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Beyond morbidity and mortality: The practicality of measuring patient-reported outcomes in trauma

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ABSTRACT

Background: The 2016 Zero Preventable Deaths report highlighted the need for comprehensive injury data to include long term outcomes such as societal and workforce re-entry. Currently, postinjury quality of life is poorly understood. We hypothesized that routine measurement of patient-reported outcomes is feasible as a part of post-discharge follow-up, and that trauma patients would report that their injury had a detrimental impact on health-related quality of life (HRQoL) after discharge.

Methods: After instruction, patients self-administered the PROMIS-29 instrument in our outpatient office (11/2019-4/2020). We surveyed 7 domains: Participation in Social Roles/Activities, Anxiety, Depression, Fatigue, Pain Interference, Physical Function, and Sleep Disturbance. Results are reported as means (SD) and compared to the U.S population by t-score (mean score=50). Higher scores in negatively-worded domains (e.g. "Depression") are worse; vice versa for positively-worded domains (e.g. "Physical Function"). Repeated scores among patients returning for a second visit were analyzed using paired t-tests.

Results: 103 patients completed the PROMIS-29. Mean (SD) age was 42.3 (17.3) years, 75% were male, and 42% suffered a penetrating injury. Median length of stay was 3 days and median time from injury to clinic visit was 18 days. Mean scores were worse than population means in every domain. Pain Interference (mean 63.5, 95%CI [61.8-65.3]) and Physical Function (38.0 [36.2-39.8]) were particularly affected. Among patients returning for a second visit (n=10; median time between clinic visits: 17.5 days), there were no significant differences in domain scores over time.

Conclusion: Trauma patients are at high risk for poor quality of life outcomes in the short term following injury. Our results highlight the need for early recognition and multidisciplinary treatment following injury.

Background

Over the last 50 years, survival in trauma patients has increased significantly, [1,2] such that over 90% survive to discharge. [3] This improvement, though, has resulted in a larger population of patients facing post-discharge physical and mental impairments after injury [4,5]. Yet, outcomes are generally only tracked to hospital discharge and are often focused solely on mortality. Despite a specific call to collect "comprehensive" data from the point of injury to societal re-entry in the National Academies of Sciences, Engineering, and Medicine's *Zero Preventable Deaths* report, [6] to date, data collection after trauma seldom moves beyond the acute phase of care [7].

Other fields of medicine have begun to focus on patient-reported outcomes (PROs), driven in part by initiatives from the Patient-Centered Outcomes Research Institute (PCORI), the National Quality Forum (NQF), and the National Institutes of Health (NIH) [8]. To date, the study of PROs has primarily been embraced by those in medical specialties, [9,10] with relative paucity of PRO re-

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search in surgery. [11] However, surgical subspecialties including orthopedics, breast, and bariatrics have begun to make significant contributions to PRO literature. [12-16] The existing evidence in trauma has demonstrated reduced HRQoL in several domains [5,17-20].

Thus far, study of HRQoL in trauma has largely been conducted via telephone interview, remote from injury [5,18,20]. Two recent U.S. studies included an overwhelmingly blunt-injured population [5] and the other solely interviewed gunshot wound (GSW) survivors. [20] Thus, we sought to more describe HRQoL outcomes in trauma using a standardized PRO instrument as part of routine in-person follow-up care. We hypothesized that standardized implementation of PRO measurement using the Patient-Reported Outcomes Measurement Information System 29 (PROMIS-29) v2.0 instrument would be practical, and that trauma patients presenting to clinic post-discharge would report detriments in HRQoL.

Methods

Our institution is an urban, quaternary care, level 1 trauma center with a relatively high proportion (20-25%) of penetrating injuries. Patients discharged from the trauma service and many seen during inpatient consultation are asked to follow up in clinic 2-4 weeks post-discharge as clinically indicated. From November 2019 to April 2020, patients were asked to self-administer the PROMIS-29 v2.0 while waiting for their appointments. This was done using an electronic tablet, following instruction by a trained medical assistant, and incorporated directly into the patient's medical record. This took approximately five to ten minutes.

