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Patient Generated Health Data and Electronic Health Record Integration: Protocol for a Scoping Review

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Patient Generated Health Data and Electronic Health Record Integration: Protocol for a Scoping Review

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ABSTRACT

Introduction: The objective of this study is to determine the extent and describe the nature of patient generated health data integration into electronic health records using systematic scoping methods to review the available literature. Patient generated health data (PGHD) have the potential to enhance decision making by providing valuable information that may not be ordinarily captured during a routine care visit. These data, captured from mobile devices such as smartphones, activity trackers and other sensors, must be integrated into clinical workflows for optimal use.

Methods and Analysis: The study aims to conduct a rigorous scoping review to explore evidence related to the integration of PGHD into electronic health records. Using the framework by Arksey and O'Malley, this review will enable the identification of types of integration and describe challenges and barriers to integrating PGHD.

Ethics and Dissemination: Database searches will be initiated in June 2019. The review is expected to be completed by October 2019. As awareness of the articles' contents emerges, the authors will summarize the characteristics related to the integration of PGHD. The findings of this scoping review will identify research gaps and implications for future research.

Strengths and Limitations of this Study

- This scoping review will utilize an existing framework by Arksey and O'Malley in order to maximize rigor.
- By examining the PGHD integration to EHRs, this work will inform the technical development of future health applications and data integration.

- Since the design and development of mobile health applications is moving at a rapid pace, it may be difficult to discover all evidence on PGHD integration.
- A formal assessment for risk of reporting bias will not be conducted because this scoping review is designed to report all evidence, regardless of quality.

INTRODUCTION

With advances in mobile health technologies, including mobile apps along with activity trackers and other sensors, patients are generating more health-related data than ever before. Mobile patient generated health data (PGHD) - data created, recorded, or gathered by or from patients (or family members or other caregivers) to address a health concern – can be used to screen for problems, monitor progress, and enhance communication between patients and their care providers [1]. Although these data have the potential to provide insights to a patient's status and behavior between care episodes, the vast amount of information continuously generated from patients remains untapped [2].

Most hospitals across the country have adopted complete electronic systems and as of 2017, 86% of physician practices have implemented a basic electronic health record [3]. Electronic health records (EHR) provide easier and secure access to patient data and have become an essential part of patient care workflows by providing functions such as patient history documentation, note writing, order entry, results management, and decision support. EHRs are intended to provide a broad view of the patient treatment and medical history to focus on the total health of the patient. PGHD can enhance the information that EHRs already have, and contribute valuable information to the overall health profile of the patient [4]. When patients offer information to healthcare providers, they are empowered as a contributor in their care and evidence shows that activated patients have higher levels of self-care and satisfaction[5]. By including PGHD in the medical record, patients may be inspired to future engagement in their care[6]. Moreover, expectations are high, and patients believe that mobile health technologies will create efficiencies and increase the convenience of healthcare services[7]. However, it is unclear as to what extent PGHD are currently incorporated in and accessed from EHRs [8].

Healthcare providers are trained to use all available information to care for patients. This includes verbal or electronic PGHD that are collected at the time of the clinical encounter. However, there are barriers to including additional PGHD sources as part of the clinical decision-making process [9, 10]. PGHD can be of suboptimal quality; they may be full of bias, noise, and variability [11]. In a systematic review by Greenwood et al., health care teams reported an increased burden due to information overload from PGHD, suggesting the data may not be usable in current forms[12]. A lack of accepted practices for providers to review or take action on PGHD may cause liability concerns, and best practices to transform these data into meaningful and actionable information have not been identified. A thorough examination of the current literature is needed for an understanding of how, when, and where PGHD are integrated into electronic health records. We believe this will be the first scoping review to identify and categorize examples of PGHD integration into EHRs.

METHODS

Scoping reviews are a type of literature review that provide an overview of the type, extent and quantity of research available on a given topic. Scoping reviews are useful in synthesizing the evidence on a topic, mapping and identifying gaps in the research knowledge base, and in providing an overview of the existing evidence[13]. Although scoping reviews have a less restrictive methodological approach compared to systematic reviews, this study will utilize an existing framework in order to maximize rigor. We utilized guidance from the Joanna Briggs Institute to prepare this protocol, and we will also use it throughout the review[13].

