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Use of Patient-Reported Outcome Measurement Information System® (PROMIS®) measures to characterize health status for patients seeking care from an orthopedic provider: A retrospective cohort

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10 Corresponding Author: Maggie E Horn DPT, MPH, PhD^{1,2}

11
12 Duke University, Box 10042, Durham, NC 27710, 919-684-1365, maggie.horn@duke.edu

13
14 Emily K. Reinke, PhD¹

15
16 Xiaofang Yang, PhD³

17
18 Sheng Luo, PhD^{2,3}

19
20 Michael P Bolognesi, MD¹

21
22 Bryce B. Reeve, PhD^{2,3}

23
24 Steven Z George PT, PhD^{1,3}

25
26
27 ¹Duke University, Department of Orthopaedic Surgery, Division of Physical Therapy, Durham, USA

28
29 ²Duke University, Department of Population Health Sciences, Durham, USA

30
31 ³Duke University, Duke Clinical Research Institute, Durham, USA

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ABSTRACT

Objectives: Characterize the health status of patients newly consulting an orthopedic specialist across eight clinical subspecialties.

Design: Retrospective cohort

Setting: 18 orthopedic clinics, including seven subspecialties (14 ambulatory and four hospital-based) within an academic health system.

Participants: 14,910 patients consulting an orthopaedic specialist for a new patient consultation who completed baseline Patient-Reported Outcome Measurement Information System (PROMIS) measures associated with their appointment from November 2017 - December 2019. Patients were 55.72 ± 5.8 years old, 61.3% female and 79.3% Caucasian, and were 13.4% Black or African American. Patients who did not complete PROMIS measures or canceled their appointment were excluded from the study.

Primary Outcome: PROMIS domains of physical function, pain interference, pain intensity, depression, anxiety, fatigue, sleep disturbance, and the ability to participate in social roles.

Results: Mean PROMIS scores for physical function was (38.1 ± 9.2), pain interference (58.9 ± 8.1), pain intensity (4.6 ± 2.5), depression (47.9 ± 8.9), anxiety (49.9 ± 9.5), fatigue (50.5 ± 10.3), sleep disturbance (51.1 ± 9.8), and ability to participate in social roles (49.1 ± 10.3). Across the clinical subspecialties, Neurosurgery, Spine, and Trauma patients were most profoundly affected across almost all domains, and patients consulting with a Hand specialist reported the least limitations. There was a moderate, negative correlation between pain interference and physical functioning ($r = -0.59$) and low correlations between pain interference with anxiety

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3 (r=0.36), depression (r=0.39) as well as physical function and anxiety (r=-0.32) and depression (r=-0.30) and
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7 sleep (r=-0.31).
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10 **Conclusions:** We directly compared clinically meaningful PROMIS domains across eight orthopedic
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12 subspecialties, which would not be possible with legacy measures alone. These results support PROMIS's
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14 utility as a common metric to assess and compare patient health status across multiple orthopedic
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16 subspecialties.
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18 **ARTICLE SUMMARY**

19 **Strengths and Limitations of this Study**

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22 ● This study demonstrated the direct comparison of health status using PROMIS measures across eight
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24 orthopedic clinical subspecialties, which was previously a challenge using legacy outcome measures.
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27 ● This study reported the association of eight clinically relevant PROMIS domains within an orthopedic
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29 cohort.
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32 ● Participants in this study completed PROMIS measures as part of routine clinical assessment
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34 associated with a new patient consultation with an orthopaedic specialist.
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- 36
37 ● We evaluated PROMIS measures at baseline only; no follow up data was analyzed in the context of
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39 downstream healthcare utilization.
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42 ● The findings' generalizability is limited by data collected within a private health system setting that may
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44 not reflect other health systems' characteristics.
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Key Words: Patient-reported outcome measures, orthopedics, health status, physical function, pain

INTRODUCTION

To determine if a patient has achieved treatment success, it is insufficient to evaluate treatment results solely on medical history, physical findings, laboratory tests, or imaging findings alone.[1] While these are essential clinical indicators, they may not reflect what is most important to a patient. Patient-reported outcome measures (PROMs) are additional indicators that come directly from the patient. PROMs may address more important patient-centered outcomes about a patient's health status's physical, mental, and social aspects. Change in health status can be one of the measures of "success" from a patient's perspective after an orthopedic procedure.[2] PROMs are increasingly being used as part of the clinical encounter to guide treatment decisions and determine intervention effectiveness. [3]

"Legacy" patient-reported outcome measures (PROs) have been used for decades; however, they have many limitations.[4] To overcome the limitations of legacy measures the NIH developed a universally accepted set of PROMs. The NIH's Patient-Reported Outcomes Measurement Information System® (PROMIS®) covers a broad range of relevant domains and has strong evidence for its validity and reliability in a broad range of populations.[5–8] In orthopedics, the use of PROMIS measures has distinct advantages because it can be used across many clinical subspecialties as a common outcome metric. [8–10] This has the opportunity to allow for the evaluation of the efficacy of different interventions and inform quality improvement initiatives.[11]

Recently, there has been an increase in the adoption of PROMIS measures as the standard outcome measurement system in Orthopaedics to assess health status in orthopedic patients.[8] However, what is unknown about the use of PROMIS measures in orthopedics is how these measures differ across patients seeking care from different orthopedic clinical subspecialties. Therefore, there are two goals of this study. First, we will characterize the health status of a cohort of patients completing PROMIS measures as part of the clinical encounter by comparing the physical health (6 domains) and mental health (2 domains) across eight different clinical subspecialty areas in a large academic medical center. Second, we will examine the correlation between the PROMIS domains in this cohort.

METHODS

Study Setting and Participants

Patients consulting an Orthopaedic specialist (surgeon or advanced practice provider- nurse practitioner or physician assistant) for a new patient consultation from November 2017 - December 2019 were included in the study. In this study, patients sought care within the Department of Orthopaedic surgery at a large academic, private medical center in Durham, NC. Inclusion criteria for the study were patients aged 18 years and over and completion of assigned PROMIS measures. We excluded patients from the study who completed PROMIS measures but canceled or did not attend their scheduled appointments. The department includes 18 adult clinics (14 ambulatory and four hospital-based clinics). The department consists of eight subspecialties (Joint Reconstruction, Spine, Neurosurgery, Sports Medicine, Trauma, Orthopaedic Oncology, Foot and Ankle, and Hand) with over 100 Orthopaedic specialists. We extracted data for this study directly from the electronic health record (EHR).

Standardized Collection of PROMIS Measures

In December of 2017, the orthopedics department implemented a standardized collection of PROMIS measures across 18 clinics and eight clinical subspecialties. The administration of PROMIS measures was linked to new patient appointments and collected and scored passively within the EHR (Epic Systems) as part of the standard of care. Therefore, informed consent was not required for the completion of the PROMIS measures. However, we obtained IRB approval for data extraction and analysis of the collected data for this study.

PROMIS Measures

From November 2017- December of 2018, we collected the short-form version of the following 8 PROMIS domains: physical function (7 items), pain interference (8 items), pain intensity (1 item), depression (8 items), anxiety (8 items), fatigue (8 items), sleep disturbance (8 items) and ability to participate in social roles (8 items). The PROMIS Physical Function domain is a patient's self-reported capability (rather than actual performance) of physical activities. The physical function domain includes the functioning of one's upper extremities (dexterity), lower extremities (walking or mobility), and central regions (neck, back), as well as instrumental activities of daily living, such as running errands.[12] PROMIS Pain Interference measures the

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3 consequences of pain on relevant aspects of one's life. The pain interference domain includes the extent to
4 which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities.[13]
5 PROMIS pain intensity consists of one question, "How would you rate your pain on average? (0-10, 0=No pain
6 10=Worst imaginable)".[14] PROMIS emotional distress domains included depression and anxiety. Depression
7 measures negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition
8 (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (loss of interest,
9 meaning, and purpose).[15] Anxiety domain measures fear (fearfulness, panic), anxious misery (worry, dread),
10 hyperarousal (tension, nervousness, restlessness), and somatic symptoms related to arousal (racing heart,
11 dizziness). [16] The PROMIS Sleep Disturbance Perceptions measure sleep quality, sleep depth, and
12 restoration associated with sleep.[17] The PROMIS fatigue domain measures a range of symptoms, from mild
13 subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely
14 decreases one's ability to execute daily activities and function normally in a family or social roles.[18] The
15 PROMIS Ability to Participate in Social Roles and Activities measures one's perceived ability to perform one's
16 usual social roles and activities.[19]

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33 Each PROMIS domain is scored separately on a T-score metric, where 50 is the mean and 10 is the
34 standard deviation of the calibration population. For all PROMIS domains (except sleep disturbance) included
35 in this study, the calibration population is the US general population. A higher score on a domain reflects more
36 of the measured concept (e.g., more Fatigue, more Physical Function). For example, a physical function score
37 of 40 indicates the sample's functioning is one standard deviation worse than the average US general
38 population.[5] Once the computer adaptive testing (CAT) instruments were available within our EHR, on
39 December 20, 2018, we transitioned to collecting a reduced set of PROMIS domains (physical function, pain
40 interference, depression, and sleep disturbance) because of concerns about the respondent burden with the
41 full eight domains. We combined these scores with the respective PROMIS short form scores for the analysis.

52 53 **Patient Demographics**

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3 Patient demographics recorded included patient age at the appointment, sex (male or female), race
4 (American Indian or Alaskan Native, Asian, Black or African American, Caucasian/White, Native Hawaiian or
5 Other Pacific Islander, Not Reported/Declined, Other and two or more races), ethnicity (Hispanic, Not
6 Hispanic/Latino, Not Reported/Declined), marital status (Divorced, Legally Separated, Life Partner, Married,
7 Single, unknown, widowed), geographical delineation (urban or rural) and primary and secondary insurance
8 type (Medicare, Medicaid, workers compensation, private).
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16 **Healthcare Process Variables**

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19 In this sample, we collected information related to the new patient consultation, including; visit date,
20 clinic location and type (ambulatory vs. hospital-based), provider type (orthopedic physician or advanced
21 practice provider-nurse practitioner or physician assistant), and provider specialty (Joint Reconstruction, Spine,
22 Neurosurgery, Sports Medicine, Trauma, Orthopaedic Oncology, Foot and Ankle, and Hand).
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28 **Data Analysis**

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31 We performed data analysis using R Statistical Software version R 4.0.2.[20]
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34 This study's primary purpose was to characterize the health status of patients seeking care from eight
35 orthopedic subspecialties in the Department of Orthopaedic Surgery. We calculated descriptive statistics to
36 characterize the cohort. Means and standard deviations were reported for continuous variables, and
37 percentages were reported for categorical variables. Cohort characteristics were compared across clinical
38 subspecialties using chi-square analysis for categorical variables and 1-way analyses of variance for
39 continuous variables. We calculated the mean and standard deviation of PROMIS domain scores for the cohort
40 and across each specialty using t-tests. We then calculated the percentage of patients in the total cohort and
41 each clinical subspecialty by severity categories for each PROMIS domain: within normal limits, mild,
42 moderate, and severe.[10,21,22] Lastly, we performed Pearson correlation analyses to determine the
43 association of the 8 PROMIS domains in the cohort. We defined the magnitude of correlation as follows: low
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correlation - 0.10-0.39, moderate correlation - 0.40-0.69, high correlation - 0.70- 0.89 and very high correlation - 0.90-1.00.[23]

Patient and Public Involvement

There was no involvement from patients or members of the public in the design, or conduct, or reporting, or dissemination plans of this study.

RESULTS

Cohort Demographics

Our study included 14,910 patients who consulted an Orthopaedic specialist for a new patient consultation and completed baseline PROMIS measures. Of the entire sample, 61.3% (n=9,137) were female with a mean age of 55.72(15.8). Most of the sample reported being Caucasian (79.3% (n=11,831)) and 13.4% (n=2,001) were Black or African American. Our sample's self-reported ethnicity was 93.7% (n=13976) Not Hispanic/Latino and 1.9% (n=285) Hispanic. The majority of patients in the sample were married (64.1%, n=9,553). The geographic dispersion of the sample included 83.8% (n=12,488) residing in urban areas and 8.6% (n=1,276) residing in rural areas in North Carolina. The primary insurance of the sample was predominantly private (90.3%, n=13,465) followed by Medicare (7.3%, n=1,088) and Medicaid (2.1%, n=311).

See table 1.

Table 1. Sample Characteristics by Clinical Specialty

Provider specialty	Foot and ankle (n=2208)	Hand (n=1858)	Neurosurgery (n=1044)	Orthopaedic Oncology (n=124)	Spine (n=3028)	Sports medicine (n=4197)	Total Joint Arthroplasty (n=2353)	Trauma (n=98)	Total (n=14,910)	P value
Age	56.72(15.2)	54.63(15.9)	56.11(15.3)	55.18(15.5)	57.2(15.3)	52.68(16.3)	59(14.9)	56.18(19.9)	55.72(15.8)	<<0.001
Gender										
Female	64.1%(1416)	61.3%(1138)	61.2%(639)	51.6%(64)	60.0%(1818)	60.3%(2532)	62.39%(1468)	63.3%(62)	61.3%(9137)	0.015
Male	35.9%(792)	38.8(720)	38.8%(405)	48.4%(60)	40.0%(1210)	39.7%(1665)	37.61%(885)	36.7%(36)	38.7%(5773)	
Race										
2 or more races	1.2%(26)	1.7%(31)	0.9%(9)	0%(0)	1.4%(42)	1.3%(55)	1.0%(24)	3.1%(3)	1.3%(190)	0.01

American Indian or Alaskan Native	0.2%(4)	0.3%(6)	0.7%(7)	0.8%(1)	0.4%(11)	0.3%(14)	0.2%(4)	1.0%(1)	0.3%(48)	
Asian	1.9%(42)	2.1%(54)	2.0%(21)	2.4%(3)	2.2%(65)	2.8%(118)	1.3%(31)	1.0%(1)	2.2%(335)	
Black or African American	12.6%(278)	14.9%(278)	13.1%(137)	14.5%(18)	12.6%(380)	13.4%(564)	14.2%(333)	13.3%(13)	13.4%(2001)	
Caucasian/White	80.6%(1780)	77.6%(1441)	80.9%(845)	79.0%(98)	80.5%(2438)	78.0%(3274)	79.9%(1879)	77.6%(76)	79.3%(11831)	
Native Hawaiian or Other Pacific Islander	0.1%(1)	0.1%(2)	0.1%(1)	0%(0)	0.1%(2)	0.1%(4)	0.1%(2)	0%(0)	0.1%(12)	
Not Reported/ Declined	2.7%(60)	2.037	1.5%(16)	2.4%(3)	2.3%(68)	3.2%(132)	2.6%(60)	1.0%(1)	2.5%(377)	
Other	0.8%(17)	0.5(9)	0.7%(8)	0.8%(1)	0.7%(22)	0.9%(36)	0.9%(20)	3.1%(3)	0.8%(116)	
Ethnicity										
Hispanic	1.7%(37)	2.4%(45)	2.2%(23)	0.8%(1)	1.9%(57)	2.0%(85)	1.4%(32)	5.1%(5)	1.9%(285)	0.013
Not Hispanic/Latino	94.4%(2085)	93.3%(1733)	94.8%(990)	92.7%(115)	94.0%(2846)	92.9%(3898)	94.3%(2218)	92.9%(91)	93.7%(13976)	
Not Reported/ Declined	3.9%(86)	4.3%(80)	3.0%(31)	6.5%(8)	4.1%(125)	5.1%(214)	4.4%(103)	2.0%(2)	4.4%(649)	
Marital Status										
Divorced	6.2%(137)	8.0%(149)	7.9%(82)	5.7%(7)	8.3%(251)	6.5%(273)	8.0%(187)	15.3%(15)	7.4%(1101)	<<0.001
Legally Separated	0.9%(20)	1.1%(21)	1.0%(10)	0.8%(1)	1.1%(32)	1.1%(47)	0.4%(9)	1.0%(1)	0.9%(141)	
Life Partner	0.8%(17)	0.6%(11)	0.5%(5)	0%(0)	0.3%(10)	0.5%(19)	0.3%(6)	1.0%(1)	0.5%(69)	
Married	65.4%(1445)	61.9%(1150)	66.6%(695)	71.8%(89)	66.1%(2002)	61.3%(2572)	66.0%(1552)	49.0%(48)	64.1%(9553)	
Single	18.4%(406)	19.8%(367)	16.6%(173)	18.6%(23)	15.9%(482)	22.4%(939)	17.3%(408)	26.5%(26)	18.9%(2824)	
Unknown	3.6%(80)	4.1%(76)	2.6%(27)	0.8%(1)	3.1%(94)	4.7%(199)	2.6%(61)	0%(0)	3.6%(538)	
Widowed	4.7%(103)	4.5%(84)	5.0%(52)	2.4%(3)	5.2%(157)	3.5%(148)	5.5%(130)	7.1%(7)	4.6%(684)	
Geographic Location										
Rural, NC	7.2%(158)	7.4%(138)	11.9%(124)	12.1%(15)	9.7%(295)	7.3%(308)	9.4%(221)	17.4%(17)	8.6%(1276)	<<0.001
Urban, NC	82.4%(1820)	87.2%(1621)	77.1%(805)	72.6%(90)	82.3%(2491)	87.5%(3671)	81.3%(1914)	77.6%(76)	83.8%(12488)	
Other	10.4%(230)	5.3%(99)	11.0%(115)	15.3%(19)	8.0%(242)	5.2%(218)	9.3%(218)	5.1%(5)	7.7%(1146)	

