Challenges and Opportunities with Governance of Personally Generated Health Data (PGHD)

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Extended abstract

With rising popularity of mobile health apps and wearable monitoring devices, patient-generated health data (PGHD) are now rapidly developing outside of clinical encounters (Deering, 2013; U.S. Department of Health and Human Services, 2016). PGHD are instead generated in many and varied settings, for instance when patients monitor their own activity or sleep patterns using wearable trackers (L'Amie, 2018), monitor and report their blood glucose levels with continuous glucose monitors (Brockman, 2019), use meditation and relaxation mobile apps with brain-wave sensing devices (Fowler, 2019), track pregnancy experiences (Harwell, 2019), or track infants' urination through "smart diapers" (Baca, 2019), to name just a few.

Healthcare leaders and policy analysts view such data as a vital resource for health system improvement and innovation and for patient engagement, but governing these data resources for patient care or research will be challenging, as PGHD are the least understood and regulated domains of digitalized personal health data (U.S. Department of Health and Human Services, 2018). Because patients themselves collect digitalized PGHD using mobile phones and "apps" provided by technology firms, often outside clinical encounters, these data fall outside of conventional health data regulation, such as HIPAA (U.S. Department of Health and Human Services, 2016, 2018). Instead PGHD are maintained primarily on the information technology (IT) infrastructure of vendors who provide the mobile apps and devices, and data are governed under the IT firm's own privacy policies and within the firm's intellectual property rights in data. Patients can view and may be able to download their data to devices they control, and they may be able share data with clinicians, thus replicating data in multiple locations. Once integrated into a clinician's HIT systems, governance of some PGHD falls under HIPAA regulations,

which may limit the degree to which personally identifiable health data can be exchanged or sold. However because the majority of PGHD are generated outside of HIPAA-regulated environments (which many health app users are unaware of), these data can be transferred, sold or used in ways that are beyond the control of the individuals, who are the subjects of those data, and in ways that may not be beneficial (or even harmful) to them (Tanner, 2016). For instance, there have been reported cases of police using Fitbit or Apple Health data in criminal investigations (Hauser, 2018; McMullan, 2018).

PGHD-generating devices and their data are not always compatible and a plethora of devices and mobile apps are in use. As a result, interoperability barriers to sharing PGHD with clinicians and researchers for health system and caregiving improvement are high. However, improving interoperability also poses a challenge to PGHD governance. For instance, if a user collects activity data using a Fitbit monitor and then shares that data with another mobile app vendor, PGHD governance shifts as well, reducing the person's (and Fitbit's) knowledge of and ability to monitor uses of these data (e.g., Hodgkins, 2019). Such data sharing among technology firms is common, as leading platforms (such as the Apple HealthKit) can ingest data from many devices. Such IT firms also accumulate other forms of Internet and activity data that are (or can be) personally identifiable, e.g., Internet searches for medical information, communication via email or messaging, financial transactions, online purchases, and detailed location data. With advances in big data processing and analytics, linking and then identifying data across platforms and data sets become increasingly likely and lucrative. For instance, activity monitoring data can be linked to sales and financial data to micro-target advertising to potential consumers.

More worrisome is the prospect of using these data to develop proxies for health-related behaviors or conditions, which can then be used as a basis for health-related discrimination. For instance, correlations have been drawn between online shopping and heart disease. It is easy to imagine more plausible proxies such as an individual's weight, food intake, and activity level generated by diet and activity trackers being developed to predict an individual's health. Further, anonymized data may be reidentified, revealing sensitive health information (Aswani & Fukuoka, 2019). In the U.S., insurers

cannot (at present) withhold health insurance based on pre-existing conditions, but such indirect proxies could be used in future to refuse health care insurance or services, or to discriminate in hiring, financial lending, life insurance, and other economic activities (Carver, 2018) based on a health condition. Laws such as the American with Disabilities Act and the Genetic Information Nondiscrimination Act (GINA) place restrictions on how such data are used, but these laws were not designed to address the complexity of PGHD and the related big data health ecosystem.

