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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

The $1,000 Genome and Laboratory Testing

IT WAS 1953 WHEN JAMES D. WATSON AND FRANCIS CRICK, working from X-ray data collected by Rosalind Franklin, described the double helix structure of the DNA molecule. That discovery inspired scientists to begin investigating the genetic basis of life.

In the 56 years since Watson and Crick published their findings, there has been steady progress at cracking open the human genome. One useful marker for this progress is the declining expenses required to sequence a base pair of DNA. In 1990, it cost $10 to sequence one base pair of DNA. Currently, **Knome, Inc.**, says it will sell a whole genome sequence to anyone for $20,000. That represents a cost of $0.0003 per base pair of DNA.

But wait! That's not all... **Complete Genomics, Inc.**, is selling a whole human genome for $20,000. That is a further reduction of 80% in the cost to sequence one base pair of DNA. *(See pages 13-16.)* These two examples demonstrate that both the cost and time required to sequence the entire human genome are rapidly falling to the goal of $1,000 and one hour.

I predict this will have a profound effect on laboratory medicine as we know it today. For the first time in human history, it will be economically feasible and scientifically possible to sequence the entire genome of individual humans. As many of you are aware, this is expected to revolutionize the prescription drug industry. It will also play a role in helping physicians make pre-symptomatic diagnoses for a variety of diseases.

But, it is the second application of cheap, fast, accurate gene sequencing that will be disruptive to pathology and laboratory testing as we know it today. Imagine the ability to use a lab-on-a-chip, operated within a hand-held device, to do sophisticated molecular analysis of a patient's specimen, for pennies per gene, that produces highly sensitive results in minutes.

To me, this is the more significant point about the race to the $1,000 whole human genome, sequenced in one hour or less. The same technologies which enable this achievement will be downsized and miniaturized for the express purpose of supporting sophisticated molecular assays to be performed in clinical laboratories, physicians' offices, point-of-care (POC) settings, and maybe even for patient self-test purposes. Although this will be disruptive to existing clinical and business models for pathology and clinical lab testing, it will also create tremendous new opportunities for the pathology profession. TDR

Costs Falling Swiftly for Whole Genome Sequence

Complete Genomics says it is now selling $20,000 sequences to researchers and pharma

CEO SUMMARY: Several companies want to be first to achieve the holy grail in sequencing: an accurate whole human genome sequence produced in an hour for $1,000. Complete Genomics announced earlier this month that it could sequence the full human genome for a materials cost of $4,400 (not including labor and overhead). Another competitor, Illumina, is selling whole genome sequences for $48,000 to private individuals—and has customers!

PROBABLY THE FASTEST-ADVANCING FIELD IN GENETIC MEDICINE is whole human genome sequencing. Multiple companies are racing to lower the cost to $1,000 or less for sequencing an individual's entire genome.

The latest breakthrough was announced by **Complete Genomics, Inc.**, of Mountain View, California. On November 5, 2009, it stated that it was now capable of sequencing whole human genomes for about $4,400 in materials (labor and overhead extra). In September, Complete Genomics disclosed that it was charging $20,000 per genome for orders of eight or more genomes.

For pathologists and laboratory directors, these developments demonstrate the unbridled pace of improvements in the speed, cost, and accuracy of the technology used to sequence whole human genomes. In turn, by lowering the cost to sequence DNA, these developing technologies will give clinical labs and pathology groups new diagnostic tools.

There are many competitors racing to achieve an accurate, whole human genome sequence in less than one hour for $1,000. What motivates these companies and their investors is a widely-held belief that the market for whole human genome sequencing will be huge, once the price for a fast, accurate full sequence falls below $1,000.

With its announcements this month, Complete Genomics is percieved to be the leader in this race—at least for the moment. What distinguishes Complete Genomics from its competitors are two strategies.

First, Complete Genomics is building a service-driven business model. This sets it apart from competitors who expect to generate revenue by selling sequencing systems to researchers, pharmaceutical

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes *THE DARK REPORT* plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

firms, and biotech companies. *(See TDR, October 20, 2008.)*

The foundation of this service model is a specialized focus on one task: sequencing the human genome. Daniel MacArthur, in his blog *Genetics Future*, says that Complete Genomics "aims to create a series of extremely automated sequence factories with a single input (human DNA) and a single output (an accurate and comprehensive list of all of the variants present in that sample's genome), operating on a massive scale. All of the steps in between will be performed using in-house sequencing technology and analytical software."

Economies Of Scale

Thus, the goal of this strategy is to apply automation and economies of scale—focused exclusively on human genome sequencing—to achieve cost advantage. The second strategy is to provide the information technology and informatics services that customers need to store, assess, and evaluate the sizeable quantities of data that result from sequencing large numbers of human genomes.

This data warehouse will need to be huge. Complete Genomics is telling the public that it will deliver 100 complete human genomes to customers by the end of this year. In the first half of 2010, it expects to complete 1,000 human genomes. It predicts it will sequence 9,000 human genomes during the second half of 2010.

It seems to be a smart move by Complete Genomics to offer customers the data storage and information processing capability on a contract basis. This enables Complete Genomics to sell a total solution to potential customers. Not only will it sequence the DNA, but it can then immediately help the customer analyze the resulting data, eliminating the need for the customer to spend additional money to create its own extensive computer and software infrastructure.

Of course, a race always needs other competitors, and in the whole genome sequencing arena, there are plenty of firms actively working toward the $1,000 whole human genome sequence. At the moment, many experts consider **Illumina, Inc.**, of San Diego, California, to be the closest competitor to Complete Genomics.

$48,000 Human Genome

Illumina has gotten plenty of publicity. For example, last June, Illumina attracted media attention when it announced that it was charging private individuals $48,000 to run their whole genome sequence.

