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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

Do Regulators Really Protect Patients, Consumers?

IMAGINE, FOR A MOMENT, THAT ONE OF YOUR LOVED ONES had gone to **Theranos** during the past two years to get lab tests. Assume that your loved one was being tested for significant biomarkers that directly affected the care provided to your family member for significant health issues and that your loved one's physician had ordered these lab tests.

Further, assume that the physician based clinical decisions on the lab test results Theranos reported. Now, imagine that you have just learned, two years later, that Theranos recently sent a letter voiding those lab test results to your family member and his/her physician. How would you feel about that news, particularly if your loved one had gotten the wrong clinical care because of an inaccurate or false lab test result that Theranos provided?

Am I describing a situation that has real consequences? Indeed, yes! Everyone in lab medicine, from phlebotomists and medical technologists to pathologists and clinical chemists, understands that every lab test result their clinical laboratories produce has a human life associated with it. That is why quality, accuracy, and reproducibility of clinical lab testing are the hallmarks of the lab medicine profession in the United States—and the envy of the world.

Next, how would you feel about the scheme of state and federal laboratory licensure and accreditation in the United States, if, in the case cited above, regulators knew about issues within Theranos, but, because of how CMS interprets the CLIA statute, it doesn't make those findings public? Thus, a lab like Theranos can operate for months and years because of a combination of forbearance by regulators and the lack of public knowledge about deficiencies, whether minor or the type described in a CMS letter to Theranos as findings "of immediate jeopardy to patient health and safety."

Set aside your role as a lab professional and take on the role of the patient or consumer. Is it good regulatory policy not to make lab deficiencies public—whether minor or major? How can a patient make an informed decision if these issues remain known to lab regulators, but not to the public?

These questions are all directly relevant to how Theranos got to this place and time. Either the regulatory system failed to detect these significant issues, or that information has been withheld from the public for many months or years. In this respect, the Theranos affair shows flaws in the existing scheme of lab regulation that Congress or CMS or both should address. TDR

Is Theranos Kowtowing To CMS over Sanctions?

Elizabeth Holmes suddenly booked to speak at AACC in August, more scientific advisors added

CEO SUMMARY: Having ignored the profession of laboratory medicine for nearly all of its 13-year corporate life, Theranos suddenly began engaging with expert laboratorians last month. The timing of this new outreach coincides with public disclosure that CMS proposed the severest sanctions against Theranos, including revocation of the Theranos CLIA certificate. An expanded scientific advisory board was announced, as was a commitment for Holmes to address the AACC this summer.

NEW CHAPTERS CONTINUE TO BE WRITTEN in the ongoing saga of **Theranos**, the once-vaunted lab testing company that said its ambition was nothing less than to disrupt the entire clinical laboratory industry.

Now facing the most severe sanctions that the federal **Centers for Medicare & Medicaid Services** can impose, per the CLIA 1988 law, Theranos finds itself at the point of:

- Having its CLIA certificate revoked;
- Losing its right to be paid by the Medicare and Medicaid programs; and,
- Having its CEO, COO, and medical director banned from owning or working at Theranos or any clinical laboratory for up to two years.

And this is just the latest of the news for the now-controversial lab company. Over the past eight months, *The Wall Street Journal* and other media sources have published a steady stream of news stories about Theranos that describe problems, internal failures, and unhappy business partners.

As if that parade of news exposés was not enough, last month the journal disclosed that Theranos is the subject of an investigation by the **Department of Justice** and a separate probe by the **Securities and Exchange Commission**. Officials at Theranos have acknowledged the existence of these two investigations.

Of all these corporate crises now shaking Theranos, the one with the biggest impact in the short term is the revocation of the Theranos CLIA license by CMS. Thus, executives at Theranos are scrambling to resolve this problem and stave off imposition of the sanctions that CMS

described in a letter it sent to Theranos in March.

Since the CMS letter proposing specific sanctions was made public in April, Theranos has taken a series of actions that—when viewed in the context of its corporate behavior over the past three years—is a significant reversal of its policy of non-engagement with the profession of laboratory medicine.

CMS CLIA Sanctions

What might be behind this change in corporate policy? One easy answer is that Theranos has a limited amount of time to make its argument to CMS that the sanctions should not be imposed.

Thus, company officials are hurrying to demonstrate that they can engage with the clinical laboratory profession. This would seem to include becoming more transparent about its diagnostic technology, and, through this increased engagement, help resolve the "severe deficiencies" CLIA inspectors observed in its Newark, California, laboratory to a degree where CMS might moderate the pending sanctions and allow Theranos to retain its CLIA certificate.

Probably the single biggest sign that Theranos realizes what danger it is in is the fact that founder and CEO, Elizabeth Holmes, is suddenly willing to present data and take questions from the biggest international gathering of clinical chemists.

Holmes To Speak At AACC

Last month, it was announced that Theranos CEO Elizabeth Holmes would speak at the *Annual Scientific Meeting & Clinical Lab Expo* of the **American Association of Clinical Chemistry** in Philadelphia. On August 1, Holmes will appear for a 90-minute session to present scientific and technical data and answer questions from the audience.

It is without precedent to now have Holmes step in front of an audience of clinical chemists, clinical pathologists, and other experts who are highly-trained and highly-experienced in laboratory medicine to explain the data and science behind the diagnostic technology that Theranos has developed and has touted as disruptive to clinical lab testing as it exists today.

In many respects, Holmes is about to walk into the proverbial den of lions. It will put her face-to-face with the people who are best-equipped to understand Therano's proprietary lab testing technology, along with all the factors and complexity that often cause even well-run labs to produce test results that are unreliable or inaccurate and must be repeated to ensure optimal patient care.

