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# Patient generated health data and electronic health record integration, governance and socio-technical issues: A narrative review

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# Patient generated health data and electronic health record integration, governance and socio-technical issues: A narrative review

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ABSTRACT

Patients' health records have the potential to include patient generated health data (PGHD), which can aid in the provision of personalized care. Access to these data can allow healthcare professionals to receive additional information that will assist in decision-making and the provision of additional support. Given the diverse sources of PGHD, this review aims to provide evidence on PGHD integration with electronic health records (EHR), models and standards for PGHD exchange with EHR, and PGHD-EHR policy design and development. The review also addresses governance and socio-technical considerations in PGHD management. Databases used for the review include PubMed, Scopus, ScienceDirect, IEEE Xplore, SpringerLink and ACM Digital Library. The review reveals the significance, but current deficiency, of provenance, trust and contextual information as part of PGHD integration with EHR. Also, we find that there is limited work on data quality, and on new data sources and associated data elements, within the design of existing standards developed for PGHD integration. New data sources from emerging technologies like mixed reality, virtual reality, interactive voice response system, and social media are rarely considered. The review recommends the need for well-developed designs and policies for PGHD-EHR integration that promote data quality, patient autonomy, privacy, and enhanced trust.

## Statement of significance

| Problem or Issue: | What is Already Known: | What this Paper Adds: |
|---|---|---|
| With increasing sources of Patient Generated Health Data (PGHD), it is important to understand the scope of PGHD, models and standards for representing PGHD and integrating it with Electronic Health Records (EHRs) and how models and standards can be leveraged to develop frameworks and systems that accommodate these new data sources. In addition, understanding the supporting governance and socio-technical environment can be helpful to adoption of PGHD in clinical care. | Integration of PGHD with EHRs has been explored in previous studies. | This review provides further insight into the state of PGHD integration with EHRs, including information about existing models, standards and policies for integration. It highlights current limitations in integrating PGHD with EHRs, identifying opportunities for enhancing the current models and standards, for example with metadata about trust, quality and provenance. The review also addresses governance and socio-technical considerations in PGHD management. |

## 1. Introduction

Modern patient care requires clinical practitioners to have access to detailed data about their patients, to enable them to provide a safe and effective patient-centered healthcare service. There has been a rise in consumer-based devices that collect, store and use significant amounts of patient generated health data (PGHD). Patients' health records at the point of care have the opportunity to include PGHD, which can

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potentially aid in personalized patient care. PGHD otherwise known as Patient Generated Data (PGD), has been commonly defined as health-related data that people keep to assist them in better understanding of their own health [1]. PGHD can consist of clinical measurements such as heart rate, temperature, height, weight, and blood pressure [2] taken by patients themselves or their authorized care givers. However, more recently, this has also included information such as observations of the daily living, for example, mood and sleep patterns [3,4]. PGHD have historically been shared with clinicians in different forms, for example paper diaries to record symptoms or email messages to share health related images and/or text-based data [4]. However, in the last decade, PGHD has also been communicated through patient portals (otherwise referred to as Patient Health Records – PHR) usually provided by healthcare providers [5].

The proliferation of Internet of Things (IoT) consumer devices (smart watches, smart speakers and bespoke trackers) which collect enormous amounts of PGHD has generated significant interest among health care providers (HCP), researchers and the general public. While manufacturers have stressed the personal wellbeing benefits of these devices as standalone non-clinical products, PGHD captured through these devices can play a significant role in improving quality of care in clinical settings. In order to do this, PGHD devices will need to be able to share data securely and appropriately with the health care system, through Electronic Health Records (EHR). Due to held beliefs or privacy concerns, Lim et al. [6] have found that patients with chronic conditions often withhold information from clinicians when communicating about what they deem important to their health and well-being, in spite of clinicians need to understand what is important in the lives of these patients. Furthermore, it is increasingly common for patients to require interdisciplinary services and PGHD can potentially augment the health information gathered during clinic visits. However, this will require novel interoperable systems, and active information sharing between patients and clinicians. While sharing more information with clinicians is demonstrated in some situations to be good, there are significant conflicts and tensions that can arise as a result. Sanger et al. [7] examine these tensions and report patients' preference to include more flexibility in data input, text-based data exchange, timely and reliable provider responses, and definite diagnoses. There is also significant concern from clinicians around how the 'tsunami' of data emerging from patients will be handled [8,9] and the reliability of PGHD [10]. In addition, secure sharing of health-related data has continued to pose significant challenges because of the difficulty in enforcing security on such data while also making it readily available and simultaneously complying with local and international regulations. Health data including PGHD creates the paradox – "difficult to share" given that it is sensitive data and requires a significant amount of privacy and security, yet the difficulty in accessing it when it is needed can potentially cause significant harm [11].

Apart from paper-based reports, the main way that integration in health care has been managed up until now has been through custom sets of electronic messages which provides some architecture for representing the communicable, longitudinal, and multi-enterprise record for any patient, that meets clinical, ethical and legal requirements [12]. These architectures are designed to allow clinical information systems and components communicate with EHR systems, to exchange health record entries. Interoperability is critical to satisfying the aim of better care for patients, better health for populations, and lowered cost due to improved delivery of care. A lack of interoperability leads to limited understanding of a patient or population's health needs, and this leads to higher costs and poor health outcomes [11]. To address this, several studies have discussed and/or applied standards such as Clinical Care Document (CCD), Clinical Care Record (CCR), Health Level 7 (HL7) Clinical Document Architecture (CDA) and Fast Healthcare Interoperable Resources (FHIR) to support interoperability [3,13,14]. These standards use semantic ontologies such as Logical Observation Identifiers Names and Codes (LOINC), SNOMED CT (Systematized Nomenclature of Medicine-Clinical Terms), and other ontologies in OntoPortals that are consistent and enable interoperability [15]. There are also studies that report PGHD integration from mobile applications and wearables to EHRs [16–18]. However, little is known about the extent of use of standards, distinctions between these standards and how new and emerging PGHD sources [19] including mixed reality (MR), Interactive Voice Response System (IVR), IoT and social media data or data elements (such as oxygen saturation, heart variability, breathing rate [20]) are accounted for or transmitted using these standards. In addition, there are human factors and usability issues that surround the development, deployment and integration of PGHD in clinical care. Poor system design, which has led to usability issues, has been recognized as a barrier to PGHD integration [21]. Similarly, a lack of understanding and assessment of lay users' workflow as well as their health literacy has impacted on the development of such systems resulting in difficulty to use and a lack of context sufficient to comprehend such datasets [22].

Systematic reviews have been conducted on how PGHD is used in clinical practice [23] and how it affects clinicians' relationships with patients [24]. However, neither of these studies had a specific focus on PGHD integration. Tiase et al. [15] recently undertook a scoping review to reveal the state of PGHD integration with EHR and key technical issues considered at each state of integration based on the data flow proposed by Shapiro et al. [4], however, we find limited information on models and standards for the integration, socio-technical and governance considerations in PGHD integration in their work. Hence, this review aims to provide further insight into PGHD integration with EHR, models and standards for PGHD exchange with EHR, PGHD-EHR policy design and development, governance and socio-technical factors in PGHD management within care networks. To guide the review, the following research questions were analyzed:

RQ1: How has Patient Generated Health Data been defined?
RQ2: How have dataflows for PGHD been defined for clinical settings?
RQ3: What are the interoperability standards for PGHD exchange with EHR?
RQ4: What are the socio-technical factors in PGHD-EHR Integration?
RQ5: What are the governance and policy issues around PGHD-EHR integration?

## 2. Methodology

This study employs a narrative review approach [21,25], which enables researchers to provide a comprehensive overview of evidence on their chosen research topic. As recommended in Simpson [21], the review was prepared by one author (AAK) and evaluated by the other two authors (DOS and LH) for quality, using the SANRA framework [25].

## 3. Search strategy

The literature search for the review was conducted on PubMed, Scopus, ScienceDirect, IEEE Xplore, SpringerLink and ACM Digital Library databases. Google Scholar was also used to account for relevant grey literature. The main keywords used were "patient generated health data", "exchange", "electronic health record". Other related terms or synonyms of each of these keywords were added to the search string in order not to miss key associated literature. Boolean operators were used for searching. The search matrix, information about database search results, and the ultimate search strings are included in Appendix 1. Due to limitations imposed on some databases (for instance Science Direct and Scopus databases do not allow queries with * and more than 8 logical operators), we used a variant of the search string to accommodate for these.

## 4. Inclusion and exclusion criteria

A total of 1572 studies were identified and exported to a reference management tool (Zotero) after duplicate records were expunged. Thereafter, papers were reviewed by title and abstract to determine eligibility and relevance. Only articles that had direct relevance to the study objectives and are within the scope of 12yrs (2010–2021) were selected. Studies that were not within the scope of this review or not directly relevant to the outcome of this review were excluded (see Table 1). At the end of the process, 79 papers were selected for this analysis, having met the outlined criteria (Fig. 1).

## 5. Data extraction

The full text of the 79 papers were uploaded to the Nvivo Software for qualitative data analysis. Each paper was read by one of the authors and relevant details were extracted based on a coding scheme. The coding scheme was used to help identify aspects relevant to the study objectives and to understand the research area. The coding scheme included the title, author, methods, limitations or gaps, data exchange, key findings, key arguments, standards, barriers, context, data provenance, data dimension, data quality, data stewardship, frameworks, meaning of data, study scales or measures, models, PGHD practice, PGHD value, governance. These codes are described in Appendix II.