At least four people have been sequenced by Illumina for this price. They are Jay Flatley, CEO and President of Illumina; Hermann Hauser, Partner at **Amadeus Capital Partners Ltd.**; Henry Louis "Skip" Gates, Jr., a Professor at **Harvard University** and Director of the **W.E.B. Du Bois Institute of African and African American Research**; and his father Henry Louis Gates.

Illumina manufactures and sells second generation sequencing systems. Demand for its systems is strong. Compared to the business strategy of Complete Genomics (total outsourcing for customers of sequencing, data warehousing, and informatics services), Illumina's strategy is more traditional.

Sells Sequencing Systems

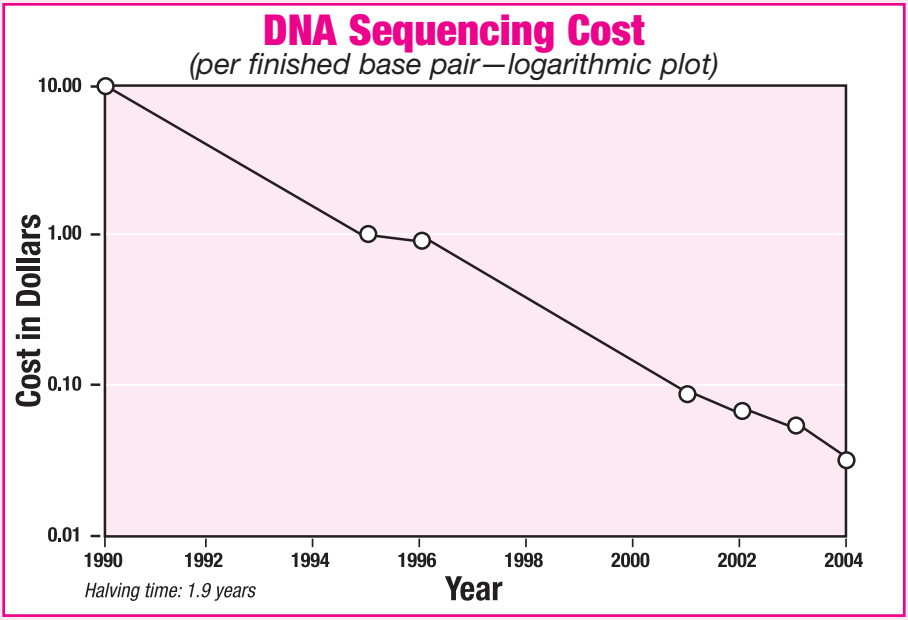
It supports customers who want to buy a sequencing system and use it in their own facilities. These customers gain flexibility, but then face the need to invest in the computing capacity required to work with the data generated by the DNA sequencing systems.

Another company selling whole genome sequences is **Knome, Inc.**, of Cambridge, Massachussetts. In early 2008, when it first launched, Knome and its Chinese partner, **Beijing Genomics Institute**, would sequence any individual's genome for $350,000. It has since lowered that price to $98,000.

Cost to Sequence a Base Pair of DNA

Just as Moore's Law has accurately predicted the price and computing power of computer chips for the past 30 years, a similar exponential dynamic can be seen in the regular decline in the cost to sequence a DNA base pair. The chart below demonstrates how the cost of a sequenced base pair declined from $10 in 1990 to under a dollar in 2004.

Currently, **Knome, Inc.**, will sequence an entire 3-billion-base-pair genome for $100,000. That represents a cost per base pair that is just $0.0003 in 2009! This is much cheaper than originally projected by inventor and futurist Al Kurzweil, who believed the 2008 cost would be $0.01 per base pair. With Complete Genome now offering a whole human genome sequence for $20,000, that represents a further 80% reduction in the cost to sequence one base pair.



Source: "The Singularity is Near," Al Kurzweil, 2005

Knome is also offering different sequencing services to the public. In May 2009, it announced a service priced at $24,500 for individuals and $19,500 per member for families. Knome will sequence the genes and provide a customized analysis of the results. With 20,000 human genes, Knome says it is offering a retail price of less than $1 per gene for sequencing and analysis.

Applied Biosystems, Inc. (ABI), a division of Life **Technologies Corporation** of Carlsbad, California, is another contender. Its sequencing systems are strong sellers. Its executives predict steady gains in sequencing speed with comparable reductions in cost per base pair sequenced.

454 Life Sciences is a business unit of **Roche** and is based in Branford, Connecticut. Besides selling its high-throughput DNA sequencing systems, it is also participating in active collaborations with such firms as **Eli Lilly and Company** and **SeqWright**.

Another company keeping pace with the race to the $1,000 whole human genome is **Helicos BioSciences Corporation** of Cambridge, Massachussetts. For third quarter 2009, it reported placing twice the number of its sequencing systems compared to third quarter 2009.

Pacific Biosciences, Inc., of Menlo Park, California, says it will release, in 2010, a high-throughput sequencing system that could enable $100 genome sequencing in 15 minutes in 2013. The company has major support from multiple venture capital companies.

Each of these firms on this short list has declared its intent to achieve a $1,000 whole human genome sequence. Collectively, they represent hundreds of millions of dollars from professional investors. Further, each company has a different technology upon which it is basing its whole genome sequencing systems. This means there is a rather broad range of technologies which may prove viable.

Zeroing In On The Goal

What is notable for the clinical laboratory profession is that the front-runners are declaring that their technology and their sequencing systems will zero in on the $1,000 genome during 2010 or 2011. This is a near-term outcome.

For laboratory managers and pathologists, these developments are a reminder that disruptive technologies are emerging from many sources that are outside the traditional practice of laboratory medicine and pathology. As can be seen with the effort to achieve cheap, fast, and accurate whole human sequencing, success in this endeavor has the potential to overturn or supplant many long-standing technologies common today in the pharmaceutical, laboratory testing, and healthcare industries.

