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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

When Should Labs Become 'Patient-centric?'

AS THE AMERICAN HEALTHCARE SYSTEM MOVES FORWARD with its transformation, several trends make it advisable that clinical labs and pathology groups consider the importance of becoming "patient-centric."

First, patients are being incentivized to become price shoppers and select their providers—including laboratories—on the basis of price and quality.

Second, more patients have insurance with high deductibles and substantial out-of-pocket requirements. This means that all providers—including laboratories—must be able to collect this money directly from the patient.

Third, in an integrated care environment, like an accountable care organization, every provider—including laboratories—must be able to identify and track individual patients as they receive healthcare services at various sites.

The three trends listed above are just for starters. My point is that our healthcare system is in the midst of a transition that makes it essential that a provider can accurately identify an individual patient, then deliver personalized care services that are tailored expressly to the needs of that patient. Accurate patient identification in real time is also essential if the provider is to collect payment from the patient at the time of service.

To date, only a small number of laboratory organizations have made the substantial investment required to create an enterprise-wide master patient index (EMPI). Even fewer labs have then added the additional informatics capabilities needed to deliver patient-centric services in real time.

Credit should be given to **Pathology Associates Medical Laboratories** (PAML) in Spokane, Washington, and **Sonora Quest Laboratories** (SQL) in Phoenix, Arizona. Each lab was among the first in the nation to put both an EMPI and supporting informatics services into place. Today, each lab has millions of patients in their respective EMPIs, along with hundreds of millions of lab test results for these same patients.

On pages 11-14, we interviewed the CIO of SQL about his lab's EMPI. You will find it enlightening as to how changes in clinical care are making it essential that a lab not just track requisitions by the ordering physician (a physician-centric service), but also by the individual patient. His insights will help you understand why an EMPI for your own lab makes it easier to deliver more value. TDR

Genetic Testing Creates New Legal Risks for Labs

In just two cases of 'wrongful' birth, juries awarded $28 million and $50 million to defendants

CEO SUMMARY: Last month, in Seattle, Washington, a jury ordered Laboratory Corporation of America and Valley Medical Center each to pay $25 million following a lawsuit about a 'wrongful' birth. At issue was how genetic tests were ordered, performed, and reported. This court case is the latest example of the heightened legal risk labs face when performing molecular diagnostic and genetic tests. Lab directors may want to update liability coverage and review their lab's workflow and gene testing policies.

EVERY NEW TECHNOLOGY comes with its own risk factors. That is certainly true for genetic testing. Recent court cases demonstrate the substantial legal exposure labs have when performing genetic testing.

How about a laboratory and a hospital that were just ordered to pay $50 million after a jury trial involving alleged errors in genetic testing? As a consequence, a child with severe disabilities was born to the Wuth family of Seattle, Washington. We provide an interview with the plaintiff's lawyer and full details of this important court decision on pages 5-8 of this issue.

The Tineo case has many of the same issues. In New Jersey, following the birth of a child with myotubular myopathy, the mother, Wanda Tineo, filed a lawsuit that was resolved in 2007. This case also dealt with errors involved in genetic testing and resulted in a jury award of $28 million. Found liable were the physician, the pathologist who directed the cytogenetics laboratory, and the lab company that performed the genetic testing. *(See TDR, June 25, 2007).*

In the Tineo case, a settlement agreement lowered the final settlement amount to $18 million. Half was paid by the physician, Aldo Khoury, M.D., and the other half was paid by **Laboratory Corporation of America**. In the original jury award, LabCorp's cytology lab director, James Tepperberg, M.D., was held liable for 10% of the amount, or $2.8 million.

In the Wuth case, the defendants were **Dynacare Laboratories Inc.**, a subsidiary of Laboratory Corporation of America; **Valley Medical Center** in Renton, Washington; and perinatologist James

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Harding, M.D. The jury excluded Harding from the settlement and ordered LabCorp and Valley Medical Center each to pay $25 million. The defendants are expected to appeal.

Huge Legal Awards

What should be considered here is the amount of the award in each case, $50 million in the Wuth case and $28 million in the Tineo case. These legal cases involving genetic testing gone wrong represent a much higher risk to laboratories than the more typical malpractice cases involving Pap smear testing or cancer misdiagnoses.

Also, these two cases involving errors in genetic testing got enough news coverage to come to the attention of THE DARK REPORT. There are other cases of genetic testing errors now winding through the court system that may similarly produce very large jury awards, possibly in the tens of millions of dollars.

Given these developments in the legal system, it would be timely for laboratories that offer molecular and genetic tests to review the legal risks associated with this type of diagnostic testing. At the same time, a review of the lab's liability coverage and malpractice insurance should also be done as part of a risk assessment process.

Design Of Internal Processes

Such a risk review should include the role of the pathologist in the lab test workflow. In the Tineo case, which settled in 2007, the plaintiffs named the pathologist who was medical director of the cytogenetics laboratory as a defendant. At question during the trial was the internal procedures the lab used and whether the cytogenetics lab medical director had followed them properly.

Both of these cases with large jury awards highlight another area that molecular and genetic tests labs should review. It is workflow and whether existing policies, procedures, and protocols have kept pace with the advances in diagnostic technology. A careful reading of the Wuth and Tineo court documents reveals that gaps existed in the work procedures the labs used when ordering the genetic tests, performing the tests, and reporting the results.

The juries in both cases learned about these gaps and how they contributed to the errors which led to an inaccurate genetic test result being reported to the ordering physicians. Every laboratory should use these $50 million and $28 million jury awards as motivation to improve their internal work processes and management checks and balances that apply to genetic testing.

