Evidence-based Practice Center Technical Brief Protocol

Project Title: ***Automated-Entry Patient Generated Health Data for Chronic Conditions: The Evidence on Health Outcomes***

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(Amendments Details-see Section VII)

I. Background and Objectives for the Technical Brief

The objective of this evidence review is to summarize the research related to consumer health technologies that provide patient-generated health data (PGHD) for the prevention or treatment of chronic disease(s). PGHD is defined differently by different organizations (Office of the National Coordinator for Health Information Technology or ONC, and the National eHealth Collaborative Technical Expert Panel). We use the ONC definition for this project (https://www.healthit.gov/sites/default/files/patient_generated_data_factsheet.pdf):

> *Patient-generated health data (PGHD) are health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern. PGHD include, but are not limited to: health history, treatment history, biometric data, symptoms, lifestyle choices. PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways: 1) Patients, not providers, are primarily responsible for capturing or recording these data. 2) Patients decide how to share or distribute these data to health care providers and others. Examples include blood glucose monitoring or blood pressure readings using home health equipment, or exercise and diet tracking using a mobile app or wearable device.*

PGHD is a rapidly growing field where the availability and development of the technologies has, in many instances, outpaced the publication of trials designed to evaluate health outcomes, usability, interoperability, and benefits and harms of these technologies. It is important to determine which of the available technologies have actually been assessed to determine efficacy related to health outcomes for consumers with (or at risk for) chronic diseases.

This report focuses on consumer technologies that provide PGHD. These are devices that are commercially available to consumers and do not require a prescription from a physician. Therefore, this report does not include medical devices that perform remote patient monitoring, which falls more broadly within the category of telehealth. A recent AHRQ Technical Brief provides an evidence map of telehealth showing that many published systematic reviews have evaluated the evidence for remote patient monitoring. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/telehealth_technical-brief.pdf

Over the past few years there has been a surge in consumer health technologies entering the US market, with the majority being products not undergoing FDA scrutiny. Consumer health technologies marketed in the US can be broadly divided into those FDA considers medical devices which are regulated (i.e., devices that claim to diagnose, prevent, or treat medical conditions), and those that FDA does not consider to be medical devices. Manufacturers of FDA regulated devices typically are required to demonstrate, through testing, that their devices meet any stated performance/clinical claims. In contrast, non-FDA regulated devices cannot legally make these claims, although manufacturers will often allude to the performance of their devices through carefully-worded marketing. Consumers and providers may find it challenging to distinguish between devices that are FDA regulated and those that are not.

Many studies evaluate multicomponent interventions, with PGHD technologies representing only one component, and they do not separately evaluate the effect of the PGHD component. While many apps or other PGHD technologies are meant to be used in combination with other interventions for chronic disease, the studies still need to be designed in a way that permits isolation of the effect of the PGHD technology. Mobile apps that have similar functions have rarely been directly compared in clinical studies to help clinicians identify the most useful apps to recommend for their patients.[1]

We recognize that many PGHD applications require manual entry of data, particularly those for depression or dementia where technology has not yet allowed for automated capture of PGHD. For this project, we will exclude such applications, focusing only on automated-entry PGHD. This focus will allow us the resources to examine the health-outcomes evidence on 11 chronic conditions.

There are several issues that may influence the effectiveness of PGHD for improving patient outcomes. There are concerns about the accuracy of some of the new devices when measuring patient health data (e.g., Apple Watch). From the patient perspective, some patients may lack access to PGHD technologies or have a low comfort level with these new technologies and as such may utilize them in a suboptimal manner, limiting their effectiveness; they may even abandon use of the device. Alternatively, even if patients can use the technologies effectively, some may be unwilling to share the data with clinicians due to privacy and security concerns.

II. Guiding Questions

1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?
    a. What study designs have been used?
    b. What were the inclusion/exclusion criteria?
    c. What statistical analysis and data were used to determine study size and power?
    d. How long were patients followed?
    e. How was adherence measured?
    f. What was the comparator?

g. Which outcomes were measured?