Moreover, the "den of lions" metaphor is accurate for another reason. For almost three years, Theranos has repeatedly criticized the current state of clinical laboratory testing—all the while asserting that its proprietary clinical lab test technology is superior in many respects.

Personification Of Theranos

And since only Holmes has spoken publicly for Theranos during these three years, she is the personification of Theranos for the clinical laboratory profession. Thus, the frustrations—even anger—of thousands of clinical laboratory scientists may be on display during Holmes' presentation at AACC this summer. (However, because lab scientists are typically reserved and polite, it is likely Holmes will be extended much courtesy by those in the audience.)

Of course, Holmes has to be aware of this pool of ill-will that Theranos created among the medical laboratory profession. So, assuming she is as smart as the media has made her out to be in their fawning coverage of Theranos in recent years, Holmes will do her homework.

That may be the reason why, within days of the disclosure of the CMS sanction letter in April, Theranos announced that

Theranos Faces CMS Sanctions for CLIA Violations, Is Also Subject of Investigations by DOJ, SEC

"WHEN IT RAINS, IT POURS" was the famous advertising tag line for **Morton Salt**. It may also be an apt metaphor for the array of crises that now beset Theranos, the high-profile lab test company based in Palo Alto, California.

In the space of just eight weeks, the American public has learned about three developments—each of which has the potential to bring down the company that was once the darling of the media and Wall Street.

Probably the biggest crisis confronting Theranos at the moment is that the federal Centers for Medicare & Medicaid Services has put Theranos on notice that it is prepared to impose the most severe sanctions possible under the CLIA 1988 law.

Many pathologists and lab administrators are aware that Theranos received a letter from CMS, dated March 18, 2016, that is the next-to-final step before sanctions for violations of CLIA are imposed.

The title of the CMS letter says it succinctly: "Proposed Sanctions–Conditions Not Met Immediate Jeopardy. Imposition Notice to Follow if Proposed Sanctions are Imposed." *(See TDR, May 2, 2016.)*

Multiple Sanctions Proposed

CMS has given Theranos notice that, per the CLIA 1988 law, it is prepared to impose sanctions against the Theranos CLIA certificate, including the following:

- Revocation of the Theranos CLIA certificate.
- Cancellation of the laboratory's approval to receive Medicare payments for all laboratory services.
- "Also, upon revocation of a laboratory's CLIA certificate... [two federal laws] ...prohibit the owners or operator(s) (including the laboratory director...) from owning or operating (or directing) a laboratory for at least two years."

It was reported that a CMS inspection team visited the Theranos laboratory in Newark, California on November 20, 2015, and identified severe deficiencies, some described by CMS as "findings of immediate jeopardy to patient health and safety."

Theranos responded to the survey findings in a document it submitted to CMS on December 23, 1015.

SEC Investigates Theranos

A second crisis for Theranos is the disclosure that it is being investigated by the Department of Justice. This news was published on April 18 by *The Wall Street Journal*.

The journal wrote that, "Federal prosecutors have launched a criminal investigation into whether Theranos Inc. misled investors about the state of its technology and operations, according to people familiar with the matter."

The third crisis was also announced in that same story on that same date. The journal revealed that the Securities and Exchange Commission was now investigating Theranos. The journal said, "In addition to the criminal probe, the Securities and Exchange Commission is examining whether Theranos made deceptive statements to investors when it solicited funding, according to people familiar with the matter."

Theranos did provide a statement about these matters to *The Wall Street Journal*. Theranos was quoted as saying, "The company continues to work closely with regulators and is cooperating fully with all investigations."

The CMS regulatory enforcement action, in conjunction with the DOJ and SEC investigations, show how Holmes, personally, and Theranos as a corporate entity, are facing significant consequences as these three agencies pursue regulatory, civil, and criminal cases in these matters.

it had expanded its scientific advisory board. The names of the full board are presented on page eight. Four of the new board members are clinical chemists who are past presidents of AACC.

COO Balwani Leaves Firm

Another corporate decision was announced on May 17. Theranos disclosed that its long-time President and COO, Ramesh "Sunny" Balwani, was departing the company. He was described as a "top associate" to Holmes. Some lab scientists believe this action is one more concession to CMS as part of the Theranos campaign to persuade federal regulators to ease the CLIA sanctions that loom against the company.

There may be more to Balwani's departure, however. The following day, on May 18, *The Wall Street Journal* once again made national headlines with its story that Theranos was in the process of correcting lab test reports for tens of thousands of patients who were tested during 2014 and 2015. According to the journal, these reports were produced on Theranos' proprietary analyzer, known as "Edison" within the company.

'Most Dramatic Steps Yet'

Moreover, the journal attributed this action, long overdue under CLIA requirements, as a response to the pending CLIA sanctions. Journal reporter John Carreyrou wrote, "The move is part of Theranos' attempt to persuade the agency not to impose stiff sanctions it threatened in the aftermath of its inspection of the company's Newark, California, laboratory. The voided and revised test results are one of the most dramatic steps yet taken by Theranos."

All of these test reports were produced while Balwani was President and COO of Theranos. Thus, the timing of his departure from Theranos may be associated with the decision to send out the correct lab test reports.

Theranos Now Correcting 'Tens of Thousands' of Reports

IT WAS ANOTHER NATIONAL MEDIA BOMBSHELL falling on Theranos. On May 19, *The Wall Street Journal* reported that Theranos was in the midst of sending tens of thousands of corrected lab test reports to patients and physicians.

In its coverage, the journal said that Theranos executives were telling CMS officials that they were in the midst of issuing these corrected reports. Theranos "was voiding some results and revising others, according to the person familiar with the matter," said the journal.

The lab test reports being corrected were primarily produced on Theranos' proprietary Edison lab analyzer, noted the journal. The tests had been performed during 2014 and 2015.

