Impact of intensive follow-up of cardiac implantable electronic devices via remote monitoring: A pilot study

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BACKGROUND The volume of remote monitoring (RM) data generates a significant workload and is generally dealt with by clinic staff during standard office hours, potentially delaying clinical action.

OBJECTIVE The purpose of this study was to determine the clinical efficiency and workflow of implementing intensive RM (IRM) in patients with cardiac implantable electronic device (CIED) when compared with standard RM (SRM).

METHODS From a cohort of >1500 remotely monitored devices, 70 patients were randomly selected to undergo IRM. For comparison, an equal number of matched patients were prospectively selected for SRM. Intensive follow-up occurred via automated vendor-neutral software with rapid alert processing by International Board of Heart Rhythm Examiners–certified device specialists. Standard follow-up was conducted by clinic staff during office hours via individual device vendor interfaces. Alerts were categorized on the basis of the level of acuity as actionable (red [high], yellow [moderate]), or green [not requiring action]).

RESULTS Over 9 months of follow-up, 922 remote transmissions were received; 339 were coded as actionable alerts (118 in IRM and 221 in SRM; $P < .001$). The median time from initial transmission to review was 6 hours (interquartile range [IQR] 1.8–16.8 hours) in the IRM group compared with 10.5 hours (IQR 6.0–32.2 hours) in the SRM group ($P < .001$). The median time from transmission to review of actionable alerts in the IRM group was 5.1 hours (IQR 2.3–8.9 hours) compared with 9.1 hours (IQR 6.7–32.5 hours) in the SRM group ($P < .001$).

CONCLUSION Intensive and managed RM results in a significant reduction in time to review alerts and number of actionable alerts. Monitoring with enhanced alert adjudication is needed to facilitate device clinic efficiency and optimize patient care.

STUDY REGISTRATION ACTRN12621001275853

KEYWORDS Remote; Workflow; CIED; Intensive; Burden; Streamline

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Introduction

Remote monitoring (RM) in patients with cardiac implantable electronic device (CIED) allows the early detection of abnormal device function and arrhythmias and has been established as a safe alternative to standard clinic follow-up.[1–8] Compelling evidence has shown a number of benefits to the strategy, including rapid response to patient and device events,[3,4] reduced risk of cardiovascular hospitalization,[3,8] and a decrease in health care utilization,[5–10] with the degree of benefit correlating markedly with patient adherence.[11] As such, an ever-increasing workload is required to appropriately manage these patients. However, CIED clinic workflow is complex and requires a significant amount of staff time,[12–14] with burden being placed on staff and physicians responsible for the management of these patients.

O'Shea et al[15] investigated the magnitude of RM burden over a 12-month period, with 205,804 transmissions occurring from 26,713 patients. Of this, 40.2% of these were alerts, with 123,000 transmissions occurring because of scheduled or patient-initiated downloads.[15] With only 6.6% of scheduled transmissions necessitating clinical action, incurring an unnecessary amount of time on clinic staff dedicated to reviewing these transmissions. In addition, the ratio of high (red) and low (yellow) acuity alerts (4.8% vs 95.2%) demonstrates that clinics are spending much of their time responding to alerts that have been predetermined as not clinically urgent.[15] Current management strategies for RM, where

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KEY FINDINGS

- Intensive remote monitoring significantly reduces median time from transmission to review.
- Intensive remote monitoring resulted in a reduced time to review for actionable alerts (red or yellow).
- Over weekends when clinics are closed, the use of remote monitoring ensures that out-of-hours response times were significantly quicker compared with standard remote monitoring during normal work hours.

most data are managed by clinic staff during typical office hours, can result in delays between events and clinical intervention, with a median reaction time of 3 days.[16,17]

Device clinics are currently being overwhelmed by the enormity of transmissions, in combination with a complex workflow. Studies have demonstrated high false-positive rates and large quantities of transmissions that require review but do not require clinical action, accounting for up to 59.8% of transmissions.[18] Multiple third-party vendor-neutral software systems have recently become available, capable of integrating various vendors into 1 user-friendly interface and streamlining the workflow. Here we undertook a pilot study of a cohort of patients undergoing intensive RM (IRM) utilizing a vendor-neutral platform with 24/7 monitoring.