The PROMIS instruments, a National Institutes of Health (NIH) initiative, are analogous to previous HRQoL instruments such as the 36-Item Short Form Survey (SF-36). [21] They have been extensively validated across a variety of populations and are publicly available. [22,23] In addition to a single-item, 10-point pain scale, the PROMIS-29 surveys 7 domains: Participation in Social Roles/Activities, Anxiety, Depression, Fatigue, Pain Interference, Physical Function, and Sleep Disturbance. Each of the 7 domains contains 4 items, scored on a 5-point scale. The full instrument is shown in Appendix 1. [24]

Trauma patients primarily treated at our institution were included if they completed PROMIS measures at clinic follow up. Basic demographic and injury data were collected on patients who did not complete the instrument but were seen in clinic over the same time period, for the sake of comparing responders to non-responders. For all patients, our institution's trauma registry was queried for admissions preceding the clinic visit in order to link demographic, injury mechanism and severity, operative details, and length of stay (LOS) data. Patients seen via consultation in the emergency department (ED) and not the trauma bay do not enter the registry. These patients therefore do not have a documented injury severity score (ISS); the remainder of data was abstracted from the electronic health record (EHR). The 11 patients who were admitted multiple times preceding the clinic visit were adjudicated such that all patients were linked to a single hospital admission representing index injury.

Patients were excluded if they had never been admitted to or evaluated at the hospital (i.e. a patient presenting to clinic for removal of a foreign body from a remote trauma) (n=3). Those who had undergone non-trauma procedures that are often performed by our group (i.e. tracheostomy in a medical intensive care unit patient) were also excluded (n=4). Finally, patients who had either been transferred to our institution but bypassed the trauma bay (i.e. a chronic patient secondary to a remote trauma at an outside institution) or were admitted to our service for sequelae of an injury initially managed elsewhere were also excluded (n=4) (Fig. 1).

Following exclusions, the data was inspected for missingness. From the overall cohort (responders and non-responders), one patient was missing a value for MOI; 2 patients were missing LOS. Thirty (11%) were missing ISS, many for the reasons described above. Finally, 32/267 were missing an ICU LOS – of note, patients not admitted to the ICU are recorded as "0"; therefore, missing values are truly missing. The cohort encompassed 103 patients who completed the PROMIS at least once, as well as 164 who had not (39% completion rate).

We first performed a descriptive analysis of the cohort. Values were reported as mean (standard deviation [SD]), number (%), or median (interquartile range [IQR]), as appropriate. Likewise, differences between groups were tested using Student's t, Fisher's exact, or Mann-Whitney U test. Results of patient self-reports were translated to t-scores using the scoring table provided with the PROMIS instrument and averaged. [24] The t-scores were generated with reference to the U.S. general population after collecting data from a large sample of individuals representing the 2000 U.S. census. By definition, an average score is 50 and the standard deviation is 10. Higher scores represent "more of" the symptom or characteristic measured. Thus, higher scores in negatively-worded domains (e.g. "Depression") are worse; vice versa for positively-worded domains (e.g. "Physical Function").

Aggregate domain scores are presented as means (SD). Subset analyses of penetrating injuries and operative patients were undertaken, with comparisons to the remainder of the sample made using t-tests. A subset of patients returned for more than one follow-up visit. To preserve independence, their first responses were used in the main analyses. Repeated scores among these were analyzed using paired t-tests. A two-tailed p-value of 0.05 was determined *a priori* to be statistically significant. This study was determined by our center's Institutional Review Board to be exempt from review. All statistical analyses were performed using Stata version 15.1 (College Station, TX).

Results

Table 1 shows characteristics of the cohort. There were no significant differences between those who completed the questionnaire and those who did not. Among those completing the questionnaire, the average age was 42.3 years, a minority were female (25%), they were moderately injured (median ISS=9). Thirty-four of the 103 patients (33%) had undergone at least one operative procedure during their admissions; 21 (20%) proceeded directly from the trauma bay to the operating room. 37% of patients completing the survey and 42% not completing it had suffered a gunshot wound (GSW) or stabbing.

At the time of first PROMIS-29 response (median [IQR] days from injury 18 [12,25]), patients reported a median [IQR] pain score of 4 (3, 7). Mean scores were worse than the PROMIS control population in every remaining domain, with means for pain interference (63.5; 95% CI 61.8, 65.2) and physical function (38.0; 95% CI 36.2, 39.8) falling beyond one SD from the U.S. population mean (Fig. 2).