The lab test recall would be among the largest ever to happen in the United States. The journal said, "Company records reviewed during the inspection showed that the California lab ran about 890,000 tests a year. The inspection found that Edison machines in the lab often failed to meet the company's own accuracy requirements."

Apparently, only some types of lab tests were involved in the recall. The journal described this situation, stating, "Theranos has told regulators that it used the Edison for 12 types of tests out of more than 200 offered to consumers and stopped using the devices altogether in late June 2015, the person familiar with the matter said."

Collectively, will all these actions by Theranos be enough to persuade officials at CMS to moderate the proposed CLIA sanctions in a significant way? "Not likely!" respond some prominent clinical pathologists when asked that question by THE DARK REPORT. They all point out that no appeal has ever overturned an action by the agency to impose sanctions under CLIA that has gotten this far in the process. TDR

Theranos CEO Holmes To Show Data at AACC

Elizabeth Holmes scheduled to present scientific data at special session on August 1

CEO SUMMARY: Theranos Founder and CEO Elizabeth Holmes will be in Philadelphia to present to the American Association of Clinical Chemistry (AACC) data about the technology developed at Theranos. Conference organizers said Holmes would answer questions to clarify the science, accuracy, and reliability of the lab company's technologies and its effect on patient care and safety. AACC members have the knowledge and experience in clinical lab science to assess Theranos' results and claims.

Is Elizabeth Holmes, the founder and CEO of **Theranos, Inc.**, finally going to describe how her company's devices work for finger-stick blood collection and small-sample-size testing? Will she also present data showing the clinical utility of the processes Theranos uses?

Clinical laboratory professionals may learn the answers to these questions on August 1 when Holmes is scheduled to address a special session at the *Annual Scientific Meeting & Clinical Lab Expo* of the **American Association of Clinical Chemistry** in Philadelphia.

In April, AACC announced that Holmes would address AACC members during a 90-minute session at the Pennsylvania Convention Center. At least half of the time will be devoted to questions from association members, stated AACC President Patricia M. Jones, PhD.

"She's promised us the science; she's promised us the data. We're just providing a forum," explained Jones, who is the Clinical Director of Chemistry at the **Children's Medical Center** in Dallas. "In recent years, the AACC members, myself included, have regularly asked, 'Where's the science?'

"Now we have the opportunity to see the science during this session," she continued. "And, not only will we hear her presentation, but there will also be a real-time question-and-answer period for our members to ask unvetted questions of Elizabeth Holmes. We're looking forward to this opportunity."

Patient Safety Questions

When it announced the event, AACC said Holmes would answer questions to clarify the science, accuracy, and reliability of Theranos' technologies and its effect on patient care and safety. Unlike many other groups Holmes has addressed in recent years, AACC members have the knowledge and experience in clinical laboratory science to assess the science and data Holmes will present.

"We invited her to bring other science people with her if she wants to do that," commented Jones. "We said, 'Bring whoever you need to bring to explain the science and the data.'"

"What's most exciting about this session is that we are experts in this field. Science and technology is what we do," emphasized Jones. "So, in that way, we can ask the best questions to make sense of the technology Theranos uses. That is one reason we hope that good things will come out of this meeting.

"It's important for every lab, including Theranos, to put the science and data out there so that other scientists know what is being done," she said. "That's what makes this meeting a prime opportunity to begin vetting their science and their data.

Scientists Prefer Openness

"Scientists prefer to be open about what they are doing," noted Jones. "We want to share what we're learning and developing with our colleagues. Doing so helps us to move diagnostic technology forward because when we are open about what we do, our discoveries and our technology get vetted by lots of people."

Since 2014, AACC has asked Holmes to address its annual scientific meeting and Holmes has declined in each of the previous two years, Jones said. "But this year she agreed, and we're excited to hear from her," she said. "Just because we invited her does not mean we are endorsing her in any way. All we've done is provide a forum for her to present the science behind the testing Theranos does."

In answer to a question, Molly Polen, AACC's Director, Communications and Public Relations, responded that Theranos did not and has never provided sponsorship funds or other forms of grants to the association.

The AACC meeting will not address the regulatory questions dogging Theranos, Jones said. Instead, the focus will be on the science and technology Holmes and her team at Theranos have developed. "It's true that the whole laboratory industry around the world is watching Holmes," she said. "But we're going to keep our focus completely away from anything that has to do with regulatory activity. We want to see the science."

AACC will allow members and possibly other members of the audience to ask questions in real time. Questions will not come from members of the audience using microphones, Jones explained. TDR

—Joseph Burns

Contact Molly Polen at 202-420-7612 or mpolen@aacc.org.

Theranos Adds Scientists To Its Advisory Board

IN APRIL, THERANOS ANNOUNCED that new laboratory and medical experts had joined its Scientific and Medical Advisory Board, including these four former AACC presidents:

- Susan A. Evans, PhD, FACB; Vice President and General Manager of **Agencourt Bioscience**, a division of **Beckman Coulter Corporation**;
- Ann M. Gronowski, PhD, DABCC, of the Department of Pathology and Immunology and the Department of Obstetrics and Gynecology at the **Washington University School of Medicine** in St. Louis;
- Larry J. Kricka, DPhil, FRCPath, of the **University of Pennsylvania**; and
- Jack Ladenson, PhD, DABCC, of the **Washington University School of Medicine**;

Others joining the advisory board were

- Bill Foege, MD, former Director of the **U.S. Centers for Disease Control and Prevention**;
- David Helfet, MD, **Hospital for Special Surgery** and **New York-Presbyterian Hospital, Weill Cornell Medicine**;
- Andy O. Miller, MD, **Hospital for Special Surgery** and **New York-Presbyterian Hospital, Weill Cornell Medicine**; and
- Steven Spitalnik, MD, **Columbia University Medical Center**.

