

In Focus

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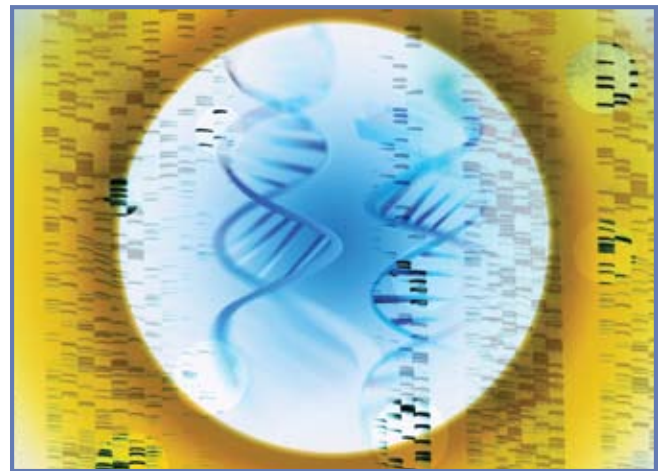
CHANGING THE WAY CARE IS DELIVERED

Predictive and Personalized Medicine

A new vision of the laboratory as a true community-based service line for the health system is predicated on achieving quality and efficiency. That quest has never held more promise than in predictive and personalized medicine, our theme for this issue of *In Focus*. Predictive and personalized medicine, which uses molecular analysis to maximize outcomes for the patient, has the potential to tie together disparate parts of health-care into the most focused patient-centric treatment regimen possible.

"...by moving from a one-shoe-fits-all perspective to one in which the shoe is sized for the foot."

It's a complex mixture of technology, data and actionable information that is translated into treatment plans. Personalized medicine is still in its infancy, but will ultimately allow care providers to custom-tailor therapy for patients based on their genetic profile. It will also allow them to identify patients at risk for specific diseases, that will ultimately enable care providers to promote wellness in a meaningful manner.



As the central player in diagnostic medicine, the laboratory is well-positioned to drive the move into personalized medicine, which like any transformation, requires at least some new language to describe its elements. In that spirit, we highlight a few key definitions in this emerging universe. (See page 2 for definitions.)

Ultimately, predictive and personalized medicine changes the way care is delivered "by moving from a one-shoe-fits-all perspective to one in which the shoe is sized for the foot," says J. Mark Tuthill, MD, head of Pathology Informatics at Henry Ford Health System in Detroit. "The end result is that not all diseases will be treated the same as is the current model of treatment, but that the disease will be treated within its setting — the patient milieu."

“Message from the President”



As we move to the new model of the laboratory as a service line, predictive and personalized medicine will take on increasing emphasis. We've chosen it as our theme for this issue of *In Focus* for that reason and because it is a natural follow-on to our previous edition, which explored the community-centered theme of outreach

and patient and physician affinity.

Few healthcare services are better suited to leadership in predictive and personalized medicine than the laboratory. As we often note — and it bears repeating — lab information can constitute as much as 80 percent of the content of an EHR, which places the lab in the center of healthcare's information revolution and at a pivotal point in the care process. With its reliance on genetic information, predictive and personalized medicine is both an extension of the information revolution and a scientific revolution in its own right.

Predictive and personalized medicine use molecular analysis to maximize outcomes for the patient. The promise is to be able to profile individuals so precisely that care teams can tailor treatment, eliminating the trial and error approach of medicine and further driving the practice of evidence-based medicine. The ramifications in the clinical and financial realms are astounding as providers will be able to identify ahead of time just which patients would be amenable to, say, a particular cancer treatment and which would not. This capability eliminates the “shotgun approach” of submitting large populations of patients to highly expensive therapies that fail to work a percentage of the time. The confluence of genomics, proteomics and cytology will also make it possible to identify patients at risk for adverse reactions to medications and to develop new therapies genetically targeted to disease.