The review focused on answering a range of research questions about PGHD, including its definition, PGHD dataflow, models and standards for PGHD exchange with EHR, socio-technical issues in PGHD management to include PGHD workflow, perceived value of PGHD in clinical settings (provider/patient perspective) and PGHD-EHR governance (organizational policies and national legislations). Below we discuss our findings relative to our research questions. For each question, we present a synthesis of what we learned from the literature including what helped us answer these questions, and what questions require more investigation.

## 6. Findings

### 6.1. Study characteristics

This review of the literature suggests a growing body of work, with significant interest in the design, standardization, and use cases of PGHD in clinical settings. An overview of the research papers consulted for the study, and findings based on the coding scheme, are given in Appendix III. The review showed that the focus of the selected studies was varied and, as such, different research methods were used. While some studies were exploratory and focused on design considerations of EHR systems that accommodate PGHD [1,27–29], others provided feasibility studies of the use of PGHD for clinical care [30,31]. There are a number of case studies that reported the use of PGHD integration with EHR for non-communicable diseases (NCDs) such as diabetes, asthma, cancer [1,30,32–34]. Some studies also discuss the use of PGHD to assess infectious disease - COVID-19 [35] and identification of health interest [36,37]. A significant number of studies have also reported models used to exchange data among PGHD sources and electronic health systems [4,8,16,17]. The sections that follow examine the findings with respect to the review's research questions.

RQ1: How has Patient Generated Health Data been defined?

Patient generated health data (PGHD), otherwise known as Patient Generated Data (PGD), has been defined as health-related data that people create or record to help them better understand their own health [1]. Woods et al. [38] extend this definition stating that PGHD captures personal, contextual information that can enrich clinical data and improve self-care of patients. However, these definitions do not account for the data generation, diversity and context of PGHD in real-life especially in relation to clinical practice and population health needs. An elaborate definition of PGHD is given by Shapiro et al. [4] as "health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—-created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern". A significant distinction between the definitions is the emphasis on how PGHD is made sense of by trusted care partners in the latter definition. Also, the reality of distributed data collection responsibility which can vary from patient to patient [39], to include partners or family members who can assist them. Most studies had reported PGHD data collected through mHealth apps (mobile and web) and wearables, with some studies [12,40] including social media posts as a PGHD source.

A closely related term to PGHD is the Patient Reported Outcome (PRO) or Patient Reported Outcome Measures (PROM). Some studies have categorized PROM as a sub-type of PGHD [41]. PGHD has been distinctly separated from patient-reported outcome (PRO) data in that PGHD is patient driven, not practitioner (service providers) or researcher driven [1]. PGHD tools and sources (mobile apps, trackers, wearables, PHRs, etc.) let patients gather diverse and granular health related data that promote self-management behaviors including healthy food and exercise, which are vital for illness prevention and management. PRO/PROMs are focused on a record of patients' health improvement status following a clinical episode or intervention, and so are usually linked to clinician or researchers' pre-defined and structured tool – with data collection and sharing being provider-initiated [42]. Hence, patient ownership is a distinguishing feature of PGHD, which sets it apart from other forms of patient generated data like PRO/M. Maintaining patient ownership of PGHD shifts the role of health care providers to one in which they decide on the "prescription" for data gathering with patients [1]. Example of standardized PROM tools include Patient-Reported Outcomes Measurement Information System (PROMIS), Supportive Care Needs Survey-Short Form (SCNS-SF), and International Physical Activity Questionnaires (IPAQ) [43]. Jointly or separately, PGHD and PRO/M can be useful for patient care. Murthy, H. S. and Wood, W.A [44]. demonstrate that a combination of PGHD and PROM can improve long-term health-related quality of life (HRQOL). PROM can take different forms, but as mentioned, most PROMs are in standardized questionnaire, checklist or item-bank formats – and are usually prescribed by the provider [44,45]. PROM allows for a better knowledge of population health [4,46–49]. PGHD on the other hand, can include but is not limited to these formats. In practice and in recent times, PGHD have focused on structured data collected through mHealth apps (mobile and web) and wearables, which can give granular data such as temperature, numeric internal device or sensor readings like accelerometer readings, sleep score, etc. That are not usually collected with PRO/Ms [50]. However, deferring to Shapiro et al. [4] definition of PGHD, the future of PGHD is a combination of these and much more that will include very unstructured data and new data sources (such as from mixed reality, social media, interactive voice response and SMS) as depicted in Fig. 2.

**Table 1**
Inclusion and exclusion criteria.

| Inclusion |
|---|
| Literature dated between 2010 and 2021 |
| Studies that discuss patient generated health data sources with/out new data sources (IoT, mobile patient health record (mPHR), wearables) |
| Include Electronic health record data exchange |
| Discuss design and/or use cases of PGHD data integration with EHR |
| Address patient and/or provider needs within PGHD data communication |
| Studies on PGHD exchange models with EHR |

| Exclusion |
|---|
| Does not provide a clear methodology |
| Not related to Patient Generated Health Data |
| Generic legal literature on PGHD |

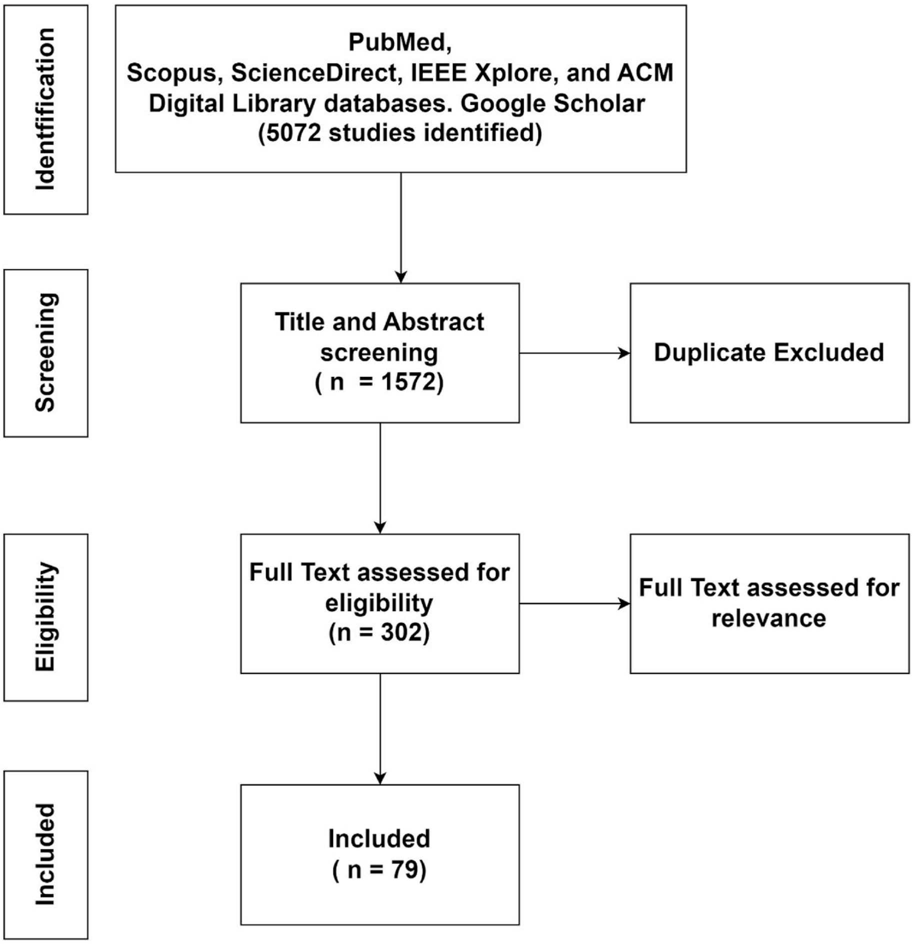


**Fig. 1.** The flow diagram describing how articles were identified and screened. Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRIMSA) framework [26].

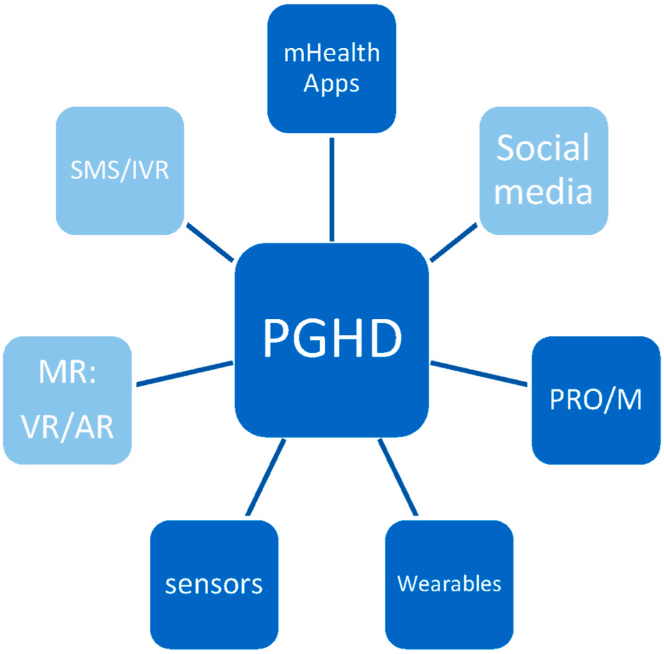


**Fig. 2.** Existing and Emerging PGHD sources.

From our review, more attention have been paid to integration of data with EHRs from sensors, wearables, mhealth apps and PROM, than other data sources (Fig. 2). PGD is interchangeably used in literature to mean PGHD [21]. However, studies [1,4] have carefully distinguished between PROM and PGHD. Sayeed et al. [41] have combined PROM with PGHD, in their proposed framework.

