AMERICAN COLLEGE of CARDIOLOGY

REMOTE PATIENT MANAGEMENT

WORKBOOK

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INTRODUCTION

Cardiology has been a field of early adoption of technology for many years with the goal of improving patient experience and outcomes, and digital devices are no exception to this early adoption mentality. Cardiologists are increasingly interested in exploring digital devices and wearable technology for remotely following chronic cardiovascular diseases such as heart failure (HF), coronary artery disease (CAD), vascular disease, and atrial fibrillation (AFib).

COVID-19 highlighted the need to limit in-person office visits in order to reduce viral exposure stimulating innovative strategies for evaluating patients through telemedicine increased exponentially in 2020. Along with the development of wearable and other digital devices that examine and assess patients from outside traditional clinical settings, sophisticated computer platforms allowing real-time measurement of data trends have increased dramatically. These data, collected away from a clinic or hospital, are considered forms of remote patient management (RPM).

Clinicians have undoubtedly been approached by a myriad of companies with promises of a "no hassle" RPM solution that will create significant income and improve patient care for their practice. On the other hand, with more RPM consumer products available on the market, such as smart watches and other wearables, patients nowadays ask their clinicians about validity and clinical importance of their wearable data - especially if they are experiencing relevant symptoms.

To date, many consumer products have been granted Food and Drug Administration (FDA) clearance, largely based on their low risk, but have not gone through formal FDA approval and extensive testing processes.[1] As a result, these devices significantly differ in diagnostic accuracy and often have a discrepancy in sensitivity and specificity between what the manufacturers claim and what clinicians see in a real world experience.[2]

In a large survey of electrophysiologists, most (53%) wanted their professional societies to provide guidance on the optimal use of direct-to-consumer devices before recommending them for AFib detection.[3] Those who did not recommend patient use of a digital device had concerns about their accuracy (30%), clinical utility of results (23%), and integration into electronic health records (EHR) (20%).

Another survey of cardiologists, led by the American College of Cardiology (ACC), found that payment model/billing (40%), clinician buy-in (38%), patient costs/lack of reimbursement (36%), and published evidence of improved outcomes (35%) were the top barriers to implementing RPM use in their practices. The majority of cardiologists would be more likely to use RPM if the devices were medical-grade (86%), if there was EHR interoperability (86%), if RPM data were more accurate (82%), and if the ACC provided clinical guidance on implementation and best practices.

In this workbook, the work group seeks to guide cardiovascular health care professionals on definition, types, clinical uses, benefits, and limitations of RPM. The work group also aims to help practices determine whether they are ready for RPM utilization and provide considerations about how to set up an RPM program.

DEFINITION OF RPM

Remote patient management (RPM) is defined as **recording, saving, transmitting, and interpretation of certain health parameters, continuously or intermittently, outside of a clinical encounter setting.**

The first three components of RPM are performed without a clinician being directly involved, whereas the interpretation can be performed by a clinician alone or augmented by or in collaboration with computerized programs leveraging artificial intelligence (AI). Moreover, with the development of more user-friendly interfaces and applications, more patients may be able to view and react to the RPM data themselves - even before a clinician reviews them.

The data gathered by RPM and interpreted by a clinician and/or patients, will be utilized to guide therapeutic, preventive, and wellness measures that can eventually improve patient outcomes; a practical feature that highlights "management" rather than simply "monitoring" in the RPM definition. The ACC released a scientific statement around consumer wearables and its influence on cardiovascular care, which can be found here.[4]

RPM should be distinguished from telehealth and telemetry. RPM is different than telehealth, which is visiting or communicating with a patient via video or phone calls; but RPM can complement telehealth visits by providing the clinicians with objective data on the patients' health status. RPM is also different than telemetry, which involves a clinician continuously monitoring patient's physiologic metrics, usually at a medical facility or sometimes remotely.

CATEGORIES OF CURRENT RPM TECHNOLOGY

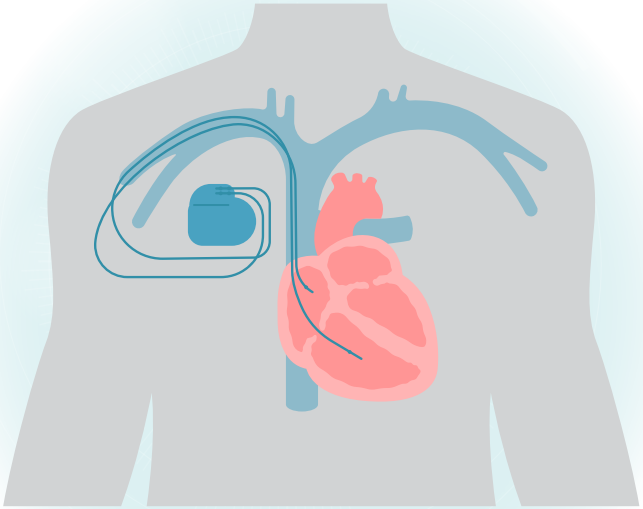
The number of consumer- and medical-grade RPM technologies available to clinicians and patients have been exponentially increasing in the past decade, and there are hundreds of companies continuously developing innovative solutions and devices that are yet to be FDA cleared for patient use. As such, a classification system can help with outlining applications, best clinical use, advantages, and disadvantages of each category of devices, and eventually, deciding on which RPM technology is the best for an individual patient.

