Effective Health Care

Remote Monitoring of Patient Generated Health Data

Results of Topic Selection Process & Next Steps

The nominator, Connected Health Initiative (CHI), is interested in a new evidence review on Remote Monitoring of Patient Generated Health Data in order to inform further coverage decisions about RM technologies with Centers for Medicare & Medicaid Services (CMS) and other payers.

This topic will go forward as a new technical brief. To sign up for notification when Effective Health Care (EHC) Program topics are posted for public comment, please go to https://effectivehealthcare.ahrq.gov/email-updates.

Topic Number and Name: 0798 Remote Monitoring of Patient Generated Health Data

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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

Background

Remote monitoring technologies overview

Remote monitoring (RM) of patient generated health data is a rapidly expanding field. Currently remote monitoring includes a wide range of technologies addressing multiple chronic conditions. including cardiovascular disease[1], diabetes[2], and asthma.[3] Proponents contend that remote monitoring technologies can empower patients to be more involved with their care, and hence have improved health care outcomes.[1]

Given the plethora of mobile health apps and RM devices, there is a considerable lack of evidence evaluating health outcomes. Recently a catalog of the evidence was recommend for mobile health apps, including an open-source directory of app evidence and standard facts label for apps.[4] For this reason, a review of the existing evidence for these RM technologies is important for patients, providers and health systems.

Topic Nomination Development

Connected Health Initiative (CHI), an advocacy and trade organization, originally nominated this topic to the AHRQ EPC Program based on interest in evaluation of the evidence on the effectiveness of these technologies in the prevention of chronic conditions. The organization's members include digital health technology companies, vendors, payers and providers, and included the American Medical Association. The Centers for Medicare and Medicaid Services (CMS) 2019 Physician Fee Schedule was finalized to include three new codes which address remote monitoring:

- 990X0: "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment";
- 990X1: "Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days;"
- 994X9: "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month."

The goal of the nominator was to further expand coverage of RM technologies with CMS and other payers.

Key question development

The initial Key Questions and population, intervention, comparators and outcomes (PICOs) were developed in consultation with the nominator. The questions focused on both primary and secondary prevention for four main chronic conditions: Obesity, asthma, cardiovascular disease (CVD) and diabetes mellitus (DM) on a wide range of outcomes (e.g., patient outcomes including disease and patient satisfaction, healthcare utilization, costs, and provider behavior/ decisions). A scoping review focused on RM technologies for the primary prevention of chronic conditions was identified and reviewed with the nominator.[5] Given this review, primary prevention was removed from the scope.

Due to the limited evidence initially identified, we focused the scope on secondary prevention and this was expanded using the input from topic experts: 1) generic chronic conditions combined with device types and remote/ambulatory facets, and 2) each of four specific chronic

conditions combined with device types and remote/ambulatory facets. This strategy markedly increased the evidence base for RM of CVD and DM, but not asthma. Please see Appendix B for the complete updated search.

Following review of abstracts, we further developed the scope to focus on tertiary prevention, or chronic disease management. These technologies focus on a disease after a diagnosis, as opposed to secondary prevention, which is screening for diseases[6,7], and on technologies that address conditions earlier on the disease spectrum, which would be more amenable to improvement using a RM technology. Therefore, we excluded technologies that connect with cardiac implantable devices, such defibrillators and resynchronization devices. We considered them not to be applicable for chronic disease management. In addition, we excluded obesity from the scope, as we considered it to be distinct from the other conditions with its own separate literature base.

Proposed guiding questions
Based on the variable level of evidence development for the different RM technologies, we propose the following guiding questions:

1) What are the specific RM technologies that have been researched to address the following physiologic parameters:
   - Blood pressure
   - Respiratory rate
   - Pulse oximetry
   - Weight

2) What outcomes have been researched that are associated with the use of these specific RM technologies?

3) What are the harms of these specific RM technologies?

Proposed PICOs
We anticipate these being refined significantly once the RM technologies are further characterized. Of note, the outcomes and comparators will depend on the stage of evidence for each technology.

- Population: adults diagnosed with a chronic condition for which one of the below remote monitoring devices is used
- Intervention: any remote monitoring device which measures one of these physiologic parameters (blood pressure, respiratory rate, pulse oximetry, weight)
- Comparator: variable (will depend on level of evidence development for each device)
- Outcomes: variable (will depend on level of the evidence development for each device. For example, if technology is being evaluated for diagnostic accuracy, outcomes would include sensitivity and specificity)
    - Any harms (e.g., anxiety due to potential data overload, overtreatment)
- Setting: outpatient

Partner Identification and Input

We contacted CMS's Center for Medicare and Medicaid Innovation (CMMI) to gauge their interest in a potential AHRQ evidence review. They reported that they would find value in an

AHRQ evidence review on this topic, particularly if the review included implementation considerations.

