Meaningful Use of Patient-Generated Data in EHRs

By William Van Doornik, MS, RHIA

There is growing interest within the healthcare payer community to promote patient engagement through various means, including the integration of patient-generated data into clinical care documentation and quality measures. This is evident in the suggestions for stage 3 "meaningful use" EHR Incentive Program requirements and in corresponding guides for increasing patient engagement. At the same time, there continues to be significant growth in healthcare applications designed for consumer mobile devices. Many of these applications allow individuals to collect, track, store, and transmit personal health information. This is creating new opportunities and challenges for care providers and HIM professionals as they develop policies for acknowledging and managing patient-generated data within their practices and facilities.

Patient engagement is one of the five goals of the federal government's meaningful use program. The Office of the National Coordinator for Health IT's (ONC) Health Information Technology Policy Committee (HITPC) published a request for comments regarding the stage 3 definition of meaningful use of electronic health records in November 2012. In this request, HITPC states that "The stage 3 vision includes a collaborative model of care with shared responsibility and accountability, building upon the previous MU objectives."[1] The committee goes on to recommend that stage 3 mark the beginning of a shift from a setting-specific focus to a collaborative patient- and family-centric approach. While many of the recommendations are, as expected, raising the thresholds on existing objectives, there are a number of new recommendations and specific questions around patient engagement.

Increasing Focus on Patient Engagement

The National eHealth Collaborative (NeHC), a public-private partnership established through a grant from ONC, promotes consumer engagement around the tools and resources available to consumers through advances in health information technology. As part of this effort, the NeHC recently published the final version of its Patient Engagement Framework and launched its Consumer eHealth Readiness Tool (CeRT)—an online tool to help health organizations track their progress on involving patients. The framework is a model to guide healthcare organizations in developing and strengthening their patient engagement strategies and is aligned with the meaningful use stages.

The excerpt from the framework shown in Figure 1 indicates the use of patient-generated data for the later meaningful use stages.[2] In the migration from stage 2 to stage 3, NeHC recommends moving from questionnaires, surveys, diaries, and assessments to specific reporting on care plan compliance and home monitoring device data. Accordingly, the HITPC included a new menu item in its stage 3 recommendations that would call for 10 percent of a provider's patients to have the ability to submit patient-generated health information to improve performance on high priority health conditions, and/or to improve patient engagement in care. In their questions and comments on this objective, the committee specifically asks what data patients and providers would consider most valuable to share and receive, and asks about the readiness of the standards to include data from home medical devices. In the Quality Measures section, under Patient Centeredness, the committee requests feedback on the suitability of patient-supplied information being incorporated into clinical quality measures for meaningful use and the use of patient-generated information for shared decision making.

Expanding Use of Patient-Facing Technologies

One growing source of patient-generated data is from an expanding array of eHealth tools that patients and their families are adopting to aid them in the management of their health. In his article "The Promise of and Potential for Patient-Facing Technologies to Enable Meaningful Use," Dr. David Ahern notes that technology resources have an influence on the way patients manage their health when they use it for such things as accessing healthcare services, communicating with providers, managing a chronic condition, or changing a behavior report. To meet current meaningful use requirements, provider EHRs now routinely extend some of this functionality to patients for online appointment scheduling, medication refills, and secure

messaging. Stage 3 meaningful use measures are likely to raise the required percentage of a provider's patients that use this type of communication.

