American Heart Association.

Using Remote Patient Monitoring Technologies for Better Cardiovascular Disease Outcomes
Guidance

Position

Remote patient monitoring (RPM) can empower patients to better manage their health and participate in their health care.[1] When used by clinicians, RPM can provide a more holistic view of a patient's health over time, increase visibility into a patient's adherence to a treatment, and enable timely intervention before a costly care episode. Clinicians can strengthen their relationships with, and improve the experience of, their patients by using the data sent to them via RPM to develop a personalized care plan and to engage in joint decision-making to foster better outcomes.[2] The American Heart Association supports initiatives that increase access to and incentivize the appropriate design and use of evidence-based remote patient monitoring technologies.

The cost of healthcare has soared to untenable heights. In the United States, federal healthcare spending is rapidly approach 20% of GDP. Furthermore, chronic disease is highly prevalent, accounting for nearly 90% of all healthcare spending in the United States. Additionally, it costs 3.5 times more to treat chronic diseases than it does other conditions, and they account for 80% of all hospital admissions. Additionally, access to care is variable based on socioeconomic issues and environmental factors. In recent years, rapid advancements in healthcare delivery models and low-cost wireless communication have spurred optimism in finding cost-effective, value-enhancing solutions to these issues. Notably, the integration of mobile communications with wearable sensors has facilitated the shift of healthcare services from clinic-centric to patient-centric delivery models such as remote patient monitoring.

Background

RPM is a subset of telehealth that facilitates patient monitoring as well as the timely transfer of patient-generated data from patient to care team and back to the patient. To capture data, RPM can employ a host of wired or wireless peripheral measurement devices such as implantables, biosensors, blood pressure cuffs, glucometers, and pulse oximetry, as well as sensors that collect data passively (e.g., beacons in a home that can transmit data on movement and specific activity/inactivity) and they are most often used in a post-discharge setting or between routine office visits. Some RPM may also allow for real-time video interactions between the patient and provider.

Similarly, RPM can transmit user-entered data, store the data in secure records systems accessible to clinicians or care monitors, flag abnormal readings or responses, and alert clinicians/caregivers to abnormalities via e-mail or text messages. In response to these alerts, clinicians/others can log into the system, review data, follow up with patients, or take other appropriate actions. Some systems have the capacity to connect patients with additional resources such as patient health records (PHRs) or electronic medical records (EMRs), targeted educational materials, interactive self-care tools, medication optimization technologies, and health care providers.

RPM -> Patient-generated Health Data

Most RPM technologies allow for patients to generate their own data. Patient-generated health data (PGHD) are data created, recorded, or gathered by or from patients (or family members or other caregivers) to support their health. This data may include variables related to health history, biometric data, symptoms, and lifestyle information. The recent proliferation of RPM has increased the frequency, amount, and types of PGHD available. These advances in RPM have the potential to allow patients and their caregivers to independently and seamlessly capture and share their health data electronically with clinicians from any location.

Effect of RPM on Cardiovascular Disease

The potential for RPM to reduce the burden of CVD has led to a burgeoning volume of research aimed at evaluating its clinical and economic effectiveness.

Hypertension

Hypertension is a major risk factor for CVD. The age-adjusted prevalence of hypertension in US adults is nearly 35%, which equates to approximately 85 million.[3] By 2035, projections show that over 42% of US adults will be hypertensive, an additional 27 million from current projections.[3] Cost projections for hypertension are similarly daunting, with 2015 figures tallying nearly $70 billion and those for 2035 soaring to over $150 billion.[3] RPM may serve as a vital conduit for improving hypertension control and reducing the economic burden that stems from the costly hospital stays that result from acute events related to hypertension.

Research has shown RPM can reduce systolic blood pressure (SBP) and diastolic blood pressure (DBP) significantly compared to usual care and self-monitoring alone.[4-10] When compared directly to usual care, RPM on the average reduced SBP and DBP.[11-13] In three-way comparisons, though self-monitoring alone may have a positive impact on blood pressure control compared to usual care, the inclusion of RPM can have a more substantive impact on SBP and DBP than does self-monitoring.[6, 7] Additional studies have shown that RPM's positive impact on SBP can increase if the intervention is long-term,[4, 14] and if the intervention includes multiple behavior change techniques.[4, 8-14] However, the results of this research have been largely heterogenous, leading to inconclusive results on the degree to which RPM can positively impact blood pressure control.

