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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

Opportunity for Labs to Help with Opioid Crisis

IT'S CALLED THE OPIOID CRISIS AND IT'S OFTEN A MAJOR STORY in the nightly news. In 2017, deaths from drug overdoses totaled 70,237, of which 68% (47,600) were opioid overdose deaths, according to the federal **Centers for Disease Control and Prevention**.

Across the nation, government health officials and healthcare providers struggle to address the problems of opioid addiction. Opioid abuse strikes wealthy and poor alike and can be found in nearly every city and town in this country. As a trend, opioid abuse has momentum and the trend is reinforced by the illegal manufacture and distribution of fentanyl—a synthetic opioid that is similar to morphine, but 100 times more potent.

This crisis, and the toll it takes on the families of opioid abusers and the communities in which they live, represents an unusual opportunity for pathologists, clinical chemists, medical technologists, and other medical laboratory professionals. Clinical labs have the knowledge, expertise, and capabilities to help health networks, physicians, and payers manage patients on chronic opioid therapy (COT).

On pages 10-16, THE DARK REPORT presents the story of how **Community Health Network** (CHN) of Indianapolis launched a program to improve the care and management of COT patients. You'll learn why laboratory test results provide one of the few sources of objective information about patient compliance or non-compliance. In fact, with urine drug testing included in CHN's care protocols, physicians were able to reduce the rate of patients with inconsistent toxicology test results from nearly 60% to just 20%.

Next, on pages 17-18, you'll read about how **AIT Laboratories**, of Denton, Texas, works with CHN to provide its physicians with toxicology testing services in support of the CHN opioid management program. Those services include analytical reports that help physicians track their COT patients and monitor how effective they are in following the program's protocols.

The success of Community Health Network's opioid management program demonstrates that appropriate use of toxicology testing can make a major difference in helping COT patients. Pathologists and clinical lab managers can take this knowledge and use it to help the hospitals and physicians they serve to achieve better patient outcomes for COT patients. TDR

Expert Sees Pros, Cons In DP and WSI Systems

With two competing DP systems in the market, pathologists have options for whole slide imaging

CEO SUMMARY: Now that the FDA has cleared two digital pathology systems for use in primary diagnosis, a growing number of pathology groups are taking up the question of whether and when they should adopt and use a digital pathology system and whole slide imaging. One pathologist with hands-on experience working with different digital pathology systems says that the technology is improving. He offers insights about the current state of the digital pathology market.

WHOLE SLIDE IMAGING SYSTEMS REACHED A MILESTONE OF SORTS in May when the **U.S. Food and Drug Administration** cleared **Leica Biosystems** to market its Aperio AT2 DX System for clinical diagnosis.

Leica's product is the second whole slide imaging system to receive FDA clearance in the United States. In April 2017, the FDA cleared the **Philips** IntelliSite Pathology Solution (PIPS) for marketing. The PIPS allows pathologists to review and interpret slides prepared from biopsied tissue. *(See TDRs, July 22, 2019, and April 24, 2017.)*

But regulatory clearance of these two systems for use in primary diagnosis may not mean that whole slide imaging systems will soon supplant the glass slides currently used by the nation's anatomic pathology labs. At their current state of development, use of a digital pathology system and whole slide images (WSIs) in a pathologist's daily workflow delivers certain benefits, along with some offsets.

One pathologist considers that the current state of technology in digital pathology and WSI is improving steadily. "My sense is that the efficiency factor of about 20% longer to read a WSI best represents the current reality that WSI is in its early phases of adoption," commented Richard Feddersen, MD, Medical Director for Immunohistochemistry and Anatomic Pathology for **TriCore Reference Laboratories** in Albuquerque, N.M. "Digital pathology vendors have and will mount reasonable arguments as to how this will improve over time.

"As an example, a standard two button-roller ball mouse (as used in these Leica studies) may not be the ideal periph-

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eral for navigating the digital slides," he explained. "I've seen efforts to substitute a roller ball or touch screen. Both would be potential enhancements for at least some diagnosticians. One idea I haven't seen tried is to adapt a high-end joystick-type game controller to the software, creating an environment akin to a flight simulator."

Pathologists interested in comparing the workflow of digital pathology systems against viewing slides through a microscope will find many advantages and disadvantages to each method, Feddersen explained. He was his site's principal investigator for the study Leica Biosystems did to support its application for FDA clearance.

In his evaluation of Leica's AT2 DX System, Feddersen found the Leica system compared favorably. Not only did he serve as the principal investigator for the AT2 DX, but previously he was one of the reading pathologists for another WSI system that, under the terms of his agreement with the second vendor, he could not name.

Assessing Image Quality

"The image quality is at least comparable to the other systems I've seen," he said of the AT2 DX. "Generating a quality digital image from material that is as optically complex as a microscope slide at a variety of magnifications is a huge technical achievement.

"And with all these vendors, you can almost take for granted that you'll get a quality image at either 20X or 40X magnification," he added. "They all seem to perform comparably. Put another way, image quality is a basic prerequisite for entering this market."

From the Leica study, Feddersen provided four key takeaways. The first, as he mentioned, was that the image quality was comparable to that of other systems.

"The second takeaway is that the Leica hardware works," he said. "By that I mean there was little need to rescan slides once they went through the instrument the first time. In the past we've reviewed competing systems where this wasn't the case, although—to be fair—I'm not up to date with all of them. Suffice to say that a system would need a slide rescan rate of under 1% as a requirement for persistence in this market.

Throughput Rate for Scans

"Here's another detail that I'd add: When assessing a scanning system's potential throughput rate from a stained slide to a digital image," commented Feddersen, "consider whether the glass slides need to be reracked individually by hand—which is far less preferable to a scanner that accepts slide racks compatible with your automated stainer.

