

## Raymond D. Aller, MD, and Hal Weiner

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### **Clinical analytics: from benefits attained to software available**

While LIS and laboratory billing software vendors tout the power of their business analytics tools to boost the laboratory's bottom line, a newer application of information technology—clinical analytics—is elevating the role of the laboratory in personalized medicine.

"It's important to differentiate between operational, or business, analytics and clinical analytics," says laboratory technology consultant Dennis Winsten, president of Dennis Winsten and Associates, Tucson, Ariz. "Operational analytics help the lab become more efficient, improve outreach revenues, and reduce costs, while clinical analytics helps labs and health care providers become more effective. The lab can now provide its data in a broader scope and have it integrated with other clinical information to help clinicians make the proper decisions." The primary benefits of clinical analytics to laboratories are not financial, Winsten adds, but "come from the satisfaction of being a major contributor to improving patient care and from broader recognition of the laboratory's contribution of critically important data to the database that makes such improvements possible."

In a presentation at the American Society for Clinical Pathology annual meeting last month, Winsten and Hal Weiner, president of Weiner Consulting Services LLC, Eugene, Ore., and co-editor of "Newsbytes," outlined the relationship of clinical analytics to personalized medicine in the context of how some laboratories are using such data analysis to improve care delivery, and they assessed the various types of software tools available.

The use of clinical analytics at Minneapolis-based Allina Health, a nonprofit health care system operating hospitals and clinics in Minnesota and Wisconsin, has benefitted patient care and institutional practices in numerous ways, Weiner and Winsten reported in the ASCP presentation. For example, it has helped Allina's pathologists and clinicians reduce by 62 percent troponins ordered more than three times after 24 hours and reduce by a staggering 96 percent its creatine kinase-MB orders, as well as reduce transfusions and lengths of stay for specific patient groups. "Allina is a good example of what can be done with test utilization," Weiner told CAP TODAY. "Clinical analytics enables the pathologist to look at clinic ordering patterns and monitor trends in actual results. They can look at which tests have the best value for a particular patient and then assist the clinician in setting up protocols within the EHR system for appropriate testing. I think these tools can help both the pathologist and the clinician address overutilization and underutilization."

Options for selecting clinical analytics software tools*		
Category	Considerations	Examples of vendors
Buy and build from an analytics platform vendor	<ul style="list-style-type: none"> <li>• Highest degree of analytic flexibility and adaptability</li> <li>• Full implementation across an enterprise requires a data-driven culture with high aspirations to view analytics as a clear business differentiator</li> <li>• Some are best suited for a culture with a higher degree of data literacy and data management skills</li> <li>• Some vendors have a quick-start model and easier end user access</li> <li>• Some vendors offer off-the-shelf departmental solutions</li> </ul>	<ul style="list-style-type: none"> <li>• Caradigm</li> <li>• Health Catalyst</li> <li>• Tableau</li> <li>• Viewics</li> <li>• Sisense</li> <li>• IBM</li> <li>• Qlik</li> <li>• Vision</li> <li>• Ayasdi</li> <li>• Others</li> </ul>
Buy from an analytics service provider	<ul style="list-style-type: none"> <li>• Best suited for cultures that want to avoid the details of analytics and data management but aspire to improve basic internal and external reporting</li> <li>• Inter-organizational benchmarking and comparative analytics is a natural part of the business model and services</li> <li>• May be easier and faster to implement</li> </ul>	<ul style="list-style-type: none"> <li>• Optum</li> <li>• Truven Analytics</li> <li>• Explorys</li> <li>• Lumeris</li> <li>• Premier</li> <li>• Others</li> </ul>
Buy best-of-breed point solutions	<ul style="list-style-type: none"> <li>• Leverages expertise and very specific analytics applications in business and clinical areas that are not always available in other options</li> <li>• Does not facilitate data integration—that is, does not provide a single analytic perspective on patient care and costs</li> <li>• May be easier and faster to implement</li> </ul>	<ul style="list-style-type: none"> <li>• Orchard</li> <li>• Sunquest</li> <li>• Altosoft</li> <li>• Medventure</li> <li>• SCC</li> <li>• Cerner</li> <li>• Midas</li> <li>• Others</li> </ul>
Buy from your enterprisewide system vendor	<ul style="list-style-type: none"> <li>• Offers the possibility of “closed-loop analytics,” driving analytics back to the point of care in the EMR and clinical workflow</li> <li>• Tends to be focused on analytics that are specific to the vendor’s data</li> <li>• Less flexible and adaptable to new sources of data and more complicated for end user use</li> </ul>	<ul style="list-style-type: none"> <li>• Epic</li> <li>• Allscripts</li> <li>• Cerner</li> <li>• McKesson</li> <li>• Meditech</li> <li>• CPSI</li> <li>• Others</li> </ul>
Build your own	<ul style="list-style-type: none"> <li>• Requires data and programming expertise</li> <li>• Requires clinical expertise</li> <li>• May be risky and time consuming</li> <li>• Can use open system tools as a starting point</li> </ul>	<ul style="list-style-type: none"> <li>• Universities</li> <li>• Health systems</li> <li>• Research organizations</li> <li>• Pharma companies</li> </ul>