RQ2: How have dataflows for PGHD been defined for clinical settings?

Dataflow is the path and stages that data goes through from the time it is generated or captured until it is archived and/or deleted. Like most electronic data created as part of a system, PGHD does not exist in a vacuum; there is a dataflow for PGHD that accounts for the state and flow of data within the multi-stakeholder environment that PGHD persists within, and in relation to a clinical setting. While past studies [4, 46–48,51] have attempted to describe PGHD dataflow, most studies [47, 48] combine dataflow description as part of workflows (which we discuss in the later part of this review). Codella et al. [51] gives a wide-ranging insight into the potential paths a PGHD can navigate through (see Fig. 3).

In describing flow of data among entities interacting with PGHD, Codella, et al. [51] identified stakeholders who directly or indirectly interact with PGHD [Fig. 3]. Stakeholders include the patient who generates the data through a manufactured device; providers (clinicians) who make sense of the PGHD towards a health decision; the device company who may also work with providers and payers directly to provide data visualization and insight data as may be permissible within their terms of service; and the payers (government) who may incentivize the providers and patients to make meaningful use of such data [51].

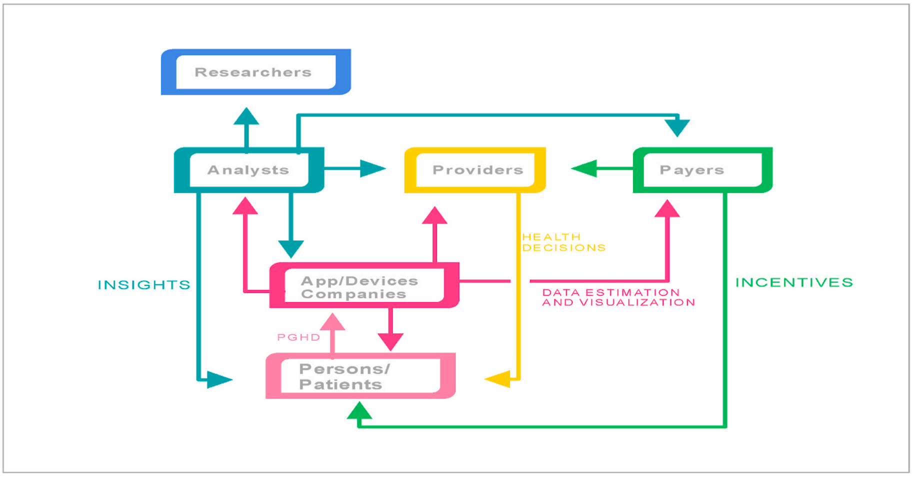
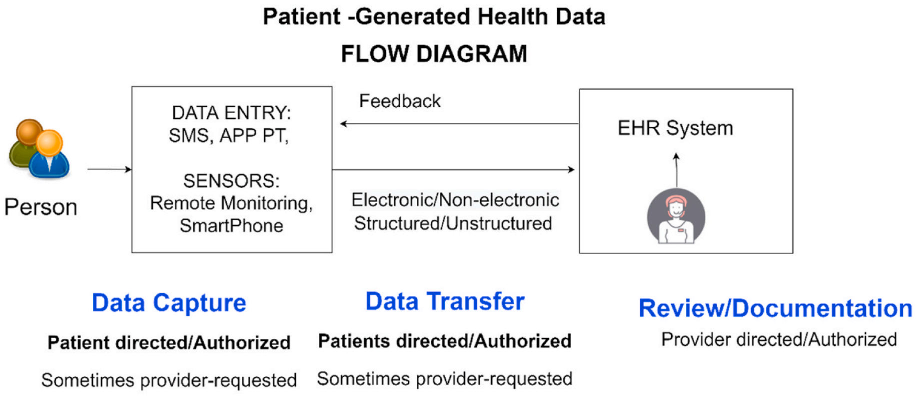


**Fig. 3.** Pghd data flow [51].

Sometimes, a third-party (analysts) gives insights to the patients, providers, device companies and researchers, for example, the work *fitabase* do with wearables [52]. Among all entities, the patients and providers are the two most important stakeholders that interact with PGHD data, hence a closer look into how data flows between them becomes critical. Essentially, we find two studies [4,46] that demonstrate a clearer depiction of PGHD data flow between patient and providers - see Fig. 4a and b.

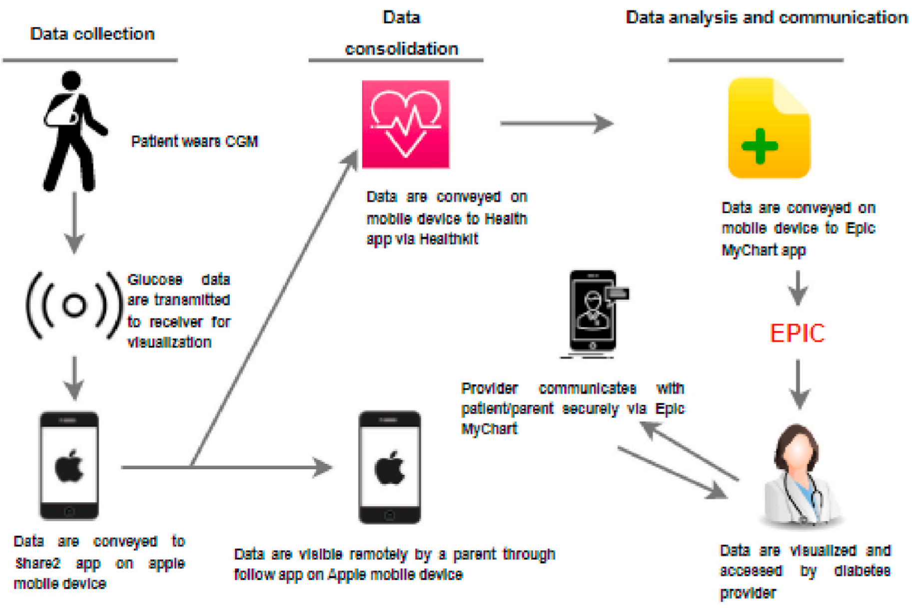
From the dataflow diagram (4a) above, Shapiro et al. [4] gave a view of the various PGHD sources that can be used to obtain PGHD, and how these data flow between the patient and the health service provider. They identified three phases of data flow which includes capturing (collection), transfer and data review/documentation (see Fig. 4a). In a similar vein, Kim et al. [46] describe a case study of Continuous Glucose Monitor (CGM) – (a PGHD source), and how that data travels or flows between different medium within a care workflow (see Fig. 4b). Similar to Shapiro et al. [4], they identified data capture and review (analysis and communication) as stages in the data flow. However, in contrast to Shapiro et al. [4], Kim et al. [46] considered a data "staging" phase they refer to as data consolidation phase (in between data capture and review/analysis), where data is first put-together before transmission or sharing with third-party applications. The data staging (or consolidation) phase in Fig. 4b may have been assumed by Shapiro et al. [4] as part of the data collection phase in Fig. 4a. This is very likely since by the design of Apple mobile application (which was used in Fig. 4b case study), health related sensor data are only available through the Apple Health Kit application, where data is then staged ("consolidated") as described in Fig. 4b before it gets transferred to a third-party application (EHR system). However, this is not the case for Android-based applications, as Android is an open-source system. This situation provides an opportunity to highlight the impact of closed systems (like Apple and Fitbit products), in the smooth flow of data among systems. In general, we can deduce that there are four (4) identified phases in the data flow of PGHDs i.e. data capture/collection, data consolidation (staging), data transfer, and data analysis/review/documentation.

Also, some commercial closed system applications have additional layers that differentiate them from open systems. Genes et al. [47] report that they had to use the ResearchKit in addition to the Apple Health kit to access aggregated data from Apple Smart Watch, and this requirement created hurdles in their study; the interaction between three systems created complexity requiring more effort in training for the research team and participating patients during the integration of PGHD with EHR. They thus suggest that for clinical use of data, a direct workflow should be developed between HealthKit and the MyChart app (the EHR) without involving ResearchKit. In addition [4], note that in some instances, some EHR architectures are modified to support the flow of PGHD. For instance, additional or separate databases or data layers – a staging area, of sorts is provided – to receive and store PGHD before the review process by clinicians. In the description of dataflow from included studies, we find that this has been limited to three main data sources viz; sensors or IoT systems, patient portal (provider controlled – e. g patientMpower, OpenEMR patient portal; or patient controlled e.g.



*a: PGHD Data Flow Diagram– adapted from Shapiro, et.al [4]*

**Fig. 4a.** PGHD Data Flow Diagram– adapted from Shapiro et al. [4].



*b: Example PGHD (CGM data) dataflow – adapted from Kim et al. [46].*

**Fig. 4b.** Example PGHD (CGM data) dataflow – adapted from Kim et al. [46].

Microsoft Health Vault, Apple Health Research Kit) [3,16–18] and application (web or mobile based) [3,4].

RQ3: What are the interoperability standards and models for PGHD exchange with EHR?

Interoperability in healthcare refers to the safe access, integration, and use of electronic health data to improve individual and community health outcomes [11]. Interoperability is essential for achieving the goals of better care for patients, improved population health, and lower costs via improved care systems. PGHD can be made interoperable with electronic medical records (EMR) and/or electronic health records (EHR) [5,53]. The terms electronic medical records (EMR) and electronic health records (EHR) are commonly interchanged in the literature.

