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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

LabCorp's Plans for Docs, Pathologists, and Labs

WHAT'S IN THE FUTURE FOR PHYSICIANS, PATHOLOGISTS, AND CLINICAL LABORATORIES if **Laboratory Corporation of America's** strategy for managing lab test utilization is deployed across the country per the company's plan?

For the nation's physicians, LabCorp's BeaconLBS system will be required when they order lab tests, such as is happening in Florida with the UnitedHealthcare laboratory benefit management program.

For pathologists and clinical laboratories, they will need to meet the standards, requirements, and payment amounts that LabCorp mandates in order to participate as providers in the BeaconLBS laboratory network. The UHC program in Florida is the first public look at how LabCorp wants to implement its BeaconLBS strategy.

LabCorp CEO David King described this strategy during the firm's first quarter earnings conference call with financial analysts and investors. He stated that:

> "...I'm pleased to update you on our progress in expanding our capabilities *to change the way care is delivered.* [Italics by THE DARK REPORT.] We are doing this through the development and commercialization of technology-enabled solutions and we now have two services in play... BeaconLBS' technology-enabled solutions are modernizing healthcare by conveniently incorporating laboratory decision support into provider workflow and we will continue to enhance LBS over time to provide broader physician decision support, as well as timely feedback to physicians about their test ordering patterns and patient compliance with the tests they have ordered. This innovation promotes the use of the appropriate test for the appropriate patient at the appropriate time to enhance care and improve outcomes. I want to commend the entire BeaconLBS team on their unstinting efforts to introduce this innovation into clinical practice... *It's our goal to expand BeaconLBS both to additional markets and to additional payers.*" [Italics by THE DARK REPORT.]

Contrast those ambitions to "change the way care is delivered" with the reaction of the physicians, pathology groups, and clinical labs in Florida to the BeaconLBS system and the UHC laboratory benefit management program. A significant number of physicians and their medical societies have voiced concerns about how the program could have serious negative consequences on patient care and disrupt office work flow. Meanwhile, of the hundreds of clinical labs and pathology groups in the state, only eight non-LabCorp lab organizations proved willing to sign agreements to be network labs under the terms BeaconLBS offered. TDR

Some Florida Docs Are Not Using BeaconLBS System

State's physicians, medical societies continue to voice objections to lab test utilization program

CEO SUMMARY: Some physicians in Florida are not complying with UnitedHealthcare's laboratory benefit management program since the claims impact took effect on April 15. Although officials from UnitedHealthcare and BeaconLBS, a business division of LabCorp, state publicly that the program is going well, physicians and several state medical associations continue to voice serious objections to several key elements of UnitedHealthcare's lab test utilization management program.

SIX WEEKS HAVE PASSED SINCE **UnitedHealthcare** launched the "claims impact" part of its new laboratory benefit management program and physicians in Florida continue to express disappointment with the program.

"Claims impact" means that, for a list of about 79 clinical laboratory tests that require pre-notification or pre-authorization, UnitedHealthcare will not pay in-network laboratories when they submit lab test claims that do not meet the requirements of the program. For physicians who fail to use the **Beacon Laboratory Benefit Solutions** system to order these tests, UHC has said that it may assess penalties against them or exclude them from its provider network. *(See TDR, March 9, 2015.)*

Since the claims impact took effect on April 15, some physicians are not using the program. They do this by ordering clinical laboratory tests without following the protocols put into place by UnitedHealthcare's vendor, BeaconLBS, a business division of **Laboratory Corporation of America**. Or, they simply continue to send lab test orders to labs that are not in the BeaconLBS network.

One such physician is Dennis Saver, M.D., a family physician and geriatrician in Vero Beach. He said his practice is not using the Beacon decision-support system. The founder of the 12-physician practice, **Primary Care of the Treasure Coast**, Saver said neither UHC nor BeaconLBS responded to numerous requests his practice made to establish an interface between the BeaconLBS system and the practice's EHR system, **eClinicalWorks**. *(See TDR, September 2, 2014.)*

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

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"Basically none of the concerns that physicians had when the BeaconLBS program was announced have been addressed," stated Saver last week. "One promise UHC and BeaconLBS made was that they were going to integrate the Beacon system with most EHR systems.

"By October 1 of last year, BeaconLBS was going to be working with three EHR systems and by December 2014, BeaconLBS was going to be working with 20-something EHRs," he explained. "That was an unfulfilled promise!

"In our practice, we repeatedly asked for an interface to eClinicalWorks, which is a fairly common EHR system," he continued. "Then, in March, a UHC rep got back to us saying he was looking into it for us. A few weeks later, he called back to say that BeaconLBS was still working on it but that eClinicalWorks didn't want to establish an interface until it issued a software update later this year.

A Question of Priorities

"I can't vouch for the accuracy of these statements," he added. "That's just what we were told."

THE DARK REPORT confirmed this fact with eClinicalWorks. A spokesperson from the EHR company wrote that: "We do have an interface [to BeaconLBS] and it will be part of the next product upgrade... It will be released in October."

Yet, on UHC's website for the laboratory benefit management program, eClinicalWorks is listed as an EHR system underneath this statement: "You can select from a variety of applications integrated with Physician Decision Support, including the following laboratory ordering systems and electronic medical records (EMR) applications."

"At this point we do not have even the possibility of working with an integrated system," observed Saver, who is an Adjunct Clinical Associate Professor at the **University of Florida School of Medicine** and a Clinical Associate Professor at the **Florida State University College of Medicine**. "This is one of those situations where the whole issue makes you wonder about whether making these connections is a priority [for the insurer]. If UHC or Beacon has to pay eClinicalWorks to build an interface, you would think UHC or BeaconLBS would be able to insist that the interface be completed by a certain date.