Assessment Against EPC Program Selection Criteria

We assessed the topic of remote technologies for tertiary prevention (e.g., chronic disease management) against the standard EPC Program Selection Criteria. Of note, this topic area is poorly defined and rapidly expanding. In addition, since the search was focused on chronic conditions and only patient outcomes, some criteria were challenging to assess with certainty.

We found that this topic fulfilled most selection criteria. Because of the area is poorly defined and rapidly expanding, the search for systematic reviews and primary studies was difficult and we had limited certainty that relevant studies were captured. Because this is an area of high importance to multiple stakeholder groups, in our assessment a technical brief is a feasible product. Please see Appendix A for a full description of assessment of selection criteria.

Discussion

Below we provide a more in-depth discussion about the rationale for recommending a technical brief for this topic.

Poorly defined topic area and need for evidence framework

We concluded that many of the technologies were at varying stages of evidence development, which could be addressed in a technical brief. Initially, we attempted to consider the RM technologies using typical PICOs format with standard patient health outcomes (which were of interest to the nominator). However, we found that it was difficult to apply the PICOs format to the varying RM technologies. Instead we needed a different framework to evaluate these technologies, which would potentially have different outcomes depending on the developmental stage of the evidence for each technology. Specifically, we relied on the 2012 AHRQ Methods Guide for Authors of Systematic Reviews of Medical Tests[10], which provides a comparison of organizing frameworks for evaluating medical tests. Remote monitoring, as such, can be considered a clinical situation similar enough to a medical test, to utilize the same organizing framework.

We, therefore, suggest using the Fryback-Thornbury Framework to evaluate these RM technologies[11]. This framework provides six steps for progressively evaluating tests (and technologies) including: 1) technical efficacy (e.g., does the test measure what it is intended to measure?); 2) diagnostic accuracy efficacy; 3) diagnostic thinking efficacy; 4) therapeutic efficacy; 5) patient outcome efficacy; and 6) societal efficacy.

Typically, nominations focus on patient outcomes (e.g., quality of life, morbidity, and mortality), the fifth stage of the above Framework. Before evaluating the effectiveness of a test on patient outcomes, however, it is important to know that a test has demonstrated effectiveness in the first four stages (e.g., technical, diagnostic accuracy, diagnostic thinking, and therapeutic). Therefore, each of these new technologies must be considered individually to determine which stage in the organizing framework that the evidence currently lies and to evaluate it appropriately.

Challenges with the literature search and proposed evidence selection

Based on the rationale above, we propose searching for evidence for a technical brief in the web as well as bibliographic databases to identify programs that have implemented remote

monitoring in chronic disease. The search and inclusion of programs, technologies, and evidence would be based on the physiologic parameters as identified by the CMS coverage codes of interest (e.g., pulse oximetry, blood pressure, weight, respiratory flow rate). Of note, an EPC would evaluate the evidence depending on the outcomes which have been addressed in the literature for each technology.

The list would begin with the programs and technologies provided in the examples provided by the nominator (please see Appendix C). In other words, the search would be based on technologies addressing the same physiologic parameter, and not based on the chronic condition. This search would include requests of information from industry and academic programs.

Additional Considerations

Based on our experience during topic development, we highlight some additional aspects of this topic which may be helpful in assessing the evidence for a technical brief.

New field with inconsistent terminology

Due to the constant evolution of this field, the terminology used to describe remote monitoring and its related concepts (e.g., telehealth, mHealth) are not consistently used in industry or in the medical literature. Given this variable terminology, additional work of reviewing multiple full text articles may be required to determine studies for inclusion.

Limited intervention description in abstracts

We found that abstracts provided limited details of the interventions. It was difficult to distinguish if the intervention focused on remote monitoring or on another aspect of telehealth. Therefore, reviewing multiple full texts articles will likely be required.

Varying evidentiary standards depending on technology

For some technologies, evidence for effectiveness on health outcomes may not be needed. For example, if the new technology aims to replace a current technology for which there is already sufficient, good quality evidence for health outcomes, then it may only be necessary to demonstrate that the new technology is more accurate than the prior technology (as long as there is no difference in risk or feasibility).