Another aspect of the drive to the $1,000 whole human genome sequence is the importance of information technology (IT) and informatics. Labs working with this data need an IT platform capable of handling the data points generated by the three billion base pairs in a single human genome. It reinforces the need for clinical laboratories and pathology groups to keep current with information technology.

Maybe the greatest surprise that lies ahead is how fast the whole human genome screening market will develop as the cost falls to $1,000 or less. As noted earlier, Complete Genomics is telling Wall Street that it will produce 10,000 whole genome sequences during 2010! This reflects the demand—and the scientific interest—for the knowledge that is currently locked up in the complete human genome. TDR

Institute for Systems Biology Buys from Complete Genomics

ON NOVEMBER 2, 2009, The **Institute for Systems Biology** (ISB) announced that it was contracting with Complete Genomics, Inc., to produce 100 whole genome sequences to support an ISB study of Huntington's Disease.

To study modifiers of the disease presentation and progression, ISB will provide samples to Complete Genomics from individuals affected by Huntington's Disease, family members, and matched controls.

The Institute for Systems Biology is based in Seattle, Washington, and was co-founded in 2000 by three scientists: Leroy Hood, M.D., Ph.D, an immunologist and technologist; Alan Aderem, Ph.D., an immunologist; and, Ruedi Aebersold, Ph.D., a protein chemist. It is devoted to the study of biological complexity and understanding how biological systems function.

Researchers from ISB are working on diagnostic methods that evaluate multiple metabolic pathways to detect pre-symptomatic and complex diseases. Experts believe that the Institute for Systems Biology will introduce diagnostic technologies that will prove disruptive to the current practice of laboratory medicine.

Explaining Certification Versus Accreditation

ISO standards make it important for labs to understand the meaning of each term

CEO SUMMARY: Early signs are that the quality management systems (QMS) most likely to find favor with hospitals and clinical laboratories in the United States will be those that meet standards developed by the International Organization for Standardization (ISO). Many hospitals and clinical labs are considering adopting ISO 9001 or ISO 15189, respectively. As they do, it will be important to understand how the terms "accreditation," "certification," and "registration" are used in the application of standards published by ISO.

In recent years, the United States has seen the first hospitals and laboratories adopt quality management systems such as ISO 9001 and ISO 15189: Medical Laboratories.

This is notable, because it heralds the arrival of quality management systems (QMS) to healthcare and laboratory medicine in the United States. At this time, many pathologists and laboratory managers in this country do not fully understand QMS and what distinguishes a QMS from, say, quality assurance (QA) and quality control (QC)—two activities which take place daily in every laboratory.

Earlier this fall, The Dark Report provided an intelligence briefing about quality management systems. A definition of QMS was provided. ISO 9001 is the world's leading QMS. It is used in many industries, including healthcare. The management system requirements in ISO 15189 are derived from the ISO 9001 QMS. ISO 15189 is designed to be a quality management system specific to the management and operation of clinical laboratories. *(See TDR, October 12, 2009.)*

For those not familiar with ISO QMS, it is common to confuse ISO use of the terms "certification" and "accreditation." That's because, for decades, certification and accreditation have been used in a variety of settings to describe how individuals and organizations qualified under a wide spectrum of academic, legal, and professional requirements.

"When it comes to ISO's quality management standards, the concepts of 'certification' and 'accreditation' need to be understood as described by the International Organization for Standardization (ISO)," stated Dan Tholen, M.S., an independent consultant in statistical methods who is based in Traverse City, Michigan.

Global Experience

A consultant who has worked for a variety national and international standards development organizations, Tholen is an expert in applying quality management and accreditation standards to testing and calibration labs, proficiency testing providers, and reference material produc-

ers in the United States and other countries worldwide.

In an interview with THE DARK REPORT, Tholen explained that most pathologists and lab directors in the United States do not understand the distinctions between accreditation and certification as defined in ISO standards. Additionally, most medical laboratory professionals in the United States don't yet fully appreciate the benefits of having a functioning quality management system implemented in their laboratory.

"The growing acceptance of QMS in healthcare signals that a profound new paradigm is poised to transform long-standing practices in healthcare and clinical laboratories," observed Tholen. "Any laboratory organization that truly embraces and implements a well-designed QMS will see everything through a different perspective—and will operate in a fundamentally different manner.

Certification To ISO 9001

"Let's set that aside for a moment and discuss the difference between certification and accreditation—as used in the context of implementing an ISO quality management system," said Tholen. "I will also briefly discuss 'registration.'

"First is certification," he stated. "ISO 9001 is a QMS standard designed to be universal and useful in almost any industry. However, ISO does not specify a means of recognition of compliance with the requirements. An organization has three ways to comply: it may simply declare compliance (first party declaration), or the organization's customers may accept compliance (second party recognition), or, the organization can seek recognition by an organization (third party certification).

"Third party certification of compliance is usually done by an organization that is accredited to meet the requirements of ISO 17021 as determined under the procedures developed by the **International Accreditation Forum** (IAF)," added Tholen.

"A comment about the accrediting bodies which issue certifications of compliance with ISO 9001 and the related ISO QMS standards," continued Tholen. "IAF has a Memorandum of Understanding with ISO for certifying compliance with the range of ISO management system standards (all of which contain the same basic elements of ISO 9001).

"In the United States, the IAF member is the **American National Accreditation Board** (ANAB), which is a cooperation between the **American National Standards Institute** (ANSI) and the **American Society for Quality** (AQC).