Unable To Evaluate System

"We have repeatedly told both UHC and BeaconLBS that we would like to be able to evaluate their offer to use the BeaconLBS system," he noted. "But because there is no interface between BeaconLBS and our EHR, we have been unable to evaluate their offer. So, for now, we are not using the system."

To date, UHC has not denied any claims that Saver's medical practice has submitted even though the practice has not followed the Beacon lab-ordering rules, he said. It regularly uses its own in-house office lab to do most tests of moderate complexity, said Saver. If his practice needs to send any lab tests out, it sends them to Laboratory Corporation of America. LabCorp is a laboratory of choice for the UHC program.

In Palm Beach County, a women's health care practice is also refusing to use the BeaconLBS program because, among other reasons, its EHR system is not integrated with the BeaconLBS system. And, in a notice posted at the clinic's front desk, this practice tells its patients that neither UHC nor BeaconLBS has provided adequate details about the program. *(See sidebar at right.)*

A Patient Care Issue

Another practice not using the BeaconLBS system is the **Arthritis and Rheumatic Care Center**, a four-physician practice in Miami. Rheumatologist Olga Kromo, M.D., said UHC's BeaconLBS decision-support system is flawed and difficult to use. In her office, the physicians send lab test orders for UHC patients to

Women's Health Clinic in Florida Posts Notice to Tell Patients It Won't Participate in UHC Program

IN FLORIDA, A SIGNIFICANT NUMBER OF PHYSICIANS CONTINUE TO BE DISSATISFIED with UnitedHealthcare's laboratory benefit management program, administered by BeaconLBS. Some physicians are outspoken about their dissatisfaction. Below is a photograph of a sign posted at the front desk of **The Women's Health Institute** on Florida's east coast. It explains to patients that this physician will not participate in the program and will thus not be ordering lab tests through the BeaconLBS system.

Recently UnitedHealthcare notified us that... they would be requiring physician's offices to get 3rd party authorization when Dr. Bernstein orders certain lab tests on its patients. The lab tests in question are mainly standard of care tests, some of which are required by Florida law and others that are part of the recommended care guidelines set forth by ACOG (The American Congress of Obstetricians and Gynecologists). The tests in question include routine Pap tests, STD tests, OB labs, genetic testing, and many others that Dr. Bernstein orders on a daily basis while caring for our patients.


The Women's Health Institute

Attention United Healthcare Patients

Thank you for choosing The Women's Health Institute and Dr. Bernstein for your care.

You or your employer, have chosen an insurance plan written or managed by United Healthcare. Our office has been a member of the United Healthcare network of providers for many years. Recently, United Healthcare notified us that starting on September 1st they would be requiring physician's offices to get 3rd party authorization when Dr. Bernstein orders certain lab tests on its patients. The lab tests in question are mainly standard of care tests, some of which are required by Florida law and other that are part of the recommended care guidelines set forth by ACOG (The American College of Obstetricians and Gynecologists). The tests in question include routine pap tests, STD test, OB labs, genetic testing, and many others that Dr. Bernstein orders on a daily basis while caring for our patients.

After a great deal of thought we have chosen not to participate with this process. We have informed United Healthcare, Labcorp, and now you of this decision. The main driving factor for our decision has been that the process required for obtaining this 3rd party authorization has not been effectively communicated to us at this time. The few details that have been given lead us to believe that it will require a significant effort on the inner workings of our office as there is currently no plan to provide automation through integration with our EMR vendor. We have requested that United Healthcare reverse their decision to implement this process or at least delay the effective date until an efficient integration with our EMR can be established and proper education and training of our staff has been completed.

Dr. Bernstein will continue to order the lab tests she believes you need based upon her sound, unbiased, and professional judgment. We hope and trust that United Healthcare will fully honor its policy of insurance to you and pay for the lab services within the scope of your policy. Should you experience any feedback from either United Healthcare or Labcorp, please let us know immediately.

The business of healthcare is complex, your office visit need not be.

Thank you again.

Sara J. Bernstein, MD, FACOG, FACS
Medical Director
The Women's Health Institute

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Quest Diagnostics Incorporated, she said. That way, the tests get done, which is important for her patients. Failure to get accurate and timely lab test results could affect patient care negatively, she added.

"We are still using the work-around with Quest Diagnostics where they offer to perform the lab tests that we request and then they can try to collect from BeaconLBS or UHC," she said.

Rheumatology Patients

Kromo, in an earlier interview with our sister publication *DarkDaily.com*, was specific about the patient care issues she believes are serious and could be detrimental to her rheumatology patients. These concerns relate to the ordering algorithms within BeaconLBS that do not appear to cover all the possibilities behind a rheumatologist's reason to order specific lab tests. This is particularly true for those patients who require frequent clinical lab testing as part of their standard of care.

"Among our patients who have lupus and uncontrolled Sjögren's, which is very common, there is a high risk of developing lymphoma," Kromo said. "A clinical laboratory test is recommended for timely monitoring of these patients, but UnitedHealthcare says that BeaconLBS must pre-authorize the test before we can run it. If long-established clinical guidelines specify that a test is recommended for lupus patients with Sjögren's, why should we physicians have to request authorization from a health insurer?"

In this interview, Kromo estimated that, if her rheumatology and arthritis practice were to use the BeaconLBS system, the phlebotomist would need to stay an extra hour to two every day. "Just the paperwork for Beacon takes about 20 to 25 minutes per patient should a patient need lab tests. Because about 95% of our patients need lab tests on almost every visit, it's obvious how this system disrupts patient flow in our office," Kromo said.

"In fact, our lab person was so upset about the need to do all this extra work that she almost quit," Kromo said. "And this is someone who has been with us for seven years."

UnitedHealthcare's laboratory benefit management program has also met with stiff resistance from Florida state medical societies. A primary concern is that the program represents an unwarranted and unsupported intrusion in how physicians practice medicine.

