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Part Two of Interview with Clinisys CEO

Michael Simpson on… New Informatics Capabilities for Clinical Laboratories, pt. 2

(See pages 10-15)

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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

Forensic Pathologist Shortage Gets News Coverage

PATHOLOGISTS ARE MAKING HEADLINES IN SEVERAL STATES, as well as nationally. But this time, the news is not about the shortage of surgical pathologists. Rather, it's about the acute shortage of forensic pathologists.

For example, *ABC News* reported last month that "Forensic pathologists in West Virginia are being asked to perform at least twice as many autopsies as the national best practice standard, resulting in significant delays, the state office of the Chief Examiner said Tuesday."

In comments to the West Virginia legislature, reported by *ABC News*, Matthew Izzo, Administrative Director of the West Virginia Office of the Chief Medical Examiner said, "he'd like around 12 pathologists to help split up the workload, but that recruiting and hiring is a challenge, as it is across the U.S. because of a massive, ongoing forensic pathology workforce shortage. In the meantime, the office has been contracting with physicians on a part-time basis to try to mitigate the backlog."

In Washington State, the *Seattle Times* reported on the consequences of an inadequate number of forensic pathologists. It said, "according to Hayley Thompson, Skagit County coroner and President of the **Washington Association of Coroners and Medical Examiners**, there are about 500 forensic pathologists in the United States. Washington has 18, three of whom work in the eastern region, and 11 of whom work through King, Pierce, and Snohomish counties."

Over the past decade, there has been wide recognition that the demand for board-certified anatomic and clinical pathologists outstrips the available supply. But less attention has been given to the supply of forensic pathologists. A survey of recent news stories written about the delays in autopsy reports by medical examiners in numerous counties throughout the United States shows that this is a growing problem and it has serious consequences as government officials prosecute crimes and investigate deaths from accidents and natural disasters.

It is unlikely that the shortage of forensic pathologists in this country can be solved in the short term. Over the longer term, counties will need to be more creative at restructuring the compensation and duties of forensic pathologists if they are to successfully attract more pathologists to this field. TDR

Whole Genome Sequencing for Newborns Gains Favor

Rapid WGS at birth is winning acceptance with physicians and coverage by some payers

CEO SUMMARY: Evidence is swiftly accumulating that use of rapid Whole Genome Sequencing (rWGS) for certain children in NICUs can enable diagnostic insights that guide effective interventions. Further, these pilot rWGS programs in childrens' hospitals are showing a solid return on investment because of improved care. It is predicted that more hospitals may soon offer rWGS.

AMID THE EXPLOSION IN THE NUMBER OF UNIQUE GENETIC ASSAYS AND MULTI-GENE PANELS being offered by clinical laboratories across the country, there has been growing acceptance of using rapid whole genome sequencing (rWGS) when newborns show indications that such a procedure would be medically appropriate.

Wider use of rWGS is notable for several reasons. First and foremost, it is evidence that the cost of sequencing a newborn's rWGS and interpreting that data has fallen to a level that makes this approach affordable, given the associated improvements in patient care.

Second, the time-to-answer continues to shorten because of these same advances in genome sequencing technologies. In turn, shorter turnaround times enable physicians to make faster diagnoses and more swiftly start appropriate therapies that have substantial benefit to the infants.

Third, with evidence accumulating in support of the clinical benefits of using rWGS with selected newborns, some Medicaid programs and major health plans have commenced coverage for this procedure.

Collectively, these developments are encouraging children's hospitals, academic centers, and tertiary care centers to look at establishing their own rWGS programs. In settings where this is appropriate, hospital and health system-based clinical laboratories have an opportunity to take an active role in helping jumpstart a newborn rWGS program in their institutions.

These developments caught the attention of *KFF Health News*, produced by the **Kaiser Family Foundation**. In a story last month about the issues associated with rWGS and reimbursement for the procedure, it wrote "Few hospitalized babies with an undiagnosed illness undergo whole

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genome sequencing—a diagnostic tool that allows scientists to quickly identify genetic disorders and guide clinicians' treatment decisions by analyzing a patient's complete DNA makeup. That's largely because many private and public health insurers won't cover the $4,000 to $8,000 expense."

But there is progress on the reimbursement front. *KFF Health News* went on to explain that "Since 2021, eight state Medicaid programs have added rapid whole genome sequencing to their coverage or will soon cover it, according to **GeneDX**, a provider of the test."

rWGS for NICUs in Japan

Similar pilot programs are happening in other countries. In its coverage of these developments, *GenomeWeb* described how clinicians in Japan followed up rWGS programs during the April 2019–January 2022 period by expanding the reach of this clinical service. It said that use of online genetic counseling "allowed the team to successfully establish a nationwide rapid-sequencing-based diagnostic network to cover approximately one-third of the 3,000-some total NICU beds in Japan [to meet the need] for rapid genetic diagnosis in NICUs across Japan."

At the **American Society of Human Genetics** (ASHG) annual meeting in Washington, DC, last week, sessions about the outcomes from using rWGS in critical care settings were presented by clinicians from several countries. This demonstrates growing recognition within the international medical community that rWGS can help physicians make faster, more precise diagnoses of genetic conditions that lead to effective treatment of these patients.

Here in the United States, the coverage offered by some payers for rWGS is probably based on the fact that it is not-for-profit childrens' hospitals that were the early adopters of this approach. These hospitals are documenting clear benefits in improved patient outcomes, avoidance of unnecessary and possibly high-risk procedures, and a reduction in the total projected care costs that would have otherwise been incurred. Pathologists in hospital-based labs will want to stay current with developments in the rWGS field. TDR

Children's Hospital Reports Outcomes with rWGS

FOLLOWING AN 11-MONTH CLINICAL PILOT PROGRAM using rapid whole genome sequencing (rWGS) on certain patients, **Nicholas Children's Hospital** of Miami published a study of the outcomes.

