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Original Articles

Automation and Simplification: Drivers of Innovative Collection and Use of Patient-Reported Outcomes Data

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Abstract

The aim was to develop an electronic data capture (EDC) system to capture patient-reported outcome (PRO) measures successfully by automating processes identified as barriers to implementation. Clinical success, research impact, and patient acceptance of this system were evaluated during a pilot and a follow-up period 2 years later. During the pilot, there were 44,831 eligible visits. Capture rate was 99.0% (44,374 visits) and completion rate was 99.4% (44,108 visits). Capture rate was 99.4% and completion rate was 95.2% during the follow-up period. Zero help desk tickets were put in for the EDC system during either time period. Patients accepted the EDC system both during the pilot (1.4% refusal rate) and follow-up period (1.2%). An automated Structured Query Language server feed provided data used to produce numerous abstracts and manuscripts. Automation was crucial to overcoming implementation barriers and delivering PRO scores to the electronic health record in real time with minimal impact on clinical workflow. Automation also has supported PRO research.

Keywords: electronic data capture, patient-reported outcomes, clinical data, process automation, software development, PROMIS

Introduction

Current health care discussion is often focused on practicing ''patient-centered care.'' Patient reported-outcome (PRO) measures incorporate the patient perspective into the treatment process[1] and can enable individualized care by driving patient-centered discussions[2] and, if integrated into clinical practice, can provide a foundation for shared decision making, which can improve quality outcomes.[3–5]

The Patient-Reported Outcomes Measurement Information System (PROMIS) was developed as a standardized metric that is valid and reliable independent of patient condition.[6] PROMIS has numerous validated assessments across 3 domains including physical, mental, and social health[6] and is available in a computer adaptive test (CAT) format. Both static and CAT PROMIS measures have been shown to have greater responsiveness and fewer floor and ceiling effects than static legacy PRO measures.[7–10] Additionally, the CAT format allows patients to complete assessments with fewer questions and lower patient burden, which can improve survey response.[9,11] The benefits of PROMIS are well suited to large-scale data collection and building data sets that can provide information on outside factors that may affect treatment outcomes[12–15] and serve as markers that can promote self-care in certain populations.[16]

Electronic data capture (EDC) is necessary to use PROMIS CATs. Compared with traditional paper-based methods, EDC improves data integrity,[17,18] accuracy,[17] and validity.[17] Patient response toward EDC has been positive overall[19] with some patients preferring EDC instead of paper forms.[20] Data collected via EDC also can be accessed quickly when needed, improving clinical care processes and reducing utilization.[21]

Many previous implementation attempts have revealed barriers that prevent widespread EDC adoption. Ease of use can be one of the most significant barriers to successful EDC implementation,[22] preventing implementation within the time and effort constraints of clinical workflows.[19,23–26] Data-related concerns also can strengthen EDC implementation barriers. Accurate data transcription between information technology (IT) systems,[27] the need to

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accurately link separate data sets together,[28] and interpretation guidelines for the data[29,30] are EDC-related concerns that can become barriers to implementation.

In 2015 a custom web-based electronic assessment delivery system (WUPRO) was created that supported the successful large-scale implementation of electronic PRO data capture for all eligible ambulatory visits within the department of orthopedic surgery. WUPRO was developed specifically to fit into existing clinical workflows, provide actionable PRO scores to providers in real time for use during clinical visits, and link to other systems to help expedite nonclinical PRO data use. By using a development philosophy balanced between system usability and staff adaptability suggested by Lorenzi et al,[31] implementation of WUPRO was uniquely successful at integrating within existing clinical workflows while simplifying, through automation, the data capture process leading to accurate, near-perfect data capture.