2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?
3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?
4. What are the harms or adverse events associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?
5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

Table 1. Inclusion and Exclusion Criteria

Category	Criteria
Populations	**INCLUDE:** Individuals with one or more of the following 11 chronic conditions: obesity, diabetes prevention, hypertension, sleep apnea, coronary artery disease, heart failure, cardiac arrhythmias or conduction abnormalities, Parkinson disease, stroke, chronic obstructive pulmonary disease, or asthma. **EXCLUDE:** Individuals with other conditions
Interventions	**INCLUDE:** Consumer health technology, defined as devices consumers use on their own to address health issues and improve quality of life. They are also referred to as direct-to-consumer medical devices, consumer health-based technologies/devices, over-the-counter devices, consumer-based medical devices, and consumer-grade medical devices. Consumer products do not require a health professional, and may be purchased directly by consumers without a prescription. The technology must collect patient data without manual input that can potentially be used by the patient or sent to a healthcare professional (data transmission could be via the same technology or a different technology). **EXCLUDE:** PGHD technologies that are not consumer technologies or that rely on manual input.
Comparators	**INCLUDE:** Any comparator is acceptable.
Outcomes	**INCLUDE:** *Health outcomes* or *full economic evaluations. For health outcomes*, we defined them differently for different clinical topics: • We universally included outcomes widely recognized to be important, such as mortality, survival, ER visits, hospital admissions, disease severity, disease progression, and quality of life. • Outcomes that *define a condition* (e.g., weight loss for obesity, HbA1c for diabetes, blood pressure for hypertension) were included for studies of that same condition, but were excluded for studies of other conditions (e.g., weight loss for diabetes, blood pressure for obesity). • Outcomes quantifying the tradeoff between cost and effectiveness of interventions, such as cost per QALY, were included if effectiveness was measured using a health outcome, as defined above. Process outcomes, such as physician-ordered changes in management (e.g., dose alteration, diagnostic testing) were extracted only from studies that reported health outcomes as defined above. **EXCLUDE:** Surrogates such as prescription filling behavior, biomarkers that do not define the condition (e.g., blood pressure in patients with obesity), disease knowledge, dietary behavior, steps per day, user satisfaction, or usability. Partial economic evaluations and other cost analyses or descriptions are out of scope as costs are unable to be directly compared across various interventions and are not standardized relative to a consumer or societal outcome of interest.
Timing/Setting	**INCLUDE:** No limitations on timing. Setting must be at home or otherwise outside of a hospital or healthcare center.

Study Designs	**INCLUDE:** Any study design with a separate comparison group of patients or single-arm registry studies. Systematic reviews will also be included. **EXCLUDE:** Narrative reviews, case reports, editorials, comments, letters, meeting abstracts
Language	**INCLUDE:** English

III. Methods

1. Data Collection

A. Discussions with Key Informants

The Key Informants (KIs) will have expertise in various fields such as consumer technologies for healthcare management. We will conduct telephone interviews with a selected set of KIs. Their input will also be used to refine the systematic literature search, identify grey literature resources, provide information about ongoing research, confirm evidence limitations, and recommend approaches to help fill these gaps. Table 1 presents potential questions to the KIs.

Table 1. Potential KI Questions

1. How important is it for us to focus on technologies that actually transmit data to a health care professional, as opposed to technologies that only provide the data back to patient themselves?
2. Which specific chronic diseases do you think are most important for us to include?
3. In terms of outcomes, this project is focused on *health outcomes*, such as symptoms and quality of life. Are there any health outcomes you believe we should certainly include or exclude?
4. What confounding factors pose a challenge to interpreting research and evaluation studies on consumer health technologies for chronic diseases, and how can future research/evaluation be designed to minimize these confounders?
5. Where do you think are the most important gaps in current knowledge, and can you recommend approaches to help fill these gaps?
6. In addition to published literature, what unpublished resources could help inform our analysis?
7. Can you suggest strategies we might use to organize, present, and disseminate our findings?

B. Gray Literature search

Gray literature sources and retrieval will be determined by the work group and may include the following sources: The National Guidelines Trust, Turning Research into Practice (TRIP) database, government websites (e.g., ClinicalTrials.gov, the Agency for Healthcare Research and Quality [AHRQ], The Centers for Medicare and Medicaid [CMS], U.S. Food and Drug Administration [FDA]), and relevant professional societies (e.g. the American Health Information Management Association [AHIMA], American Medical Informatics Association [AMIA], Healthcare Information and Management Systems Society [HIMSS]). The websites for application developers, mHealth products, and app stores may also be consulted to identify commercial applications, white papers, and information on unpublished manufacturer/developer sponsored studies.

C. Published Literature search

Consistent with our evidence-based searching protocol, information professionals will search the following external databases: MEDLINE and EMBASE (via EMBASE.com), in process Medline and PubMed-unique content (via PubMed.gov), the Cochrane Database of Systematic Reviews, and the Association for Computing Machinery (ACM) digital library. Searches will be designed to identify unique reviews.

