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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 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Clinical Decision Support Systems Arrive

FORWARD THINKERS IN CLINICAL LABORATORIES and anatomic pathology groups have always recognized the substantial, but as yet unharvested, potential that would accrue to the healthcare system were clinicians to make better use of laboratory testing.

All of us know stories and anecdotes about how certain of these forward thinkers tried to get their hospital or healthcare system to respond to projects which would add immense value through better application of certain laboratory tests. During the past decade, almost without exception, these initiatives proved disappointing. The reasons are legion and include turf issues, perceptions by clinicians that the lab is "telling them how to practice medicine," and the decision by hospital administrators to shelve such projects in favor of other priorities.

However, the arrival of a new generation of clinical decision support systems may soon change this status quo. As you will read on pages 9-14, **Vanderbilt University Medical Center** in Nashville, Tennessee has implemented such a system. Called "WizOrder", it is generating impressive benefits, some of which involve laboratory test utilization. What is equally interesting is that **McKesson Corporation** was impressed enough with WizOrders that it has licensed the right to offer it to other hospitals and health systems. It will use the brand name "Horizon Expert Orders™."

McKesson has already linked the use of Horizon Expert Orders to better hospital performance in the clinical decision support criteria set out by the **Leapfrog Group** *(see TDR, February 18, 2002).* An early purchaser of Horizon Expert Orders is **St. Luke's Episcopal Hospital**, located in Houston, Texas. St. Luke's has stated publicly that it considers the knowledge library, which contains 900 different clinical protocols, outlines, rules, and advisories, to be a "starter set" for its own guidelines on ordering and treatment recommendations.

I recommend that lab executives and pathologists pay close attention to this current generation of clinical decision support systems. I predict that they will transform the way physicians order lab tests and use the resulting data, not the least because electronic systems can capture and rank physician performance. But more importantly, I make this recommendation because it will open new opportunities for trained laboratorians and pathologists to contribute greater value to the healthcare community they serve. TDR

Shortage of Med Techs Stimulates Innovation

Lab division of West Tennessee Health gets serious about recruitment & retention

CEO SUMMARY: ***In Western Tennessee, a seven-hospital rural health system is pulling out all stops to solve the staffing crisis in its laboratory division by implementing programs that address both retention and recruiting. "Bench bonuses," college loan repayment programs, recruitment bonuses, and shift differentials are just a few of the methods used to attract and keep qualified laboratory technologists.***

WHEN IT COMES to having adequate medical technologists to staff the laboratories of **West Tennessee Healthcare** (WTH), Leo Serrano finds it easy to describe the situation as "acute."

"It's been a painful effort to keep our labs fully staffed over the past four years," stated Serrano. "But the situation really turned grim about two years ago."

Serrano is Director of Laboratory Services for the seven-hospital system, which is headquartered in Jackson, Tennessee and serves rural areas in the western part of the state. "Currently there is a 15% vacancy factor in our technical positions," he noted. "This is a direct challenge to our ability to deliver a full range of lab services to our clinicians because we run a very lean operation. The inability to hire enough technical staff for the laboratory has motivated us to become uncommonly creative."

Serrano reports that, of the 151 hospital-based technical positions in his lab division, there are currently 20 openings. "This number has been as high as 28," he noted. "So retention and recruitment are high priorities with us."

Including technical and non-technical positions, WTH's lab division employs 349 FTEs and performs about 3.5 million billable tests per year. Its core laboratory is at **Jackson-Madison County General Hospital**, located in Jackson. The other hospital labs are supported by limited service labs. Serrano also has lab staff working in clinic labs

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and physician office laboratories owned by the health system.

When the lab staffing problems became more severe about two years ago, system administrators encouraged Serrano to develop creative ways to retain existing lab staff and recruit new employees.

Insuring Wage Parity

"Our first move was to study wage rates in our region," recalled Serrano. "Our area is about 80 miles from Memphis, so it was easy to believe that many med techs might leave the rural area for work in the big city. But a study of staffing turnover indicated that was not the case.

"Of the 30 med techs who left our core lab in the past couple of years, only about one-third left the community," he observed. "Seven transferred to other labs within WTH and almost half, 12 people, stopped working to devote their full energies to raising children.

"Although we weren't losing people to the metropolitan market, our first strategy was to create a wage differential favorable to us," said Serrano. " So, on January 1, 2001, we raised wages by $2.00 across the board. This placed us above the average med tech wage in Memphis."

Because the lab division at WTH must staff multiple lab locations at odd hours, the next management decision was to create a pay package that would encourage people to opt for second and third shifts.

Second & Third Shift Pay

"We increased the money paid in the following way," explained Serrano. "For medical technologists with a B.S. degree, second shift differential is $2.00 per hour and third shift differential is $3.00 per hour. For medical technicians, the second and third shift differentials are $1.50 and $2.50 per hour, respectively.

"This has helped us staff these time periods," he continued. "To further encourage med techs to stay hands-on with testing, we created a 'bench bonus.' For anyone whose job description requires them to spend at least 80% of their time at the bench generating test results, we pay an additional 50¢ for each hour worked. This particular incentive has really proven effective."

Employee retention was the primary objective in the management strategies presented above. In recruiting, WTH recognized not only the need to fill open positions within its various laboratory sites, but the fact that employee demographics would work against staffing goals as time passed.

Median Age By Department

"We looked at the age of our staff by departments," commented Serrano. "In histology, toxicology, and the core lab, median age ranged between 41 and 43. Staff in blood bank and microbiology had the youngest median age, under 40.