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Appendix A. EPC Program Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes. Remote patient monitoring devices are available in the US.
1b. Is the nomination a request for a systematic review?	Yes, the nominator requests a systematic review.
1c. Is the focus on effectiveness or comparative effectiveness?	Yes. The nomination is focused on effectiveness of remote monitoring programs.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes. It is plausible that remote patient monitoring technologies may improve management of chronic conditions, but the evidence appears to be at differing stages depending on the technology.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes. Tertiary prevention of chronic conditions (e.g., chronic disease management) of diabetes, cardiovascular diseases, and asthma affect large proportion of the population.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes. These technologies continue to expand, along with the coverage for them. An evidence review would be helpful to CMS and other payers.
2c. Represents important uncertainty for decision makers	Yes. CMS included new codes for remote monitoring in its 2019 Physician Fee Schedule. The evidence for these technologies, however, is variable.
2d. Incorporates issues around both clinical benefits and potential clinical harms	Yes, the guiding questions incorporate issues of benefits and harms.
2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes. The chronic conditions of interest (e.g., cardiovascular disease, diabetes mellitus, and asthma) are common and very costly.
3. Desirability of a New Evidence Review/Duplication	
3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)	N/A. We did not review for duplication, as the original search was based on chronic condition and patient outcomes. Based on the results from that search, we now recommend literature search to start with technologies addressing the same physiologic parameter.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Yes the standard of care is unclear for remote monitoring technologies.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	There is no consistent current practice with remote monitoring technologies on which to evaluate practice variation.

5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	The size of the literature base for these technologies is uncertain. As per the guiding questions, part of the review will be to search for evidence for remote technologies, including from the manufacturers and academic programs. We had challenges determining if the interventions were remote technologies based on abstract review.
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Yes, this is an expanding field of technology with frequent new innovations. Now that the CMS 2019 Physician Fee Schedule includes new remote monitoring codes, there is additional interest in this topic from patients, payers, and providers.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	CHI was a very interested partner, which also includes the American Medical Association. In addition, CMMI expressed interest in remote monitoring interventions if they were to generate cost-savings.

Abbreviations: AHRQ= Agency for Healthcare Research and Quality; CMS= Centers for Medicare & Medicaid Services; KQ= key question; CMMI= Centers for Medicare & Medicaid Innovation.

Appendix B. Search Strategy

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to November 29, 2018

Date Searched: November 30, 2018
Searched by: Robin Paynter, MLIS

	Searches	Results
1	Chronic Disease/	251516
2	(chronic adj2 (disease* or condition* or illness*)).tw,kf.	209648
3	or/1-2	419587
4	Blood Pressure Monitoring, Ambulatory/ or Electrocardiography, Ambulatory/ or Fitness Trackers/ or Mobile Applications/ or Monitoring, Ambulatory/ or Remote Sensing Technology/ or Wearable Electronic Devices/	32843
5	(ambulatory or bluetooth or broadband or digital or home or mobile or outpatient* or out-patient* or remote or smartphone or wear* or android-watch* or apple-watch* or fitbit or "generated health data" or mhealth or m-health or "mobile applications" or telemonitor* or tele-monitor* or transmission* or transmit* or wireless).ti,ab,kf. and (Monitoring, Physiologic/ or Oximetry/ or Telemetry/ or is.fs.)	62047
6	(((ambulatory or bluetooth or broadband or digital or home or mobile or outpatient* or out-patient* or remote or smartphone or transmission* or transmit* or wireless or wear*) adj3 (app or apps or data or device* or mhealth or m-health or "mobile applications" or monitor* or oximet* or sensor* or technolog* or telemetry)) or android-watch* or apple-watch* or fitbit or "generated health data").ti,ab,kf. or tele*.ti,kf.	109881
7	or/4-6	177543
8	Secondary Prevention/ or Preventive Health Services/ or pc.fs.	1219541
9	(complication* or delay* or exacerbat* or prevent* or progression or relaps*).ti,ab,kf.	3011474
10	or/8-9	3789029
11	and/3,7,10	1074
12	limit 11 to english language	996
13	12 and (controlled clinical trials as topic/ or randomized controlled trials as topic/ or non-randomized controlled trials as topic/ or controlled clinical trial.pt. or randomized controlled trial.pt. or (randomized or placebo or randomly).ab. or trial.ti.)	216
14	limit 13 to yr="2013 -Current"	122
15	limit 12 to (meta analysis or systematic reviews)	64
16	limit 15 to yr="2015 -Current"	42