"ANAB currently accredits 46 organizations to offer certificates of compliance with ISO 9001 and other ISO management system standards," he explained. "In addition, ANAB recognizes accreditation by all other IAF members, so accredited organizations from other countries may provide certification in the United States.

"Next is the term 'registration,'" continued Tholen. "ISO itself states that, in the context of ISO 9001, there is not much difference in the use of the words 'certification' and 'registration'," he added. "The words are used interchangeably. Certification is the preferred term globally, while in North America and a few other countries, registration is often used.

Defining Accreditation

"That leaves accreditation," he commented. "The ISO draws an important distinction for this term. Lab managers and pathologists should understand the precise meaning of accreditation and the role it plays in the relationship between ISO, IAF, and the **International Laboratory Accreditation Cooperation** (ILAC). ILAC is a separate organization of accreditation bodies, specifically for accreditation of laboratories, including their QMS. Accreditation by members of ILAC signifies a demonstration of *competence* for specific activities, according to other standards, in addition to complying with ISO 9001 QMS.

Accreditation versus Certification: Understanding The Differences in How ISO Defines the Terms

COPYRIGHT PREVENTS DIRECT QUOTATION of ISO definitions, but they can be rephrased for testing laboratories. The following information was paraphrased by Dan Tholen from "ISO/IEC 17000:2004 Conformity Assessment—Vocabulary and General Principles."

This standard is the responsibility of the ISO **Committee on Conformity Assessment** (ISO CASCO), on which Tholen serves as a member. The terms and definitions below all cascade from "conformity assessment," which was first coined for this purpose by the U.S. **National Bureau of Standards** (NBS—now the **National Institute of Standards and Technology**, or NIST). Tholen points out that the extremely delicate distinction between conformity assessment and accreditation is the product of many years of debate and negotiation within ISO.

- **"Conformity Assessment"** is an activity to demonstrate that a stated need or expectation is met, related to a particular object. Certification and laboratory testing are both considered to be conformity assessment activities, but accreditation is not.
- **"Conformity Assessment Body"** is any organization conducting conformity assessment activity. The definition specifically excludes accreditation bodies. This includes testing laboratories, inspection bodies, and certification bodies.
- **"Object of Conformity Assessment"** includes any "material, product, installation, process, system, person or body" that can be assessed for conformity. It can include any organization that is not a conformity assessment body. Laboratory patient samples are objects of conformity assessment, but the laboratory is not.
- **"Certification"** is a third party statement that an object of conformity assessment meets specified requirements. This has to be the result of a review. The definition notes that this is sometimes called "registration," but there is no definition for "registration" in ISO/IEC 17000.
- **"Accreditation"** is a third party statement that a conformity assessment body has demonstrated competence to carry out specific conformity assessment activities.
- **"Accreditation Body"** is an authoritative body that provides accreditation; with its authority usually coming from government.

"'Certification' signifies only that an organization has a QMS in place that conforms to the ISO 9001 standard," said Tholen. "There are no requirements for technical competence. Accreditation affirms a laboratory's competence in addition to the QMS. This is why testing laboratories should be recognized as 'accredited' and not as 'certified."

The objective of this intelligence briefing is to help pathologists and lab managers develop an appropriate road map for their laboratory's strategy concerning adoption of a quality management system.

Having introduced clients and regular readers of THE DARK REPORT to a description of quality management systems and the basic definitions of certification, registration, and accreditation, an upcoming issue will provide a detailed overview of the accreditation process as it applies to testing labs (including medical laboratories). TDR

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CEO SUMMARY: Every health reform proposal makes it a high priority to implement a universal electronic medical record (EHR). Because lab test data is the essential component of a successful EHR, laboratory managers and pathologists may soon have a once-in-a-lifetime opportunity to use EHR implementation to boost the value to lab testing services. This is exactly what the laboratory at Geisinger Health has achieved in the 15 years since the system first implemented its integrated EHR solution.

Integrated EHR allows clinicians to use lab test data to greater effect

Geisinger's Use of EHR Creates Opportunity for Lab to Add Value

ONE ELEMENT that is common to every healthcare reform proposal is rapid adoption of a universal electronic health record (EHR). All stakeholders in healthcare seem to agree that implementation of a universal EHR will trigger substantial benefits.

Laboratory test data represents the largest single component of the average patient's health record. Therefore, widespread adoption of EHRs will be both a threat and an opportunity for clinical laboratories and pathology groups.

With recent passage of a major health reform bill in the House, and with the Senate now debating its own version, lab executives and pathologists should be ready for a time of accelerated EHR deployment and implementation. Since lab test data underpins an effective EHR system, labs must get it right the first time.

For inspiration, laboratory professionals can look to the experience of the laboratory at **Geisinger Health System**. For more than 15 years, it has supported what many experts consider to be one of the nation's most successful deployments of EHR within a large, integrated health system. It was 1994 when Geisinger, based in Danville, Pennsylvania, introduced its first EHR system.

Founded in 1915, the Geisinger Health System serves some 2.6 million residents in central and northeastern Pennsylvania. Geisinger also runs the Geisinger Health Plan, which has 212,000 members.

Employing 11,000 full-time equivalent employees, the Geisinger Health System is one of the nation's largest health systems. Similar in structure to the **Mayo Clinic**, Geisinger has 45 practice sites in 31 counties in Pennsylvania, along with 700 physicians in a closed staff-model group practice. It owns two hospitals. One is **Geisinger Medical Center**, a 422-bed tertiary hospital in Danville, and the other is 242-bed **Geisinger Wyoming Valley Medical Center** in Wilkes-Barre.

Geisinger's laboratory services are fully integrated across all inpatient, outpatient, and outreach environments. The laboratory performs about 4.9 million tests per year. Around 5.6% of this volume is outreach testing.