"These demographics encouraged us to identify two strategic goals. First, we want to maintain an active recruitment program," he offered. "We want the community to know there are good opportunities available in our laboratory division. This will help us fill openings in years to come. Second, we want to encourage our existing people to develop their professional skills. That also has long-term benefits to our lab staffing needs."

The obvious method to make recruitment more attractive was to offer signing bonuses, which WTH does. But the other method is a generous, but unorthodox, opportunity.

"Our recruitment bonus is $5,000 for a third shift hire and $3,000 for a second shift hire," Serrano stated. "For new hires accepted in our student loan

Creativity in Med Tech Recruiting and Retention Supported by Health System Administration

IT'S NO ACCIDENT that the laboratory division of West Tennessee Healthcare (WTH) has such a creative menu of programs for recruiting and retaining trained laboratory technical staff. System administrators and lab directors have a close working relationship.

"Our administration understands the essential role of laboratory testing," said Leo Serrano, Director of Laboratory Services at WTH. "They know we must have the staff to do the work and they get credit for the unique management environment we have here. They tell us to be innovative on staffing issues and they are willing to fund these programs."

Serrano admits that he always has an eye out for good ideas and borrows freely. "We've taken many of our ideas from the nursing department," he explained. "Nurses are very visible in a hospital. Everyone, including the patients, sees the nurses. So nursing usually gets lots of support when it comes to retaining staff and filling vacant slots.

"But unseen personnel in the hospital, like laboratory staff, usually don't get the same type of incentives as does nursing," he continued. "It is a testimony to our administration that they are willing to extend similar recruitment and retention incentives to our laboratory."

forgiveness program, at the end of the first year, WTH will pay down $3,000 of the student loan. For each year of employment completed thereafter, WTH will pay the student loan down by an additional $3,000. The maximum amount that can be earned in this program is $20,000."

Of course, WTH offers scholarships and financial assistance to existing lab employees. "This is an ongoing benefit within our health system," Serrano said. "It's been paying dividends for the lab. In the past year, five of our MLTs earned Bachelors' Degrees. We also have four non-technical staff enrolled in the two-year clinical training program."

Recruiting Bonuses

"Recruitment bonuses come from the health system's human resources budget because there are many positions outside of laboratory services that offer similar bonuses. Scholarships and student loan redemptions are paid out of the laboratory division's budget," commented Serrano.

The budget impact of these retention and recruiting programs illustrate how the economics of lab medicine are changing. "For 2002, the lab division's labor costs are 5.5% over budget," observed Serrano. "Compared to the previous year, our labor costs are up 8.8%."

According to Serrano, cost of technical labor is up 12% over the previous year while clerical labor increased only 3.7% and lab management is actually 15% under this year's budget.

"We know the extra spending affects overall laboratory costs," he added. "But administration has made it clear that the strategic priority is to maintain the staffing levels necessary to deliver the targeted menu of lab testing services. It's a quality decision and the economic impact is assessed in the context of the health systems' needs."

Serrano's comments show how the value of lab testing to an integrated delivery network (IDN) is changing the way administration supports its

laboratory division. In recent years, lab administration moved aggressively to implement several management strategies simultaneously. There has been the creation of a core lab and consolidation of testing. Instruments and tests have been standardized across the seven hospitals, as has LIS and information system capabilities.

"You name it, we've tried it!" he exclaimed. "We are flexible, innovative, and will consider any reasonable approach to match people's work preferences with our staffing needs."

A thriving lab testing outreach program has generated steady increases in specimen volume. This has not only brought in additional revenue, but has allowed Serrano and his executive team to reduce the year-to-year increase in average cost per test for hospital inpatient work.

"Throughout this period, we've been dogged by unfilled technical positions," noted Serrano. "Despite our successes in many operational areas, unfilled technical positions are always a major limiting factor in our planning."

Still Have 15% Open Slots

A lab automation project was implemented in the core lab following consolidation. One of the major goals of the automation was to free up med techs for assignment to other duties. "We implemented task-targeted automation solutions," Serrano said. "It allowed us to reallocate 11 FTEs. In a lab our size, that was a major gain. But even after that success, we find ourselves with a 15% vacancy factor for technical staff."

Another strategy Serrano's team uses is flex-time scheduling. The lab has offered 10-hour and 12-hour shifts, as well as 3-day and 4-day schedules. "You name it, we've tried it!" he exclaimed. "We are flexible, innovative, and willing to consider any reasonable approach to match people's work preferences with our staffing needs."

The experience of West Tennessee Healthcare is increasingly shared by other labs around the United States. Although some metropolitan regions still report adequate numbers of med techs, there are a growing number of cities where the shortage of trained technical lab staff is acute—and increasing.

It is a lab industry problem without a lab industry solution. At WTH, both health system administrators and the lab director have acknowledged the problem, made fixing it a priority, and backed this organizational goal with an increased budget to both hire new lab staff and retain the existing team.

Substituting For Lab Labor

But few laboratories, and even fewer hospitals, are either willing, or have the financial resources, to match the willingness to be creative and spend extra dollars to maintain lab staffing at desired levels. Most likely, the market will respond to this situation by developing "labor substitution" options for lab testing.

This can already be seen in the steady flow of new products from the diagnostics manufacturers. These products have one thing in common—they require less technical labor to accomplish the same amount of work, and, in some cases, can improve the quality of the testing performed.