More than merely participating in this revolution, Sunquest is committed to helping lead it. Our diagnostic IT products, described in more detail by Richard Batch later in this issue, empower lab services to leverage their unique nexus in the flow of clinical information for better patient outcomes and more robust revenue generation for the hospital and health system. Sunquest's continuing innovations in diagnostic IT can help ensure that predictive and personalized medicine places the patient at the center of the emerging integrated community of care. ■

PREDICTIVE AND PERSONALIZED MEDICINE: Key Definitions

- **Predictive medicine** is a rapidly emerging field of medicine that involves predicting disease and implementing preventative measures to either avoid the onset of disease altogether or significantly decrease its impact on the patient. While different prediction methodologies exist — genomics, proteomics, and cytology — the most fundamental way to predict disease is based on genetics.
- **Personalized medicine** is the use of genetic information — genotype or gene expression — and clinical data about a particular patient to select medication, therapy or preventative measures suited to that patient at that moment in their life.
- **Genomics** is the study of an organism's genome and the expression of the genes. Genomics has the potential of offering new therapeutic methods for the treatment of some diseases, as well as new diagnostic methods.
- **Genetic molecular testing** includes all tests to identify a disease or predisposition for a disease by analyzing DNA and RNA. Molecular diagnostics determines how genes and proteins interact in a cell. ■

Nationwide Children's Hospital

Columbus-based Nationwide Children's Hospital has long been pivotal to the health of Ohio's children, making it critical for the hospital to maintain state-of-the-art laboratory services.

Founded in 1894, Nationwide Children's is the primary pediatric healthcare provider for 37 counties, with more than 800 medical staff and 6,000 employees, and provides pediatric services to Ohio State University College of Medicine. The 352-bed hospital's laboratory performs in excess of 2 million billable procedures a year and more than 1,000 outreach requisitions a day.

In a decade-long initiative, it has leveraged that leading position to expand its specialty pediatric services, first establishing a successful local outreach program, which grew to a national and then international business line.

Nationwide Children's launched their pediatric reference laboratory in 2003. Molecular testing for infectious disease and genetic disorders form a mainstay of the test menu and has been a catalyst to fueling the growth of the business for the past three years.

The reference laboratory, part of the Department of Pathology and Laboratory Medicine at Nationwide Children's, provides comprehensive pediatric laboratory diagnostic testing and consultative services to private physician offices and other health care institutions throughout central Ohio and beyond. The lab interfaces to both inpatient and physician office systems for electronic laboratory results reporting.



The Molecular Infectious Diseases Diagnostics Laboratory located within the Department performs more than 20,000 PCR- or TMA-based nucleic acid amplification tests a year on a variety of clinical samples for more than 20 infectious agents, including tests to detect *Bordetella pertussis* (whooping cough), *Mycoplasma*

pneumoniae, herpes simplex virus, cytomegalovirus, parvovirus B19, adenovirus, enterovirus, *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

Nationwide Children's Hospital at a Glance

- Location: Columbus, Ohio
- Beds: 352
- Inpatient discharges (annual): 15,418
- Inpatient days (annual): 105,563
- Ambulatory visits (annual): 743,646

Also, the anatomic pathology system manages more than 5,000 procedures a year for a range of genetic tests for cystic fibrosis, bone-marrow transplants and other conditions using technologies like nucleotide micro-arrays and FISH (fluorescent in situ hybridization). Contrast that to ten years ago, when the lab reported fewer than 2,000 results on what are now considered simple nucleic acid amplification procedures, testing for only six different infectious disease agents.

Their Sunquest LIS supports all the information management demands for infectious disease testing and reporting. Capturing results in the LIS means the results are automatically integrated into the patient's electronic medical record.

With its ability to quickly add new test offerings, provide professional reports and coordinate billing for both inpatient and reference laboratory testing, the LIS has allowed them to significantly increase customer satisfaction, as well as revenues.

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CASE STUDY: NATIONWIDE CHILDREN'S HOSPITAL *(Continued from page 3)*



The success of any laboratory outreach program is determined largely by the

service levels the laboratory can provide. In Nationwide Children's case, one example of proactive service enabled by IT is managing proactively phoned results requiring provider attention, either because of the results' critical nature or because of client service agreements. Based on customer-defined rules, the system notifies technologists or the call center when a result is ready to be phoned and provides an audit trail of call data to meet regulatory requirements.

Timely and accurate invoicing is also integral to service quality. The previous outreach client-billing system relied on a custom-built database that took up to five days to generate invoices. Also, the lab had trouble accurately tracking accounts receivables, and weren't able to track sales generated by each sales representative. After implementing Sunquest's outreach billing system, invoices are now generated in a day — an 80% improvement over the previous turnaround time; second and third statements and aged-receivable reports are all generated with ease. Collections have improved by more than 50%, enabling the application to pay for itself in a matter of a few months.

"The laboratory's financial system was imperative in our ability to provide accurate, timely invoices to our customers, which is one of the fundamentals of stellar customer service," says Cheryl Hamon, Nationwide Children's director of laboratory business development and client services. "Another key component of the entire Sunquest package is the feature to manage our call logs. We have dramatically improved our Client Services area by taking advantage of the system's flexibility and configuring it to our reporting policies."