Methods

Development work began with a requirement-gathering process during which a project manager documented existing clinical workflows after meeting with a cross section of clinical stakeholders. This group included physicians, high and mid-level clinical administrators, and clinical staff who would be using WUPRO within clinic. After further refinement of the clinical workflow, discussions moved forward concerning proposed features and how clinical stakeholders ideally wanted them to work outside of workflow considerations. The project manager regularly communicated, discussed, and refined these requirements with the technical development team whereby subsequent technical solutions were conceptualized. After gathering initial requirements, further development of WUPRO features was flexible, with communication between different stakeholder groups on technical and clinical sides. As features were developed, input from a collaborating group of multidisciplinary personnel (software development, project management, clinical providers, and administration) was provided regularly and resembled the team science for implementation approach.[31] Clinical stakeholders then determined what features worked best or needed further refinement to minimize workflow impact while satisfying requirements. Upon completion, technical and clinical stakeholders worked together to test individual features in an environment that closely emulated that of the clinics. After completion of a minimum viable feature, development continued to refine and expand features based on staff feedback.

WUPRO was built as a web-based assessment delivery application using current Microsoft platform technologies. To be implemented successfully within existing workflows, WUPRO was designed to be integrated with preexisting technological systems including patient scheduling/clinical electronic medical record (EMR; GE Allscripts, Chicago, IL), local active directory authentication, and new systems including Northwestern University's Assessment Center Application Programming Interface (ACAPI). To communicate with existing clinical software, WUPRO uses a trimmed down HL7 messaging system (Figure 1).

While WUPRO's basic assessment delivery functions were in development, a clinical workflow analysis was conducted on the preexisting paper-based PRO collections and assessment selection was identified for automation to speed up and simplify the process. Paper-based collections involved identifying patients manually via provider rules or chart review, printing assessments, and manually attaching them to the patient's clipboard, a burdensome process that needed to be completed the day before the clinical visit.

To automate assessment selection, WUPRO features a customizable rule system whereby department administrators use a self-service control panel to create assessment selection rules (Figure 2). As WUPRO receives HL7 messages from the scheduling system, scheduling information (eg, provider) is interpreted and the appropriate assessments are selected by WUPRO automatically. With WUPRO, staff only have to open a provider's schedule, find the patient, press the assign button, and scan a WUPRO-generated quick response code with an iPad mini.

Previously, after completion, existing PRO assessment results collected during clinical visits were manually entered into the patient chart, usually through a process of scanning the paper form as a pdf attachment. The time required for this process meant results generally were not available for use during the clinical visit at which they were collected. Additionally, result data cannot be queried within the EMR and access requires manually opening PDF files, finding answers, and/or calculating scores.

To provide actionable data to providers, the PROMIS CATs are scored automatically through the ACAPI and WUPRO automatically inserts the t-score into a result HL7 message that is delivered to the EMR. The EMR picks up this result and places this value into the patient chart as a discrete queryable alphanumerical data value. This value is treated in an analogous manner to a lab result and can be viewed graphically as well as in a table showing previous scores (Figure 3).

To support data access outside of clinical applications, a subscription-based Structured Query Language (SQL) feed from the WUPRO data warehouse automatically provides current PRO data into a ''mixing bowl'' to be joined with clinical data from the EMR by a unique field that ensures data accuracy between the 2 sources. A simple query request to get joined data from both sources replaces a burdensome, manual joining process that required chart review. Additionally, WUPRO also can send data directly into REDCap projects. Utilizing a REDCap API key, researchers upload a patient/visit list and WUPRO automatically searches for PRO data in the warehouse that corresponds with the event table in the REDCap study. Staff verify and select the appropriate found visit data for download into score instruments within the REDCap study.

Alongside automating direct EDC processes, related support processes also were identified as critical to implementation. Administrative reports provide quantitative evidence to track staff performance, measure implementation success, and provide evidence of data integrity. Initially, administrative reports would be compiled manually by reviewing the daily clinic schedule and checking a second list of patients who did not receive assessments. For patients who did not receive assessments, administration manually reviewed staff notes indicating why patients were excluded (eg, refused) and manually computed administrative statistics.

