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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

Everyone Has an Opinion about Healthcare

IT'S NOT TOO OFTEN THAT YOU SEE A HEADLINE LIKE "U.S. Health System Care Has Collapsed." Not only is it a startling proposition, but it is grammatically incorrect. The source of this proposition is His Holiness Maharishi Mahesh Yogi.

In a press release dated February 23, 2003 from New Delhi, India, the Yogi "declared the U.S. health care system 'an appalling failure' and dismissed concerns by health leaders that the system is near collapse. 'The U.S. health system is not near collapse—it collapsed years ago'."

The Yogi did have some advice for all of us. "Maharishi called for those in charge of the U.S. health system—'those with an incomplete concept of health'—to be replaced by younger physicians who understand the most up-to-date scientific connections between mind and body, between consciousness and the physiology."

Besides advice, the Maharishi does have something to offer the American healthcare system, probably for a price. "He will soon launch his Vedic sound therapy," said the press release. "which utilizes sounds from the Vedic literature of ancient India to remedy disorders in the physiology...This is the correct approach to the prevention and cure of disease. The knowledge is available. We invite governments to make use of it as soon as possible."

At a minimum, the Maharishi Mahesh Yogi reminds us that not everyone views the world and its problems the same way. It is easy to recognize the problems with our healthcare system as it is today. It is more difficult to identify and implement reforms and solutions. Notwithstanding the current conflict in the Middle East, lawmakers in Washington continue to debate the future of Medicare and Medicaid.

It is unlikely that any substantial and far-reaching reform will be enacted. Democracies are messy and the partisanship on both sides of the aisle work against rational compromise. That's because everyone has an opinion, but no one wants to let another's proposal take effect. Expect the status quo to continue pretty much as it is today. For my part, I'd like to see the government try experimenting with "health vouchers." It would be interesting to see what happens when Medicare and Medicaid beneficiaries buy private insurance that best meets their needs. TDR

Why Patient Safety Is Change Agent for Labs

Emphasis on reduction of medical errors and raising quality will alter lab operations

CEO SUMMARY: In the 1990s, managed care was the dominant change agent to the nation's healthcare system. During the 2000s, it will be patient safety. However, unlike the unpleasant consequences of HMOs, capitation, and utilization risk, patient safety will prove to be a benevolent trend for physicians, hospitals, and laboratories.

By Robert L. Michel

THROUGHOUT the American healthcare system, priorities are shifting to include improvements in patient safety as a major objective.

Because of this fact, patient safety is a unique and identifiable trend within the American healthcare system. More importantly, patient safety is a trend that is making fast inroads.

Accrediting bodies are working swiftly to incorporate patient safety goals into their organization's accrediting guidelines. Because almost every healthcare organization of significance is accredited in some way, it is guaranteed that accrediting requirements designed to improve patient safety will force healthcare organizations to change many aspects of how they provide healthcare services.

But accrediting bodies are not the only force for change in healthcare. Policymakers in government and not-for-profit institutions are funding studies to identify where patient safety initiatives can yield the greatest benefit. As this data is made public, employers and consumers will demand high quality healthcare without medical errors.

In studying the patient safety movement and speaking to a variety of experts in this field, it is my conclusion that patient safety will be the primary change agent of this decade. Moreover, I believe the clinical laboratory industry will be extensively reshaped by patient safety during the coming years.

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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).

Today there is common agreement that the decade of the 1990s was dominated by managed care. It was the primary change agent until about 1998, when consumer rejection of the closed-panel gatekeeper HMO model became obvious to both employers and insurers.

Three Primary Changes

I can identify at least three primary changes that managed care brought to the laboratory industry by the end of the 1990s. First is the payer contracting model which gives all the business to just one or more selected laboratories. Non-contract laboratories in that region are excluded from providing services to that plan's beneficiaries.

Second is rock-bottom reimbursement by private payers. Whether capitation (which is still with us) or highly-discounted fee-for-service, payers at the end of the 1990s were paying a lot less for laboratory testing services than at the beginning of the decade.

Third is consolidated laboratory services. Because large regional HMOs wanted to transact business with a single laboratory provider capable of serving all beneficiaries in that region, laboratories found it desirable to develop those regional capabilities. Consolidation and regional laboratory networks were common solutions.

IDNs Were A Response

Everyone is familiar with the acquisitions and consolidations in the commercial laboratory sector. However, most hospital laboratories overlook the fact that multi-hospital "integrated delivery networks" (IDNs) came into existence because hospital administrators recognized the same need to have regional coverage as a way to support exclusive managed care contracts and have clout in contract negotiations with payers.

Plenty has been written on these pages about how hospital laboratory consolidation was a direct consequence of several hospitals coming under common ownership and management. This was a consequence of consolidation by the parent institutions.

Certainly managed care stimulated some other changes to the clinical laboratory industry during the 1990s. But the three items I've listed here are overwhelmingly dominant. And—they are permanent! No one today talks of undoing consolidated laboratories. There is no expectation that fee-for-service reimbursement will return to a provider's "usual and customary" fees. The same is true for exclusive contracting. Payers like dealing with a select number of laboratories.

Reasons Behind The Trend

This explanation serves two purposes. One, it demonstrates why I define managed care as the primary change agent of the last decade. Two, it identifies three important characteristics of the laboratory industry that were changed because of managed care.

