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Electronic Patient Symptom Management Program to Support Patients Receiving Cancer Treatment at Home During the COVID-19 Pandemic
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ABSTRACT

Objectives: Remote patient monitoring became critical for patients receiving cancer treatment during the COVID-19 pandemic. We sought to test feasibility of an electronic patient symptom management program implemented during a pandemic. We collected and analyzed the real-world data to inform practice quality improvement and understand the patient experience.

Methods: Eligible patients had breast, lung, or ovarian cancers, multiple myeloma, or acute myeloid leukemia and 12 weeks of planned chemotherapy. Patients were notified that a symptom survey with common symptoms derived from the National Cancer Institute’s Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events was available to complete using a smartphone, tablet, or computer. Patients recorded their symptoms and results were sent to the provider. Patients received care guidelines for mild/moderate severity symptoms and a phone call from the provider for severe reports.

Results: A total of 282 patients generated 119,088 data points. Patients completed 2,860 of 3,248 assigned surveys (88%), and 152 of 282 patients (54%) had symptom reports that generated an immediate notification to the provider. Longitudinal data were analyzed to determine whether previous reports predicted a notification alert and whether symptoms resolved after the alert was addressed.

Conclusions: An electronic patient symptom management program was implemented in the midst of the COVID-19 pandemic. Enrollment of 282 patients and a high survey completion (88%) demonstrated feasibility/acceptance. Patients reported symptoms at severe levels of 54% of the time and received self-management instructions and provider phone calls that resolved or decreased the severity of the symptom. A standard approach and validated instrument provide opportunities for improving and benchmarking outcomes.

Keywords: cancer treatment symptom management, remote symptom monitoring.
severe symptoms became paramount. This report details data on 284 patients who enrolled between September 2020 and October 2021.

Methods

Goals

The primary goal of this study was to test feasibility of implementing an ePSMS by the number of patients enrolled at each site, survey adherence, and survey completeness. Our secondary goal was to collect and describe the alerts reported to inform practice quality improvement and better understand the real-world patient experience. Given that remote symptom management was considered standard of care at the participating sites and all participants sign an end-user license agreement to allow use of their deidentified data, the institutional review board determined the study was exempt from institutional review board oversight.

Procedures

The design uses rolling enrollment methodology with patient PROs collected on a weekly basis and alerts conveyed to providers on a real-time basis. Eligible patients had one of 5 cancer diagnoses (breast, lung, or ovarian cancers, multiple myeloma, or acute myeloid leukemia), had a minimum of 12 weeks of planned chemotherapy, were 18 years or older, and had access to a smartphone, tablet, or computer. The selected cancers represent the initial diagnoses supported in the ePSMS with others in development for future expansion of the program. The 12-week minimum for weekly surveys is used by the sites as a criterion to justify the effort associated with enrollment and ongoing patient management remotely. The ePSMS was implemented at 3 US cancer centers, 2 academic centers in the Southeast, and 1 community center in the Mountain West.

Patients were enrolled in the cloud-based platform and notified via text or email that a symptom survey was available to be completed. Patients signed into a secure site to record their symptoms using a smartphone, tablet, or computer, and results were sent to the provider through the electronic medical record (EMR). Specified symptom levels such as severe or very severe or in some cases such as fever that is present, yes or no, were set to trigger a provider notification. Patients received written care guidelines for mild or moderate severity symptoms and a phone call from the care team for management of alerting symptoms. Of note, patients with acute myeloid leukemia who were hospitalized on an inpatient clinical team.

Instrument

Patients complete weekly symptom reports as long as they are receiving treatment. Surveys delivered weekly include a core set of common symptoms derived from the National Cancer Institute’s Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®). The PRO-CTCAE library contains 124 items to measure 78 symptomatic adverse events. Reeve et al. (2014) identified a core set of 12 symptoms prevalent across diverse cancer populations (fatigue, insomnia, pain, appetite loss, dyspnea, cognitive problems, anxiety, nausea, depression [sadness], neuropathy, constipation, and diarrhea). Per the participating physicians, these symptoms, excluding cognitive problems, are part of the week survey along with some additional symptoms requested by providers (rash and mouth/throat sores).

Given that the PRO-CTCAE is a well-established instrument with proven reliability and validity, patients did not receive specific instructions about the measures before starting the surveys. When the symptom occurs, severity is reported as mild, moderate, severe, or very severe. Additional questions about frequency and interference with daily activities are included for some symptoms. A composite score of all attributes for each symptom is derived using an algorithm for mapping individual items for any given adverse event to a single (composite) numerical grade.