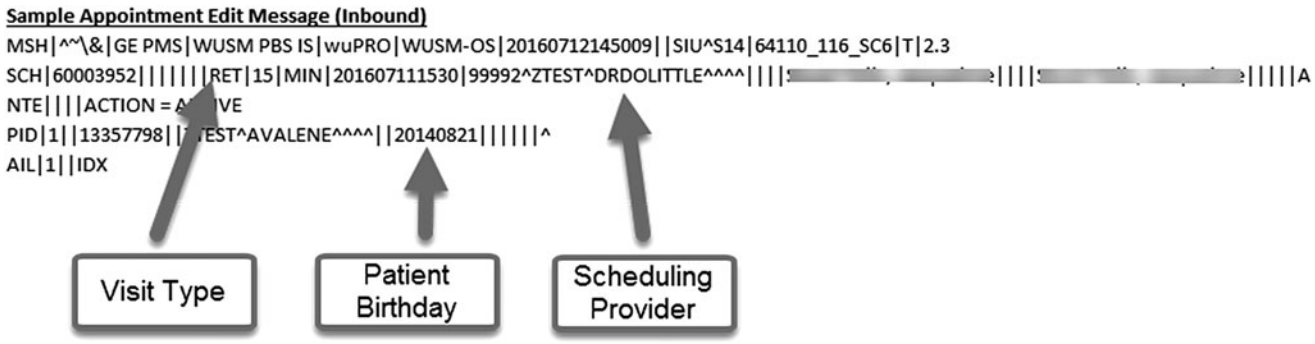


FIG. 1. HL7 message.

WUPRO automatically provides staff with a list of patients who did not receive assessments so that staff can specify why. This information is automatically combined with other system information to compile administrative reports. Administrators can generate and view reports on user performance, clinic performance, and specific reports (eg, refusals) in WUPRO in minutes (Figure 4).

Once basic EDC functionality was developed, implementation began with the goal of delivering the PROMIS Physical Function, Pain Interference, and Depression CATs to patients while staff registered them for their ambulatory visit in the waiting room. A tiered schedule was drafted to implement individual ambulatory clinics throughout the department of orthopedic surgery. The order of clinics scheduled was determined by WUPRO's technical readiness to handle the clinic population, proximity to campus, IT resources, and patient volume.

Within 2 weeks of clinic go-live, the project manager and administrators held an educational session for clinical staff who would use WUPRO. Staff had 1:1 hands-on training and an opportunity to ask questions. For providers, a brief overview on PROMIS was provided during a faculty meeting with the project manager, department chair, and physician champion available as resources for faculty members who wanted further information regarding EDC and PROMIS.

On clinical go-live days the project manager and clinical administrator provided on-site support as necessary for staff. Implementation progress was evaluated weekly using administrative reports generated in WUPRO for indicators of success. Indicators included the overall assessment delivery percentage to eligible patients (capture rate), the self-sufficiency of the EDC process, measured by the number of Help Desk tickets put in related to technical problems, and

