Augmenting an Enterprise-Wide HIT System with a Best-of-Breed Anatomic Pathology LIS

Your AP Lab’s Information System Commute: When is ‘Taking the Bus’ More Flexible than ‘Driving Your Car’?

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Introduction

Healthcare institutions of all types now depend on health information technology (HIT) to store, organize and transfer healthcare data. Although this is a trend consistent with the availability of computing power, it was also helped along by regulations such as The Patient Protection and Affordable Care Act (PPACA), the Health Care and Education Reconciliation Act, the American Recovery and Reinvestment Act (ARRA), and The Health Information Technology for Economic and Clinical Health Act (HITECH).

These various laws all included incentives to increase the adoption of HIT, especially the adoption of electronic health records (EHR), electronic medical records (EMR), and laboratory information systems (LIS), including anatomic pathology LIS (APLIS). Very often, larger institutions such as hospitals and healthcare systems invest a great deal of time and money into an enterprise-wide EHR.

The disadvantage of these systems is that although they are very good for a “big picture” application for a system, they often ignore or are insufficient for the specific needs of the clinical diagnostic and pathology laboratories.

More specifically, many EHR systems provide some form of LIS module specific to the needs of the general clinical diagnostic laboratory, but are insufficient for the complexities of the anatomic pathology (AP) laboratory and the AP laboratories’ specific needs in terms of workflow, data mining, imaging and results formats.

Bruce A. Friedman, MD, Emeritus Professor of Pathology at the University of Michigan Medical School and a leader with the Association of Pathology Informatics (API), said in a 2012 Pathology
Informatics workshop 1, “An enterprise-wide-solution with an embedded, suboptimal LIS can harm lab efficiency and increase costs. It will probably fall short in various functionality categories.”

Several vendors have developed best-of-breed LIS for specialty laboratory areas such as anatomic pathology and blood bank. By utilizing an enterprise-wide EHR augmented with a best-of-breed LIS system, particularly for anatomic pathology, laboratories can have the best of both worlds.

This white paper provides an overview of the challenges involved in selecting either or both an enterprise-wide health information system and a best-of-breed, purpose specific, laboratory information system. The differences between enterprise-wide EHR systems and general lab information systems and anatomic pathology-specific systems are discussed, along with a list of the essential elements of an anatomic pathology LIS, and the pros and cons of utilizing a cloud-based APLIS versus a locally installed APLIS, with the option of a hybrid system.

Finally, the white paper will present four case studies of how different anatomic pathology laboratories have utilized a best-of-breed anatomic pathology-specific laboratory information system to improve quality, increase efficiency, and result in improved patient care.
Chapter 1:

Essential Elements of an Anatomic Pathology LIS

The anatomic pathology laboratory is complex, with complicated workflows and numerous subspecialties. The Digital Pathology Association cites 16 different steps in the anatomic pathology workflow, starting with Order, then to Collection and Transport, moving through Histology, Case Selection, and eventually ending with Results Delivery. Each of those steps may include multiple steps.

In addition, there are at least 14 anatomic pathology subspecialties. The Louisiana State University Health Sciences Center School of Medicine lists the following subspecialties:

- Cytopathology
- Dermatopathology
- Forensic Pathology
- Neuropathology
- Pediatric Pathology
- Surgical Pathology
- Renal Pathology
- Cardiovascular Pathology
- Pulmonary Pathology
- Gastrointestinal Pathology
- Gynecologic Pathology
- Genitourinary Pathology
- Musculoskeletal Pathology
- Hematopathology
Many anatomic pathology laboratories cover more than one testing specialty. While the APLIS in use doesn’t have to be customized for each subspecialty, each subspecialty will certainly place unique demands on the system.

At its core, an APLIS helps the laboratory record, track, and distribute anatomic pathology test results. The anatomic pathology workflow, as mentioned above, is complex. For example, a sample from certain types of cancers can yield multiple paraffin blocks, which are then used to create multiple slides. Patient samples may start out in two or three containers, but are typically processed into thirty or forty related samples used for multiple tests. Those thirty or forty subsamples are multiplied dozens or even hundreds of times a day in the typical anatomic pathology laboratory.

Two further complications that differentiate anatomic pathology from most other areas of clinical diagnostics are digital imaging and reporting.

**Digital Imaging**

Increasingly anatomic pathology (AP) laboratories are utilizing digital imaging to produce quantitative results. These images and results need to be incorporated into patient reporting in a seamless way.

At the same time, labs will take the necessary steps to implement virtual slide imaging because of the promised benefits of the technology. While whole slide imaging for AP is not yet generally approved for diagnostic purposes, stained slides for surgical specimens will still need to be produced and the overall processing will still take place – unlike radiology for instance. As a result, the workflow of the AP lab does not change much with digital imaging except that selective traditional photography may be eliminated at the end and replaced by a selection from the digital slides.
However, whole slide imaging of AP slides creates very large data files, which place high demands on LIS storage capabilities. While not as problematic as it used to be because of the exponential growth in computer storage, it’s useful to note that—when digitized—a single pathology slide can take up to 50 gigabytes (GB) or more depending on the magnification levels chosen and the number of focal plans. A day’s worth of cases in a busy pathology practice can require multiple terabytes (TB) of data. Some lab information systems allow digital images to be attached or embedded in final test reports. Storing digital microscope slide images requires significantly more digital storage capacity than radiology.

**Reporting**

Reporting of anatomic pathology procedures also has unique complexities. For example, the typical clinical diagnostic laboratory test provides a value range or a yes/no answer that is all the clinician needs to know. This is not generally the case with anatomic pathology testing. For surgical specimens, stained glass slides are still evaluated manually by a pathologist. Then, in order to produce the diagnostic report, the pathologist must often write or dictate a text-based analytical report.

During the reporting process, an image, or images, are evaluated typically by a pathology professional who must document the following:

- the gross appearance of the specimen;
- descriptions about the case that use free text, structured data, canned text, micros, dictation, or voice recognition; and most importantly,
- the pathologist’s diagnosis.
This data collection and the thorough evaluation of each slide that follows requires significantly more time from the pathologist and the staff at the lab for each case. It stands to reason that the APLIS that supports the pathology lab professionals must have robust and easily-customizable data gathering and reporting features as compared to the general HIS or clinical LIS.