Process Improvement

On this point, labs that use Lean, Six Sigma, and other process improvement methods have a head start in fixing these sources of legal exposure and malpractice risk—while also improving patient safety. One goal of these management methods is for labs to design a "system of prevention" in which each process in the workflow is designed to produce perfect work and perform at a Six Sigma level of 3.4 defects per million events.

Finally, another interesting area of genetic testing that has yet to be rigorously tested by the court system is the clinical standard of care. As the **23andMe** battle with the FDA has demonstrated, the public is learning that different labs look at different gene sequences when evaluating an individual's risk for the same disease. What happens when malpractice lawyers get into this evolving area of gene testing and genetic medicine?

Meanwhile, all labs have the time to fix internal problems associated with the handling and genetic testing of specimens. The goal is to eliminate the clerical, workflow, and procedural errors that, during the Wuth and Tineo pregnancies, led those parents to make a decision about their unborn children, with the result that a wrongful birth occurred and an expensive lawsuit was initiated. TDR

Hospital and LabCorp Hit with $50 Million Verdict

Lawyer cites series of errors in ordering of genetic lab tests and in lab testing procedures

CEO SUMMARY: In King County Superior Court, a jury found that Valley Medical Center in Renton, Washington, and Dynacare Laboratories Inc., a subsidiary of Laboratory Corporation of America, were each 50% responsible in the case of a wrongful birth. A child born with a genetic abnormality now needs care around the clock for the rest of his life, court records show. The family's lawyer said that medical professionals involved failed to request additional genetic testing or to ask for more information.

LAWYERS CALL IT A 'WRONGFUL BIRTH.' When no one spots an error in prenatal genetic testing processes, a wrongful birth can result, and that's what happened in a case that ended last month with a jury award of $50 million to a family in Burien, Washington.

Defendants **Valley Medical Center** in Renton, Washington, and **Dynacare Laboratories Inc.**, a subsidiary of **Laboratory Corporation of America**, in Burlington, North Carolina, were each ordered to pay 50% of the $50 million award. The jury excluded a third defendant, obstetrician and perinatologist James Harding, M.D., from paying any part of the settlement to the family.

The case is an example of the substantial legal risks pathologists and medical laboratories face as they perform genetic testing and provide interpretations of the results.

"At the heart of this case is a series of errors that began at the Valley Medical Center and continued at Dynacare Laboratories," stated Todd W. Gardner, the personal injury lawyer with **Swanson Gardner**. He represented the plaintiffs in this case who were the child, Oliver L. Wuth and his parents, Brock and Rhea Wuth.

"Any one of many medical professionals might have spotted the need for additional diagnostic testing, the need to ask more questions, or the need to request more information," noted Gardner. "But no one did and now the Valley Medical Center and LabCorp are liable to pay $25 million each to the family, pending appeal."

Appeal Expected

Gardner expects an appeal of the jury verdict announced December 10, in King County Superior Court. During the appeals, the Wuths will await payment to help cover the costs of care for Oliver Wuth, born July 12, 2008, with profound physical and cognitive disabilities as a result of a genetic defect known as unbalanced chromosome translocation, Gardner said in an interview with THE DARK REPORT. The child will need care 24/7 for the rest of his life.

Knowing this risk, Brock Wuth chose to have a chromosome study to assess the risk of fathering a child with this condition. This testing was done at **Children's Hospital &**

Regional Medical Center in Seattle in 2003. These tests showed Brock Wuth had a balanced chromosome translocation identified as 46,XY,t(2; 9)(q37.1;q34.3), court records show. Any future pregnancies for Brock and Rhea Wuth had a 50% chance of conceiving a fetus with an unbalanced chromosome translocation, according to the court filings.

Referred for Genetic Testing

When Rhea Wuth became pregnant in 2007, her obstetrician referred her to Valley Medical's **Maternal Fetal Medicine Clinic** for genetic counseling and a CVS. The purpose of the referral was to determine if the fetus had an unbalanced chromosome translocation, court records show.

In December 2007, the cascade of errors began. Court records show that, upon being referred to Valley Medical, Brock and Rhea Wuth were given an appointment for December 31, despite the fact that no genetic counselor was scheduled to work that day.

Meeting with a genetic counselor was important to the Wuths "because they did not wish to give birth to a child with genetic defects," court records show. In an orange folder, they had the results of Brock Wuth's previous genetic testing, Gardner said, adding that Valley Medical also had copies of those lab test results that Rhea's physician sent with the referral.

"The biggest problem from the standpoint of the Valley Medical Center was they had understaffed the center so no genetic counselors were there on the day Rhea Wuth arrived for cytogenetic counseling," Gardner told THE DARK REPORT. "At Valley Medical Center, the genetic counselor fills out the test requisition paperwork, selects the tests to be done, and determines what clinical information needs to go with the test request.

"However, staff cuts at the center had reduced the number of days genetic counselors worked at the center from three days each week to once a week," explained Gardner. Physicians had complained that more genetic counselors were needed, court records show. Also, records established that patient volume had doubled at this clinic in the past year, Gardner said.

"Not having a genetic counselor available for the Wuths that day was a mistake because the staff did chorionic villus sampling (CVS) and ordered a standard chromosomal analysis karyotype but did not send any additional paperwork that would have alerted LabCorp's subsidiary, Dynacare Laboratories, that additional testing would be needed," Gardner stated.

"The requisition says, 'Check this box if paperwork is sent with the sample.' That box was not checked," he continued. "And no additional paperwork is referenced on the LabCorp report.

"This disaster could have been avoided if the staff at Valley Medical simply sent in the father's prior lab test results that demonstrated that he had a balanced translocation of chromosomes 2 and 9 and where the exact break points occurred in that translocation," explained Gardner.

No Call To The Lab

"The genetic counselor testified that if she had worked that day, she likely would have called the lab to ask if she needed to order any additional tests other than the standard chromosomal analysis karyotype," he said.

