Enhancing Oncology Side Effect Management Using a Remote Monitoring System

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IV oncology treatments are associated with severe side effects (SEs) that can decrease patients' quality of life and lead to increased hospitalizations. However, improved reporting with remote monitoring systems (RMSs) may decrease patients' treatment-related SE burden and improve quality of life. For this project, participants wore the BioIntelliSense BioSticker™, a medical-grade remote monitoring device. Data on participants' heart rates, respiratory rates, and temperatures were collected and transmitted, which alerted clinicians to follow up with participants for SE management if clinical data were outside of target ranges. All project variables except for hospitalizations showed a statistically significant decrease from pre- to post-test. Of the 13 SEs evaluated, 3 showed a statistically significant decrease in severity from pre- to post-test.

AT A GLANCE

- The BioSticker can improve the reporting of oncology treatment–related SEs, leading to significant decreases in patients' SE burden.
- RMS alerts can notify clinicians of patient vital sign data to inform assessments and mobilize earlier management.
- The project's findings support using RMSs to improve patients' treatment-related SE burden and reinforce the importance of effective patient–provider communication.

KEYWORDS
remote monitoring; side effect management; hospitalizations; quality of life

DIGITAL OBJECT IDENTIFIER
10.1188/23.CJON.491-495

An estimated 86% of patients with cancer receiving treatment report at least one side effect (SE), with an estimated 65% reporting a grade 3 or higher SE during treatment (Pearce et al., 2017; Winstead, 2022). In addition, an estimated 15% of patients report experiencing SEs that never resolve (Lee et al., 2022). The SE burden of oncolytic treatment is highly individualized and affects patients' and caregivers' overall well-being and quality of life (QOL) (Hassen et al., 2019; Mohammadzadeh Nimekari et al., 2019; Padmaja et al., 2017).

More than one-third of patients with cancer are hospitalized annually (Whitney et al., 2018). Although some hospitalizations are the result of complications from the cancer itself, others are preventable and attributable to poor management of treatment-related SEs (Whitney et al., 2018). Hospitalizations add to the already high financial burden of cancer care (Roeland et al., 2018). Evidence-based discharge programs and structured discharge checklists reduce hospital readmissions (Beaver & Magnan, 2016; Rohlfs, 2022). However, to improve the efficiency of healthcare delivery and reduce costs, strategies to prevent initial hospitalizations are needed.

Reductions in treatment-related SE burden and hospitalizations can improve QOL for patients with cancer and their caregivers (Fjell et al., 2020; Hassen et al., 2019; Lee et al., 2022; Padmaja et al., 2017). To improve QOL and potentially reduce mortality throughout treatment, patients must understand treatment-related SEs and how to manage them (Olver et al., 2018). However, many patients are incapable of monitoring SEs daily and often delay reporting SEs that require prompt management (Almohammadi et al., 2020; Maguire et al., 2021; Olver et al., 2018).

Although professional oncology organizations have established guidelines for healthcare providers (HCPs) to better manage treatment-related SEs, no gold standard for SE reporting exists (Bray et al., 2018; Hesketh et al., 2017; LeFebvre et al., 2020). HCPs rely on timely and accurate patient self-reporting in the decision-making process for dose modifications and supportive care (Batra et al., 2020; Pearce et al., 2017; Sodergren et al., 2016). By enhancing patient communication and access to resources, RNs and other HCPs can reduce hospitalizations, improve patient outcomes, and improve patients' personal health management (Almohammadi et al., 2020; Bayraktar-Ekincioglu & Kucuk, 2018; Fjell et al., 2020).

Remote monitoring systems (RMSs) are innovative technology platforms used to manage chronic diseases, monitor complex conditions, and prevent

hospitalizations (American Hospital Association, 2023; Taylor et al., 2021). In addition, RMSs can improve overall health and QOL for patients with cancer by stimulating proactive SE management, which can decrease the severity of SE burden related to treatment (Kaler et al., 2022; Lee et al., 2022; Maguire et al., 2021; Seven et al., 2022). The purpose of this pilot project was to compare the efficiency and effectiveness of SE management using the BioIntelliSense BioSticker™ (www.biointellisense.com) RMS versus standard monitoring for patients receiving IV chemotherapy and/or immunotherapy. The overall goals of the project were to improve SE management and reduce hospitalizations.