\*Other options available

Courtesy of Dennis Winsten and Hal Weiner

In a marriage of laboratory diagnostics and big data analytics, Quest Diagnostics partnered with IBM last year to launch Watson for Genomics, a service that combines the cognitive computing power of IBM Watson with genomic tumor sequencing to help generate personalized patient treatment plans. “Quest has added a 50-gene solid tumor panel that analyzes the patient’s sample and compares the results against the Watson database,” says Weiner. “The database, [which] contains clinical studies, pharmacopoeia, and rules created by leading cancer centers, then generates a report that says, ‘Here’s the most appropriate therapy that applies to that patient.’” Watson for Genomics receives data from approximately 10,000 scientific articles and 100 new clinical trials each month.

In a similar manner, ORIEN (Oncology Research Information Exchange Network), a collaboration of 15 U.S. cancer centers that uses molecular analyses of biological specimens to facilitate research of targeted therapies, applies clinical analytics to data stored in biorepositories. The institutions have collected data from more than 175,000 cancer patients, with most of them contributing tissue for research. The cancer centers are sharing both the molecular results of the testing and the ways in which the data are being used in cancer research, Weiner says. “It’s both accelerating cancer discovery and collaborative learning as researchers have access to all the data in a common format. You can look at which cancer treatments are most appropriate to a particular gene set.”

Laboratories interested in purchasing software tools for clinical analytics have a range of options, yet the purchase decision may not be theirs, Weiner notes. “A lot of that selection is going to be driven by the C-suite rather than the laboratory,” he says. “For those pieces of analytics that the lab is interested in, if they’re able to access tools provided by their enterprisewide system [EWS] vendor or their LIS vendor, that’s a good start.”

Obtaining clinical analytics tools from the EWS vendor is a common approach, Winsten adds. One advantage of this, he continues, is that it’s typically relatively easy to implement these tools because the EWS database is already in place and only one vendor is involved. On the flipside, the EWS tool may not be as rich because such products tend to focus on analytics that are specific to the vendor’s data. And they may not be able to access as many databases outside the enterprise as the software offered by vendors dedicated to clinical analytics.

Another option is to buy analytics software and tools from a dedicated analytics platform vendor and create customized applications, usually with the help of the vendor, or contract with a provider of software-as-a-service offerings, Winsten says. The software marketed by analytics platform vendors tends to have the highest degree of analytic flexibility and adaptability. And some platform vendors offer a quick-start model with easier end user access, he notes. Some of these vendors target the laboratory with tools that allow end users to quickly create

their own dashboards and queries and that are pre-interfaced with the LIS, Weiner adds.