Another error occurred when the lab ran the karyotype but did not add a FISH test, Gardner said. "Once the lab got the result of the first test, if it had the paperwork, it would have determined that a FISH test would have been needed to determine if this translocation was present," he explained.

"At this point in the testing, the lab should have called Valley Medical to ask why a standard chromosomal analysis karyotype was ordered but no additional test was listed on the requisition," said Gardner. "This is simple and it is the standard of care.

"During the trial, it was admitted that the only way to know of a family history of unbalanced translocation is if someone in the family had been tested in the past," he

Lawyer Asks: Does Business of Medicine Trump Delivery of High-Quality Patient Care?

IS THE FOCUS ON INCREASED productivity and efficiency among the reasons a medical center and a clinical laboratory in Washington state were hit with $50 million jury verdict in a wrongful birth case?

That's the question a lawyer in this case has asked. Todd W. Gardner, a personal injury lawyer with Swanson Gardner in Renton, Washington, said the focus on productivity in healthcare and the focus on turn-around time in clinical labs are worrisome.

"I'm very concerned about the corporatization of medicine," he said in an interview with THE DARK REPORT. "I'm concerned that the business of medicine has become more important than the practice of medicine.

"There is nothing wrong with earning a living and making a profit in medicine. But some entities are getting awfully big and it seems as if some of the focus on quality and patient care is being lost as a result," he added.

"Management seems to have a focus on productivity, efficiency, and profitability, and medical providers are not as much in the management loop as they used to be," he said. "This is true in hospitals and health systems, such as Valley Medical Center, and it's the same thing at LabCorp.

"People who testified during the trial said LabCorp had productivity requirements for their technologists and these requirements resulted in errors because the technologists feel they had to get a certain number of tests done each week. When that happens, it means the laboratory scientist is overly focused on productivity and turnaround time.

"This case is a good example because there was a cascade of problems associated with the genetic testing that were just tragic," Gardner added. "In this case, a trainee medical technologist did the karyotype analysis at LabCorp, and that analysis was not reviewed by a supervisor. Yet, during the progress of the case, this trainee said the analysis should be reviewed by a supervisor. In addition, the trainee had given his two-week notice and was three days away from his last day on the job. So he was the ultimate short-timer.

"You can see another example at Valley Medical Center where throughout 2007 the perinatologists said they needed more genetic counselors available for coverage," he continued. "Every other perinatal center in the greater Seattle area has full-time genetic counselors but at Valley they had someone there only once a week. Then that counselor went on maternity leave and there was no manager of the unit to look for her replacement because the manager had quit. So, they borrowed someone from a different hospital one day a week.

Safe, Appropriate Staffing

"The question then becomes: Who has authority to make sure there is safe and appropriate staffing?" Gardner asked. "The physicians there were saying they needed more coverage because of understaffing. Instead the Center reduced its staffing. In the meantime that center was hugely profitable.

"When you don't have enough people, you lose all the checks and balances that had been built into the system," he said. "And look what happened: The medical assistant who submitted the test requisition paperwork to the reference laboratory failed to include a copy of the father's lab report—even though the physicians had instructed her to do so. With something as serious as cytogenetic testing, which could result in a life changing case for a family or a test for cancer, patient safety makes it essential to have checks and balances built into the system and they were not in this case.

"Still, patients put an enormous amount of reliance on lab results. Patients don't pick the lab where their samples are sent. They assume they are getting correct results. When those lab results come back, patients don't think that the lab might have gotten it wrong," concluded Gardner.

emphasized. "And, in fact, Brock's previous lab test results were available. But there is no mention that those earlier lab test results were sent with the test requisition.

"LabCorp had a specific error-prevention policy that said if clinical information is missing, the lab needs to call the ordering facility," said Gardner. "In this case, LabCorp should have called Valley Medical, and asked, 'What information do you have in the family's clinical history that would let us know where to look?'

"Also, the medical technologist running the karyotype should have asked for more information," he commented. "The med tech doing the testing should have recognized that it was a test for translocation, and asked, 'What specifically am I looking for?'

"And the associate medical director in the lab also has an obligation to recommend additional necessary tests," Gardner added. "The associate medical director should have said, 'We don't know what specific chromosomes we are looking for. Has anyone called to find out if we got more information?'

Additional Testing Needed

"In the lab, the associate medical director is the pathologist with the most knowledge," he said. "This individual has the authority to recommend additional tests, which in this case would have been a FISH study with probes at those locations to see if the translocation was there or not."

All of these errors resulted in an incomplete and inaccurate report that failed to show that Oliver Wuth had the genetic abnormalities that his parents feared. "There should have been specific language in the lab test result report, saying, 'We were not advised of the break points for the chromosomes involved. Therefore, we can't rule out a translocation," noted Gardner.

When the results arrived at Valley Medical Center on January 8, 2008, the staff failed to question the results, Gardner said.

"At Valley Medical, the genetic counselor gets the lab test results, then reports to the doctor and to the family," he explained. "When these results came back, the genetic counselor called Rhea and said, 'Good news. The test is normal.' Then the counselor asked if Rhea wanted to know the gender and Rhea said, 'Yes.' The counselor said, 'It's a chromosomally normal male.'

No Lab Report In Letter

"The counselor then sent a letter to the family and to the doctor saying the same thing, but the letter did not include the lab test report," he added. "In the letter, there was no suggestion that there may be unanswered questions or the need for additional tests.

"The report says, 'chromosomally normal male.' The report also says there is an indication of translocation but does not reference the chromosomes and does not have the break points or the ISCN reference, meaning the International System for Human Cytogenetic Nomenclature," Gardner said. "At that point, Valley Medical should have asked, 'Did we ever send the lab the information we have here in the file?'

