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QUALITY IMPROVEMENT

The Use of Remote Monitoring in Care Management for Bone Marrow Transplant Patients

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Abstract

Cytotoxic chemotherapies and immunotherapies cause harmful side effects in over half of patients with cancer. Early intervention is critical for improving outcomes, but in outpatient settings, patient self-assessment and patient-initiated pursuit of follow-up care often cause delays. Digital health technologies for remote patient monitoring (RPM) can minimize these delays. This study assessed the feasibility and perceived user experience of RPM technology for early detection of febrile neutropenia and infection in allogeneic bone marrow transplant (BMT) patients. Ten BMT patients between the ages of 18 and 89 years wore biometric monitoring devices for up to 90 days post-transplant. Devices sent real-time alerts to clinicians in response to elevated temperature, heart rate, or respiratory rate. Patients and caregivers completed surveys about their experience at 30 and 90 days post-transplant; patients were asked to participate in interviews at these time points. Providers completed surveys at the end of the study. Biometric and health utilization outcomes and responses to survey items were analyzed through descriptive statistics. Rapid content analysis of survey data and interview data was conducted to explore emergent themes. Seven patients wore RPM devices until study completion. 369 alerts were generated, with 101 requiring follow-up. Two patients had infections during the study. One had infection detected through alert data and received outpatient treatment; the second stopped wearing their device prior to symptom onset and required hospitalization. Overall, RPM technology was perceived as generally acceptable, comfortable, and easy to use. Refinements to alerting practices and technology performance are recommended to improve adoption and use as intended in the outpatient setting.

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Patients with cancer often receive treatment with cytotoxic and myelosuppressive chemotherapies of varying intensity. One particularly deleterious side effect of this treatment is fever that occurs in the context of low neutrophil counts, or "febrile neutropenia" (FN), which frequently heralds the development of serious and life-threatening infections (Casanovas-Blanco & Serrahima-Mackay, 2020; De Bock & Middelheim, 2000; Lyman et al., 2014). The Infectious Diseases Society of America defines FN as a single oral temperature at or above 38.3°C (101°F) or a temperature at or above 38.0°C (100.4°F) sustained over 1 hour (Freifeld et al., 2011). On average, FN with associated infection occurs in up to 50% of patients overall who receive chemotherapies, depending on factors such as type of treatment, comorbidities, catheter status, and genetic susceptibility (Baus et al., 2023; Celebi et al., 2000; De Castro Carpeño et al., 2015; Nesher & Rolston, 2019; Schroeder et al., 2023). Febrile neutropenia leads to significant morbidity in 25% to 30% of patients, with mortality as high as 10% (Nesher & Rolston, 2019; Taplitz et al., 2018a). Bone marrow transplant (BMT) patients in particular represent a subgroup of patients at extremely high risk due to irradiation and immunosuppression in advance of BMT, which significantly reduces BMT patients' defenses against infection and results in FN incidence as high as 80% (Carmona-Bayonas & Jimenez-Fonseca, 2018; Clarke et al., 2011; Flowers et al., 2013; Klastersky et al., 2013; Taplitz et al., 2018a; Taylor, 2018; Zheng et al., 2020; De Bock & Middelheim, 2000; Sahin et al., 2016; Winston et al., 1979).

Bone marrow transplant patients with FN should be treated as quickly as possible with intravenous antibiotics. Clinical practice guidelines recommend that antibiotics ideally be administered within 1 hour of triage, with subsequent monitoring for at least 4 hours to determine appropriateness of discharge vs. admission to the hospital (Taplitz et al., 2018b). Delays in administration of intravenous antibiotics and other supportive care for FN can result in prolonged hospital stays, intensive care unit transfers, and increased morbidity and mortality. Time to antibiotic administration for FN has been independently linked with 28-day mortality, with each hour's additional delay in antibiotic administration associated with an 18% higher risk of mortality within 28 days of the initial event (Rosa & Goldani, 2014). An examination of mortality rates for patients presenting with septic shock symptoms, which included FN patients, found that delaying antibiotic administration past 1 hour of triage increased patient mortality (Gaieski et al., 2010). Unfortunately, antibiotic administration delays for patients with FN in the outpatient setting are all too common due to dependence on manual temperature checks and patient self-report for detection (Taplitz et al., 2018b).