Our scoping review is based on a five-stage framework for scoping reviews described by Arksey and O'Malley: identification of the research question; identification of relevant studies; study selection; charting relevant data from the studies; and collecting, summarizing and

reporting the results[14]. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol PRISMA-P 2015 Checklist will inform the protocol development and enhance transparency and reproducibility. This protocol was developed, reviewed and agreed upon by all members of the research team.

Stage 1: Identification of the Research Question

The following question based on elements of Population, Concept, and Context (PCC) will guide the scope of the inquiry[13]:

"What evidence has been reported on patient generated health data being integrated into electronic health records?"

To further guide the search, we will utilize secondary questions related to the integration:

What types of integration have been explored?

What barriers to integration have been reported?

What is know about best practices for PGHD integration?

Population

The primary target population of this scoping review is any patient or family member or caregiver that is generating data that can be electronically shared with health professionals (with health professionals as the secondary target population). This review will consider studies that involve patients in all types of care or treatment. Similarly, the data may be shared with any types of health professional that is caring or treating patients and there are no restrictions on the care provider or setting. There will be no direct patient or public involvement in this research.

Concept

The concept of this review is PGHD and we will use the definition provided by the United States Office of the National Coordinator for Health Information Technology[1]. PGHD supplement existing clinical data and may include treatment history, symptoms or patient-reported outcome measures. The concept of PGHD is intentionally broad in order to include all types of health data irrespective to collection method - activity trackers, sensors, smart technologies, mobile health applications or manual tracking. We will consider PGHD that are manually entered into a mobile health application as part of the concept, however, data obtained verbally from a patient and manually entered by a healthcare provider will not be considered.

Context

The context is the health care provider's use of PGHD that are integrated into EHRs. The context is broad to cover any type of EHR integration and does not stipulate a specific method of integration, health care context (i.e., inpatient or outpatient), or type of EHR. The study is focused on actual integration of PGHD into the EHR. Therefore, this scoping review will only consider studies that allow healthcare providers to access PGHD from EHR workflows.

Stage 2: Identification of Relevant Studies

Two trained nurse researchers (WH, VT) will operationalize the review following an *a priori* protocol. We will search scholarly databases and identify relevant articles using a systematic search strategy. The strategy will consist of a targeted, iterative searching technique, identified by Morris et al., to keep track of new keywords as articles are screened[15]. The search strategy stage involves two steps performed in collaboration with a University of Utah librarian:

1. Conduct a limited search in MEDLINE/PubMed to analyze the text words in the titles and abstracts of articles retrieved and the index terms used to describe the article. Any new keywords found will be incorporated into the initial search.

2. Using the keywords and index terms, conduct a second search across all databases and grey literature.

An information specialist (MM) will develop the strategy for our primary database, MEDLINE/PubMed, then translate for other databases. Peer review of search strategies will be conducted by library colleagues. Databases will include - Medline(Ovid) 1946-2019, Embase (embase.com) 1974 - 2019, CINAHL Complete (Ebscohost) 1937-2019, Scopus (scopus.org) 1970-2019 and Web of Science Core Collection (Clarivate Analytics) 1900-2019, Academic Search Ultimate (Ebscohsot) 1965 – 2019, Dissertations & Theses Global (ProQuest) 1861-2019, IEEE Xplore (IEEE.org) 1988 – 2019 and INSPEC (Elesevier.com) 1989 – 2019. We will search conference proceedings from organizations such as the American Medical Informatics Association (AMIA) and the International Conference on Healthcare Informatics (ICHI). No filters, such as date, language or study type will be applied.

Unpublished studies and grey literature—industry and trade papers—will be identified using web searching using the Google (Google LLC) search engine. Using consistent search terms, the screening process will be limited to the first fifty results returned for purposes of feasibility[16]. To facilitate the transparency of web searching, for each website we will report the URL, dates searched, search terms, and the citation details of any included literature.