"Instead, the staff at Valley Medical made the assumption that because the paperwork should have been sent, it must have been sent. But it was never sent, the lab never called to get it, and that is the crux of the problem," Gardner said. "This is one of those cases where there were multiple opportunities to catch this error."

The Valley Medical Center stated publicly: "We are very sorry for the tragedy the Wuth family has suffered. We continue to believe that the Valley Medical Center staff members acted appropriately." There was no comment about plans for an appeal.

The Seattle newspaper quoted a statement from LabCorp, saying, "We believe the facts and the law do not support the verdict. LabCorp acted properly and diligently in performing the test that was ordered by the physician. We will consider all available options, including post-trial motions and appeal, if necessary." TDR

—Joseph Burns

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Tricare, DOD Not Paying for MoPath Codes, LDTs

Policies are inconsistent, causing confusion, and may force patients to pay for their testing

CEO SUMMARY: It turns out that labs serving Tricare patients are going unpaid for certain LDTs, molecular, and genetic tests. The issue of nonpayment began in January 2013 when Tricare stopped paying for these tests that were billed under the new molecular CPT codes that replaced the previous stacking codes. Among the tests in question for which labs are not being paid are tests for cancer, cystic fibrosis, fragile X syndrome, and spinal muscular atrophy.

ONCE AGAIN, CLINICAL LABORATORIES are awaiting payment for molecular pathology tests, only this time it's the labs serving Tricare patients. Tricare has also stopped paying for certain laboratory-developed tests (LDTs).

Last week, *Stars and Stripes,* a newspaper for military members, reported that Tricare beneficiaries may have to pay out of pocket for certain diagnostic genetic tests ordered by their civilian physicians. These tests would be considered inappropriate or medically unnecessary according to the **Defense Health Agency** (DHA) which runs **Tricare**, the newspaper added. Tricare is the health agency for the federal **Department of Defense** (DOD). The Defense Health Agency manages payment for Tricare.

Labs Are Owed Millions

Stars and Stripes reported that labs have continued to perform these tests on behalf of patients in good faith and they are owed over $10 million for these unreimbursed tests. The tests in question are for cancer, cystic fibrosis, fragile X syndrome, and spinal muscular atrophy, among others, as described in a letter to Tricare from Julie Khani, a Senior Vice President with the Washington, DC-based **American Clinical Laboratory Association** (ACLA).

The issue of nonpayment by Tricare began in January 2013. That's when Medicare contractors also stopped paying for certain molecular and genetics tests that had new CPT codes, Khani said. Medicare contractors have since started paying for molecular tests and never stopped paying for LDTs.

"Even though the nonpayment has persisted since last year, labs have continued to run these tests for patients while awaiting payment from Tricare," noted Khani. "Now patients may need to pay for these tests themselves. Also, they may need to pay for certain LDTs, some of which Tricare has refused to cover as well.

"Last year, Tricare stopped paying for certain molecular tests billed under certain of the new molecular CPT codes," recalled Khani. "Previously, these tests were billed using stacking codes and there was some confusion about how to use the new molecular CPT codes.

"When the switch to the new molecular CPT codes occurred at the beginning of 2013, Tricare placed the new CPT codes for more than 100 molecular pathology codes on the No-Government-Pay-Procedure-Code List," she continued. "At that point, labs stopped being reimbursed for these claims, despite the fact that they continued to provide these vital services to Tricare patients."

The Military Coalition (TMC), a consortium of military members and veterans' organizations, has written to the DOD to seek assistance in restoring Tricare payment of these tests. In a letter dated January 9, the commission wrote, "We were recently informed that, after years of reimbursing for MoPath lab testing, Tricare suddenly and without notice placed these tests on the No-Government-Pay-Procedure-Code List. Since that time, Tricare has denied reimbursement for these critical medical tests."

Labs Are Awaiting Payment

Many labs were hopeful that the lack of payment that started in January 2013 would be favorably resolved. "Initially there was an assumption among the labs that there was confusion about the new codes," Khani said. "After all, these were not new tests. They were the same tests being billed under the new codes.

"However, repeated attempts to work with Tricare to resolve payment issues involving these critically important tests have been unsuccessful," she added. "Now there is a growing concern about how non-payment for these tests will affect patient care. Labs continue to provide these vital services without being reimbursed, and that is not sustainable."

Medicare contractors did not start paying labs that used the new codes until May at the earliest. Moreover, Medicare contractors declined to cover some tests or approved coverage at much reduced rates. It appears that the Defense Health Agency did not follow the lead of Medicare contractors.

"We fundamentally disagree with Tricare's interpretation that LDTs are medical devices and they cannot be covered without FDA approval.," explained Khani. "Just to be clear, LDTs are not devices, and FDA approval is not required.

Interpreting Regulations

"It is also important to note that Tricare's regulations on coverage of LDTs has not changed," she continued. "DHA's interpretation of its policy has changed. We are very concerned that patients will lose access to diagnostic services. Eventually, patients will be forced to go without these tests unless they pay for them out of pocket.

"As we looked into this issue of non-payment, we discovered multiple inconsistencies in how the DHA has interpreted its own rules," Khani said. "For example, DHA has stated it will not cover LDTs. Yet in many cases, LDTs such as Pap tests are covered.

"DHA's policy is also inconsistent depending on where patients choose to receive care," stated Khani. "DHA will pay for the lab tests in question when these tests are ordered at a military treatment facility (MTF).

Site of Service

"But that is not the case if a military member or someone from his/her family goes to one of Tricare's network providers and a civilian physician orders these tests," she added. "In this case, DHA will not reimburse the lab. Yet these are the same tests for which DHA will reimburse when ordered by a physician at an MTF!