"A third takeaway would involve my attempt to encapsulate all the wonderful possibilities that become available when you gather and archive a whole slide digital image," Feddersen commented. "I'll begin with image analysis: both the Leica and Philips systems offer robust image-analysis software that layer right into the digital image product and can interface with the major anatomic pathology LIS systems. To me, they both appear to be quite satisfactory, at least in demonstration mode.

"Beyond image analysis, a competitive software package enables any number of colleagues to conference on a case from remote sites or mitigate the cumbersome aspects of an extra-mural consultation," he said.

Benefits of Using Digital Path

"Software also allows pathologists to prepare well-organized interdisciplinary presentations in less time with more content, to prepare teaching slide sets much more readily than before, and to quickly gather and permanently associate important measurements and other annotations with a slide, thus documenting one's reasoning," he added.

Pathologist Offers Candid Views on How Firms Could Boost Performance of Digital Pathology

BASED ON HIS EXPERIENCE evaluating and working with digital pathology systems, pathologist Richard Feddersen, MD, has a wish list for what these vendors should address next. As the Medical Director for Immunohistochemistry and Histology Co-Director for TriCore Reference Laboratories, Feddersen suggested vendors make enhancements to slide viewers, image analysis software, file storage, and artificial intelligence.

Slide viewers. "Digital pathology system vendors need to keep working on their slide viewers, the interface that enables a user to display and navigate the histologic image," he said. "The current default is to use a standard mouse, but there may be more intuitive and efficient alternatives, and a single solution may not be best for all diagnosticians.

Image analysis. "As it relates to quantitative immunohistochemistry, image analysis is already available at a high level," he commented. "What remains is to continue fine tuning algorithms to deal with problem cases: such as poorly cohesive tumors, tumors with heavy inflammatory infiltrates, and suboptimal histologic preparations, to name a few.

"Image analysis may have unrealized potential for discovering very rare events, a lone organism in an AFB preparation, for example, or single metastatic cells in lymph nodes," he commented.

Throughput. "The sequential leaps in slide scanning automation and throughput over the past 10 years have been remarkable," he said, adding that vendors should, "Keep it up!

"Also, a low-tech yet substantial throughput enhancement has been the standard slide rack used between two of the robotic H&E stainers on the one hand, and the Philips and Leica scanners on the other, eliminating the need for slides to be individually unloaded and reloaded by hand," he explained.

"It would be great if there were a standard rack across the entire histology robotics industry," he said. "The onus for this feature rests mainly with the designers of the automated stainers.

File storage. "The vendors must develop and constantly refine a menu of image file storage solutions which cost-effectively meet the needs of individual clients," he suggested.

Artificial intelligence. "While artificial intelligence may or may not ever be able to replace a trained human microscopist, it would certainly be interesting to watch an advanced AI system's differential diagnosis appear along the side of the screen while examining a digital slide!" said Fedderson.

"For labs with pathologists working at scattered satellite locations, software can solve the logistical headaches of delivering materials in a timely way, something that is often a big problem in the afternoons," he said.

Value in Digital Archives

"And finally, depending on a lab's case volume and scanning capacity, there is the potential for a transition to digital slide archiving, eliminating once and for all the labor-intensive physical storage and retrieval of glass slides, problems that we've always known and not loved," Feddersen commented.

"I should emphasize that while there is only a small handful of big firms marketing high-throughput slide scanners, there are at least two handfuls of small software enterprises innovating ways to view standard digital image file formats, and perform all the image analysis and other functions I mentioned above," he added.

"Some of these companies are getting into diagnostic artificial intelligence applications," he said. "Competition in this field appears rather intense right now.

"My fourth and last takeaway is more cautionary," he suggested. "A quality whole slide image is a densely granular thing, and the data storage and retrieval requirements can be huge, especially if the goal is 100% digital slide archiving.

"Just doing a thumbnail calculation, I'd say that to scan and archive all the slides our lab would need 150 terabytes of new file storage each year," he estimated. "Therefore, pathologists have a lot of calculations to work out in advance, such as the mix of onsite and cloud data storage and expectations about retrieval time for current, recently archived, and older cases.

"From what I can tell, the WSI vendors could be a little more proactive in offering prepackaged solutions modeled to fit client needs," he commented. "If they don't do so, some of the small software startups will. At present the plan seems to be an assumption that 'Our IT people will work with your IT people,' a phrase that triggers alarm bells for many of us in laboratory medicine."

A Question of Throughput

After describing his four primary takeaways, Feddersen addressed the key question many pathologists have: How does the throughput of the AT2 DX perform in a busy practice?

"I would say the AT2 DX is comparable or superior to other workflows, although the current Philips system is doing so at a higher resolution," he commented. "That said, Leica and Philips may be leapfrogging right now, and I don't have enough experience with **Hamamatsu** and other vendors to comment on them.

"There are several practice scenarios where one or more of these instruments should fulfill a group's long-term needs," he added. "For example, any pathology group would benefit if all the doctors are ready to transition to routine digital diagnosis at once. Or, failing that, a group would benefit if they all work in the same office complex or if digital slide archiving is deferred to the future, and only some subset of the slide output is to be scanned. These instruments also benefit a lab that is able to finish all or most of its slide output on the night shift."

A Paced Adoption of DP

TriCore's 20 pathologists in Albuquerque are in two practices spread out over a large metro area.

"They want to adapt to the new digital format at their own pace, which I personally think is a good idea," Feddersen commented. "They view 1,200 to 1,500 routine slides per day, and then generate around 500 special requests.