That brings us to the present. Just as managed care was a dominant change agent during the past decade, I believe patient safety will be the dominant change agent for this decade.

For laboratory executives and pathologists, this is invaluable insight. When developing strategic plans for laboratory organizations, it provides context for understanding what types of forces will shape healthcare throughout this decade. It makes it easier to anticipate and prepare the laboratory staff to deal with these challenges.

For laboratories and pathology practices, strategic planning should center around two themes. First, what are the factors which make patient safety such a potent change agent? Second, how will patient safety initiatives change the way laboratories are organized and managed?

In earlier issues of THE DARK REPORT, we've written about why patient safety has emerged as a powerful trend. The trigger to this movement was the **Institute of Medicine's** (IOM) widely-publicized report on medical errors. It estimated that between 45,000 and 98,000 people die in hospitals each year as a result of medical errors.

Essentially, the patient safety movement is a way for employers to get the attention of healthcare providers and encourage them to reduce medical errors, to reduce the overall cost of care, and to improve outcomes.

What gave a different impetus to the IOM's report was the return of double-digit increases in annual healthcare spending. The nation's employers had recognized that the closed-panel gatekeeper model HMO was a failure in suppressing healthcare cost increases. Employers were looking for a way to control healthcare costs while improving quality.

Employer organizations like the **Leapfrog Group** and the **Midwest Employers Group on Health** developed a healthcare spending strategy that uses patient safety as the theme for reducing medical errors, while simultaneously reducing the costs associated with medical errors. Essentially, the patient safety movement is a way for employers to get the attention of healthcare providers and encourage them to reduce medical errors, to reduce the overall cost of care, and to improve outcomes.

Employers know that healthcare providers must manage their organizations differently if they are to meet patient safety goals. First, providers will need to accurately measure the existing status of medical errors. Measurements will be much more rigorous and detailed than was common in past years.

Second, providers will need a management method to use measurement data in a way that allows them to reduce medical errors. Again, compared to past years, this requires a different management mindset—and a different toolbox of management methods.

Third, along with measuring progress toward fewer medical errors, providers will be asked to improve quality. "Evidence-based medicine" is a hot topic in recent years because it requires clinicians to document that specific medical procedures are clinically effective *and* cost effective.

All of these factors logically point toward an interesting conclusion: to achieve deliberate and sustained improvement in the reduction of medical errors while simultaneously improving quality, healthcare providers will be forced to change both the management methods they've traditionally used, as well as the structural form of their organization.

Looking At Laboratories

Let me focus specifically on laboratories from this point forward. I put forward the premise that the overall performance of clinical laboratories has not changed significantly since the mid-1980s. From the time a specimen is collected, through accessioning, testing at the bench, resulting, coding, and billing, most of the nation's laboratories are doing about the same quality today as they did 15 years ago.

One confirmation of this comes from labs undergoing IS0-9000 and Six Sigma management projects. When individual work processes are

accurately measured, they typically score at 2.2 to 3.3 sigma. Three-sigma performance is 99.37% accuracy, or 7,300 "defects" per million events.

Operationally, laboratories today are performing all functions at about the same level of quality as they did prior to 1990. Probably the major gain in quality has come from diagnostic technology which has improved the sensitivity and specificity of individual assays.

Here is where patient safety will be the impetus to change this operational status quo. Accrediting agencies, payers, and employers will want laboratories to provide specific and detailed information on error rates and quality. Moreover, laboratories will need to document that, over time, they are continuously improving.

Boosting Performance

That means taking existing work processes, which today might generate a three-sigma level of quality in the typical laboratory, and moving them to higher levels of performance. A six sigma-level of quality means 3.4 errors per million events. To achieve this, laboratory administrators and pathologists will need a different management philosophy and a different set of tools than those used in the past 15 years.

These different management philosophies will be rooted in the quality principles first developed by W. Edwards Deming, Joseph Juran, and other pioneers in this field. What will be different for laboratories, indeed, the entire healthcare industry, is that accrediting requirements will reinforce the use of these types of management approaches.

Remember that old saying "if you want to understand why something is happening, follow the money?" In the case of patient safety, the money motive comes from employers. With good reason, their tolerance for a historical level of medical errors is ending. Episodes like the transplantation of incompatible organs into the young girl at **Duke University Medical Center** is an outcome from the "old" management method used by healthcare. Employers and consumers are changing their expectations about quality. Physicians, hospitals, and laboratories must recognize this change and respond appropriately.

Benevolent Change Agent

Unlike managed care as the change agent of the 1990s, patient safety will be a benevolent change agent in the 2000s. Everyone in the laboratory wants to do a better job. The goal of reducing medical errors and improving quality has universal appeal, just like motherhood and apple pie.

However, I believe that, unlike managed care, the patient safety trend will generate deep-rooted changes in laboratory operations. By the end of this decade, the structural form of laboratories will be much different than we know today. This will be a direct result of two things: the application of a different philosophy of management and the contribution of new technologies in diagnostics, information management, and the Internet.

Finally, I think it is important to remind you of something we've noted many times in THE DARK REPORT. One consequence of these changes will be that provider performance will be measured, ranked, and made public. This will be true of individual physicians, hospitals, pathologists, and laboratories. Now is the time to assess your laboratory's performance and prepare for this eventuality.

