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Patient generated health data use in clinical practice: A systematic review

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ABSTRACT

Background: Precision health calls for collecting and analyzing large amounts of data to capture an individual's unique behavior, lifestyle, genetics, and environmental context. The diffusion of digital tools has led to a significant growth of patient generated health data (PGHD), defined as health-related data created, gathered or inferred by or from patients and for which the patient controls data collection and data sharing.

Purpose: We assessed the current evidence of the impact of PGHD use in clinical practice and provide recommendations for the formal integration of PGHD in clinical care.

Methods: We searched PubMed, Ovid, Embase, CINAHL, Web of Science, and Scopus up to May 2018. Inclusion criteria were applied and four reviewers screened titles and abstracts and consequently full articles.

Findings: Our systematic literature review identified 21 studies that examined the use of PGHD in clinical settings. Integration of PGHD into electronic records was extremely limited, and decision support capabilities were for the most part basic.

Discussion: PGHD and other types of patient-reported data will be part of the health care system narrative and we must continue efforts to understand its impact on health outcomes, costs, and patient satisfaction. Nursing scientists need to lead the process of defining the role of PGHD in the era of precision health.

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Introduction

Precision health calls for collecting and analyzing large amounts of data to capture an individual's unique behavior, lifestyle, genetics, and environmental context to inform tailored and personalized delivery of health services (Akdis & Ballas, 2016). The growth of consumer technologies including smartphone apps and wearables has led to the design and use of tools that allow individual consumers to collect their own health related data. Such data pertain to their well-

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being and behavioral patterns as well as the environment in which they find themselves. In the United States, 46% of consumers in 2016 were considered active digital health adopters, having used 3 or more categories of digital health tools (Adams, Shankar, & Tecco, 2016). Nearly a third of people who downloaded a health app did so because the app was recommended by their doctor and nearly a quarter of Americans owned a wearable device such as an activity tracker in 2016, up from 12% in 2015 (Adams et al., 2016).

The implementation of digital tools has led to a significant growth of so-called patient generated health data (PGHD). PGHD are defined by the Office of the National Coordinator for Health Information Technology (ONC) 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" (Shapiro, Johnston, Wald, & Mon, 2012). This definition emphasizes that patients, not providers, are primarily responsible for capturing or recording these data and it is patients who direct the sharing or distributing of the data to stakeholders (Shapiro et al., 2012). PGHD from self-tracking has been envisioned as a means to bridge a gap, supplementing data from clinical visits, with a rich picture of a person's daily behaviors, environment, and lifestyle. This approach has the potential to inform better clinical decision making, with patients engaged in the decision-making process (Shapiro et al., 2012). PGHD tools are perceived as ways to capture and even "amplify" the patient voice in the health care system and strengthen the patient-provider relationship, increasing patient safety and information access (National eHealth Collaborative, 2013).

Patients may utilize a broad spectrum of platforms to capture such data (ranging from paper-based tools to wearable or implantable devices). Similarly, such platforms may have varying degrees of sophistication in how data are handled and analyzed. For example, the platforms may include alerts for individual data points, predictive analytics, natural language processing or artificial intelligence. The data may also be communicated and shared in numerous ways including integration into the patient's record, graphical, text- or audio-based summaries that can be shared with clinicians and others. The use of information technology for capturing and transmitting PGHD allows for the generation of new types of data that can now be generated outside of a clinical setting without sole reliance on self-report. These might include data related to overall physical activity, mobility, sleep quality, nutrition, social interactions, water, and air quality. Table 1 showcases the breadth of PGHD types and sources as well as potential tools to capture such data.

The use of PGHD can have utility for patients across the lifespan and in various conditions. PGHD systems have been designed for pediatric patients (Adams et al., 2003; Barrett et al., 2018; Johansen et al., 2004; Miller et al., 2016), students (Lau et al., 2013), adults, and older adult patients (Quinn et al., 2008). In regards to age and gender, researchers in one study found significantly greater use of an app that supported the upload of continuous health data for health management (e.g., blood pressure, blood glucose, weight) among older users ($p < .001$) and men ($p < .001$) (Park et al., 2018). Similarly, PGHD have been used to monitor and manage a spectrum of diseases and conditions. For example, PGHD have been used for cancer (Basch et al., 2007; Chung & Basch, 2015; Holch et al., 2017), stress and sleep in physically active adults (Peake, Kerr, & Sullivan, 2018), CVD and metabolic syndrome (Park et al., 2018), asthma (Adams et al., 2003; Barrett et al., 2018), diabetes (Albisser, En Chao, Parson, & Sperlich, 2001), depression and anxiety (Bauer et al., 2018), lung transplant care (Jiang, Sereika, DeVito Dabbs, Handler, & Schlenk, 2016), and uncontrolled blood pressure (Lv et al., 2017).

While opportunities have been identified in integrating PGHD into clinical workflow and care management, there are also identified concerns. Health care providers have expressed concerns over the potential added burden of reviewing PGHD outweighing any potential for added efficiencies (Shapiro et al., 2012). In a simulation study to understand changes to a health system with adding PGHD, researchers identified indirect consequences of additional time and cognitive demand, increase in labor cost with additional time required to assimilate PGHD (Steward, Hofler, Thaldorf, & Milov, 2010). Specifically, workday and patient visits were extended in duration and became less predictable to schedule, with nurse utilization rates of the PGHD system increasing over time while physicians' utilization rates remained relatively unchanged. Authors concluded that the impact of PGHD is nontrivial and would cause longer workdays or mandate sacrifice of other activities. Other concerns include whether the data will be usable and of high enough quality to support decision making, what the financial impact may be, and whether there may be potential liability concerns (Chung & Basch, 2015). For individuals unable to track PGHD based on disease make-up, access to devices, or medical coverage, for example, there are concerns about creating or contributing to inequities. Furthermore, questions remain about determining content and frequency that would be most helpful. Concerns of accuracy and completeness of PGHD have been identified (Weissmann, Mueller, Messinger, Parkin, & Amann-Zalan, 2016). Clinicians may have reservations in utilizing PGHD in their clinical decision making as such data sets may be new and an unfamiliar source of information. In one study many patients who shared self-tracking data with their providers expressed their dissatisfaction with the level of provider engagement with these data (Chung et al., 2016).

Despite these concerns, some health systems are moving forward with efforts to use PGHD to improve care. For example, the U.S. Department of Veterans Affairs is striving to implement the enterprise-wide capability to collect and use PGHD in order to improve the patient health care experience, and promote shared decision making (Woods, Evans, & Frisbee, 2016). To date evidence of the effectiveness of integrating PGHD into clinical settings