Stage 3: Study Selection

We will use Endnote (X9.1, Clarivate Analytics) to manage citations and remove duplicates, and then export results into Covidence systematic review software (Veritas Health

Innovation, Melbourne, Australia). We will document the process in a diagram according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. Our inclusion criteria are:

1. Data must meet the definition of PGHD: data created, recorded, or gathered by or from patients (or family members or other caregivers) to address a health concern.

2. Integration of PGHD into the EHR must allow healthcare providers to view the data within the EHR without having to log into a separate application.

We will include only original articles. Study types such as chart reviews, opinion papers, case reports and editorials will be excluded. Examples of partial or in progress integration will be included. However, studies that simply describe the potential to integrate in the future will be excluded. We will derive additional inclusion criteria from the first step of the search strategy.

The study selection stage will consist of two levels of screening: title and abstract during level 1 screening, and full-text review in level 2 screening. During level 1, each member of the research team will test the above screening criteria on a sample of abstracts to ensure they are robust enough to capture eligible articles. In level 2 screening, the two researchers will assess each full-text independently to determine eligibility. The two researchers (VT, WH) will meet regularly to review data collection, discuss selection of literature and strive for full agreement. If necessary, a third researcher will arbitrate disagreements regarding study inclusion[17]. We will produce discrepancy reports in Covidence to facilitate consensus conversations. Criteria may be clarified based on sources of disagreement. Once full agreement is reached, we will proceed with the screening of all full text articles.

Stage 4: Charting Relevant Data

After the screening process, the research team will extract or 'chart' data from the relevant articles. Using variables related to existing conceptual frameworks, we developed extraction fields in advance. We will extract relevant data, both quantitative and qualitative, into an Excel spreadsheet using the extraction fields in Table 1.

Table 1

Eligible Article Extraction Fields

Study Characteristics	Research Question Specific
Authors	PGHD content/type
Year of Publication	Technical Integration Method
Study Location	Workflow Integration Method
Aims/Purpose	Adoption and Use
Study Population and Sample Size (if applicable)	Implementation Details
Study Design and Methodology	Challenges
Study Setting	Facilitators
Intervention type and comparator (if applicable)	
Duration of the intervention (if applicable),	
Outcomes measured	

Once relevant data are abstracted, we will iteratively develop a coding and classification scheme from the extraction fields to assign categories to the extracted data[18]. We will import the extracted data of each included study into Dedoose (Dedoose Version 7.0.23, Los Angeles, California: SocioCultural Research Consultants, LLC, www.dedoose.com), a qualitative data analysis web application, to facilitate coding and classification. To attend to rigor in the process, each researcher will independently categorize 10% of the articles retrieved against the coding scheme. Cohen's Kappa statistic will be calculated to measure interrater reliability between the

two coders and we will consider a Kappa value greater than 0.90 as good agreement [19,20]. If agreement is not reached initially, differences will be resolved through discussion and if needed, a third researcher will assist. Once agreement is reached and the final list of categories obtained, we will proceed with categorizing the entire set of articles. We will add emerging, inductive codes to the deductive codes as needed. The results will include a description of any disagreements with how the differences were resolved and consensus reached.

Stage 5: Collecting, Summarizing and Reporting Results

In the data analysis stage of the scoping review framework, we will collect the extracted data in a table format and create higher level codes, categories, and themes dependent on findings. To describe the data, we will draft a narrative summary to address the research question and perform a frequency analysis by calculating the counts and percentages of articles per each category or theme identified in the coding process. There may be clustering of the extracted data on various levels depending on the number of articles that correspond with each category. An analysis of these results will be presented in a graph or tabular format as needed. An assessment of study quality will not be performed since the purpose of this scoping review is to map the literature, and quality assessments are not routinely used in scoping reviews [13].

ETHICS and DISSEMINATION

Consultation with health sciences librarian services was conducted in early 2019. Database searches will be initiated in June 2019. The review is expected to be completed by October 2019. Ethical approval is not required for this scoping review and exempt from IRB oversight because it is not human subjects research[21].

The strengths of this scoping review are the use of a systematic framework, and the contribution of knowledge to advance the use of PGHD. Due to the novel, mobile sources of PGHD, there is little scientific guidance for using PGHD within EHR workflows. This work will inform the technical development of future health applications and PGHD integration.