"To be clear, laboratories are not providing these tests to Tricare for free," emphasized Khani. "These labs continue to seek reimbursement and at this point they have not received payment for these critical services." TDR

—Joseph Burns

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Sonora Quest Builds EMPI To Serve Patients and ACOs

Enterprise-wide master patient index anchors a growing number of patient-centric lab services

CEO SUMMARY: Probably no state has seen a faster transition to ACOs, medical homes, and other types of integrated clinical care organizations than Arizona. Recognizing that this change created a new opportunity to add more value with clinical lab testing services, Sonora Quest Laboratories (SQL) developed an enterprise-wide master patient index. This gives SQL the ability to build and maintain a complete longitudinal record of an individual patient's laboratory test data.

With the American healthcare system beginning its transition to integrated care, it is timely for pathologists and lab administrators to think about developing the new capabilities required to succeed in the era of accountable care organizations (ACOs) and patient-centered medical homes (PCMHs).

As hospitals, physicians, and other providers come together in a single organization, the emphasis will be on improving patient outcomes. Remuneration will evolve away from fee-for-service. Both trends portend profound changes in how clinical laboratories deliver lab testing services and get paid for their efforts.

Essential Capability

One essential capability that every lab serving an ACO will need to develop is an enterprise-wide master patient index (EMPI). The EMPI underpins all the patient-centric services that tomorrow's clinical laboratory must support to be successful at meeting the needs of ACOs, PCMHs, and other emerging models of integrated clinical care.

Only a handful of clinical laboratories has created an effective EMPI. That is because the current generation of laboratory information systems (LISs) used throughout the United States were designed to be physician-centric, not patient-centric. It is also because building an EMPI requires extensive capital and special information technology (IT) expertise—resources that many clinical lab organizations do not have available at this time.

One lab that has built an EMPI and now uses it daily in support of patient-centric services is **Sonora Quest Laboratories/Laboratory Services of Arizona, Inc.** (SQL), based in Tempe, a suburb of Phoenix.

SQL's EMPI is the essential element that allows SQL to bring together all the data on a specific patient and then use that data to deliver high-value services to the patient, the patient's physician, the ACO, any health information exchange (HIE) with which SQL has a working interface, and the health insurers that may be part of individual ACOs.

Certainly all pathologists and lab administrators recognize the value of a complete longitudinal record of an individual patient's laboratory test data. "We saw this need as one way we could deliver a patient-centric service," stated David N. Moore, Chief Information Officer at SQL. "Once we have the capability to associate different lab test services to a single patient and create that longitudinal record, then we differentiate ourselves in the lab marketplace and we give multiple ACOs a reason to select us as a provider.

"The problem of correctly matching patient data is straightforward, but an EMPI is required to solve it," explained Moore. "An EMPI is the essential tool.

"A properly-designed EMPI allows a laboratory to have confidence that it has correctly identified a patient," he noted. "Then the lab can assemble all the clinical and other data associated with that patient."

Tracking A Single Patient

Every laboratory manager is familiar with the challenge of following a single patient across all sites where care may be provided. "For example, there are times when a patient in an ACO goes to a provider outside of the ACO's network," observed Moore. "The ACO may not have all of that patient's lab test records from that out-of-network service on file.

"If true, it means the ACO does not have a complete medical record for that patient or for any other patient who gets care out of network," he said. "This inability to collect data from out-of-network providers is a problem for patients and for ACOs.

"In fact, this is the problem ACOs—as integrated clinical care providers—are designed to solve," noted Moore. "If ACOs cannot collect and store all the data from each patient's past encounters with the healthcare system, then much time and money was invested in the ACOs' systems for nothing.

"Further, who knows better than pathologists and lab managers that different information systems used by various ACOs and provider networks are not always compatible," he emphasized. "At SQL, we saw this as an opportunity to step up with a patient-centric service that was of value to all the participants in an ACO.

Eliminating Fragmented Care

"We did two things," continued Moore. "First, we built an EMPI. Second, we created a layer of informatics to work in concert with our EMPI. Among other things, these other IT layers helped automate the process of matching different spellings of a patient name to a specific individual.

"Our collaborator in this effort was **Atlas Development**," he said. "Our goal was to minimize manual matching of patient names by the staff and use IT to automate those functions as much as possible.

"This capability is now integrated into our workflow," he commented. "Each time a patient presents at one of our patient service centers to provide a specimen, our staff looks in the EMPI to match that patient."

With this patient-centric capability in place, SQL was positioned to go a step further in building a complete longitudinal record for each patient in its EMPI. "Now we could solve the problem of incomplete and fragmented patient records that plagues ACOs and hospitals," observed Moore.

LIS Interfaced to HIEs

"For example, SQL is interfaced to several HIEs," he stated. "To augment the existing data we have on patients, we can poll HIEs in our region and combine information from the HIEs into to our existing data. This allows us to construct a longitudinal patient record instead of having fragmented data.

"Let's say a patient in Phoenix who would normally go to his or her in-network doctor has an emergency one week-

Arizona's Providers and Insurers Moving Fast With ACOs, HIEs, and Integrated Clinical Care

ARIZONA IS AHEAD OF MOST OF THE UNITED STATES in its efforts to develop integrated clinical care organizations. Not only are there multiple accountable care organizations (ACOs) currently in full operation in Arizona, but one health information exchange (HIE) in the state already has hospitals representing 47% of the state's beds feeding data into the HIE.

This raises the stakes for Sonora Quest Laboratories (SQL) as one of the state's largest providers of clinical laboratory testing. It can gain a competitive advantage—and deliver more value to providers—if it can follow a single patient from one doctor to another and across different care settings. Such a capability, anchored by an enterprise-wide master patient index (EMPI), allows it to maintain a complete longitudinal record of that patient's laboratory test data.

