



**To:** IEHP- GQ P4P IPA Participants, Medi-Cal PCPs & Medi-Cal IPAs  
**From:** IEHP – Provider Relations  
**Date:** April 2, 2020  
**Subject:** COVID-19 Impact to 2020 Global Quality P4P Program

In support of federal, state, and local recommendations to reduce potential exposure to COVID-19, IEHP has created the following guidance to address Providers’ questions around providing Global Quality P4P services to IEHP Members during this unprecedented time. Please note that IEHP will assess the COVID-19 impact to population targets/goals for the 2020 measurement year and will share those updates at a later time. IEHP’s main goal is to be flexible and relieve burden on our health care system so that healthcare professionals can focus on COVID-19.

IEHP encourages all Providers to adhere to the latest CDC guidelines for patient care and stay connected on the latest updates posted on IEHP’s website:  
[www.iehp.org](http://www.iehp.org) > For Providers > Plan Updates > Coronavirus (COVID-19) Advisory.

Please note: The guidance in the following table does not replace the Provider’s responsibility in clinical decision-making for an individual patient. The decision regarding whether a telehealth visit is clinically appropriate and safe in place of an in-office visit is ultimately at the Provider’s discretion and must be based on the clinical judgement of the Provider. This includes assessing the clinical need for a physical examination or the assessment of vital signs.

GQ P4P Measure Name	COVID-19 Guidance
Comprehensive Diabetes Care - HbA1c Control <8	Delay non-urgent/routine testing at this time.
Controlling Blood Pressure	Remote patient monitoring allowed. Remote patient monitoring is the collection of physiologic data (for example, blood pressure) digitally stored and/or transmitted by the patient or caregiver or both. For more information on Remote Patient Monitoring for blood pressure see the American Heart Association article attached. Use CPT code: 99091 <u>in addition</u> to BP results codes noted in Program Guide for measure.

GQ P4P Measure Name	COVID-19 Guidance
Post Discharge Follow Up	Telehealth visits may be used to meet this measure if determined by the Provider to be clinically appropriate. Bill using Place of Service code: 02 and Modifier 95 <u>in addition</u> to codes noted in Program Guide for measure.
Screening for Clinical Depression in Primary Care	Telehealth visits may be used to meet this measure if determined by the Provider to be clinically appropriate. Bill using Place of Service code: 02 and Modifier 95 <u>in addition</u> to codes noted in Program Guide for measure
Breast Cancer Screening	Delay non-urgent/routine testing at this time. Schedule for a later date
Cervical Cancer Screening	Delay non-urgent/routine testing at this time. Schedule for a later date
Chlamydia Screening in Women	Delay non-urgent/routine testing at this time. Schedule for a later date
Timeliness of Prenatal Care	Follow latest ACOG recommendations: <a href="https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-obstetrics">https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-obstetrics</a> . Patient–physician discussion regarding a plan for alternate prenatal care in the setting of the COVID-19 pandemic should be documented in the medical record. Patient-level determinations should be made
Adolescent Well-Care Visits Well-Child Visits 3-6 Years of Life	Telehealth visits may NOT be used to meet this measure. Reschedule well-visits for those in middle childhood and adolescence to a later date. Keep a list of rescheduled appointments to facilitate patient recall later
Childhood Immunizations - Combo 10	<b>Prioritized measure. See DHCS recommendations for office practices/protocols to keep 0-24-month-old children up to date on immunization schedule. See attached document from California Vaccines for Children (VFC) program on latest recommendations.</b>
Immunizations for Adolescents - Combo 2	Telehealth visits may NOT be used to meet this measure. Delay offering non-urgent/routine services at this time
Well-Child Visits (all age groups) First 15 Months of Life	Telehealth visits may NOT be used to meet this measure. Delay offering non-urgent/routine services at this time
Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents – all sub measures	Telehealth visits may be used to meet this measure if determined by the Provider to be clinically appropriate. Bill using Place of Service code: 02 and Modifier 95 <u>in addition</u> to codes noted in Program Guide for measure