17	exp Diabetes Mellitus/ or exp Diabetes Complications/ or exp Metabolic Syndrome/	414252
18	(diabet* or T2DM or iT2DM or T1DM or iT1DM or T2D or iT2D or T1D or iT1D or NIDDM or IDDM).ti,ab,kf.	572448
19	or/17-18	643409
20	and/7,10,19	1908
21	limit 20 to english language	1758
22	21 and (controlled clinical trials as topic/ or randomized controlled trials as topic/ or non-randomized controlled trials as topic/ or controlled clinical trial.pt. or randomized controlled trial.pt. or (randomized or placebo or randomly).ab. or trial.ti.)	414
23	limit 22 to yr="2013 -Current"	228
24	limit 21 to (meta analysis or systematic reviews)	107
25	limit 24 to yr="2015 -Current"	59
26	(exp Cardiovascular Diseases/ or exp Heart Diseases/) and is.fs.	67456
27	((atrial or cardiac or cardio* or heart or myocardia*) adj3 (disease* or condition)).ti,ab,kf.	352476
28	or/26-27	416690
29	and/7,10,28	2686
30	limit 29 to english language	2346
31	30 and (controlled clinical trials as topic/ or randomized controlled trials as topic/ or non-randomized controlled trials as topic/ or controlled clinical trial.pt. or randomized controlled trial.pt. or (randomized or placebo or randomly).ab. or trial.ti.)	390
32	limit 31 to yr="2013 -Current"	194
33	limit 30 to (meta analysis or systematic reviews)	99
34	limit 33 to yr="2015 -Current"	54
35	obesity/ or Obesity Hypoventilation Syndrome/ or Obesity, Abdominal/ or Obesity, Metabolically Benign/ or Obesity, Morbid/ or Pediatric Obesity/	188871
36	(obese or obesity).ti,ab,kf.	267053
37	or/35-36	309526
38	and/7,10,37	783
39	limit 38 to english language	746
40	39 and (controlled clinical trials as topic/ or randomized controlled trials as topic/ or non-	172

	randomized controlled trials as topic/ or controlled clinical trial.pt. or randomized controlled trial.pt. or (randomized or placebo or randomly).ab. or trial.ti.)	
41	limit 40 to yr="2013 -Current"	120
42	limit 39 to (meta analysis or systematic reviews)	31
43	limit 42 to yr="2015 -Current"	21
44	Asthma/ or Asthma, Aspirin-Induced/ or Asthma, Exercise-Induced/ or Asthma, Occupational/ or Status Asthmaticus/	120959
45	asthma*.ti,ab,kf.	148274
46	or/44-45	167041
47	and/7,10,46	250
48	limit 47 to english language	231
49	48 and (controlled clinical trials as topic/ or randomized controlled trials as topic/ or non-randomized controlled trials as topic/ or controlled clinical trial.pt. or randomized controlled trial.pt. or (randomized or placebo or randomly).ab. or trial.ti.)	65
50	limit 49 to yr="2013 -Current"	35
51	limit 48 to (meta analysis or systematic reviews)	18
52	limit 51 to yr="2015 -Current"	13

Appendix C. Technology Examples from Nominator

Below is a list of technologies of interest provided by the nominator. A grey literature review revealed that all focused on chronic disease management. In addition, some technologies were excluded based on addressing an intervention or setting outside of the scope:

- Rimidi Diabetes Platform (https://rimidi.com/)
    - Monitors diabetes, heart failure, and fatty liver
      One 2014 ongoing study comparing Rimidi's Diabetes + Me platform with usual care for hemoglobin A1c[8] (no published results)

- University of Mississippi Medical Center Remote Monitoring Program (https://www.umc.edu/Healthcare/Telehealth/Remote%20Patient%20Monitoring.html)
    - Four to six-month program where patients given tablets, and nurse checks on patients via messaging and video chats.
    - 2016 preliminary data: use of remote monitoring program effect on hemoglobin A1c and medication adherence[9] (no published results)

- Locus Health System used by the University of Virginia (https://www.locushealth.com/solutions/remote-patient-monitoring/);
    - Provides iPads for patients in various clinic contexts (congenital heart disease, transplant, hematology, neonatal intensive care [NICU] discharge)
    - No results found

- A&D Medical's Wellness Connected (https://medical.andonline.com/home)
    - Mobile apps and Bluetooth Smart-enabled devices for blood pressure, weight, BMI, steps, and calories
    - No results found

- Philips Healthcare's EncorePro 2 (https://www.usa.philips.com/healthcare/product/HC1054785/encorepro-2-patient-data-management-software/overview)
    - Desktop-based system designed to record patient sleep and respiratory data
    - No results found

<u>Excluded technologies below</u>:

- Biotronik Home Monitoring
    - Collects data from implantable cardiac devices – intervention not of interest
- Boston Scientific's Latitude NXT
    - Monitoring of pacemakers and defibrillators – intervention not of interest
- GE Healthcare's Apex Pro CH
    - EK-Pro clinical algorithm processes and analyzes five independent, simultaneous ECG leads for hospital use- setting not of interest