Because the traditional LIS is mostly a physician-centric system, SQL has adopted a strategy of layering different informatics solutions on top of its LIS in order to provide patient-centric services to providers, ACOs, health insurers, and others. *(See TDR, December 2, 2013.)* This gives SQL the capability to establish records keyed to the patient's name and identifiable information rather than to a physician's name.

Practical Value For Labs

This capability has practical value in the daily interactions SQL has with providers. "Take the example of a call to our patient service team with a question about a test or about a test result," noted David N. Moore, Chief Information Officer at SQL. "Once we establish the identity of that patient, we can see at a glance every interaction that patient has had with our lab and our health system.

"This real-time access to the patient's full record enables us to support clinical care and compliance with medical protocols," added Moore. "Maybe the patient calling us needs follow-up testing as a result of a test done earlier. Possibly the patient needs a screening test of some kind. Our service team can now use that phone call to schedule a visit."

In this regard, SQL is out in front with the deployment of its patient-centric features. Moore explained why existing laboratory information systems cannot be patient-centric in the manner required to appropriately service patients in ACOs, medical homes and similar integrated care organizations.

"Today, in most larger labs and with older LISs that are not patient-centric, all the data is linked to the ordering physician's name," observed Moore. "The patient's name was not even a variable that the LIS addressed.

"To run a test, the lab needed to know only the patient's date of birth, gender, and the client physician's name who was ordering the test," he said. "If the patient's name on the requisition was unreadable as written, the lab could still run the test and call the doctor's office the next day.

"But what happened when a test was done incorrectly?" asked Moore. "If the lab didn't have the patient's name, staff would have no idea how to contact that patient to re-run a test. That would be a problem for the lab and for the health insurance company.

"How about instances where your lab's patients in New York go away every winter to vacation in Florida or Arizona and have lab work done that doesn't get into the system your lab has established?" he asked. "Even some of the big national labs have this problem because they cannot track a patient who gets a test in one state and then goes somewhere else for a vacation or for part of the year and has other lab testing done. There is no longitudinal record of all of that patient's encounters.

"Here at Sonora Quest, we rectified this problem," concluded Moore. "It required us to invest time and resources to layer in the informatics capabilities required to offer patient-centric services that deliver more value."

end while out of the area," Moore said. "That patient goes to an urgent care center that is out of the network.

"In this instance, the patient's health insurer in Phoenix would have no idea about that patient encounter," he explained. "However, because our lab serves both the in-network physicians and the out-of-network urgent care centers, SQL will contain the longitudinal record on that patient.

More Patient-Centric

"The point is that we have gone from having a provider-centric LIS and the associated information systems that were cutting edge in the 1980s and 1990s, and—by adding additional layers of functionality—we have made these systems more patient-centric.

"The LIS itself is still provider-centric and we have left that untouched," he said. "What makes our entire IT system patient-centric are the new informatics systems we layered on top of the LIS.

"This sounds simple when you say it that way, but it's a significant shift in focus and in output," declared Moore. "In fact, we haven't changed anything inside the LIS other than to feed it the additional patient-centric data that we want it to have.

"That feed into our LIS complements all the information we gather from accessioning specimens when they arrive at the lab," he said. "A program within the new informatics solutions analyzes the accessions and the demographics associated with them. It then matches the incoming requisitions to other patient data that it has from past patient encounters.

Building Confidence

"Now the question to ask is what level of confidence do we have with our system's ability to correctly match the data we give it with the data it stores from past encounters?" noted Moore. "We studied this closely and determined that about 96% of all orders are matched correctly the first time. Then our health information management systems team validates the suggested matches and gets the rate of overall validation above 98%."

Due to continuous improvement programs, the error rate is declining. "Each time we deal with the various errors the system encounters, we implement a fix. We believe we will be able to approach a Six Sigma level of accuracy in our automated processes for patient identification.

"From our analysis of incoming requisitions, we know that, on average, about 3% to 4% of requisitions contain incorrect patient information," he explained. "We also know that about 90% of all accessions verify correctly when they arrive. By using the algorithms Atlas Development has developed for us, our automated informatics solution can identify and correct errors about 99% of the time. That's impressive.

"Best of all, this additional layer of information systems doesn't affect lab operations at all," emphasized Moore. "In fact, we are installing an LIS from **NeTLIMS** that has the ability to implement specific quality control measures that we will select. Our existing system with the additional layers for the EMPI simply allows us to speed up the registration part of patient throughput.

Identifying Next Steps

"Looking ahead to the next few years, SQL plans to introduce a patient loyalty program," he said. "A patient who signs up will get a card to swipe upon entering any of our patient service centers.

"The card would tell the system the name of the patient and perhaps would allow the patient to get expedited service, and other benefits," Moore explained. "With SQL's EMPI and the ability to be patient-centric, we want to use the patient loyalty program as a way to create strong relationships with our patients." **TDR**

—Joseph Burns

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Claritas Is Example of New Lab Business Model

Once part of Boston Children's Hospital, molecular lab is now an independent company

CEO SUMMARY: One by one, new business models for clinical laboratory testing are popping up. Each is a response to healthcare's rapid evolution, the ongoing decline in lab test reimbursement, and the growing role for molecular diagnostics and genetic testing. In Cambridge, Massachusetts, Claritas Genomics, formerly the molecular lab at Boston Children's Hospital, is one such example. It seeks to leverage its next-generation gene sequencing expertise in multiple ways.

NEW BUSINESS MODELS in clinical laboratory testing are starting to emerge. These are lab companies organized to offer a different menu of laboratory testing services.

One such company is **Claritas Genomics** of Cambridge, Massachusetts. For 15 years, it operated as the **Genetic Diagnostic Lab** at 396-bed **Boston Children's Hospital** (BCH).

