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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

Coming Soon to a Doctor's Office Near You!

IT'S TIME FOR ALL CLINICAL LABS AND ANATOMIC PATHOLOGY GROUPS to pay closer attention to the advances in genetic medicine and precision medicine. Events are moving even faster than most experts have predicted.

As you will read on pages 3-4, two innovative health networks are on the verge of offering sophisticated genetic tests to patients visiting their primary care clinics. Both **Geisinger Health** and **Sanford Health**, of Danville, Pa., and Sioux Falls, S.D., respectively, have announced plans to offer such gene sequencing services in coming months.

THE DARK REPORT predicts there will be a swift response to this development by other innovative health networks. That will happen for two reasons. One is because of the desire of some institutions to always be seen as at the cutting edge of modern medicine. The second is the ongoing cascade of new research findings into the workings of the human genome.

Consider cancer care as the model. Today, a cancer patient is diagnosed using a very different array of lab tests than just five years ago. The number of relevant genetic mutations and companion cancer drugs is increasing at a remarkable pace. Survival rates for patients with certain types of cancers are climbing.

In parallel with this progress in oncology, something similar is happening in the field of pharmacogenomics. There is a continuous stream of peer-reviewed studies that demonstrate how certain genetic sequences can be used to predict the benefit an individual patient will get from a specific therapeutic drug, what dose would be most effective, and whether the patient might experience negative side effects from that drug.

But all this new research and evidence is only half the story. The other half is the ongoing improvements in the technologies of gene sequencing and software used to analyze the data. This means that the speed of sequencing, the accuracy, and the cost of sequencing are all improving at a pace that will make it easier for more health networks, hospitals, and local clinical laboratories to offer state-of-the-art gene sequencing services in support of clinical care, even in primary care settings.

These are reasons why your lab should update its strategy for precision medicine. It is also why we can confidently say, "Gene sequencing and precision medicine are coming soon to a doctor's office near you!" TDR

More Primary Care Docs Will Offer Genetic Tests

Two prominent health networks see benefits in offering precision medicine, genetic testing

CEO SUMMARY: This summer, both Geisinger Health and Sanford Health will introduce genetic tests designed specifically for use by primary care physicians in their daily practice. This is a significant milestone on the road to wider deployment of precision medicine services. In the case of Sanford Health, it plans to offer patients a $49 genetic test that looks at susceptibility for 60 diseases and 30 drug-gene interactions. The test won't be billed to insurers, but will be paid for by the patient.

IN RECENT MONTHS, several innovative health networks announced plans to provide genetic tests to patients being seen in primary care clinics. This is a development that has important implications for clinical laboratory administrators and pathologists across the United States.

Until now, genetic tests have primarily been used for specialized care, such as in oncology and for hereditary diseases. One reason for this has been the expense of gene sequencing and analysis of that data.

However, improvements in gene sequencing technologies mean that exomes and whole human genomes can be sequenced faster and more accurately—and at less cost—than ever before. In turn, that changes the cost-clinical benefit analysis in ways that support expanded use of gene sequencing in many other areas of clinical care.

These are all factors in the decision of **Geisinger Health**, of Danville, Pa., to begin offering DNA sequencing to patients as part of routine preventive care. In May, Geisinger officials announced that this service would launch in the next six months.

Similarly, **Sanford Health** of Sioux Falls, S.D., is ready to offer a $49 genetic test panel in its primary care clinics. It plans to initiate the service by mid-year.

Both health networks have been at the forefront of collecting genetic information from patients and using that data in various research programs and clinical studies. Their respective plans to offer genetic tests in primary care settings are a logical next step for them.

Geisinger is preparing to provide gene sequencing to its patients as a regular part of routine preventive care. The program

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will start this summer and the clinical pilot will involve 1,000 patients in several Geisinger clinics.

Exomes for $300 to $500

Exomes will be sequenced at a cost expected to be between $300 and $500 per patient. Patients will not be charged. Geisinger estimates that the program will cost $5 million and the money will come from donors and from the Geisinger health plan.

"We're going to start doing it the same way we would talk to patients about getting a cholesterol check," stated Dave T. Feinberg, MD, on a conference call with reporters in May. He is confident that this genetic testing service will demonstrate its value in patient care. "We think by scaling it we'll hopefully more quickly show the cost-effectiveness of it, and it will become pretty obvious that everybody should be getting this," noted Feinberg.

At Stanford Health, there are high expectations that offering genetic tests will be welcomed by patients. "Nobody else in the world is doing this," declared Nate White, Executive Vice President of **Sanford Health Fargo**. "What we're after is the primary care setting."

Markers for Diseases, Drugs

Sanford officials said that its genetic test includes markers for such conditions as aortic aneurysms, thyroid cancer; Lynch syndrome (a hereditary form of colorectal cancer); hereditary breast and ovarian cancer; retinoblastoma (a form of eye cancer usually developed by children); Wilms' tumor (a type of cancer that starts in the kidneys); and Wilson disease (which causes copper to accumulate in the liver, brain and eyes).

The choice of genetic markers for the 60 diseases and 30 prescription drugs included in Sanford Health's genetic test panel is based on the fact that each marker is clinically-actionable. The result should be measurable improvement for patients.

Geisinger Wants to Push Gene Tests into Daily Care

AS IT PREPARES TO OFFER genetic testing in primary care settings, Geisinger Health is building on several years of research it has conducted that includes the gene sequences of Geisinger patients.

That is the MyCode research program. According to Geisinger CEO David T. Feinberg, MD, the research study is testing 59 different genes for 27 conditions. The final mix of conditions that will be included in the primary care clinical pilot has yet to be determined, but could include BRCA mutations, Lynch syndrome (which indicates a higher risk for colon cancer) and familial hypercholesterolemia.