GQ P4P Measure Name	COVID-19 Guidance
Initial Health Assessment	<p>Telehealth visits may be used to meet this measure if determined by the Provider to be clinically appropriate. Bill using Place of Service code: 02 and Modifier 95 <u>in addition</u> to codes noted in Program Guide for measure. Please note that the physical exam portion of the IHA will <u>not</u> be required for IHA visits conducted during this period of time where social contact is being restricted. The IHA must still include all of the following components:</p> <ul style="list-style-type: none"> <li>- Complete mental health exam</li> <li>- Comprehensive medical history including a complete social history</li> <li>- Individual Health Education Behavior Assessment (IHEBA)</li> <li>- <b>A plan for provision of appropriate preventive services must be documented in the medical record</b></li> <li>- <b>A plan for a follow-up comprehensive physical exam at a later time must be documented in the medical record</b></li> </ul>
After-Hours Availability Call measures	Survey Calls will be made at a later date. All surveys on hold due to COVID-19
Appointment Availability Call measures	Survey Calls will be made at a later date. All surveys on hold due to COVID-19
Member Satisfaction Survey measures	Survey Calls will be made at a later date. All surveys on hold due to COVID-19

As a reminder, all communications sent by IEHP can also be found on our Provider portal at: [www.iehp.org](http://www.iehp.org) > For Providers > Plan Updates > Correspondence **or** [www.iehp.org](http://www.iehp.org) > For Providers > Plan Updates > Coronavirus (COVID-19) Advisory.

If you have any questions, please do not hesitate to contact the IEHP Provider Relations Team at (909) 890-2054 or email IEHP's Quality Department at [QualityPrograms@iehp.org](mailto:QualityPrograms@iehp.org).

Enclosures: Routine Childhood Immunizations during COVID-19 Pandemic  
 Using Remote Patient Monitoring Technologies for Better Cardiovascular Disease Outcomes Guidance



SONIA Y. ANGELL, MD, MPH  
State Public Health Officer & Director

State of California—Health and Human Services Agency  
California Department of Public Health



GAVIN NEWSOM  
Governor

March 27, 2020

IZB-FY-19-20-11

TO: California Vaccines for Children (VFC) Providers

FROM: Sarah Royce, MD, MPH, Chief   
Center for Infectious Diseases  
Division of Communicable Disease Control, Immunization Branch

SUBJECT: Routine Childhood Immunizations during COVID-19 Pandemic



**Key takeaways from this letter include:**

- Maintaining childhood immunizations during pandemic:
  - ✓ Prioritization of immunizations for children 0-24 months
  - ✓ Strategies for modifying clinic operations
  - ✓ Approval for Alternate/Temporary VFC locations
  - ✓ AAP and CDC resources

**BACKGROUND**

The COVID-19 pandemic continues to affect communities across the United States. Maintaining childhood immunizations during this period may not be feasible due to current impact of COVID-19 community transmission, staffing, and parental concerns. However, the American Academy of Pediatrics (AAP) and the Centers for Disease Control and Prevention (CDC) have issued the following recommendations for prioritizing childhood immunizations during this pandemic period, and strategies which can be implemented across pediatric practices to slow the spread of disease.

**PRIORITIZING IMMUNIZATIONS OF YOUNG CHILDREN**

Because of personal, practice, or community circumstances related to COVID-19, some providers may not be able to provide well child visits, including provision of immunizations, for all patients in their practice.

- If a practice can provide only limited well child visits, healthcare providers are encouraged to **prioritize newborn care and vaccination of infants and young children (through 24 months of age) when possible.**
- Reschedule well visits for those in middle childhood and adolescence to a later date. Keep a list of rescheduled appointments to facilitate patient recall later on.



## **STRATEGIES TO MODIFY CLINIC STRUCTURE FOR ENSURING DELIVERY OF PRIORITIZED CARE**

Ensuring the delivery of newborn and well-child care, including childhood immunization, requires different strategies. The following are strategies recommended by AAP:

- Separating well visits from sick visits. Scheduling well visits in the morning and sick visits in the afternoon.
- Separating patients spatially, such as by placing patients with sick visits in different areas of the clinic.
- Clinics with multiple practice sites may consider using one office location to see all well visits (staffed by those in higher risk categories) and another location for sick visits.
- Collaborating with providers in the community to identify separate locations for holding well visits for children.
- If available, pediatricians are encouraged to increase their capacity to deliver telehealth and utilize “drive through” dedicated COVID-19 testing sites.

**IMPORTANT:** Local Health Departments (LHDs) immunization clinics may be impacted by current COVID-19 response activities led by public health staff. As a result, some may have also reduced or closed immunization clinics and may not be able to immunize patients at this time. Please check with your LHDs before any referrals.

