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Patient-Led Data Sharing — A New Paradigm for Electronic Health Data

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William Gordon, MD, MBI, Aneesh Chopra, MPP & Adam Landman, MD, MS, MIS, MHS

Partners Personalized Medicine
CareJourney
Brigham & Women's Hospital

As electronic health records (EHRs) have moved from paper to computers over the past decade — nearly 90% of office-based physicians now have an EHR — "Can't you just look it up on the computer?" has become an increasing refrain from patients expecting their medical history to be at their physician's digital fingertips. For integrated health care systems with robust electronic health records, access to information is profound. Providers can read notes, interpret labs, view imaging and beyond, all from a screen, instantaneously.

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Across disparate institutions, however, the story is very different. Substantial effort has been made to achieve interoperability between organizations, such as through regional health information exchanges,

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among others, with meaningful results. Yet such efforts have assumed institutions at the center of interoperability. What if we empowered patients to be digital stewards of their health data — allowing them to cut across their myriad physician office visits, home health encounters, and increasingly retail services such as flu shots or blood pressure readings?

Under the Health Insurance Portability and Accountability Act (HIPAA), there is little ambiguity as to whether patients have the right to access their health information. The Privacy Rule requires that HIPAA-covered entities give individuals access to their data, upon request, with some exceptions such as psychotherapy notes. Before wide-scale adoption of EHRs, this usually entailed paper records, in-person requests to hospital health information management offices, and a fee. The increasing digitization of clinical records has improved access to some clinical data, through patient portals and initiatives such as OpenNotes. This has been motivated in part by regulatory incentives.

For example, the Center of Medicare and Medicaid Services (CMS) "Meaningful Use" program (recently rebranded "Promoting Interoperability") has required progressively more electronic access to clinical data for patients — from electronic copies of data and discharge summaries (stage 1); to the ability to view, download, or transmit this information to a third party (stage 2); to the third and current stage, which requires patients have the ability to connect third-party applications to their medical records through Application Programming Interface (API) technology, a mechanism for software applications to communicate directly with EHRs. The 21st Century Cures Act accelerates this even further, defining interoperability ("access to a patient's data . . . without special effort") and spelling out an API requirement for the certification of EHRs.

In the context of this increased regulatory pressure, there has been a flurry of recent activity accelerating patient access to their electronic health data. In February 2017, the

Health Level Seven (HL7) International Argonaut Project, a standards acceleration effort involving the major EHR vendors, released an industry-developed open API built on the HL7's Fast Healthcare Interoperability Resources (FHIR) standard to be made freely available to any application developer or EHR vendor. In January 2018, Apple announced an update to their Health app that would enable consumers to directly retrieve medical data from the EHRs of participating providers that adopted that standard through consumer-facing APIs. This was followed by a June announcement of a forthcoming Apple Health Records API, which would enable a third-party ecosystem of consumer-facing applications to be built using these data in Apple iOS products.

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In March, the U.S. Department of Veterans Administration, along with a consortium of providers and vendors, signed the Open API pledge to expand the set of data resources available to patients, physicians, and care teams through APIs standardized by the HL7 Argonaut Project. In a March speech at the Health Information and Management Systems Society (HIMSS) conference, Seema Verma, Administrator of CMS, stated: "CMS believes the future of health care depends on the development of open APIs." She also announced several new initiatives designed to empower patients to gain access to their health data. Particularly exciting is that these efforts dock into the very same HL7 FHIR Argonaut Project, among other standards-based efforts. Finally, in an August event at the White House, Amazon, Google, IBM, Microsoft, Oracle, and Salesforce all pledged to further reduce interoperability barriers. While details are scant, this is yet more evidence of the industry's convergence toward an open health care API standard.

Building a Sustainable Ecosystem of Safe, Patient-Driven Digital Health Care

We view increased patient access to clinical data as a positive direction, with numerous benefits. First, better access to data can help increase patient engagement — early evidence from the OpenNotes initiative, for example, suggests that providing patients with visit notes increases health understanding, relationships with providers, adherence, and self-care. A second benefit to increased access to data is around record portability. Patients would not have to rely on two doctor's offices to exchange information — they could more easily bring this clinical information themselves when seeking care, reducing friction.