Primary Insurance										
Medicare	25.2%(556)	20.8%(387)	25.9%(270)	23.4%(29)	27.2%(823)	17.6%(738)	28.9%(679)	32.7%(32)	23.6%(3514)	<<0.001
Medicaid	0.5%(10)	0.9%(17)	2.5%(26)	3.2%(4)	1.9%(58)	0.8%(33)	0.6%(15)	2.0%(2)	1.1%(165)	
Worker's Compensation	0.9%(20)	1.9%(35)	0.6%(6)	0.8%(1)	0.4%(12)	1%(42)	0.9%(21)	1.0%(1)	0.9%(138)	
Privately Insured	73.5%(1622)	76.4%(1419)	71.1%(742)	72.6%(90)	70.5%(2135)	80.6%(3384)	69.6%(1638)	64.3%(63)	74.4%(11093)	
Secondary Insurance										
Medicare	7.7%(169)	6.5%(121)	8.0%(83)	7.3%(9)	7.8%(235)	5.5%(229)	9.8%(231)	11.2%(11)	7.3%(1088)	<<0.001
Medicaid	1.3%(28)	1.5%(28)	3.7%(39)	3.2%(4)	3.0%(90)	1.6%(67)	2.1%(49)	6.1%(6)	2.1%(311)	
Worker's Compensation	0.3%(6)	0.4%(8)	0.3%(3)	0%(0)	0.3%(8)	0.3%(13)	0.3%(7)	1.0%(1)	0.3%(46)	
Privately Insured	90.8%(2005)	91.6%(1701)	88.0%(919)	89.5%(111)	89%(2695)	92.6%(3888)	87.8%(2066)	81.6%(80)	90.3%(13465)	
Questionnaire Type Completed										
PROMIS Short Forms (8 domains)	74.7%(1650)	70.8%(1316)	71.7%(749)	76.6%(95)	74.1%(2243)	68.6%(2879)	64.9%(1526)	69.4%(68)	70.6%(10526)	<<0.001
PROMIS CAT (4 domains)	25.3(558)	29.2 (542)	28.3(295)	23.4%(29)	28.9 (785)	31.4 (1318)	35.2(827)	30.6(30)	29.4 (4384)	
Year PROMIS Questionnaire Completed										
2017	2.9%(65)	2.5%(47)	3.5%(37)	6.5%(8)	4.9%(149)	3.3%(138)	3.3%(77)	3.1%(3)	3.5%(524)	<<0.001
2018	66.2%(1462)	63.2%(1175)	63.1%(659)	65.3%(81)	64.8%(1961)	61.6%(2587)	57.5%(1353)	61.2%(60)	62.6%(9338)	
2019	30.8%(681)	34.2%(636)	33.3%(348)	28.2%(35)	30.3%(918)	35.1%(1472)	39.2%(923)	35.71%(35)	33.9%(5048)	

*mean(sd), %(n)

PROMIS Scores

The highest volume of patients in the sample sought care from a sports medicine provider (28.1%, n=4,197) or a spine provider (20.3%, n=3,028), followed by total joint (15.8%, n=2,353), foot and ankle (14.8%,

n=2,208) and hand 12.5%, n=1,858). Orthopedic oncology, neurosurgery, and trauma had fewer than 10% of the total volume of patients in the sample.

As presented in **table 2**, the mean scores for the PROMIS domains for the entire cohort were 38.14(9.2) for physical function, 58.84(8.1) for pain interference, 4.58(2.5) for pain intensity (on a 0 to 10 scale), 47.87(8.9) for depression, 49.86(9.5) for anxiety, 50.49(10.3) for fatigue, 51.08(9.8) for sleep disturbance and 49.05(10.3) for ability to participate in social roles. Higher pain interference and lower physical function were at least 0.5 and 1.0 standard deviations away, respectively, from the average US general population.

Table 2. Summary of Scores for PROMIS Domains by Clinical Subspecialty

	Foot and ankle (n=2208, 14.81%)	Hand (n=1858, 12.46%)	Neurosurgery (n=1044, 7.0%)	Orthopaedic Oncology (n=124, 0.8%)	Spine (n=3028, 20.31%)	Sports medicine (n=419, 28.15%)	Total Joint Arthroplasty (n=2353, 15.78%)	Trauma (n=98, 0.66%)	Total (n=14,910, 100%)
Physical Health Domains									
Physical function	39.49(9.0)	41.85(9.5)	35.04(9.0)	38.35(10.5)	35.45(8.7)	39.51(8.8)	36.58(8.5)	31.6(10.8)	38.14(9.2)
Ability to participate in social roles	50.48(10.2)	52.32(10.4)	44.32(10.4)	47.56(10.8)	46.27(10.0)	50.98(9.8)	47.78(9.7)	43.58(11.5)	49.05(10.3)
Pain intensity	4.08(2.5)	3.73(2.5)	5.47(2.5)	3.99(2.7)	5.34(2.4)	4.25(2.4)	4.91(2.4)	4.79(2.6)	4.58(2.2)
Pain interference	57.2(8.6)	55.65(8.56)	61.53(8.1)	57.23(9.7)	61.13(7.3)	58(7.6)	60.21(7.7)	61.02(8.4)	58.84(8.1)
Fatigue	49.22(9.0)	48.67(10.7)	54.88(10.4)	52.04(10.6)	53.18(10.1)	48.81(10.0)	50.21(9.8)	53.93(10.5)	50.49(10.3)
Sleep	49.07(9.3)	49.82(9.8)	53.77(10.3)	50.5(9.7)	52.85(9.9)	50.55(9.6)	51.31(9.8)	53.42(10.9)	51.08(9.8)
Mental Health Domains									
Anxiety	48.66(9.0)	49.14(9.8)	52.59(9.9)	53.1(9.2)	51.59(9.6)	48.9(9.2)	49.31(9.3)	52.06(10.2)	49.86(9.5)
Depression	46.99(8.3)	47.3(89.0)	50.16(9.8)	48.93(9.2)	49.22(9.1)	46.98(8.5)	47.75(8.6)	50.91(9.4)	47.87(8.9)

*mean(sd)

Table 3 provides more context to the range of observed health status scores by categorizing scores into degrees of severity: within normal limits, mild, moderate, and severe.[10,21,22] In this cohort, 24.9% of all

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3 patients reported their physical functioning within normal limits; the majority of patients (75%) reported mild,
4 moderate, or severe limitations in physical functioning. There is a similar trend for pain interference, where
5 73% of patients reported mild, moderate, or severe limitations with pain interference. The majority of the cohort
6 reported within normal limits for the ability to participate in social roles (63.5%), fatigue (68.0%), and sleep
7 disturbance (66.0%). For the mental health domains (anxiety and depression), across the samples, most
8 patients reported normal limits for anxiety (69.6%) and depression (76.8%). Few patients reported severe
9 symptoms of anxiety (1.7%) and depression (1.1%).
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Table 3: PROMIS Severity Categories by Clinical Subspecialty

	Foot and ankle (n=2208)	Hand (n=1858)	Neurosurgery (n=1044)	Orthopaedic Oncology (n=124)	Spine (n=3028)	Sports medicine (n=4197)	Total Joint Arthroplasty (n=2353)	Trauma (n=98)	Total (n=14,910)
Physical Health Domains									
Physical function									
Within Normal limits	29.6%	40.5%	16.2%	32.3%	15.7%	29.1%	16.6%	11.3%	24.9%
Mild	22.9%	20.7%	13.1%	11.3%	15.0%	22.1%	20.0%	8.3%	19.5%
Moderate	30.7%	26.4%	38.9%	33.1%	40.5%	33.3%	40.2%	29.9%	35.0%
Severe	16.7%	12.5%	31.8%	23.4%	28.8%	15.4%	23.2%	50.5%	20.6%
Ability to participate in social roles									
Within Normal limits	67.2%	74.3%	42.2%	51.6%	52.8%	72.8%	60.6%	44.6%	63.5%
Mild	18.3%	13.9%	23.4%	24.2%	21.3%	14.2%	18.9%	15.4%	17.8%
Moderate	11.5%	9.6%	24.9%	20.0%	19.5%	10.3%	16.1%	24.6%	14.4%
Severe	2.9%	2.2%	9.5%	4.2%	6.4%	2.7%	4.4%	15.4%	4.3%
Pain interference									
Within Normal limits	33.8%	43.7%	16.3%	33.1%	16.7%	29.8%	20.3%	21.7%	27.0%
Mild	23.6%	24.3%	16.7%	16.5%	21.4%	28.4%	24.3%	13.0%	24.1%
Moderate	39.4%	28.8%	59.7%	46.3%	55.8%	38.0%	49.0%	55.4%	44.1%
Severe	3.2%	3.3%	7.4%	4.1%	6.2%	3.7%	6.5%	9.8%	4.8%
Fatigue									
Within Normal limits	73.4%	73.9%	50.7%	63.2%	57.2%	74.4%	70.6%	55.2%	68.0%
Mild	12.3%	11.3%	17.7%	13.7%	17.1%	12.3%	13.8%	17.9%	13.9%
Moderate	12.0%	12.2%	24.6%	20.0%	21.8%	11.0%	13.2%	20.9%	15.1%
Severe	2.3%	2.7%	7.0%	3.2%	3.9%	2.3%	2.4%	6.0%	3.1%
Sleep									
Within Normal limits	74.3%	71.5%	54.3%	67.2%	58.0%	69.0%	64.8%	55.3%	66.0%

Mild	13.7%	14.1%	17.5%	18.0%	18.1%	14.4%	16.0%	13.8%	15.5%
Moderate	10.5%	11.7%	22.3%	11.5%	19.3%	13.7%	16.1%	23.4%	15.1%
Severe	1.6%	2.7%	5.9%	3.3%	4.7%	2.9%	3.0%	7.5%	3.3%
Mental Health Domains									
Anxiety									
Within Normal limits	74.6%	71.6%	59.7%	55.8%	62.0%	73.4%	72.5%	60.6%	69.6%
Mild	14.0%	14.8%	16.2%	22.1%	17.2%	14.7%	15.2%	16.7%	15.4%
Moderate	10.5%	11.4%	20.2%	19.0%	18.9%	10.9%	10.7%	19.7%	13.4%
Severe	0.9%	2.1%	3.9%	3.2%	1.9%	1.1%	1.6%	3.0%	1.7%
Depression									
Within Normal limits	80.7%	78.3%	66.5%	71.9%	71.5%	79.9%	78.6%	65.6%	76.8%
Mild	12.1%	12.0%	15.9%	14.9%	14.9%	12.2%	12.5%	20.0%	13.1%
Moderate	6.5%	8.2%	15.2%	12.4%	12.3%	7.3%	8.0%	12.2%	9.1%
Severe	0.6%	1.5%	2.5%	0.8%	1.4%	0.7%	1.0%	2.2%	1.1%

In **table 4**, we examine the correlation of PROMIS domains in the cohort. As expected, we found high correlations between depression and anxiety ($r=0.76$) and pain interference and pain intensity ($r=0.75$). Additionally, we found moderate correlations between commonly administered PROMIS domains in Orthopaedics - physical function and pain interference ($r=-0.60$) and physical function and pain intensity (-0.52). There was a low correlation found between anxiety and pain intensity ($r=0.30$), anxiety, and pain interference ($r=0.36$), anxiety, and physical function ($r=-0.32$). Similar trends were found with depression where low correlations between depression and pain intensity ($r=0.29$), depression, and pain interference ($r=0.39$), depression, and physical function ($r=-0.30$).

Table 4: Correlation of PROMIS Domains

	Participation	Anxiety	Depression	Fatigue	Pain Intensity	Pain Interference	Physical Function	Sleep Disturbance
Participation	-	-0.48	-0.51	-0.66	-0.52	-0.69	0.67	-0.45
Anxiety	-0.48	-	0.76	0.58	0.30	0.36	-0.32	0.44
Depression	-0.51	0.76	-	0.58	0.29	0.39	-0.30	0.43
Fatigue	-0.66	0.58	0.58	-	0.42	0.52	-0.48	0.54
Pain Intensity	-0.52	0.30	0.29	0.42	-	0.75	-0.52	0.39

Pain Interference	-0.69	0.36	0.39	0.52	0.75	-	-0.60	0.45
Physical Function	0.67	-0.32	-0.30	-0.48	-0.52	-0.60	-	-0.31
Sleep Disturbance	-0.45	0.44	0.43	0.54	0.39	0.45	-0.31	-

*all correlations were statistically significant $P < 0.001$

PROMIS Scores by Major Clinical Specialties

Foot and Ankle

Patients consulting with a foot and ankle orthopedic specialist scored less than 0.5 SD from the mean for all domains except for pain interference, where patients reported a mean score of 57.2(8.6). When looking at the clinically interpretable categories for physical function, 30.7% of patients reported moderate limitations and 16.7% severe limitations. For pain interference, 39.4% reported moderate and limitations, and 3.2% reported severe limitations.

Hand

Patients who consulted with a hand orthopedic specialist reported scores less than 0.5 SD from the mean for all domains except pain interference and physical function. Patients reported a mean score of 55.7(8.8) and 41.85(9.5), respectively. For physical function, 26.4% of patients reported moderate limitations, and 12.5% reported severe limitations.

Neurosurgery and Spine

Patients either consulting with a neurosurgeon or a spine orthopedic specialist reported between 1- 1.5 standard deviations from the US mean for pain interference and physical functioning. Neurosurgery patients reported higher levels of pain interference (61.53(8.1)) compared to spine patients (57.23(9.7)) and also reported more limitations in physical functioning (35.0(9.0)) as compared to spine patients (38.35(10.5)). For physical function, a majority of neurosurgery patients reported moderate (38.9%) and severe (31.8%) limitations, and this was similar in spine patients (moderate- 40.5%, severe 28.8%). Pain interference, most neurosurgery (59.7%) and Spine patients (55.8%) reported moderate limitations, and a small percentage of neurosurgery (7.4%) and spine patients (6.2%) reported severe limitations.

Sports Medicine

Patients seeking care from a sports medicine specialist reported less than 0.5 SD from the US mean in all domains except physical function (39.51(8.8)) and pain interference (58.0(7.6)) where their scores were between 0.5-1.0 SD from the US mean. 33.3% of patients reported moderate limitations in physical function, and 15.4% reported severe limitations. For pain interference, 38.0% of patients reported moderate limitations, and 3.7% reported severe limitations.

Total Joint Arthroplasty

Patients consulting a Total Joint Arthroplasty Orthopaedic Surgeon reported less than 0.5 SD from the US mean in all domains except physical functioning (36.58(8.5)) and pain interference (60.21(8.4)). Most patients reported moderate limitations in physical functioning (40.2%) and pain interference (48.9%), and 23.2% reported severe limitations in physical function, and only a small percentage reported severe limitations for pain interference (6.5%).

We did not report on Trauma or Orthopaedic Oncology due to low sample sizes in each of these subspecialties.