In most cases, integration is made through standardized document exchange formats such as Clinical Care Document (CCD), Clinical Care Record (CCR) and Health Level 7 (HL7) Clinical Document Architecture (CDA) [ [2,3,3–14]. These document formats also make use of semantic and syntactic interoperability standards. Some of the widely used semantic standards include LOINC, SNOMED CT and ICD (International Classification of Disease) [54]. LOINC is the semantic standard for recording laboratory data, ICD is the standard for general epidemiological issues, and it has a wide range of clinical applications. SNOMED-CT on the other hand, is a set of core terms that encode the meanings of health-related terms in order to improve clinical data recording and patient care in EHRs [54].

While many studies have reported clinic-based data that have been integrated with EHRs including genome data [55], there are studies that attempt to integrate PGHD into EHRs [5,16–18]. In their study, Jung, et al. [5] integrated PGHD (lifelogs) from Samsung S-Health and Apple Health apps into EMR-tethered PHRs. There are also studies that report PGHD integration from mobile applications and wearables [16–18] to EHRs, to support management of diseases including diabetes and hypertension. In developing their ontology [56], incorporate the FHIR standard as part of the standardization of PGHD medical data; however their approach focused on sensor data, which is only one source of PGHD. Similarly, Sayeed, et al. [41] have employed FHIR standards on PROs as part of integration with EHRs, however, it is not known if this can be made generalizable to other PGHD sources. In addition, information models that facilitate and extend the capabilities of these standard data exchanges are being studied [3,54], [56, p.], [57]. For instance, Plastiras et al. [3] designed an information model that facilitates exchange of PGHD and observations of daily living (ODL) data between PHRs and EHRs. Similarly, Alamri, A [54]. proposed a middleware for integration of IoT data into EHRs.

Despite these efforts at integration and enhanced capabilities, the lack of a common ontology for PGHD limits the syntactic and semantic interoperability of measurements between institutions, limiting the generalizability of measurements [41]. Similarly, capturing contextual information is not well developed in existing standards, and imposing same standards for normal clinical data to PGHD can sometimes be misleading, especially if such contextual data have clinical relevance. The right kinds of PGHD elements and metadata are essential for different clinical situations. For instance, similar to a recorded laboratory results (say., cholesterol = 120 mg/dl) which can come with data such as a date/time, sample type, reference range, sample collection time, etc., PGHD (e.g., blood pressure of 120 systolic and 85 diastolic from a wearable) interpretation and flow into clinical systems will require several pieces of contextual information. These could include the data source (e.g., Omicron BP, model 143), reliability data (e.g., calibration of the device) metadata (point of action: e.g. left arm, position: e.g standing), and other such data that will aid to verify the device identity, user context, identity and so forth [4]. Sachdeva, S. and Bhalla [57], represented what a contextually fit blood pressure concept in an EHR might look like (Fig. 5).

Evidence suggests that some existing health IT standards have been leveraged to document and communicate PGHD to clinicians [16–18]. Similarly, extending the capabilities of these standards and ontologies is being explored [3,56]. However, given the breadth of data items, devices, communication methods, and workflows covered by PGHD, new and emerging PGHD sources or data elements, metadata, and contextual information are rarely accounted for or transmitted using these standards. Thus, Woods [38] suggests that there is a need to develop industry wide PGHD standards that will include data provenance and context. They argue that PGHD data sources require metadata which

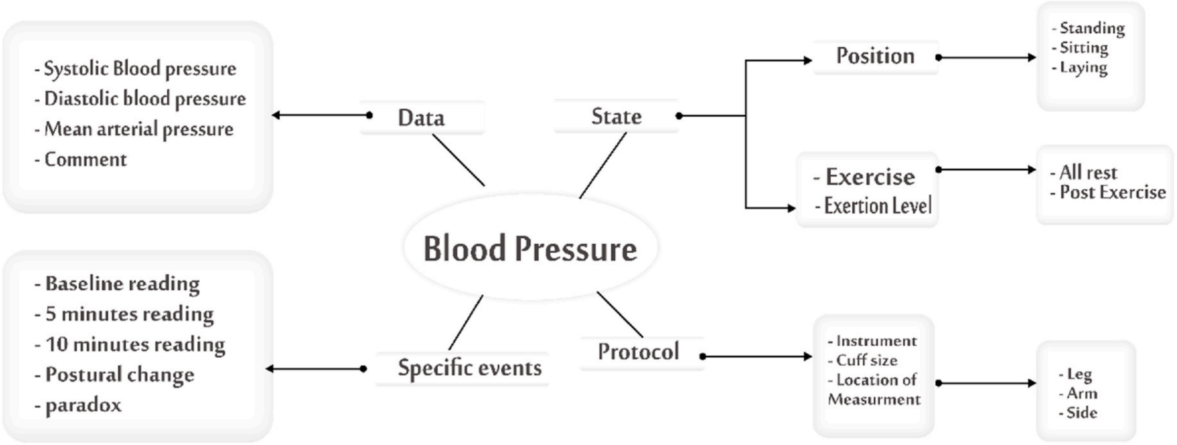


**Fig. 5.** Blood pressure as a concept in EHR – [57].

allows clinicians to distinguish patient-sourced data from other data in EHR [38,58]. Data provenance, a form of metadata refers to the history of a data element starting from its original sources through to its current state, and this includes information about its transformations, lineage and processes [59]. Provenance is useful for audit trailing, attribution, and replication. A technique for recording provenance is the use of phantom lineage, defined as lineage information that remains concerning data even after it has been erased or lineage that traces the reason a data was deleted (as opposed to how it was created) [59]. This keeps track of a data's existence from the time it is created until it is deleted and is used in applications like auditing. Data provenance could also refer to how PGHD is differentiated from clinically generated data, hence [59], suggest a visual differentiation in the EHR is necessary, to clarify which data has been submitted by the patient and which has been entered by clinical staff. Given that different methods could be used to generate similar PGHD, it is increasingly becoming expedient to document the algorithms (or scale used) behind the data generation [60].

RQ4: What are the socio-technical considerations in PGHD-EHR Integration?

Whetton [61] refers to the connections between technology and the social, professional, and cultural context in which it is employed as the sociotechnical considerations of an information system. As with most technological systems, there are social aspects to their design, use and adoption. A socio-technical approach to designing and managing the use of PGHD will help balance the technology with human aspects [62,63]. Poor system design of EHRs may cause information overload [8]. Trust, Identity, Privacy and Security (TIPS) are important socio-technical concerns in sharing PGHD [21,64]. In the following section, effort is made to understand the socio-technical issues in PGHD management and integration with EHRs from the reviewed literature. We examine how existing health care practices and systems are socially affected by PGHD, and how these may have changed or need to change social norms to maximally realize the benefits of PGHD-EHR integration.

### 6.1.1. *Understanding patient-provider workflow*

In this section, we explore two workflows (Figs. 6 and 7), and compare them, to understand patient-provider workflow practices. In Fig. 6, Gene et al. [47] depicted the actions that a patient and provider undertake to collect, process and use PGHD. In this patient-provider scenario case study, the patient will usually download and enroll on an mHealth app (a PGHD source), record the data, and then share the data following provider request. The provider request is made via the EHR (which will usually specify the frequency and threshold for notifications for the PGHD). However, data is only shared when the patient enables sharing (therefore the patient has initial control of data). Thereafter, the provider can view and act on the shared data and/or alert notifications. This workflow case study is similar to Sayeed et al. [41] in Fig. 7 and Kim et al. [46] workflow described in Fig. 4b.

However, in the case of Kim et al. [46], the primary PGHD source is the CGM sensor data, which is later consolidated over a mobile health

