

Feasibility of the collection of patient-reported outcomes in an ambulatory neurology clinic

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ABSTRACT

Objective: To determine whether patients could self-report physical and mental health assessments in the waiting room and whether these assessments would be associated with modified Rankin Scale (mRS) and Quality of Life in Epilepsy (QOLIE-10) scores.

Methods: We offered iPad-based surveys to consecutive adult neurology patients at check-in to collect patient-reported outcome measures (PROMs). We collected demographic and clinical data on 6,075 patients through survey or administrative claims and PROMs from participating patients. We compared demographic characteristics of participants and nonparticipants and tested associations between physical and mental health scores and mRS and QOLIE-10.

Results: Of 6,075 patients seen by neurologists during the study period, 2,992 (49.3%) participated in the survey. Compared to nonparticipating patients, participating patients more often were privately insured (53.5% vs 42.7%, $p < 0.01$), married (51.5% vs 47.9%, $p < 0.01$), and seen in general neurology (nonsubspecialty) clinics (53.1% vs 46.6%, $p < 0.01$) and more likely to report English as their preferred language (50.1% vs 38.4%, $p < 0.01$). Participating patients had a mean physical health T score of 28.7 (SD 15) and mental health T score of 33 (SD 15), which were 3 and 2 SD worse than the average for the US general population, respectively. Mean T scores in every category of the mRS were different from every other category ($n = 232$, $p < 0.01$). Patient Reported Outcomes Measurement Information System-10 T scores were linearly associated with QOLIE-10 scores ($n = 202$, $p < 0.01$).

Conclusions: Systematic digital collection of PROMs is feasible. Differences among survey participants and nonparticipants highlight the need to develop multilingual measurement tools that may improve collection from vulnerable populations. *Neurology*® 2016;87:2435-2442

GLOSSARY

mRS = modified Rankin Scale; **PROM** = patient-reported outcome measure; **PROMIS** = Patient Reported Outcomes Measurement Information System; **QOLIE-10** = Quality of Life in Epilepsy; **RPDR** = Research Patient Data Registry; **WHO** = World Health Organization.

In recent years, the medical community has placed an increased emphasis on quantifying the quality of neurology care to improve outcomes.¹ The Institute of Medicine highlighted these priorities in its recent annual report.² Chief among these priorities was the development and validation of national performance metrics, including both care delivery and patient-centered measures.²

With this focus, the NIH sponsored the Patient Reported Outcomes Measurement Information System (PROMIS), a project that developed patient-reported outcome question banks to assess health metrics within and across diseases.³ The NIH PROMIS-10 is a short form that measures a patient's perceived physical and mental health.⁴ The PROMIS-10 has been validated in populations with different neurologic diseases (e.g., stroke, epilepsy, Parkinson disease) and without neurologic diseases and may represent a valuable tool for quality improvement projects involving multiple disease domains.

Supplemental data
at Neurology.org

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However, patient-reported outcomes are still not routinely collected in most outpatient neurology clinics.^{5,6} In fact, patient and physician engagement and logistic challenges are the most commonly cited barriers to collecting outcomes from patients.⁷⁻⁹

We tested the hypotheses that patients or their proxies can self-report PROMIS-10 data in the waiting room using customized iPads and that PROMIS-10 T scores are associated with validated disease-specific scales: the modified Rankin Scale (mRS) in patients at a stroke clinic and the Quality of Life in Epilepsy (QOLIE-10) among patients at an epilepsy clinic. We explored the demographic and procedural characteristics of patients who participated vs those who were unable or unwilling to participate in the survey.

METHODS This study was a retrospective review of data collected as part of an ongoing quality improvement project implemented in neurology ambulatory clinic practices that began July 2015. The e-supplement at Neurology.org contains a comprehensive description of the participants, procedures, and measurements used in this study.