Methods

Study cohort

The intervention group of the study represented the initial cohort of patients who were monitored using a novel comprehensive RM platform as a pilot experience. This included 70 patients who were randomly selected before commencing the study from a population of >1500 remotely monitored patients as 30 patients with pacemaker, 20 patients with implantable cardioverter-defibrillator, and 20 patients with implantable loop recorder (ILR) (Figure 1). These patients were enrolled across different manufacturers. Of note, we included only first generation Medtronic ILRs to minimize the variation in sensitivity and alert frequency between companies. The IRM group was randomly selected from the entire cohort of patients undergoing RM at the Centre for Heart Rhythm Disorders. These patients were matched by age, sex, device type, and manufacturer to an equal number of patients who make up the standard follow-up group. Comprehensive RM workflow data were prospectively collected from September 2020 to June 2021 using the PaceMate LIVE platform, a vendor-neutral software system capable of automatic integration of remote transmissions from multiple device vendors into a single streamlined interface.

This study has adhered to the National Health and Medical Research Council guidelines on human research and has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621001275853). Owing to the nature of the study not involving patient care but rather device transmission data only, patient consent was waived. Q7

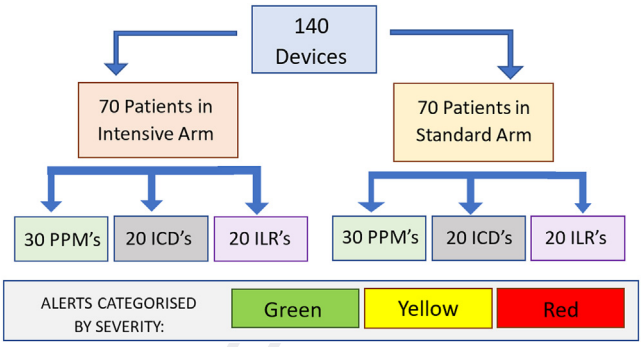

Figure 1 Patient selection. Consort diagram of the patient selection. ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PPM = permanent pacemaker.

IRM

Monitoring with IRM was via a cloud-based, automated, vendor-neutral commercial software system. This system uses a combination of automated transmission integration together with adjudication of each alert by International Board of Heart Rhythm Examiners (IBHRE)–certified device specialists. These device specialists are located at a variety of time zones to facilitate timely adjudication, which was available 24 hours a day, 7 days a week. Processed data were accessible for review by clinic staff via a single, secure Internet-based interface.

High acuity alerts were prioritized for review by technicians in the intensive group. In the event of a high acuity alert, the technician contacts the physician directly to notify them of the alert to avoid delay. After analysis, a concise written summary is made available for access via the software interface, allowing clinical staff to review alerts and prioritize the review of the entire transmission. This allows a near-instantaneous exclusion of normal transmissions or those that are false positives, with the availability of electrograms when required.

Standard RM

Patients in the standard RM (SRM) arm were monitored by clinic staff during typical office hours, Monday to Friday, 8:30 AM to 5:00 PM, with transmissions accessed via individual device vendor Internet-based interfaces as per standard clinic practice. Transmissions were categorized according to the device manufacturer and treating physician preferences.

Alert classification

Transmissions were classified on the basis of the significance of the findings as follows:

Table 1 Baseline characteristics stratified by type of remote monitoring

Characteristic	Standard (n = 70)	Intensive (n = 70)	*P*
Age (y)	74.4 ± 12.3	74.7 ± 12.4	1.0
Male sex	41 (59)	39 (56)	.89
Height (cm)	170.4 ± 8.8	169 ± 10.7	1.0
Weight (kg)	80.9 ± 17.6	79.8 ± 19.7	1.0
BMI (kg/m^2)	28.1 ± 6.5	27.8 ± 5.6	1.0
Device type	30 (43)	30 (43)	1.0
PPM	29 (96.7)	29 (96.7)	
Dual chamber	1 (3.3)	1 (3.3)	
Biventricular	20 (28.5)	20 (28.5)	
ICD	18 (90)	18 (90)	
Standard	2 (10)	2 (10)	
CRT	20 (28.5)	20 (28.5)	
ILR			
Device manufacturer	36 (51)	36 (51)	1.0
Medtronic	14 (20)	14 (20)	1.0
Abbott	11 (16)	11 (16)	1.0
Boston Scientific	9 (13)	9 (13)	1.0
Biotronik			
Sinus node disease	16 (23)	20 (28)	.58
AV block	7 (10)	6 (9)	1.0
Atrial fibrillation	37 (53)	43 (61)	.67
Paroxysmal	20 (54)	24 (56)	.61
Persistent	5 (14)	14 (33)	.08
Permanent	11 (31)	5 (11)	.19
VT/VF	16 (23)	10 (14)	.3
Hypertension	46 (66)	45 (64)	1.0
Heart failure	3 (4)	2 (3)	1.0
Coronary artery disease	4 (6)	7 (10)	.53
Ischemic heart disease	12 (17)	8 (11)	.48
Cardiomyopathy	11 (16)	22 (31)	.12
Diabetes	11 (16)	6 (9)	.31
Stroke/TIA	16 (23)	8 (11)	.18
Hyperlipidemia	28 (40)	22 (31)	.51
Obesity	12 (17)	17 (24)	.42
Obstructive sleep apnea	9 (13)	11 (16)	.81