Presentations on how patient safety initiatives will impact laboratories will be part of this year's *Executive War College* on May 6-7. Those who attend will get a head start on understanding this important healthcare trend. TDR

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Medicare "Bill Back" Policies Vary By Lab

Different approaches to compliance may generate competitive advantage

CEO SUMMARY: When it comes to the subject of Medicare medical necessity, the classic "compliance conundrum" is again at work. Laboratories with conservative, strict compliance policies believe they are at a disadvantage at retaining physician-clients and winning new accounts when compared to other laboratories in their city which may be operating with more liberal, looser compliance policies.

MEDICARE MEDICAL NECESSITY DENIALS remain one of the thorniest issues in Medicare compliance for the coding and billing of laboratory tests.

The well-publicized competitive battles for market share of laboratory testing, particularly in North Carolina, has stimulated an extra level of scrutiny among lab competitors on a host of operational, sales, and compliance practices. Among other things, it seems that differences in how individual laboratories handle Medicare medical necessity denials has become a point of interest and debate.

Lab executives and pathologists are familiar with the problem. Whenever a referring physician fails to provide either appropriate documentation, diagnosis codes to support the medical necessity of the ordered tests, or valid ABNs, then Medicare denies payment and the laboratory which performed the test is left with a decision. Should it bill the cost of the test back to the referring physician? Or should the laboratory just eat the cost of the unreimbursed Medicare test?

Today the problem is not as severe as it was when new Medicare requirements for medical necessity were instituted in the second half of the 1990s. Most physicians have adjusted to this new fact of Medicare life and have done a better job of providing the documentation and information needed by the laboratory to correctly and successfully file reimbursement claims.

Troublesome Situation

But despite this improvement in physician cooperation, the situation remains troublesome for laboratories. First, a lab faces the unending dilemma of whether it should aggressively "back bill" physician-clients for tests denied by Medicare on grounds of inadequate documentation of medical necessity.

To not bill the physician means the laboratory must absorb the cost of the unreimbursed test. To "back bill" the physician for such tests creates stresses in what otherwise may be a strong business relationship.

Second, a lab faces competitive pressure in the marketplace whenever

other laboratories in the same city pursue a more liberal policy, even going so far as to seldom "back bill" a physician who habitually fails to provide the needed documentation for lab tests ordered on Medicare patients.

Strict Versus Loose Policies

Because such decisions involve dollars, there are always physicians who will direct their laboratory testing business to labs which are less aggressive at back billing their physician-clients. Call it the "compliance conundrum." Laboratories which take a strict and conservative approach in their Medicare compliance policies feel like they lose client accounts to laboratories which offer looser, more liberal compliance policies. Since Medicare regulators are notoriously reticent to issue clear regulations and opinions, laboratories are left to make difficult and subjective decisions about their compliance programs.

Intensified marketing wars in different regions around the country have again brought this issue to the forefront, particularly in the Carolinas. In some cases, laboratories are asking their legal counsel to review the Medicare medical necessity policies of their competitors.

Legal Review Requests

"I am seeing more such requests, particularly in cities where the competition is extremely intense," stated Jane Pine Wood, an attorney at **MacDonald, Hopkins** of Cleveland, Ohio. "Labs call me with rumors that another laboratory in their community is more lenient in requesting the required information from physicians, and may not be back-charging the physicians for all the Medicare tests which were denied because of inadequate documentation of medical necessity. Commonly they say something like 'this other lab doesn't require as much information as we do and the doctor is directing his account to that lab for that reason.'

"In such cases, it is difficult to properly assess the situation," explained Wood. "My laboratory client is frequently responding to information it got from a physician. Because the physician may have a financial motive to beat down the price of laboratory tests, particularly in states that allow a physician to mark up lab tests, the reliability of their statements about the policies and practices of competing labs must be questioned."

Conservative Compliance

Wood correctly identifies the competitive problem with a conservative laboratory compliance program. Some physicians do direct their laboratory testing business to labs which take a more liberal position on Medicare/Medicaid compliance.

"Laboratories with a relatively looser policy on compliance walk a very fine line," observed Wood. "At some point, their approach to compliance can put them in violation of several Medicare and Medicaid statutes.

"First is the obvious violation. By not diligently requiring the physician to provide necessary documentation prior to the test being billed to Medicare, the laboratory is failing to comply with the basic statutes governing medical necessity," said Wood. "Physicians are required by federal law to provide diagnostic information."

"Second, a relatively lax requirement for documentation may trigger anti-kickback issues," she continued. "For example, since the physician and staff are *not* providing all the information, it is saving them time and money. This could be considered inducement. Moreover, such a lax policy might also be encouraging the physician's non-compliance with appropriate Medicare statutes.

"Third, Medicare expects every laboratory to make an effort to bill and collect for the tests it performs. If the labo-

ratory's general policy is to never back bill the referring physician for Medicare tests denied due to chronic inadequate documentation of medical necessity, then the laboratory may be in violation of this Medicare requirement.

"Fourth, there are some interesting issues about whether this creates discrimination among Medicare patients," said Wood. "Assume two doctors are clients of the same laboratory that has a lax back-billing policy. Doctor A is diligent about medical necessity documentation and ABNs and Dr. B is not. If the laboratory is not back billing Dr. B, then his Medicare patients are getting free services that Dr. A's patients are not."