To this point, the **Coalition of State Rheumatology Associations** wrote a letter to UnitedHealth on September 11, 2014, and stated that: "Requiring trained, certified [physician] specialists to obtain authorization from a less qualified person or entity using a rote, inflexible algorithm is not only unnecessary, but insulting. We are not insensitive to issues regarding the control of medical costs, but absent the provision of data demonstrating the inappropriate use of laboratory tests by rheumatologists, we cannot support, and will do all that is necessary, to controvert this policy.

'Pursue Reversal Of Policy'

"We are going to suggest to our members that they investigate all ethical and legal means to resist this policy and we will pursue the reversal of this policy with our state and national societies through every regulatory, legislative, and public means possible," concluded Michael C. Schweitz, M.D., President of CSRO and author of the letter.

UnitedHealthcare and BeaconLBS were asked by THE DARK REPORT to comment on the concerns of rheumatologists and the issues described in the letter from the **Coalition of State Rheumatology Associations** to UHC. No comment on these points, nor about the integration capability of eClinicalWorks, has been received.

For their part, labs in Florida have "voted with their feet" against this program. Among the hundreds of clinical labs and pathology groups serving patients in Florida, as of last fall, only 13 labs chose to sign agreements with BeaconLBS to be "laboratories of choice" and five of those are LabCorp—the owner

Pathologists in Florida Remain Concerned About Claims Denial Phase of UHC & BeaconLBS System

IN MARCH, UnitedHealthcare notified physicians, clinical laboratories, and other providers that it was revising its laboratory benefit management program that BeaconLBS administrates. At the time, UHC said these changes were the result of comments and criticisms from physicians.

Pathologists in Florida got some relief. One original requirement was that pathologists get a secondary review for certain specimens. After the change, UHC said it would accept either a single review from a subspecialist or a secondary review from an anatomic pathologist for dermatopathology, cytopathology, and hematopathology.

Last year, the **Florida Society of Pathologists** estimated that about 40% of the state's pathology groups would have trouble meeting this second-opinion pre-certification requirement in the BeaconLBS program. Few pathology groups in Florida have the size or composition of subspecialtists to meet the requirement, pathologists said. *(See TDR, January 5, 2015.)*

But Brett Cantrell, M.D., FSP's past president, said that his six-physician practice, **Consolidated Laboratory Services** at **St. Vincent's HealthCare** in Jacksonville, Florida, might not have qualified under the former rules. The group might have needed to arrange for subspecialty review, he said.

He welcomed the change from UHC. "The second-opinion modification is a major concession from UHC and makes this much more palatable from the private pathology lab's standpoint," he stated. "A second review of initial cancer diagnosis by another anatomic pathologist but not a subspecialty-boarded pathologist is standard practice in many groups and is not unreasonable.

"The subspecialty retraction was something we pushed hard to achieve, but I suspect United was feeling pressure from multiple sources on that issue, which offered no economic reward to United but did perhaps provide an incentive to utilize certain labs over others," he wrote in an email. "Single pathologist practices will have to find some arrangement with another practice to meet that requirement but most labs will be able to comply with the review requirement without difficulty.

"While we may feel like celebrating the subspecialty retraction, the reality is we are still left with a cumbersome program that will be fraught with noncompliance by clinicians, leaving the pathology labs holding an unreimbursed bag. What percentage of labs participate will be an economic decision," he concluded.

of BeaconLBS—and its different lab business units. Only eight non-LabCorp labs chose to participate despite aggressive marketing efforts by representatives of UHC and BeaconLBS to encourage these labs to participate in the program.

The ultimate irony to this story for UHC and LabCorp is that ongoing resistance by physicians to this program could lead to a Florida state law that governs lab test utilization programs such as BeaconLBS. In a story about UHC and BeaconLBS titled "UnitedHealthcare pilot to curb lab costs draws protest," *Modern Healthcare* wrote that the "...Florida Medical Association has drafted legislation to block insurers from implementing similar programs. Doctors say complying with the new program takes too much time."

On this subject, *Modern Healthcare* quoted Tampa orthopedist Michael Wasylik, M.D., Chairman of the medical association's medical services committee. He stated that: "Soon we won't be able to see patients, we'll just spend all our time documenting everything. It makes me want to puke just talking about it." **TDR**

—Joseph Burns

Contact Dennis Saver, M.D., at drdsaver@msn.com; Brett Cantrell, M.D., at Brett.Cantrell@jaxhealth.com; Olga Kromo, M.D., at olya@kromo.com.

Molecular Test Update

Some Labs Report Faster Pay For Molecular, Genetic Tests

Medicare's MolDx Program and use of Z-codes can speed coverage/reimbursement decisions

DURING RECENT MONTHS, some labs are reporting improvement in how their claims for certain molecular and genetic tests are being reimbursed. This is progress from the financial crises experienced during 2013 for many labs performing molecular and genetic tests.

Disruption in these payments was one of the clinical lab industry's biggest stories during 2013. There was a major upheaval in coverage and payment guidelines associated with molecular and genetic tests because both government and private payers were not prepared to deal with the implementation of 114 new CPT codes for specific molecular assays and genetic tests.

No Claims Paid In Early 2013

In fact, during the first four months of 2013, few labs reported getting any payment from Medicare for lab test claims involving the new molecular CPT codes. It was not until May of 2013 that some labs began to see a flow of regular payments for some of these molecular test claims. *(See TDR, May 28, 2013.)*

There was a bigger aspect to this story than simply the introduction of new CPT codes for molecular and genetic tests. It was the Molecular Diagnostic Services Program (MolDX), a pilot program developed and administered by **Palmetto GBA**, a Medicare Administrative Contractor, with the approval of CMS.