Currently available RPM technologies can be categorized as:

Non-Invasive RPM:

1. Wearables: smart watches, step trackers, chest straps.
2. Point of Care Digital Devices: pulse oximeters, smartphones, glucose monitors (e.g., AliveCor KardiaMobile, Eko, etc).
3. Ambulatory Cardiac Monitors: continuous electrocardiogram (ECG) monitor straps, event monitors, patch and button monitors, external loop recorder (ELR) (e.g., Holter, Zio-Patch, LifeVest, etc).
4. Mobile Cardiac Outpatient Telemetry (MCOT): real-time monitoring and analysis by a clinician. As discussed above, telemetry is not considered a RPM solution for the purpose of this document.

Invasive RPM:



1. Subcutaneous Implantables: implantable loop recorders (ILR), chemical sensors (e.g., continuous glucose monitors [CGM]).
2. Intravascular Sensors: pulmonary artery pressure monitors, future structural and vascular devices (e.g., CardioMEMS, etc).
3. Electrophysiology (EP) devices: pacemakers, defibrillators

OBJECTIVES OF RPM

As briefly mentioned above, objectives and applications of RPM have been dramatically expanding over the past few years, and include but are not limited to:

1. Increase access to medical care by monitoring patients in remote or underserved areas.
2. Monitor patients for a longer period of time to increase sensitivity and diagnostic power.
3. Detect disorders that may not be captured during a single clinical visit such as arrhythmias (e.g., high-grade heart block) or masked hypertension. Also, those manifestations that may change during clinical encounters, such as white coat syndrome.
4. Detect disease deterioration or decompensation early enough to inform management strategies that can prevent major cardiovascular events such as hospitalization, heart attack, life-threatening bleeding, intubation, etc.
5. Improve patient's lifestyle by monitoring treatment effectiveness and guiding treatment adjustments.
6. Minimize treatment side effects and complications.
7. Improve perioperative and periprocedural outcomes, discharge timing, and safety.
8. Screen for under-detected health conditions in high-risk populations.

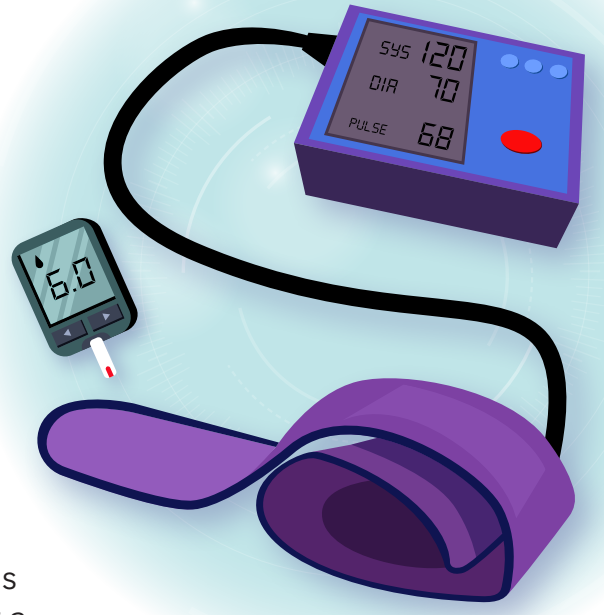
EVIDENCE BASE

The current evidence about the applications, indications, and outcomes of RPM is mostly limited to observational, retrospective, small-size, or short-term prospective studies. Randomized controlled trials (RCT) and large-scale prospective studies have been scarce; however, a number of published studies have been steadily increasing over the past few years, especially after the addition of the ECG monitoring function to the Apple Watch Series 4 in 2018 and the results of the first study showing the smart watch could successfully detect paroxysmal AFib in many cases.

Most of the published studies have been focused on diagnostic capabilities of RPM devices. However, to what extent these diagnostic capabilities will change patient outcomes, such as survival, major cardiovascular events, and quality of life is yet to be determined in longer-term follow-up studies, particularly RCTs. On the other hand, no official guidelines or appropriate use criteria have been released by cardiovascular professional societies thus far. This document is one of the first attempts to fill this gap and aims to assist clinicians and health care practices in adopting and incorporating RPM use into routine patient care.

RPM has been used in various categories of cardiovascular health conditions which will be discussed later in this document; however, the two domains with the largest quantity of studies have been arrhythmia and HF.

LIMITATIONS AND OPPORTUNITIES



Rapid expansion of the RPM field has its own limitations and has brought new unmet needs to our attention, which in turn can be used as opportunities for companies to tackle these barriers. The very first question for both clinicians and patients is how to distinguish "medical-grade" RPM devices from commercially available non-medical-grade or "direct-to-consumer" devices, and what are the acceptable accuracy limits for non-medical-grade RPM technologies? Next, are the federal regulatory agencies like the FDA efficiently updating their evaluation and classification system and are they capable of enforcing these systems?

One of the major gaps in RPM services include the inability to offer one comprehensive solution for multiple different use cases. Finding a one-size-fits-all solution for various acute and chronic medical conditions is impossible at this point. Each company has a single or a few devices that measure a limited set of health metrics, such as specific vital signs.

From a medical practice and financial standpoint, who will pay for the device? Do the insurers cover the device cost? Are there enough and appropriate codes for billing? Is the proposed reimbursement amount sufficient for the clinicians given the amount of time and energy they spend to interpret RPM data? Also, how can clinicians deal with the huge amount of data gathered by the RPM devices individually, i.e., per patient device, and for hundreds of patients of busy practices?