Table 1 – Range of PGHD Types and Sources

Data Type	Data Element Examples	Modality for Data Capturing Examples
Personal profile	Life goals, values	Online/patient portal (Kneale, Choi, & Demiris, 2016)
Preferences	Notifications	
	Communication	
	Delegation or identification of proxy	
Health data review	Edits/ updates to health record data (e.g., list of allergies)	
Health and family history	Updates to personal and family health history and health events	
Medication information	Updates to over the counter medication	
	Medication adherence	Connected medication dispensing unit (Brath et al., 2013; Forni Ogna et al., 2013)
Biometric tracking	Blood pressure	Wireless blood pressure cuff/Bluetooth to Smartphone application (Ciemins et al., 2018; Evans et al., 2016)
	Weight	Digital weight scale (Demiris et al., 2013)
	Body temperature	Digital thermometer (Ask, Ekstrand, Hult, Lindén, & Pettersson, 2012)
	Oxygen saturation	Wireless pulse oximeter (Velardo et al., 2017)
	Blood glucose level	Digital glucose monitor (Lee et al., 2017)
	Lung function	Digital spirometer (Shakkottai, Kaciroti, Kasmikha, & Nasr, 2018)
	Heart rate	Wrist-worn activity tracking device (Thiebaud et al., 2018)
Behavioral tracking	Activity level	Pedometer watch/Accelerometer (Actigraph) (Hooke, Gilchrist, Tanner, Hart, & Withycombe, 2016; Joseph, Stromback, Hagstromer, & Conradsson, 2018)
	Calorie burning	Fitness tracker with calorie burning calculator (Franco, Fallaize, Lovegrove, & Hwang, 2016)
	Sleep quality	Bed sensor strip with ballistocardiography sensor (Kortelainen, van Gils, & Pärkkä, 2012)
	Daily hygiene routine	Water sensors, motion sensors (Chung et al., 2017)
Environmental tracking	Room temperature	Temperature sensor (Bock et al., 2016)
	Noise	Indoor sound level sensor (Risojević, Rozman, Pilipović, Češnovar, & Bulić, 2018)
	Luminosity	Home digital luminosity sensor (Bock et al., 2016)
	Humidity	Indoor air quality sensor (Bock et al., 2016)
Social interactions tracking	Number of visitors	Door sensor (Skubic, Guevara, & Rantz, 2015)
	Time spent outside the home	
	Number of calls	Phone usage summary app (Deave et al., 2018)
	Time spent online	Online monitoring app (Chen & Schulz, 2016)
Genetic information	Predictive and presymptomatic testing	Direct to consumer genetic testing kit
Mental health assessment	Screening for depression	Online/patient portal (Leveille, Huang, Tsai, Weingart, & Iezzoni, 2008)
	Anxiety assessment	Smartphone app (Alyami, Giri, Alyami, & Sundram, 2017)
Symptom tracking	Symptom frequency, intensity, side effects	Online/patient portal (Kneale et al., 2016)
Patient reported outcomes	Condition-specific outcomes, quality of life	Online/patient-portal (Kneale et al., 2016)
Multimedia observations	Video- or photo-recordings	Telehealth video-camera (Gunter et al., 2016)
Care goals	Patient review of health care team goals	Personal health record (Lum et al., 2019)
Patient experience	Patient satisfaction	Online/patient-portal (Kneale et al., 2016)
Legal documentation	Advanced directive	Paper-based/ online (Lum et al., 2019)
Ad hoc requests	Request for health data amendment	Online/patient-portal (Kneale et al., 2016)
Administrative data	Contact information, caregiver(s)	

may be limited and many questions still remain, such as: How can we integrate patient generated data into the electronic health record? What strategies can be pursued to effectively mine and analyze these data to support clinical decision-making? What are the barriers and challenges in the integration of patient generated data into health information systems? How can we facilitate patient engagement and empowerment while addressing ethical concerns associated with the use of pervasive and ubiquitous monitoring? The purpose of this paper is to assess the current evidence of the impact of PGHD use in clinical practice and/or the use of PGHD for clinical decision making (e.g., for diagnosis, treatment, monitoring, or management) and discuss opportunities and challenges associated with the formal integration of PGHD in clinical care.

Methods

We conducted a systematic literature review to examine the use of PGHD in clinical practice. We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009).

Search Strategy

We searched PubMed, Ovid, Embase, CINAHL, Web of Science, and Scopus. We started to search the MeSH term, "Patient Generated Health Data" and because it was newly introduced in 2018 as MeSH, only a few articles were identified. To identify all relevant studies, we added several keywords and synonyms. First, we entered keywords such as "patient," "person," "peer," and "caregiver" to expand targets who can create, record, and gather data. Also, we put common data capturing modalities (e.g., self-tracking, wearable, mobile health, and m-health). Moreover, we included "patient reported outcome (PRO)" as a common form of PGHD. All keywords and synonyms related to patient-generated health data and decision making were searched in May 2018. Table 2 outlines our search strategy which was finalized after review by a Health Sciences librarian. We were broadly inclusive of digital or paper as the means of self-tracking, but limited to articles in English, human participants, and articles in which full-text was available (but not constrained to free article access). We augmented this search with 11 papers known to us but not returned by keyword search.

Table 2 – Search Strategy Outline

Search Terms	Combination			
"patient generated health data"[Mesh]	OR		OR	OR
"patient generated health data"				
"patient-generated health data"				
"patient generated health information"	OR			
"patient-generated health information"				
"patient generated data"	OR			
"patient-generated data"				
"patient generated"	OR	OR	AND	
"patient-generated"				
"person generated"	OR			
"person-generated"				
"caregiver generated"	OR			
"caregiver-generated"				
"peer generated"	OR			
"peer-generated"				
"data" or "information"				
"patient reported outcome measures" [Mesh]	OR			
"patient reported"				
"patient-reported"				
"self tracking"	OR			
"self-tracking"				
"body-worn sensor*"				
wearable				
smartphone*	OR			
mhealth				
"mobile health"				
"personal health record"				
Combine all above and below with "AND"				
"clinical decision making"	OR			
"clinical decision-making"				
"medical decision making"				
"medical decision-making"				

Selection Criteria

Given the focus of this review on actual PGHD use for clinical decision making in a clinical setting (unlike use of PGHD for the sole purpose of collecting data for a research protocol or without involvement of clinicians), inclusion was based on three main criteria: (a) The article must have been peer reviewed, and represent empirical work (data, whether qualitative or quantitative, collected as part of the study and reported in the article). This excluded opinion papers, vision statements, literature surveys, and similar pieces. It also excluded a number of papers discussing PGHD issues, and papers describing the architecture of particular systems or apps. Articles in which the data were simulated or fabricated for test purposes were also excluded. (b) We adhered to the ONC definition of PGHD, requiring that the patient initiate data collection and control data sharing. This excluded clinician-initiated data collection such as clinical telemonitoring and most implantable devices, because in those cases the patient did not control data collection or data sharing. Patient-reported outcomes were commonly reported but most were excluded from this review because the data were retrospective and gathered at a fixed schedule mandated by the research study protocol (patients did not control the "self-monitoring" process). (c) The self-monitoring data had to have been used for clinical decision making or during a patient-clinician encounter. This excluded social media groups and online

discussion forums, which typically focused on peer-to-peer interactions, and platforms for self-improvement or self-reflection.

We used the *Covidence* systematic review software (Veritas Health Innovation LtD, Melbourne, Australia) to manage the review process. The software automatically removed duplicates. We required that at least two people from our team review the title and abstract for each article. When there were conflicts, we resolved those by a third person vote or, if the third person was also uncertain, used group discussion to reconcile the conflicts. We used a similar process for full text screening, allowing one person to vote to retain an article but requiring at least two for article exclusion, with group discussion to resolve conflicts.

Analysis

Papers were read in full by members of the research team to identify and tabulate features of the studies (such as design and sample). All papers were read by at least two team members. Two team members derived themes to describe the tabulated findings. The themes were reviewed and refined by all team members.

