

# Performance of first pacemaker to use smart device app for remote monitoring



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**BACKGROUND** High adherence to remote monitoring (RM) in pacemaker (PM) patients improves outcomes; however, adherence remains suboptimal. Bluetooth low-energy (BLE) technology in newer-generation PMs enables communication directly with patient-owned smart devices using an app without a bedside console.

**OBJECTIVE** To evaluate the success rate of scheduled RM transmissions using the app compared to other RM methods.

**METHODS** The BlueSync Field Evaluation was a prospective, international cohort evaluation, measuring the success rate of scheduled RM transmissions using a BLE PM or cardiac resynchronization therapy PM coupled with the MyCareLink Heart app. App transmission success was compared to 3 historical “control” groups from the Medtronic de-identified CareLink database: (1) PM patients with manual communication using a wand with a bedside console (PM manual transmission), (2) PM patients with wireless automatic communication with the bedside console (PM wireless); (3) defibrillator patients with similar automatic communication (defibrillator wireless).

**RESULTS** Among 245 patients enrolled (age  $64.8 \pm 15.6$  years, 58.4% men), 953 transmissions were scheduled through 12 months, of which 902 (94.6%) were successfully completed. In comparison, transmission success rates were 56.3% for PM manual transmission patients, 77.0% for PM wireless patients, and 87.1% for defibrillator wireless patients. Transmission success with the app was superior across matched cohorts based on age, sex, and device type (single vs dual vs triple chamber).

**CONCLUSION** The success rate of scheduled RM transmissions was higher among patients using the smart device app compared to patients using traditional RM using bedside consoles. This novel technology may improve patient engagement and adherence to RM.

**KEYWORDS** Digital health; Pacemaker; Remote monitoring; Smart devices; Telemedicine

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## KEY FINDINGS

- Bluetooth low-energy technology enables direct communication between the pacemaker and the patient-owned smart device using an app that transmits the remote monitoring data to a secured network.
- Bluetooth-enabled pacemakers demonstrated a higher rate of scheduled transmission success compared to historical predicate remote monitoring technologies.
- The results suggest that remote monitoring using the app could positively transform the care of cardiac implantable electronic device patients, by improving remote monitoring success and enhancing the patient and provider experience.
- Future studies are needed to assess the impact of this novel technology on clinical outcomes.

## Introduction

The 2015 Heart Rhythm Society Consensus Statement recommends remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) over in-person-only device follow-up.<sup>1</sup> This is largely owing to the body of evidence supporting the use of RM and confirming its value in early arrhythmia detection, identification of lead or device malfunction, minimizing healthcare cost, and, most importantly, improving patient outcomes.<sup>2–8</sup> RM may take place periodically through scheduled transmissions or via an automatic alert transmission if certain abnormal criteria are detected.<sup>1,9–12</sup> Data transmission occurs wirelessly to a console located at the patient's bedside, which transmits the data through an analog phone land line or a cellular network to the manufacturer's central repository for storage and retrieval by healthcare providers.

Despite the value of RM in improving outcomes, adherence rates have remained suboptimal, ranging from 49% to 89%, with higher rates reported for wireless CIED systems.<sup>10,13–15</sup> The console could be problematic for some patients to activate, and according to a recently reported real-world database analysis, which analyzed RM adherence among pacemaker (PM) patients using wired, analog monitors, among 156,426 patients, only 76% successfully activated their monitors.<sup>16</sup> RM can also represent a challenge to patients who travel, change residence in different seasons, or prefer not to have a device in their bedrooms. The lack of clear feedback to patients to assure successful transmission of their data represents another limitation. Failure of patients to engage and adhere to RM transmission schedules impedes the potential benefits in patient outcomes and challenges device clinic efficiency.<sup>10,14,17,18</sup>

Progression of RM using advanced technologies has led to the development of innovative options that provide more choices for patients. An app has been developed that enables direct communication between Bluetooth low-energy (BLE)–equipped PM and CRT-P (cardiac resynchronization

therapy pacemaker) devices and patient-owned smart devices, without the need for a traditional bedside console or handheld reader. The BlueSync Field Evaluation was conducted to evaluate the success rate of scheduled RM transmissions using this new platform for RM and to assess the feedback of both patients and healthcare providers using this technology.