DISCUSSION

This study described approximately 15,000 orthopedic patients across eight different clinical subspecialties who completed the PROMIS measures associated with a new patient consultation to an orthopedic specialist at an academic medical center. We found across the Orthopaedic department that most patients reported within 0.5 SD from the US mean on all domains except pain interference and physical functioning. These findings are expected, where the primary drivers of seeking care for orthopedic issues are decreased physical functioning and increased interference with activities due to pain.[24],[25] When further examining the difference of PROMIS scores between the clinical subspecialties for the physical health domains, we found that patients seeking care from hand specialists reported less overall physical health impairments. However, we may in part attribute this to administering the generic physical function measure rather than the upper extremity physical function PROMIS measure, which is more specific to upper extremity conditions.[26] Patients seeking care from a Neurosurgery, Spine, or a Trauma specialist reported significant

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3 physical health impairments. When examining the mental health domains, most patients across clinical
4 subspecialties reported that their anxiety and depression symptoms were within normal limits; however,
5 between 11.4%-- 24.1% reported moderate or severe anxiety and 7.1-17.6% reported moderate or severe
6 depressive symptoms. Following a similar trend for physical health domains, patients seeking care from a
7 Neurosurgery, Spine, or Trauma specialist reported the highest anxiety and depression symptoms. This
8 relationship is consistent with literature supporting patients with spine conditions, and orthopedic trauma has
9 higher anxiety levels than other orthopedic conditions.[27,28]
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18 Our study has noted strengths. First, our study is novel in that we reported eight PROMIS domains
19 across eight different orthopedic clinical subspecialties. The use of PROMIS measures in clinical practice and
20 research has been increasing in prevalence in spine, total joint, sports medicine, upper extremity disorders,
21 trauma, and lower extremity disorders.[29] However, this is the first study we are aware of to compare
22 differences in these health domains across clinical subspecialties. These comparisons would not be possible if
23 using region-specific measures common to orthopedic practice and research. By implementing PROMIS
24 measures, we can draw inferences about differences in patient-reported health status across orthopedic
25 populations that are typically not compared. Second, our study reported clinical interpretation of PROMIS
26 scores addressing the reported barrier to PROMIS use uptake.[8,30] Providing the clinical interpretation is vital
27 because often there is a disconnect between mean PROMIS scores(i.e., physical functioning score- 38.2)and
28 how to interpret this information (moderate limitations in physical functioning).[30] Our study is not without
29 limitations. First, this was a cross-sectional cohort analysis, so we did report PROMIS measures beyond
30 baseline. Therefore, we cannot compare the change in PROMIS scores or downstream utilization of
31 Orthopaedic procedures or rehabilitation services. Second, our findings may have limited generalizability. For
32 example, the setting was a private hospital. It may not capture the broad diversity of non-white individuals in
33 the area (79.3% of individuals reported being Caucasian). Our instruments were only available in English,
34 limiting data collection on non-English speaking patients. Moreover, in some clinical subspecialties reported
35 (i.e., trauma and orthopedic oncology), small sample sizes were limiting these findings' generalizability. Lastly,
36 we did not compare upper extremity physical function PROMIS measure or legacy measures as part of this
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3 study. However, the relationship between legacy measures in orthopedics and PROMIS measures is well
4 documented in the literature. [31]

7 Our study's findings are consistent with other literature regarding orthopedic populations' physical and
8 mental health status. [32] Our study found that the potential drivers for seeking care limitations in physical
9 function and pain across all clinical subspecialties consistent with the literature.[33–35] In comparison to a
10 study by Perruccio et al. (2013) using the SF-36 as the outcome measure to physical and mental health in
11 patients seeking care for musculoskeletal disorders, we found similar results where patients with spine
12 disorders reported the most impairments in the cohort. [32] Additionally, consistent with our results, they found
13 hand upper extremity/hand patients were the healthiest, and total joint arthroplasty patients demonstrated low
14 levels of physical functioning. Our study's unexpected finding low levels of sleep disturbance, fatigue, and
15 depression reported across clinical subspecialties. Sleep disruption and pain frequently co-occur; both are
16 uniquely linked with depressed mood [36–39] and various forms of functional disability [40–42]. Depression
17 appears to play a substantial role in the sleep-pain linkage, particularly where the pain is severe. [43] However,
18 in our study, we did not find this relationship between pain, physical function, sleep disturbance, and
19 depression in the cohort, despite the research supporting these relationships. [43]

22 Reporting patients' health status consulting an Orthopaedic provider using a standard set of outcome
23 measures across various clinical subspecialties has numerous clinical care and research implications.
24 Understanding the health status and clinical examination measures may improve patient and provider
25 communication during the clinical encounter [44] and be used as part of the prognostic evaluation. [45]
26 Moreover, this study can provide a context for informing bundled care or value-based care models. Classifying
27 heterogeneous orthopedic patients' baseline status on a standard metric could better inform the effectiveness
28 and cost of treatment pathways.[46] Lastly, reporting PROMIS scores has allowed the direct comparison of
29 eight meaningful constructs across orthopedic subspecialties. This comparison would not be possible with
30 legacy measures, which is a noted strength of PROMIS measures. These comparisons allow unique insights to
31 be made for orthopedic departments and align clinical and research data collection with value-based care
32 initiatives outside of orthopedic departments. Clinicians and administrators can use this information to improve

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3 the delivery and the efficiency of care, improve and inform referral practices, and inform subspecialty-specific
4 education to improve patient outcomes from orthopedic care.
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34 **Data Availability:** Data are not available in accordance with protections provided by the HIPAA privacy
35 information policy.
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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5-6
		(b) For matched studies, give matching criteria and number of exposed and unexposed	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	7
		(d) If applicable, explain how loss to follow-up was addressed	7
		(e) Describe any sensitivity analyses	7
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	tables
		(c) Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-10
		(b) Report category boundaries when continuous variables were categorized	n/a
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Use of Patient-Reported Outcome Measurement Information System® (PROMIS®) measures to characterize health status for patients seeking care from an orthopedic provider: A retrospective cohort study

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3 Title: Use of Patient-Reported Outcome Measurement Information System® (PROMIS®) measures to
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6 characterize health status for patients seeking care from an orthopedic provider: A retrospective cohort study
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10 Corresponding Author: Maggie E Horn DPT, MPH, PhD^{1,2}

11
12 Duke University, Box 10042, Durham, NC 27710, 919-684-1365, maggie.horn@duke.edu

13
14 Emily K. Reinke, PhD¹

15
16 Xiaofang Yang, PhD³

17
18 Sheng Luo, PhD^{2,3}

19
20 Michael P Bolognesi, MD¹

21
22 Bryce B. Reeve, PhD^{2,3}

23
24 Steven Z George PT, PhD^{1,3}

25
26
27 ¹Duke University, Department of Orthopaedic Surgery, Division of Physical Therapy, Durham, USA

28
29 ²Duke University, Department of Population Health Sciences, Durham, USA

30
31 ³Duke University, Duke Clinical Research Institute, Durham, USA

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ABSTRACT

Objectives: Characterize the health status of patients newly consulting an orthopedic specialist across eight clinical subspecialties.

Design: Retrospective cohort

Setting: 18 orthopedic clinics, including eight subspecialties (14 ambulatory and four hospital-based) within an academic health system.

Participants: 14,910 patients consulting an orthopaedic specialist for a new patient consultation who completed baseline Patient-Reported Outcome Measurement Information System (PROMIS) measures associated with their appointment from November 17 2017 - May 13 2019. Patients were 55.72 ± 5.8 years old, 61.3% female and 79.3% Caucasian, and were 13.4% Black or African American. Patients who did not complete PROMIS measures or canceled their appointment were excluded from the study.

Primary Outcome: PROMIS domains of physical function, pain interference, pain intensity, depression, anxiety, fatigue, sleep disturbance, and the ability to participate in social roles.

Results: Mean PROMIS scores for physical function was (38.1 ± 9.2), pain interference (58.9 ± 8.1), pain intensity (4.6 ± 2.5), depression (47.9 ± 8.9), anxiety (49.9 ± 9.5), fatigue (50.5 ± 10.3), sleep disturbance (51.1 ± 9.8), and ability to participate in social roles (49.1 ± 10.3). Across the clinical subspecialties, Neurosurgery, Spine, and Trauma patients were most profoundly affected across almost all domains, and patients consulting with a Hand specialist reported the least limitations or symptoms across domains. There was a moderate, negative correlation between pain interference and physical functioning ($r = -0.59$) and low correlations

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3 between pain interference with anxiety ($r=0.36$), depression ($r=0.39$) as well as physical function and anxiety
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5 ($r=-0.32$) and depression ($r=-0.30$) and sleep ($r=-0.31$).
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8 **Conclusions:** We directly compared clinically meaningful PROMIS domains across eight orthopedic
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10 subspecialties, which would not be possible with legacy measures alone. These results support PROMIS's
11
12 utility as a common metric to assess and compare patient health status across multiple orthopedic
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14 subspecialties.
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16 17 18 **ARTICLE SUMMARY**

19 20 **Strengths and Limitations of this Study**

- 21
22 • This study demonstrated the direct comparison of health status using PROMIS measures across eight
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24 orthopedic clinical subspecialties, which was previously a challenge using legacy outcome measures.
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27 • This study reported the association of eight clinically relevant PROMIS domains (six physical health
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29 and two mental health domains) within an orthopedic cohort.
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31 • We evaluated PROMIS measures at baseline only as part of routine clinical assessment associated
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33 with a new patient consultation with an orthopaedic specialist; no follow up data was analyzed in the
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35 context of downstream healthcare utilization.
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37 • The findings' generalizability is limited by data collected within a private health system setting that may
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39 not reflect other health systems' characteristics.
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44 **Key Words:** Patient-reported outcome measures, orthopedics, health status, physical function, pain
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INTRODUCTION

To determine if a patient has achieved treatment success, it is insufficient to evaluate treatment results solely on medical history, physical findings, laboratory tests, or imaging findings alone.[1] While these are essential clinical indicators, they may not reflect what is most important to a patient. Patient-reported outcome measures (PROMs) are additional indicators that come directly from the patient. PROMs may address more important patient-centered outcomes about a patient's health status's physical, mental, and social aspects. Change in health status can be one of the measures of "success" from a patient's perspective after an orthopedic procedure.[2] PROMs are increasingly being used as part of the clinical encounter to guide treatment decisions and determine intervention effectiveness. [3]

"Legacy" patient-reported outcome measures (PROs) have been used for decades; however, they have many limitations.[4] To overcome the limitations of legacy measures the NIH developed a universally accepted set of PROMs. The NIH's Patient-Reported Outcomes Measurement Information System® (PROMIS®) covers a broad range of relevant domains and has strong evidence for its validity and reliability in a broad range of populations.[5–8] In orthopedics, the use of PROMIS measures has distinct advantages because it can be used across many clinical subspecialties as a common outcome metric. [8–10] This has the opportunity to allow for the evaluation of the efficacy of different interventions and inform quality improvement initiatives.[11]

Recently, there has been an increase in the adoption of PROMIS measures as the standard outcome measurement system in Orthopaedics to assess health status in orthopedic patients.[8] However, what is unknown about the use of PROMIS measures in orthopedics is how these measures differ across patients seeking care from different orthopedic clinical subspecialties. Moreover, there is limited data regarding the burden of disease in patients presenting to orthopedic clinics for initial care. Therefore, there are two goals of this study. First, we will characterize the health status of a cohort of patients completing PROMIS measures as part of the clinical encounter by comparing the physical health (6 domains) and mental health (2 domains) across eight different clinical subspecialty areas in a large academic medical center. Second, we will examine the correlation between the PROMIS domains in this cohort.

METHODS

Study Setting and Participants

Patients consulting an Orthopaedic specialist (surgeon or advanced practice provider- nurse practitioner or physician assistant) for a new patient consultation from November 17, 2017 - May 13, 2019 were considered. In this study, patients sought care within the Department of Orthopaedic surgery at a large academic, private medical center in Durham, NC. Inclusion criteria for the study were patients who completed assigned PROMIS measures associated with the visit type of new patient appointment. We excluded patients from the study who 1) were under 18 years of age at time of appointment, 2) completed assigned PROMIS measures but canceled or did not attend their scheduled appointments 3) who attended a visit with a provider that was not classified as an orthopaedic specialist or a provider that did not have a provider speciality designation within the EHR. The department includes 18 adult clinics (14 ambulatory and four hospital-based clinics). See Figure 1 for study eligibility. The department consists of eight subspecialties (Joint Reconstruction, Spine, Neurosurgery, Sports Medicine, Trauma, Orthopaedic Oncology, Foot and Ankle, and Hand) with over 100 Orthopaedic specialists. We extracted all data for this study directly from the electronic health record (EHR).

Standardized Collection of PROMIS Measures

In December of 2017, the orthopedics department implemented a standardized collection of PROMIS measures across 18 clinics and eight clinical subspecialties. The administration of PROMIS measures was linked to new patient appointments and collected and scored passively within the EHR (Epic Systems) as part of the standard of care. Therefore, informed consent was not required for the completion of the PROMIS measures. However, we obtained IRB approval from Duke University for data extraction and analysis of the collected data for this study (Pro00091740)

From November 2017- May 2019, we collected the short-form version of the following 8 PROMIS domains: physical function (7 items), pain interference (8 items), pain intensity (1 item), depression (8 items), anxiety (8 items), fatigue (8 items), sleep disturbance (8 items) and ability to participate in social roles (8 items). On December 20, 2018 our health system transitioned to administering the computer adaptive testing

(CAT) version of PROMIS domains instead of short form as the (CAT) instruments were then available within our EHR. As part of the transition from short form to CAT, we reduced the set of PROMIS domains collected to physical function, pain interference, depression, and sleep disturbance. This change was done in response to feedback from clinicians regarding respondent burden with eight domains and perceived clinical utility of information gained. Studies to date suggest CATs and SFs will produce very similar mean scores for a given sample and demonstrate similar accuracy range with SFs are greater than 4 items such as in this study. [12–14] Therefore we combined these scores with the respective PROMIS short form scores for the analysis.

The PROMIS Physical Function domain is a patient's self-reported capability (rather than actual performance) of physical activities. The physical function domain includes the functioning of one's upper extremities (dexterity), lower extremities (walking or mobility), and central regions (neck, back), as well as instrumental activities of daily living, such as running errands.[15] PROMIS Pain Interference measures the consequences of pain on relevant aspects of one's life. The pain interference domain includes the extent to which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities.[16] PROMIS pain intensity consists of one question, "How would you rate your pain on average? (0-10, 0=No pain 10=Worst imaginable)".[17] PROMIS emotional distress domains included depression and anxiety. Depression measures negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (loss of interest, meaning, and purpose).[18] Anxiety domain measures fear (fearfulness, panic), anxious misery (worry, dread), hyperarousal (tension, nervousness, restlessness), and somatic symptoms related to arousal (racing heart, dizziness). [19] The PROMIS Sleep Disturbance Perceptions measure sleep quality, sleep depth, and restoration associated with sleep.[20] The PROMIS fatigue domain measures a range of symptoms, from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely decreases one's ability to execute daily activities and function normally in a family or social roles.[21] The PROMIS Ability to Participate in Social Roles and Activities measures one's perceived ability to perform one's usual social roles and activities.[22,23]

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4 Each PROMIS domain is scored separately on a T-score metric, where 50 is the mean and 10 is the
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6 standard deviation of the calibration population. For all PROMIS domains (except sleep disturbance) included
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8 in this study, the calibration population is the US general population. A higher score on a domain reflects more
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10 of the measured concept (e.g., more Fatigue, more Physical Function). For example, a physical function score
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12 of 60 indicates the sample's functioning is one standard deviation better than the average US general
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14 population and lower score is less of the measured concept.[5] To increase the interpretability of findings,
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16 PROMIS scores can then be categorized into the categories of "Within Normal Limits" indicating less than a
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18 0.5 SD from the mean; "Mild" indicating a score 0.5 SD from mean; "Moderate" indicating 1.0 SD from the
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20 mean; and "Severe" s indicating 2.0 standard deviations from the mean. These categories were developed by
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22 evaluating the percentage of participants from large scale calibration testing that would then fit into each
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24 category.[10,24]
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130 **Patient Demographics**

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30 Patient demographics recorded included patient age at the appointment, sex (male or female), race
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32 (American Indian or Alaskan Native, Asian, Black or African American, Caucasian/White, Native Hawaiian or
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34 Other Pacific Islander, Not Reported/Declined, Other and two or more races), ethnicity (Hispanic, Not
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36 Hispanic/Latino, Not Reported/Declined), marital status (Divorced, Legally Separated, Life Partner, Married,
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38 Single, unknown, widowed), geographical delineation (urban or rural) and primary and secondary insurance
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40 type (Medicare, Medicaid, workers compensation, private).
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137 **Healthcare Process Variables**

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46 In this sample, we collected information related to the new patient consultation, including; visit date,
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48 clinic location and type (ambulatory vs. hospital-based), provider type (orthopedic physician or advanced
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50 practice provider-nurse practitioner or physician assistant), and provider specialty (Joint Reconstruction, Spine,
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52 Neurosurgery, Sports Medicine, Trauma, Orthopaedic Oncology, Foot and Ankle, and Hand).
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142 **Data Analysis**

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3 We performed data analysis using R Statistical Software version R 4.0.2.[25]
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6 This study's primary purpose was to characterize the health status of patients seeking care from eight
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8 orthopedic subspecialties in the Department of Orthopaedic Surgery. We calculated descriptive statistics to
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10 characterize the cohort. Means and standard deviations were reported for continuous variables, and
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12 percentages were reported for categorical variables. Cohort characteristics were compared across clinical
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14 subspecialties using chi-square analysis for categorical variables and 1-way analyses of variance for
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16 continuous variables. We conducted ordinary least squares (OLS) linear regression and reported the mean
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18 and 95% CI standard deviation for PROMIS domain scores across each specialty and for the entire cohort. We
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20 included the variables of age, sex (male, female), race (collapsed into caucasian/white, black/african american,
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22 and other), ethnicity (collapsed into non-hispanic, hispanic and not reported) and instrument type (short form or
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24 CAT). These variables were included to control for the effects of differences in demographic factors and
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26 questionnaire type across specialities when comparing mean PROMIS scores. We then calculated the
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28 percentage of patients in the total cohort and each clinical subspecialty by severity categories for each
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30 PROMIS domain: within normal limits, mild, moderate, and severe.[10,24,26] Lastly, we performed Pearson
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32 correlation analyses to determine the association of the 8 PROMIS domains in the cohort. We defined the
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34 magnitude of correlation as follows: low correlation - 0.10-0.39, moderate correlation - 0.40-0.69, high
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36 correlation - 0.70- 0.89 and very high correlation - 0.90-1.00.[27]
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40 **Patient and Public Involvement**

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43 There was no involvement from patients or members of the public in the design, or conduct, or reporting, or
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45 dissemination plans of this study.
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48 **RESULTS**

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51 **Cohort Demographics**

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53 Our study included 14,910 patients who consulted an Orthopaedic specialist for a new patient
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55 consultation and completed baseline PROMIS measures. Of the entire sample, 61.3% (n=9,137) were female
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with a mean age of 55.72(15.8). Most of the sample reported being Caucasian (79.3% (n=11,831)) and 13.4% (n=2,001) were Black or African American. Our sample's self-reported ethnicity was 93.7% (n=13976) Not Hispanic/Latino and 1.9% (n=285) Hispanic. The majority of patients in the sample were married (64.1%, n=9,553). The geographic dispersion of the sample included 83.8% (n=12,488) residing in urban areas and 8.6% (n=1,276) residing in rural areas in North Carolina. The primary insurance of the sample was predominantly private (90.3%, n=13,465) followed by Medicare (7.3%, n=1,088) and Medicaid (2.1%, n=311).