Focus On Finances

Attorney Wood's observations highlight the dichotomy of the law versus actual practice in the marketplace. Because many Medicare laws and regulations are written ambiguously and without clarity, providers struggle to implement a compliance program which meets both the requirements of the law and the intent behind the law.

But this same ambiguity opens the door for some providers to adopt a liberal, more lax compliance policy. With medical necessity documentation for laboratory testing, one laboratory's more liberal compliance policy can generate competitive advantage if it encourages a physician to select it over a laboratory which maintains a more conservative compliance program.

Not surprisingly, this compliance dichotomy surfaces most frequently in regions of the United States where two or more laboratories are fighting fiercely to expand their share of the physicians' office testing market. Most recently, North Carolina fits this description. If some physicians consider a lab's more lax compliance policy on Medicare necessity documentation and "bill-backs" to be in their financial benefit, the laboratory with the more liberal Medicare medical necessity documentation policies can win the account.

This is how competitive advantage accrues to a laboratory that chooses to operate a relatively loose compliance program. Until healthcare regulators from the federal government offer more detailed guidance, or take enforcement action against laboratories they deem to have violated existing laws and regulations, the "compliance conundrum" will continue to create an unequal playing field among laboratory competitors in cities around the United States. TDR

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NHIC Issues Reference About Medicare Policy

IN ITS APRIL 1992 Educational Outreach publication, the NHIC referenced the following on page 17:

Information has come to the carrier that some providers are telling their clinical labs that these requirements are too prohibitive and that they'll take their business to another clinical lab where they don't require ABNs or ICD-9 codes. Medicare must obviously take exception. If another clinical lab truly is not requiring diagnosis codes from the physician, then one of two things is occurring:

1) The laboratory is billing, taking the denials as a loss, and hoping to make a profit with the provider's other tests. This is referred to as "inducement" and could constitute fraud under Medicare.

2) The laboratory is plugging in payable diagnosis codes from the carrier's published local medical review policies. This is fraudulent activity on the part of the lab.

If you know that a clinical laboratory is practicing either of these two fraudulent activities, please call the fraud and abuse hotline at 800/952-8627 or 800/HHS-TIPS.

Early TLA Effort in London, England

Royal Free Hospital Is First Big British Lab Automation Project

CEO SUMMARY: To date, only a handful of total laboratory automation (TLA) projects have been implemented in Great Britain. One of those first TLA projects is at the Royal Free Hospital, Hampstead, located in the northern suburbs of London. Design work started in 1998 and the first phase became operational in 2000. Despite Britain's single-payer health system, most of the management themes and challenges were essentially the same as those encountered by early-adopter laboratories in Canada and the United States that were first to install total laboratory automation.

When it comes to lab automation, clinical laboratories in the United Kingdom (U.K.) have lagged behind their counterparts in Canada and the United States.

In North America, the earliest projects to implement total laboratory automation (TLA) became operational in the mid-1990s. In contrast, it was not until 2000 that the first major laboratory in the United Kingdom had an operational TLA installation.

The U.K.'s first TLA site was the laboratory at the **Royal Free Hospital**, Hampstead. Located in the northern suburbs of London, the Royal Free Hospital has 1,200 beds and is part of **University College Medical School**.

Tour Of The Royal Free Lab

During The Dark Report's visit to Great Britain last month to co-produce and speak at the first "Frontiers in Laboratory Medicine" program, it toured the Royal Free's laboratory. Tour host was Dr. Michael Thomas, Clinical Head of Service, Pathology and Head of Department, Clinical Biochemistry.

Royal Free Hospital is both a tertiary care center and a teaching hospital. Annually it serves 94,500 inpatients, 311,000 outpatients, and 58,000 "accident and emergency" patients. Laboratory services are extensive. The lab gets 1,500 requisitions per day and each requisition averages 9 tests.

"The Royal Free handles sizeable numbers of liver, kidney and bone marrow transplants," Thomas said. "We are also the largest treatment center for HIV in London and the U.K. Because of the large volume of potentially infectious samples handled here, we believed that laboratory automation in our biochemistry lab would improve both staff safety and the quality of our test results, all to the benefit of patients.

"Another goal was to consolidate a variety of testing technologies onto an automated line," he explained. "There are several obvious efficiencies that result from such a step."

However, the structure of laboratory services at the Royal Free made laboratory automation a daunting challenge. "Pathology comprises nine separate departments, ranging from biochemistry and haematology to virology and histopathology," recalled Thomas. "Each department had its own test order form. This meant we had lots of primary sample tubes which generated lots of aliquots. In fact, we estimated we could save more than U.S.$80,000 per year just by adopting a single type of primary sample tube.

Other Automation Challenges

"Another challenge was logistics and accessioning," he observed. "We have a complex method for picking up specimens in both the hospital and affiliated clinics, getting them into accessioning, and then distributing them out to the appropriate laboratory department. At the time we started this project, we also lacked a computerized order entry system. It wasn't until lab specimens reached accessioning that information was entered into the computer."

These challenges have a familiar ring to North American laboratorians. But the use of nine separate laboratory test requisitions within the Royal Free's lab division certainly is a complex factor seldom encountered in North American laboratories. Because of this and other factors, the effort needed to gain support and develop consensus about the need for an automated biochemistry and immunoassay testing line at the Royal Free's laboratory should not be underestimated.

