1

Electronic Patient-Generated Health Data for Healthcare

Maurice Mars[1] • Richard E Scott[1,2]

[1]Department of TeleHealth, University of KwaZulu-Natal, Durban, South Africa; [2]Department of Community Health Sciences, University of Calgary, Calgary, Alberta, Canada

Author for correspondence: Maurice Mars, Department of TeleHealth, University of KwaZulu-Natal, Durban, South Africa. E-mail: mars@ukzn.ac.za

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Abstract: Gathering and sharing by individuals of their health-related data to enhance their medical care or personal wellness are popular and growing rapidly. As a relatively new field, nomenclature is variable, but this is termed patient-generated health data, person-generated health data, or simply PGHD. This chapter introduces the concept of PGHD. Essential nomenclature is provided, and a model of the purpose, flow, and use of PGHD is presented and discussed. Benefits and challenges are noted, and legal, regulatory, and ethical issues are briefly outlined. Although benefits of PGHD are perceived or inherently believed, the available empirical evidence for improved and collaborative healthcare monitoring and management is slight. Also, there are many challenges. Some of these noted challenges include smart device regulation and reliability, data quality, integration into healthcare processes (adoption), and data integration into records (interoperability). Furthermore, there are legal, regulatory,

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and ethical issues. Widespread adoption and use of PGHD will require more definitive research into evidence of benefits, and efficient and effective resolution of the challenges.

Keywords: digital health; patient-generated health data; person-generated health data; PGHD; smart devices

INTRODUCTION

Globally, medicine is moving toward a more patient-centered approach, embracing self-care, patient engagement, shared decision making, precision medicine and patients having access to their health records (1, 2). People are taking a more active role in managing their chronic conditions and their general well-being. This is particularly important given the rising cost of healthcare and ageing populations and, more recently, the restricted or at least revised (physically distanced) access to routine care caused by the COVID-19 pandemic. The rapid evolution of technology and information and communication technologies has facilitated data acquisition outside hospitals and clinical settings. Health-related data can be gathered by sensors, smart wearable devices, smartphones, external devices, cameras and microphones and people can complete digital questionnaires and document and record their health-related experiences. The data may be analyzed in mobile phone apps, device-specific software or transmitted elsewhere for interpretation, or taken to their healthcare provider. Linking these two fundamental sources of data for enhanced healthcare is becoming the norm, although challenges exist (3–5). The data may be for personal use, such as observations of daily living, or using fitness apps to monitor and guide health-related behavior. Alternately clinicians may use the patient data to monitor or manage existing problems, diagnose new conditions, and promote self-management. Further, large volumes of data from one or many people, such as published through social media or gathered in electronic records, can be analyzed for research or surveillance.

The concept of patient-generated health information is not new. It is the foundation of the oral medical history, which begins the medical consultation. Writings from the Greeks show they took a careful history asking and recording their patients' description of symptoms (6). More recently, patients have been asked to keep records of medical or other events such as symptom frequency, dietary logs, number of asthmatic events, blood glucose concentration records, self-assessment of mood. This information provides a longitudinal record of events between formal consultations that can assist in clinical management or diagnosis.

The miniaturization of sensors, advances in wireless technologies, and artificial intelligence have facilitated data acquisition, transfer, and analysis, allowing patients to track parameters as diverse as cardiac arrhythmia (7), surgical wound healing (8), mole mapping (9), sleep (10) and mood (10). Patients are serially tracking changes in their health, the adequacy of their treatment, their compliance with treatment, biometric physiological parameters, and mental health. However, the effective use of patient-generated health data (PGHD) is still evolving. While many people are generating health data from fitness and wellness apps, doctors have yet to fully embrace the concept of PGHD, and data are not yet easily imported into electronic

medical records or visualized in a useful way (5). The COVID-19 pandemic, with its related safety issues and restrictions on movement, has stimulated more widespread adoption of PGHD for both personal and clinical use.

This chapter introduces the concept of PGHD and provide a description of the process by which PGHD are being gathered and used. The benefits and challenges to its use, including legal and ethical issues, are described. Future directions are identified.

