12-12-2021

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Repository Citation

Praus, T., Li, J., Barbarash, S., Proenza, M., Bondmass, M. D. (2021). Improving Care For Patients With Atrial Fibrillation Through the Use of a Personal Electrocardiogram. *Journal of the American Association of Nurse Practitioners, 33*(12), 1307-1313.
http://dx.doi.org/10.1097/JXX.0000000000000550

Quality Improvement Report

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Improving care for patients with atrial fibrillation through the use of a personal electrocardiogram

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ABSTRACT

Background: Atrial fibrillation (AF) is the most common arrhythmia affecting more than six million people in the United States. The economic burden is estimated to be >$6 billion annually with catastrophic events dramatically increasing expenditure. When patients experience symptoms, they commonly present to an acute care facility; this can be costly and anxiety provoking.

Local problem: Same-day access issues prohibit patients from communicating directly with their cardiology provider, forcing them to use resources and increasing psychological burden.

Methods: A convenience sample, made up of 43 patients, was given a KardiaMobile device. Eligible patients had ≥2 AF-related emergency department (ED) or urgent care (UC) visits over 12 months, needed rate control with medication titration, or were monitored for AF reoccurrence after reestablishing sinus rhythm.

Interventions: Patients emailed recordings daily and when experiencing symptoms. The recordings were reviewed by a nurse practitioner (NP); abnormal readings were followed by a phone call, telehealth, or in-person visit.

Results: An independently designed survey was conducted online; almost all respondents (97%) found value in the project and the device. Virtually all respondents (97%) felt that the program improved access. A majority (86%) reported decreased anxiety. Had the respondents not been in the program, 34% indicated that they would have presented to an ED and 25% would have presented to an UC, realizing a cost savings of $81,950 in reduced ED visits alone.

Conclusion: A personal electrocardiogram, with NP oversight, to manage AF is cost-effective and reduces unnecessary resource utilization. It is patient centered, improves access, and empowers patients to manage their symptoms.

Keywords: Ambulatory ECG; atrial fibrillation; cardiac arrhythmia; remote patient monitoring.

Journal of the American Association of Nurse Practitioners 33 (2021) 1307–1313, © 2021 American Association of Nurse Practitioners

DOI# 10.1097/JXX.0000000000000550

Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia; it can result in ineffective atrial contraction and suboptimal ventricular filling, which can lead to hemodynamic compromise, and heart failure (HF). Consequences of AF and hemodynamic compromise vary from person to person; AF can manifest as symptoms of dyspnea, chest discomfort, palpitations, fatigue, hypotension, or syncope. Moreover, the psychological burden, such as anxiety and helplessness, cannot be overlooked. Finally, AF predisposes patients to cardiac thrombus formation, placing them at a fivefold increased risk for stroke. Stroke and HF further increase the risk of morbidity and mortality related to AF (Morillo et al., 2017).

Problem and significance

The current number of people in the United States with AF is estimated to be between 2.7 and 6.1 million and predicted to increase twofold by the year 2050 (Morillo et al., 2017). The current economic burden, solely related to AF, is estimated

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Received: *27 August 2020; revised: 28 October 2020; accepted 4 November 2020*

to be more than $6 billion annually; as the number of patients double, it is reasonable to assume the economic burden will concomitantly increase (Thompson et al., 2014).

In 2018, in a multispecialty group of a large health care system, there were 43,054 patient visits associated with various cardiac disease processes, of which 10,852 were assigned a diagnosis code related to AF. A needs assessment was performed to evaluate same-day access to cardiology providers; it was noted that patients would present to an urgent care (UC) or an emergency department (ED) on the day they experienced symptoms as a result of poor access. Many such cases, however, may have been managed in the outpatient setting and would not have required a visit to an acute care facility, as long as rhythm and rate could be assessed and symptoms managed virtually or from a distance (Anczykowski et al., 2016).

Based on hospital claims data for this health care system, the cost of hospitalizations related to AF from June 2017 through May 2018 was in excess of $4 million. During this same period, it was noted that 36 patients had two or more hospitalizations; the average cost for these admissions was estimated at $7,450 each.