We identified search terms by: (1) reviewing relevant systematic reviews and previously published guidelines on similar topics identified by members of the research staff; (2) incorporating manual and text-mining methods to review how other relevant studies are indexed, their subject heading terms, and their keywords; (3) reviewing the MeSH, and EMTREE thesauri for relevant and appropriate terms; and (4) discussions with local subject experts. Appendix 1 provides a sample search strategy. After reviewing these we will identify a combination of subject headings and keywords. Team members and the medical librarian will review the search strategies developed using these terms. Date limits and study design filters will be applied based on recommendations from the work group. Specific apps/devices identified through the above processes will be incorporated into a secondary search of the resources mentioned above. Scopus and Google Scholar will be used for citation searching as necessary.

To find in-progress studies, we will conduct searches of clinicaltrials.gov. Hand searches may be done using reference lists of published systematic reviews or other studies. Data to be extracted include the chronic condition that the technology is intended to benefit, details about the technology, the study design, the number of patients enrolled, comparator(s), health outcome(s), and time points.

Five reviewers will screen titles/abstracts against the inclusion criteria. We will all screen the same 20-30 abstracts in order to ensure a consistent approach. After this initial set, each abstract will be screened by 2 screeners separately, and if either screener felt the full text should be ordered for possible inclusion, we will order the full text. For full-text screening, each article will be screened by two people, with disagreements resolved by a 3rd person.

2. Data Organization and Presentation

A. Information Management

We will extract information from each included study into tables in Microsoft Word. This will include details about the patient population (e.g., demographics), the technology, comparators, outcomes, and time points. Regarding outcomes to be extracted from included studies, we will extract health outcomes (as defined above), cost-effectiveness outcomes, and process outcomes.

B. Data Synthesis

We will use qualitative synthesis to summarize the included evidence on each technology. For each technology, we will judge whether, on the whole, the evidence indicates effectiveness for improving health outcomes. As this is a Technical Brief and not a Systematic Review, we will not grade the strength of evidence. Because AHRQ Technical Briefs focus on emerging and rapidly changing technologies, strength of evidence assessments are not typically conducted, and we will not evaluate strength of evidence in this review. Our judgments of effectiveness, separately for each clinical condition and each technology, will instead be based on the team's examination of the

pertinent evidence. We will use a modified coding system developed by the Pacific Northwest Evidence-Based Practice Center to summarize SR findings.[2] The results for each evidence base will be coded as likely no effect, unclear, possible positive effect, or likely positive effect based on an assessment of outcomes reported in a given review. If the results have a consistent positive effect for one of the relevant outcomes, we will code it as "likely positive effect." If the results consistently demonstrate the lack of an effect (via narrow confidence intervals around a null effect), we will code it as "likely no effect." If the results for another outcome have inconsistency in direction of effect and/or study authors could not reach a conclusion, the findings will be coded as "unclear" for that outcome. If one or more outcomes have minor inconsistency in findings, the findings will be coded as "possible positive effect."

For consistency between reports, we will use the same risk-of-bias assessment tool described in the recent AHRQ technical brief on diabetes mobile applications.[3] We will also record whether published studies used some type of framework or tool to evaluate performance or other outcomes of PGHD technologies.

Direct (hands on) usability and performance testing will be restricted to those technologies that are freely available and for which the accumulated published evidence indicates effectiveness or harm (as described above) for clinical outcome(s). If there are no such technologies, then we will expand this testing to include any technologies that have been investigated in at least 2 separate studies reporting health outcomes.

C. Data Presentation

We will present data in evidence tables in appendices. These tables will include details about the study designs, enrolled patients, technologies employed, and outcomes reported. If time permits, the team will produce a graphical and/or interactive summary of the evidence, in order to enhance the usability of the Technical Brief.

IV. References

1. ECRI Institute. Evaluation criteria for prescribing mobile health apps. Plymouth Meeting (PA): ECRI Institute; 2018 Feb. 28 p. (Special HTA Report; Also available: https://www.ecri.org/components/SpecialReports/Pages/24722.aspx.

2. Totten AM, Womack DM, Eden KB, et al. Telehealth: mapping the evidence for patient outcomes from systematic reviews. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No.16-EHC034-EF. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2016 Jun. (Technical Brief; no.26). Also available: http://www.effectivehealthcare.ahrq.gov/reports/final.cfm..