Since time is the most valuable commodity, the pathology laboratory wants two main benefits from its APLIS. One is speed and efficiency of result entry by the pathologist performing the diagnosis. The second is fast turn-around-time that meets and exceeds the expectations of the referring physician and his or her patient.

The pathology report will also include a wide range of information such as gross appearance, microscopic descriptions, and diagnoses. This content will include free text, structured data, pre-written responses, dictation, images, diagrams, tables and disclosures. For clarity of reporting, an entire page (or more) of formatted text with highlights including supporting materials such as images, tables and diagrams that help in communicating the diagnostic conclusion to the patient must be presented to the clinician. Generic big box systems are generally not equipped to handle the different types of information captured and tend to require workarounds and a lot more time and workflow adjustments that translate into overhead to meet the needs of AP reporting.

In addition, many EHR systems reduce AP reports to an unformatted, single-font stream of text. Meaning is often garbled and AP reports are difficult to read. This problem can be avoided by the APLIS creating a PDF report, and the EHR displaying this PDF to the clinician exactly as it was formatted.
Optimal APLIS Functionality

There are five broad areas that are generally considered necessary in a modern APLIS. They are workflow, patient safety, data mining, functionality, and database infrastructure. Although not comprehensive, these are elements to consider within each of these areas.

Workflow

- Utilizing bar codes for specimen identification
- Paperless operations
- Authorized user access from anywhere
- In-laboratory tracking and linking of cassettes, and slides
- Live view with filtering for pending work lists
- Voice recording and recognition integration
- LEAN Management, for benchmarking and monitoring case progress
- Automatic reflex testing notification
- Send-out tracking for slides that are sent out for consultation
- Ability to modify reports within the APLIS prior to sign-out

Patient Safety

- Dictation, allowing a dictated wave file to be attached to the case
- Positive patient ID—scanning of the patient’s barcoded wristband (or radiofrequency ID bracelet) in the OR to generate the specimen label, scanning of the specimen label to accession the case, and rigorous tracking of the specimen and its pieces throughout the department
• Voice recognition, allowing the spoken word of the pathology professional to populate designated fields of the APLIS

• Interfaces to other software and hardware systems to allow patient demographic and diagnostic result data to transfer into and out of the APLIS with minimal probability of error

Data Mining

• Built in search engines for data extraction from the APLIS and management report generation

• Key word and “sound-alike” search capability

• Standard management report templates that can be used to filter and search data

• Expandable list of management reporting options

• Ad-Hoc query capabilities

Functionality

The Association for Pathology Informatics has developed a checklist of 850 specific LIS Functionality Statements for both clinical laboratory and anatomic pathology lab information systems. Broad categories include:

• ADT & Registration

• Auditing

• Billing

• Clinician Record

• Collections/Specimen Procurement

• Communication

• Data Conversion
An important aspect of any vendor-supported information system is the degree to which the vendor focuses on that particular domain.

- Database Maintenance
- Foreign System Interfaces
- Instruments & Handheld Devices
- Inventory
- Labels & Barcodes
- Notifications & Barcodes

For a full list, visit: http://www.pathologyinformatics.org/sites/default/files/Appendix%20I%20-%20LIS%20Functionality%20Statements%20-%20V%200.0.pdf

Database and Network Infrastructure and Security

- Mobile device connectivity and auto-delivery
- Well supported and widely adopted relational or other database technologies (Oracle, Microsoft SQL, others)
- Built-in Rich Text Formatting Capable Database
- Virtual Private network (VPN) and Citrix compatibility
- Virtual environment capable
- Temporal Database structure, which allow for functionality beyond HIPAA requirements, including audit trails and identification of case changes
- Group permissions
- Customizable field names

An important aspect of any vendor-supported information system is the degree to which the vendor focuses on that particular domain. EHR vendors typically have so many irons in the fire that anatomic
pathology gets short shrift at best. Some things to consider to help clarify the focus question:

1. Is there a separate anatomic pathology users conference, focusing only on anatomic pathology, at a different time and in a different city from their general nursing/physician user group? Some vendors will claim that anatomic pathology is included in their general users conference, but one finds that the AP users are submerged in a sea of clinicians, nurses, pharmacists, etc. A benefit of the separate users conference is that it tends to focus the vendor, as well as the users. Also, a separate users conference provides an excellent venue for users to talk to other users, and discover creative ways of implementing solutions for their own practice.

2. Are development needs for anatomic pathology separately categorized, prioritized, and implemented?

3. With a separate system design and database architecture, the vendor can make quick decisions that are optimal for the needs of anatomic pathology. On the other hand, AP systems that are tied into a monolithic architecture may languish because changes appropriate for AP would negatively impact other departments.
Chapter 2:

Understanding the Hidden Traps Associated with Enterprise-Wide and Limited-Function Pathology LIS Products

Several companies with familiar names dominate the EHR market: Epic, Cerner, Meditech, and McKesson for example. They often offer enterprise-wide EHR solutions that include a lab system. The LIS is typically more fully developed for the clinical laboratory and less so for the anatomic pathology laboratory. In certain instances, the LIS does not include AP at all or is to be developed.

Other things being equal, hospital and health system CIOs prefer the simplicity of one vendor, one system, one bill, one database, one operating system, etc. But other things are not equal: the problem for many laboratories, particularly anatomic pathology laboratories, is that the LIS offered as part of the enterprise-wide EHR does not always offer the necessary functionality, let alone the desired one.

Added to that, the EHR vendor may not provide focused support for the anatomic pathology practice. There may be well-thought out reasons explaining why the AP lab is underserved by the enterprise vendors. However, these reasons don’t remedy the gap that the AP labs experience especially when considering the net revenue generated from AP.

The most critical issue to evaluate when choosing an information system is the quality of support provided by the vendor. The functional capabilities of the system will evolve over time, but you
will be in a 15-year partnership with this vendor—what level of support will it provide? You would rather be working with a vendor who provides stellar support to a system which is still evolving, rather than an “integrated” system where you cannot get the vendor to repair or evolve an unsatisfactory aspect.

How does one assess the vendor’s culture of support? The most reliable is to get a list of at least a dozen or more current sites from that vendor, then call and talk to a random assortment of those sites. If the vendor refuses to provide a comprehensive list, and only provides “selected” or “representative” sites, the appropriate assumption is that they have something to hide, and you should look elsewhere.

Having selected a few vendors with stellar support records, then it is appropriate to look at current functionality.

