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Remote Monitoring for Cardiac Arrhythmia: Its Legacy and Growing Importance in Advancing Clinical and Economic Outcomes

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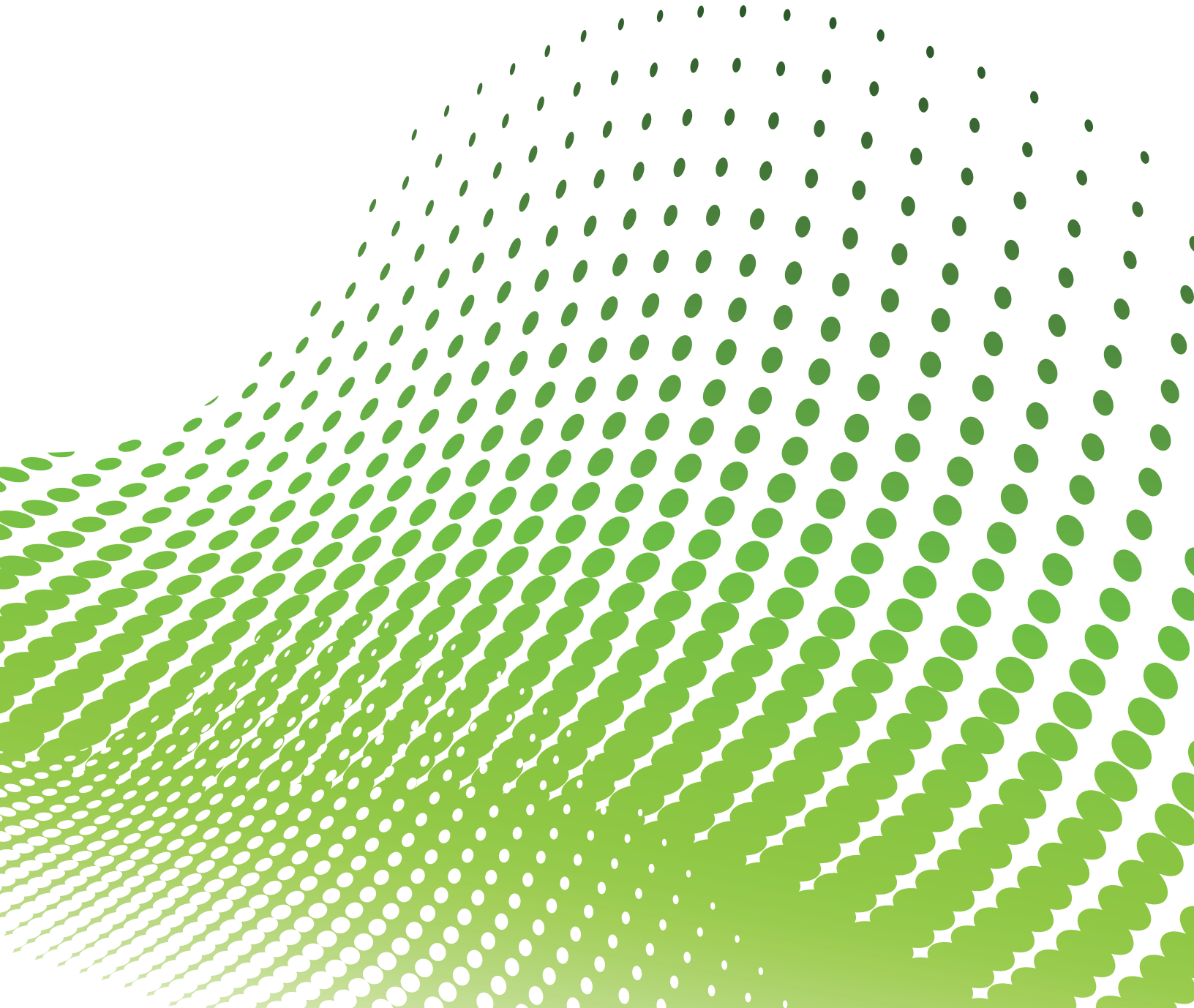