Feinberg gave a specific example of how such gene sequencing can benefit a patient. He noted that familial hypercholesterolemia is a genetic condition that causes high cholesterol and an increased risk for cardiovascular disease, heart attack, and stroke. Its incidence in the population is one in 250 people. Clinical guidelines call for this condition to be treated, starting at the age of eight. But, as Feinberg pointed out, such treatment seldom happens because "nobody knows who has it because nobody is testing broadly besides us."

Sanford Health's confidence in moving ahead with genetic testing in primary care settings is a result of the research it has conducted since it received a $125 million donation in 2014 from benefactor Denny Sanford, for whom Sanford Health is named.

Geisinger Health and Sanford Health may be first-movers in offering genetic testing to primary care patients. But a growing number of health networks are developing similar plans for deployment of genetic tests within their health system. TDR

Rural Hospital Group Says Lab Billing Model Is Legal

70/30 rule exemption governs billing, says President of National Alliance of Regional Hospitals

CEO SUMMARY: In recent years, many rural hospitals have entered into agreements to expand their laboratory outreach businesses. In an interview, the president of the National Association of Rural Hospitals said rural hospitals often bill for lab outreach services under Medicare's 70/30 shell rule. This rule, as modified by the Omnibus Budget Reconciliation Act of 1989, specifically allows rural hospitals to bill for outreach, the NARH executive explained.

ACROSS THE NATION, health insurers and government regulators now recognize that many rural hospitals are using clinical laboratory tests to generate outsized streams of new revenue.

How outsized? Writing for *Modern Healthcare*, Tara Bannow reported last month that an analysis of Medicare data showed 21 hospitals had outpatient lab charges that exceeded 30% of the hospital's total annual charges in their most recent reports, either 2016 or 2017.

In some cases, lab charges—billed mostly to private insurers but also to government payers—accounted for more than 80% of hospitals' total charges in a single year, Bannow wrote. The data came from an analysis by **Modern Healthcare Metrics** and the analytics firm **Franklin Trust Ratings**, she added.

"For comparison, the average outpatient lab-to-total charges ratio among all of the nearly 5,000 hospitals that filed cost reports was less than 9% in 2016 and about 12% so far for 2017," Bannow reported.

Such billing numbers are the result of the desperate financial situation of many rural hospitals. These small hospitals—faced with the choice of bankruptcy or closure—have signed agreements with promoters of strategies that use rural hospitals as in-network providers to bill for large volumes of lab tests from patients who typically live hundreds or thousands of miles away from the hospital billing for these tests.

Pass-Through Billing

Critics point out that these arrangements can violate both state and federal laws, as well as the managed care contracts that rural hospitals have with health insurers. One common element in these arrangements is the practice known as pass-through billing. Using this practice, a hospital would submit bills for lab tests that were performed in laboratories located outside of the hospital's facilities. The question for many clinical lab directors is whether pass-through billing is legal. *(See TDRs, Oct. 30, 2017, and Jan. 22, 2018.)*

Michael Murtha, President of the **National Alliance of Rural Hospitals** (NARH), an organization founded in 2016, said that members of NARH are not using pass-through billing. And, he said, the billing practices these hospitals use are definitely legal. The strategy that hospitals in the NARH use is called a "lab outreach

Missouri Company Acquires, Manages Rural Hospitals

IN FEBRUARY, THE EMPOWER GROUP of Miami, Fla., said it planned to continue to acquire and manage rural and critical access hospitals through its subsidiary EmpowerHMS of Kansas City, Mo.

In a press release, EmpowerHMS said it sought, "… to identify, assess, and take over operations of distressed hospitals across the United States in order to avert their closure. The current number in Empower's network is nearing 20 and growing." At the time, EmpowerHMS said it was a leader in the healthcare billing and coding industry.

In the announcement, EmpowerHMS quoted CEO Jorge Perez explaining the company's model as follows: "We have expanded in numerous areas that were unheard of in a rural hospital setting. As an example, all our facilities have a three-day detox to attack the opioid crisis, we have a common cardiology program that is doing life-saving procedures, and we have lab programs that serve the local clinics and physicians' offices."

Health insurers, government officials, and competitors have challenged what EmpowerHMS calls its "disruptive innovation" for rural hospitals.

In the same release, EmpowerHMS quoted Dylan Gauldin, Empower's general counsel, saying, "People are used to identifying rural hospitals with failure and don't readily accept anything that veers from that path. However, the transparency and controls we have invested in go beyond all benchmarks." To this comment, Perez added, "Without compliance, there is no sustainability."

business model," Murtha added. NARH is in Tallahassee, Fla.

THE DARK REPORT sought to interview Jorge Perez, the Chairman of NARH and CEO of **EmpowerHMS**, a subsidiary of the **Empower Group**, of Miami, Fla.

EmpowerHMS, in Kansas City, Mo., acquires and manages rural and critical access hospitals. During a conference call for this interview, Murtha said Perez could not join the call. Instead, Murtha explained the association's response to assertions that critics have made about the billing practices of some rural hospitals.

"The lab outreach business model for rural hospitals is a good fit because the historic business model for rural hospitals is doomed to fail," explained Murtha.

"Our members continue to invest in the technology and personnel to do as much of the testing on-site as possible," he added. "We strongly object to referring to these programs as 'pass-through billing' or 'shell labs.' Those terms are a gross mischaracterization. But, a high volume use of off-site reference labs can lead to just such characterizations." Murtha further noted, however, that rural hospitals are not limited in their use of reference labs because Medicare has what he called the 70/30 rule.