Technology-assisted remote patient monitoring (RPM) potentially offers a solution to these challenges through support for early and reliable detection of elevated temperature and other relevant physiologic changes that represent signs of infection. Remote patient monitoring systems and wearable devices have demonstrated the ability to improve early detection of worsening clinical indicators (Alvarez et al., 2021; Itelman et al., 2022; van der Stam et al., 2023), improve health outcomes post-surgery (Bolam et al., 2021; Mehta et al., 2020), and improve care for patients with cancer (Hasan Shandhi et al., 2020; Jacobsen et al., 2022). To investigate the potential for successfully using technology-assisted in-home oncology care, including RPM, telemedicine, and home-based health care services to support improved care management and appropriate referral to treatment for BMT patients, this study explored the use of RPM for early detection of FN and infection among allogeneic BMT patients for up to 90 days post-transplant.

METHODS

Study Design and Clinical Pilot Program

This study was designed to assess the feasibility and perceived acceptability of using technology-assisted in-home RPM for early detection and treatment of FN and infection among allogeneic BMT patients. The study was reviewed and approved as minimal risk by the Advarra Institutional Review Board (#Pro00060432). Study participants continued to receive routine post-transplant care from their BMT care teams, with RPM devices and real-time monitoring by advanced practice nurses and registered nurses on a virtual care

team provided by an external company, Reimagine Care. The combination of RPM and virtual care team services is referred to as the Cancer Care at Home program. In the event of an alert or if RPM parameters of concern were detected, the virtual care team notified the BMT triage team for follow-up with the patient according to routine clinical practice. Patients enrolled and completed onboarding into the study post-transplant and prior to hospital discharge. At onboarding, patients were introduced to the virtual care team; received, affixed, and activated a wearable RPM device; and reviewed their customized care plans and completed patient education. Patients were asked to wear the RPM devices 24 hours per day, 7 days a week, and to check and log their temperatures manually twice per day. Patients also received replacement RPM devices for use during months 2 and 3 post-transplant. To avoid sole dependency on RPM alerts, patients were also asked to monitor their temperature manually twice a day as they would be expected to do during routine care and were provided with an oral thermometer to use. Patients were instructed to notify their BMT care teams if they observed an oral temperature greater than or equal to 100.4°F (38.0°C) for 1 hour or one reading of greater than or equal to 101°F (38.3°C).

Remote patient monitoring data were monitored in real time around the clock by the virtual care team. When elevated temperatures or other alerts of clinical interest as potential signals of infection were detected, virtual care personnel first confirmed temperatures or symptoms and then notified the patients' BMT care team by telephone for clinical evaluation and management. Bone marrow transplant care team members contacted patients to follow up according to their established care protocols. Alert criteria requiring follow-up for clinical evaluation and management were defined by the RPM device manufacturer and reviewed and approved by clinicians on the research team. Criteria included a mean skin temperature increase of 2.5 times standard deviation from patient baseline over 1 hour with a maximum threshold of 98.5°F, a pulse greater than 120 beats per minute or 30% above patient baseline for 1 hour, or a new respiratory rate of greater than 24 breaths per minute or 30% over patient baseline that does not return to baseline following exertion. Technical alerts requiring follow-up included if device connection was lost for an extended period without being restored or if the device remained in an off-body state longer than would be anticipated for adhesive replacement, a shower, or similar temporary removal.

