HIT Think New standard can 'FHIR up' precision medicine

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On February 25, President Obama at the White House celebrated the one year anniversary of his announcement of the Precision Medicine Initiative. The Initiative, first announced in the President's State of the Union Address last year, initially invested $215 million in this research approach.

Most medical treatments are designed to treat the average patient. This broad approach fails to account for the differences in genetics, physiology, environments and lifestyles that greatly affect the effectiveness of therapies. Precision medicine works to overcome these shortcomings by conducting research into the efficacy of the available treatments in different patients using these and additional factors.

For example, Warfarin is a drug used in anticoagulation therapy for patients who need to prevent blood clots from forming (for example, patients with implanted heart valves or who recently suffered a stroke), and it showcases the value of precision medicine research.

Not to get too technical, but the CYP2C9 gene encodes one of the main enzymes involved in the metabolism of Warfarin. In addition, there are several variants of the gene that reduce the enzyme activity, thus affecting how quickly the drug is metabolized. The speed with which it is metabolized affects the length of time after a dose is taken that the drug is effective as an anticoagulant.

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 on the individual patient's efficiency in metabolizing the Warfarin as determined by the patient's variant of the CYP2C9 gene. The titration process can take several weeks as the dose is adjusted up and down. In the meantime, the patient is put at risk for clotting – too little Warfarin – or excessive bleeding – too much Warfarin.

Application of a precision medicine approach would short circuit this currently acceptable methodology used to determine appropriate Warfarin therapy. As precision medicine takes into account the genetic makeup of patients, in addition to other factors, clinicians applying this medical research would 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. Warfarin is just one of many drugs where genetic makeup impacts metabolism.

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

Unfortunately like paper records, the failure to foster true interoperability as part of the Meaningful Use criteria used to guide EMR implementations left the industry with valuable data locked up in 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 discreet elements that are more useful to researchers.

That brings us to HL7's proposed FHIR (Fast Healthcare Interoperability Resources) specification. HL7's release of the proposed FHIR standard (Welcome to FHIR, 2015) attempts to unlock the data within EMRs and make it available for other applications to utilize. In doing so it creates the opportunity for a slew of new HCIT applications that can interchange data in ways that are easier, faster, more fine-grained and more cost effective than previously possible.

FHIR is the key to driving the Precision Medicine Initiative. If adopted, it can facilitate the transfer of patient information on a scale that enables stratification of populations by genetics and other factors. Last month, the President announced an additional $200 million for the Precision Medicine Initiative. The National Institutes of Health NIH), the Department of Health and Human Services, the Department of Veteran Affairs, and the Department of Defense already are engaged in projects to advance this initiative.

Specifically, the NIH, in conjunction with the Office of the National Coordinator for Healthcare Information Technology (ONC), sees FHIR as a technology that would enable individual 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 the Vice President'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 a tight technology leash on their provider clients, intend to roll out their FHIR APIs. Options include embedding it in an upgrade or releasing it as a bolt-on application, and the potential cost worries many provider organizations that initially 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 is the impact FHIR can have on the delivery of precision medicine and improved healthcare for all