Participants. Since July 2015, all ambulatory neurology patients in the outpatient waiting room ≥ 18 years of age have been offered the iPad survey on registration, except for unaccompanied non-English speakers and unaccompanied patients with severe cognitive impairment, with both criteria determined by front desk staff on the basis of an observed inability to follow the very simple survey directions.

Procedures. This study combines information from the survey with linked administrative and clinical data using a Research

Patient Data Registry (RPDR) query tool. For the survey, in ambulatory neurology clinics, patients were checked in by the front desk staff before being seen by the provider (figure 1). For the RPDR query tool, to determine the primary predictors of participation, we gathered additional demographic information using the data registry for all patients (both participating and nonparticipating) seen in the ambulatory neurology clinics during the same time interval according to the scheduling software.

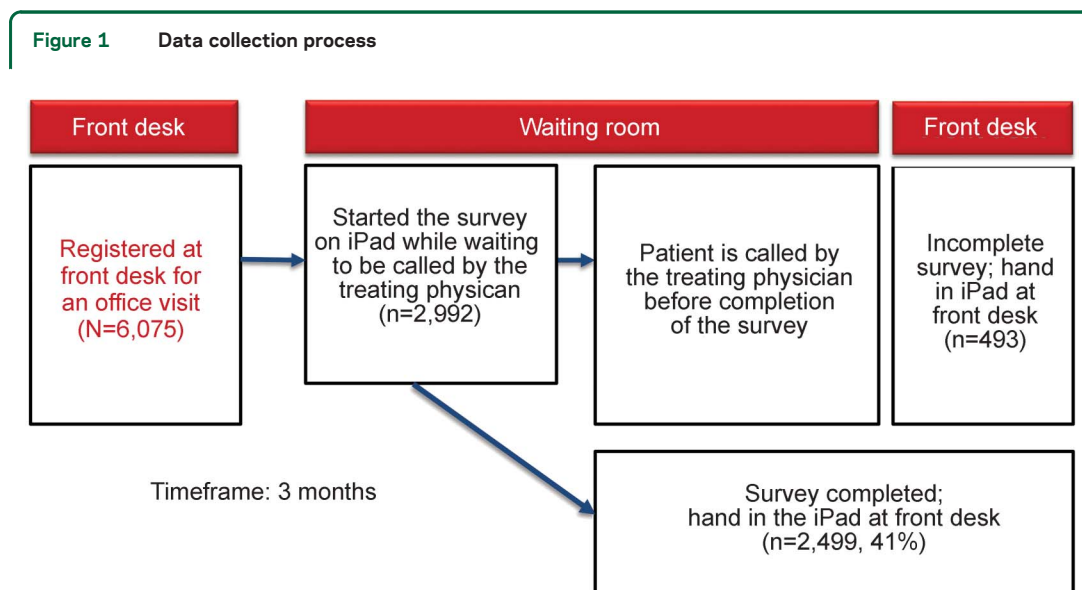
Measurements. The survey had 4 parts: an introduction, demographic questions, disease-specific surveys, and the PROMIS-10 survey, which are described in the e-supplement. Results of the RPDR query identified patients scheduled for an ambulatory neurology clinic visit at the medical center from July 5, 2015, to November 30, 2015. The RPDR query and screening process described in the e-supplement and figure e-1 yielded a sample of 6,075 eligible patient encounters.

Statistical analysis. The final sample was descriptively categorized according to the survey participation (participating vs nonparticipating). We used the χ^2 test of independence to determine whether the following categorical variables were associated with increased rates of participation: sex, ethnicity, preferred language, insurance type, marital status, and clinic type, as categorized in table 1.

To assess the sociodemographic characteristics associated with successful participation in the survey, we used logistic regression. We defined completion, which is different from participation, as providing an answer to the last question of the survey.

We then describe the patient-reported outcomes (PROMIS-10, mRS, and QOLIE-10). The PROMIS-10 T score was used as a continuous number normalized to the US general population at 50 ± 10 . We tested the hypothesis that PROMIS-10 physical and mental health T scores would be associated with the mRS. Because mRS displays an ordinal scale of 6 clinically meaningful categories, we used analysis of variance to test this hypothesis.