Findings

The original keyword search returned 7,994 articles and with screening and review of text, resulted in a final 21 articles that were included in the review. Figure 1 shows

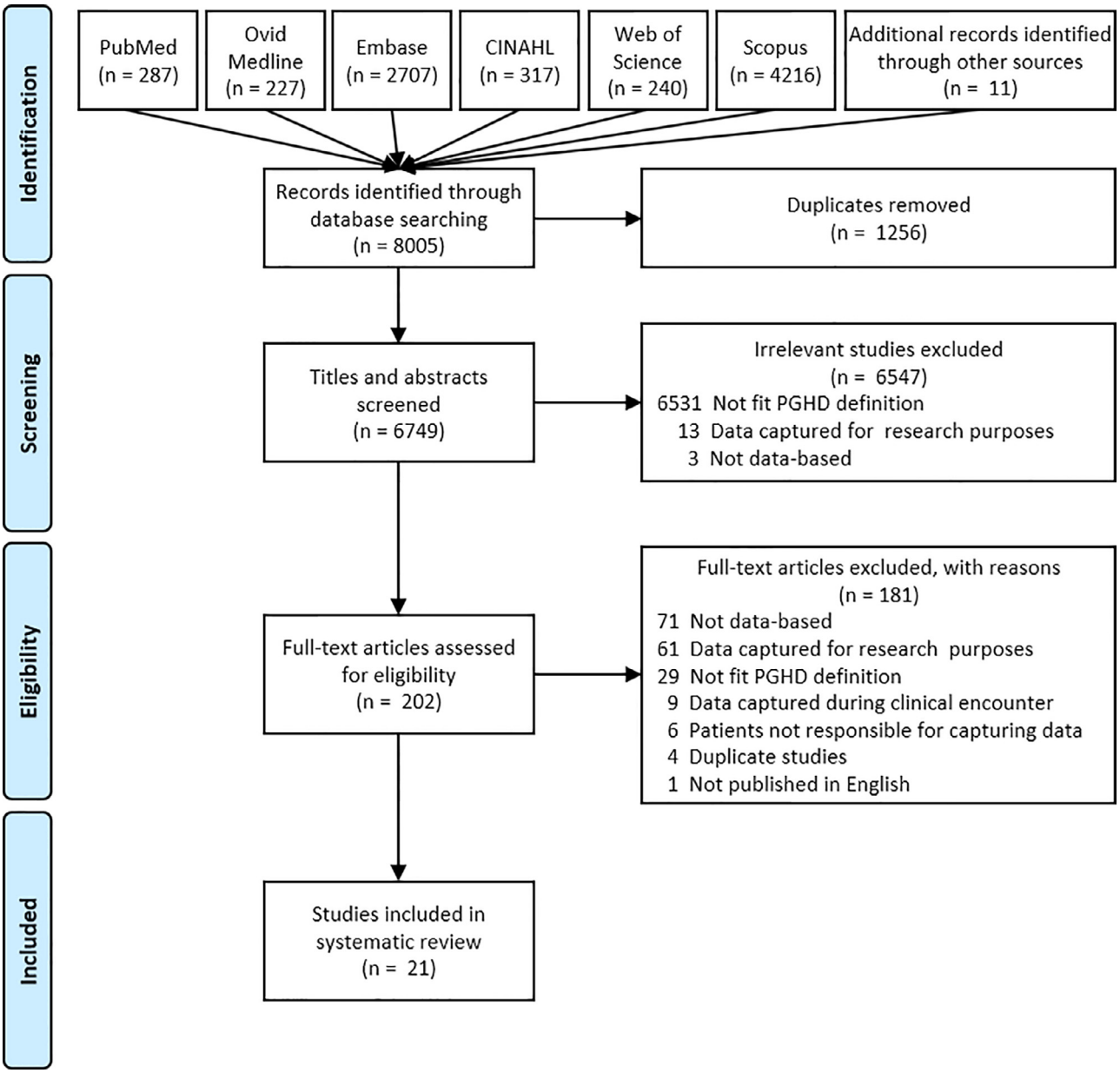

Figure 1 – PRISMA diagram.

our PRISMA diagram and includes the primary reason for exclusion for the articles in which full text was reviewed. In the larger set of articles, we eliminated 1,256 duplicates. Most of the articles in the abstract/title search were excluded because of not meeting the PGHD definition used in this study, including more than 200 articles that included formal or informal patient-reported outcomes (but missing some element, most commonly not meeting the requirement that patient/participant controlled the timing of data collection or the decision about whether to share the data). Similarly, the most common reason for excluding studies of sensors was lack of information about whether the patient had any control over the data collection or sharing. Other common reasons for exclusion were that the study did not include actual participant data (e.g., fabricated data sets, or description of architecture without actual data collection). There was only one article excluded for not being English-language, however the English-language abstract for that article appeared not to meet the PGHD definition. There were no articles that were excluded on the basis of full-text being unavailable.

We found that, while there are articles discussing the vision or need for PGHD in clinical care (at least 40), and more than 200 articles describing data collected from patients or caregivers, empirical research meeting the ONC definition of PGHD was scarce. Table 3 summarizes the final 21 articles. Publication dates for the articles ranged from 2001 to 2018. An initial slow start (less than one article per year) was followed by increasing number of articles starting in 2016. As shown in Table 3, study locations included USA, UK/Europe, Australia, and Asia, with location not specified for two studies. Participant ages covered the lifespan from pediatrics to older adults. Studies examined a wide variety of conditions and symptom foci (see Table 3).

Most of the studies were at exploratory or developmental stages. Two studies were randomized controlled trials, with sample sizes of 40 (Hsu et al., 2016) and 96 (Jiang et al., 2016). A third (Andy et al., 2012) described their 61-patient study as a randomized trial but did not provide information about the groups and reported the results like an observational study. Six studies were observational or cross-sectional designs (Barrett et al., 2018; Lau et al., 2013; Lv et al., 2017; Marceau, Link, Smith, Carolan, Jamison, 2010; Miller et al., 2016; Weissmann et al., 2016). More than half (12 of 21, 57%) described the study as *beta test, pilot, feasibility* or *case study* (Adams et al., 2003; Albisser et al., 2001; Basch et al., 2007; Bauer et al., 2018; Johansen et al., 2004; Lindroth, Islind, Steineck, & Lundin, 2018; Martinez, Marquard, Saver, Garber, Preusse, 2017; Peleg et al., 2017a, 2017b; Quinn et al., 2008; Smith et al., 2012). Sample sizes for these early stage exploratory studies ranged from 4 (Johansen et al., 2004) to 142 (Albisser et al., 2001), with most having 30 or fewer participants (Table 3).

Article Quality

We were not reporting the effects of PGHD *per se*, and most of the studies reported very early stage projects, with less than half of the articles as randomized controlled trials or prospective observational studies. Due to the preponderance of early, developmental, and pilot studies we did not use a standard appraisal tool to formally evaluate study quality. However, we qualitatively examined article quality. Some of the articles met traditional quality metrics. For example, the observational study by Weissmann et al. (2016) had a fairly large sample, well-described participant characteristics, and provided detail about their study processes.

We also noted several limitations on study quality in some of the studies. Participant characteristics were largely unreported. The study by Adams et al. (2003), a striking example, did not report any participant characteristics including the number of participants. As shown in Table 3, in multiple studies the age range was not specified but presumed to be adult based on the study description. Most were single center, and often single unit within a center, with only the study by Weissmann et al. (2016) explicitly described as multicenter. Some effects were reported but not actually measured; for example, in the study by Barrett et al. (2018), potential clinical effects were only hypothesized. The PGHD systems were evolving and undergoing iterative refinement (particularly for studies described as pilot or beta-testing). The study by Albisser et al. (2001) for example, explicitly noted the system was being actively refined during the time the study was being conducted. Refinement is a natural part of tool development processes but can be a challenge to reproducibility. We noted other design and methodology issues, some reported by the authors, including high attrition (Marceau et al., 2010), recall bias, and ascertainment bias (Peleg et al., 2017a).