## **TEMPORARY RELOCATION OF VFC PARTICIPATING LOCATION**

In order to support practices with the implementation strategies to prioritize immunizations of young children, the VFC program will expedite the enrollment of temporary alternative sites, as well as grant approval of the relocation of immunization services for an enrolled location. Guidance can be found at <https://eziz.org/vfc/enrollment/>.

## **CDC AND AAP GUIDANCE**

- AAP: <https://services.aap.org/en/pages/covid-19-clinical-guidance-q-a/>
- CDC: <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html>.

## **QUESTIONS?**

If you have any questions, please call the VFC Customer Service Center at 877-243-8832 (877-2GET-VFC).



## 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> By 2035, projections show that over 42% of US adults will be hypertensive, an additional 27 million from current projections.<sup>3</sup> Cost projections for hypertension are similarly daunting, with 2015 figures tallying nearly \$70 billion and those for 2035 soaring to over \$150 billion.<sup>3</sup> 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.<sup>4-10</sup> When compared directly to usual care, RPM on the average reduced SBP and DBP.<sup>11-13</sup> 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.<sup>6,7</sup> Additional studies have shown that RPM's positive impact on SBP can increase if the intervention is long-term,<sup>4,14</sup> and if the intervention includes multiple behavior change techniques.<sup>4,8-14</sup> 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,<sup>15,16</sup> 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,<sup>17-22</sup> results from larger-scale, randomized control trials have been inconsistent with some showing no or negative effects,<sup>23-30</sup> and others showing decreases in HF-related admissions, emergency department visits,<sup>31-33</sup>

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).<sup>34</sup> With the aging of the US population, this number is expected to increase to 7.1 million by 2035.<sup>35</sup> Approximately 2% of people younger than age 65 have AF, while about 9% of people aged 65 years or older have AF.<sup>34</sup> AF is associated with a reduced quality of life and an

**Policy Guidance:** Using Remote Patient Monitoring Technologies for Better Cardiovascular Disease Outcomes

increased number of adverse outcomes such as stroke, heart failure, increased number of hospitalizations, and mortality.<sup>36-38</sup> 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.<sup>17, 18, 39, 40</sup> Recent clinical guidelines strongly recommend the use of RPM for AF detection in both stroke and non-stroke patients.<sup>41</sup> However, RCTs have not conclusively shown such a reduction in hospitalization rates compared to in-office follow-up.<sup>42</sup> RCTs have also not convincingly shown any differences in cardiovascular mortality and all-cause mortality compared to traditional in-office follow-up.<sup>42</sup> 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.<sup>42</sup>

***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.”<sup>43</sup> 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.<sup>44, 45</sup> RPM that does not include a user-centered design can lead to low uptake and adherence rates.<sup>46-48</sup> Further, user errors can result from poor usability.<sup>49, 50</sup> 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.<sup>51-54</sup> 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.<sup>55</sup>

**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.”<sup>56</sup> 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.<sup>57</sup> Data accuracy helps in evaluating health, assess effectiveness of interventions, monitor trends, inform health policy and set priorities.<sup>58</sup> Lack of data accuracy and can cause serious harm to patients and limit the benefits of RPM.<sup>59, 60</sup>

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.<sup>61</sup> Inaccurate readings, insufficient amount of data, movement and physical activities also contribute to inaccurate data provided through the mHealth devices.<sup>62</sup> Concerns associated with data accuracy and integrity are persistent and can become a risk to patients’ safety.<sup>63</sup>

