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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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R. Lewis Dark

Founder & Publisher

Major Events Hit Pathology Profession

ACROSS THE AMERICAN HEALTHCARE SYSTEM, numerous trends tug at pathologists and the laboratory medicine services they provide. Both clinical pathologists and anatomic pathologists find themselves confronted with a growing number of demands for change. Increasingly these demands can no longer be ignored or deferred, but require a response.

This issue of THE DARK REPORT provides examples of this quandary. At the **Centers for Disease Control and Prevention** (CDC), first steps were taken to organize a laboratory Quality Institute (QI). *(See pages 2-7.)* In keeping with the need to improve patient safety and reduce medical errors, the goal is to identify relevant measures of quality in laboratory testing services, then survey the nation's labs about these quality parameters. The QI will then issue a national report and launch a monitoring system to track the performance of laboratories in reducing errors and improving quality. If everything goes according to schedule, within 24 months, clinical laboratories may be reporting these quality monitors on a regular basis.

Next is the power blackout that impacted 50 million people in the Eastern United States and Canada last week. Laboratories in affected areas lost power and their emergency response procedures were tested without advance notice. *(See page 8.)* In just two years, terrorist threats, emerging diseases like SARS, and last week's reminder about the possibility of power outages have required lab directors and pathologists to devote considerable time and resources to crisis planning and training.

The turbo-charged environment of change at **Kaiser Permanente Northwest's** (KP-NW) laboratory division in Portland, Oregon is another example of a trend starting to change lab operations. *(See pages 9-14.)* After deploying the ISO-9000 quality system in its lab, KP-NW has harvested considerable gains in productivity, quality, and employee morale. This is a real-world validation of how quality management systems can improve lab operations. It will inspire other lab leaders to embrace these management tools.

Finally, following a decade of declining reimbursement, pathology group practices find it tougher to meet demands for compensation, equity, and retirement benefits with existing group business models based on a 1980s fee-for-service healthcare world. *(See pages 16-17.)* Experts will convene in Atlanta on October 24-25 to present new approaches and business models that help pathology groups enrich their existing cash flows to provide better financial rewards to pathologists in the group. TDR

National Lab Standards Coming For Patient Safety

CDC incubates lab Quality Institute to develop a national report and standards for lab safety

CEO SUMMARY: Because lab test data plays such an important role in medical decision-making, the Centers for Disease Control and Prevention (CDC) has launched a national effort to evaluate the quality of clinical and public health laboratories. In forming a Quality Institute, the goal is to issue a National Report on the Quality of Laboratory Services and develop quality indicators and guidelines that reflect best practices.

By June G. Smart, Ph.D.

INITIAL STEPS HAVE BEEN TAKEN at the **Centers for Disease Control and Prevention** (CDC) to develop the first-ever national report on patient safety in clinical and public health laboratories.

The CDC, in partnership with 40 other organizations, held a Quality Institute (QI) Conference to pursue three objectives. One, to develop the framework and content for a National Report on the Quality of Laboratory Services. Two, to identify criteria for indicators that measure the quality of laboratory services. Three, to create an ongoing system that would collect and analyze data related to the quality of laboratory services in the United States.

This project can potentially affect lab testing services in significant ways. For that reason, laboratory administrators and pathologists should track the progress of the CDC's laboratory Quality Institute as it goes about its work.

During the April conference, participants discussed the concept of forming a Quality Institute. Stakeholders representing the interests of laboratory professionals, industry representatives, clinicians, patient advocates, legislators, healthcare administrators, and accrediting organizations were present. The meeting's objective was to provide the CDC with input and insights from all stakeholders and establish a task force to pursue the formation of the Quality Institute and achieve its three primary goals.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

Several weeks later, on May 6-7 at the *Executive War College* in New Orleans, attendees were first to learn about the outcomes of the QI Conference. They were also briefed on the first draft of plans to develop a national report on quality of laboratory services, as well as monitors that would regularly measure the patient safety of laboratories in the United States.

Reducing Medical Errors

"Medical errors are the eighth leading cause of death in the United States," stated Ana K. Stankovic, M.D., Ph.D., Co-Chair of the 2003 QI Conference in Atlanta. "Laboratories can play a major role in the effort to reduce these errors.

"Each year, more than 7 billion laboratory tests are performed in the United States," she continued. "The results of these lab tests influence about 70% of medical decisions. Activities of the Quality Institute could help identify ways that laboratories can contribute to a reduction in medical errors and ongoing improvements in patient care."

Stankovic is passionate about quality in the laboratory. At the time of the Atlanta QI Conference and the *Executive War College*, she was a member of the CDC's Division of Public Health Practice Program Office. She recently accepted a position at **Becton Dickinson** as its Worldwide Medical Director for Pre-analytical Solutions, but continues with her role on the Executive Committee of the CDC's Quality Institute.

Patient Safety Priorities

"Patient safety is now a major initiative across all sectors of the American healthcare system," said Stankovic. "The **Institute of Medicine's** (IOM) 1999 report on medical errors determined that between 45,000 to 98,000 people per year die in hospitals as a result of medical errors. This is a staggering statistic and does not include errors that affect outpatients!

"Besides the tragic impact on individual lives, it is estimated that costs associated with preventable medical errors in hospitals total as much as $17 billion annually. That number is even higher if we include medical errors that occur to outpatients."

Stankovic observed that laboratories themselves are the source of some medical errors. It is the goal of the Quality Institute to identify sources of medical errors in laboratory testing services, then develop ways to reduce and eliminate such errors.