Types of Data Collected

We extracted descriptions of the wide variety of data collected in the studies and grouped them by data elements. Not surprisingly, almost all the PGHD systems collected data about *symptoms, physiological measurements,* and *behaviors*. With the exception of the study by Hsu et al. (2016), the PGHD system Hsu evaluated focused on blood glucose values and medication adherence although the patients also participated in virtual visits with their health care provider via videoconferencing. Some of the system did not just ask if symptoms were present but also included extent of symptom interference or quality of life metrics. The study by Basch et al. (2007) included formal PRO measures as well as study-specific questionnaires to measure symptoms, and used validated measures of quality of life. The study by Bauer et al. (2018) included the validated instruments PHQ-9 to measure depression and GAD-7 to measure anxiety. As shown in Table 3, most studies were focused on condition-specific topics, and consequently data collected in the systems focused on the condition-specific symptoms. Also commonly reported were lifestyle and health behaviors such as activity/exercise and diet, risk behaviors (such as smoking), and preventive measures

Table 3 – Description of the Included Studies

Reference	Overview	Study/System	Findings
Adams et al. (2003)	Model information system that integrates patient health information to support monitoring and care of children with persistent asthma Focus: Asthma Location: USA	Study: Feasibility/proof of concept. Ages: Children and adults (parents) *N* = Unreported System: Telephone-linked communication (TLC-Asthma) with symptom monitoring and automated phone-based education, web-based alert and nurse case-management, EHR (Epic) communications	Monitoring includes severity-treatment mismatch, use of peak flow meter, changes in symptom frequency or severity. Level 1 alerts: patient advised to seek care immediately, fax sent to dedicated line and phone call to clinic personnel. Level 2 alerts recorded to a log and reviewed by nurse
Albisser et al. (2001)	Glucose clamping algorithm for patient use (clamping defined as efforts to maintain glucose in a specified range through glucose or insulin administration). Focus: Diabetes Location: Unspecified	Study: Described by authors as "system beta testing" Ages: Not specified, presumably adult *N* = 142 patients for 1 year (approx. 100,000 messages) System: Data entry via touch tone phone/voice response hardware (HumaLink).	Clinical outcomes improved (rate of hyperglycemia, hypoglycemia, or symptoms; and Hemoglobin A1c level).
Andy et al. (2012)	Personal health record for diabetes care, based on American Association of Diabetes Educators guidelines. Focus: Diabetes Location: Asia (Taiwan)	Study: Developmental evaluation. (Described as randomized but not reported as such) Data collected are application feedback, outcomes monitoring, usage Ages: Not specified, presumably adult *N* = 61 (36 intervention, 25 control) System: Un-named; Web based app + unspecified interaction with care managers. Generates HL7 Continuity of Care Document (CCD).	Decreased HbA1C in intervention group (66% of patients vs. 40% in control group)
Barrett et al. (2018)	Study of AIR Louisville, a public health collaboration to improve asthma Focus: Asthma Location: USA	Study: Pragmatic single arm, interventional (CBPR) Ages: Adults and children *N* = 497 Electronic sensors to monitor medication usage (Propeller Health). FDA-approved system includes inhaler sensors, digital health platform. Also did environmental monitoring.	78 percent reduction in rescue inhaler use and a 48 percent improvement in symptom-free days
Basch et al. (2007)	Monitoring symptoms of chemo toxicity in lung cancer patients (eRapid; study-specific system) Focus: Cancer Location: USA	Study: Prospective observational study. Ages: Adults *N* = 124 enrolled. Interviews with 13 patients, 9 advocates, 19 staff. System was self-reported via questionnaires and based on NCI Common Terminology Criteria for	Targeted advice based on national guidelines. Self-reporting found to be feasible. Patients could use system on their own but seldom used system between visits, unless prompted by explicit reminders or clinician feedback.

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Table 3 – (*Continued*)

Reference	Overview	Study/System	Findings
		Adverse Events (CTCAE), mandated reporting for NCI-funded studies	
Bauer et al. (2018)	Testing the feasibility and acceptability of a mobile health platform (patient-facing smartphone application) supporting collaborative care for patients with depressive and anxiety disorder. Focus: Depression/anxiety Location: USA	Study: Mixed method pilot study (4-week study period) Ages: Adult N = 17. System: The platform supports the transmission of patient data to care manager via an online dashboard. Smartphone sensor data were also collected, mainly about patients' movement and communication. The dashboard offered providers an overview of patient basic information and graphing of patients' report of their mood and symptoms.	Only 6 participants retained in the study, 15 completed weekly reports with a lower response rate on daily measures (i.e. medication use).
Holch et al. (2017)	Describing the development of eRAPID (electronic patient self-Reporting of Adverse-events: Patient Information and aDvice) for cancer patients to self-report and manage significant adverse events during and after cancer treatment. Focus: Cancer Location: UK	Study: Usability and functionality Ages: Adult N = 13 patients, 9 advocates, 19 staff System: The eRAPID system. Algorithms imbedded in the system allows patients to receive tailored advice for low to moderate adverse events or contact hospital for severe adverse events. Integrated with electronic record at Leeds Teaching Hospital	The eRAPID system allows patients to report adverse events and guide patients to better manage these events.
Hsu et al. (2016)	Examining the effects of a cloud based diabetes management system on glycemic control as compared to control group receiving standard care among patients with type 2 diabetes. Focus: Diabetes Location: USA	Study: Randomized controlled trial Ages: Adult N = 40 System: Patients with type 2 diabetes starting basal insulin therapy, who were in the intervention group, received a cloud-based diabetes management program for communication, collaboration and decision making between patients and health care providers. Control group = usual care	Patients in the intervention group achieved a better hemoglobin A1c control and satisfaction than those in the control group.

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Table 3 – (*Continued*)

Reference	Overview	Study/System	Findings
Jiang et al. (2016)	Describing factors associated with usage of advice from a mobile health application among lung transplant patients. Focus: Transplant Location: USA	Study: Cross-sectional study examining app usage, extent to which recommendations are followed, as well as predictors of usage and following recommendations. Ages: Adult *N* = 96 System: Mobile health app called Pocket PATH for daily health self-monitoring; system generated suggestions.	Patients with moderate use of Pocket PATH were less likely to follow system recommendations than high or low users. Usage of recommendations from system were associated with gender, past experience with technology, income, hospital stay, and self-monitoring frequency among lung transplant patients.
Johansen et al. (2004)	Parents of burns patients are involved in patient care by capturing suitable pictures without intensive training and cost. Focus: Burns Location: Australia	Study: Feasibility study Ages: Pediatric burn patients, study enrolled parents *N* = 4 System: Email, cell phone camera. Study examined extent to which parents of burns patients can take clinically suitable pictures for follow-up communication with healthcare providers via email.	Low-resolution images were satisfactory for diagnosis and email messages from parents were adequate for clinical decision making. Parents reported the easiness and convenience of taking photographs.
Lau et al. (2013)	Personally controlled health management systems (PCHMSs) with social and self-reflective features were designed to support self-maintaining and self-management of physical and emotional well-being. Focus: Physical and emotional well-being Location: Australia	Study: Single-group pre/post-study over 4 months Ages: University students and staff *N* = 709 System: Personally controlled health management systems (PCHMSs) with social and self-reflective features. Study examined how students used the features.	Social features were considered most engaging. Self-reflective feature (i.e., diary) was associated with higher levels of professional health seeking behaviors.
Lindroth et al. (2018)	Describing how patient generated data via mobile apps were used by nurses and how these data transformed patient care. Focus: Cancer Location: Europe (Sweden)	Study: Case study Ages: Adult *N* = 10 System: Mobile app developed for the study	Patient generated data introduces changes in communication and decision-making between patients and nurses by providing more precise descriptions of health problems.
Lv et al. (2017)	EMPOWER-H that enables capture of home blood pressure (BP) data via a smartphone. Focus: Hypertension Location: USA	Study: Pre-post study Ages: Adult *N* = 149 EMPOWER-H is an interactive Web-based disease management system integrated with the	EMPOWER-H significantly improved the usage of patients' office-measured and home-monitored BP in patient care.