THE DARK REPORT predicts another source of "labor substitution" in the laboratory will be POCT solutions that move testing outside the core lab, to be performed by other types of healthcare professionals. **TDR**

Contact Leo Serrano at leo.serrano@wth.org.

Catfight in New York Over Lab Supplies Law

New inducement regs trigger maneuvering as labs try to maintain competitive position

CEO SUMMARY: All labs serving physicians' offices worry about the delicate balance between complying with laws governing inducement and protecting clients against competing labs who interpret those same laws more liberally. Recent events in New York state graphically demonstrate the compliance dilemma, particularly when regulators are shy about taking enforcement actions against offenders.

FINAL REGULATIONS for implementing the Stark Law became effective in January 2002. Among other things, these regulations provide more detailed guidelines on inducement issues specific to the business relationship between laboratories and their physician-clients.

The major impact of the newly-implemented regulations is that labs can now only provide physicians' offices with supplies that are used solely for collecting, processing, storing, or transporting laboratory test specimens. Providing "dual use" supplies, such as gloves, band aids, gauze pads, and other common items, would put a laboratory in violation of the Stark Law.

Preparing For Compliance

This is not news to the laboratory industry, which has closely monitored the actions of federal regulators in crafting these new laws. In fact, at least two state laboratory trade associations, in California and New York, anticipated these guidelines and took efforts prior to January 1 to prepare laboratories for compliance with these new laws.

However, in New York state, laboratories found themselves embroiled in a catfight over when individual labs would begin compliance. Because it was expected that physicians would react negatively to the loss of supplies such as sterile gloves, speculums, and other items, labs were maneuvering to avoid losing business if their compliance was not matched by competing laboratories.

The fear was that labs first to comply would be at a competitive disadvantage. Their physician-clients, irate at losing supplies traditionally provided by clinical labs, might switch to a competing lab which was either delaying its compliance—or viewed the new regs with a more liberal interpretation.

There was another compliance factor in New York that intensified the situation. On December 26, 2001, revisions to the Laboratory Business Practices regulations and the Health Care Practitioner Referral regulations

became law. These detailed new regulations described what lab activities would be considered inducement and addressed the specifics of how a lab may legally create a patient service center (PSC) in a physician's office.

Supported By Lab Industry

These changes had been supported by the **New York State Clinical Laboratory Association** (NYSCLA). They were intended to eliminate ambiguities in the regulations and create a level playing field for all laboratories competing in the state.

The law took effect on December 26, 2001 and allowed a 60-day grace (until February 25, 2002) "in which equipment and supplies in the practitioners' possession on December 26, 2001 must be returned by the practitioners; purchased by the practitioner at a price consistent with fair market value; or reclaimed by the laboratory." There was a parallel 60-day grace period to bring PSCs into compliance or terminate their operation.

These new laws, both state and federal, represent a major change in the long-standing business practices between clinical laboratories and their physician-clients. There was justified trepidation among labs in New York that physicians would react most strongly to the loss of these types of supplies. Thus, laboratories first to comply with the law might find themselves singled out for criticism by some physicians.

Compliance Dilemma

In fact, the situation in New York state perfectly illustrates the "dual dilemma" that has constantly challenged laboratories over the last 15 years. First, is the lab properly complying with laws and regulations? Or can its business actions place it at risk of enforcement action?

Second, how does the lab maintain compliance and retain its client base when competing labs may not be complying—or take a liberal view of what compliance requires?

Not surprisingly, the implementation of new compliance requirements by labs in New York turned into a royal catfight. Whether intentional or not, decisions by **Quest Diagnostics Incorporated** as to when it would implement compliance made it a lightening rod in the developing controversy.

In January 2002, Quest Diagnostics issued a letter to its physicians announcing that it would begin complying with the new laws on March 15, 2002. (See sidebar at right.) Meanwhile, during the first eight weeks of 2002, executives from Quest's Philadelphia area offices called lab competitors in New York. In general, the caller wanted to ask about how and when the lab intended to comply with the new laws, and to inform the lab that Quest Diagnostics would notify the **New York State Department of Health** (NYDH) about instances of noncompliance by competing laboratories.

Controversial Actions

Not surprisingly, these actions were viewed as controversial by competitors. On the surface, here was Quest Diagnostics picking its own implementation date—March 15—contrary to the specific directives of the Department of Health and also "threatening" to turn in labs which were not in compliance.

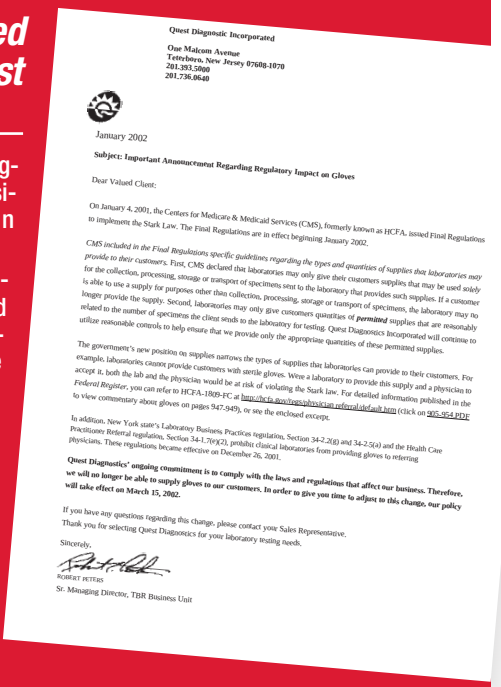
To defuse the growing controversy, NYDH had its Associate Director for Regulatory Affairs, Betty Kusel, speak in early March at a regularly-scheduled NYSCLA meeting. Kusel, in a testy mood, declared that the law clearly stated compliance was to have begun on December 26, 2002 and any labs not complying with this law would be be subject to immediate enforcement action by NYDH. She also noted that NYDH had sent Quest Diagnostics a

The Letter That Launched A Lab Compliance Tempest In New York State

Shown at right is the letter Quest Diagnostics Incorporated sent to its physician-clients in New York state in January.

