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Raymond D. Aller, MD, and Hal Weiner

Collaborative prepares pilot on managing genomic data in EHRs

As genetic testing travels the path from rare to routine, it simultaneously provides answers and poses problems. One such problem is rooted in the question, How can electronic health record systems organize and display genomic information in a standardized, interoperable format that best supports clinical decision-making?

Formed last year, the Institute of Medicine's DIGITIZE Action Collaborative, which falls under the purview of the National Academies of Sciences, Engineering, and Medicine, is tackling this issue by developing frameworks and implementation guidelines that leverage existing standards. The collaborative is also preparing a pharmacogenomic pilot project that will evaluate how to optimally record, manage, and present genetic data that may, in certain patients, contraindicate the use of abacavir sulfate for treating and preventing HIV/AIDS or the use of azathioprine for treating autoimmune disorders and preventing organ rejection after transplants.

An acronym for Displaying and Integrating Genomic Information Through the EHR, DIGITIZE consists of nearly 60 members—individuals representing EHR companies, laboratory information system vendors, academic medical centers, pathology laboratories, standards organizations, and federal agencies.

"It really is a collaborative effort of many institutions," says DIGITIZE co-chair Sandy Aronson, executive director of information technology for Boston-based Partners HealthCare Personalized Medicine. "We are focused on increasing support for genetics in the electronic health record—in particular, genetic clinical decision support. We realized that in order to make a difference, we had to pool together the relevant stakeholders."

Operating under the auspices of the Institute of Medicine's Roundtable on Translating Genomic-Based Research for Health, the DIGITIZE collaborative is open to new members and generally meets twice a month via conference call, Aronson adds. The collaborative has divided into two subgroups, one focusing on pilot projects and the other on new use cases.

One might expect such a large and diverse group to come up with complex solutions, but that has not been the case, Aronson says. The collaborative has reached consensus on the need for simplification and a step-wise approach to confronting the challenge of integrating genomic data into EHRs.

That's why the pilot will concentrate on just two use cases: incorporating results from the screening test for the HLA-B*5701 allele, which indicate whether an HIV/AIDS patient will likely be hypersensitive to abacavir, and incorporating results from the test for thiopurine S-methyltransferase enzyme activity, which indicate whether an immunocompromised patient will likely develop severe side effects from azathioprine. The collaborative

anticipated finalizing its implementation guide and kicking off detailed pilot planning by CAP TODAY press time.

Currently, laboratorians and clinicians record genetic information in a multitude of ways because of differences among EHR systems, points out DIGITIZE member Brian H. Shirts, MD, PhD, an assistant professor of laboratory medicine at the University of Washington in Seattle. For example, some EHRs allow genetic information to be placed in computable fields, while others have only text fields for the data. "Often valuable information is presented as separate pieces of text," Dr. Shirts explains. "When we talk about implementing genomic medicine, or precision medicine, our goal is to be able to display genetic information in a way that it can be integrated with other pieces of information and retrieved efficiently, so physicians can access the data they need over the course of a patient's lifetime."

Genomic information can be classified according to its immediate usefulness, and not all of the data collected on an individual necessarily belongs in the EHR, adds DIGITIZE co-chair John David Nolen, MD, PhD, MSPH, senior director and general manager for laboratory medicine at Cerner Corp. Dr. Nolen divides genetic variants into three categories: those that are clinically relevant to a patient's health right now, those that are clinically significant but not immediately relevant, and those that might have clinical significance and relevance in the future.

The genetic information in the first category definitely belongs in the EHR, Dr. Nolen says. However, the DIGITIZE collaborative is still trying to figure out where the information in the second and third categories belongs. To illustrate the second category, he offers this example: "Imagine we have a child who is being seen for seizures, and we survey the whole genome of the patient. In addition to variants directly related to the patient's seizures, we find the child has a variant that would affect his reaction to an anti-cholesterol drug. That patient likely will not need to worry about this until years later. Do we need to keep track of that variant? Yes. Do we need to place it in the chart where it would get in the way? No. How to handle that information is what we're trying to figure out as a group."

The collaborative is far from determining what to do with genomic information that may never be significant or relevant. "We don't know where it's going to go," Dr. Nolen says. "It will need to go somewhere to help drive the research process."

The overriding goal of the collaborative is to improve clinical decision-making, Aronson re-emphasizes. "DIGITIZE is really focused on patient care. And it's focused on creating solutions in the form of inter-institutional infrastructure that will enable better use of genetic information—not only in academic medical centers but also in the community." *—Carolyn Schierhorn*

ONC finalizes nationwide interoperability roadmap

After nine months and extensive comments from stakeholders, the Office of the National Coordinator for Health Information Technology issued, last month, the final version of the report, "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap."

"We are committed to helping consumers easily and securely access their electronic health information when and where they need it most; to enabling individual health information to be shared with other providers and refrain from information blocking; and to implementing federally recognized, national interoperability standards and policies so that we are no longer competing between standards, but rather innovating on a set of core standards," the national coordinator for health information technology, Karen DeSalvo, MD, said in an open letter introducing the roadmap.

The ONC's interoperability goals for the next 10 years, outlined in the report, are to send, receive, find, and use priority data domains to improve health care quality and outcomes (2015–2017); to expand data sources and the number of users in the interoperable health IT ecosystem to improve health and lower cost (2018–2020); and to achieve nationwide interoperability to enable a "learning" health system, with the person at the center of a system that can continuously improve care, public health, and science through real-time data access. (The ONC defines a

learning health system as one in which all stakeholders can contribute, share, and analyze data.)