RPM Devices

This study used the commercially available BioSticker System (BioIntelliSense, Inc.) for RPM, with real-time monitoring accomplished through use of AlertWatch software. The BioSticker System is comprised of an FDA-cleared wearable sensor device (the BioSticker) that enables automatic continuous collection and secure transmission of biometric data in combination with the BioSync mobile phone app. When worn as intended, the device collects skin temperature, heart rate (HR), and respiratory rate (RR) data along with other biometric measures. It is intended for use as a general patient monitor for adults to collect physiological data as an aid to diagnosis and treatment. The BioSticker is 3.2 inches long by 1.5 inches wide and 0.3 inches in height, weighs 23 grams, and adheres to the upper left chest for continuous wear using a replaceable adhesive on the back of the device. It has an effective battery life of up to 30 days, after which the device is discarded and replaced with a new BioSticker. The app was augmented by use of a stand-alone device installed in the home environment (the BioHub) as a backup to prevent data loss or transmission delay should the mobile phone app be unavailable.

Both the BioHub and the BioSync app connect automatically to the BioSticker and transmit data securely over cellular networks. Biometric data transmitted from the wearable device are received by monitoring servers and presented through the AlertWatch software for virtual care team review and response. While all data can be reviewed, values outside defined ranges and thresholds trigger actionable alerts to the virtual care team.

Setting and Participants

Patients and their caregivers were recruited for the study through the UCHealth Blood Disorders and Cell Therapies Center (BDCTC) in Aurora, Colorado. Patients were identified by the principal investigator as potential study candidates from

a list of those scheduled for upcoming allogeneic BMT procedures based on medical record review and clinical judgment. Patients were eligible for the study if they were between 18 and 89 years old, had received an allogeneic BMT, were determined by their care provider to be stable for discharge to home and follow-up outpatient care, were intending to reside within 45 minutes of the BDCTC for at least 90 days post-transplant, had in-home caregiver support around the clock, and had reliable internet access and mobile phones capable of running the mobile app for the study. Patients were excluded from participation if they were unwilling to wear study devices as indicated or if the principal investigator or their BMT care providers believed participation would not be in their best interests for clinical reasons. A total of 30 patients were identified as potential participants due to having allogeneic BMT scheduled during the enrollment period, of which 14 were identified by the principal investigator as being medically appropriate for outpatient RPM. Patients were approached by research personnel sequentially according to their scheduled BMT dates until the goal of 10 enrolled patients was reached. Enrollment was limited to 10 patients for this study to assess process outcomes and overall feasibility with the intent of identifying and solving potential problems and implementation issues prior to widespread deployment across large numbers of patients in one or more health systems.

Outcomes

A combination of descriptive statistics and qualitative analysis was used to assess study outcomes. Metrics evaluated included the number of RPM alerts detected among patients, the number of patients managed at home without infection, the number of patients with infection but without need for hospitalization, and the number of hospitalizations. User experience in combination with perceptions of the in-home RPM program was assessed qualitatively.

Data Collection and Analysis

Remote patient monitoring data were reported at a minimum of once per hour while devices were worn, 24 hours per day, 7 days per week. Biometric data included skin temperature, estimated body temperature, HR, RR, activity level, body position, and sleep duration. Alert data were exported from the database at the line level (individual event level) and provided to the research team for analysis. Additional metrics of interest including hospitalizations, length of stay, and mortality were obtained from patient medical records.

Patients and caregivers were asked to complete electronic surveys after the first 30 days and at 90 days post-transplant. Providers were asked to complete surveys at the end of the study period. Survey data were securely collected through REDCap (Harris et al., 2019; Harris et al., 2009). Patients were also asked to participate in brief interviews after the first 30 days and at 90 days post-transplant to solicit feedback on perceived quality of care, patient-provider communication, and integration with existing care practice.

Biometric and health utilization outcomes and responses to fixed-choice survey items were analyzed through descriptive statistics. Rapid content analysis of open-ended survey data and interview data was conducted to explore emergent topics and themes among responses. A dual-read approach was used, in which an initial review of interview data was used heuristically to create a comprehensive list of topics observed among all respondents, with the second review being used to identify commonalities and emergent themes across respondents. Data from 30-day and 90-day interviews from a single respondent were considered together as a single response to avoid overemphasizing individual results.

RESULTS

A total of 10 patients and their caregivers participated in the study. Most patients were male, between 40 and 64 years old, and all were White. Of the 10 patients who enrolled, 7 completed full study participation. Patient demographics are summarized in Table 1.