The 43 patients who had suffered GSW or stabbing injuries demonstrated a mean (SD) pain score of 5.1 (3.1) and similar deviations from the population mean in the remaining 7 domains, though the "fatigue" mean score failed to meet statistical significance. There was no significant difference between penetrating- and blunt-injured patients, in any domain (Table 2).

Among patients who underwent an operation, there was a median (IQR) pain score of 5.5 (3,8) and scores in the remaining domains were all worse than PROMIS controls. For example, ability to participate in social roles and activities mean score was 41.0 (37.4, 44.5), physical function mean score was 35.9 (32.7, 39.0), and the mean pain interference score was 64.6 (61.6, 67.7). There were

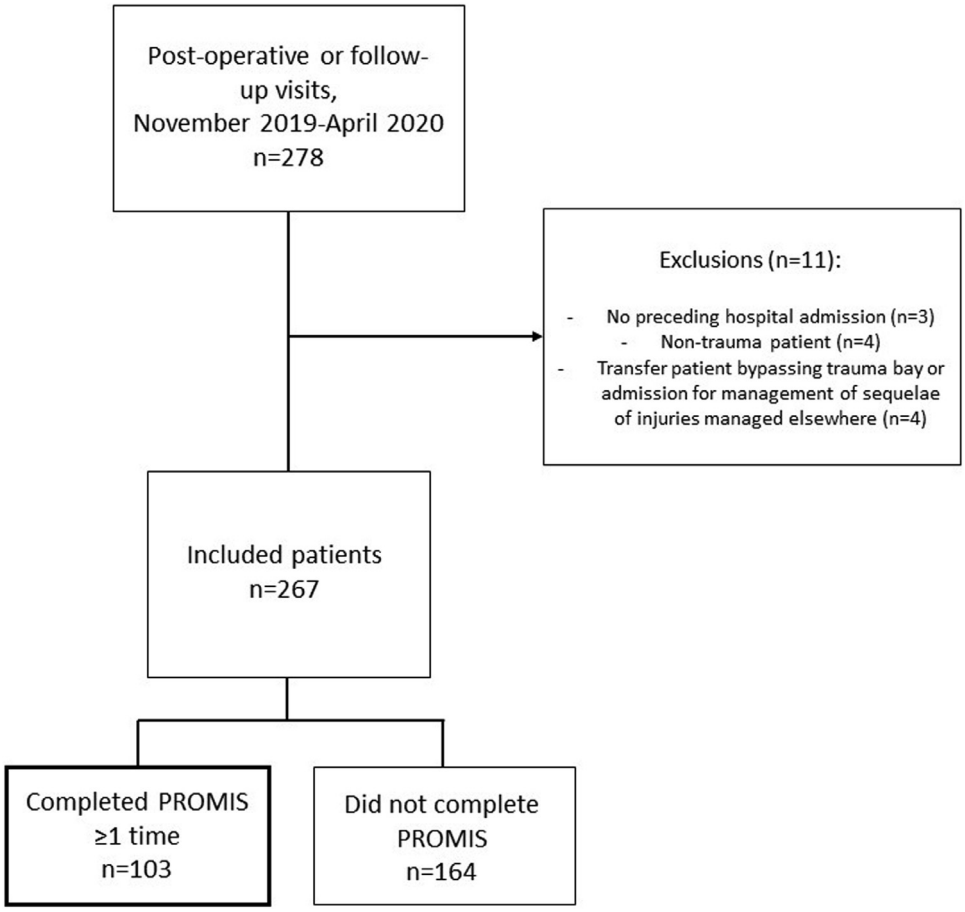

Fig. 1. Inclusion and Exclusion criteria.

Table 1
Cohort characteristics. SD, standard deviation; ISS, Injury Severity Score; IQR, interquartile range; LOS, length of stay; ICU, intensive care unit; PROMIS, Patient-Reported Outcomes Measurement Information System. * indicates Student's t-test was applied, † indicates Fisher's exact test was applied, and ‡ indicates Mann-Whitney U test was applied.