Federal Law Exemption

Murtha explained: "The 70/30 rule says that if you have a lab outreach program, you have to do 70% of your testing onsite, and you can refer out 30% to other labs. But the federal Omnibus Budget Reconciliation Act of 1989 exempted rural hospitals from Medicare's 70/30 payment rule for lab outreach."

Under the reasoning at the time, Congress sought to prevent outright fraud as a result of sending a great volume of testing to other labs, Murtha explained. "They did that because there were labs funneling tests through third-party labs while saying they were doing lab outreach work," he said.

"In response to this development, Medicare and Medicaid added the 70/30 rule so that they could exempt some individuals and labs from that 70/30 rule," he continued. "Among those entities that were specifically exempt were rural hospitals.

"There were several reasons for this exemption, not the least of which is the fact

that it costs money to start a lab outreach program," explained Murtha. "To start lab outreach programs, hospitals needed up-front revenue to buy equipment for these programs.

"At the time, some government officials explained the rule and the exemption," he said. "After hearing these explanations, some folks decided to do lab outreach in rural hospitals because these hospitals have the facilities and the insurance contracts, and are licensed to do this work. They saw the 70/30 exemption of rural hospital as a way to keep the community hospital afloat and build some revenue. Otherwise, these hospitals would need to close.

Challenge From Payers

"When this trend started happening, some critics of this business model—such as health insurance companies—said 'we're not thrilled with it,'" Murtha added. "That's fine. They don't have to be thrilled with it. They can renegotiate their contracts and require rural hospitals to do this lab testing in a different way."

Health insurers were critical because they were paying for such testing, Murtha said. Rather than negotiate with these hospitals, health insurers decided it would be better to simply put them out of business, he added. "Instead of renegotiating contracts, health insurers said they would preclude hospitals from doing this testing and billing in this way," explained Murtha. "They said, 'We're going to crush you.' And they did so by filing lawsuits.

"Insurance companies make a lot of money and they like to make certain that they have control over their networks," he added. "Rather than renegotiating existing managed care contracts, they all file lawsuits and that's what some of our member hospitals are going through right now.

"What's troubling about how insurers act is that the administrators in rural hospitals know that these facilities are dying all over the country," he said. "And they can't save these hospitals without strong cash flow. The technology that's necessary to run a hospital today, the licensure, and the premiums for liability insurance are just unbearable for rural hospitals. You just cannot make money on it." TDR

—Joseph Burns

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Rural Hospitals Struggle To Survive Financially

IT'S NO SECRET THAT RURAL HOSPITALS are struggling financially. Since 2010, more than 80 such hospitals have closed and almost 673 rural hospitals could close in the coming years, according to a report last year from the **National Rural Health Association** in Leawood, Kan. Those 673 facilities represent about one third of the number of hospitals serving rural areas, NRHA said. NRHA is not affiliated with the National Alliance of Rural Hospitals.

"Continued cuts to hospital payments have taken their toll, forcing closures, creating medical deserts across rural America, and leaving many of our nation's most vulnerable populations without timely access to care," NRHA said last year.

For struggling rural hospitals, some business professionals running clinical laboratories have a solution to their financial troubles. By increasing the volume of clinical laboratory testing they do, these hospitals could boost revenue significantly, these laboratory operators contend.

Insurers have questioned these solutions, saying that hospitals enter into these agreements to bill for an increased number of lab tests, many of which are not performed in the hospitals' labs. Insurers recognize that rural and other hospitals have higher operating costs and so pay more for these tests than they pay for the same tests run at independent clinical laboratories. Sometimes, these hospitals bill insurers for patients' lab tests when those patients have no connection to the hospitals.

Lab Compliance Update

Attorney Explains 70/30 Rule, Pass-Through Bill Arrangements

Lab outreach billing strategies used by some rural hospitals need to meet compliance laws

HOW THE LAB OUTREACH BUSINESSES of rural hospitals originate lab specimens and bill for lab tests is getting increased scrutiny. The reason for this rise in interest is that a growing number of rural hospitals are generating almost as much revenue from laboratory outreach testing as they get from all other inpatient services.

Most rural hospitals that have business contracts with third parties—including lab companies—to build their lab outreach revenues, rely on two billing and collections strategies. They are pass-through billing and an exception from the Medicare 70/30 shell lab rule.

To address any potential confusion about these strategies, THE DARK REPORT asked Jeffrey J. Sherrin of the law firm of **O'Connell and Aronowitz, PC**, in Albany, N.Y., to explain the legal implications of each one.

"Medicare's 70/30 rule basically means that, if lab A refers out more than 30% of its testing, it cannot bill Medicare for work that it refers out," he wrote via email. "Lab A can always bill Medicare for work that it does itself.

"What we generally mean when we use the term 'pass-through billing' is that when a specimen comes into Lab B, and Lab B does the testing, it cuts a deal with Lab A because Lab B is not in network," Sherrin explained. "Lab A bills for the test as if it had done the work, gets paid for that test, and then shares the revenue with Lab B.

"In this case, Lab A never made a referral, so the 70/30 rule is not applicable," he added. "My understanding, therefore, is that the 70/30 rule has nothing to do with pass-through billing. If the hospital actually got the specimen and referred it out—such as it might with an inpatient specimen—that is not what is typically referred to as pass-through billing."

Are Rural Hospitals Exempt?

Sherrin also addressed the issue of whether rural hospitals have an exemption under the 70/30 rule. "While federal law includes an exemption of rural hospital labs from the 70/30 shell lab rule, it is not an exemption from the risk that what we call 'pass-through billing' may be a false claim," he wrote. "There has to be a true referral from the rural hospital lab to the reference lab.