PATIENT-GENERATED HEALTH DATA AND ASSOCIATED NOMENCLATURE

In evolving fields, there are often several terms or words used to describe similar concepts. Some have unique definitions others are broad terms, and there may be overlap in what is meant and described. The commonly used terms are discussed in this section.

Patient-generated health data

This is a term developed by the Office of the National Coordinator for Health and Information in the USA. It is defined as "health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern." (11). "PGHD include, but are not limited to, health history, treatment history, biometric data, symptoms, and lifestyle choices. PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways: (i) patients, not providers, are primarily responsible for capturing or recording these data; and (ii) patients decide how to share or distribute these data to health care providers and others. Examples include blood glucose monitoring or blood pressure readings using home health equipment, or exercise and diet tracking using a mobile app or wearable device" (12). The definition relates to addressing 'a health concern'. Health was defined by the World Health Organization in 1948 as "A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (13). The New European Policy for Health—Health 2020—states that "Well-being includes physical, cognitive and social and emotional dimensions and is influenced by biomedical, social, economic and environmental factors across the life course" (14). With an increasing focus on wellness, individuals may also collect data not necessarily intended for clinical use, leading to the creation of an alternate term—'Person Generated Health Data'—not everyone need be a patient at any given point in time (15).

Patient

Patient is defined as "a person receiving or registered to receive medical treatment" (16).'Patient' generated health data is appropriate when health data are gathered as part of the process of their medical treatment and 'person' generated health data when a healthy person manages their well-being or a patient gathers health data not related to their illness or condition. In this chapter, the terms patient-generated

health data and person-generated health data are used collectively, and abbreviated as PGHD, and refers to electronic data (ePGHD) (15) unless otherwise stated.

Data and information

There is a distinction between data and information. Data are the facts or details from which information is derived. The digital data derived from a sensor needs to be converted into information. These two words may be used incorrectly; for example, data generated on a smartphone may have already been converted into information before it is transmitted to a server for monitoring or further analysis.

Self-tracking

Self-tracking is another term that has been used to describe serially acquiring health data. It "involves practices in which people knowingly and purposively collect information about themselves, which they then review and consider applying to their lives" (17).

Patient-reported outcomes

Patient-reported outcomes are health outcomes directly reported by the patient, who experienced it (18). It stands in contrast to an outcome reported by someone else, such as a physician-reported outcome, a nurse-reported outcome, and so on.

Observations of daily living

These are the patterns and realities of daily life that until recently have not been considered to be part of one's health record, such as diet, physical activity, quality and quantity of sleep, pain episodes and mood (19).

Remote patient monitoring

Remote patient monitoring is "a coordinated system that uses one or more home-based or mobile monitoring devices that transmit vital sign data or information on activities of daily living that are subsequently reviewed by a healthcare professional." (20). As smartphones are a common source of PGHD this constitutes mHealth, defined by the World Health Organization as "medical and public health practice supported by mobile devices, such as mobile phones, patient-monitoring devices, personal digital assistants (PDAs), and other wireless devices" (21). mHealth is dependent on software applications (apps) to organize, analyze and transmit data that is entered either manually or obtained digitally from sensors or medical devices.

mHealth 'apps'

A piece of software that can be installed and run on a computer, tablet, smartphone or other electronic devices. Apps are divided into two categories for regulatory purposes based on function and associated risk. Those apps that work on

generic consumer 'off the shelf' devices such as smartphones or tablet computers are termed software as 'a medical device' and are defined as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.". An example being a digital diet logbook. The second is software 'in a medical device': both the software and the hardware required for the device to operate. This category of app is regulated as a medical device (22).

Smart device

Smart device is an electronic device, physically or wirelessly connected to other devices or networks (e.g., Bluetooth) that can operate to some extent interactively and autonomously to collect and transmit specified data. They include smartphones, smartwatches, tablets, pacemakers, wearable sensors intended to monitor physiological parameters, and even smart refrigerators (23).