Alerts

A total of 369 alerts were generated between April and October 2022, of which 101 required follow-up communication with the patient, their provider, or both. A summary of alert types and frequencies is presented in Figure 1. One patient exhibited infection-like alerts during the study period, with subsequent clinical evaluation. Out of the health

status alerts set, temperature alerts most frequently required follow-up. All HR alerts that required follow-up were found to be associated with normal levels of physical activity. No RR alerts required intervention; only minimal elevation was observed. "No data" and "off-body" alerts largely represented technical issues or patient noncompliance.

SURVEYS

Seven patients and three caregivers completed surveys administered at 30 days post-transplant. Five patients and caregivers completed surveys at 90 days post-transplant. Three providers completed end-of-study surveys. Surveys explored perceptions of remote patient monitoring, technology use, and methods and timing of contact with the monitoring and care teams. Due to variation among respondents at the 30- and 90-day marks, results were considered in aggregate for each time point rather than examining change over time at the individual level. Fixed-choice responses were reported on a Likert scale with positive ratings encompassing values of "strongly agree," "agree," and "slightly agree," and negative ratings representing values of "slightly disagree," "disagree," and "strongly disagree."

Overall, four of seven patients felt remote patient monitoring to be useful at the 30-day mark, represented by positively-rated answers to questions about whether RPM made the patient feel better cared for by their health-care team and whether RPM increased their understanding of their plan of care. Three of five patients reported positive perceptions of RPM-associated care at the 90-day mark, but only two of five patients reported increased understanding of their plans of care due to RPM after 90 days. It is unclear if this change in patients' opinion is due to attrition among respondents or a meaningful change in perceived need and value over time. Most patient respondents reported feeling sufficiently trained in how to use the wearable monitoring technology (n = 7), perceived it as easy to use (n = 5), and felt that it was comfortable (n = 5). Caregiver perceptions generally mirrored patient perceptions but are not reported separately given low caregiver response rate (n = 3). Providers saw potential in the use of technology-assisted RPM but expressed some concerns about increased workload attributable to time spent responding to non-urgent alerts that were referred to them by the virtual care team. Detailed results from patient surveys are shown in Table 2.

Table 1. Patient Demographics

	N	%
Age (years)		
18–39	3	30%
40–64	4	40%
65+	3	30%
Gender		
Male	8	80%
Female	2	20%
Race/ethnicity		
White	10	100%

Interviews

Seven patients completed interviews about their experience with the program at 30 days post-transplant, and five completed a second

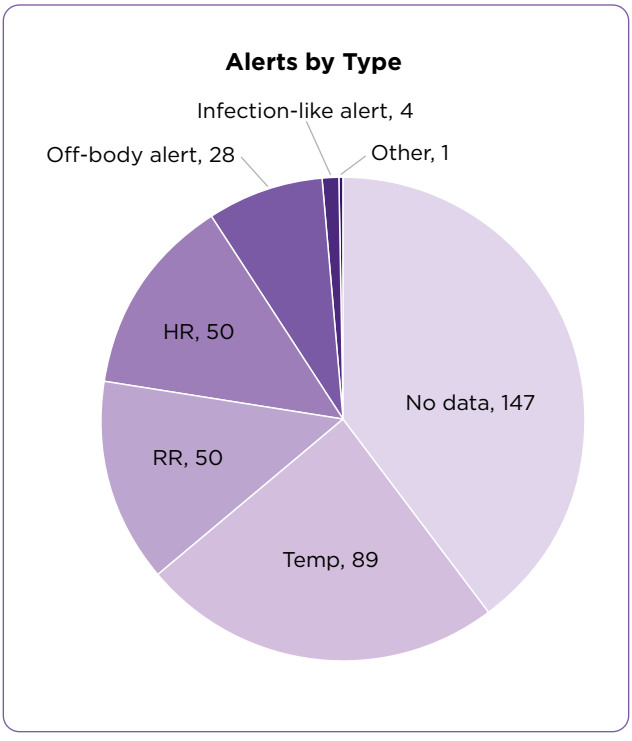

Figure 1. Alerts by type. RR = respiratory rate; HR = heart rate.