The laboratory generates invoices for clients, while patient direct bills are generated by the hospital billing department. Nonetheless, the laboratory tracks all charge captures in the outreach system. In this way, they can easily monitor the hospital billing department's activities, and they have a single view of all their outreach financials — the "Holy Grail" for many hospital-based outreach businesses.

"Our philosophy," says Doug Salamon, CLSpMB(NCA), SV(ASCP), Specialist III, Molecular Microbiology Laboratory, "has always been firstly to add new tests based on the needs of our hospital-based medical staff to diagnose and manage infectious diseases of acutely ill pediatric inpatients. Secondly, it's to aid our community pediatricians in the diagnosis and management of diseases typically managed as outpatients. We'll continue to add tests to our menu with this philosophy

in mind. When such tests can be marketed to other clients as well, the added value is apparent both in patient care and revenue."

Research into childhood diseases is an important part of Nationwide's mission. The LIS includes the capability to "mine" laboratory data and automatically e-mail information to researchers or store the information on a central server for easy access. Time spent on extracting information and recreating lost reports has decreased by as much as 75%.

"Our LIS has become an effective partner in meeting our service demands," says Charles Dudley, Laboratory Administrative Director. "With our excellent staff of analysts, it has allowed us to remove obstacles by providing solutions that work in our environment. Having an integrated LIS and anatomic pathology system enables us to enhance our capabilities and plan next steps with our external client program." ■

Laboratory Highlights

- Billable tests (annual): 2,000,000
- Outreach requisitions (daily): more than 1,000
- ChildLab launched in 2003
- PCR tests (annual): 20,000
- Cytogenetic tests (annual): 5,000

FROM THE EXECUTIVE SUITE:

Richard Batch, VP Product Development



Molecular and genetic-based information is quickly transforming the future of healthcare and, in the process, placing additional responsibilities on diagnostic IT. Data, the foundation of evidence-based medicine, will be more heavily relied upon in predictive and personalized medicine. Of course, accurate and timely data is the key to efficient

processes and quality outcomes. In the new era of healthcare, implementing an infrastructure capable of managing data is imperative for hospitals and reference laboratories.

Diagnostic IT plays a crucial role in both managing data and translating it into actionable information. Common nomenclature, common data models and a centralized data repository provide access to the same data, and associated information, regardless of source. This permits the development of intelligent decision support and analytics modules which are capable of quickly correlating information gathered from disparate sources and providing a composite picture of relevant information to the diagnostician.

With a solid data foundation along with a business intelligence analytics framework, this type of LIS infrastructure creates better investigative and reporting tools. The complexity of diseases becomes better understood when LIS collates and correlates information from disparate sources — molecular, therapeutic drug monitoring, biomarkers, toxicology, pharmacy — with clinical decision support. After “reading” the enormous amount of data, relevant information is presented in a format designed to facilitate the cognitive processes of the end user. A common portal allows intelligent aggregate reporting to be tailored to the needs of the end user, thereby creating an appropriate configuration of information for specific diagnostic roles. It is imperative that care providers are not the point of integration for one vendor’s pathways or EMR. Instead, the interactive experience is tailored to the end user by understanding the provider roles and the needs of those roles.

The modern LIS is more than a clearing house for data. It is a powerful engine for clinical intelligence and diagnostic support that can help drive and develop new best practices for medicine and patient care. ■

SUNQUEST EXCLUSIVE INTERVIEW:

“The Dark Report’s” Robert Michel on Predictive Medicine

Sunquest is pleased to feature the third in a three-part exclusive interview series with Robert L. Michel, Editor-in-Chief of the Dark Report and President of The Dark Intelligence Group, Inc. Robert is an industry-renowned commentator, consultant, author, editor, speaker and entrepreneur. He is also a leading expert on the management of clinical laboratories and anatomic pathology group practices.

The topic for this interview is how hospital laboratories are preparing to lead healthcare into the era of molecular diagnostics and predictive medicine.

What do you see as the impact in the next five years of predictive medicine and technologies on the overall healthcare industry and specifically for hospitals, laboratories, pathologists and physicians?

Let’s start with laboratory medicine as a consultative resource because that’s a critical factor in implementing

predictive medicine — particularly from the lab’s perspective. It’s not news to laboratory professionals that pathologists, lab PhDs and other skilled laboratory professionals understand when it is timely in a patient’s life to order particular lab tests and how to best develop a care plan to follow, as indicated by the test results.