A PROPOSED PGHD PROCESS MODEL

There is no formal classification of PGHD. Self-tracking of health data has been categorized in terms of purpose (self-use, behavior change, clinical use, and research), management of a condition (diabetes, hypertension); data type (physiological, behavioral, environmental), mode of data capture (using sensors, external devices, implanted devices, patient portals, online surveys and manual entry), and whether the process is active, passive or mixed. A classification for the legal and ethical issues related to selfie telemedicine has been proposed (24). This was based on the interaction between the health professional, the patient, the insurer, and direct to consumer websites and described in terms of either 'doctor-initiated' or 'patient-initiated' selfie telemedicine. This approach can be adapted to PGHD data in general to describe the process and use of digital patient-generated health data, taking into consideration the flow, purpose, and use of the data (Figure 1).

The *purpose* will be either for the benefit of a clinician (e.g., patient management) or the person themselves (e.g., behavior change). When PGHD are *captured, recorded, or collected* at the request of a clinician or an insurer, it can be termed 'Clinician Initiated', and when done so for personal use it can be termed 'Person Initiated' and if sent to a clinician, 'Patient Initiated'.

In terms of *flow* of the process, when Clinician Initiated, the patient collects, records, or creates the 'data' (*data acquisition*), which is sent electronically (*transmission*) for retention on another app, device, or server (*storage*) for immediate or subsequent examination (*analysis*). After analysis, some response must be given (*feedback*) and acted upon (*action*) by healthcare providers based on the findings. This cyclic process is depicted by the broad, solid arrows around the perimeter in Figure 1.

When Person Initiated, as seen to the right of Figure 1 (broad dashed arrows), the individual may also independently acquire health-related data. Although acquired for a different purpose, these data then proceed through the same cycle (broad solid arrows) and may require some action by the individual. Of note is that

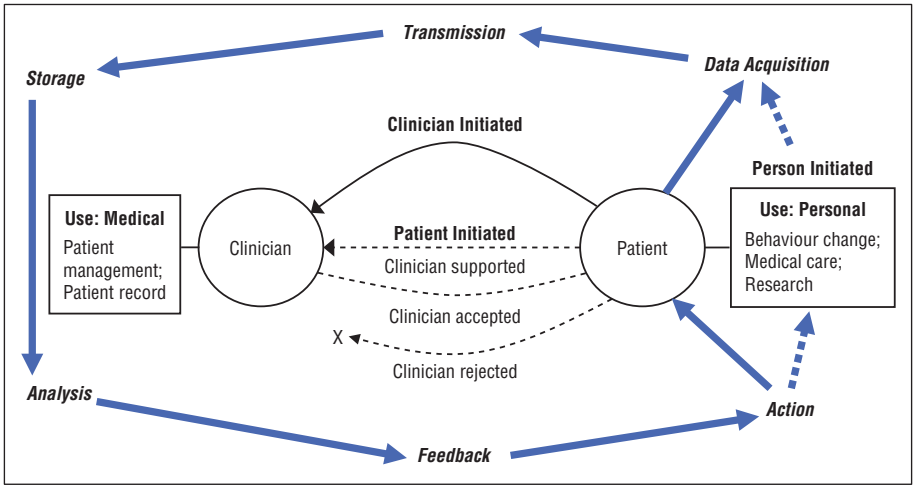

Figure 1. The purpose, flow, and use of electronic PGHD.

these PGHD may subsequently transition to use for medical care at some point in time (Patient Initiated). Regardless, the patient is at the heart of the process.

With regard to *Use*, PGHD is most commonly initiated for personal use, e.g., for their own well-being, behavior change, or self-education and understanding. The individual may even take on responsibility for analysis, providing self-feedback, and taking what they perceive to be appropriate actions. They may also elect to share that data with their doctor if they feel it is of relevance, or enter it in their personal health record, patient portal, quantified self-site, social media site(s), store it for self-use or submit it to an online service provider.