A third benefit is around enabling a patient-facing app ecosystem with the ability to exchange health information with EHRs. One of the first applications to use the Apple Health Records API, for example, is Medisafe, a company that enables patients to better manage their medications. Another example is an app that might notify family members when a patient is admitted to a hospital. A final use case is research participation. Patients could directly contribute their EHR data to research efforts. Sync for Science, a pilot program within the national "All of Us" research effort, is just one example of this.

Selected Advantages of Improved Patient Electronic Access to Clinical Data

Category	Description
Patient engagement	Enabling access to clinical data could increase patient engagement with their care.
Record portability	Accessing digital health records would allow patients a comprehensive, organized, and centralized view of their health care, which would reduce barriers when seeking new providers.
3rd-party applications	Patients could share their data automatically with 3rd-party digital health applications for various purposes – for example, symptom monitoring or patient-reported outcome measures.
Research participation	Patients could voluntarily share their clinical data with research programs. For example, Sync for Science uses APIs to facilitate data sharing for the All of Us research program.

Source: The authors.

Click To Enlarge.

Despite the recent public and private focus on this area, other areas will need further development to make patient-led data sharing successful and sustainable. First, the amount of data available to patients electronically will need to expand. The Office of the National Coordinator for Health IT (ONC) provides certification criteria for EHRs, which includes specific data requirements for APIs. The ONC 2015 Certification Criteria, for example, includes a definition of the Common Clinical Data Set (CCDS). The CCDS includes a total of 21 data fields for frequently used clinical data, such as demographics, medication lists, problem lists, and laboratory results. There are notable gaps, however. Not included in this data set are provider notes and imaging, which are absolutely essential for patient record portability. Also not required are appointment information and cost and payment data, important for patient engagement with a provider organization.

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Recognizing the need to expand the baseline data requirement, the U.S. Core Data for Interoperability Task Force (part of the Health Information Technology Advisory Committee, established by the 21st Century Cures Act) has issued draft documentation outlining a mechanism for expanding U.S. Core Data for Interoperability beyond the CCDS — with an initial step to add clinical notes and provenance to the CCDS. A roadmap for numerous candidate data elements is also included in this draft documentation for items such as admission/discharge dates, functional status, care team members, encounter information, and imaging interpretations.

Anticipating these requirements, the HL7 Argonaut Project has picked up the hard work of mapping some of these data elements to FHIR, but it would benefit from greater industry demand for such standardization. That said, we anticipate that over the next 5 years, the amount of data made available to patients through EHR APIs will significantly expand.

A second area that will need further development is patient privacy. Provider organizations as data gatekeepers is a well understood paradigm, with carefully specified laws and regulations, like HIPAA. Moving data out of these organizations and directly into the digital hands of patients challenges this paradigm. The HIPAA privacy rule, for example, applies to narrowly defined covered entities, and does not include consumer applications, social media, fitness trackers, etc., nor health data as a class of data.

Will patients understand that when they authorize electronic data release of their EHR data to a third-party application, the provider organization no longer has any ability to monitor, audit, or secure that data? Health applications have inconsistent (and often

missing) privacy policies, and while carefully crafted consent language may minimize provider liability, it does little to get at the underlying issues: that individuals often do not read consent documentation, and that simple transparency — e.g., exposing a privacy policy to an individual — is not sufficient privacy protection. It is perhaps time to rethink the regulation of health data to better reflect the usage of clinical data in the context of emerging technologies like APIs, akin to a fiduciary standard for health information.

> *These new marketplaces will need close, multi-stakeholder input to ensure revenue incentives do not lead to stifled innovation and information blocking."*

Third, while much of the acceleration of increased digital access to data has been motivated through regulation, continued incentives and/or a sustainable business model will be essential for long-term success. Major EHR vendors have already recognized the opportunity for revenue generation. For example, the Epic App Orchard and the Cerner App Gallery are nascent marketplaces for the purchasing of applications; similar to other app marketplaces (e.g., the Apple App Store or Google Play Store), the vendors receive a percentage of revenue generated from the purchase of software from their stores.