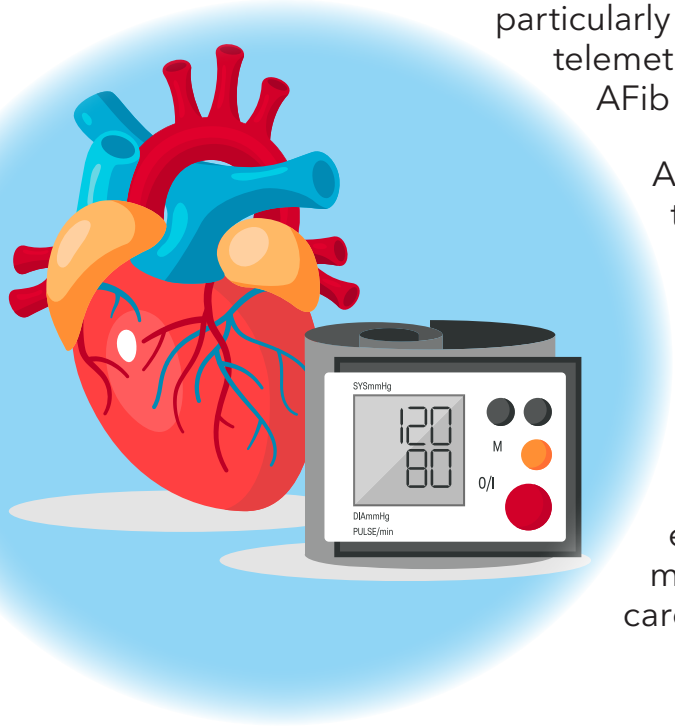
Logistically, most RPM data platforms are not yet incorporated into major EHR systems and reports are often scanned and uploaded manually by the medical staff. In order to enhance adoption by health care clinicians, RPM platforms need to be consolidated into a single dashboard and integrated into EHRs.

CONSIDERATIONS BEFORE STARTING AN RPM PROGRAM

What Conditions Can You Monitor?

Chronic cardiac conditions, like HF where small daily changes of physiologic parameters can signal patient deterioration, are best suited for remote monitoring. Tracking daily blood pressure (BP), weight, oxygen (O_2) saturation and heart rhythm changes often uncover early markers of disease exacerbation or progression. Trends in these vital signs, when measured in real-time, have the potential for identifying patients in need of expedited attention – suggesting a decompensated state and potentially reducing emergency hospitalizations and other more severe outcomes.

Several studies comparing traditional office-based monitoring vs. telemonitoring, which forms a collaboration between patient and clinician, have shown better outcomes and reduced health care costs with telemonitoring.[5-7] In general, when considering RPM, the clinician may think of useful vital signs that could change the treatment algorithm for a patient if the clinician had the information during a regular office visit. For patients with diabetes, CGM devices have provided real-time feedback and have proven to reduce hospitalizations for ketoacidosis if caught early. Additionally, patients with hypertension transmitting regular remote BP monitoring with trend analysis, avoiding erroneously elevated "white coat" BP values, can assist clinicians with identifying better BP control and antihypertensive medication dosing strategies. Patients with high suspicion for arrhythmias, particularly paroxysmal AFib who remain undiagnosed despite telemetry monitoring, could also benefit from continuous AFib detection watches.



As more devices are developed, it makes sense that a tailored approach to monitoring a disease state would come from a single agnostic platform transmitting vital physiologic data from several devices, which collectively increase the clinician's remote monitoring capability and preventive intervention prior to adverse patient outcomes, such as emergency department (ED) visits or hospitalizations, that are costly.[8-10] This approach would also be especially beneficial for clinicians who need to monitor patients with other co-incident established cardiac conditions.

Which Devices Should You Choose?

The number of wearable devices has exploded in the past decade and include medical-grade and commercially available consumer-grade over-the-counter devices. Some are coupled with a proprietary mobile application and others are part of a digital solution with a platform allowing for direct communication with a clinician. Some of these platforms are also integrated into EHR through backend application programming interfaces (APIs) while others are not.

Some devices available directly to consumers are FDA cleared, but most devices available to consumers are not FDA approved or cleared.

Since many popular devices are not FDA cleared or approved, or deemed medical-grade, this section will only focus on FDA cleared or approved devices with accurate and reliable data that have been validated by the FDA regulatory process for digital medical devices.

From a clinician's standpoint, there are several basic features which should be present when considering adoption of physiologic monitoring devices:

1. Is the monitoring device part of a platform that does not rely on a patient's accessibility to WiFi and cellular signal?
2. Is the platform user-friendly? In order for technology to be adopted by consumers, it is recommended to consider patient circumstances and access to technology.
3. Is the platform secure and does it protect patient confidentiality?
4. Does the device include disease-based physiologic measurements for disease monitoring like BP cuffs, weight scales, O_2 sensors for HF or does the digital device measure a single parameter, like sleep pattern etc.? It is recommended to consider monitoring solutions instead of single point systems, each with individual applications.
5. Does the device require a proprietary application without integration into the greater EHR or other devices?
6. Does the device being considered have engagement tools, such as text reminders and symptom checkers, built in? Introducing RPM and chronic care management (CCM) services during routine visits and adopting a device with engagement tools increases the likelihood of achieving the required amount of patient/clinician interaction time and having a successful RPM program.

Do I Need to Hire More Staff for RPM?

Simply answered, no. However, that depends on the volume of patients being followed by RPM services and the number of platforms or applications adopted by the practice or cardiology section. A well-organized team of medical assistants, nurse practitioners (NP) and physician assistants (PA) with direct access to physicians in a practice setting can independently manage several hundred patients safely and with an excellent patient experience. Alternatively, as the number of patients and conditions being monitored increases, consider outsourcing to 3rd party turnkey RPM solution companies (e.g., Medify Health, Cadence, etc) to maintain high quality time-stamped data for billing.

The most important process in a successful RPM program is a specific set of rules for escalation. For instance, just like a Holter or telemetry monitor reviews multiple hours of normal or unactionable data, such as normal sinus rhythm, having a process for a single event of non-sustained ventricular tachycardia which may require immediate clinician review must be in place.