The pilot program was called Project Baby Manatee and determined that—not only was rWGS beneficial when used appropriately—but it generated a return on investment (ROI) of 76.5%. These are the summary findings from its study:

- Completed rWGS on 50 children and families and provided diagnoses for 20 children and families (40%).
- Led to change in care for 19 patients (38%), either through finding appropriate treatment or through avoiding unnecessary, invasive, or high-risk procedures.
- Diagnosed 23 rare genetic conditions.
- Achieved a 2.5-day turnaround time for provisional results for ultra-rapid cases and a 4-day turnaround for rapid cases.
- Reduced healthcare costs and downstream spending primarily by empowering doctors to eliminate unnecessary procedures and discharge children sooner.
- Offered referrals for mental health counseling to 18 parents experiencing elevated levels of depression.
- Saved $3,764,250 by using rWGS instead of standard of care, yielding a $2,884,250 return on investment.

Laboratory Update

Q3 2023 Financial Reports Show Growth at Labcorp, Quest

Both firms focused on partnerships and acquisitions, specialty testing, technology, direct-to-consumer tests

BLOOD BROTHERS **LABCORP** AND **QUEST DIAGNOSTICS** SHOWED MOMENTUM beyond COVID-19 testing and toward areas that grew base business revenue in their third quarter (Q3) 2023 financial reporting.

Company leaders called attention to more partnerships and acquisitions of hospital laboratories and outreach lab services. Both companies also launched unique assays—such as blood tests for diagnosis of Alzheimer's disease, expanded companion diagnostics relationships with pharma, and added direct-to-consumer offerings.

The publicly-traded clinical laboratory companies also plan to enhance use of automation, technology, and artificial intelligence, and they announced intent to add more specialty tests.

Here is an overview of key financial results, recent accomplishments, and plans shared by Labcorp and Quest Diagnostics.

Labcorp: Increases Revenue 6.9% in Q3

Labcorp, Burlington, N.C., announced Q3 2023 financials as compared to Q3 2022:

- Company revenue was up 6.9% to $3.06 billion as compared to $2.8 billion.
- Base business revenue grew 14%.
- Diagnostics laboratories revenue increased 6.2% to $2.3 billion from $2.2 billion.
- Biopharma laboratory services revenue was up 7.9% to $719.1 million from $666.4 million.

During an earnings call, CEO Adam Schechter updated analysts on Labcorp's strategies related to clinical laboratory partnerships.

Labcorp, he said, increased its "presence" during Q3 in the Northeast and West laboratory markets with relationships as follows:

- **Tufts Medicine**, Boston: Labcorp anticipates by end of 2023 expanding the relationship of standardized testing to include management of Tufts Medicine inpatient hospital laboratories.
- **Baystate Health**, Springfield, Mass.: Labcorp, as part of a new relationship, will acquire Baystate outreach laboratory business and "select operating assets including laboratory service centers in western Massachusetts."
- **Legacy Health**, Portland, Ore.: Labcorp's new relationship entails acquisition of "select assets" of the outreach laboratory business and management of inpatient hospital laboratories.
- **Providence Health and Services**, Renton, Wash.: Labcorp finalized acquisition of the outreach laboratory during the quarter.

Innovation and technology advancements during the quarter include the following, according to Schechter:

- ATN Profile: Labcorp's new blood-based test "to assess biological changes associated with Alzheimer's disease"

with multiple diagnostic biomarkers, including amyloid plaques, tau tangles, and neurodegeneration.
- Labcorp OnDemand Menopause Test: a direct-to-consumer test addressing hormonal factors.

Also, specialty testing is focused on oncology, women's health, autoimmune disease, and neurology, "which we anticipate will outpace the growth of other therapeutic areas," Schechter said.

Labcorp is happy with growth in its direct-to-consumer lab testing business. During a question and answer session, Schechter alluded to contribution of the OnDemand consumer tests to the bottom line. "We see it growing very substantially, but it's not necessarily at the point where we would break it out and give specific numbers for it."

He addressed a question regarding the possibility of recessionary signals on diagnostics and changes in consolidation opportunities.

"When you look at the volume that we see, it remains very strong and it's broad–based across the country in esoteric and routine testing," he said. "I think the macro environment for the health systems and for local smaller regional laboratories is very strong for us to continue to find ways to do business development and find additional partnerships. It's actually a good environment for us to compete."

Quest Diagnostics™

QUEST DIAGNOSTICS: BASE BUSINESS REVENUE UP 4.6% IN Q3

Quest Diagnostics, Secaucus, N.J., reported the following for Q3 2023 as compared to Q2 2022:
- Company revenue was down 7.7% to $2.3 billion from $2.4 billion.
- Base business was up 4.6% to $2.2 billion from $2.1 billion.
- COVID-19 testing revenue plunged 92% to $26 million from $316 million.

During the earnings call, CEO Jim Davis discussed areas of emphasis during the third quarter. These areas included professional lab services and hospital system acquisition opportunities, advanced diagnostics, and operational improvements such as Quest's use of automation and artificial intelligence.

Quest "continued progress," he said, with professional lab services for **Northern Light Health**, Portland, Maine; **Lee Health**, Fort Myers, Fla.; and **Tower Health**, West Reading, Penn.

"Our hospital strategy is to help health systems improve productivity and patient care ... We continue to manage a robust pipeline of professional lab services and hospital outreach acquisition opportunities," Davis told analysts. "Health systems continue to face labor and cost pressures, which prompt more of them to reach out to us for help with their lab strategy and—in some cases—monetize their hospital outreach business."