Additional digital health innovation platforms and marketplaces may emerge from outside the traditional health care information technology ecosystem. As mentioned above, Apple's recently announced Health Records API product may exert pressure on health care systems — in the form of more than 80 million U.S. iPhone users — to increasingly allow patient access to data. For a nominal developer account fee, third-party developers can build iOS apps and access patients' health information using the new Apple Health Records API. For patient-facing applications, Apple may be more cost effective and less restrictive than EHR vendor app stores. Application vetting — clinical content review, validation, and security audit — is yet another revenue generation opportunity.

These new marketplaces will need close, multi-stakeholder input to ensure revenue incentives do not lead to stifled innovation and information blocking. For example, the extent to which vendors or provider organizations should be allowed to charge for access to data beyond the minimum required set is unclear. There are also usability features — such as allowing an application "persistent" access to receive new EHR data automatically (without requiring that a patient log in every time) — that are at risk of being heavily monetized to the detriment of patients and application functionality. Further clarity from federal oversight organizations such as the ONC may be necessary to craft guardrails for vendors, provider organizations, and app developers.

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Finally, we note that while much of the initial focus has been providing patients with improved access to their health data, these same APIs could be repurposed to allow for more traditional data exchange between other entities, such as employers, payers, or accountable care organizations. These groups often have contractual rights to exchange patient data, but currently operate with significantly more friction than the "plug and play" functionality associated with API access. In fact, the 2019 Medicare Inpatient Prospective Payment System's proposed rule includes the development of a pilot program that would allow eligible hospitals to utilize APIs for population-level data exchange in exchange for credit under the Public Health and Clinical Data Exchange objective. In this model, APIs are the first point of interoperability and the main access point for electronic health data exchange between all stakeholders.

Ultimately, how this plays out — how costs and revenue are shared between vendors, hospitals, payers, software developers, and patients (while still meeting regulatory

requirements around data access); or how privacy regulations are modernized in the face of new technologies; or how open EHRs truly become around electronic patient data access — is yet to be fully realized. But the pieces are in place for a truly disruptive shift in how patients can access and use their own clinical data to improve their health, increase record portability, enable the use of novel third-party applications, and facilitate participation in research studies.

William Gordon, MD, MBI
Medical Director, Health Innovation Platform, Partners Personalized Medicine; Instructor of Medicine, Harvard Medical School; Associate Physician, Hospital Medicine Unit, Division of General Medicine and Primary Care, Brigham & Women's Hospital

Aneesh Chopra, MPP
President, CareJourney; Former Chief Technology Officer, United States (2009–2012)

Adam Landman, MD, MS, MIS, MHS
Chief Information Officer, Vice President of Information Systems, Brigham & Women's Hospital; Associate Professor of Emergency Medicine, Harvard Medical School; Emergency Medicine Physician, Brigham & Women's Hospital

Dennis Steed

This is absolutely what needs to be done.

It is interesting that the original definition of the medical home back in the 1960's, the medical home was the place that a patient's medical records were accumulated in common:

"For children with chronic diseases or disabling conditions, the lack of a complete record and a 'medical home' is a major deterrent to adequate health supervision. Wherever the child is cared for, the question should be asked, 'Where is the child's medical home?' and any pertinent information should be transmitted to that place"

We need data banks where people can manage their medical information just like we have financial banks for money.

November 28, 2018 at 10:38 am **REPLY**

Peter A. MacIsaac

REDCap 'SMART on FHIR' functionality supports the embedding of REDCap forms within the EMR user interface to support structured collection of data for research (extracting data from EMR) or for real time capture of additional data during the encounter to "enrich" what can be collected through the EMR interface. Could be also used for research or adding to the richness of structured data collection where such forms are not able to be implemented in the native EMR

November 28, 2018 at 3:39 pm **REPLY**

Stephen B. Strum, MD, FACP

I have been in medicine for more than 4 decades and jumped on to computer use at its earliest inception going back to the late 60's and early 70's with FORTRAN. In my clinical practice I routinely use the computer and all my patient's records are in digital format. The article by Gordon, Chopra and Landman is of extreme importance for a number of reasons but it also has some key areas of deficiency.