Values are presented as mean ± SD or n (%).

AV = atrioventricular; BMI = body mass index; ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PPM = permanent pacemaker; TIA = transient ischemic attack; VF = ventricular fibrillation; VT = ventricular tachycardia.

- Red: high acuity requiring urgent clinical action
- Yellow: lesser acuity requiring nonurgent clinical response
- Green: normal

Programming of alert definitions and acuity/color for all patients occurred via the individual vendor platforms of the relevant device manufacturer and were modified as per treating physician preferences. While alerts can be programmed as per physician preferences, common examples of a red or high acuity alert include abnormal lead impedance measurements, occurrence of high-voltage therapies, and battery life reaching estimated replacement interval. Common examples of a yellow or lesser acuity alert include atrial fibrillation episodes, ATP therapy, and pacing percentages above or below the limit. In the IRM group, transmissions were then integrated into the PaceMate system and reviewed by the clinical specialist, who had the ability to escalate or de-escalate

Table 2 Breakdown of total transmissions received

		Severity		Device type			Out-of-hours transmissions	
Variable	Total	Green	Yellow/red	PPM	ICD	ILR	After hours	Weekend
Standard	402	181	221	95	160	147	305	106
Intensive	520	402	118	147	75	298	408	153
Total	922	583	339	242	235	445	713	259

The table highlights the number of transmissions received between each arm, by device and alert type.

ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PPM = permanent pacemaker.

Table 3 Type of transmission

Variable	Standard (n = 402)	Intensive (n = 520)
No alert	207 (51.5)	387 (74.4)
Heart failure/fluid	9 (2.2)	0 (0)
Ventricular arrythmias	10 (2.5)	23 (4.4)
Atrial arrhythmias	94 (23.4)	83 (16)
Pauses	13 (3.2)	9 (1.7)
Sensing issues	17 (4.3)	6 (1.2)
Lead noise	51 (12.7)	10 (1.9)
Recommended replacement	1 (0.3)	2 (0.4)

transmissions if deemed necessary to determine the final classification presented to the clinic. Clinical response to actionable transmissions was left to the discretion of the treating physician.

Data collection and monitoring

Comprehensive data on the workflow of device alerts, transmission date and time, time to action, and baseline characteristics were collected by technicians through the completion of a written worksheet after receipt of and action regarding alerts. Investigators were blinded to the patient group. Outcomes assessed included time from event to alert review, time from alert transmission to alert review, time spent per review, and technical costs. To determine the length of time to review for alert types, we divided the time into quartiles. In order to determine the time spent per review, the technicians would record different time points in which the task of reviewing the download was performed. This allowed time spent to be calculated and extrapolated to a larger population.

Statistical analysis

The sample size of the study was calculated on the basis of the current clinical review time within our service (median 13 hours). To identify at least 25% reduction in median time to review in the intensive arm, with 80% power and at 5% significance level,[19] we required a total of 140 subjects (70 patients per arm).

Continuous variables are summarized as mean ± SD or median (interquartile range [IQR]), as appropriate. Categorical variables are presented as number (percentage). Between-group differences were analyzed using the Student *t* test or Mann-Whitney *U* test for continuous variables and the χ^2 test for categorical variables. A *P* value of <.05 was considered statistically significant. Statistical analysis was performed with SPSS version 27.0 (IBM Corporation, Armonk, NY).