"As one of the hospital's CLIA-certified laboratories, it provided the advanced molecular diagnostic testing services used by the hospital," stated Patrice M. Milos, Ph.D., CEO of Claritas Genomics. "However, BCH was challenged to provide the capital and resources needed for the molecular lab to grow.

"This was due to the rapid pace of genetic discovery, ongoing advances in gene sequencing technologies, and the difficult financial environment in healthcare," recalled Milos. "Thus, to make it easier for the lab to grow, the hospital spun out the lab and created Claritas Genomics in February 2013."

As an independent lab company, Claritas moved quickly to seize opportunities created by healthcare's evolution toward personalized medicine and integrated clinical care. One of its first successes was to win a role in the Million Veteran Program (MVP).

Million Veterans' Project

In October 2013, Claritas Genomics disclosed that it would participate in a $9 million deal with the **U.S. Department of Veterans Affairs** (VA). Claritas is doing exome sequencing of samples from veterans, including those from the Million Veteran Program. This project is one of the largest sequencing initiatives ever undertaken in the United States.

"Because of this partnership with the VA, Claritas is performing exome sequencing for research use at a very large scale," commented Milos. "This project supports the growth of our infrastructure and will enable us to scale up on the clinical side as well."

The point here is that Claritas benefits in multiple ways from this relationship with the VA. First, it gains cash flow. Second, it can use this cash to acquire the gene sequencing system and staff expertise in

next-generation sequencing technologies. Third, it is developing the informatics infrastructure needed to collect, store, and analyze large volumes of genetic data.

Just last month, Claritas entered into another non-traditional business relationship. This time it involved one of the nation's largest health informatics companies. On December 5, 2013, Claritas and **Cerner Corporation** of Kansas City, Missouri, jointly announced their partnership.

The two companies said they seek to advance personalized medicine by building tools and connectivity systems to integrate next-generation sequence (NGS)-based diagnostic testing into health care practice more efficiently than health systems can do now. Specifically, the two companies said they would collaborate to develop a system "for molecular diagnostics that is tailored to NGS workflows, which are more complex and generate much more data than traditional molecular diagnostic tests."

Investment for Growth

Among the keys to this partnership are the following:

- Cerner invested in Claritas and took an ownership interest in the lab firm.
- Clay Patterson, head of Cerner Ventures, joined Claritas' board of directors.
- Claritas will implement the Cerner Millennium Helix system, which is software for managing specimen and workflow tracking in labs.
- The two companies will jointly develop a laboratory information management system (LIMS) specifically for clinical labs primarily focused on next-generation sequencing.
- Claritas will join Cerner's Reference Lab Network, an electronic hub that enables lab test orders and results reporting among participating hospitals and physicians.

"In terms of this collaboration, one barrier to the use of genomics in medicine is the challenge of integrating the complex information derived from large-scale genomic measurements into a patient's medical record and clinical practice," explained Milos. "Our mutual goal is to develop the informatics tools that support clinical use of genetic data."

Business Strategy

For its part, Claritas has another non-traditional business strategy. "Our lab company is working with pediatric institutions specifically to advance clinical knowledge in a number of ways," she said. "For example, we are facilitating a research network by connecting patients with experts who can provide care and by licensing assays from the hospitals where the discoveries that lead to diagnostic tests are made.

"Also, in this business model, we can receive investment from outside sources such as we have from two of our Series A investors, **Life Technologies** and Cerner," added Milos. "Claritas also has additional partnerships from other hospitals. These include **Cincinnati Children's Hospital**, which is another Series A investor.

"All of these investments allow us to address the testing needs at BCH and at other hospitals as well," emphasized Milos. "In this way, we see Claritas as a relevant laboratory business model for other hospitals to join, as Cincinnati Children's has done. It is a way that the pediatric community can work together to address the complexities of genomics in medicine, instead of spending precious resources duplicating both effort and infrastructure."

Leveraging Core Competency

What distinguishes the business strategy at Claritas is how it is leveraging its core competencies to serve a network of children's hospitals and other pediatric organizations in a value-based approach. TDR

—Joseph Burns

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Reimbursement Update

CMS Cuts BRCA Price by 49% in Response to Competition

Federal agency uses gap-fill procedure and reduces payment for BRCA genetic test to $1,438

IN THE FINAL WEEKS OF 2013, the federal **Centers for Medicare & Medicaid Services** (CMS) announced that it would reduce the price it pays for the BRCA genetic test by 49%, to $1,438, effective on January 1, 2014.

For **Myriad Genetics, Inc.**, this was not welcome news. Its share price fell by as much as 20% over the fall months, based on earlier guidance by CMS that the agency intended to pay significantly less for CPT codes 81211 and 81214. These are the two codes which cover the BRCA 1 and 2 gene tests.

However, of greater concern to pathologists and clinical laboratory executives is what CMS may be signaling to the lab testing industry about the process and criteria it wants to use to determine coverage guidelines and establish prices for individual molecular diagnostics tests going forward.

For Myriad Genetics, the CMS decision to slash the price it pays for BRCA tests is another negative consequence to the Supreme Court ruling issued last June. In a 9-0 decision, the Supreme Court said that natural genes could not be patented.

Competing Laboratories

Following that decision, several lab companies announced their intention to offer gene tests based on the BRCA 1 and 2 genes—and at much lower prices than what Myriad charges. For its part, Myriad declared it would defend its intellectual property and filed lawsuits against several competing lab companies.

However, due to the Supreme Court decision, the cat was already out of the bag. Myriad now faces competition from labs willing to charge much less for a BRCA gene test. Myriad's stated price for its most comprehensive BRCA test is $3,340. Medicare reimbursed the BRCA test at $2,795 during 2013.