First, medical care in the USA and abroad has declined insofar as time spent by physicians with patients and the ability to deliver optimal care. My HemOnc practice is focused on prostate cancer and I see patients from around the world in consultation. I routinely receive and review their complete medical records. There has been overt abuse to the extent of fraud vis-à-vis the computer to copy and paste medical records & charge insurance and/or patient for the highest level of service. More often than not, 95% of the office visit has been "fudged" by this method. There is little evidence of cognitive work on the part of the so-called "examining" physician. In fact, less and less of the physical exam is done nowadays by physicians and more reliance on labs and imaging (i.e., testing rather than history).

Second, insofar as access of patients to medical records is concerned, there have been many patient portals that I have accessed, including my own, that are ridiculous in how they make digital records available. For example, my portal has each and every component of the CBC needing to be printed separately to get the CBC report. It is nothing like getting a one page PDF from a national lab like LabCorp or Quest but 20x as onerous. Third, getting office visits is not the case. The patient can get labs, imaging but not have access to consultations or office visits. Currently, I am a patient getting chemotherapy and I cannot get my weekly treatment info without requesting in real time a print out from the pharmacist.
Fourth, generating derivative data like graphs is available on some portals but not others. This is valuable info re TREND. Lastly, not having a simple icon to click on or keystroke to select to print to a digital format like PDF is absurd given computer technology. There is a lot more that could be said on this topic which is of extreme importance given that I believe the future will involve more patient-directed health care and less coming from the MD given the limitations of numbers of physicians and what has now become fast-food medicine.

December 13, 2018 at 11:59 am **REPLY**

Bob Flora

Medical records are a very sore point with me that I have battled with providers over. A patient should have immediate access to all his medical records. Yet some providers refuse to release records without the consent of the physician. How can someone claim ownership to MY records? Release of the records improves care. I once had the results of a test misrepresented to me. I would have loved to have seen the written results so that I had full and correct information in making decisions.

Another issue is privacy. The patient should be in complete control of who has access. I once picked up a refill prescription for a family member that was almost delayed due to potential interaction with two other drugs. The first was a one time administration and the second had been completed, so it was not an issue. What I could not find out was how the pharmacy knew about the first. No HIPAA release was signed. And then, why was the second prescription previously filled by the same pharmacy in light of the interacting drug, when the same potential interaction should have come up?

Patient access to and control of medical records is critical.

January 10, 2019 at 10:35 pm **REPLY**

Peter Leeflang - Global NAAION support group

It sounds like the socialized medicine players that put the patient out of control are in a panic that their data is really worthless unless the only important stakeholder, the patient, collaborates.
As a patient advocate and founder of several patient support groups I will advise against joining this type of pseudo-empowerment efforts. All it is meant for is for government to snoop into our private information to use it to ration our care. Not in our interest.
Our interest is to be fully liberated and to fully control our health care data and be able to cut out ANY player in the health care industry, be it insurer, government, pharma company, even doctor, when their access is not in our interest. Only those who offer a win/win to us patients should have access. Otherwise there will never be a win/win as there will be no incentive for providers to actually put our interests first. Instead they will cater to government's care rationers like they do now.
What our providers do not realize is that we ought to run the show, not them. They are paid by us and we are the customer whose fete they need to kiss to get our business. If it worked that way we would see competition for our assets, our health care data instead of the current entitlement attitude.
For example: Why would I provide data to a drug company that does not cater to my disease, or has it as a low priority (spending few funds) or shows poor research results. Instead I will only help those drug companies that have my disease(s) at the front of their pipeline, spend good amounts of money on it and show good results.
Our data is gold. It would save lots of businesses lots of time and money to get it, but it is not free. When something is free it only creates a lack of accountability and little or no progress in improving outcomes, so in the ultimate goal of any patient. Our interest is to move forward our outcomes not continue this situation of stagnation and rationing.

February 08, 2019 at 7:27 am **REPLY**