He said Q3 revenue grew in "double digits" in areas including neurology, women's and reproductive health, cardiometabolic and infectious diseases, and immunology. The company had "strong demand" for its Quest AD-Detect, a blood test aimed at assessing Alzheimer's disease risk and was profitable in its consumer health testing channel, Davis added.

During Q3, Quest received **U.S. Food and Drug Administration** (FDA) breakthrough designation for the Adeno-associated virus (AAV) Test, a companion diagnostics it reportedly developed with **Sarepta Therapeutics**, Cambridge, Mass., for Duchenne muscular dystrophy gene therapy. "This FDA designation places us at the forefront of AAV test innovation in the growing area of cell and gene therapies," Davis said.

Quest plans to acquire **Haystack Oncology, Inc.**, of Baltimore, Md. The deal will position Quest to enter "the high-growth liquid biopsy area of minimal residual disease," Davis added. TDR

Legal Update

Healthcare Fraud Cases Include Decades-Long Cases of Deceit

Among the most notable are a $359 million lab test fraud case and 20-plus-year sentences

HEALTHCARE FRAUD CASES CONTINUE TO RECEIVE HARSH PENALTIES from the federal government as indicated in the case of a California clinical laboratory owner and her husband who attempted to defraud the government of millions of dollars.

Lourdes Navarro and husband Imran Shams attempted to defraud insurances and government entities of $359 million during the COVID-19 pandemic. A deeper dive on the pair, who admitted their guilt, unmasks a web of healthcare deceit that spans decades.

Duo's History of Fraud

Navarro, owner of Baldwin Park, Calif.-based **Matias Clinical Laboratory**, dba **Health Care Providers Laboratory** (HCPL) and Shams gathered nasal swab specimens from June 2020 through April 2022 with the purported intention of testing for COVID-19. They gathered their samples from assisted living and rehab facilities, staff, and students of primary and secondary schools, and residents and staff of nursing homes.

But instead of simply testing for COVID-19, the pair tacked respiratory pathogen panel (RPP) tests to some of the specimens despite the tests not being ordered by a physician. The RPP tests were both "medically unnecessary and expensive," the federal **Department of Justice** (DOJ) stated in a press release.

Test claims were submitted through HCPL to **Medicare**, the **Health Resources and Services Administration** COVID-19 Uninsured Program, and a private health insurance company, all to the tune of $359 million of which they were reimbursed approximately $54 million.

The couple made large cash withdrawals, using acquired funds to purchase real estate, luxury items, and to help pay for household items and travel.

Navarro pleaded guilty to conspiracy to commit healthcare fraud and wire fraud and is slated to be sentenced on January 23, 2024, with a possible maximum 20-year prison sentence. Her partner in crime, Shams, also pleaded guilty and will be sentenced January 9, 2024.

Navarro and Shams have repeated convictions of fraud and had each received bans from billing programs. As far back as 1990, Shams received his first conviction. The duo spent years craftily finding a way back to continuing their fraud. The sidebar on page 9 details the history of deceit and trickery these two perpetrated on the federal government.

Genetic Testing Scheme

In another case, Minal Patel, a 44-year-old who owned **Lab Solutions LLC** in Atlanta, recently landed a 27-year prison sentence for his $463 million genetic testing scheme that spanned from July 2016 to August 2019.

Patel's company "conspired with patient brokers, telemedicine companies, and call centers to target Medicare beneficiaries with telemarketing calls falsely

stating that Medicare covered expensive cancer genetic tests.

"After the Medicare beneficiaries agreed to take a test, Patel paid kickbacks and bribes to patient brokers to obtain signed doctors' orders authorizing the tests from telemedicine companies.

"To conceal the kickbacks and bribes, Patel required patient brokers to sign sham contracts that falsely stated that the brokers were performing legitimate advertising services for Lab Solutions, when, as Patel well knew, the brokers were deceptively marketing to Medicare beneficiaries and paying kickbacks and bribes to telemedicine companies for genetic testing prescriptions," a DOJ press release stated.

Of the $463 million in claims, Medicare paid more than $187 million and Patel received more than $21 million in proceeds himself. His convictions included fraud, wire fraud, conspiracy to defraud the United States, conspiracy to commit money laundering, and payment of illegal kickbacks.

As a result of his conviction, he was ordered to "forfeit over $187 million in fraud proceeds including over $30 million seized from personal and corporate bank accounts, a 2018 Red Ferrari Spider, a 2019 Land Rover Range Rover, and real property," the DOJ reported.

Telemarketing Fraud Scheme

Jose Goyos of West Palm Beach, FL, was convicted for "tricking physicians into authorizing thousands of genetic tests that were completely unnecessary and not used in the treatment of Medicare beneficiaries who took them," the DOJ reported.

Goyos and his co-conspirators placed misleading telemarketing calls from the so-called "doctor chase" division he managed in the call center where they worked to connect with thousands of Medicare beneficiaries and their physicians.

The group tricked primary care physicians of Medicare beneficiaries "into ordering and authorizing medically unnecessary genetic tests based on medical paperwork that the call center created," the DOJ reported.

They would act as if the Medicare beneficiaries they were calling about were shared patients, claiming these patients had medical conditions requiring genetic tests they were requesting, when they did not have these conditions nor request these tests. The team then used those doctors' authorizations to submit claims to Medicare for said genetic tests.

Fraudsters Used Shell Labs

"In reality, the labs were shells; they had no equipment, did not conduct a single test, and had no lab personnel. Goyos and his co-conspirators referred all the genetic tests to other labs, which conducted them at a small fraction of the price that Goyos and his co-conspirators charged to Medicare.