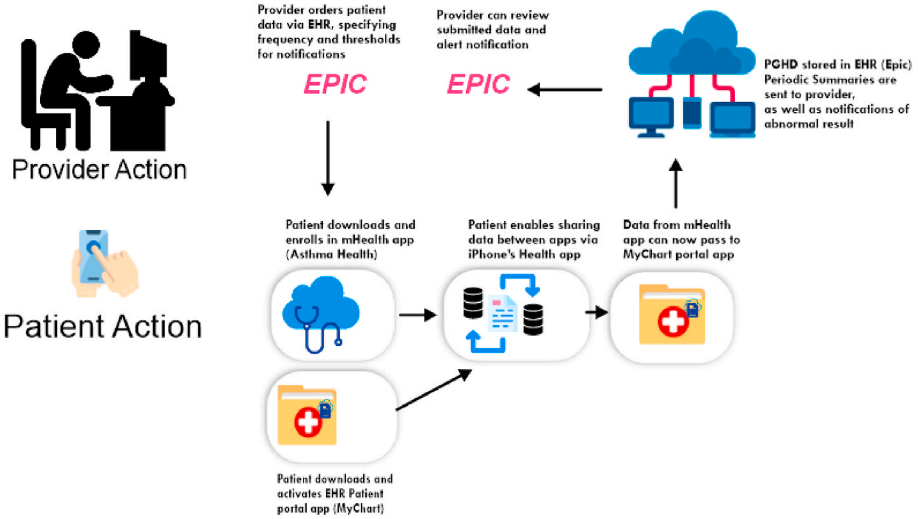


**Fig. 6.** Patient - provider workflow I – [47].

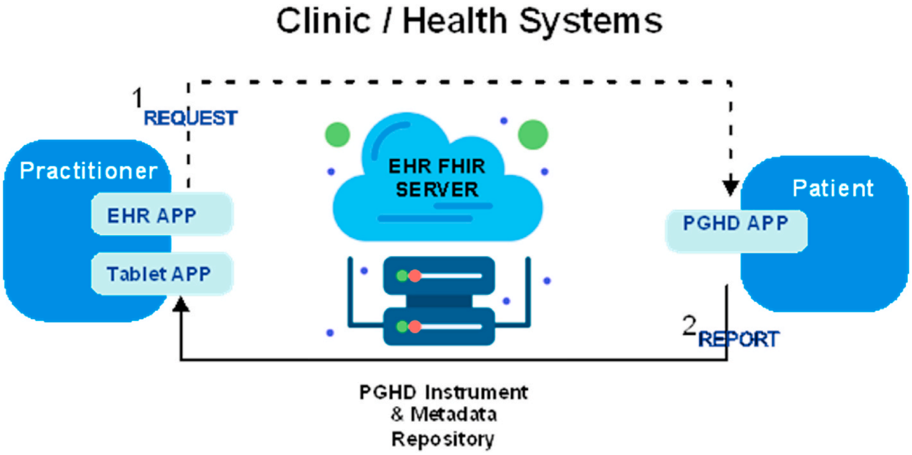


**Fig. 7.** Patient – Provider Workflow [41].

application (SHARE2 app), and later transmitted to the EHR (Epic). However, given that in this instance, the patient is a child, data is also shared with the parent through another app (FOLLOW). This demonstrates the role of third party (family members or network of care) in managing PGHD. Patients can often do, choose to share PGHD with trusted third parties (family or caregivers) where this is deemed expedient to providing care.

### 6.1.2. *New patient and provider role in PGHD collection, demand and use*

Data change the condition of work [30], thus PGHD impacts on the work of clinicians and other actors in PGHD management. Lordon et al. [24] provide examples of the impact of PGHD on the workflow of clinicians and the value of PGHD to other stakeholders. Islind et al. [39] elucidate this by explaining the new way of work (role) that this new healthcare data source brings to include the new distributed role of data collection (that now includes patients taking a large role in data collection) which then leads to a shift in the kinds of questions clinicians ask during clinic visits following receipt of PGHD. There is also the new ad-hoc role patients take in the decision-making – of 'self translating' or interpreting data [35,39]. When patients can view the trend in the PGHD collected, they develop some competency in making sense of the status of their health, whether or not it has improved. However, most times, patients will not be able to confidently relate or confirm which factors are the most significant in the improvement, and what they will need to do going forward or differently to achieve their health goals, hence the revised role of the clinician in the PGHD-EHR interactions – which is to further expound on the factors during patient-clinician interactions. This is a modification from how patients and clinicians would engage with patients during clinical episodes, where clinicians completely take up the responsibility of data collection, translation, and most often decision making.

### 6.1.3. *Perceived value of PGHD in clinical settings*

Value is a measure of benefit derivable from a service or product. The value of PGHD varies among stakeholders. Most practitioners value the information provided by patients and would advise them to keep such records [65]. The value of using patient-generated health data in the day-to-day management of chronic conditions (like diabetes, cancer care, hematologic malignancies, cardiac arrhythmias, cirrchotic ascites etc.) has been explored in previous studies [44,66–70]. Ancker et al. [66] describes how PGHD uploads were associated with improvements in blood glucose control and BMI. Purswani et al. [68] reveal that PGHD can support routine patient monitoring, personalized medicine and information sharing in cancer care and diabetes. Patients with type 1 diabetes need exogenous insulin and blood glucose monitoring multiple times per day to keep the glucose levels under control [56]. This will require checking blood glucose levels several times a day. Based on these monitoring data, as well as other factors (e.g. exercise and food intake), clinicians can decide what types of insulin patients will need, when to inject it, and how much; types of food to consider, and in what quantities; what intensities and types of exercise to engage in. However, because there are limited resources available for such monitoring, PGHD can play a critical role in overcoming the inconveniences associated with clinical visits. A continuous glucose monitoring (CGM) device (a PGHD source) can monitor a diabetes patient's glucose level in real time (every 5 min, for example), generating and injecting insulin as needed [46], in addition to keeping a record of this.

Some of the key benefits of PGHD in clinical environments include better insight into a patient's condition especially between clinic visits, facilitating review of care plans for improved health goal achievement, and avoiding unnecessary clinic visits [1]. PGHD has also been considered helpful in providing more accurate patient information, particularly when it is of clinical relevance [29,44,71]. PGHD also promote patient health awareness and communication with clinicians [24]. Clinicians identified PGHD use to include patient empowerment and opportunities to evaluate and reinforce therapeutic improvement through collective data review and interpretation [72]. Despite these identified benefits, a study [67] has however found the effect of PGHD interventions on health outcomes for obesity and hypertension unclear [73]. Also, clinicians are slow in embracing the use of PGHD unless the process is incentivized, reimbursed or promoted through targeted implementation efforts [66]. This seems to be because PGHD can result in time pressure or technostress, and eventual burnout for clinicians [74]. However, seeing the need and cost benefit to healthcare, the US national government has introduced the meaningful use policy to incentivize patient's use of PGHD for self-management [75].

### 6.1.4. *Trust, security and privacy in PGHD integration*

The lack of PGHD-EHR integration can be further explained by many other non-technical challenges, including trust, privacy and security concerns. Research on trust suggests that most patients are happy to share health-related information with clinicians where this is done only to aid in decision making [76]. Alaqra and Kane [77] reports that patients are willing to share measured stress data with employers for the common good, however data protection measures will need to be in place. Trust is often shaped by perception, previous experiences or knowledge; a perceived decline in trust can deter patients from sharing their information [21]. Patients do not like their data shared with third-parties such as insurance companies or marketing agencies [78]. Similarly, the protection of personal privacy and the capacity to offer secure storage of personal data and information are also considered significant. Security while PGHD is transferred, and perception of control over the data, account for some concerns around the security of PGHD integration [21]. In the wake of data leaks experienced by commercial organizations, governance and privacy regulations that espouse transparency, accountability and above all dignity to the patient becomes desirable in a PGHD-EHR integrated system.

#### 6.1.5. *Design of PGHD-EHR systems*

Understanding the relationship between the design of technology and stakeholder behavior can help designers/developers realize the challenges of incorporating PGHD into patient and provider workflows [28]. For instance, in a study of diabetes patients [18], 77% of patients had complete PGHD data available at 2-week follow-up and only 59% at 6-week follow-up. This was due to noncompliance with the use of the wearable devices issued over time. It is not known if the wearable design influenced this; however, participants preferred wrist-based sensors compared to belt-sensors [18]. Similarly, out of seventeen (17) participants who participated in a 6-month study in generating PGHD for managing chronic conditions – Hypertension or Type II Diabetes Mellitus (DM2) [28], only two (2) participants produced daily responses for the duration of their study. In this case, no reason was given for this low participation. Both studies however indicate a problem of attrition that will require further investigation over short- and long-term scenarios. Austin et al. [79] reported strong engagement of participants in their 4-month study using a mobile health application as a PGHD source for rheumatoid arthritis, however, they acknowledge that it is not known how much longer participants would do this willingly, given the effect of long-term daily tracking and increased screen time. Research has identified key design considerations in the design and development of PGHD-EHR systems. Sanger et al. [7] identified four areas of agreement (between patients and providers) for the design: provision of contextual metadata, actionable and accessible data presentation, leveraging existing socio-technical systems, and process transparency. On actionable data representation [80], indicate that changes rather than absolute values may provide more benefit in objectively assessing some health conditions like pre- and post-operative arthroplasty. Making PGHD easily accessible within the EHR minimizes workload [24]. In practice, PGHD is used in different ways by different clinicians or service providers based on treatment plans, Cohen, et al. [1] suggest groupware development, which identifies steps for developing products to benefit different types of group members.

#### 6.1.6. *EHR readiness*

Austin et al. [48] find that up to seventy percent (70%) of the PGHD cases examined in their study had no integration capabilities with the electronic health record (EHR), and only 12% reported full EHR integration. Uploading data from the collecting device to an associated web site was the most common method for getting PGHD from the patient. Users were likely to store PGHD in several locations after receiving it, including research portals and manual EHR uploads. However, before PGHDs are integrated to existing EHRs, Shapiro et al. [4] suggest that an EHR readiness assessment needs to be conducted. They suggest that EHR readiness for adding PGHD should be evaluated in terms of data definition consistency (being able to record PGHD accurately and without altering meaning) and workflow support (including being able to record "status" information such as "not reviewed" or "reviewed") [4]. Studies that will evaluate EHR readiness for PGHD integration will be valuable in providing the needed foundation for seamless data exchange, demand and use.

RQ5: What are the governance and policy issues around PGHD-EHR integration?

To promote the integration of PGHD into health information systems, health organizations require good governance, policies, and data stewardship [38]. The future of digitally enabled healthcare will be guided and determined by good policies. Establishing policies and procedures for dealing with PGHD and ensuring transparency regarding the use of the patient's information can help to reduce or mitigate potential liability [23]. Based on the findings from this review, policy development and adoption in numerous areas is still necessary to further provide direction for the use of PGHD in health care settings. Policy areas include, but are not limited to, data use, data protection, data quality assessment, device and system compatibility, defining standards for monitoring, liability and privacy issues, and assisting in the development of reimbursement structures [23,60,81]. Acceptance of PGHD, expectations of physician review, and copying of PGHD into existing EHR systems are all policies that must be determined in order to facilitate the flow and use of PGHD by clinicians [4]. Patients and their providers can make informed decisions about when and how to develop and share PGHD using data use policies. Similarly, determining the frequency or intervals of tracking and analysis, measurement methodologies, and how providers should maintain the data are all examples of tracking modality [23,46]. Determining who is liable for analyzing the data – the provider or the vendor of the digital tool – and to whom the data analysis be delegated, are all liability problems that require policy statements. Delegation of responsibilities for reviewing specific types of PGHD, for example, to designees such as nurse or other personnel, as well as protocols for responding to emergency notification or abnormal data, will be critical areas for which policies will be needed.