"We never have all this work done by 8 am," he added. "We would love to transition to digital archiving from glass-slide storage. We'd prefer to scan all the freshly-prepared slides at the core lab before delivering them to the satellites, although gathering them up from the periphery after diagnosis is a less elegant possibility.

"So, we have a long—and some might say an unreasonable—wish list, for which the throughput capacity of today's current digital pathology scanners would be hard-pressed to fulfill," he concluded. "I don't know how many anatomic pathology operations around North America share our needs, but I suspect there may be a few."

Because of his hands-on experience with multiple digital pathology systems and scanners as part of formal studies and evaluations of this equipment, Feddersen's observations and recommendations should be useful for any anatomic pathology laboratory considering when and how to take the plunge and "go digital" with its daily workflow. TDR

—Joseph Burns

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ASCP, CAP Ask Anthem to Roll Back Price Cuts

Two pathology associations say deep cuts mean pathology groups won't recover cost of these tests

CEO SUMMARY: One association representing pathologists says new payment rates that Anthem, Inc., is introducing in 14 states do not cover the costs of performing anatomic pathology and clinical lab testing for the tests in question. Another association says the steep payment cuts threaten the viability of small and rural pathology groups. State-by-state, Anthem is instituting cuts in what it pays for most pathology CPT codes and some clinical lab tests by 50% to 80%. The financial consequences for pathologists will be significant, as Anthem insures 40 million Americans.

PAYMENT CUTS FOR PATHOLOGY SERVICES AND CLINICAL LABORATORY TESTS that **Anthem Blue Cross and Blue Shield** is implementing do not cover the costs of such testing and threaten the ability of small and rural pathology groups to continue to serve patients, according to letters from two groups representing pathologists.

In July, two national pathology associations—the **College of American Pathologists** (CAP) and the **American Society for Clinical Pathology** (ASCP)—sent letters to Anthem sharply criticizing the deep cuts Anthem has made since late last year in payment for pathologists' services and clinical lab testing in the 14 states where Anthem operates.

ASCP said Anthem welcomed the chance to discuss its new rates and expects to meet with Anthem officials in the coming weeks. CAP said Anthem does not plan to rescind or revisit its fee schedule changes. *(See sidebar, "Anthem Remains Firm on Payment Cuts," page 9.)*

In the ASCP's letter to Anthem President and CEO Gail K. Boudreaux, the pathology asssociation said it was concerned that Anthem's new payment rates for anatomic pathology services "are unreasonably low and in many cases do not cover the costs of performing these services." ASCP sent copies of the letter to pathologists in Anthem's 14 states: California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia, and Wisconsin.

Seeking More Information

In the letter dated July 31, ASCP President Melissa P. Upton, MD, asked for an explanation of the cuts. The society was unable to find any information about why the rates were being reduced so much or about what methodology Anthem used to set such low rates, she wrote.

"Moreover, we are unaware of other medical specialties being affected by such significant rate cuts," Upton wrote. "We would like to know why pathology and laboratory medicine have been singled out for these cuts. We believe targeting pathology and laboratory medicine reveals a fundamental lack of understanding of the value of these services to patient care."

As reported earlier, national and state pathology and laboratory groups and pathologists themselves are deeply concerned about the potential adverse financial effects such cuts could have on pathology practices and on laboratory medicine. Pathologists also are concerned about the potential negative effects such cuts could have on patient care and patients' costs. *(See "Anthem's Cuts in AP Fees Could Put Patients at Risk" and "Few Options for Pathology Groups Facing Anthem's Payment Cuts," TDR, Sept. 3, 2019.)*

➤Pathology Payment Cuts

The ASCP had similar concerns, with Upton writing, "As a result, these payment rates could influence pathologists and clinical laboratories to decline to participate in-network with Anthem, increasing the likelihood that patients could be exposed to out-of-network costs."

In her letter, Upton said Anthem was setting a national uniform rate for laboratory services similar to what Medicare does under the clinical laboratory fee schedule. "Anthem Blue Cross and Blue Shield's recently announced rates for many high-volume pathology and clinical laboratory services are exceedingly low in comparison to Medicare's payment amounts," Upton wrote.

She cited examples of such low payment rates from Missouri and Ohio and compared them with what Medicare pays.

"In Missouri, Anthem announced it will reduce payment for CPT 88305-26 (level IV, surgical pathology, gross and microscopic examination) from $66 to $14.43, a cut of almost 80%," she said. "Medicare's rate of $39.64 is almost triple Anthem's new Missouri rate.

"In Ohio, the payment rate for 88342-26 (immunohistochemistry, antibody, first stain) is being cut from $50.73 to $16.34, almost 70%, while CPT 88342TC is being cut 35% to $29.66," she added.

"The result is that Medicare's payment of $37.12 for the professional component will be 127% more than the Anthem rate, while the Medicare TC payment of $71.36 will be 140% more than the Anthem rate."

Upton then compared Anthem's payment rates in California with the Medicare CLFS rates. "In California, Anthem already cut CPT code 88305-26 (level IV, surgical pathology, gross and microscopic examination) from $36.67 to $24.13, a reduction of almost 35%," she wrote. "In contrast, Medicare's rate ($39.64) is almost 65% more than Anthem's rate."

Upton also criticized Anthem for making deep cuts in payments for clinical laboratory tests. "Anthem intends to reimburse CPT 80053 (metabolic panel) at $5.99, about half of the revised Medicare CLFS payment of $11.74," she wrote. "For CPT 85025 (complete blood cell count), Anthem's rate of $3.68 is only 57% of the Medicare CLFS rate of $8.61. For CPT 80061 (lipid panel), Anthem's payment ($6.02) is 46% lower than the Medicare amount, $11.23."