## Methods

### Evaluation app

BlueSync™ technology incorporates a free, downloadable smart device MyCareLink Heart™ app (hereafter referred to as the app) that facilitates the transfer of information from the patient's implantable device to the CareLink™ (CL) Network, a server-based repository for CIED data. Pairing between the CIED and the app can happen at the implanting center and requires only a patient's smart device (phone or tablet). The CIED communicates directly with the smart device through BLE signals, bypassing the need for any handheld reader ([Supplemental Figure 1](#)). The smart device acts as the vehicle that facilitates the transfer of information to the network through cellular or Wi-Fi internet connection. By using BLE, the technology enables the app to automatically and securely communicate with the patient's implantable device using smart devices. Data are encrypted in the PM using National Institutes of Standards and Technology standard encryption. The app allows patients to view the status of their RM transmissions and transmission history, track physical activity, and optionally add vital signs and symptoms ([Supplemental Figure 2](#)). Additionally, the app provides access to educational information. While the app is now available for both Android and iOS operating systems, at the start of enrollment for the evaluation the app was only available for the iOS operating system, so compatible devices included iPhone 5s (Apple Inc, Cupertino, CA) or higher or an iPad Pro/Air/Mini (Apple Inc) with an iOS 10.0 (or newer) operating system.

### Evaluation overview

The BlueSync Field Evaluation was a multicenter, international, prospective evaluation study to assess the performance of using BlueSync Technology by analyzing the number of scheduled transmissions that are successfully completed within a prescribed time (ie, transmission success). The evaluation also obtained surveys from screened patients, enrolled patients and clinicians, and device clinic nurses responsible for their care. This survey feedback was quantified to understand RM adoption with the app and if the app improves the patient experience with RM. The evaluation is registered in [ClinicalTrials.gov](https://clinicaltrials.gov) (ID: NCT03518658). A complete listing of participating centers is provided in [Supplemental Table 1](#). The evaluation was conducted in accordance with the Declaration of Helsinki. Although Ethics Committee review was not required as a part of this evaluation, participating institutions had the option of submitting the evaluation to their local Ethics

Committee. No personal health information or medical history was collected. Additionally, no diagnostic procedures or medical interventions were conducted; thus, the project was not classified as a clinical study.

All patients indicated for a PM or CRT-P were screened to determine eligibility for participation. For enrollment, patients had to be willing to use the app for the 12-month duration of the evaluation and were required to have a compatible device. The detailed inclusion/exclusion criteria are listed in Supplemental Table 2.

Each patient completed a survey at the time of device pairing between their implanted device and the CL Network and another survey at their annual follow-up visit at the end of the evaluation period. Patients' experience was measured in terms of perceived utility, connection over time, assessment of ease of use, value of information, and satisfaction. A parallel survey was completed by the clinician (device clinic nurse or physician) at the time of patient screening, at device pairing, and at the end of the evaluation. In the United States, clinicians completed the screening survey to determine patient eligibility for the evaluation, while in Europe the screening survey was completed after determining patient eligibility; therefore, screening survey results were restricted to patients from the United States only. An overview of the evaluation plan is shown in Figure 1.

For the BlueSync evaluation patients, sites were encouraged to schedule 6 transmissions during the 12 months of follow-up: 2 within the first month, at 2 and 4 weeks after enrollment; and 4 quarterly at 3, 6, 9, and 12 months of follow-up. However, sites were also allowed to follow their standard of care for scheduling transmissions.