The highest volume of patients in the sample sought care from a sports medicine provider (28.1%, n=4,197) or a spine provider (20.3%, n=3,028), followed by total joint (15.8%, n=2,353), foot and ankle (14.8%, n=2,208) and hand 12.5%, n=1,858). Orthopedic oncology, neurosurgery, and trauma had fewer than 10% of the total volume of patients in the sample. See **table 1**.

Table 1. Sample Characteristics by Clinical Specialty

Provider specialty	Foot and ankle (n=2208)	Hand (n=1858)	Neurosurgery (n=1044)	Orthopaedic Oncology (n=124)	Spine (n=3028)	Sports medicine (n=4197)	Total Joint Arthroplasty (n=2353)	Trauma (n=98)	Total (n=14,910)	P value
Age	56.72(15.2)	54.63(15.9)	56.11(15.3)	55.18(15.5)	57.2(15.3)	52.68(16.3)	59(14.9)	56.18(19.9)	55.72(15.8)	<<0.001
Gender										
Female	64.1%(1416)	61.3%(1138)	61.2%(639)	51.6%(64)	60.0%(1818)	60.3%(2532)	62.39%(1468)	63.3%(62)	61.3%(9137)	0.015
Male	35.9%(792)	38.8(720)	38.8%(405)	48.4%(60)	40.0%(1210)	39.7%(1665)	37.61%(885)	36.7%(36)	38.7%(5773)	
Race										
2 or more races	1.2%(26)	1.7%(31)	0.9%(9)	0%(0)	1.4%(42)	1.3%(55)	1.0%(24)	3.1%(3)	1.3%(190)	0.01
American Indian or Alaskan Native	0.2%(4)	0.3%(6)	0.7%(7)	0.8%(1)	0.4%(11)	0.3%(14)	0.2%(4)	1.0%(1)	0.3%(48)	
Asian	1.9%(42)	2.1%(54)	2.0%(21)	2.4%(3)	2.2%(65)	2.8%(118)	1.3%(31)	1.0%(1)	2.2%(335)	
Black or African American	12.6%(278)	14.9%(278)	13.1%(137)	14.5%(18)	12.6%(380)	13.4%(564)	14.2%(333)	13.3%(13)	13.4%(2001)	
Caucasian/White	80.6%(1780)	77.6%(1441)	80.9%(845)	79.0%(98)	80.5%(2438)	78.0%(3274)	79.9%(1879)	77.6%(76)	79.3%(11831)	
Native Hawaiian or Other Pacific Islander	0.1%(1)	0.1%(2)	0.1%(1)	0%(0)	0.1%(2)	0.1%(4)	0.1%(2)	0%(0)	0.1%(12)	

Not Reported/ Declined	2.7%(60)	2.037	1.5%(16)	2.4%(3)	2.3%(68)	3.2%(132)	2.6%(60)	1.0%(1)	2.5%(377)	
Other	0.8%(17)	0.5(9)	0.7%(8)	0.8%(1)	0.7%(22)	0.9%(36)	0.9%(20)	3.1%(3)	0.8%(116)	
Ethnicity										
Hispanic	1.7%(37)	2.4%(45)	2.2%(23)	0.8%(1)	1.9%(57)	2.0%(85)	1.4%(32)	5.1%(5)	1.9%(285)	0.013
Not Hispanic/Latino	94.4%(2085)	93.3%(1733)	94.8%(990)	92.7%(115)	94.0%(2846)	92.9%(3898)	94.3%(2218)	92.9%(91)	93.7%(13976)	
Not Reported/ Declined	3.9%(86)	4.3%(80)	3.0%(31)	6.5%(8)	4.1%(125)	5.1%(214)	4.4%(103)	2.0%(2)	4.4%(649)	
Marital Status										
Divorced	6.2%(137)	8.0%(149)	7.9%(82)	5.7%(7)	8.3%(251)	6.5%(273)	8.0%(187)	15.3%(15)	7.4%(1101)	<<0.001
Legally Separated	0.9%(20)	1.1%(21)	1.0%(10)	0.8%(1)	1.1%(32)	1.1%(47)	0.4%(9)	1.0%(1)	0.9%(141)	
Life Partner	0.8%(17)	0.6%(11)	0.5%(5)	0%(0)	0.3%(10)	0.5%(19)	0.3%(6)	1.0%(1)	0.5%(69)	
Married	65.4%(1445)	61.9%(1150)	66.6%(695)	71.8%(89)	66.1%(2002)	61.3%(2572)	66.0%(1552)	49.0%(48)	64.1%(9553)	
Single	18.4%(406)	19.8%(367)	16.6%(173)	18.6%(23)	15.9%(482)	22.4%(939)	17.3%(408)	26.5%(26)	18.9%(2824)	
Unknown	3.6%(80)	4.1%(76)	2.6%(27)	0.8%(1)	3.1%(94)	4.7%(199)	2.6%(61)	0%(0)	3.6%(538)	
Widowed	4.7%(103)	4.5%(84)	5.0%(52)	2.4%(3)	5.2%(157)	3.5%(148)	5.5%(130)	7.1%(7)	4.6%(684)	
Geographic Location										
Rural, NC	7.2%(158)	7.4%(138)	11.9%(124)	12.1%(15)	9.7%(295)	7.3%(308)	9.4%(221)	17.4%(17)	8.6%(1276)	<<0.001
Urban, NC	82.4%(1820)	87.2%(1621)	77.1%(805)	72.6%(90)	82.3%(2491)	87.5%(3671)	81.3%(1914)	77.6%(76)	83.8%(12488)	
Other	10.4%(230)	5.3%(99)	11.0%(115)	15.3%(19)	8.0%(242)	5.2%(218)	9.3%(218)	5.1%(5)	7.7%(1146)	
Primary Insurance										
Medicare	25.2%(556)	20.8%(387)	25.9%(270)	23.4%(29)	27.2%(823)	17.6%(738)	28.9%(679)	32.7%(32)	23.6%(3514)	<<0.001
Medicaid	0.5%(10)	0.9%(17)	2.5%(26)	3.2%(4)	1.9%(58)	0.8%(33)	0.6%(15)	2.0%(2)	1.1%(165)	
Worker's Compensation	0.9%(20)	1.9%(35)	0.6%(6)	0.8%(1)	0.4%(12)	1%(42)	0.9%(21)	1.0%(1)	0.9%(138)	
Privately Insured	73.5%(1622)	76.4%(1419)	71.1%(742)	72.6%(90)	70.5%(2135)	80.6%(3384)	69.6%(1638)	64.3%(63)	74.4%(11093)	
Secondary Insurance										
Medicare	7.7%(169)	6.5%(121)	8.0%(83)	7.3%(9)	7.8%(235)	5.5%(229)	9.8%(231)	11.2%(11)	7.3%(1088)	<<0.001

Medicaid	1.3%(28)	1.5%(28)	3.7%(39)	3.2%(4)	3.0%(90)	1.6%(67)	2.1%(49)	6.1%(6)	2.1%(311)	
Worker's Compensation	0.3%(6)	0.4%(8)	0.3%(3)	0%(0)	0.3%(8)	0.3%(13)	0.3%(7)	1.0%(1)	0.3%(46)	
Privately Insured	90.8%(2005)	91.6%(1701)	88.0%(919)	89.5%(111)	89%(2695)	92.6%(3888)	87.8%(2066)	81.6%(80)	90.3%(13465)	
Questionnaire Type Completed										
PROMIS Short Forms (8 domains)	74.7%(1650)	70.8%(1316)	71.7%(749)	76.6%(95)	74.1%(2243)	68.6%(2879)	64.9%(1526)	69.4%(68)	70.6%(10526)	<<0.001
PROMIS CAT (4 domains)	25.3(558)	29.2 (542)	28.3(295)	23.4%(29)	28.9 (785)	31.4 (1318)	35.2(827)	30.6(30)	29.4 (4384)	
Year PROMIS Questionnaire Completed										
2017	2.9%(65)	2.5%(47)	3.5%(37)	6.5%(8)	4.9%(149)	3.3%(138)	3.3%(77)	3.1%(3)	3.5%(524)	<<0.001
2018	66.2%(1462)	63.2%(1175)	63.1%(659)	65.3%(81)	64.8%(1961)	61.6%(2587)	57.5%(1353)	61.2%(60)	62.6%(9338)	
2019	30.8%(681)	34.2%(636)	33.3%(348)	28.2%(35)	30.3%(918)	35.1%(1472)	39.2%(923)	35.71%(35)	33.9%(5048)	

*mean(sd), %(n)

PROMIS Scores

As presented in **table 2**, the adjusted mean scores for the PROMIS domains for the entire cohort were 38.14(38.00,38.28) for physical function, 58.84(58.71,58.98) for pain interference, 4.57(4.53,4.62) for pain intensity (on a 0 to 10 scale), 47.87(47.73,48.01) for depression, 49.85(49.67,50.03) for anxiety, 50.49(50.29,50.68) for fatigue, 51.08(50.92,51.24) for sleep disturbance and 49.06(48.86,49.25) for ability to participate in social roles. Higher pain interference and lower physical function were at least 0.5 and -1.0 standard deviations away, respectively, from the average US general population.

Table 2. Summary of Scores for PROMIS Domains by Clinical Subspecialty

	Foot and ankle	Hand	Neurosurgery	Orthopaedic Oncology	Spine	Sports medicine	Total Joint Arthroplasty	Trauma	Total Cohort	Sample Size
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Physical Health Domains										
Physical function	39.82(39.46, 40.17)	41.79(41.41, 42.18)	35.13(34.61, 35.65)	38.41(36.92, 39.89)	35.71(35.41, 36.02)	39.13(38.88, 39.39)	36.61(36.27, 36.96)	31.60(29.92, 33.28)	38.14(38.00, 38.28)	n=14,748
Ability to participate in social roles	50.53(50.05, 51.01)	52.32(51.77, 52.86)	44.30(43.59, 45.02)	47.49(45.48, 49.49)	46.30(45.89, 46.72)	50.88(50.51, 51.25)	47.93(47.42, 48.44)	43.65(41.23, 46.08)	49.06(48.86, 49.25)	n=10,451
Pain intensity	4.07(3.96, 4.19)	3.71(3.58, 3.84)	5.48(5.31, 5.65)	4.02(3.54, 4.50)	5.35(5.25, 5.45)	4.26(4.17, 4.35)	4.90(4.78, 5.03)	4.79(4.20, 5.36)	4.57(4.53, 4.62)	n=10,424
Pain interference	57.25(56.92, 57.58)	55.65(55.29, 56.02)	61.56(61.08, 62.04)	57.47(56.08, 58.86)	61.21(60.93, 61.49)	58.01(57.77, 58.25)	60.03(59.71, 60.35)	60.97(59.37, 62.56)	58.84(58.71, 58.98)	n=14,474
Fatigue	49.13(48.65, 49.62)	48.61(48.06, 49.15)	54.94(54.22, 55.66)	52.14(50.12, 54.15)	53.22(52.81, 53.64)	47.78(48.42, 49.15)	50.31(49.80, 50.82)	53.82(51.42, 56.21)	50.49(50.29, 50.68)	n=10,452
Sleep disturbance	49.20(48.80, 49.61)	49.73(49.29, 50.17)	53.85(53.26, 54.43)	50.83(49.14, 52.51)	53.08(52.73, 53.42)	50.36(50.07, 50.66)	51.26(50.87, 51.65)	53.46(51.54, 55.39)	51.08(50.92, 51.24)	n=14,465
Mental Health Domains										
Anxiety	48.61(48.16, 49.06)	49.00(48.49, 49.51)	52.65(51.99, 53.32)	53.18(51.32, 55.04)	51.69(51.30, 52.07)	48.72(48.37, 49.06)	49.64(49.17, 50.11)	52.00(49.77, 54.24)	49.85(49.67, 50.03)	n=10,351
Depression	47.07(46.70, 47.44)	47.27(46.87, 47.67)	50.22(49.69, 50.76)	49.22(47.68, 50.77)	49.36(49.05, 49.68)	46.87(46.61, 47.14)	47.66(47.31, 48.02)	50.85(49.06, 52.64)	47.87(47.73, 48.01)	n=14,391

*mean(95% CI)

*regression models adjusted for age, sex, race, ethnicity and questionnaire type

Table 3 provides more context to the range of observed health status scores by categorizing scores into degrees of severity: within normal limits, mild, moderate, and severe.[10,24,26] In this cohort, 24.9% of all patients reported their physical functioning within normal limits; the majority of patients (75%) reported mild, moderate, or severe limitations in physical functioning. There is a similar trend for pain interference, where 73% of patients reported mild, moderate, or severe limitations with pain interference. The majority of the cohort reported within normal limits for the ability to participate in social roles (63.5%), fatigue (68.0%), and sleep disturbance (66.0%). For the mental health domains (anxiety and depression), across the samples, most

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300 patients reported normal limits for anxiety (69.6%) and depression (76.8%). Few patients reported severe
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501 symptoms of anxiety (1.7%) and depression (1.1%).
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Table 3: PROMIS Severity Categories by Clinical Subspecialty

	Foot and ankle	Hand	Neurosurgery	Orthopaedic Oncology	Spine	Sports medicine	Total Joint Arthroplasty	Trauma	Total
Physical Health Domains									
Physical function									
Within Normal limits	29.6%	40.5%	16.2%	32.3%	15.7%	29.1%	16.6%	11.3%	24.9%
Mild	22.9%	20.7%	13.1%	11.3%	15.0%	22.1%	20.0%	8.3%	19.5%
Moderate	30.7%	26.4%	38.9%	33.1%	40.5%	33.3%	40.2%	29.9%	35.0%
Severe	16.7%	12.5%	31.8%	23.4%	28.8%	15.4%	23.2%	50.5%	20.6%
Ability to participate in social roles									
Within Normal limits	67.3%	74.3%	42.2%	51.6%	52.8%	72.8%	60.6%	44.6%	63.5%
Mild	18.4%	13.9%	23.4%	24.2%	21.3%	14.2%	18.9%	15.4%	17.8%
Moderate	11.5%	9.6%	24.9%	20.0%	19.5%	10.3%	16.1%	24.6%	14.4%
Severe	2.9%	2.2%	9.5%	4.2%	6.4%	2.7%	4.4%	15.4%	4.3%
Pain interference									
Within Normal limits	33.8%	43.7%	16.3%	33.1%	16.7%	29.8%	20.3%	21.7%	27.0%
Mild	23.6%	24.3%	16.7%	16.5%	21.4%	28.4%	24.3%	13.0%	24.1%
Moderate	39.4%	28.8%	59.7%	46.3%	55.8%	38.0%	49.0%	55.4%	44.1%
Severe	3.2%	3.3%	7.4%	4.1%	6.2%	3.7%	6.5%	9.8%	4.8%
Fatigue									
Within Normal limits	73.4%	73.9%	50.7%	63.2%	57.2%	74.4%	70.6%	55.2%	68.0%
Mild	12.3%	11.3%	17.7%	13.7%	17.1%	12.3%	13.8%	17.9%	13.9%
Moderate	12.0%	12.2%	24.6%	20.0%	21.8%	11.0%	13.2%	20.9%	15.1%
Severe	2.3%	2.7%	7.0%	3.2%	3.9%	2.3%	2.4%	6.0%	3.1%
Sleep disturbance									
Within Normal limits	74.3%	71.5%	54.3%	67.2%	58.0%	69.0%	64.8%	55.3%	66.0%