Results

Baseline demographic characteristics

A total of 140 patients with CIED were enrolled in equal groups into the 2 arms of the study. The baseline characteristics of the 2 groups are listed in Table 1. There were no significant between-group differences in age (74.4 ± 12.3 years vs 74.7 ± 12.4 years), gender (41 men vs 39 men), or body mass index (28.1 ± 6.5 kg/m^2 vs 27.8 ± 5.6 kg/m^2) between the standard and intensive groups, respectively. Indications for implantation were similar between groups with sinus node disease (16 patients vs 20 patients; *P* = .6), atrioventricular block (7 patients vs 6 patients), and ventricular tachycardia/ventricular fibrillation (16 patients vs 10 patients), while patients with atrial fibrillation (37 vs 43) were also similar between SRM and IRM groups, respectively.

Types of alerts and devices

Over the follow-up period, 922 remote transmissions were received: 520 from the IRM cohort and 402 from the SRM cohort (Table 2). Of the 922 transmissions received, 242 (26%) were from pacemakers, 235 (26%) from implantable cardioverter-defibrillators, and 445 (48%) from ILRs (Table 2). There were 583 transmissions received that were coded as green/low acuity (402 in IRM and 181 in SRM; *P* < .001) and 339 that were coded as yellow and red/high acuity (118 in IRM and 221 in SRM; *P* < .001). Types of transmissions are listed in Table 3.

Time to transmission review

The median time from transmission to review was 6 hours (IQR 1.8–16.8 hours) in the IRM arm compared with 10.5 hours (IQR 6.0–32.2 hours) in the SRM arm (*P* < .001) (Table 4). The median time from transmission to review for actionable alerts (red and yellow) was 5.1 hours (IQR 2.3–8.9 hours) in the IRM arm compared with 9.1 hours (IQR 6.7–32.5 hours) in the SRM arm (*P* < .001). The median time from transmission to review for green transmissions was 6.5 hours (IQR 1.7–22.3 hours) in the IRM arm compared with 12.2 hours (IQR 4.5–31.5 hours) in the SRM arm (*P* < .001) (Figure 2). There were only 4 red alerts received: 3 in the IRM group and 1 in the SRM group. The mean time to response for IRM was 26.7 minutes compared with 554 minutes (9.2 hours) for SRM (*P* < .001).

To further evaluate the overall time to review of alerts, we divided the proportion of alerts reviewed into quartiles of time: Q1 <3 hours, Q2 3–8 hours, Q3 8–23 hours, and Q4 >23 hours. The percentage of actionable alerts (yellow and red) reviewed inside the first quartile (<3 hours) was 30.5% in the IRM group compared with 11.8% in the SRM group (*P* = .01). In the second quartile (3–8 hours), the

Table 4 Time to transmission review

Variable		Median (h)	Interquartile range (h)	*P*
Green	Standard	12.2	31.5–4.5	<.001
	Intensive	6.5	22.3–1.7	
Yellow/ red	Standard	9.1	32.5–6.7	<.001
	Intensive	5.1	8.9–2.3	
Total	Standard	10.5	32.2–6.0	<.001
	Intensive	6.0	16.8–1.8	

The table highlights the median and interquartile range of time to review between each arm by severity of alert.

