Lab Information as the Ultimate Value-Add:

Why IVDs Are Competing with Software Firms

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My Four Objectives!

- **One:** Review definitions of middleware.
- **Two:** Look at primary trends in healthcare that influence use of IT.
- **Three:** Look at current state in laboratories' use of IT.
- **Four:** Evaluate IVD vendor's opportunities and strategies involving middleware.

What is middleware?

Wikipedia's Definition

- In computing, ***middleware*** consists of software agents acting as an intermediary between different application components. It is used most often to support complex, distributed applications. The software agents involved may be one or many.

Wikipedia goes on to say…

- Middleware is now used to describe database management systems, Web servers, application servers, content management systems, and similar tools that support the application development and delivery process. Middleware is especially integral to modern information based on XML, SOAP, Web services, and service-oriented architecture.

Thefreedictionary.com…

- Software that functions as a conversion or translation layer. It is also a consolidator and integrator. Custom-programmed middleware solutions have been developed for decades to enable one application to communicate with another that either runs on a different platform or comes from a different vendor or both. Today, there is a diverse group if products that offer packaged middleware solutions as outlined in the following examples. See application integration.
- *http://computing-dictionary.-thefreedictionary.com/middleware*

Answers.com…

- mid·dle·ware (mĭd'l-wâr') *n.*
- Software that serves as an intermediary between systems software and an application.
- http://www.answers.com/topic/middleware

Klingenstein weighs in…

- **1.2. Middleware Definition (Klingenstein)**
- The term "middleware" is defined by one's point of view. Many interesting categorizations exist, all centered around sets of tools and data that help applications use networked resources and services. Some tools, such as authentication and directories, are in all definitions of middleware. Other services, such as co-scheduling of networked resources, secure multicast, object brokering, and messaging, are the particular interests of certain communities, such as scientific researchers or business systems vendors. This *breadth of meaning* is reflected in the following working definition: Middleware is "the intersection of the stuff that network engineers don't want to do with the stuff that applications developers don't want to do." —Klingenstein K. J.: Middleware: The Second Level of IT Infrastructure
- ***Kenneth J. Klingenstein (Ken),*** *Director, Internet2 Middleware and Security, University of Colorado at Boulder, Boulder, CO*

Healthcare Trends in USA

Healthcare Informatics: 9 Tech Trends

✓ =*Involves Lab Data*

- ✓ Disaster Preparedness
- ✓ Disease Management
- ✓ Electronic Medical Records
- ✓ E-Prescribing
- ✓ National Standards
- ✓ Pay-for-Performance
- ✓ Personal Health Records
- ✓ Regional Health Information Organizations
- ✓ Wireless Security

Four Basic Sources of Change In U.S Healthcare Market

- **One:** Consumers as primary buyers of healthcare. (Private and Medicare/Medicaid.)
- **Two:** Major commitment to universal electronic medical record (EMR) and integration of healthcare data.
- **Three:** New diagnostic & lab technology: genetic-based lab tests, automation, POCT.
- **Four:** Widespread introduction of Deming-based quality management methods into healthcare and clinical laboratory profession.

Consumers as Force for Change

- Growth in Consumer-directed health plans (CDHPs) is making more consumers primary buyers of healthcare. *(HSA growth is metric.)*
- As buyers, consumers have higher expectations for accessing health services (appointments, referrals, ancillary services, etc.).
- As buyers, consumers want fast access to information: medical records, new test results, e-mail consults with docs, etc.

Drive to Universal EMR

- Federal government taking lead role in fostering development of universal EMR (electronic medical record).
- Hospitals and health systems scurrying to integrate existing data repositories and create “single view” patient record.
- Enterprise IT integration is soaking up majority of hospital IT budgets.
- Digitizing radiology images and work processes is another expensive drain on hospital IT dollars.

Follow the Hospital's Money

- With hospitals spending to integrate IT, major healthcare IT vendors re-orient to serve that market demand.
- Lesser resources going into added functions for LIS and other clinical software systems.
- IT vendors' self-reinforcing loop: since latest generation LIS products have less incremental value over existing systems, labs are less motivated to upgrade to latest generation LIS.

Labs Have Inadequate $s

- Labs face ongoing budget squeeze: each year they must do more with fewer resources.
- This trend, dating back to early 1990s, has now lasted long enough that *forceful economics* are pushing lab administrators and pathologists into more drastic action.
- Need for acceptable solutions now encourages lab leaders to actively seek relevant solutions—even outside healthcare.