**Policy Guidance:** Using Remote Patient Monitoring Technologies for Better Cardiovascular Disease Outcomes

**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.**

## Policy Guidance: Using Remote Patient Monitoring Technologies for Better Cardiovascular Disease Outcomes

1. Kvedar J, Coye MJ and Everett W. Connected health: a review of technologies and strategies to improve patient care with telemedicine and telehealth. *Health Aff (Millwood)*. 2014;33:194-9.
2. HIMSS. The Value of Patient-Generated Health Data (PGHD). 2014;2018.
3. Nelson S, Whitsel L, Khavjou O, Phelps D and Leib A. Projections of cardiovascular disease prevalence and costs. 2016.
4. Liu S, Dunford SD, Leung YW, Brooks D, Thomas SG, Eysenbach G and Nolan RP. Reducing blood pressure with Internet-based interventions: a meta-analysis. *Can J Cardiol*. 2013;29:613-21.
5. Burke LE, Ma J, Azar KM, Bennett GG, Peterson ED, Zheng Y, Riley W, Stephens J, Shah SH, Suffoletto B, Turan TN, Spring B, Steinberger J, Quinn CC, American Heart Association Publications Committee of the Council on E, Prevention BCCotCoCHCoC, Stroke Nursing CoFG, Translational Biology CoQoC, Outcomes R and Stroke C. Current Science on Consumer Use of Mobile Health for Cardiovascular Disease Prevention: A Scientific Statement From the American Heart Association. *Circulation*. 2015;132:1157-213.
6. Agarwal R, Bills JE, Hecht TJ and Light RP. Role of home blood pressure monitoring in overcoming therapeutic inertia and improving hypertension control: a systematic review and meta-analysis. *Hypertension*. 2011;57:29-38.
7. Tucker KL, Sheppard JP, Stevens R, Bosworth HB, Bove A, Bray EP, Earle K, George J, Godwin M and Green BB. Self-monitoring of blood pressure in hypertension: A systematic review and individual patient data meta-analysis. *PLoS Medicine*. 2017;14:e1002389.
8. Logan AG, Irvine MJ, McIsaac WJ, Tisler A, Rossos PG, Easty A, Feig DS and Cafazzo JA. Effect of home blood pressure telemonitoring with self-care support on uncontrolled systolic hypertension in diabetics. *Hypertension*. 2012;60:51-7.
9. Kiselev AR, Gridnev VI, Shvartz VA, Posnenkova OM and Dovgalevsky PY. Active ambulatory care management supported by short message services and mobile phone technology in patients with arterial hypertension. *J Am Soc Hypertens*. 2012;6:346-55.
10. Morikawa N, Yamasue K, Tochikubo O and Mizushima S. Effect of salt reduction intervention program using an electronic salt sensor and cellular phone on blood pressure among hypertensive workers. *Clin Exp Hypertens*. 2011;33:216-22.
11. Omboni S, Gazzola T, Carabelli G and Parati G. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: meta-analysis of randomized controlled studies. *J Hypertens*. 2013;31:455-67; discussion 467-8.
12. Verberk WJ, Kessels AG and Thien T. Telecare is a valuable tool for hypertension management, a systematic review and meta-analysis. *Blood Press Monit*. 2011;16:149-55.
13. Mills KT, Obst KM, Shen W, Molina S, Zhang H-J, He H, Cooper LA and He J. Comparative Effectiveness of Implementation Strategies for Blood Pressure Control in Hypertensive Patients: A Systematic Review and Meta-analysis. *Annals of internal medicine*. 2018;168:110-120.
14. Margolis KL, Asche SE, Bergdall AR, Dehmer SP, Groen SE, Kadrmas HM, Kerby TJ, Klotzle KJ, Maciosek MV, Michels RD, O'Connor PJ, Pritchard RA, Sekenski JL, Sperl-Hillen JM and Trower NK. Effect of home blood pressure telemonitoring and pharmacist management on blood pressure control: a cluster randomized clinical trial. *JAMA*. 2013;310:46-56.
15. Bashi N, Karunanithi M, Fatehi F, Ding H and Walters D. Remote Monitoring of Patients With Heart Failure: An Overview of Systematic Reviews. *J Med Internet Res*. 2017;19:e18.
16. Kitsiou S, Pare G and Jaana M. Effects of home telemonitoring interventions on patients with chronic heart failure: an overview of systematic reviews. *J Med Internet Res*. 2015;17:e63.
17. Saxon LA, Hayes DL, Gilliam FR, Heidenreich PA, Day J, Seth M, Meyer TE, Jones PW and Boehmer JP. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTIUDE survival study. *Circulation*. 2010;122:2359-67.
18. Varma N, Piccini JP, Snell J, Fischer A, Dalal N and Mittal S. The Relationship Between Level of Adherence to Automatic Wireless Remote Monitoring and Survival in Pacemaker and Defibrillator Patients. *J Am Coll Cardiol*. 2015;65:2601-2610.
19. De Simone A, Leoni L, Luzzi M, Amellone C, Stabile G, La Rocca V, Capucci A, D'Onofrio A, Ammendola E, Accardi F, Valsecchi S and Buja G. Remote monitoring improves outcome after ICD implantation: the clinical efficacy in the management of heart failure (EFFECT) study. *Europace*. 2015;17:1267-75.
20. Portugal G, Cunha P, Valente B, Feliciano J, Lousinha A, Alves S, Braz M, Pimenta R, Delgado AS, Oliveira M and Ferreira RC. Influence of remote monitoring on long-term cardiovascular outcomes after cardioverter-defibrillator implantation. *Int J Cardiol*. 2016;222:764-768.