"Several studies on errors in the laboratory demonstrate the problem and the opportunity," said Stankovic. "For example, Bonini, et.al., wrote an excellent article, "Errors in Laboratory Medicine," (*Clinical Chemistry* 2002, 48:691-8). The authors stated that about 12.5% of laboratory errors have some affect on patient health. It was also noted that, when an adverse patient event occurs, it is usually a combination of defects on multiple levels."

Labs Do Make Errors

"Studies conducted by the CDC and others show that laboratory errors occur in 34-per-100,000 patient events and 1-in-8,300 laboratory results," she added. "Either way, these numbers are not good. If we compare these numbers with what should be achieved in a Six Sigma laboratory, we see a significant difference.

"Most laboratories currently perform in the three to four Sigma range, which is 93.3% to 99.4% accuracy," she continued. "This performance is not as good as it appears, because it equates to 6,210 errors per million test results, which is unacceptable. Compare this to a laboratory operating at five Sigma quality, which is 99.98% accuracy, or 233 errors per million tests performed. A six Sigma laboratory performs at 99.99%, or 3.4 errors per million tests.

Quality Institute Committee Plans To Launch National Lab Quality Awards

WITHIN ANOTHER YEAR OR SO, the laboratory industry may see the Steering Committee for the Quality Institute announce the first national laboratory quality awards recognizing innovative practices.

"To make national awards in laboratory quality a reality, we need to first develop relevant criteria about attributes which contribute to quality, then develop indicators and measurements of laboratory quality and overall patient safety," stated Ana K. Stankovic, M.D., Ph.D., co-chair of the CDC's Quality Institute Conference. "This fall, a team will be formed to pursue this goal. I was selected to lead this team.

"Two other teams will be the quality indicators team, led by Lee Hilborne, M.D., Associate Professor of Pathology at the **University of California at Los Angeles**. It will look into defining a set of core quality indicators," noted Stankovic. "The other team is the sentinel laboratory team, led by Michael Noble, Ph.D., Associate Director, Department of Pathology and Laboratory Medicine, **University of British Columbia**. Wherever possible, we want to use existing networks and laboratory quality indicators.

"We will meet in September to begin developing this information and identifying relevant indicators of laboratory quality," she added. "The challenge is to develop deliverables that add value to both laboratories and the healthcare system itself, without creating unnecessary burdens."

Work on this project and the awards will proceed rapidly. "At this stage, we are still in the planning stages of the awards process; everything is going to be much clearer in September," observed Stankovic. "Once the criteria for the award selection is determined, the team will then identify candidates who have made contributions to improving laboratory quality. Our plan is to recognize these individuals and entities, then distribute the awards at the Institute Conference in the fall of 2004.

"At the 2003 Quality Institute Conference, we spoke about dividing the total laboratory testing process into five major phases for study," noted Stankovic. "These phases are pre-pre-analytical, pre-analytical, analytical, post-analytical, and post-post-analytical.

"Initial studies indicate that most laboratories are doing well in the analytical phase, but there is a lot of work to be done in the other phases," she explained. "Two areas that have traditionally received the least attention by lab directors and those involved in the healthcare system are the pre-pre-analytical phase, which is selecting the right test for a particular clinical scenario, and the post-post-analytical phase, which relates to the use of lab results by clinicians. Everyone in the healthcare system must do more in these areas if they are to make a greater contribution to patient safety and improved healthcare outcomes."

Defining the correct tests for patient diagnoses and interpreting complex results has become more important in such areas as coagulation, genomics, and proteomics. Stankovic observed that clinicians cannot keep up with the explosion of new laboratory tests. Pathologists and clinical laboratory scientists need to provide more guidance and support to aid physicians in the care they provide patients.

Labs Should Expand Role

"Collectively, laboratories generally do not have an effective way to allow interaction with clinicians and receive feedback after laboratory test results are reported," she noted. "Too often laboratory test reports simply provide a number or are too verbose, making it tough for clinicians to clearly understand the results of the tests and their relevance to the patient's condition.

"For example, a lab test report may identify and name an antibody, like Anti-Kell. But the report will often fail to mention that the presence of this antibody can cause hemolytic disease of the newborn, which represents the most relevant clinical information," explained Stankovic. "The laboratory needs to contribute more to the care of the patient. The [lab's] knowledge is there, it just does not appear on the chart. As another example, how much more valuable would lab test data be if a representative from the laboratory was present when rounds are conducted?

"Having said this, I'd also like to point out that the laboratory profession is much further ahead of other clinical specialties, particularly in the analytical phase," she added. "There is licensing, proficiency testing, certification, accreditation bodies, regulatory oversight (CLIA 88), quality assurance, and quality control. But we still have a long way to go."

"As another example, how much more valuable would lab test data be if a representative from the laboratory was present when rounds are conducted?"

Stankovic next addressed the work of the Steering Committee for the QI. "At the April meeting, we started with 40 partners," she said, "including healthcare providers, payers, insurers, policy makers, professional organizations in both the laboratory and diagnostic industries, government, patient advocates, and independent laboratories.

"The purpose of that three-day meeting in April was to bring people together, look at the issues, and develop a realistic vision," stated Stankovic. "Eight work groups were formed to focus on three different topics. Three of these groups were primarily focused on assessing the need for development of a National Report on Laboratory Quality. They discussed, in broad terms, its format and content. Primary hurdles in this effort are cost and legal issues."

Lab Quality Measures

"Three work groups spent time at the meeting discussing the need for reliable quality indicators of laboratory services, such as access to health care, timeliness, and appropriate use of laboratory tests," noted Stankovic. "These groups will have to work through many questions regarding participation, reporting, access to data, privacy, tracking, and confidentiality, just to name a few.