Best practices would include limiting the number of RPM devices with separate platforms or using dashboards to monitor specific disease states or use cases to allow for a more streamlined review of data. For instance, consider following HF patients with a single platform with a BP cuff, weight scale and an O_2 saturation device all connected to a reporting format with an easy-to-read dashboard. In addition, consider setting up practice-based escalation rules for abnormal (red) or normal (green) findings on the site, which will allow for easy patient intervention when necessary. A typical workflow often includes abnormal results first reviewed by the medical assistants, then sent to advanced practice providers (NPs or PAs); then and only if serious, elevated to the physician for review.

An audit of the system should be performed monthly to allow for quality assurance with random patient dashboard reviews. This alleviates the two most common concerns frequently heard from busy cardiologists: first, concern regarding how to manage the large volume of data from RPM and second, the liability of missing important physiologic data. Both are easily handled with the strategies suggested.

What is the Role of AI in Remote Monitoring?

The hope for the collection of large volumes of data is to be able to identify subtle differences that may suggest early warning signs for clinical change. For instance, when considering a clinical hypothesis such as the change in weight as a parameter for worsening HF, weight data in conjunction with tools such as AI algorithms can be used to help identify a clinical change early. However, multiple studies indicate that weight change is likely a late parameter to predict clinical worsening in HF.

By deploying "unsupervised" learning instead, data elements such as weight change can become earlier or more accurate markers for disease expression or exacerbation. For example, in large population studies looking at coronary calcification scores which were previously not linked to maternal outcomes, it was determined they were associated with worsening outcomes in pregnant women, including pre-eclampsia and gestational diabetes.[11] The use of AI on large pooled data from multiple patients could help researchers identify previously unrecognized early signals for worsening cardiovascular disease or risk factors.

These data may assist clinicians to more accurately care for patients using remote monitoring devices.

In addition to vital signs and sensor-based data, social determinants of health and other less obvious predictors may be identified as associated factors of patient outcomes that need to be addressed as we transition from the fee for service to the fee for value health care world.

Is Anyone Willing to Pay for RPM?

The question that inevitably seems to get asked whenever new innovations are introduced in health care is "Who's going to pay for it?" Adoption of novel solutions often precede payment in cardiovascular disease, but often with proof, reimbursement catches up to innovation. RPM, on the other hand, already has approved Current Procedural Terminology (CPT) payment codes from Medicare and commercial payors that have been established since January 2019. In 2020, the Centers for Medicare & Medicaid Services (CMS) doubled down by stating they would pay for several new CPT codes that would not only reimburse clinicians for various types of care they may already be providing in the interest of keeping patients healthier and out of the hospital, but would also open new potential revenue streams to help ease the transition into value-based care.

The Nuts and Bolts of Coding for RPM:

Code 99453 covers the set-up of devices in an episode of care and patient education, while code 99454 covers the cost of device(s) with daily recording(s) or programmed alert(s) and can be billed each 30 days **(Table 1)**.

These CPT codes, in addition to the chronic care management CPT codes, offer reimbursement for providing the patient with a device as defined by the FDA **(Table 2)**. Code 99457 covers the first 20-minutes each calendar month of remote physiologic monitoring treatment management services, of clinical staff/clinician/other qualified health care professional time requiring interactive communication with the patient/caregiver during the month.

CMS began paying for CPT code 99458 on January 1, 2020. The new code covers each additional 20 minutes (each calendar month) spent on treatment management services. Another important change that began January 1, 2020, CPT codes 99457 and 99458 became designated as care management services by CMS, which means they can be furnished under general rather than direct supervision of the billing provider. The net effect is that the clinician or other qualified health care professional supervising the delivery of RPM services does not have to be located at the same site as the clinical staff actually delivering them.

Table 1: **REMOTE PATIENT MANAGEMENT (RPM) CPT CODES** [12]

CPT Code*	Description
99453	Initial setup configuration of devices
99454	Provider supplied device w/ daily monitoring
99457	20 minutes of RPM time
99458	20 additional minutes of RPM time (no limit)

*Multiple codes can be billed in a one-month cycle per device per practice, but each code can only be billed once every month per patient, except 99458. CPT code 99458 is an add-on code of 99457 and can be billed an unlimited number of times each calendar month.

Table 2: **CHRONIC CARE MANAGEMENT (CCM) CPT CODE** [13,14]

CPT Code*	Description
99490	First 20 minutes of clinical staff time
99439	Additional 20 minutes of clinical staff time (add-on to 99490)
99491	First 30 minutes of chronic care management services provided personally by clinician or other qualified health care professional
99437	Additional 30 minutes of chronic care management services by clinician or other qualified health care professional (add-on to 99491)
99487	Complex chronic care management services with the following required elements: • Multiple chronic conditions expected to last at least 12 months • Chronic conditions putting patient at significant risk of death, exacerbation or functional decline • Establishment or substantial revision of comprehensive care plan • Moderate or high complexity medical decision making • 60 minutes of clinical staff time directed by clinician or other qualified health care professional
99489	Additional 30 minutes of clinical staff time (add-on to 99487)

*Multiple codes can be billed in one month cycle per device per practice, but each code can only be billed once every cycle per patient, except 99439 and 99437. CPT codes are 99439 and 99437 are add-on codes and can be billed twice per month. CCM codes can be billed along with RPM codes but to avoid duplicative payment, the time of interaction with the patient cannot be duplicated.

Guidance on How to Document Billing:

Implementing an RPM solution that meets the documentation requirements to allow for billing compliance is key for optimizing reimbursements and maximizing patient adherence **(Figure 1 on next page)**.