The enrolled patients in the evaluation (hereafter referred to as the app group) were compared to 3 discrete "control" historical groups generated from retrospective data from

the Medtronic de-identified CL database and included the following: (1) PM patients with manual communication using a wand with a bedside console (PM manual transmission), (2) PM patients with wireless automatic communication with the bedside console (PM wireless); and (3) defibrillator patients with similar automatic communication (defibrillator wireless). All transmissions studied in all cohorts were office-scheduled. Additional analysis on scheduled transmission success was performed targeting patients who were using the same app for RM extracted from the Medtronic CL RM system and who were not part of this evaluation. The following inclusion criteria were used to select the analysis control groups from CL comparable to the app group: (1)  $\geq 18$  years of age at implant; (2) patient activated (first received CL transmission with respective monitor) in CL from January 1, 2016 to December 1, 2018; (3) patient followed for at least 1 year after activation with a minimum of 1 scheduled transmission in this year, (4) US patients, (5) patient did not perform transmission with another monitor for at least 1 year after activation.

### Endpoints

The primary objective of the evaluation was to assess the success rate of scheduled RM transmissions among BlueSync evaluation patients who use the app-based platform for RM and compare it to the scheduled RM transmission success rate among patients in the first historical control group with manual communication using a wand with a bedside console (PM manual transmission). Post hoc analyses were performed to compare the success rate of scheduled RM transmissions between BlueSync patients and patients in the 2 additional historical control arms who use automatic bedside consoles (PM patients with wireless automatic

## Bluesync Study Design

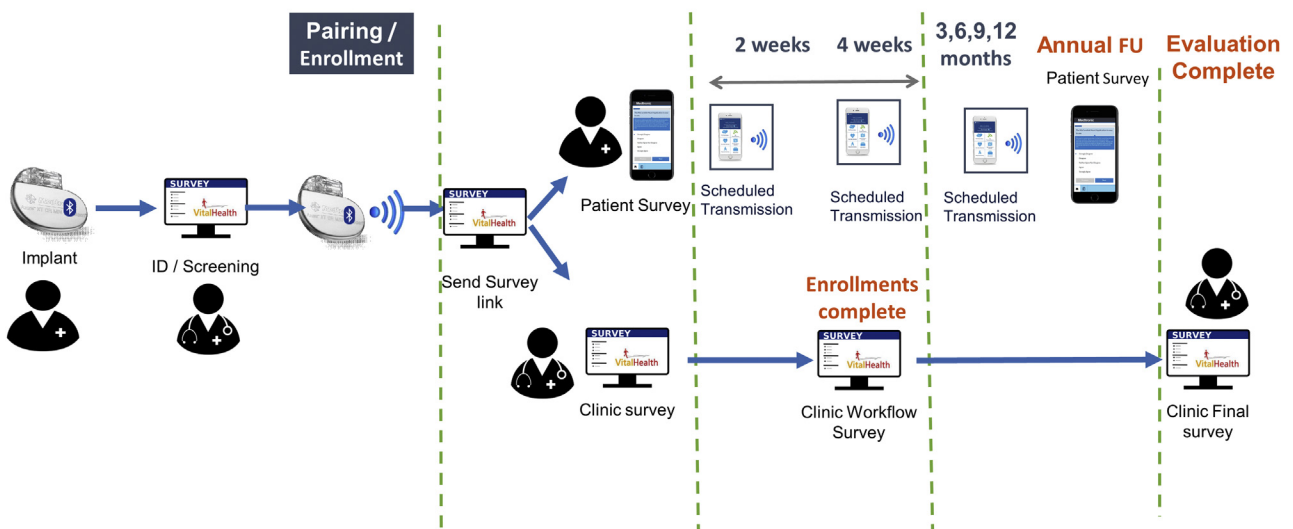


Figure 1 BlueSync Field Evaluation design schematic. Evaluation workflow from implant through completion.

communication with the bedside console and defibrillator patients with similar automatic communication). A scheduled transmission was considered completed successfully if a transmission was received by the CL system within a window starting 1 day before and ending 5 days after the scheduled transmission date.

An ancillary objective was to assess the benefit perceived by the patient using the app. These inputs were collected at baseline and during the 12-month follow-up period using a web-based proprietary survey tool.