"Finally, after the tests were conducted, the results often were not sent to the Medicare beneficiary's primary care physicians and were not used in the treatment of the beneficiary," the DOJ stated.

Goyos' team ran this scam from June 2020 to July 2021, submitting more than $67 million false claims to Medicare. They were paid more than $52 million.

He will be sentenced on December 21 for his actions and was convicted for conspiracy to commit wire fraud and conspiracy to commit money laundering. The maximum penalty for Goyos is 20 years in prison on the conspiracy to commit wire fraud charge and 10 years in prison for conspiracy to commit money laundering.

The other defendants in the case will be sentenced in December as well.

THE DARK REPORT believes it is important that clinical lab administrators working in different lab settings understand both the nature of Medicare fraud involving medical laboratory tests and the magnitude of the dollars involved in a single case. Just the two cases of lab test fraud described here involved $359 million and

Two Individuals at Center of $359 Million Test Fraud Have 20-Year History of Defrauding Medicare

LOURDES NAVARRO AND IMRAN SHAMS HAVE BEEN HARD AT WORK deceiving the government for years. Here's a timeline of their fraudulent activities.

1990: Shams was convicted of Medicaid fraud in New York.

1991: Shams was banned for five years from participating in any Medicare, Medicaid, or federal programs. The sentence was handed down by the **U.S. Department of Health and Human Services' Office of Inspector General** and left him needing to reapply to the agency for reinstatement.

2000: Navarro was "convicted of felony grand theft related to billing fraud involving Medicare and **Medi-Cal** programs in California."

2001: Shams was convicted of "felony grand theft related to billing fraud involving Medicare and the Medi-Cal program, a California program that provided benefits to low-income people."

2002: Navarro was banned "from participating in federal programs" by the Office of Inspector General. Her ban would be for 15 years, and, like Shams, she would need to apply for reinstatement.

2004: Office of Inspector General gave Shams a 10-year ban, preventing his participation in federal programs. He would be required to apply for reinstatement.

2017: In New York, Shams pleaded guilty to "conspiracy to commit money laundering, conspiracy to receive and pay kickbacks, and conspiracy to defraud by obstructing the Internal Revenue Service."

2018: Navarro was reinstated through the Office of Inspector General by providing what prosecutors say was a "false and fraudulent" application that stated she didn't work in federal programs during her ban.

2023: Navarro and Shams were convicted for $359 million worth of fraud and scheduled to be sentenced in January 2024.

$463 million respectively in lab test claims submitted to the Medicare Program.

National Headlines

These federal prosecutions of Medicare fraud involving lab tests gain national headlines and paint the entire profession of laboratory medicine with a black brush. At the same time, those same news headlines motivate Congress and federal agencies to implement new laws and regulations designed to curb such fraud.

But those new statutes and regulations often make it more time-consuming and expensive for the nation's honest clinical laboratory and pathology organizations to deliver high-quality testing services to physicians and patients while diligently following the requirements of these new laws.

There is another side to this issue that is seldom covered by journalists. That issue is why it takes the federal government years to uncover specific cases of Medicare fraud and take action to shut down the schemes and bring the perpetrators to justice.

In the cases of Lourdes Navarro and Imran Shams, their history of Medicare fraud goes back 33 years to as early as 1990. Yet, they repeatedly surfaced with new schemes to defraud Medicare every few years and managed to get their fraudulent Medicare claims paid for some time before federal healthcare investigators caught up with them.

Another reason why there are "serial Medicare fraudsters" is that federal prosecutors often will accept a civil settlement involving lab fraud and decline to file criminal charges against lab managers. This allows them to go organize a new lab company and repeat their fraud. TDR

NEWSMAKER INTERVIEW

Michael Simpson

Machine Learning Poised to Give Clinical Labs New Capabilities

"One of the first questions I ask the laboratory team is 'do you want to continue to be a factory or do you want to be a change agent in healthcare?' They all answer that they want contribute to positive change." —Michael Simpson

CEO SUMMARY: Expanding on insights shared in part one of this two-part interview, Clinisys CEO Michael Simpson explains new developments in digital technologies that will expand the value and role of lab test data. He predicts that labs will use artificial Intelligence (AI)—rooted in machine learning, natural language processing, and neural networks—to create operational efficiencies while producing intelligence that doctors can use to improve patient care.

EDITOR'S NOTE: In part two of this interview, Clinisys CEO Michael Simpson outlines how more advanced laboratory information systems (LIS), and laboratory information management systems (LIMS), will interact with artificial intelligence (AI) and machine learning (ML). Part one of the Q&A featured Simpson's thoughts about direct-to-consumer testing, cloud computing, and other trends that directly affect the future of the clinical lab industry. *(See TDR, "Clinisys CEO Discusses Strategic Changes Labs Need to Make," October 23, 2023.)*

SECOND OF TWO PARTS

EDITOR: In recent years, the widely known **Sunquest Information Systems** has evolved into today's Clinisys. During this time, Clinisys acquired **HORIZON Lab Systems**, **ApolloLIMS**, and **Promium**, all with laboratory information systems (LISs) that are in other areas of science and industry. What should labs currently using Sunquest and Clinisys know about this acquisition strategy?

SIMPSON: One primary strategy at Clinisys is to serve health and safety. We all recognize that different types of laboratories have many elements in common, such as processes, workflows, QA/QC requirements, sample transport, sample integrity, results reporting, and data storage. Because analytical testing laboratories share most of the basic workflows, a common platform can serve their needs.

EDITOR: In addition to the established markets of clinical laboratory and anatomic pathology LISs, what other testing areas have been added to your company?