Legal Update

UnitedHealth Sues 5 Tox Labs, Says It Was Defrauded of $50M

FLORIDA IS ONCE AGAIN GROUND ZERO for a major case of lab testing fraud. **UnitedHealthcare** has filed suit against five toxicology laboratory companies, three general partners in those companies, eight urinalysis referral sources, and other entities, claiming the defendants defrauded the health insurer of more than $50 million.

Filed last month in U.S. District Court for the Southern District of Florida, UHC's lawsuit named **Sky Toxicology**, **Frontier Toxicology**, **Hill Country Toxicology**, **Eclipse Toxicology**, and **Axis Diagnostics** as the defendant lab companies. UHC named **Sky Toxicology Lab Management**, **FT Lab Management**, and **Eclipse Lab Management** as general partner defendants.

In the lawsuit, UHC also named William "Wade" White, MD (the chief executive officer for each lab defendant); Lance Hupfeld (the chief sales officer for each lab defendant); Bradley West (chief operating officer of each lab defendant).

The referral sources named as defendants are **Elements Behavioral Health**, **South Florida Recovery Center**, **Solid Landings**, Kory Avarell, Stephen Fennelly, Elizabeth Perry, **Ferriel Consulting Group**, Jeffrey L. Cohen, and **LLJ Consultants Inc.**, the suit says. Also named as defendants were 150 individuals referred to as John and Jane Does.

In the lawsuit, UHC said the defendants defrauded UnitedHealthcare, "through a pattern of deceptive and unfair trade practices related to health insurance claims for urinalysis tests." The labs offered kickbacks to referral sources to refer large quantities of urinalysis (UA) tests to the defendant labs, the lawsuit said, adding that, "to disguise the kickbacks, referring defendants 'invest' in the lab defendants by purchasing limited partnership shares in the lab to which they refer UA tests. The referring defendants then receive monthly distributions of tens of thousands of dollars, based on their limited partnership shares."

Kickbacks Disguised

The toxicology labs also encouraged and demanded that referral sources increased UA test volume by referring unnecessary or unauthorized UA tests, the suit explained.

In the scheme, the labs waived UHC members' responsibilities to pay part of the fee for the lab test work and the labs then submitted claims but did not disclose that fees were waived, the lawsuit said. Florida law identifies the waiving of fees for lab tests "as a species of fraud," it added.

"United makes payments to lab defendants based on the fraudulent claims and then individual defendants funnel the money back to the referring defendants and themselves through limited partnership shares in lab defendants and/or their respective general partner. Defendants have created and utilize myriad entities to disguise and add layers to the kickback scheme, which is calculated to make tracing funds more difficult," the lawsuit explained.

UnitedHealthcare's lawsuit is a sign that insurers are becoming more aggressive in taking legal action against this type of fraud in toxicology testing. This current lawsuit shows that one major payer is also ready to pursue the providers as well as labs. TDR

—Joseph Burns

CEO SUMMARY: Two years ago, the rate of hemolysis in blood drawn in the Cleveland Clinic's Emergency Department was about nine times higher than the ASCP recommended rate of 2%. With a two-year cooperative agreement and funding from the federal Centers for Disease Control and Prevention, the ED and clinical lab staff developed a quality improvement program to identify the causes of hemolysis and train staff to reduce those rates. Their efforts were successful in driving the rate down to the recommended 2% and sustaining it at that level.

High rates increase wait times, costs, drive down patient satisfaction

Lab, ED at Cleveland Clinic Reduce Hemolysis Rates

IN HOSPITALS THROUGHOUT THE NATION, labs continually find themselves dealing with the ongoing problem of hemolyzed specimens. Not only can hemolyzed specimens have a significant negative effect on patient care, but each hemolyzed specimen increases the cost of care, an important issue when hospital finances are being squeezed.

This was true at the emergency department at the **Cleveland Clinic Main Campus**, because staff was mostly unaware and unconcerned about hemolysis in blood samples. As in any busy ED, the staff was concentrating on providing timely and appropriate care to a steady stream of patients, most of them seeking immediate attention.

However, a big change happened at the Cleveland Clinic after it was awarded a grant from the CDC to study the problem of hemolysis and develop ways to reduce the number of hemolyzed specimens that originated in the ED. Hemolyzed specimens averaged about 13% at the start of a two-year process improvement project. At the end of 24 months, that rate fell to 2%, thus generating better patient outcomes, significant cost savings, and improved patient satisfaction.

"At the national level, baseline hemolysis from ED samples is an unquantified concern," stated Michael P. Phelan, MD, an emergency medicine physician and an associate professor at the **Learner College of Medicine at Case Western Reserve University**, who was one of the leaders of this study. "There has also been very little historical progress in addressing this problem."

To address the lack of evidence, the Laboratory Medicine Best Practices Program of the federal **Centers for Disease Control and Prevention** gave the Cleveland Clinic and Phelan, as principal investigator, funding to study the issue in 2014 and 2015.

"The goal of our study was specifically to gather evidence and develop best practices in how to prevent hemolyzed lab specimens," noted Phelan.

"In the literature, the hospital ED was identified as a major source of hemolyzed samples, and the leading cause of unsuitable specimens was hemolysis," Phelan said. "What's more, the hemolysis rate in the ED is significantly elevated compared with that of other departments in the typical hospital.

"The literature shows that the rate of hemolysis in the ED runs anywhere from 6.8% to 30%!" he added. "The **American Society of Clinical Pathology** says the baseline should be at about 2%.