Who has the rights to use, reuse, or even sell PGHD is not clear. IT firms such as Apple and Fitbit are increasingly striking arrangements with insurers and employers, as part of wellness initiatives sanctioned by the Affordable Care Act (ACA) (Muoio, 2019). While employers are generally prohibited from viewing an employee's personal health data without their authorization, except where laws require it (U.S. Department of Health and Human Services, 2017), it is unclear whether the health-related behavioral data generated by these devices will be (or are being) shared with employers in ways that can easily (re)identify employees, so as to track their behaviors and potentially to sanction them for failing to meet program-specified target and goals. For example, ACA wellness programs allow diverting funds to employee wellness programs. Some firms already economically coerce employees to participate in biometric screenings; the prospect of requiring employees to use PGHD-generating devices and to meet prescribed goals such as weight loss or activity levels is not farfetched (Chen, 2019).

There are of course potential benefits of using PGHD to "nudge" individuals (consumers, employees, insurance subscribers) towards healthy behaviors, although there is as yet very limited data on the efficacy of these approaches (Finkelstein, 2016; Gremaud, 2018). However, relying on PGHD in such circumstances is problematic for a host of technical, social, and ethical reasons. PGHD-generating technologies are advancing rapidly, but nonetheless most devices are not completely accurate or reliable and thus provide data with questionable quality. Such data may be useful to an individual for addressing his or her own healthy behaviors in their own ways, but inaccurate data should not be used to determine economic sanctions. Moreover, the quality of data and thus data interpretation depend on contextual

circumstances, which in turn depend on how individuals are able to integrate devices into their daily activities and on their capabilities to manage these devices. Difficulties using mobile health apps and wearables might, for instance, be indicative of socioeconomic class, native language, education level, and generally other social determinants of health.

How should (and could) PGHD be governed, by whom and for what purposes? Data governance literature generally refers to management of an organization's data and is viewed as the responsibility of the organization that generates the data through IT systems (Data Governance Institute, nd, para. 2). A plethora of practitioner literature specifies and advocates data governance practices within organizations, such as steering committees or policy-setting boards to formulate policies, standards, accountabilities, and enforcement methods (Weill & Ross, 2004). Such organizational structures are a starting point for formulating organizational-level governance of PGHD, but conventional approaches are unlikely to be sufficient to address the tensions arising between PGHD economic value in commercial activities and ethical, socially valuable uses of PGHD. Similarly, privacy legislation such as HIPAA and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) have limited the flow of protected PHI data (Lane & Schur, 2010), but since much PGHD fall outside of these regulatory domains, significantly different regulatory structures will be needed. In the European Union, the general data protection regulation (GDPR) specifies how firms must deal with personally identified data overall, but whether these regulations will suffice to direct IT firms regarding PGHD remains to be seen.

Research is needed to advance understanding of ethically responsible and economically viable governance of PGHD and to inform regulatory policy making as well as the design and specification of PGHD-generating apps and devices. As a starting point, we highlight the following areas in a research stream focused on governance of PGHD:

- Systematic review of the privacy policies of PGHD-generating vendors to establish a baseline understanding of current data governance policy and to identify gaps and conflicts in the values and interests of various stakeholder groups (e.g., employers, insurers, consumers, IT firms).

- Focused investigations of the data sharing and other arrangements between IT vendors of PDHG mobile devices/apps and other health sector actors, including employers (for wellness programs) and insurers for incentive programs (see Ingraham, 2018).

- Investigations of the integration of PGHD into electronic health record systems (EHRs) and implications for provider practices and patient-provider interactions.

- Studies of the efficacy and use of PGHD-generating mobile devices and applications in daily-practices, with particular focus on their uses in socially disadvantaged populations.

- Consideration of definitions of protected data to explicitly address PGHD by regulatory agencies and institutions participating in self-regulatory regimes (Montgomery, Chester & Kopp, 2018).

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