SIMPSON: We now deliver laboratory solutions in support of public health, toxicology, environmental, water quality testing, and agriculture laboratory solutions. We are also developing a LIMS for the clinical research organization sector.

EDITOR: Doesn't this get complicated, given the different types of samples being tested?

SIMPSON: As noted earlier, all types of labs have common processes and activities. We have a platform that supports all basic functions and activities. We then add the necessary pieces to customize that platform to support environmental testing or water quality testing, for example. These are workflows and capabilities predefined to help each type of laboratory, while at the same time improving productivity and effectuating the transition to the cloud for our lab customers.

EDITOR: Shifting back to clinical laboratory needs, there is a huge pool of of diagnostic data sitting in different IT systems, ranging from lab analzyers to middleware and the LIS. This valuable data is not being used to its full potential. Is Clinisys in conversations with any big *in vitro* diagnostics (IVD) companies, for example, about how to collect data in real time from their lab analyzers and convert it into clinically actionable intelligence?

SIMPSON: Clinisys [with its Sunquest LIS] has always been the aggregator of all the IVD data that is produced in a clinical laboratory. We work closely with the IVD vendors so as to get more effective data from their systems. Laboratories must

keep that equipment in top-notch condition every day and make sure that—as they receive that data—they understand how it fits within all of the vendor devices. Even if a lab is a diehard **Thermo Fisher** or **Siemens** customer, it has other vendors' equipment in its lab as well. The lab must be able to manage all those instruments and data together. The Clinisys Platform brings all of this data together from all of the IVD companies.

EDITOR: Along with aggregating lab data from these multiple sources, can clinical laboratories use AI and machine learning to make decisions based on the data aggregated by Clinisys?

SIMPSON: Creating knowledge from data is our goal. There are some great algorithms that can point towards a diagnosis. For example, imagine developing an algorithm that uses data from 14 different types of lab tests to then give an indication that a patient has a propensity toward colon cancer. But in reality, a laboratory can't figure that out today because four of those 14 tests are on **Sysmex**, three of the tests are on Thermo, three are on Siemens, and four are on **Roche Diagnostics**. Labs need a tool to aggregate that data.

EDITOR: Are there other aspects to consider?

SIMPSON: Assume, in this example, that if the lab is to perform this colon cancer test, somebody has to manually grab that patient's tube out of the fridge, re-aliquot it, and put it on a different instrument track. That's a tremendous amount of wasted effort. And, many times, the lab needs to go back to a general practitioner and ask permission to do the added test.

EDITOR: How does your product fit into this discussion?

SIMPSON: The Clinisys Platform aggregates all the information from those instruments and then enables AI and machine learning solutions to analyze the data in real time. When sample analysis determines a patient should have other tests, before that sample gets off the track, it's re-aliquoted and on the track for those other tests. That speeds up diagnosis.

EDITOR: And also increases efficiency within the lab?

SIMPSON: That's right. Machine learning has a chance to change the way that labs operate, and it can improve efficiency.

EDITOR: In that regard, are you looking at the opportunity for your LIS to incorporate algorithms to guide reflexive testing, when approprite for a patient? As your platform aggregates data in real time on a patient test request, does it have algorithms that alert the lab in real time about which tests should be added as the first round of results come in?

SIMPSON: We're absolutely looking at this capability, but I don't expect it to come to market until late 2025. A lot of Clinisys systems must either be certified under ISO 13485 for medical devices or receive clearance under 510(k) from the federal **Food and Drug Administration**. Making sure that the algorithms are correct is critical in those cases.

Michael Simpson

➤"We've invested many tens of millions in our laboratory platform to enable AI and advanced data management across all sectors of laboratory activity."

EDITOR: How does Clinisys ensure the algorithms work properly?

SIMPSON: Clinisys has several partnerships in different countries under which we send data in real time to a partner. The partners run the aggregation and the algorithm, and then they send back the suggested result. We put that result back in front of the clinician at the laboratory to make a decision.

EDITOR: This is consistent with the drive to convert data into knowledge that enables pathologists to deliver more value to referring physicians and their patients.

SIMPSON: To be clear, we are not authorized to do this in the United States yet because the test result still has to go back to the patient's practitioner. A laboratory person cannot make that decision today. But by the time we get to 2025, I see healthcare regulations starting to change to where the laboratory could take a more proactive step in helping to solve these problems.

EDITOR: In the meantime, what features are you developing for release in the next 12 to 24 months that will help a lab better meet its needs?

SIMPSON: In July 2023, we launched Clinisys Laboratory Solutions. This is a discipline-specific laboratory information management system built upon the Clinisys Platform, that includes a shared services architecture and a data model for SaaS (software as a service) laboratory informatics. This set of laboratory solutions goes across multiple laboratory types, such as environmental, water, food, toxicology, public health, and hospitals. The ability to aggregate all that data in the same system is key. We've invested many tens of millions in this laboratory platform to enable AI and advanced data management across all sectors of laboratory activity.

EDITOR: So, this is consistent with your wide approach to testing for health.

SIMPSON: I believe my current health is defined by what I ate in my 20s, by the water I drank in my 30s, and by the air that I breathe here in my 50s. And now I suffer the consequences of those decisions. If we had better control of the environment, the food, agriculture, all of those components, we would absolutely improve overall health. I don't want any more water quality problems like in Flint, Michigan. I don't want any more contaminated lettuce, such as in Northern California. We need to head that off before a patient is admitted and tests confirm those health problems in the hospital laboratory. That is the approach Clinisys will drive across all of these lab sectors over the next 10 years.

EDITOR: Do you have any future products to help a lab deal with new assays coming to market? New diagnostic technologies are enabling more sensitive assays that use different specimens and produce much more data.