"That was the year that Geisinger began rolling out an electronic health record system in all its hospitals and physicians' offices throughout central and eastern Pennsylvania," stated Jay B. Jones, Ph.D., Director of Chemistry & Health Group Labs for Geisinger. "From the very first days of EHR use, our lab has delivered robust and complete lab test data into the Geisinger EHR." Jones was speaking at the *Executive War College* in New Orleans earlier this year.

"Over these 15 years, Geisinger has spent about $80 million building and upgrading our EHR," noted Jones. "From the start, the EHR has been a core tool to improve clinical effectiveness. And, at the heart of that EHR system is laboratory test data."

Lab Recognized Opportunity

"From the start, our laboratory considered the EHR to be an opportunity," recalled Jones. "The key to understanding this opportunity lies in the fact that Geisinger is an integrated health system. During the past two decades, our health system has actively consolidated and integrated our healthcare continuum.

"For example, at one time, we had 75 smaller practices," he said. "Today, these smaller groups are being brought together into hub sites. As a consequence, our centralized clinics increasingly have between 20 and 40 multi-specialty physicians practicing in outpatient settings.

"Back in 1994, our first **Epic** EHR was initially deployed in the outpatient areas," said Jones. "In the second phase, the EHR was implemented in inpatient services. Geisinger now has what is essentially a paperless inpatient and outpatient environment throughout the health system. It must be emphasized that the laboratory is at the

core of this EHR system. The EHR would not function to its full potential without that laboratory component.

"To make the concept of integrated care work across the inpatient, outpatient, and outreach environments, it is essential that the clinical data needed by physicians and caregivers be available at the point of care," added Jones. "That requires all our laboratory facilities to be linked in ways that allow us to collect lab data from patients anywhere it is generated, feed it into our LIS, and use this data to populate the EHR in real time.

"We've learned lots of lessons on how the clinical laboratory should properly support a system-wide EHR," he explained. "The first goal back in the 1990s was to reduce variability of laboratory test results at all testing locations. During that time, we worked hard to standardize testing at all hospital and clinic sites and make sure that the lab test data generated at every testing site came into our LIS. Consolidation of laboratory testing was another strategy we used to help standardize testing across our integrated health system.

Capturing All POCT Results

"After the consolidation and standardization phase was completed, our next strategic lab goal was to support the EHR's effectiveness by capturing all point of care (POC) test results and ensuring these results were part of a complete patient lab test record in our LIS," continued Jones. "This project took place between 2000 and 2002. Today, across the many POC testing sites within the Geisinger system, our LIS captures nearly all those test results—mostly in real time and without manual input of the data.

"Keep in mind that, to support the effective EHR used in our integrated care continuum,' he added, "our LIS needed to capture all this standardized lab test data and create a well-defined and traceable clinical archive. Not only has that been achieved, but our lab now has a data base of lab test information reaching back more than a decade. This lab data repository now supports serial population outcomes studies and similar clinical research.

Integrating Care

"As our laboratory gained experience in supporting the EHR and working with it, we identified another opportunity to add value," commented Jones. "Once the EHR was installed, we quickly recognized that it could be used for more than clinical documentation. Because we can access all the data from every patient encounter through the EHR, it became a great enabler for improving clinical effectiveness. We describe this activity as 'enterprise analytics.'

"The goal of having an enterprise analytics system is to collect and store data on all the lab testing that we do across the entire enterprise," observed Jones. "This includes at the point of care, in the core lab, in the rapid response labs, and in our outpatient clinics. At the same time, the objective is to reduce variability in laboratory test results.

"Regardless of where a lab test is performed in the care continuum, we capture that data and maintain a well-defined and traceable clinical archive in our LIS," he added. "That enables us to fulfill the primary mission of our integrated health system: each time a patient comes to the Geisinger system, he/she gets accurate and prompt test results for that encounter.

Using Lab Data To Add Value

"However, our laboratory wants to do more than that," he said. "We want add additional value to the system. We believe it is also a responsibility of the laboratory to archive that data so that it can be used to practice population medicine.

"This is where the EHR plays another role for us in the laboratory," noted Jones. "Efforts are underway to develop a hybrid system within Geisinger Health. One ele-

ment is to do what most health plans and hospitals do: deliver the best care for each individual encounter with a rapid response time.

"The second element is what sets Geisinger apart and what challenges our laboratory to find additional ways to add value: we aim to be the gold standard for population studies," he explained. "That requires us to produce lab test data in a form that makes it useful for population studies, as well as to improve our clinical effectiveness.

Scaleable Analyzer Solutions

"One way our laboratory pursues this goal is to install scaleable analytical platforms," stated Jones. "We've asked our vendors for chemistry and immunology instrumentation to deliver systems that fit both our smaller rapid response labs and our core lab. Similarly, we use the same reagent system throughout our laboratory organization, along with the same test codes, and the same reference ranges. All these elements are standardized through the LIS.

"Again, much of this standardization was driven by the need to properly support the use of the EHR while at the same time producing a complete data base of lab test results," he explained.

"An early step was to standardize test codes in the LIS," commented Jones. "Within our system, a blood glucose test is the same regardless of what instrument or which location performed the test. This happens because our lab runs identical reagents on platforms that are from the same vendor.

"In turn, having the same method codes, reference ranges, and critical limits supports standardization of results across 23 different lab testing sites within Geisinger Health," he added. "This standardization of laboratory testing had another benefit for our parent health system.

"Many people are aware that, since 2005, Geisinger has been one of 10 pilot sites for the Medicare Physician Pay-for-Performance (P4P) Demonstration project," noted Jones. "Our standardized and complete lab test data for patients, fed into the EHR in real time, played an essential role in supporting documented improvements in patient outcomes. Accordingly, Geisinger has done quite well with this pay-for-performance demonstration." *(See TDR, February 14, 2005.)*

It is this functional, deployed EHR which allows the Geisinger laboratory to regularly identify new opportunities to add value and advance clinical care. That helps Geisinger to be well-positioned as long-discussed healthcare reforms finally take place.