Similar to the PROMIS-10, the QOLIE-10 produces a continuous distribution without specific categorical cutoffs. We examined the associations between PROMIS-10 physical and mental health T scores and QOLIE-10 scores using linear regression.



The survey administration process in which patients were handed an iPad preloaded with the survey questions. On completion, patients could place the iPad on the cart or return it to a medical assistant.

Table 1 Demographic characteristics of participating vs nonparticipating patients (n = 6,075)

Demographic characteristics	Participating (n = 2,992)	Nonparticipating (n = 3,083)	p Value
Mean ± SD age, y	56 ± 18	57 ± 19	0.03
Male sex, %	46.3	45.5	0.67
Insurance, n (%)			<0.01
Private	1,745 (51.2)	1,662 (48.8)	
Medicare	1,083 (47.6)	1,190 (52.4)	
Medicaid	124 (42.6)	167 (57.4)	
Other ^a	40 (38.5)	64 (61.5)	
Preferred language for care English (vs all others), % ^b	94.2	91.0	<0.01
Hispanic (vs all others) (n = 387), n (%)	178 (46.0)	209 (54.0)	0.14
Married, partnered (vs single) (n = 3,204), n (%)	1,651 (51.5)	1,553 (48.5)	0.01
Specialty clinic (vs general neurology clinic), n (%) ^c	1,671 (46.6)	1,915 (53.4)	<0.01

^a Other insurance includes international insurances, self-pay insurance, and no insurance.

^b Patients were asked what language they prefer to discuss health-related concerns and dichotomized between English as the preferred language vs all other languages.

^c Specialty clinic includes the following: ataxia (n = 117), epilepsy (n = 520), memory (n = 473), movement (n = 1,057), neuromuscular (n = 291), neurobehavioral (n = 376), sleep (n = 224), and stroke (n = 528) clinics. General neurology clinic includes n = 2,489.

Standard protocol approvals, registrations, and patient consents. This study was conducted under a protocol approved by the Partners Healthcare Institutional Review Board.

RESULTS Participation characteristics. There were 6,075 eligible patients during the study time period, and 2,992 (49.3%) participated in the survey. Of those 2,992, 2,499 (83.5%) successfully completed the entire survey, allowing a PROMIS-10 score calculation. The completion rate among patients seen at the epilepsy clinic was 44.8% (233 QOLIE-10 assessments of 520), and the completion rate among patients seen at the stroke clinic was 38.3% (202 mRS assessments of 528).

Participation varied according to the study time period, with 368 (12.3%), 1,529 (51.1%), and 1,095 (36.6) participating in the first, second, and third months of data collection, respectively. Multivariable logistic regression showed that participating patients more often were privately insured, reported English as their preferred language for medical care, were married, and were seen in a general neurology (vs subspecialty) clinic compared to nonparticipating patients (figure 2).

Table 1 and table e-1 summarize the demographic characteristics of the participation groups. In handling missing data with respect to ethnicity (e.g., Hispanic vs not), we performed 2 additional logistic regressions as sensitivity analysis: assuming that every patient with the ethnicity field incomplete was

Hispanic and assuming that every patient with the ethnicity field incomplete was not Hispanic. These 2 sensitivity analyses yielded similar results compared to the analysis using only completed cases (figure 2).

Table e-2 shows the living situation, education level, and occupational status of the patients who fully participated in the survey and provided information not available by query in the administrative database.

Associations between PROMIS-10 vs mRS and QOLIE-10. Participating patients had mean physical health T score of 28.7 (SD 15) and mental health T score of 33 (SD 15), which were 3 and 2 SD worse than the average for the population used to validate the PROMIS-10 survey. The study sample included normally distributed outcomes (PROMIS-10 physical and mental health, QOLIE-10, and mRS scores).