Adler-Milstein [82] state that uncertainty around the value of PGHD, from both patients and providers can limit policy adoption; however, the transparency that policies bring, which include discussions about patient expectations and physician concerns, can help build trust, allowing both sides to benefit maximally from the use of PGHD [12]. Shapiro et al. [4] posit that some provider organizations have well-defined informal practices for what can/should be documented in an EHR, by whom, with what approvals and notification policies, etc., however they also maintain that there is a need that these policies (both formal and informal) be compared such that any variations and best practices are observed, documented and eventually used to develop model policies [1, 62]. At the national level, legal and quality standards are being developed and enforced by state regulatory agencies; some common examples are the HIPAA regulations in the USA, and HIQA in Ireland [83,84].

#### 6.1.7. *PGHD data ownership and control*

Data ownership and privacy are common issues whenever data storage and exchange through information systems are considered [19, 85]. Patient records from patient visits at the facility is kept by the service provider – because the service providers document it; it is however unclear who owns PGHD shared with the service provider – i.e. whether such should be subjected to similar ownership framework as other clinical data recorded within the clinical facilities. Questions such as who owns PGHD when it is stored in an EHR, and whether it can be used without patient consent for good reasons such as population health or for provider/device manufacture self-serving reasons such as advertisement? What level of autonomy does the patient have and what policies can be in place for them that restore patient agency and autonomy if they are deliberately or inadvertently taken away by the service provision and/or profit generation? Does the patient have the right for PGHD to be forgotten as a fundamental human right as prescribed in extant law like the GDPR? As suggested by Woods [38], other options, such as keeping these data as part of a patient-owned record, may make it easier to avoid privacy concerns. While this simplistic approach would keep ownership of these data with patient and leave it to their discretion, it begs the question of how and when should these data should be shared with health care professionals in a way that gives maximum value.

#### 6.1.8. *Improving PGHD value through FAIR*

FAIR (Findability, Accessibility, Interoperability, Reusability) principles provide humans and machines easy means to discover data and metadata in a secure manner. FAIR data enable meaningful inquiries and analysis that are typically needed to address research problems. By making PGHD FAIR, patients will be able to extract some research value from them, including saving time and cost [86]. Muzooraa et al. [87] have proposed to employ FAIR on PROs, however little is known about employing FAIR on PGHD.

## 7. Discussion

This review followed a narrative review approach [25], and it looked at past studies on PGHD including its integration with EHR, with a view to understanding its scope, dataflows, governance and socio-technical challenges. Most of the literature reviewed has discussed the role of PGHD in improving healthcare, and there is a strong interest to integrate it into EHR for improved patient care [79,80,85]. We find that the scope of PGHD has evolved significantly, from data collected through mHealth apps (mobile and web) [18,77] and wearables [30], to data collected from social media. It has also been differentiated from PRO/M data in that PGHD is patient driven and can be very unstructured [87]. However, the definition of PGHD is still emerging and may include a combination of PRO and PROM, and other unstructured data and new data sources (such as from MR, IVR and IoT) as depicted in Fig. 2. PGHD sources suitable for integration are not limited to sensors or IoT systems, patient portals, web or mobile applications; however, research has focused more on these sources than others. PGHD data can emerge from low-end legacy technologies (SMS, IVR) that are widely used in constrained settings or network limited areas [88]. While the most widely considered PGHD sources require Internet connection to communicate with EHR or an application that interface directly with the EHR, legacy technologies may not require this. Similarly, standardized integration of these new data sources is not captured in the literature. Also, although, PGHD has been interchanged with PGD in literature [21], it will be preferred and more sustainable that PGHD is taken as the standard terminology for describing patient captured data because in the future, PGD may include other data that are patient related, but not describing their health condition, for example socio-economic data.

Towards developing standard formats for integrating new PGHD sources, it is also important to understand existing standards with a view to identifying their limitations and developing enhanced standards that will be future proof. PGHD in EHRs will require metadata which allows clinicians to differentiate patient-sourced data from other data in an EHR. Given that different methods could be used to generate similar PGHD, it is important to document the algorithms (or scale used) behind the data generation [60]. The creation and adoption of data representation and transmission standards is a critical component in establishing the secure environment required for PGHD to thrive [12]. Hence, in addition to standards such as SNOMED-CT and/or LOINC, an industry-grade PGHD ontology needs to be developed which addresses PGHD complexities. Similarly, the capabilities of document exchange formats need to accommodate recent PGHD sources in the EHR system. Past studies have proposed an ontology-based middleware that integrates IoT data with EHR systems. However, this can be improved upon to account for more PGHD data sources (e.g patient portal, mobile health app, SMS, IVR and PHRs). Furthermore, it is pertinent to investigate which PGHD are most useful to be integrated to EHRs from a clinician's perspective and how those data should be represented in an EHR to provide a view of health status relevant to a clinician [3,4]. In our review, we find that there is emerging work on PGHD data sources integration that employ HL7 FHIR standards [89]. The HL7 FHIR format can be exploited to incorporate new data formats and elements using extensions.

Also, while staging was considered as data consolidation by Kim et al. [46] as in Fig. 4b, data consolidation in a PGHD flow can connote many things depending on the phase in the data flow. For instance, at the data capture phase, data consolidation could either mean any or all of data aggregation i. e raw sensor data that is transformed into a score (e.g. sleep data score), data staging i. e data collected together or data visualization (e.g. charts, figures or trend analysis). Similarly, at the data document/review phase, data can be consolidated by re-staging, and/or visualizing. This imply that a standardize way to define stages in PGHD dataflow will be require as part of metadata, to enable proper understanding of context.

Our review also reveals that there are limited studies done on data quality in the PGHD-EHR context which include accuracy, completeness of records, consistency of information, correctness of data entered and provenance [90]. There will be the need to develop and exert data quality control measures for PGHD exchange with EHR in a way that it is not prohibitive, detested by any of the stakeholders or creates usability issues. As an example, a phantom lineage technique [59] could be explored for data provenance.

Data sovereignty is also a profound governance issue identified in literature [19,86]. Most commercial applications limit access to raw data from sensing devices (Fitbit or Apple products) providing only aggregated data, or information about scales and algorithms used, usually due to proprietary benefit rather than patient benefit. These situations are very prohibitive and disempowering and can create significant hurdles in integration with systems. A framework or standard for the minimum information that device manufacturers must provide (including scales used) and regulated access to raw data by patients will be necessary to promote PGHD-EHR integration.

Data lifecycle can be analogous to the lifecycle of a living thing, it can be “birthed” i.e. created, can be “rested” i.e. stored, “in motion” – shared, “or “dead” i.e. destroyed. The notion that data can be at “rest” and “in motion” presents an opportunity to understand and manage security and privacy concerns of PGHD flow within the system. Also, how PGHD is archived or destroyed - “rested” in a clinical setting require further investigation. In our review, attention on the data flow had stopped at the point where it is used (reviewed and/or documented) in the system. It will be worthwhile to understand how and in what circumstances will data be made “dead” or forgotten, for instance where highly granular data from wearables might be deleted when it has been analyzed or when a patient so desires at any given point in time.

The review showed that patients are willing to share their PGHD with trusted entities under a governance and privacy framework that demonstrate accountability and transparency. Policies on data demand, use, protection, liability, privacy are invaluable to the success of PGHD-EHR. Current organizational policies require standardization. Current state of the art research on access control is yet to enable patients to choose who has access to their PGHD within EHRs [19,53]. Furthermore, present EHR systems do not consider consent revocation to be a necessary feature. To provide the highest level of safety and transparency, a solution to authenticate, authorize, and validate that patients have control over their PGHD within the EHR is required [19]. PGHD can change the nature of work for clinicians, providing a new workflow that gives distributed roles to patients and clinicians; with the patient also playing an active role in data collection and data interpretation. Nevertheless, clinicians request that the PGHD-EHR be incentivized to enable them to make use of PGHD in clinical care. It is not known how much PGHD should be collected, but the design of the PGHD source can also influence the success or otherwise of integration efforts. The choice of PGHD source, type and amount of data should be influenced by co-design considerations as suggested by Refs. [7,18,24]. Given that some PGHD sources have no integration capabilities with EHRs, an EHR readiness assessment was suggested by Shapiro et al. [4]. In a multi-institution and multi-provider patient world, there is also an opportunity to develop PGHD-EHR systems to comply with the concept of FAIR data [91]. However, our review reveals limited use of FAIR for PGHD. Employing FAIR for PGHD can promote the application of data to research, creating both individual and population-level value, by generating new insights into the nature of health and disease. Even then, it needs to be understood how patient privacy concerns will be respected while doing so.