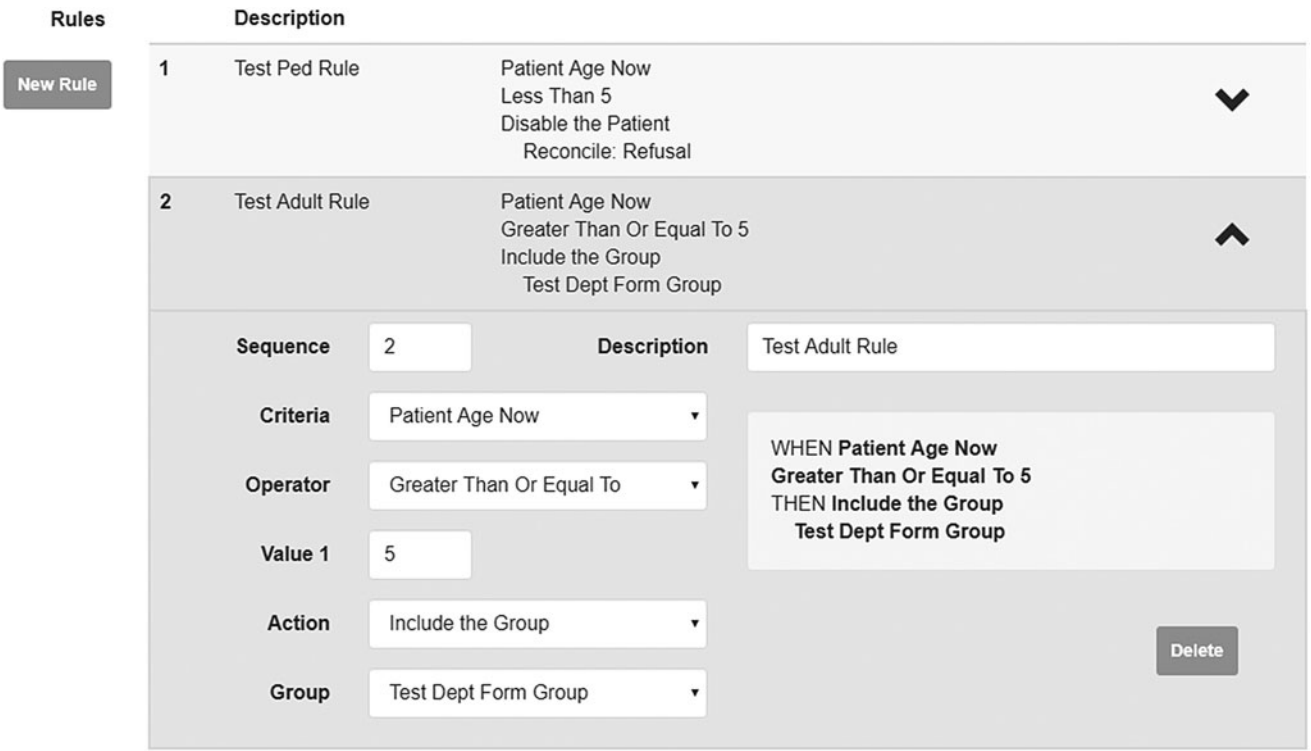


FIG. 2. Rule system dashboard.