The mRS scores (n = 232) were distributed across the range of 6 functional categories, with 74.7% of patients reporting a score of 0 to 2, indicating functional independence with no more than mild disability (table e-3).

The PROMIS-10 physical and mental health T scores were significantly associated with mRS scores (both $p < 0.01$). In clinically meaningful words, the mean PROMIS-10 scores were distributed differently among the functional mRS categories (figure 3). This suggests that PROMIS-10 (physical and mental health) T scores may surrogate mRS scores.

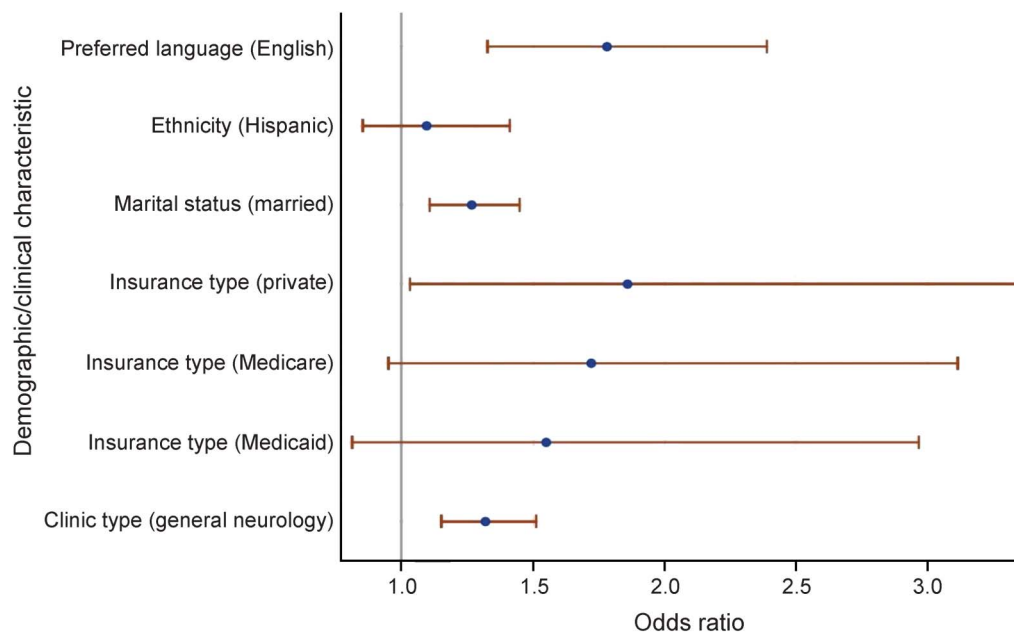
Similarly, PROMIS-10 T scores were linearly associated with the QOLIE-10 scores (figure 4). The associations were similar for both physical and mental health T scores ($p < 0.01$ for both).

Exploratory analysis: Outcomes by patient vs proxy. There were 2,463 assessments (84.73%) by patient report and 444 (15.27%) by proxy (i.e., a family member, caregiver, or legal guardian who accompanied the patient during the office visit). All survey data entry was performed independently of study staff.

Physical and mental health scores reported by patients were better overall compared to proxies (i.e., mean physical health T scores 42.8 [SD 12] vs 38.9 [SD 11], $p < 0.01$; mean mental health T scores 47.1 [SD 12] vs 41.8 [SD 9], $p < 0.01$). Table e-4 details this comparison and includes the comparison of assessments of QOLIE and mRS scores in stroke patients.

