Integrating Patient-generated Digital Health Data into Electronic Health Records (EHRs) in Ambulatory Care Settings: EHR Vendor Survey and Interviews

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Abstract

Data traditionally collected in a clinic or hospital setting is now collected electronically in everyday environments from patients, known as patient-generated health data (PGHD). We conducted informal interviews and collected survey data from major ambulatory care EHR vendors that serve the majority of the U.S. market to collect information on how their clients are integrating PGHD into EHRs. Of the 9 EHR vendors contacted, 6 completed the survey and 5 participated in a 45-minute interview. Feedback from the vendors included how PGHD use has steadily risen over the past decade and how the COVID-19 pandemic accelerated PGHD use. Pathways for data from devices or surveys to be brought securely into the EHR are increasing. While promising, adoption of health IT systems has its challenges. There are disparities in EHRs, devices, and applications. We concluded that more supportive policies are needed to advance PGHD integration.

Introduction

The U.S. healthcare system is in a transitional period. Data traditionally collected in a clinic or hospital setting is now able to be collected electronically from patients. These data are known as patient-generated healthdata (PGHD). PGHD are "health-related data created, recorded, or gathered by or from patients (or family membersor other caregivers) to help address a health concern."¹ The potential for PGHD to impact health is significant. By providing insights into the day-to-day health of an individual, patients and clinicians can employ better strategies to prevent and manage acute and chronic conditions, and clinicians and scientists can use these data to generate and apply analytical techniques to improve risk prediction and diagnoses.² The benefits of PGHD reach across care facilities and diverse geographic locations through web-based interoperable data exchange to deliver more precise treatment and self-management assistance to broad populations.

As healthcare moves beyond EHR implementation, the integration of PGHD from connected devices, including mobile health technologies, is gaining speed. Companies like Apple Inc. have the ability for patients to aggregate their health records from multiple sources on an iPhone and integrate data via authentication into health system patient portals such as Epic's MyChart. It is also possible to integrate third-party data, such as patient- generated blood glucose levels, into the EHR via Apple HealthKit.³ PHD integration capability is quickly expanding to Android platforms with Google Fit and through data aggregation companies such as Validic and Xealth.^{4,5}

Ambulatory care practices with access to PGHD in their electronic health records (EHRs) may be able to improve patient outcomes, care coordination, quality, and cost-effectiveness. The opportunity and need for PGHD became apparent

in 2020 when the novel coronavirus pandemic abruptly replaced many in-person primary and specialty care visits with telehealth—such as eVisits and telephone calls. Yet identifying which data are needed and supporting patients and clinicians through data capture and transfer into EHRs is highly complex. Effective use of PGHD in clinics poses many challenges, including clinician and patient burden, poor usability, workflow integration challenges,⁶ and the potential to exacerbate health inequities. The Office of the National Coordinator for Health Information Technology (ONC) outlines multiple technical challenges related to accuracy of measurements, data provenance, interoperability, implementation, and privacy and security concerns in the data lifecycle (i.e., collection, transmission, storage, and analysis).¹ In addition, selecting valid devices from an increasing number of options, integration into new care delivery models, costs for patients, equitable access to technology, and inadequate information technology (IT) literacy are among the many challenges facing adoption of PGHD nationwide.

The Agency for Healthcare Research and Quality (AHRQ) commissioned an environmental scan to inform the development of a practical guide that ambulatory care settings can use as they approach the use of PGHD for patient care.⁷ As part of the environmental scan, from November 2020 to February 2021, we collected survey data and interviewed major ambulatory care EHR vendors that serve the majority of the U.S. market to collect information how their clients are integrating PGHD into EHRs.

Methods and Approach

Survey and Interview Guide Development and Approach. We contacted ambulatory EHR vendors (N=9) that serve 95% of the U.S. market to collect information on how their clients are integrating PGHD into EHRs. We assessed what PGHD their clients are using or plan to integrate into their EHR, including PGHD type (e.g., biometric, patient activity, questionnaires, health history), PGHD transfer (e.g., active, passive), and technical approaches (e.g., HL7, APIs, Bluetooth). We asked about interoperability standards (e.g., SMART, FHIR, HL7v2, web services, extensible markup language [XML], and consolidated-clinical document architecture [C-CDA]); whether design schemas such as Open mHealth and standardized medical coding terms are leveraged (e.g., SNOMED, LOINC, RxNORM); and what developer platforms (e.g., Apple HealthKit, Google Fit) and which tools, products, and 3rd-party companies (e.g., Fitbit, Garmin) integrate data into their EHRs.