Quest's letter details how new compliance laws at both the federal and state level will change the way it provides supplies to the physicians. The letter also announces that Quest will begin implementation of these new laws, on March 15, 2002.

However, since New York mandated that compliance with the new laws was to begin on December 26, 2001, Quest Diagnostics' public decision to implement at a later date made it vulnerable to criticism by both the New York State Department of Health and competing laboratories.



Quest Diagnostic Incorporated

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January 2002

Subject: Important Announcement Regarding Regulatory Impact on Gloves

Dear Valued Client:

On January 4, 2001, the Centers for Medicare & Medicaid Services (CMS), formerly known as HCFA, issued Final Regulations to implement the Stark Law. The Final Regulations are in effect beginning January 2002.

CMS included in the Final Regulations specific guidelines regarding the types and quantities of supplies that laboratories may provide to their customers. First, CMS declared that laboratories may only give their customers supplies that may be used solely for the collection, processing, storage or transport of specimens sent to the laboratory that provides such supplies. If a customer is able to use a supply for purposes other than collection, processing, storage or transport of specimens, the laboratory may no longer provide the supply. Second, laboratories may only give customers quantities of ***permitted*** supplies that are reasonably related to the number of specimens the client sends to the laboratory for testing. Quest Diagnostics Incorporated will continue to utilize reasonable controls to help ensure that we provide only the appropriate quantities of these permitted supplies.

The government's new position on supplies narrows the types of supplies that laboratories can provide to their customers. For example, laboratories cannot provide customers with sterile gloves. Were a laboratory to provide this supply and a physician to accept it, both the lab and the physician would be at risk of violating the Stark law. For detailed information published in the *Federal Register*, you can refer to HCFA-1809-FC at http://cfo.hcfa.gov/fraud/physician-referral/default.htm (click on 905-954.PDF to view commentary about gloves on pages 947-949), or see the enclosed excerpt.

In addition, New York state's Laboratory Business Practices regulation, Section 34-2.2(8) and 34-2.5(a) and the Health Care Practitioner Referral regulation, Section 34-1.7(e)(2), prohibit clinical laboratories from providing gloves to referring physicians. These regulations became effective on December 26, 2001.

Quest Diagnostics' ongoing commitment is to comply with the laws and regulations that affect our business. Therefore, we will no longer be able to supply gloves to our customers. In order to give you time to adjust to this change, our policy will take effect on March 15, 2002.

If you have any questions regarding this change, please contact your Sales Representative.
Thank you for selecting Quest Diagnostics for your laboratory testing needs.

Sincerely,

ROBERT PETERS
Sr. Managing Director, TBR Business Unit

letter in February to note deficiencies in Quest's compliance with the December 26 trigger date and request compliance with same.

Labs Finally Get Serious

Following this meeting, most labs in New York began to seriously implement the new regulations. Consequently, it was only in recent weeks, on a wide scale, that the flow of lab supplies into physicians' offices has begun to dry up. It is thus too early to gauge the true impact of these new laws, since only a small number of physicians have protested the loss of supplies with their laboratory or the NYDH.

For the collective lab industry, New York's experience teaches an important lesson. A tenuous balance continues to exist. On one side are the pressures to run a tight compliance program. On the other side is the need for a lab to continually protect its clients from competing labs which may either blatantly violate the law or simply have a more liberal interpretation.

In numerous interviews with lab executives from New York, attorneys, and other involved parties, THE DARK REPORT believes it is likely Quest Diagnostics Incorporated was trying to take a lead role in implementing compliance by publicly declaring an implementation date (its January 2002 letter to physicians with a March 15 target), thus signaling its plans to other laboratories. This was followed by discreet contacts with competing labs to verify that industry-wide compliance would occur at or around that date.

No lab executive or pathologist would be surprised at the catfight which resulted as New York's labs jockied to comply with the new law in such as way as to not anger their physician-clients. **TDR**

Contact Robert Michel at 503-699-0616.

CEO SUMMARY: Vanderbilt University Medical Center's "WizOrder" demonstrates that a well-designed clinical decision support system can help physicians make better use of laboratory tests. The early successes of WizOrder demonstrate that the need for improved utilization and application of laboratory tests will be ongoing. It reinforces, once again, that there is an opportunity for lab administrators and pathologists to proactively add value for the clinicians they serve.

VANDERBILT HELPS PHYSICIANS PRACTICE BETTER MEDICINE

Clin Decision Support System Improves Lab Test Ordering

IT IS WIDELY-RECOGNIZED THAT CHANGING the way physicians practice medicine is, at best, extremely difficult. This is particularly true when it comes to ordering laboratory tests and using test result data in different ways.