"However it happens, the coming major reforms in healthcare are going to ask a lot of clinical laboratories," predicted Jones. "One specific aspect will be supporting the added volume of testing that results from universal healthcare, which creates the need to serve large numbers of newly-insured patients.

> ***"Our standardized and complete lab test data for patients, fed into the EHR in real time, played an essential role in supporting documented improvements in patient outcomes."***

"Think about the increased volume of tests for cholesterol, PSA screening, and other assays required to support early detection, active intervention, and effective patient monitoring across the entire population of the United States.

"We think our lab's experience with the Geisinger EHR and the Medicare P4P program provides a window into how laboratories will operate in the future," said Jones. "It takes the laboratory down the road of practicing population medicine and using practice parameters to deliver best practice medicine.

"Both concepts are elements of what our doctors call 'Proven Care'," explained Jones. "This is the name we gave to our focus on delivering the best patient care.

"Since Proven Care was instituted at Geisinger, the data collected demonstrates that our physicians deliver better and more effective care," he noted. "This is validated by measurable improvements in patient outcomes at Geisinger Health.

Numbers Tell The Tale

"The numbers tell the tale," continued Jones. "Since the start of Proven Care, Geisinger's 30-day readmission rate after cardiac surgery has dropped 44%. The rate of patients with any complications dropped 21%, while our rate of re-operations for bleeding dropped 55%! If you are a patient, these improvements in outcomes are both welcome and help to distinguish Geisinger as a source of excellent care.

"To be more specific, diabetes provides a good example of how Proven Care works at Geisinger," he explained. "It also illustrates how the EHR can cue the laboratory as to new ways to add value to clinical services.

"A team of clinicians developed practice parameters and best practice alerts to be associated with diabetes," commented Jones. "The laboratory provided input to this team. These practice parameters and best practice alerts were then embedded into the EHR. This allowed all our doctors to get these alerts on their screens whenever they see a patient coded for diabetes.

"Geisinger's EHR has the ability to guide the physician on how to order 'smart tests'," noted Jones. "These are combinations of tests that match best practices for patients with diabetes. The EHR also supports the use of pre-filled referrals. These are used if a patient with diabetes needs to be referred to the smoking cessation clinic, for example.

"The 'smart tests' feature is unique," he said. "When the physician sees a patient with diabetes, the EHR presents a pop-up box," stated Jones. "This pop-up box says, 'Diagnosis of diabetes mellitus.' Next, it lists the tests needed: 'Hemoglobin A1c every six months (the standard is get each patient's number to below 7%); microalbumin every 12 months; and, LDL every 12 months.'

"If the doctor clicks the box once, all those lab test orders automatically flow into the EHR, which immediately transmits these test orders to the laboratory," he commented. "Physicians don't need to click around on the computer to look for the various orders to put into the EHR. Everything is summarized for them.

"Similarly, it's just a click away to order their medications and other diagnostic tests in the EHR system," he observed. "This makes our EHR not just an efficient practice tool, but also a quality practice tool.

"Our pathologists and lab scientists can use the EHR to view the patient visit summaries," he added. "They can also access the decision support information provided to physicians and the patient-specific and disease-specific summary screens. All this information allows us to drill down to see how we are doing collectively in managing the 20,000 patients with diabetes in the Geisinger system.

Improved Patient Scores

"As a result of all these steps, we have improved patient care, supported by measurable results," he recounted. "We know, for example, that from January 2006 to the middle of 2006, the percentage of patients with diabetes that hit the 7% hemoglobin A1c target rose from 28% of all patients to 33%. That's an improvement of 5%.

"Because of this improvement in patient test scores, Geisinger expects its diabetes patients to have fewer eye problems, fewer foot problems, and potentially fewer amputations," he said. "In turn, given the Medicare program's focus on P4P and efficiency, we are confident that

How Medicare's Pay-for-Performance Demo Motivates and Incentivizes Physicians

USE OF THE ELECTRONIC HEALTH RECORD (EHR) system at Geisinger Health System is one tool to improve patient outcomes. Another aspect is the financial incentives that are related to the Medicare Pay-for-Performance Demonstration that has been under way at Geisinger since 2005.

"As it is organized at Geisinger Health, our physicians have a financial incentive to follow the best practice alerts that are part of the EHR system," observed Jay B. Jones, Ph.D., Director of Chemistry & Health Group Labs at Geisinger. "The incentive puts 20% of each doctor's salary at risk. If they practice according to best practice alerts they win back that 20%. Therefore, being compliant with best practices is a pocketbook issue for them.

"Here's how it works," Jones explained. "In 2005, CMS wanted to incentivize health care systems like ours to get diabetes under control." Medicare gave us practice parameters derived from national guidelines. One parameter involved getting hemoglobin A1c levels down under 7% for 90% of our patients with diabetes. Another goal was to collect urine albumin levels for these patients every year. For patients with hypertension, the Medicare P4P program wanted patients to achieve certain cholesterol levels.

"Data from our EHR told us that we had 20,000 patients with a diagnosis of diabetes," he continued. "That would require us, as a participant in the P4P demonstration, to provide lab values and other data on those patients to the government. Because of our earlier standardization and the implementation of an integrated EHR throughout our health system, we already had everything in place to demonstrate improved patient outcomes. That is just one way that these investments are paying off for our laboratory and the parent health system today."

we are doing the right thing and having the right impact."

