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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

Primary Care's Shift to Telehealth and Pharmacies

PRIMARY CARE PATIENTS ARE A MAJOR SOURCE OF LAB TEST REFERRALS to the nation's clinical laboratories. Until recent years, the typical primary care clinic was located in or near the medical campus of the local hospital and was probably owned by the doctors who staffed the clinic.

Three things are changing this traditional model of primary care: Millennials, telehealth, and owners of retail pharmacy chains. Lab managers and pathologists will want to understand and track these three forces that are transforming the delivery of primary care in the United States.

Millennials are a force for change in the delivery of primary care for two reasons. First, by 2025, Millennials will make up 75% of the workforce and the patient population. Second, they access healthcare much differently than the two generations that proceeded them (Gen X and Baby Boomers). Millennials want speedy access to their healthcare and are comfortable using digital channels to access medical information and interact with their caregivers.

Telehealth is a force for change in how patients access primary care physicians (along with specialist physicians). One consequence of the pandemic is how it triggered increased use of telehealth and virtual doctor visits by both physicians and patients alike over the past 18 months. Today, surveys indicate that more than 50% of doctors and patients surveyed are willing to utilize telehealth services.

Retail pharmacy chains can be expected to be the most disruptive factors in shifting primary care visits away from traditional, stand-alone family practice clinics and toward primary care centers located in or next door to chain pharmacy stories. Our coverage of **Walgreens'** $5.2 billion investment in **VillageMD**, a primary care provider already partnering with Walgreens, is just the latest market development confirming this trend. *(See page 7.)*

Collectively, these three powerful forces are now working to transform the long-standing model of primary care. Clinical laboratories that serve primary care physicians will want to understand these trends and develop strategies to serve both sides of a primary care visit: the physician who needs to order the clinical lab tests and the patient who is interested in the lab test results. The good news is that there is time for labs to study these three trends and use this knowledge to organize lab testing services that meet the different and unique needs of tomorrow's primary care delivery model. TDR

Pathologist Makes News at Elizabeth Holmes Trial

Testimony of ex-Theranos laboratory director illustrates the risks that come with lab oversight

CEO SUMMARY: During the trial, a pathologist who formerly was CLIA lab director at Theranos testified about the little regard Theranos executives had for federal proficiency testing regulations labs must follow to retain their CLIA license. Another point of contention was how this pathologist had sent himself copies of emails to document management decisions designed to override his responsibility to fulfill his requirements as the CLIA laboratory director.

RECENTLY, A PATHOLOGIST MADE NATIONAL HEADLINES FOR SEVERAL DAYS because of his testimony in the federal court case against Elizabeth Holmes, the discredited founder and ex-CEO of **Theranos**, the defunct medical laboratory company. At the same time, this pathologist's testimony under oath is a teaching moment for any pathologist who is on the license of a CLIA laboratory as lab director.

The pathologist who was grilled on the witness stand was Adam Rosendorff, MD. He served as the laboratory director for Theranos from April 2013 through December, 2014. During this 21-month period, Theranos used a lab testing agreement with **Walgreens** to gain national attention. Theranos then launched testing operations using a number of Walgreens pharmacies in Palo Alto, Calif., and Phoenix, Ariz., as patient service centers to collect blood specimens from consumers and patients. *(See TDR, "Theranos Won't Discuss Disruptive Lab Technology," and "Walgreens to Go National with Lab Tests in Retail Stores," Sept. 30, 2013.)*

As many pathologists and lab administrators know, Theranos quickly became a national—if not global—sensation. Elizabeth Holmes was universally lauded as a clever entrepreneur poised to successfully disrupt the entire clinical laboratory industry. She claimed Theranos could provide consumers and patients with a better medical laboratory test, at a price just 50¢ on the Medicare dollar, using a drop of blood, and with results delivered in two hours.

The false edifice came tumbling down in October 2015. That was when *Wall Street Journal* (*WSJ*) reporter John

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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Carreyrou's first exposè of the problems at Theranos was published. By then Rosendorff had been gone from Theranos for 10 months.

Pathologist's Time at Theranos

Yet, his time at Theranos covered the period when Holmes was working to demonstrate that the company's proprietary diagnostic technology could deliver. It also included the period when Theranos first began providing testing to consumers and to physicians who referred their patients to Theranos for lab tests.

As the CLIA lab director on the Theranos license, Rosendorff had "responsibility for the overall operation and administration of the laboratory," as described in CLIA regulations.

For federal prosecutors, Rosendorff is the witness who can testify to facts and details of how Holmes and her team ignored evidence of serious problems with lab tests at Theranos in ways that violated federal and state clinical laboratory laws. This testimony is expected to support the criminal charges filed against Holmes by the federal **Department of Justice** (DOJ.)

The opposite is true of the defense. Holmes' lawyers argue that Rosendorff, as the CLIA lab director, was responsible for many of the problems, ranging from ongoing instances of inaccurate test results to improper use of FDA-cleared lab analyzers, and failure to properly perform proficiency testing and self-report the lab's problems to CLIA officials.

However, it is important to remember that the criminal charges filed against Holmes in this case are not directly related to the failures of the clinical laboratory to comply with state and federal laws or the inaccurate lab tests reported to physicians, patients and consumers.

Adam Rosendorff, MD, who served as CLIA Laboratory Director at Theranos from April 2013 through December, 2014.

Rather, the criminal charges against Holmes are two counts of conspiracy to commit wire fraud and nine counts of wire fraud.

The same charges were filed against Ramesh "Sunny" Balwani, former Theranos Chief Operating Officer and ex-boyfriend of Holmes who will be tried separately. As noted in a DOJ press release, "According to the indictment, the charges stem from allegations that Holmes and Balwani engaged in a multi-million-dollar scheme to defraud investors, and a separate scheme to defraud doctors and patients."