When Clinician Initiated, the primary *Use* will be for the ongoing medical care of the patient, prompting consideration of changes in management if necessary. Furthermore, the relevant findings, decisions and appropriate data will need to be entered into the patient's medical record, be it paper or electronic. In addition, depending on the circumstances and with the patient's consent, the PGHD can be added to existing data registries for further analysis of large data sets. The clinician may also have to deal with unsolicited self-tracking data provided by a patient (or person). They can respond in one of three ways: acknowledge and accept the data and provide any necessary ongoing support; accept the data solely for noting in the patient's medical record, or reject receipt of the data and provide neither support nor feedback leading to patient dissatisfaction (narrow dashed lines between the Clinician and Person in Figure 1) (5).

There are nuances. For Clinician Initiated PGHD, the healthcare provider has several roles: advising the patient to gather the data and providing advice on what device or application to use, how and when to use it, and how to return the data for analysis and feedback. Also, the data may be sent directly to the clinician or go through an intermediary, as in a monitoring service. The monitoring service may generate alerts or alarms when data are outside of a set range, and they may even interact with the patient before escalating the problem to the clinician. Similarly, this may occur in Person Initiated PGHD use, when an application with alerts

advises the person to send the data to their doctor or take some other form of action themselves.

DETAILED DESCRIPTION OF THE 'PGHD MODEL'

The general steps of PGHD creation are data acquisition and storage, its transmission, analysis, the provision of feedback, resulting in action taken (Figure 1). This starts the next cycle of data capture. The process differs slightly depending on the methods used and the purpose.

Why do people generate health data?

Whether person or clinician-initiated, personal health data are generated to derive benefit, real or perceived, from its acquisition and use. People may self-track their data for personal use, such as keeping check on their heart rate after exercise, the number of cigarettes they smoked, monitoring fertility or the frequency of a certain symptom. They may act on the data or ignore it, or they may post the data to social media sites and consider the responses they receive. Some data gathered for personal use may also be shared with their health professional if considered relevant.

In contrast, clinician-initiated PGHD is requested to monitor a pre-existing condition or response to treatment, guide clinical management of an illness or other health condition or as a form of surveillance of potential associated clinical problems. The data can be used for assessing or improving wellness, behavior change, monitoring specific measurable parameters (blood pressure, blood glucose, oxygen saturation, mental health), managing a specific disease or condition (diabetes, congestive heart failure, hypertension), educating people in self-management of their condition, or for research (25). When used for clinical care, the health professional gains insight into what is occurring between routine consultations.

Again, whether person, patient, or clinician-initiated, motivation is an important aspect of adopting and continuing to use self-tracking. The motivation for self-tracking for personal use includes self-healing, self-discipline, self-association, self-entertainment and self-design (26), and the gratification of controlling one's health status (27). Goal setting, such as increasing steps taken, or weight loss is also a motivator. Self-tracking adoption may be linked to personal technology adoption patterns (28). When clinician-initiated, patient motivation to use a patient portal is self-determined, but also influenced by external factors (satisfaction with the technologies usability; lack of some desired feature) (29). This is reminiscent of traditional technology adoption research using Technology Acceptance Models (TAM) and the Unified Theory of Acceptance and Use of Technology (UTAUT) (30).

Data acquisition

The data can be broadly classified into physiological, environmental, mood and social interaction. It may be biometric, or related to behavioral response, environmental setting, mental health status, symptoms, care goals, patient experiences, photographs, video, social interaction, medication adherence, adverse reactions,

and quality of life (25, 31). The nature of the data influences the ways in which it can be obtained which may be active, passive, or a combination (32).

Active patient participation usually involves having to manually enter data or information, e.g., when keeping a log or completing a questionnaire, and/or actively transmitting these data for storage and analysis. They may have to use and interact with an external smart device such as a peak flow meter, glucometer, smartphone, or a camera to generate the electronic data. These data are 'patient-generated' in that the patient has actively participated in the collection and recording of the data.

Passive data collection usually involves sensors that are connected to a computer, tablet, smartphone app, smartwatch, and may be worn, embedded, or placed within the residential setting. The data are collected continuously or at fixed intervals and automatically stored and / or transmitted. The patient's role is limited to wearing, carrying, or activating the smart device and ensuring that the criteria for data upload from the sensor to the linked device are met. These data are 'patient-generated' in that the patient has agreed to and facilitated the process. In some instances, the process can be a combination. For example, passively acquired data may have to be actively transmitted or forwarded on for analysis by the patient.

