understanding domain of the CG-CAHPS question (OR 0.51, P < .001) and had decreased odds of high patient activation compared to control subjects (OR 0.67; P = .005). Among the most socially disadvantaged patients, there was no difference in control and intervention subjects in their likelihood of having high patient activation (P = .09).

Conclusion: Highly rated foot and ankle surgeons who show and discuss PROM results may not improve patient experience or activation and may, in fact, decrease understanding or patient activation in select populations. Future work is needed to determine when PROM discussions are most beneficial and how best to present PROMs data, as we suspect that how the information was presented—and not the use of PROMs—resulted in our findings. Health literacy tools and/ or communication training may better engage different patient groups regarding PROMs.

Level of Evidence: Level I, randomized controlled trial.

Experience, and Satisfaction?

Keywords: patient experience, satisfaction, activation, Patient Activation Measure, PROMIS, PROMs, patient-reported outcome measures, value-based health care

Introduction

There is an ongoing paradigm change in health care with the focus shifting from quantity to quality of care delivered. The ultimate goal is to increase health care value – defined as health outcomes achieved per dollar spent.²⁰ Patient-reported outcome measures (PROMs) are one way to provide patients with a greater voice in their own health care

and help improve the value of care delivered by accurately and robustly capturing what is most important to patients (eg, functional status, pain). With this understanding, there is a growing call for surgeons to continue to implement PROMs into day-to-day practice.^{3,19}

The clinical benefits of routine PROM collection and use continues to be better understood as research progresses. PROMs have been shown to be of substantial value in

assessing patients with a variety of foot and ankle conditions,⁶ including in better understanding those patients who may or may not clinically improve with surgical intervention.^{2,14} In addition to strengthening clinical research, PROMs can help assess clinical outcomes and alert surgeons to patients who may be struggling from a functional, pain, or mental health standpoint, for example. However, there remains a paucity of research assessing how the collection and use of PROMs may drive improved patient experience, well-being, and a patient's willingness to "take control" of their own care at a higher level. One retrospective, single-center study demonstrated that PROM use during an orthopaedic surgery clinic visit may lead to an improved patient experience, as measured by Clinician & Group Survey–Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS).5 Another study highlighted that patient activation—or willingness to "take control" of one's own health—can improve with interventions focused on confidence, for example, which, in turn, can lead to improved clinical outcomes. 10 Discussing PROMs with patients could help boost patient understanding and confidence in their health, though this relationship and then its association with patient activation have yet to be studied. Further, it is well documented that disparities exist in patient activation, 11 so understanding whether PROM use and discussion can help address this is worthy of investigation. The limited literature in this area highlights the need for a robust, prospective study that assesses whether the routine use and discussion of PROMs can act as a catalyst to improve the patient experience and become an intervention that improves patient activation, including across sociodemographic factors.

In this randomized, controlled trial (RCT) study, we had 3 objectives: (1) to determine if the active use and discussion of PROM scores during new patient visits are associated with patient satisfaction and experience; (2) to determine if the active use and discussion of PROM scores during new patient clinic visits are associated with patient activation; and (3) to determine if the objectives 1 and 2 differ based on surgeon or sociodemographic factors.

Materials and Methods

This Institutional Review Board (IRB)–approved singled-masked RCT was registered prior to data collection on ClinicalTrials.gov (*NCT04654910*).

Between February 24, 2021, and April 11, 2022, consecutive new patients presenting to a single academic medical

center foot and ankle clinic to be evaluated by one of 3 foot and ankle fellowship-trained, board-certified orthopaedic surgeons were approached for inclusion in the study. Regardless of study participation, Patient-Reported Outcome Measurement Information System (PROMIS) physical function, pain interference, and depression computerized adaptive tests were completed as part of routine clinical care at our institution at their initial visit. Each questionnaire typically takes about 1 minute or less to complete. Developed with support from the United States National Institutes of Health, the PROMIS is a validated, general health status PROM that utilizes item response theory (IRT) as part of a computerized adaptive test. Historically, PROMIS is one of the preferred PROMs within foot and ankle surgery.