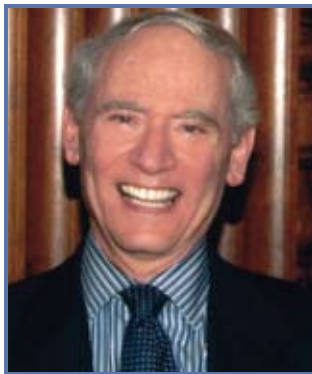
Unfortunately, many clinicians do not engage pathologists and other lab professionals as consultative partners in developing patient care plans, determining the right lab testing protocol and — as those lab results and other diagnostic information are received — evaluating that information to make diagnostic decisions and select appropriate therapies.

Progressive hospitals and health systems should seek to create active programs that bring this laboratory consultative expertise to clinicians at appropriate points in the care continuum. (Continued on page 7)

IN THE SPOTLIGHT:

The Emergence of Predictive and Preventive Medicine and Their Relationship to the LIS

by Bruce A. Friedman, M.D.



Predictive and preventive medicine are emerging as key components of the healthcare delivery system. Predictive medicine specialists take advantage of the entire spectrum of diagnostic tools available to forecast the future diseases of individual patients or large populations of them. Preventive medicine is a

related field and entails physician treatment of patients or consumer-initiated programs designed to avoid or delay the onset of those diseases that were previously predicted.

Most physicians today will probably be slow to incorporate predictive and preventive medicine measures into practice. Physicians are trained and rewarded for the diagnosis and treatment of *current* diseases. Similarly, most patients present in physician offices when they are symptomatic from disease and not before. However, there is no lack of resources devoted to predictive and personalized medicine today outside of the traditional healthcare delivery system.

The clinical laboratory industry — about 210,000 certified labs with estimated 2007 revenues of \$51.7 billion — will play a pivotal role in predictive and personalized medicine because lab testing is the least expensive and most non-invasive way to diagnose future diseases. The emergence of sophisticated biomarkers and broad panels of such tests will only accelerate this trend. Radiology is likely to play a complementary role in predictive medicine but is more expensive and puts the patient at more risk than lab testing. Nevertheless, radiology will surely play a critical role, with lab medicine, in the development of the Early Health Model (EHM), which is the diagnosis of pre-clinical pre-symptomatic disease. The EHM is inextricably linked to predictive and personalized medicine.

The Relationship of the LIS to Predictive and Preventive Medicine

Given that laboratory medicine and pathology will play a pivotal role in predictive and personalized medicine and that its importance is growing, it follows that the laboratory information system (LIS) will serve an important role, both directly and indirectly, in its growth. After all, the LIS is the

tool by which lab professionals communicate with their customers, largely physicians but increasingly healthcare consumers as they assume greater responsibility for their own wellness.

First, in terms of indirect communication, hospital LISs replicate all test results to hospital EMRs because they are now the major clinical reporting engines in hospitals. The most common form of personal health records (PHRs) will be web-enabled and linked to hospital EMRs. Most lab test results under today's healthcare information technology architecture will be replicated to these PHRs and made conveniently accessible to consumers. In the long-run, this feed of PHRs with most hospital-generated lab test results is inevitable because it provides the most popular and accepted form of clinical data among consumers. Most progressive health systems have already embraced PHRs. Competition will force others to follow suit.

The Relationship of the LIS to Hospital EMRs

While it's standard practice for hospital-based LISs to report test results to hospital physicians primarily via EMRs, this will become increasingly challenging as lab medicine and molecular diagnostics grow increasingly complex. Evolving science is raising concerns that legacy EMR systems may only be able to accommodate "top level" lab genomic/proteomic test results, which is to say the conclusion or diagnosis of such reports.

Hospital labs will have to rely on their LISs to report complex molecular diagnostic results in their entirety to physicians and consumers.

This emerging challenge will require a new generation of LISs; web-enabled and ultimately based on "cloud computing architecture", where computer processing and storage will occur in servers distributed across the Internet. This migration to the web and "cloud" will develop over the next decade, driven by cost, storage, and processing factors. The adoption of digital pathology will accelerate the trend because of its immense digital file storage requirements.