Table 2. Patient Survey Responses

	30 days (*n* = 7)		90 days (*n* = 5)	
Survey question	**Positive**	**Negative**	**Positive**	**Negative**
Remote patient monitoring, overall				
Remote patient monitoring makes me feel better cared for by my healthcare team.	4	3	3	2
Remote patient monitoring increased my understanding of my plan of care.	4	3	2	3
Remote patient monitoring, specific operations[a]				
Were you contacted at night regarding a vital sign change or BioSticker issue by the health care team?	5	2	N/A	N/A
Would you have preferred direct phone or text message access to the monitoring team for questions about your vital signs or the BioSticker?	5	2	N/A	N/A
Wearable monitoring technology				
The training I received on the BioSticker was acceptable.	7	0	4	1
The BioSticker was easy for me to use.	5	2	4	1
The BioSticker was comfortable to wear.	5	2	4	1
The BioSticker adhesive stayed attached to my skin.[b]	4	2	4	1
It was easy to remove the BioSticker for an adhesive change.	6	1	5	0
The BioSync app on my smartphone was easy for me to use.	4	3	5	0
The BioSticker paired well with the BioSync app.	4	3	5	0
Did the BioSticker cause any skin irritation?[c]	6	1	N/A	N/A

Note. [a]Questions included in the 30-day survey only.
[b]Responses not received from all survey respondents.
[c]Positive answer represents no irritation; negative answer represents irritation experienced.

interview at 90 days post-transplant. Interviews explored patient perceptions and experiences with remote patient monitoring in the home setting and patients' experiences with early detection and treatment of febrile neutropenia or infection.

Study patients found the RPM experience overall to be positive. They reported a passive awareness of being monitored rather than it being something that required cognitive burden. Four patients specifically noted finding a sense of comfort and peace of mind from the monitoring: "It was an extra level of assurance." A study patient commented, "If I was running hot, like having a fever or something like that, they call me without me having to call them. That would be great, you know?" Another participant said, "It's all this potential thing of...being able to relax to know that...somebody's monitoring you at all times while away from the hospital." Although some patients experienced technical issues, all seven who were interviewed reported perceiving the system as a whole as easy to use.

Study patients found all components of the technology to be unobtrusive. The in-home hubs were perceived as easy to use, with participants commenting "Once it's set up on the phone, then unless the device battery dies... [I] don't have to pay attention to it," "I just forget about it," and "There was nothing to experience, I barely had to do anything."

The mobile app on patients' phones was also found to be easy to use, although some patients reported difficulty with data synchronization (5 persons). While the wearable was also perceived positively, patients reported difficulties with early battery discharge (2 persons), challenges with the device remaining adhered to the body (4 persons), and concerns about inaccurate alert triggering (2 persons).

Study patients were reassured by knowing that they would be contacted by their care team

if an alert was detected but also reported some concerns about alerts being registered despite no clinically significant issues. Examples reported included alerts due to physical activity (2 persons) and temperature change during sleep (2 persons). Patients also reported some disruption from the nighttime contact process itself: "I had just gone to bed. I think...[my] body temperature had decreased and...I had my phone on silent mode, so [my] caregiver got a call, and then it was just, like, this big...bolt of anxiety that kind of overtook the house...once I was awake and everything was okay, we had to go through the front desk...to get them back on the line."

Infection Case Reports

Two patients experienced infections requiring clinical follow-up during the study period. Patient A was admitted on two occasions. Their first admission was due to a neutropenic fever and possible bacteremia with *Staphylococcus epidermidis* in addition to new findings on their CT scan. They were treated with IV antibiotics and discharged after 9 days in the hospital. On their second admission, Patient A presented with severe dyspnea, hemoptysis, and fatigue and was found to have pneumonia and bacteremia with *Staphylococcus epidermidis*. They were eventually discharged to acute rehabilitation after 8 days in the hospital. Patient A had removed their wearable device several days prior to admission; therefore, preadmission remote patient monitoring data were not available.