SIMPSON: You are correct that clinical labs will see a surge of new diagnostic tests across a span of disciplines and incorporating new technologies. Already today, most organizations limp along with their legacy LIS or LIMS system because it can handle a one-answer question. But when you start to think about the multiple assays and much larger gene panels that are coming to market, labs run into problems.

EDITOR: Please explain.

SIMPSON: For example, Medicare has limits on what it pays for multigene panels, and reimbursement doesn't cover the cost of clinicians' applied time to generate the reports. With advances in AI and ML, labs will want to start running more multigene panels to check for multiple conditions. Labs are not going to be able to do that with legacy LIS or LIMS. Instead, they're going to need newer, advanced data systems to pull that information together.

EDITOR: Will storage of all this data also be a concern for labs?

SIMPSON: Yes. Their systems will need to store more information about specific variant challenges and deviations of variants, and that is going to be stored in a modern LIMS system. There will be pieces of that data going to EMRs too, and you'll see laboratory data mixing with pharmacogenetics data. The complexity of lab data is increasing.

EDITOR: THE DARK REPORT has been following a new phenomenon of "dry labs" and "virtual CLIA labs"—in other words, third-party organizations that take molecular and genetic data generated by a

"wet lab" and analyze it for the referring physician. Is Clinisys having any conversations with these virtual labs, and is there a solution suite that would come out of your LIS that helps a hospital lab perform whole genome sequencing locally and then deliver this data to the right players for analysis?

SIMPSON: We do not foresee ourselves ever being the owners or the creators of that type of data. But we will absolutely enable the collection of that data and then tie it into lab reports. Today, our conversations with different lab scientists centers around the reporting aspect. How do we bring these pieces together? Today, pathologists get the data and report it, and then general practitioners have to go to a textbook, find the variant, and then go to online resources to learn more. During that process, they might go through 15 different clicks and 11 different websites to actually get the information they need. It's not efficient.

EDITOR: Thus, the need for more advanced analytics?

SIMPSON: Real-world data analytics as a trend in the broader healthcare industry has gained momentum and is increasingly becoming relevant for clinical labs and innovative solution providers. While the LIS remains the centerpiece of every laboratory, functionality is becoming modularized, requiring vendors to provide easy integration capabilities.

EDITOR: How might labs move stepwise to adopt these modularized tools?

SIMPSON: Clinisys started—and this was back in its old Sunquest days—with a product called VUE, which was a diagnostic console designed as a first effort to bring all of this data together. But we quickly found that we didn't have enough reporting features in VUE. Over the next 18 months, we're going to work on these features. If a pathologist has a tumor specimen or a genetic report coming in, we want to be able to help the pathologist by tying those results into public research and the other systems. We want the physician to have one place to go for an answer.

EDITOR: Clinical laboratories and pathology groups have an opportunity to increase their collaboration with pharma and bio-research in ways that can generate a new source of revenue for them. Outside the United States, do you engage with pharma and clinical trial organizations that work with clinical labs where Clinisys creates a cloud platform that meets the objectives of each of those entities?

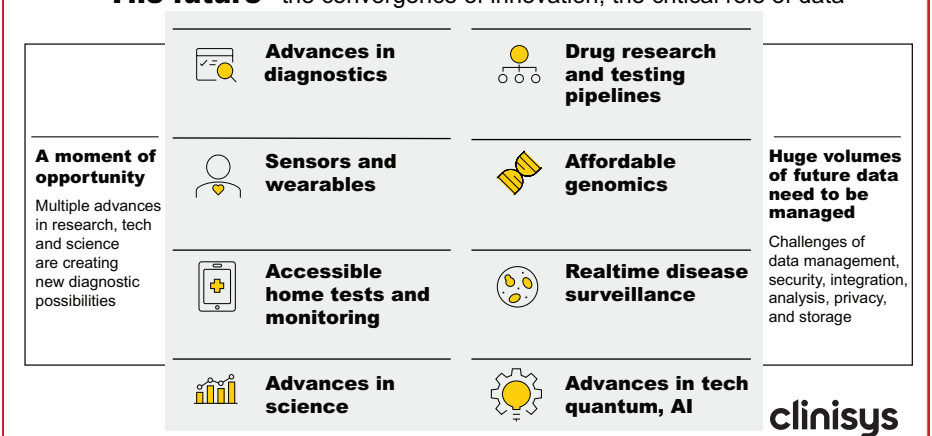
SIMPSON: We work with a few contract research organizations (CROs) today. We're working to package a Clinisys contract research LIMS. Soon, we will announce our Clinisys Contract Services Laboratory solution. Laboratory real-world data represents over 70% of the electronic health record and contains phenotype and genotype data. Personalized medicine relies on the availability of large-scale datasets, which are suited to clinical real-world data studies. This real-world data that clinical laboratories generate is extremely valuable to biotech and pharmaceutical companies and there is an opportunity for laboratories to monetize that data.

EDITOR: In what way?

SIMPSON: Real-time analytics in labs currently focuses on business analytics but is increasingly moving towards value-based care that can drive clinical decision support. Our core system drives the common data structure, but on top of it, based on the type of lab to which we are selling, we have specific solutions. These are workflows predefined to help that type of laboratory effectuate that change to cloud and improve productivity. Whether it's an environmental lab, a water quality lab, or anatomic pathology lab, we don't believe that any of these vertical markets can be served by a single LIS or LIMS. There needs to be specific content packages and decision-making features on top of the core product that are designed around what a lab needs to accomplish.

Looking Forward, Data Forms the Foundation for Knowledge to Improve Patient Outcomes

CONTINUING ADVANCES IN A VARIETY OF TECHNOLOGIES are predicted to enable new capabilities in the delivery of healthcare. The executive team at Clinisys believes that diagnostics and clinical laboratories will have multiple roles to play, as shown in the chart below.