Methods

Project Design, Setting, and Sample

This pilot project used a pre-/post-test design and collected quantitative SE data from patients with cancer receiving treatment who used the BioSticker RMS. To improve management of treatment-related SEs, a needs assessment was conducted at Optum–Cancer Care in New Albany, Indiana, an outpatient hematology-oncology infusion clinic. The project's sample had the following inclusion criteria: (a) being aged 18 years or older, (b) receiving IV chemotherapy and/or immunotherapy at the clinic, and (c) being able to consent. All patients meeting these criteria were eligible to participate.

This project was guided by symptom management theory, which presents a framework for improving the symptom experience through assessment and treatment. According to symptom management theory, symptom outcomes are determined by a clear, measurable change in symptom status (Bender et al., 2018). A SWOT (strengths, weaknesses, opportunities, and threats) analysis was then applied to the project's design. The pilot project received approval from the University of Southern Indiana Institutional Review Board. The BioSticker is a U.S. Food and Drug Administration–approved, 510(k) Class II wearable medical device. The device did not require investigational new device exemptions.

Procedures

Eligible participants were asked to wear the BioSticker for at most 90 days, with exchanges of the device every 30 days because of its battery life. During the initial placement of the BioSticker, participants were provided with a 10-minute in-person education session, and the BioSticker was placed on their upper left chest. Participants were instructed to wear the device and continue the clinic's current SE monitoring and management regimen, which consisted of weekly laboratory appointments, pretreatment nursing assessments, and a 24-hour telephone line for patient self-reporting of SEs.

Through the BioSticker, data were collected for resting heart rates, resting respiratory rates, and skin temperature. The vital sign data were collected remotely at participants' homes via Bluetooth and transmitted to the clinic's system. Email and telephone alerts notified the project team leader and members of the clinic's staff of data points outside the participants' target ranges, which prompted follow-up telephone calls to participants. Alerts for heart and respiratory rates were personalized to participants' baseline rates. Alerts for skin temperature were set to greater than 37.5°C during the day and greater than 37°C overnight.

Data Collection and Analysis

Project variables were number of hospitalizations, emergency department (ED) visits, and treatment dose reductions; timeliness to report and manage treatment-related SEs; and severity of 13 treatment-related SEs. Baseline pretest data (from the time before participants were using the BioSticker but still receiving IV oncology treatment) were collected from participants' chart audits and organized using a tracking tool. Post-test outcome variables and BioSticker alert data were recorded with a tracking tool. Of note, data for treatment dose reductions included held, delayed, or discontinued treatments, as well as decreases in the dose of an oncology drug.

"Data from remote monitoring systems can help manage treatment-related side effects and enhance oncology nursing clinical practice."

Treatment-related SEs reported pretest (prior to BioSticker application) and post-test (while wearing the BioSticker) were scored using a four-point SE severity scale (0 = SE does not require intervention or was not experienced; 1 = SE requires intervention, no treatment change necessitated; 2 = SE requires intervention and treatment change; and 3 = SE requires hospitalization).

Pre- and post-test data from the tracking tool were compared for timeliness for participants to report SEs, timeliness for the clinic's staff to address SEs, hospitalizations, ED visits, dose reductions, and improvement in severity of 13 treatment-related SEs. For the statistical analysis of the seven variables and the severity scale data for the 13 SEs, paired-samples t tests were used to calculate means, SDs, and 95% confidence intervals.

Results

The project's target accrual was at least 30 participants. Of 45 potential participants, 32 (16 male and 16 female) agreed to

participate and were included in the project's sample. Participants wore the BioSticker for an average of 56.5 days. Based on the results from this pilot project, the means of all variables, except hospitalizations, decreased to a statistically significant extent among participants while wearing the BioSticker (see Table 1). In addition, statistically significant decreases in severity in the following three SEs were found: neutropenia (t = 3.0884, p = 0.002), nausea/vomiting (t = 3.5699, p = 0.001), and peripheral neuropathy (t = 2.7089, p = 0.005) (see Table 2).