Mild	13.7%	14.1%	17.5%	18.0%	18.1%	14.4%	16.0%	13.8%	15.5%
Moderate	10.5%	11.7%	22.3%	11.5%	19.3%	13.7%	16.1%	23.4%	15.1%
Severe	1.6%	2.7%	5.9%	3.3%	4.7%	2.9%	3.0%	7.5%	3.3%
Mental Health Domains									
Anxiety									
Within Normal limits	74.6%	71.6%	59.7%	55.8%	62.0%	73.4%	72.5%	60.6%	69.6%
Mild	14.0%	14.8%	16.2%	22.1%	17.2%	14.7%	15.2%	16.7%	15.4%
Moderate	10.5%	11.4%	20.2%	19.0%	18.9%	10.9%	10.7%	19.7%	13.4%
Severe	0.9%	2.1%	3.9%	3.2%	1.9%	1.1%	1.6%	3.0%	1.7%
Depression									
Within Normal limits	80.7%	78.3%	66.5%	71.9%	71.5%	79.9%	78.6%	65.6%	76.8%
Mild	12.1%	12.0%	15.9%	14.9%	14.9%	12.2%	12.5%	20.0%	13.1%
Moderate	6.5%	8.2%	15.2%	12.4%	12.3%	7.3%	8.0%	12.2%	9.1%
Severe	0.6%	1.5%	2.5%	0.8%	1.4%	0.7%	1.0%	2.2%	1.1%

In **table 4**, we examine the correlation of unadjusted PROMIS domains in the cohort. As expected, we found high correlations between depression and anxiety ($r=0.76$) and pain interference and pain intensity ($r=0.75$). Additionally, we found moderate correlations between commonly administered PROMIS domains in Orthopaedics - physical function and pain interference ($r=-0.60$) and physical function and pain intensity ($r=0.52$). There was a low correlation found between anxiety and pain intensity ($r=0.30$), anxiety, and pain interference ($r=0.36$), anxiety, and physical function ($r=-0.32$). Similar trends were found with depression where low correlations between depression and pain intensity ($r=0.29$), depression, and pain interference ($r=0.39$), depression, and physical function ($r=-0.30$).

Table 4: Correlation of PROMIS Domains

	Participation	Anxiety	Depression	Fatigue	Pain Intensity	Pain Interference	Physical Function	Sleep Disturbance
Participation	-	-0.48	-0.51	-0.66	-0.52	-0.69	0.67	-0.45
Anxiety	-0.48	-	0.76	0.58	0.30	0.36	-0.32	0.44
Depression	-0.51	0.76	-	0.58	0.29	0.39	-0.30	0.43
Fatigue	-0.66	0.58	0.58	-	0.42	0.52	-0.48	0.54
Pain Intensity	-0.52	0.30	0.29	0.42	-	0.75	-0.52	0.39
Pain Interference	-0.69	0.36	0.39	0.52	0.75	-	-0.60	0.45

Physical Function	0.67	-0.32	-0.30	-0.48	-0.52	-0.60	-	-0.31
Sleep Disturbance	-0.45	0.44	0.43	0.54	0.39	0.45	-0.31	-

*all correlations were statistically significant $P < 0.001$

PROMIS Scores by Major Clinical Specialties

Foot and Ankle

Patients consulting with a foot and ankle orthopedic specialist scored less than 0.5 SD from the mean for all domains except for pain interference, where patients reported a mean score of 57.2(8.6). When looking at the clinically interpretable categories for physical function, 30.7% of patients reported moderate limitations and 16.7% severe limitations. For pain interference, 39.4% reported moderate and limitations, and 3.2% reported severe limitations.

Hand

Patients who consulted with a hand orthopedic specialist reported scores less than 0.5 SD from the mean for all domains except pain interference and physical function. Patients reported a mean score of 55.7(8.8) and 41.85(9.5), respectively. For physical function, 26.4% of patients reported moderate limitations, and 12.5% reported severe limitations.

Neurosurgery and Spine

Patients either consulting with a neurosurgeon or a spine orthopedic specialist reported between 1- 1.5 standard deviations from the US mean for pain interference and physical functioning. Neurosurgery patients reported higher levels of pain interference (61.53(8.1)) compared to spine patients (57.23(9.7)) and also reported more limitations in physical functioning (35.0(9.0)) as compared to spine patients (38.35(10.5)). For physical function, a majority of neurosurgery patients reported moderate (38.9%) and severe (31.8%) limitations, and this was similar in spine patients (moderate- 40.5%, severe 28.8%). Pain interference, most neurosurgery (59.7%) and Spine patients (55.8%) reported moderate limitations, and a small percentage of neurosurgery (7.4%) and spine patients (6.2%) reported severe limitations.

Sports Medicine

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4 Patients seeking care from a sports medicine specialist reported less than 0.5 SD from the US mean in
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6 all domains except physical function (39.51(8.8)) and pain interference (58.0(7.6)) where their scores were
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8 between 0.5-1.0 SD from the US mean. 33.3% of patients reported moderate limitations in physical function,
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10 and 15.4% reported severe limitations. For pain interference, 38.0% of patients reported moderate limitations,
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12 and 3.7% reported severe limitations.

13 14 15 Total Joint Arthroplasty

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17 Patients consulting a Total Joint Arthroplasty Orthopaedic Surgeon reported less than 0.5 SD from the
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19 US mean in all domains except physical functioning (36.58(8.5)) and pain interference (60.21(8.4)). Most
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21 patients reported moderate limitations in physical functioning (40.2%) and pain interference (48.9%), and
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23 23.2% reported severe limitations in physical function, and only a small percentage reported severe limitations
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25 for pain interference (6.5%).

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27 We did not report on Trauma or Orthopaedic Oncology due to low sample sizes in each of these
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29 subspecialties.

30 31 DISCUSSION

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33 The goal of PROMIS was to create a measurement system that could standardize of PROs across
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35 chronic conditions to better enable comparisons across different disease conditions.[14] To this end, we
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37 described approximately 15,000 orthopedic patients across eight different clinical subspecialties who
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39 completed PROMIS measures associated with a new patient consultation with an orthopedic specialist. We
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41 found across an orthopaedic department at an academic medical center, that most patients reported scores
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43 within 0.5 SD from the US mean on all domains except pain interference and physical functioning; where they
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45 reported approximately 1.0 SD US mean on pain interference and physical functioning . These findings are
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47 expected, where the primary drivers of seeking care for orthopedic issues are decreased physical functioning
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49 and increased interference with activities due to pain.[28][29] When further examining the difference of
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51 PROMIS scores between the clinical subspecialties for the physical health domains, we found that patients
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53 seeking care from hand specialists reported less overall physical health impairments. However, we primarily
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55 attribute this finding to administering the generic PROMIS physical function measure rather than the upper
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4 265 extremity physical function PROMIS measure, which is more specific to upper extremity conditions and may
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6 266 better reflect limitations in this group.[30] Patients seeking care from a Neurosurgery, Spine, or a Trauma
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8 267 specialist reported significant physical health impairments. When examining PROMIS mental health domains,
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10 268 most patients across clinical subspecialties reported that their anxiety and depression symptoms were within
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12 269 normal limits; however, up to 24.1% reported moderate or severe anxiety and up to 17.6% reported moderate
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14 270 or severe depressive symptoms. Following a similar trend as the specialties across the PROMIS physical
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16 271 health domains, patients seeking care from a Neurosurgery, Spine, or Trauma specialist reported the highest
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18 272 anxiety and depression symptoms. This relationship is consistent with literature supporting patients with spine
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20 273 conditions, and orthopedic trauma have higher anxiety levels than other orthopedic conditions.[31,32]

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22 274 Majority of patients seeking care in orthopaedics across clinical subspecialties do so because of
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24 275 limitations in physical function and pain.[33–35] Measurement of these constructs can be done using PROMs.
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26 276 Many legacy measures commonly used in orthopaedics measure more than one construct. This makes it
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28 277 difficult to elucidate limitations or symptom contributions from a specific construct on a patient's perception of
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30 278 their health status. For example, a patient seeking care for knee osteoarthritis may report more limitations in
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32 279 physical functioning rather than pain. Using traditional, concise legacy measures such as Knee Injury and
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34 280 Osteoarthritis Outcome Score Junior (KOOS Jr) [36] to evaluate stiffness, pain, function and activities of daily
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36 281 living using 7 items would be challenging to isolate the relative limitations in physical functioning compared to
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38 282 the other constructs included in the KOOS Jr. Whereas, PROMIS PF can be administered to capture this
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40 283 construct separately and concisely, giving a valid estimate of a patient's perception of their physical function.
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42 284 PROMIS PF and has been shown to be equal or superior in regard to floor and ceiling effects when compared
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44 285 with previously established legacy PROM in several patient populations including trauma, shoulder, elbow,
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46 286 hand, spine, and knee; making this measure applicable across patient populations and range of severity of
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48 287 symptoms. [37] However a noted limitation is, to date, not all PROMIS measures have been evaluated for floor
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50 288 and ceiling effects across multiple populations or found to be as responsive as PROMIS PF for Orthopaedic
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52 289 patients. In particular, PROMIS measures that capture emotional distress and psychosocial illness impact have
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54 290 not been extensively researched for wide-spread use in Orthopaedics [31].
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Strengths and Limitations

Our study has noted strengths. First, our study is novel in that we reported eight PROMIS domains across eight different orthopedic clinical subspecialties. The use of PROMIS measures in clinical practice and research has been increasing in prevalence in spine, total joint, sports medicine, upper extremity disorders, trauma, and lower extremity disorders.[38] In a systematic review on the uptake of PROMIS measures in Orthopaedics, they found that studies typically report around three PROMIS domains.[38] Our study is the first that we are aware of to report and directly compare differences in these eight health domains across orthopaedic clinical subspecialties, providing baseline for PROMIS scores in orthopaedic. The direct comparisons reported in this paper would not be possible if using region-specific measures common to orthopedic practice and research. By implementing PROMIS measures as a standard set of outcome measures, we can draw inferences about differences in patient-reported health status across orthopedic populations that are typically not compared. Second, our study reported a clinical interpretation of PROMIS scores addressing the reported barrier to PROMIS use uptake.[8,39] Providing a clinical interpretation is vital because often there is a disconnect between mean PROMIS scores (i.e., physical functioning score- 38.2) and how to interpret this information (moderate limitations in physical functioning).[39]

Our study is not without limitations. First, this was a cross-sectional cohort analysis, so we did not report PROMIS measures beyond baseline. Therefore, we cannot identify predictors of clinical outcomes or compare the change in PROMIS scores across subspecialties over time or downstream utilization of Orthopaedic procedures or rehabilitation services associated with baseline scores. Second, our findings may have limited generalizability. For example, the setting was a private hospital. It may not capture the broad diversity of non-white individuals in the area (79.3% of individuals reported being Caucasian). Our instruments were only available in English, limiting data collection on non-English speaking patients. Moreover, in some clinical subspecialties reported (i.e., trauma and orthopedic oncology), small sample sizes potentially limit generalizability of these findings. Lastly, we did not compare PROMIS upper extremity physical function or legacy measures to our PROMIS measures as part of this study. Therefore we cannot make direct

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comparisons of the performance of the eight reported PROMIS domains in this study to legacy or PROMIS upper extremity. However, the relationship between legacy measures in orthopedics and PROMIS measures is well documented in the literature. [40]

Our study's findings are consistent with other literature regarding orthopedic populations' physical and mental health status. [41] In comparison to a study by Perruccio et al. (2013) using the SF-36 as the outcome measure to physical and mental health in patients seeking care for musculoskeletal disorders, we found similar results where patients with spine disorders reported the most impairments in the cohort. [41] Additionally, consistent with our results, they found hand upper extremity/hand patients were the healthiest, and total joint arthroplasty patients demonstrated low levels of physical functioning. Our study's unexpected finding low levels of sleep disturbance, fatigue, and depression reported across clinical subspecialties. Sleep disruption and pain frequently co-occur; both are uniquely linked with depressed mood [42–45] and various forms of functional disability [46–48]. Depression appears to play a substantial role in the sleep-pain linkage, particularly where the pain is severe. [49] However, in our study, we did not find this relationship between pain, physical function, sleep disturbance, and depression in the cohort, despite the research supporting these relationships. [49]

Conclusions

Reporting patients' health status consulting an Orthopaedic provider using a standard set of outcome measures across various clinical subspecialties has numerous clinical care and research implications. Understanding the health status and clinical examination measures may improve patient and provider communication during the clinical encounter [50] and be used as part of the prognostic evaluation. [51] Moreover, this study can provide a context for informing bundled care or value-based care models. Classifying heterogeneous orthopedic patients' baseline status on a standard metric could better inform the effectiveness and cost of treatment pathways.[52] Lastly, reporting PROMIS scores has allowed the direct comparison of eight meaningful constructs across orthopedic subspecialties. This comparison would not be possible with legacy measures, which is a noted strength of PROMIS measures. These comparisons allow unique insights to be made for orthopedic departments and align clinical and research data collection with value-based care

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3 initiatives outside of orthopedic departments. Clinicians and administrators can use this information to improve
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5 the delivery and the efficiency of care, improve and inform referral practices, and inform subspecialty-specific
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7 education to improve patient outcomes from orthopedic care.
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13
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17

18
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23 profit sectors

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25 **Ethics Statement:** We obtained IRB approval from Duke University for data extraction and analysis of the
26
27 collected data for this study (Pro00091740)
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30 **Author Contributions:** Maggie Horn contributed to the work's conception, design of the study, data
31
32 acquisition, and writing of the manuscript. Steven George contributed to the conception of the work, design of
33
34 the manuscript's study, and writing. Emily Reinke contributed to the conception of the work, design of the
35
36 study, data acquisition, and writing the manuscript. Xiaofang Yan and Sheng Luo contributed to the study's
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38 design and statistical analysis. Michael Bolognesi contributed to the design of the manuscript's study and
39
40 writing. Bryce Reeve contributed to the design of the manuscript's study and writing. All authors had final
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42 approval of the manuscript.
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45 **Data Availability:** Data are not available in accordance with protections provided by the HIPAA privacy
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47 information policy.
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FIGURE 1: Flow diagram for cohort selection.