History and development of innovative technology

Electrocardiography has evolved from the detection of changing cardiac electrical potentials in 1887 by Ludwig and Waller. Einthoven, the "father of electrocardiography" developed recordings of the electrical signals in 1901. Soon thereafter, the first mobile cardiac monitoring unit was developed by Norman Holter in 1947, which led to the event monitor, providing the ability to extend monitoring up to 30 days (Garabelli et al., 2017). Real-time telemetry was the next evolution followed by implantable loop recorders and, most recently, smartphone technology. Improvements in technology have increased the utilization of mobile devices to deliver care at a distance; it has also shown to be an effective intervention to decrease anxiety and unnecessary hospitalizations and visits to EDs and UCs (Demeester et al., 2018). Successful applications thereof to cardiac conditions in general—and AF in particular—have improved care, reduced symptomatology, and improved the quality of life. The purpose of this nurse practitioner (NP)–led quality improvement project was to improve patient outcomes, decrease resource utilization, and reduce anxiety related to AF through the use of a personal, single-lead electrocardiogram (ECG).

Methods

An NP belonging to a cardiology division of a large, multispecialty group, which is a subsidiary of a national health care organization, conducted a quality improvement project to evaluate the impact of providing patients with a personal single-lead ECG and telehealth access. Outcomes of AF-related resource utilization, the patient's level of anxiety, and patient satisfaction with care and access were evaluated.

Population

Eligibility criteria included adult patients who (1) had two or more AF-related ED or UC visits in the past 12 months, (2) needed rate control with medication titration, or (3) needed monitoring for AF reoccurrence after reestablishing sinus rhythm—either by chemical or direct current cardioversion. Additionally, participants needed to be established with the clinic, able to understand and consent to participation, and have comfort using the personal ECG device and application on their smartphone. Forty-three patients were identified and participated in the project.

Intervention

Patients who participated received a KardiaMobile (KM) device, provided by the practice. The AliveCor KM device consists of two electrodes with the ability to record a 30-second Lead I rhythm strip. The ECG recording can be viewed in real time through the smartphone application. The recording was then emailed to an NP for review and potential management. The patient is able to view an instant analysis of their cardiac rhythm alerting them to "potential atrial fibrillation," "bradycardia," "tachycardia," or "normal sinus rhythm." Other arrhythmias that may be considered "unclassified" by the device algorithm were interpreted by an NP.

The KM device first received FDA 510k clearance in 2012 and was available by prescription only in 2013. The device became available to patients for over-the-counter purchase in 2014 (Garabelli et al., 2017); in 2019, the device cost averaged $99. Numerous studies, with varying comparisons and outcomes, have validated and supported the use of the KM device (Bumgarner et al., 2018; Halcox et al., 2017). To further improve access, a telehealth platform, NowClinic, was also implemented to provide an alternate method of communication; patients are then able to log in whenever and wherever for a face-to-face visit.

Protocol and data collection

Following institutional review board approval, informed consent was obtained; patients were provided with a KM device and assisted with downloading the Kardia and NowClinic applications on their smartphone. Enrollment and distribution of the KM devices occurred over several weeks. This time frame included ample time to assist with the use of the KM device and emailing ECG recordings to the dedicated email address at the practice. A baseline rhythm recording was obtained and emailed, during the enrollment visit. Patients were followed for eight weeks

and instructed to record and email an ECG at least once daily as well as when symptomatic. Symptoms were defined as, but not limited to, chest discomfort, shortness of breath, palpitations, lightheadedness, and dizziness.

An NP would review the ECGs daily. Patients were aware that ECGs would be read Monday through Friday between the hours of 8:00 a.m. and 5:00 p.m.; patients were advised to proceed to an UC or ED if symptomatic outside of those hours. If the recordings were normal, daily transmissions continued. If abnormal, attempts were made to contact the patient within an hour of ECG review, by telephone or email; once contact was made, the patient was offered a NowClinic visit, although most were comfortable with telephone follow-up. **Figure 1** shows the project flow and protocol.

All demographic information and patient characteristics were obtained from the respective patients' medical records and recorded at the time of enrollment. ECG recordings were reviewed and then forwarded to medical records to be scanned into the patient's chart.