Remote Monitoring for Cardiac Arrhythmia:
Its Legacy and Growing Importance in Advancing Clinical and Economic Outcomes

Remote Monitoring (RM) forged a path to advance the care of cardiac arrhythmias. More than a decade ago, RM became wireless and cellular and, since, numerous studies have established and demonstrated its clinical and economic value. RM's developments have advanced providers' abilities to improve care and manage workflow issues—both of which are particularly important today considering the relentless tide of new patients produced by an aging population and increased pressure to reduce the cost of services. RM of implantable cardiac devices stands as an exemplar of what the late Dr. Max Schaldach, a cardiac rhythm pioneer, referred to as "technology helping to heal."

Implantable cardioverter defibrillators (ICD) have proven mortality benefit not only for survivors of sudden cardiac arrest, but as primary prevention devices for patients at risk, whether from heritable arrhythmias or heart failure[1]. Developed by Dr. Michel Mirowski, the first ICD was implanted in 1980 by Dr. Levi Watkins at The Johns Hopkins Hospital. It has since become a cornerstone of cardiac rhythm management. Pacemaker and ICD innovations have fostered the growth of new specialties such as electrophysiology and new industries[2] such as biomedical device making. Device manufacturing firms, in collaboration with their clinical partners, have achieved notable innovations that have elevated devices from a static "appliance stage" to the "adaptable tool stage."[3] As device programmability evolved, innovators began to imagine the power of liberating data from the patient's device and remotely transmitting the data to detect and manage arrhythmias.

Remote monitoring of ICDs transformed imagination to reality, fundamentally altering the traditional care model for cardiac arrhythmias and multiplying the benefits of ICDs. Along with technological advances, other forces—the aging population, the rising incidence of cardiovascular disease, the expansion

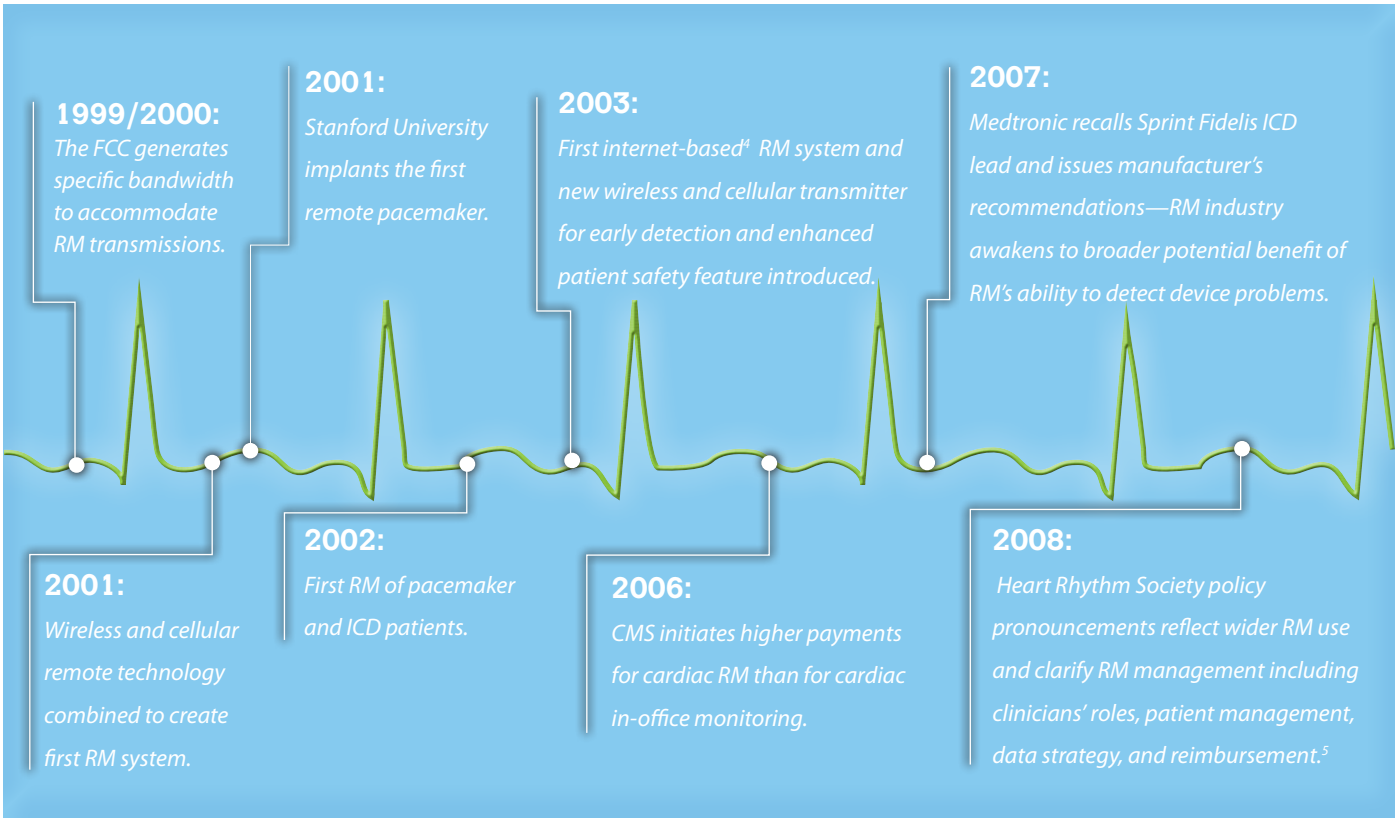
At the dawn of the 21st century, cardiac arrhythmia treatment experienced the next great leap—the use of RM to monitor arrhythmias and long-term integrity of cardiac rhythm devices.