Essentially, one important strategy of the defense during this trial is to blame the pathologist who served as laboratory director for many of the serious problems in specimen testing at the clinical laboratory operated by Theranos.

These issues were identified by *WSJ* reporter Carreyrou and later by CLIA officials from the federal government who visited the Theranos laboratory facility. *(See TDR, "Is Theranos Kowtowing to CMS over CLIA Sanctions?" May 23, 2016.)*

Proficiency Testing Issues

Rosendorff, who is board-certified in clinical pathology, first took the stand in the week of Sept. 24. At that time, the jury heard him testify about how the staff at Theranos had little regard for the federal proficiency testing regulations that labs must follow diligently.

Rosendorff testified about Theranos' failure to comply with proficiency testing. He also testified that he sent himself copies of emails to document management decisions designed to override his responsibility to fulfill his requirements as the CLIA laboratory director.

Rosendorff's role in this trial highlights why the position of laboratory director in

Details Emerge about the Safeway, Walgreens Deals with Theranos; a Med Tech Testifies

MANY FASCINATING DETAILS HAVE COME TO LIGHT during the trial of Elizabeth Holmes, founder of Theranos, who is on trial facing two counts of conspiracy to commit wire fraud and nine counts of wire fraud. If convicted, Holmes faces as much as 20 years in prison.

Last week, for example, executives from two national retail chains—**Safeway** and Walgreens—admitted that they did not closely examine Theranos' blood testing device before committing to investing in the clinical laboratory company and using the machine to test patients' blood.

Theranos persuaded executives from both retail chain stores to believe the clinical lab company's claims about its testing technology.

According to reporting in *The Wall Street Journal* (*WSJ*) on Oct. 13, court testimony indicated that it was Theranos' assertions that it had undertaken years of due diligence and consultations with attorneys and medical experts that had convinced both Safeway and Walgreens to enter into agreements with Theranos.

"What was missing from the diligence, according to court testimony over the past two days, is that neither company spent significant time studying the Theranos device itself and testing it for reliability or accuracy," the newspaper added. Ultimately, negotiations between the two chain stores and Theranos collapsed, the *WSJ* added.

But this reporting is only one of the many stories coming from the trial. In its reporting of the trial, *Ars Technica* reported in September that staff at Theranos routinely cherry-picked data to make the lab company's results look better than they were. In fact, the court heard testimony that Theranos' Edison device failed at least 25% of the time, *Ars Technica* added.

When she took the stand in September, Erika Cheung, a company whistleblower, said the Theranos lab manual did not say how outliers should be identified. Therefore, to get the company's proprietary blood-testing devices to pass quality checks, employees could decide which results to keep, she testified. Essentially the staff was cherry-picking data, she added. Cheung is a Clinical Laboratory Scientist who worked at Theranos from October 2013 through April 2014.

The *WSJ* quoted Cheung saying, "It was very concerning in a research context because once that translates to a patient setting, it's giving you a good indication that the [the lab testing] system isn't working reliably enough to feel confident and comfortable in running patient samples."

a CLIA-certified laboratory has significant risk. In his testimony for the prosecution, Rosendorff describes, in detail, how his advice, recommendations, and attempts to fulfill the requirements of CLIA certification were opposed or negated by Holmes and her COO, Bulwani.

Cross-Examination

However, during cross-examination, Holmes' defense attorneys presented emails, documents, and testimony from witnesses that, they asserted, show Rosendorff did not fulfill his duties in a compliant manner. Defense attorneys claimed that it was Rosendorff who should be held responsible for the inaccurate lab test results which put patients at risk of harm—as well as the failure to properly perform proficiency testing and follow federal and state lab regulations.

Pathologists would find a review of the questions asked of Rosendorff by attorneys for the defense useful for under-

standing how a hostile attorney can attack a lab director who oversaw a laboratory's operation during a time when it had serious problems and was reporting lab test results that put patients at risk of harm.

New Lab Director Hired

Another development in the Holmes trial will be of interest. Following the resignation of Rosendorf as laboratory director, Theranos replaced him with a new laboratory director in early 2015. The new lab director was Sunil Dhawan, MD, who, as the *WSJ* reported, was a "dermatologist without a degree or board certification in pathology or laboratory science." *(See TDR, "Medical Director Needed for Theranos' CLIA Lab," Nov. 16, 2015.)*

On Oct. 15, Dhawan appeared in court to testify. The jury learned that Dhawan got his position as laboratory director of Theranos because he was "the longtime dermatologist of Theranos' ex-COO, Sunny Balwani."

In its coverage of Dhawan's testimony, *Ars Technica* wrote, "Dhawan agreed to serve as Theranos' lab director so long as it didn't interfere with his day job as a dermatologist or his family life. 'The time commitment is very minimal,' Balwani assured him."

Never Cashed His Checks

In its story, *Ars Technica* wrote that "Dhawan testified that he went to Theranos twice and that he worked a total of five to ten hours between November 2014 and June 2015. During that time, he basically signed whatever Balwani sent him. Theranos agreed to pay him $5,000 per month, though Dhawan says he never cashed any checks and once asked to be paid in stock options instead."

This court testimony indicates that Holmes, Balwani, and the management team at Theranos operated for months without a board-certified clinical pathologist as the laboratory director on the lab's CLIA license. Even more surprising, Dhawan's statements indicate that the lab director of record at Theranos during this time was not present daily in the clinical laboratory to oversee ongoing operations and compliance with CLIA requirements.