In contrast, remote patient monitoring alerts indicating potential infection (see Methods) were generated for Patient B and reported to the care team for evaluation and follow-up. Patient B was advised to go to the emergency room for timely treatment according to BMT care team protocols. They were admitted with left knee pain, swelling, and fever and were found to have *Staphylococcus epidermidis* from a knee aspiration culture. Patient B was treated with IV antibiotics and discharged after 3 days in the hospital. While these case reports are not statistically conclusive, they are examples that may be indicative of the potential for the Cancer Care at Home program to have the desired impact on early detection of events necessitating clinical intervention.

CONCLUSIONS

The purpose of this study was to assess the feasibility and acceptability of using technology-assisted RPM for in-home care for oncology patients, specifically for allogeneic BMT patients during the 90-day post-transplant period. Findings indicate the general feasibility of providing such care in the home setting. Findings also reflect generally positive user experiences among the patients enrolled in this study with both RPM monitoring overall and with the technology used to provide in-home monitoring services, although areas for improvement and program refinement were identified and acceptability in a broader population is yet to be explored.

Certain classes of events generated alerts that required follow-up but were not found to represent issues of clinical concern. Two examples observed were temperature changes during sleep that were not due to febrile events and routine physical activity that elevated heart rates beyond the alert threshold, such as walking from a parking lot to a clinician's office. Technical issues such as challenges with data synchronization resulting in "no data" alerts and difficulties with adhesives leading to off-body alerts also contributed to the potential for over-alerting. Resultant provider concerns about alert-related burden and patient concerns about the trustworthiness of alert data may also act as bellwethers for an issue that could significantly contribute to alert fatigue if not addressed prior to implementation at scale. Further testing and refinement of alerting thresholds based on improved technical thresholds and specific population characteristics are necessary and could also support alert calibration specifically tailored for this patient population in the future. Assessment of false vs. true positive and negative alert rates in a study at scale will also contribute to evaluating clinical effectiveness.

As new technologies are developed and brought into clinical practice, functionality testing with smaller groups is of critical importance to identify and address unexpected issues and overcome challenges before they can impede adoption and use at the broader level. While unexpected rapid battery discharge, size, and profile of the wearable device and difficulties with adhesive failure hindering device wear may have impaired

patient adherence and adoption for this study, discerning these issues has also allowed for workflow and solution adaptation for the future prior to an expanded rollout. Workflow processes to more effectively manage alert volume are being explored. Technical issues have been addressed with the wearable device vendor to improve future performance and new versions of the device will be significantly smaller.

This study was intended as a feasibility pilot and was not intended to assess direct program impact on health outcomes. Our results should be interpreted in that context, and conclusions from this study are not intended to be generalizable beyond the enrolled population. Other limitations include lack of direct comparison to other RPM-based and cancer care programs beyond usual care in a single health system and the possibility of unintended bias in terms of technology readiness among the enrolled population, which may have been reflected in enrollment demographics. Future analysis of datasets for more numerous populations and across multiple practice settings is needed to address these limitations. This analysis will also support discernment of infection events at a scale sufficient to draw statistically supported conclusions regarding health outcomes.

The integration of technology-assisted RPM into at-home care for patients with cancer will potentially reduce the need for patient visits to the emergency room, hospital admissions, iatrogenic exposures, and complications of medical error. While we cannot draw population-level conclusions from this feasibility study, even a 10% improvement in FN outcomes may affect approximately 2,000 persons annually for patients receiving BMT alone. The potential impact could be transformational if realized at scale for patients with all types of cancer. These efforts will likely result in improved patient outcomes including but not limited to reduced morbidity and mortality, increased patient satisfaction, and reduced burden on the health-care system. Further studies to explore acceptability in larger and additional patient populations, to assess potential impact on the cost of care, and to examine clinical effectiveness and influence on health outcomes will be necessary to fully realize the potential benefit of these solutions.

Disclosure

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