New Test/Technology Dilemma

- Labs face need to offer ever-growing number of new tests.
- Molecular technologies increase complexity of managing the laboratory.
- Molecular technologies generate scads of data—soon to overwhelm “classic” LIS products still in use.
- Then there’s a wave of new automation products, many of which are process-oriented or task-targeted.

Quality Management Finally Arrives in Healthcare & Labs

- Make no mistake! Quality systems puts hospitals and laboratory operations into an entirely new game!
- Whatever the flavor—ISO-9000, Lean, Six Sigma—management emphasis shifts to using proven methods to reduce and eliminate errors in work processes; also reduce waste.
- Requires “holistic” management thinking and meeting customer requirements.

Quality Makes Labs Different Consumers of IT Products

- That's because everything is now accurately measured and measurements drive decisions.
- Work flow redesign, single piece & small batch processing, intervention in real time—all require better access to information.
- Hospital labs with outreach have IT needs in two dimensions: internal (inpatient & outpatient) and external (outreach).

Now Let's Begin to Put It Together

- All these factors drive laboratories' demand for IT solutions.
- Widely recognized that general demand for upgrades to newest-generation LIS is weak, relative to past years.
- Labs have increased need for specific IT solutions:
  - 1) that improve lab operations;
  - 2) that move information among different users;
  - 3) that support an ever-shrinking number of MTs.

Technology & Clinical Innovation

- Technology is a wild card in predicting change.
- Peter Drucker: 40 years between a fundamental scientific breakthrough and widespread applications in society.
  - ***DNA**-1953, **transistor**-1952, **laser**-1958*
- Information technology is supporting rapid changes. i.e.: real-time capture of data for healthcare outcomes.
- Example of “speedy” identification of negative drug reactions.

Hospital Lab's Needs: Internal

- **Shortage of labor:**
  one solution is targeted automation (not TLA).
- Creates a need:
  Laboratory Automation Software (LAS) to track/direct specimens through the system.

A Word About Lab Automation

- Since the introduction of TLA (total laboratory automation) in mid-1990s, robust LAS (lab automation system) options have lagged.
- Labs were frustrated.
- Mechanical systems could perform, but LAS solutions to direct tubes and instruct automated stations lacked the necessary sophistication.
- This unrealized potential motivated labs to look for middleware solutions.

Hospital Lab's Needs: Internal

- **Rules engines:**
  to replace manual review and "routine" decisions—allows MTs to put skills on the exceptions.
- Solution:
  software applications that can be speedily (and inexpensively) installed between instruments, automated systems, and LIS.

Hospital Lab's Needs: Internal

- **Need to collect and aggregate data:** from any site where testing is conducted. *(Geisinger's example.)*
- Solution:
  software applications between actual test site and central LIS. *(Geisinger uses a PC to collect POCT and POL test results, then feed that data into LIS.)*

Hospital Lab's Needs: Internal

- **Send lab test data to appropriate users:** regardless of their location and access to the enterprise LAN.
- Solution:
  software applications that can pull data from LIS and transmit to authorized users. *(Clinical decision support systems for docs, wireless devices, etc.)*

Hospital Lab's Needs: Internal

- To summarize: hospital laboratories want IT solutions:
  - That can be implemented quickly,
  - That come with a reasonable price tag for the benefit,
  - That can be upgraded swiftly and cheaply when needed.

Hospital Lab's Needs: External

- Hospital administration recognizes basic economics of laboratories: more specimens yields a lower average cost per test.
- **Outreach** is the source of specimens to achieve these benefits.
- Outreach can also generate profits.
- Outreach uses the lab at slack times (second shift)—puts excess capacity to productive use.

Hospital Lab's Needs: External

- Thus, over last seven years, the number of hospital laboratories with active outreach programs has climbed steadily.
- However: outreach programs need resources and IT crunch-power that many LIS's cannot provide.
- Time-to-implement and cost-to-implement these capabilities from big IT vendors motivates labs to look for other solutions.

Hospital Lab's Needs: External

- A few of the outreach functions needed:
  - Courier support and specimen tracking outside the hospital
  - Electronic test ordering/results reporting systems between lab and docs' offices
  - Customer service
  - Electronic test catalog—clinical updates
  - Compliance / coding / billing / collections
  - HEDIS data for payers

Dilemma for Hospital Labs

- Internal and external operational and business needs can not be met by most installed LIS products.
- Where do labs get the needed functions?
- Middleware!
- I suggest that laboratory middleware is a ***customer-driven marketplace***.
- This is a pull-versus-push market.

Who Has Middleware Solutions?