"The remaining two groups concentrated on the need for an ongoing Quality Institute," she added. "So far, these two groups have agreed that the mission of the QI should be in surveillance of laboratory services and as a resource to the laboratory profession. It should also educate public payers about the value of laboratory testing services and act as a data clearing house on laboratory services, both for the laboratory profession and the healthcare industry in general."

The reason for the conference and its goals are described in the QI Conference White Paper: "An Approach to Medical Errors and Patient Safety in Laboratory Services." (Go to *http://www.phppo.cdc.gov/mlp/qiconference.)* It was developed by Marc Silverstein, M.D., who is also a member of the Executive Committee for the QI.

With the CDC facilitating a national effort to improve the laboratory's contribution to patient safety, THE DARK REPORT predicts that the resulting monitors will reinforce the need for labs to shift their management emphasis toward outcomes that meet the expectations of clinicians and patients. TDR

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Gauging The Impact Of Lab Patient Safety

Plans to collect and report on patient safety in the nation's labs will trigger big changes

CEO SUMMARY: Within 18 months, the Laboratory Quality Institute plans to issue a national report on the quality of laboratory services. Not only will this bring a new level of public attention and scrutiny to clinical laboratory operations, but it will require everyone involved in delivery, use, or payment for laboratory services to respond. Labs will need to take tangible steps to reduce errors and improve quality.

WHEN THE FIRST-EVER *National Report on the Quality of Laboratory Services* is formally released by the Quality Institute, it will have significant impact on the safety and quality of laboratory testing services.

That's because the National Report will be accompanied by implementation of a national system of laboratory quality monitors. At the *Executive War College* in New Orleans last May, the 2003 Quality Institute Conference Co-Chair Ana K. Stankovic, M.D., Ph.D. made the first public statements about the shape and direction of this initiative.

Industry-Wide Monitors

"Succinctly, one outcome for our effort is that the Laboratory Quality Institute is to develop and monitor indicators that will be continuously reported in the National Report," said Stankovic. "The objective is to promote changes in the laboratory community that directly improve patient safety and healthcare outcomes."

The Quality Institute intends to stimulate fundamental changes in the way the nation's laboratory services are incorporated into the patient safety movement.

Release of the first National Report on the quality of laboratory services will be a landmark event for the laboratory industry, for several reasons. First, it will be the first influential national authority to issue findings about the quality of laboratory testing services across the United States, based on a measurement process that will be transparent to the public.

Second, it begins the process of: 1) collecting specific data about the performance of laboratory testing services to help identify best practices; then, 2) compiling these data into a national number; and, 3) regularly reporting the results to the public. Among other goals, these reports are aimed at educating the public about the important role that laboratory services have within the healthcare system, as well as helping the public understand that their laboratory tests are safe and of high quality.

JCAHO Releases 2004 Patient Safety Initiatives

BEGINNING JANUARY 1, 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) will emphasize seven primary patient safety initiatives.

Just released last week, the seven initiatives include areas, such as nosocomial infections and accurate patient identification, that will directly involve hospital-based laboratories. Here are JCAHO's seven patient safety initiatives for 2004:

GOAL 1: Improve the accuracy of patient identification.

GOAL 2: Improve the effectiveness of communication among caregivers.

GOAL 3: Improve the safety of using high-alert medications.

GOAL 4: Eliminate wrong-site, wrong-patient and wrong-procedure surgery.

GOAL 5: Improve the safety of using infusion pumps.

GOAL 6: Improve the effectiveness of clinical alarm systems.

GOAL 7: Reduce the risk of health care-acquired infections.

Third, these national laboratory quality monitors will directly motivate laboratory directors and pathologists to change the operational structure of their laboratory organization. The need to demonstrate acceptable levels of patient safety—and to improve that performance over time—will require laboratory managers and those using laboratory services to rethink work processes and effect changes in their laboratory so it performs to the level of best practices.

Almost two years ago, THE DARK REPORT was first in the lab industry to predict that the **Institute of Medicine's** (IOM) report on deaths in hospitals from medical errors would trigger intense pressure for reform by payers, employers, and government health officials.

From the **Leapfrog Group** to the **Joint Commission on Accreditation of Healthcare Organization's** (JCAHO) persistent drive to initiate outcomes-based patient safety goals, THE DARK REPORT has given laboratory administrators and pathologists early warning about the shape and direction of the patient safety movement. The Laboratory Quality Institute is another development of significance in this ongoing trend.

Affects Every Laboratory

The quality monitors developed for the clinical laboratory profession by the Quality Institute will require a strategic response from every laboratory organization in the United States. These monitors accelerate the timeline for measurement—and public accountability—for the performance of laboratory testing services. Since many errors in the delivery of laboratory services occur outside of the laboratory, this will require a renewed effort to communicate and collaborate with users of laboratory testing services and those that provide reimbursement for such services.

THE DARK REPORT already sees evidence that the patient safety movement is accelerating the adoption of quality management principles in laboratories. That's because these quality systems, such as ISO-9000, Lean, and Six Sigma, were developed specifically to continuously reduce the rate of errors in work processes while improving quality and lowering costs. Those outcomes were certainly one result of the ISO-9000 certification by the **Kaiser Permanente Northwest Laboratory** in Portland, Oregon, reported on pages 9-14. TDR

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Lab Crisis Planning

Last Week's Power Outage Affects Labs in Many Regions

With municipal power out, labs continue to perform critical tests and report results

EVERY AFFECTED LABORATORY knows the precise time. Somewhere between 4:00 and 4:15 P.M. EST last Thursday is when the local power company stopped feeding electricity in cities ranging from New York City west to Toledo, Detroit and parts of Canada.