Yet it is also widely-recognized that better utilization of lab testing can generate substantial gains in the quality of healthcare outcomes, accompanied by a lower cost per episode of care. But to date, most efforts by lab executives and pathologists to implement fundamental changes in how physicians order lab tests and use the resulting information have failed, often generating ill-will in the process.

Against this background of widespread frustration, there is a notable exception. At **Vanderbilt University Medical Center** (VUMC) in Nashville, Tennessee, efforts to move physicians' clinical behavior closer to desired "best practices" models are not only succeeding, but generating ongoing improvements.

Two Lab Functions Targeted

Among specific clinical practices targeted are two that directly involve laboratories. One goal is to improve laboratory test ordering patterns and the other goal is to insure that clinicians act properly in response to lab test data generated by the specific tests they order. Martha Miers, VUMC's Executive Director of Clinical Laboratories, tells THE DARK REPORT that "for example, in the first hospital units where the clinical decision support system was implemented, the volume of routine chemistry tests performed has fallen by as much as 30%."

But this success did not come overnight. VUMC's journey to its current system for clinical decision support began in the late 1980s. "The main objective of this effort is to reduce variability in how our physicians practice medicine," stated William Stead, M.D. Associate Vice Chancellor for Health Affairs at Vanderbilt University Medical Center. "Within our system, we could see differences in outcomes and costs which could be attributed to variability in how individual clinicians practice medicine.

"Our first effort was in 1989, funded by a grant from the Robert Wood Johnson Foundation," said Dr. Stead. "By the mid-1990s, we had developed collaborative care pathways covering about 80% of our admissions. One of our earliest care pathways dealt with radical prostatectomy. We provided clinicians with raw data on variability. As a result, costs fell by 40% and there were measurable improvements in morbidity.

"The earliest steps toward our current clinical decision support program began about seven years ago," he continued. "In the mid-1990s, we went live with a physician-ordering system that turned out to be rather unfriendly to doctors. So, for the next five years, we created a different type of system, one that supported the way physicians worked 'pre-computer.' That allowed us to begin adding data from the patient record, as well as supporting their decisions with appropriate information."

"Through in-house efforts, we've created two software products that anchor our clinical decision support system," he explained. "One is a decision support tool we call 'WizOrder.' The other is 'StarChart', which is our integrated patient record.

"We began down this path when administration noticed that variability in the healthcare system was a real problem," commented Dr. Stead. "Data showed that there was considerable variability in costs across different regions, yet there was no discernable difference in outcomes. That means extra money spent in one area did not translate into better healthcare.

"Vanderbilt adopted a strategy of reducing variation in clinical practices," he continued. "We started with this

McKesson Licenses WizOrder for Sale

CLINICAL DECISION SUPPORT SYSTEMS may be coming soon to a hospital or health system near you. Vanderbilt University Medical Center (VUMC) has licensed WizOrder to **McKesson Corporation**.

The current performance of WizOrder has been impressive enough to attract the interest of McKesson. It is already marketing the system to other healthcare systems under the name "Horizon Expert Orders™." One of the earliest customers for this product is **St. Luke's Episcopal Hospital** of Houston, Texas.

premise: 'Our fundamental job is to take variability out of the practice of medicine.'

"Our strategy was simple. It was to help clinicians develop 'best practices' protocols, then provide them with information they need at various clinical decision points so that their patients were treated in accordance with clinical 'best practices'."

This is where Vanderbilt's WizOrder plays the key role. "One important place to influence variability is when a clinician decides to order procedures he/she considers appropriate for the patient," noted Dr. Stead. "This is the moment where our clinical decision support system is designed to provide the clinician with the right information in the appropriate context."

Dr. Stead emphasizes that WizOrder is not simply an order entry system. "This is a sophisticated clinical tool," he said. "It has practice algorithms developed by our medical staff, full access to patient data, and supporting knowledge needed to provide clinicians with all the information they need to make an informed decision about their patient."

This is key to understanding why Vanderbilt's WizOrder has proved to be an effective clinical decision support tool. Unlike a simple order entry system, WizOrder is built upon three basic components, each designed to give physicians information they need to make informed decisions.

WizOrder's first component involves the "best practices" algorithms. "These are developed by our medical staff," Dr. Stead observed. "Where laboratory tests are involved, pathologists work with other clinical leaders to provide written guidelines. These clinical practice protocols are the heart of WizOrder."

The second component is access to patient records. "Our 'StarChart' contains an integrated patient record that can be accessed through WizOrder," he stated. "In real time, it shows the physician which tests and procedures have already been ordered, as well as results from those tests.

"The objective is to provide physicians with information necessary to make sound clinical decisions," continued Dr. Stead. "As well, it prevents the physicians from ordering unnecessary tests."

Avoid Unnecessary Tests

"In the laboratory, this has impacted test utilization in an obvious way," added Miers. "We see fewer test orders because WizOrder cues the physician that either: 1) the test results are already available; or 2) the same test was ordered earlier and results are pending; or 3) trended results of the same test over time indicate that repeat testing may be unnecessary. This is one way WizOrder reduces the amount of redundant testing that is common in most hospitals."

WizOrder's third component is the knowledge base which supports best-practices protocols. "At the time a

physician is ready to make an order, the knowledge base provides supplemental information necessary for him/her to decide which clinical procedure might be most appropriate for the patient," said Dr. Stead.

Knowledge Data Base

"Part of the knowledge data base involving laboratory tests was developed by our pathologists," noted Miers. "Screens with desired information pop up within WizOrder as the clinician searches for supporting information."