When evaluating APLIS options, especially in terms of evaluating the enterprise-wide EHR versus a best-of-breed APLIS or module, one critical issue is the maximum total LIS functionality (T-LIS). The Association for Pathology Informatics (API) published a major report in 2013 titled “Use of the LIS Functionality Assessment Toolkit: A Methodology for Assessing LIS Functionality and Enabling Comparisons Among Competing Systems.”

Reasons to use a maximum-functionality system include:

“First, the deployment of such an LIS will result in lower labor costs for the labs that, in turn, will result in a lower cost-per-test for the department of pathology.”

Secondly, a high quality LIS assists in optimizing laboratory workflow, “which results in greater work efficiency and higher quality and lower costs.”
Third, due to long-existing and continuing shortages of medical technologists, “lab automation plus a highly functional LIS can serve as a substitute for labor.”

Laboratories, especially laboratories such as anatomic pathology and blood bank, which often do not have modules in the enterprise-wide solutions, may feel that the enterprise-wide solutions are inadequate for their needs.

Concerns on the part of laboratories include:

- The laboratory professional wants maximum computer functionality with system-wide integration as a secondary goal
- Enterprise-wide systems typically do not have capabilities for outreach laboratory business, which is a significant revenue generator for both laboratory and the institution
- An integrated, single vendor system may not be flexible enough for the constantly changing business conditions associated with the anatomic pathology industry
- Integrated systems aren’t easily adapted for a multi-entity business model, i.e., the various components such as laboratory, pharmacy, etc., are not easily modified when business or regulatory changes affect the entire integrated system

Some institutions solve the conflict by investing in an enterprise-wide EHR and LIS, but supplement it with best-of-breed solutions for specific laboratory departments such as anatomic pathology and blood bank.
Other institutions implement the enterprise-wide EHR and the vendor’s integrated LIS and have the AP laboratory, blood bank, etc., make do until the EHR vendor develops a lab-specific LIS module. The pros and cons of this approach include:

**Pros**

- The enterprise-wide LIS provides initial, but partial integration into the overall EHR
- The laboratory staff more quickly becomes familiar with the enterprise-wide EHR user interfaces and transactions
- When the enterprise-wide APLIS module is eventually implemented, there is only an incremental amount of adaptation required on the part of staff

**Cons**

- Money, efficiency and market share is lost while you wait
- Loss of productivity
- Not serving customers effectively
- Not providing optimal patient care
- Quality improvement that would have been provided by a dedicated LIS is missed

At the same time, there are pros and cons to immediately utilizing a best-of-breed APLIS.

**Pros**

- Mature, complete APLIS with proven interfaces with current EHR
- High priority applications are available immediately
It is important to consider gaps in operations.

- New or developing needs, such as outreach, can be met more swiftly than an enterprise-wide product, thus improving the pathology lab’s competitive position
- Least disruptive in terms of system transitions

**Cons**

- Non-enterprise-wide LIS may decrease overall enterprise integration
- A multi-component/multi-vendor LIS (the enterprise EHR/LIS and the best-of-breed APLIS) interface creates complex laboratory operations
- When the enterprise-wide LIS modules are eventually installed, it will create multiple disruptions in HIT services

It is important to consider gaps in operations. The API report has an appendix that lists 850 functionality statements (FSs) related to all laboratory work that an ideal LIS would have. The FSs are broken into nine sections, with a specific section on Anatomic Pathology. Other sections include General Laboratory, Blood Bank, Quality Control, etc.

The first section, Weights, provides a way of scoring (weighing) each of the FSs. “All of this should be taken to mean that most labs, particularly the larger and more complex ones, should seek to select best-of-breed LISs that provide all or most of the 2-4 weighted tasks and certainly all of the weight 3’s and 4’s.”

Examples of anatomic pathology FSs that rate 3’s and 4’s include “Ability for staff to manually assign an accession number” and “supports lab-defined case numbers and groups.” Examples of AP FSs that rate 2’s include “Audit trail for electronic billing” and “Interfaces to cassette labeler, slide etcher, slide sorter.” Suggesting the importance of full functionality to the APLIS, there are no FSs weighted as 1.
Given the emerging safety importance of robust cassette and slide tracking, some would now rate interfaces to cassette labeler and slide printer as a 4.

The API report\(^2\) states: “Installing an LIS with the maximum total LIS functionality (T-LIS) will generally result in lower labor costs for the laboratories which, in turn, will lower the cost-per-test. Systems with high functionality will also serve as a guide for achieving optimum workflow within the laboratories which results in greater efficiency.”

Although the argument against the best-of-breed cites problems with seamless dataflow, proven interfaces suggest that dataflow problems are minimal.

Perhaps most important is to evaluate the value of a best-of-breed APLIS, as compared to the “cost,” by looking at the impact on quality, productivity, improved competitiveness, service levels, and workflow maximization.

In his Pathology Informatics workshop, Dr. Friedman said, “The most efficient way to optimize Total Laboratory Information System Functionality (T-LISF) is with a best-of-breed (BoB) LIS plus supplemental modules and middleware. The goal is creation of an integrated laboratory database.”\(^1\)

Often, the enterprise CIO may choose the APLIS module of his or her EHR over a best-of-breed alternative because he/she has the idea that the EHR module is “free.” While the EHR vendor may not be charging an additional license fee for the LIS, other costs are levied. Installation, training, and ongoing maintenance of the LIS will often be more costly than an entire best-of-breed implementation.
If facing claims that the AP module is “free,” ask your CIO for the written assurance from the EHR vendor that there will be no charge for hardware, implementation, maintenance, or ongoing support. Remember the “free” razor—the holder is free, but the blades are top dollar; and the “free” inkjet printer—the manufacturer is not giving away the ink cartridges.

On this point, only rarely does a CIO want a monolithic EHR to balance all of these costs when compared to what it would cost to pursue a best-of-breed strategy for an APLIS. Equally significant, seldom does the health system administration consider the additional costs to the hospital in circumstances where the choice of lesser-performing APLIS means that the pathology laboratory may be less productive and have less-than-desired quality.

If facing claims that the AP module is ‘free,’ ask your CIO for the written assurance from the EHR vendor that there will be no charge for hardware, implementation, maintenance, or ongoing support.
Chapter 3:

To Cloud or Not To Cloud: On-Site Pathology LIS Vs. Remote-Host LIS

In today’s health information technology environment, laboratory leaders and healthcare executives have major options in terms of where to house their servers and HIT applications. In 2014, healthcare IT spending is expected to reach nearly $35 billion overall. Healthcare cloud services are predicted to increase by 21% over the next five years, double that over the 10.5% overall healthcare IT spending on technology solutions.