Patients who agreed to participate completed an informed consent process. Clinical research coordinators not directly involved in patient care then randomized the patients, alerting the surgeon prior to entering the examination room whether he or she should view on the computer screen in the electronic health record (EHR) and discuss the patient's PROMs using a preset standard script (Appendix 1) or whether he or she should not view and discuss the patient's PROM data with the patient. At the conclusion of the clinic encounter, patients were asked to complete the CG-CAHPS and PAM questionnaires. These are validated measures of patient experience¹ and patient activation, ^{12,13} respectively. The CG-CAHPS questionnaires were developed through the Agency for Healthcare Research and Quality.1 In this study, the specific CG-CAHPS questions of interest focused on surgeon listening ability, surgeon respect, feeling of surgeon time taken during the encounter, and whether patients felt they understood what was discussed during the encounter. There was also a question asking to rate the surgeon overall. The specific questions asked can be seen in Appendix 2. Patients were grouped based on whether they selected the "top box" (ie, highest possible positive rating) or "below the top box." This method of reporting CG-CAHPS results has been shown to be appropriate in research conduct by the Robert Wood Johnson Foundation.²¹ PAM scores were determined using the methodology developed by Insignia Health, 16 which takes the raw PAM scores out of 100 and categorizes patients into one of 4 activation groups. Thus, PAM score was assessed by both mean (out of 100 possible points) and by comparing proportions of patients who answered the PAM questions suggestive of poor activation (1 or 2) or high activation (3 or 4).

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Bernstein et al 483

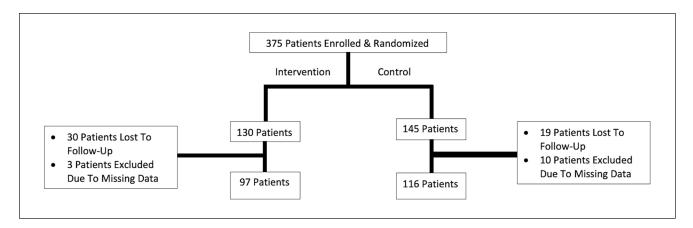


Figure 1. CONSORT flow diagram outlining participant flow through each stage of the randomized, controlled trial.

Patient sociodemographic information was recorded, including state and national level area deprivation index (ADI) scores; these scores represent sociodemographic disadvantage at the Census Block Group neighborhood level.¹⁷ Proportions and scores were compared between the intervention and control groups overall and stratified for surgeon and sociodemographic factors, such as ADI. Student t tests and chi-square tests, using Fisher exact test when indicated, were used for all stratified analyses. Potential interaction effects were evaluated using the Breslow Day Test of Homogeneity. Because the surgeon was responsible for discussing the PROMIS results with the patient for those who were assigned to the treatment group, we accounted for potential correlated data due to individual variability in practice style. To do this, we used generalized estimating equation regression models clustering on individual surgeon using an exchangeable correlation matrix. This approach addresses any potential differential delivery of the intervention across the surgeons in the study.

The sample size was determined based on testing for mean differences on the PAM scores between the intervention and control groups. We estimated that the sample mean on the PAM was 56 with an SD of 12.9 and a range of 16.5 to 100. Assuming a mean score of 56 in the control group, and a meaningful clinical difference of 5 scaled score points, 105 subjects per group were required to address our primary research hypothesis with 80% power and a 5% type I error rate. Given this sample size, we are able to detect a 9% difference in scores or larger on the communication question of the CG CAHPS with 80% power and a type I error rate of 5%. Further, because of concerns of missing data and potential attrition over the follow-up period, we set an a priori goal to oversample by 20%. This resulted in a final target sample size of 252 subjects. Significance was set at P < .05.

Results

In total, 375 patients were enrolled and randomized over the study timeframe, with 130 in the intervention group and

145 in the control group. After accounting for those lost to follow-up or with missing data, 97 patients remained in the intervention cohort and 116 patients in the control cohort (Figure 1). Thus, despite oversampling as designed, we were slightly underpowered. Nonetheless, there was no difference in baseline patient characteristics between the 2 groups (Table 1), suggesting that our randomization process balanced potential confounders between intervention and control groups.

We found that the active use and discussion of PROM scores during new patient visits led to no difference in patient experience (as measured by 5 CG-CAHPS questions) between patients in the intervention vs control groups (all comparisons, P > .05) (Table 2). When clustered by surgeon, intervention subjects were less likely to indicate "top box" scores for the understanding domain of the CG-CAHPS questions (OR 0.51, 95% CI 0.36-0.71, P < .001) (Table 3). There were no significant differences in the other CG-CAHPS questions after clustering on individual surgeon.