In her conclusion, Upton asked Anthem, "to immediately cease implementation of these reduced payments for pathology and laboratory services," and she asked Anthem to explain why it changed its fee schedule for pathology and laboratory services, what methodology the insurer used to establish new pathology and laboratory fees, and what economic effects the new rates will have on pathology practices and clinical laboratories in each state.

➤CAP Outlines Concerns

In its letter, CAP wrote to Paul Marchetti, Anthem's Senior Vice President, Network and Care Delivery Transformation. Dated July 16, the CAP letter is unsigned. As the ASCP did, CAP had several concerns, the most important of which was the effect on smaller pathology practices.

"While we hope primarily to address issues related to information and notification, the CAP has serious concerns with policies that make it increasingly difficult

for pathologists to continue to provide essential diagnostic services to patients and continue to serve the rural and smaller hospitals that have relied on them," CAP wrote. "Especially for many smaller pathology practices, this kind of significant change could determine the financial viability and continued ability for pathologists to provide care to patients."

Seeking Clarification

Also, CAP raised the issue of why Anthem was making these changes. "Given the magnitude of this change, the CAP is requesting a more comprehensive explanation of the reasons that led to the new rates and clarification about how Anthem is valuing pathology services," the letter said.

CAP also was concerned about the short time Anthem gave pathologists between the announcement of the new rates and the implementation date. "On the information front, confusion continues surrounding the context, reasons, and methodology for Anthem's fee schedule changes," CAP wrote.

"On a May 3, 2019, phone call with staff from the CAP, Anthem representatives indicated that the changes were necessary to remedy disparity across parts of the network and rebalance rates regardless of setting," CAP wrote. "However, we have heard differing explanations from CAP members, including that the pathology changes may be tied to increases in evaluation and management (E&M) codes.

"Other CAP members report hearing the rates are meant to mirror those paid to large national laboratories, which would not be sustainable for smaller pathology practices," the letter added. "There have been questions about multispecialty groups versus single-specialty groups and the scope of the term 'ancillary service providers.'"

The CAP letter closed with a request for more information. "As a result, we are asking Anthem to provide us with a clear and formal explanation of the changes and the current valuation of pathology services as well as additional guidance and resources on exactly who is impacted by this change and where pathologists can go with concerns or questions," the letter said.

In response to questions, Anthem stated, "Anthem's adjustment to office-based lab fee schedules is an effort to address the wide disparity in prices for this service." TDR

—Joseph Burns

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Anthem Remains Firm on Payment Cuts

AFTER A CONFERENCE CALL last month with executives from **Anthem Blue Cross and Blue Shield**, representatives of the **College of American Pathologists** (CAP) concluded that Anthem does not plan to rescind or revisit its fee schedule changes, according to a report on the CAP website. The report also said Anthem's executives will "monitor the market response" and suggested that pathologists call their regional network managers to discuss their concerns.

During the call on Aug. 28, CAP pressed its case to have Anthem reverse its new payment cuts. "The CAP argued that the cuts would undermine the viability of pathologists' practices and limit patient access to care for pathology services, particularly those provided in rural communities," a CAP spokesperson said. "The CAP also argued that this action could result in quality of care issues and downstream costs for Anthem."

CAP executives said Anthem's new rates would be unsustainable for some groups and that pathology practices could close as a result. Representatives from the California and Virginia societies of pathologists also have met with Anthem officials.

CEO SUMMARY: When developing a program to identify and treat patients who misused opioids or needed chronic opioid therapy, Community Health Network (CHN) of Indianapolis recognized that clinical lab toxicology tests were one of the few sources of objective data about patient compliance. When CHN developed its Chronic Opioid Therapy (COT) program, protocols were included that called for physicians to regularly use toxicology tests. Use of these tests reduced inconsistent toxicology results and the number of patients misusing opioids.

Indiana health system finds lab test results are useful data for patient compliance

Monitoring Patients on Opioids Is Opportunity for Clinical Labs

First of Two Parts

One big opportunity for clinical laboratories seeking to improve patient care is to assume a larger role in helping physicians manage some of the 24-million Americans who are on chronic opioid therapy (COT) for pain.

Clinicians, health insurers, and government health officials are perplexed about how to deal with the immense problem behind the large numbers of Americans addicted to opioids and illicit drugs and who have died of drug overdoses and related causes. **The National Institute on Drug Abuse** (NIDA) estimates that drug overdose deaths doubled in the past decade and that overdoses of illicit drugs and prescription opioids killed more than 70,200 Americans in 2017. The total number of overdose deaths involving all drugs from 1999 to 2017 in the United States rose from 16,849 in 1999 to 70,237 in 2017, NIDA reported.

In many ways, the opioid crisis is a perfect healthcare storm. Health plans, physicians, and policymakers are seeking a solution that can improve patient outcomes while reducing the cost of care for these patients.

Experts in the management of patients who need chronic opioid therapy have begun to recognize the significant role that clinical laboratories can play in helping to manage the opioid-abuse crisis. One of those experts is Gina M. Cooper, a registered nurse and the Pain Management Coordinator for **Community Health Network** (CHN) in Indianapolis.

As a specialist in the management of pain for adults over 18 who have been prescribed chronic opioid therapy, Cooper explained that clinical laboratory testing is one of the most important and yet overlooked keys to keeping these patients compliant and safe with opioid treatment

"To identify aberrant drug-related behaviors—meaning the patient's use of the opioid went against how it was prescribed or against the agreed-upon treatment plan—CHN developed a monitoring plan for managing the care of these patients," Cooper said during a presentation at the *Executive War College* in New Orleans in May. "That plan includes regular toxicology testing as part of a comprehensive patient monitoring program."