[1] *Matthew R. Reynolds and Mark E. Josephson. 2003. MADIT II (Second Multicenter Automated Defibrillator Implantation Trial) Debate : Risk Stratification, Costs, and Public Policy, Circulation. 2003;108:1779-1783*

[2] *Parsonnet, V. & Bernstein, A.D. 1989. Transvenous pacing: A seminal transition from the research laboratory. Annals of Thoracic Surgery, 48:738-740.*

[3] *Jeffrey, K. & Parsonnet, V. 1998. Cardiac pacing, 1960–1985: A quarter century of medical and industrial innovation, Circulation, 97: 1978-1991. doi: 10.1161/01.CIR.97.19.1978*

Timeline: Milestones in Remote Monitoring



The Remote Care Model – Cardiac Rhythm Care's Leap Forward

At the dawn of the 21st century, cardiac arrhythmia treatment experienced the next great leap—the use of RM to monitor arrhythmias and long-term integrity of cardiac rhythm devices. Over this period, the RM industry experienced a number of innovative milestones from the introduction of the first RM system to the first internet-based system. Shortly after the FCC allocated a specific bandwidth to accommodate RM transmissions, Stanford University physicians implanted the first pacemaker capable of being remotely monitored. In 2001, Biotronik combined wireless and cellular technology receiving FDA approval for the first RM system. In the fast-paced RM arena, technology, policy, and an evidence base have all contributed to the modality's maturation. Some sentinel industry drivers follow:

of indications for ICDs, and favorable advances in reimbursement—are each contributing to increasing ICD and RM use.