As of press time, many labs in affected cities lacked even phone service. THE DARK REPORT was able to reach several hospital labs, however, for an early assessment of how the power blackout affected their operations.

Waiting For Full Power

At **Detroit Medical Center** (DMC), William Neeley, M.D., Medical Director of Laboratories was blunt. "Right now I'm sitting in the dark with no air conditioning. It's a catastrophe that's challenged both our hospital and our lab," he declared.

"Our UPS and battery back-ups allowed us to safely shut down the instrument systems when the power failed," said McNeeley. "Using emergency power from the hospital generators, we've kept some instruments operational. All critical testing has been maintained. We are hand-entering orders and hand-delivering lab test reports.

"Our computers are operating, but without air conditioning, they can't be used," he continued. "In the computer room, the temperature is 90 degrees and chillers were brought in to help lower the temperature."

Another unexpected problem from the city-wide power outage is the lack of running water in the lab. "As a result, we don't have de-ionized water for certain instruments," stated McNeeley. "Another impact on the laboratory is that, because only certain bathrooms in the hospital are functional, our people have to travel quite a ways. As of Friday noon, we've had no word as to when full power may be restored."

Across the border in the Canadian Providence of Ontario, pathologist Murray Treloar, M.D., Director of Laboratory Services at **Lake Ridge Health** in Oshawa, was in the process of catching up. "Power was returned to our laboratory around 4:00 a.m. this morning. So we are back-entering orders and results.

"We had the usual hiccups when the power failed and we shifted to our back-up systems," he said. "One instrument didn't survive the change-over, but that was the exception. With only one elevator working in the hospital, our lab staff had plenty of exercise throughout the night, drawing specimens, getting them to the lab, and delivering results by hand."

In New York City, the impact of the power outage was more significant on laboratories. Because phone systems were down on Friday, specific details of unique lab management issues will not be known for several more days. TDR

Big Victory for Kaiser Permanente Northwest Laboratory Division

First ISO-Designed Clinical Lab Improves Outcomes, Costs

Second of Two Parts

CEO SUMMARY: In the first 14 months of operation, Kaiser Permanente Northwest's new automated regional laboratory facility, the nation's first designed by an ISO-9000-certified lab organization, is yielding big gains in both productivity and outcomes. In its high-volume core lab, productivity more than doubled, while the new laboratory's average cost-per-test declined by 8.7% during that same 14-month period. As this second and final installment demonstrates, quality management systems like ISO-9000 are proving their worth in laboratory operations.

IN BECOMING THE NATION'S FIRST ISO-9000-certified laboratory to design and build a new automated lab facility, **Kaiser Permanente Northwest** (KP-NW) Laboratories, based in Portland, Oregon, faced two unique challenges.

In part one of this two-part series, THE DARK REPORT described the first challenge: how to apply the principles of ISO-9000 to create a laboratory design unlike anything seen in the United States today. *(See TDR, July 26, 2003.)*

In this concluding installment, THE DARK REPORT looks at the other big challenge tackled by KP-NW Laboratories: how to successfully bring the new regional lab facility into full operation, once construction was complete.

No "Traditional" Lab Depts.

As noted in installment one, this new laboratory was *not* designed to accommodate traditional lab departments. Instead, it was designed around specimen volume and similar work processes. That fundamental difference changed virtually all aspects of how this new lab facility was to be staffed and operated.

Although this design philosophy promised significant gains in quality, enhanced lab testing services, turnaround time, and productivity, it meant new job descriptions and different work processes for the 200+ employees at the new regional lab facility. Simply put, lab administration had to resolve multiple difficult issues with people and operations before it could harvest the significant benefits that would result from its use of ISO methods in the design and operation of the new regional laboratory facility.

KP-NW Laboratories earned its ISO-9000 certification in October 2000, the same year it received authorization to build its new regional lab facility (February 2000). That new laboratory was designed, built, and put into operation by April 2002. "Independent of the performance metrics, this new lab design has radically changed our management capabilities," observed Dixie McFadden, Administrative Director of Laboratories at KP-NW. "Our quality system allows the management team to know *exactly* what's happening in every function of the lab—and gives us the ability to take the right action, immediately!

"It's the combination of two things," she continued. "First, as our entire lab team has learned to work under ISO's philosophy and methods, we are faster at recognizing both operational opportunities and problems. The ISO tools allow us to implement improvements rapidly.

"Second, having used the ISO philosophy to redesign work processes in our new regional lab facility, we've already eliminated many types of problems often found in clinical labs," observed McFadden. "Additionally, these same work processes are monitored and continuously improved. Collectively, all these factors contribute to higher quality and productivity while allowing us to better control our costs."

McFadden's comments will probably resonate with lab directors and pathologists. Too many labs still lack accurate and timely performance data. This makes it difficult for lab management to understand problems when they occur and identify opportunities for improving their lab's quality of services. At KP-NW, the new regional lab facility, because of its design and quality system, gives its management team those capabilities.

Lots Of New Job Descriptions

The radical design and workflow through the new lab did generate a substantial challenge for the entire laboratory staff. "By moving to a lab organized around specimen volume and work processes, we literally created new job descriptions for almost the entire staff," noted McFadden. "This was an unexpected outcome from the planning process.

"The skills and experience required for positions did not change," she continued. "But the actual duties for positions changed, both in how the direct work was performed and in how that position related with others in the laboratory. So we needed to re-bid positions in the new laboratory facility."