Tangible planning for the laboratory automation project was launched in 1998. "This has been years in the planning and execution," said Thomas. "It's required us to remodel the laboratory, to replace our existing chemistry and immunoassay analyzers, implement a laboratory information management system, and reorganize staff responsibilities."

Royal Free Lab Serves Nearby Doc's Offices

GREAT BRITAIN'S single-payer health system uses regional health trusts to fund and manage healthcare services.

Because administration and payment is handled by a regional trust, there is more operational and clinical integration between hospitals and physician's offices than typically found in the United States. In the example of the Royal Free Hospital, its laboratory provides almost all the daily testing needed to support affiliated physician clinics in the neighborhoods near the hospital.

In contrast to the United States, the Royal Free Hospital laboratory picks up lab specimens from these physicians' offices and feeds these specimens into the lab throughout the day. Thus, by days' end, almost all routine testing has been done and the results reported to the referring clinic. Very little testing is done in the laboratory during the evening and night shifts.

This same-day turnaround time is unmatched by most labs in the United States, which pick up specimens from physicians' offices at the end of the working day, perform the tests during the night, and report most routine results by 8 a.m. the following morning.

Obtaining capital for a TLA project at the Royal Free Hospital laboratory was an essential first step. In contrast to capital budgets within most U.S. hospitals, in the United Kingdom, funding for capital improvements must come from a combination of the local health trust and the U.K.'s **National Health Service** (NHS). Like most the health programs of governments around the world, the NHS is strapped for cash.

"All areas of medicine are competing for capital for improvement projects," noted Thomas. "We considered ourselves fortunate that our funding requests were accepted. The NHS, centrally through its Modernisation Programme, provided the funding necessary to acquire the automated equipment and purchase a pre-analytical software system. whilst a lease agreement was reached between the hospital and the vendor for other components of the TLA system (analzyers, reagents, and consumables.)"

TLA Project Went To Bid

In 1998, the laboratory at Royal Free Hospital placed a "European Tender Bid" for its automation project. The tender was shortlisted down to three diagnostic vendors, each of which provided a detailed bid.

"The three bids involved **Bayer Diagnostics**, **Roche Diagnostics**, and a consortium of **Olympus**, **Diagnostic Products Company** (DPC), and **Labotix**," stated Thomas. "For a variety of reasons, we selected the Roche bid. Based on the products it could offer us in 1998, we believed they had the best solution for our laboratory's needs."

THE DARK REPORT also reminds readers that diagnostic instrument systems and test menus vary from country to country. This happens because there are differences in medical practices and differences in how national regulators review and approve diagnostic technology. That is why there would be notable differences in the mix of instrument and test menu choices offered to Royal Free's lab in 1998 (and other European laboratories) than what would be offered by these same vendors to labs in the United States.

Three-Phase Project

"Having selected Roche, it was decided to implement our automation project in three phases," Thomas said. "Phase one, started in 2000, was installation of the automated chemistry line. This included the analytical modules for chemistry tests. We selected an instrument configuration with a throughput of 800 col-

orimeteric tests per hour per module (2,400 tests per hour overall), plus 1,800 ise tests per hour.

"Phase two came six months later," he continued. "This involved connecting pre-analytical functions to the automated testing line, including the capabilities of centerfugation, cap and decap, and on-line and off-line aliquoting. The laboratory information system (LIS) we use is WinPath (**William Woodward Associates**), which is not available in the United States.

"Phase three saw the addition of immunoassay analyzers to the automated line. This was completed in early 2002. We have 42 assays on the automated chemistry and 26 assays on the immunoassay lines," added Thomas.

Thomas and his colleagues consider the automation project to be successful. "Our major goal was to maintain laboratory costs, post-project, at the level of 1998, before the automation project was launched," he noted. "We've done that even as we've gained additional test capacity and improved several important measures of laboratory performance.

Reduction in Average TAT

"For example, sample preparation times went from averages of 45 to 90 minutes down to averages of 17 to 27 minutes. There's been no change in average analytical times of 10 to 20 minutes. Overall averages before were between 60 and 120 minutes. Post-automation, our average is under 60 minutes," observed Thomas.

This accomplishment is all the more impressive because it not only includes the hospital's inpatient and outpatient work, but also specimens from nearby physicians' offices. Throughout the day, couriers pick up from the physicians' offices hourly. As a result, when the laboratory's day shift ends in the late afternoon, virtually all automated chemistry and immunoassay testing has been completed and reported to referring physicians. Office-based testing is about 15% of the total testing volume at Royal Free's laboratory.

Thomas claims the implementation went relatively smoothly. "Of course we had our share of glitches and unpleasant surprises," he conceded, "but the overall project went forward steadily, without major setbacks. We didn't experience major disruptions."

Evaporation Problem

One issue that proved a surprise was evaporation from sample tubes. "In our laboratory layout, during the time it took for the on-line aliquot tubes to get through pre-analytical to the analyzer itself, there was enough evaporation to affect test results," recalled Thomas. "Our solution was to install an additional air conditioning unit. The reduced laboratory temperature solved the evaporation problem."

Attention was also devoted to solving such problems as getting tests added or deleted while the specimen was on the automated line, centrifuge spin time, and false rack information alarms. "In hindsight, our selection of a primary tube was not the best because they can't be auto-recapped," said Thomas. "However, at the time this decision was made, nine different laboratory departments needed to agree on a primary tube. This illustrates the challenges we faced moving from our existing operational structure to the fully-automated chemistry and immunoassay line."