It is imperative to have a program operator that can document five aspects of patient interaction to meet all billing requirements:

1. RPM staff must first receive and document the patient's consent to participate in the RPM program. This documentation is filed in the patient's chart in the EHR.
2. The RPM staff must distribute RPM devices that possess the technology to remotely provide real time data to the staff. Cellular data is recommended to minimize the technological capabilities and requirements of the patient. Selecting remote devices with these capabilities allows the RPM administrator to produce reports with daily readings that can be shown for selected periods of time within a dashboard. The documentation of these readings is essential to meet the billing requirements fo code 99454 to demonstrate that at least 15 data points have been recorded over the monthly billing cycle for that patient.
3. All encounters with the patient to discuss the setup and use of the device are documented by the administering staff member during and after the conversation. To bill code 99453, these encounter notes are included in the patient's chart within the practice's EHR.
4. Encounters between the administering staff member and the patient to discuss the readings taken by the patient are conducted each month. These conversations are documented and recorded in the patient's chart in the EMR to provide additional commentary regarding the data and allow for the practice to bill code 99457.
5. The documentation must include a time stamp to reflect the duration of each conversation. The cumulative time spent discussing RPM readings with a patient may result in the practice billing code 99458 if more than 20 minutes were dedicated to the patient within the last month of the billing cycle. Documenting the duration of the conversations between the staff and the patient is important for billing compliance and to ensure the practice is being reimbursed appropriately for the time spent administering the RPM program.

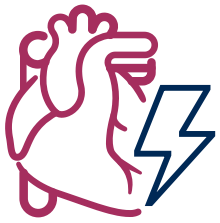
Generating and providing these documents to ensure accurate billing for each enrolled patient is central to maximizing reimbursements by billing the appropriate codes. Having the right operator in place to document all these aspects of an RPM solution not only benefits the practice but enhances the patient's experience.

Figure 1: **Establishing RPM in the Clinic**

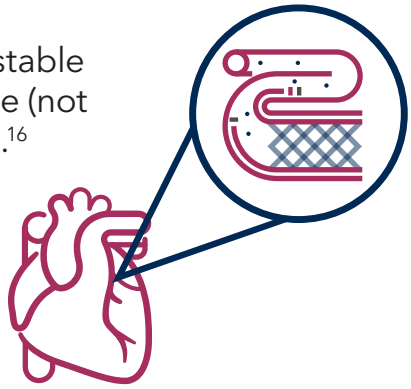
KEY CLINICAL USE CASES

Multiple studies have been conducted that demonstrate the utility of RPM for patients with a variety of cardiovascular conditions. Some of the evidence supporting RPM for specific conditions is briefly summarized in this section; these summaries are only intended to include a brief snippet of published evidence **(Table 3)**. Further, there is often significant overlap across data supporting RPM use for multiple conditions.

Post-MI, Post-PCI, and Post-CABG



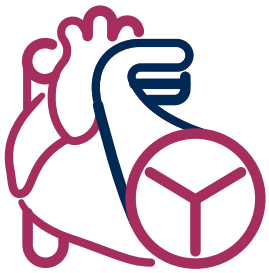
Among patients recovering post-myocardial infarction (MI), one study conducted at 4 hospitals demonstrated that an RPM solution that combined vital sign and activity tracking (relying on a smart watch and wireless BP monitor), along with medication reminders, education, and outpatient care coordination indicated possible lower risk of 30-day readmissions.[15] Although this study was nonrandomized (relying on propensity score matching for a comparator group), it offered initial evidence of a benefit to a multi-pronged strategy relying on RPM to assess and inform interventions.



For patients undergoing percutaneous coronary intervention (PCI) for stable CAD, RPM can be particularly helpful in supporting same-day discharge (not relevant for STEMI or NSTEMI patients, which would fall under post-MI).[16] Although supporting data are limited to mostly observational studies and small RCTs, patients who meet specific criteria may qualify. Same-day discharge has been noted in an ACC Expert Consensus Decision Pathway to demonstrate improved patient satisfaction, hospital flow, reduced costs, with no difference in safety-related patient outcomes.

Selected patients undergoing coronary artery bypass graft (CABG) surgery may also benefit from early discharge and transition to cardiac rehabilitation if there are reliable RPM solutions available. In one study of 2340 post-CABG patients who were followed for a mean of 79 days, 6.1% had potentially life-threatening complications detected early using the telemedicine system with an RPM tool installed on their smartphone. The tool included BP, pulse, pulse oximetry, temperature, blood glucose, and ECG as well as a Holter device. The telemedicine system also sent patients medication reminders and suggested daily activities and diet/nutrition plans through a communication platform, which included videoconference, voice messaging, and text messaging.[17]

Post Valve Surgery or TAVR



One of the most prevalent complications following transcatheter aortic valve replacement (TAVR) is conduction defects, including new-onset left bundle branch block (LBBB) and high degree atrioventricular (AV) block - which may necessitate a pacemaker implantation and therefore increase the patient's morbidity. Most of the time, these conduction defects will develop within the initial 24-hours post-procedure, but delayed occurrences also occur.

TAVR procedures are progressing towards shorter hospital stay (24-48 hours) and, in some cases, same-day discharges; therefore, this information about potential conduction defects and atrial tachyarrhythmias may not be available prior to discharge.

Accordingly, ambulatory ECG monitoring in the early post discharge period (15-30 days) is now emerging as a useful tool to evaluate for delayed arrhythmic events. High-risk patients for post-procedure pacemaker are those with new post-procedure ECG changes or with a baseline right bundle branch block (RBBB). Ambulatory ECG monitoring not only allows for earlier patient discharge, but also facilitates a quicker recovery at home while reducing the risk of hospital-acquired complications.