RM Adoption Lags other Innovations—Fighting for "Mindshare"

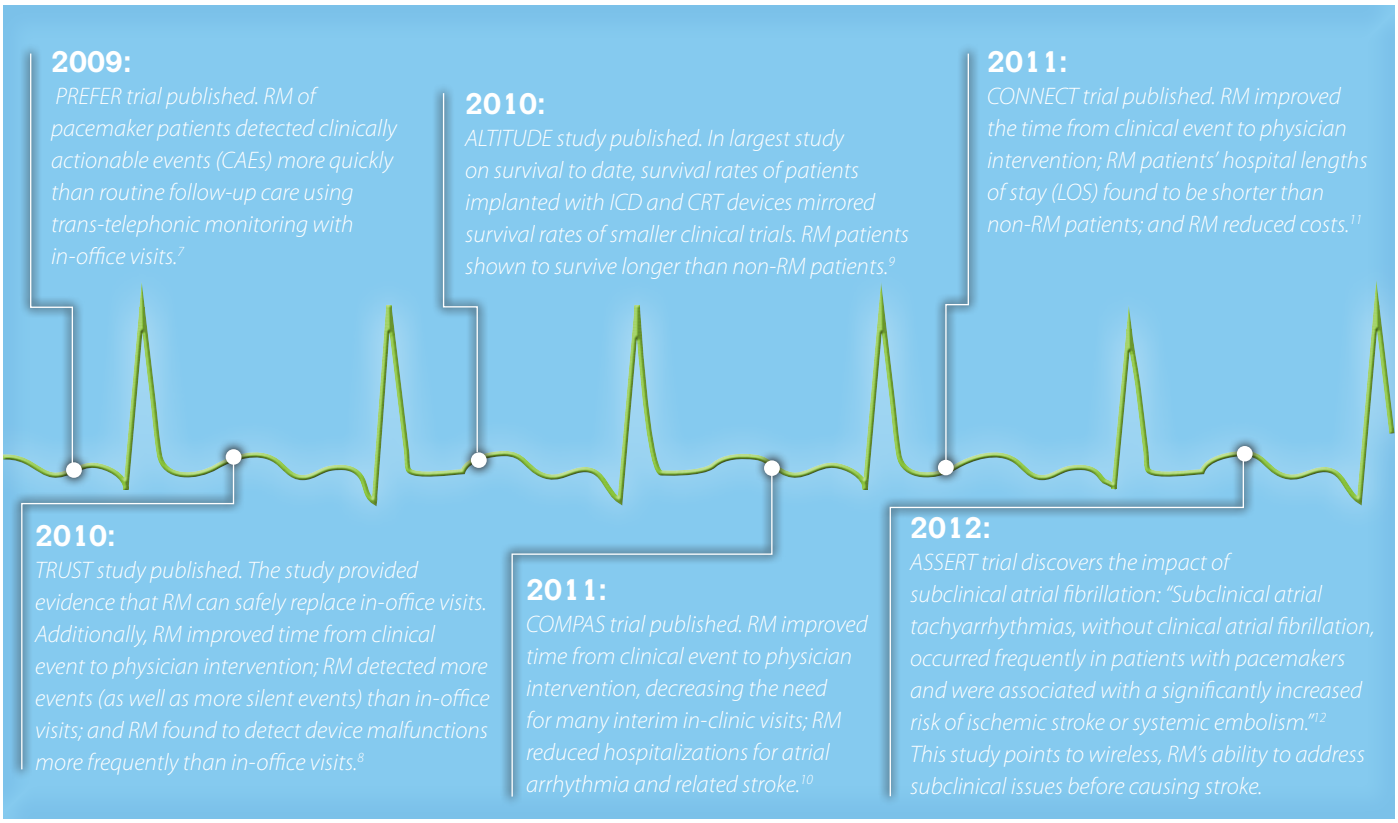
Health care reform will demand demonstrations of comparative patient outcomes, and payment reforms will reduce fee-for-service activities. Despite the technological advancements and sound evidence base to validate remote monitoring, the RM model still competes with a traditional care model for ICD patients. In the traditional model, a patient with an implanted device visits the physician's office for regularly scheduled quarterly or semi-annual visits.[6] During these visits, the provider interrogates the device, assessing for device functionality and clinical information that the ICD has captured since the last in-office visit (usually 3-6 months). During the interrogation, clinicians and patients alike hope for unremarkable reports on the functioning of the battery and leads as well as clinical abnormalities.