For peer review only

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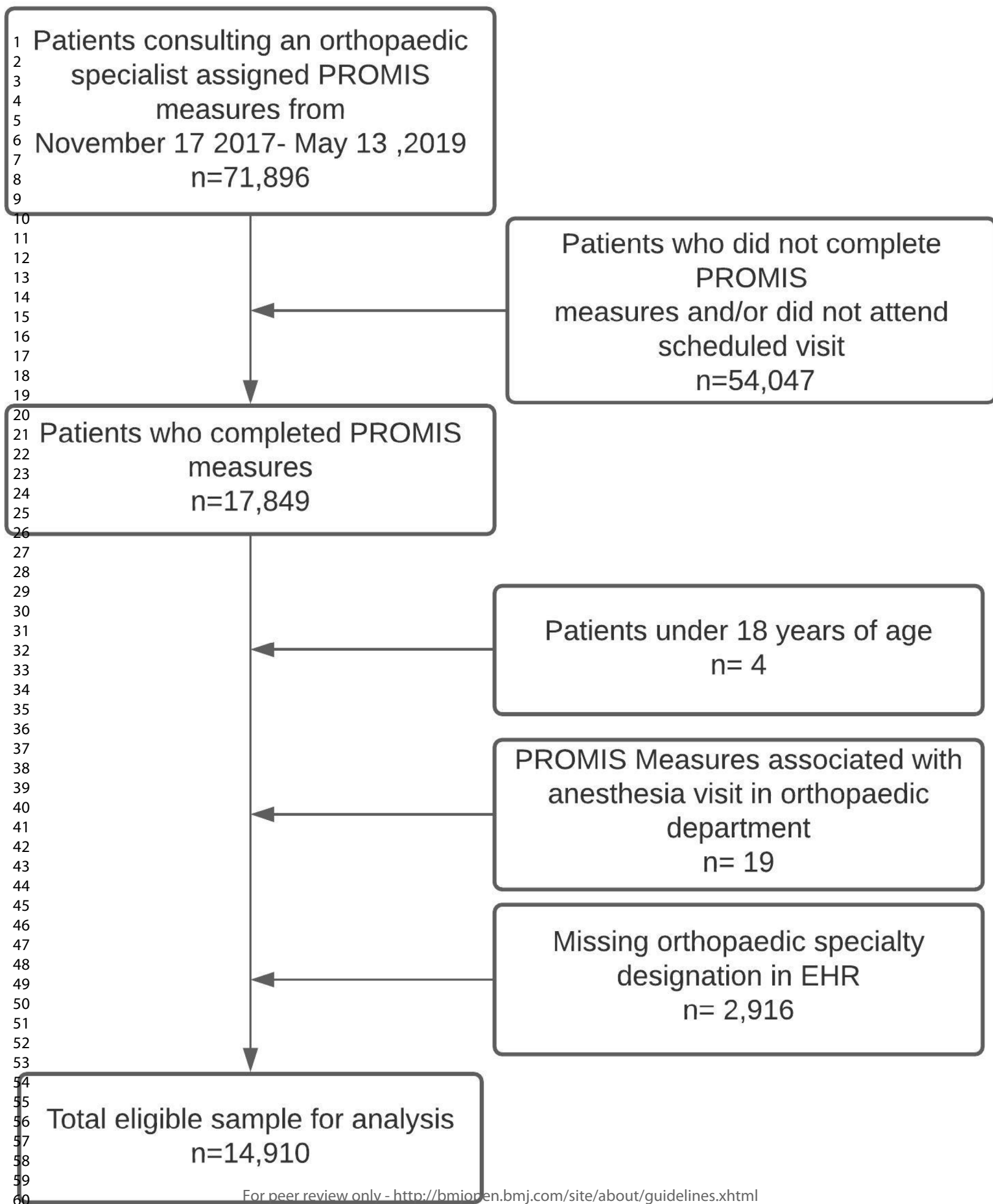
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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5-6
		(b) For matched studies, give matching criteria and number of exposed and unexposed	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	7
		(d) If applicable, explain how loss to follow-up was addressed	7
		(e) Describe any sensitivity analyses	7
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	8 n/a n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	8 tables n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	8-10 n/a n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Use of Patient-Reported Outcome Measurement Information System® (PROMIS®) measures to characterize health status for patients seeking care from an orthopedic provider: A retrospective cohort study

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Primary Subject Heading:	Health services research
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3 Title: Use of Patient-Reported Outcome Measurement Information System® (PROMIS®) measures to
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6 characterize health status for patients seeking care from an orthopedic provider: A retrospective cohort study
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10 Corresponding Author: Maggie E Horn DPT, MPH, PhD^{1,2}

11
12 Duke University, Box 10042, Durham, NC 27710, 919-684-1365, maggie.horn@duke.edu

13
14 Emily K. Reinke, PhD¹

15
16 Xiaofang Yang, PhD³

17
18 Sheng Luo, PhD^{2,3}

19
20 Michael P Bolognesi, MD¹

21
22 Bryce B. Reeve, PhD^{2,3}

23
24 Steven Z George PT, PhD^{1,3}

25
26
27 ¹Duke University, Department of Orthopaedic Surgery, Division of Physical Therapy, Durham, USA

28
29 ²Duke University, Department of Population Health Sciences, Durham, USA

30
31 ³Duke University, Duke Clinical Research Institute, Durham, USA

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36 **Word count:** Abstract, 288; Body, 3514

ABSTRACT

Objectives: Characterize the health status of patients newly consulting an orthopedic specialist across eight clinical subspecialties.

Design: Retrospective cohort

Setting: 18 orthopedic clinics, including eight subspecialties (14 ambulatory and four hospital-based) within an academic health system.

Participants: 14,910 patients consulting an orthopaedic specialist for a new patient consultation who completed baseline Patient-Reported Outcome Measurement Information System (PROMIS) measures associated with their appointment from November 17 2017 - May 13 2019. Patients were 55.72 ± 5.8 years old, 61.3% female and 79.3% Caucasian, and were 13.4% Black or African American. Patients who did not complete PROMIS measures or canceled their appointment were excluded from the study.

Primary Outcome: PROMIS domains of physical function, pain interference, pain intensity, depression, anxiety, fatigue, sleep disturbance, and the ability to participate in social roles.

Results: Mean PROMIS scores for physical function was (38.1 ± 9.2), pain interference (58.9 ± 8.1), pain intensity (4.6 ± 2.5), depression (47.9 ± 8.9), anxiety (49.9 ± 9.5), fatigue (50.5 ± 10.3), sleep disturbance (51.1 ± 9.8), and ability to participate in social roles (49.1 ± 10.3). Across the clinical subspecialties, Neurosurgery, Spine, and Trauma patients were most profoundly affected across almost all domains, and patients consulting with a Hand specialist reported the least limitations or symptoms across domains. There was a moderate, negative correlation between pain interference and physical functioning ($r = -0.59$) and low correlations

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3 between pain interference with anxiety ($r=0.36$), depression ($r=0.39$) as well as physical function and anxiety
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5 ($r=-0.32$) and depression ($r=-0.30$) and sleep ($r=-0.31$).
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8 **Conclusions:** We directly compared clinically meaningful PROMIS domains across eight orthopedic
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10 subspecialties, which would not be possible with legacy measures alone. These results support PROMIS's
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12 utility as a common metric to assess and compare patient health status across multiple orthopedic
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14 subspecialties.
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16 17 18 **ARTICLE SUMMARY**

19 20 **Strengths and Limitations of this Study**

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22 • This study demonstrated the direct comparison of health status using PROMIS measures across eight
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24 orthopedic clinical subspecialties, which was previously a challenge using legacy outcome measures.
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- 26
27 • This study reported the association of eight clinically relevant PROMIS domains (six physical health
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29 and two mental health domains) within an orthopedic cohort.
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31 • We evaluated PROMIS measures at baseline only as part of routine clinical assessment associated
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33 with a new patient consultation with an orthopaedic specialist; no follow up data was analyzed in the
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35 context of downstream healthcare utilization.
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37 • The findings' generalizability is limited by data collected within a private health system setting that may
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39 not reflect other health systems' characteristics.
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44 **Key Words:** Patient-reported outcome measures, orthopedics, health status, physical function, pain
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INTRODUCTION

To determine if a patient has achieved treatment success, it is insufficient to evaluate treatment results solely on medical history, physical findings, laboratory tests, or imaging findings alone.[1] While these are essential clinical indicators, they may not reflect what is most important to a patient. Patient-reported outcome measures (PROMs) are additional indicators that come directly from the patient. PROMs may address more important patient-centered outcomes about a patient's health status's physical, mental, and social aspects. Change in health status can be one of the measures of "success" from a patient's perspective after an orthopedic procedure.[2] PROMs are increasingly being used as part of the clinical encounter to guide treatment decisions and determine intervention effectiveness. [3]

"Legacy" patient-reported outcome measures (PROs) have been used for decades; however, they have many limitations.[4] To overcome the limitations of legacy measures the NIH developed a universally accepted set of PROMs. The NIH's Patient-Reported Outcomes Measurement Information System® (PROMIS®) covers a broad range of relevant domains and has strong evidence for its validity and reliability in a broad range of populations.[5–8] In orthopedics, the use of PROMIS measures has distinct advantages because it can be used across many clinical subspecialties as a common outcome metric. [8–10] This has the opportunity to allow for the evaluation of the efficacy of different interventions and inform quality improvement initiatives.[11]

Recently, there has been an increase in the adoption of PROMIS measures as the standard outcome measurement system in Orthopaedics to assess health status in orthopedic patients.[8] However, what is unknown about the use of PROMIS measures in orthopedics is how these measures differ across patients seeking care from different orthopedic clinical subspecialties. Moreover, there is limited data regarding the burden of disease in patients presenting to orthopedic clinics for initial care. Therefore, there are two goals of this study. First, we will characterize the health status of a cohort of patients completing PROMIS measures as part of the clinical encounter by comparing the physical health (6 domains) and mental health (2 domains) across eight different clinical subspecialty areas in a large academic medical center. Second, we will examine the correlation between the PROMIS domains in this cohort.

METHODS

Study Setting and Participants

Patients consulting an Orthopaedic specialist (surgeon or advanced practice provider- nurse practitioner or physician assistant) for a new patient consultation from November 17, 2017 - May 13, 2019 were considered. In this study, patients sought care within the Department of Orthopaedic surgery at a large academic, private medical center in Durham, NC. Inclusion criteria for the study were patients who completed assigned PROMIS measures associated with the visit type of new patient appointment. We excluded patients from the study who 1) were under 18 years of age at time of appointment, 2) completed assigned PROMIS measures but canceled or did not attend their scheduled appointments 3) who attended a visit with a provider that was not classified as an orthopaedic specialist or a provider that did not have a provider speciality designation within the EHR. The department includes 18 adult clinics (14 ambulatory and four hospital-based clinics). See Figure 1 for study eligibility. The department consists of eight subspecialties (Joint Reconstruction, Spine, Neurosurgery, Sports Medicine, Trauma, Orthopaedic Oncology, Foot and Ankle, and Hand) with over 100 Orthopaedic specialists. We extracted all data for this study directly from the electronic health record (EHR).

Standardized Collection of PROMIS Measures

In December of 2017, the orthopedics department implemented a standardized collection of PROMIS measures across 18 clinics and eight clinical subspecialties. The administration of PROMIS measures was linked to new patient appointments and collected and scored passively within the EHR (Epic Systems) as part of the standard of care. Therefore, informed consent was not required for the completion of the PROMIS measures. This study was determined exempt by the Duke University Institutional Review Board (Pro00091740).

From November 2017- May 2019, we collected the short-form version of the following 8 PROMIS domains: physical function (7 items), pain interference (8 items), pain intensity (1 item), depression (8 items), anxiety (8 items), fatigue (8 items), sleep disturbance (8 items) and ability to participate in social roles (8 items). On December 20, 2018 our health system transitioned to administering the computer adaptive testing

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3 (CAT) version of PROMIS domains instead of short form as the (CAT) instruments were then available within
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5 our EHR. As part of the transition from short form to CAT, we reduced the set of PROMIS domains collected
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7 to physical function, pain interference, depression, and sleep disturbance. This change was done in response
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9 to feedback from clinicians regarding respondent burden with eight domains and perceived clinical utility of
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11 information gained. Studies to date suggest CATs and SFs will produce very similar mean scores for a given
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13 sample and demonstrate similar accuracy range with SFs are greater than 4 items such as in this study. [12–
14] Therefore we combined these scores with the respective PROMIS short form scores for the analysis.

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17 The PROMIS Physical Function domain is a patient's self-reported capability (rather than actual
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19 performance) of physical activities. The physical function domain includes the functioning of one's upper
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21 extremities (dexterity), lower extremities (walking or mobility), and central regions (neck, back), as well as
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23 instrumental activities of daily living, such as running errands.[15] PROMIS Pain Interference measures the
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25 consequences of pain on relevant aspects of one's life. The pain interference domain includes the extent to
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27 which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities.[16]
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29 PROMIS pain intensity consists of one question, "How would you rate your pain on average? (0-10, 0=No pain
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31 10=Worst imaginable)".[17] PROMIS emotional distress domains included depression and anxiety. Depression
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33 measures negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition
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35 (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (loss of interest,
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37 meaning, and purpose).[18] Anxiety domain measures fear (fearfulness, panic), anxious misery (worry, dread),
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39 hyperarousal (tension, nervousness, restlessness), and somatic symptoms related to arousal (racing heart,
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41 dizziness). [19] The PROMIS Sleep Disturbance Perceptions measure sleep quality, sleep depth, and
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43 restoration associated with sleep.[20] The PROMIS fatigue domain measures a range of symptoms, from mild
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45 subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely
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47 decreases one's ability to execute daily activities and function normally in a family or social roles.[21] The
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49 PROMIS Ability to Participate in Social Roles and Activities measures one's perceived ability to perform one's
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51 usual social roles and activities.[22,23]
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4 Each PROMIS domain is scored separately on a T-score metric, where 50 is the mean and 10 is the
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6 standard deviation of the calibration population. For all PROMIS domains (except sleep disturbance) included
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8 in this study, the calibration population is the US general population. A higher score on a domain reflects more
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10 of the measured concept (e.g., more Fatigue, more Physical Function). For example, a physical function score
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12 of 60 indicates the sample's functioning is one standard deviation better than the average US general
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14 population and lower score is less of the measured concept.[5] To increase the interpretability of findings,
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16 PROMIS scores can then be categorized into the categories of "Within Normal Limits" indicating less than a
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18 0.5 SD from the mean; "Mild" indicating a score 0.5 SD from mean; "Moderate" indicating 1.0 SD from the
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20 mean; and "Severe" s indicating 2.0 standard deviations from the mean. These categories were developed by
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22 evaluating the percentage of participants from large scale calibration testing that would then fit into each
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24 category.[10,24]
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130 **Patient Demographics**

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29 Patient demographics recorded included patient age at the appointment, sex (male or female), race
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31 (American Indian or Alaskan Native, Asian, Black or African American, Caucasian/White, Native Hawaiian or
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33 Other Pacific Islander, Not Reported/Declined, Other and two or more races), ethnicity (Hispanic, Not
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35 Hispanic/Latino, Not Reported/Declined), marital status (Divorced, Legally Separated, Life Partner, Married,
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37 Single, unknown, widowed), geographical delineation (urban or rural) and primary and secondary insurance
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39 type (Medicare, Medicaid, workers compensation, private).
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137 **Healthcare Process Variables**

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45 In this sample, we collected information related to the new patient consultation, including; visit date,
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47 clinic location and type (ambulatory vs. hospital-based), provider type (orthopedic physician or advanced
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49 practice provider-nurse practitioner or physician assistant), and provider specialty (Joint Reconstruction, Spine,
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51 Neurosurgery, Sports Medicine, Trauma, Orthopaedic Oncology, Foot and Ankle, and Hand).
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142 **Data Analysis**

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3 We performed data analysis using R Statistical Software version R 4.0.2.[25]
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6 This study's primary purpose was to characterize the health status of patients seeking care from eight
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8 orthopedic subspecialties in the Department of Orthopaedic Surgery. We calculated descriptive statistics to
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10 characterize the cohort. Means and standard deviations were reported for continuous variables, and
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12 percentages were reported for categorical variables. Cohort characteristics were compared across clinical
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14 subspecialties using chi-square analysis for categorical variables and 1-way analyses of variance for
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16 continuous variables. We conducted ordinary least squares (OLS) linear regression and reported the mean
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18 and 95% CI standard deviation for PROMIS domain scores across each specialty and for the entire cohort. We
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20 included the variables of age, sex (male, female), race (collapsed into caucasian/white, black/african american,
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22 and other), ethnicity (collapsed into non-hispanic, hispanic and not reported) and instrument type (short form or
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24 CAT). These variables were included to control for the effects of differences in demographic factors and
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26 questionnaire type across specialities when comparing mean PROMIS scores. We then calculated the
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28 percentage of patients in the total cohort and each clinical subspecialty by severity categories for each
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30 PROMIS domain: within normal limits, mild, moderate, and severe.[10,24,26] Lastly, we performed Pearson
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32 correlation analyses to determine the association of the 8 PROMIS domains in the cohort. We defined the
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34 magnitude of correlation as follows: low correlation - 0.10-0.39, moderate correlation - 0.40-0.69, high
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36 correlation - 0.70- 0.89 and very high correlation - 0.90-1.00.[27]
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40 **Patient and Public Involvement**

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43 There was no involvement from patients or members of the public in the design, or conduct, or reporting, or
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45 dissemination plans of this study.
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48 **RESULTS**

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51 **Cohort Demographics**

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53 Our study included 14,910 patients who consulted an Orthopaedic specialist for a new patient
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55 consultation and completed baseline PROMIS measures. Of the entire sample, 61.3% (n=9,137) were female
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with a mean age of 55.72(15.8). Most of the sample reported being Caucasian (79.3% (n=11,831)) and 13.4% (n=2,001) were Black or African American. Our sample's self-reported ethnicity was 93.7% (n=13976) Not Hispanic/Latino and 1.9% (n=285) Hispanic. The majority of patients in the sample were married (64.1%, n=9,553). The geographic dispersion of the sample included 83.8% (n=12,488) residing in urban areas and 8.6% (n=1,276) residing in rural areas in North Carolina. The primary insurance of the sample was predominantly private (90.3%, n=13,465) followed by Medicare (7.3%, n=1,088) and Medicaid (2.1%, n=311).