Furthermore, monitoring of body temperature and BP allows for the assessment of post-procedure infection and hemodynamics. This is particularly beneficial in high-risk patients with history of congestive heart failure (CHF) and chronic kidney disease (CKD).

Additional data in this field are essential. However, the clinical benefits are evident. In the long term, automated notifications to clinicians and the TAVR team regarding changes in arrhythmia, monitoring, and vital signs can be implemented.

An essential consideration is to establish an organized structure for follow-up to ensure that none of the data are lost in the process of appropriate post-procedure monitoring and care.

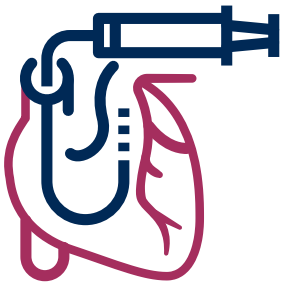
Post Ablation/Post Cardioversion

Atrial fibrillation (AFib) is the most prevalent arrhythmia evaluated and treated by cardiology. While immediate success rates post cardioversion are good, there is a substantial rate of relapse, especially in the first 2 weeks post procedure. Recurrence of AFib is a common cause of hospital readmission. Moreover, health care clinicians' offices and practices are often already booked, posing a challenge in accommodating these patients for follow-up visits within the critical 2-week post-cardioversion window.

Utilization of ambulatory ECG monitoring post-cardioversion allows for timely notification to the cardiology care team if the patient reverts out of sinus rhythm, allowing consideration and implementation of alternate therapies. In high-risk patients with history of CHF, addressing AFib could prevent tachycardia-induced cardiomyopathy and help prevent further deterioration of health and reducing hospital readmission rates.

Similarly, in the 90-day post AFib ablation period, patients are at high risk of recurrence of the arrhythmia and often will necessitate a simple cardioversion. Early detection of AFib in post-ablation patients enables the prompt restoration of sinus rhythm. Especially given that patients are being discharged home quickly post ablation, remote monitoring is important. A recent single- center study showed success in same-day discharge for certain AFib ablation patients.[18]

Early detection of AFib in post ablation patients allows for restoration of sinus rhythm sooner.

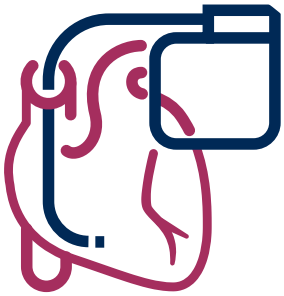


Furthermore, for patients who have undergone successful ablation, ambulatory ECG monitoring proves valuable in assessing whether anticoagulation therapy can be safely discontinued.

This proactive monitoring approach allows for an effective means to optimize patient care in these clinical settings.

Post-CIED

For all patients undergoing cardiac implantable electronic device (CIED) placement with pacemakers and implantable cardioverter-defibrillators (ICDs); remote monitoring is a Class 1, Level of Evidence A consensus recommendation from the Heart Rhythm Society because studies have demonstrated improvements in key clinical outcomes including reduced mortality, reduced ED visits and hospitalizations, and improved patient quality-of- life.[19,20] In fact, two RCTs have shown similar cardiovascular outcomes at 24 months between patients without any routine in-person evaluation compared to patients who were followed through remote monitoring instead.[21,22]



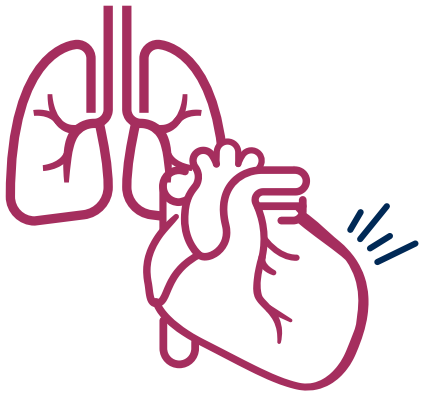
Similarly, ILRs may be placed for multiple indications to detect arrhythmias: palpitations, cryptogenic stroke, AFib management (post-ablation or suspected AFib), syncope, and ventricular tachycardia, among others.

The standard of care is remote monitoring for these devices to enable clinical action, as appropriate, as soon as an arrhythmia is detected. Examples of clinical actions include initiation of anticoagulation after detection of AFib or placement of a pacemaker or ICD depending on rhythm-related findings.

Additionally, without remote monitoring, there may be multiple clinically significant events that cannot fit in the storage of the device and, thus, are overwritten if depending solely on in-person evaluations.

Finally, some ILRs can also be remotely reprogrammed, which allows customization in response to false positives or identified arrhythmias.

HF



Three types of RPM in HF exist including:[23-26]

1) vital sign monitoring (weight, BP, heart rate)

2) lung congestion monitoring (thoracic impedance/ dielectric sensing i.e., the ReDS vest, some ICDs have this built in functionality) and,

3) implantable hemodynamic monitoring (wireless PA pressure sensor such as the CardioMEMS device).

One emerging source of data is voice. Subtle voice changes are emerging as key early indicators of exacerbation. There are multiple indications for utilization of remote monitoring in HF, although patient selection is key and literature for CHF (both HFpEF and HFrEF) is mixed. Key outcomes examined generally include HF-related hospitalizations, HF mortality, and all-cause mortality.