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Table 3 – (*Continued*)

Reference	Overview	Study/System	Findings
		electronic health record. Study explored how home BP data gendered by patients with uncontrolled BP influenced clinical decision making.	
Marceau et al. (2010)	Describing the experiences of using electronic diaries with summary feedback in the care of patients with chronic pain. Focus: Pain Location: USA	Study: Described as 10-month follow-up study Ages: Adult *N* = 134 Study: Electronic diaries with feedback or paper diaries without feedback– to monitor and manage pain.	About 23% of patients reported electronic diaries improved care. About 77% of participants reported satisfaction with the app.
Martinez et al. (2017)	Describing diabetic patients' and clinicians' experiences of using the CONDUIT-HID for the management of BP. Focus: Diabetes, hypertension Location: Unspecified	Study: Qualitative interview Ages: Presumably adult *N* = 21 patients, 5 clinicians System: CONDUIT-HID Patients can upload BP data into HealthVault (personal health record) via internet; Patients have choices to allow HealthVault to send their data to Reliant Medical Group's EHR via HL7; protocol driven feedback loop was used to adjust medications if BP was not controlled; nurses can schedule phone calls with patients between office visits when alerts were triggered.	System that supports users' workflow and minimizes users' cognitive efforts is important for the successful adoption.
Miller et al. (2016)	Describing the use of digital images captured by parents of pediatric patients receiving ambulatory surgery. Focus: Postsurgical wound healing Location: USA	Study: Retrospective chart review Ages: Pediatric patients age 0–17years (parents enrolled) *N* = 166 enrolled, 129 included System: Cell phone camera, email A structured review of the electronic health record was conducted to explore how the digital images of post-operative wounds taken by parents of pediatric patients were used in the patient care.	Of 166 participants who reported sending digital images to the clinician, 121 participants' images were documented, and corresponding changes in patient care were noted.
Peleg et al. (2017a)	Evaluating whether the MobiGuide (mobile decision-support system) facilitated the compliance to system's recommendations, satisfaction, and quality of life among patients with AF or GDM and their HCPs. Focus: Atrial fibrillation (AF), Gestational diabetes (GDM) Location: Europe (Italy/Spain)	Study: Developmental/feasibility study Ages: Older adults, adults *N* = 10 AF; 20 GDM	A high compliance to system recommendations was noted. Quality of life for patients was uncertain.

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Table 3 – (*Continued*)

Reference	Overview	Study/System	Findings
		System: MobiGuide is a chronic patient management system that has, patient-empowering innovative functionalities based on the interaction of patients' activity and clinical guidelines. Incorporates data from mobile sensors via Bluetooth, self-report of symptoms, computer interpretable clinical guidelines, compliance-checking functions Data from electronic health records can be pulled into the PGHD system (semantic data integration)	
Peleg et al. (2017b)	Describing MobiGuide users' experiences in terms of sustainable usage, patients' perceptions of usage, and HCP's views of patient data. Focus: Atrial fibrillation (AF), Gestational diabetes (GDM) Location: Europe (Italy/Spain)	Study: Developmental/feasibility study Ages: Older adults, adults *N* = 10 AF; 20 GDM MobiGuide, a personalized evidence-based decision-support system.	Hypothesis of sustainable usage of MobiGuide, positive perceptions of MobiGuide usage, and clinician usage of patient data were supported.
Quinn et al. (2008)	Adult patients with type 2 diabetes can benefit from the use of WellDoc. Focus: Diabetes Location: USA	Study: Feasibility and usability, randomized to intervention and control Ages: Adult ages 18–70 *N* = 30 The feasibility of using WellDoc, a mobile diabetes management system in conjunction with web-based analytics to manage A1C by patients and HCPs.	Better A1C control among patients who used WellDoc. HCPs reported the system facilitated clinical decision making. The majority of patients and physicians were satisfied with the system.
Smith et al. (2012)	Reporting mHealth-based EMA and two-way interactive text messaging for providing treatment feedback for the care of veterans with mTBI and/or PTSD. Focus: Mild traumatic brain injury (mTBI), post-traumatic stress disorder (PTSD) Location: USA	Study: Pilot study to assess feasibility, potential utility Ages: Adult *N* = 27 System: Un-named, described as an electronic survey tool that supports data collection from personal digital assistants, commercial SMS text messaging Study examined ecological momentary assessment (EMA) and two-way interactive text messaging as communication modes in the care of veterans with mTBI and/or PTSD.	mHealth-based support in conjunction with traditional mental treatment are feasible for the treatment of veterans with mental health concerns. Users' prior mobile experiences and clear data presentation are important for the design of such a system.

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Table 3 – (Continued)

Reference	Overview	Study/System	Findings
Weissmann et al. (2016)	Study of information management system, Accu-Chek Smart Pix system to improve the self-monitoring of blood glucose for patients with type 1 and type 2 diabetes in outpatient settings. Focus: Diabetes Location: Europe (Denmark/Germany)	Study: Observational prospective study Ages: Adult $N = 965$ System: Information management system, Accu-Chek Smart Pix system	Significant reductions in HbA1c from baseline were noted, and reports from the information management system were used for therapy adjustment.

Note. AF, atrial fibrillation; BP, blood pressure; CONDUIT-HID, CONtrolling Disease Using Inexpensive Technology-Hypertension in Diabetes; EMA, ecological momentary assessment; GDM, gestational diabetes Mellitus; Mtbi, mild traumatic brain injury; PTSD, post-traumatic stress disorder.

(like foot or eye exam). Medication usage or adherence was examined in several PGHD systems (Adams et al., 2003; Andy et al., 2012; Barrett et al., 2018; Hsu et al., 2016; Marceau et al., 2010; Peleg et al., 2017a, 2017b; Quinn et al., 2008).

Many of the studies included physiologic measurements from a device, such as a blood glucose monitor (Albisser et al., 2001; Andy et al., 2012; Hsu et al., 2016; Peleg et al., 2017a, 2017b; Quinn et al., 2008; Weissmann et al., 2016), vital signs such as blood pressure or heart rate (Andy et al., 2012; Jiang et al., 2016; Peleg et al., 2017a, 2017b), body weight (Lv et al., 2017), or spirometry or peak flow (Adams et al., 2003; Jiang et al., 2016). The device data in some studies was manually entered by the patient into the PGHD system with notable exceptions reported by Andy et al. (2012) and by Peleg et al. (2017a, 2017b) which explicitly noted the sytem, allowed data to upload from commercial blood glucose monitors. The Weissmann et al. (2016) report also included a device reader that could pull data from blood glucose monitors. The paper by Martinez et al. (2017) used an automated blood pressure cuff that uploaded data to the Microsoft HealthVault personal health record.