"When we started this program, our rate in the ED for moderately hemolyzed results for one week was 18.5% of chem-lab tests," noted Phelan. "This compared to a rate of 2.3% for all other draws at the main campus. We defined moderately hemolyzed as having a hemolysis index of greater than 80.

"Our main campus hospital is an acute care, tertiary referral center with a 60-bed ED that gets 70,000 visits per year," noted Phelan. During a session at THE DARK REPORT'S *Executive War College* in New Orleans in April, Phelan and pathologist Edmunds Z. Reineks, MD, PhD, described the efforts of their collaborative program between the ED and the clinical laboratory staff at the Cleveland Clinic to identify the causes and costs of hemolysis and reduce the rate of this pre-analytic problem. Reineks was part of the project and is the Laboratory Director of the Automated Chemistry Laboratory at the main campus.

"In addition to having a much higher rate of moderately hemolyzed specimens, the ED at the main campus also had a rate of grossly hemolyzed specimens of 4.3% versus 0.8% for all other locations at the main campus," Phelan explained. "We defined grossly hemolyzed specimens as those having a hemolysis index of 300 or more."

Clearly, the ED at the main campus had a significant issue with hemolysis that Phelan and Reineks addressed in a stepwise fashion. First, they quantified the problem and estimated the cost of the hemolyzed speci-

mens that originated in the ED. Second, they assembled a team of clinicians to educate nurses and medics about ED hemolysis and some of the most effective methods to minimize hemolysis.

Third, they conducted a performance improvement project centered around "plan-do-study-act" (PDCA) cycles to improve their methods for collecting, handling, and transporting lab specimens.

Patient Satisfaction Issues

Reineks explained the problem from the lab's perspective. "When blood samples are hemolyzed, there's interference in some 39-odd different lab tests, most importantly to potassium results," he said. "Unreliable lab tests are a particular concern for potassium results because falsely elevated potassium may indicate a life-threatening abnormality, and low potassium also is critical for the ED.

"Another concern is the delay in care from the time you recognize a problem with a hemolyzed sample to the time you get a final result back," he added. "Imagine the time it takes to have a blood sample drawn, resulted, and realize that result is abnormal—then add another sample to be re-run that requires significant rework by both nursing in the ED and lab technologists.

"There is the additional problem of low patient satisfaction because a hemolyzed sample causes delays in care," he said. "There is also a cost, which we estimated at about $73,000 for the Main Campus hospital or about $1.13 per patient. If each of our 10 hospitals has costs in that range, then the potential savings are more than $700,000."

Step 1: Identify the Problem

"In our first year, we wanted to quantify and define the problem by gathering data and establishing a baseline hemolysis rate," he said. "Then, in the second year, we planned to introduce the interventions designed to improve our hemolysis rates."

After Phelan established the need for the program, Reineks described the role the laboratory staff played in defining and measuring hemolysis and how the lab could contribute to reducing the rate.

"The fundamental goal is to avoid hemolysis because the lab wants a quality specimen that will produce a good result, which, in turn, optimizes the care process for the patient," observed Reineks. "So in that way our lab's goal aligns well with that of the ED."

As this project began, the team needed to gather data. "The first step in our improvement programs was to define a level of hemolysis in the specimens originating in the ED," noted Reineks. "Therefore, each time the lab received a specimen with a hemolysis index of 80, we added a cautionary comment to the result. Anytime a specimen's hemolysis index was above 300, the lab rejected the sample and didn't report that result.

"With a hemolysis index of 300, it's impossible to get a normal potassium on a sample," he said. "That is why the lab rejects those samples.

"One important role for the laboratory was data collection and interpretation. At about this time we started using a business intelligence system called **Altosoft**," Reineks said. "We use it because it downloads data from our **Sunquest** laboratory information system and reorganizes it so that we can search it, create dashboards, and export that data to spreadsheets—all without doing any coding.

A Need for High Value Data

"When we got this system, it updated the data every six hours," said Reineks. "Refinements to this software now deliver critical management data in real time. We generate dashboards and report that data in a few minutes to anyone who needs it. It's been a great help in both managing the lab and in conducting research."

Having good data allowed Reineks and Phelan to understand how hemolysis affected two aspects of throughput: lab test results and ED patients' length of stay.

Using Smaller Tubes for Blood Draws Contributes To Reduction of Hemolysis Rates to 2% in ED

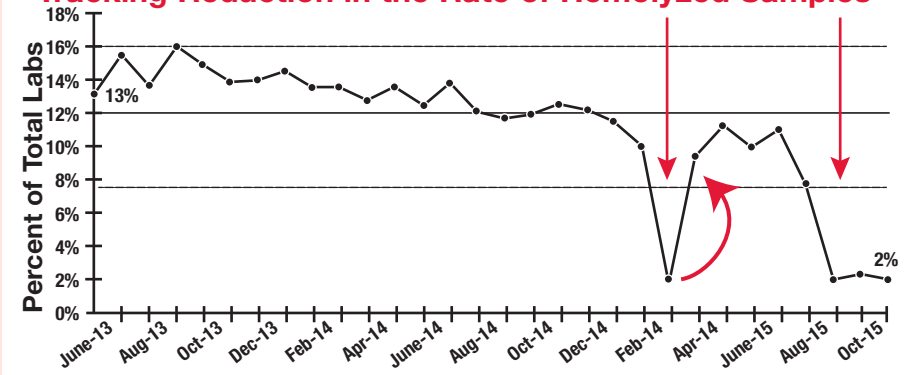
AS PART OF A TWO-YEAR COOPERATIVE AGREEMENT WITH THE **CDC**, a team at the Cleveland Clinic worked to quantify the rate of hemolyzed samples originating in the Emergency Department, then identified ways to reduce the rate of hemolyzed samples. Two physicians and one nurse took a leading role in this effort. One was Michael P. Phelan, MD, an emergency medicine physician. The other was Edmunds Z. Reineks, MD, PhD, a pathologist. Annmarie Kovach, MSN, RN Nurse Manager of ED Main Campus, was the leader from nursing.