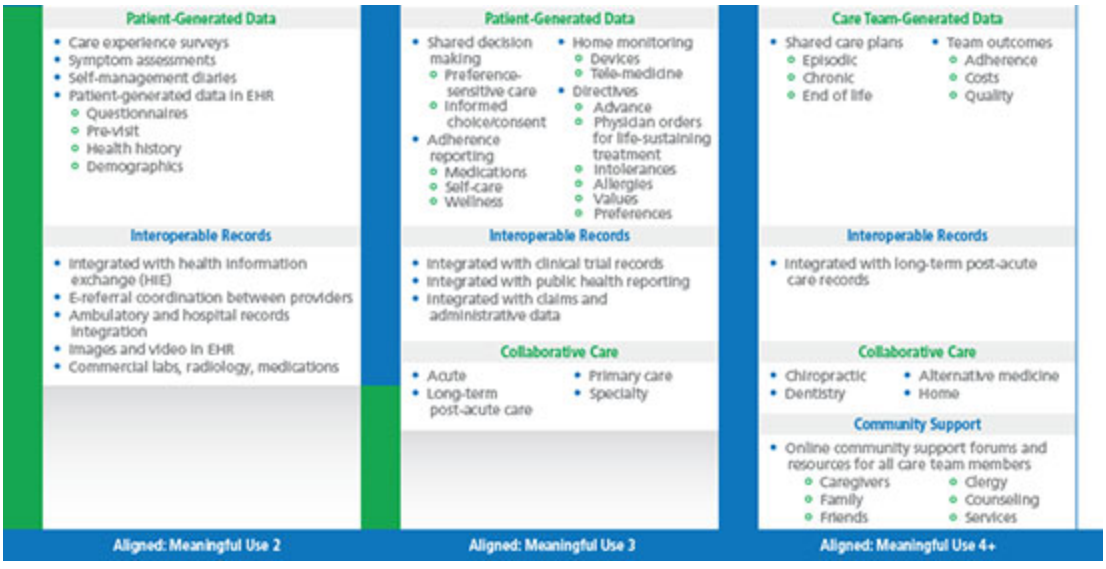
There also continues to be an increase in the use of remote monitoring devices for managing patients with chronic diseases such as chronic obstructive pulmonary disease, congestive heart failure, and diabetes. These telehealth devices are usually provided through a home health agency or other certified care provider who is also responsible for support of the devices and interpretation of the data. This type of technology has proved effective in improving the overall health status of patients with chronic diseases and reducing the incidence of emergency interventions. Medicare readmission penalties and payment incentives for coordinated care built into the accountable care organizations (ACOs) and patient-centered medical home programs will likely drive growth in the use of these devices.

A newer trend is patients using eHealth tools and services outside of those provided or prescribed by their care providers. Many patients use personal health records (PHRs) to manage their medical information and social media sites that provide health-related support communities (i.e., CarePages; PatientsLikeMe). More recently, however, the rapid growth in mobile technology like smartphones and tablets has given rise to an increasing number of patients using health-related applications on these devices. Many of these apps provide tools for behavior modification (i.e., weight loss, smoking cessation) or logging observations of daily living (i.e., sleep, diet, exercise, medication regimen), but newer apps and mobile device attachments now allow individuals to directly collect vital statistics like heart rate and blood pressure. Some of these apps purportedly conduct diagnostic tests such as ECGs, melanoma screening, and even blood tests, often with little or no verification of accuracy. The lack of oversight along with the rapid growth in the number and popularity of these apps is creating concern and calls for greater regulation by groups such as the US Food and Drug Administration (FDA).

In a hearing before the Senate's Health, Education, Labor and Pensions Committee on April 25, 2012, Senator Michael Benett noted that "Between 2010 and 2011 the number of medical apps available in the iTunes AppStore that could be subject to FDA evaluation under draft guidance increased by 250 percent. Estimates indicate that the number of smartphone users using medical apps will grow to 500 million by 2015."[3]

Figure 1: Excerpt from National eHealth Collaborative's Patient Engagement Framework

This chart shows the various patient engagement initiatives that are expected to be included in the later stages of the meaningful use program.



Source: NeHC. "Patient Engagement Framework."

Data Source Validation Essential

There are several factors to consider when assessing the validity of patient-generated data derived through technology. One is the intended use and reliability of the technology itself. For example, a smartphone with a built-in microphone and an application loaded on it might be able to function as a stethoscope or heart monitor. However, if the device or application is not intended for this purpose, this data would likely not be considered clinically reliable in the care of a patient.