We found that the active use and discussion of PROM scores during new patient visits led to no difference in patient activation (as measured by PAM scores) between the 2 groups (intervention: 70.99 [SD: 15.35] vs 72.38 [SD: 14.84], P=.50). Among intervention subjects, 82 (85%) were classified at a PAM level of 3 or 4 compared with 105 (91%) of control subjects (P=.34) (Table 2).

When clustered according to individual surgeon, subjects randomized to the intervention had decreased odds of achieving a PAM score of 3 or 4 when compared to control subjects (OR 0.67, 95% CI 0.51-0.88; P=.005) (Table 3). There was evidence of a potential interaction effect by social deprivation, but this did not reach statistical significance (P=.19). Among patients whose ADI national percentile was below the 50th percentile (ie, patients with lesser disadvantage), there was a similar percentage of subjects whose PAM score was either a 3 or 4 among intervention and control subjects (85.37% vs 85.00%; P=.96) (Figure 2). Among patients whose ADI national percentile was above the 50th percentile (ie, patients with greater

Table 1. Comparison of Patient Characteristics by Control and Intervention Groups.

	Control (n=117) n (%) or Mean (SD)	Intervention (n=96) n (%) or Mean (SD)	P Value
Sex			.71
Male	35 (29.91)	31 (32.29)	
Female	82 (70.09)	65 (67.71)	
Race			.51
White	114 (97.44)	92 (95.83)	
Other Race	3 (2.56)	4 (4.17)	
Ethnicity	, ,	, ,	.25
Hispanic	4 (3.42)	I (I.04)	
Non-Hispanic	113 (96.58)	95 (98.96)	
Education level	, ,	, ,	.44
College degree or higher	71 (60.68)	58 (60.42)	
Some college or less	46 (39.32)	38 (39.58)	
State Area Deprivation Index	, ,	, ,	.97
High deprivation (8-10)	71 (60.34)	58 (60.82)	
Low deprivation (≤7)	46 (39.66)	38 (39.18)	
National Area Deprivation Index	, ,	, ,	.21
High deprivation	57 (48.72)	55 (57.29)	
Low deprivation	60 (51.28)	41 (42.71)	
Age, y, mean (SD)	56.79 (13.85)	55.83 (14.38)	.62
PROMIS pain interference, mean (SD)	58.03 (6.92)	57.70 (7.43)	.73
PROMIS physical function	43.27 (7.59)	43.16 (7.82)	.91
PROMIS depression	47.81 (8.57)	47.82 (8.98)	.99

Abbreviation: PROMIS, Patient-Reported Outcome Measurement Information System.

disadvantage), intervention subjects were not more or less likely to have a PAM score of 3 or 4 compared to controls (85.45% vs 94.74%; P=.09) (Figure 2).

Discussion

PROMs are becoming an integral part of clinical care across orthopaedic surgery, In fact, the US Centers for Medicare & Medicaid Services (CMS) has begun to require routine PROMs collection as part of alternative payment models for total hip arthroplasty (THA) and total knee arthroplasty (TKA).¹⁸ Although these instruments provide patients a greater say in how they feel a treatment has affected their health, the benefit of PROMs from a patient experience and activation standpoint has not been well understood. In the present study, we found that the discussion of PROMs in the foot and ankle surgery clinic setting did not improve the patient experience, nor did it increase patient activation overall. However, surprisingly, when clustering by surgeon (ie, within surgeon variability), patients who had the PROMs discussed were less likely to understand their surgeon and less likely to have high patient activation. This may be related to the concept that there can be too much information (or too many choices), which can lead to

decreased satisfaction²³; perhaps it also leads to more confusion, not clarity, as well. Further, we found the most socially deprived patients in our sample who were randomized to viewing and discussing their PROM results had lower patient activation compared to those who were less socially deprived, though this did not reach statistical significance. Important to add, all patient groups assessed their providers highly. Unfortunately, however, our sample size was too small to cluster by both surgeon and social deprivation simultaneously, limiting our ability to definitively state the role of social determinants of health factors on our study outcomes, though we suspect these may play a critical role. Ultimately, we believe our findings reflect the need for altered presentations of the data or specific training for health literacy or communication to better engage different patient groups, though we acknowledge further research is needed.