Change in Tube Size

One factor that made a significant contribution to the reduction of hemolyzed samples from 13% down to 2% was the use of a rainbow draw protocol and adoption of a smaller tube.

- At Cleveland Clinic Main Campus ED, the rainbow draw includes 2x6 ml lithium heparin tubes, along with other (smaller) tubes.
- Heyer and colleagues had suggestive data regarding use of small tubes, but the data were not definitive.
- Switched to drawing 3x2 mL lithium heparin tubes.

Tracking Reduction in the Rate of Hemolyzed Samples



During the term of the study, the improvement team twice introduced the use of a smaller tube for sample collection. Each time, the ED's measured rate of hemolyzed specimens, originally at 13%, fell to 2%. That 2% rate was sustained following the second introduction of smaller tubes.

"I can't tell you how important it was to get data from the LIS because one of our most significant struggles was getting data out of our EHR," Phelan said. "We wanted to know the effect on ED patient throughput from hemolyzed samples and we wanted to know how those samples affected time in the department.

"Data from the lab told us that any discharged patient who had a hemolyzed specimen spent an additional 49 minutes longer in the department," he stated. "Any admit-

ted patient who had a hemolyzed specimen was spending, on average, 23 minutes longer in the department.

"Thus, reducing hemolysis improves patient throughput because it decreases the need for re-work, which is a key factor for ED nurses," continued Phelan. "When you reduce rework you also increase patient satisfaction because patients won't have to wait around while we do the redraw and run more tests.

"Determining the cost of hemolysis can be difficult because most of the costs are due to staff labor and we did not have very good models," he observed. "There are some increased costs for lab analytes, but the highest costs consist of labor for re-drawing samples and re-running them, both in the ED and in the lab.

"As explained earlier, our model showed that we could save approximately $73,000 at the main campus hospital if we could cut our hemolysis rate to about 2%," Phelan added. "If one hospital can save about $70,000 per year and your health system has 10 or 12 hospitals, then the costs can add up quickly."

Step 2: Identify Opportunities

With data now available, the next step was to assess existing workflow."In doing our work on this project, we found that there was a wide variation of practice among those who draw blood and the training they receive," explained Phelan. "Nurses and medics do our blood draws because we do not have phlebotomists in the ED. Some hospitals in our system have phlebotomists, but it is not at all typical.

"There was no standardized approach or road map for sample collection, which meant that our practices were done according to personal preferences," he added. "You could ask anyone and the method of blood draw would be different because it would be influenced by training and job description. Also, we learned there were a lot of myths about blood draws.

"Another problem we identified was the lack of documentation about how blood samples were collected at our facility," noted Phelan. "We thus built into our EHR a lab documentation module for our nurses and medics to better capture methods and try and correlate those methods with our hemolysis results.

Assembling The Team

"Once we had the data we needed, we put a team together that included the ED professional staff, front line nurses, and nursing leaders," he said. "We also had data analysts, biostatisticians, and experts in continuous quality improvement as well as our vendor (BD) to help focus our attention on the data and to get front line workers' input on possible solutions.

"Over time, we learned that the most important members of the team were those in nursing," emphasized Phelan. "We explained to them that this effort had the potential to affect patients significantly, and that was an important selling point for them.

"Once we had the team in place, we educated them about the causes of hemolysis and identified possible interventions," he said. "For example, use of a straight stick resulted in a significant reduction in hemolysis. But, it also would change the culture significantly since at our main campus ED we draw the majority of our labs through an IV. The reason we do this is to avoid a potential second stick if blood and an IV are required (which may not be apparent when the patient is triaged).

"Although there was limited and conflicting data, the team wanted to try using the smaller volume/vacuum tubes as a first improvement step and because it was simply a change in equipment," he said.

Step 3: Implement And Learn

"So, to start, we didn't settle the straight-stick question because the ED staff was concerned about the issue of two needle sticks if the patient later needed an IV,"

recalled Phelan. "But it was agreed to use the smaller 2ml tubes with heparin. BD helped us make that switch to drawing blood into the 2ml tubes with heparin. The result was amazing: Immediately following the switch to smaller tubes, our hemolysis rate dropped to 2%!

"To accomplish this, we had to change every tube in the main campus ED," he continued. "Of course, there were some problems associated with this change. The lab staff could not get some of the readings they needed, labeling and filling issues cropped up, and so after one week, we went back to using the larger tubes. At that point, the hemolysis rate shot right back up. *(See chart on page 13.)*

"We next instituted two other projects," stated Phelan. "For one, we asked a select group of medics to change their practice and increase use of straight sticks to obtain blood samples first. This change followed the literature and it showed a statistically significant reduction in hemolysis. However, this was not clinically significant. That may be due to our limited number of patients getting the direct stick, since the vast majority of samples were still obtained from an IV.

Other Process Improvements

"For the other change, we attempted ED-wide hemolysis online education for our nurses and medics," he stated. "While we saw statistically significant improvement of at least 1% to 2%, we did not see clinically significant changes as we did with the small tubes.

"Having tried these other approaches, toward the end of the second year of our agreement with the CDC, we finally replaced the larger tubes with small tubes," Phelan stated. "Once again, we saw a clinically significant reduction of hemolysis back to around 2%.

"So, what did we learn?" Phelan asked. "We learned that when we gave frontline staff the information and education about best practices, they were empowered to assimilate the knowledge and decide which best practices to implement.