DISCUSSION In the present study, we demonstrate the feasibility of administering tablet computer (iPad) surveys to collect patient-reported outcome measures (PROMs) in an ambulatory neurology clinic. Our participation rate (49%) was similar to rates reported by other tablet-based PROM acquisition studies.^{10–14} Tablet-based survey administration

Figure 2 Adjusted odds ratios and 95% confidence intervals of the association between demographic characteristics and survey participation



Results of the multivariable logistic regression showing that participating patients more often were privately insured, reported English as their preferred language for medical care, were married, and were seen in a general neurology (vs subspecialty) clinic compared to nonparticipating patients. The results above represent the sample of completed cases in which *p* values are as follows: English as preferred language, *p* < 0.01; Hispanic, *p* = 0.14; married partner, *p* < 0.01; private insurance, *p* < 0.0001; Medicare, *p* = 0.07; Medicaid, *p* = 0.46; and general neurology clinic, *p* < 0.01. Sensitivity analysis assuming that every patient with the ethnicity field incomplete was Hispanic yielded similar results: English as preferred language, *p* < 0.01; Hispanic, *p* = 0.55; married partner, *p* < 0.01; private insurance, *p* = 0.16; Medicare, *p* = 0.41; Medicaid, *p* = 0.61; and general neurology clinic, *p* < 0.01. Likewise, a second sensitivity analysis assuming that every patient with the ethnicity field incomplete was not Hispanic yielded the following results: English as preferred language, *p* < 0.01; Hispanic, *p* = 0.52; married partner, *p* < 0.01; private insurance, *p* = 0.17; Medicare, *p* = 0.41; Medicaid, *p* = 0.64; and general neurology clinic, *p* < 0.01.

permitted both collection of large-scale PROMs data and verification of critical demographic information such as occupational status, education level, and living situation in the population studied. This study highlights the differences between participants and nonparticipants in the routine collection of PROMs.

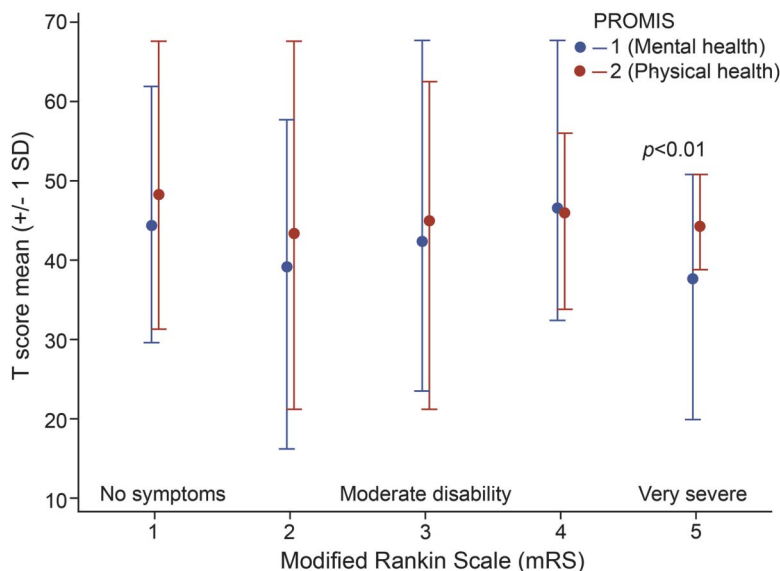
Despite growing evidence supporting the utility of PROM collection in outpatient clinics, systematic collection of PROMs has not gained widespread application. Barriers to use appear to be primarily logistic. The literature suggests 3 essential considerations for feasible collection of PROMs: use of modern survey delivery methods, patient engagement, and care provider collaboration.¹⁵ While our study does not provide direct data to support each of these 3 components exactly, we have listed the characteristics of our study that demonstrate the feasibility of our data collection method.