"Another point to consider is that the 70/30 rule is for Medicare billing, but it does not apply to work for commercial health insurers," explained Sherrin. "For lab test referrals made to commercial health insurers, and whether the 70/30 threshold is met, the rule limits only what the referring lab can bill to Medicare," explained Sherrin. "Labs [and rural hospitals] using the pass-through billing practice may be attempting to circumvent the network contracts of commercial payers.

"When the testing lab is out-of-network, it wants to use the in-network and possibly rural hospital lab so that it can get paid, or perhaps get paid at a higher rate.

"In addition, it is unlikely that commercial payer contracts have 70/30 rules," he said. "Rather, commercial payers usually say that a lab cannot refer out to another lab if the reference lab is not in network."

Sherrin said the applicable law comes from 42 U.S.C.S. §13951 as follows:

"In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part [42 USCS §§ 1395j et seq.] on an assignment-related basis or under a provider agreement under section 1866 [42 USCS § 1395cc], payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice.

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30% of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II))[,] receives requests for testing during the year in which the test is performed[,] are performed by another laboratory… " TDR

Health Insurers Seek End to Pass-Thru Lab Billing

IN RESPONSE TO INCREASED REPORTS that clinical laboratory companies were using pass-through billing, some of the nation's largest health insurers have sought to end the practice.

In April, **UnitedHealthcare** and **Anthem** filed court documents in cases they have filed against lab testing companies that use pass-through-billing arrangements in ways the insurers charge are fraudulent.

On April 19, **Blue Cross and Blue Shield of Georgia** and 24 health insurers and other companies affiliated with Anthem filed suit against a lab company and others, saying the defendants engaged in a scheme to bill for laboratory services that were fraudulent. *(See TDR May 7, 2018.)*

On April 18, UnitedHealthcare Insurance filed a lawsuit against five individuals and three lab companies saying the defendants illegally induced requests for lab testing services and used financially-struggling rural hospitals as fronts to conceal the identity of the lab companies that actually performed the testing services.

Last year, **Aetna** said it would deny pass-through billing for most lab charges from a facility or a non-facility provider. The policy went into effect on October 1. "The provider that performs the tests must bill for these services," Aetna said. "We'll pay for pass-through billing during an inpatient hospital admission. We'll also pay facilities for pass-through billing for members receiving outpatient services at the facility when the specimen collection occurs at the facility on the same day as other services."

—Joseph Burns

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CEO SUMMARY: As health networks and hospitals consider outsourcing their lab outreach programs, the lab team at Dartmouth-Hitchcock Medical Center (D-H) offers lessons about the value of retaining outreach. D-H is now in the eighth year of a sustained expansion of its laboratory outreach business. It has combined its lab outreach strategy with a proven plan of implementation. This combination is proving attractive to office-based physicians and community hospitals in New Hampshire and some surrounding states.

More lab volume from physicians' offices contributes to patient care

Dartmouth-Hitchcock Builds Strong Lab Outreach Business

HOSPITALS AND HEALTH NETWORKS often fail to integrate clinical lab testing from their affiliated, office-based physicians, especially if those referrals are going out of doctors' offices that are located near the main campus.

Ten years ago, when the **Dartmouth Hitchcock Medical Center** (D-H) in Hanover, N.H., noticed this problem, it implemented a strategy to integrate that testing into its core lab testing volume. The first phase started with physicians' offices in Southern New Hampshire. The process of integrating lab testing from doctors' offices then was replicated in other regions of the state and into neighboring Vermont. D-H's strategy to build the lab outreach program has paid dividends in standardization of testing platforms, increased test volume, and lower costs per test.

In 2010, Dartmouth developed and implemented a system to ensure that physicians in the out-of-area clinics owned by the health system would send their routine clinical pathology specimens to the main D-H lab in Lebanon, N.H. Previously, these physicians sent their routine clinical pathology lab tests to commercial lab companies.

"The first step in our planned integration process involved putting infrastructure in place in Lebanon," said Ellen J. Dijkman Dulkes, MS, MT(ASCP), Outreach Services Manager in D-H's Department of Pathology and Laboratory Medicine. "We needed a million-dollar capital plan to accommodate the increased test volume.

"Therefore, we invested in technology, including high throughput analyzers and improved connectivity to manage the increased test volume," she added. "The lab invested in hematology and chemistry automation and upgraded its laboratory information technology with the connectivity solutions needed for such a project."

At the same time, the lab team also made plans to replace the commercial laboratory that was then operating phlebotomy and stat laboratories in buildings owned by D-H in Manchester and Nashua. D-H also had phlebotomy draw sites in other D-H clinic locations such as in Bedford, Milford, and Merrimack, she said.

In 2010, the D-H Lebanon lab assumed operation of these locations in Southern New Hampshire and since then has continued to expand its clinical laboratory outreach business based on this early model.

"Since then, our health system has used that same process to bring in lab tests from other hospitals in New Hampshire and Vermont," Dulkes said. "In other words, the process that worked so well in 2010 to encourage physicians to use their health system lab is the same model we use today to corral lab test referrals from hospitals and physicians' offices in other areas."

Integrating outreach testing from affiliated practices began more than eight years ago when D-H identified several reasons for making the changeover: better patient care because the test results would be available in the D-H patients' records and lower costs per test due to increased volume.

Integration of Lab Testing

Previously, a national lab company was running the tests for physicians associated with D-H in those Manchester and Nashua clinics. Routine lab testing from Concord was integrated later when D-H assumed operation of the Concord clinic laboratory.