Quick To Enter The Market

Competitors such as **Ambry Genetics** and **Quest Diagnostics Incorporated** were quick to enter the market. For their respective BRCA 1/2 tests, Ambry said it would charge $2,200 and Quest Diagnostics posted a price of $2,500. **DNATraits** priced its test at $995.

CMS and the Medicare Administrative Contractors (MACs) noticed what was happening in the competitive marketplace. In explaining its decision to set the national limitation amount (NLA) for BRCA tests at $1,438.14, CMS said, "Prior to a Supreme Court decision earlier this year, only one laboratory was providing tests for the BRCA gene.

"Following the Supreme Court decision, additional laboratories began providing the test," continued CMS. "The MACs received data on the pricing by the laboratories offering the test. Based on that new information, the MACs submitted pricing information for CPT code 81211 that resulted in a NLA of $1,438.14."

CMS used the gap-fill method to establish the BRCA test price. On its web-

site, CMS wrote that, based on information provided by the MACs, it understood "laboratories are offering the CPT code 81211 test for prices that range from approximately $900 to $2,900."

Molecular Test Chaos In 2013

As clients and long-time readers of THE DARK REPORT know, 2013 was a chaotic year for molecular diagnostics and genetic testing. CMS and private payers were not ready to implement the new molecular CPT codes that became effective on January 1, 2013. As a consequence, labs went unpaid for their molecular test claims many months into the year. *(See TDRs, April 15 and May 28, 2013.)*

For these and other reasons, the lab industry is on high alert as to what procedures CMS is using to establish coverage guidelines and prices for individual molecular test CPT codes. Experienced laboratory executives and consultants are calling for more transparency on these matters by CMS officials.

That is why the use of the gap-fill procedure by CMS to lower the price the Medicare program pays for the BRCA gene test is being questioned. Essentially, CMS is saying that its gap-fill process may have been based solely on looking at the prices charged by competing labs (who themselves have not been in the market more than a few months) and not on any other consideration, including clinical value.

Lab Industry Concerns

Both the clinical laboratory profession and the *in vitro* diagnostics industry have valid concerns that CMS is not giving appropriate consideration to the clinical data and R&D investment associated with the development and validation of these molecular and genetic tests. Further, a number of recent actions taken by CMS, when viewed collectively, show a pattern of more aggressive steps to reduce the cost of lab testing to the Medicare program.

Myriad Faces Competition For BRCA Gene Testing

FOR THE FIRST TIME IN ALMOST 20 YEARS, Myriad Genetics of Salt Lake City, Utah, faces competition in the market for BRCA gene testing. Several lab companies now offer their own version of a BRCA gene test at a much lower price.

Medicare officials used those lower BRCA gene test prices as part of their gap-fill process for CPT codes 81211 and 81214, the BRCA test codes. For 2014, CMS will pay just $1,438.14 for the BRCA test.

Wall Street analysts estimate that 10% of Myriad's BRCA test volume comes from Medicare patients. Based on that number, several analysts reduced their estimates of fiscal year 2014 revenues at Myriad from about $715 million to about $695 million.

What is likely to be of greater impact—and of more significant interest to pathologists—is how quickly private health insurers follow Medicare's lead. Because BRCA testing makes up about 80% of Myriad's annual revenue, were private payers to also cut the price they pay for BRCA testing by 40% to 50%, this would substantially reduce the company's annual revenue.

However, it should be noted that Myriad Genetics has ample resources it can call upon to respond to these developments. Not only does it have a strong gene-sequencing and interpretation capability, but it has $500 million of cash on its balance sheet and 400 people on its sales force ready to promote other gene testing services.

How this plays out in the next few years remains to be seen. After all, experience shows that any industry that wants to challenge its federal regulator enters a game with most of the rules stacked against it. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Currently there are 119 operational health information exchanges (HIEs) in the United States. This number is 58% greater than the 75 HIEs that were operational in 2010. These numbers were reported in *Health Affairs*. The study was authored by researchers at the **University of Michigan**. They also determined that 30% of the nation's hospitals and 10% of ambulatory practices now participate in at least one of these 119 operational HIEs. Most notably, only 25% of HIEs reported that they are able to cover operating costs with revenue from participating providers and healthcare organizations.

DATA INNOVATIONS BUYS DAWNING

There's been another round of consolidation among lab middleware vendors. Last month, **Data Innovations** of Burlington, Vermont, said it had acquired the assets of **Dawning Technologies, Inc.**, of Fort Meyers, Florida. Terms of the sale were not disclosed. Both companies provide middleware solutions for clinical laboratories.

PATHOLOGY ADMIN NAMED "WOMAN OF THE YEAR"

Last month, the **National Association of Professional Women** (NAPW) named Judy Frost, BSN, RN, ACMPE, as "Professional Woman of the Year." Frost is the Business Manager of **Midwest Pathology Associates, LLC**, in Kansas City, Missouri. NAPW is the nation's largest organization of women, with 600,00 members in 400 chapters.

TRANSITIONS

- **Halfpenny Technologies** of Blue Bell, Pennsylvania, announced that Jack Redding has joined the company as its Vice President of Sales and Marketing. He has previously held positions at **Lifepoint Informatics**, **Specialty Laboratories**, **Cigna Intercorp**, **Keystone Health Plans**, and **Siemens Healthcare**.

- Rick Malik joined **MedAssets** of Atlanta, Georgia, as its Senior Vice President of Enterprise Solution Sales. Previously he held executive positions at **Ortho-Clinical Diagnostics**, a division of **Johnson & Johnson Company**.

- **Vermillion, Inc.**, of Austin, Texas, has appointed James T. LaFrance as a member of its board and its Chairman of the Board. LaFrance held executive positions at **Omnyx, LLC**, **Ventana Medical Systems**, and **Bayer Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 3, 2014.