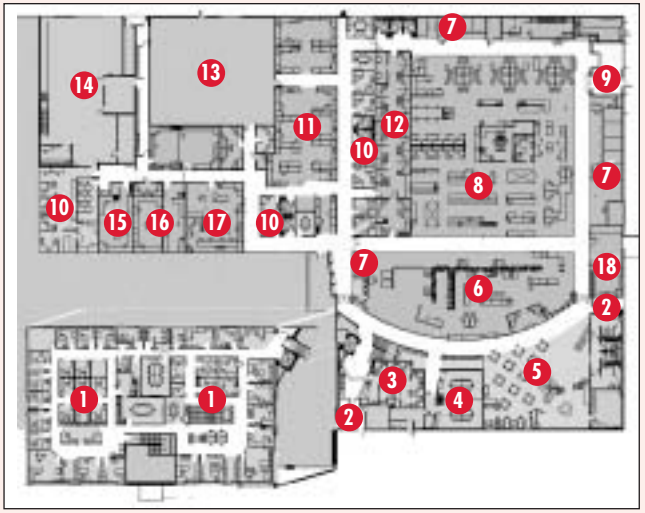
More than 200 people were directly affected by this process. "Certainly lots of the staff had trepidation about this process," explained McFadden. "They asked

Volume and Similar Work Processes Key to Design of Kaiser NW's New Lab

HERE IS THE ACTUAL FLOOR PLAN of the new automated regional laboratory built by Kaiser Permanente Northwest in Portland, Oregon. Using the principles of ISO-9000, the lab team decided not to use traditional laboratory departments. Instead, after mapping work processes, it designed the laboratory using specimen volume and similar work processes. The result is an unconventional design—one that is delivering substantial gains in productivity, quality, turnaround time, and employee satisfaction.

Floor plan for Kaiser Permanente Northwest's regional laboratory facility

1. Administration
2. Entry
3. Client Services
4. Conference
5. Common Area
6. Core Lab
7. Automated Storage
8. Prep and Read
9. Freight
10. Offices
11. Semi-Automated Lab
12. Microscopy
13. Future
14. Mechanical
15. Virology
16. Mycology
17. Toxicology
18. Receiving



us to provide job descriptions prior to bidding for the 'new' positions, which we did. Each staff member gave us a first, second, and third choice of their favored position.

"On the up side, 92% of the people involved in the job re-bid got their first or second choice," she added. "One validation that we had done a good job is that there were no grievances and no appeals.

"On the downside, a tremendous amount of time and resources went into the process of communication prior to the job re-bid, then training after new positions were assigned," stated McFadden. "To be brutally honest, our 'shared preparation' neighborhood turned out to be the biggest challenge."

As noted in part one of this series, the KP-NW laboratory used "neighborhoods" to describe areas organized by function, not by clinical department. 'Shared preparation' was a neighborhood designed to handle specimens for histology, cytology, microbiology, special chemistry, and anatomic pathology.

"Shared prep was such a unique design concept that we had no comparable place in our existing laboratory system to train people prior to the opening of the new regional lab facility," recalled McFadden. "During the first five months of operation in the new laboratory, we struggled to get staff oriented and trained to these new ways of handling the specimen flow.

"Once training had been accomplished, there were clear benefits in both quality and productivity," noted McFadden. "The radical design concept of shared prep was validated by its performance. Also, during that time, the shared prep teams re-jiggered work processes to take advantage of opportunities not anticipated during the planning stage."

Two Different Approaches

Another interesting reason why training was a major challenge lies in how each of the two unions decided to handle assignment to new positions. One union used experience and knowledge to establish priority for bids on new positions. The other union used seniority. As a result, many of those individuals needed refresher sessions to insure their skills were appropriate to their new duties.

"The concept of neighborhoods—not departments—caused concern among our pathologists and Ph.D.s," McFadden stated. "Rightly so, they asked 'with no conventional lab departments, how will clinicians know which pathologist or lab scientist is the right individual to call with their questions?' After all, we no longer had the traditional list of department directors.

Helping Clinicians

"We understood that we would have to help clinicians with the transition," she explained. "That led us to provide orientation programs and materials to our clinicians and improve the visibility of our pathologists and Ph.D.s. Based on feedback, we eventually divided up responsibilities by medical specialty, such as endocrinology, pulmonary, OB-Gyn, and the like. At the pathologist/Ph.D. level, each assumed responsibility for specific medical specialties."

The radical work flow concepts are easily visible when touring the new regional laboratory. It handles about 6,300 specimens per day and serves Kaiser Permanente's insured beneficiaries with lab testing for its hospitals, clinics, and medical offices.

"At the front door of the regional laboratory, high-volume tubes go left and lower volume non-tubes go right," stated McFadden. "In our core lab neighborhood, specimens are tested and results delivered in less than one hour. Also, tubes are loaded onto the automated line at accessioning. At the end, they are racked and carried by 'sneaker power' to an automated storage system."

Inventory is kept in an automated storage system, driven by bar codes. "By design, our inventory forces FIFO (first in, first out)," observed McFadden. "Our payback on this automated inventory system will take less than 48 months. Its design is the result of how ISO-9000 methods changed our thinking."

Problem-Solving Help

Another sign of this change in management perspectives is easily seen in a walk around the laboratory. At numerous work stations, large posters are hung in visible locations. The poster describes a problem that a particular work team is currently trying to solve, provides relevant information, and invites anyone with an idea or solution to contact the team leader.