Jones may be understating things on that point. Geisinger Health is so confident that it can deliver high quality care that it has offered a warranty to patients related to errors. For example, if a coronary bypass patient develops an infection, neither that patient nor the health plan will need to pay for care related to the infection. These warranties are advertised to the public in a variety of ways.

This public "stake in the ground" to stand behind the quality of its clinical services is more evidence of how the integration of its EHR across inpatient, outpatient, and outreach settings is paying dividends. It is this type of innovation that shows the true path to worthwhile reforms of the American healthcare system.

Moreover, the accomplishments of the Geisinger laboratory, as shared here by Jones, provide inspiration and a road map for all laboratory administrators and pathologists who want to help their laboratory organization develop into an innovative source of clinical value.

In particular, for those laboratories in hospitals and healthcare systems yet to implement a fully-integrated EHR, the approaches used by the Geisinger lab to advance clinical care and support improved patient outcomes demonstrate why it is important for the laboratory to embrace the implementation of an effective EHR. An integrated EHR actually becomes an enabler for labs to step up and offer physicians innovative ways to add value. **TDR**

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Molecular Update

"Liked the Product–Bought the Company," BD Acquires HandyLab and Jaguar System

IT WAS 1979 WHEN VICTOR KIAM jump-started sales of Remington electric razors with his classic, witty ad campaign, "I liked the product so much, I bought the company!" Now the same thing is happening with a benchtop-sized automated system for molecular PCR testing.

In this case, it is **Becton Dickenson and Company** (BD) which liked **HandyLab, Inc.'s** Jaguar Automated PCR System so much that it bought the company. BD announced the agreement to acquire HandyLab, of Ann Arbor, Michigan, on October 23, 2009.

This acquisition came only five months after HandyLab and BD announced a deal where BD would private label the HandyLab Jaguar system. BD began selling the Jaguar system to its lab customers under the name "BD MAX." It used the BD MAX system as a way to automate its BD GeneOhm menu of molecular tests used to detect major pathogens associated with healthcare-associated infections (HAIs).

Need For More Education

For pathologists and lab administrators tracking developments in the molecular testing marketplace, the BD-HandyLab relationship has several useful insights. One is that smaller companies may be able to develop innovative molecular assays and automated molecular testing systems, but the sizeable resources and sales effort required to achieve profitable market share often exceed the capability of young companies with limited funds.

HandyLab's Jaguar system was considered to be a robust solution for automating real-time PCR testing, including specimen prep, amplification, and extraction. As an open system, it was designed to be an attractive solution that community hospital labs could use to automate molecular tests that were being performed manually.

BD recognized that HandyLab's Jaguar system was a robust solution for such hospital lab customers. "As hospital screening and testing programs expand, they will require flexible, state-of-the-art automation systems like BD MAX [formerly the HandyLab Jaguar] to support their evolving needs," said Colleen T. White, Director of Corporate Communications at BD. "In particular, it provides us with the industry's best automation platform for molecular diagnostics to support our BD GeneOhm platform. The flexibility of this novel platform will allow further expansion of the BD molecular diagnostic menu."

The acquisition of HandyLab by BD also continues the trend of consolidation among *in vitro* diagnostics (IVD) companies. Because of scale and substantial resources, the billion-dollar IVD giants are in a position to buy promising molecular assays and testing systems, then support them with a substantial marketing program.

In fact, the GeneOhm assays that BD now runs on the BD Max/Jaguar automated system were acquired by BD in just this fashion. It was January 2006, when BD announced an agreement to buy **GeneOhm Sciences, Inc.**, of San Diego, California.

Thus, the BD Max, running GeneOhm assays, represents a molecular product line developed by two smaller, emerging biotech companies, each of which was then acquired by BD. TDR

Health IT Update

Xerox, Dell, and Hewlett-Packard Each Buy Into IT Outsourcing Market

Growth opportunities are expected in outsourcing of information technology services to providers

IN RECENT WEEKS, TWO BIG PLAYERS spent billions to buy seats at the healthcare information technology (IT) table. Just one week apart, **Xerox Corporation** and **Dell, Inc.**, acquired **Affiliated Computer Services, Inc.**, and **Perot Systems Corp.**, respectively.

This rash of transactions is noteworthy for several reasons. One, it continues a trend of consolidation within the IT industry. Two, it also continues a trend of major IT companies using acquisitions as a way to enter the healthcare IT market. Third, it sends a strong signal that clinical labs and pathology groups should have a proactive strategy for health informatics within their organizations.

It was September 28 when Xerox announced an agreement to acquire Affiliated Computer Services, Inc., for a price of $6.4 billion. Affiliated Computer Services has annual revenue of $6.5 billion. It offers information technology outsourcing services to industries that include healthcare, telecommunications, education, and transportation.

Just days earlier, on September 21, Dell Corporation and Perot Systems Corp. jointly announced that Dell would purchase Perot Systems for $3.9 billion. This was a big deal in the healthcare informatics sector, because Perot Systems holds a major share of the outsourcing market in this IT sector.

"If you look at the outsourcing business in healthcare, Perot seems to own the market," observed Mike Smith, General Manager of Financial and Services Research at **KLAS**, a health informatics research firm based in Orem, Utah. According to *Modern Healthcare*, of the hospitals in the United States that outsource their IT, roughly half are clients of Perot Systems. Perot Systems reported a 2008 net income of almost $2.8 billion. Nearly half of that was from its healthcare operations.

Dell, Xerox, Hewlett-Packard

It is significant that both Xerox and Dell bought their way into the health informatics sector. It was just last year when **Hewlett-Packard Co.** did its own acquisition of a billion-dollar IT outsourcing company that holds a significant share of the market for health IT services.

