Newsbytes

Taking the guesswork out of measuring ROI for lab systems

June 2021—ROI is the holy grail of pathology laboratories purchasing laboratory information systems and analyzers. The abbreviation stands for "return on investment," but it should also mean "rarely obtained information," jokes health care consultant Dennis Winsten.

What most laboratories don't understand, says Winsten, president of the Tucson, Ariz.-based health care systems consultancy Dennis Winsten & Associates and CAP TODAY "Newsbytes" editor, is that gathering rarely obtained information can lead to a higher return on investment. In other words, it takes "ROI" to get ROI, quips Winsten, who discussed this topic in a presentation at the 2021 Pathology Informatics Summit last month and in an interview with CAP TODAY.

"Many laboratories implement major systems and don't follow up on whether they have actually realized the benefits anticipated," says Winsten. "They expect that the changes that were predicted to happen have actually occurred."

For large capital acquisitions, such as purchasing information systems, large analyzers, or automation systems, laboratories often conduct a pro forma ROI based on projections of costs and benefits. The pro forma ROI typically is created by a laboratory team that needs a new system, with the assistance of a vendor that wants to sell the system, and it is structured in a manner that justifies the large purchase to senior management, Winsten explains.

Winsten

Yet hospital and laboratory management rarely go back after a system is installed to evaluate whether the initial assumptions about ROI have been met, he says. And even if they do, he adds, it is "virtually impossible" to determine the direct benefits of the system or analyzer, outside of whether a baseline standard has been met, without having begun a multi-step, systematic evaluation process prior to installation.

To recognize the benefits that can be directly attributed to the large-ticket item, the laboratory needs to perform a comprehensive operational benefits realization assessment, or COBRA, Winsten explains. This involves establishing and recording a baseline metric of significant parameters and key performance indicators, before installation begins, that will serve as the basis for a post-implementation audit that remeasures the parameters and KPIs. "Comparison of the metrics from the pre-installation baseline and post-implementation audit will indicate whether or not the expected benefits of the new system or analyzer have been achieved," he says.

A COBRA should be included as a budget item for any large capital expenditure, Winsten continues. To offset the expense, he encourages laboratories to insist, during contract negotiations, that the vendor underwrite the costs to perform the benefits realization assessment. "The assessment can be done internally or independently but, preferably, not by the vendor," he says. "Further, the vendor should agree to include the pre-installation baseline document as an attachment to the contract, to accept the results of the post-implementation audit, and attempt, at no additional cost [to the laboratory], to remedy any shortfalls or deficiencies identified."

The combined pre- and post-installation COBRA analysis costs for large information system and analyzer installations vary, Winsten adds, based on the type of system or equipment being installed and the number of

laboratory benchmarks being measured.

Nonetheless, a benefits realization assessment is critical for all major purchases, Winsten says. “I’m sort of frustrated that I don’t see more of it because it’s a relatively low-cost way to ensure that you are getting better quality, achieving what you were looking to do, and getting what you paid for.” *—Renee Caruthers*

Orchard purchases Corwen

Orchard Software has acquired Corwen LLC to enhance the molecular capabilities offered via its comprehensive laboratory information systems portfolio.

Among Corwen’s offerings is the PRSQRL molecular solution, a smart platform that automates sample tracking, orchestrates workflows and instrument operations, and automatically converts complex data from genetic analyses into reportable results.

“Corwen’s molecular solution will work alongside Orchard’s broader LIS and point-of-care testing solutions,” according to a press release from Orchard. “This will also allow Orchard to further enhance its support of COVID-19 testing to include sample pooling and liquid handler integration.”

The companies have collaborated through the years and have mutual customers conducting high-volume molecular testing.

Orchard Software, 800-856-1948

Medbaye releases application for interpreting test results

Medbaye has announced the availability of its Clirra application for simplifying the process of interpreting diagnostic test results.

The application combines content from a proprietary database of peer-reviewed research with patient information entered by the clinician to create a single value indicating the probability of a patient having a specific disease. Clirra received approval under the FDA guidance document “Policy for Device Software Functions and Mobile Medical Applications.”

“Clirra draws from its database of peer-reviewed research and applies advanced Bayesian analysis to the clinician’s initial suspicion and the available diagnostic test results to provide a clear probability that the patient has a particular disease,” according to a press release from Medbaye. “The result of this analysis is the display of a single probability value of disease presence for use in differential diagnosis decisions.”

Clinicians can also use Clirra to perform “what if” simulations for diagnostic tests that indicate how test results may affect disease probability prior to ordering such tests, thereby fine-tuning test selection.