As a functioning clinical decision support system, WizOrder presents the physician with a very complete information resource. "Keep in mind that WizOrder has evolved from all our earlier efforts over the past seven years to provide physicians with healthcare informatics tools," said Dr. Stead. "We've learned how to support physicians' decisions in a way that maintains their control.

"WizOrder allows the clinician to see the patient history," he continued, "and supports decisions with appropriate information. 'Alerts' are one active feature of WizOrder. As the clinician works through the case, alerts will appear at appropriate moments.

"Alerts are interactive messages which pop up," he commented. "It could be a potential negative drug-to-drug reaction. Or the patient may have an allergic reaction to the drug being considered."

Protocols Used As Guides

"If the physician wants to order a procedure that falls outside 'best practices' protocols, then WizOrder asks that physician to justify that procedure," Dr. Stead noted. "WizOrder cues the physician if his/her order might not be most optimal and prompts the accepted practice, helping to guide physicians to the right decision for a particular patient.

"Remember, Vanderbilt's goal is to eliminate variability," he emphasized. "We want our doctors to oscillate around 'best practices' protocols by helping them make the right decision at the time of the order."

Alerts are one way to monitor progress toward this goal. Each day, between 500 and 800 alerts are issued. "The number of alerts tells us how physicians are responding to 'best practices' protocols," stated Dr. Stead. "Certainly fewer alerts would indicate that physicians are incorporating the guidelines into their daily clinical practice."

Although WizOrder was not designed first to be just an order entry system, it has changed the way clinicians order within VUMC. "In the typical hospital, the physician will write an order in shorthand—then a staff member will execute it. That's not what happens with WizOrder. As the physician works through his/her case, he/she is directly ordering the procedure. This eliminates the need for support staff to perform this task."

High Acceptance

Dr. Stead indicates that physician acceptance of WizOrder has been high because physicians retain control over the process. "As they realize they have more complete information at the time of decision, it makes it easier for us to make small improvements in 'best practices' protocols," he said.

Widespread physician acceptance of WizOrder is evidence that it meets their needs. The system is used extensively in VUMC's inpatient settings. "This is because we have fairly complete data sets," noted Dr. Stead. "In electronic form, StarChart includes all the data we have, including text and images. However, we've not yet tried to do online or bedside charting.

"In the outpatient setting, order entry is more difficult to implement,"

he added. "Care can be fragmented and it takes longer to access the patient record. However, we are working to overcome these obstacles."

Vanderbilt's successes have been significant. Besides the reduction in routine chemistry tests ordered in units where WizOrder has been implemented, there are other measurable benefits.

"WizOrder is also having a big impact on pharmacy. VUMC can track $5 million in savings from improved ordering and use of drugs. A sizable amount of this is attributable to drug substitutions," said Dr. Stead.

Because detailed cost accounting is not easy to develop, VUMC allows each clinical unit to define its goals and identify how it will measure savings and clinical improvements. Administration wants to track this performance because it uses those savings to justify additional investment in information technology.

Vanderbilt's IT Spending

"Vanderbilt's budget for information technology (IT) has been increasing, on average, by more than 10% per year," observed Dr. Stead. "On the performance side, the goal is to reduce the cost per unit of care by 3% annually."

Because laboratory testing is integral to many clinical decisions, Vanderbilt's laboratory department is fully engaged in the "best practices" strategy. "In hospital units where WizOrder has fully deployed, we've seen a reduction of up to 30% in the volume of routine chemistry testing from improved lab test ordering patterns," said Miers. "This volume reduction has allowed our lab to absorb increasing test volumes from other areas without significant budget increases. We plan to measure other areas of testing affected by WizOrder so we can quantify the benefits."

THE DARK REPORT observes that Vanderbilt's success with its evolving clinical decision support system validates the potential of such tools to help clinicians improve the quality of care while reducing or eliminating unnecessary costs.

It also identifies one method that allows clinical pathologists and lab administrators to support improvements in how clinicians order lab tests and act upon lab test results—in a way that clinicians see as beneficial and non-threatening.

"Smart" Clinical Systems

Vanderbilt's WizOrder is an early example of the type of "smart" clinical systems which will support more effective decisionmaking by physicians and other providers. It demonstrates how an information bundle that includes: 1) an electronically-accessible and complete patient record; 2) patient care algorithms; and 3) medical knowledge resources, can become a valuable tool for clinicians.

THE DARK REPORT predicts clinical decision support systems can be expected to increase the importance of laboratory executives and pathologists. After all, laboratorians are experts in diagnostic medicine. It is they who know best how to organize and deliver the most appropriate laboratory testing services for the healthcare providers they serve. TDR

Contact William Stead, M.D. at 615-936-1424 and Martha Miers at 615-343-1545.

Dr. Stead Scheduled to Speak at the EXECUTIVE WAR COLLEGE

Dr. Stead will discuss the impact of the clinical decision support system at this year's EXECUTIVE WAR COLLEGE, scheduled for Tuesday-Wednesday, May 7-8, 2002 at the Astor Crowne Plaza Hotel in New Orleans. Call 800-560-6363 for information or to register.

WizOrder Can Provide Clinicians With Full Range of Lab Results

Shown below is an actual screen from Vanderbilt University Medical Center's clinical decision support system, called "WizOrder." This popup screen displays trends of chemistry tests for a particular patient. It also highlights certain lab test ordering rules. Buttons at the bottom allow the clinician to view five other categories of lab tests, such as liver and pancreas, arterial blood gases, and cardiac/muscle enzymes.