"Our original scope of the work called for shifting lab tests that were going out of our community group practices in Manchester and Nashua," Dulkes said. Those tests were going from D-H clinics to a large national lab company that Dulkes did not wish to identify.

"While these three physician groups were Dartmouth-Hitchcock owned clinics, they weren't affiliated formally with our main campus," she noted. "Instead, in these early years, these physician groups were sort of a separate entity, and because of that, they

were not fully a part of the Dartmouth-Hitchcock health system.

"Of course, the lab knew these clinics were not sending their tests to the main lab in Lebanon, N.H.," she added. "The commercial lab leased space in the D-H clinics, its staff wore its company-branded lab coats, and it operated its own courier transportation system to move our D-H specimens to their central commercial hub for testing.

"As well, the commercial lab company had its own lab set up in our D-H clinics," recalled Dulkes. "At those sites, the commercial lab was well integrated into our D-H clinics, using leased space and its own staff and couriers.

Bring Tests In-House

"But then a few years before 2010, our lab team started talking about all the reasons it would be best to do those lab tests in-house," she said. "The first and most important reason was to improve patient care. Having those tests done in-house allows us to collect the data on those patients' test results and include that data in each patient's chart and electronic health record. We couldn't do that when those tests were going to another lab company.

"The second reason is that—as is the case with all outreach programs—running those tests in our own lab lowers our unit-cost per test while providing us with the additional specimen volume needed to bring more tests in house," she said.

"As a first step, we recognized the need to make certain infrastructure improvements in our Lebanon lab," she noted. "Once we did that, then having outreach specimens performed anywhere else made no sense.

"Next, we needed a plan to make the change in a way that would minimize the disruption to the physicians' practices, to patients, and to the commercial lab that was running those tests," Dulkes said. "We had no ill will toward that lab company and it turned out that they had no ill feelings toward us either.

"The commercial laboratory worked well with us on a smooth transition plan for the patients and the employees," she stated. "Everyone knew that we were making this shift strictly on the basis of improving patient care and bolstering the finances of our own lab and parent organization.

"Nevertheless, we didn't disclose our plans to bring those lab tests in-house until about 150 days before the go-live date," recalled Dulkes. "That go-live date came in 2010, when all locations went live on the same day, at the same time.

"Prior to 2010, we laid the foundation to support this expanded lab outreach effort by putting a plan in place to bring those tests to our lab in Lebanon, N.H.," she added. "That was actually the first step in what became a multi-year effort to shift all tests that were going elsewhere into our own lab.

"Because we did this planning covertly, we named the project 'Operation Rosebud' and decided not to tell the commercial lab until there were 150 days to go," she said. "In addition, we told everyone not to discuss the project with anyone outside of the D-H lab unless absolutely necessary.

Bring in New Lab Staff

"We wanted to do as much of the work behind the scenes as possible," she commented. "That meant we needed to figure out how to bring in new lab workers through human resources, we had to determine a salary structure for each new staff member, and we had to assign new courier routes so that we could move specimens four times a day.

"We knew that the commercial lab company had stat labs in Manchester and Nashua, so we wanted to mimic those services as much as possible," Dulkes explained. "In an important step, we met with the medical staffs in Manchester and Nashua to

ask what they wanted on-site and what we could do to meet or exceed the services they had with the commercial lab.

How to Be a Better Lab

"At this time, we knew that the commercial lab was CLIA-certified, we knew its hours of operation, its test menu, stat lab services, turn-around times, courier routes, staffing levels, its lab-results reporting system, and we knew how its lab staff interacted with our physicians," Dulkes said. "We wanted to be better in each of these areas, which meant our lab would be CLIA- and CAP-certified, we would have longer hours of operation, better test menus, faster TAT, and more.

"We also recognized the importance of partnering with regional hospitals in those areas, such as **Catholic Medical Center** and **Elliot Hospital**, both of which are in Manchester," she added. "We needed regional partners for testing some time-sensitive specimens because it wouldn't be sustainable to send them all to Lebanon. We needed these partners to provide services that we couldn't provide on-site. And, again, we developed all of this covertly.

"We used the state inspection at each site as a milestone, following which we had what we called a Thanksgiving dinner at each site," she commented. "The dinner allowed everyone to meet each other and it helped everyone feel like they were a member of the same team.

Go-Live Date

"By end of winter in 2010, we had a go-live date for Manchester and Nashua of March 15," said Dulkes. "That was a Monday and the commercial lab vacated the premises in the phlebotomy draw sites on the Friday before. The commercial lab did not vacate the stat labs, however, until Sunday, on the night before we went live. Their staff left at about 8 pm or 9 pm that night and we cleaned the labs and moved in our equipment that same night. We did all that work with lab staff from the Lebanon campus who volunteered their time. It was a huge undertaking.

"Several years later, we followed the same process in Concord," she added.

"For the entire outreach project, we hired about 30 or so full-time equivalent staff, including a new supervisor, team leaders, clinical laboratory scientists, and phlebotomists, and many of them came from the commercial lab," she said. "We also arranged a van to drive the new phlebotomy staff from the south up to Lebanon for training prior to go-live.

Lab Projected 48-Month Return on Investment

WHEN DRAFTING THE PLAN to integrate clinical lab services from three physician groups in Southern New Hampshire, the clinical lab staff at Dartmouth-Hitchcock (D-H) estimated it would take four years to get a return on the investment.

"When this project started, we knew that D-H was paying the commercial lab to run our own tests," said Ellen J. Dijkman Dulkes MS, MT(ASCP), D-H's Outreach Services Manager.