Although the capabilities and convenience of these products and services come with a higher price tag, Weiner says, “the vendors that are only concentrating on clinical analytics and the tools that they bring to the table are what we believe will be leading the charge until the EWS vendors expand the capabilities of their products.” —*Jan Bowers*

## **ONC relaxes meaningful use certification requirements**

In an effort to increase the efficiency of the ONC Health IT Certification Program and reduce the burden on health IT users and developers, the Office of the National Coordinator for Health Information Technology announced two major changes last month.

The agency reported that it is exercising discretion with regard to randomized surveillance of certified health IT products and making more than 50 percent of test procedures self-declarable.

The ONC is loosening its policy that ONC-Authorized Certification Bodies conduct randomized surveillance, including the mandate that they conduct randomized surveillance for at least two percent of the health IT products they certify. The agency will not audit ONC-ACBs for compliance with the requirement nor undertake other forms of enforcement, it reported.

“This . . . will permit ONC-ACBs to prioritize complaint-driven, or reactive, surveillance and allow them to devote their resources to certifying health IT to the 2015 Edition,” wrote Elise Sweeney Anthony, director of the ONC’s Office of Policy, and Steven Posnack, director of the ONC’s Office of Standards and Technology, in a Health IT Buzz blog post.

The ONC also announced that it revised its approved test procedures for 30 of the 55 certification criteria that support the Centers for Medicare and Medicaid Services Quality Payment Program to render the criteria self-declaration only.

“This means that health IT developers will self-declare their products’ conformance to these criteria without having to spend valuable time testing with an ONC-ATL [ONC-Authorized Testing Laboratory],” Anthony and Posnack wrote.

The blog post noted that the criteria that are now self-attestation only are focused on functionality rather than interoperability. “By making this change,” Anthony and Posnack reported, “ONC enables ONC-ATLs and health IT developers to devote more of their resources and focus on the remaining interoperability-oriented criteria, aligning with the tenets of the 21st Century Cures Act.”

## **ONC enhances feedback form for reporting health IT issues**

In the wake of recent highly publicized health care IT-related lawsuits, the Office of the National Coordinator for Health Information Technology has updated its online health IT feedback form.

The revised form, available at [www.healthit.gov/healthit\\_feedback](http://www.healthit.gov/healthit_feedback), contains additional categories through which the public can log health care IT-related complaints, questions, or concerns. Respondents can also attach supporting documentation.

“While legal and administrative constraints prevent us from responding to feedback, all information submitted through this form is carefully reviewed and shared with appropriate ONC officials,” the website states.

The agency advises health care providers to try to resolve issues about certified health IT products with the product developers or sellers, and, if that fails, with the ONC-Authorized Certification Bodies if an issue relates to

the product's certified capabilities, before submitting problems through the feedback form.

Respondents have the option of supplying their first and last names or remaining anonymous.

"Please note that while we will endeavor to keep the information you share with us confidential, federal or state laws may require us to disclose certain information in some circumstances," the website states.

The feedback form is not intended for health information privacy issues. The ONC advises filing such complaints with the HHS Office for Civil Rights.

## **DotHealth marketing .health website domain extension**

Members of the health care industry have until Nov. 30 to secure a .health domain extension for their websites under the industry access phase of DotHealth's rollout of its domain extension.

The intent of the domain extension is to signal that websites contain reliable health information, the company reported.

DotHealth introduced the .health extension earlier this year and opened enrollment to hospitals, health care professionals, pharmaceutical companies, and other health care industry groups at large in July. It will extend enrollment to the general public, as long as respondents agree to adhere to the company's terms and conditions of use, beginning Dec. 5.

"The .health domains are launching in a phased process to ensure domains are available as soon as possible to the appropriate communities," the company reported on its website.

DotHealth was awarded the rights to the domain extension by the Internet Corporation for Assigned Names and Numbers, or ICANN. Pricing varies based on the domain registrar used.

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