Heart Failure

Heart failure (HF) is a chronic and life-threatening condition that places a substantial burden on health care systems worldwide with high rates of hospitalizations, readmissions, and outpatient visits. In the US, it is estimated that nearly 6 million adults currently have HF, a number that is expected to increase by 40% by 2035. Limited research has been published on the potential for RPM to improve clinical outcomes for heart failure patients, and the results have been mixed.

Although recent systematic reviews and meta analyses have shown a positive effect on HF-related admissions and mortality rates and all-cause mortality rates,[15, 16] the bulk of the literature consists of low-quality and inconsistent evidence about the beneficial effects of RPM. More specifically, though better evidence from randomized control trials has been unfavorable, it still stands in contrast to the favorable evidence gained from non-randomized trials. For example, while RPM has been shown to lower the risk of all-cause and HF mortality, and all-cause and HF hospital admissions in cohort analyses and non-randomized trials,[17-22] results from larger-scale, randomized control trials have been inconsistent with some showing no or negative effects,[23-30] and others showing decreases in HF-related admissions, emergency department visits,[31-33]

Future research should focus on understanding the process by which RPM works in terms of improving HF-related outcomes, identify optimal strategies and the duration of follow-up for which it confers benefits, and further investigate whether there is differential effectiveness between chronic HF patient groups and types of RPM technologies.

Atrial Fibrillation

An estimated 2.7 to 6.1 million in the United States have been diagnosed with atrial fibrillation (AF).[34] With the aging of the US population, this number is expected to increase to 7.1 million by 2035.[35] Approximately 2% of people younger than age 65 have AF, while about 9% of people aged 65 years or older have AF.[34] AF is associated with a reduced quality of life and an increased number of adverse outcomes such as stroke, heart failure, increased number of hospitalizations, and mortality.[36-38] Therefore, an early diagnosis of this arrhythmia is crucial in order to adopt the most appropriate treatment strategy.

According to non-randomized trials, RPM has the potential to improve outcomes by enabling accurate and early detection and decreasing all-cause mortality rates and hospitalizations.[17, 18, 39, 40] Recent clinical guidelines strongly recommend the use of RPM for AF detection in both stroke and non-stroke patients.[41] However, RCTs have not conclusively shown such a reduction in hospitalization rates compared to in-office follow-up.[42] RCTs have also not convincingly shown any differences in cardiovascular mortality and all-cause mortality compared to traditional in-office follow-up.[42] However, the relative equivalence in overall clinical outcomes with guidelines-consistent office-based follow-up should provide reassurance to patients and providers in health systems and geographic regions where RPM may be the only option for AF follow-up.[42]

Guidelines for the Appropriate Design and Use of RPM

Usability and Access

The efficacy of RPM is highly dependent on its design and usability. The term usability refers to "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use."[43] RPM often involves the interaction between multiple user groups through a digital system, or with GP at their office. Communication in these use scenarios is usually multimodal, which makes it crucial to know between whom, how and when the information transmission and personal communication occur.

In device development, a user-centered design approach involves end-users in all the stages and helps to understand users' needs and the context of use, which are key elements for the construction of a system framed within a clinical workflow.[44, 45] RPM that does not include a user-centered design can lead to low uptake and adherence rates.[46-48] Further, user errors can result from poor usability.[49, 50] Research has shown that a user-centered design appeals to a wide variance of ages and health and digital literacy levels, and increases patient satisfaction.[51-54] Thus, because ensuring adequate usability is of the essence for the individual patient, effective RPM requires a detailed analysis of end-users' needs to inform system designers.[55]

Guiding Principle: Remote Patient Monitoring technologies should reflect evidence-based, user-centered design principles, human factors science, and best practices.

Guiding Principle: Remote Patient Monitoring technologies should be rigorously evaluated in clinical trials to ensure patient efficacy.

Guiding Principle: Remote Patient Monitoring technologies should address the needs of all patients without disenfranchising financially disadvantaged populations or those with low literacy or low technologic literacy.

Guiding Principle: Remote Patient Monitoring technologies should not create an unnecessary burden on end users.

Guiding Principle: Remote Patient Monitoring technologies should be customizable to users' specific needs.

Guiding Principle: Training and support must be available for all users of Remote Patient Monitoring technologies with a duration of support dependent upon user capabilities.

Interoperability and Integration

Interoperability is defined as "health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and does not constitute information blocking."[56] HIPAA currently allows for protected health information (PHI) (any health-related data that personally identifies a patient) to be shared as long as both the sender and receiver have a relationship with the patient, the information being shared pertains to the healthcare relationship, and the information being shared is necessary for the healthcare being provided.