Biometric data are usually physiological parameters such as heart rate, oxygen saturation, or weight. Behavioral data may be steps taken per day, units of alcohol consumed, or monitoring of tooth brushing techniques when wearing dental braces. Mental health surveys can be completed on a regular basis as part of surveillance, treatment monitoring or at a specific time after an event as part of research into the effects of the event. Medication adherence can be linked to 'selfie videos' of drug ingestion or electronic records generated when opening and using automated pill dispensers (25). Patients may indirectly generate data from fall sensors or movement sensors placed in their homes, and during the COVID-19 pandemic people have been generating data related to proximity and interaction with other people through their mobile phones.

Wearable smart devices (including smartphones, fitness trackers, ECG monitors, blood pressure monitors) can contain a variety of inbuilt sensors (e.g., accelerometers, global positioning systems (GPS), gyroscopes, magnetometers, pressure sensors, ambient light sensors, microphones, and cameras with high-quality image sensors (33). The data acquired can be relevant to many medical fields (25, 31). Examples of clinically useful data collected by these sensors are equally diverse, and include skin lesion images, audiology testing, voice assessment of stress, heart rate, heart rate variability, ECGs, respiratory rate, spirometry, pulse oximetry, activity, falls, posture analysis and joint position.

The combinations and permutations regarding the spectrum of data acquired, the reasons for gathering it, and the situations in which it is gathered, are numerous. Regardless, to be of clinical use and to be used safely and with confidence, the data obtained must be of suitable quality and quantity.

Transmission and storage

Following acquisition, the PGHD must be transmitted and/or stored. These are considered together because, although moot, data may be stored on a device—even if only for microseconds—before transmission, and certainly in servers or

other devices after transmission. The most basic mode of electronic data transmission is when the patient physically takes the data to their healthcare provider e.g., showing a digital photograph of a skin lesion stored on their phone, sharing data on wellness or a log of symptoms. Alternatively, patients may transmit data by email, or text message to their healthcare provider, but most data transmission is either from the source device to a software application on a smartphone, tablet, or computer, or by wireless connection to an intermediary server. This may be the server of a health monitoring service or a server of a device or application vendor. It may also be sent directly to the healthcare provider.

A number of smart devices used to initially capture the data have been designed or adapted to acquire and send it to computers, laptops, tablets or smartphones (34). Some require a physical cable connection, but most facilitate transmission via Bluetooth, or are an integral part of smartphones and communicate with a relevant mobile application. Current smartphones are sophisticated communication tools that not only have the computing power to run software applications and process data, but also the ability to connect to cellular networks or the Internet to facilitate data transmission. In addition, they have significant storage capacity with PGHD stored locally on either the smartphone itself, the device to which it is attached, or transmitted from the device or smartphone to a server elsewhere before data review and analysis. Data storage, in this instance, does not refer to healthcare professionals storing or keeping records of the data.

Analysis

For a benefit to be obtained, the data must be analyzed. This can be done electronically by software or by the health provider, the patient, or others. Similar to storage, data may be analyzed in any of multiple locations: within the associated software in the smartphone app, smart device, or another device to which it is linked; by software on the app vendor's server; by software or people in intermediary monitoring services; the health professional, the patient, or by people on social media groups and patient registries. Ideally, the PGHD should not be analyzed in isolation, but in consideration with existing clinical data available on the patient, for example, stored in e-records of one type or another (e.g., electronic medical records, electronic health records, personal health records, mobile personal health records). Although desirable, this raises issues in relation to ensuring PGHD is incorporated into such e-records, which is not straightforward (35, 36).

Feedback

Feedback comes in several forms. Software may automatically provide alerts warning the user that a parameter is outside of a set range or to remind the user to undertake some activity (exercise, medication, rest). Alternatively, the healthcare provider may be alerted and contact the patient if concerned about the data or when the patient attends the next consultation. Feedback serves the obvious purposes of warning when there is something abnormal, or there is a negative trend in the data, but also providing reassurance when all is normal. The healthcare professional can adjust the care program to improve the management and

control of a condition being monitored. When done in concert with the patient and using PGHD, this is now termed personalized care (37). The patient may determine their own feedback based on their understanding of the data, or others may provide feedback from social media or other portals.