To create a foundation for long-term success, the roadmap states, health IT stakeholders should move from a fee-for-service to a value-based payment model; further develop new standards and approaches to technology, such as the use of application programming interfaces; clarify and align federal and state privacy and security requirements; and promote and create consistent policies and business practices that support interoperability while addressing efforts to impede interoperability.

Among the numerous steps to success laid out in detail in the report is a plan to have the Centers for Medicare and Medicaid Services, by the end of next year, administer 30 percent of Medicare payments to providers via alternative payment methods that reward quality and value and encourage interoperability. The total would jump to 50 percent by the end of 2018 and move upwards from there until, in 2024, CMS uses value-based models as the dominant mode of payment to providers.

By 2020, more than half of technology developers will provide access to electronic health information via standard, public application programming interfaces, rising to more than 75 percent by 2024, the report states. And by the end of 2020, the ONC intends to have standards development organizations agree on semantic standards, including vocabulary and data sets, for health data domains.

Through these actions and numerous others detailed in the roadmap, the ONC asserts, people should, by 2024, be able to seamlessly integrate and compile longitudinal electronic health data across online tools and mobile platforms to manage their care.

“The roadmap is intended to be a living document,” the ONC reports. “As we move forward to create a learning health system, the roadmap will be updated and new versions will be created when milestones are met and new challenges emerge.”

NovoPath introduces clinical results management module

NovoPath has released a clinical results management module for its NovoPath anatomic pathology software.
“With this module, NovoPath provides flexibility to the AP labs to produce integrated anatomic pathology reports containing clinical pathology results, a standalone AP report, or just a clinical pathology report,” says Rick Callahan, vice president of sales and marketing at NovoPath. “In addition, the clinical information can be imported from other software systems or instruments and displayed in tabular form in NovoPath for quick referencing by the pathologists.”

The module also allows labs to correlate AP and CP results using discrete data and produce customized trend reports.

***NovoPath**, 732-329-3209*

AHIMA offering service for coding questions

The American Health Information Management Association has introduced AHIMA Code-Check, a coding service in which the association’s credentialed members will answer ICD-10-CM, ICD-10-PCS, CPT, and HCPCS coding questions from AHIMA members and nonmembers within one business day.

“AHIMA Code-Check doesn’t just provide answers to questions,” says AHIMA CEO Lynne Thomas Gordon, “but will show all the key steps for how the correct code was arrived at. It can be an important and ongoing source of continuing education.”

All answers provided via the service are based on coding guidelines published in AHA Coding Clinic and the AMA’s CPT Assistant.

Reporting tools break down questions by classification system, specialty topic, and subtopic, making it easier for managers to view and share their staffs' questions and the corresponding solutions and thereby target specific areas that need further clarification.

AHIMA Code-Check can be purchased by individuals and organizations on a subscription or as-needed basis.

Sunquest releases new version of genetics software

Sunquest Information Systems and Partners HealthCare have announced the general availability of GeneInsight Lab v5.3.1, a tool to assist laboratories with genetic variant knowledge management and interpretive report generation.

GeneInsight Lab v5.3.1 is intended for labs performing genome and exome sequencing. It sorts through large numbers of variants and identifies those requiring in-depth analysis. Furthermore, it stores large variant data sets. The product's scalable infrastructure enables laboratories to build their own local genetics knowledge base.

GeneInsight Lab v5.3.1 also offers annotated VCF file storage, a tree-branch style user interface for macro filtering, flexible filtering for microfiltration, and Excel export capability.

Sunquest developed this latest version in cooperation with Partners HealthCare Personalized Medicine's Laboratory for Molecular Medicine.

***Sunquest Information Systems**, 877-239-6337*

UniConnect adds modules to molecular lab system

UniConnect has unveiled toxicology and pharmacogenomics additions to its Precision Molecular Diagnostics, or PMDx, LIS/LIMS suite.

The new PMDx-Tox module, with workflows embedded in the PMDx system, allows toxicology labs to add pharmacogenomics to their practices via a system that bridges toxicology and molecular diagnostics.

UniConnect has also added next-generation sequencing functionality to its PMDx suite.

The company has established plug-and-play connectivity to Translational Software for pharmacogenomics and to Tute Genomics for next-generation sequencing.

"With the new reporting enhancements for PMDx, clients can still use their own resources to create PGx and NGS reports," William S. Harten, CEO and chief technology officer for UniConnect, told CAP TODAY. "Additionally, they can opt to deploy the excellent services of Translational Software and Tute Genomics….The integration with these two providers expedites deployment of the full PMDx system, thus delivering full benefits faster."

***UniConnect**, 801-428-1700*

Inspirata partners with EMC to enhance digital path solution

Inspirata has reported that it will power its digital pathology solution with technologies from EMC Corp. EMC will provide the on-premise and cloud-based utilities required for anatomic pathology image storage, intelligence-driven data retrieval, and data security for Inspirata's customers, which include cancer centers and teaching hospitals.

"Inspirata digitizes glass pathology slides and then leverages the high-resolution images to provide pathologists with new decision-support aids, such as computational image analytics and content-based image retrieval," says

Inspirata CEO Satish Sanan. “This process requires petabytes of data storage and real-time image retrieval, so we needed to find a partner who could provide us with a highly reliable, scalable, secure, and flexible big data analytics platform. EMC’s data lake offers everything we need to automate the pathology workflow.”

***Inspirata**, 813-570-8900*

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