A limitation of this scoping review is that it may not capture all work in this area. The design and development of mobile health applications is moving at a rapid pace. As such, research on integration may as yet be rarely studied or published, making it difficult to discover. Using grey literature searching techniques, we hope to mitigate this concern and include as many articles as possible. Another limitation, found with scoping reviews in general, is that a formal assessment for risk of reporting bias will not be conducted. The goal of this scoping review is to report all evidence, regardless of quality.

A feedback loop between patients and providers is essential to maintain patient engagement with collecting and sharing their data. Without successful integration into the EHR, healthcare providers may not be able to view or use PGHD. Best practices and technical requirements to facilitate optimal PGHD integration are unknown. The types of PGHD best suited for EHR integration are not evident. A thorough understanding of integration methods may support further exchange of PGHD and lessons learned from the literature could be shared with developers to create efficiencies and reduce costs in future implementations.

The findings of this scoping review will be used to understand the current work, explore best practices and gain insights into where the inclusion of PGHD is working well and where there is still work to be done. The research team will disseminate findings through publications and presentations at informatics related conferences.

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FOOTNOTES

Author's Contributions: VT designed the review, developed the research question and contributed meaningfully to the drafting and editing. MM and WH aided in the development of the study methods and contributed meaningfully to the drafting and editing. KS, GD, CS, CW and MC contributed meaningfully to the drafting and editing and approved the final manuscript.

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Competing Interest: None declared.

Provenance and peer review: Not commissioned; externally peer reviewed.

Data sharing statement: No additional data are available.

Supplementary Table 1. PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☐	☒	N/A
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	16
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	16
Sponsor	5b	Provide name for the review funder and/or sponsor	☐	☒	N/A
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☐	☒	N/A
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	4-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	6-7
METHODS					

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	7-8
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	8
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	8-9
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	8-9
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	10-11
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	12
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☒	☐	10-11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	N/A
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☒	☐	11
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	11
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☒	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☐	☒	N/A

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Methods and Analysis: This study aims to conduct a rigorous scoping review to explore evidence related to the integration of PGHD into EHRs. Using the framework developed by Arksey and O'Malley, we will create a systematic search strategy, chart data from the relevant articles, and use a qualitative, thematic approach to analyze the data. This review will enable the identification of types of integration and describe challenges and barriers to integrating PGHD.

Ethics and Dissemination: Database searches will be initiated in June 2019. The review is expected to be completed by October 2019. As the content of the full-text articles emerges, the authors will summarize the characteristics related to the integration of PGHD. The findings of this scoping review will identify research gaps and present implications for future research.

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With advances in mobile health technologies, including mobile applications, activity trackers, and other sensors, patients are generating more health-related data than ever before. Patient-generated health data (PGHD) - data created, recorded, or gathered by or from patients (or family members or other caregivers) to address a health concern - can be used to screen for problems, monitor progress, and enhance communication between patients and their care providers [1]. Although these data have the potential to provide insights to the status and behavior of patients between care episodes, the vast amount of information continuously generated from patients remains untapped [2].

As of 2017, most hospitals across the country have adopted complete electronic systems, and 86% of physician practices have implemented a basic electronic health record [3]. Electronic health records (EHRs) provide quick and secure access to patient data and have become an essential part of patient care workflows by enabling functions such as patient history documentation, note writing, order entry, results management, and decision support. EHRs provide a broad view of treatment plans, past medical history, and current problems with a focus on the total health of patients. PGHD can enhance the information that EHRs already have and contribute to the overall health profile of the patient [4]. When patients offer information to healthcare providers, they are empowered as contributors to their care, and evidence shows that activated patients have higher levels of self-care and satisfaction[5]. By including PGHD in the medical record, patients are inspired to engage in future care episodes[6]. Moreover, expectations are high, and patients believe that mobile health technologies will create efficiencies and increase the convenience of healthcare services[7]. However, it is unclear as to what extent PGHD are currently incorporated in and accessed from EHRs [8].