The highest volume of patients in the sample sought care from a sports medicine provider (28.1%, n=4,197) or a spine provider (20.3%, n=3,028), followed by total joint (15.8%, n=2,353), foot and ankle (14.8%, n=2,208) and hand 12.5%, n=1,858). Orthopedic oncology, neurosurgery, and trauma had fewer than 10% of the total volume of patients in the sample. See **table 1**.

Table 1. Sample Characteristics by Clinical Specialty

Provider specialty	Foot and ankle (n=2208)	Hand (n=1858)	Neurosurgery (n=1044)	Orthopaedic Oncology (n=124)	Spine (n=3028)	Sports medicine (n=4197)	Total Joint Arthroplasty (n=2353)	Trauma (n=98)	Total (n=14,910)	P value
Age	56.72(15.2)	54.63(15.9)	56.11(15.3)	55.18(15.5)	57.2(15.3)	52.68(16.3)	59(14.9)	56.18(19.9)	55.72(15.8)	<<0.001
Gender										
Female	64.1%(1416)	61.3%(1138)	61.2%(639)	51.6%(64)	60.0%(1818)	60.3%(2532)	62.39%(1468)	63.3%(62)	61.3%(9137)	0.015
Male	35.9%(792)	38.8(720)	38.8%(405)	48.4%(60)	40.0%(1210)	39.7%(1665)	37.61%(885)	36.7%(36)	38.7%(5773)	
Race										
2 or more races	1.2%(26)	1.7%(31)	0.9%(9)	0%(0)	1.4%(42)	1.3%(55)	1.0%(24)	3.1%(3)	1.3%(190)	0.01
American Indian or Alaskan Native	0.2%(4)	0.3%(6)	0.7%(7)	0.8%(1)	0.4%(11)	0.3%(14)	0.2%(4)	1.0%(1)	0.3%(48)	
Asian	1.9%(42)	2.1%(54)	2.0%(21)	2.4%(3)	2.2%(65)	2.8%(118)	1.3%(31)	1.0%(1)	2.2%(335)	
Black or African American	12.6%(278)	14.9%(278)	13.1%(137)	14.5%(18)	12.6%(380)	13.4%(564)	14.2%(333)	13.3%(13)	13.4%(2001)	
Caucasian/White	80.6%(1780)	77.6%(1441)	80.9%(845)	79.0%(98)	80.5%(2438)	78.0%(3274)	79.9%(1879)	77.6%(76)	79.3%(11831)	
Native Hawaiian or Other Pacific Islander	0.1%(1)	0.1%(2)	0.1%(1)	0%(0)	0.1%(2)	0.1%(4)	0.1%(2)	0%(0)	0.1%(12)	

Not Reported/ Declined	2.7%(60)	2.037	1.5%(16)	2.4%(3)	2.3%(68)	3.2%(132)	2.6%(60)	1.0%(1)	2.5%(377)	
Other	0.8%(17)	0.5(9)	0.7%(8)	0.8%(1)	0.7%(22)	0.9%(36)	0.9%(20)	3.1%(3)	0.8%(116)	
Ethnicity										
Hispanic	1.7%(37)	2.4%(45)	2.2%(23)	0.8%(1)	1.9%(57)	2.0%(85)	1.4%(32)	5.1%(5)	1.9%(285)	0.013
Not Hispanic/Latino	94.4%(2085)	93.3%(1733)	94.8%(990)	92.7%(115)	94.0%(2846)	92.9%(3898)	94.3%(2218)	92.9%(91)	93.7%(13976)	
Not Reported/ Declined	3.9%(86)	4.3%(80)	3.0%(31)	6.5%(8)	4.1%(125)	5.1%(214)	4.4%(103)	2.0%(2)	4.4%(649)	
Marital Status										
Divorced	6.2%(137)	8.0%(149)	7.9%(82)	5.7%(7)	8.3%(251)	6.5%(273)	8.0%(187)	15.3%(15)	7.4%(1101)	<<0.001
Legally Separated	0.9%(20)	1.1%(21)	1.0%(10)	0.8%(1)	1.1%(32)	1.1%(47)	0.4%(9)	1.0%(1)	0.9%(141)	
Life Partner	0.8%(17)	0.6%(11)	0.5%(5)	0%(0)	0.3%(10)	0.5%(19)	0.3%(6)	1.0%(1)	0.5%(69)	
Married	65.4%(1445)	61.9%(1150)	66.6%(695)	71.8%(89)	66.1%(2002)	61.3%(2572)	66.0%(1552)	49.0%(48)	64.1%(9553)	
Single	18.4%(406)	19.8%(367)	16.6%(173)	18.6%(23)	15.9%(482)	22.4%(939)	17.3%(408)	26.5%(26)	18.9%(2824)	
Unknown	3.6%(80)	4.1%(76)	2.6%(27)	0.8%(1)	3.1%(94)	4.7%(199)	2.6%(61)	0%(0)	3.6%(538)	
Widowed	4.7%(103)	4.5%(84)	5.0%(52)	2.4%(3)	5.2%(157)	3.5%(148)	5.5%(130)	7.1%(7)	4.6%(684)	
Geographic Location										
Rural, NC	7.2%(158)	7.4%(138)	11.9%(124)	12.1%(15)	9.7%(295)	7.3%(308)	9.4%(221)	17.4%(17)	8.6%(1276)	<<0.001
Urban, NC	82.4%(1820)	87.2%(1621)	77.1%(805)	72.6%(90)	82.3%(2491)	87.5%(3671)	81.3%(1914)	77.6%(76)	83.8%(12488)	
Other	10.4%(230)	5.3%(99)	11.0%(115)	15.3%(19)	8.0%(242)	5.2%(218)	9.3%(218)	5.1%(5)	7.7%(1146)	
Primary Insurance										
Medicare	25.2%(556)	20.8%(387)	25.9%(270)	23.4%(29)	27.2%(823)	17.6%(738)	28.9%(679)	32.7%(32)	23.6%(3514)	<<0.001
Medicaid	0.5%(10)	0.9%(17)	2.5%(26)	3.2%(4)	1.9%(58)	0.8%(33)	0.6%(15)	2.0%(2)	1.1%(165)	
Worker's Compensation	0.9%(20)	1.9%(35)	0.6%(6)	0.8%(1)	0.4%(12)	1%(42)	0.9%(21)	1.0%(1)	0.9%(138)	
Privately Insured	73.5%(1622)	76.4%(1419)	71.1%(742)	72.6%(90)	70.5%(2135)	80.6%(3384)	69.6%(1638)	64.3%(63)	74.4%(11093)	
Secondary Insurance										
Medicare	7.7%(169)	6.5%(121)	8.0%(83)	7.3%(9)	7.8%(235)	5.5%(229)	9.8%(231)	11.2%(11)	7.3%(1088)	<<0.001

Medicaid	1.3%(28)	1.5%(28)	3.7%(39)	3.2%(4)	3.0%(90)	1.6%(67)	2.1%(49)	6.1%(6)	2.1%(311)	
Worker's Compensation	0.3%(6)	0.4%(8)	0.3%(3)	0%(0)	0.3%(8)	0.3%(13)	0.3%(7)	1.0%(1)	0.3%(46)	
Privately Insured	90.8%(2005)	91.6%(1701)	88.0%(919)	89.5%(111)	89%(2695)	92.6%(3888)	87.8%(2066)	81.6%(80)	90.3%(13465)	
Questionnaire Type Completed										
PROMIS Short Forms (8 domains)	74.7%(1650)	70.8%(1316)	71.7%(749)	76.6%(95)	74.1%(2243)	68.6%(2879)	64.9%(1526)	69.4%(68)	70.6%(10526)	<<0.001
PROMIS CAT (4 domains)	25.3(558)	29.2 (542)	28.3(295)	23.4%(29)	28.9 (785)	31.4 (1318)	35.2(827)	30.6(30)	29.4 (4384)	
Year PROMIS Questionnaire Completed										
2017	2.9%(65)	2.5%(47)	3.5%(37)	6.5%(8)	4.9%(149)	3.3%(138)	3.3%(77)	3.1%(3)	3.5%(524)	<<0.001
2018	66.2%(1462)	63.2%(1175)	63.1%(659)	65.3%(81)	64.8%(1961)	61.6%(2587)	57.5%(1353)	61.2%(60)	62.6%(9338)	
2019	30.8%(681)	34.2%(636)	33.3%(348)	28.2%(35)	30.3%(918)	35.1%(1472)	39.2%(923)	35.71%(35)	33.9%(5048)	

*mean(sd), %(n)

PROMIS Scores

As presented in **table 2**, the adjusted mean scores for the PROMIS domains for the entire cohort were 38.14(38.00,38.28) for physical function, 58.84(58.71,58.98) for pain interference, 4.57(4.53,4.62) for pain intensity (on a 0 to 10 scale), 47.87(47.73,48.01) for depression, 49.85(49.67,50.03) for anxiety, 50.49(50.29,50.68) for fatigue, 51.08(50.92,51.24) for sleep disturbance and 49.06(48.86,49.25) for ability to participate in social roles. Higher pain interference and lower physical function were at least 0.5 and -1.0 standard deviations away, respectively, from the average US general population.

Table 2. Summary of Scores for PROMIS Domains by Clinical Subspecialty

	Foot and ankle	Hand	Neurosurgery	Orthopaedic Oncology	Spine	Sports medicine	Total Joint Arthroplasty	Trauma	Total Cohort	Sample Size

				y			asty			
Physical Health Domains										
Physical function	39.82(39.46, 40.17)	41.79(41.41, 42.18)	35.13(34.61, 35.65)	38.41(36.92, 39.89)	35.71(35.41, 36.02)	39.13(38.88, 39.39)	36.61(36.27, 36.96)	31.60(29.92, 33.28)	38.14 (38.00, 38.28)	n=14,748
Ability to participate in social roles	50.53(50.05, 51.01)	52.32(51.77, 52.86)	44.30(43.59, 45.02)	47.49(45.48, 49.49)	46.30(45.89, 46.72)	50.88(50.51, 51.25)	47.93(47.42, 48.44)	43.65(41.23, 46.08)	49.06(48.86, 49.25)	n=10,451
Pain intensity	4.07(3.96, 4.19)	3.71(3.58, 3.84)	5.48(5.31, 5.65)	4.02(3.54, 4.50)	5.35(5.25, 5.45)	4.26(4.17, 4.35)	4.90(4.78, 5.03)	4.79(4.20, 5.36)	4.57(4.53, 4.62)	n=10,424
Pain interference	57.25(56.92, 57.58)	55.65(55.29, 56.02)	61.56(61.08, 62.04)	57.47(56.08, 58.86)	61.21(60.93, 61.49)	58.01(57.77, 58.25)	60.03(59.71, 60.35)	60.97(59.37, 62.56)	58.84(58.71, 58.98)	n=14,474
Fatigue	49.13(48.65, 49.62)	48.61(48.06, 49.15)	54.94(54.22, 55.66)	52.14(50.12, 54.15)	53.22(52.81, 53.64)	47.78(48.42, 49.15)	50.31(49.80, 50.82)	53.82(51.42, 56.21)	50.49 (50.29, 50.68)	n=10,452
Sleep disturbance	49.20(48.80, 49.61)	49.73(49.29, 50.17)	53.85(53.26, 54.43)	50.83(49.14, 52.51)	53.08(52.73, 53.42)	50.36(50.07, 50.66)	51.26(50.87, 51.65)	53.46(51.54, 55.39)	51.08(50.92, 51.24)	n=14,465
Mental Health Domains										
Anxiety	48.61(48.16, 49.06)	49.00(48.49, 49.51)	52.65(51.99, 53.32)	53.18(51.32, 55.04)	51.69(51.30, 52.07)	48.72(48.37, 49.06)	49.64(49.17, 50.11)	52.00(49.77, 54.24)	49.85(49.67, 50.03)	n=10,351
Depression	47.07(46.70, 47.44)	47.27(46.87, 47.67)	50.22(49.69, 50.76)	49.22(47.68, 50.77)	49.36(49.05, 49.68)	46.87(46.61, 47.14)	47.66(47.31, 48.02)	50.85(49.06, 52.64)	47.87 (47.73, 48.01)	n=14,391

*mean(95% CI)

*regression models adjusted for age, sex, race, ethnicity and questionnaire type

Table 3 provides more context to the range of observed health status scores by categorizing scores into degrees of severity: within normal limits, mild, moderate, and severe.[10,24,26] In this cohort, 24.9% of all patients reported their physical functioning within normal limits; the majority of patients (75%) reported mild, moderate, or severe limitations in physical functioning. There is a similar trend for pain interference, where 73% of patients reported mild, moderate, or severe limitations with pain interference. The majority of the cohort reported within normal limits for the ability to participate in social roles (63.5%), fatigue (68.0%), and sleep disturbance (66.0%). For the mental health domains (anxiety and depression), across the samples, most

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300 patients reported normal limits for anxiety (69.6%) and depression (76.8%). Few patients reported severe
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501 symptoms of anxiety (1.7%) and depression (1.1%).
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For peer review only

Table 3: PROMIS Severity Categories by Clinical Subspecialty

	Foot and ankle	Hand	Neurosurgery	Orthopaedic Oncology	Spine	Sports medicine	Total Joint Arthroplasty	Trauma	Total
Physical Health Domains									
Physical function									
Within Normal limits	29.6%	40.5%	16.2%	32.3%	15.7%	29.1%	16.6%	11.3%	24.9%
Mild	22.9%	20.7%	13.1%	11.3%	15.0%	22.1%	20.0%	8.3%	19.5%
Moderate	30.7%	26.4%	38.9%	33.1%	40.5%	33.3%	40.2%	29.9%	35.0%
Severe	16.7%	12.5%	31.8%	23.4%	28.8%	15.4%	23.2%	50.5%	20.6%
Ability to participate in social roles									
Within Normal limits	67.3%	74.3%	42.2%	51.6%	52.8%	72.8%	60.6%	44.6%	63.5%
Mild	18.4%	13.9%	23.4%	24.2%	21.3%	14.2%	18.9%	15.4%	17.8%
Moderate	11.5%	9.6%	24.9%	20.0%	19.5%	10.3%	16.1%	24.6%	14.4%
Severe	2.9%	2.2%	9.5%	4.2%	6.4%	2.7%	4.4%	15.4%	4.3%
Pain interference									
Within Normal limits	33.8%	43.7%	16.3%	33.1%	16.7%	29.8%	20.3%	21.7%	27.0%
Mild	23.6%	24.3%	16.7%	16.5%	21.4%	28.4%	24.3%	13.0%	24.1%
Moderate	39.4%	28.8%	59.7%	46.3%	55.8%	38.0%	49.0%	55.4%	44.1%
Severe	3.2%	3.3%	7.4%	4.1%	6.2%	3.7%	6.5%	9.8%	4.8%
Fatigue									
Within Normal limits	73.4%	73.9%	50.7%	63.2%	57.2%	74.4%	70.6%	55.2%	68.0%
Mild	12.3%	11.3%	17.7%	13.7%	17.1%	12.3%	13.8%	17.9%	13.9%
Moderate	12.0%	12.2%	24.6%	20.0%	21.8%	11.0%	13.2%	20.9%	15.1%
Severe	2.3%	2.7%	7.0%	3.2%	3.9%	2.3%	2.4%	6.0%	3.1%
Sleep disturbance									
Within Normal limits	74.3%	71.5%	54.3%	67.2%	58.0%	69.0%	64.8%	55.3%	66.0%

Mild	13.7%	14.1%	17.5%	18.0%	18.1%	14.4%	16.0%	13.8%	15.5%
Moderate	10.5%	11.7%	22.3%	11.5%	19.3%	13.7%	16.1%	23.4%	15.1%
Severe	1.6%	2.7%	5.9%	3.3%	4.7%	2.9%	3.0%	7.5%	3.3%
Mental Health Domains									
Anxiety									
Within Normal limits	74.6%	71.6%	59.7%	55.8%	62.0%	73.4%	72.5%	60.6%	69.6%
Mild	14.0%	14.8%	16.2%	22.1%	17.2%	14.7%	15.2%	16.7%	15.4%
Moderate	10.5%	11.4%	20.2%	19.0%	18.9%	10.9%	10.7%	19.7%	13.4%
Severe	0.9%	2.1%	3.9%	3.2%	1.9%	1.1%	1.6%	3.0%	1.7%
Depression									
Within Normal limits	80.7%	78.3%	66.5%	71.9%	71.5%	79.9%	78.6%	65.6%	76.8%
Mild	12.1%	12.0%	15.9%	14.9%	14.9%	12.2%	12.5%	20.0%	13.1%
Moderate	6.5%	8.2%	15.2%	12.4%	12.3%	7.3%	8.0%	12.2%	9.1%
Severe	0.6%	1.5%	2.5%	0.8%	1.4%	0.7%	1.0%	2.2%	1.1%

In **table 4**, we examine the correlation of unadjusted PROMIS domains in the cohort. As expected, we found high correlations between depression and anxiety ($r=0.76$) and pain interference and pain intensity ($r=0.75$). Additionally, we found moderate correlations between commonly administered PROMIS domains in Orthopaedics - physical function and pain interference ($r=-0.60$) and physical function and pain intensity ($r=0.52$). There was a low correlation found between anxiety and pain intensity ($r=0.30$), anxiety, and pain interference ($r=0.36$), anxiety, and physical function ($r=-0.32$). Similar trends were found with depression where low correlations between depression and pain intensity ($r=0.29$), depression, and pain interference ($r=0.39$), depression, and physical function ($r=-0.30$).

