



Patients Gain Control of Personal Health Information With the 21st Century Cures Act and OpenNotes

By Susan Carr, Senior writer

Including patients as active members of the care team is central to efforts to improve diagnosis.¹⁻⁴ And to participate effectively, patients must have access to information and be able to contribute and give feedback based on their experience. They are uniquely able to report on things such as current symptoms, past history, and the effect of medications and therapies. Patients who have access to their medical records are in a favorable position to catch errors, keep track of follow-up testing and procedures, monitor treatment, inform their caregivers, and more.

Although widely accepted, this vision of informed and activated patients, empowered and enabled to quickly give and take information, has been slow to be realized. Patient portals—interfaces that allow patients to at least view their electronic health records (EHRs)—began to appear in the late 1990s,⁵ after the federal Health Insurance Portability and Accountability Act granted patients the right to “review and obtain” a copy their records.⁶ To meet requirements for “meaningful use” of EHRs for the 2009 HITECH Act, hospitals and physician practices had to provide patients with access via portals or digital records according to a schedule of deadlines in 2017.⁷

Although some health systems see large numbers of patients accessing electronic records, others do not, and sustained use of portal interfaces by patients has generally been disappointing.⁸⁻¹⁰ Furthermore, most patients who access their medical records online do so in a “look but don’t touch” environment, not allowed to comment or contribute.

After decades of incremental progress and isolated success stories, there are significant developments regarding patient access to medical records. Recent federal legislation, to be implemented over the next few years, will afford patients new opportunities to view, download and share their personal health information in secure, user-friendly formats.^{7,11} Concurrently the coronavirus pandemic is stimulating other changes. Across healthcare, innovation has accelerated, including advancements in connectivity and technology that may improve the patient’s ability to access and control their records.¹²

21st Century Cures Act

The U.S. 21st Century Cures Act, signed by President Barack Obama in December 2016, includes provisions that the Dept of Health and Human Services says “...will give patients unprecedented safe, secure access to their health data.”¹³ The Cures Act assures the patient’s right to timely access and easy download of all of their electronic health information free of charge. It also requires that health systems

and providers make that information available to a variety of apps that patients can download and use on their smartphones. The apps will be tested and certified by the federal Office of the National Coordinator for Health Information Technology (ONC) according to accepted standards used across the healthcare system.^{7,14} This will shift control of the digital interface from health systems—typically their EHR vendors—to the patient.

Donald Rucker, MD, head of the ONC, highlights this power shift, saying that one goal of the Cures Act is “...to give the patient **agency**. Rather than the patient being purely subject to whatever the large payors and providers have negotiated, this is a way to give patients the consumer power they have in the rest of their lives.”^{15(np)}

The ONC is responsible for establishing ground rules and implementing sections of the Cures Act that relate to interoperability, certification, transparency, and health information access. Following lengthy rulemaking, the ONC published the Final Rule on May 1, 2020.¹⁴ It will go into effect on April 5, 2021, with individual provisions rolling out through 2023.^{16,17}

OpenNotes Program

One approach to granting patients electronic access to their records has been especially successful. [OpenNotes](#) — a program for sharing notes with patients shortly after clinical visits — has grown from 20,000 patients in a pilot program of 3 organizations in 2010 to currently more than 40 million patients across the United States and Canada.⁵

Beth Israel Deaconess Medical Center (BIDMC) in Boston, an innovator in patient portal technology,¹⁸ developed the original OpenNotes program and participated in the pilot.⁵ Today OpenNotes is a non-profit organization based at BIDMC. With funding from the federal government and philanthropies including Gordon and Betty Moore Foundation and the Commonwealth Fund, it performs research and supports the interests of users and efforts to spread the program. OpenNotes refers to itself as a “movement,” reinforcing the message that patient access to personal health information is a right and an important part of patient empowerment.

The ONC’s Final Rule extends the functionality of OpenNotes to all patients. Eight types of notes, part of a national core data set,¹⁹ must be included in medical records available electronically to patients:

- Consultation notes
- Discharge summary notes
- History & physical
- Imaging narratives
- Laboratory report narratives
- Pathology report narratives
- Procedure notes
- Progress notes¹⁶

[OurNotes](#) is a new feature of OpenNotes that has been piloted in primary care practices across the country since 2015. With OurNotes, patients co-generate the clinical note by filling out a pre-visit form with their recent health information and questions.²⁰ Recently, the questionnaire was adapted at

Healthcare Associates (HCA), the primary care practice at BIDMC, to help solve a specific issue related to the COVID-19 pandemic.¹²

The problem and adaptation are described in [NEJM Catalyst](#)¹² by Gila Kriegel, MD, a primary care doctor at HCA. In early March 2020, COVID-19 restrictions caused many of her patient visits to shift from in-person appointments to telemedicine. Dr. Kriegel missed having the prework normally done by medical assistants for the in-person visits—interval history, medication lists, new problems and more. One of her patients, however, was enrolled in the OurNotes pilot and through that program submitted a pre-visit survey for a telemedicine appointment, which solved Dr. Kriegel’s prework problem.

Dr. Kriegel shared that learning with her colleagues at HCA and they quickly adapted the original pre-visit forms for telemedicine. The new form adds questions about medications and allows patients to record data, such as weight and blood pressure measurements, they may be monitoring with equipment at home, in addition to recent history and questions.