### Statistical analysis

Generalized estimating equations for binomial distribution were used to determine transmission success. For the analysis assessing long-term transmission success, all scheduled transmissions between 1 and 12 months were included in the analysis. An unmatched analysis was performed to compare the proportion of successful transmissions between the app group and the control groups. Additionally, individual matching was performed using a greedy algorithm to create matched control groups comparable to the app group. Subjects were matched exactly based on age ( $\pm 2$  years), sex, and type of device (single-, dual-, or multi-chamber). For the app group patients' age at screening was used, while for the historical control cohorts age at implant was available. A range of 2 years was chosen because age at implant and age at screening should be within 2 years for the app group, with most patients having zero years between screening and implant. For app users extracted from CL, an additional analysis was performed using age groups based on quartiles as variables in the generalized estimating equations model.

Categorical data were summarized as counts and/or percentages. Continuous variables were summarized by mean, standard deviation, median, quartiles, minimum, and maximum as applicable. *P* values for assessing superiority

of the app with regard to transmission success were based on 1-sided significance testing using a level of .025. Confidence intervals are reported as 2-sided 95% confidence intervals.

The analysis was performed using SAS software version 9.4 (SAS Institute, Cary, NC).

## Results

### Evaluation patients

Two hundred-fifty-seven patients were eligible and completed the patient device pairing survey and enrolled from 20 sites in the United States, the United Kingdom, France, and Italy from April to December 2018. Among the 257 enrolled patients, 4 had data loss in CL owing to early exit, 1 was never paired in CL, and 252 (98%) were successfully paired in CL. Of the successfully paired patients, 245 had at least 1 scheduled transmission between 1 and 12 months to be included in the analysis (Figure 2). Baseline characteristics for these 245 patients showed a diverse distribution of educational background and smart technology experience (Table 1). Almost half of the patients had less than 5 years of experience with smart devices. Patient baseline characteristics for the app group and control groups are presented in Table 2 and of note, patients in the app group tended to be younger.

### Scheduled RM transmission success

Between 1 and 12 months of follow-up, 245 app patients had a total of 953 scheduled transmissions, of which 902 were successfully completed (94.6%). In comparison, scheduled transmission success rates were 60% for PM manual transmission patients, 77.3% for PM wireless patients, and 86.7% for defibrillator wireless patients (Supplemental Table 3). Matched analysis of the groups was performed with regard to age, sex, and device type, and the app was

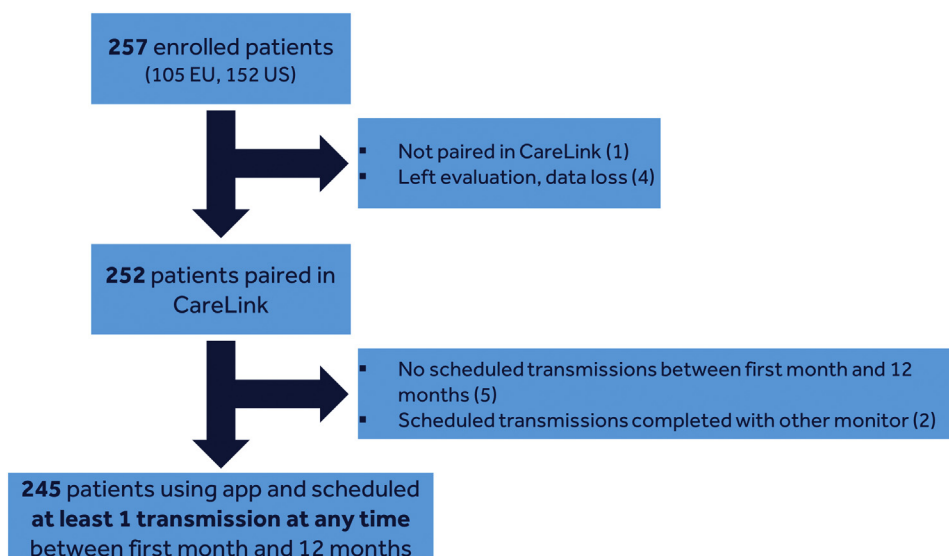


Figure 2 Patient flowchart. Disposition of patients enrolled in the BlueSync Field Evaluation.