It is important to mention that the term “cloud services” in the healthcare context may be referring to different things. The term encompasses multiple hosting configurations, varying software solutions, and multiple pay models. For instance, a lab may have its own dedicated hardware configured to function and operate independently with proprietary software configured specifically for the needs of the lab with access to its own employees only at a third party “cloud” vendor using a virtual local area network – this configuration is usually referred to as “dedicated hosting.” Another lab may accept the risks involved in being on a shared platform with other customers on the vendor’s proprietary software “cloud” system. Yet another lab may choose to go with a cloud-hosted web browser-based software solution provided initially by the vendor and then later maintained by another IT provider (sometimes called cloud provider). These examples may have different pay models as well; some may have fixed monthly or yearly fees for a specified duration, while
others may be metered based on utilization, bandwidth, time, or other factors without any time limits.

Clearly cloud-based solutions in the healthcare setting are a major consideration because they offer an opportunity to save on IT costs under the right conditions, but they are not necessarily the right solution for every department and every healthcare entity when considering assumed risks and other hidden and long term costs. Today there is a wealth of data available for a decision-maker to support a measured decision in favor or against cloud alternatives. Such analysis should demonstrate the costs and benefits of the cloud services under consideration for the specific situation at hand. In other words, cloud anything/everything should not be thought of as a magic bullet.

**Benefits of the Cloud**

**IT Responsibility Shifts To Vendor**

One of the primary benefits of a “cloud approach” is that the primary responsibility for physical IT infrastructure goes to the vendor. This typically results in less personnel expenses because of the reduced IT administration, and the shifting of the responsibility of Internet uptime and backup, firewalls and network security, data storage, server backup, data backup, remote access, electric consumption, electric power backup, cooling and environmental controls and physical security to the vendor. This of course assumes that the vendor is able to offer a strong value proposition as compared to existing IT running costs or when these required functions are not performed at all by the facility/department.

It is important to mention that this benefit only materializes if ALL systems are moved to the cloud vendor. In other words, if one or more systems must remain at the lab’s facilities this benefit goes away.
because the functions still need to be performed by a qualified IT professional and that leads to duplication of costs and efforts.

**Universal Access**

Increasingly, healthcare providers are utilizing a wide variety of mobile devices to access healthcare information—smart phones, tablets, laptops—from many geographic locations. Even if a laboratory, pathology group, or healthcare facility has multiple locations, data and intelligence stored at one location can be easily made available.

**Decreased Start-UP Costs**

Obviously, not having upfront hardware costs and IT personnel on a full-time basis is one area of savings even when factoring in the services of an IT professional during the initial selection. A cloud-approach offers several pay models that are attractive in the short term. These include fixed term contracts, subscription-based, and volume or usage based pricing models.

**HIPAA and Security**

This is often cited as a concern regarding use of a cloud-based application, because protected health information (“PHI”) is being stored outside the medical institution and, in fact, is being transmitted via the Internet, which increases security concerns. Putting primary responsibility of HIPAA compliance and security on the shoulders of the vendor does not absolve the laboratory or pathology group from responsibility but it places a significant part of the costs and protocols onto the vendor.
It is important to request a HIPAA compliance statement from the cloud vendor when considering such an endeavor. Many cloud vendors today still don’t know what HIPAA is and what compliance means.

**Concerns About the Cloud**

**Higher Ongoing Costs**

Vendors operating cloud-based LIS/EHR solutions have profit margins, and will typically utilize hosting fees, which often exceed in-house system depreciation and personnel costs. “If you factor in the cost of annual increases and volume fluctuations … ongoing fees are generally higher than in-house processing.”

Over time, costs often add up as the lab grows in users as volume increases. A Break Even Analysis should be conducted based on current and anticipated volume and users. On average, Break Even Points of Cloud based systems relative to Client Hosted Server applications are 2-3 years. This favors the start-up lab in the short term but as the lab grows and as time progresses, the Return on Investment will favor the client hosted solution.

**Implementation Quality**

Many cloud-based solutions advertise the speed with which they can implement the service. The concern is that this tends to short change customization and workflow review. Unless considering a dedicated hosting solution (which in most respects resembles a traditionally hosted system), the client will have to use what is available from the vendor as is and will have to put up with any limitations imposed by the vendor.
Security Liability

As mentioned in the benefits, some liability for security shifts to the cloud vendor. However, most contracts will limit vendors’ liability, so it’s important that before purchasing a cloud-based EHR/LIS, the vendor’s security protocols are evaluated and audited.

Complexity

As commercial cloud vendors grow in size, they grow in complexity. Clients may find that identifying problems and fixing them in tandem with the cloud vendor becomes more complex, more difficult, and more time-consuming because of the many layers of support that may be involved and the wider potential impact of any changes made.

Catastrophic Single Point of Failure

On occasion, some cloud vendors have suffered major failures at their national data center. In one case, a mistaken network setting caused over half of the vendor’s clients to be down “hard” for several hours to over a day.4

Loss of Flexibility and Expertise

By outsourcing IT, labs lose the expertise in-house to know how to adjust system functionality to achieve a desired outcome; it may be difficult to express these needs to staff at the cloud vendor, and the correction may take a long time to implement.

Technology Trends

It is evident that technology advances will continue to drive the evolution of how healthcare professionals and lab professionals specifically will serve their patients. Technology today is enabling
location transparency in all aspects of digital life. It is also going towards smaller and more nimble Apps (mini applications) that do a small and defined set of things very well.

**Location Transparency**

Technology today makes it possible for institutions that prefer to have control over their IT needs to utilize an installed system with all the benefits of location transparency while keeping full control of IT assets and associated costs. Other labs and institutions may achieve the same goals using a cloud-based approach. Some vendors offer both solutions to their lab clients or even a combination of partially-installed/partial-cloud solutions, to accommodate the specific needs of their lab clients. NovoPath, for example, offers client-hosted, cloud-based, and web-based technology solutions and combinations of client-hosted and cloud/web based to take advantage of the best that today’s technology has to offer in serving laboratories and their patients.