Table 4: Correlation of PROMIS Domains

	Participation	Anxiety	Depression	Fatigue	Pain Intensity	Pain Interference	Physical Function	Sleep Disturbance
Participation	-	-0.48	-0.51	-0.66	-0.52	-0.69	0.67	-0.45
Anxiety	-0.48	-	0.76	0.58	0.30	0.36	-0.32	0.44
Depression	-0.51	0.76	-	0.58	0.29	0.39	-0.30	0.43
Fatigue	-0.66	0.58	0.58	-	0.42	0.52	-0.48	0.54
Pain Intensity	-0.52	0.30	0.29	0.42	-	0.75	-0.52	0.39
Pain Interference	-0.69	0.36	0.39	0.52	0.75	-	-0.60	0.45

Physical Function	0.67	-0.32	-0.30	-0.48	-0.52	-0.60	-	-0.31
Sleep Disturbance	-0.45	0.44	0.43	0.54	0.39	0.45	-0.31	-

*all correlations were statistically significant $P < 0.001$

PROMIS Scores by Major Clinical Specialties

Foot and Ankle

Patients consulting with a foot and ankle orthopedic specialist scored less than 0.5 SD from the mean for all domains except for pain interference, where patients reported a mean score of 57.2(8.6). When looking at the clinically interpretable categories for physical function, 30.7% of patients reported moderate limitations and 16.7% severe limitations. For pain interference, 39.4% reported moderate and limitations, and 3.2% reported severe limitations.

Hand

Patients who consulted with a hand orthopedic specialist reported scores less than 0.5 SD from the mean for all domains except pain interference and physical function. Patients reported a mean score of 55.7(8.8) and 41.85(9.5), respectively. For physical function, 26.4% of patients reported moderate limitations, and 12.5% reported severe limitations.

Neurosurgery and Spine

Patients either consulting with a neurosurgeon or a spine orthopedic specialist reported between 1- 1.5 standard deviations from the US mean for pain interference and physical functioning. Neurosurgery patients reported higher levels of pain interference (61.53(8.1)) compared to spine patients (57.23(9.7)) and also reported more limitations in physical functioning (35.0(9.0)) as compared to spine patients (38.35(10.5)). For physical function, a majority of neurosurgery patients reported moderate (38.9%) and severe (31.8%) limitations, and this was similar in spine patients (moderate- 40.5%, severe 28.8%). Pain interference, most neurosurgery (59.7%) and Spine patients (55.8%) reported moderate limitations, and a small percentage of neurosurgery (7.4%) and spine patients (6.2%) reported severe limitations.

Sports Medicine

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4 Patients seeking care from a sports medicine specialist reported less than 0.5 SD from the US mean in
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6 all domains except physical function (39.51(8.8)) and pain interference (58.0(7.6)) where their scores were
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8 between 0.5-1.0 SD from the US mean. 33.3% of patients reported moderate limitations in physical function,
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10 and 15.4% reported severe limitations. For pain interference, 38.0% of patients reported moderate limitations,
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12 and 3.7% reported severe limitations.

13 14 15 Total Joint Arthroplasty

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17 Patients consulting a Total Joint Arthroplasty Orthopaedic Surgeon reported less than 0.5 SD from the
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19 US mean in all domains except physical functioning (36.58(8.5)) and pain interference (60.21(8.4)). Most
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21 patients reported moderate limitations in physical functioning (40.2%) and pain interference (48.9%), and
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23 23.2% reported severe limitations in physical function, and only a small percentage reported severe limitations
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25 for pain interference (6.5%).

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27 We did not report on Trauma or Orthopaedic Oncology due to low sample sizes in each of these
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29 subspecialties.

30 31 32 DISCUSSION

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34 The goal of PROMIS was to create a measurement system that could standardize of PROs across
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36 chronic conditions to better enable comparisons across different disease conditions.[14] To this end, we
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38 described approximately 15,000 orthopedic patients across eight different clinical subspecialties who
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40 completed PROMIS measures associated with a new patient consultation with an orthopedic specialist. We
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42 found across an orthopaedic department at an academic medical center, that most patients reported scores
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44 within 0.5 SD from the US mean on all domains except pain interference and physical functioning; where they
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46 reported approximately 1.0 SD US mean on pain interference and physical functioning . These findings are
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48 expected, where the primary drivers of seeking care for orthopedic issues are decreased physical functioning
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50 and increased interference with activities due to pain.[28][29] When further examining the difference of
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52 PROMIS scores between the clinical subspecialties for the physical health domains, we found that patients
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54 seeking care from hand specialists reported less overall physical health impairments. However, we primarily
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56 attribute this finding to administering the generic PROMIS physical function measure rather than the upper
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4 265 extremity physical function PROMIS measure, which is more specific to upper extremity conditions and may
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6 266 better reflect limitations in this group.[30] Patients seeking care from a Neurosurgery, Spine, or a Trauma
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8 267 specialist reported significant physical health impairments. When examining PROMIS mental health domains,
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10 268 most patients across clinical subspecialties reported that their anxiety and depression symptoms were within
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12 269 normal limits; however, up to 24.1% reported moderate or severe anxiety and up to 17.6% reported moderate
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14 270 or severe depressive symptoms. Following a similar trend as the specialties across the PROMIS physical
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16 271 health domains, patients seeking care from a Neurosurgery, Spine, or Trauma specialist reported the highest
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18 272 anxiety and depression symptoms. This relationship is consistent with literature supporting patients with spine
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20 273 conditions, and orthopedic trauma have higher anxiety levels than other orthopedic conditions.[31,32]

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22 274 Majority of patients seeking care in orthopaedics across clinical subspecialties do so because of
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24 275 limitations in physical function and pain.[33–35] Measurement of these constructs can be done using PROMs.
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26 276 Many legacy measures commonly used in orthopaedics measure more than one construct. This makes it
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28 277 difficult to elucidate limitations or symptom contributions from a specific construct on a patient's perception of
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30 278 their health status. For example, a patient seeking care for knee osteoarthritis may report more limitations in
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32 279 physical functioning rather than pain. Using traditional, concise legacy measures such as Knee Injury and
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34 280 Osteoarthritis Outcome Score Junior (KOOS Jr) [36] to evaluate stiffness, pain, function and activities of daily
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36 281 living using 7 items would be challenging to isolate the relative limitations in physical functioning compared to
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38 282 the other constructs included in the KOOS Jr. Whereas, PROMIS PF can be administered to capture this
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40 283 construct separately and concisely, giving a valid estimate of a patient's perception of their physical function.
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42 284 PROMIS PF and has been shown to be equal or superior in regard to floor and ceiling effects when compared
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44 285 with previously established legacy PROM in several patient populations including trauma, shoulder, elbow,
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46 286 hand, spine, and knee; making this measure applicable across patient populations and range of severity of
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48 287 symptoms. [37] However a noted limitation is, to date, not all PROMIS measures have been evaluated for floor
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50 288 and ceiling effects across multiple populations or found to be as responsive as PROMIS PF for Orthopaedic
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52 289 patients. In particular, PROMIS measures that capture emotional distress and psychosocial illness impact have
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54 290 not been extensively researched for wide-spread use in Orthopaedics [31].
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Strengths and Limitations

Our study has noted strengths. First, our study is novel in that we reported eight PROMIS domains across eight different orthopedic clinical subspecialties. The use of PROMIS measures in clinical practice and research has been increasing in prevalence in spine, total joint, sports medicine, upper extremity disorders, trauma, and lower extremity disorders.[38] In a systematic review on the uptake of PROMIS measures in Orthopaedics, they found that studies typically report around three PROMIS domains.[38] Our study is the first that we are aware of to report and directly compare differences in these eight health domains across orthopaedic clinical subspecialties, providing baseline for PROMIS scores in orthopaedic. The direct comparisons reported in this paper would not be possible if using region-specific measures common to orthopedic practice and research. By implementing PROMIS measures as a standard set of outcome measures, we can draw inferences about differences in patient-reported health status across orthopedic populations that are typically not compared. Second, our study reported a clinical interpretation of PROMIS scores addressing the reported barrier to PROMIS use uptake.[8,39] Providing a clinical interpretation is vital because often there is a disconnect between mean PROMIS scores (i.e., physical functioning score- 38.2) and how to interpret this information (moderate limitations in physical functioning).[39]

Our study is not without limitations. First, this was a cross-sectional cohort analysis, so we did not report PROMIS measures beyond baseline. Therefore, we cannot identify predictors of clinical outcomes or compare the change in PROMIS scores across subspecialties over time or downstream utilization of Orthopaedic procedures or rehabilitation services associated with baseline scores. Second, our findings may have limited generalizability. For example, the setting was a private hospital. It may not capture the broad diversity of non-white individuals in the area (79.3% of individuals reported being Caucasian). Our instruments were only available in English, limiting data collection on non-English speaking patients. Moreover, in some clinical subspecialties reported (i.e., trauma and orthopedic oncology), small sample sizes potentially limit generalizability of these findings. Lastly, we did not compare PROMIS upper extremity physical function or legacy measures to our PROMIS measures as part of this study. Therefore we cannot make direct

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comparisons of the performance of the eight reported PROMIS domains in this study to legacy or PROMIS upper extremity. However, the relationship between legacy measures in orthopedics and PROMIS measures is well documented in the literature. [40]

Our study's findings are consistent with other literature regarding orthopedic populations' physical and mental health status. [41] In comparison to a study by Perruccio et al. (2013) using the SF-36 as the outcome measure to physical and mental health in patients seeking care for musculoskeletal disorders, we found similar results where patients with spine disorders reported the most impairments in the cohort. [41] Additionally, consistent with our results, they found hand upper extremity/hand patients were the healthiest, and total joint arthroplasty patients demonstrated low levels of physical functioning. Our study's unexpected finding low levels of sleep disturbance, fatigue, and depression reported across clinical subspecialties. Sleep disruption and pain frequently co-occur; both are uniquely linked with depressed mood [42–45] and various forms of functional disability [46–48]. Depression appears to play a substantial role in the sleep-pain linkage, particularly where the pain is severe. [49] However, in our study, we did not find this relationship between pain, physical function, sleep disturbance, and depression in the cohort, despite the research supporting these relationships. [49]

Conclusions

Reporting patients' health status consulting an Orthopaedic provider using a standard set of outcome measures across various clinical subspecialties has numerous clinical care and research implications. Understanding the health status and clinical examination measures may improve patient and provider communication during the clinical encounter [50] and be used as part of the prognostic evaluation. [51] Moreover, this study can provide a context for informing bundled care or value-based care models. Classifying heterogeneous orthopedic patients' baseline status on a standard metric could better inform the effectiveness and cost of treatment pathways.[52] Lastly, reporting PROMIS scores has allowed the direct comparison of eight meaningful constructs across orthopedic subspecialties. This comparison would not be possible with legacy measures, which is a noted strength of PROMIS measures. These comparisons allow unique insights to be made for orthopedic departments and align clinical and research data collection with value-based care

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3 initiatives outside of orthopedic departments. Clinicians and administrators can use this information to improve
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5 the delivery and the efficiency of care, improve and inform referral practices, and inform subspecialty-specific
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7 education to improve patient outcomes from orthopedic care.
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18
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20
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23 profit sectors

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28

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32 acquisition, and writing of the manuscript. Steven George contributed to the conception of the work, design of
33
34 the manuscript's study, and writing. Emily Reinke contributed to the conception of the work, design of the
35
36 study, data acquisition, and writing the manuscript. Xiaofang Yan and Sheng Luo contributed to the study's
37
38 design and statistical analysis. Michael Bolognesi contributed to the design of the manuscript's study and
39
40 writing. Bryce Reeve contributed to the design of the manuscript's study and writing. All authors had final
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42 approval of the manuscript.
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45 **Data Availability:** Data are not available in accordance with protections provided by the HIPAA privacy
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47 information policy.
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FIGURE 1: Flow diagram for cohort selection.

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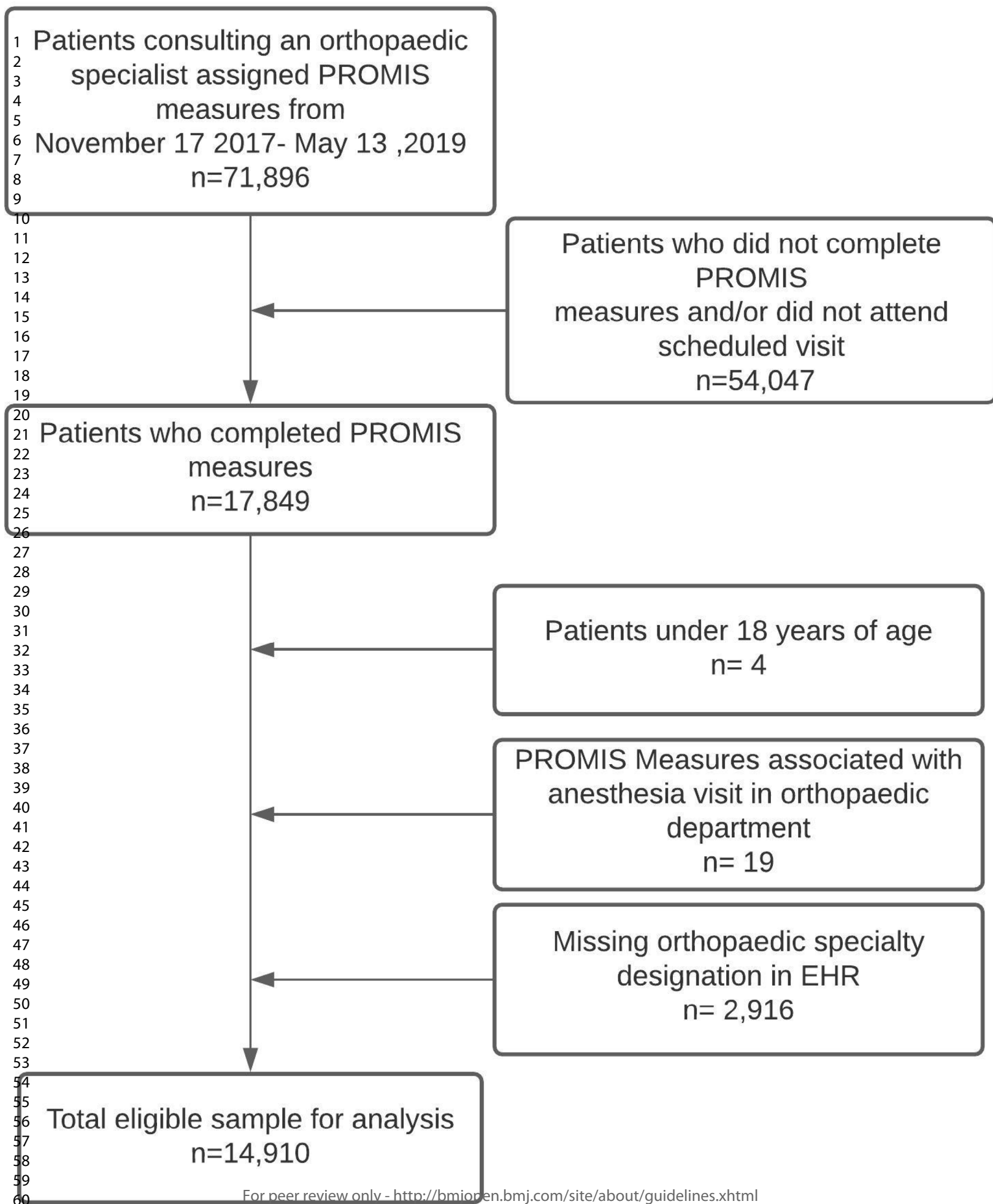
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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5-6
		(b) For matched studies, give matching criteria and number of exposed and unexposed	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	7
		(d) If applicable, explain how loss to follow-up was addressed	7
		(e) Describe any sensitivity analyses	7
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	8 n/a n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	8 tables n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	8-10 n/a n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.