This fact would seem to strengthen the argument of the prosecution that Holmes and Balwani did oversee the operation of the laboratory—unquestionably during the time that Dhawan was laboratory director. Testimony by several prosecution witnesses, including at least three whistleblowers, describes how serious problems with the performance of the lab's testing instruments were brought to the attention of Holmes and Balwani.

This testimony also included—as noted earlier—how several experienced medical laboratory professionals, along with the lab director, told Holmes and Balwani about specific problems and matters concerning the lab's non-compliance with CLIA requirements.

Proving the Fraud Charges

The prosecution will use this testimony and associated evidence to support the criminal charges that Holmes and Balwani (when his trial commences) committed the type of wire fraud described in the indictments. Prosecutors will assert that Holmes and Balwani knew that their company was incapable of delivering what was promised to investors and represented to the public and to regulators. Thus, these representations while raising capital were violations of federal law.

Further, as noted above, the evidence, the testimony, and the line of questioning by both the prosecution and defense about how the Theranos lab operated offers invaluable insights into risks that can confront laboratory directors of CLIA-certified labs. In an upcoming issue, The Dark Report will provide analysis of the testimony and comments from attorneys experienced in compliance with CLIA and other federal and state laws. TDR

Lab Market Update

By 2027, Walgreens Wants 1,000 Primary Care Clinics

Pharmacy chain giant wants to compete against the primary care clinics operated by CVS, Walmart

PRIMARY CARE IS COMING TO A RETAIL CLINIC NEAR YOU! It may not happen overnight, but it will happen. **Walgreens Boots Alliance** just announced its goal of building 1,000 primary care clinics at its retail pharmacies by 2027. **CVS** and **Walmart** have similar plans.

These plans were announced last week, when Walgreens disclosed that it would spend $5.2 billion to acquire a 63% interest to become the majority owner of **VillageMD**. Founded in 2013 in Chicago, VillageMD has already opened 52 primary-care clinic locations at Walgreens stores and may have 33 more such clinics up and running by year's end.

CVS Pharmacy, Inc., (which owns **Aetna**, the health insurance company), has opened 1,100 HealthHUBs in its retail pharmacies and plans to expand this service into nearly all of its 9,967 locations.

Similarly, Walmart is building primary care clinics as part of its superstores. It has 20 such clinics in operation and 22 more clinics are under construction.

The trend of putting full-service primary care clinics in retail pharmacies is a significant development for the clinical laboratory industry. These clinics will need clinical laboratory testing and can be expected to shift patients away from traditional medical clinic sites for two reasons—lower price and convenience—since they will be located around the corner from where people live and work.

For these reasons health system lab outreach programs will want to develop strategies to serve this new type of primary care service provider. It would be timely to study this trend, since Walgreens, CVS, and Walmart are already expanding their respective networks of clinics. TDR

In its press release about its $5.2B investment in VillageMD, Walgreens included this photo showing how the VillageMD primary care clinic can be incorporated into existing Walgreens retail pharmacy stores. Lab testing will be one service offered at these sites.

Federal Rule to Revise Out-of-Network Billing

New surprise billing rule taking effect on Jan. 1 may be an unwelcome financial surprise for pathologists

CEO SUMMARY: Remaining out of network with health insurance companies may boost revenue for providers, including anatomic pathologists and emergency room physicians. But the good times may soon end. Last month four federal agencies issued rules that implement new requirements under the No Surprises Act. Data on how much certain specialists charge for out-of-network care show about half of all pathologists file at least some out-of-network claims.

PATHOLOGISTS MAY NOT BE AWARE THAT THEY ARE IDENTIFIED in a federal report on surprise medical billing as one of six medical specialties responsible for a significant proportion of out-of-network (OON) bills, according to data published earlier this month.

This fact should get the full attention of pathologists, their practice administrators, and their financial advisors. Approximately 75 days from now—on Jan. 1, 2022—the new federal interim rule on surprise billing will become effective. This rule has the potential to significantly reduce the amount of money certain pathologists have been paid for out-of-network claims in recent years.

Most pathologists and lab administrators know that out-of-network bills can often result in consumers getting unanticipated "surprise" medical bills. Bowing to criticism from patients and consumer groups, Congress passed the No Surprises Act on Dec. 27, 2020, as part of the Consolidated Appropriations Act.

Next, on Sept. 30, four federal agencies issued new rules to implement the law. One requirement in the surprise billing rule specifies arbitration between the provider and the patient. Thus, if pathologists and other providers continue to submit bills that consumers do not expect, they could end up in arbitration with patients who are unhappy about those bills.

Out-of-Network Bills

In an Oct. 1 report published on his blog, "Discoveries in Health Policy," which was based on a 2017 study of six medical provider specialties: anesthesiology, behavioral health and psychiatry, cardiology, emergency room physicians, pathology, and radiology *(see table on page 9),* Bruce Quinn, MD, showed that emergency room physicians and pathologists filed the most out-of-network bills.

Quinn's company, **Bruce Quinn Associates LLC**, advises pathologists and clinical and genomics laboratories, among other providers, on federal payment and coverage policies.

In his blog, Quinn cited "Requirements Related to Surprise Billing; Part II," a report that four federal agencies—the federal departments of **Health and Human Services**, **Labor**, and **Treasury**

Out-of-Network Billing Report Was Issued in 2020 by Health Care Cost Institute (HCCI)

IN THEIR OWN REPORT ABOUT THE SURPRISE BILLING RULE, four federal agencies drew heavily from a report on out-of-network billing published by the **Health Care Cost Institute** (HCCI) in 2020. The table below is reproduced as presented in the federal rule and commentary, and published in the *Federal Register* as "Requirements Related to Surprise Billing; Part II."