3. Veazie S, Winchell K, Gilbert J, et al. Mobile applications for self-management of diabetes. (Prepared by:Scientific Resource Center, under Contract Nos. 290-2012-0004-C and -290-2017-0000-3C) AHRQ Publication No. 18-EHC010-EF. Technical Brief No. 31. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2018 May. 73 p. Also available: https://effectivehealthcare.ahrq.gov/topics/diabetes-mobile-devices/technical-brief. PMID: 30088878.

V. Definition of Terms

Not applicable.

VI. Summary of Protocol Amendments

We incorporated the following protocol amendments during the course of this project.

Date	Section	Original Protocol	Revised Protocol	Rationale
3/17/20	Table 1, Populations	**INCLUDE:** Individuals with one or more of the following 11 chronic conditions:	**INCLUDE:** Individuals who have (or may potentially develop) one or more of the following 11 chronic conditions:	To clarify that the scope of the report included prevention as well as treatment of the 11 chronic conditions.
3/17/20	Table 1, Populations	**EXCLUDE:** Individuals with other conditions.	**EXCLUDE:** Individuals with other conditions, pregnant women, post-partum women.	The team felt that pregnant and post-partum women with one or more of the 11 chronic conditions comprised a unique population for whom the findings of PGHD interventions would not be generalizable to other populations.
3/17/20	Table 1, Interventions	**INCLUDE:** The technology must collect patient data without manual input that can potentially be used by the patient or sent to a healthcare professional (data transmission could be via the same technology or a different technology).	**INCLUDE:** The technology must collect and store patient data without necessitating manual input that can potentially be used by the patient or sent to a healthcare professional (data transmission is not required, but could be via the same technology or a different technology). We will include both U.S.-marketed and non-U.S.-marketed technologies that meet these criteria. However, any technology subject to FDA approval must have received FDA approval to be included. To determine whether a device was a consumer product, we will require that the device name or model number be provided.	The team added additional details to clarify that automatic data collection was required but automatic transmission to a healthcare professional was not required. The requirement for automatic transmission would have excluded many devices that otherwise fit the definition of PGHD technologies. We also wanted to clarify that we were including worldwide PGHD technologies, not just devices marketed in the U.S., and the requirement for FDA approval for devices subject to FDA approval. Finally, we clarified that a study provided a device model name or number because in most cases this was the only way to determine whether the device was a consumer product. Although all pedometers are consumer devices, we still consider the device name/model to be important because there may be variability in the quality

Date	Section	Original Protocol	Revised Protocol	Rationale
				and performance of different pedometers.
3/17/20	Table 1, Comparisons	**INCLUDE:** Any comparator is acceptable.	**INCLUDE:** Comparators can include non-PGHD interventions or other PGHD interventions. **EXCLUDE**: Comparators that include the same PGHD intervention do not address the efficacy/safety of the PGHD intervention and will be excluded.	The team decided to focus on those comparators most likely to isolate the effect of the PGHD intervention.
3/17/20	Table 1, Outcomes	**INCLUDE:** Outcomes quantifying the tradeoff between cost and effectiveness of interventions, such as cost per QALY, were included if effectiveness was measured using a health outcome, as defined above.	**INCLUDE:** Outcomes quantifying total costs as a function of the valuations on the effectiveness of multiple interventions (or intervention and active control/usual care), were extracted if the study also reported one of the two outcome categories above. We will note whether cost analyses were reported.	The team modified the wording to clarify that cost-effectiveness outcomes would be extracted from studies that also reported either a health outcome or an outcome that defines a clinical condition of interest. An additional sentence was added to clarify that we would note whether included studies reported a cost analysis that did not relate cost to effectiveness.
3/17/20	Table 1, Outcomes	**INCLUDE:** Process outcomes, such as physician-ordered changes in management (e.g., dose alteration, diagnostic testing) were extracted only from studies that reported health outcomes as defined above.	**INCLUDE:** Other outcomes were extracted only from studies that reported health outcomes or condition-defining outcomes as defined above. These other outcomes included process outcomes, such as physician-ordered changes in management (e.g., dose alteration, diagnostic testing), and outcomes on interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or	The team felt that the list of other outcomes should be expanded based on the questions guiding this technical brief, particularly guiding question 2.