**The “Apps” World**

Apps are by definition a purpose-specific (or best-of-breed). App advantages are obvious. Apps can be improved quickly and independently and frequently without impacting the rest of the ecosystem. By inference, a similar approach should be taken when considering healthcare systems. A best of breed, purpose-specific approach, especially AP and other underserved areas in the lab, will allow maximum flexibility in responding to technology advances (cloud or otherwise) and will maximize the use of the healthcare dollars being spent for a maximum return on investment.
Chapter 4:

The Anatomic Pathology LIS as a Cornerstone of Your AP Lab’s Growth Strategy

In today’s competitive healthcare environment, laboratories and healthcare providers need to use every tool available to achieve three goals: increase volume and offer more services, streamline workflow, and reduce the probability of error. There can often be a dichotomy between how these needs are met from an enterprise-wide level and department/laboratory level.

When evaluating an LIS, CIOs tend to look at the value from an enterprise-wide level; laboratories, however, tend to look at value from a department level.

When evaluating an LIS, CIOs tend to look at the value from an enterprise-wide level; laboratories, however, tend to look at value from a department level. Integrating the two by utilizing both an enterprise-level approach augmented with a best-of-breed LIS at the departmental level to allow both institution and individual laboratories to maximize performance can be a win-win solution for everyone. Further, there is often no full evaluation of how the enterprise-level LIS can handle the needs of the anatomic pathology laboratory. This is because the enterprise-level LIS was generally designed to support the clinical laboratory.

To evaluate a best-of-breed LIS versus an enterprise-wide system, it’s useful to perform a “gap analysis” on the systems. This will identify what specific components an enterprise-wide system might be missing that exist in a best-of-breed system. Then, after determining what is and is not yet available, one can prioritize their importance to the three goals: low, medium, high, or critical.
Often EHRs have APLIS solutions that allow results to be transferred via an HL7 interface. However, some of those systems do not accept a PDF. Yet anatomic pathology laboratories often have outreach programs; in many cases, independent anatomic pathology groups provide AP services to hospitals and healthcare systems.

Often, laboratories focused on AP outreach want to be able to send out reports to clients in a PDF. This can be a useful solution when these clients may not be interfaced with the hospital or the health system’s EMR. As a result, reports printed and faxed or mailed may be garbled or do not have appropriate institution/path group logos in them. NovoPath’s Anatomic Pathology Software solution has algorithms that allow the reports to be transferred via HL7 in a text format, resulting in a clean, organized report result. It can also be generated as a PDF. This provides not only branding opportunities, but a professional, easy-to-use appearance.

**Partners**

Another consideration when evaluating a best-of-breed LIS is whether the vendor is partnering with an EMR vendor or vendors. Although it would be expected that any APLIS would be able to interface with an EMR, the reality is that this can oftentimes be a difficult task requiring either a great deal of compromise or an expensive and lengthy interface build.

**Pathology Outreach**

Laboratories have an exceptional opportunity to expand their outreach activities with anatomic pathology and a smartly-integrated APLIS solution can underpin and enable profitable growth of outreach activities. For example, hospitals and health systems are purchasing the medical practices of office-based physicians. It is logical and
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natural for the parent organization to provide clinical laboratory and anatomic pathology testing services to these physicians.

What further reinforces the opportunities in outreach is the fact that many hospital administrators recognize that more specimens coming in from the community helps make it possible to expand the lab’s in-house menu of tests. Not only can this generate additional revenue, but it also reduces average cost per test for inpatient testing and improves the turnaround time for test results to both inpatients and outreach clients.

Of course, having the ability to establish robust and highly-functional interfaces between the laboratory’s APLIS and the client’s EMR is important to the success of an outreach program. Physicians want a fast, clean, and functional interface with the lab that enables electronic lab test ordering and results reporting. NovoPath’s strategy to support its customers is to work directly with the EHR vendor to ensure these goals are met.

Lab administrators and pathologists looking for this type of effective APLIS capability should research how the software will support physicians as they:

- Pull reports from the Website of the lab (PDF or Text);
- View reports using iPhones, IOS devices, Android devices, HL7 interfaces; and,
- Utilize features like remote printing.

Workflow and Specimen Management

When a laboratory is considering changing its APLIS, it is quite common for the decision makers to overlook a highly-desired feature found in the best software systems available in today’s market. It
is the ability to support all the workflow needs of the pathology laboratory.

As discussed in this white paper, the histology lab and the anatomic pathology workflow has many unique and demanding requirements. Perfection in specimen handling and management is essential today, for two reasons.

First, a tissue specimen is often irreplaceable, thus making it one-of-kind. Yet, the opportunities for human error in specimen transport, specimen reception, grossing, and the other steps leading to the finished slides exist—no matter how diligent lab staff is when handling specimens. Having an APLIS with full capabilities to track specimens and alert staff when appropriate is an invaluable contribution to patient safety.

Second, a tissue specimen is now an invaluable source of diagnostic information—not just when making the primary diagnosis, but following treatment and for years into the future. Today, molecular diagnostics and genetic tests may require the lab to handle the specimen in such a way that multiple diagnostic procedures can be performed. Then, when the specimen goes into storage in the APLIS, there may be need for follow-on testing in subsequent years due to either changes in the patient’s condition or new diagnostic technologies that were not available at the time of the original diagnosis.

It is for these reasons that the bar is being raised on how pathology labs handle patient specimens. A full-function APLIS should support these types of activities:

• Managing specimen workflow;
• Supporting patient safety with a temporal database auditing feature (which is the ability to view all “saved” changes within the APLIS);
• Verification at different points in workflow;
• Managing pending lists;
• 2D label printing
• Interfacing with instruments; and,
• Image capture and grossing and diagnosis.
Chapter 5:

EHR Vendors Recognize the Importance of a Best-of-Breed LIS

In some cases, comprehensive EHR vendors rely on best-of-breedsolutions for one or more portions of the laboratory. Examples:

1. McKesson has entered into an agreement with NovoPath Inc. to combine a best-of-breed APLIS application with the McKesson enterprise-wide health information system. As strategic business partners, the interfaces between NovoPath and McKesson are more comprehensive than a typical best-of-breed AP connected to a generic EHR. One benefit of such an approach is that the APLIS can interface with individual McKesson physician and patient portals. This feature thus provides the experience of a single, fully-integrated platform.