Participants completed two online surveys. One survey, administered by the organization's patient experience team, assessed satisfaction with access to care, reduction in ED visits, and a reduction in the level of anxiety. A link to this survey was emailed anonymously to all participants at the end of the 8-week period. The organizational satisfaction survey is made up of nine questions. These questions address how the patient perceives access and communication with a cardiology provider, if unnecessary hospitalizations were avoided, and if anxiety levels were decreased. In addition, the survey queried disposition—where the patient stated that they would have sought care—were the program not available. Options for disposition on the survey include an ED, UC, office visit, or done nothing.

A second tool, the Hospital Anxiety and Depression Scale (HADS), is a cost-effective, validated tool that has been used in both the hospital and community settings (Stern, 2014). This self-rating, screening scale is composed of 14 questions (7 assessing anxiety and 7 assessing depression), takes approximately 2–5 minutes to complete and facilitates early detection of anxiety and depression (Snaith, 2003). Score calculation and results interpretation indicate the severity of the mood disorder. A link was emailed to each patient within the first week and then again at the end of the 8-week period to determine if there was a change in pre- and post-anxiety levels. For this quality-improvement project, the level of anxiety as it relates to the diagnosis of AF was evaluated.

Results

Table 1 displays the patient characteristics; of the 43 patients enrolled, 53% were men (n = 23); the mean calculated age was

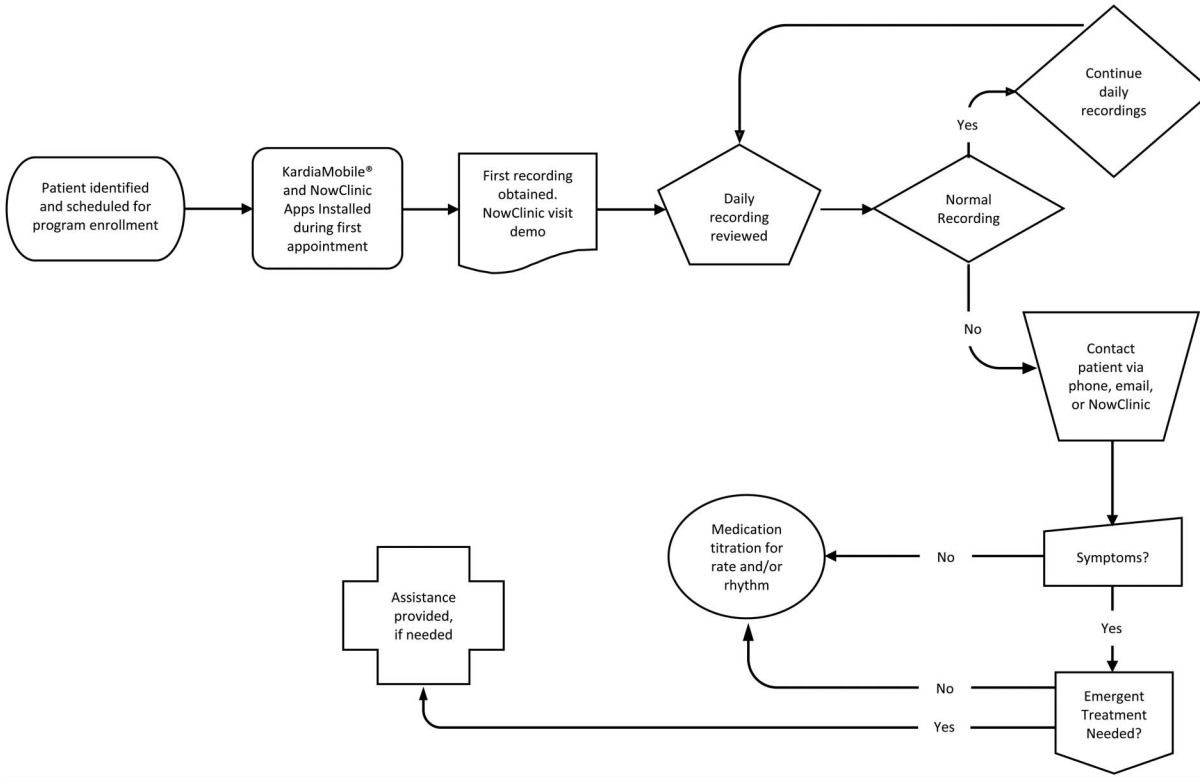

Figure 1. The project flow and protocol.