"At the time, capital costs for this project were estimated to total about $2.4 million, including $84,000 for new furniture, $1.75 million for new medical equipment, $50,000 to prepare the building, and $550,000 for new information technology systems," she said. "In addition to our capital costs of about $2.4 million, we would need to spend more than $707,000 to hire 27.5 FTEs for a total estimated investment of $3.1 million.

"Once we had those numbers, we estimated that the increased testing volume would generate a margin of almost $800,000 annually," she said. "At that rate, it would take us about 48 months to earn back this investment. Our actual numbers showed that we were just about on target for our return on that investment."

"Our goal was to have the new staff become familiar with how our lab operated and we wanted those same processes in place in the physicians' offices and in the new D-H stat labs as well," Dulkes continued. "Also, we required our new staff to get their ASCP certifications, which they didn't need when working for the commercial lab.

"As a result of all our preparation and planning, as each project went live, there were only a few problems," she said. "Most of the problems involved phlebotomy. We did not anticipate the need for more phlebotomists and quickly contracted with a temp agency who filled the gap until we could train and hire permanent staff.

Standardized Platforms

"The technical staff performed quite well," stated Dulkes. "That was because we mimicked the equipment that the Lebanon-based laboratory was using. By using similar testing platforms, reference ranges were now standardized across the health system, and we had the technical staff trained in Lebanon prior to go-live. Therefore, the new lab staff members were already familiar with our equipment.

"Although the problems were few, we did have one clinical practice difference that we needed to address," she said. "Under the previous commercial lab's procedures, physicians could order any test they wanted. But at D-H, we require physicians to order tests that comply with best practices.

"For example, in Manchester and Nashua, the physicians would often order a test for ova and parasites, in part because they have a high refugee population," she explained. "At D-H, we order different assays. Instead of running tests for ova and parasites, we run a test for *cryptosporidium* and *giardia*. We don't do a true ova and parasite test unless a patient has a significant travel history, meaning they've been to an area where such parasites are endemic.

Lab Developed Detailed Plan to Expand Outreach Program

BEFORE 2010, THE CLINICAL LABORATORY at Dartmouth–Hitchcock had medical directors in four of the hospitals in the surrounding area and these hospitals were sending anatomic pathology specimens to the D-H lab. But most of the clinical lab testing from those facilities was not coming to the health system's core lab in Lebanon, N.H.

Under a plan the lab and health system staff developed, the lab prepared to integrate clinical lab specimens from many of the hospitals in the state, and from some physicians' offices as well, said Ellen J. Dijkman Dulkes MS, MT(ASCP), D-H's Outreach Services Director.

"In 2010, we took outreach testing back from three physicians' offices in Southern New Hampshire and that was the first step in a project that continues even today," Dulkes said. "In 2014, we put in medical directors for clinical pathology and anatomic pathology in four hospitals in the Lebanon region.

"Those four facilities are **Alice Peck Day Hospital** (in Lebanon, N.H.), **New London Hospital** (in New London, N.H.), **Mount Ascutney Hospital** (in Windsor, Vt.), and **Valley Regional Hospital** (in Claremont, N.H.). Later that same year, those four hospitals began sending more of their tests to Lebanon," she said.

"Last year, **Cheshire Medical Center** (in Keene, N.H.) became an affiliate and we are working more closely now with **Brattleboro Memorial Hospital** (in Brattleboro, Vt.)," she added.

"To address this issue, we sent our subspecialty pathologist down to do in-service training and education with their medical staff and to smooth out these kinds of bumps as they arose," she concluded. "Outside of that, the problems we faced during this transition were minimal." TDR

—Joseph Burns

Contact Ellen Dulkes at 603-650-7487.

Pap Test Errors in Ireland Attributed to Quest, CPL

Cervical cancer screening tests for Irish women were sent to Quest Diagnostics and CPL in U.S.

CEO SUMMARY: In Ireland, the big story in healthcare at the moment is the discovery that the nation's cervical cancer screening program has failed hundreds of women who had pre-cancerous conditions or cervical cancer, but, as alleged in numerous court cases, their tests were inaccurate or the results not communicated to their physicians, or both. These cervical cancer screening tests were performed by Quest Diagnostics and Clinical Pathology Laboratories (CPL) in the United States.

ONCE AGAIN, THE DISCOVERY of serious lab test errors stretching over multiple years has become a national story. This time the national story is in Ireland but the case has significant implications for two American lab companies: **Quest Diagnostics Inc.** and **Sonic Healthcare's Clinical Pathology Laboratories** (CPL) in Austin, Texas.

In Ireland, errors on screening tests for cervical cancer have dominated the headlines in recent months amid reports that 209 women in Ireland have been misdiagnosed in the nation's cervical cancer screening program.

Cervical Cancer Screening

Last week, *The Irish Times* reported that nine new legal cases involving errors in cervical cancer screening were identified, bringing the number of pending court cases to 28. In addition, two more cases may be filed and, and two other cases have been settled after plaintiffs reached multi-million euro settlements.

One case was closed June 28 when Quest agreed to pay the plaintiff €7.5 million ($8.76 million in U.S. dollars). Previously, CPL and the **Irish Health Service** settled another case for about US$3 million, the *Irish Times* reported.

The nine new cases were filed against Ireland's National Screening Service. In each case, women claimed their cervical cancer was misdiagnosed, the newspaper reported.

The patient in the Quest case who settled is Emma Mhic Mhathúna. She charged that she was mistakenly cleared of cancer years ago.

CBS News reported that Mhathúna is a single mother of five children, who won a legal battle but is still fighting for her life. "I'm 37, learning about the process of dying," she told *CBS News* reporter Roxana Saberi. "It's not fair for children to have to go through that process."

