Powering Laboratory Performance: The Future of Middleware

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Traditionally, middleware's function is to enable communications between laboratory analyzers and the laboratory information system (LIS), the laboratory portal to the broader network of health information systems. Over time, middleware functions have expanded to handle pre and post analytics and data management, tasks not readily available from the analyzer or the LIS. With the advent of automation, middleware is often integral to workflow management. Indeed, middleware today plays a major role in improving quality and efficiency by automatically verifying patient results (autoverification) and adding new dimensions in quality control (QC), such as the use of patient moving averages. And middleware is pushing new frontiers in business intelligence by providing laboratory management with metrics and key performance indicators (KPIs). These advances in middleware are especially important as we seek to continuously improve the cost efficiency and quality of healthcare. The capabilities of state-of-the-art middleware are a major factor in the increasing recognition of the importance of clinical diagnostics.

Middleware today

To articulate a vision for the future of middleware, we begin by understanding where we are today and taking a look at current trends and critical needs. How are laboratories responding to the continuing need for cost reduction and improved care? One trend is consolidation. At Hospital Clínic de Barcelona (Barcelona, Spain), increasing workloads and shrinking budgets drove a recent project to strategically consolidate diagnostic testing to a single, fully automated core laboratory, processing an average of 4,500 incoming patient specimens and 18,000 results a day. With the trend toward bigger laboratories, the concept of a factory—an information factory—is now embraced and appreciated. The performance criteria for this new hospital information factory are no different from what they have always been: quality, efficiency, and turnaround time. But the demands are significantly higher than ever.

Just what role does middleware play in this new information age? How well are we doing today? What do we need to maximize impact, not only on laboratory performance, but also on healthcare performance as a whole?

An expanding role

Conversations with laboratories around the world suggest that middleware today may have the biggest impact on cost by increasing efficiency and improving quality, while shortening turnaround time. By automating tasks such as reviewing and releasing unexceptional results, autoverification enables exception management, directing laboratory personnel specifically to those results that require human attention. While autoverification rate varies depending on patient population and laboratory protocols, some laboratories report that as many as 99% of results do not require human attention. Regardless of the percentage of results that are autoverified, improvement in efficiency is shown. Since the autoverification process ensures that the same review criteria are applied to every result, minimizing the effect of variations among laboratory personnel, an improvement in quality is noted. Most middleware supports quality control result management, making it possible for the laboratory to take advantage of increasing patient test volumes and easy access to quality assurance while managing patient results. Incorporating Delta checks, as another example, can be can be useful to identify specimen collection issues. Utilizing a patient moving average can ensure an additional measure of consistency and quality for applicable analytes in certain circumstances.

Middleware is assuming a significant role in workflow management, especially in the track based automated laboratory. As test orders and patient information come in from the LIS, middleware provides information to the track to direct where each sample should go, which preanalytic processes are needed, and which samples should receive the highest priority. Middleware can utilize information on QC status and redirect sample flow to analyzers that meet QC performance. Where required, such as in infectious-disease testing, interpretive algorithms can be applied to ensure consistency in process and reduce the need for human intervention and possible delays.

The vision

Middleware continues to evolve taking into account the learnings, experiences, and new functionalities of the past decade. New features continue to be introduced that streamline, automate, and and centralize laboratory operations such as inventory management and automated reordering. One significant step forward would be immediate access to continuously updated, real-time information about virtually every process and operational parameter on the system. This not only would offer deeper insight into day-to-day operations, enabling the laboratory to fine-tune processes to make sure turnaround time commitments are met, but also would provide immediate feedback on the effectiveness of corrective actions or workflow improvements made in the continuous pursuit of enhancing laboratory processes.

But we believe that there is room for middleware to take major steps forward, even if no new features are added. One opportunity is the ongoing improvement in ease of use, which will drive increased accessibility of existing middleware features in two ways: First, it will enable the performance improvements experienced by leading laboratories to be replicated in laboratories with fewer resources and less infrastructure. Second, it will encourage fuller utilization of current middleware by laboratories that have not deployed some of the key features due to real or perceived challenges in learning, and making these part of routine use. Related to this

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is the lack of standardization, which makes integration difficult. Many laboratories are all too familiar with analyzers that cannot communicate with each other or the need to maintain and use multiple or ancillary software packages to manage day-to-day laboratory operations. Due to their higher volume, larger laboratories have more data to analyze, and they usually have more resources to devote to analysis and implementation. Standardization is equally advantageous for smaller laboratories; however, due to their limited resources, lower adoption rates have been observed. Industrywide improvements in standardization and interoperability will improve integration and expand the reach of such benefits to laboratories of all sizes.

A call for action

To fully realize the potential of middleware and achieve the highest thresholds of quality, cost efficiency, and turnaround time, a collaborative effort among laboratories, industry, academia, and the government is required. Such collaboration can accelerate the ability of the industry as a whole to respond to the laboratory's needs and translate them into real-world solutions. One example is the IVD Industry Connectivity Consortium, whose mission is to establish the adoption of a unified connectivity standard among instrument manufacturers, software developers, and laboratories to simplify and streamline data exchange between IVD testing systems and healthcare informatics systems. Today, the draft standard guidelines are in review at the Clinical and Laboratory Standards Institute (CLSI).

Looking ahead

As middleware functionalities extend beyond data exchange to data management, quality control, and workflow management, middleware will continue to drive laboratory performance by enabling new achievements in quality, efficiency, and consistent, predictable turnaround time. The impact on healthcare performance is direct and immediate—improving patient safety and reducing the time it takes for clinical decisions to be made. Equally important is the ability to provide metrics for quantifying laboratory performance and firmly establish the value of clinical diagnostics in improving healthcare.

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