		Did not complete PROMIS-29 (n=164)	Completed PROMIS-29 (n=103)	p-value
Age, mean (SD)		45.7 (20.9)	42.3 (17.3)	0.16*
Female, n (%)		47 (29%)	26 (25%)	0.58†
ISS, median (IQR)		10 (2, 16)	9 (2, 17)	0.92‡
Mechanism	Gunshot Wound	43 (26%)	29 (28%)	0.79†
	Stabbing	18 (11%)	14 (14%)	
	Fall	38 (23%)	21 (20%)	
	Motor Vehicle Accident	36 (22%)	19 (18%)	
	Motorcycle Accident	1 (1%)	3 (3%)	
	Pedestrian Accident	11 (7%)	6 (6%)	
	Other	17 (10%)	10 (10%)	
	Missing	0 (0%)	1 (1%)	
LOS, median (IQR)		5 (1, 11)	3 (1, 9)	0.12‡
ICU days, median (IQR)		0 (0, 3)	0 (0, 3)	0.48‡
Underwent operative procedure, n (%)		57 (35%)	34 (33%)	0.79†

no significant differences between operative and nonoperative patients in any domain, though there was a trend towards decreased ability to participate in social roles and activities in operative patients (t-scores 41.0 vs 45.4, p=0.06) (Table 3). It is worth noting that, despite a lack of statistically significant difference between groups, the scores in non-operative patients were generally closer to 50, potentially suggesting less impairment in these patients.

Ten patients completed the questionnaire a second time. The median time from first questionnaire to second questionnaire was 17.5 days. Among these patients, there were no significant differences in any domain between the first and second administrations of the PROMIS-29 (Fig. 3). Of note, this subset was more severely injured than the overall cohort; median (IQR) ISS was 21 (10, 33), 8/10 (80%) were admitted to the ICU for a median of 3 days, and 8/10 (80%) underwent an operation.

Discussion

In this study, we aimed to assess feasibility of standardized PRO measurement at the time of follow-up and quantify post-discharge trauma patients' HRQoL through self-administration of the PROMIS-29 instrument. We demonstrated that administration of the instrument in clinic is practical and can be instituted as a standard component of follow-up care. The most important finding

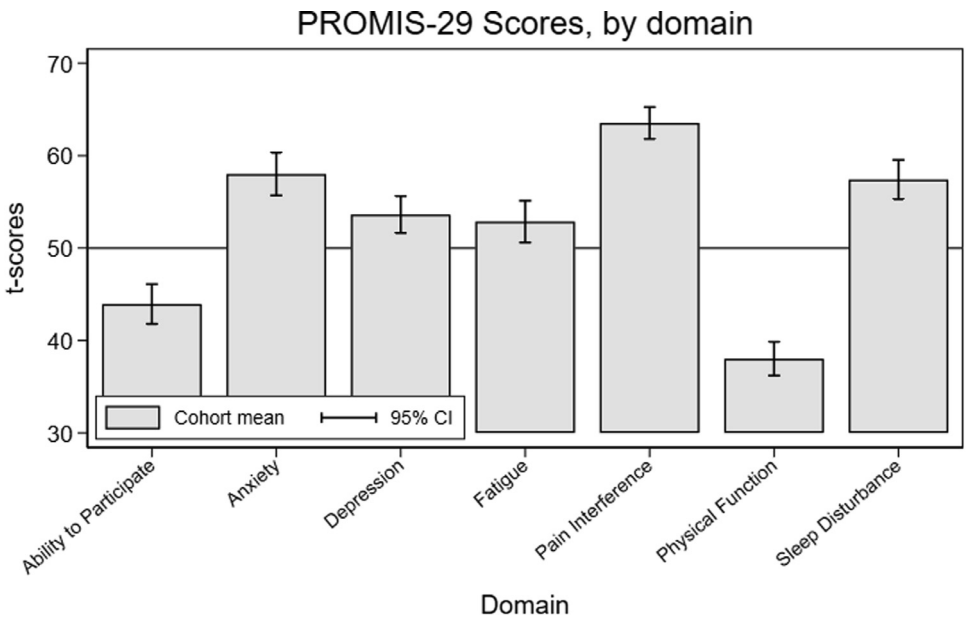

Fig. 2. Mean scores, by domain, at the time of first questionnaire completion. t-score of 50 represents average in the United States population. Higher scores are "better" in Ability to Participate in Social Roles and Activities and Physical Function; higher scores are "worse" in all other domains. CI, confidence interval.