Those outcomes have been examined in a variety of observational, lower quality studies as well as higher quality randomized clinical trials. Results are varied, with some studies revealing improvements in outcomes, specifically reduction in HF hospitalizations and others showing no difference. This variation originates from three sources including:

1) differences in enrolled patient populations (HF is such a heterogeneous disease, especially HFpEF)

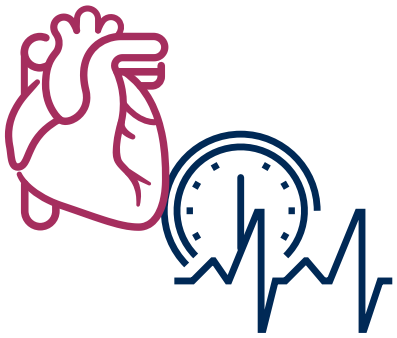
2) differences in the technologies used and,

3) differences in patient and clinician behaviors in using and obtaining data.

Finally, emerging and promising use cases include deployment of RPM technologies to aid in implementation of guideline-directed medical therapy (GDMT)/regimens, up-titration of meds, as well as for hospital at home CHF management.[27] These technologies aim to use data from remote monitoring technologies to inform clinical decision support for clinicians to guide them and make it easier to quickly up-titrate GDMT to goal. More evidence development is needed and is underway in this space.

AFib

RPM can have a role for both patients with known atrial fibrillation (AFib) as well as those who do not have AFib but in whom detection of AFib and subsequent treatment as indicated (e.g., oral anticoagulation) could reduce adverse outcomes. These adverse outcomes that could be reduced include stroke and other thromboembolic events as well as HF. Prior to the availability of current RPM technology, ILRs were generally the most common approach used for long-term monitoring. RPM modalities now available, such as wearable devices, point of care digital devices, and ambulatory cardiac monitors can provide such monitoring without an implanted device.

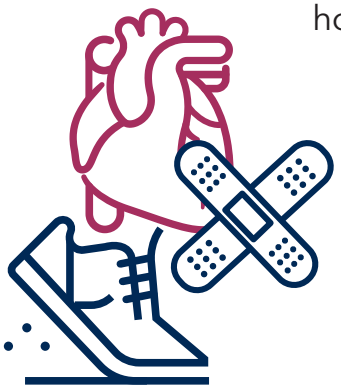


Patients with known AFib may receive RPM to determine overall rate control and to assess the impact of rate control strategies on controlling ventricular rates. Similarly, patients who have received a rhythm control intervention (e.g., ablation, cardioversion, anti-arrhythmic drug therapy) or who developed AFib in a specific setting (e.g., post-operative, ICU stay, post-chemotherapy) may receive RPM to assess for recurrence of atrial tachyarrhythmias, which may inform risk/benefit management decisions such as the need to remain on anticoagulation.

Detection of AFib among patients who do not have known AFib may also inform management in some circumstances, such as among patients who have suffered a cryptogenic stroke in whom detection of AFib may change management with the goal of reducing the risk of recurrent stroke. In the 2021 American Heart Association/American Stroke Association clinical practice guideline for secondary prevention of ischemic stroke, long-term rhythm monitoring to detect intermittent AFib among patients with cryptogenic stroke is a Class 2a recommendation.[28]

Cardiac Rehabilitation

Cardiac rehabilitation (CR) is a Class 1, Level of Evidence A recommendation from cardiology professional societies for multiple conditions, given the robust evidence supporting clinical outcome benefits among patients who engage in cardiac rehabilitation. Delivery of home-based CR programs (HBCR), although put in place long before the pandemic, was transformed during the COVID pandemic due to increased adoption.[29] However, CR remains underutilized in patient populations, both in terms of clinician referral but also patient completion of a full "dose" of CR."



There are many barriers to uptake of CR including lack of referral, inflexible hours of in-person centers, lack of transportation, lack of privacy, and disintermediation from home routine. HBCR has the potential to help surmount those barriers by helping bring CR to the patient. Several CR platforms have arisen through the pandemic, which make robust use of remote monitoring technologies, including BP cuff, HR monitor, scale, and accompanying web-based platform.

Additionally, they incorporate novel engagement techniques based in behavioral science to ensure continued engagement with patients, and have advantage of being able to digitally measure patient engagement, which can engage beyond traditional three months of CR (during phase 4 maintenance period).

Finally, the evidence base has developed to help support outcomes around HBCR, including safety of CR in low-intermediate risk patients.[30,31]

PAD

As with patients post-PCI, for selected patients, RPM could expedite discharge after vascular surgery or endovascular intervention among patients with peripheral arterial disease (PAD). Supervised exercise therapy is an evidence-based recommendation for patients with PAD who have claudication;[32] use of wearable devices could help to ensure that patients are adherent to regimens and gradually increasing their physical activity. In one pilot single-blinded RCT, patients with PAD randomized to receive a mobile intervention that involved patients self-tracking their activity in addition to standard of care increased their mean walking distance, whereas patients in the control arm did not.[33]

