Beyond connectivity: middleware’s shifting shape

Anne Paxton

April 2016—Middleware was always about connectivity. But when it emerged on the scene some 20 years ago, connectivity involved basically one mandate: getting laboratory instruments to talk electronically to a hospital’s laboratory information system, accept orders, and deliver results to the right shelves in the LIS warehouse.

“Laboratory connectivity was traditionally a space where middleware vendors played an important role in allowing an instrument to communicate with the LIS and really provide the low level physical connection and data-mapping capability,” explains information technology consultant Serge Jonnaert, president of the IVD Industry Connectivity Consortium.

A batch of trends, some leading analysts believe, have pushed middleware outside that envelope. These include increased order entry by physician offices and clinics, the expansion of device operators, regulatory programs like meaningful use, the new dominance of the enterprisewide system in managing the electronic medical record, continuing health care consolidation, the dynamic nature of the processes and information needed for clinical decision-making, and the push for interoperability.

“What’s happening is middleware is adding much more capability, and it is starting to take a lot of the functionalities that used to be in the LIS out of the LIS,” says Hal Weiner of Weiner Consulting Services in Eugene, Ore. As an example of this change, he points to Data Innovations for its expansion into functionality in autoverification, expert rule management, and a number of tasks traditionally done within the purview of the LIS. At the same time, “Much of the functionality that was in the LIS is now in the EWS [enterprisewide system]. Very few labs do inpatient order entry through the LIS anymore.”

Weiner envisions a shift in role for both the LIS and middleware. “I see the LIS as being more inwardly focused and working on the new technology requirements, such as for molecular genomics, some of the things that are required and are unique to the inside of the lab itself. But I also see work area managers expanding and taking over the functionality of managing particular work areas like hematology or chemistry.”

Traditional LISs are under pressure, in Weiner’s view, because even though the LIS companies can count on maintenance revenues from the large number of legacy systems in place, many hospitals are choosing to buy their enterprisewide system and LIS from the same vendor. “The revenue from new LIS system sales across the industry in total has decreased for standalone vendors. Cerner has both an EMR and sells an LIS. Epic has an EMR and sells an LIS, Beaker. So that’s taken a piece of the market away from the vendors out there.”

Weiner

Another area of growth with potential implications for middleware, Weiner points out, is the group of companies called LIMS, or laboratory information management systems. “They basically ran pharmacy labs, public health labs, and other specimens that didn’t have patients attached to them. Many of those companies have now added patient-focused capability into their systems, and they are significantly less costly than the full-fledged best-of-breed LISs.”

“They’re not really middleware companies. They’re LIS vendors, but they have their own middleware component because they have to develop their own lab instrumentation and interfaces. And there are hundreds and hundreds of those LIMS vendors out in the marketplace.”

Across the spectrum of LISs and LIMS, Weiner says, “I think there will always be a niche for standalone vendors. But a large majority of hospital-based LISs will eventually be either replaced by the enterprisewide vendor solution, or by lower-cost WAMs [work area managers] that will take over the capabilities of what was the traditional LIS.” Over the long term, “I see middleware growing to be a more robust component of LIS deployment.”

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Second in a series. Last month: “Broadening the productivity spectrum with middleware”

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There is hope that the whole process of connecting laboratory instruments will become easier soon, with the launch of a major new industrywide connectivity standard. The IVD Industry Connectivity Consortium in collaboration with Integrating the Healthcare Enterprise recently released the new Laboratory Analytical Workflow (LAW) profile global connectivity standard. The LAW profile replaces the Association for Computing Machinery ASTM E1391/E1394 standards that go back nearly two decades, Serge Jonnaert says. “These standards have been used in the laboratory since then but were never updated to today’s networking capabilities, so they were definitely due for replacement.”

Hammered out during the past six years by IVD manufacturers and middleware and LIS companies, the LAW profile standardizes the flow of patient and QC test data and related work order steps between instruments, middleware, and laboratory information systems. It is based on Health Level Seven International (HL7) and supports up to gigabit wired and wireless network bandwidth (TCP/IP), as well as network configurable security to ensure the safeguarding of protected health information. The Clinical and Laboratory Standards Institute plans to release its AUTO16 standard document, derived from the LAW profile, late this year. AUTO16 will replace the LIS01 and LIS02 standards.

For immunoassay, clinical chemistry, hematology, microbiology, and molecular testing, the standard promises plug-and-play capabilities including unique order identification, simplified order download, device identification, improved message interface to support IVD instrument rule evaluation, unique identification of runs, support for rerun and reflex testing, and more.

Despite industry consolidation and the turn toward enterprisewide systems, Jonnaert does not see a phase-out of traditional LISs anytime soon. “Over time you will definitely see more and more consolidation of functionality across larger laboratory and hospital systems. But at the end of the day, from a global perspective, I think there will continue to be a space for both middleware as well as lab information systems for small and midsize laboratories. It is ultimately all a function of where lab tests will be conducted in the future.”

Jonnaert

Jonnaert envisions smaller, more integrated multiplexing instruments, and more tests being done in physician office labs and smaller regional, rural laboratories, which will also require more integrated operational and

administrative functions. Those evolutions will definitely not lead to the disappearance of the LIS, he says.

“What’s important here is that a simple connectivity standard can be the enabler for a comprehensive, global data standardization program that could address much larger health care data analysis issues—epidemiological cluster analysis, for example—but that is a whole other topic altogether.”

He views the LAW profile standard as possibly moving some of the middleware functions. “The low level physical connectivity and data mapping that was the middleware vendors’ traditional space, that of course goes away as you adopt standards like the LAW profile. But the LAW profile is also a lot more—and essentially it could over time move more middleware functions to the LIS.”

How would this happen? “You can have the work instructions sent directly from an LIS or from a bigger system to an instrument. And you would have a work order for this and this and this test. ‘Are you able to execute it?’ And the instrument can reply, ‘Yes, I’m available,’ or ‘No, I’m not. Send it down the track to another instrument that may be able to do it.’ All of that is defined in this LAW profile standard.”

In essence, “This standard will absolutely promote a sleeker, more efficient, less cluttered stream of data management,” Jonnaert says. “First of all, it will significantly reduce the costs to connect new instruments in the lab to an LIS, still ranging between $3,000 and $20,000. Now, it truly becomes a plug-and-play scenario, and the data format is standardized.”

If you walk into a laboratory today, “you will still find a lot of instruments that have ‘dongles’ hanging on the back that do conversions from a serial port to the network. And some of the middleware and LIS companies made these custom connections.”

“With the LAW profile, all of that goes away. You connect the instrument to the network, you have your LIS already on the network, you establish a connection, and you open a data stream—done.” Since the standard is now commercially available and ready for implementation, he says, it is important that laboratories start including it as a requirement in their requests for proposals and demand support for the standard as they work with their vendors.

More than likely, as adoption of the LAW profile expands, “we will see less use of middleware as it no longer fulfills the basic connectivity function,” Jonnaert says. Nevertheless, “Middleware will continue to play an important role for many years to come because we have a lot of legacy instruments, and the middleware vendors are now offering more essential LIS-like functionality.”

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