Action

There is an expectation that the feedback will lead to action (38) with resultant change in health or wellness. Patient's acceptance of the feedback and whether they implement change is a function of the confidence they have in the advice given, any difficulty in changing, and their interpretation of the need to effect change.

BENEFITS OF PGHD

Research on the impact and benefits of PGHD is nascent. The potential for PGHD to enhance care delivery and outcomes has been cited (39), but there is little empirical evidence to support this.

Access to PGHD and patient reported outcomes (PRO) is suggested to change the communication process, and patient-clinician relationship, with several primary effects identified (4). Use of PGHD and PRO during clinical visits may promote patient health awareness, improve patient-clinician communication, and support clinician activities, but how to use them is unclear. Furthermore, PGHD platform design impacted patient-clinician collaboration. Patients with chronic disease (diabetes, hypertension) are more likely to collect PGHD, and merely collecting PGHD changed their attitude to health maintenance (40).

In examining PGHD in the context of parents and newborns with feeding issues, it was felt that PGHD had potential as a valuable addition by providing temporal insight and context for incidents involving the newborns. Trade-offs in communication 'costs and benefits' were found, requiring greater effort by both parents and clinicians to engender a common understanding of the reported subjective experiences. Overall, it was stated the main finding was "… data collection and sharing is about a lot more than the data itself, …" (41). The timing of the use of PGHD during consultations altered their impact (42), with use early in consultation leading to patient collaboration (offering of new information) and use later in the consultation leading to patient corroboration and acceptance of proposed actions and treatments. Clinicians occasionally disregarded PGHD if it did not fit into their clinical assessment.

Implications of benefit are clear in several papers. These include closure of healthcare gaps and supporting personalized healthcare (43), positively impacting prevention-relevant outcomes (32), heightening of health information exchange (44), and improving the patient healthcare experience and promoting shared decision making (45). However, these were minor or incidental findings.

Strong evidence of the positive impact of PGHD is currently absent, with most studies being developmental or feasibility studies and reflecting an 'early adopter' stage of development (25). Focused research is required to gather clear evidence and examples of clinical or other substantive benefits of gathering and using PGHD.

CHALLENGES OF PGHD

There are many challenges to acquiring and using PGHD. These can be grouped in terms of people, technology, processes, legal, and regulatory issues. Several of these have already been described. The individual has to be motivated to gather the data and analyze it, and this requires time, effort and self-discipline (26). Many apps are downloaded and used only for a short while. The app may not meet expectations, it may not be user friendly or present the data in an easily understood format or it may not provide value for money. The doctor has to buy into the concept and use of PGHD with the associated burdens: the volume of data to be analyzed, some of it urgent; the cognitive demand; the labor costs of storing and managing the data; and increased consultation time discussing the additional data (46). The process may affect the doctor-patient relationship through misalignment of goals and expectations. The technology may be expensive, difficult to use and the resultant data difficult to interpret. Lack of adherence to existing standards for data format impedes the interoperability of devices and systems (5). This is of particular importance in the process of integrating PGHD or information into electronic medical or health records. Other challenges may be as mundane as being able to keep devices charged (47).

PGHD: LEGAL, REGULATORY, AND ETHICAL ISSUES

PGHD traverses several legal, regulatory, and ethical domains as it flows from acquisition to action. Relevant laws and regulations on health, privacy, data protection, telecommunications, and medical devices must be adhered to, as must medical ethics when the use of PGHD involves clinicians. The common legal and ethical issues relevant to PGHD are privacy, liability, jurisdiction, data storage and security, record keeping, mobile app and device regulation, licensure, autonomy, consent, the doctor-patient relationship, confidentiality, authentication, quality of care, quality of information, continuity of care and app prescription (24). PGHD-relevant aspects of some of these need to be explored. When using an app or medical device to produce PGHD for personal use how are *autonomy* "the right of a competent adult to make informed decisions about their own medical care" (48) and *consent*, the expression of autonomy addressed? A person decides to use a health app but have they been adequately informed of the benefits, possible risks and alternative options?