Healthcare providers are trained to use all available information to care for patients. This includes verbal or electronic PGHD that are collected at the time of the clinical encounter[9]. However, there are barriers to including PGHD as part of the clinical decision-making process[10]. PGHD can be of suboptimal quality, and may be full of bias, noise, and variability [11]. In a systematic review by Greenwood et al., health care teams reported an increased burden due to information overload from PGHD, suggesting that the data may not be usable in current forms[12]. A lack of accepted practices for providers to review or take action on PGHD may cause liability concerns, and best practices to transform these data into meaningful and actionable information have not been identified. A thorough examination of the current literature is needed to understand how, when, and where PGHD are integrated into EHRs. We believe this will be the first scoping review to identify and categorize examples of PGHD integration into EHRs.

METHODS

Scoping reviews are a type of literature review that provide an overview of the type, extent, and quantity of research available on a given topic. Scoping reviews are useful in synthesizing the evidence on a topic, mapping and identifying gaps in the research knowledge base, and providing an overview of the existing evidence[13]. Although scoping reviews have a less restrictive methodological approach compared to systematic reviews, this study will utilize an existing framework in order to maximize rigor. We utilized guidance from the Joanna Briggs Institute to prepare this protocol, and we will also use it throughout the review[13].

Our scoping review is based on a five-stage framework for scoping reviews described by Arksey and O'Malley:

- identification of the research question;

- identification of relevant studies;
- study selection;
- charting relevant data from the studies;
- and collecting, summarizing and reporting the results[14].

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol PRISMA-P 2015 Checklist will inform the protocol development and enhance transparency and reproducibility. This protocol was developed, reviewed, and agreed upon by all members of the research team.

Stage 1: Identification of the Research Question

The following question based on elements of Population, Concept, and Context (PCC) will guide the scope of the inquiry[13]:

"What evidence has been reported on the integration of patient-generated health data into electronic health records?"

To further guide the search, we will utilize secondary questions related to the integration:

What types of integration have been explored?

What barriers to integration have been reported?

What is know about best practices for PGHD integration?

Population

The primary target population of this scoping review is any patient, family member, or caregiver that is generating data that can be electronically shared with health professionals (with

health professionals as the secondary target population). This review will consider studies that involve patients in all types of care or treatment. Similarly, the data may be shared with any type of health professional that is caring for or treating patients, and there are no restrictions on the care provider or setting. The use of PGHD for prevention and wellness activities will also be considered.

Concept

The concept of this review is PGHD, and we will use the definition provided by the United States Office of the National Coordinator for Health Information Technology to guide our inquiry[1]. PGHD supplement existing clinical data and may include treatment history, symptoms, or patient-reported outcome measures. The concept of PGHD for this review is intentionally broad in order to include all types of health data irrespective to collection method: activity trackers, sensors, smart technologies, mobile health applications, videos, audio recordings, or manual tracking. We will consider PGHD that are manually entered by the patient or family into a mobile health application as part of the concept. However, data obtained verbally from a patient and manually entered directly into the EHR by a healthcare provider will not be considered.

Context

The context is PGHD that are integrated into EHRs for use by healthcare providers. The context is broad in order to cover any type of EHR integration and does not stipulate a specific method of integration, health care context (i.e., inpatient or outpatient), or EHR type. EHRs encompass any digital technology used to collect longitudinal electronic health information from an individual. We will consider EHRs that are locally hosted or cloud-based and those that are

partially implemented. The study is focused on PGHD that are currently integrated into the EHR. Therefore, this scoping review will only consider studies that allow healthcare providers to access PGHD from EHR workflows that are in production. We will include PGHD from patient portals or personal health records if the PGHD are viewable from within the EHR.

Stage 2: Identification of Relevant Studies

Two trained nurse researchers (WH, VT) will operationalize the review following an *a priori* protocol. We will search scholarly databases and identify relevant articles using a systematic search strategy. The strategy will consist of a targeted, iterative searching technique, identified by Morris et al., to keep track of new keywords as articles are screened[15]. The search strategy stage involves two steps performed in collaboration with a University of Utah librarian:

1. Conduct a limited search in MEDLINE/PubMed to analyze the text words in the titles and abstracts of articles retrieved and the index terms used to describe the article. Any new keywords found will be incorporated into the initial search.