"We learned that when the ED staff implemented the smaller volume/vacuum tubes, we saw a significant drop in hemolysis rates," he continued. "There was some reduction in hemolysis that resulted from the increased number of straight sticks for obtaining blood samples, but nothing like the clinically significant hemolysis reduction we saw with the use of smaller volume/vacuum tubes.

"We also learned from our analysis that straight stick and IV antecubital locations reduced hemolysis significantly," observed Phelan. "In addition we found that shorter tourniquet time and using a larger gauge needle were associated with lower hemolysis. We found no association between syringe vs. vacuum tubes and lower hemolysis rates.

Sticking Once or Twice?

"Now, getting everyone to follow recommendations, such as using straight sticks for ED samples consistently, is probably not feasible. Here's why: You may want to use a straight stick for every patient but there are other factors to consider, especially in those cases where ED patients are difficult blood draws. They are hemodialysis patients, or transplant patients, or they are morbidly obese and do not want to be stuck twice," he said.

Phelan further observed that, "We do what works for our culture, and that would be my recommendation for other hospitals as well."

For his part, Reineks summed up by saying, "We also didn't anticipate that trying to change practices in a busy environment with scarce resources would be such a challenge. Having said that, we worked through those challenges and produced meaningful results nonetheless." TDR

—Joseph Burns

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Payers Ask for Repayment When Labs Waive Fees

➤Labs face audits, automatic pay reductions for failing to collect deductibles from patients

➤➤CEO SUMMARY: Health insurers appear to have stepped up their efforts to warn clinical laboratories not to waive patients' fees in return for specimen referrals. Consultants also say that payers are increasing enforcement efforts. There are cases where, when insurers discover labs have not collected fees from patients, they have hit labs with automatic payment reductions. Other insurers have conducted audits months later, then demanded repayment as a result of the audit findings.

ONE TREND GAINING MOMENTUM in the area of managed care contracting is that health insurers are auditing more clinical laboratories that fail to collect all the money due from patients.

"When a payer finds that a clinical lab failed to collect patients' copayments and deductibles, the payer demands repayment," stated Rina Wolf, Vice President of Commercialization Strategies, Consulting and Industry Affairs for **Xifin**, a revenue cycle management company for labs. "Another development related to this issue is that insurers are reducing payments to labs that do not comply with rules to collect such fees from patients.

"For a number of years, managed care companies have warned clinical laboratories not to waive or cap patients' fees," she said. "Labs that do not comply may face payment reductions to their billed pricing that reflects what the insurer believes is their capped price. Insurers continually monitor lab websites to determine if a lab has these types of policies. Some insurers are demanding recoupment of the difference between the billed and capped price even years later!

"Payers, including **UnitedHealthcare** and **Cigna**, are sending warning letters to clinical labs that notify these labs that they could potentially be guilty of filing false claims," noted Wolf. "Also, insurers could deny such claims by saying the services are not covered if labs do not follow the insurers' rules to collect patients' copayments and deductibles.

➤Letters From Health Insurers

"In presentations that I've done since 2013, I have letters from United, Cigna, and other payers that address the same issue of laboratories that routinely discount or waive patients' share of costs," she continued. "The issue of waiving fees is not new.

"Recently we have seen insurers take action, such as the civil cases filed by **Aetna** and Cigna against **Health Diagnostic Laboratory**, a now-bankrupt and closed laboratory that had operated in Richmond, Virginia," noted Wolf. *(See TDR, September 14, 2015.)*

"In some cases, health insurers are doing audits 12 to 18 months after the date of service," stated Wolf. "So a lab might

think it got its money, but months later the lab learns it won't get to keep those funds.

"Another problem is that health insurers look at a lab policy of capping the patient share of the lab test cost as, essentially, setting the price for that test," explained Wolf. "For example, if a lab sent in a claim for $3,000 and the payer knows the lab has a policy stating that the maximum patient share of cost is $300, such a policy means that the lab has effectively reset its price of that test to $300.

Insurers Resetting Rates

"Then the insurers tell those labs, 'We don't want to see any more claims from you for anything above $300,'" she continued. "In addition, the insurer seeks recoupment of the difference between $3,000 that it was billed initially and the new 'reset' price of $300. In this case, the lab would get a bill from the insurer for $2,700 for each such claim! Plus, the insurer will apply the out-of-network penalty to the reduced amount.

"Labs that get audited can lose out in a big way," noted Wolf. "These penalties are real. So, when a lab says it doesn't believe there are any consequences to waiving copayments and deductibles, we can say we have seen what happens with insurers and it's not good.

"Keep in mind that what patients have had to pay in terms of copayments and deductibles has risen significantly over the past few years," stated Wolf. "In many cases, that means labs are now collecting a substantial sum from their patients. This is particularly true at the beginning of the year when many patients are responsible for the full payment because they have not yet met their deductibles for the year.

"We've had discussions with labs about waiving or capping fees and when we do, we hear from our lab clients that they want to see evidence that a health insurer or federal or state governments have taken action against labs that have these policies," she continued. "These labs say, 'Show me the case' or 'Show me the fine or the sentence that some lab got.'

"Some lab companies view fee waivers as one way to stay competitive," she said. "They say, 'Although this may not make compliance sense, if all my lab competitors

Payer Worries: Rising Costs, Waiver of Patient Fees

HEALTH INSURERS ARE INCREASINGLY CONCERNED ABOUT TWO TRENDS regarding clinical laboratory tests: the rising costs of some genetic and biomarker tests, and the policy of some labs to tell physicians it's okay to waive patients' copayments and deductibles, stated Consultant Paul von Ebers, President of Prospective Health LLC in Fargo, N.D.