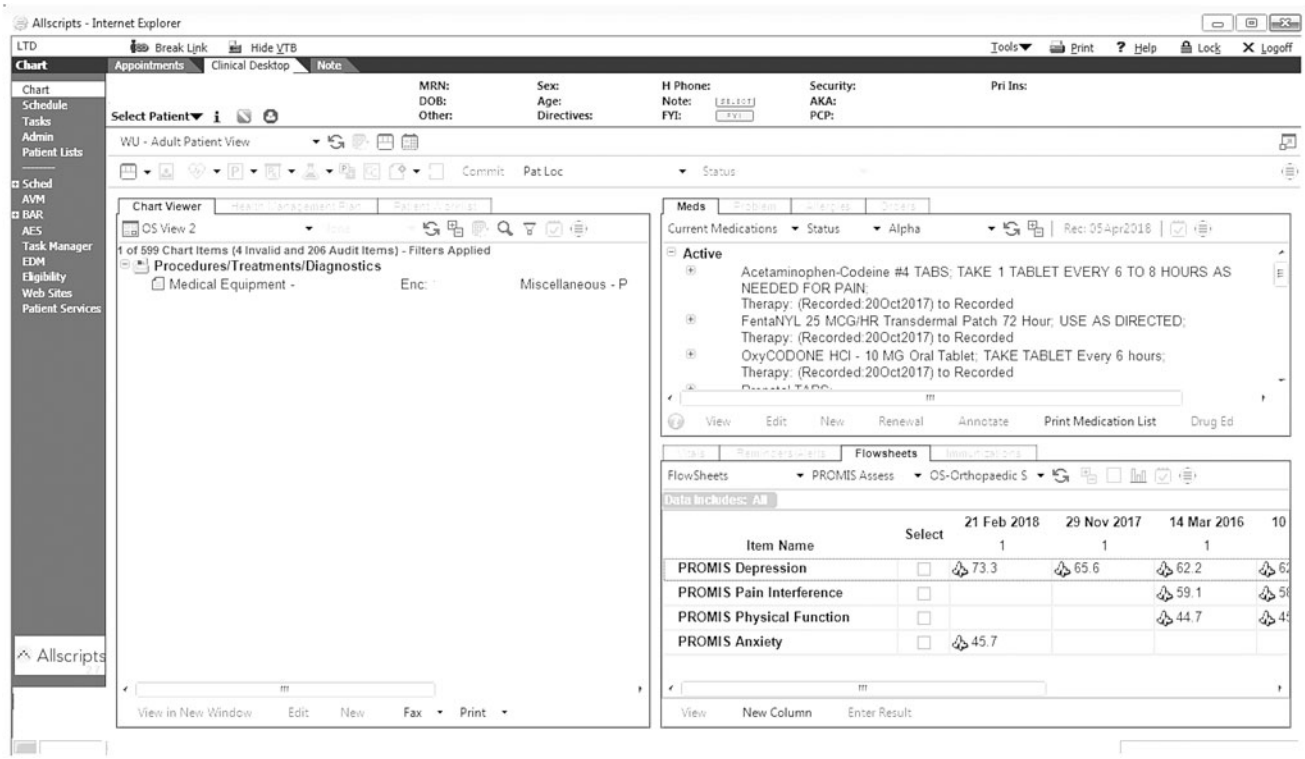


FIG. 3. Results displayed in chart. Figure 3 can be viewed in greater detail online at www.liebertpub.com/pop

patient acceptance of the EDC process, measured by refusal rate for the assessment battery. Department directive established that patients at all ambulatory visits were to get PROMIS CATs excluding patient refusals, nonresponsive patients, patients younger than age 5 years, and patients bypassing standard visit registration (eg, professional athletes). To measure the implementation process accurately, the remaining population who did not meet exclusion criteria formed the eligible patient population used to measure capture rate.

Overall implementation success was evaluated during a pilot period of June 22, 2015–December 9, 2015. Reevaluation of long-term success was performed during the 8-week period surrounding the 24-month anniversary of the pilot (May 29, 2017–July 22, 2017). To determine EDC impact on research, the number of PRO data requests through the REDCap interface or SQL feed were counted. This analysis was a retrospective quality improvement project that included no Protected Health Information and was exempt from institutional review board review.