Staff Productivity Goes Up

Thomas described several other benefits from the automation project. "From a staffing perspective, we do more work with a reduced staff. There was measurable improvement in sick time, which dropped from 10% to 5%. Staff turnover rates have also declined," he added.

"Improvements to our work processes are significant," continued Tho-

mas. "Post-automation, error rates dropped. Not only were turnaround times reduced, but variability in turnaround times declined as well. Our lab can handle increased workloads and we utilize floor space more effectively."

As one of the first efforts to implement TLA in Great Britain, the Royal Free Hospital's laboratory seems to have avoided some of the serious operational issues which plagued the earliest automation attempts in North America. "I think one reason why that's true is because our automation equipment represents several generations of improvements," observed Thomas. "Throughout the multi-year process of bidding and planning, we saw our equipment options change as vendors introduced new features and capabilities. Some of the automation systems we finally installed in 2000 were not available during the bid process in 1998."

Management Differences

Another interesting difference in laboratory management in the United Kingdom versus the United States is the relative lack of intense focus on cost inputs, such as labor, supplies, and capital expenditures. Most lab directors and pathologists in the U.S. are keenly aware of productivity measures such as average cost per test, average med tech FTE productivity, and similar measures.

That is not the case in the United Kingdom. THE DARK REPORT observed that, during conversations between British lab administrators and pathologists and their North American counterparts, the North Americans invariably know specific numbers about their lab's costs, productivity, and related performance measures.

In contrast, most of their British peers did not have similar command and recall about their laboratory's performance in these areas. There seems to be an interesting explanation why this difference exists between each side of the Atlantic Ocean. During the 1990s, laboratories in both Canada and the United States saw significant year-to-year reduction in laboratory funding.

With less money available to reimbursement for laboratory testing, economic survival in Canada and the U.S. required laboratory administrators to look diligently for ways to eliminate unnecessary costs and improve productivity—even as they maintained or improved the laboratory testing services they provided to physicians in their community. In North America, survival required a more intense management of laboratory assets and resources.

Meanwhile, during the same decade in Britain, funding for laboratory services was not reduced in a comparably dramatic manner. Pathologists and lab directors could maintain a focus on clinical services. They did not have to cope with the extreme reimbursement pressure faced by so many of their North American counterparts during most of the 1990s.

Capital Funding Strategies

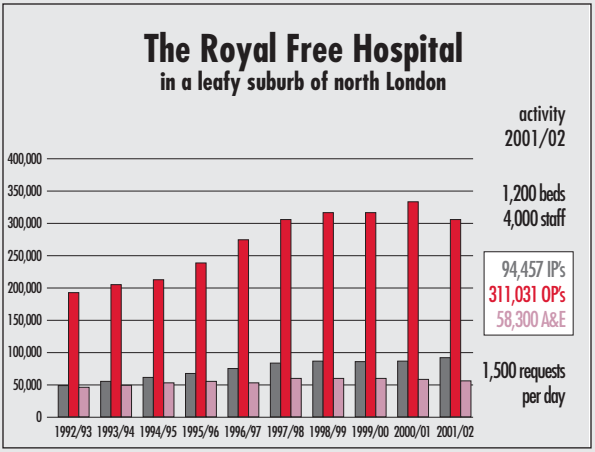
Capital funding is another reason why North American lab directors give so much attention to laboratory operations relative to their British colleagues. In the United States, hospital administration is much more likely to provide capital for laboratory improvements if the laboratory executive team can demonstrate the rate of return that will result from that capital investment.

In simplest terms, North American hospital lab directors recognize the fastest way to get the money they need to improve their laboratory is to demonstrate how such money will be deployed to reduce laboratory costs, improve productivity, and create a bet-

Rapid Growth in Patient Volume Supports Need For TLA in Lab

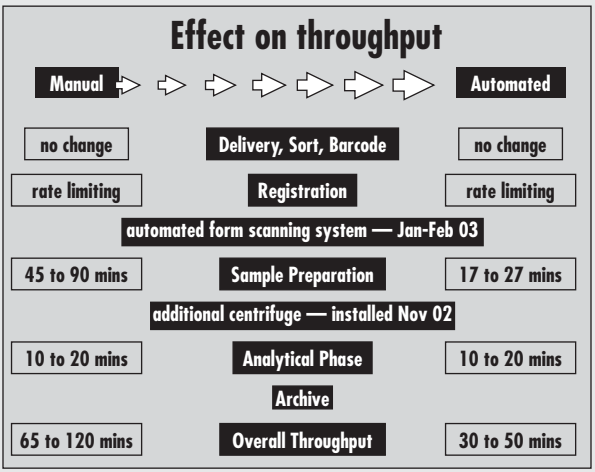
Annual Number of Patients

With the number of outpatients increasing 50% in the five years prior to 1998, the laboratory at Royal Free Hospital in London, England needed to expand throughput, improve productivity, and offer enhanced lab testing services. The chart at right shows the year-to-year totals for inpatient, outpatient and emergency (A&E) services.



TLA Outcomes At Royal Free Hospital Laboratory

Royal Free Hospital's laboratory automation project cut turnaround times by impressive amounts. The table at right shows that the biggest impact on turnaround times was in sample preparation and overall throughput. Other benefits were improved productivity, enhanced quality, and improved staff safety.



ter cash flow that returns capital back to the hospital.