2. Using the keywords and index terms, conduct a second search across all databases and grey literature.

An information specialist (MM) will develop the strategy for our primary database, MEDLINE/PubMed, then translate for other databases. Peer review of search strategies will be conducted by library colleagues. Databases will include: Medline (Ovid) 1946-2019, Embase (embase.com) 1974 - 2019, CINAHL Complete (Ebscohost) 1937-2019, Scopus (scopus.org) 1970-2019 and Web of Science Core Collection (Clarivate Analytics) 1900-2019, Academic Search Ultimate (Ebscohsot) 1965 – 2019, Dissertations & Theses Global (ProQuest) 1861-2019, IEEE Xplore (IEEE.org) 1988 – 2019, and INSPEC (Elesevier.com) 1989 – 2019. We

will search conference proceedings from organizations such as the American Medical Informatics Association (AMIA) and the International Conference on Healthcare Informatics (ICHI). No filters, such as date, language, or study type will be applied. A draft literature search strategy using Medline can be found in Supplementary file (1).

Unpublished studies and grey literature, such as industry and trade papers, will be identified using web searching using the Google (Google LLC) search engine. Using consistent search terms, the screening process will be limited to the first fifty results returned for purposes of feasibility[16]. To facilitate the transparency of web searching, for each website we will report the URL, dates searched, search terms, and the citation details of any included literature. Examples of potential keywords include: patient generated health data (MeSH term), user generated health data, personal tracking, self-report, and mobile health.

Stage 3: Study Selection

We will use Endnote (X9.1, Clarivate Analytics) to manage citations and remove duplicates, and then we will export results into Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia). We will document the process in a diagram according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. Our inclusion criteria are:

1. Data must meet the definition of PGHD: data created, recorded, or gathered by or from patients (or family members or other caregivers) to address a health concern.

2. Integration of PGHD into the EHR must allow healthcare providers to view the data within the EHR without having to log into a separate application.

We will include only original articles. Examples of partial or in progress integration will be included. However, studies that simply describe the potential to integrate in the future will be excluded. We will also exclude the following study types: chart reviews, opinion papers, case reports, and editorials. We will derive additional inclusion criteria from the first step of the search strategy.

The study selection stage will consist of two levels of screening: title and abstract during level 1 screening, and full-text review in level 2 screening. During level 1, each member of the research team will test the above screening criteria on a sample of abstracts to ensure they are robust enough to capture eligible articles. In level 2 screening, the two researchers will assess each full-text independently to determine eligibility. The two researchers (VT, WH) will meet regularly to review data collection, discuss selection of literature, and strive for full agreement. If necessary, a third researcher (MM) will arbitrate disagreements regarding study inclusion[17]. We will produce discrepancy reports in Covidence to facilitate consensus conversations. Criteria may be clarified based on sources of disagreement. Once full agreement is reached, we will proceed with the screening of all full text articles.

Stage 4: Charting Relevant Data

After the screening process, the research team (VT, WH) will extract or chart data from the relevant articles. Using variables adopted from the Joanna Briggs Institute standardized data extraction tool and expert opinion, we developed extraction fields in advance[13]. We will extract relevant data, both quantitative and qualitative, into a spreadsheet using the variables listed in Table 1. Since some of the variables are broad, we do not anticipate the need for changes to the extraction form. Scoping review methodology does allow for iterative additions to the a priori

data charting elements during extraction, allowing for greater magnitude in mapping the literature[13].

Once relevant data are abstracted, we will iteratively develop a coding and classification scheme from the extraction fields to assign categories to the extracted data[18]. We will import the extracted data of each included study into Dedoose (Dedoose Version 7.0.23, Los Angeles, California: SocioCultural Research Consultants, LLC, www.dedoose.com), a qualitative data analysis web application, to facilitate coding and classification. To attend to rigor in the process, each researcher will independently categorize 10% of the articles retrieved against the coding scheme. Cohen's Kappa statistic will be calculated to measure interrater reliability between the two coders and we will consider a Kappa value greater than 0.90 as good agreement [19,20]. If agreement is not reached initially, differences will be resolved through discussion, and, if needed, a third researcher (MM) will assist. Once agreement is reached and the final list of categories obtained, we will proceed with categorizing the entire set of articles. We will add emerging, inductive codes to the deductive codes as needed. The results will include a description of any disagreements with how the differences were resolved and consensus reached.