In May, 2008, Hewlett-Packard acquired **Electronic Data Systems** (E.D.S.), which is another Texas-based healthcare IT entity founded by Ross Perot. It paid $13.9 billion for E.D.S., which had annual revenues of $22 billion at the time of the acquisition announcement. E.D.S. is a major IT outsourcing vendor. It manages more than 100 data centers worldwide and has an active healthcare business.

Collectively, Xerox, Dell, and Hewlett-Packard spent $24.2 billion to acquire large IT companies which each hold sizeable market shares in the healthcare IT outsourcing sector. It is significant when three major Fortune 500 companies decide to enter the information technology outsourcing business within weeks and months of each other.

And they are not the only major corporate players trolling for opportunities to buy their way into the health IT sector. Just a few weeks ago, on October 22, **General Electric Co.**, announced the launch of its new $250 million fund to invest in healthcare technologies. This is part of GE's "Healthymagination" initiative to invest $6 billion by 2015 to develop and introduce technologies with the potential to transform healthcare.

GE's new fund is targeting three broad areas of health for investment. One is healthcare information technology, including electronic medical records, clinical information systems, healthcare information exchanges, and value-added data services. The other two investment areas are diagnostics and life sciences.

Strategic Insights

For pathologists and clinical laboratory managers, these various developments provide several useful strategic insights. First, the fact that Xerox, Dell, and Hewlett-Packard ponied up billions of dollars to acquire businesses that are among the leaders in IT outsourcing services indicates their confidence that IT outsourcing will be a high-growth sector in coming years.

This has interesting implications for hospital laboratories and pathology groups that service community hospitals. Should more hospitals and health systems decide to outsource their IT to third party companies, this will require laboratories and pathology groups to be ready for the consequences of these arrangements. Labs and pathology groups should understand what is needed to deal with an outside vendor running their hospital's IT services.

Second, the outsourcing businesses acquired by Xerox, Dell, and Hewlett-Packard have customers across many industries besides healthcare. This is a reminder to pathologists and clinical lab directors that technology adoption outside of healthcare tends to move much faster than within healthcare. Thus, any lab or pathology group that wants to implement a proactive informatics strategy would do well to study IT outsourcing innovations outside healthcare. That will give them a head start at understanding how health systems, hospitals, and physicians are likely to utilize IT outsourcing arrangements.

Dell's Perot Systems Is Major VistA IT Source

PERHAPS THE BIGGEST UNKNOWN regarding Dell, Inc.'s acquisition of Perot Systems Corp. will be its impact on the evolving market for open-source healthcare IT. In the United States, the primary open source product is the VistA IT system, developed for clinicians by the **Veterans Affairs Department**.

"Dell is going to be inheriting one of the top three corporate pools of VistA knowledge in the country; **DSS, Inc.,** and **Medsphere Systems Corporation** being the other two," stated Fred Trotter, founder of Houston's **Liberty Medical Software Foundation**. "The question is: Does Dell recognize what it's got, and does it plan to pursue an open-source strategy?"

Cloud Computing

Each of the acquisitions done by Xerox, Dell, and Hewlett-Packard affirm another trend: cloud computing. This is the provision of informatics services over the Internet as a utility.

New technologies are making it feasible to manage ever-larger data centers at reduced cost. In turn, that makes it possible for major corporations to save substantial amounts of money by migrating their in-house IT structure to an outsourcing arrangement based on cloud computing.

Examples of clinical labs and pathology groups using cloud computing are still uncommon today. However, that may change in the next 24 months. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Identity theft was a key part of a financial fraud that Adeniyi Adeyemi, 27, used to steal approximately $1 mllion from accounts belonging to 11 not-for-profits and trusts. Among the victims was the **American Association of Clinical Chemistry** (AACC). Adeyemi was a computer technician at the **Bank of New York Mellon**. The Manhattan District Attorney's office indicted Adeyemi on 149 criminal counts, alleging he ran the fraud between 2001 and April 2009. The crimes include grand larceny, identity theft, money laundering, scheme to defraud, computer tampering, and unlawful possession of personal identification information.

MORE ON: *Fraud*

The criminal complaint states that Adeyemi stole the identities of more than 150 of his coworkers. He used this information to open brokerage accounts under these names. Next, using his access as a computer tech, Adeyemi stole money from the accounts of the 12 trusts and and not-for-profit organizations. Officials from the DA's office noted that, because such organizations often make their bank account information available online to facilitate donations, that probably made it easier for Adeyemi to access the bank accounts of charities and non-profits. This crime is reminder that lab administrators and pathologists should have protections in place that restrict access to confidential information, including bank account numbers and passwords.

TRANSITIONS

• **Aperio Technologies, Inc.**, of Vista, California, hired Jared N. Schwartz, M.D., Ph.D., to be its Chief Medical Officer. Schwartz was Director of Pathology and Laboratory Medicine at **Presybterian Healthcare** in Charlotte, North Carolina, and is immediate past president of the **College of American Pathologists**.

• There's a new Laboratory Executive Director at **The Joint Commission**. Jennifer F. Rhamy, MBA, MA, MT (ASCP), was appointed to the position. Rhamy was formerly Vice President of Laboratory Services for the **Indiana Blood Center** in Indianapolis, Indiana. She holds a certification in Lean Six Sigma.

• Kenneth A. Berlin became the new President and CEO of **Rosetta Genomics Ltd**, earlier this month. Berlin came to Rosetta from **Johnson & Johnson**, where he held a number of positions over the past 15 years. Most recently he was General Manager of J&J's **Veridex** division.

• Russell Duke, formerly CEO of **TriCore Laboratories** of Albuquerque, New Mexico, died in his home in Dallas, Texas, on November 1, 2009.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...why most clinical laboratories and pathology groups still lack an effective succession plan, even as the first wave of Baby Boomer lab managers are setting their retirement dates.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 14, 2009.