The fact that our study did not show a significant relationship between showing and discussing PROMs data with patients and CG-CAHPs overall does run contrary to a larger, albeit retrospective, study that examined this question across all orthopaedic surgery subspecialties. However, a retrospective study on this topic is fraught with bias, including indication bias, 22 that cannot be adequately

Bernstein et al 485

Table 2. Comparison of CG-CAHPS and PAM Scores Between Control and Intervention Patient Groups.

	Control (n=117) n (%)	Intervention (n=96) n (%)	P Value
PAM			.34
I or 2	12 (10.26)	14 (14.58)	
3 or 4	105 (89.74)	82 (85.42)	
CG-CAHPS	, ,	, ,	
Understand			.08
Top box	104 (88.89)	77 (80.21)	
Below top box	13 (Ì1.11)	19 (19.79)	
Respect			.35
Top box	107 (91.45)	84 (87.50)	
Below top box	10 (8.55)	12 (12.50)	
Listen			
Top box	100 (85.47)	80 (83.33)	.67
Below top box	17 (14.53)	16 (16.67)	
Time			.49
Top box	97 (82.91)	76 (79.17)	
Below top box	20 (17.09)	20 (20.83)	
Provider	. ,	, ,	.73
Top box	107 (91.45)	89 (92.71)	
Below top box	10 (8.55)	7 (7.29)	

Abbreviations: CG-CAHPS, Clinician & Group Survey-Consumer Assessment of Healthcare Providers and Systems; PAM, Patient Activation Measure.

Table 3. Effect of Intervention vs Control on PAM and CG-CAHPS Clustering by Surgeon.

	OR	95% CI	P Value
PAM	0.67	(0.51, 0.88)	.005
CG-CAHPS		,	
Understand	0.51	(0.36, 0.71)	<.001
Listen	0.87	(0.53, 1.42)	.56
Time	0.80	(0.47, 1.37)	.42
Respect	0.66	(0.31, 1.39)	.27
Overall Provider	1.13	(0.61, 2.09)	.70

Abbreviations: CG-CAHPS, Clinician & Group Survey—Consumer Assessment of Healthcare Providers and Systems; OR, odds ratio; PAM, Patient Activation Measure.

controlled for in an appropriate manner. Indeed, the patients in the larger retrospective study likely had a factor that led to the discussion of (or lack of discussion of) PROMs in the clinic. Although it is certainly possible that the findings in this study are accurate and would be the same if repeated with larger numbers, we would caution readers of taking that conclusion for granted because of a couple of key reasons. The high patient ratings of included surgeons at baseline (ie, greater than 90% of patients marking the "top box") makes it incredibly challenging to appreciate any small

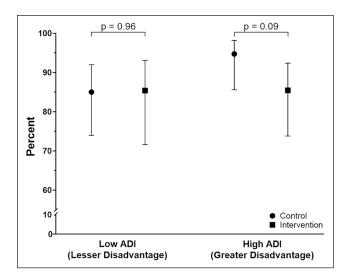


Figure 2. An illustration of the effect of the intervention on Patient Activation Measure (PAM) stratified by Area Deprivation Index (ADI). The *y* axis represents the percentage of subjects whose PAM score was either a 3 or 4, whereas the *x* axis groups patients by low ADI and high ADI.

difference in ratings at the extremes with any intervention. This is true unless a very large number of patients is utilized, and the study is powered to appreciate such a small difference. Thus, there appears to be a ceilinglike effect that is being appreciated in which differences, while they may exist, are not captured. Thus, further research is warranted to determine whether routine PROM collection and use by surgeons rated lower by patients has a positive impact on improving the patient experience and their subsequent activation level. However, our work does show that when clustered by surgeon, the discussion of PROMs may actually decrease the odds of patient understanding. One limitation of this finding is that we were underpowered to evaluate the interaction effect by social deprivation in our multivariable model clustering by surgeon. Results from our stratified analyses suggest there may be differential effect of our intervention based on ADI. Among patients classified as having less social deprivation, there was no difference in the percentage of patients achieving high PAM scores between intervention and control groups, but among patients classified as having more social deprivation, our data suggests those randomized to the intervention group less frequently achieved high PAM scores compared to controls. Our sample size calculation was based on the primary effect, and we did not have adequate sample size to formally test the interaction. Nevertheless, despite being underpowered, the directionality of our findings can provide preliminary evidence for future hypothesis generation. Ultimately, it may be the more socially deprived patients treated by certain surgeons who do not fully appreciate or understand how PROMs can help them quantify the

severity of their foot and ankle problem and how treatments may help or improve their condition. Lastly, the new patients were selected for this study population and there is the possibility that follow-up patients may demonstrate more activation as the PROMs are followed over time. It is true our work does not demonstrate the hypothesized improvement in patient experience with the discussion of PROMs in the clinic. Thus, although other benefits of routine PROMs collection and use certainly exist,³ it remains to be seen how much PROMs may—or may not—impact the new patient experience as future research progresses in this area.