Of particular interest for pathologists is "TABLE 2: Physicians with Out-of-Network Claims," which was included in the federal report. The HCCI analysis showed that, during 2017, pathology had the second highest percentage of providers submitting at least one out-of-network (OON) claim that year. Pathology ranked second behind emergency physicians for the "mean percent of visits with services billed OON."

TABLE 2: Physicians with Out-of-Network Claims

	Number of Active Physicians	Percent of Providers with at Least One Out-of-Network Claim, 2017		Mean Percent of Visits with Services Billed Out-of-Network for Providers Who Billed Out-of-Network at Least Once	
		Inpatient	Outpatient	Inpatient	Outpatient
Emergency	45,134	44.1%	49.3%	14.7%	34.3%
Pathology	12,640	44.0%	33.0%	44.3%	31.4%
Radiology	28,017	27.7%	32.5%	11.0%	17.9%
Anesthesiology	42,249	57.0%	31.8%	11.3%	28.4%
Behavioral Health / Psychiatry	38,778	29.8%	14.9%	21.4%	24.4%
Cardiovascular	22,514	17.9%	17.0%	6.8%	8.3%

Source: Federal Register, "Requirements Related to Surprise Billing: Part II," Oct. 7. 2021.

and the federal **Office of Personnel Management**—published on Sept. 30 as part of an interim final rule. The rule is part of the departments' efforts to implement the No Surprises Act.

Days later, this interim rule was published in *The Federal Register* on Oct. 7. In commentary, the four agencies noted that those six medical specialties issued more surprise bills than other specialists because consumers generally cannot shop for those services. "Surprise billing occurs more often in specialties that are not shopped," the report noted.

The source for the data in *The Federal Register* comes from a report the **Health Care Cost Institute** (HCCI) published, last year, titled, "How Often Do Providers Bill Out of Network?"

In that report, HCCI researchers noted that most healthcare providers who submit out-of-network claims do so less than 10% of the time. HCCI also noted that pathologists were outliers among these six medical specialists. Some providers, "always, or almost always billed out of network," the report said.

"For instance, 36% of pathologists billing out of network for inpatient visits and 20% of pathologists billing out of network for outpatient visits did so more than 90% of the time," the report noted. "In contrast, virtually no cardiologists billed out of network this often."

As *The Federal Register* explained, the data from HCCI came from researchers who examined claims from 13.8 million visits to 35,000 providers in six specialties

in 2017. From that data, the researchers estimated the percentage of providers who had at least one out-of-network claim and whether the procedure was inpatient or outpatient. "The survey found that less than half of specialist providers surveyed billed at least once on an out-of-network basis," the *Federal Register* added.

29,227 Laboratories

The four agencies that issued the interim rules on Sept. 30 under the No Surprises Act estimated that the rules will affect 29,227 diagnostic and medical laboratories, although some labs might be counted twice in these estimates, particularly facilities that have in-house laboratories, the report noted.

In addition, the rules will affect 16,992 emergency and other healthcare facilities, 6,090 hospitals, 270 independent freestanding emergency departments, 9,280 ambulatory surgical centers, and 1,352 critical access hospitals.

The No Surprise Act is designed to protect patients from surprise billing and excessive cost sharing, and it implements consumer protections against surprise medical bills, such as an independent dispute resolution process and a patient-provider dispute resolution process. The act also calls for all providers to provide good-faith estimates for uninsured or self-pay patients and gives consumers more rights for external review of surprise bills.

The CAP Pushes Back

THE DARK REPORT reached out to the **College of American Pathologists** (CAP) for comment on the HCCI data. In response, the CAP said the HCCI data are misleading by saying that nearly half of pathologists regularly bill out-of-network.

In addition, the CAP said, "There are two big problems with Table 2 *[shown on page 9.]* First is the number of pathologists reported and second is the potentially misleading use of data from HCCI and from AAMC [**Association of American Medical Colleges**] estimates of workforce sizes.

"The HCCI numbers are accurate but presented in a somewhat misleading manner," the CAP added. "The HCCI data is extremely heavy on the tail-end of the distribution, which makes the average appear so high. Table 2 [in the federal report] focuses only on the frequency of billing, not the size of the bills, and pathologists have some of the smallest out-of-network bills of any specialty. Frequency of billing is only half the story.

"The median national average size of out-of-network bills for pathology and lab services in the HCCI study was about $67 in the inpatient setting and about $78 in the outpatient setting, making pathology and laboratory service bills some of the smallest compared to other specialties," the CAP noted.

In addition, the CAP said, a moderate percentage of pathologists appear to have made out-of-network claims at least once, and most do not do so regularly. "Fewer than half of pathologists bill out of network, and about half of those bill out of network less than 10% of the time," the CAP added.

"The CAP took issue with the HCCI's data when those numbers were released last year," the CAP added. "It's unclear if the HCCI data include only pathologists billing out-of-network claims, or pathologists and others in the clinical laboratory business that also bill claims for a wide range of pathology and laboratory services."

The CAP next addressed the pathology workforce numbers in the HCCI report. "With regards to the number of physicians billing pathology, a 2020 study by members of the CAP found data compiled by the Association of American Medical Colleges undercounted the pathology workforce by 40%," the CAP said.

"The **American Medical Association** Database Products Division recorded 21,292 active pathologists in 2019. The CAP has recommended that the AAMC alter the way it reports the pathology workforce so that it includes all physicians in the AMA master file who are active practicing pathologists." TDR

Managed Care Update

UnitedHealth's Lab Test Registry Implementation Delayed Again

ANOTHER DELAY WAS ANNOUNCED FOR IMPLEMENTATION of **UnitedHealthcare's** Laboratory Test Registry Protocol, which requires clinical laboratories to register each of their tests with the health insurer. This latest delay likely is the result of operational issues on behalf of the managed care company and does not spell an end to the test registry altogether.