- At this time, it's not the "BIG IT" vendors which are serving the need for specific IT solutions of their biggest hospital laboratory customers.
- It's a group of emerging vendors with specialized solutions.
- 1998-2002: class of companies appeared offering Web browser-based lab test ordering and results reporting. *(Atlas, Abiton.com, Labtest.com, et. al.)*

Now for IVD Manufacturers

- IVD firms have their own dilemma, which is fundamental to their business.
- What is the primary product, produced by every clinical laboratory in the world?

Answer? Information!

- It's that simple.
- Laboratories produce information.
- Thus, business opportunity for labs and their vendors: how to boost the value of information to users of lab test data.
- Users of laboratory test data include referring clinicians, patients, payers, employers, policy makers.

Introduced at the 2002 *Executive War College*

"Nike Sports Shoe Paradox" Is Lab Industry's Dilemma

- Contract shoe manufacturers get paid $5 per pair from Nike Corporation.
- Nike then sells these same shoes for $120 per pair.
- The market places high value on Nike's "brains" in engineering, design, sales, marketing; very little value in manufacturing the shoes themselves.

Lab Industry Dilemma...cont.

- Clinical laboratories spend virtually all their management time and resources manufacturing "sports shoes" at $5 per pair. *(Reimbursement for routine chemistry and hematology tests.)*
- Value-added—and the real profits—comes from converting lab data into useful clinical knowledge, and helping clinicians successfully apply that knowledge. *(Myriad Genetics and Genomic Health offer $3,000 predictive tests for breast cancer.)*

"Sweet Spot" for IVD Firms

- As suppliers of instruments and reagents, IVD firms—in one sense—are providing raw materials to the contractor who fabricates the Nike sports shoe.
- In this sense: they sell "commodity products" which labs try to buy at lowest price.
- Thus: "sweet spot" for IVD firms is how to move up the value equation.

IVD's Two Value Strategies

- IVD firms are moving outside their core competencies of instruments and reagents.
- One strategy is offering laboratory customers services in management and operational consulting. *(OCD's Px business.)*
- A second strategy is offering laboratory customers software capabilities that add value for the laboratory—and even possibly for its referring clinicians. *(Sysmex and Molis.)*

Lab Needs Intersect With IVD's Strategic Interests

- Why are IVD firms moving into the middleware arena?
- Because their customers are looking for these products to solve problems in their laboratories.
- Remember, this is a customer-pull market, not vendor-push.
- It allows IVD firms to help labs create additional value from their information, while reducing the cost to produce it.

How Does Middleware Evolve?

- Look to Europe for hints.
- In Europe, IVD firms have a long history of providing LIS and middleware solutions to laboratories.
- That's because, as automated instruments emerged in the 1980s, most European laboratories did not have an IT or LIS budget.
- Thus, IVD firms—in order to sell boxes and the juice—helped labs with their IT needs.

Why Now and Not Earlier?

- Significant differences in the LIS and laboratory IT market in Europe versus North America.
- In Europe, no equivalent to the multi-product, integrated menu offered by the Cerners McKessons, Meditechs, et. al., such as in the USA.
- Further—business strategies of the same IVD firm differed in USA and Europe. Thus, little cross-fertilization in the LIS/middleware arena.
- *Until now…!*

Let's Tie "IT" All Together!

- Main drivers in healthcare system are:
  - Consumers
  - Universal EMR
  - New technology adoption
  - Quality management—Lean/Six Sigma.
- Business priority of largest IT vendors is supporting IT integration in hospitals.
- That leaves an IT product vacuum for their laboratory LIS customers

Lab's Have Unmet Needs

- Labs turning to targeted automation solutions to substitute for labor.
- That increases the need for software to direct work flow.
- Lab leaders—under pressure to cut costs and boost productivity—are willing to buy solutions to achieve these benefits.
- Thus, growing interest and demand to use middleware solutions for QC, operations, outreach, etc.

IVD Firms See Opportunity

- Offering middleware and management consulting resources helps boost the IVD value proposition to lab customers.
- Providing middleware fills a product vacuum—and builds stronger customer relationships.
- Thus, both market demand by lab customers and evolution of healthcare system logically bring IVD companies into the middleware marketplace.

In Conclusion…

- Expect lots of competition in middleware for laboratories.
- Independent companies will pop up with targeted and effective solutions.
- IVD vendors will get more sophisticated in how their middleware interacts with instruments, the LIS, and lab workflow.
- **Key insight:** the game is now shifting to targeted middleware solutions that help a lab achieve specific goals.

…and a Prediction about LIS

- Predict that “classic” LIS is a dinosaur on its way to extinction…in as little as five years.
- Already have hospital labs operating withouth LIS.
- Universal EMR reinforces this trend.
- Laboratories will have a data repository, but it will serve different functions than the “classic” LIS.