Pretest, 14 hospitalizations occurred because of treatment-related SEs. The most common SEs requiring hospitalization were nausea/vomiting (n = 3), anemia (n = 2), neutropenia (n = 2), and weight loss (n = 2). The most commonly reported SEs were nausea/vomiting (n = 14), peripheral neuropathy (n = 13), neutropenia (n = 12), diarrhea (n = 9), and weight loss (n = 7). Nine hospitalizations from treatment-related SEs occurred post-test, with increased serum creatinine (n = 3) and anemia (n = 2) being the most common. The most common SEs reported while wearing the BioSticker were peripheral neuropathy (n = 6), thrombocytopenia (n = 5), and diarrhea (n = 5).

During the project, the following 11 alerts were recorded: 4 for core temperature, 4 for resting heart rate, and 3 for resting respiratory rate. Each participant was contacted by the principal investigator after each alert, and only 3 of the 11 alerts required intervention. The BioSticker also notifies HCPs when participants do not have the device on their bodies, known as an off-body alert. Off-body alerts were not recorded during the project.

Discussion

Based on this project's results, the BioSticker RMS resulted in a statistically significant decrease in the severity of the three most reported pretest SEs. Nausea/vomiting and neutropenia were also among the leading causes of pretest hospitalizations, which supports the need for RMSs to monitor and manage oncology treatment–related SEs. These results support previous findings that RMSs can lower the burden of physical SEs (Fjell et al., 2020).

Of note, one participant was called after the BioSticker sent a tachypnea alert. During the follow-up telephone call, the participant denied any physical distress; however, they disclosed feelings of anxiety related to their diagnosis. This example demonstrates the potential for the BioSticker to be used to monitor psychological effects as well. This experience aligns with reports from patients in a study by Seven et al. (2022), who used a symptom management mobile application for patients with breast cancer receiving chemotherapy and noted decreased sadness and depression. Maguire et al. (2021) also concluded that RMSs significantly decrease patients' psychological symptoms and outcomes as measured by the Global Distress Index on the Memorial Symptom Assessment Scale.

In addition, based on BioSticker alerts recorded during this project, six of seven variables showed a significant reduction post-test compared to pretest. Previous studies have shown that different modalities of remote patient monitoring, such as mobile applications and continuous monitoring systems, significantly improve healthcare productivity and patient–provider communication (Kaler et al., 2022; Maguire et al., 2021). The reported benefits of RMSs align with this project's results because using the BioSticker device promoted improvements in the overall well-being, correspondence, SE reporting burden, and SE severity in patients with cancer (Fjell et al., 2020; Kaler et al., 2022; Maguire et al., 2021; Seven et al., 2022).

Limitations

Participants had various cancer diagnoses and received different oncology treatments. Some participants received IV immunotherapy alone, which is associated with less toxic SEs (Ferrara et al., 2021). Some participants received neoadjuvant or adjunct radiation therapy, which may have increased their potential for hospitalizations and treatment complications (Majeed & Gupta, 2022; Tonse et al., 2022). Participants' ages also varied from 48 to 83 years, which may have influenced their vulnerability (Mohile et al., 2018).

The time frame for data collection pre- and post-test also differed among participants, creating inconsistent time ranges for the data. In addition, several participants intermittently transmitted data during the project's data collection period because of connection issues and not wearing the device. Although BioSticker off-body alerts were not recorded, the principal

TABLE 1.
PRE AND POST MEAN SCORES FOR 7 VARIABLES

	PRE		POST		
VARIABLE	$\bar{X}$	SD	$\bar{X}$	SD	p
Dose reductions	1.56	2.03	0.5	0.76	0.002
ED visits	0.22	0.49	0.03	0.18	0.028
Hospitalizations	0.5	1.16	0.34	0.7	0.262
SEs reported in less than 24 hours	4.5	5.41	1.56	1.88	0.003
SEs reported in more than 24 hours	6.72	6.45	1.22	1.43	< 0.001
SEs managed in less than 24 hours	10.13	8.74	2.53	3.07	< 0.001
SEs managed in more than 24 hours	0.44	0.88	0.06	0.25	0.016