In prior research, patient activation has been shown to be associated with better health outcomes. In fact, the US Centers for Disease Control and Prevention (CDC) continues to support scholarly activity in this area. Therefore, any documented way to increase patient activation should be prioritized. Unfortunately, our study showed no such relationship between the discussion and viewing of PROM scores and patient activation across the entire new patient clinic sample. When clustered by surgeon, patients in the intervention cohort had decreased odds of having high patient activation.

Among the most deprived patients in our study, those who discussed and viewed the PROMs data with the surgeon had lower PAM scores than those in the control group, though this was not significant. It is critical to put these findings into perspective. First, as with our CG-CAHP analysis, we are limited by our sample size to assess patient activation when clustering by both surgeon and including an interaction term for social deprivation simultaneously, which limits our work and is an area for future research. While the more socially deprived patients had lower patient activation in the intervention group, it was not significantly different from the less socially deprived patients. We were underpowered to fully assess such a relationship, which was a secondary analysis, and future work is needed in this area, as any difference could mean that patients of high social deprivation are simply trying to get the care they need and discussing PROMs is less important and perhaps thought of as unnecessary—or even confusing. As we continue to tackle health disparities and inequities, further work will be needed to determine whether this hypothesis is true or not. We hypothesize it may be more related to healthy literacy differences or communication differences that can be addressed from the orthopaedic surgeon's side.

Limitations to this study include the lack of surgeon masking, the fact that patients being consented were informed that an impact of care was being studied, which may have caused them to act differently in this clinic visit, and that this study was not powered to assess socioeconomic differences between or within groups. It is possible that different foot and ankle conditions (eg, bunion vs midfoot arthritis) or severity of conditions could impact the

relationship between PROMs and CG-CAHPS and/or PROMs and PAM. However, given the questionnaires used are universal in nature (ie, not condition-specific) and all visits were new patient encounters (therefore, patients were seeking care for one reason or another), we do not suspect this would have a major impact on our findings. Future research designed to determine if differences exist by condition, other demographic factors, or by presenting symptom severity (as measured by PROMIS scores) is warranted. In this study, the surgeons were generally rated highly overall across patients prior to the enrollment, and this could provide a ceiling effect on analyzing change with viewing or not viewing PROMs with patients. Despite these limitations and those discussed in detail above, this study offers important preliminary findings regarding PROMs and their use in clinical care.

Conclusion

Overall, we found that simply collecting and discussing PROM scores with patients using a standardized script in a foot and ankle clinic setting does not appear to improve the patient experience (as measured by CG-CAHPS), nor increase patient activation (as measured by the PAM) when the orthopaedic surgeon is highly rated by patients already. Highly satisfied patients with highly regarded foot and ankle surgeons limits the discriminatory ability of the present study and the findings of this study. Perhaps surgeons or clinicians who score poorly on CG-CAHPS may improve their ratings based on PROM sharing and discussion. This remains to be seen. Further, our work suggests that there may be a relationship among patient activation, experience, satisfaction, surgeon, and social deprivation. We hypothesize there may be some health disparities among these patients in this study, including differences in health literacy to control for in the future. PROMs have demonstrated value in shared clinical-decision making discussions, improved patient selection for surgical and non-surgical treatment recommendations, and helped to standardize and increase the robustness of clinical research. Given the well documented benefits of PROMs in the literature, we feel it is very likely that how the data were presented, and not the use of PROMs themselves, led to our findings. All patients may not need, want, or understand a discussion of PROMs in the clinic space in the same way. Future work is needed to determine when PROMs discussions are most beneficial and how best to present PROMs data. Health literacy tools and/or communication training may also be needed to better engage different patient groups regarding PROMs.

Ethical Approval

This project was approved by the University of Rochester Medical Center Research Subjects Review Board (STUDY00005316).

Bernstein et al 487

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. ICMJE forms for all authors are available online.

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Supplemental Material

Supplementary material is available online with this article.

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