To collect this information, we invited vendor representatives (from November 2020 to February 2021) to complete an online survey, and then participate in a follow-up interview. Vendor representatives were familiar with the processes involved and the state of PGHD integration into their company's EHR. The survey and interview guide were developed by our team with feedback and expert opinion from a pre-identified technology expert panel (TEP). Through iteration we refined the question set with approval from AHRQ (See Appendices C and D). We contacted vendors at least twice in attempt to have them complete an online survey in Qualtrics. Data were analyzed using descriptive statistics.

Following completion of the survey, we invited vendors to a 45-minute video interview. Vendors were asked 10 questions exploring factors contributing to the successes and challenges of integrating PGHD into EHRs. Interviewers took notes during the interview and asked permission to record interviews. Data regarding the successes, challenges, and resources of PGHD were analyzed using content analysis to identify recurring themes in the interviews.⁸ We described other feedback from vendors as a summary narrative.

Results

Of the 9 EHR vendors contacted, 6 completed the survey and 5 participated in a 45-minute interview. Vendors interviewed serve approximately 80% of the US ambulatory care market.⁹ EHR vendors described factors that contribute to integration of PGHD into EHRs. Table 1 displays results from the survey. Table 2 describes themes thatarose around success, challenges, and resources needed.

EHR vendor survey. Of the six vendors who responded, nearly all (n=5, 83%) stated they allow for PGHD to be integrated (ingested). The timeline since integration began ranges between two to ten or more years. The five that allow for PGHD to be ingested are further described. All (n=5, 100%) provide pre-built and custom-built functionality to process and manage PGHD, and PGHD is part of the original contract for some (n=3, 60%) and an add-on for others(n=2, 40%). Nearly all (n=4, 80%) allow for a 'bring your own device' (BYOD) model, and most (n=3, 60%) allow for PGHD to be received outside out of the patient portal.

Some described functionality to notify providers and patients (n=3, 60%) if PGHD need action or are out of range. Vendors provided further details as comments to these questions. It is an implementation decision between vendors and clients to select what type of notifications the client (clinic) may want based on the PGHD. PGHD may appear in a dashboard for clinicians to review to identify patients with high risk in need for outreach. Triggers can automatically send messages to providers or page a nurse pool based on incoming data. Notifications can also be developed that remind patients to complete patient reported outcomes, submit data, or perform action based on data received.

All (n=5, 100%) stated their EHR has the capability to send patient data from the EHR to mobile health apps. All use iOS HealthKit (n=5, 100%), some use Android's Google Fit (n=2, 40%) and other partner platforms (n=2, 40%) to integrate PGHD. HealthKit is easier for vendors to leverage due to the maturity of the Health App which provides data and security standardization. Three vendors (60%) explained their tool provided these data from mobile health apps in graphical format for clinicians within the EHR. The variety of data that could be ingested varied by the aggregator source. iOS HealthKit allows for a variety of data to be tethered to the Apple Health App. Thus, any data integrated with HealthKit could be pulled. Similarly, partnering with a data aggregator company like Validic or Raziel Health allows for additional types of data to be pulled into an EHR. Other partner vendors reported included Livongo, TytoCare, IdealLife, Fitbit, Garmin, Omron, Qardio, iHealth, Welch-Allen, and Withings. While it may be technically possible to pull in dozens if not hundreds of data types from remote health monitors and surveys, the need or value to do so must be tied to a care delivery model.

With regard to the transfer of data, all (n=5, 100%) allow for passive transfer while most (n=4, 80%) allow for push, active, and pull. The technical approach by vendors varies with FHIR (n=4, 80%) standard APIs (n=3, 60%), and web services (n=3, 60%). The use of standardized medical coding terminologies (e.g., SNOMED, LOINC) varied across vendors. Leveraging FHIR was recommended and encouraged to create data standards across the industry to facilitate integrating mobile health app data into EHRs. None of the vendors use design schemas such as Open mHealth or IEEE P1752 standards process.