In 2016, Mhathúna was diagnosed with cervical cancer and later said that Quest missed the warning signs on screening tests she had undergone earlier.

Two years before, in 2014, government auditors found that the two U.S. labs and an Irish lab mistakenly cleared 209 women who were later diagnosed with cervical cancer, *CBS News* reported.

"Since then, 18 of those women have died," Saberi wrote. "But most of the women affected were never told."

Bad News in Audit Report

One of those women who was not told about her diagnosis learned about the bad news by reading her own medical file earlier this year, *CBS News* reported. At the time, that patient, Vicky Phelan, did not know that she'd had cancer since 2011. Phelan was the first woman to sue and, in April, reached a settlement of some US$3 million with Ireland's Health Service and CPL, according to *CBS News*.

After the case was settled, CBS quoted Phelan as saying, "My settlement will mostly be spent on buying me time and for paying for clinical trials to keep me alive, and to allow me to spend more time with my children."

Attorney Cian O'Carroll is representing more than 60 women who say they were misdiagnosed, including five who are terminally ill, *CBS News* reported. O'Carroll told *CBS* that in the many of the cases he has reviewed, there are multiple errors. A high rate of errors means patients in the United States should be concerned, he added. "Not only did they get the tests wrong, but they got them very, very wrong," he told *CBS News*.

U.S. Labs Asked to Comment

In a statement to *CBS News*, CPL said, "No screening program is 100% effective," and, "We adhere to the highest clinical standards." When asked for a comment by THE DARK REPORT, Quest refuted the reporting of *CBS News* and others that conveyed cervical cancer screening as a diagnostic test. We will publish Quest's full comments about this matter in our next issue.

As a result of the misdiagnoses in Ireland, the **College of American Pathologists** is investigating CPL but it is not investigating Quest's lab in Teterboro, N.J., which produced the report on Mhathúna's case, *CBS News* reported. CAP could not be reached for comment before our press deadline.

The federal **Centers for Medicare and Medicaid Services** (CMS) declined a request from *CBS News* to say if it was investigating CPL or Quest. A CMS spokesperson said, "It's CMS policy not to speculate on ongoing or forthcoming survey activities."

On the issue of error rates, the CMS spokesperson said there is no federal "error rate" when reporting on cervical cancer test errors in the United States. "Each laboratory is free to design and monitor error rates for their own facility," the spokesperson added.

For the *Journal* in Ireland, Sean Murray reported that Phelan, who is age 43, explained that her results from a routine Pap smear test in 2011 were normal. "While a smear test does not diagnose cervical cancer, an abnormal result would lead to further examinations to test the patient for cancer," he explained.

Doctor Was Not Informed

In 2014, Phelan's missed diagnosis of cancer was revealed during an audit of Pap smear test results. That same year, she had a second Pap smear test and this second test showed she could have cervical cancer, Murray added.

"Her doctor wasn't informed of this diagnosis until 2016, and she herself wasn't informed until a further year had passed," he wrote. "In January of this year, she was given between six and 12 months to live."

Phelan told Murray that there is no cure for her form of cancer. "Unfortunately, I don't see the day, unless a breakthrough comes in the next couple of years, where I'm going to be able to say I'm cured," she told Murray.

The current program for cervical cancer screening in Ireland was created almost a decade ago. In 2008, the Irish Health

Pathologist, Other Physicians Were Concerned About Ireland's Plan to Outsource Pap Tests

WHEN OFFICIALS IN IRELAND were considering a national cervical cancer screening program, a pathologist warned about potential problems. His warnings seem prescient now.

This spring, Denise Calnan reported for the *Independent* in Ireland that a pathologist who worked for the **National Cervical Screening Programme** (NCSP) said he raised concerns 10 years ago about sending Pap smear tests outside of Ireland for testing. He predicted quality assurance problems would manifest in about 10 to 15 years, Calnan wrote.

At the time, Dr. David Gibbons was chair of the Cytology/Histology Group within the Quality Assurance Committee of the NCSP. This spring he was interviewed on *RTE Radio One's* Morning Ireland show, saying he warned Tony O'Brien, who at the time was the chief executive officer of National Cancer Screening Programme. Gibbons said he told O'Brien that the outsourcing of cervical Pap smear tests to labs in the United States would lead to missed cases or misdiagnoses, Calnan reported. At the time, Gibbons predicted that these problems would show up in 10 to 15 years.

Concerns Were Dismissed

After raising these concerns, and then learning that officials dismissed their concerns, Gibbons said he and other "very well-qualified scientists" resigned, Calnan reported.

In those early years of the program, Gibbons was not alone. Dr. Andrew Jordan, Chairman of the **National Association of General Practitioners**, said he and other GPs were unhappy that screening tests were being sent outside of Ireland. "We were embracing a system where women were getting an annual smear, where we were telling women they would be okay for three to five years," he told Calnan.

"We would obviously prefer smears to be examined and looked at here in Ireland," he added. "We have an excellent pathology service and some of the best trained doctors in the world."

One member of the pathology service in Ireland was Gibbons, who ran a large screening lab in Dublin and who from 2006 to 2008 was the Quality Assurance chair of the Quality Assurance committee for the NCSP. "At that time, we had a backlog due to underresourcing," Gibbons told Calnan.

Fewer Pre-Cancer Cases

One issue, in particular, caused concern. The labs in the United States were finding fewer cases of pre-cancer, he said. "They were predicting fewer pre-cancer cases in a batch of similar population size to us," Gibbons said of the labs in the United States. "We were finding 1.8 cases per 100; they were finding 1.2. This was a third of a difference."