Table 1. Patient Characteristics

No. of Patients	*N* = 43
Age, years, mean ± SD	66.79 ± 9.78
Gender, male, *n* (%)	23 (53)
Ethnicity, *n* (%)	
Caucasian	31 (77)
African American	4 (10)
Hispanic	3 (8)
Asian	2 (5)

66.79 ± 9.78 years (median = 69.00 years; range = 35 years). The cohort ethnicity was made up of 77% Caucasian, 10% African American, 8% Hispanic, and 5% Asian. Moreover, 84% of the patient population resided in the city where the practice is located, 11% in the surrounding area, and 5% in a neighboring county, approximately 63 miles west of the city.

Cardiac rhythm

A total of 1,501 ECG recordings were received and reviewed by the end of eight weeks. Results of the KM device instant rhythm analysis revealed that 710 recordings were interpreted as normal sinus rhythm and 537 were interpreted as possible AF; of these, 74 had rapid ventricular rates. There were 173 unclassified interpretations, 46 bradycardic, 24 tachycardic, 8 deemed uncategorized (due to artifact), and 3 recordings were too short to be interpreted.

Unclassified readings occur when the rhythm cannot be categorized as normal, possible AF, bradycardia, or tachycardia. Of those designated as "unclassified," the majority came from two patients. The first patient's baseline rhythm was sinus arrhythmia; the other patient's baseline rhythm was sinus with a first-degree atrioventricular block and left bundle branch block. These two patients' recordings made up 44% of the unclassified rhythm strips.

One other patient, whose recordings demonstrated short bursts of supraventricular tachycardia, had a total of 13 instant rhythm assessments categorized as unclassified. The remaining 84 recordings were made up of a combination of sinus rhythm with premature atrial contractions (34), sinus rhythm with a significant number of premature ventricular contractions (30), or too much artifact to be interpreted (20).

Of the 43 patients, 17 required medication titrations for rate control, symptom control, or both. Of interest 3 of the 17 patients were thought to have been rate controlled. These patients were asymptomatic and experiencing high ventricular rates (HVRs), defined as ≥115 beats per minute. Of the three, one patient lived in a neighboring county, 63 miles from the clinic. Management of that patient's care was accomplished by coupling the use of the KM device with telehealth; communication resulted in several adjustments to medications and prompted a referral to an electrophysiologist for consideration of ablation. The other two patients were able to be rate controlled and converted back to sinus rhythm. During the monitoring period, two patients had cardiac ablation and subsequently remained in sinus rhythm.

Patient surveys

The patient experience and satisfaction surveys were completed by 33 patients (response rate of 77%). The majority of patients gave top ratings for the program's ability to decrease anxiety level (62% rated 5), provide empowerment to manage health concerns (72% rated 5), and increase ability to communicate with a provider and health care team (84% rated 5), as shown in **Table 2**. Ratings were on a Likert-scale, with "1" representing that the program did not meet the question objective and "5" representing that the program did meet the question objective.

Table 2. Patient Experience and Satisfaction Survey: Rating results

Question, *n* (%)	1—Did Not	2	3	4	5—Did	Mean Rating
Has the program decreased your anxiety level?	1 (3)	1 (3)	2 (6)	7 (24)	18 (62)	4.4
Has the program empowered you to manage your overall health concerns?	0 (0)	0 (0)	4 (12)	5 (15)	24 (72)	4.6
Has the program increased your ability to communicate with your provider and health care team?	0 (0)	0 (0)	0 (0)	5 (15)	28 (84)	4.8
How likely are you to recommend this device to other patients with atrial fibrillation?	0 (0)	0 (0)	1 (3)	1 (3)	30 (90)	4.8

Table 3. Patient Experience and Satisfaction Survey: Binary results

Question, *n* (%)	Yes	No
Did you find value in the mobile pilot's additional service as well as the device?	32 (97)	1 (3)
Has the program improved your ability to directly access your provider?	32 (97)	1 (3)
Has the program reduced unnecessary emergency department visits?	29 (87)	4 (12)

When considering the ratings as scores, the overall average was 4.4 for the ability of the program to decrease anxiety level, 4.6 for being empowered to manage health concerns, and 4.8 for increased ability to communicate with a provider and health care team. Respondents were highly satisfied with 90% of them giving a rating of 5 when asked how likely they were to recommend the KM device to other patients diagnosed with AF. The survey also asked three yes/no questions (**Table 3**). Almost all respondents (97%) found value in the additional services and the device. Virtually, all respondents (97%) also felt that the program improved their ability to directly access their provider, and the majority of the respondents (87%) also felt that the program reduced unnecessary ED visits.