One vendor (20%) stated they were able to consume or translate incoming PGHD into another language, Spanish, although it was unclear if anyone has done this yet. Three (60%) provide PGHD resources through their patient portal. These resources may include instructions for connecting devices, collecting and uploading data, and what to do if results are out of normal range. Some vendor systems allow patients to connect to supported devices without practice assistance or tech support (n=3, 60%), and some require a clinic to activate prescribed devices (n=3, 60%).

Question	Answer	Number (%)
Does your EHR allow for PGHD to be ingested? (N=6)	Yes	5 (83)
	No	1 (17)
n=5 below		
Do you allow for a bring your own device (BYOD) model?	Yes	4 (80)
	No	1 (20)
To process and manage PGHD does your EHR require custom-built or pre-built functionality, or both?	Both	5 (100)
Is PGHD inclusion part of the original contract with clients or an add-	Original contract	3 (60)
on?	Add-on	2 (40)
Can PGHD be received outside of the patient portal?	Yes	3 (60)
	No	2 (40)
Is PGHD accessible by providers/health system to intervene?	Yes	4 (80)
	No	1 (20)
Does your EHR have functionality to notify providers regarding	Yes	3 (60)
PGHD (e.g., exists, needs action, or is out of range)?	No	2 (40)
Does your EHR have functionality to notify patients regarding PGHD	Yes	3 (60)
(e.g., exists, needs action, or is out of range)?	No	2 (40)
Does your EHR have the capability to send patient data from the EHR	Yes	5 (100)
to mobile health apps?	No	0 (0)

Table 1. EHR vendor survey responses (N=6)

Question	Answer	Number (%)
Does your EHR allow for the push/active or pull/passive transfer of PGHD?	Push, active and pull	4 (80)
	Passive	5 (100)
What technical approach to PGHD integration does your EHR support?	HL7	4 (80)
	FHIR	4 (80)
	Standardized APIs	3 (60)
	Web services	4 (80)
Does your EHR use design schemas such as Open mHealth? (OmH; IEEE P1752 standards process)?	Yes	0 (0)
	Not sure	4 (60)
	No	2 (40)
What platforms does your EHR partner with to integrate PGHD?	iOS HealthKit	5 (100)
	Android Google Fit	2 (40)
	Other	3 (66)
Does your EHR have the ability to translate PGHD in different languages?	Yes	1 (20)
	Not sure	1 (20)
	No	3 (60)
Does your EHR have the ability to consume PGHD in different languages?	Yes	1 (20)
	Not sure	1 (20)
	No	3 (60)
Are there readily available resources through your patient portal for patients about PGHD?	Yes	3 (60)
	Not sure	1 (20)
	No	1 (20)
Patients have the ability to easily connect to supported devices	Yes	3 (60)
without practice assistance or tech support	X.	2 ((0))
Patients require a clinic to activate prescribed devices	Yes	3 (60)

EHR vendor interviews. Table 2 describes themes and descriptions from EHR vendors on the successes, challenges, and resources needed to make the integration of PGHD actionable. Organizational support and readiness to use PGHD in a meaningful way are needed for success. A variety of factors influence the success of PGHD to improve health outcomes and create value. This includes clinical champions, a patient-focused approach, and data and device governance in which PGHD are part of a targeted care delivery model. Other factors include interoperability and economic viability. Vendors described that challenges arise when a well-resourced plan with all stakeholders is not the approach. Resources such as educational support and technical support are key.

Table 2. EHR vendor interview themes: Factors that contribute to the success and challenges of making PGHD integration actionable and resources needed to support PGHD

Successes: Factors that contribute to the success of making integration of PGHD actionable

- **Organizational support and readiness.** Organizations need to invest and prepare for the use of PGHD. This requires consistent organization-wide processes on how to leverage PGHD, marketing representation to create value for patients, and buy-in across the enterprise.
- *Clinical champions.* Physicians, nurses, case managers, social workers, and other stakeholders need to advocate and champion the use of PGHD for patient care. Champions must be maintained over time, or interest may fade.
- **Robust care delivery model.** PGHD need to be tied to a clinical focus (e.g., congestive heart failure [CHF], hypertension). This allows for data and devices to be selected that are appropriate for specific clinical outcomes and targeted to the care delivery model allowing patient self-management and clinical decision-making. This permits data governance and protocol development to understand how to act upon the data by patients and providers. Processes must be used to create value and not increase burden on the care team.
- **Data governance.** PGHD need to be valid, accurate, and well managed with rules to make them useful, timely, interpretable, and effective. Collection and interpretation must be tailored to the clinical focus and population. Protocols and triggers need to be incorporated into the EHR to encourage patient self-management and clinician decision making. Data analytics are needed to discern signal from noise. Decisions need to be made as to how data will be analyzed over time and in a tailored time window. Data density, when data are missing or too frequent, requires protocols for how to deal with changes in data frequency over time. Data need to be aggregated across sources and visualized in a dashboard with clinical decision support tools.