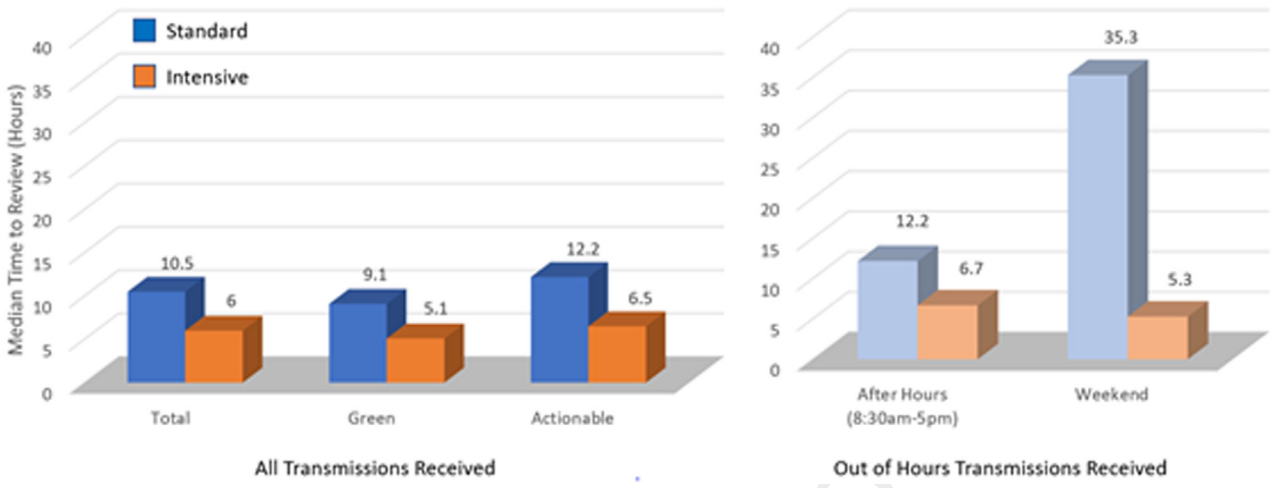

Figure 2 Time to transmission review. Bar graph highlighting the median and interquartile range of time to review between each arm by severity of alert. Q21

percentage of yellow alerts reviewed in the IRM group was 39% compared with 29.9% in the SRM group ($P = .4$). In the third quartile (8–23 hours), the percentage of yellow alerts reviewed in the IRM group was 28.8% compared with 26.7% in the SRM group ($P = .9$). The percentage of yellow alerts reviewed in the fourth quartile (>23 hours) was 1.7% in the IRM group compared with 31.7% in the SRM group ($P < .001$) (Figure 3). The percentage of alerts reviewed before the median was 69.5% in the IRM group compared with 41.7% in the SRM group.

Out-of-hours management

To assess the impact of 24/7 monitoring, a response time comparison between transmissions received during office hours and outside office hours (8:30 AM to 5 PM) was done. The median response time for transmissions received outside office hours was 6.7 hours (IQR 2.0–16.1 hours) for IRM compared with 12.2 hours (IQR 7.8–33.6 hours) for SRM ($P < .001$). The median response time for transmissions received over weekends was 5.27 hours (IQR 1.4–22.1 hours) for IRM compared with 35.3 hours (IQR 26.9–53.0 hours) for SRM ($P < .001$) (Graphical abstract).

Cost of RM

The average gross yearly income of an IBHRE-certified technician in South Australia is between A$98,157 and A$105,285. Based on this analysis, the hours of RM undertaken in the clinic for the 70 patients in the standard monitoring group over the 9-month follow-up period was 26.6 hours total, or 3.96 minutes per alert. For a cohort of 1000 patients, this equates to 507 hours per year reviewing alerts alone (not including missed downloads,

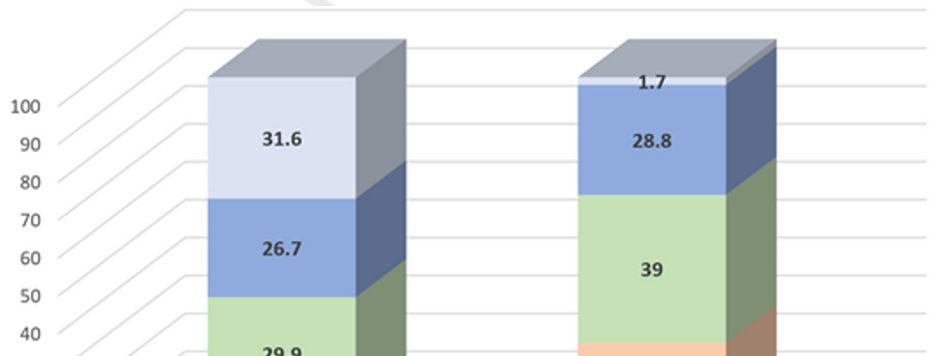

Figure 3 Percentage of transmissions reviewed in time quartiles. Bar graph demonstrating the percentage of yellow/red alerts reviewed in each time quartile between arms.

disconnects, contacting patients for management, or after hours). For a full-time technician earning $100,000 per year, $24,390 of their salary is dedicated to this process, representing the cost saving in the IRM group. The time saved through the utilization of a third-party service would allow clinic staff to provide more focused attention to actionable alerts.

Discussion

Main findings

This single-center prospective cohort study with the collection of comprehensive RM workflow data demonstrates the following outcomes resulting from the use of an IRM program:

1. A significant reduction in the number of actionable alert burden for review by clinic staff
2. A significant reduction in time to review and action RM transmissions for patients with CIED
3. This benefit is particularly apparent during "out of hours" and weekends

IRM allowed the more expeditious review and rapid segregation by alert acuity as well as facilitated the clinic staff's ability to preferentially focus on those alerts that required attention. Such workflow improvements are needed to improve the burgeoning burden of RM of devices.