Clinisys provided the copyrighted graphic above.

EDITOR: Michael, you have provided valuable insights on some of the major forces for change in healthcare and how clinical laboratories and pathology practices should craft their strategy for managing data and using that data to create value. Many thanks for your time.

SIMPSON: I appreciate the opportunity to share these insights, along with where our profession—and our company—is heading. And, you know, THE DARK REPORT is always on my desk. I do appreciate that. It's been a kind of Bible for everyone in the clinical laboratory profession that has guided us on how to actually survive over the last 25 or so years. It's where you go to learn what's going to happen two years from now. So, THE DARK REPORT has been a phenomenal source of value to lots of us over the years. We really appreciate it.

EDITOR: Do you have any predictions for clinical lab managers and pathologists?

SIMPSON: Let me close with what I tell every candidate I interview who may come to work for our company. I tell them that this is the best time on the planet to come into laboratory science because we will see the most dramatic change we've ever seen in our lifetime.

EDITOR: Why is this true?

SIMPSON: Because of these technology advances, we are watching lab data—along with other types of data—become an asset that is transformed into true intelligence that allows for actionable items, for real benefits, and for healthier and safer communities. Our job is to now make this a reality that benefits physicians, patients, and society.

EDITOR: Michael, thank you for this broad-ranging conversation. We appreciate the time you've spent with us.

SIMPSON: I hope lab professionals recognize that this is an exciting time for laboratory medicine and the value it can deliver to physicians and patients. TDR

Contact Michael Simpson via Paul Jackson at Paul.Jackson@clinisys.com.

Michael Simpson

NEWSMAKER INTERVIEW

Virchow
Medicine ➤ Money ➤ Managed Care

This column is named after the famous German pathologist, Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

How Certain Labs Can Crack into Health Plans' Closed Networks

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

It's possible that a clinical laboratory manager or director reading this has been told by a health plan that its network is closed to new laboratory providers. But that is not always true.

Many so-called closed networks are never fully closed off to laboratories that want to join. But if a payer states that its network is closed, many inquiring labs simply respond, "Oh, okay," and hang up the phone.

➤ Yes. Payer Networks Narrowed

It is true that, over the past decade, major health insurers substantially narrowed their networks. For example, hospital laboratory outreach programs that had in-network status for years suddenly found that payers would not renew their managed care contracts. At the other end of the spectrum, new laboratories entering the market were repeatedly denied network status.

Today, the popular wisdom is that private payers have narrow networks and are happy with their panel of in-network laboratories. But the reality is much different because every health plan has specific needs that it must meet with the mix of providers in its network. Thus, when seeking to gain provider status with a payer, savvy lab managers understand that they need to spend more time and effort figuring out how to get through that payer's door to become an in-network laboratory provider.

➤ 'Our Network is Adequate'

When I worked for a payer, we had a standard response when a new lab called and asked if it could get in-network. Our response basically thanked the lab for its interest but noted that our health plan was not adding more labs in-network because our service levels were satisfactory.

If a clinical laboratory inquired about a closed network through the payer's website, those requests got triaged by a special group within the company. To maintain a sense of fairness, the group would send back a three-page questionnaire to the laboratory.

A committee met once a month to go over the answers that labs provided to their questionnaires. And the number one question that committee members always asked was, "Do we need this lab? Who else is in their area is offering the same thing that we already have in-network?"

Most times, the network already had several labs offering similar services, so

the new lab that inquired with us would get a "Dear Laboratory Manager" letter that basically said, "thanks, but no thanks." If a lab was persistent, the committee would research whether the laboratory's CLIA certificate was current or if its accreditation with the **College of American Pathologists** was up to date.

Unbelievably, some clinical laboratories would apply to be in-network and not even make sure their licensure was valid. That's because somebody in the lab was sending in this request as a side task instead of understanding how important it was.

The kicker was that if a lab got the "Dear Laboratory Manager" letter, that lab could not reapply to be in-network for 12 months.

On the Surface, a Fair Approach

I want to stress that legally, payers try to treat every lab the same when it comes to requests to join a network. It keeps payers from being sued for denying providers entry into a network.

I can recall some laboratories that weren't allowed in-network going to their representatives in **Congress** to complain. Those officials would contact the payer on behalf of the lab, and we would emphasize that we treated the lab in question just like every other lab. And usually, the lab in question didn't meet specific criteria and certain licensure requirements that the payer mandated.

Payers keep all kinds of documentation about their interactions with laboratories. So, it's easy to show a Congress member or other public official the correspondence that was sent, the responses the payers got back from the lab, what was missing in the application, and whether anything innovative was being offered.

All that said, a health plan's closed network is never truly closed.

In the last issue, I discussed in the Virchow column how laboratories that want to be in-network often need to provide something unique to a payer. After all, if an insurance plan already has a dozen labs in-network that do basic chemistry, why does the plan need another chemistry lab? *(See TDR, "To Get In-network, Consider Where a Lab Offers Services," Oct. 23, 2023.)*

In order to get the payer's door to crack open, a laboratory needs to do something innovative. If Lab A offers mobile phlebotomy services or will go into patient's

Out-of-Network Labs Can Make Payers Want Them

SOMETIMES A CLINICAL LABORATORY would prefer to stay out of network, likely because it is doing fine attracting patient volume and earning revenue on its own.

Those labs do get noticed by payers, however. If one of those labs rebuffs a payer's offer to join a network, the payer might begin a "redirection campaign." When that tactic occurs, the payer sends out letters to all the in-network providers that use the laboratory in question.