HCA physicians now use the new, more comprehensive form for all visits, whether performed in person, by telephone or video connection. The group will continue to improve the forms based on experience and feedback and have make them available on the [OurNotes webpage](#) for all to download and adapt for their own use.

Dave deBronkart (aka ePatient Dave), co-founder with his primary care physician, Danny Sands, MD, of the [Society for Participatory Medicine](#), used the new OurNotes form prior to a recent annual physical. DeBronkart, an early advocate of patient access to information and OpenNotes,²¹ has proactively provided pre-visit information for years. He reports in a blog post that the form made preparing for the visit easier by providing a structure for his information.²²

Dr. Kriegel and her coauthors are aware that the original, structured format may not be best for all patients. They intend to study structured vs unstructured questionnaires and may decide to offer patients a choice.

Work Lays Ahead

These promising developments, however, do not deliver the interactive, interoperable patient-controlled medical records that many advocates espouse. Adrian Gropper, MD, chief technology officer of [Patient Privacy Rights](#), points out limitations with the ONC implementation of the Cures Act. Although patients will decide which app they want to use to access their records and be able to share them with whomever they please, true interoperability is still not achieved:

The problem with these consumer apps is that very few doctors can or will access them in the normal course of events. The apps all present different and unfamiliar interfaces, are not accessible unless the patient is in the room and cannot easily transfer information into whatever EHR the clinician is using.^{23(np)}

Dr. Gropper advocates for a truly patient-controlled, longitudinal health record that everyone—patients, physicians, hospitals, clinics, family caregivers and more—can access and update, to ensure that everyone involved in the patient’s care is “on the same page.”^{23(np)}

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New Grants Focus on Interventions to Improve Diagnosis

[Research has demonstrated](#) that diagnostic errors are the most common, catastrophic and costly of all causes of preventable medical harm. Given the magnitude of diagnostic error burden, the Society to Improve Diagnosis in Medicine (SIDM) launched the DxQI Seed Grant Program, a competitive grant process to fund interventions to improve diagnosis. In September, 17 grantees were selected to receive awards of up to \$50,000. In January, SIDM will issue the second call for proposals.

The DxQI program is focused on a "bottom up" approach, where frontline health professionals and patients develop and test plausible solutions that have the potential for scale and spread.

"There are few proven, easily replicable, real-world solutions to improve diagnostic quality and safety," said Gerard M. Castro, PhD, MPH, PMP, director of quality improvement at SIDM. "Through the work of the DxQI grantees, we are learning about the tools and practices to integrate into the diagnostic process that help ensure that patients receive a diagnosis that is accurate, timely, and effectively communicated."

Most of the [grantees](#) selected in this first round are focused on developing interventions to reduce diagnostic errors in three specific disease categories: cancers, vascular events, and infections. Together, those categories account for [about half](#) of inaccurate or delayed diagnoses that result in serious harm or death, according to a study published in [Diagnosis](#). Several grantees are developing improvement projects that address racial and gender disparities in diagnosis.

Ultimately, the DxQI program will help clinicians, hospitals, and health systems take specific steps to reduce diagnostic errors and support an evidence base of effective interventions. These interventions will be added to a clearinghouse of interventions intended to catalyze adoption by healthcare organizations across the country.

Funding for the DxQI program is made possible with the support of the Gordon and Betty Moore Foundation.

The next grant application period opens in January 2021. Organizations can learn more at www.ImproveDiagnosis.org/dxqi/.

New National Action Plan Released to Advance Patient Safety

The National Steering Committee (NSC) for Patient Safety has released a National Action Plan intended to provide health systems with renewed momentum and clearer direction for eliminating preventable medical harm. [***Safer Together: A National Action Plan to Advance Patient Safety***](#) draws from evidence-based practices, widely known and effective interventions, exemplar case examples, and newer innovations.

The Action Plan calls on health systems to make improving patient safety an organizational priority by engaging “patients, families, and care partners in the co-production of care. Healthcare leaders and healthcare professionals need to fully engage with patients, families, and care partners in ongoing co-design and co-production of their care” and to involve “patients as equal partners in the diagnostic process and in decisions about their care using evidence-based patient decision aids and reporting tools for patient-reported outcomes.”

The NSC is made up of [27](#) influential federal agencies, safety organizations and experts, and patient and family advocates, first brought together in 2018 by the [Institute for Healthcare Improvement](#). Of these members, several Coalition to Improve Diagnosis in Medicine members were represented in the Steering Committee, including the Society to Improve Diagnosis in Medicine.

“The way in which diverse groups and patient advocates who are interested in patient safety came together to forge the National Action Plan is unprecedented, and it underscores the necessity to work together to create the safest health care possible,” said NSC Co-Chair Jeffrey Brady, MD, MPH, who directs the Center for Quality Improvement and Patient Safety at the U.S. Agency for Healthcare Research and Quality. “Over the past 20 years, the field has amassed a tremendous body of knowledge to improve healthcare safety. What’s been missing is the use of this knowledge for more coordinated action. That’s what we want to rectify.”

For more information on the National Action Plan to Advance Patient Safety, [click here](#).

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