Precision Requires FHIR

By Barry P. Chaiken, MD, MPH

On January 20, 2016, President Barack Obama celebrated the one-year anniversary of his announcement of the Precision Medicine Initiative. The initiative, first announced in the president's 2015 State of the Union address, initially included $215 million in research funding ("Precision Medicine Initiative," n.d.).

Most medical treatments are designed to treat the average patient. However, this broad approach fails to account for differences in genetics, physiology, environments, and lifestyles, all of which greatly impact the effectiveness of therapies. Precision medicine works to overcome such shortcomings by conducting research into the efficacy of available treatments in different patients while taking into account these and additional factors.

For example, warfarin, a drug used in anticoagulation therapy for patients who need to prevent blood clots from forming (e.g., patients with implanted heart valves or who have recently suffered a stroke), showcases the value of precision medicine research. The CYP2C9 gene encodes one of the main enzymes involved in metabolizing warfarin. In addition, there are several variants of the gene that reduce the enzyme's activity, therefore impacting how quickly warfarin is metabolized, which in turn affects how long the drug is effective as an anticoagulant after a dose is taken.

Typically, physicians prescribe warfarin at an average dose. They then conduct multiple lab tests (i.e., blood draws) to adjust the dose up or down depending upon the individual patient's efficiency in metabolizing the warfarin as determined by his or her variant of the CYP2C9 gene. The titration process can take several weeks; in the meantime, the patient is put at risk for clotting (too little warfarin) or excessive bleeding (too much warfarin).

Applying a precision medicine approach would short-circuit this currently acceptable methodology. As precision medicine takes into account the genetic makeup of patients, in addition to other factors, clinicians could start patients on the proper warfarin dose at the beginning of therapy rather than needing to employ a trial-and-error approach to discover the correct dose. This approach could also aid in the administration of other drugs for which a patient's genetic makeup impacts metabolism.

On FHIR

Precision medicine research requires patient information that, until recently, was locked up in paper records and too difficult and expensive to extract. With passage of the HITECH Act, which facilitated the deployment of electronic medical records (EMR), this valuable patient information is now digitized and available for use by researchers.

Unfortunately, the failure to foster true interoperability as part of the meaningful use criteria used to guide EMR implementation has left valuable data still locked up, though in different ways such as proprietary formats and incompatible data definitions. Although CCD and CCD-A standards allow for some degree of interoperability, these formats transfer information in large bundles rather than discrete elements more useful to researchers.

That brings us to HL7's proposed FHIR® (Fast Healthcare Interoperability Resources) specification. The proposed standard ("Welcome to FHIR," 2015) attempts to unlock the data within EMRs and make it available for other applications.

FHIR's ability to isolate and describe data elements frees the data from the singular clinical database for a wide variety of uses. Using an application program interface (API) to access the data, innovative developers can create stand-alone applications that use FHIR-enabled data elements to deliver information to patients and clinicians independent of the EMR. The developers use metadata embedded in the data element to intelligently "route" the data, which makes applications much smarter and more useful than they would be without FHIR. Without relying on data that's imprisoned by the predetermined structure, workflow, and user interface of the EMR, applications can be developed that satisfy the specific needs of both clinical staff and patients (Chaiken, 2016).

FHIR is the key

FHIR is the key to driving the Precision Medicine Initiative. If widely adopted, it can facilitate the transfer of patient information on a scale that allows stratification of populations by genetics and other factors. By extracting only the key data elements required in a standardized interoperable format, rather than an entire patient record burdened by a proprietary data structure, FHIR allows the rapid construction of a problem-specific clinical database that can be quickly analyzed. The content within the data set contains only those data elements of interest to researchers, such as age, sex, ethnicity, genetic markers, diagnosis, and laboratory results.

Using our earlier example, FHIR could be used to construct a warfarin-response data set that contains CYP2C9 results combined with demographics, diagnoses, and other factors. With this data, researchers could explore the relationship among characteristics such as CYP2C9 gene variant, diagnosis, age, sex, BMI, ethnicity, and warfarin dose. Such results would drive protocols for

use on patients who are candidates for warfarin anticoagulation therapy.

People power

In February, the president announced an additional $200 million for the Precision Medicine Initiative. The National Institutes of Health (NIH), Department of Health and Human Services, Department of Veterans Affairs, and Department of Defense are already engaged in projects to advance this initiative.

Specifically, the NIH, in conjunction with the Office of the National Coordinator for Healthcare Information Technology, sees FHIR as a technology that will allow patients to withdraw their own medical information directly from EMRs and make it available to the NIH for medical research. This clearly is an important component of Vice President Joe Biden's Cancer Moonshot program.

Technologies to FHIR-enable EMRs through an API are currently under development by EMR and interoperability vendors. It is unknown how the EMR vendors, who have their provider clients on a tight technology "leash," intend to roll out their FHIR APIs. Options include embedding them in an upgrade or releasing them as bolt-on applications, and the potential cost worries many provider organizations that have already spent huge sums implementing their EMRs.

Non-EMR vendors see a short, 12-month window to develop the technology and beat the EMR vendors to market. The potential revenue is huge. Even bigger, though, is the impact FHIR can have on the delivery of precision medicine and on improved healthcare for all of us.

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