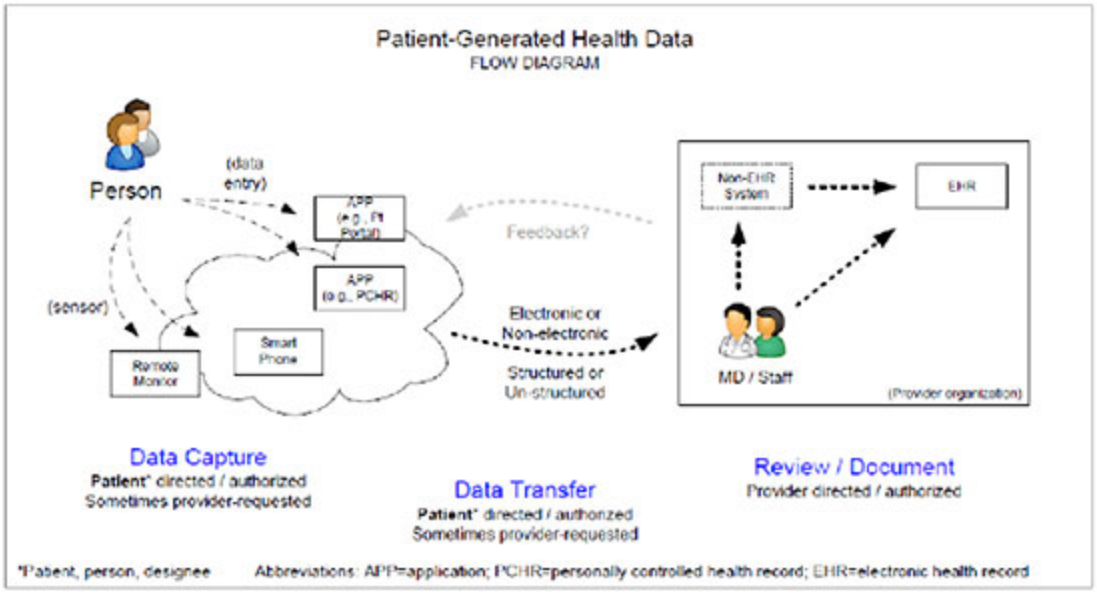
Due to this proliferation of health-related applications for mobile devices and the increasing complexity of their capabilities, the FDA published "Draft Guidance for Mobile Medical Applications" in July 2011. Over the course of the following year, the FDA received comments and suggestions on the draft document, along with solicited feedback from providers, manufacturers, and investment companies. On November 26, 2012, as part of the new FDA Safety and Innovation Act (FDASIA), the FDA included "Final Guidance for Mobile Medical Applications" as a "priority A" document. These are documents that the FDA, as of press time, planned to publish by October 1, 2013.

During their recent deliberations on the guidance, the FDA has reported that it is seeking to find the right balance between over-regulation and protecting the public health. In his comments at a September 12, 2011 FDA public workshop on the draft guidance, William Maisel, MD, MPH, deputy center director for science at the FDA Center for Devices, discussed how the FDA must balance its role. "We clearly at FDA believe we have an important role to play in both fostering innovation and encouraging the development of new applications that will help make healthcare delivery better," Maisel said. "We also have a responsibility to oversee the mobile medical applications that present risks to patients."[4] Maisel also noted that the FDA will not be regulating the sale of the actual smartphones or tablets that are capable of hosting health-related apps. The FDA's intention is to only regulate mobile medical applications that are used as an accessory to a medical device that is already regulated by the FDA (i.e., diagnostic reading of an image on a smartphone), Maisel noted, or those applications that transform a mobile device into a regulated medical device by using attachments, sensors, or other devices (i.e., attaching leads to a tablet for an ECG tracing). In recognizing the need for the FDA to limit its oversight scope, this obviously leaves a significant number of mobile health applications that it will not regulate.