[4] *http://www.biotronik.com/files/4D1DF554BFF0E53FC125786900463 47A/$FILE/Press%20release%20HM%2010th_EN.pdf*

[5] *http://www.hrsonline.org/ClinicalGuidance/upload/cieds_guidelines.pdf*

[6] *Heart Rhythm Society guidelines recommend one office visit per year.*

Timeline: Milestones in Remote Monitoring Continued



The only way a patient or a clinician would know if any problems exist between office visits is if the patient experiences symptoms and reports them to a care provider. Asymptomatic conditions would be discovered only during scheduled, in-office checks, or worse, after a significant event has triggered an alert to their physician.

Overcoming Adoption Challenges

Like so many other product advancements in our society, RM's innovations have disrupted clinical tradition. Buoyed by wireless radio frequency (RF) technology in implantable devices, RM-enabled pacemakers and ICDs can continuously communicate a patient's clinical status as well as a device's functional status, e.g., battery life and lead integrity—increasingly critical benefits in light of continued industry challenges with lead reliability. When needed, a physician can pre-program the device with instructions to signal the computerized service center to generate an event notification when clinically relevant changes occur. Thus, the physician receives an event alert via email, SMS[13] , or fax, enabling the physician to act expeditiously. To complete the cycle, if a patient needs therapy, the service center automatically sends the patient

[7] *http://www.medtronic.com/for-healthcare-professionals/products-therapies/cardiac-rhythm/patient-management-carelink/medtronic-carelink-network-for-cardiac-device-patients/clinical-outcomes/index.htm*

[8] *Circulation editors' picks: Most read articles highlighting cardiovascular devices. 2012. Circulation, 125, e374.*

[9] *Saxon, L.A., Hayes, D.L., Gilliam, F.R., et al. 2010. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: The ALTITUDE survival study. Circulation, 122:2359-2367.*

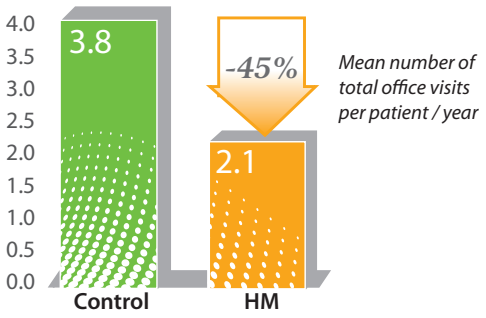
[10] *Mabo, P., Victor, F., Bazin, P., et al. 2011. A randomized trial of long-term remote monitoring of pacemaker recipients (the COMPAS trial). European Heart Journal. doi:10.1093/eurheartj/ehr419*

[11] *Crossley, G.H., Boyle, A., Vitense, H., et al. 2011. The CONNECT (clinical evaluation of remote notification to reduce time to clinical decision) trial: The value of wireless remote monitoring with automatic clinician alerts. Journal of the American College of Cardiology, 57(10):1181-1189. doi:10.1016/j.jacc2010.12.012*

[12] *Healey, J.S., Connolly, S.J., Gold, M.R., et al. 2012. Subclinical atrial fibrillation and the risk of stroke. New England Journal of Medicine, 366:120-129. doi:10.1056/NEJMoa1105575*

[13] *SMS stands for Short Message Service (also known as a text message).*

Wireless Remote Monitoring vs. Traditional In-Office



Source: TRUST Study

an alert (pre-programmed by the physician), or the physician notifies the patient with instructions. All told, advancements in the ability of remote monitoring ICDs to capture functional status and clinical values have been proven to deliver significant value to physicians and patients alike.