CHN's patient monitoring program evolved over time. The first step was to develop and implement standardized patient monitoring protocols that included the use of toxicology testing for all patients prescribed chronic opioid therapy, she said.

"Our protocols started with national guidelines, such as those from the federal **Centers for Disease Control and Prevention** (CDC) and state regulations," she added. "Next, we applied additional rules to cover best practice recommendations and to guide clinical decision-making." The CDC's guidelines are found online as "CDC Guideline for Prescribing Opioids for Chronic Pain."

After implementing these protocols, CHN saw a significant decrease in inconsistent toxicology results. "It is important to point out that the primary way we measured success was through confirmatory toxicology testing," Copper commented.

"The early phase of the program produced a clear and simple conclusion: Better patient monitoring led to better patient behavior," she added.

CHN's program succeeds, in part, because it relies on clinical laboratory test data to help physicians treating these patients to manage their care after being prescribed opioid therapy for pain—especially those being treated with chronic opioid therapy—meaning the therapy continues for longer than three months.

Toxicology Test Results

"When treating these patients, our physicians have limited access to objective data on patients' behavior," she explained. "That makes the toxicology test results particularly useful as a way to monitor these patients."

Most data that physicians have on these patients comes from what the patients themselves report. A problem with patients'

self-reports is that the data can be unreliable because the patients could be struggling with dependency, addiction to opioids or other substances, or may fear uncontrolled pain.

CDC data show that among the 24-million Americans on COT, almost half (11.5 million) have misused opioids, and an estimated 1.7 million suffer from opioid use disorder.

During her presentation, Cooper explained the details of a case study on how CHN relied on clinical laboratory test data to help physicians manage the care of these patients. An innovator in pain management and stewardship of controlled substances, CHN has five acute care hospitals and more than 200 primary care physicians working in 60 primary care centers throughout Indiana, Cooper said.

Indiana State Guidelines

"CHN developed its pain-management program after the Indiana legislature passed guidelines in 2013 that physicians and other providers must follow when prescribing opioids to patients on a chronic basis," she explained. "

"Within that legislation were several requirements that providers follow during each patient encounter, including patient monitoring," Cooper explained. The legislation established Indian's Prescription Drug Monitoring Program (PDMP) under the Indiana Scheduled Prescription Electronic Collection and Tracking (INSPECT) program.

"Once the legislation became effective, Community Health Network developed and implemented standardized patient monitoring protocols for all patients prescribed chronic opioid therapy," explained Cooper.

Included in the legislation—which Cooper said was among the most comprehensive prescribing guidelines in the country—are five rules for physicians and other providers to follow when monitoring for signs of medication misuse:

1. Risk assessments: Physicians and other providers assess each patient for the risk of misuse, stratify patients according to their levels of risk, and monitor accordingly.
2. Opioid agreements: Under these agreements, patients and providers agree on the expectations for each patient, and the agreements address medication safety. The agreements are documented in each patient's medical record and are reviewed as needed.
3. PDMP checks: Physicians and other prescribers must consult Indiana's PDMP-INSPECT before prescribing or refilling a prescription for controlled substances.
4. Urine drug testing: Over the course of treatment, physicians and other providers order randomized urine drug tests according to the risk-stratified protocol.
5. Pill counts: During patient visits, physicians and other providers compare the pills on hand with the number the patient should have based on the dosing instructions.

CHN's protocols include each of these five steps, along with other requirements that CHN added. "While developing our compliance monitoring plan, we began with what the state law requires as well as national guidelines," said Cooper. "From there we also added additional layers to our monitoring to include best practices. Among those best practices were requirements for consistent urine-drug testing and regular monitoring of toxicology test results."

Lab Testing Frequency

After implementing its monitoring protocols—including confirmatory testing—CHN added steps that defined the frequency of toxicology lab testing according to each patient's risk classification.

"Our requirements include adjustments in risk levels based on each patient's behavior and risk," Cooper said. "CHN added clinical-level staffing sup-

How Providers Can Watch for Opioid Abuse, What Laboratories Can Do to Help Physicians

WHEN DESCRIBING THE CURRENT SITUATION WITH THE OPIOID EPIDEMIC during his session at the *Executive War College* last May, R. Scott LaNeve, Senior Vice President, High Value Care at **hc1.com** of Indianapolis, provided the following lists of information to help clinical laboratory leaders understand the major issues associated with opioid abuse.

What does it mean to watch for signs of misuse?

1. **Risk Assessments:** Assess each patient for the risk of misuse, stratify them into risk levels, and monitor them accordingly.
2. **Opioid Agreements:** Make sure every patient understands the rules, the "do's and don'ts", document it in the medical record.
3. **PDMP Checks:** Consult the PDMP before prescribing or refilling a prescription for controlled substances.
4. **Urine Drug Testing:** Conduct randomized urine drug tests periodically over the course of treatment.
5. **Pill Counts:** Count the pills a patient has on-hand to ensure quantity is correct compared to prescription (not over or under).

MANAGING PATIENTS WHO ARE IN A CHRONIC OPIOID THERAPY (COT) PROGRAM can be complex for physicians and other caregivers. However, clinical laboratories have the expertise and the capabilities to help physicians in other ways besides simply providing accurate, timely toxicology test results. LaNeve identified the following steps clinical labs can take to help physicians:

- Be aware of what your providers have to do to manage these patients.
- Know the "five activities" and their value in managing patients.
- Help with clinical interpretation and convenience.
- Use the patient med list to provide interpretive results for the provider.
- Provide patient trend reports or historical results.
- List common drug brand names as well as compounds on your lab test reports.
- Identify compounds which are expected metabolites of parent drugs.
- Make the Prescription Drug Monitoring Program (PDMP) data easier to access for your providers, integrate PDMP into the EMR (through Appriss Health).
- Pull the PDMP data and compare the results to your lab report for your providers (hc1.com's Opioid Advisor).

port for physicians and other providers, and added a step to allow for continuous review, analysis, and reporting on patients' results.