Much of this will change for laboratories in the United Kingdom, however. The National Health Service is pushing for "pathology modernisation" which requires the nation's laboratories to consolidate lab testing services across several facilities and develop regionalized lab service organizations. For this reason, there will be lots of changes in the laboratory system which supports healthcare in the United Kingdom. TDR

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Pathologist Profile

Oldest "Working" Pathologist Dies at 104 on March 9

William Sunderman, M.D., Ph.D., Sc.D, a key figure in pathology profession during 20th Century

WORKING EIGHT-HOUR DAYS until a few weeks before his death on March 9, pathologist F. William Sunderman, M.D., Ph.D., Sc.D., lived a remarkable life.

During his 104-year life, Dr. Sunderman played a key role in founding the **Pennsylvania Association of Clinical Pathologists** in 1946 and is credited with developing one of the earliest proficiency testing programs. He served as President of the **Association of Clinical Pathologists** and was a founding Governor of the **College of American Pathologists**.

Career Accomplishments

His accomplishments are numerous. Dr. Sunderman developed a method for measuring glucose in blood (the Sunderman Sugar Tube). He was one of the first physicians to use insulin to bring a patient out of a diabetic coma.

Dr. Sunderman was a medical director for the Manhattan project at Los Alamos during World War II. He was a medical consultant for the space project at the Redstone Arsenal from 1947 to 1969 and served as Chief of the Clinical Pathology Department at the **Communicable Disease Center** in Atlanta, Georgia.

Born on October 23, 1898 near Altoona, Pennsylvania, Dr. Sutherman received his M.D. and Ph.D. from the University of Pennsylvania and became an intern at **Pennsylvania Hospital**, in Philadelphia. At the time of his death, he was still working at the hospital, editing journals and papers.

With a lifetime interest in music, Dr. Sunderman played the violin. He collected quality violins and the one he played most was a Stradivarius made in 1694 for Spain's Bishop Cardiz. During his travels in the 1960s to play with professional musicians, he discovered lost chamber music manuscripts by Rachmaninoff and Borodin in a Moscow music store. At the age of 100, Dr. Sunderman played his violin at a Carnegie Hall concert, fulfilling a lifelong ambition.

A prolific writer, Dr. Sunderman authored 300 scientific papers and 16 scientific books. He founded and edited the journal *Annuals of Clinical and Laboratory Science*.

Nation's Oldest Worker

In 1999, **Green Thumb, Inc.**, a federal work training program, recognized Dr. Sunderman as the nation's oldest worker. He was then 100 years old. At this time, when asked about the secret of his longevity, he decided to pursue the subject scientifically.

Dr. Sunderman wanted to analyze the blood of the 600-year-old tortoises in the Galapagos Islands. He traveled to the islands, but was unsuccessful at collecting blood samples. TDR

Lab Industry Briefs

BIO-REFERENCE LABS POSTS 20% INCREASE IN ANNUAL NET REVENUE

LAST YEAR'S FRENZY of laboratory acquisitions left **Bio-Reference Laboratories, Inc.** of Elmwood Park, New Jersey as the nation's third-largest public laboratory company focused primarily on physicians' office testing.

For that reason, Bio-Reference's ability to grow and sustain profits even as it competes against the two blood brothers makes it a useful marker for trends in the lab services marketplace. Earlier this year, Bio-Reference reported its fiscal 2002 earnings.

For fiscal 2002, Bio-Reference posted net revenues of $96.6 million. This was a healthy growth rate of 20.0% compared to 2001's net revenues of $80.6 million. Growth in net income was 108.4%, totaling $4.9 million in 2002 against $2.3 million in 2001.

Bio-Reference provides laboratory testing services to physicians located in New York and New Jersey. It has invested considerable resources in recent years to develop an e-health strategy. The goal is to provide added value beyond simply reporting laboratory test results to its referring physician-clients.

To further that objective, it has a joint venture with **Roche Diagnostics, Inc.** to collaborate in marketing CareEvolve, a Web-based laboratory test ordering and resulting system. It also announced the launch of a new hemostasis and thrombophilia laboratory under the direction of Yale Arkel, M.D. Bio-Reference wants to develop specialty testing services as part of its added-value lab services menu.

To position these new products and services more successfully, Bio-Reference Laboratories hired John Littleton to be its Vice President of Sales and Marketing. Littleton formerly was a sales executive at both **Specialty Laboratories, Inc.** and **Quest Diagnostics Incorporated**.

Bio-Reference has substantial sales momentum already. It has posted seven consecutive quarters of record revenue. Its success at building specimen volume and net revenue shows there is still opportunity to laboratories willing to invest in expanding market share.

SPECIALTY LABORATORIES WORKS TO REGAIN ITS REVENUE BASE

FOR LOTS OF REASONS, 2002 was a challenging year for **Specialty Laboratories, Inc.** of Santa Monica, California.

Early in 2002, Specialty Labs was hit by two adverse events. In February, Quest Diagnostics Incorporated announced that it would purchase Specialty's largest customer, **Unilab Corporation**. Then, in April, Specialty disclosed its licensure problems with state and federal laboratory regulators. These problems were resolved in July 2002. *(See TDR, August 5, 2002.)*

Both situations contributed to a decline in specimen volume and revenue at Specialty Labs. During fourth quarter 2002, the company posted net revenues of $29.9 million. This was down 31% from its net revenues of $43.3 million for fourth quarter 2001. During 2002, Specialty's net loss was $13.4 million, compared to its net profit of $13.1 in 2001.