Date	Section	Original Protocol	Revised Protocol	Rationale
			integration into electronic health records.	
3/17/20	Table 1, Outcomes	**EXCLUDE:** Surrogates such as prescription filling behavior, biomarkers that do not define the condition (e.g., blood pressure in patients with obesity), disease knowledge, dietary behavior, steps per day, user satisfaction, or usability. Partial economic evaluations and other cost analyses or descriptions are out of scope as costs are unable to be directly compared across various interventions and are not standardized relative to a consumer or societal outcome of interest.	**EXCLUDE:** Surrogates such as prescription filling behavior, biomarkers that do not define the condition (e.g., blood pressure in patients with obesity), adherence, disease knowledge, beliefs, opinions, dietary behavior, activity level, and steps per day.	Based on a preliminary review of literature, the team added to the list of excluded surrogate outcomes. The sentence on partial economic evaluations and other cost analyses was deleted based on the earlier amended text regarding cost outcomes.
3/17/20	Table 1, Study designs	**INCLUDE:** Systematic reviews will also be included.	**INCLUDE:** Systematic reviews will only be used for the purpose of screening their included studies to ensure none were missed by the database searches. **EXCLUDE:** studies with <10 patients/arm at follow-up.	After a preliminary review of the literature, the team concluded that most systematic reviews did not provide enough information on the PGHD devices used in individual studies, so the decision was made to only include individual studies in this Technical Brief. Systematic reviews were used only for screening of their reference lists. The exclusion criteria of <10 patients per arm was simply to clarify that very small studies would be excluded.

Date	Section	Original Protocol	Revised Protocol	Rationale
				This is because the findings of very small studies are often not reproducible or generalizable to larger patient populations,
3/17/20	2A. Information Management	This will include details about the patient population (e.g., demographics)	This will include details about the patient population (e.g., demographics, in particular whether the population was rural),	This addition was made to indicate particular interest in rural populations.
3/17/20	2B. Data Synthesis	No reference to how economic evaluations would be assessed.	Studies that performed economic evaluations will be evaluated by standard methodological quality assessment tools as recommended by the 2012 AHRQ Methods report.	This sentence was added to clarify how the team would assess the methodological quality of economic evaluations.
3/17/20	2B. Data Synthesis	Direct (hands on) usability and performance testing will be restricted to those that are freely available and for which the accumulated published evidence indicates effectiveness or harm (as described above) for clinical outcome(s). If there are no such technologies, then we will expand this testing to include any technologies that have been investigated in at least 2 separate studies reporting health outcomes.	Direct (hands on) usability and performance testing will be performed on select PGHD technologies deemed by the team (including both the TA group and the HD group) to be of high interest to users.	The team realized that the original proposed approach to direct usability and performance testing was not feasible given the large literature base and limited timeline of this Technical Brief. We instead adopted a revised approach deemed to be feasible within the scope and time limits noted above.

VII. Key Informants

Within the Technical Brief process, Key Informants serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient or policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are crosschecked against available literature and statements from other Key Informants. Information gained from Key Informant interviews is identified as such in the report. Key Informants do not do analysis of any kind nor contribute to the writing of the report and will not review the report, except as given the opportunity to do so through the public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

VIII. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the draft report are considered by the EPC in preparation of the final report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and may be published three months after the publication of the Evidence report.

IX. EPC Team Disclosures

Potential Reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $5,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

X. Role of the Funder

This project was funded under Contract No. xxx-xxx from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The AHRQ Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Appendix 1. Sample Search Strategy

Set Number	Concept	Search statement
1	mHealth	'mHealth' OR 'm-Health'
2		'cell phone' OR 'iPhone' OR ((mobile OR wireless OR Bluetooth OR cellular) NEAR/2 (health* OR device OR phone OR internet OR application OR app))
3		'Mobile phone'/de OR 'wireless communication'/de OR 'mobile application'/de
4		'social media'/de OR 'social media' OR twitter OR tweet OR Facebook OR Instagram* OR snapchat*
5		(wearable NEAR/3 (device* OR monitor* OR sensor* OR biosensor*)) OR fitbit OR hexoskin OR (biometric NEAR/3 (shirt* OR vest* OR garment*)) OR ((fitness OR activity) NEAR/2 (monitor* OR track*)) OR accelerometer/de OR accelerometer*
6		laptop OR (tablet NEAR/3 computer*) OR iPad OR chromebook
7		'smartphone' OR 'smartwatch' OR 'Apple watch' OR 'personal digital assistant' OR 'information technology-based' OR 'app-based' OR 'application based' OR Android OR jawbone OR 'web 2.0' OR sensewear OR iwatch
8		#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
9	Apps	'app':ti OR 'apps':ti OR 'application':ti OR 'mobile application'/exp OR 'software':de OR "web based" OR 'web-based' OR 'internet-based' OR bluetooth
10	Biosensors or wearables	Biosens* OR ((remote OR passive OR wearable) NEAR/3 (device* OR monitor* OR sensor* OR sensing*)) OR fitbit OR hexoskin OR (biometric NEAR/3 (shirt* OR vest* OR garment*)) OR ((fitness OR activity) NEAR/2 (monitor* OR track*)) OR accelerometer/de OR accelerometer*
11	Patient generated data/remote monitoring	(patient NEXT/2 generat*) OR pghd OR ((self* OR home) NEAR/3 monitor*) OR telemonitor* OR telehealth* OR tele-monitor* OR tele-health* OR telemedicin* OR tele-medicin*
12	Combine sets	#9 OR #10 OR #11
13	Combine sets	#8 AND #12
14	Remove unwanted publication types	#13 NOT (abstract:nc OR annual:nc OR book/de OR 'case report'/de OR 'case study'/de OR conference:nc OR 'conference abstract':it OR 'conference paper'/de OR 'conference paper':it OR 'conference proceeding':pt OR 'conference review':it OR congress:nc OR editorial/de OR editorial:it OR erratum/de OR letter:it OR note/de OR note:it OR meeting:nc OR sessions:nc OR 'short survey'/de OR symposium:nc)
15	Limit to english & human	#14 AND [humans]/lim AND [english]/lim