MolDX was implemented only in the JE (formerly J1) region of California, Nevada, Hawaii, and the Pacific Territories (now administered by **Noridian Administrative Services**) and then expanded into the J11 region of South Carolina, North Carolina, Virginia, and West Virginia (currently administered by Palmetto GBA). It is not yet a national program.

When a lab has a molecular or genetic test that it would like to submit to Palmetto for coverage and reimbursement decisions, it needs to follow the requirements of the MolDx program. This includes registering the molecular or genetic test with MolDx. One method to accomplish this is to obtain a unique Z-code identifier for that assay from the **McKesson** Diagnostics Exchange, then submit the necessary documentation concerning this lab test to the Medicare program.

MolDx officials can then use the Z-code number and supporting documentation for that unique molecular or genetic test to answer this question: should the test be covered by Medicare as reasonable and necessary? All affirmative coverages are published on the Palmetto website as LCD updates. From that point, the lab can submit the claim with the Z-ID and an appropriate CPT charge code. Covered Z-IDs are paid promptly.

To update this important story, THE DARK REPORT contacted a number of lab companies that perform proprietary molecular or genetic tests to learn about their experience at getting paid for these tests. In some cases, it seems that the MolDx program and use of the Z-code system has played a role in improving

how quickly some health plans pay for genetic and molecular tests.

One clinical lab director who asked not to be named explained that the Z-codes have improved payment processing of claims for his lab's unique molecular test. This was particularly true for claims submitted to Palmetto GBA. "At our lab, the McKesson Z-code system has played a critical role in helping us obtain payment via the MolDx program," noted the lab director. "Throughout 2013, our lab went unpaid because of the changes Palmetto put in place for the Medicare coverage determination and reimbursement process for advanced molecular tests.

"For our lab, Z-codes resolved a significant problem that Palmetto officials have openly discussed—namely the need to identify specific laboratories and assays so that Palmetto could adjudicate claims appropriately for advanced molecular tests that lacked distinct codes when the molecular stacking codes were eliminated," continued the lab director. "Under the MolDx program, Z-codes allowed Palmetto to price and reimburse for our unique advanced molecular test. Otherwise, we would need to bill with a miscellaneous and unspecific molecular pathology code.

Payment For Lab Claims

"As most lab managers know, use of miscellaneous molecular pathology codes on a claim makes it more difficult to get paid for that advanced molecular test," he noted. "When a lab files claims that way, payers default to asking for medical documentation, which delays payment even when the test is covered under medical policy.

"With the Z-codes, our lab's claims for covered services have been adjudicated and paid quickly and consistently," added the lab director. "That said, we are also learning that having a Z-code does not guarantee payment. No coding system can do that.

"But our experience is that, by giving payers the information they need to understand what test they're paying for and the medical necessity for those tests, our lab is experiencing faster processing speeds for those claims," he said.

According to this lab director, one major health insurer in the Northeast currently uses the Z-code registry in an effective way. "What we have seen is that our use of the Z-codes with this payer enables more timely resolution of claims for those specific molecular assays," he explained. "That is because the payer's reviewers can make a more rapid determination of the medical necessity. It also means that we are asked for medical necessity documentation less frequently. That's because now, when they get our lab's molecular test claims, they know the clinical purpose for those tests." TDR

—Joseph Burns

Dissatisfaction Remains About Coverage Decisions

WHATEVER POSITIVE PROGRESS some labs report in getting claims paid for their advanced molecular and genetic tests, there remain plenty of lab executives who are dissatisfied with how government and private payers are making coverage and payment decisions for these tests.

Critics within the lab industry point out that there are potential conflicts in the way federal laws, including the recently-enacted Protecting Access to Medicare Act, require government health officials to collect data needed to make coverage and reimbursement determinations and then how that data are used to establish appropriate guidance and payment for these molecular and genetic tests.

One example is the uncertainty about the specific roles of CPT codes and the MolDx test registry (which incorporates Z-codes) in the overall processes CMS and the Medicare Administrative Contractors use. These and related issues will be the subject of ongoing dispute between labs and government and private payers.

CEO SUMMARY: Since the launch of a laboratory test utilization program in 2011 at the Cleveland Clinic, more than 35,000 duplicate or inappropriate test orders have been stopped. The test utilization team introduced five initiatives that are not designed to cut spending but to introduce evidence-based and consensus-driven methods to lab-test ordering. Another benefit is that needless blood draws are being eliminated, thus improving patient care and satisfaction.

Program Targets Routine and Expensive Send-out Tests

Lab Test Utilization Delivers Big Gains at Cleveland Clinic

THERE IS A NEW BUDGET-BUSTER for hospital and health system laboratories. It is the ongoing and sizeable increase in money spent on expensive reference and esoteric lab tests that must be sent out.

THE DARK REPORT is one of the first to report on the significance of this trend. Some major hospitals acknowledge that reimbursement from health insurers only covers one-third to one-half of the money they paid to the reference labs that performed the more expensive molecular and genetic send-out tests. *(See TDR, April 20, 2015.)*

For this reason, pathologists are finding that hospital administrators and medical staffs now welcome efforts by their lab teams to implement programs designed to improve how physicians utilize clinical laboratory tests.

As most pathologists know, even a modest lab test utilization management program can generate significant cost savings. Similarly, more sophisticated and long-running programs not only save substantial sums by eliminating needless testing but also improve the culture of lab test ordering, while increasing patient care and satisfaction at the same time.

This has been the experience at the **Cleveland Clinic**. Its lab test utilization program, established in 2011, is one of the longest-running lab test utilization management (UM) programs in the nation. Since its introduction, the program has saved multiple millions from the introduction of five separate cost-control initiatives.

According to Gary W. Procop, M.D., M.S., the Medical Director, Enterprise Test Utilization and Pathology Consultative Services, since the first initiative was implemented in 2011, the program has stopped more than 35,000 duplicate test orders and produced savings of almost $2.7 million.