21. Kurek A, Tajstra M, Gadula-Gacek E, Buchta P, Skrzypek M, Pyka L, Wasiak M, Swietlinska M, Hawranek M, Polonski L, Gasior M and Kosiuk J. Impact of Remote Monitoring on Long-Term Prognosis in Heart Failure Patients in a Real-World Cohort: Results From All-Comers COMMIT-HF Trial. *J Cardiovasc Electrophysiol*. 2017;28:425-431.
22. Piccini JP, Mittal S, Snell J, Prillinger JB, Dalal N and Varma N. Impact of remote monitoring on clinical events and associated health care utilization: A nationwide assessment. *Heart Rhythm*. 2016;13:2279-2286.
23. Chaudhry SI, Mattera JA, Curtis JP, Spertus JA, Herrin J, Lin Z, Phillips CO, Hodshon BV, Cooper LS and Krumholz HM. Telemonitoring in patients with heart failure. *N Engl J Med*. 2010;363:2301-9.
24. Koehler F, Winkler S, Schieber M, Sechtem U, Stangl K, Bohm M, Boll H, Baumann G, Honold M, Koehler K, Gelbrich G, Kirwan BA, Anker SD and Telemedical Interventional Monitoring in Heart Failure I. Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: the telemedical interventional monitoring in heart failure study. *Circulation*. 2011;123:1873-80.
25. Konstam V, Gregory D, Chen J, Weintraub A, Patel A, Levine D, Venesy D, Perry K, Delano C and Konstam MA. Health-related quality of life in a multicenter randomized controlled comparison of telephonic disease management and automated home monitoring in patients recently hospitalized with heart failure: SPAN-CHF II trial. *J Card Fail*. 2011;17:151-7.
26. Ong MK, Romano PS, Edgington S, Aronow HU, Auerbach AD, Black JT, De Marco T, Escarce JJ, Evangelista LS, Hanna B, Ganiats TG, Greenberg BH, Greenfield S, Kaplan SH, Kimchi A, Lombardo D, Mangione CM, Sadeghi B, Sadeghi B, Sarrafzadeh M, Tong K, Fonarow GC and Better Effectiveness After Transition-Heart Failure Research G. Effectiveness of Remote Patient Monitoring After Discharge of Hospitalized Patients With Heart Failure: The Better Effectiveness After Transition -- Heart Failure (BEAT-HF) Randomized Clinical Trial. *JAMA Intern Med*. 2016;176:310-8.
27. Boriani G, Da Costa A, Quesada A, Ricci RP, Favale S, Boscolo G, Clementy N, Amori V, Mangoni di SSL, Burri H and Investigators M-CS. Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multicentre randomized controlled trial. *Eur J Heart Fail*. 2017;19:416-425.
28. Luthje L, Vollmann D, Seegers J, Sohns C, Hasenfuss G and Zabel M. A randomized study of remote monitoring and fluid monitoring for the management of patients with implanted cardiac arrhythmia devices. *Europace*. 2015;17:1276-81.
29. Bohm M, Drexler H, Oswald H, Rybak K, Bosch R, Butter C, Klein G, Gerritse B, Monteiro J, Israel C, Bimmel D, Kaab S, Huegl B, Brachmann J and OptiLink HFSI. Fluid status telemedicine alerts for heart failure: a randomized controlled trial. *Eur Heart J*. 2016;37:3154-3163.
30. van Veldhuisen DJ, Braunschweig F, Conraads V, Ford I, Cowie MR, Jondeau G, Kautzner J, Aguilera RM, Lunati M, Yu CM, Gerritse B, Borggrefe M and Investigators D-H. Intrathoracic impedance monitoring, audible patient alerts, and outcome in patients with heart failure. *Circulation*. 2011;124:1719-26.
31. Abraham WT, Adamson PB, Bourge OC, Aaron MF, Costanzo MR, Stevenson LW, Strickland W, Neelagaru S, Raval N, Krueger S, Weiner S, Shavelle D, Jeffries B, Yadav JS and Group CTS. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. *Lancet*. 2011;377:658-66.
32. Landolina M, Perego GB, Lunati M, Curnis A, Guenzati G, Vicentini A, Parati G, Borghi G, Zanaboni P, Valsecchi S and Marzegalli M. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. *Circulation*. 2012;125:2985-92.
33. Hindricks G, Taborsky M, Glikson M, Heinrich U, Schumacher B, Katz A, Brachmann J, Lewalter T, Goette A, Block M, Kautzner J, Sack S, Husser D, Piorkowski C, Sogaard P and group\* I-Ts. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. *Lancet*. 2014;384:583-590.
34. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC, Jr., Conti JB, Ellinor PT, Ezekowitz MD, Field ME, Murray KT, Sacco RL, Stevenson WG, Tchou PJ, Tracy CM, Yancy CW and Members AATF. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the Heart Rhythm Society. *Circulation*. 2014;130:2071-104.
35. Heidenreich PA, Trognon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, Finkelstein EA, Hong Y, Johnston SC, Khera A, Lloyd-Jones DM, Nelson SA, Nichol G, Orenstein D, Wilson PW, Woo YJ, American Heart Association Advocacy Coordinating C, Stroke C, Council on Cardiovascular R, Intervention, Council on Clinical C, Council on E, Prevention, Council on A, Thrombosis, Vascular B, Council on C, Critical C, Perioperative, Resuscitation, Council on Cardiovascular N, Council on the Kidney in Cardiovascular D, Council on Cardiovascular S, Anesthesia, Interdisciplinary Council on Quality of C and Outcomes R. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. *Circulation*. 2011;123:933-44.