**Table 1** BlueSync Field Evaluation baseline characteristics

Subject characteristics	App group (n = 245)
Education (highest degree/level), n (%)	
Less than high school	17 (6.9%)
High school	105 (42.9%)
Bachelor	82 (33.5%)
Master	23 (9.4%)
PhD/doctorate	18 (7.3%)
How comfortable is the patient with smart technology? n (%) <sup>†</sup>	
Not comfortable, eg, non-user	6 (2.4%)
Less comfortable, eg, uses tech but not often	28 (11.4%)
Moderately comfortable, eg, has smart phone/tablet but uses in limited fashion	62 (25.3%)
Comfortable, eg, regular user	74 (30.2%)
Very comfortable, eg, uses more than 1 social media application	74 (30.2%)
How long has the patient owned a smart device (smartphone/tablet)? n (%)	
Up to 2 years	37 (15.1%)
2 to 5 years	72 (29.4%)
5 years or more	136 (55.5%)

<sup>†</sup>1 missing response.

superior to all 3 matched control cohorts concerning transmission success ( $P < .001$ ) (Table 3 and Figure 3).

There were 30 patients accounting for 51 missed transmissions within the app group. On average, the app group sent

fewer unscheduled transmissions (3 transmissions on average) than both the PM wireless and defibrillator wireless groups (on average 3.9 and 3.6 unscheduled transmissions, respectively; Supplemental Table 4). The percentage of patients in the app group that did not send any unscheduled transmissions was also larger than those in the PM and defibrillator wireless groups (46.5% vs 31.5% and 36.4%).

The success rate of scheduled transmissions among 811 patients ( $69.1 \pm 12.2$  years, 62.3% men) using the app in the real world outside of the evaluation for at least 12 months was found to be 92.8% (2365 scheduled and 2194 completed), suggesting that the real-world experience outside of the BlueSync field evaluation is similar. Transmission success within the general app cohort outside of the field evaluation was not significantly different between age groups: 91.7% for age group  $\leq 63$  years (reference group), 94.3% for 63 to  $\leq 71$  years ( $P = .22$ ), 93.0% for age group 71 to  $\leq 77$  years ( $P = .60$ ), and 92.0% for age  $> 77$  years ( $P = .91$ ).

### Device pairing survey results

At the time of device pairing, the majority of patients agreed/strongly agreed that the device pairing process was easy to do (78%) and that they would be comfortable using the app (91%) (Supplemental Table 5). At the time of their annual follow-up, most patients were satisfied with the app (85%), felt it was easy to use (87%), and felt more connected with their doctor and clinic (73%). In the subset of 32 patients

**Table 2** Baseline characteristics for all cohorts

Subject characteristics	App group (n = 245)	PM manual (n = 128,607)	PM wireless (n = 69,313)	Defibrillator wireless (n = 47,457)
Device and monitor				
Device type	BlueSync PM/CRT-P	PM/CRT-P	PM/CRT-P	ICD/CRT-D
Monitor mode	Automatic	Manual	Automatic	Automatic
Monitor type	App-based	Bedside	Bedside	Bedside
Monitor name (model)	MCL Heart	CareLink	MyCareLink	MyCareLink
Monitor model	-	2490	24952	24952
Age (years)				
Mean (SD)	64.8 (15.6)	72.2 (11.5)	74.7 (11.7)	66.4 (12.8)
Median	68.0	74.0	77.0	68.0
25 <sup>th</sup> – 75 <sup>th</sup> percentile	56–76	66–80	69–83	59–76
Minimum–maximum	20–90	18–90	18–90	18–90
Sex (n, %)				
Male	143 (58.4%)	66,652 (51.8%)	37,084 (53.5%)	33,272 (70.1%)
Female	102 (41.6%)	61,604 (47.9%)	32,014 (46.2%)	14,102 (29.7%)
Unknown	0 (0.0%)	351 (0.3%)	215 (0.3%)	83 (0.2%)
Device type (n, %)				
Single-chamber	9 (3.7%)	10,550 (8.2%)	4996 (7.2%)	10,052 (21.2%)
Dual-chamber	185 (75.5%)	114,296 (88.9%)	55,911 (80.7%)	18,115 (38.2%)
CRT-P/CRT-D	51 (20.8%)	3761 (2.9%)	8406 (12.1%)	19,290 (40.6%)
Replacement vs initial device (n, %)				
Replacement	117 (47.8%)	35,592 (27.7%)	14,616 (21.1%)	21,164 (44.6%)
Initial device	125 (51.0%)	93,015 (72.3%)	54,697 (78.9%)	26,293 (55.4%)
Missing	3 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Patients aged  $> 90$  were analyzed as 90 years of age.