All data are collected either directly into the Carevive platform via integration with the site EMR and data entered directly by the site staff and from the patient surveys. A security and privacy provider manages all protected health information and any access to it. Carevive supports operations at all sites and has Health Insurance Portability and Accountability Act Business Associate Agreements in place with all data providers.

Data Structure

Data manipulation and analyses were performed using SAS version 9.4 and SPSS version 27.0. The analyses focused on 3 data structures: (1) demographics with one record per patient (number of records = 282), (2) weekly data captured across all variables for each patient within a given week (number of data points = 119,088), and (3) patient-/week-level data set where data were aggregated at the weekly report level and then nested within a given patient (number of weekly nested reports = 2790). Patients provided a range of 1 to 57 weekly surveys with an average of 12.17 weeks (SD 9.54) of data; 55 of 282 patients (20%) had completed treatment and were no longer using the platform at the time of this analysis.

A critical focus of this work was to examine symptom levels immediately before an alerting episode (look back) and immediately after an alerting episode (look forward). We explored the relationship of the symptom report before the symptom alert report and the relationship of the symptom report after the alert report to explore whether an intervention was effective or not. Preliminary results showed mild symptom profiles accelerated within 1 week to trigger an alert. In the look back analyses, only

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Table 1. Sample characteristics (N = 282).

| Cancer diagnosis          | Mean (SD) |
|---------------------------|-----------|
| AML                       | 29 (10.3) |
| Breast                    | 178 (63.1)|
| Lung                      | 19 (6.7)  |
| Myeloma                   | 39 (13.8) |
| Ovarian/gyn               | 17 (6.0)  |

AML indicates acute myeloid leukemia; gyn, gynecological.
“naive” alerts were studied, naive meaning that the alerting episode was either the first episode for a patient, or for patients with one or more alerting reports, an alert was considered naive if there was at least 1 nonalerting symptom report immediately before the alerting report of interest. In this look back process, the immediately preceding symptom levels were juxtaposed with the symptom alert levels to compute the alert change scores to indicate improvement, no change, or worsening of the symptom levels.

In the look forward process, the symptom report immediately after an alerting report was examined for change in symptom level immediately after an alert. In a process like the selection of naive alerts in the look back analysis, only those records after an alert that themselves were nonalerting records were examined. In this process, the record immediately after an alert was juxtaposed with the alerting levels that generate the alert, and as above, change scores were computed to indicate improvement, no change, or worsening of the symptom levels.

In these processes (look back and look forward), the changes in symptom levels were quantified by computing change scores (Rising_delta = CompositePrealert – CompositeAlert). The same process was used to examine resolution. Change scores were computed as (Resolution_delta = CompositePostalert – CompositeAlert). These change scores could range from “worsening by 3 points” to “no change” to “improving by 3 points.” Both Rising_delta and Resolution_delta scores were examined for patterns of change overall and specifically for comparing patterns of change using divergent stacked bar charts as per recommendation by Zhou et al (2018).

Results

Participants had a mean age of 58.96 years (SD = 13.18), were mostly female (85.5%), were white (72.4%), and had a diagnosis of breast cancer (63.1%) (see Table 1). Patients completed 2860 of 3248 assigned surveys (88.0%), and 152 of 282 patients (54.0%) had symptom reports that rose to the level of an immediate notification sent to the provider. The most common symptoms reported were fatigue (84%), pain (54%), decreased appetite (52%), insomnia (51%), and nausea (50%) (see Table 2). The top symptoms that triggered alert reports were pain (42%), fatigue (32%), and insomnia (27%) (see Table 2). The top symptom alerts across the sample by cancer type, race, and sex were examined. These analyses were limited by sparse cells, and only the most robust were reported here. Cancer type was significantly associated with generation of pain alerts ($\chi^2(4) = 11.38\ P = .03$.) The nature of this association was that patients with breast cancer were significantly more likely to trigger pain alerts. In addition, females were more likely than males to trigger pain alerts ($\chi^2(2) = 4.62\ P = .03$). Finally, we found no association between race and generation of alerts.

With regard to the look back and look forward analyses, the change scores as discussed earlier were graphed as divergent stacked bar charts and are provided in Figure 1A,B. In general, these figures show the improvement percentage and worsening percentage in composite scores between 1 week before an alert report (rising delta) and 1 week after an alert report (resolution delta) for 6 symptoms: pain, nausea, and insomnia in Figure 1A and fatigue, constipation and diarrhea in Figure 1B (graphs are separated only for ease of presentation). The graphs summarize data in a way that can be quickly compared. For instance, in Figure 1A, the change from the prepain alert to the pain alert indicated 18.5% patients showed worsening by 3 composite score points, 44.0% showed worsening by 2 points, and 24.7% showed worsening by 1 point (the negative sign to the worsening percentages are a function of how the data are graphed.) In this figure, 12.4% showed no change from the week before the alert report to the alert report. In contrast, we see in the corresponding element immediately below, in the postpain alert, 23.2% of the patients showed improvement by 3 points, 34.8% improved by 2 points, and 16.8% improved by 1 point. Notably, 23.8% showed no change and a small percentage (< 3%) showed a worsening by 1 point.