Current management strategies for RM can result in delays in the processing of various alerts, typically those received after hours or across weekends, resulting in a lag between the occurrence of critical events and the clinical intervention. In addition to significantly reducing the median time to review alerts from 10.5 to 6 hours, IRM removed the upper range of review times present in the SRM group. Only 2 yellow alerts (1.7%) were reviewed outside of 23 hours in the IRM group compared with 70 (31.7%) in the SRM group. These data are supported by Ricci and coworkers,[16,17] who demonstrated a median reaction time to transmissions of 3 days. This is due in large part to the high proportion of transmissions, which are received outside standard clinic hours, including 21.3% occurring over weekends.[20] This delay in review is not present in the IRM group, as the 24/7 nature of the service eliminates any significant delays that are present in the SRM group, minimizing the associated risk and quickly identifying patients who may need intervention over weekends or public holidays.

Studies have shown that both remote and in-person follow-up require a mean staff time per remote transmission review between 9.4 and 13.5 minutes, as opposed to between 37.8 and 51.0 minutes for an in-person visit.[12,13] While RM results in rapid response to clinically significant events as compared with standard follow-up, when extrapolated to large device clinics, this service puts a significant time burden on staff, which can be reduced by outsourcing to allow 24/7 processing of alerts. Compelling evidence has shown various RM benefits, including rapid response to patient and device events,[3,4] reduced risk of cardiovascular hospitalization,[3,8] and decrease in health care utilization,[5–10] with the degree of benefit correlating markedly to patient adherence.[11]

While all CIEDs generate RM data, ILRs contribute a disproportionately high alert volume. One CIED cohort study demonstrated transmission of 50.1% of all RM alerts attributable to ILRs, while they accounted for only 18.8% of the study population.[15] Only 1.7% of these were high acuity (red) alerts,[19] while up to 86% of alerts are attributable to false-positive detections.[18,21] The significantly higher proportion of alerts attributable to ILRs in combination with a substantial rate of false positives has the potential to overwhelm RM systems, dilute significant and actionable data, and put unnecessary burden on staff.

Vendor-neutral software systems managed by trained staff is unique in that it can escalate transmission, with qualified technicians providing third-party adjudication and preferential review of high acuity alerts, with processed data and triaged alerts accessible by clinical staff via a single, secure Internet-based interface. This streamlined approach to workflow may allow clinical staff to redirect their energy to more clinically significant events while also allowing critical alerts to be reviewed outside typical office hours.

Technical and nursing staff are often tasked with the workload of reviewing RM. Many institutions have had to employ extra staff to manage the enormity of the workload. While we were not able to add in extra time and undertake a comprehensive cost comparison associated after hours work, with calling patients, chasing up disconnections, and contacting physicians, this analysis did show a time-saving of 507 hours per year per 1000 patients. This may allow the clinic to then be able to operate equally as effectively with less staff, permitting for the cost savings of a full-time IBHRE-certified technician or nurse.

Limitations

This was a single-center study, and staff numbers or workflow can vary between clinics, thus making it difficult to generalize the results. Although alerts were managed and the impact on review time and clinic workflow was assessed, clinical outcomes were not considered in this study and would require a prospectively powered study to evaluate outcomes. Because of the availability of the software within Australia, we were unable to compare the cost of RM in clinic with that of IRM. The cost analysis was a basic example of cost expenses for the SRM group. A more comprehensive cost analysis including associated cost from the IRM group would be required for more detailed information. Further, larger studies are required to determine the accuracy of vendors, to support the implementation of intensive remote follow-up as standard practice, to explore complex cost analysis, and to determine the impact this has on patient outcomes.

Conclusion

Implementation of an intensive and managed form of RM significantly reduced the time from alert transmission to

review when compared with SRM, with this association seen across all alert types. Utilization of an IRM platform has the potential to streamline remote clinic workflow and reduce the significant burden on clinical staff.

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Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent: Owing to the nature of the study not involving patient care but rather device transmission data only, patient consent was waived.

Ethics Statement: This study has adhered to the National Health and Medical Research Council guidelines on human research and been approved by the Central Adelaide Local Health Network Human Research Ethics Committee and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621001275853).

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