In addition to the yes/no question regarding unnecessary ED visits, the questionnaire asked what respondents would have done if the program were not available to them; this question provided more detailed insight into patient-reported reductions in utilization. Had the respondents not been in the program, 34% (n = 11) reported that they would have presented to an ED, and 25% (n = 8) would have presented to an UC facility; this is shown in **Figure 2**.

A total of 86 HADS surveys were administered; there were 30 preintervention surveys returned, and 21 postintervention. The HADS scoring identifies patients who are likely to have clinical anxiety or depression. Of the 30 preintervention surveys, 18 patients did not have anxiety; nine patients had borderline anxiety, and three patients were rated as having abnormal anxiety-related to AF. Of the 21 postintervention surveys completed, 15 did not have anxiety, 2 were borderline, and 4 were found to have anxiety.

Although depression was not a prespecified outcome of this project, depression results from the HADS are presented. Three patients were found to be depressed, two had borderline depression, and 25 did not have any reported depression. The post-survey rated two patients with depression, both of whom were receiving treatment from their primary care provider; two patients were rated with borderline depression, and 17 patients without depression. Because of the small number of respondents with both a baseline and follow-up survey results, statistical comparison of the pre- and post-results was not conducted.

Discussion

In the current environment, telehealth and remote patient monitoring (RPM) is more important than ever. Medication management can be difficult to perform remotely and often results in the patient seeking care in an UC or ED. Not only is this costly to the health care system but also causes anxiety in patients and their caregivers, which is a symptom that is often neglected.

Technological advances have increased providers' ability to better manage their patients, especially when access to care has proven more challenging. The KM device, monitored by an NP, is a convenient and cost-effective example of such technology that enables more proactive and higher-quality patient care. Patients' data can be measured at any time, and from anywhere, with the use of a smartphone; moreover, the component of the provider's immediate intervention plays a critical role. More proactive and immediate feedback to patients when they were experiencing abnormal rhythms not only avoided costly resource utilization, but also reduced psychological burden for the patient. Patients also felt empowered to manage their AF and less anxious about their condition.

Some patients experienced multiple episodes of abnormal rhythms. The actual number of avoided resource utilization is higher than the patient responses to the survey; however, if considering 11 patients who avoided an ED visit, this quality-improvement project realized a cost savings of $81,950, using the previously calculated average for an ED visit. This is significantly underestimated because potential hospitalizations and diverted UC visits are not included. Remote monitoring also has the potential to extend its reach to rural and underserved areas. This distance monitoring was demonstrated by those patients who sent recordings from the neighboring city more than 60 miles away, while on a

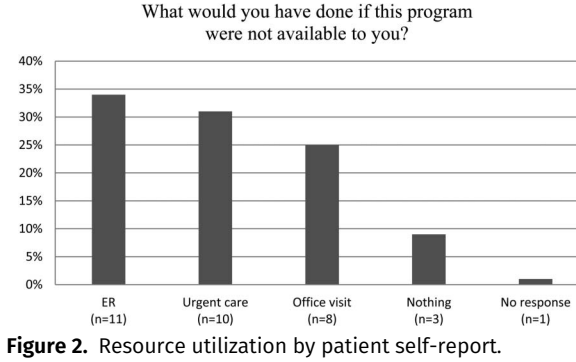

Figure 2. Resource utilization by patient self-report.

cruise ship vacation, and from other countries such as Mexico.

Of interest, patients who were thought to be rate controlled were identified as experiencing HVRs. The significance of rate control translates to hemodynamic stability and prevention of tachycardia-induced cardiomyopathy, which may further result in HF. Cardiac decompensation, in the absence of rate control, can result in symptoms experienced by the patient and further drive health care expenditure. Notwithstanding the advantages of the technology used, the value of the expert clinician is a critical component of this type of care delivery.