> *"In daily use, this screen provides clinicians with trended lab test results. The objective is to help clinicians decide whether or not repeat testing may be necessary. It is our experience that presentation of trended laboratory test data has helped our clinicians reduce overall volume of lab orders."*
>
> ***— Martha Miers***
> *Executive Director of Clinical Laboratories at VUMC*

Managed Care Update

New Lab Test Technology Must Meet Five Payer Requirements

HOSPITALS ARE NOT THE ONLY healthcare player wary of the high cost of new diagnostic test technologies. Insurance companies all over the United States have increased their scrutiny of new medical technology, including laboratory tests.

In a visit to Wall Street last week, THE DARK REPORT attended **Bank of America Securities'** conference on "Genomics & Diagnostics: How Close Are We To The Future?" The conference was well-attended by professional money managers, a fact which indicates high interest in laboratory companies and diagnostic opportunities.

Payer acceptance of new lab tests is of particular interest to investors (and the laboratories which will perform the tests), so a panel was devoted to "A Payer Perspective: Will They Pay?" Panelists agreed that new laboratory test technology is now put under much greater scrutiny by payers now, as compared to past years.

Critical Of Some New Tests

Robert Derek Prentice, M.D., Medical Director at **Blue Cross/Blue Shield of North Carolina**, was particularly critical of laboratory tests which failed to demonstrably improve clinical care. In particular, he noted that liquid preparation Pap smears didn't address the real problem in cervical cancer screening—the women who die of cervical cancer because they didn't visit a doctor for timely Pap smear testing.

"From a payer perspective, our concern is that the increased cost of these new Pap tests may discourage patient access because it raises the cost of testing, thus increasing the cost of health insurance premiums and reducing the number of women covered by health insurance," observed Dr. Prentice.

Payers Were "Harangued"

That Dr. Prentice was somewhat biased on this subject was revealed by his answer to a question from a financial analyst in the audience about why the nation's health insurers accepted this test in the first place. "Payers were harangued by patients, physicians, and legislators to adopt this test," he recalled. "The managed care industry gave in to the pressure."

Dr. Prentice later identified the five criteria used by the national Blue Cross/Blue Shield organization's technology committee to evaluate new medical technologies for acceptance. They are: 1) Technology must be government-approved. 2) Scientific evidence must prove the conclusions about clinical effect [benefit]. 3) There must be a net measurable improvement in health outcomes. 4) New technology must be as good as existing technology. 5) Improvement must be attainable outside the development setting.

Panelists had clear agreement on one point: until government and private payers agree to establish billing guidelines and adequate levels of reimbursement, manufacturers of new, FDA-approved diagnostic test technologies will find it difficult and expensive gain widespread clinical acceptance. TDR

Lab Industry Update

First-Ever "Black Belt" Certified In an American Hospital Lab

Grant Riverside Hospital's laboratory is first unit to implement Six Sigma project

IT WAS A BIG DEAL in the laboratory of **Grant Riverside Hospital** of Columbus, Ohio when Lab Site Manager Sandra Hood received her certification as a Six Sigma Black Belt on January 23, 2002.

That's because hospital administrators had selected the laboratory to be hospital's guinea pig. Their goal was to gauge the effectiveness of Six Sigma and Lean management methods in improving quality and in reducing or eliminating waste and unnecessary costs. Hood's certification as a Black Belt in January marked the completion of the laboratory's first Six Sigma project.

Sandra Hood
First hospital lab Black Belt

Milestone Event

Hood's certification was also a milestone for the hospital lab industry. THE DARK REPORT believes she is the first hospital-based laboratorian in the United States to become a Black Belt.

"When this Six Sigma project started last July, I was the Manager of Transfusion Services," recalled Hood. "I was selected as the Interim Project Manager for Process Excellence, which is the management program offered by **Johnson & Johnson Company** that incorporates Six Sigma and Lean methods.

"Our lab project was to eliminate a wasteful step that was called 'pre-storage review,' she stated. "After testing, our med techs would do a check on every specimen as a way to catch errors that might have originated from any of six causes, such as label generation, accessioning, routing, and specimen handling.

"The project was scheduled for six months and ended within days of our target date," noted Hood. "We totally eliminated the need for 'pre-storage review.' The measurable results were impressive. We saved 11 hours of med tech time per day and three hours of phlebotomist time per day. Net savings recognized were $117,000 per year."

"The next project for the laboratory will incorporate 'lean' methods to redesign workflow from registration through testing," explained Hood. "We have a sizeable outreach business and those specimens have been handled separately from inpatient specimens.

"However, because the first lab project freed up so much med tech time, we now have the opportunity to utilize our lab more efficiently. So one component of the lean project is to develop a single process to feed both

inpatient and outreach specimens to the instruments in the most productive manner possible," said Hood.

Management Perspective

Her experience with Six Sigma and Lean has changed Hood's management perspectives in fundamental ways. "This is an exciting way to manage," she enthused. "Everyone in the lab has caught the fever. In fact, as news of our pilot project spread throughout the hospital, our laboratory staff gained a new respect. Moreover, other departments want to do their own Six Sigma projects and the hospital currently has six more people in black belt training."

Hospital administration at Grant Riverside Hospital is equally enthusiastic about the effectiveness of Six Sigma and Lean. One of Hood's new roles is as spokesperson for the Process Excellence program at the hospital. "Not only have I done presentations for our Board," recalled Hood, "but I represent this program at various public events. This is all very exciting from someone who has spent most of her time quietly working away in a laboratory."