Less commonly seen data element categories were *contextual data, goals/preferences,* and *miscellaneous*. Contextual elements included patient demographics and events such as illness or predefined psychosocial contexts such as being at work (Albisser et al., 2001; Andy et al., 2012). Goals or preferences were occasionally reported in the PGHD system (Barret et al., 2018; Peleg et al., 2017b). Miscellaneous data included problem-solving activities or journal functions in which the patient could choose what to document (Andy et al., 2012).

Usability and Satisfaction

Some of the studies reported that the PGHD system/app included built in surveys or questionnaires evaluating the application itself, reactions to using the system, or issue tracking. However, despite the clearly formative nature of most of these evaluations, few of the developmental studies reported formal usability evaluations and reported satisfaction or reactions in broad terms. Some assessed usability or satisfaction externally to the PGHD system. The study by Andy et al. (2012) for example, predominantly reported what functions were used, and noted in the conclusions that they received "user feedback including either device problems or browser compatibility problems" (p. 6 of 6). Jiang et al. (2016) used a satisfaction survey but then noted that the distribution of scores was highly skewed so dichotomized to fully satisfied or less than fully satisfied (p.6). Johansen et al. (2004) noted that families were "happy to participate" and found it "easy and convenient" (p. S1:55) but also provided qualitative comments to illustrate responses. Despite having ease of use in the title, the study by Martinez et al. (2017) did not report any ease of use or

usability metrics. Similarly, Quinn et al. (2008) had satisfaction in their study title but what they evaluated was satisfaction with the clinical outcome rather than satisfaction with the PGHD system. Smith et al. (2012) did not describe their survey other than to note it was a brief, forced-choice questionnaire, and reported broadly "participants generally found the messaging program useful" (p. 300), with percentages of respondents who found selected features of the system "helpful" (p. 301).

A few of the studies were more informative. Barrett et al. (2018) described their study as a crowdsourced application. Although not describing a formal evaluation in detail, they reported participant experiences from 57 patients, noting 80% were satisfied with the sensor and found it easy to use, 81% reporting feeling more confident in being able to avoid an asthma attack. Basch et al. (2007) noted that they used a satisfaction survey with items adapted from measures used in similar research, and reported "Satisfaction with the system was high (90%), but only 51% felt communication was improved" (p. 5375). Bauer et al. (2018) reported "the app was easy to use and the amount of time was reasonable" but added detail including a table with responses to individual items on their questionnaire. Hsu et al. (2016) conducted a qualitative exit interview and reported example user comments organized around themes of reduced anxiety, empowerment, and connecting glucose level to behavior (p. 63–64). Marceau et al. (2010) noted satisfaction as a main study outcome, and described their questionnaires as adapted for the study from previously published questionnaires and reported not only questionnaire results, but also qualitative comments, both positive and negative. Peleg et al. (2017b) reported in detail the results of a usability survey with detailed responses in a table. Weissmann et al. (2016) reported high levels of physician satisfaction ("satisfied or perfectly satisfied") along with a number of domains such as time for decision making, quality of patient interactions, speed of report generation, clarity of records, and other domains (p. 81).

PGHD Systems/Apps

Most of the PGHD systems were study-specific. A few (5) used commercial systems or included off-the-shelf components (Albisser et al., 2001; Barrett et al., 2018; Miller et al., 2016; Quinn et al., 2008; Weissmann et al., 2016). Data were predominantly manually entered. In many of the studies, patients had to manually record even device data into the PGHD system. There were five studies (Andy et al., 2012; Hsu et al., 2016; Martinez et al., 2017; Quinn et al., 2008; Weissmann et al., 2016) that indicated they pulled data from a limited number of very specific devices, such as specified glucometers. Voice or phone touch-tone was used for data entry in two studies (Adams et al., 2003; Albisser et al., 2001). Digital images were used in the studies by Johansen et al. (2004) and Miller et al. (2016), and as an option for recording food intake in the study by Andy et al. (2012). Bauer et al. (2018) included data from sensors built into the phone or tablet, such as location, movement, phone usage, and app usage data.

Data storage was predominantly not reported. A few studies discussed a study or app-specific survey, or integrated with REDCap or similar data collection tools. Data transfer methods included Bluetooth (for those that captured data from devices to phone) and Wi-Fi (phone to server). Web portals were reported in multiple studies. Some had no data transfer (data were entered and viewed directly on a central server). Data transfer methods were sometimes unspecified ("secure data transfer" or "patients could upload").

Electronic Health Record Integration

Interestingly, two of the studies used paper (printed reports) for sharing data with the clinicians (Albisser et al., 2001; Basch et al., 2007). Only four studies claimed electronic health record (EHR) integration of PGHD data Adams et al., 2003; Holch et al., 2017; Lv et al., 2017; Martinez et al., 2017). The system examined by Peleg et al. (2017a, 2017b) interacted with EHR data in the other direction, pulling clinical data into the PGHD system. Integration with EHRs was discussed as a potential for future development using terms such as *HL7 compatible* (Martinez et al., 2017) or *formatted to support semantic integration* (Peleg et al., 2017a, 2017b). Andy et al. (2012) created a report formatted as an HL7 Continuity of Care Document, which is a national standard accepted by the U.S. Department of Health and Human Services for sharing clinical information (HL7 International, 2019).

Decision Support

The articles in this review used mostly very simple forms of decision support. The predominant form of decision support was information presentation, in a variety of summaries, reports, or status dashboards. This included progress reports stored centrally (Albisser et al., 2001), visualizations of patient data viewed by the nurse and used to adjust interview questions for face to face consultations (Lindroth et al., 2018), and weekly summaries correlating medication adherence and blood glucose values with reminders to also consider diet and exercise effects and links to communications tools (Hsu et al., 2016). Blood glucose profiles, statistics, graphs and other visualizations were also provided in reports by Weissman et al. (2016). Johansen et al. (2004) asked families to e-mail a summary to the burn team. Well constructed reports and information displays are known to support communication between patients and providers and facilitate collaborative decision making. Weissman et al. (2018) for example, explicitly noted that the reports were used during clinic visits to guide collaborative decision making, as did Hsu et al. (2016). Marceau et al. (2010) used direct patient and health care provider communications as the primary means of decision support. Similarly, Smith et al. (2012) used

data shared with the treatment team as a primary form of decision support. Some of the reports and information presentation features targeted specifically the patient or provider. Miller et al. (2016) presented wound images to the providers, leaving it to the provider to interpret. Lau et al. (2013) specifically designed their electronic diary to support participant self-reflection, with links to communications portals that would allow people to choose to communicate with clinicians.