"It's probably technical issues on their end, but it is coming," stated Mick Raich, President of **RCM Consulting**. Raich is the former President of **Vachette Pathology**, which was recently acquired by **Lighthouse Lab Services** of Charlotte, N.C. "I don't expect the delay to last," he added.

UnitedHealthcare (UHC) announced the delay on July 1, noting that the delay only applies to non-genetic tests. The Lab Test Registry is still in effect for genetic and molecular tests. UHC announced earlier this year that its lab test registry would replace the test registry used by **BeaconLBS** (a company owned by **Labcorp**) and that it would take over prior authorizations for genetic and molecular tests from BeaconLBS.

The test registry for non-genetic testing was originally scheduled to take effect on Oct. 1, 2021. That date was pushed back to Jan. 1, 2022. UHC's policy requires in-network, freestanding, and outpatient hospital laboratories to include the laboratory's unique test code on claims for most laboratory test services. Each test code submitted on a claim must match a corresponding laboratory test registration provided in advance to UHC, or the claim will be denied.

As defined by UHC, a laboratory test code is the laboratory's unique identifier used by a physician to order a test. UHC has not specified which values or coding method labs should use to uniquely identify tests. Clinical laboratories may use their own test codes if those codes are registered with UHC.

Jim O'Neill, Vice President for sales for the clinical laboratory division at **Advanced Data System Corporation** (ADSC), a revenue cycle management company based in Paramus, N.J., agrees with Raich that, while the lab test registry may be delayed, it is not dead.

Reasons for the Delay

"Due to COVID-19 and the number of new laboratories that have entered the market, UnitedHealthcare may not have the proper resources to ensure all the U.S.-based laboratories would be set up properly," O'Neill commented, adding that ADSC is making its clients aware of UHC's Laboratory Test Registry Protocol and is prepared to assist with portal questions and file downloads when needed.

Currently, UHC already requires clinical laboratories to register genetic and molecular lab tests of single genes, multigene panels, and other molecular tests using genetic-based methodologies, such as gene expression profiles of tumors or multiplex PCR assays of pathogens.

In addition to registering genetic and molecular tests, UHC also recommends that every test also includes a Genetic Testing Registry (GTR) ID. TDR

Contact Mick Raich, 517-403-0763 or mraich@vachettepathology.com; Jim O'Neill, 609-517-6242 or jim.o@adsc.com.

SUNY Hospital Uses Drones to Move COVID Test Kits

Overseas, drone technology firms in Scotland and Ghana transport lab specimens up to 40 miles

CEO SUMMARY: One healthcare trend accelerated by the SARS-CoV-2 pandemic is the use of drones to move COVID-19 test kits, specimens, and medical supplies. Earlier this year, the SUNY Upstate Medical University Hospital in Syracuse tested the reliability of drones to move unused COVID-19 test kits between locations on its campus. In Scotland and Ghana, drones are in regular use to move supplies, kits, and specimens between suppliers, hospitals, and other providers.

Use of aerial drones to move COVID-19 test kits, specimens and medical supplies is happening here in the U.S. as well as in other countries, including Scotland and Ghana.

In the U.S., the **State University of New York** (SUNY) **Upstate Medical University** in Syracuse tested medical deliveries with drones during a year-long project that commenced January. As part of this project, the SUNY Upstate Medical University team completed drone deliveries of unused COVID-19 test kits from one rooftop to another on SUNY's campus, according to a *Syracuse.com* article.

The proof-of-concept trip from the campus' hospital to its clinical laboratory showed how drones could slash the time required to move test kits. Delivery by drone was completed in two minutes instead of the usual seven minutes via ground transportation.

The motive behind this demonstration project was to identify the viability of using drones to get specimens to the lab—especially when the specimens are human organs, blood products, and tissue removed from patients during surgery.

Long-term, this New York hospital aims to use drones to help avoid hurdles in transporting supplies and specimens during a highway construction project that is expected to severely impede traffic between the main campus (where the hospital is situated) and the surgery center.

"[The surgeons] are not going to want to wait 20 minutes for a tissue sample to get to the lab because the highway is coming down," said Tony Basile, COO, **NUAIR** (Northeast UAS Airspace Integration Research) Alliance, a nonprofit organization that focuses on the testing of unmanned aircraft systems, in the *Syracuse.com* article.

SUNY Upstate Medical University partnered with NUAIR and **DroneUp**, a Chesapeake, Va.-based drone technology solutions company, to make medical deliveries with drones. The project also entailed other drone deliveries, including the transport of supplies from the hospital to a laboratory and to a surgery center.

"This has been a dream of mine since the day I came to Upstate as a pathologist, when I looked at the ability of Upstate to use drones to send medical materials, per-

SUNY Upstate University Hospital in Syracuse Explores How Drones May Cut Delivery Times

PICTURED ABOVE IS A CLOSE-UP OF THE DRONE MODEL used by the team at 420-bed SUNY Upstate Medical University Hospital earlier this year to demonstrate the viability of moving unused COVID-19 test kits between the hospital and a nearby building on the medical campus. The drone project was done in conjunction with NUAIR and DroneUp.

haps specimens, to our labs all over town," said Robert Corona, DO, CEO of **Upstate Medical University Hospital**, in a blog post announcing the successful flight of unused COVID-19 test kits.