2. Epic, the largest EHR vendor, which emphasizes monolithic architecture in most of the enterprise, embraces best-of-breed solutions for its blood bank and transfusion services.
3. Another large EHR vendor, Cerner, has been trumpeting the use of its single, monolithic database for automating healthcare. However, about 15 years ago it acquired a number of LIS vendors. Most of these were at the end of their life cycle, and were simply sunssetted. However, one of its acquisitions was an industry-leading best-of-breed APLIS. At first, industry mavens thought the EHR vendor would sunset the APLIS (and the vendor has given occasional hints of this—but not carried through); instead, the EHR vendor has continued to develop and enhance the APLIS, holding separate user group meetings, and devoting development resources. Why? One major advantage is that the separate APLIS provides a more flexible, versatile development and experimentation environment. One does not need to modify the massive EHR database structure to add a capability in AP. Once capabilities have been added to the APLIS, that design can then be used as a prototype for building similar capabilities into the EHR-based integrated AP module.

This is one of a very few instances in which an EHR vendor maintains a separate database and code set for a functional module. It would appear that the nature of AP data and workflow is so disparate from the routine clinical model that a separate underlying database design is worthwhile.

4. Other EHR vendors have recognized that attempting to build an anatomic pathology or blood bank module would be an unwise use of resources that could be better applied on the clinical side. Therefore, they actively cooperate in connecting best-of-breed anatomic pathology systems into their EHR.
Chapter 6:

Case Studies

Southeast Missouri Hospital
Cape Girardeau, Missouri

Prior to April 2013, the Southeast Missouri Hospital laboratory was utilizing the Meditech system as their Laboratory Information System. This system did not specifically provide functionality for the anatomic pathology laboratory or several other of the laboratory specialty areas, so their IT department and the laboratory started shopping for a system that would more closely meet the specialty areas’ needs. The institution itself was switching over to a HIS, which didn’t offer an anatomic pathology LIS.

Jay McGuire, Director of Information Systems for Southeast Missouri Hospital says, “Meditech has more of an integrated lab package, where the laboratory, blood bank, and pathology are basically all on the same system.” The new system doesn’t offer a laboratory information system, so when McGuire and his team looked for options, it came down to NovoPath and one other company. After an evaluation, they decided on the NovoPath Anatomic Pathology Software.

Southeast Missouri Hospital is a private, not-for-profit hospital, part of Southeast HEALTH, a regional system of healthcare providers serving patients in southeast Missouri, as well as individuals in parts of southern Illinois, western Kentucky, and northern Arkansas. Southeast Hospital has 227 beds and approximately 80 owned physician practices. Southeast Hospital currently utilizes the NovoPath Anatomic Pathology Software solution.
The health system has three smaller hospitals that will be using NovoPath as they come online with the new lab system. Implementation for those three hospitals will start in 2015.

McGuire says the workflow of the NovoPath system is good and it has a very easy-to-use user interface. “All vendors claim their systems are easy to use, but the proof is in using it. The NovoPath system really streamlines your workflow or, at the very least, doesn’t get in your way. It has far better workflow than with the Meditech system and far greater usability. It’s easier to learn and gets more hands-on use by the pathologists. From my standpoint I don’t hear complaints about it.”

Although the NovoPath system can be remotely hosted, Southeast Missouri Hospital elected to host it themselves. McGuire says, “We have a data center where we’re hosting everything else dealing with the HIS and all our other systems, so it’s just another virtual server for us.”

Interestingly, the Missouri Delta Hospital, which is not part of the Southeast Health System, uses the same NovoPath system as Southeast Missouri Hospital via their data center. McGuire says, “They’re about half the size of the Southeast Hospital. Our data center hosts their servers. In some cases they’re on the same servers with us, only their data has a facility indicator of Missouri-Delta on it. They use NovoPath as well.”

Implementation of the NovoPath system was straightforward on the part of NovoPath. Making it more complicated was that the health system wanted what McGuire calls a “big bang go-live with the HIS” system, and in the context of implementing an entire health system HIS changeover, NovoPath’s Anatomic Pathology Software was a small part of the overall implementation. “Working with NovoPath was very good. I give them very high marks for being flexible because we had to reschedule our go-live date three times. None of it
was NovoPath’s doing; whatever we came up with for the HIS had to flow through for pathology. NovoPath was always good at working with us to make it happen.” He points out that the HIS also does not have a blood banking module, so they also have an independent blood bank system integrated into their HIS and LIS as well.

The result has been excellent. McGuire says, “We’ve been happy with our choice. This company is good to work with and attentive to our requests. No complaints at all.”

**Pathologists’ Laboratory, PC**
**Hermitage, Tennessee**

It took a while for larger companies to enter the laboratory-specific LIS arena. For some time, especially in the 1990s and early 2000s, there were a number of “homegrown” LISs designed either by programmers who saw a need, but didn’t necessarily have the ability to market in a widespread fashion, or by pathologists who saw a need and had a system built for themselves, which they then offered to other laboratories. Pathologists’ Laboratory in Hermitage, Tennessee is an example of a laboratory that used one of those homegrown systems until it no longer met their needs. Sometimes these systems just aren’t sophisticated for the full functionality necessary for today’s HIT needs, or because of their limited business models weren’t able to provide technical support or evolve with the changing trends.

Pathologists’ Laboratory, PC (PLPC) is a full-service pathology laboratory with five pathologists. It covers three hospitals with two gastrointestinal groups. The hospitals are Summit Medical Center (Hermitage, TN), University Medical Center (Lebanon, TN), and Hendersonville Medical Center (Hendersonville, TN). It also provides work for physicians’ offices. It handles about 20,000 specimens annually.
Prior to implementing NovoPath’s Anatomic Pathology Software solution, PLPC was using a small group system developed by a pathologist on the west coast of the U.S. It was essentially a home-built system and was no longer being developed or maintained. PLPC decided it needed a new LIS and interviewed two groups, one of whom was NovoPath.

Dr. Brian Carlson, MD, President and Co-Owner of PLPC, says, “NovoPath seemed a good fit for our group. We had good chemistry and we hit it off with them. They also seemed to be better adapted to a medium-sized group like ours as opposed to a large big-box vendor.”

PLPC’s original system had several limitations. Carlson indicates that one of the biggest of these issues was the ability to track and monitor follow-up studies. “We would have a diagnosis requiring additional studies or follow-up studies. For example, when cancer of the breast and ER/PR studies were pending, the existing system could not track such activities. It was up to the pathologist and the staff to remember these steps in completing the follow-on studies. The NovoPath system handles follow-ups. These immediately go on a pending list and are displayed on the desktop with a reminder.