The application can be deployed as a mobile or desktop solution or embedded within other clinical data-management and decision-support tools. Its intuitive dashboards are designed to fit within common clinical workflows and present probability information in an easy-to-understand format.

“Clirra represents a significant improvement in how physicians perform a differential diagnosis,” said Eric Gluck, Medbaye cofounder and chief medical officer, in the press statement.

Medbaye, 978-298-5780

IICC releases article calling for consistency among IVD firms to bolster lab data reporting

The following is an excerpt of the article “Implementing the HHS Reporting Requirements for Test Results of COVID-19 and Future Epidemics: A Call to IVD Companies for Immediate Action,” written by Serge Jonnaert,

president of the IVD Industry Connectivity Consortium, and Ed Heierman, PhD, chief technical officer of the IICC. To read the full article, go to https://ivdconnectivity.org/implementing-the-hhs-requirement *or "CAP TODAY Recommends" at* www.captodayonline.com.

In response to the rapidly evolving COVID-19 crisis, the Department of Health and Human Services (HHS) issued a laboratory data reporting guidance for COVID-19 testing on June 4, 2020 to assure the timely and quality data reporting to state and federal public health agencies of SARS-CoV-2 diagnostic test results, using LOINC and SNOMED-CT in electronic reporting systems. For the purpose of this article, we will focus only on how this requirement affects CLIA certified laboratories, excluding POC CLIA waived tests. While CLIA waived tests were placed under the same mandate, in most cases, there is by default no vehicle for automatic data collection, aggregation, and submission through an LIS or otherwise.

The resulting confusion and frustration was properly chronicled in the November 2020 CAP Today article "Checklist, CLIA line up on COVID reporting" by Anne Paxton. CAP also expressed concerns regarding the call for 18 'required' data elements and more. The intent was right. Unfortunately, the needed infrastructure was not yet in place. While most of the 18 elements could be accommodated through related standards that were already well defined, mature, and published, the device identification to support tracking at the test kit level was not, and neither were the additional questions HHS wanted to get answered for each sample, e.g. Order Entry Question Codes (AOE), calculation input and documenting patient status that could affect result interpretation. These are not the traditional ask at order questions (even though they had to be labeled as such). Neither industry nor clinical laboratories were ready to implement all requirements, thereby avoiding the called for enforcement.

The IVD Industry Connectivity Consortium (IICC) and Regenstrief Institute are two of several organizations that have long touted the benefits of standardized coding of laboratory results and the resolution of related semantic and interoperability issues for the aggregation of big health data for improved real-time epidemiology, comprehensive and geo-specific population health data analysis, and the analysis of non-obvious multi-correlates that can lead to new discoveries. Little did we know that this need would become so acute with the COVID-19 pandemic.

ONC announces termination of interoperability road map

The Office of the National Coordinator for Health Information Technology reported that it has sunsetted its shared, nationwide interoperability road map, which originally was slated to end in 2024.

The ONC issued the road map in 2015 to guide policy development and other actions pertaining to such areas as information blocking, electronic health information exchange, application programming interfaces, and the HL7 Fast Healthcare Interoperability Resources, or FHIR, standard.

"Collectively, we have all made solid progress on many of the early milestones identified by the road map," said Steven Posnack, ONC deputy national coordinator for health information technology, in a Health IT Buzz blog post. "It's important to recognize those successes while at the same time acknowledging that the road map itself no longer drives our work."

The road map will remain on the HealthIT.gov website for referential purposes.

National health care coalition issues framework for patient ID

Patient ID Now, a coalition of more than 40 health care organizations, has released a framework for a national patient-matching strategy that addresses data standardization and quality, security, interoperability, and other measures intended to ensure patient privacy and safety.

In the document "Framework for a National Strategy on Patient Identity: A Proposed Blueprint to Improve Patient Identification and Matching," the Patient ID Now coalition calls for the federal government to collaborate with the private sector and public health authorities to create and implement a national strategy to ensure accurate patient

identification.

The framework recommends that the Department of Health and Human Services build a national strategy through multiple measures, including the following:

- Provide guidance and standards for calculating error rates across health information technology systems and organizations and identify minimum acceptable levels of accuracy.
- Use public and private sector resources from such organizations as the Office for Civil Rights and National Institute of Standards and Technology to address patient privacy.
- Define the minimum standardized data set needed to achieve patient identification and matching.

"Advancing policies laid out in this framework will improve the nation's pandemic response and overall public safety," said Blair Childs, senior vice president of public affairs at Premier, in a Patient ID Now press release. "It will also remove obstacles to care coordination and nationwide interoperability, as well as save millions in associated costs for the health care system."

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