Tablet computers were used to administer surveys because of the strong evidence suggesting that this approach proves more accurate and less labor-intensive than paper-based and Internet-based surveys.^{10,16–24} This finding has been established across

multiple comprehensive centers, specialties, and age groups.^{15,25}

However, delivery models described in the literature contain substantial methodological differences, including various clinical settings, patient characteristics collected, and survey technologies.^{15,17,26–29} Many cases fail to report participation rate.^{17,30} A prior study demonstrates the collection of patient-reported outcomes (i.e., PROMIS physical functional scale) at an academic cerebrovascular clinic using an electronic platform over a time frame of 33 months, reaching 1,946 stroke patients. The novelty of our study lies in the demonstration of the feasibility of collecting patient-reported outcomes in a neurology clinic, reaching 2,992 patients over 3 months, as well as our record of the participation rate. The participation rate of our study was comparable to that of studies that reported the participation rate and targeted a sample size of at least 500 patients (participation rate 38%–73%).^{15,28,29} Likewise, our methods share strategic elements used in the most successful studies, including a well-designed electronic survey system, algorithms for tailoring item selection, and integration with patient health records.¹⁷

Figure 3 Association between physical and mental health T scores and modified Rankin Scale (mRS) score



Mean T scores \pm 1 SE for NIH Patient Reported Outcomes Measurement Information System (PROMIS) physical health (red) and mental health (blue). T scores (y axis) plotted vs the mRS (scored from 0 = no symptoms to 5 = severe disability) reported by patients or proxies at the time of the medical appointment. Detailed data are available in table e-2.

Study feasibility is contingent on the level of patient engagement. Our survey completion rate of 83.5% among participants was reasonable but not excellent and could be improved. Although not used in this study, prior studies validate individualized recruitment strategies to increase patient engagement.^{10,13,26} Possible explanations for our observed response rate may stem from the accessibility and convenience of tablet-based surveys. One group found that e-mail-based follow-up of patients who declined initial survey resulted in a significant response rate, with responders of this approach reporting that a direct approach and immediate survey access contributed to their amenity to engagement.^{10,30}

Finally, study feasibility relied heavily on strong administrative and care provider staff training and support. This study used broad institutional support for PROM-based monitoring and evaluation of clinical care. For instance, this study benefited from a system-wide initiative that provided software development services that included interaction with electronic medical records and integration of the patient survey data and the RPDR. In addition, departmental funds supported the inclusion of one medical assistant dedicated to the processes of patient participation at the front desk. In addition to this immediate interest in and support of PROM acquisition, there was medical professional support due to the perceived value of verified sociodemographic and clinical patient data and their utility in the improvement of clinical care.⁶

Provider engagement was driven by leadership from each division who were consulted several times as we developed the survey strategy.

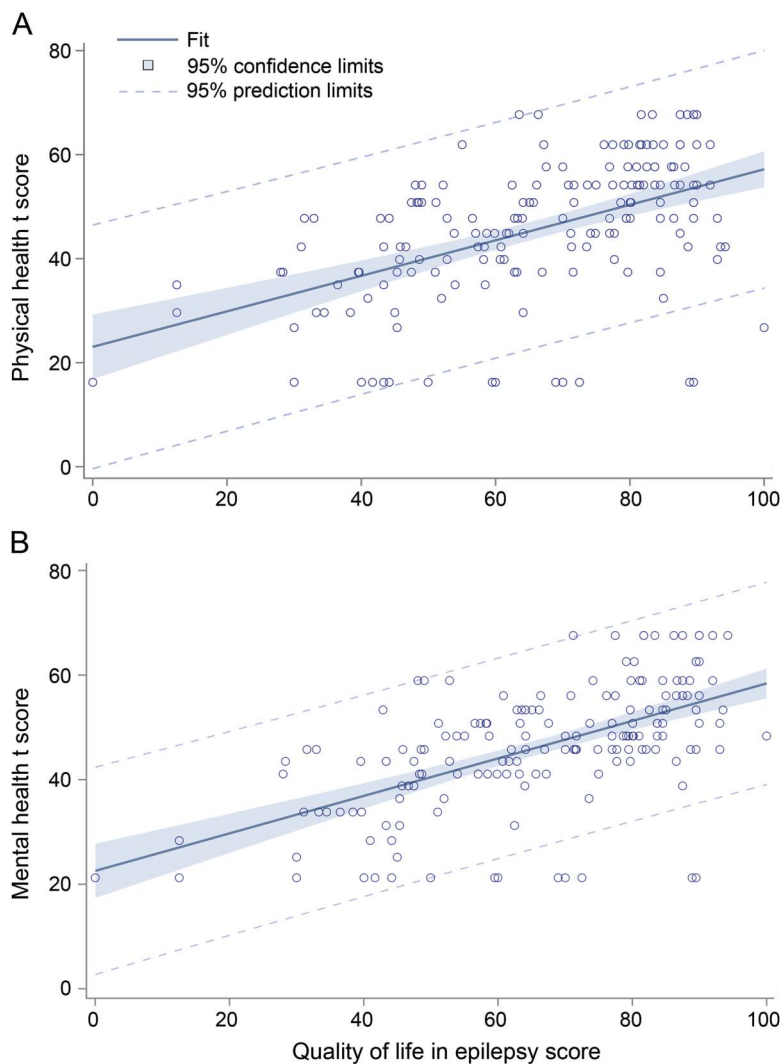
PROM acquisition limitations and future directions were identified. A substantial proportion of patients whose preferred language was not English were excluded from participation. To reduce health disparities in vulnerable populations, the present study highlights the need to develop multilingual measurement tools.^{27-29,31}