Proven Management Tool

THE DARK REPORT believes the arrival of Six Sigma and Lean is an important development for hospital laboratories. It is a proven tool that allows lab directors and pathologists to simultaneously improve quality while reducing costs—all in a controlled manner with full support by the entire lab team.

Hood believes that laboratorians will embrace this approach, once they understand it. "Lab people have an analytical nature that is a natural complement to Six Sigma and Lean," she observed. "It's been widely-accepted in our lab because it makes positive things happen in a deliberate way."

A handful of other hospitals are in the early stages of launching Process Excellence projects, so adoption of Six Sigma and Lean should grow over time as the results of these efforts become public. In the commercial laboratory sector, **Quest Diagnostics Incorporated** was the first lab company to make implementation of Six Sigma a strategic business priority. *(See TDR, October 23, 2000.)*

THE DARK REPORT considers the arrival of Six Sigma and Lean to the laboratory industry as an important development because it gives lab executives and pathologists the ability to reshape their organizations to meet the clinical and financial challenges of the healthcare marketplace. That is why THE DARK REPORT will closely track the the successes of early lab adopters. TDR

Contact Sandra Hood at 614-566-5754.

Requirements To Earn Six Sigma "Black Belt"

"THERE ARE FOUR STEPS REQUIRED to earn a black belt certification," stated Sandra Hood, Site Manager for the labs at Grant Riverside Hospital and the nation's first-ever hospital laboratory professional to earn such a certification.

"First, a candidate must attend four weeks of training—one week for four months," she said. "I did my training with **Ortho-Clinical Diagnostics** in Rochester, New York.

"Second, at the end of training, there is a skills assessment," she continued. "The third requirement is to complete a project in the work environment that incorporates Six Sigma methods.

"Fourth, to apply for certification, it is necessary to submit a notebook that contains documentation of the project and pass an oral examination conducted by a panel of master black belts."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Genaissance Pharmaceuticals Inc. announced it has identified genetic markers useful in identifying which people will respond best to cholesterol-lowering drugs. A study of 500 patients taking Lipitor, Pravachol, and Zochor compared their response to drugs over 16 weeks with a genetic profile that analyzed 100 genes. Among other things, the company says it may use the information to patent a genetic test that, as a drug comes off patent, would be packaged with the drug to extend the patent life of the drug.

MAYO CLINIC CREATING BIG PATIENT DATA BASE

It's another example of how valuable a large data base of clinical information can be. On March 26, **Mayo Clinic** disclosed that it was computerizing patient records. By July, it expects to have 4 million of its 6 million patient records into the data base. In a later phase, Mayo wants to include genetic profiles on as many patients as possible.

MORE LAB TESTING IS RECOMMENDATION OF FED GOVERNMENT

Last week the **Department of Health and Human Sciences** officially recommended that more testing be done to identify the 16 million Americans between 40 and 74 years old with "prediabetes." Doctors are asked to screen patients to identify those with higher-than-normal blood glucose, but below the level that trigger a diagnosis of diabetes. Officials declared diabetes to be the nation's most expensive health problem, costing $97 billion in 1997.

ADD TO: Glucose Testing

Of particular interest for laboratorians is a new twist. Part of this campaign will include steps to make patients aware of their blood glucose level. "People should know their blood glucose level, just as they know their cholesterol levels," commented Francis Kaufman, President-Elect of the **Diabetes Association**. Over time, labs should see a build-up in blood glucose testing, accompanied by an increase in consumer interest and need for more consumer information about these types of tests.

CareEvolve.com Gets New CEO

Cory Fishkin has surfaced at **CareEvolve.com**, where he will be the CEO. CareEvolve.com. based in Elmwood Park, New Jersey, is a physicians' Web portal that is owned by **Bio-Reference Laboratories, Inc.** and **Roche Diagnostics, Inc.** Fishkin had started a consulting business after leaving **McKesson** when it closed down Abaton.com as a separate business unit.

MORE ON: Bio-Reference

Bio-Reference Laboratories (BRLI) recently created the position of Vice Chairman for Marvin Topfer, who acquired a significant amount of BRLI stock last year. Topfer is best known for his role in helping Michael Dell build **Dell Computer**, where Topfer served as Vice Chairman and Co-CEO.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 22, 2002.

PREVIEW #7

EXECUTIVE WAR COLLEGE

May 7-8, 2002 • Astor Crowne Plaza • New Orleans

Case Study: Grant Riverside Hospital

In Columbus, Ohio, this 460-bed teaching hospital operates a thriving lab outreach program, built around a consolidated laboratory organization. It is one of the first hospitals in the United States to embrace Six Sigma and "Lean" techniques for management improvement, which were first introduced into the laboratory. Learn how the successes from early efforts are now diffusing throughout the lab.

Full program details available now—call 800.560.6363
or visit www.darkreport.com

UPCOMING...

- ***Quest Diagnostics' CEO Ken Freeman Discusses AML and Unilab Acquisitions.***
- ***Getting a Handle on HIPAA: What Shrewd Labs are Learning about Compliance.***
- ***Busting the Budget: How Hospitals are Coping with the High Cost of Specialty Testing.***
- ***Squeezing More Value from Lab Test Data: Motivated Clinicians Support Boosting Reimbursement for Laboratory Services.***

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