Remote management of ICDs, which sounds promising *and* has proven its worth, has yet to result in widespread adoption. In a healthcare system and society mesmerized by better, faster, more efficacious treatment, one must question why RM has not become the standard of care. Factors that have contributed to the latency in broader adoption include the level of required patient involvement and compliance in data collection; physician concern about a data "barrage;" medico-legal issues; managing a new remote workflow; the desire of physicians to see demonstrable, clinically relevant studies proving RM; assurances of device safety; and finally an awareness of RM's financial impact. One can understand the hesitance of the physician community to adopt RM "blindly" considering any combination of these adoption barriers; however, remote monitoring of ICDs has been repeatedly borne out as an effective clinical solution—a solution that can also translate into economic benefits for physicians and address broader health system expenditure issues.

Remote Monitoring: A Proven Solution

For more than a decade, physicians have utilized wireless-capable devices with their patients. Throughout this time, large-scale studies have been conducted to examine RM in detail; and the evidence demonstrates RM's benefits for both patients and providers. Studies show that when compared to in-office care, RM demonstrates the following important benefits:

- detects clinically actionable events sooner[14] enabling physicians to react more quickly to clinical events[15]
- prospectively identifies device malfunctions[16]
- reduces the number of hospital visits[17] as well as the LOS and costs associated with each visit[18]
- improves survival[19]

Evidence Abounds

In 2010, a steering committee of U.S. electrophysiologists and cardiologists published the results of a prospective, randomized trial, TRUST, designed to test the rapid detection of symptomatic and asymptomatic cardiac events using 1,443 ICD patients. The goals of Biotronik's TRUST study demonstrated that a remote monitoring system could safely reduce in-office follow-ups, detect arrhythmias earlier, and provide remote triage. The study demonstrated that RM reduced the time from arrhythmia onset to evaluation from 35.5 days for the in-office group to 1.0 days for the RM group. The RM system detected 81% of clinically relevant device-related events with a daily transmission success rate per patient of more than 90%. The ICD transmission rate reflects a huge achievement in ICD safety as well as a major stride in overcoming patient compliance issues.

[14] *PREFER trial*

[15] *CONNECT trial*

[16] *Varma, N., Epstein, A.E., Irimpen, A., et al. 2010. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: The Lumos-T safely reduces routine office device follow-up (TRUST) trial. Circulation, 122: 325-332. doi: 10.1161/CIRCULATIONAHA.110.937409*

[17] *COMPAS trial*

[18] *CONNECT trial*

[19] *ALTITUDE study*

Further, this randomized trial made the case that the traditional in-office model would yield to a new paradigm, one leaning toward RM. This research resulted in exclusive approval by the FDA for data from one RM system, Home Monitoring[20] to be used as a *replacement* for device interrogation during in-office follow-up visits, meaning that patients—for whom the transmission data show nothing unusual and, in the past would have made a trip to the office only to receive confirmation that the device is functioning normally and that no abnormal cardiac findings exist—would no longer have to make an in-office visit. Instead, the provider conducts quarterly data reviews, or more frequently in the case of ICMs and receives payment for having checked the data to make sure everything is fine.

Biotronik's COMPAS trial demonstrated a 66% reduction of hospitalizations for atrial arrhythmia and a 75% reduction in hospitalization for device-related adverse events.

Several other sentinel clinical trials have provided strong evidence that shifting to a remote model is both safe and effective. In one study, researchers sought to determine if the traditional office follow-up model was more effective than a RM model for capturing clinical events. Specifically, researchers asked if RM could reduce the time from a clinical event to clinical decision making for arrhythmias? The study concluded that wireless RM with automatic clinician alerts, when compared to traditional in-office follow-up, dramatically reduced the time between a clinical event and clinician's response from 22.0 days for traditional in-office patients to 4.6 days for RM patients ($p < .0001$).[21] Another trial found that RM detected arrhythmic events from 21 to 35 days earlier than the traditional office visit method.[22]