"This approach to problem-solving is transforming our laboratory," noted McFadden. "Each of our team members contributes solutions and ideas for improvements as part of our revamped work environment. Because they have responsibility for fixing things in their own work group, the enthusiasm is infectious.

"More specifically, what drives this new dynamic in our laboratory system is the concept of continuous improvement," McFadden explained. "Anyone can submit an 'improvement

request.' This triggers analysis of the situation, feedback, and implementation of a solution.

"How successful has this quality system been to our laboratories?" asked McFadden. "Between May 2002 and April 2003, our 400 employees, working at 21 laboratory locations, submitted 845 improvement requests, an average of 70 per month! The person originating these requests hears back in 14 days and, during that one-year period, 57% of those requests generated an implemented solution. Because measured outcomes are attached to these improvements, we know the cumulative difference this is making in our laboratory's quality and productivity.

High-Performance Lab

"I am proud to say that this is one of the traits of a high-performance organization," she noted. "Kaiser Permanente is committed to a collaborative working relationship with our labor partners. Along with the example of the improvement requests above, this includes development of self-directed work teams. Our new social design is a necessary component of our work environment and it contributes to this type of staff creativity and initiative."

Performance of the new laboratory facility validates the effectiveness of its unique design and ISO-influenced work processes. "During the first 14 months of operation, our average cost-per-test decreased by 8.7% while the average number of tests-per-FTE increased by 12.7%," observed McFadden.

"These numbers continue to move in the right direction," she added. "Our new lab facility is designed to support the application of quality management principles, as laid out in ISO-9000 and similar systems. But the real credit goes to the entire laboratory team. The quality management principles of ISO-9000 have truly given our entire laboratory team a new set of tools. Our staff now has an improved ability to understand work processes and respond with more directed solutions.

"Because of that fact, we expect to deliver continuing and substantial gains in both costs and productivity into future years," declared McFadden. "And there's more to come. We are working to optimize our courier runs, which cover 7,000 square miles, to meet or exceed the highly automated laboratory connectivity that already operates in our medical offices and hospital laboratories.

"There's also the need to support evolving efforts to improve patient safety and the laboratory's role in providing enriched clinical information to physicians and patients. Within Kaiser Permanente's integrated health system, our laboratory must be prepared to respond to a wide range of clinical and organizational initiatives," noted McFadden.

One big home run hit by the new laboratory is the performance of the high-throughput core lab. "The uptime performance of our automated line jumped from 60.5% to 99%," she said. "During the first 14 months of operation, productivity in this neighborhood more than doubled, increasing by 108%."

Two Simultaneous Changes

There is another important dimension to the story of KP-NW's laboratory division. "During the past 24 months, we have designed, built and radically changed all of the work processes in the new regional laboratory facility, even as we changed the organizational culture," declared McFadden. "I don't know of any other comparably-sized laboratory in the United States which has simultaneously achieved both goals in such a short time."

From the perspective of THE DARK REPORT, the accomplishments of Kaiser Permanente Northwest's ISO-9000-certified laboratory division and its new automated regional lab facility are noteworthy for several important reasons. First, ISO-9000 techniques allowed lab management to change the work culture and performance outcomes in ways that were impossible prior to adoption of the ISO system. Both lab staff and management now have greater control of work processes and outcomes.

Relevance Now Established

Second, the design, operation, and improved outcomes of the new automated regional laboratory facility is a real-world validation that quality management systems can take clinical labs and pathology groups beyond today's performance status quo. It is one answer that lab administrators and pathologists can use to further improve their own laboratory's productivity and outcomes.

Third, the impact of a quality system like ISO-9000 on the KP-NW laboratory division has been so positive that "there is no going back." Because it gives both lab staff and lab management better control over work processes, outcomes, and overall operations, this philosophy of management is now a permanent characteristic.

Most importantly, THE DARK REPORT observes that other early-adopter laboratories implementing ISO-9000, Six Sigma, Lean, and similar quality management systems are having the same positive experience as the KP-NW lab division. These are the early validations that quality management systems will steadily transform the way our nation's clinical laboratories are organized and operated. TDR

Contact Dixie McFadden at 503-258-6823.

Measured Gains From New Lab

By applying its ISO-9000 skills, Kaiser Permanente Northwest's new regional laboratory facility in Portland, Oregon is delivering significant improvement in productivity and quality measures. Listed below are recorded statistics from the opening in April 2002 through mid-June, 2003:

- 82.6% of all tests performed in the KP-NW laboratories are performed at the new regional lab
- Cost-per-test decreased 8.7%
- Tests-per-FTE increased 12.7%

Core Lab Neighborhood

(high-volume, high-throughput instrumentation)

- Autoline system uptime improved from 60.5% to 99%
- 108% productivity increase, relates to non-tubes handled by Prep & Read
- Routine hematology TAT runs at 13 minutes to 1 hour
- Chemistry TAT runs 30-40 minutes
- TAT for manual testing of coagulation and urines are within 1 hour

Shared Prep Neighborhood

(Consolidation of specimen prep for microbiology, histology, cytology, hematology, and core lab)

- Increased productivity by 50%

Read Neighborhood

- Microbiology productivity increased 20%
- No productivity increase in cytology and histology

Automated Storage

(highly sophisticated system of inventory control and specimen storage)

- Increased productivity by 50%
- Decrease in urgent orders saves $30,000
- Reduced expired inventory saves $15,000
- On-hand inventory reduced by $738,000
- FTEs reduced by 10%

Lab Industry Briefs

ARUP SNAGS MAJOR HOSPITAL SEND-OUT PACT WITH ASCENSION HEALTH

FOLLOWING AN EXHAUSTIVE RFP PROCESS, **Ascension Health** has selected **ARUP Laboratories, Inc.** to be its sole source provider of reference laboratory testing.