Assessing Patients' Risk

"The first requirement for providers is to do a patient risk assessment by evaluating the patient's mental health status and risk for medication misuse, commented Cooper. "In addition, we do a focused pain assessment.

"The second step involves establishing expectations for patient behavior with what are called 'controlled-substance agreements,'" she said. "These agreements establish expectations between the patient and the provider.

"Providers also do a PDMP check by reviewing patients' records in the INSPECT database," she added. "In addition, they order confirmatory toxicology testing and do pill counts." Pill counts help to keep patients accountable for the controlled medications dispensed to them. Any patient who has an inconsistent pill count may be misusing the medication and may need education on how to take the medication accurately or need education on the safe storage of medication."

After Community Health Network introduced the monitoring program for chronic opioid treatment within its network, administrators convened a multidisciplinary group of physicians and other providers to consider additional best practice recommendations.

"Our multidisciplinary team aimed to determine if there were any gaps in following the federal guidelines and Indiana's requirements under the law," Cooper explained. "If possible, we wanted to improve on the requirements that were in place. Also, we wanted any additions to our protocol to be in line with best practices.

Implementing Best Practices

"These extra layers included defining our laboratory testing frequency by risk classification," she commented. "Instead of having a one-size-fits-all approach to patient monitoring, we wanted to individualize patient care wherever possible.

"That meant if we classified a patient as low risk, we would require toxicology test monitoring for that patient less frequently than if we classified a patient as high risk," noted Cooper.

"Next, we did classification adjustments based on behavior and risk factors," she said. "As we all know, risk assessment tools can be flawed because patients have different ways to manipulate their test results by answering the questions inaccurately. One of these tools is the 'Screener and Opioid Assessment for Patients with Pain,' a 24-question assessment patients are instructed to answer.

"While such tools are flawed and can be manipulated easily, we can gain historical information about the patient by using them," Cooper explained. "This helps us to establish a risk classification baseline. Then, we can make adjustments as needed based on behavior and toxicology test results.

Test Results Show Variance

"For example, if a patient's risk assessment score showed that a patient was a low risk, but their toxicology results indicated a variance, that told us that the patient in question was not truly a low-risk patient," she explained. "In those cases, we would increase that patient's risk level and monitor the patient accordingly."

After CHN implemented these steps, the staff recognized that more clinical lab testing could reveal additional patient concerns that were unknown previously. More concerns meant physicians would need more resources during each patient visit.

"After identifying all the steps we wanted our providers to follow, our next goal was to support our physicians and other providers in completing these steps," Cooper commented.

"In the network, some providers had large panels of patients on opioids," she added. "We knew these providers would require additional time just to initiate the first steps needed to follow the protocols for each of their 200 or so patients on opioids.

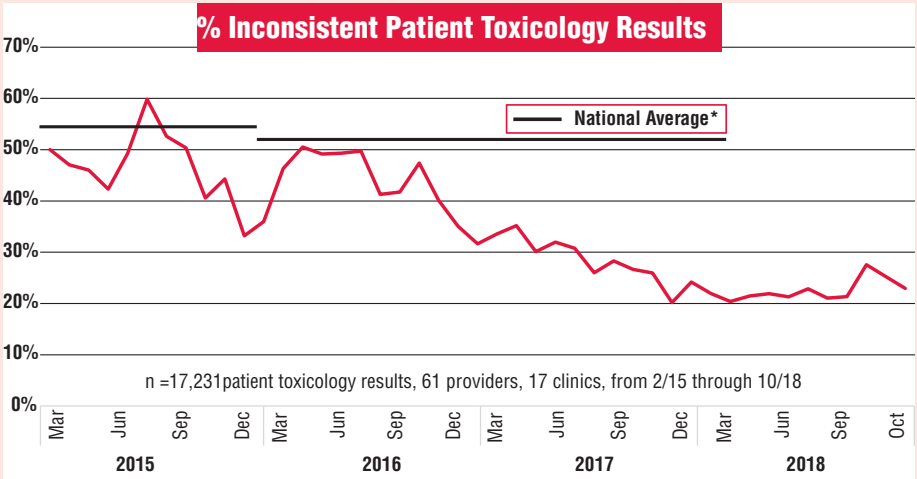
Need for Intervention

"Before being tested regularly, these patients were getting routine care," Cooper commented. "But once we got the urine-drug test results, we expected to find that some patients might need more complex care or an intervention of some sort.

How Appropriate Utilization of Toxicology Testing Improves Compliance of Patients on Opioid Therapy

ONE WAY TO MEASURE THE EFFECTIVENESS OF INCLUDING TOXICOLOGY TESTING as part of managing patients on chronic opioid therapy (COT), is to look at the percentage of patients whose toxicology lab test results show they are out of compliance.

In her session at the *Executive War College* last May, Gina Cooper, RN, Pain Management Coordinator for Community Health Network (CHN) of Indianapolis, presented the chart below. It shows the percent of patients not in compliance with the COT program at Community Health Network. Between February 2015 and October 2018, the percent of patients with inconsistent toxicology results fell from a range of 50% to 60% to just above 20%. That's an impressive improvement and is based on 17,231 patient toxicology results during that 45-month period.