Table 2
Mean scores, by domain, at the time of first questionnaire completion, penetrating vs blunt injured patients. Differences tested using Student's t-test, except for pain intensity, which was tested using the Mann-Whitney U test. Pain intensity rated on 10-point scale; remainder of domains expressed as t-scores with mean=50 and SD=10. Higher scores are "better" in Ability to Participate in Social Roles and Activities and Physical Function; higher scores are "worse" in all other domains. SD, standard deviation; CI, confidence interval; IQR, interquartile range.

Domain	Penetrating (n=43) mean (95% CI)	Blunt (n=60) mean (95% CI)	p-value
Ability to Participate in Social Roles and Activities	45.6 (42.0, 49.1)	42.8 (40.1, 45.5)	0.21
Anxiety	58.4 (54.9, 61.9)	57.7 (54.5, 60.9)	0.77
Depression	53.5 (50.2, 56.8)	53.7 (51.1, 56.3)	0.92
Fatigue	52.1 (48.5, 55.6)	53.4 (50.4, 56.5)	0.56
Pain Interference	63.4 (60.5, 66.3)	63.6 (61.4, 65.8)	0.92
Physical Function	39.0 (36.1, 41.8)	37.3 (34.9, 39.8)	0.39
Sleep Disturbance	58.6 (55.1, 62.1)	56.5 (53.8, 59.2)	0.34
	Penetrating (n=43) median [IQR]	*Blunt (n=60) median [IQR]*	*p-value*
Pain Intensity	5 [3,8]	4 [3, 6.5]	0.35

Table 3
Mean scores, by domain, at the time of first questionnaire completion, operative vs nonoperative patients. Differences tested using Student's t-test, except for pain intensity, which was tested using the Mann-Whitney U test. Pain intensity rated on 10-point scale; remainder of domains expressed as t-scores with mean=50 and SD=10. Higher scores are "better" in Ability to Participate in Social Roles and Activities and Physical Function; higher scores are "worse" in all other domains. SD, standard deviation; CI, confidence interval; IQR, interquartile range.

Domain	Operative (n=34) mean (95% CI)	Nonoperative (n=69) mean (95% CI)	p-value
Ability to Participate in Social Roles and Activities	41.0 (37.4, 44.6)	45.4 (42.7, 48.1)	0.06
Anxiety	59.6 (56.2, 63.0)	57.2 (54.2, 60.3)	0.34
Depression	54.4 (51.1, 57.7)	53.2 (50.7, 55.8)	0.60
Fatigue	54.8 (51.0, 58.7)	51.9 (49.1, 54.7)	0.23
Pain Interference	64.6 (61.6, 67.7)	63.0 (60.9, 65.1)	0.38
Physical Function	35.9 (32.7, 39.0)	39.1 (36.8, 41.3)	0.10
Sleep Disturbance	59.1 (55.3, 62.8)	56.6 (54.0, 59.2)	0.28
	Operative (n=34) median [IQR]	*Nonoperative (n=69) median [IQR]*	*p-value*
Pain Intensity	5.5 [3,8]	4 [3,6]	0.11

of our study is that, at a median follow up more than two weeks from hospital discharge, patients reported moderate ongoing pain intensity and scores worse than average in all 7 other domains of the instrument. Furthermore, in the subset of patients presenting for a second follow-up visit, there was no difference in scores between clinic visits.

Our first important finding was that, contrary to previous belief that extensive infrastructure would be required, [25] the standardized administration of a PRO instrument in follow-up clinic was practical. Clinic administration has been done in other populations [26] and has, in fact, been shown to yield favorable completion rates, with 64% of breast reconstruction patients completing an instrument at 3 different time points (pre- and two post-operative visits) in one study. [27] But, to date, studies of trauma patients have largely been completed via telephone interview [5,18,20]. While these studies have shown impressive completion rates – as