This national agreement covers all 67 hospitals Ascension Health operates in 20 states. With $8.5 billion in annual revenues, Ascension Health is one of the nation's largest health systems.

This new contract is notable, not the least because it excludes reference testing providers like **Quest Diagnos-tics Incorporated** and **Laboratory Corporation of America**. Ascension Health had at least three primary objectives in putting reference testing out to bid.

One, it wanted all participating hospital labs to steadily evolve toward one primary source for reference testing. Two, it wanted a reference testing partner willing to transfer technology and help it set up sophisticated tests in its hospital labs. Three, because many of its member hospitals had competitive lab outreach programs, Ascension Health wanted a reference laboratory that would not be competing against its hospitals for specimens originating in physicians' offices.

All of Ascension Health's three primary objectives reflect the needs of other large hospitals and health systems in the United States. In particular, Ascension's interest in a reference testing partner willing to help it move send-out tests back in-house to meet evolving needs of clinicians or economies of scale, and its choice of ARUP over one of the two blood brothers, may reflect the health system's concern that publicly-traded lab companies are "specimen vacuum cleaners." Their motivation is to maximize the volume of send-out work—and revenues—they generate from their reference testing clients.

Similarly, the stated objective that Ascension Health would prefer to select a primary reference testing laboratory that was *not* competing for physicians' office testing work reflects another marketplace reality. This puts the two blood brothers, with their extensive market share of physicians' office testing, at a disadvantage when bidding RFPs like the one completed by Ascension Health.

Over the past year, a growing number of larger hospitals and health systems have rejected one or both of the two national labs when selecting their primary reference testing provider. Taken collectively, their decisions may be early evidence that the business model used by the blood brothers is not compatible with the evolving needs of big hospitals and integrated delivery systems.

IMPATH'S PROBLEMS TRIGGER SPECULATION

TRADING IN **IMPATH, INC.** SHARES was suspended at the end of July when the company announced that the audit committee of its board was investigating "accounting irregularities regarding its accounts receivable."

As of press time, trading in IMPATH shares was still suspended. This is highly unusual and points to significant troubles within the company. Another problem is that IMPATH is short of cash. At the end of first quarter, it reported $1 million in cash and $4.8 million in marketable securities. That's not much cash to support operations for a company with 2002 annual sales of $226 million. TDR

Pathology Group Conflicts Over Equity Vs. Salary

Arrival and departure of pathologists in a group practice triggers difficult issues

***CEO SUMMARY:** During the next two years, two of every three pathology group practices will see a change in pathologists, either through new hires or by resignation and retirement. These events fundamentally change the financial situation of the group, but since most groups are organized under the business models of 1980s medicine, they struggle to find the right combination of compensation, equity, and retirement benefits.*

DURING THE 1990S, managed care damaged the pathology profession in many profound ways. Some are widely-recognized, such as reduced reimbursement. But others, like the unfavorable impact on pathology group practice shareholder arrangements, have yet to receive much public attention.

In recent years, THE DARK REPORT has watched different pathology groups around the United States attempt to address the question of equity versus compensation in their financial planning process. Unfortunately, conventional methods that proved successful during the 1980s are proving inadequate in today's environment of meager reimbursement for professional services and increasingly complex compliance requirements.

Struggles For Consensus

Because the "old ways" no longer meet the financial needs of today's healthcare marketplace, many pathology groups now find it extremely difficult to develop a consensus among their pathologists over issues of annual compensation, equity, productivity, and retirement benefits. Frequently, discussions about these topics generate conflict and rancor, as individual pathologists realize their group practice does not have enough cash flow to meet all the financial demands of its member-pathologists.

To help pathology groups develop effective strategies that are relevant for today's healthcare marketplace, THE DARK REPORT is convening a special symposium titled "How to Craft Effective Compensation & Shareholder Agreements for Pathologists" in Atlanta on October 24-25, 2003.

This special symposium will cover the A-Z of issues involving compensation agreements, shareholder arrangements, funding retirement plans, and developing productivity models linked to compensation. It is designed to meet the needs of pathology group practice administrators and pathologist-leaders, as well as individual pathologists interested in learning how to best negotiate their own compensation

Powerful Agenda Covers Pathologist Compensation

TO BE CONDUCTED ON OCTOBER 24-27, 2003 at the Hyatt Regency Hotel in Atlanta, "How to Craft Effective Compensation & Shareholder Agreements for Pathologists" features presentations on these topics and more:

Friday, October 24:

- Understanding Conflicting Interests in How Pathologists Want to Divide the Group's Revenue Stream
  – Richard Cooper, Attorney, McDonald Hopkins
- Financing a Shareholder-Pathologist's Buy-In or Buy-Out: Strategies and Financial Tools that Make Sense
  – Chris Jahnle and Kirk Rebane, Directors, Haverford Healthcare Advisors
- Pathology Practice Shareholder & Partnership Agreement Basics
  – Jane Pine Wood, Attorney, McDonald Hopkins
- Panel Discussion and Case Studies—The Balancing Act: Methods to Satisfy Retiring Pathologists Without Limiting Potential for Younger Pathologists

Saturday, October 25

- Critical Issues in Structuring Equity and Compensation Agreements from the Group's Perspective
  (Session A for practice administrators and pathologist-leaders, session B for individual pathologists)
- Financial Tools Used to Fund Compensation and Stockholder Agreements Between Pathologists and Their Group Practice
  (Session C for practice administrators and pathologist-leaders, session D for individual pathologists)
- Crafting A Good Pathologist Employment Contract
- Recruiting Surprises: What Today's Candidates Want from Their Prospective Pathology Group
  – Richard Cornell, Integro Medical Services
- Tax, Legal, ESOP, and Life Insurance Planning Issues
  – Thomas Ledbetter, J.D., Garrett Prather & Co.
- Breaking the Decision-Making Logjam in Pathology Groups: Proven Methods for Achieving Alignment Behind the Business and Professional Goals of the Group Practice
  – Greg Nelson, Development Dimensions, Inc.