But unlike UM programs in many labs, these five initiatives are not aimed at cutting costs, noted Procop. "Our guiding principle is best practice. We never talk about cost control.

"Instead, we talk about which evidenced-based and consensus-driven methods will be best to improve lab-testing ordering," stated Procop, who is the Director, Molecular Microbiology, Virology, Parasitology and Mycology Laboratories at the Cleveland Clinic and Professor of Pathology, Cleveland Clinic Lerner College of Medicine.

His explanation of the Cleveland Clinic's lab test UM program came during a webinar that *Hospitals & Health Networks* and the **College of American Pathology** sponsored last month.

"Once we find an initiative to improve care, we work with whatever area of the clinic that can implement that initiative," stated Procop. "Then, as reimbursement declines, we also are decreasing unnecessary costs.

"Plus, just by eliminating needless blood draws, we have had a positive effect on patient care," he continued. "No patient likes to get woken up in middle of the night for a needle stick, especially if it's not needed. From the patient's perspective, a blood draw at midnight or later leads to decreased patient satisfaction.

"From a physician's perspective, when we eliminate unneeded blood draws, we decrease the chances that the patient will develop iatrogenic anemia, which can lead to poor wound healing and higher infection rates."

Procop's Enterprise Test Utilization Committee has introduced five utilization management initiatives since 2011. They are:

1. Hard Stop Initiative
2. Regional Smart Alerts
3. Restricted-Use Initiative
4. Lab-based Genetic Counseling
5. Expensive Test Notification

"For the hard stop initiative, our medical team went through the entire test menu to determine which ones meet the criteria for a hard stop," he said. "These are lab tests that never need to be ordered more than once a day. There are more than 1,200 tests on the same day Hard Stop list. If any of these lab tests are ordered more than once a day, then on the subsequent times, the provider gets a pop-up warning notice on the computer screen.

"The warning explains that the test was ordered that day, and—in most cases—another one is unneeded," noted Procop. "But if the physician does require another of these tests, he or she must call client services to tell us why.

Unique Twist To Lab Orders

"When programming this warning feature, the informatics team added information to the warning that is just genius," he noted. "We know these doctors are looking for results. Thus, the IT team suggested displaying the previous test results for the test the physician wants to order. The screen shows the date and time of the test, who ordered it, and the results.

"Thus, not only do we stop the needless test, but we give them the lab test results they want," stated Procop. "Therefore, the informatics team is helping these physicians to improve their workflow processes. That's a brilliant addition.

"Since we put in this hard stop, we have tracked every time the intervention fires electronically," he continued. "We record the first time and then each subsequent attempt to order a duplicate test. We can see that some doctors don't read the pop-up warning and continue to try to order the test without calling us.

"Cumulative data from January 2011 through December 2014 show that we stopped more than 23,000 unneeded duplicate orders," said Procop. "Because we know the material cost and cost of the labor to do these tests, we calculated a cost-avoidance figure. Over this time, the savings totaled just over $361,000.

"This intervention is live every day," he added. "Over the past three years, it has become embedded in our culture. It's part of the way we practice."

The second initiative involved developing a partnership with our regional hospitals to reduce duplicate testing," he stated. "All the physicians at our main campus are employed. However, the regional hospitals have a mix of employed and affiliated doctors. So those hospitals face different challenges than those we have at the main campus.

"For example, in the regional hospitals, the computerized physician order-entry system is not always used," noted Procop. "CPOE is available, but some doctors prefer to write out lab test orders on paper and have a nurse enter the order. We didn't want to put nurses in the middle, if a physician ordered a test and the computer system didn't allow its placement. Also, when this initiative went live in the regional hospitals, we did not have the ability to allow the ordering doctor to bypass the warning.

"So, for the regional hospitals, we built a different system, which we called a Smart Alert," he said. "It functioned just like a hard stop, but the difference was that physicians could bypass the warning at the computer screen without calling the lab to request an override.

"That's why this intervention has only a 41.7% success rate compared with the 93% success rate of the hard stops at the main campus," explained Procop. "Still, for the period of March 2013 through December 2014, we averted 11,000 duplicate tests for a savings of over $90,000 with this intervention.

Expensive Molecular Tests

"The third initiative is designed to improve the ordering of expensive molecular tests," he said. "Almost every hospital and health system today is hemorrhaging costs from sending out expensive molecular tests. For this initiative, we looked at how other departments manage high-cost orders.

"In cancer care, only oncologists can order certain chemotherapy medications and other physicians are restricted from ordering those drugs," noted Procop. "Similarly, infectious disease specialists can order certain antibiotics for certain patients, but other physicians cannot. We argued that, similarly, certain complex

At Cleveland Clinic, Only Deemed Physicians Are Allowed to Order Certain Clinical Lab Tests

AS CLINICAL LABORATORIES DEVELOP test-utilization methods, one of their goals is to limit the ordering of duplicate, incorrect, and expensive tests while continuing to work collaboratively with all ordering physicians.

Clinical laboratory directors certainly don't want to antagonize treating physicians and they are not interested in arguing clinical appropriateness over every test. Instead, these pathologists would prefer to improve the culture of test ordering.

Gary W. Procop, M.D., MS, Medical Director, Enterprise Test Utilization and Pathology Consultative Services at the Cleveland Clinic, said the lab test utilization management (UM) program at the Cleveland Clinic is designed to improve patient care. "It's about finding common ground for the patient's benefit," he said.

"When we started this program we didn't want to exclude some physicians and include others," he said. "We also did not want to start having academic arguments either.

"So we took the approach that, if some physicians commonly order these tests in their practices, then they know how to use them," stated Procop. "Those physicians became our deemed users.

"Additionally, if a complex and expensive lab test is one a physician orders extremely infrequently, or orders it just out of interest, then that physician probably shouldn't be ordering that test," he explained. "But there are other ways these physicians can order tests. They can consult with a geneticist or get a consultation from the deemed users group. For these tests, they would need to justify the order.