Also commonly reported were a variety of unspecified feedback or reminders, or simple alerts based on thresholds (like a blood pressure that was above guideline thresholds). Patients were generally advised to consult with their clinician, rather than being offered specific actionable advice. A few systems included automatically generated emails that could be sent to the providers for certain alert conditions. Examples of these alerts and feedback include:

- Symptom-treatment mismatch notice to the patient, with alerts sent to a clinician (Adams et al., 2003)
- Out of range vital signs (Andy et al., 2012)
- Dashboard showing asthma control, medication adherence, as well as notification of local air pollution levels (Barrett et al., 2018)
- Patient alerted to contact clinician if symptom severity of grade 3 or higher was reported (Basch et al., 2007). This study had no automated reporting to clinicians.
- App (for patients) plus dashboard (for care managers) that include ability to graph findings over time; dashboard flagged patients with specified alerts such as persistent symptoms or isolation based on movement/communication, or if patient response indicated thoughts of self-harm. Care managers and clinicians responded to patient by phone (Bauer et al., 2018)
- Alerts for symptoms that passed critical thresholds, with feedback message about when and what to report to the transplant coordinator (Jiang et al., 2016)
- Dashboard alert for nurse case manager if individual blood pressure measurements cross a specified critical level (Lv et al., 2017)
- Feedback about how entered blood glucose value compared to patient-specific target (Quinn et al., 2008)

Patient education was specifically called out as a form of feedback or advice in some of the studies. Albisser et al. (2001) provided self-management instructions, and Andy et al. (2012) provided standardized educational messages. Similarly the system evaluated by Quinn et al. 2008) provided patient feedback/education about nutrition, lifesyle, stage of change, and self-management skills. Sometimes the messages were somewhat tailored. Adams et al. (2003) provided behavioral reinforcement education tailored to the patient data. Barrett et al. (2018) tailored education based on guidelines.

Three of the more recent studies provided actionable advice, coupled with clinician notifications. The sytem evaluated by Holch et al. (2017) provided immediate targeted advice based on local and national guidelines for low-to-moderate severity events. For severe events, the system provided advice to contact the hospital and email was sent to clinicians. The system evaluated by Martinez et al. (2017) used a protocol to evaluate data and provided feedback to adjust medications if blood pressure was not controlled, along with alerts sent to diabetes care nurses. The system evaluated by Peleg et al. (2017a, 2017b) included a formal clinical decision support system that provided feedback based on patient data and clinical guidelines, but gave patients control over how to use the system.

A care manager (often a nurse care manager) or other intermediary was an important part of the decision support workflow for several studies. Adams et al. (2003) triaged alerts into level 1 (high priority) with alerts sent directly to a care manager, and level 2 (lower priority) alerts which were reported into a document that could be reviewed by the care manager at their convenience. The care manager determined when to contact the primary care provider. In the system used by Albisser et al. (2001), the case worker was the primary day to day reviewer of data in the system and providers reviewed printed reports biweekly or monthly. The system examined by Andy et al. (2012) gave the patient the ability to initate a message with a case manager. In the study by Basch et al. (2007), the primary intermediary was the nurse at a clinic visit. However, only one in seven of the nurses reported that they discussed PGHD findings with patients "frequently," with time as the biggest barrier to discussing the data with patients. In the study by Johansen et al. (2004), research staff acted as the intermediary. Patients were asked to send emails to the burn team, but those emails were delivered to the research staff and then collated and forwarded by research staff to the burn team. The collated emails added a checklist for the burn team to use in evaluating the image quality. Responses from the burn team were sent to the research staff, who then forwarded messages back to the family. The importance of nurses as an intermediary continued into more recent studies. In the study by Lv et al. (2017) nurse case managers and registered dieticians actively accessed the dashboard, contacting patients as needed, using system-supported bidirectional secure messaging. In the study by Martinez et al. (2017), diabetes care nurses phoned patients between office visits and when an alert was generated.

Discussion

In this review, we examined scientific literature to attempt to understand the extent to which the vision of using PGHD to inform clinical decision-making has

been realized. We found literature that showed predominantly developmental and feasibility studies, and studies that look at impact or outcomes are just emerging. The PGHD systems were highly diverse in terms of what data were collected, and how data were collected, stored, and shared. Despite the rapid growth in personal sensors (such as activity trackers) and general positive attitudes about "quantified self" in popular literature, we found only limited usage of these devices in the studies. This slow start and gradual growth aligns with the PGHD adoption curve projected by the Office of the National Coordinator for Health IT (Cortez, Hsii, Mitchell, Riehl, & Smith, 2018), which suggested that we are currently in an *early adopter* stage for PGHD in clinical care and research.

The scarcity of empirical research that included both PGHD and clinical processes was similar to that reported in a recent synthesis looking at PGHD information quality (West, Van Kleek, Giordano, Weal, & Shadbolt, 2017). Due to our narrow focus and the scarcity of literature that met our review criteria, we also examined the excluded studies, at a high level, to try to evaluate why these studies returned on the keyword search but were excluded. We saw that people sometimes used PGHD keywords to represent data collection methods, such as interviews or questionnaires that are aimed at the patients or caregivers (Chung & Basch, 2015; Peeples, Iyer, & Cohen, 2013). In many cases, papers were excluded that included study protocols, a number of scale or instrument development or validation studies, and system architecture descriptions. Some used only fabricated or synthetic data and lab testing. We also excluded a number of drug studies or intervention evaluations, in which the "patient-reported information" was limited to intervention effects or "reportable" drug adverse effects.

In terms of clinical decision support features for PGHD data, we identified in most cases a very basic level of decision support. This rudimentary form of clinical decision support may be a reflection of the emergent state of PGHD systems (Shameer et al., 2017). It may also be that developers could be intentionally avoiding giving actionable recommendations because such usage might place the devices into the realm of being a "medical device" per FDA definitions and therefore subject to additional oversight, which can be prohibitive for devices that are still in developmental process (Tung et al., 2018). Personal devices that are low-cost enough for widespread use (*consumer-grade devices*) are in some cases known to have issues with accuracy and precision (West et al., 2017). Finally, data from these devices can be difficult to use in rigorous research studies, with no standard formats defined (as yet) and data from many devices are often stored in a manner that is proprietary to the system developer (Quinn et al., 2008).

Our findings highlight that efforts to integrate PGHD to support clinical decision making are growing in recent years, however, further work is needed to allow for its broader application and use. Our recommendations fall under the following categories: research; policy; system design, EMR integration, regulating hardware and software; engaging the clinical workforce, and consumer education.

Research

Findings from our systematic review highlight the need to further explore several areas to ensure clinical decisions can be made appropriately when PGHD are used. Research using rigorous methods and larger sample sizes are needed to evaluate the impact of PGHD on, for example, health outcomes, or cost of care. Further research should address quality, accuracy, and reliability of the data produced in various settings and case scenarios. Data accuracy and reliability will be increasingly important as more individuals decide to share their data and providers use it to guide their care (Sitapati et al., 2017; Tung et al., 2018). Researchers have described an anticipated enhanced patient engagement using these technologies, however, this assumption should be directly assessed (Park et al., 2018). Unintended consequences have also been suggested, such as the potential for increased patient anxiety due to a heightened awareness of health decline (Harrison, Koppel, & Bar-Lev, 2007; Steward, Hofler, Thaldorf, & Milov, 2010). The unanticipated consequences need to be closely monitored and further described to help mitigate poor outcomes or to identify who may benefit most using PGHD. Other areas of further exploration include how PGHD influences shared decision making, care coordination, new models of patient-centered care delivery, health care utilization, and workflow and provider efficiencies. Usability studies will help to integrate the patient voice and elucidate user issues and satisfaction with the mobile and sensing tools and determine how to meaningfully provide feedback to patients and families (Woods, Evans, & Frisbee, 2016).

The analytic processes for assessing PGHD is another area primed for further development. As we move from historically aggregated, population-based data to individual, longitudinal data more advanced methodologies need to be applied to identify an individual's patterns, changes in patterns and outliers. Advanced methodologies for interpreting PGHD include, for example, predictive analytics (the branch of analytics that uses various techniques to predict future events based on existing large data sets), machine learning (the use of algorithms by computer systems to complete tasks relying on inferences over time), deep learning (that focuses on learning data representations rather than tasks), artificial intelligence, and other complex analysis (Bhavnani et al., 2017; Peake et al., 2018; Shameer et al., 2017). We also recommend being proactive in making patients and families part of the analytic team to make better sense of the data.