The scope of proposed FDA oversight is understandably quite narrow, leaving thousands of health-related mobile applications with little, if any, independent oversight. Most of the major application distributors like Apple's Appstore, the Android Marketplace, and Blackberry's App World have a selection process as well as user reviews, but nothing that validates how well a device or application meets the unique demands of healthcare. Dermatologists at the University of Pittsburgh studied smartphone applications designed to help non-clinicians determine whether skin lesions are benign or malignant, and found a misdiagnosis rate of 30 percent or more with most apps tested.[5]

In an interview at the HIMSS 2012 mHealth Summit, Kate Berry, CEO of the National eHealth Collaborative, commented on the explosion of health-related mobile applications and the need for both patients and providers to have some level of trust in the applications that they use to manage their health.[6] In response to this rising demand, there have been some initiatives by healthcare providers and private industry to develop mobile application stores specifically designed for healthcare apps. These new stores provide a more granular classification of apps and have even introduced application certification and technical testing standards. Such efforts are needed and may help both patients and providers determine the validity and limitations of the data being generated with these tools.

Figure 2: Flowchart for Integrating Patient-Generated Health Data in the EHR



Source: Research Triangle Institute. "Patient Generated Health Data." April 2012.

Documentation of Patient-Generated Data

With the push for greater patient engagement through incentive programs and the tremendous growth in both numbers and potential of mobile health applications, the issue of how to manage patient-generated data will be a challenge for HIM professionals. In its meaningful use stage 3 Request for Comments, the HITPC acknowledges public concern about the integration of EHR-derived data with patient-generated data and questions the need to segregate the two. There are examples of data being incorporated into EHRs from devices implanted or worn by patients like blood glucose meters, halter monitors, data patches, and external transceivers. Often this data is downloaded into an intermediate system where the data is analyzed by a technician or care provider, who then determines a subset of the data that is clinically relevant and representative and imports this information into the EHR. Many home health organizations and physician offices import telehealth data—such as blood pressure, pulse oxygenation, and weight—electronically and directly from patients in their homes. Similarly this data may be imported from another system or fed in its entirety directly into the provider's EHR. In their April 2012 white paper on patient-generated health data for ONC's Office of Policy and Planning, the Research Triangle Institute diagrammed this patient-generated health data collection process (see Figure 2).[7]

When data is from a device that is regulated and provisioned by the healthcare provider, there is generally little concern about the data's veracity, use in diagnosis and treatment, and inclusion as part of the patient's designated record set in the EHR. Data from FDA-approved mobile health apps would logically become an extension of this record-keeping practice. Now, as healthcare providers independently endorse mobile apps for patient use, the resulting data should be treated in the same manner: validate and selectively incorporate the data into the EHR. In instances where information is provided by patients using their own personal mobile devices with unregulated apps, most healthcare providers will, at most, reference that data within their own documentation, noting its source and limitations.

If this data is taken into consideration in diagnosing or treating a patient, at a minimum, a summary or interpretation of the data should be documented by the healthcare provider in the medical record. If the data was not solicited by the care provider and not used in determining the care of the patient, it would not generally be incorporated into the EHR.

When it is determined that patient-generated data coming from an unverified source is to be incorporated into the EHR, the data should be tagged or segregated in the EHR in a manner that clearly designates it as such. This practice could indicate the unverified nature of the data and still accommodate the use of the data to promote the HITPC objective of shared decision making. This would also be in keeping with proposed Health Level 7 data header standards that would designate data as patient-generated and indicate the author as a person or device. However, additional data tagging may be necessary within the EHR to indicate the veracity of the author, such as, "Was the device and/or app regulated or otherwise prescribed by the care provider?"

The incorporation of patient-generated data into the EHR will also be necessary to satisfy HITPC's stage 3 recommendations for incorporating patient-reported data into future meaningful use clinical quality measures. However, to use patient-generated data in this capacity, it will need to be from standard, verified sources to obtain measures that are valid for comparison across time, providers, and patient populations. Additional standardization of the devices and apps used to collect and transmit such data will be needed to accomplish this objective.

Notes

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