Discussion

This report describes the initial results of implementation of remote symptom management using an ePRSM system. Due to the challenges of patient care during the COVID-19 pandemic,
enrollment was significantly less than expected; nevertheless, adherence and completion rates were higher than anticipated and comparable with clinical trial reports of 70% to 90% adherence. High adherence is attributed to patients knowing that the reports were being monitored.

In addition, known barriers to adoption such as a lack of EMR integration and a lack of effective processes for clinical workflow integration were overcome through integration of the ePSMS with the EMR and intense support for workflow design during the implementation period. Additional funds for staff support were provided and welcomed during the time of staffing shortages and reassignment. Other keys to adoption have been identified such as the immediate scoring and reporting, longitudinal display, clear workflow as to who receives and responds to alerts, and guideline-supported recommendations available. The ePSMS includes each of these features.

The acceptability of digital PRO systems is growing with many clinical trials demonstrating decreased symptom severity with automated self-management and calls for poorly managed symptoms.39-42 Analyzing the longitudinal symptom reports to track response to interventions provides the clinical practice feedback needed for continuous quality improvement. With more patients and further analysis of specific interventions, the potential usefulness of the data increases. In the look back for each
symptom, patients who reported the symptom that did not rise to the level of an alert in the week before the alerting symptom report can be examined for effectiveness of the self-management measures and potential need for earlier calls by the care team. The look forward data can provide insight into the effectiveness (or ineffectiveness) of interventions after the alert. Using a standard approach and a validated PRO symptom instrument provides opportunities for benchmarking and sharing best practices.

Implementing the ePSMS in 3 institutions during the COVID-19 pandemic provided both opportunities and challenges. Patients with cancer are more at risk of morbidity and mortality with COVID-19 infection because of age, comorbidities, and the immunosuppression related to the tumor itself or treatment effects. Millions of patients were transitioned to telemedicine visits to decrease risk for patients and staff alike, and treatments were modified or delayed to reduce in person patient visits. Not surprisingly, patients reported higher symptom burden and stress during the COVID-19 pandemic.

The ePSMS was welcomed as a tool to support patient care, yet widespread adoption was hampered by reduced personnel because of positive test results or reassigning staff to support the increased demand for inpatient care. Staff spent enormous effort rescheduling patients for telemedicine visits, prescreening those who continued receiving treatments for COVID-19 symptoms, and adapting to evolving procedure and policy changes. Although these barriers were not addressed with ePSMS, enrollment of patients into the ePSMS supported efficient screening of patients and symptom management at home. In addition, staff could also quarantine at home and securely access the patient reports to assure continuity of care.

There are several limitations in this study. Patients were not educated on the meaning of symptom responses before taking a survey; therefore, internal consistency and reliability were not established. In addition, self-reporting of symptoms can potentially bias the responses. There is a preponderance of women in the study because of the diagnoses of breast and gynecological cancer and the sex imbalance may affect results. Eligibility required access to a smartphone, tablet, or computer. Implementation of this symptom reporting and management system may not be feasible or accessible to underserved and disadvantaged populations.

The look back and look forward analyses as portrayed in the divergent stacked bar graphs provide a useful snapshot of the rise and resolution of symptoms. Future analyses will focus on the interventions made in response to the alerting symptom reports to determine the effectiveness of the interventions in resolving the symptom. We will investigate unexpected findings such as the relatively large percentage of patients who did not improve or got worse after an alert, including the clinical and demographic factors associated with this lack of change. With increased sample size with continual enrollment, we expect to extend the prealert measurement to more than a single prealert measure so that we can better quantify the process of symptom change leading to an alert. In addition, we anticipate the use of clustering techniques to uncover latent groups of individuals based on change scores and to examine predictors of cluster membership and the impact of cluster membership on outcomes.

Conclusions

This article describes an ePSMS implemented at 3 institutions in the midst of the COVID-19 pandemic. Feasibility and acceptance were demonstrated through enrollment of 282 patients undergoing cancer treatment with a high rate of weekly survey completion. Patients reported symptoms at severe levels of 54% of the time and received self-management instructions and provider phone calls that resolved or decreased the severity of the symptom. Continued aggregation of homogenously reported symptoms provides opportunities for quality improvement, benchmarking outcomes, and sharing of best practices.

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