Deemed-users Group

"When we looked at who was ordering high-cost tests, it was often medical genetics, neurology, or pediatric neurology," he commented. "They were ordering these tests frequently and so it was natural to put them into the deemed-users group."

What comes next for utilization management at the Cleveland Clinic? "We've considered implementing more restrictions, but further restrictions create more challenges," noted Procop. "In addition, we don't want to end up micromanaging physicians' decisions. That is not the role of our pathologists, since ordering physicians should have some autonomy within reason. It's their patient, after all. And remember, our goal is a utilization management program that is a win-win for everyone.

"This is why our emphasis is on patient care, not cost control," concluded Procop. "If we are collaborating to deliver the best care for each patient, then we will always find common ground with physicians as to how to use clinical lab tests most appropriately."

and expensive tests should be restricted to other providers who are qualified to interpret and use the results from such tests. That's why we call it the restricted-use initiative.

"The lab tests targeted with this third initiative are so expensive and complicated that some physicians are not well versed in the use of these tests," he explained. "They could give a patient the wrong test or they could misunderstand the results or both. In other words, there are patient-care and patient-safety aspects to this initiative.

Expensive, Complex Tests

"To restrict these tests only to those physicians who are experienced in ordering these tests and in explaining the results, we created a list of deemed users," he commented. "These are mostly medical geneticists and some specialists.

"If a physician is not one of the deemed users, then we require a consult from a medical geneticist or another deemed user," Procop said. "Because this is an electronic intervention, it operates without any additional work on the lab's part.

Improved Test Ordering

"We started this program in November 2011 and through December 2014, we stopped 349 tests and saved $784,127," he stated. "Not only were there fewer tests ordered, but often, the geneticists recommended a different test."

In the May issue of the *Journal of Molecular Diagnostics*, Jacquelyn D. Riley, Procop, and colleagues published an article on this initiative, "Improving Molecular Test Utilization through Order Restriction, Test Review, and Guidance." (J Mol Diagn 2015, 17: 225—229; http://tinyurl.com/pr9wwje)

"Our data show that when a non-deemed physician orders a test in the ambulatory setting, about half (48%) are abandoned," noted Procop. "In other words, they drop the order.

"When there's a referral to a clinical geneticist, 31% of the orders go through," he said. "We have about 13% of restricted use tests that are re-ordered by a deemed user. And only 8% are reordered by the non-deemed user. For inpatient orders, 75% of orders are canceled and the rest are referred for a clinical geneticist consult.

Appropriate Subspecialists

"What's important here is we are pushing patients to the appropriate subspecialists," emphasized Procop. "Those patients who need genetics counseling now get that counseling and that translates into better patient care.

"For our fourth intervention, we hired a lab-based genetic counselor," Procop said. "Each day, this person goes over the send-out list and calls up the ordering physician if there is an issue with the test being ordered. The genetic counselor must have great communication skills and good emotional intelligence.

"She reviews the patient history, the ordering physician, and the test being ordered," he continued. "If everything looks fine, the order goes right through. And if she has a question, she calls the ordering physician. Since September 2011, this counselor has made 452 interventions and cleared more than $1 million in savings.

"Currently, we are considering the expansion of the genetic counseling group," observed Procop. "The employment of a lab-based genetics counselor not only saves the hospital money, but most importantly this individual can help guide less experienced physicians to the appropriate genetic test."

Genetic Counseling Program

In fact, the return on investment for this position is swift. "Evidence shows that the genetics counselor covered her salary in the first two months of work," he added. "This makes for a good argument with hospital administration if your lab wants to expand a similar genetic counseling program.

"Since September 2011, the data we collect shows that out of 152 test orders, 88 (58%) were canceled after a consult with the genetic counselor, 37 orders (24%) were changed, and 27 (18%) orders were sent through," recalled Procop. "In the 24% of the tests that were changed, she helped direct the ordering physician to a more appropriate test. In that way we are contributing to a team-based care approach, which is the future of medicine.

"When we looked back to 2007, we saw that genetic test volume was mostly flat until 2011 and that costs were rising steadily," observed Procop. "Following introduction of genetic counselor intervention in 2011, both cost and volume dropped sharply.

"One reason both costs and volume decline is physicians are no longer ordering

Effect of Restricted Use and Genetic Counselor/MGP Triage Interventions

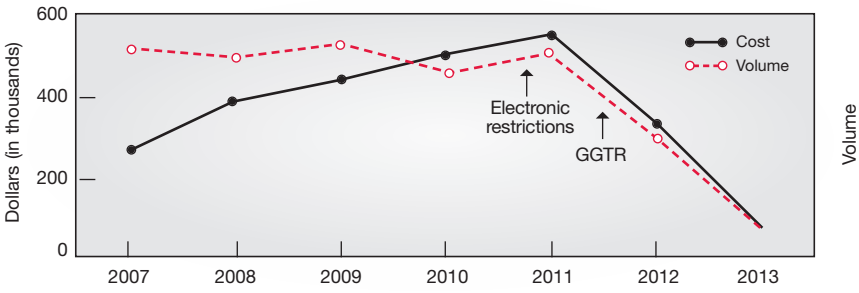

Chart courtesy of Gary Procop, M.D. M.S., at Cleveland Clinic

IMPLEMENTATION OF THE THIRD INITIATIVE within the Cleveland Clinic's lab test utilization management program involved improving patient care through better collaboration in the ordering of expensive molecular and genetic tests.

Physicians familiar with these expensive tests were put on a "deemed user" list and could order these tests as needed. Physicians who are not deemed users must consult with a medical geneticist, triggered by an electronic notice at time of test order. The lab employs its own genetic counselor. As shown by the chart above, following implementation of electronic restrictions on lab test orders and the genetic counselor review requirement in 2011, both the volume of expensive molecular tests and the costs of this testing plummeted substantially.

the wrong test," he said. "That means we are not double paying because the lab would pay for the first test and then—if that was wrong—our lab would need to order the correct test and pay for that one too.