Finally, Biotronik's COMPAS trial demonstrated that RM of pacemakers improved physician intervention for clinically relevant events by almost four months compared to the control group. Bing Liem, M.D., Director of the Electrophysiology and Cardiac Rhythm Device Laboratory at El Camino Hospital, enjoys the benefits of remote monitoring. Trained as an EP fellow in the 1980s, Dr. Liem appreciates the advancement that RM provides for his patients and his practice. He notes that "clinically it is very useful for the early identification of clinical issues that we are either treating or that we may not even expect." The sole EP in his practice, he stated, "I am able to manage the remote monitoring system myself. I get roughly ten alerts to my phone in the morning and they provide me with insight into whether I need to take further action. One of the best advancements is the ability to set alert parameters to my comfort. My patients are thankful for this technology. I actually give them my cell phone and email (some of my colleagues thought I was crazy doing so). I have found that patients are very respectful, and they only call or email when something is really happening. It can save a trip to the office or ER."

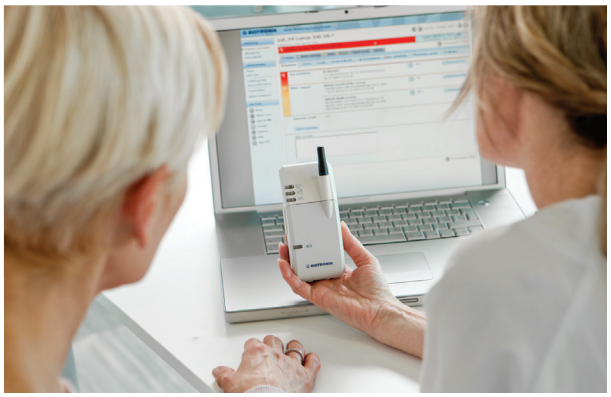
The Power to Know

While capturing the event sooner appears to be a scientific advance, it begs the question of whether or not earlier notification contributes to survival. With events such as atrial fibrillation, the most common arrhythmia which has been associated with an increased risk of stroke, heart failure, and death, would knowing sooner matter? The ALTITUDE

[20] *Home monitoring refers specifically to Biotronik's RM solution.*

[21] *CONNECT Trial*

[22] *TRUST study*



Technological advances now allow physicians to follow patients around the globe.

study demonstrated that annual and total survival was improved significantly for patients transmitting device information to a remotely monitored network. Additionally, follow-up using the network was associated with a 50% relative reduction in the risk of death.[23] Biotronik's COMPAS trial demonstrated a 66% reduction of hospitalizations for atrial arrhythmia and a 75% reduction in hospitalization for device-related adverse events. With ample evidence of RM's strong clinical benefits, studies have also addressed safety issues. The TRUST study examined whether or not RM with automatic, daily surveillance is safe and effective for ICD follow-up over one year. TRUST researchers found no difference in the number of adverse events observed between the Home Monitoring and conventional groups, supporting RM's safety claims. The COMPAS trial corroborated these safety findings.

Early Forays in Remote Monitoring

Biotronik spurred remote monitoring innovation with market-leading technology, manufacturing, and a deep commitment to clinical trials. In 2001, Biotronik was the first device maker to receive FDA approval for wireless Home Monitoring, and its RM system is the only one used in the U.S. with an FDA-approved claim that information from its system may be used as a replacement for device interrogation during routine, in-office, follow-up visits. In addition, Biotronik's Home Monitoring System is the only one in the U.S. that the FDA has approved the claim that it has shown to extend the time between scheduled, in-office follow-up visits.