For Information or to Register, call:
800-560-6363
or visit: www.darkreport.com

agreement, shareholder arrangement, and retirement package.

Struggle For Consensus

THE DARK REPORT believes that the difficulties in developing consensus about compensation, equity, and retirement issues is a major problem within the pathology profession. For example, when the **College of American Pathologists** (CAP) conducted its Practice Characteristics Survey in 2000, it determined that, in the previous two years, 62% of the nation's group practices had brought in a new pathologist and 52% of the groups had seen at least one pathologist depart. Of the departures, 49% were retirement.

Taken collectively, the numbers from the CAP study indicate that more than two-thirds of the nation's 3,300+ pathology group practices are dealing with financial issues relating to the arrival or departure of pathologists during any two-year period. Since the majority of pathology group practices have less than five pathologists, decisions about compensation, equity, productivity, and retirement planning have significant impact.

To present the pathology profession with new business models better-suited to today's reimbursement and compliance environment, THE DARK REPORT has assembled experts in law, finance, valuation, retirement planning, pathologist recruitment, and strategic leadership.

Relevant Business Models

Their charter is to update existing business models for pathology group practices. They will provide detailed strategies, techniques, and methods for developing effective agreements that help pathologists meet their personal financial needs while contributing to the ongoing clinical and financial success of their pathology group practice. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Recently **Laboratory Corporation of America** recruited and rehired three DIANON sales reps who had left the company following its acquisition by LabCorp earlier this year. On its second quarter conference call, LabCorp officials, under criticism for numerous departures of DIANON sales stars following the acquisition, pointedly noted that three of the ex-DIANON sales reps had "come back" to LabCorp. However, there's more to the story. THE DARK REPORT has learned, from multiple sources that LabCorp offered these three individuals promotions and compensation packages of a surprisingly sizeable amount. It appears that LabCorp paid a substantial price to woo back these three sales reps.

One of the nation's largest private laboratory companies still focused almost exclusively on physicians' office testing is expanding into new geography. **Clinical Pathology Laboratories** (CPL) the $100+ million firm based in Austin, Texas, has acquired a small lab company in Northern Virginia and will use it as a base to expand in that region.

DOC INCENTIVE PROGRAM ACTIVE IN BOSTON AREA

Bridges to Excellence, a consortium of large employers, area payers, physicians, and other healthcare entities is several months into a pilot program that will potentially reward top-performing physicians with additional reimbursement. The program focuses on chronic diseases. To calculate the incentive pool, payers calculated how much money they would save if care improved. For example, actuarial analysis estimates the program will save $350 per diabetic patient per year. Employers such as **Ford Motor Company**, **Procter & Gamble**, and **UPS** have committed to pay physicians with the best outcomes a bonus of up to $100 per diabetic patient. The goal is to give physicians and healthcare providers a direct financial incentive for actively improving the healthcare outcomes for patients they treat. Top-performing physicians will also be highlighted in the provider directories published by **Aetna**, **Cigna**, **UnitedHealthcare** and other participating health plans.

ADD TO: Doc Incentive

These types of incentive programs will impact pathologists and lab administrators in two ways. First, clinicians will want a higher level of lab testing services as one tool to help them achieve improved healthcare outcomes. Second, at some point pathologists themselves will be able to participate in these types of incentive programs.

LAB ADMINISTRATOR LIVES DOUBLE LIFE

Even as Dixie McFadden, Administrative Director of Laboratories, was dealing with the challenges of ISO-9000 certification and the design and construction of a new automated regional laboratory facility for **Kaiser Permanente Northwest** in Portland, Oregon *(see pages 9-14)*, she was in nightly training for her passion: country dance competition. The effort paid off. This May, McFadden earned "First Place Overall" in the Pro-Am Classic Female Silver Novice category at the Country Dance Competition in Fresno, California. McFadden also competes internationally, recently placing 11th in the CW World's competition in Nashville, Tennessee.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 8, 2003

PREVIEW #2

PATHOLOGY INCOME & EQUITY

October 24-25, 2003 • Hyatt Regency Hotel • Atlanta

Topic: Solutions for Resolving Conflicting Interests in How Pathologists Want to Divide Their Group's Revenue Stream

Explore the reasons why pathologists, at different points in their careers, have different financial objectives in terms of income, equity, and differing workload expectations. Then learn proven solutions and approaches to balance these different needs among pathologists in the group that also reinforces the continued growth and financial viability of the pathology group itself.

Full program details available soon! Call 800.560.6363
or visit darkreport.com

UPCOMING...

- ***Quantum Leap Forward in Lab Management: Achieving Huge Productivity Gains in the Core Chemistry/Hematology Laboratory.***
- ***Point-of-Care-Testing at the Veterans Administration: Success at Electronically Capturing Orders and Results.***
- ***Molecular Diagnostics Finds Profitable Home at Academic Center Laboratory.***

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