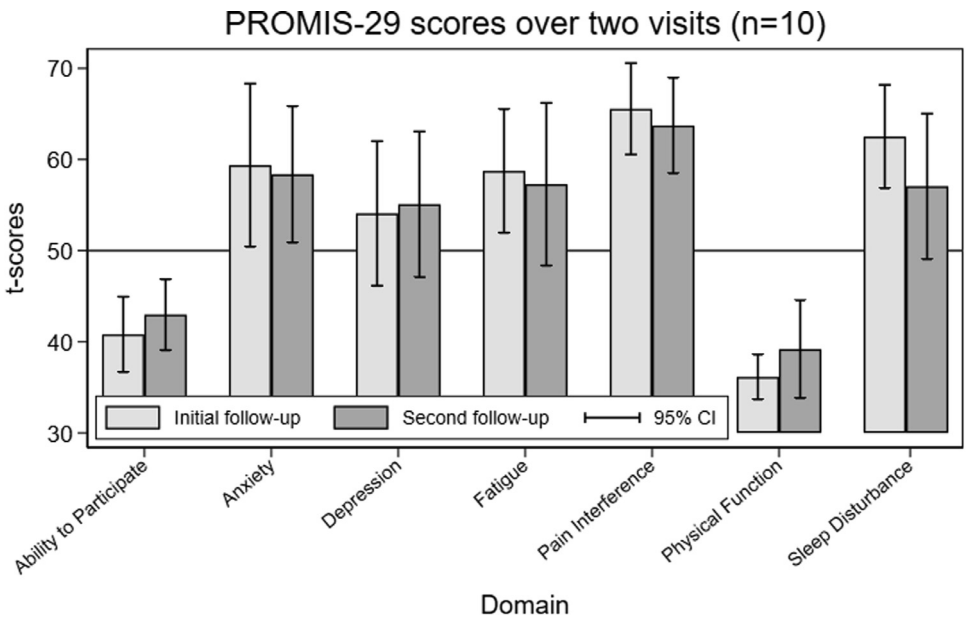

Fig. 3. PROMIS scores over time, among patients completing the questionnaire twice (n=10). Median time between tests: 17.5 days. t-score of 50 represents average in the United States population. Higher scores are "better" in Ability to Participate in Social Roles and Activities and Physical Function; higher scores are "worse" in all other domains. CI, confidence interval.

high as 85% in one Australian study [18] – inclusion of PROs as part of routine trauma follow-up may both improve rates of patient participation and transform such data collection from a research activity to a patient care practice. In addition to being a crucial part of trauma outcomes research, collection of PRO data should inform our clinical care. Implementing PRO assessment into routine clinical follow up prepares us to act on these metrics immediately, though further research is required to determine how best to intervene. These metrics should also inform the ongoing quality improvement efforts that are the hallmark of a well-functioning trauma system.

Much of the previous work on PROs in trauma has focused on mental health outcomes [28-31] and the associations between mental health and functional outcomes. [30-32] Several have focused on mental health outcomes following assault or intentional injury. [29,33,34] Interestingly, one qualitative study specifically compared intentional to non-intentional injuries [34] and suggested poorer outcomes in victims of intentional injuries – this is contrary to our data, which little difference in PROMIS outcomes between penetrating (GSW and stab) and blunt (overwhelmingly unintentional) mechanisms. Studies of other functional outcomes and pain do exist, but are more limited. [35-37] Two recent studies have taken a relatively broad look at PROs in trauma in this country. One examined only gunshot wound victims and thus may lack generalizability to a broader population. [20] The other was a study of a broader population, but included only a small number of penetrating trauma patients, which may be less applicable to an urban center like ours, with a considerably higher percentage of penetrating trauma.

The present study adds to this existing literature both in that it demonstrates the feasibility of streamlined clinic administration of a widely validated instrument, as opposed to lengthy interviews, either by telephone or dedicated appointment. [29,33-36] We also demonstrate HRQoL detriments in a broad population of U.S. urban trauma patients. While it may be unsurprising that the severe multisystem injury patient or the GSW patient requiring emergent laparotomy continue to have deficits several weeks after injury, our findings were relatively consistent across subsets of our population. The results presented herein are concerning and should prompt increased attention to trauma patients' HRQoL measures going forward. We have uncovered evidence of ongoing suffering in our injured patients. Improving their holistic recovery should be a core mission of clinicians and the trauma systems in which they work. In particular, the subset of patients who completed this questionnaire twice, who tended to be those who were more severely injured, demonstrated no improvement in scores between visits – which were often weeks apart. It is noted, however, that the mean scores in the majority of domains were closer to 50, and the lack of statistically significant difference may be in part due to a small sample size. Nonetheless, this may represent a particularly high-risk group that may be an appropriate starting point for focused interventions.