## 8. Conclusion

PGHD has become a contemporary concept in modern healthcare management. Studies have been undertaken to explore various aspects of this new data format. This review attempts to understand the state of PGHD-EHR integration. Our findings reveal the importance of documenting contextual data that accounts for PGHD peculiarities but also provenance, in such a way that it provides maximal value and confidence to the clinician and patient. There is limited work on standardized PGHD integration that account for new data sources, new data elements, context, data quality, and provenance; it is proposed that a PGHD-ontology and interface that accounts for these be developed. Trust and privacy are cardinal to PGHD sharing, hence, to provide the highest level of trust and transparency in a PGHD-EHR environment, systems that ensure that patients have control over their PGHD within the EHR is required. The review also identifies the need for well-developed policies to govern PGHD integration; there is a current lack of formal organizational policies for PGHD-EHR integration. Studies that will evaluate other socio-technical aspects such as EHR readiness for PGHD integration, and how PGHD is used in decision-making will be valuable in providing the needed foundation for seamless but secured PGHD exchange, demand and use.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.imu.2022.101153.

## References

[1] Cohen DJ. Integrating patient-generated health data into clinical care settings or clinical decision-making: lessons learned from project HealthDesign. JMIR Hum Factors 2016;3(2). https://doi.org/10.2196/humanfactors.5919.

[2] Chung A. Potential and challenges of patient-generated health data for high-quality cancer care. J Oncol Practice 2015;11(3):195–7. https://doi.org/10.1200/JOP.2015.003715.

[3] Plastiras P. Exchanging personal health data with electronic health records: a standardized information model for patient generated health data and observations of daily living. Int J Med Inf 2018;120:116–25. https://doi.org/10.1016/j.ijmedinf.2018.10.006.

[4] Shapiro M, Johnston D, Wald J, Mon D. Patient-generated health data. RTI International, https://www.rti.org/publication/patient-generated-health-data-white-paper/fulltext.pdf; April, 2012 [Online]. Available:.

[5] Jung SY. Development of comprehensive personal health records integrating patient-generated health data directly from samsung s-health and apple health apps: retrospective cross-sectional observational study. JMIR mHealth uHealth 2019;7(5). https://doi.org/10.2196/12691.

[6] Lim C, et al. ' it just seems outside my health' how patients with chronic conditions perceive communication boundaries with providers. In: Proceedings of the 2016 ACM conference on designing interactive systems; 2016. p. 1172–84. presented at the.

[7] Sanger PC. A patient-centered system in a provider centered world: challenges of incorporating post-discharge wound data into practice. J Am Med Inf Assoc 2016; 23(3):514–25. https://doi.org/10.1093/jamia/ocv183.

[8] Collins SA, Bakken S, Vawdrey DK, Coiera E, Currie L. Model development for EHR interdisciplinary information exchange of ICU common goals. Int J Med Inf 2011; 80(8):e141–9.

[9] Tiase VL. Navigating the patient-generated health data deluge. Nurs Manag 2017; 48(12):7–8. https://doi.org/10.1097/01.NUMA.0000526919.69840.2e.

[10] Reading MJ. Converging and diverging needs between patients and providers who are collecting and using patient-generated health data: an integrative review. J Am Med Inf Assoc 2018;25(6):759–71. https://doi.org/10.1093/jamia/ocy006.

[11] IBM, "Interoperability in Healthcare," what is interoperability in healthcare? https://www.ibm.com/topics/interoperability-in-healthcare (accessed May 23, 2022).

[12] Petersen C. Legal and regulatory considerations associated with use of patient-generated health data from social media and mobile health (mHealth) devices. Appl Clin Inf 2015;6(1):16–26. https://doi.org/10.4338/ACI-2014-09-R-0082.

[13] Brajovic S. Validating a framework for coding patient-reported health information to the medical dictionary for regulatory activities terminology: an evaluative study. JMIR Med Info 2018;20(8). https://doi.org/10.2196/medinform.9878.

[14] Cook EL. Could interoperability between IoT and ehr make healthcare more efficient? Present Proc Appalachian Res Bus Symp 2020;1.

[15] Tiase VL. Patient-generated health data and electronic health record integration: protocol for a scoping review. BMJ Open 2019;9(12). https://doi.org/10.1136/bmjopen-2019-033073.

[16] Lv N. Personalized hypertension management using patient-generated health data integrated with electronic health records (EMPOWER-H): six-month pre-post study. J Med Internet Res 2017;19(9). https://doi.org/10.2196/jmir.7831.

[17] Marceglia S. Point of Care Research: integrating patient-generated data into electronic health records for clinical trials. In: AMIA ... Annual Symposium proceedings. AMIA Symposium; 2017. p. 1262–71. 2017.

[18] Nundy S. Using patient-generated health data from mobile technologies for diabetes self-management support: provider perspectives from an academic medical center. J Diabet Sci Technol 2014;8(1):74–82. https://doi.org/10.1177/1932296813511727.

[19] Asghar M. A review of privacy and consent management in healthcare: a focus on emerging data sources. 2017. In: Proceedings - 13th IEEE international conference on eScience, eScience; 2017. p. 518–22. https://doi.org/10.1109/eScience.2017.84.

[20] Fitbit.com. Health metrics," *SpO 2, heart rate variability | Fitbit technology*. https://www.fitbit.com/global/us/technology/health-metrics; May 03, 2022.

[21] Simpson E. Understanding the barriers and facilitators to sharing patient-generated health data using digital technology for people living with long-term health conditions: a narrative review. Front Public Health 2021;9. https://doi.org/10.3389/fpubh.2021.641424.

[22] Ancker JS, Witteman HO, Hafeez B, Provencher T, Van de Graaf M, Wei E. The invisible work of personal health information management among people with multiple chronic conditions: qualitative interview study among patients and providers. J Med Internet Res 2015;17(6):e4381.

[23] Demiris G. Patient generated health data use in clinical practice: a systematic review. Nurs Outlook 2019;67(4):311–30. https://doi.org/10.1016/j.outlook.2019.04.005.

[24] Lordon RJ. How patient-generated health data and patient-reported outcomes affect patient–clinician relationships: a systematic review. Health Inf J 2020;26(4): 2689–706. https://doi.org/10.1177/1460458220928184.

[25] Baethge C, Goldbeck-Wood S, Mertens S. SANRA—a scale for the quality assessment of narrative review articles. Res Integr Peer Rev 2019;4(1):1–7.

[26] Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group*. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Ann Intern Med 2009;151(4):264–9.

[27] Hussein R, Crutzen R, Gutenberg J, Kulnik ST, Sareban M, Niebauer J. Patient-generated health data (PGHD) interoperability: an integrative perspective. Stud Health Technol Inf May 2021;281:228–32. https://doi.org/10.3233/SHTI210154.

[28] Danis C. Incorporating patient generated health data into chronic disease management: a human factors approach. Healthc Info Manag Syst 2016. https://doi.org/10.1007/978-3-319-20765-0_10.

[29] Dimaguila G, Gray K, Merolli M. In: Enabling better use of person-generated health data in stroke rehabilitation systems: systematic development of design heuristics. Journal of Medical Internet Research; 2020 [Online]. Available: https://www.jmir.org/2020/7/e17132/.

[30] Miyaji T. Patient-generated health data collection using a wearable activity tracker in cancer patients—a feasibility study. Support Care Cancer 2020;28(12):5953–61. https://doi.org/10.1007/s00520-020-05395-z.

[31] Rodriguez S. Connecting home-based self-monitoring of blood pressure data into electronic health records for hypertension care: a qualitative inquiry with primary care providers. JMIR Format Res 2019;3(2). https://doi.org/10.2196/10388.

[32] Salvi E. Patient-generated health data integration and advanced analytics for diabetes management: the AID-GM platform. Sensors 2020;20(no. 1). https://doi.org/10.3390/s20010128.

[33] Teixeira PA, Gordon P, Camhi E, Bakken S. HIV patients' willingness to share personal health information electronically. Patient Educ Counsel 2011;84(2): e9–12.

[34] Tiase VL. Patient-generated health data in pediatric asthma: exploratory study of providers' information needs. JMIR Pediatr Parent 2021;4(1). https://doi.org/10.2196/25413.

[35] Shapiro A, Marinsek N, Clay I, Bradshaw B, Ramirez E. In: Characterizing COVID-19 and influenza illnesses in the real world via person-generated health data. Patterns; 2021 [Online]. Available: https://www.sciencedirect.com/science/article/pii/S2666389920302580.

[36] Hartzler AL. Evaluating health interest profiles extracted from patient-generated data," *AMIA ... Annual Symposium proceedings/AMIA Symposium*. AMIA Symposium; 2014. p. 626–35. 2014.

[37] Gollamudi SS. A framework for smartphone-enabled, patient-generated health data analysis. PeerJ 2016;2. https://doi.org/10.7717/PEERJ.2284. 2016.

[38] Woods SS. Integrating patient voices into health information for self-care and patient-clinician partnerships: veterans Affairs design recommendations for patient-generated data applications. J Am Med Inf Assoc 2016;23(3):491–5. https://doi.org/10.1093/jamia/ocv199.

[39] Islind AS. Shift in translations: data work with patient-generated health data in clinical practice. Health Inf J 2019;25(3):577–86. https://doi.org/10.1177/1460458219833097.

[40] Covec EL, Ghanem E. Patient-generated health data (social media) are a potential source for ADR reporting. In: SAS Conference Proceedings: pharmaceutical Users Software Exchange; 2017. https://www.lexjansen.com/phuse/2017/dh/DH01.pdf.

[41] Sayeed R. SMART Markers: collecting patient-generated health data as a standardized property of health information technology. npj Digit Med 2020;3(1). https://doi.org/10.1038/s41746-020-0218-6.

[42] Priebe S. Patient-reported outcome data generated in a clinical intervention in community mental health care - psychometric properties. BMC Psychiatr 2012;12. https://doi.org/10.1186/1471-244X-12-113.