There were significant workflow and quality advantages from that application alone. “There’s better quality care if you do these follow-up studies in a timely manner. I think the financial advantage was that our volume has gone up and we haven’t had to add additional people,” says Carlson. When they brought in the NovoPath system he points out that it didn’t cut down on their workforce, but without it he believes they would have had to add several transcriptionists.

Implementing an LIS can often be a disruptive process, but Carlson says the NovoPath implementation went smoothly. “I thought there was almost certainly going to be glitches and we wouldn’t be
Increasingly, large HIS vendors that focus on enterprise-wide IT solutions see a need to implement their broader systems with best-of-breeds LISs. In some cases, rather than develop modules for anatomic pathology or blood bank, large HIS vendors partner with best-of-breeds vendors to offer such specialized systems along with their HIS programs. The HIS vendors can then focus on the bigger picture while partnering with specialty vendors. St. Elizabeth Medical Center Laboratory in Utica, New York is a good example of this arrangement.

St. Elizabeth Medical Center is a 201-bed facility in Utica, New York. In 2003 their laboratory installed the NovoPath Anatomic Pathology Software system. Prior to that, they had no laboratory information system. At the time their lab test volumes were getting larger and they needed an LIS to better handle the workload. They evaluated several anatomic pathology LIS’s, settling on NovoPath.

Christine M. Goldman, MT(ASCP), Laboratory Quality Management Supervisor, indicates that it was the pathologists who were the primary decision-makers on the NovoPath acquisition. “They liked the user-friendliness of it. It fit our needs.”
St. Elizabeth uses Paragon®, a comprehensive hospital information system by McKesson. At the time of implementation, NovoPath was not partnering with McKesson; however, beginning in 2012 McKesson and NovoPath partnered to provide McKesson clients with NovoPath’s anatomic pathology LIS.

The comprehensive interface between the NovoPath and McKesson products provides a tightly integrated pathology solution. The pathology laboratory maintains the best of both worlds—a seamless integration of a best-of-breed anatomic pathology LIS in tandem with a flexible, outstanding enterprise-wide solution.

Goldman indicates, that for their part, the integration between McKesson and NovoPath has worked out very well.

More than anything else, Goldman says that the ease of usability, the user-friendliness of the NovoPath Anatomic Pathology Software system is what sets it apart. “We don’t spend much time training people, they just pick it up. If a new or temporary pathologist comes in, for example to fill in for a pathologist on vacation, they can pick it up and be reporting in no time at all.”

In addition, Goldman says the NovoPath system has really complemented their laboratory workflow, and has improved patient safety as well as being cost effective.

University of California Davis Dermatopathology Service
Sacramento, California

Laboratories and institutions often find that their needs evolve as their business models or business itself evolves. Examples include bringing on outreach business, which places unique demands on health
information systems and LISs. Although some laboratories develop an outreach program that is indistinguishable from their in-house testing programs, some laboratories keep them as separate business entities, often with separate facilities and laboratory information systems.

The University of California Davis Dermatopathology Service is a hospital-based dermatopathology practice within a university-based health system. In addition, the doctors that support the service are full-time medical school faculty. The Dermatopathology Service was started in 2003 and at the time was performing tests on fewer than 4,000 specimens annually. It has grown continually since and is expected to receive 30,000 specimens in 2014.

In terms of laboratory information systems, the UC Davis Dermatopathology Service utilizes two systems. NovoPath Anatomic Pathology Software is one, the other is Meditech, which was in place prior to the implementation of NovoPath. Dr. Maxwell A. Fung, MD, Director of the Service, says, “We divide our cases by the referral source. All cases that come in from the UC Davis system use the Meditech LIS. At the time that I started there was no referral-based or outreach service. When I came I started building up the outreach side, so we have many private doctors from the area, mostly dermatologists and pathologists, who send specimens from patients that are not otherwise from UC Davis. For that we needed an outside system, so we selected NovoPath.”

Dr. Fung points out that the NovoPath system has several features that the Meditech system doesn’t have, which he thought was necessary in order to compete in their local environment. “One was web-based reporting of pathology reports. And the second was image capture, pictures of the biopsies in the pathology reports. Those were both things that established pathology groups in the area had and we needed to manage that.”
In addition, he adds, the NovoPath Anatomic Pathology Software was offered at a price that the health system was willing to invest in. “We compared to a few others and this one priced out favorably.”

Because of the way NovoPath’s system runs in parallel with UC Davis’s Meditech LIS, there were no integration issues. Dr. Fung does say that there is a system-wide plan to integrate all EHRs with the Meditech system, but NovoPath hasn’t been integrated into it yet. Over time they are having interfaces built directly to their outreach physician clients.

Dr. Fung says it’s been easy to work with NovoPath. “I have no system to compare it with, really. Meditech is run by the pathology group and I only deal with them when there are problems and there generally haven’t been any. The NovoPath system has required some customization, as would be expected, and there have been software upgrades every few years, largely built on feedback we have provided. Otherwise NovoPath has been very responsive and got the job done when it needed to be.”
One potential solution is to invest in a best-of-breed anatomic pathology-specific laboratory information system.

Conclusion

The United States healthcare system is undergoing unprecedented change due to major healthcare reform initiatives accompanied by major new capabilities in health information technology. Clinical diagnostic laboratories, anatomic pathology laboratories, hospitals and healthcare systems are in the position of needing—and in many cases, being required—to implement health information technology to leverage health data capabilities, streamline workflow, improve efficiency, and increase competitiveness and cost effectiveness.

Although the CIO and other administrators in a healthcare institution have to evaluate the overall HIT needs of the enterprise, they also need to take into consideration the HIT needs of the individual components of the institution, from departments to laboratories, and how those HIT needs will work with the larger needs of the institution’s clients. Many large health information system vendors have developed excellent enterprise-wide EHRs and even LISs, but those solutions often do not meet the specific needs of individual departments, such as anatomic pathology laboratories.

One potential solution is to invest in a best-of-breed anatomic pathology-specific laboratory information system. This allows the enterprise to work effectively with an institution-wide EHR system, while still serving the needs of the individual laboratories and departments.