For app group subjects, age at screening is used. For other subjects, age at implant is used.

CRT-D = cardiac resynchronization therapy defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; PM = pacemaker.

**Table 3** Transmission success – matched analysis

	App group	PM manual	PM wireless	Defibrillator wireless
Device type	BlueSync PM/CRT-P	PM/CRT-P	PM/CRT-P	ICD/CRT-D
Monitor mode	Automatic	Manual	Automatic	Automatic
Monitor type	App-based	Bedside	Bedside	Bedside
Monitor name (model)	MCL Heart	CareLink (2490)	MyCareLink (24952)	MyCareLink (24952)
Control	Field evaluation	Historical real-world retrospective	Historical real-world retrospective	Historical real-world retrospective
Number of patients	245	979	980	980
Scheduled transmissions	953	2719	2859	3587
Completed transmissions	902	1531	2201	3125
Transmission success (95% CI)	94.6% (91.8%–96.6%)	56.3% (53.7%–58.9%)	77.0% (74.4%–79.4%)	87.1% (85.2%–88.8%)
Difference to app group (95% CI)	-	38.3% (34.8%–41.9%)	17.7% (14.3%–21.1%)	7.5% (4.6%–10.5%)
P value superiority	-	<.001	<.001	<.001

CRT-D = cardiac resynchronization therapy defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; ICD = implantable cardioverter-defibrillator; PM = pacemaker.

who were remotely monitored with a prior cardiac device, the majority (84%) were more satisfied with the app than their previous monitor (Supplemental Table 6). Patient-reported experience with the system was associated with high rates of feeling safe (81%) and reassured (87%) (Supplemental Table 7).

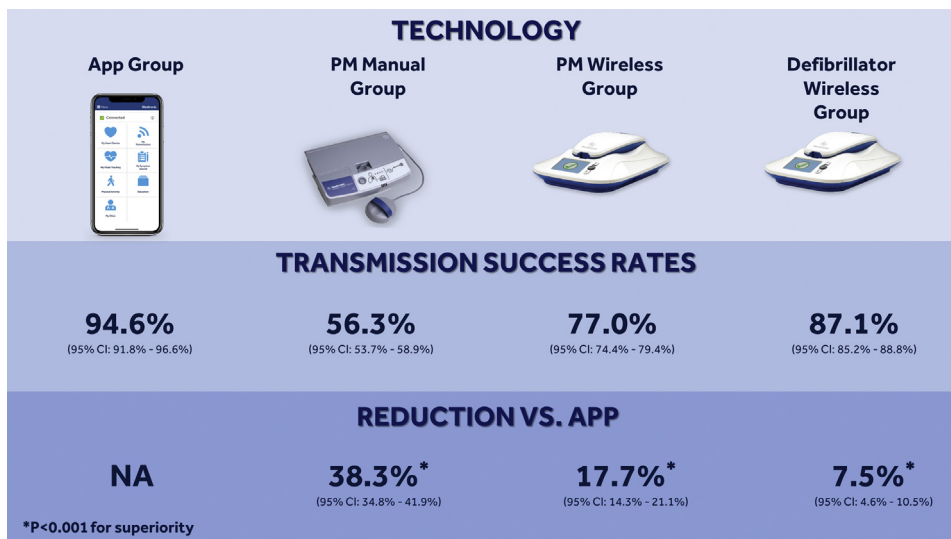
**US patient screening survey results**

In the United States, 768 patients were screened. Screening survey results showed that of a total of 648 screened patients with Medtronic devices, 362 (56%) owned a smart device and of those, 237 (65%) had a compatible smart device (with iOS). Among patients with both compatible smart devices and a compatible device implant, 92% (208 patients) were willing to be remotely monitored; and of those, 87% (181 patients) were willing to use a mobile app as their remote monitor (Figure 4).