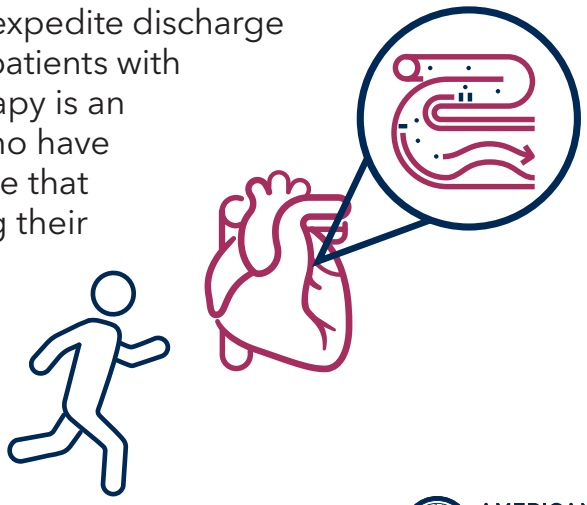


Table 3: **CLINICAL SCENARIOS**

Ideal Patient Population *(and patients for whom RPM may be suboptimal)*	**Data Elements to be Monitored**	**Specific Implementation Considerations**
Post-MI Post-PCI	Blood pressure Heart rate Rhythm Scale Activity (steps and intensity)	Team member to triage *Reimbursement:* • CR – 3 months • Recently updated CPT codes *Other Considerations:* • Post-MI o Safety vs. patients preferred for in-person CR. Consider risk score • Post-PCI o More important for same-day discharge for non-MI patients o Consider monitoring patient-reported outcomes in PCI for stable CAD
Post-CABG Post-operative valve procedures Post-transcatheter valve procedures (TAVR, TMVR)	As above More focus on rhythm (e.g., post-op AF and bradyarrhythmia) Temperature Consider pulse oximetry for post-transcatheter valve procedures (TAVR, TMVR)	• Ability to use RPM devices and support to use these (applies to all patients, maybe more for this group as they have undergone a complex procedure)
Post-ablation or cardioversion for arrhythmias Post-CIED placement Post-ILR placement	Heart rate Rhythm Activity (steps and intensity) Temperature (in addition to what CIED monitors)	• Post-ILR placement: o Staff plan for reprogramming for remotely reprogrammable ILRs

Ideal Patient Population *(and patients for whom RPM may be suboptimal)*	**Data Elements to be Monitored**	**Specific Implementation Considerations**
HF (ACC Stages A-C, exclude Stage D)	Blood pressure Heart rate Rhythm Weight scale Activity (steps and intensity) 6-min walk Max O_2 consumption	Any, particularly recurrent, hospitalizations Patients not responding to out-patient medical therapy Patients being titrated on guideline-directed medical therapy
AFib and supraventri-cular tachycardias	Heart rate Rhythm Activity (steps and intensity)	
CR – tailor based on specific evidence-based indications	Blood pressure Heart rate Blood pressure Pulse ox Rhythm Activity (Steps and intensity) 6-min walk Max O_2 consumption	Components of CR, e.g.,: -Psychological counseling -Behavioral change -Medication adherence -Smoking cessation counseling
PAD	Activity (steps and intensity) Heart rate Foot sensors (monitor temperature) Footwear adherence	

SUMMARY/CONCLUSION

The enthusiasm from digital health companies to develop wearables and sensor devices has been fueled by the enormous investment from venture capital firms over the last several years. The tech companies responsible for the development have followed the traditional motto of making devices and "failing fast" in the consumer market. More recently, clinicians have questioned the validity of device data and demanded higher standards of sensitivity and specificity, including FDA authorization.

Although CMS has approved RPM codes, challenges exist in developing a cogent strategy at the practice level specifically for implementation and device choice. Systems which represent disease specific solutions as opposed to only single vital sign measurement tools will likely be the winners in this race.

Devices which integrate into clinician workflow will truly lead the transition to untether cardiovascular care from traditional bricks and mortar office or hospital visits to a more decentralized monitoring program that holds potential to improve patient outcomes.

APPENDIX I

Abbreviations

AFib = atrial fibrillation
AI = artificial intelligence
APIs = application programming interface
AV = atrioventricular
BP = blood pressure
CABG = coronary artery bypass graft
CAD = coronary artery disease
CCM = chronic care management
CGM = continuous glucose monitor
CIED = cardiac implantable electronic device
CKD = chronic kidney disease
CMS = Centers for Medicare & Medicaid Services
CPT = Current Procedural Terminology
CR = cardiac rehabilitation
ECG = electrocardiogram
EHR = electronic health record
ELR = external loop recorder
EP = electrophysiology
FDA = Food and Drug Administration
GDMT = guideline-directed medical therapy
HBCR = home-based cardiac rehabilitation
HF = heart failure
HFpEF = heart failure with preserved ejection fraction
HFrEF = heart failure with reduced ejection fraction
ICD = implantable cardioverter-defibrillator
ICU = intensive care unit
ILR = implantable loop recorder
LBBB = left bundle branch block
MCOT = mobile cardiac outpatient telemetry
MI = myocardial infarction
NP = nurse practitioner
NSTEMI = non-ST-segment elevation myocardial infarction
O_2 = oxygen
PA = physician assistant
PAD = peripheral arterial disease
PCI = percutaneous coronary intervention
RBBB = right bundle branch block
RCT = randomized controlled trial
RPM = remote patient management
STEMI = ST-segment elevation myocardial infarction
TAVR = transcatheter aortic valve replacement

APPENDIX II

WEARABLE TECHNOLOGY & YOUR HEART HEALTH

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MORE RESEARCH is needed to understand which wearables work and how best to use them.

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- Privacy concerns
- Clinical trials and how you might benefit from them

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- Set goals and reminders
- Increase motivation, accountability
- Track symptoms

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AUTHOR DISCLOSURES

Dr. Das is a consultant for IntelliH, Arineta, Medify, Elucid, Heartbeam, and Boston Scientific. Dr. Adusumalli reports equity in CVS Health Corporation; and is an employee at CVS Health Corporation. Dr. Chitsaz reports equity in Edwards Lifesciences; and is a consultant for Edwards Life Sciences and Egnite Health Inc. Dr. Dhruva reports equity in Apple and Google; and is a consultant for the Institute for Clinical and Economic Review California Technology Assessment Forum.

All other authors have reported that they have no relationships relevant to the contents of this workbook to disclose.

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