Speedier Patient Diagnosis

"In such a situation, the lab pays twice, and there is a lot of time lost before the patient gets the right diagnosis," stated Procop. "So this intervention is helping physicians order the right test and—if it isn't the right test on the initial order—we help them find the right test for their patients.

"Our fifth and final intervention is our expensive test notification initiative," noted Procop. "This program is for tests that exceed a certain monetary threshold. Clearly this intervention is badly needed. For any of these tests, the CPOE system shows a warning that says, 'Please consider carefully if this test is absolutely necessary.'

"The warning also explains that the test costs the Cleveland Clinic more than $1,000 (or $2,000, $3,000, etc.) and the patient's insurer may not cover it," he continued. "If the insurer does not cover the test, then the patient may be billed directly. For these tests, the ordering physician can proceed or not. Since we implemented this initiative in April 2013, we have stopped 165 tests and saved $262,221.

"For these five types of interventions, we prevented 9,436 duplicate laboratory test orders last year and saved $706,495," Procop commented. "And, the cumulative totals through last year were 35,338 duplicate test orders stopped, saving almost $2.7 million." TDR

—Joseph Burns

Contact Gary Procop, M.D., at procopg@ccf.org or 216-444-8845.

RFID Lab Inventory System Saves $465K in First Year

By automating inventory management, lab freed staff for other duties and reduced errors

CEO SUMMARY: Seeking ways to automate every aspect of work flow, the clinical laboratory at St. Francis Health System in Tulsa, Oklahoma, implemented a unique automated laboratory inventory management system that utilizes RFID. In the first four months, the system helped the hospital cut the value of inventory on hand by $296,000. Another direct cost savings was a 75% reduction in staff time required for inventory control. Payback from this investment was swift and lab administration says it is saving more than $169,000 each year because of this system.

WHAT IF YOUR CLINICAL LABORATORY could immediately cut lab costs by about $300,000 and then save almost $169,000 annually, simply by managing inventory more effectively? "Of course you would want to do it!" declared Sharon Cox, MT(ASCP)SC, Core Laboratory Supervisor, at **Saint Francis Hospital**, in Tulsa, Oklahoma.

During her presentation at the *Executive War College on Lab and Pathology Management* in New Orleans last month, Cox explained the value of a new inventory control system that uses radio-frequency identification (RFID) technology. "This system not only saved our lab almost $500,000, in the first year," she noted, "but it also cut inventory management costs by 40% annually when compared with previous spending for inventory control.

"The good news doesn't stop there," said Cox. "In addition, the inventory control system has achieved a 96% reduction in costly inventory errors while also cutting staff time devoted to inventory.

"Completing the annual inventory reconciliation process used to take two of us 10 hours each," she explain. "Now it takes only 15 minutes. Obviously, going from 20 hours to 15 minutes is impressive. But what is more important is that the staff can now devote that time to more meaningful work."

These cost savings and productivity improvements came within months following the lab's implementation, in November 2013, of Inventory Manager, the new inventory management system from **Abbott Laboratories** in Abbott Park, Illinois.

Fewer Errors, Lower Costs

"In the first four months, the system helped us decrease the value of inventory we keep on hand by $296,000," said Cox. "Also, we cut staff time associated with managing inventory by 75%, even as our inventory error rate dropped from 27% to 1%.

"The industry standard for getting a return on investment from a new system is typically six months or more," she added. "But our lab got this installed in a week and almost immediately started to save money and staff time.

"In addition to cost control, there are other important features in this system that

help us run the lab more efficiently than we have in the past," she noted. "For example, at the start of every day, we know exactly what our stock levels are and the expiration dates on our supplies.

"That means I don't have to worry about getting a phone call from the lab late at night about something being out of stock," said Cox. "Med techs like the system because they no longer go to replenish a reagent and find that it is past its expiration date.

Volume Requires Automation

"Many lab managers overlook the opportunity to improve inventory management," she added. "For one thing, it generally requires a lot of staff time. And, until now, few hospitals had found ways to automate inventory processes, despite the need for labs to do so.

"Our lab illustrates the opportunity," stated Cox. "To serve the two-hospital St. Francis Health System, we have nine labs and run about 8.8 million clinical lab tests every year, including 6.8 million clinical chemistry tests and about 1 million immunoassays. We draw about 5,000 to 5,500 tubes every day, and all those tubes have to be transported to the core lab. Just running those tests requires a large amount of reagents and consumables every day as well.

"Our lab's ongoing goal is to automate as many parts of the lab testing process as possible," commented Cox. "This is also consistent with our health system's big focus on quality improvement. We constantly strive to reduce errors while improving efficiency.

"That's why we have dashboard systems, remote monitoring of our instruments, and a lot of big screen monitors in the lab," she continued. "It's much easier for our staff to look at a graph on the screen quickly than it is to look at a spreadsheet. For three years now we've been following moving averages in a continuous process to reduce errors coming off of our assays.

Using Automation to Make Lab Staff More Productive

"OUR NEW AUTOMATED LABORATORY inventory management system is simple to manage," noted Sharon Cox, MT(ASCP), Core Laboratory Supervisor, at Saint Francis Hospital. "Once a week, we put in an order for reagents and supplies to Abbott. We generate that order every Monday at 2 am. That purchase order goes electronically to Abbott via electronic data interchange.

"By 6 am every Monday, the warehouse has our lab's order for the week and it starts to fill that order," she said. "All our products get two-day shipping. As those products leave the warehouse, a manifest is transmitted to us electronically that contains all the reagent lot numbers and expiration dates.