Results

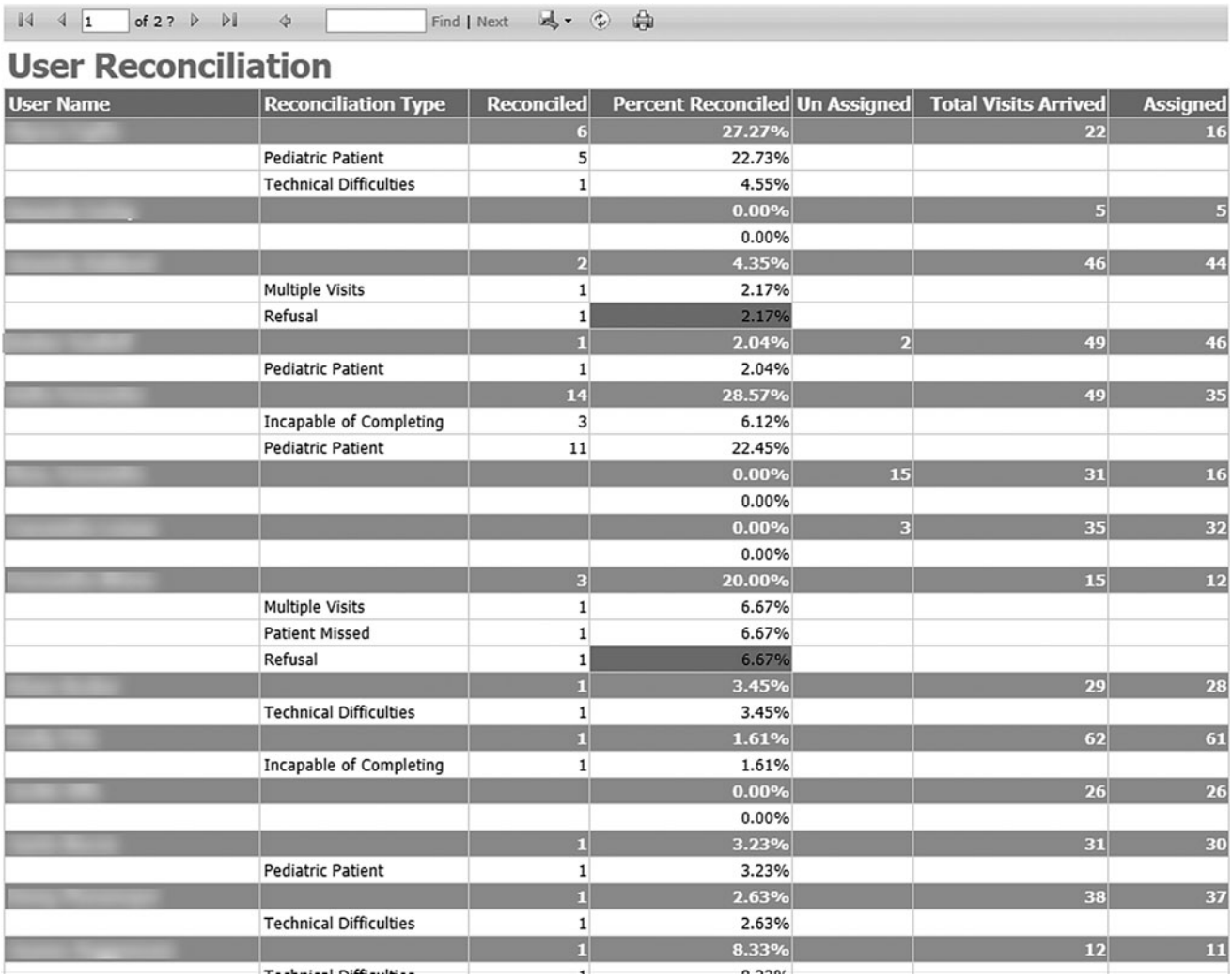
During the pilot period there were 49,463 total ambulatory visits. Of these, patients at 649 visits (1.3%) refused the assessment. After exclusion of ineligible patient visits, 44,831 (91% of total ambulatory visits) patient visits were eligible to receive the PROMIS CATs via WUPRO. Of the eligible visits, staff achieved a 99.0% (44,374/44,831 visits given assessments) capture rate. Among the patients who were given assessments, 99.4% (44,108) completed the battery. The number of help desk tickets put in by staff for technical problems with WUPRO was zero. There were no opportunities to collect PRO data lost related to outside technical problems (eg, networking, Wi-Fi issues).

During the reevaluation period, there were 24,154 total ambulatory visits. Patients refused the assessments in 249 visits (1.2%). After exclusion of ineligible patient visits, staff reached a 99.4% capture rate, giving assessments to 21,134 of 21,257 eligible visits. Patient assessments were completed at 20,122 of these visits (95.2%). There were zero help desk tickets put in by staff for technical problems with WUPRO during this period. Again, there were no opportunities to capture PRO data lost related to outside technical problems during the period of this study.