In the United States, the standard of care calls for a Pap smear test is as often as yearly. Ireland has a three-year screening system.

"So even though they do the tests quickly in the United States, they do it once a year," Gibbons told Calnan. "So they have a substandard screen, but more often. We were getting one third of the high-grade cases we were finding in our population."

When he expressed those concerns, Gibbons said the lower numbers were dangerous and would lead to problems that would not become apparent for 10 years, Calnan reported. Unfortunately for the more than 200 women in Ireland who had a missed diagnosis, it turns out Gibbons' prediction was correct.

Back in 2008, Mary Harney, then the Minister for Health, defended the contract by observing that the price submitted by Quest Diagnostics was one-third less than any bid put forth by an Irish laboratory—while also noting that Quest's services were "quality assured" and it would meet the 10-day turnaround requirement.

Service was concerned that it would not have the capacity to screen all Irish women aged 25 to 60 for cervical cancer. Its solution was to partner with clinical labs from the United States to outsource that testing. *(See TDR, Aug. 31, 2009.)*

Ireland's new national cervical cancer screening program was launched on September 1, 2008. It is called "CervicalCheck." Quest Diagnostics was awarded a contract to do nearly 100% of the pap testing. On July 1, 2008, just 60 days prior to that introduction, the Pap test outsourcing contract with Quest took effect.

By 2010, **Sonic Healthcare Ltd**, of Sydney, Australia, had won a contract to perform about half of the Irish pap tests annually. It opened up **MedLab Pathology Ltd**, in Dublin, Ireland, and split its share of these tests between that location and its Clinical Pathology Laboratory division in Austin, Texas.

Screening Tests

As part of this national screening service, women aged 25 to 60 are invited to see a general practitioner or a designated clinic for a free smear test once every three years to check for possible signs of cervical cancer. The tests are designed to identify abnormalities or changes to the cells of the cervix which can be a precursor to cancer, O'Doherty explained. The test is not designed to catch already-existing cancer.

Since the screening program was established in 2008, the numbers of women getting screened has risen each year. Current statistics show that more than 270,000 women get such a test every year and about 80% of women due a Pap smear test in any given year now have it, O'Doherty reported.

According to the most recent annual data from 2016, 187 women who were screened were diagnosed with cervical cancer, she wrote. Each year about 90% of Pap smear tests are declared normal. If there is a finding of concern, then about 18,000 women are referred for a colposcopy. In about half of those 18,000 cases, pathologists will identify pre-cancerous abnormalities, O'Doherty explained. "Most will undergo treatment as outpatients, while some will not need treatment yet but will be scheduled for a repeat test within a year," she added.

More Cases to Be Reviewed

O'Doherty also reported that, in addition to the 209 women identified to date, at least 1,500 other women diagnosed with cervical cancer over the past 10 years did not have their cases reviewed to see if they were previously screened and, if so, if that screening should have led to an earlier cancer detection.

The National Cancer Registry was notified about these cases, she reported, but the CervicalCheck system was not notified. "CervicalCheck says it has a policy of sharing data with the registry because it asks women for their consent to do so, but that isn't reciprocated by the National Cancer Registry," she wrote. "CervicalCheck says it is now working on a data-sharing partnership with the registry."

What Action Will Be Taken?

There are many troubling issues raised by these developments. At least one experienced Irish cytopathologist is on record as pointing out that the U.S. laboratories are detecting about one-third fewer cases of "pre-cancer" than Irish labs.

It would seem that government healthcare regulators in both the United States and Ireland would want to investigate this significant difference in testing outcomes. It would be appropriate for healthcare officials from both countries to collaborate on a detailed inquiry to determine if there is a quality and/or accuracy difference in how labs in both countries perform cervical cancer testing. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Wake Forest Baptist Medical Center of Wake Forest, N.C., has been notified by the **Centers for Medicare and Medicaid Services** (CMS), in a letter dated June 15, that it is back in compliance with Medicare Conditions of Participation. Earlier this year, following inspection of the hospital and its anatomic pathology department, federal and state officials identified deficiencies that were an immediate threat to patient health and safety. As reported by local media and THE DARK REPORT, errors in pathology tests had caused some patients to get medically-unnecessary and life-changing surgeries and treatments. *(See TDR, April 16, 2018.)*

MORE ON: *Wake Forest Medical Center*

Following its inspection of Wake Forest Medical Center, on Feb. 8, CMS issued a 23-page list of deficiencies. Six weeks later, on March 26, CMS issued a revised list of deficiencies that identified the need for the medical center to review 9,291 pathology cases dating from June 2014 to August 2017. It was determined that at least 25 patients were affected by faulty pathology lab test results.

100,000 EXOMES SEQUENCED BY GENEDX

Here is a notable milestone. **GeneDx**, a division of **Bio-Reference Laboratories, Inc.**, reported that it has now done exome sequences on 100,000 unique individuals. It said this represents "one of the largest cohorts of sequenced exomes by an independent laboratory in the world." The company says it has compound annual growth of 55% since its inception, demonstrating how the demand for clinical gene sequencing services continues to increase.

TRANSITIONS

- **Konica Minolta** appointed Kenneth Bloom, MD, to be the Chief Medical Officer of Advanced Pathology and Genomic Services at both **Invicro** and **Ambry Genetics**, each of which are divisions of Konica Minolta. Bloom previously held positions at **Human Longevity**, **Clarient**, and **US Labs**.

- Michael Sullivan was selected as Chief Science Officer for **Caris Life Sciences**. Sullivan previously held executive positions at **Roche Diagnostics**, **Ortho Clinical Diagnostics**, **IDEXX Laboratories**, and **Abbott Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 30, 2018.