- *Device governance*. Device management could be a BYOD model, managed by clinics or by a vendor. Devices could bedelivered as a kit that collects data specific to the clinical focus. Multiple devices may be needed but can contribute to complexity. The approach may be influenced by the type of EHR vendor the clinic or health system contracts with.
- *Interoperability*. Data need to be exchanged seamlessly across geographic boundaries between disparate organizations, systems, and sources. Consistent standards are critical and may include HL7 and FHIR.
- *Patient-focused approach*. Data and devices need to be useable and appropriate for the target population. The demographics of the patient population need to be considered (e.g., use of iOS or Android, technical literacy, broadband access, physical dexterity).
- *Technical support*. A fundamental requirement is to provide support for patients across the lifespan in diverse environments. Support ought to be provided by a technical person from the clinic or organization, the device manufacturer, or outsourced. Clinical staff, such as RNs, are not the best fit for this role.
- *Economic viability*. The use of PGHD needs to be incorporated into the business model of the organization to demonstrate revenue generation or cost savings.

Challenges: Factors that contribute to challenges of making integration of PGHD actionable

- *Lack of regulations and industry standards.* Data need to be standardized across the industry. There are disparities in EHRs, devices, and applications. Not all EHR vendors use consistent standards, such as FHIR. Standards for some EHR vendor platforms are not as mature as others.
- *Poor data governance*. Protocols are needed to create value from PGHD. Analysis of disparate data sources and determining how and when to act upon data are critical. Organizations may struggle with the legality of PGHD.
- *Patient technology hurdles*. Technical and data literacy must be considered for the target population. Access to broadband internet, particularly in rural locations, may be a hurdle. Patients need to be proficient with how to use devices, particularly multiple devices, which can be amplified for patients who have multiple chronic illnesses and who are often older.
- *Manual data entry and lack of analytics*. Automated data entry is needed when possible. Resources should be dedicated so that data are programmed to be automatically ingested by software to create meaning and value for patients and clinicians.
- *No care delivery model.* Responsibility for the data is needed and it needs tobe tied to health outcomes to select the most appropriate data type and device in order to create value. There remains a lack of national standards around care models for PGHD.

Resources needed to support PGHD

- *Clinical application and data processes.* Organizational investment is needed to develop use cases for PGHD in a variety of care models. Data procedures include governance, protocols, and processes that guide the use of PGHD for clinical decision making and patient self-monitoring that meet patient outcome, regulatory, and legality needs.
- *Clinical workflow capacity*. Clinicians need dedicated time to incorporate PGHD into their clinical workflow.
- *Educational support for patients and providers*. Education and training need to be provided to all end users to understand the benefits and limitations to PGHD.
- *Technical support*. Technical support to patients across the lifespan in diverse environments provided by a technical person.

Vendors described that most clients collect PGHD through surveys that are offered through their patient portal. This may include information being collected before or between clinic visits. COVID-19 has increased use of surveys to collect information on symptoms, exposure, and testing. Less common is the use of remote monitoring devices.

The use of remote monitoring devices is offered in a variety of ways, depending on the relationship between ambulatory care clinics and the EHR vendor. The vendor may offer devices in a 'kit model,' where the patient receives a suite of devices tethered toward a clinical target area. For example, patients with hypertension may receive a Bluetooth-enabled blood pressure monitor and in-home wireless scale. Similar kits for COVID-19 symptoms are on the rise for temperature, blood pressure, and pulse oximetry remote monitoring. The rise of the Hospital at Home model is a similar and quickly growing care delivery model that is accelerating the use of PGHD

integration. Third-party vendors may offer device kits and provide tech support. These are negotiations between the clinic or health system, EHR vendor, and device vendor.

Vendors described that decisions to implement are driven by the clinical side, while the EHR and device vendor provide development support. Development, implementation, and testing usually takes 6-12 months, though prioritized topics can have accelerated timelines. Development and development costs are unique to the EHR vendor and their relationship with the clinics. This influences the way in which PGHD is financed, which could be by perpatient transaction.