Between January 2, 2016, and July 17, 2017 there were 27 research data queries completed that specifically included PROMIS data coming from the SQL-fed mixing bowl of PRO and EMR data. Two studies currently in review will utilize the REDCap export function to automatically move PRO data from WUPRO into REDCap.

Discussion

The high capture rate during both the pilot and reevaluation periods suggests that the simple, automated EDC process facilitated by WUPRO was able to be completed and sustained without too much disruption or burden to staff. Simplifying the assessment selection process so the department administrator can set up or modify assessment selection rules and WUPRO can automatically select the correct assessments for all ambulatory visits was essential in



1 of 2 ? Find | Next

User Reconciliation

User Name	Reconciliation Type	Reconciled	Percent Reconciled	Un Assigned	Total Visits Arrived	Assigned
		6	27.27%		22	16
	Pediatric Patient	5	22.73%			
	Technical Difficulties	1	4.55%			
			0.00%		5	5
			0.00%			
		2	4.35%		46	44
	Multiple Visits	1	2.17%			
	Refusal	1	2.17%			
		1	2.04%	2	49	46
	Pediatric Patient	1	2.04%			
		14	28.57%		49	35
	Incapable of Completing	3	6.12%			
	Pediatric Patient	11	22.45%			
			0.00%	15	31	16
			0.00%			
			0.00%	3	35	32
			0.00%			
		3	20.00%		15	12
	Multiple Visits	1	6.67%			
	Patient Missed	1	6.67%			
	Refusal	1	6.67%			
		1	3.45%		29	28
	Technical Difficulties	1	3.45%			
		1	1.61%		62	61
	Incapable of Completing	1	1.61%			
			0.00%		26	26
			0.00%			
		1	3.23%		31	30
	Pediatric Patient	1	3.23%			
		1	2.63%		38	37
	Technical Difficulties	1	2.63%			
		1	8.33%		12	11

FIG. 4. Administrative reports (user report).

turning a time-consuming process previously completed the day before clinic into a 3 mouse clicks and scan process completed in less than 10 seconds. The EDC process was simple enough to be integrated easily into an existing clinical workflow at patient registration with minimal staff burden. The simplicity of using WUPRO allowed for a more effective 1:1 hands-on training approach to learn WUPRO, leaving more time for questions and input. WUPRO's ability to automatically provide accurate, quantitative data through administrative reports was crucial to ensuring staff accountability and supporting successful data collection. By providing specific reports in real time, administration could access and reference up-to-date reports as necessary when reviewing department and staff performance without the need for additional staff, such as a data officer,[32] to provide process compliance reports. The self-sufficiency enabled by WUPRO's administrative reporting enables timely performance analysis and targeted process improvement actions to support a high level of data collection.

Utilizing a team approach throughout the development process improved buy-in for WUPRO across divisions, similar to other implementations.[32] By including input from across staff levels individuals did not feel WUPRO was forced on them, but rather was a tool they helped build to simplify assessment delivery and support better care. This perception was strengthened by a number of ''quality of life'' improvements made based upon their input. Examples of these improvements include hiding excluded visit types on schedules, disabling assign buttons on excluded patients, and automatically providing reconcile system data on certain excluded visits used in administrative reports.

Because PRO collections are voluntary, the very low refusal rate suggests that most patients were not averse to the EDC process. WUPRO makes the EDC process simpler for patients by allowing them to receive and complete PROMIS CATs via an iPad mini during registration, a time when the patient usually is not busy with other tasks. The speeds at which most patients can complete the PRO batteries usually ensures assessments are completed before a patient is called to the clinical area, where EDC is disruptive and can complicate the clinical visit. The very low refusal rate at the 24-month window suggests providing the patient with PROMIS assessments at every visit did not negatively affect long-term patient acceptance of the EDC process.