ED—emergency department; post—post-test; pre—pretest; SE—side effect
Note. Pre data represent participants' baseline data while receiving chemotherapy and/or immunotherapy, which were obtained via chart audits. Post data represent data collected while participants wore the BioIntelliSense BioSticker™ (www.biointellisense.com).

investigator made follow-up telephone calls when intermittent data transmission was noted. The calls lead to triages about participants' statuses.

Patients receiving care from two oncologists with differing assessment and documentation styles participated in the project, which may have affected the data. In addition, one participant was seen by an oncologist outside of the clinic before the project, so no baseline pretest data could be collected for that participant.

Implications for Nursing

Data from RMSs can help manage treatment-related SEs and enhance oncology nursing clinical practice. Results from this pilot project suggest that use of the BioSticker RMS significantly improves SE management and decreases ED visits for patients receiving IV chemotherapy and immunotherapy. RMS alerts can notify clinicians of patient vital sign data that is outside of target ranges, which can inform RN assessments and mobilize earlier management of treatment-related SEs. As illustrated by this pilot project, data and alerts from the BioSticker can improve the reporting of life-altering and deadly SEs of oncology treatment, leading to significant decreases in patients' SE burden (Fjell et al., 2020; Mooney et al., 2017). Other oncology care organizations with similar populations can implement RMSs to improve patients' experiences and nursing care. The implications of this project warrant additional research. A larger study with a more focused population may determine how effective an RMS is for different types of cancer diagnoses and treatments.

TABLE 2.
PRE AND POST MEAN SEVERITY SCORES FOR 13 SEs

	PRE		POST		
SE	$\bar{X}$	SD	$\bar{X}$	SD	p
Anemia	0.31	0.78	0.19	0.74	0.201
Constipation	0.19	0.59	0.09	0.53	0.261
Diarrhea	0.38	0.66	0.22	0.66	0.163
Edema	0.13	0.34	0.03	0.18	0.092
Fatigue/weakness	0.22	0.66	0.13	0.42	0.261
Increased liver enzymes	0.16	0.57	0.09	0.53	0.331
Increased serum creatinine	0.19	0.54	0.32	0.9	0.789
Nausea/vomiting	0.66	0.94	0.13	0.34	0.001
Neutropenia	0.63	0.94	0.13	0.42	0.002
Peripheral neuropathy	0.63	0.87	0.19	0.4	0.005
Thrombocytopenia	0.28	0.73	0.22	0.66	0.356
Tinnitus	–	–	–	–	–
Weight loss	0.39	0.84	0.19	0.54	0.123

post—post-test; pre—pretest; SE—side effect
Note. Pre data represent participants' baseline data while receiving chemotherapy and/or immunotherapy, obtained via chart audits. Post data represent data collected while participants wore the BioIntelliSense BioSticker™ (www.biointellisense.com).
Note. SE severity scores were assessed using the following 4-point scale: 0 = SE does not require intervention or was not experienced; 1 = SE requires intervention, no treatment change necessitated; 2 = SE requires intervention and treatment change; and 3 = SE requires hospitalization.

Conclusion

Based on the results of this pilot project, the BioSticker RMS improved the effectiveness and efficiency of SE management for participants receiving IV chemotherapy and/or immunotherapy. All project variables except for hospitalizations significantly decreased through use of an RMS. The three most reported SEs at pretest, nausea/vomiting, peripheral neuropathy, and neutropenia, significantly decreased in severity post-test. The project's findings not only support using RMSs to improve treatment-related SE burden in patients, but also reinforce the importance of effective patient–provider communication.

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The authors take full responsibility for this content and did not receive honoraria or disclose any relevant financial relationships. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Society.

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