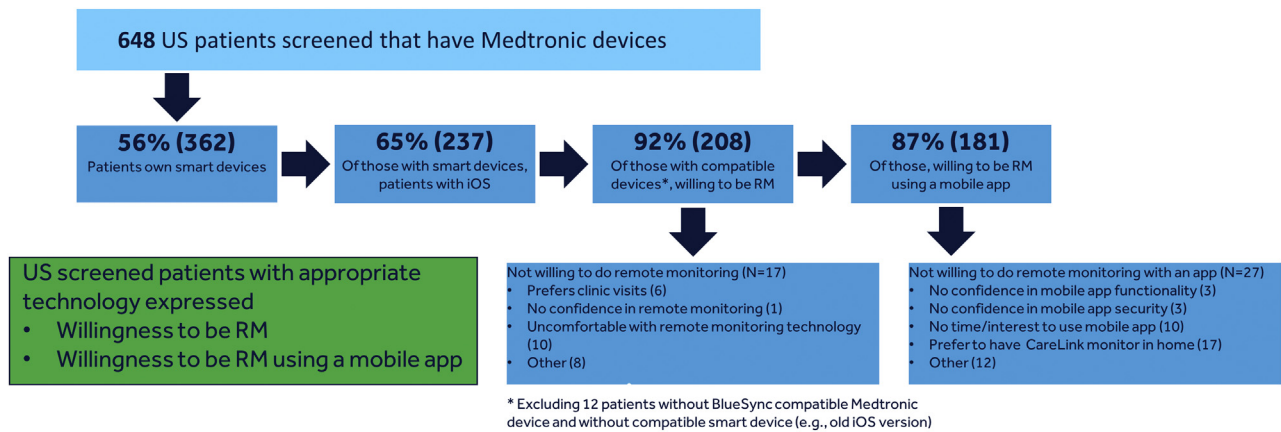
**Discussion**

The current evaluation showed the success rate of scheduled RM transmissions using an app on the patient’s own smartphone or tablet was 94.6% and outperformed traditional console-based RM systems even after matching groups by age, type of device, and sex. A similar scheduled transmission success rate was observed among patients using the same platform in the real world outside of the evaluation (92.8%). Furthermore, patients reported a positive experience with the process after 12 months of use, including high rates of perceptions of safety and reassurance. Collectively, these results suggest that improved transmission can be achieved via reduced patient burden and increased automaticity with strategic initiation and system ease of use.

Perhaps it is expected that the app-based RM would outperform the modality that depends on manual communication using a wand with a bedside console, but it was



**Figure 3** Remote monitoring transmission success by technology. Comparison of scheduled transmission success rates between 1 and 12 months follow-up between app group, pacemaker (PM) manual group, PM wireless group, and implantable cardioverter-defibrillator wireless group. Matched analysis of the groups was performed with regard to age, sex, and device type.



**Figure 4** United States remote monitoring acceptance. Remote monitoring acceptance among screened patients (prior to enrollment) from the United States.

interesting to see that it also outperformed other modalities of wireless automatic communication with a bedside console (PM or defibrillator wireless). The app provides users with the ability to view transmission schedule (but does not send reminders for transmissions) and provides automatic reminders to keep the app connected, and sends a notification if a transmission is missed. It is possible that the combination of the features of the app, as well as the ease of portability of the smartphone vs a bedside console, might explain its better performance.