This white paper provides an overview of the challenges involved in selecting either or both an enterprise-wide health information system and a best-of-breed laboratory information system, gives a list of the essential elements of an anatomic pathology LIS, and discusses the pros and cons of utilizing a cloud-based LIS versus a locally installed...
LIS, with the option of a hybrid system. It also discusses a way to approach “gap analysis” to determine which approach would be best for the health system and laboratory.

It describes how several EHR vendors (including Epic, Cerner, and McKesson) have embraced the best-of-breed strategy for certain laboratory functions, and describes how the best-of-breed approach provides advantages to EHR architecture.

It also provided four case studies of anatomic pathology laboratories, from a medium-sized group practice, a hospital-based system, a university-based hospital system, and a hospital utilizing a McKesson health information system, and how they utilized the NovoPath Anatomic Pathology Software solution to meet their HIT needs to improve workflow, increase efficiency, and provide the best possible patient care.
References


Appendices
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About NovoPath

NovoPath, Inc. develops and markets software solutions for the Anatomic Pathology Laboratory market segment that includes local, regional, national, and in-house laboratories as well as community and university teaching hospitals and medical centers. Since the release of its flagship product in 1999, NovoPath, Inc. has focused exclusively on Anatomic Pathology. NovoPath’s mission is to provide unique and unparalleled solutions and services to all aspects of the Anatomic Pathology sector in a way that improves workflow, reduces the probability of human error, ensures results accuracy for greater patient safety, protects patient confidentiality, and above all, produces more precise and informative diagnostic outcomes. More information is available at www.NovoPath.com.
About Mark Terry

Mark Terry is a freelance writer and editor specializing in clinical diagnostics, telemedicine, and biotechnology. He worked for 18 years in clinical genetics prior to turning to writing, and has published over 700 magazine and trade journal articles, 19 books, and dozens of white papers and book-length market research reports related to the clinical lab industry. He is a member of the Association of Health Care Journalists and the Association of Genetic Technologists. For more information, visit his website at www.markterrywriter.com.
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About DARK Daily

“Dark Daily is a concise e-news/management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession. New developments, new technology, and changing healthcare trends make it imperative to stay informed to be successful. At the same time, the Internet, cell phones, blackberries, laptop computers and wireless devices are overwhelming any one individual’s ability to absorb this crushing Tsunami of data.

DARK Daily is a quick-to-read, easy-to-understand alert on some key development in laboratory medicine and laboratory management. It has no counterpart in the lab world. Why? Because it is produced and written by the experts at THE DARK REPORT and The Dark Intelligence Group, who know your world, understand your needs and provide you with concise, processed intelligence on only those topics that are most important to you!

You will find DARK Daily to also be an exceptionally valuable resource in laboratory and pathology management. Some of the lab industry’s keenest minds and most effective experts will be offering their knowledge, their insights and their recommendations on winning strategies and management methods. Many of these experts are unknown to most lab directors. As has proven true with THE DARK REPORT for more than a decade, DARK Daily will be your invaluable—and unmatched—resource, giving you access to the knowledge and experience of these accomplished lab industry professionals.
About The Dark Intelligence Group, Inc. and THE DARK REPORT

The Dark Intelligence Group, Inc., is a unique intelligence service, dedicated to providing high-level business, management and market trend analysis to laboratory CEOs, COOs, CFOs, pathologists and senior-level lab industry executives. Membership is highly-prized by the lab industry’s leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner. This gives them first access to new knowledge, along with the expertise they can tap to keep their laboratory or pathology organization at the razor’s edge of top performance.

It offers qualified lab executives, pathologists and industry vendors a rich store of knowledge, expertise and resources that are unavailable elsewhere. Since its founding in 1996, The Dark Intelligence Group and THE DARK REPORT have played in instrumental roles in supporting the success of some of the nation’s best-performing, most profitable laboratory organizations.

The Dark Intelligence Group (TDIG) is headquartered in Austin, Texas. This location makes it very accessible for any laboratory organization seeking input, insight and support in developing their business operations, creating effective business strategies and crafting effective sales and marketing programs that consistently generate new volumes of specimens and increasing new profits. The Dark Intelligence Group, Inc. owns and operates two Web sites in the TDIG Website network:


http://www.DarkDaily.com
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About the *Executive War College on Laboratory and Pathology Management*

Every spring since 1996, the lab industry’s best and brightest gather at the *Executive War College on Laboratory and Pathology Management* to learn, to share and to network. Many consider it to be the premier source of innovation and excellence in laboratory and pathology management.

Each year, a carefully selected line-up of laboratory leaders and innovators tell the story of how their laboratories are solving problems, tackling the toughest challenges in lab medicine and seizing opportunities to improve clinical care and boost financial performance. The *Executive War College* is the place to get practical advice and solutions for the toughest lab management challenges. A unique case study format brings participants face-to-face with their most successful peers. They tell, first hand, how their laboratory solved intractable problems and successfully used new technology.

Many lab management secrets are shared, along with specific “what-not-to-do’s” gained from hard-won experience! It’s not pie-in-the-sky theory, but useful knowledge that can be put to use in any lab. The *Executive War College* offers superlative networking, with lab administrators and pathologists attending from countries as far away as the United Kingdom, Germany, Brazil and Australia. It makes the *Executive War College* a melting pot for all the best ideas, new lab technologies and management strategies now reshaping the laboratory industry. It’s also become a recruiting ground used by headhunters and major lab organizations.

In the United Kingdom, The Dark Intelligence Group and the Association of Clinical Biochemists (ACB) have co-produced a meeting every February since 2003. Known at *Frontiers in Laboratory Medicine* (FiLM), it attracts laboratory leaders and innovators in the United Kingdom. Also featuring a case study format, this meeting pioneered the international laboratory side-by-side case study, where a North American laboratory and a United Kingdom laboratory prepare a comparison of best practices and an operational assessment of their two organizations.
In September 2005, a laboratory management meeting called *Executive Edge* was conducted in Toronto, Ontario, Canada, by The Dark Intelligence Group and QSE Consulting. It provided pathologists and lab directors in Canada with a customized meeting devoted to the strategic and operational issues of laboratory management in Canada.
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About Rick Callahan

Rick Callahan, VP of Sales and Marketing at Princeton New Jersey’s NovoPath, has more than 30 years of sales and marketing experience, some 15 of which have been spent in the medical IT solutions niche directed toward pathology and radiology segments.
Augmenting an Enterprise-Wide HIT System with a
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