## Policy Guidance: Using Remote Patient Monitoring Technologies for Better Cardiovascular Disease Outcomes

36. Camm AJ, Kirchhof P, Lip GY, Schotten U, Savelieva I, Ernst S, Van Gelder IC, Al-Attar N, Hindricks G, Prendergast B, Heidbuchel H, Alfieri O, Angelini A, Atar D, Colonna P, De Caterina R, De Sutter J, Goette A, Gorenek B, Heldal M, Hohloser SH, Kolh P, Le Heuzey JY, Ponikowski P, Rutten FH and Guidelines ESCCFP. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). *Europace*. 2010;12:1360-420.
37. Stewart S, Hart CL, Hole DJ and McMurray JJ. A population-based study of the long-term risks associated with atrial fibrillation: 20-year follow-up of the Renfrew/Paisley study. *Am J Med*. 2002;113:359-64.
38. Wattigney WA, Mensah GA and Croft JB. Increased atrial fibrillation mortality: United States, 1980-1998. *Am J Epidemiol*. 2002;155:819-26.
39. Akar JG. Use of remote monitoring is associated with improved outcomes among patients with implantable cardioverter defibrillators. . Paper presented at: Heart Rhythm Society Annual Scientific Sessions; 2014; San Francisco, CA.
40. De Simone A, Leoni L, Luzi M, Amellone C, Stabile G, La Rocca V, Capucci A, D'onofrio A, Ammendola E and Accardi F. Remote monitoring improves outcome after ICD implantation: the clinical efficacy in the management of heart failure (EFFECT) study. *Ep Europace*. 2015;17:1267-1275.
41. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC, Jr., Ellinor PT, Ezekowitz MD, Field ME, Furie KL, Heidenreich PA, Murray KT, Shea JB, Tracy CM and Yancy CW. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation. *Circulation*. 2019;CIR0000000000000665.
42. Parthiban N, Esterman A, Mahajan R, Twomey DJ, Pathak RK, Lau DH, Roberts-Thomson KC, Young GD, Sanders P and Ganesan AN. Remote Monitoring of Implantable Cardioverter-Defibrillators: A Systematic Review and Meta-Analysis of Clinical Outcomes. *J Am Coll Cardiol*. 2015;65:2591-2600.
43. National Institute of Standards and Technology. *Health IT Usability*. 2018.
44. Goldberg L, Lide B, Lowry S, Massett HA, O'Connell T, Preece J, Quesenberg W and Shneiderman B. Usability and accessibility in consumer health informatics current trends and future challenges. *Am J Prev Med*. 2011;40:S187-97.
45. Jaspers MW. A comparison of usability methods for testing interactive health technologies: methodological aspects and empirical evidence. *Int J Med Inform*. 2009;78:340-53.
46. Scherr D, Kastner P, Kollmann A, Hallas A, Auer J, Krappinger H, Schuchlenz H, Stark G, Grander W, Jakl G, Schreier G, Fruhwald FM and Investigators M. Effect of home-based telemonitoring using mobile phone technology on the outcome of heart failure patients after an episode of acute decompensation: randomized controlled trial. *J Med Internet Res*. 2009;11:e34.
47. Goldberg LR, Piette JD, Walsh MN, Frank TA, Jaski BE, Smith AL, Rodriguez R, Mancini DM, Hopton LA, Orav EJ, Loh E and Investigators W. Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: the Weight Monitoring in Heart Failure (WHARF) trial. *Am Heart J*. 2003;146:705-12.
48. Cleland JG, Louis AA, Rigby AS, Janssens U, Balk AH and Investigators T-H. Noninvasive home telemonitoring for patients with heart failure at high risk of recurrent admission and death: the Trans-European Network-Home-Care Management System (TEN-HMS) study. *J Am Coll Cardiol*. 2005;45:1654-64.
49. Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE and Strom BL. Role of computerized physician order entry systems in facilitating medication errors. *JAMA*. 2005;293:1197-203.
50. Ash JS, Berg M and Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. *Journal of the American Medical Informatics Association*. 2004;11:104-112.
51. Rahimi K, Velardo C, Triantafyllidis A, Conrad N, Shah SA, Chantler T, Mohseni H, Stoppani E, Moore F, Paton C, Emdin CA, Ernst J, Tarassenko L, Investigators S-H, Rahimi K, Velardo C, Triantafyllidis A, Conrad N, Ahmar Shah S, Chantler T, Mohseni H, Stoppani E, Moore F, Paton C, Tarassenko L, Cleland J, Emptage F, Chantler T, Farmer A, Fitzpatrick R, Hobbs R, MacMahon S, Perkins A, Rahimi K, Tarassenko L, Altmann P, Chandrasekaran B, Emdin CA, Ernst J, Foley P, Hersch F, Salimi-Khorshidi G, Noble J and Woodward M. A user-centred home monitoring and self-management system for patients with heart failure: a multicentre cohort study. *Eur Heart J Qual Care Clin Outcomes*. 2015;1:66-71.
52. Pecina JL, Vickers KS, Finnie DM, Hathaway JC, Hanson GJ and Takahashi PY. Telemonitoring increases patient awareness of health and prompts health-related action: initial evaluation of the TELE-ERA study. *Telemed J E Health*. 2011;17:461-6.
53. Or C and Tao D. Usability study of a computer-based self-management system for older adults with chronic diseases. *JMIR Res Protoc*. 2012;1:e13.
54. Chantler T, Paton C, Velardo C, Triantafyllidis A, Shah SA, Stoppani E, Conrad N, Fitzpatrick R, Tarassenko L and Rahimi K. Creating connections - the development of a mobile-health monitoring system for heart failure: Qualitative findings from a usability cohort study. *Digit Health*. 2016;2:2055207616671461.
55. El-Gayar O, Timsina P, Nawar N and Eid W. Mobile applications for diabetes self-management: status and potential. *J Diabetes Sci Technol*. 2013;7:247-62.
56. .
57. Organization WH. *Improving data quality: a guide for developing countries*: Manila: WHO Regional Office for the Western Pacific; 2003.
58. van Velthoven MH, Car J, Zhang Y and Marušić A. mHealth series: New ideas for mHealth data collection implementation in low- and middle-income countries. *Journal of global health*. 2013;3.
59. Cabitza F and Batini C. Information quality in healthcare *Data and Information Quality*: Springer; 2016: 403-419.
60. Kahn JG, Yang JS and Kahn JS. 'Mobile' health needs and opportunities in developing countries. *Health Aff (Millwood)*. 2010;29:252-8.
61. Patnaik S, Brunskill E and Thies W. Evaluating the accuracy of data collection on mobile phones: A study of forms, SMS, and voice. *Information and Communication Technologies and Development (ICTD), 2009 International Conference on*. 2009:74-84.
62. Mena LJ, Felix VG, Ochoa A, Ostos R, Gonzalez E, Aspuru J, Velarde P and Maestre GE. Mobile Personal Health Monitoring for Automated Classification of Electrocardiogram Signals in Elderly. *Comput Math Methods Med*. 2018;2018:9128054.
63. Kloss LL. Information integrity: a high risk, high cost vulnerability. *Health Data Manag*. 2012;20:44-5.