This intervention was successful in integrating WUPRO with the EMR, and PRO results were displayed in the patient chart in real time for clinical use. Although this feature was identified previously as being transformative[24] and was a key requirement for the study institution's providers, availability of the data in the clinical chart did not drive any notable examples of clinical use. Based on provider feedback, the lack of clinical meaning attached to PRO scores remains a strong barrier to their widespread use. Instead, the clearest impact of WUPRO was supporting PRO research initiatives. The simplified process enabled by the WUPRO SQL feed sped up data request fulfillment times. The number of research requests fulfilled via the WUPRO SQL Server-EMR linked data set suggests provider interest in PRO measures, and research on this data ultimately may help inform best clinical practices using PRO measures. Also, the use of a unique identifying field common to both data sources improves the level of data integrity over previously manual methods of data joining.

The focus on automation also has been applied with very basic PRO data interpretation to support clinical care. A threshold feature is being developed to provide automatic interpretation and guidance to providers based upon a patient's PRO scores. Initially, this feature will be used to address heightened anxiety and depression scores that could warrant mental health intervention based on departmental guidelines derived from established score walkways.[33] Patients with PRO scores surpassing threshold designations will be flagged within WUPRO for designated staff and they can print supplemental material for the patient via a simple button. Automating the process of identifying patient scores and selecting the appropriate documents for the patient will speed up and simplify the process without detrimentally affecting existing workflows. After successful initial implementations in the hand and tumor divisions, the threshold function has supported the clinician's ability to now consider mental health at the point of care. Based on 2016 score data, once fully implemented across the department the threshold is expected to trigger for approximately 3416 unique patients (14.9%) comprising 4940 patient visits (5.1%) when set to a score of 65 on the depression CAT.

Limitations

One limitation of this study is that the study team cannot definitively say why patients who refused did so. However, the team believes that patients willing to complete the assessment battery at the visit were accepting of the EDC process. It is unclear what the decrease in completion rate indicates; however, the team feels that fatigue is not a factor given the low burden associated with CATs.

Another limitation of this study is the inability to quantitatively analyze the effect of the EDC process on PRO usage by providers in clinic. Although there was enthusiastic support from the department chair and physician champions, there was no mandate for the use of PRO data. Additionally, a formal education process on the new PROs was not provided and, at the time of implementation, literature on scores and clinical meaning was limited.

The study team also could not directly compare data request fulfillment times. Prior to WUPRO implementation, no standardized process was in place to request data, so researchers may have had to make multiple requests from multiple sources, manually transcribe data from the chart directly, and/or manually join all of the data together, making it infeasible to compare with the new method. Because of the recent release, the team was unable to analyze the use of the WUPRO REDCap export feature; however, the team expects that as PRO research and REDCap usage increase, so will the use of this feature.

Lastly, although the study team did not lose any data capture opportunities related to outside technical problems during the study windows, some intermittent problems occurred outside of those windows. The largest problems encountered were related to networking certificate changes disrupting iPad Wi-Fi connections that required a manual update for all affected iPads. The total data capture opportunity lost is an unknown number; however, collections were negatively affected for 2 days.

Conclusion

Successfully integrating PRO EDC into existing clinical workflows was only possible by simplifying the EDC process by automating formerly manual steps. Identifying key steps in existing workflows for automation during software development through the team science approach led to WUPRO-enabled EDC that fit into clinical workflows by simplifying existing assessment delivery processes. Clinical implementation also was supported by automation of allied processes including on-demand administrative reports generation used for performance reviews, and problem identification, as well as rules to make schedules easier to view. Although automation was key to implementing EDC and providing actionable data for clinicians, the automations themselves had no effect on clinical usage of PRO data.

Implications

The strong, high-integrity data collection enabled by this system creates a strong foundation to clinically incorporate PRO data into visits and drive clinical change. Additionally, as clinical change occurs, this flexible, customized system is well suited to expand functionality and continue to simplify clinical processes, supporting clinical initiatives not otherwise possible.

Author Disclosure Statement

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