When a test costs $3,000, a patient paying a copayment of 20% would owe $600 at the time of service. "Not collecting that amount from the patient worries health insurers, particularly for genetic and biomarker testing," stated von Ebers, the former President and CEO of Blue Cross of North Dakota. "These tests are usually expensive, meaning that waiving copays, coinsurance, or deductibles can be a significant factor in whether the patient agrees to pay for the lab test.

"When physicians or labs waive patient payment amounts, they have removed any financial incentive for restraint on the part of the patient or doctor," he added. "Some genetic testing labs have clearly articulated charity or financial assistance policies to waive patient payments for people in significant financial need. As long as these policies are reasonable and applied consistently, the health insurers are not likely to come after the lab for waiving these payments.

"I'm aware of lawsuits that in the not-too distant-past were filed by Cigna and some Blue plans against hospitals, physicians, labs, and others who have tried to waive patient pay amounts," he concluded.

waive or cap patient fees and we don't do it, then we are not going to have a company.'

"That's why you see some lab companies that absolutely insist on waiving patient fees," she emphasized. "These labs even go to the extent that they leave materials behind in physicians' offices and advertise on the web that—no matter what the payer pays—they will hold patients responsible only for $200 or $300 or something in that range.

Financial Assistance

"The only bona fide way to help manage patients' share of costs is through a true financial assistance program that's created and managed compliantly and consistently," she explained. "Whenever a lab has a patient that gets some form of financial assistance from a lab or pharmaceutical company, it is essential to be able to document that patient's qualification for financial assistance. In the event of an audit, the lab will need that documentation to show it followed a compliant and consistent policy involving that patient's fees."

One important factor when dealing with a health plan is the insurer's benefit design, stated Paul von Ebers, former President and CEO of **BlueCross and BlueShield of North Dakota**.

"The ability of insurance companies to recoup payment or impose other penalties will be rooted in either the provider contract or the benefit contract that applies to the member," explained von Ebers, President of **Prospective Health, LLC**, in Fargo, ND. "If the provider has a contract with the insurer, that contract may include rules for collecting co-pays, co-insurance and deductibles.

"If the provider is out of network, then no contract exists between the provider and the insurer," he said. "In these situations, the insurer would look to the benefits contract. This contract might limit what the insurer will pay. Payment then could be limited to no more than the covered benefit portion or the lower of the provider's normal charge or a fee schedule that applies to out-of-network care.

"In either case, the insurer may be working on an 'implied charge' logic," noted von Ebers. "If the charge to the insurer is $3,000 and the consumer is supposed to pay 20% (or $600), but the co-insurance is waived, the insurer will say: 'Well, if 20% of your normal charge is equal to zero, then 80% of the normal charge must also be zero.'

"Similarly, if the lab caps the consumer out of pocket at $300, the insurer might argue that if $300 is equal to 20%, then the full normal charge must be $1,500 not $3,000," he noted. "I have not heard of situations where the insurer has claimed that the total charge is actually $300.

"When a payer does that, then the argument must be that if a provider would charge a patient only $300 regardless of whether the insurer pays anything, then the normal charge must be $300," emphasized von Eber.

Different List Prices

"In all these cases, the insurer is saying that providers—including labs—can't have different list prices for different customers," he added. "A provider can have different negotiated fees, but not different standard prices for different people walking in off the street.

"The other way that a lab could get in trouble would be from violations of false claim acts," said von Ebers. "If the patient is covered by a benefit plan from any local, state, or federal government entity, and lab bills $3,000 to that benefit plan, but routinely charges others only $300, I think a false claim act case could be made. I am not a lawyer, but I would worry about this situation if I were a lab." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Patients of **Health Diagnostic Laboratories** who were tested between 2009 and 2014 are now being dunned by a collection agency! Creditors in the HDL bankruptcy case have engaged a Florida collection agency to go after 9,000 accounts. As reported by *The Wall Street Journal*, the amount of these bills totals $50 million, according to bankruptcy court documents.

MORE ON: *HDL Patients*

What makes this situation even more unique is that, according to court papers filed in the federal whistleblower lawsuit against HDL, the lab company regularly told physicians and patients that no bills would ever be sent to patients. Thus, these 9,000 patients are learning for the first time since they were tested by HDL between two and seven years ago, that a collection agency wants them to pay hundreds and thousands of dollars for those lab tests. The Internet is full of messages from patients who are angry and upset about these collection notices. Some patients are even threatening to band together, find a lawyer, and fight this collection effort as a group.

ACLU COMPLAINS TO FEDS ABOUT MYRIAD AND DATA

Do patients have a right to the genetic data generated when they are tested by medical laboratories? According to *Reuters*, that is at the heart of a complaint against **Myriad Genetics, Inc.**, that was filed by four patients and the **American Civil Liberties Union** with the **U.S. Department of Health and Human Services Offices of Civil Rights** earlier this month. Reuters wrote, "The complaint says Myriad had violated the federal Health Insurance Portability and Accountability Act, which guarantees patients access to their medical records, by providing test reports that included only findings Myriad deemed clinically actionable." Myriad says that, because it has changed its policy and is releasing this data to patients, that "the ACLU's claim is without merit." An ACLU spokesman said that the group would continue to pursue the complaint because it wants a "determination that patients have a right to all their genetic information."

TRANSITIONS

- **Personal Genome Diagnostics** of Baltimore, Maryland, hired Douglas Ward to be its new CEO. Ward has held executive positions with **Ventana Medical Systems**, **GE Healthcare Life Sciences**, **Siemens Healthcare**, **Bayer Diagnostics**, **Chiron Corporation**, and **Ciba Corning Diagnostics**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

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...the news that the Medicare program is ahead of schedule with its transition away from fee-for-service and toward new reimbursement models. It wanted a third of traditional payments moved away from FFS by the end of 2016, but hit that goal in January 2016.

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