Specimen volume for fourth quarter was 614,000. This was down 23%

from fourth quarter 2001, when specimen volume was 790,000. Significantly, fourth quarter test volume was down 10.5% from third quarter 2002, when it was 685,000 specimens. This indicates that there may still be some client defections as a result of its licensure problems.

However, since CEO Douglas Harrington, M.D. assumed his duties last spring, Specialty Laboratories has undergone a comprehensive makeover. Harrington has used Specialty's moment of crisis as an opportunity to revamp operations, refocus the company's extensive menu of esoteric testing, and put a new public face on the company. These changes should become visible throughout the remainder of the year.

QUEST DIAGNOSTICS ADDS TRIPATH'S SUREPATH TO ITS LIQUID PREP MENU

AS EXPECTED BY MANY, Quest Diagnostics Incorporated announced on March 5 that it had signed a collaborative agreement with **TriPath Imaging, Inc.** to add TriPath's Pap smear testing products to its test menu.

The agreement covers Tripath's SurePath™ liquid preparation kit, the PrepStain™ slide processor, and the FocalPoint™ slide profiler. Quest Diagnostics will place these products in selected locations for evaluation.

Under an earlier multi-year agreement with **Cytyc Corporation**, Quest Diagnostics offered Cytyc's ThinPrep™ test exclusively. Observers believe that Quest Diagnostics wanted leverage against Cytyc to improve pricing and other terms. Because its exclusive agreement with Cytyc had ended, the company was free to look at other products for Pap smear screening. Quest Diagnostics has not yet disclosed how it intends to market both products.

EMERGING DISEASE USES TECHNOLOGY FOR QUICK REPONSES

THERE'S A NEW DISEASE attracting headlines worldwide. Severe acute respiratory syndrome, called SARS, was swiftly recognized as a potential threat when the first cases were identified in recent months.

The disease emerged from China and is believed to have infected at least 300 people outside that country. By mid-March, investigators in Hong Kong had identified the source. **The Centers for Disease Control** (CDC) said today that the leading suspect is a new virus in the coronavirus family, known to cause common colds in humans.

Now the race is on to develop a treatment for SARS. Within the United States, the CDC is investigating 13 people who may have the disease. All have traveled to Asia or had close ties with someone who did.

What is astonishing to watch is the speed with which the international public health community responded to this new threat. Last week, it was announced that investigators in Hong Kong had identified the carrier who brought the disease from China into that city as Dr. Liu Jianlun. He was a professor and kidney specialist who caught SARS in mid-February while in China working at a hospital that was treating patients with the disease.

He then traveled to Hong Kong. While in the hotel, Professor Liu infected at least seven people who either stayed on the same floor as he or who visited that floor. One of the hotel guests who caught SARS was an American citizen who traveled to Vietnam and infected people there.

The positive aspects of this story are the rapid successes by the public health labs of many countries to quickly identify the disease and track its spread from nation to nation. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Wholesale prices for general acute care hospitals has climbed steadily in recent months. As tracked by the **U.S. Labor Department's** Wholesale Producer Price Index, hospital prices increased 0.5%. For the 12 months ending in February, hospital prices were up 4.7%. This is almost double the annual rate tracked by the Labor Department in 1999 and 2000. The hospital price index climbed 3.4% in 2002, which was the highest increase since 1995.

Here's a new book you might find interesting. *The Hitchhiker's Guide to Improving Efficiency in the Clinical Laboratory* was co-authored by Fredrick L. Kiechle, M.D. and Rhonda Ingram Main of **Beaumont Health System Laboratories** in Detroit, Michigan. It covers a variety of laboratory management issues to help cope with declining reimbursement and managed care. The book was published by the **AACC Press**.

MASSACHUSETTS BLUE CROSS TO PAY FOR ON-LINE ADVICE

In Massachusetts, **Blue Cross Blue Shield** is launching a pilot program that pays physicians for on-line consults with patients. The goal is to increase patient access to doctors for non-urgent medical problems. Blue Cross will pay physicians $20 for email consults about medical issues which meet certain clinical criteria. The physician will also get a co-pay from the patient of between $5 to $15. About 500 physicians will participate in the first phase of this program.

MORE ON: E-Consults

The action by Massachusetts Blue Cross Blue Shield to initiate reimbursement for email consults between patients and physicians shows how consumer demand is changing long-standing medical practices. Use of the Internet to provide healthcare services will continue to increase. As payers, physicians, and patients increase their use of Internet-based services, THE DARK REPORT expects the legal and cultural barriers against wider use of telemedicine will fall. This should benefit laboratories, because it will give them a viable way to provide added-value services in laboratory medicine, regardless of where the physician or patient is located.

QUOTE OF NOTE

Now and then THE DARK REPORT runs across a pithy comment that is worth passing along because it succinctly changes the way one might look at an issue. Today's gem comes from Thomas Sculley, Chief Administrator of the **Centers for Medicare and Medicaid Services** (CMS). In a talk at a **Blue Cross/Blue Shield** briefing on hospital costs last December, Scully had this to say: "As an insurance model, Medicare is a joke. It's a big price-fixing government monster that's slow to react when we make mistakes."

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 14, 2003