*Data from Quest Diagnostics Health Trends™, Drug Misuse in America 2018, Diagnostic Insights from Clinical Drug Monitoring into the Opioid Epidemic, Sep-18

"It would be unrealistic to ask physicians to follow these protocols and then ask how they were doing after a few weeks or a few months," she said. "That wasn't going to work. Plus, we didn't want our providers to stop prescribing opioids out of frustration because many of their patients benefit from opioids. Maybe some of their patients had failed other treatment modalities, which could mean that opioids were the best way to manage those patients.

"We certainly did not want our providers to step away from a care plan that was working for those patients," Cooper added. "Therefore, we needed a way to support physicians who treat patients whose toxicology tests showed a requirement for additional care.

"We wanted to add clinical and medical resources for physicians and other providers, so when they discuss difficult cases peer-to-peer, they could develop the best treatment plan for each patient moving forward," she commented.

Using Results to Track Trends

CHN also added a reporting process that included analyzing data to monitor results physicians and other providers could use to improve patient management. "We added this reporting step because we wanted to use the results to recognize trends," she said.

To implement this step, Community Health Network used urine-drug test results. "For the patients we tracked in our

monitoring program, we plotted inconsistent toxicology test results over time," she commented.

CHN compared the results it collected in its drug-monitoring program to national averages that **Quest Diagnostics** published in the report, "Drug Misuse in America 2018: Diagnostic Insights into the Changing Opioid Epidemic."

"Once we recognized trends, then we could implement new educational initiatives for our providers," Cooper explained. "We knew that if we tailored patient education based on the trends we identified, then they could target education to each individual patient, which ultimately is what brings about the behavior change.

➤High-risk Patients

"In our data set, we had more than 3,400 enrolled patients, and from that data we saw that 54% of patients were low risk and 17% were high risk. The remainder fell into the moderate risk category," she said.

Then CHN compared the results shown in the PDMP data with the results CHN collected from all patients' urine-drug test results. The results in the PDMP database showed inconsistent results in only 1% of patients, and areas of concern for only 1% of patients, both of which were much lower than the corresponding rates that CHN showed from the data gathered from monitoring patients over time, Cooper said. The remaining 98% of patients in the PDMP data showed no inconsistent results.

"In our results from the third quarter of 2018, we saw that the toxicology pie graph shows an errancy rate (meaning inconsistent results) of 19% and consistent toxicology results of 72%," she explained.

"The rest of the graph shows areas of potential concern, which means that someone on our staff would need to do a deeper dive," she commented. "Maybe the toxicology results showed something that wasn't on the patient's medication list. Maybe it was just something we didn't expect."

After comparing the PDMP data against the data they had from regular monitoring of urine-drug test results, Cooper and other clinicians found an area of significant concern. "When we compared the inconsistent results on the PDMP side versus the toxicology side, we saw a large gap where patients can potentially fall through," she explained.

Comparing CHN's results against national averages from Quest and other sources, CHN's numbers were similar to the national average data, Cooper concluded. "In 2015, for example, we can see that our results were pretty well in line with the national average," she explained. "But then our numbers of patients with inconsistent results started to decrease, and they continued to drop over time."

The data show the numbers of patients with inconsistent results rising and falling over time. *(See chart in sidebar on page 15.)* "The ups and downs represent the points in time when we brought in more providers and clinics into the program," she said. "That's because we didn't roll out the whole program across our entire network in one big push.

"Instead, we did a slow and controlled roll out so that we could provide appropriate resources for providers as we added more physicians and more clinics," she said. "Still it's possible to see that over time, we had a significant decrease in the proportion of inconsistent results by the end of 2018.

➤Managing Patients' Pain

"For us, these results are important because all the data we have in healthcare represents the people we treat—meaning the patients we care for," she concluded. "The data show that we are producing better patient outcomes in our chronic opioid treatment program." TDR

—Joseph Burns

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Lab Monitors Compliance of Chronic Opioid Patients

Health systems use AIT Laboratories to monitor compliance of patients with opioid prescriptions

CEO SUMMARY: Hospitals and health systems developing programs to manage patients on chronic opioid therapy (COT) are finding that an essential element of these programs is regular toxicology testing. In its role as the toxicology test provider for a health network in Indiana, AIT Laboratories of Denton, Texas, has found that COT patients improved their compliance with their physicians' orders under a program of regular monitoring with urine-drug testing. Also, physicians become more consistent in following the program's protocols with their patients.

Second of Two Parts

PATIENTS ON CHRONIC OPIOID THERAPY UNDERGO undergo regular laboratory tests to verify that they are in compliance with physicians' orders. Clinical laboratories that do such testing have an opportunity to help physicians, hospitals, and health systems to manage some portion of the 24-million Americans who are on chronic opioid therapy and need urine-drug testing to ensure that they are complying with physicians' orders.

Since 2015, **AIT Laboratories** in Denton, Texas, has worked with **Community Health Network** of Indianapolis (CHN) to conduct such testing in CHN's five hospitals and 60 primary care centers in Indiana. AIT's role is to test CHN patients to ensure they are complying with the protocols CHN developed to monitor those patients on chronic opioid therapy (COT).

Clinical laboratory testing has an essential role in confirming that COT patients are complying with physicians' orders and following the protocols to ensure their safety under opioid treatment.

In 2015, AIT Laboratories recognized that Community Health Network needed a comprehensive opioid-testing program for its patients on COT. At the time CHN was implementing monitoring protocols consistent with the recommendations of the federal **Centers for Disease Control and Prevention**, including toxicology testing.

Develop Pilot Opioid Program

"We understood that CHN needed a prescription drug monitoring program," said Greg Blankenship, AIT Labs Senior Vice President of Operations. "We worked together to develop a pilot program."