[43] Snyder CF, et al. When using patient-reported outcomes in clinical practice, the measure matters: a randomized controlled trial. J Oncol Practice 2014;10(5):e299–306.

[44] Murthy H, Wood W. The value of patient reported outcomes and other patient-generated health data in clinical hematology. Curr Hematol Malign Rep 2015;10(3):213–24. https://doi.org/10.1007/s11899-015-0261-6.

[45] Dimaguila G, Gray K, Merolli M. In: Measuring the outcomes of using person-generated health data: a case study of developing a PROM item bank," *BMJ health & care informatics*; 2019 [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/pmc7062343/.

[46] Kim K, Jalil S, Ngo V. Improving self-management and care coordination with person-generated health data and mobile health. Consum Info Digit Health 2019. https://doi.org/10.1007/978-3-319-96906-0_12.

[47] *NPJ digita* Genes N, Violante S, Cetrangol C, Rogers L. From smartphone to EHR: a case report on integrating patient-generated health data, [Online]. Available: https://www.nature.com/articles/s41746-018-0030-8, ; 2018.

[48] Austin E. Use of patient-generated health data across healthcare settings: implications for health systems. JAMIA Open 2021;3(1):70–6. https://doi.org/10.1093/JAMIAOPEN/OOZ065.

[49] Yu D, Jordan K, Bailey J, Peat G, Wilkie R. 338 Modelling the population distribution of patient-reported outcomes using electronic health records: a UK study. Int J Epidemiol 2021;50(Supplement_1):dyab168–739.

[50] Lai AM. Present and future trends in consumer health informatics and patient-generated health data. Yearb Med Info 2017;26(1):152–9. https://doi.org/10.15265/IY-2017-016.

[51] Codella J, Partovian C, Chang H. Data quality challenges for person-generated health and wellness data. IBM J Res Dev 2018;62(1) [Online]. Available: https://ieeexplore.ieee.org/abstract/document/8269766/.

[52] Fitabase.com. Fitabase - research device data and analytics. 2022. Accessed: Apr. 03, 2022. [Online]. Available: Fitabase.com.

[53] Heart T, Ben-Assuli O, Shabtai I. A review of PHR, EMR and EHR integration: a more personalized healthcare and public health policy," *Health Policy and Technology* [Online]. Available: https://www.sciencedirect.com/science/article/pii/S2211883716300624; 2017.

[54] Alamri A. Ontology middleware for integration of IoT healthcare information systems in EHR systems. Computers 2018;7(4):51.

[55] Devi G, Rizvi S. Integration of genomic data with EHR using IoT," presented at the 2020 2nd international conference on advances in computing, communication control and networking. ICACCCN); 2020. p. 545–9.

[56] El-Sappagh S, Ali F, Hendawi A, Jang J-H, Kwak K-S. A mobile health monitoring-and-treatment system based on integration of the SSN sensor ontology and the HL7 FHIR standard. BMC Med Inf Decis Making 2019;19(1):1–36.

[57] Sachdeva S, Bhalla S. Semantic interoperability in standardized electronic health record databases. J Data Info Qual (JDIQ) 2012. https://doi.org/10.1145/2166788.2166789.

[58] Fountain V. Using data provenance to manage patient-generated health data. J AHIMA/Am Health Info Manag Assoc 2014;85(11):28–30.

[59] Simmhan YL, Plale B, Gannon D. 69. In: A survey of data provenance techniques. vol. 47405. Bloomington IN: Computer Science Department, Indiana University; 2005.

[60] Wood WA. Emerging uses of patient generated health data in clinical research. Mol Oncol 2015;9(5):1018–24. https://doi.org/10.1016/j.molonc.2014.08.006.

[61] Whetton S. Health informatics: a socio-technical perspective. South Melbourne: Vic; 2005.

[62] Sands D. Transforming health care delivery through consumer engagement, health data transparency, and patient-generated health information. Yearb Med Info 2014;9:170–6. https://doi.org/10.15265/IY-2014-0017.

[63] Cresswell KM. Five key strategic priorities of integrating patient generated health data into United Kingdom electronic health records. J Innovat Health Inf 2018;25(4):254–9. https://doi.org/10.14236/jhi.v25i4.1068.

[64] Nittas V. Electronic patient-generated health data to facilitate disease prevention and health promotion: scoping review. J Med Internet Res 2019;21(10). https://doi.org/10.2196/13320.

[65] Huba N, Zhang Y. Designing patient-centered personal health records (PHRs): health care professionals' perspective on patient-generated data. J Med Syst 2012. https://doi.org/10.1007/s10916-012-9861-z.

[66] Ancker JS. Early adopters of patient-generated health data upload in an electronic patient portal. Appl Clin Inf 2019;10(2):254–60. https://doi.org/10.1055/s-0039-1683987.

[67] Treadwell JR, Reston JT, Rouse B, Fontanarosa J, Patel N, Mull NK. Automated-entry patient-generated health data for chronic conditions: the evidence on health outcomes. 2021.

[68] Purswani JM, Dicker AP, Champ CE, Cantor M, Ohri N. Big data from small devices: the future of smartphones in oncology. Present Semin Radiat Oncol 2019;29(4):338–47.

[69] Laverty L, et al. Using patient-generated health data in clinical practice: how timing influences its function in rheumatology outpatient consultations. Patient Educ Counsel 2022;105(3):625–31.

[70] Bloom P, et al. A smartphone app to manage cirrhotic ascites among outpatients: feasibility study. JMIR Med Info 2020;8(9):e17770.

[71] Jeevanandan N. Patient-generated health data in the clinic. Stud Health Technol Inf 2020;270:766–70. https://doi.org/10.3233/SHTI200264.

[72] Ng A. Provider perspectives on integrating sensor-captured patient-generated data in mental health care. Proc ACM Hum-Comput Interact 2019;3. https://doi.org/10.1145/3359217.

[73] Bradley SM. Use of mobile health and patient-generated data-making health care better by making health care different. JAMA Netw Open 2020;3(4). https://doi.org/10.1001/jamanetworkopen.2020.2971.

[74] Ye J. The impact of electronic health record-integrated patient-generated health data on clinician burnout. J Am Med Inf Assoc : JAMIA 2021;28(5):1051–6. https://doi.org/10.1093/jamia/ocab017.

[75] gov HealthIT. Meaningful use definition & objectives. Accessed: Apr. 22, https://www.healthit.gov/faq/what-meaningful-use; 2022 [Online]. Available:.

[76] Agaku IT, Adisa AO, Ayo-Yusuf OA, Connolly GN. Concern about security and privacy, and perceived control over collection and use of health information are related to withholding of health information from healthcare providers. J Am Med Inf Assoc 2014;21(2):374–8.

[77] Alaqra AS, Kane B. Wearable devices and measurement data: an empirical study on eHealth and data sharing," presented at the 2020 IEEE 33rd international symposium on computer-based medical systems. CBMS); 2020. p. 443–8.

[78] Stutzman FD, Gross R, Acquisti A. Silent listeners: the evolution of privacy and disclosure on Facebook. J Priv Confidentiality 2013;4(2):2.

[79] Austin L. Providing 'the bigger picture': benefits and feasibility of integrating remote monitoring from smartphones into the electronic health record. Rheumatology 2020;59(2):367–78. https://doi.org/10.1093/rheumatology/kez207.

[80] Bendich I. Changes in prospectively collected longitudinal patient-generated health data are associated with short-term patient-reported outcomes after total joint arthroplasty: a pilot study. Arthroplasty Today 2019;5(1):61–3. https://doi.org/10.1016/j.artd.2019.01.005.

[81] Abdolkhani R. Patient-generated health data management and quality challenges in remote patient monitoring. JAMIA Open 2019;2(4):471–8. https://doi.org/10.1093/jamiaopen/ooz036.

[82] Adler-Milstein J. Early experiences with patient generated health data: health system and patient perspectives. J Am Med Inf Assoc 2019;26(10):952–9. https://doi.org/10.1093/jamia/ocz045.

[83] Bhartiya S, Mehrotra D. Exploring interoperability approaches and challenges in healthcare data exchange," presented at the International Conference on Smart Health. 2013. p. 52–65.

[84] Hiqaie, "Health information and quality authority: about us." health information and quality authority. Accessed: May 3, 2022. [Online]. Available: https://www.hiqa.ie/about-usc.

[85] Park YR. Managing patient-generated health data through mobile personal health records: analysis of usage data. JMIR mHealth uHealth 2018;6(4). https://doi.org/10.2196/mhealth.9620.

[86] van Reisen M, et al. Design of a FAIR digital data health infrastructure in Africa for COVID-19 reporting and research. Adv Genet 2021;2(2):e10050.

[87] Muzoora MR, Schaarschmidt M, Krefting D, Oehm J, Riepenhausen S, Thun S. Towards FAIR patient reported outcome: application of the interoperability principle for mobile pandemic apps. In: Applying the FAIR principles to accelerate health research in Europe in the post COVID-19 Era. IOS Press; 2021. p. 85–6.

[88] Kawu AA, SMS! M. Exploring design and privacy of a mobile health application for older people. 2016.

[89] Saripalle RK. Fast Health Interoperability Resources (FHIR): current status in the healthcare system. Int J E Health Med Commun 2019;10(1):76–93.

[90] Chan KS, Fowles JB, Weiner JP. Electronic health records and the reliability and validity of quality measures: a review of the literature. Med Care Res Rev 2010;67(5):503–27.

[91] Wilkinson MD, et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data 2016;3(1):1–9.