There are limitations to acknowledge. First, our completion rate among those who presented to clinic was <40%, which may introduce selection bias. As our goal for this study was to implement standardized HRQoL measurement with as few additional resources as possible, we did not interview patients who declined to complete the instrument regarding their reasons for doing so. Furthermore, patients who never present for follow-up – approximately 20% at our institution – are also missed. Even at our busy urban Level I center, a cohort consisting of 37% GSW and stab wound patients may not be representative. However, the proportion of penetrating injury patients in the group not completing the instrument was similar, if not slightly higher. We collected very little data in March and April 2020, due to a minimal number of clinic visits in the setting of the COVID-19 pandemic. Finally, we lack baseline data. An ideal way to quantify the effect of injury on HRQoL would be to measure scores in these domains both before and after injury—clearly a methodological challenge. However, going forward, valuable information might be gleaned from a robust collection of longitudinal data, beginning with a time point soon after injury.

As future research in this realm is pursued, it will be important to improve upon the low completion rate and more accurately de-

scribe the population facing issues post-discharge. While we have demonstrated the *practicality* of PROMIS administration in follow-up clinic, efforts to address the other areas of feasibility, such as acceptability, demand, and implementation, are needed. [38] Incentives for survey completion may be required to achieve higher yield. In addition to exploring ways to increase participation at initial follow-up, investigation into measurement of longitudinal outcomes will be key. We recognize that, with an already low completion rate at initial follow-up, in-person survey administration at later time points may be impractical. Methods for collecting data at additional time points may vary between centers, but use of text/email messaging via the EHR may be useful. Certainly, continued administration of a PRO instrument only in patients returning to clinic for other reasons would generate a biased sample, as those who present for multiple follow-ups are likely to differ from the remainder of the cohort.

Next steps should include a more thorough evaluation of this problem through a multi-institutional collaboration, followed soon thereafter by widespread measurement of PROs in trauma. Routine inclusion of PROs in trauma registries is not something that is frequently pursued in the US, but may be helpful. [25] As noted above, an attempt at more routine use of a PRO instrument would require investigation into the reasons a majority of declined to complete such an instrument. Beyond measurement, statistical modeling may help elucidate demographic, injury, and therapeutic characteristics associated with a high risk of poor HRQoL and inform the development of targets for intervention. While this has been done to an extent with respect to select predictors and outcomes, [29,37,39] broader work remains to be done. Finally, study into the interventions that may improve patients' HRQoL – or whether the act of completing a PRO instrument improves satisfaction in itself – could then inform changes to processes of care. We have made enormous progress in the acute care of trauma patients; it is now time to give some attention to these patients' wellbeing beyond discharge from the hospital.

Conclusion

PRO measurement is practical and should be implemented as a standard component of follow-up trauma care. We have demonstrated that trauma patients report poor HRQoL across all domains of the PROMIS-29 following hospital discharge. While more robust and longitudinal data are needed, this study provides evidence that the PROMIS-29 may be useful as one component of a strategy for monitoring long-term outcomes.

Declaration of Competing Interest

No authors have conflicts to declare. This project received no funding.

CRediT authorship contribution statement

Justin S Hatchimonji: Conceptualization, Data curation, Formal analysis, Writing - original draft, Writing - review & editing. **Elinore J Kaufman:** Writing - original draft, Writing - review & editing. **Kristen Chreiman:** Data curation, Writing - review & editing. **Jordan B Stoecker:** Writing - review & editing. **Patrick M Reilly:** Writing - review & editing. **Brian P Smith:** Writing - original draft, Writing - review & editing. **Daniel N Holena:** Conceptualization, Data curation, Formal analysis, Writing - review & editing. **Mark J Seamon:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Writing - review & editing.

Meetings at which this material will be presented

American College of Surgeons Clinical Congress, Chicago, IL, October 2020.

Brief Title: Trauma Patient-Reported Outcomes

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2020.11.034.

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