AIT was based in Indianapolis before being acquired by **HealthTrackRx**, a company in Denton that helps healthcare providers and health systems to ensure appropriate use of opioids and antibiotics.

"We talked with CHN about what their providers needed in terms of monitoring patients on prescription drugs," explained Blankenship. "From there, we figured out what we could do to help, including urine-drug testing and testing for other substances. With our tests we

look for the presence of up to 30 drug classes or the equivalent of up to 125 drug analytes, depending on the physician's lab test orders." The lab has a staff of 260 employees, and all of its tests are run using mass spectroscopy.

AIT and CHN worked out a protocol in which HealthTrackRx staff would collect specimens in CHN's five hospitals and in some of CHN's 200 physicians' offices in Indiana. CHN pays for the HealthTrackRx staff to collect those specimens. The expected turnaround time for results is within 24 hours of when specimens arrive at AIT's lab, Blankenship said.

In addition, AIT provides quarterly reports to CHN on how the urine-drug testing program is helping the health system manage patient compliance.

Compliance with Protocols

"For example, CHN wants to ensure that their doctors and their patients are adhering to their protocols," Blankenship explained. "CHN wants to identify all patients who are not adhering to their prescription orders, meaning those patients who are deviating.

"CHN also wants to know the percentages of physicians who are in compliance with the program's protocols," he added. "We work with CHN to spot aspects of the COT patient management program that may need additional attention.

"For example, if our data on test utilization and test results show a discrepancy between what's expected and what's happening, it gives CHN the information necessary to address that discrepancy with physicians and their patients," he noted.

"Early analyses of our data indicate that both patients and physicians are getting better at meeting CHN's COT program goals," Blankenship commented.

"Our evaluation of the data shows that, once patients are monitored with regular toxicology testing, there is improvement in their compliance," he added. "We also see an improvement because physicians are paying attention to compliance."

Lessons Learned from Tox-Testing Program

GREG BLANKENSHIP HAS ADVICE FOR CLINICAL LABORATORIES seeking to develop urine-drug testing programs for hospitals and health systems managing some of the 24-million Americans on chronic opioid therapy.

As the senior vice president of operations for AIT Laboratories, Blankenship suggested that labs should understand the urine-drug testing protocols for patients on COT in each state. AIT has toxicology testing programs in 37 states.

"The first thing any lab would need to do is to become aware of the guidelines in each state, county, city, or town," said Blankenship. "Also, there are guidelines from the Centers for Disease Control and Prevention.

"Once a lab learns what the guidelines are for prescribing and monitoring patients, then labs need to analyze how they help physicians, hospitals, and other providers with patient monitoring," he said. "To do that, labs need to develop testing menus and turnaround times to help providers follow their own testing protocols and to help health systems enforce those protocols.

"Labs can help physicians, hospitals, and other providers through good reporting and educating providers on how to interpret the test results," he added. "Many labs provide too little support today. That creates an opening for us to come in with best practices for this kind of testing and compliance monitoring."

In addition to testing for drugs of abuse, AIT also does specimen-validity testing. This is to ensure that patients are not trying to use adulterants or substitutes for their own urine in an effort to fool the urine-drug test. TDR

—Joseph Burns

Contact Greg Blankenship, 940-383-2223 or greg.blankenship@healthtrackrx.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Spectra Laboratories, a division of the national dialysis company **Fresenius Medical Care**, will soon open a new 200,000 square foot laboratory facility in Memphis. The new lab will employ more than 300 people and will be located only 15 minutes from the Memphis International Airport and the Memphis world hub operated by **FedEx Corporation**. The choice of Memphis for this new laboratory facility shows the importance of logistics to help shorten lab test reporting times.

MORE ON: *Spectra Lab*

Spectra already operates sizeable clinical laboratories on the east coast in Rockleigh, N.J., and on the west coast in Milpitas, Calif. Both laboratories are **CAP**-accredited and ISO 15189-accredited through the **American Association for Laboratory Accreditation** (A2LA).

ELLKAY AQUIRES LEGAL EASY, INC.

In a deal to improve interoperability between healthcare information technology products, **Ellkay, LLC**, of Elmwood Park, N.J., announced its acquisition of **Legal Easy, Inc.**, of Tampa. Ellkay believes Legal Easy's X-Link medical software interfacing solution will help it assist providers—including clinical laboratories—meet federal goals for interoperability, as well as reporting federal quality measures for which providers can earn incentives or penalties from the Medicare program.

TRANSITIONS

- **Quest Diagnostics** of Madison, N.J., named Manuel O. Méndez as its Senior Vice President and Chief Commercial Officer. Méndez previously held executive positions at **Qiagen**, **bioMérieux**, **OraSure Technologies**, **Thermo Electron**, and **Abbott Laboratories**.

- The federal **Centers for Medicare and Medicaid Services** announced the appointment of Paul Mango as the new CMS Chief Principal Deputy Administrator and Chief of Staff. Mango retired from **McKinsey & Company** and is a veteran of the 82nd Airborne Division and a graduate of the **United States Military Academy at West Point**. Mango was involved in the clinical laboratory industry for several years in the 1990s. While working with **The Institute for Transfusion Medicine** in Pittsburgh in the mid-1990s, Mango organized the **Reference Laboratory Alliance**, which was a regional hospital laboratory network with 40 participating hospitals.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 14, 2019.

New This Year!
Smart Ways to Cut Costs

★SPECIAL SESSION!★

New and Better Ways to Use Lean in Your Lab and Pathology Group

Katja Lehmann, PhD

Global Manager, Solution Discovery and Workflow Optimization, Diagnostic Systems, Becton, Dickinson and Co., Sparks, Md.

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