In the included studies, we found variability in the data that were presented. We recommend authors use, and journals require, a standardized reporting framework to assess the quality of the produced data. For example, the Mobile Health Evidence Reporting and Assessment reporting framework has been

adapted to support health system evaluation of technology promoting the capture and use of PGHD to deliver patient-centered care (Agarwal et al., 2016).

Policy

Policy will help to guide and determine the future of digitally enabled health care. Based on our findings, there are several areas where policy development is important to further examine and provide guidance for the use of PGHD in health care delivery. Policy areas include, but are not limited to, guiding interoperability of devices and systems; establishing standards around tracking modalities; addressing issues of liability and privacy; and to help inform reimbursement structures. Tracking modality issues may include, for example, determining the frequency or intervals of tracking and analysis, methods of measuring, and how providers should manage the data. When technological advances occur too quickly, for existing health care practices to keep up, a mismatch between development and preparedness of the system to effectively integrate and utilize the data can occur (Bhavnani et al., 2017). Liability issues include determining who is responsible for analyzing the data——the provider, the vendor of the digital tool; to whom can the data analysis be delegated? Potential liability may be reduced or mitigated by establishing policies and proceedures for handling PGHD and maintaining transparency about the use of the patient's information (HIMSS, 2014). It will be important to determine the delegation of responsibilities for review of certain types of PGHD, for example, to designees such as a nurse, care manager, or other staff and guidelines for responding to alerts or concerning data. Despite the value of PGHD to extend or expand care for individuals, there is a tension that this approach to care management/delivery is not yet reimbursed by the current payment structures limiting the integration of PGHD in practice. There is a need for the innovations to align with institutional objectives and for business cases that incorporate payment models and value based reimbursements (Bhavnani et al., 2017). Establishing a reimbursement structure could promote broader use or more rapid uptake. With clinical measures increasingly tied to performance and payment metrics, ensuring that data accurately reflects the health status of patient population is critical (West et al., 2017).

System Design, EHR Integration, Regulating Hardware and Software

As PGHD tools become more widely available to become formally integrated to standard processes of care, applying principles of user-centered design can facilitate the implementation of systems that more effectively address stakeholder and workflow needs (Poole, 2013). The integration of PGHD into the EHR systems is not fully examined and efforts to date highlight the need for wide adoption of interoperability standards in the industry (Mandel, Kreda, Mandl, Kohane, & Ramoni, 2016). When considering regulating PGHD related hardware and software, several challenges have been identified. Many mobile applications or sensors on the market are considered "lifestyle devices" and do not undergo FDA approval. The FDA has adapted new strategies to address the growing concern for regulation (U.S. Food and Drug Administration, 2013, 2015). Although FDA reviews medical devices, it does not require the device to be rigorously tested to show if it has had an impact on health outcomes (IMS Institute for Healthcare Informatics, 2015).

Engaging the Clinical Workforce

In addition to integrating data into EHRs, there is a need for clinical workforce training on interpretation of PGHD. Establishing best practices for integration into clinical workflow is essential. For example, real-time alert systems that align with the health systems' workflow can help providers and staff quickly sift through a large quantity of data to identify when follow-up action is needed (National eHealth Collaborative, 2013). Adams et al. (2003) established protocols and built algorithms to determine responses to alerts. For example, level 1 required immediate response, whereby a nurse was alerted and and patient/parent was notified to seek medical care, while level 2 alerts were reviewed by a study nurse. All alerts and their corresponding responses were entered into the EHR. Providers will also need guidance for identifying tools to recommend to their patients when they choose to take advantage of self-tracking options. For example, a framework has been developed to assist health care professionals in recommending quality applications to match patients' needs for diabetes self-management (Hale, Capra, & Bauer, 2015).

Implications for Nursing Science

As nurse scientists frequently examine biological underpinnings of symptoms that are inherently self-reported or captured by patients outside clinical settings, PGHD systems can become powerful tools in capturing or predicting vulnerability to changes in health. As Hickey et al. (2019) points out, nurse scientists can integrate precision health to better understand disease burden and facilitate symptom management and improvement of quality of life. Given the comprehensive focus on health and well-being in different settings, nurses are uniquely poised to assist patients in capturing information about their physiological, mental, and cognitive well-being as well as exposure to environmental parameters (aspects of what is referred to as "phenotypic characterization" in the Nursing Science Precision Health Model (Hickey et al., 2019). Nursing scientists can use their holistic lenses as reflected in the Nursing Science Precision Health Model to lead the process of defining the role of PGHD in the era of precision health.

Consumer Education

Health consumers will need education in how to select accurate and reliable tools, interpret their data, discuss, and understand expectations of how their data will inform clinical decision making or lifestyle choices. In this context, we must remain aware of the potential for widening health disparities and be proactive in identifying strategies to mitigate this potential unwanted outcome, such as actively seeking to reduce digital divides and developing novel ways to assure digital data privacy for small populations (Zhang et al., 2017). Challenges include not only the level of access to digital tools and necessary infrastructure but also challenges of health literacy and also "data literacy," the extent to which users understand the meaning of their data, how they are stored and transmitted and who has or may have access to them (Lor, Koleck, Bakken, Yoon, & Dunn Navarra, 2019; van der Vaart & Drossaert, 2017).

Limitations of Our Review

In this review we pursued a narrow focus, requiring that the study include interaction with clinicians for decision making, but that data collection and sharing be patient-initiated. Requiring that there be a clinician-patient decision-making interaction, excluding social media platforms and similar emerging forms of patient initiated health data. We tightly adhered to the ONC definition of PGHD, but the use of this term has clearly evolved over time in addition to other, broader definitions. Due to our tight adherence to this specific definition, we excluded many studies where patient generated data were facilitated for the purposes of a research study without actual use in clinical practice. However, the findings of these studies may inform the next step of actual translation of this work into clinical settings. In particular, we excluded many studies that used patient reported outcomes but did not meet the nuances of the selected PGHD definition, most often because the data were collected only at investigator-specified intervals or only at the prompting of a clinician during a clinic visit. Our choice of search terms may have also limited our findings. We chose many synonyms for "patient generated health data" but we still found surprisingly few articles that included sensors or monitoring technologies. For example. It is possible that had we searched for specific types of sensors (such as actigraph or activity tracking) without looking for PGHD phrasing, we might have found more relevant literature.

Conclusion

Our systematic literature review found a few studies that implement the full scope and intent of the ONC definition of PGHD. Integration of PGHD into electronic records was extremely limited, and decision support capabilities were for the most part basic/rudimentary. PGHD will be part of the health care system narrative and we must continue efforts to understand its impact on health outcomes, costs, efficiency, and patient satisfaction. This will require an iterative design and implementation process with patients, health care providers, and researchers. To accomplish the integration of use of PGHD in daily practice, policies and guidelines will be needed to accommodate the vast arrangement of data types and use case scenarios to be able to use PGHD in daily practice effectively. We conclude that the use of PGHD in clinical practice is in the promising stage and inevitable but needs further work for widespread adaption and seamless integration into health care systems. Nursing scientists need to be at the forefront of this research and lead the process of defining the role of PGHD in the era of precision health.

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