Limitations

The project involved a single, cardiology practice and may not be representative of patients in other practices or geographic locations. Statistical testing could not be conducted given the small number of participants. The KM device has the potential for long-term monitoring; thus, a project with longer follow-up would be needed to examine the use of KM beyond eight weeks. Furthermore, 4 of the 43 participants had already been using their own KM device prior to enrollment; therefore, they may have already experienced a reduction in anxiety levels through their use and comfort with the device prior to the project period. Utilization reductions were based on patient self-report and did include clinical review of the episodes to document the clinical pathway of the patient; moreover, patient recall could be an issue with completion of the survey at the end of the project period. Finally, there are many uses of the KM device that were not included, such as screening high-risk patients for AF, investigation of symptomatic patients (e.g., palpitations) for AF, and the like. Future projects should explore more of the potential uses for KM.

The KM device also has some limitations. The KM algorithm interpreted three recordings as possible AF. Upon review, the recordings were noted as sinus rhythm with frequent premature atrial contractions. As previously mentioned, there are many arrhythmias, such as sinus arrhythmia or bundle branch blocks, that are interpreted by the device as "unclassified." The ability for an NP to review ECGs, interpreted as "unclassified," is critical to proactive patient care and identifying potentially high-risk arrhythmias. Patients with atrial flutter and regular R-to-R intervals were also interpreted as normal. Furthermore, those with permanent pacemakers are not able to use the device because it creates interference or noise, which results in an unreadable interpretation.

Patients with movement disorders, such as Parkinson's disease, may not be able to produce a quality recording because patients must remain stationary for a period of 30 seconds. The KM device does not have the capability for continuous monitoring beyond a brief time frame; therefore, patients who require observation around-the-clock would necessitate a traditional Holter or a continuous event monitor.

Potential for sustainability

Learnings from this quality-improvement project were helpful in understanding the long-term sustainability of using the KM device more widely in our practice. The need for near real-time review of patients' ECG recordings would require additional personnel, cardiovascular technicians, who could assist in reviewing ECGs. Additionally, it is helpful to integrate the ECG recordings directly into the patients' medical record. Integration of the KM device recordings with our practice's cardioserver will eliminate the delay of transferring an ECG into a patient's chart; once a provider confirms the interpretation, it will be available for immediate review in the electronic medical record.

The project also illustrated that use of the KM device is cost effective for our practice. The use of KM for this project falls under RPM and is reimbursed under the Current Procedural Terminology codes: 99457 for RPM with a minimum of 20 minutes of treatment and management per month and are billable by an NP. Additional codes, such as 99453 for RPM set up and education, are also applicable. With these RPM codes and the savings from reduced utilization, the KM device is a cost-effective option for our practice, even when including the cost of additional support staff. Moreover, the organization's cardiology Holter and event monitor access would significantly improve because many patients do not require around-the-clock monitoring. The wait time for availability of these devices could be substantially reduced with the use of KM. Thus, the project has confirmed the overall benefits of implementing the use of KM.

Suggestions for further research

As discussed previously, replicating this project across multiple sites with a larger sample size and the inclusion of all potential use cases would be beneficial in addressing limitations. Asymptomatic AF has become increasingly common in the aging population and may not present until the patient experiences a devastating event. Patients aged 65 years or older may benefit, with the use of the KM device and clinician oversight, by submitting recordings for routine screening, which would allow for early detection of AF, which may in turn curtail potential catastrophic events, further decreasing health care expenditure. Additionally, and more particularly related to this project, further research using the KM device, with a larger cohort and for an extended period of time, is warranted to evaluate anxiety related to AF, patient satisfaction with access to care, and the overall reduction of resource utilization.

Conclusion

This quality-improvement project provides evidence that implementing the use of a personal, single-lead ECG to manage AF patients is cost effective and improves patient outcomes while reducing unnecessary resource utilization. It is also patient centered as patients become more empowered in the management of their AF, whereas anxiety, related to their AF is reduced. Most importantly, patients feel they have better access to their cardiology providers, and patients living in isolated areas, or traveling to other cities and countries, can be managed remotely.

Authors' contributions: *T. Praus is the primary author, developed the protocol, collected chart data, implemented the interventions, and communicated with the patients. M. D. Bondmass was the DNP committee chair, secondary author, and provided assistance with analyses. J. Li conceptualized the idea for the project. S. Barbarash had oversight of the project completion.*

Competing interests: *M. Proenza obtained funding from Southwest Medical, part of OptumCare for the KardiaMobile devices, and coordinated with Southwest Medical's IT department.*

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