In contrast to RM systems that require patients to perform initial home set-up and thereafter daily engagement to activate transmission from the device to the monitoring system, Biotronik's system requires simply that a patient plug in the monitor. Engineered with patient compliance in mind, patient compliance with daily transmission of patient information with the Biotronik Home Monitoring system exceeds 90%, making it significantly more effective than in-office monitoring ($p < 0.001$).[24] As a global company, Biotronik realized that the lack of international standards for phone technology would inhibit adoption and compliance. Thus, Biotronik built their technology on a cellular system, in anticipation of the widespread proliferation of cellular technology and infrastructure. To ensure that cellular technology would not excessively shorten battery life, Biotronik collaborated with an Israeli company, founded by former military specialists, to develop a cellular network with low energy demands. Also, if needed, landlines are available in the U.S. and Japan. This cellular capability stands ready to support patients in many arenas including rural populations, remote and telemedicine patients, and traveling and international populations. William Bailey, M.D., who practices in Louisiana, has deployed remote monitoring with populations far and wide since its inception. Dr. Bailey states, "We have people as far away as 200 miles we follow. I can follow anyone in the world with a GSM capable unit. We have had people go to Sri Lanka, the Caribbean, Hawaii, Japan, and travel cross country in a motor home. I have tracked patients while at a conference in

[23] *ALTITUDE study*

[24] *ALTITUDE study*

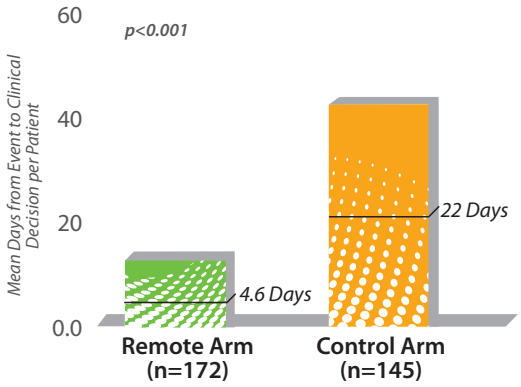
Tokyo and while on a beach in Florida. They know we are there to provide care—where we provide that care from and the patient's location have been diminished as barriers."

Conclusion

Today, pacemakers and ICDs are common parlance in the lexicon of managing arrhythmias with the goal of detecting silent arrhythmias and cardiac events much more quickly so that more immediate action can be taken. The RM field has produced a large body of research to demonstrate RM's safety and clinical benefits—so much so that the Heart Rhythm Society backs RM's use. In addition, the FDA has issued an exclusive claim to BIOTRONIK Home Monitoring® as the only remote monitoring system approved to replace device interrogation during in-office follow-up visits. More schedule openings will be "what the doctor ordered" when the rising incidence of CVD in an aging U.S. population, along with a projected physician shortage and impending changes in Medicare and private payment systems, increase demand and exacerbate barriers to accessing care.

Fortunately, physicians who have used RM for the past decade have solved thorny staffing and workflow issues leading to the question of how anyone can thrive without RM—a technology solution that has proven itself repeatedly. The traditional model has served patients and physicians well, but the inevitable intersection between growing patient populations, payment reform, and the proven impact of RM provide the impetus to supplant tradition. Today, practices are facing new forces including the burgeoning of EHRs and their integration with RM systems, unified user interfaces, and the ability of patients to access their own information through portals. Colin Movsowitz, M.D., of the Cardiology Consultants of Philadelphia, P.C.,

Distribution of Time From Clinical Event Decision per Patient



Source: CONNECT Study

notes, "Remote monitoring is the future of the EP. We are not just going to insert devices. We need to be integrally involved in their follow-up. Mastering the workflow to facilitate the data from the device to the internet, mine it, and ultimately put it into the context of the EMR for better decisions—that is the holy grail."

About the Authors:

Don McDaniel, Chris DeMarco, Ph.D. and Dan D'Orazio are executives with Sage Growth Partners (SGP), a health care strategy and technology firm. SGP provides consulting, technology and sourcing solutions to growth-minded heath care organizations, including providers, insurers, technology, device and analytics firms, and various industry and specialty groups. McDaniel and D'Orazio are also members of the Professional Faculty of Carey Business School, Johns Hopkins University. Dr. DeMarco holds a Ph.D. from the Maxwell School of Citizenship and Public Affairs at Syracuse University and an MBA in Business Medicine from Carey Business School at The John Hopkins University.