Those letters might remind the providers that their contract states they must use an in-network lab. It gets nasty. From the payer's perspective, if a lab offering a unique service is not going to work with them, then the lab is going to be the subject of redirection letters.

A while back, THE DARK REPORT detailed one example of this approach involving **Aetna**. We wrote "in a letter sent to at least one network physician, Aetna warned the physician that—if the doctor continued to refer patients to out-of-network labs—Aetna would take actions against the physician that may include exclusion from participating in Aetna's network." *(See TDR, "Aetna Threatens to Expel Doctors for Out-of-Network Clinical Laboratory Referrals," July 8, 2013.)*

homes for blood draws—and Lab A is willing to take the payment rate from the plan—that constitutes something unique.

As I noted in my previous column, this is the point where a lab needs a skilled negotiator to say, "Lab A will take the rate, but here's what the lab wants in return."

For example, perhaps the negotiator can secure reimbursement rate increases year over year if the lab is able to scale its innovative offerings to other communities or regions. Or maybe the lab gets a rate bump from providing services to difficult patients, such as nursing home residents.

Payers May Seek Out Labs

On the flip side, health plans also pay attention to the market. If they are aware that Lab A is out of network but is serving many patients in a community and bringing in millions of dollars in reimbursement, you better believe the payers are going to be calling Lab A to try to get the laboratory into the network.

It's a business, and payers have numbers they need to hit. If a clinical laboratory offers a unique service—and if there's a large volume of out-of-network dollars being generated by that lab—the idea of a closed network goes out the door because the payer wants that lab.

Closing Thoughts

In wrapping up, I want to emphasize two points:

- Closed networks are likely never truly off limits to new laboratories.
- To edge into these networks, clinical labs must offer uniqueness or innovation that has value to the health plan.

If a lab can jump through the hoops that a payer sets up for a closed network, it has a chance to enter that network if it can live with the test rates that the payer offers.

As mentioned earlier, my recommendation is that the lab engage an experienced, skilled negotiator when applying to become an in-network provider. As the applicant lab makes its case that it has geographical coverage and a service mix that is useful to the health plan, the lab's negotiator can work to obtain better pricing and terms from the payer.

My message today to clinical lab executives and pathologists is simple. A payer may say "no," but that no does not mean never! Persistent labs that understand how to present the ways they can deliver value to the payer and its panel of physicians can often win network status. TDR

UHC Closed its Network to New Laboratories

When it established a closed network for laboratories—also sometimes called preferred networks—**UnitedHealthcare** (UHC) didn't completely shut off other labs, according to past coverage from The Dark Report.

In July 2019, UHC launched a new preferred laboratory network with seven lab companies. However, the payers said that physicians and patients could continue to use hundreds of other in-network labs—but it would come at a price.

"One goal is to give patients a choice of labs based on price, with preferred labs offering the lowest costs," The Dark Report noted. *(See TDR, "UHC Sets July 1 Launch for New Preferred Network," April 29, 2019.)*

Depending on which lab a plan member chose, costs were as follows:

- The seven preferred network labs offered the lowest cost for services.
- Other in-network labs (more than 300 nationwide) cost a bit more.
- Out-of-network labs (thousands nationwide) cost the most.

UHC further stated that preferred laboratories would have shorter wait times and online scheduling at patient service centers.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Federal regulators recently confirmed that Dec. 4 remains the deadline for public comment on the proposed rule that the federal **Food and Drug Administration** (FDA) would use to regulate laboratory developed tests (LDTs). This was confirmed during a public webinar for the lab and *in vitro* diagnostics (IVD) industry conducted by the FDA's Center for Devices and Radiological Health on Oct. 31.

MORE ON: *FDA LDT Proposed Rule*

MedTech Dive said that, during the webinar, FDA officials disclosed that 1,000 public comments have been submitted to the agency since the draft LDT rule was issued on Oct. 3. This started the 60-day period for public comment. Lab executives and pathologists now have only about two weeks remaining to submit their comments to the FDA before the public comment period ends on Dec. 4.

TWO BIG SYSTEMS CALL OFF MERGER

For the second time this year, another attempt by two large multi-hospital systems to merge has been called off. Last month, **UnityPoint Health** of Des Moines, Iowa, and **Presbyterian Healthcare Services** of Albuquerque, N.M., announced they would not proceed with their merger. If completed, it would have involved 48 hospitals in four states with $11 billion in annual revenue. No reason was given for the decision not to merge. Earlier this year, **Sanford Health** of Sioux Falls, S.D., announced plans to acquire **Fairview Health** of Minneapolis. This transaction would have created a 58-hospital health system but was stopped.

LEADERSHIP CHANGE AT JOINT PATHOLOGY CENTER

Earlier this fall, the **Joint Pathology Center** (JPC) of the **Department of Defense** transitioned to new leadership. Colonel Mark Lyman, a pathologist, was named as the new Director of JPC. He has a 26-year career with the U.S. Air Force. Stepping down as the JPC Director is pathologist and Army Colonel Joel T. Moncur, who served in that role since August 2018. The Joint Pathology Center has the world's largest repository of slides and tissue blocks. Under Moncur, JPC began the process of digitizing slides and other archival material to support research and development of algorithms that incorporate machine learning.

TRANSITIONS

- Phil Febbo, MD, joined **Veracyte** as its Chief Scientific Officer and Chief Medical Officer (CMO). He held prior positions at **Illumina**, **Varian Medical Systems**, **Genomic Health**, and **UCSF**.

- **GeneDx** announced the selection of Melanie Duquette as Chief Growth Officer. Duquette previously held executive positions at **Invitae** and **DNA Genotek**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 4, 2023.

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