But can drone dreams become daily drone deliveries? **U.S. Department of Transportation Federal Aviation Administration** (FAA) regulations prohibit medical material transport by drone due to potential "risk to the public in the event of a crash," Basile said.

NY Hospital Got FAA Waiver

However, the FAA-approved DroneUp 107.39 waiver makes it possible for the company to fly drones over people and moving vehicles, said Melanie Harris, DroneUp Sales Director, in a blog post.

"There has been a lot of hype around drone delivery companies. There are regulation hurdles, equipment challenges, and standard operating procedures," she added.

A December 2020 FAA Final Rule requires remote identification of drones, and allows operators to fly over people and at night in certain conditions, a news release explained.

As to medical deliveries, the FAA is still debating the type of drone that can be used, according to reporting by *DroneDJ*, which speculated that drones with six to eight motors will likely get the go-ahead since they can fly even if two motors fail.

SUNY Upstate Medical University is not the only provider to conduct medical delivery projects with drones. THE DARK REPORT's intelligence briefing in 2019 on **WakeMed Health and Hospital's** use of drones—in partnership with **UPS** and **Matternet** of Menlo Park, Calif.,—addressed transport of specimens from a hospital physician's office and a draw station to a lab at the provider's Raleigh, N.C. campus.

The trip was the first FAA-sanctioned use of a drone for routine revenue flights

in the U.S. *(See TDR, "WakeMed Uses Drone to Deliver Patient Specimens," April 8, 2019.)*

Meanwhile overseas, drones are carrying COVID-19 test samples, test kits, and personal protective equipment to Scotland's west coast Argyll and Bute region. The 40-mile route includes deliveries to three hospitals and a medical practice. The route is operated by **Skyports**, a London-based drone firm that has approval from the UK Civil Aviation Authority (CAA) to carry diagnostic specimens by drone, according to the *Daily Mail*.

"Using drone deliveries within supply chains can create significant time and cost savings. This initiative is a natural progression from our recent trials with the **NHS** in Scotland as we scale our operations, supporting a wider network of hospitals and medical practices as they continue to respond to the COVID-19 pandemic," said Duncan Walker, Skyports' CEO, in the *Daily Mail*.

During the proof-of-concept last year, drones operated by Skyports delivered test kits between two hospital locations in rural Scotland. A usual 45-minute trip by ferry was cut to 15 minutes by drone, the *Daily Mail* reported.

Use of Drones in Ghana

And in Ghana, COVID-19 test samples travel about 45 miles in drones provided by **Zipline,** a San Francisco-based company, in partnership with the country's **Ministry of Health** to move samples from rural areas to lab testing centers in urban environments. *The World* describes the loading and transport process as follows:

- Test samples are packed in red **World Health Organization** boxes and put inside the drone.
- The automated drone flies to a destination (monitored by a human as needed).
- Upon arrival, the drone automatically drops the red box of COVID-19 samples by a parachute.

Zipline also has started SARS-CoV-2 vaccine distribution via drones throughout Ghana as well. The company's plan is to deliver 2.5 million doses by air.

"Not only does this make Ghana the world's first country to deploy drones on a national scale for the delivery of COVID-19 vaccines, but it is also a giant effort in ensuring equitable access and enabling Ghana to fully utilize its healthcare infrastructure to deliver vaccines," Zipline CEO Keller Rinaudo told *Business Insider*. TDR

Use of Drones to Deliver COVID-19 Test Kits

DRONE DELIVERY OF COVID-19 TEST KITS could help contain the pandemic, according to a recent article by Austrian researchers in the journal, *Transport Policy*.

The authors, who are affiliated with the **University of Klagenfurt**, suggested drones as a feasible alternative for contactless test distribution and noted they could, most likely, be deployed with existing drone industry capacity.

"We propose the use of drones to support and enable testing of potentially infected patients in a decentralized manner. Not only are drones independent in regard to potential on-the-ground infrastructural issues, but, more importantly, they enable a contactless alternative for testing people," the researchers wrote.

"With the use of drones, COVID-19 self-test kits and other essential goods can be transported without the need for direct human contact, thus reducing infection risks among involved people.

"The novel approach that we develop in this study does, however, not aim at creating new drone fleet capacities, but rather relies on utilizing existing drone infrastructure," the authors added.

CAP Introduces Features to Aid CLIA Inspections

Today's multi-site laboratory organizations have new needs when undergoing a CLIA inspection

CEO SUMMARY: Clinical labs are changing in multiple ways and the College of American Pathologists regularly revises its CLIA accreditation processes in response to these changes. One such change is the growth in the number of integrated delivery networks that operate multiple hospitals and multiple medical clinics, creating a multi-site clinical lab service. To meet the evolving needs of these labs, the CAP introduced several services and features designed to expedite the CLIA inspection process.

Interesting changes are happening to the process of inspecting labs for compliance with the federal **Clinical Laboratory Improvement Amendments** (CLIA) of 1988. Organizations with deeming authority from the federal **Centers for Medicare and Medicaid Services** to conduct CLIA inspections are introducing new services to help clinical laboratories comply with CLIA requirements.

New Ways of Operating

These new services are needed because market forces have caused clinical laboratories to evolve in response to new technologies, the ongoing regionalization of hospitals and providers, and the new capabilities offered by more fully-automated lab testing instruments.

To assist labs as they change, the **College of American Pathologists** (CAP) has launched several new features designed to help its lab clients manage the CLIA inspection process more efficiently and with less effort.

The CAP introduced these new features in response to the fundamentally different way that labs are organized, how they operate, and the more complex menu of tests they perform today—particularly compared with how labs operated in 1992, when federal officials published the final CLIA 88 rule.