By increasing the automaticity of RM further, transmission success with RM may improve and therefore could decrease healthcare costs and clinical workload while improving outcomes. Published reports on the impact of patient noncompliance on clinic workload indicate that additional telephone follow-up of patients who missed transmissions took an average of 55 minutes per day, assuming an average of 22 patients were called.<sup>7,10</sup>

Understanding the patient experience of using the app and its potential to impact the management of cardiac disease is an essential component of the BlueSync Field Evaluation. Studies have evaluated patient experiences with RM and reported high levels of patient acceptance and satisfaction among patients using their RM systems.<sup>19–24</sup> Similarly, in the present analysis, the willingness to perform RM in general (92%) or via an app was high (87%) among the screened US patients with a compatible smart device and compatible implanted device. However, the results of the US patient screening survey highlight the challenge that not all PM recipients own a smart device and that we still need to provide different options for RM to meet the needs of our patients. While ownership and comfort level in using smart devices continue to be a challenge, adoption of these technologies is expected to continue to rise as current device users will become older. In general, most patients want to be knowledgeable about their device information; however, the level of this knowledge varies widely in the current era and is partially due to lack of access to data from their devices or remote transmission processes.<sup>25</sup> Patients participating in the BlueSync Field Evaluation reported

that the app provided usability and increased connection, reported improved satisfaction, and indicated a preference for using app-based monitoring compared with traditional monitoring. Despite a new process for device pairing, patients reported favorable perceptions related to using the app. Notably, this ease of use did not translate into overuse of the system. Specifically, patients using the app sent fewer unscheduled transmissions (3 on average) than patients with traditional RM options, and nearly half of these patients did not send any (46.5%).

Long-term use of the app provides additional insights into the patient experience. For example, patients felt that the longevity feature increased their perception of security, and knowledge of successful transmission gave them security in the process. The app also provides information related to activity, to which patients previously did not have access. However, patient feedback indicated varying levels of benefit from this information. The MyCareLink Heart app provides a platform to potentially allow for greater patient access to data regarding their health in the future, which may further improve patients' understanding of their condition, the efficacy of interventions, and perception of health benefits.

## Limitations

There are limitations associated with the BlueSync Field Evaluation. The results are limited to patients using compatible smart devices with the iOS operating system, as the app was not available for Android devices at the start of the evaluation. Additionally, the evaluation was conducted using patient-owned smart devices and the results may not be translatable to an app-based system using manufacturer-provided smart devices or transmitters. The comparison groups are controls extracted retrospectively from 1 manufacturer (Medtronic CL RM system). Some evaluation patients could be present in the real-world app comparison group. While matching was performed to create similar historical control groups, this matching was restricted to the information available from the CL system. The evaluation was designed not to measure RM clinical outcomes but to assess the technical

performance and compliance among patients using this new platform. The study was also designed to allow for flexibility in maintaining routine clinical practice; therefore, there were limitations on the controls of mandating the scheduling of transmissions and survey completions. In the case of scheduled transmission, 57.6% had 4 scheduled transmissions, while 2.9% only had 1 scheduled transmission.

## Conclusion

Long-term experience with Bluetooth-enabled pacemakers demonstrated a high rate of transmission success compared to predicate RM options and similar to patients using the app outside of the evaluation for at least 12 months. The results of the BlueSync Field Evaluation suggest that RM using the app could positively transform the care of CIED patients, by improving RM success and enhancing the patient and provider experience. Future studies are needed to assess the impact of this novel technology on clinical outcomes.

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## Authorship

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

## Patient Consent

All patients provided written informed consent.

## Ethics Statement

The evaluation was conducted in accordance with the Declaration of Helsinki. Although Ethics Committee review was not required as a part of this evaluation, participating institutions had the option of submitting the evaluation to their local Ethics Committee. No personal health information or medical history were collected. Additionally, no diagnostic procedures or medical interventions were conducted; thus, the project was not classified as a clinical study.

## Appendix Supplementary Data

Supplementary data associated with this article can be found in the online version <https://doi.org/10.1016/j.hroo.2021.07.008>.

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