EHR vendors stated their systems undergo full security assessments. Data are more protected once they come into the EHR ecosystem, which could be through a patient portal or via API from a device company. Security with devices and their associated apps needs to be worked out with the respective device companies. Risk is held on the patient's side before data cross into the EHR, and data may not fall under privacy and security regulations. Patients should be encouraged to use standard security approaches, such as user authentication, and to limit health information exchange with third-party apps. Limited regulations around PGHD and consumer-based devices makes this an ongoing challenge.

Discussion

The COVID-19 pandemic accelerated the use of digital health. As social distancing measures were enforced, care providers were motivated to collect data from patients remotely. While initially focused on telehealth models of care using video visits, as the pandemic unfolded, other models of care that integrate PGHD grew. While telehealth programs expanded, EHR vendors described how COVID-19 slowed implementation of projects nationally for PGHD in the beginning of the pandemic. At the same time, the rapid shift to remote care delivery promoted pockets of innovation in the use of PGHD for monitoring COVID-19-positive patients. One such example was a partnership between Cleveland Clinic and Epic. As reported by news media, they developed a 14-day interactive care plan through the patient portal where patients can enter symptoms, temperature, and oxygen at home, while clinicians monitor them from afar.¹⁰

Feedback from the EHR vendors described how PGHD use has steadily risen over the past decade as access to the internet and smartphones have proliferated. Pathways for data from devices or surveys to be brought securely into the EHR are increasing. Geographic barriers are falling and allowing for PGHD to be transmitted in near real-time from environments that patients spend more of their lifetime in. There are a variety of models that can be adopted in the integration of PGHD. Ambulatory care clinics are able to partner with EHR vendors, and other partner vendors such as data aggregators (e.g., Validic, Raziel Health) or device companies (e.g., Omron, Qardio, Withings) to build frameworks and support for PGHD to be used for a variety of clinical needs.

Vendors reported using iOS to integrate a variety of PGHD to their EHRs and largely support the Apple ecosystem. Android was only supported by 40% of respondents. This is a concern, given that approximately 38% of the U.S. market is Android.¹¹ Few vendors allow for multi-language support, with only one reporting to allow for data to be ingested in Spanish. These factors have the potential to contribute to disparities in healthcare access among underserved populations.

There are disparities in EHRs, devices, and applications. Vendors discussed the lack of regulations and enforced standards around PGHD. While standards such as FHIR are encouraged, they are not used exclusively. Fortunately, new interoperability rules from ONC, under the 21st Century Cures Act, will boost the exchange of data through APIs and FHIR standards.

A growing number of telehealth vendors provide technology-enabled services that integrate PGHD.¹² Banner Health, for example, partners with Cerner and Xealth to simplify how clinicians prescribe digital health for telehealth and remote patient monitoring. Clinicians can prescribe digital therapeutics, smartphone, and internet apps as tools that connect with the EHR for chronic disease management, behavioral health, maternity care, and surgery preparation and post-surgical monitoring.¹³ *Limitations*. While we attempted to collect data from vendors that serve over 95% of the U.S. ambulatory care market, we were not able to collect data and conduct interviews with all vendors contacted. Questions did not focus on implementation at the vendor versus level. We did not assess issues around accuracy, reliability and utility of PGHD. Future research should address these issues and conduct similar inquiries with health systems and care providers.

Conclusion

Capturing PGHD facilitates patients and clinicians to better understand and predict illness dynamics and to develop approaches to improve health outcomes and deliver personalized care. The COVID-19 pandemic accelerated the use of PGHD, as care providers were encouraged to collect data from patients remotely. Feedback from the EHR vendors highlighted the evolution that PGHD is undergoing as tools for patient care delivery. Over the past decade, PGHD use has steadily risen as access to the internet and smartphones have proliferated. Pathways for data from devices or surveys to be brought securely into the EHR are increasing. While promising, adoption of health IT systems has many challenges. There are disparities in EHRs, devices, and applications. Vendors discussed the lack of regulations and enforced standards around PGHD. While standards such as FHIR are encouraged, they are not used exclusively. The ONC Cures Act Final Rule has provided much-needed regulation, structure, and incentives to help alleviate challenges.¹⁴ Nevertheless, more supportive policies are needed to support integration of PGHD into EHRs and clinical care.

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