This is highly dependent on what constitutes a patient's care team. As such, standards governing the flow of health data should allow for a flexible definition of a care team and standards should permit data to be shared across clinicians, lab, hospital, pharmacy and patient regardless of the application being used to share the data. In order to attain a truly interoperable system and to fully realize the benefits of RPM to healthcare systems, achieving the highest level of interoperability is essential.

A further dimension to interoperability is the integration of RPM with the existing clinical workflow. Many RPM technologies, rather than being stand alone, are designed to support delivery of existing clinical services that will already have an established workflow in place. The integration of RPM should be designed in such a way that it doesn't add burden to the clinical workflow. Rather, RPM should enhance the clinical workflow. Therefore, data from RPM must be integrated into healthcare systems, particularly those that use EHRs. This will provide easier and faster access to patient data, protect patient safety, allow for better diagnoses and a higher quality of treatment, and enhance consumer choice.

Guiding Principle: Remote Patient Monitoring technologies must allow the user the ability to access or request any of his/her health information collected, stored and/or transmitted by the device.

Guiding Principle: Data collected by Remote Patient Monitoring technologies should be fully integrated into patient EHRs.

Guiding Principle: Full interoperability must be established between Remote Patient Monitoring technologies and EHRs, which must include the exchange of data from providers to patients and from patients to providers.

Data Accuracy and Patient Safety

The quality of healthcare data impacts every decision made along the patient care lifecycle. Using RPM to make healthcare decisions necessitates the need for RPM technologies to produce accurate data and information integrity. According to WHO, accuracy is defined as the variable of health information quality that is intended to achieve desirable objectives using legitimate means.[57] Data accuracy helps in evaluating health, assess effectiveness of interventions, monitor trends, inform health policy and set priorities.[58] Lack of data accuracy and can cause serious harm to patients and limit the benefits of RPM. [59, 60]

Additionally, intentional and unintentional wrong data entry and the speed at which data is collected can be misleading. Misleading data results in misallocating resources or interventions when needed for the patients.[61] Inaccurate readings, insufficient amount of data, movement and physical activities also contribute to inaccurate data provided through the mHealth devices.[62] Concerns associated with data accuracy and integrity are persistent and can become a risk to patients' safety.[63]

Guiding Principle: Remote Patient Monitoring technologies should be rigorously evaluated in clinical trials to ensure that their usage does not compromise patient safety.

Guiding Principle: Documentation of appropriate patient informed consent for the use of Remote Patient Monitoring technologies must be obtained and maintained and should include provider and patient identification, provider credentials, full disclosure of how the technology will be used, liability and malpractice procedures, and details on data security measures and potential risks to patient privacy.

Guiding Principle: The prescription of Remote Patient Monitoring technologies must be consistent with state scope of practice laws.

Guiding Principle: The use of Remote Patient Monitoring technologies must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care, and positive health outcomes.

Guiding Principle: Remote Patient Monitoring must always deliver accurate data to ensure delivery of quality healthcare and patient safety.

Guiding Principle: To enable providers to make healthcare decisions based on meaningful and useful data, standards must be established to screen, select, and verify data communicated by Remote Patient Monitoring technologies.

Data Privacy

Traditionally, the medical information shared between provider and patient has remained within the confines of a healthcare facility. RPM changes the paradigm by gathering electronic data into a data repository that is remote from the health facility, yet readily accessed and shared with various health care providers involved in a patient's care or can be used for research or educational purposes. With accessibility, however, come challenges to maintaining the privacy of patient health information and potential issues related to liability and reimbursement for RPM-related services.

HIPAA places the burden of securing a patient's health information squarely on physicians and healthcare organizations. Most importantly, loss of patient control over confidential and sensitive health information threatens the confidential communication between doctors and patients. Confidentiality ensures that patients seek out care, and that they are open and honest with their providers. Ultimately impacting all stakeholders in the healthcare ecosystem, patients who fear a loss of control over their private medical information may lose faith in their provider--and in the health care system itself.

Guiding Principle: The use of Remote Patient Monitoring technologies should meet or exceed applicable federal and state legal requirements of medical information privacy, including compliance with the Health Insurance Portability and Accountability Act (HIPAA) and state privacy, confidentiality, security laws.

Guiding Principle: Patients and providers should be educated as to what data are collected through Remote Patient Monitoring technologies, how it will be used, and what other users and entities will have legitimate access to these data.

Guiding Principle: Remote Patient Monitoring technologies should contain patient controlled privacy settings to determine who has access to the data they collect, store, and transmit.

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