Consent

Consent is fundamental to many data protection acts, which require people to consent to having their data gathered, its subsequent use, and how *privacy* will be maintained through secure data storage. To conform with this, many health apps require the user to set permissions (consent) within the software related to how the data are to be used, the type of networks that can be used, access to the device's storage media, stored contact information, location, Bluetooth, cookies and in app purchases (49). This information is usually in the terms and conditions of use or a privacy statement, sections that over 90% (50) of people do not read, especially when the "I agree" button is on the same page as the link to the privacy statement.

In order to use an app, users have no choice but to accept the privacy statement and the terms and conditions, both of which are usually long and couched in user-unfriendly language. The site of health data storage is also important. Within the European Union health data must be stored in the E.U. When data are gathered from popular wellness apps used in many countries what is required for compliance? If data are stored locally on a mobile phone, what steps such as biometric identification and password protection has the owner taken to make their data secure (51)?

Liability

Liability in medicine refers to liability for damage inflicted to a patient by a health service provider. A doctor would be considered liable if they made a poor medical decision based on PGHD. If the doctor acted in good faith using inaccurate PGHD, would they be liable for any resultant damage? Are they required to verify the accuracy of data from health apps, devices, or patients? Is the patient liable in any way for having provided incorrect data? This would depend on whether they knowingly falsified the data or if they too acted in good faith and accepted the data as produced by the application or device. Does liability then reside with the vendor, or is there fine print in the terms and conditions absolving them of risk?

Quality of information

Quality of information has long been a concern in telemedicine as it impacts on quality of care. When patients are generating data for their personal use, it is assumed that the data are both valid and accurate (52). Much of the data derived from sensors is processed using proprietary algorithms and software. It is uncommon for mobile apps to undergo clinical trials or adequately powered field tests (53), and it is still uncommon for clinicians and end-users to be involved in app design.

Secondary use

Secondary use of PGHD is an emerging issue. There is an ethical imperative to put the vast amount of data and information being gathered to good use (54), but who owns patient data and information? In many jurisdictions, the doctor or health organization own the data in an EMR or EHR, as they own the infrastructure (55). Patients retain ownership when they enter personal information into an electronic patient health record, a health portal or keep it on their phone or device. Ownership of data on vendors' servers is dependent on the terms and conditions and privacy policy. Sale of de-identified health data from electronic records of providers, organizations and vendors is a growing industry (56). Further legal and ethical issues related to PGHD will arise as technology advances.

FUTURE

The development of international interoperability standards will facilitate device interoperability and the storage of PGDH in electronic records. Allied to

this will be international standards for medical devices with some consumer grade wearable brands evolving into approved software in medical devices providing 'medical grade' data, which will be prescribed for both prevention and treatment. The large quantity of data from devices used for different purposes, both personal and clinical, will be consolidated and assimilated into a patient dashboard, providing an overall picture of the patient's state of wellness and health. Combined with artificial intelligence, disease prediction and outcome of disease will be feasible. With growing volumes of data from many sources, PGHD will facilitate and form part of the investigation of Wild's concept of the 'exposome'—the effect of all environmental exposures throughout their life on a person's health (57).

CONCLUSION

Many forms of PGHD data are being created on a daily basis and the use of consumer grade wearable devices and smartphones continues to grow. Individuals and healthcare providers are becoming more and more comfortable with generating, sharing, and using the data. The International Medical Device Regulators Forum is working towards pre and post-market review processes for medical devices, personalized medical devices, and software as a medical device that will include pre-market evidence-based review and post-market surveillance. This should improve the quality, reliability and safety of PGHD. Identified challenges notwithstanding, a future can be visualized where individuals use embedded or worn sensors to passively transmit rich and contextualized data whose analysis serves to maintain or manage personal and population health.

Conflict of Interest: The authors declare no potential conflicts of interest with respect to research, authorship and/or publication of this manuscript.

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