Table 1

List of variables to be extracted

Aspects	Variables
Study Characteristics	• Authors • Year of Publication • Study Location • Aims/Purpose

- Study Population and Sample Size (if applicable)
- Study Design and Methodology
- Study Setting
- Intervention type and comparator (if applicable)
- Duration of the intervention (if applicable)
- Outcomes measured

Research Question Specific

- PGHD content/type
- Technical Integration Method
- Workflow Integration Method
- Adoption and Use
- Implementation Details
- Challenges
- Facilitators

Stage 5: Collecting, Summarizing and Reporting Results

In the data analysis stage of the scoping review framework, we will collect the extracted data in a table and create higher level codes, categories, and themes dependent on findings. To describe the data, we will draft a narrative summary to address the research question and perform a frequency analysis by calculating the counts and percentages of articles per each category or theme identified in the coding process. There may be clustering of the extracted data on various levels depending on the number of articles that correspond with each category. An analysis of these results will be presented in a graphical or tabular format as needed. An assessment of study quality will not be performed since the purpose of this scoping review is to map the literature, and quality assessments are not routinely used in scoping reviews [13].

Patient and Public Involvement

There will be no direct patient or public involvement in this research, nor were patients or the public involved in the design or planning of the study.

ETHICS and DISSEMINATION

Consultation with health sciences librarian services was conducted in early 2019. Database searches will be initiated in June 2019. The review is expected to be completed by October 2019. This scoping review is categorized as exempt from IRB oversight because it is not human subjects research[21].

The strengths of this scoping review are the use of a systematic framework and the contribution of knowledge to advance the use of PGHD. Due to the novel, electronically-derived sources of PGHD, there is little scientific guidance for using PGHD within EHR workflows. This work will inform the technical development of future health applications and PGHD integration.

A limitation of this scoping review is that it may not capture all work in this area. The design and development of mobile health applications is moving at a rapid pace. As such, EHR integration may as yet be rarely studied or published, making it difficult to discover in the literature. Using grey literature searching techniques, we hope to mitigate this concern and include as many articles as possible. Another limitation with scoping reviews in general is that a formal assessment for risk of reporting bias will not be conducted. The goal of this scoping review is to report all evidence, regardless of quality.

The findings of this scoping review will be used to understand the current work, explore best practices, and gain insights into where the inclusion of PGHD is working well and where

there is still work to be done. The research team will disseminate findings through publications and presentations at informatics related conferences.

CONCLUSION

A feedback loop between patients and providers is essential to maintain patient engagement with collecting and sharing their data. Without successful integration into the EHR, healthcare providers may not be able to view or use PGHD. Best practices and technical requirements to facilitate optimal PGHD integration are unknown at this time. The types of PGHD best suited for EHR integration are not evident. A thorough understanding of integration methods may support further exchange of PGHD, and lessons learned from the literature could be shared with developers to create efficiencies and reduce costs in future implementations.

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FOOTNOTES

Author's Contributions: VT designed the review, developed the research question and contributed meaningfully to the drafting and editing. MM and WH aided in the development of the study methods and contributed meaningfully to the drafting and editing. KS, GD, CS, CW and MC contributed meaningfully to the drafting and editing and approved the final manuscript.

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Competing Interest: None declared.

Provenance and peer review: Not commissioned; externally peer reviewed.

Data sharing statement: No additional data are available.

Supplementary Table 1. PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☐	☒	N/A
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	16
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	16
Sponsor	5b	Provide name for the review funder and/or sponsor	☐	☒	N/A
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☐	☒	N/A
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	4-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	6-7
METHODS					

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	7-8
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	8
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	8-9
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	8-9
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	10-11
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	12
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☒	☐	10-11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	N/A
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☒	☐	11
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	11
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☒	N/A

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☐	☒	N/A