To learn more about what's changing with CLIA lab inspections at the CAP, the editors of The Dark Report interviewed members of the CAP's accreditation and marketing teams during a Zoom call last month. On the call were:

- Mary de Sousa, Senior Vice President, Sales and Marketing;
- William Groskopf, Vice President, Laboratory Quality Solutions, which include the proficiency testing and laboratory accreditation programs among others; and
- Denise K. Driscoll, MS, MT(ASCP) SBB, Senior Director for Laboratory Accreditation and Regulatory Affairs.

Three Factors Driving Change

As a starting point for the discussion, the CAP's accreditation team identified three significant factors driving change in the clinical laboratory profession that have affected how laboratory managers and

pathologists approach compliance with CLIA requirements.

"One factor is the growing number of multi-hospital, multi-provider health systems," Groskopf noted. "Within a single health system, clinical laboratory testing is performed at different hospitals and in different provider settings. Consequently, compliance with CLIA becomes a multi-site challenge.

Consolidation of Hospitals

"Over the years we've continued to see consolidation of hospitals and medical offices into integrated delivery networks (IDNs) which created a new type of customer—if you will—for CLIA accreditation," he continued. "Pathologists and lab leaders in these settings need to oversee regulatory compliance across many lab testing sites and sometimes across a large geographic region."

"Another factor involves advances in information technology and the integration of different sources of data," de Sousa commented. "These new IT capabilities make it possible to eliminate paper, a factor that makes it easier to share data and documentation digitally. This trend is the basis for several new assessment tools that the CAP brought to market in recent years."

Driscoll added a third factor. "We have also noticed another trend across the clinical laboratory industry, and that is the increased challenge of managing all the different lab sites within a health system," she said.

Uniformity Across All Sites

"When a system has multiple sites, most often they find a need to standardize operations at each site," Driscoll explained. "Pathologists and lab leaders want uniformity across all testing sites. That starts with standardizing analyzers and assays. But there is also the need to standardize other activities across all lab sites. For example, labs must document lab staff competency and keep those records updated. When they do that, they can have the flexibility to move staff to different lab facilities within the system."

CAP's accreditation program is continually working to adapt to these developments, Groskopf commented. "One of the most popular innovations we launched in recent years is a performance analytics dashboard," he stated. "This dashboard gives the laboratory system a holistic and an individual view of many quality metrics that feed into their system.

"One dashboard feature proving to be of high value involves previous deficiencies," Groskopf observed. "We load several years' worth of data on prior deficiencies at a client's laboratory sites into the dashboard. This feature has a hierarchy of access. The health system's leadership can view prior deficiencies across the entire organization. Other managers can view only prior deficiencies at their lab facility."

Access to Past Deficiencies

Having the ability to look back at earlier inspections has significant value for lab managers and directors, Driscoll commented. "A lab director can see if the same deficiency was identified within several of their laboratories," she explained. "This information is useful when labs within the same IDN are not on the same two-year inspection cycle.

"If lab managers detect that there were similar issues cited at different lab sites, the dashboard data helps them achieve uniformity across the integrated delivery network," she said. "We see labs grab this data from the dashboard and use it to come up with simple solutions. That avoids having, say, 50 different solutions in the same network."

"Clinical lab directors and managers also find it useful that the dashboard data are not limited to information only about accreditation," Groskopf added. "The dashboard includes data on proficiency testing (PT), for example. We can now show PT data at the system level and the individual lab level.

SARS-CoV-2 Pandemic Created Need for Virtual CLIA Laboratory Assessments

WHEN THE CORONAVIRUS PANDEMIC BEGAN RAGING NATIONWIDE LAST YEAR, CLIA inspectors from the College of American Pathologists (CAP), were like inspectors from all organizations with deeming authority from the federal Centers for Medicare and Medicaid Services in that they needed to move away from doing as many on-site inspections as they had done in previous years.

In place of on-site work, CAP inspectors turned to virtual inspections for about 20% of the inspections they did last year, said Denise K. Driscoll, MS, MT(ASCP)SBB, the CAP's Senior Director for Laboratory Accreditation and Regulatory Affairs.

"We've always had what we call our traditional model for doing inspections of labs," said William Groskopf, the CAP's Vice President, Laboratory Improvement Programs. "The traditional model is the standard on-site inspection. We continued to do those inspections, but when there's a big spike in COVID-19 infections, we can also turn to our virtual inspections.

"When the inspection will be virtual, we offer the labs a chance to send us the documentation before the inspection begins," he explained. "For that, we've launched a new system for laboratories so that they can upload documentation to our website so the inspection team can do a pre-review of those documents.

"Doing a pre-review means the inspectors can stay in their offices to begin the inspection," he noted. "That process improves the efficiency of the inspector and streamlines the time onsite while maintaining the quality of the inspection."

Driscoll added that the CAP inspectors can supplement the document pre-review with a virtual tour of the lab.

Virtual Laboratory Tour

"That virtual tour happens when someone from the lab staff uses a device with a video camera and walks around the lab," she added. "When I'm on an inspection team, I might say, 'Oh, let's stop here,' or I'll ask, 'What was that?' Or I might ask to get a closer look at test tubes to see how they're labeled, for example.

"For a safety walk-through as part of a virtual inspection, the camera view from the lab being inspected is very important," Driscoll noted. "I might want to see the exits, for instance, or I might want to see where the fire extinguishers are located. We also do some of the virtual walk-throughs with a smartphone.

"When we combine the virtual walk through with the advanced document pre-review, we get a good idea of what's happening in each lab," she added.

"In addition, we added a specific system report to spotlight successful, unsuccessful, and repeat unsuccessful PT analyte performance for laboratories, as well as PT analytes that are at risk of potentially becoming unsuccessful," he explained.