Secondary findings that support the potential applications of tablet-based PROM approaches were also observed in the present study. Specifically, associations were found between PROMIS-10 scores and mRS scores in stroke patients and between PROMIS-10 and QOLIE scores in patients with epilepsy. In fact, these associations are not unexpected considering that each of the scales used (i.e., PROMIS-10, mRS, and the QOLIE scores) has been previously validated. Likewise, the fact that physical and mental health scores reported by patients were better overall compared to proxies was expected because proxies usually accompany more disabled patients.^{3,4,7,32-34}

Similarly, a strong correlation has been found between patient-reported Stroke Impact Scale scores and the Fugl-Meyer upper extremity pegboard assessment in survivors of ischemic stroke.⁷ Another group has also demonstrated the association between patient-reported physical function (PROMIS) and the validated Stroke Impact Scale-16 in ischemic stroke patients.³⁰ Patient-reported surveys have also been used to assess migraine prophylactic drug adherence, paving the way for the identification of noncompliance risk factors.³⁵ In 2013, a World Health Organization (WHO) quality-of-life 26-question short form was used to compare 149 patients with epilepsy to 1,238 healthy English citizens, contributing valuable insights to psychosocial disease effects.³⁶ In fact, a series of studies have suggested that the WHO Disability Assessment Schedule 2.0 is useful for monitoring outcomes in a wide range of clinical and service settings. One advantage of adopting an internationally accepted instrument is the ability to allow cross-country comparisons. However, modules that cover impairments in body functions and structures were missing in the WHO Disability Assessment Schedule 2.0 but are present in NIH PROMIS (e.g., general physical function, upper and lower limbs), which puts the latter at a relative advantage for longitudinal tracking of ambulatory neurologic patients.³⁷

Despite these correlations, the general physical and mental health assessment (NIH PROMIS-10) should not be seen as a replacement for disease-specific scales (e.g., mRS), and further support for the utility of the routine collection of these measures remains needed.

Figure 4 Association between physical and mental health T scores and Quality of Life in Epilepsy (QOLIE-10) score



(A) Patient Reported Outcomes Measurement Information System (PROMIS-10) physical health and (B) PROMIS-10 mental health. T scores (y axis) plotted vs QOLIE-10 (scored from 0 = worse possible quality of life to 100 = best possible quality of life) reported by patients or proxies at the time of the medical appointment. The PROMIS-10 T scores were linearly associated with the QOLIE-10 scores for both (A) physical and (B) mental health (all $p < 0.01$).

