

Emerging technologies push data integration

By Richard R. Rogoski

In an ideal world, patient data, reference intervals, and test results from both anatomic pathology and clinical laboratories flow seamlessly between systems, then into an electronic medical record where a physician can access all the information she needs. Most hospitals and clinics do not operate in such an ideal world yet. While writing interfaces between best-of-breed lab systems can solve some of the problems, the growth of fields such as genomics, proteomics, and molecular testing is signaling a trend toward an integrated system with a single database.

Challenges at the basic level

Reference intervals, or “levels,” are typically health-associated, derived from a reference sample of many healthy individuals. It is from this sampling — based on factors such as age and gender compiled over time — that normal levels for lab tests are determined. But because federal regulations require that instrument manufacturers’ reference intervals be appropriate for a lab’s patient population, these reference intervals often vary greatly from lab to lab.

In addition, reference intervals can vary from patient to patient, says Dale Sanders, vice president and CIO of Chicago-based Northwestern Medical Faculty Foundation at Northwestern University, which is affiliated with the 897-bed Northwestern Memorial Hospital. Sanders gives as an example a patient who, due to certain health issues, has a high level or low level, which is “normal” for that particular patient, even though the lab’s reference intervals put that level in an abnormal range.

If the physician is using an electronic medical record or EMR that incorporates a physician-preferences feature, Sanders says he can adjust reference intervals on a patient-to-patient basis. Furthermore, these changes can be made within some laboratory information systems (LIS), says Curt Johnson, vice president of sales and marketing at Carmel, IN-based Orchard Software Corp. “In our system, there is a rules engine built in so you can set the ranges to the patient level.”

Even so, physicians may still find it difficult to access all the levels of data they want, says Sanders. At Northwestern Memorial, physicians are “grabbing information” from both the pathology lab system and from the clinical lab system, he says. “We are going directly to the sources,” he explains. “Our EMR is not granular enough, so a lot of information related to analyzing samples, for example, which is workflow related, is being stripped out in the EMR.” Plus, he notes, “There is no EMR that can handle genomics because of the graphical-rich nature of that data.”

Sanders also says that since genomics is a relatively young science, “There are still no clear reference intervals.” Because the medical entities at Northwestern are actively involved in genetic testing and compiling genetic and family-related data, Sanders says he is currently building an enterprise data warehouse in order to match clinical outcomes data with genomic data. The problem that still remains, though, is getting all relevant data to the point of care.

Data convergence

With the advent of new tests and treatments on the genetic and molecular levels, “There is a blurring of lines between the pathology lab and clinical lab,” says Brian Keefe, director of marketing for clinical products at Milford, MA-based Psyche Systems Corp. “With cytogenetics and molecular diagnostics, a lot is falling under pathology. But pathology systems were not designed to handle a lot of graphical information.”

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And since a clinical LIS is best at handling data points and numbers, the data from both systems need to be merged. “You have to have a single, relational database designed so data is accessible by pathology and clinical and by the physician,” Keefe says. As a result, Keefe says test results from both pathology and clinical labs can be presented in a single report.

The importance of generating a single report from both labs also was stressed by Johnson, who gave as an example a physician who orders a Pap smear and an HPV test. Since the Pap smear is run in the pathology lab and the HPV test is done in the clinical lab, the physician not only has to wait for each set of test results but also will receive two separate reports on the same patient. “In our system, we integrated anatomic pathology and clinical labs, and molecular testing into one system with a single database,” Johnson says. But he also notes: “Even if I have one lab system, I still need to integrate it into an EMR.”

Using a traditional HL7 interface would still present a challenge, he says. “An HL7 interface works well with quantifiable data; less well with quantitative data; and poorly with images.” One solution is to embed .pdf files in the HL7 transmission. But Johnson adds, “The future is Web services interfacing. That is where we need to go.” □

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Changes in test values crucial to quality lab reports

By Rami Jaschek

As modern day labs struggle to stand out from the crowd, a proven ability to provide a more dependable and understandable result report to clients is a major goal. Physicians are monitoring patients more closely than ever and need to know what they can make out of changes in patients' test values.

Assuring the changes to patient results stem from true variability and not from testing errors was traditionally handled by following strict quality-control (QC) procedures. Much focus has been given to setting the most appropriate target values, selecting the right Westgard rules to apply to each analyte, and addressing questions of required testing frequency.

Traditional QC methods cover only a small segment of the entire testing process. Numerous pre-analytical factors that can change patient results tremendously are not monitored by this system. Travel conditions and timings, potentially incorrect blood-draw techniques, storage conditions, centrifuge alignments, and many other factors do not affect

control-material usage and, as such, are not the target of traditional quality control.

The true goal of a quality program is to ensure that patient results released today can be compared to those released yesterday. The law of large numbers tells us that when dealing with a large number of random values, overall leading parameters such as average, median, and standard deviation of the values can be expected to remain constant from one day to the next. Monitoring patients' daily values for consistency must become part of the routine of any lab seeking to improve its bottom line. That requirement can actually be taken one step further by plotting daily (or any other periodicity) values on a Levy-Jennings graph for ease of analysis and the ability to treat those values as yet another control in the QC system.

Taking this concept to the next step involves treating the stream of patient results coming from the analyzer as yet another control that can be tracked. Many quality managers are familiar with requests to halt approval on the lab in the

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case of a lengthy stream of abnormal results. Tracking for such incidents allows for capture of errors and problems occurring in between control runs. Checking for 10 abnormal results in a sequence, however, is actually just an application of a Westgard concept to patient results with relevant adaptation due to the fact that a more highly variable element such as patient results is being dealt with rather than results of a fixed control material.

Why stop here? Many other rules can be easily applied with great success to the same patient results. For example, if the "2of3-2s" rule is applied to control values, perhaps "4of5-2s" can be applied to patient controls and so on. Unifying control values together with patient-result streams and daily averages under the Levy-Jennings display and the Westgard testing framework allows for a more unified, comprehensive and, most importantly, bottom-line oriented quality program.

Keeping in mind that physicians are looking for the ability to understand the difference in patient results and assign a level of clinical significance to that difference. Making the lab analytical error as small as possible is only a preamble to the more complete discussion in significance of change. Variability in patient results stems both from the analytical variability in the lab and the biological variability within

each patient. The changes that can be expected in patient results when looking at cholesterol testing, for example, are not the same ones expected when looking at results of thyroid stimulating hormone.

Tables of biological variance are available on numerous online sites but may be omitted from discussion simply as a critical decision as to whether the treatment to lower a patient's cholesterol level is working or not. Providing a more complete service to clients, labs can indicate on their results reports an indicator for the significance level of the change seen in patient results. Combining the publicly available biological-variance information together with the analytical variance learned from the internal QC results provides the lab with a simple total variance calculation. This number can then easily be used as the basis for a clear indication of significant (2 "sd" change) and very significant (3 "sd" change) changes in patient values.

Taking these steps will allow labs to provide not only more accurate information but also comprehensive, decision-supporting information that enables physicians to make better, more informed decisions and, ultimately, provide better care to their patients. □

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