"Our customers value having the ability to look at proficiency testing performance by site," he added. "These proficiency testing metrics allow laboratory managers to identify how consistently their lab sites are meeting specifications."

Dashboard Can Flag Issues

Another popular feature of the dashboard is the ability to identify potential problem areas, Driscoll noted. "The dashboard has triggers that will flag specific activities or metrics that are worth a closer look for the lab team," she said. "These flags appear on the landing page. This feature includes

data on both deficiencies and proficiency testing.

"For clinical laboratories that want to evaluate themselves against similar labs, the dashboard tool can run a comparison of the client's lab against a broader group of similar accredited laboratories," she added. "Now the laboratory can benchmark itself against peer labs."

Advance Document Upload

Another feature of CAP's accreditation services is designed to make inspections easier and simpler for lab staff and for inspectors. "It is now possible for labs to upload documentation in advance of an inspection," de Sousa said.

"Labs come to our website and upload documentation—such as the quality management plan—so that the inspection team can review those documents before they arrive on-site. This feature gives laboratories the option to make certain documents and records available to the inspection team before the video conference portion of the inspection.

"This pre-review process optimizes the time spent while the inspection team is on-site and streamlines the work being completed virtually," she explained. "It also allows the inspectors and the lab staff almost instant access to any relevant documents during the inspection."

Mix of New Features

This mix of new features that the CAP has introduced demonstrate how this deeming organization is working to streamline the laboratory accreditation process. These new features are also consistent with a trend for deeming organizations to introduce new capabilities that add value to the clinical laboratory organizations undergoing the CLIA accreditation process.

Today's generation of clinical laboratories are much more complex organizations than clinical labs were in 1992, when the CLIA 88 regulations became effective. At that time, hospitals, clinical laboratories, and other healthcare providers were heavily reliant on paper to document many work processes and activities.

Fast forward 30 years and a host of new technologies and informatics solutions now make it possible for clinical laboratories and anatomic pathology groups to eliminate paper across the entire enterprise. This is not yet widespread across the clinical laboratory profession, but there are examples of labs that have successfully eliminated paper in nearly all of their activities.

Mary de Sousa

➤"This pre-review process optimizes the time spent while the inspection team is on-site and streamlines the work being completed virtually. It also allows the inspectors and the lab staff almost instant access to any relevant documents during the inspection."

The CAP saw this opportunity to move paper-based CLIA accreditation processes to a digital platform. This raises the bar in the competitive marketplace while also giving its lab clients a feature that helps them to be more productive while streamlining a CLIA accreditation process introduced in 1992.

Another market factor is that both government and private payers have been slashing what they spend on clinical lab tests in recent years. When lab revenue is reduced, managers are motivated to find new ways to improve productivity and reduce costs. That naturally motivates clinical lab managers to study the CLIA accreditation process and its cost to identify how to meet those federal requirements at less cost and with fewer disruptions to normal lab testing activities. TDR

Contact Mary de Sousa at 847-832-7578 or mdesous@cap.org.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

One interesting development from the SARS-CoV-2 outbreak is a new ability to collect genetic data on the virus and its variants from a growing number of countries across the globe. *The World* reported that "In March, the one millionth genomic sequence for the new coronavirus came from Chile; in late May, the two millionth from Mexico; in August, the three millionth from Singapore; and in September, the four millionth from Republic of Congo." This is a result of the ongoing improvements in genome sequencing instruments that make sequencing faster, cheaper, and more accurate. More nations are acquiring gene sequencing systems and training the scientists needed to do the sequencing and interpret the results.

MORE ON: *Global Gene Sequencing*

In the same story, *The World* interviewed Christian Happi, a virologist who works at **Redeemer's University** in Nigeria, and wrote that "Happi estimates that now, at least half of the countries in Africa are able to do some level of local genomic sequencing. It's a stark contrast to just a few years earlier during the West African Ebola outbreak when only his lab was able to do this. Scientists instead had to send their samples elsewhere, which can create critical delays in information."

NORDSTROM TO SELL MICROBIOME TEST

Consumers seem to be fascinated with microbiome testing. **Nordstrom**, the national department store chain, announced that it will sell a microbiome test from **Viome Life Sciences**, a company based in Seattle.

TRANSITIONS

• Jeff Schmalz is the new Chief Commercial Officer at **Premier Medical Laboratory Services** of Greenville, S.C. He previously held positions at **Labcorp** and **Abbott Diagnostics**.

• Karen McFadden, **Labcorp's** long-serving Senior Vice President of Managed Care, retired earlier this year. Notably, she served 47 years at Labcorp, starting in 1974 as a medical technologist in hematology for **Roche Clinical Laboratory** (later merged into Labcorp).

• **Health Network Laboratories** of Allentown, Penn., announced the appointment of Warren Erdmann as Chief Clinical Officer. His prior positions were with **Genesis Healthcare**, **BioReference Laboratories, Inc.**, and **MediLabs**.

• **Foundation Medicine** of Cambridge, Mass., appointed Dymeka Harrison as Chief Commercial Officer. She previously held executive positions with **Abbott Laboratories**, **Qiagen**, and **bioMérieux**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 8, 2021.

Publisher: Robert L. Michel *rmichel@darkreport.com*
Executive Publisher: Bob Croce *bcroce@darkreport.com*
Editor-In-Chief: Robert L. Michel *rmichel@darkreport.com*
Managing Editor: Michael McBride *michaelmcbride58@gmail.com*
Senior Editor: Joseph Burns *joeburns@capecod.net*
IVD Reporter: Donna Marie Pocius *donna11019@att.net*
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