"Two days later when those products tagged with RFID chips hit the receiving dock, a portal on the receiving dock detects all those items automatically," she explained. "The system checks those products into our lab's inventory system and sends a receipt message to the Abbott software. It also sends a message straight into the hospital's SAP accounting system.

"The software automatically detects any discrepancies between what's on the electronic manifest and what products are actually received at the lab," stated Cox. "That's our first way to pick up an error.

"On the loading dock, our receiving personnel simply need to put that inventory on a pallet," she continued. "That pallet then goes up the freight elevator into the hospital where we have a series of portals and RFID readers. Thus, at any point between receiving and the lab, we know where those products are within the hospital.

"When that product is used, the software updates the inventory list and messages are sent into SAP and to the Abbot software," she noted. "At the end of every week, we generate a new purchase order that is electronically transmitted to the supplier."

"So it was natural to look at inventory management as an opportunity to automate to reduce errors, save money, and free up staff time," she said. "Inventory costs are huge just for reagents and consumables.

"Before installing the inventory system, we had almost $1 million in immunoassay reagents sitting in our refrigerators," explained Cox. "That's how much we needed to have on hand. Reagents for immunoassays are the most expensive product we have in our laboratory. Those reagents are high-dollar items, so it is essential to have an accurate inventory.

"Plus, inventory is not only costly, but it takes up a considerable amount of storage space, which we lack, and we don't have a big walk-in refrigerator," Cox explained. "Without much storage space, we had to get reagents shipped in each week.

"Further, before we implemented automated inventory control with RFID, we had a completely manual process," she recalled. "Staff would break down those weekly shipments and put the inventory into storage. That manual process had a 27% error rate, which was costing us $68,000 every year.

"Why was the error rate so high?" asked Cox. "Because we had to affix a label to every item that came into our lab. Anytime staff touches something, the potential for human error exists.

Manual or Automatic?

"Most labs have one of two manual methods of inventory," she said. "First, staff members may take a clipboard and go into the refrigerator to identify what inventory items need to be ordered. Most labs use this method, either weekly or monthly. Second, some laboratories have barcode systems, which are automated. But barcodes require direct line of sight from the barcode reader to the barcode.

"We wanted to automate the entire inventory process and so Abbott made us a beta site for their Inventory Manager system," stated Cox. "It uses an RFID label and a unique, serialized global identification number for each product. Now, every item that's shipped to us is labeled at the warehouse and arrives at our lab pretagged. That removes 100% of the errors.

"Now, the beauty or the genius of RFID is the staff does not need to maintain direct line of sight with reader and bar code when scanning supplies into the system," explained Cox. "Moreover, a refrigerator turns out to be one of the best conduits for RFID technology because it's a big metal box. Within a refrigerator, the RFID radio waves bounce off the walls and come back through the products. Thus, read rates are 100% in a refrigerator jam-packed with reagent boxes.

Automated Check-In

"Thus, we have completely automated the entire inventory cycle for these products from the time they are received until we use them and generate a new purchase order at the end of the week," emphasized Cox. "The only human intervention required is when the product gets into the core lab where staff unboxes that inventory and puts it away.

"Another useful feature is that we have an electronic receipt of all of the lot numbers and each product has a unique identification number so we can tie specific patient results to that number," observed Cox. "That gives us an important traceability in our system that allows us to more precisely track our costs of care.

"The electronic manifest in the inventory system tells us exactly when every wedge pack of reagents is shipped in and when each one is used as well. When each wedge pack is used, we know every patient for which it was used. Thus we can match that use to costs and to inventory. This feature is particularly useful if a reagent manufacturer recalls a reagent because we can track our use by patient." TDR

—Joseph Burns

Contact Sharon Cox at 918-494-6571 or sscox@saintfrancis.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It's a laboratory acquisition that is worth US$1.3 billion. In Europe, **Cinven**, a private equity company, will acquire **Labco SA** of Paris, France. Labco operates medical laboratories in France, Spain, Italy, Portugal, Belgium, and the United Kingdom. It reports annual revenue of US$714 million, performs 150 million clinical laboratory tests yearly, and employs more than 6,000 people.

MORE ON: *Labco SA*

Labco SA had announced plans to sell shares on the Euronext Paris stock exchange during May. A poor market environment caused executives at the lab company to consider the purchase offer from Cinven. In such countries as Belgium and the United Kingdom, Labco competes against business units of **Sonic Healthcare, Ltd.**, of Sydney, Australia. Sonic's labs generate annual revenue of about US$920 million in Europe, where it operates laboratories in Belgium, Germany, United Kingdom, Ireland, and Switzerland.

HTG MOLECULAR COMPLETES IPO

On May 6, **HTG Molecular Diagnostics, Inc.**, of Tucson, Arizona, became the latest molecular diagnostics company to complete an initial public offering (IPO). It raised about $60 million and its shares trade under the symbol HTGM on the NASDAQ exchange. HTG says that it has automated systems and software to address "molecular profiling applications, including tumor profiling, molecular diagnostic testing, and biomarker development." The President and CEO of HTG is Tim "TJ" Johnson, who formerly worked at **Ventana Medical Systems**.

XIFIN ACQUIRES IMAGING COMPANY

Earlier this month, **XIFIN, Inc.**, of San Diego, California completed its acquisition of **VisualShare**. Based in Salt Lake City, Utah, VisualShare has a "cloud-based medical imaging management solution and image collaboration platform." The two companies have worked collaboratively for several years already and the VisualShare service has been integrated into XIFIN's clinical products.

TRANSITIONS

- **Sysmex America Inc.**, announced the appointment of Ramon Simon-Lopez, M.D., as Medical Director. Simon-Lopez was formerly with **Beckman Coulter Corporation**, and held clinical positions at **La Alianz Clinic** and **Hospital Clinic of Barcelona** in Spain.

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