For instance, remote extension of PROM acquisition may serve to supplement virtual visits, to reduce hospital visits, and to provide valuable population-based information on disease processes. Further study is also warranted to determine whether PROM data can be used to improve health outcomes in patients with modifiable determinants of health.

The clinical significance of each of the PROMIS-10 physical and mental health scores merits further validation. Currently, the survey results in T scores with the indication that a higher physical or mental health T score represents better health. In comparison, each of the mRS categories provides more clinically meaningful information. For instance, an mRS score of 4 indicates the inability to walk without

assistance, whereas an mRS score of 5 indicates that the patient is bedridden and incontinent, requiring constant nursing care and attention.

This study presents the patient-reported outcomes at a single time point for each patient. Future studies may examine how the patient-reported outcomes vary over time for established patients with multiple follow-up visits. For this analysis, the data coding should allow serial survey analysis (e.g., longitudinal regression models). A particular characteristic of our survey that allows longitudinal analysis is that a unique number is generated every time a survey is completed. This number is independent of the patient identification number. In addition, for patient information protection, the patient identification number was converted to a different meaningless number based on a random mathematical rule (e.g., patient identification number divided by 236 and then multiplied by 12 to give a new study subject number). This transformation rule was kept secure. If necessary and justifiable to the ethics review board, a link to a unique patient can be performed by transforming back the new study subject number in the original patient identification number (e.g., new study subject number divided by 12 and multiplied by 236).

The current study has certain methodological limitations. Notably, we were unable to distinguish between patients who declined to participate and those who were not approached as a result of the aforementioned exclusion criteria or administrative errors and patients who did not have time to complete the survey before their visits. The absence of this data prevents further characterization of potentially confounding participant vs nonparticipant differences.

Time taken to complete the survey was also not measured by our survey software. In those patients whom we had the opportunity to time, survey completion occurred at an average of 7 minutes, which may have decreased the accuracy of survey responses as a result of patient fatigue.³⁸ Similar to previous studies, this study has limited generalizability to non-academic medical centers.^{10,21}

Incomplete RPDR administrative data also limited the results of this study. For instance, missing data (38.4%) on Hispanic ethnicity may mask confounders between groups. However, the sensitivity analysis suggests that missing data on Hispanic ethnicity did not substantially change the conclusions of this study.

An important limitation of this study was the lack of information about the effect of the survey data provided to the treating physicians on therapeutic interventions. For instance, it remains unknown whether the group of patients with low mental health scores received pertinent related interventions such as a referral for psychiatric evaluation.

Another limitation of this study was the inability of capture the treating physician's opinion about the accuracy of the survey responses. In one example, a patient with well-controlled idiopathic generalized epilepsy who came for maintenance of health without any neurologic complaint had reported a low PROMIS-10 physical health score. In further discussion about the score, the patient disclosed recent involvement in a motor vehicle accident. Both the physician and patient agreed that the physical health scores were not related to the patient's neurologic problem.

Finally, the cost of tablet computers is high relative to the cost of paper-and-pencil surveys.¹¹ Additionally, 2 tablet computers went missing during the study, which has prompted exploration of antitheft systems for future use. Although not a factor at our medical site, another foreseeable limitation could arise in areas with limited or unreliable Internet connections because online survey data collection may be required. Although the initial cost investment may be higher for tablet-based surveys, cost-effectiveness is achieved in large-scale studies in which data entry may be streamlined and complete.

This study demonstrates that systematic digital collection of patient-reported outcomes is practical and instructive in a neurologic clinical setting.

AUTHOR CONTRIBUTIONS

Lidia Moura and Eli Schwamm contributed to study design, data collection, data analysis, and manuscript draft and review. Valdey M. Junior contributed to data analysis and manuscript draft and review. Michael Seitz, Andrew Cole, and John Hsu contributed to manuscript draft and review. Lee Schwamm contributed to study design, data collection, data analysis, and manuscript draft and review.

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DISCLOSURE

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