

BMJ Open 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 (PGHD) integration into electronic health records (EHRs) using systematic scoping methods to review the available literature. PGHD have the potential to enhance decision making by providing the valuable information that may not be ordinarily captured during a routine care visit. These data which are captured from mobile devices, such as smartphones, activity trackers and other sensors, should be integrated into clinical workflows to allow for optimal use by clinicians.

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 analyse 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 summarise the characteristics related to the integration of PGHD. The findings of this scoping review will identify research gaps and present implications for future research.

INTRODUCTION

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 behaviour of patients between care episodes, the vast amount of information continuously generated from patients remains untapped.²

Strengths and limitations of this study

- This scoping review will use an existing framework developed by Arksey and O'Malley in order to maximise rigour.
- By examining the patient-generated health data (PGHD) integration into electronic health records, 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 related to 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.

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 (EHR).³ EHRs provide quick and secure access to the 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, 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*, healthcare 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 the 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 that this will be the first scoping review to identify and categorise 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 synthesising 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 with systematic reviews, this study will use an existing framework in order to maximise rigour. We used 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.
- ▶ Collecting, summarising and reporting the results.¹⁴

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocol 2015 Checklist will inform the protocol development and enhance transparency and reproducibility (online supplementary file 1). This protocol was developed, reviewed and agreed on 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 will guide the scope of the inquiry¹³:

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

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

What types of integration have been explored?

What barriers to integration have been reported?

What is known 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 US 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, healthcare context (ie, 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 and VLT) will operationalise 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 analyse 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 (MMM) 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 (EBSCOhost) 1965–2019, Dissertations & Theses Global (ProQuest) 1861–2019, IEEE Xplore (IEEE.org) 1988–2019 and INSPEC (Elsevier.com) 1989–2019. We will search conference proceedings from the organisations such as the American Medical Informatics Association (AMIA) and the International Conference on Healthcare Informatics. No filters, such as date, language or study type, will be applied. A draft literature search strategy using Medline can be found in (online supplementary file 2) .

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 50 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: PGHD (Medical Subject Headings 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 PRISMA 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 (VLT and WH) will meet regularly to review data collection, discuss selection of literature and strive for full agreement. If necessary, a third researcher (MMM) 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 (VLT and WH) will extract or chart data from the relevant articles. Using variables adopted from the Joanna Briggs Institute standardised data extraction tool and expert opinion, we developed extraction fields in advance.¹³ We will extract the 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 V.7.0.23, Los Angeles, California, USA: SocioCultural Research Consultants, LLC, www.dedoose.com), a qualitative data analysis web application, to facilitate coding and classification. To attend to rigour in the process, each researcher will independently categorise 10% of the articles retrieved against the coding scheme. Cohen's kappa statistic will be calculated to measure inter-rater 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, the differences will be resolved through discussion, and, if needed, a third researcher (MMM) will assist. Once agreement is reached and the final list of categories obtained, we will proceed with categorising 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

PGHD, patient-generated health data.

Stage 5: collecting, summarising 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 the 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 categorised as exempt from Institutional Review Board 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 the 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 the 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 learnt from the literature could be shared with developers to create efficiencies and reduce costs in future implementations.

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Contributors VLT designed the review, developed the research question and contributed meaningfully to the drafting and editing. MMM and WH aided in the development of the study methods and contributed meaningfully to the drafting and editing. KAS, GDF, CS, CW and MRC contributed meaningfully to the drafting and editing and approved the final manuscript.

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