The "web-cloud" hospital LIS will communicate directly with physician clients instead of through the EMR and will be tethered directly to PHRs, enabling these consumer-controlled systems to store test results ordered and processed outside

(Continued on page 7)

THE EMERGENCE OF PREDICTIVE AND PREVENTIVE MEDICINE (Continued from page 6)

of the hospital labs. Consumers will directly order and pay for an increasingly large share of lab tests using web-based direct-access-testing lab sites. In the future, many consumers will opt for yearly “biochemical physical exams”, the results of which will be stored in their PHRs for year-to-year comparisons. Alternative medicine practitioners and physicians, with a consumer’s permission, will access these PHRs and submit an electronic analysis of the consumer’s wellness status.

Summary and Conclusion

Healthcare is undergoing a revolution based on greater consumer involvement in health maintenance and greater access via the web to sophisticated healthcare information. A key element in this revolution will be greater emphasis on

predictive and preventive medicine. Laboratory medicine will be integral to this trend as will the LIS. Lab test results will be reported to hospital physicians and those in private practice directly through the EMR and across the web. Test results will also be made accessible to healthcare consumers via linked PHRs. These changes, which will require a new generation of LISs that is both web-based and located in the “cloud”, will take about a decade to mature. ■

Bruce A. Friedman, M.D., is an Active Emeritus Professor of Pathology in the Department of Pathology, University of Michigan Medical School. He was an active member of the department for 33 years and Director in the Division of Pathology Informatics at the time of his retirement. He managed the departmental LIS for 24 years. His daily views about pathology informatics and lab medicine can be read at this blog, http://labsoftnews.typepad.com/lab_soft_news/

“THE DARK REPORT’S” ROBERT MICHEL ON PREDICTIVE MEDICINE (Continued from page 5)

This will position their institutions to be seen as leaders in implementing predictive medicine. It will also help these hospitals and health systems improve patient outcomes in ways that are acknowledged by payers, particularly in the form of higher pay-for-performance reimbursement.

A good example is selection of the right coagulation tests for cardiologists, neurologists and OBGYNs as they see patients with conditions the lab recognizes as likely arising from coagulation anomalies that affect the individual patient’s ability for normal blood clotting or thinning. In a tragic example of what can happen when appropriate expertise is not brought to bear, there are documented cases where men faced legal action after being reported as abusive parents, the result of a mistaken diagnosis of “shaken baby syndrome”. Infants were brought to an ER with bruises and internal bleeding resulting from normal play that at first appeared to be symptoms of abuse, but turned out to be the result of a coagulation defect in the child. A traumatic family experience on many levels, some of which would have been avoided with proper laboratory expertise.

Word is just starting to get out on this issue.

It’s a particularly compelling example of the consultative role that pathologists can play. In this case, being experts on coag pathology can very much help a clinician who’s treating patient conditions rooted in coagulation disorders and not other clinical problems.

How do you see this playing out for predictive medicine?

As new technologies and science associated with predictive medicine—which we might also characterize as genetic and molecular-based diagnostics—enter the clinical marketplace during the next five years, it will transform clinical practices for one disease-state pathway after another.

The model for this exists in testing for leukemia, lymphoma, breast cancer, HIV and several other infectious diseases. This is where a new level of sophisticated diagnostic tests comes into play to (A), diagnose the disease, (B), determine appropriate therapies for the disease, and (C), monitor the patient’s progress against those therapies.

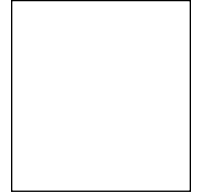
The example of HIV viral-load and mutation testing offers a good demonstration of this model, as the viral load guides the physician over time as to the effectiveness of the drug cocktail prescribed for the patient. And if the viral load begins to increase, then the HIV mutation testing done at the genetic level informs the doctor as to how the HIV virus has mutated against which specific prescription drugs. Armed with that knowledge the physician can change the drug protocol with the goal to observe viral load dropping as a measure of the new drug regimen’s effectiveness.

At the end of the next five years we may very well look back and see hundreds of disease states affected by this sequential introduction of useful new molecular diagnostics.

Go to www.sunquestinfo.com/PressEvents/ to read more.



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AACC - Booth #470, July 21-23, Chicago, IL
www.AACC.org

Emis National Users Group Meeting, September 9-11,
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Pathology Visions, September 13-15, San Diego, CA
www.pathologyvisions.com

APIII, September 20-24, Pittsburgh, PA
<http://apiii.upmc.edu/>

Lab Institute Conference, September 23-25, Arlington, VA
www.g2reports.com

IBMS Healthcare 2009, September 28-30, Birmingham, UK
www.ibmscongress.com

Lab Quality Confab, September 29-30, Atlanta, GA
www.labqualityconfab.com

CAP09, October 11-14, Washington, D.C.
www.cap.org

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