Set Number	Concept	Search statement
Selected Chronic Conditions		
16	COPD	'chronic obstructive lung disease'/exp OR ((chronic NEXT/1 obstruct* NEXT/2 (lung* OR pulmonary*)):ti) OR copd*:ti
17	Asthma (terms from EPC39)	asthma/exp OR 'allergic asthma'/exp OR 'asthmatic state'/exp OR 'extrinsic asthma'/exp OR 'intrinsic asthma'/exp OR 'mild intermittent asthma'/exp OR 'mild persistent asthma'/exp OR 'nocturnal asthma'/exp OR 'occupational asthma'/exp OR 'severe persistent asthma'/exp OR asthma*:ti
18	Hypertension (from VA search)	hypertension/exp OR 'elevated blood pressure'/exp OR hyperten*:ti OR ((high OR elevat*) AND “blood pressure”):ti
19	Obesity	'obesity'/exp OR 'body weight loss'/exp OR 'bariatric surgery'/exp OR 'bariatrics'/exp OR obese:ti OR obesity:ti OR bariatric*:ti OR ((weight NEAR/3 (loss OR lose OR reduc*)):ti)
20	Coronary Artery Disease	'coronary artery disease'/exp OR (coronar*:ti AND arter*:ti AND (disease*:ti OR syndrome*:ti OR atheroscleros*:ti OR anomal*:ti OR occlus*:ti OR thrombos*:ti OR calcif*:ti))
21	Heart Failure	'heart failure'/exp OR (((heart OR cardio* OR cardiac OR cardiogen*) NEAR/2 (failure OR shock OR death OR infarc* OR arrest*)):ti)
22	Stroke	'cerebrovascular accident'/exp OR 'brain ischemia'/exp OR stroke*:ti OR (((cerebrovasc* OR brain OR cerebral) NEXT/1 (accident* OR attack* OR infarct* OR insult* OR ischem* OR ischaem* OR clot* OR thromb* OR embol*)):ti)
23	Diabetes Prevention	'diabetes mellitus'/exp/dm_pc OR ('diabetes mellitus'/exp AND ('primary prevention'/exp/mj OR 'secondary prevention'/exp/mj OR 'tertiary prevention'/exp/mj OR 'prevention'/mj)) OR (diabet* AND prevent*):ti
24	Combine conditions	#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23
25	Combine sets	#15 AND #24
26	RCT filter	'randomized controlled trial'/exp OR 'randomization'/de OR 'double blind procedure'/de OR 'single blind procedure'/de OR 'placebo'/de OR 'crossover procedure'/de OR placebo* OR random*:de,ti OR crossover* OR 'cross over' OR ((singl* OR doubl* OR tripl* OR trebl*) AND (blind* OR mask* OR sham*)) OR 'latin square' OR isrtcn* OR actrn* OR (nct* NOT nct)
27	SR/MA filter	'research synthesis' OR pooled OR 'systematic review'/de OR 'meta analysis'/de OR (('evidence base' OR 'evidence based' OR methodol* OR systematic OR quantitative* OR studies OR search*) AND ('review'/de OR review/it))
28	Combine sets – RCT	#25 AND #26
29	Combine sets – MA/SR	#25 AND #27
30	Combine	#28 OR #29