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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

International Tempest in Lab Industry Teapot

MAYBE ALL OF US IN THE LABORATORY PROFESSION GOT A GOOD LESSON in the deficiencies of the national and international media during the past month. I am referring to the screaming headlines last month about how four laboratory proficiency testing (PT) programs sent 4,000 laboratories virology PT kits with live H2N2 influenza virus. *(See pages 10-14.)*

THE DARK REPORT collected a wide range of news stories about the issue. Reporters wrote stories with headlines about the "deadly" H2N2 virus and how public health organizations had acted swiftly to prevent the possibility that a laboratory accident could expose a lab worker to the H2N2 strain and cause it to spread into general population. Yet, these same reporters did not research the important details of how proficiency test programs are run, the differences in PT kits designed to test for culture method and antigen method, and the possibility that, after four decades, the H2N2 strain may be attenuated to the degree that it has lost the virulence that caused so many deaths during the 1957-58 world pandemic.

My point is that all the media outlets we reviewed covered this story only from one angle. They listened to the press conferences conducted by public health organizations, then called public health laboratory officials for further background and information. What was missing through all this coverage was the voice of the clinical laboratorian, specifically the clinical laboratories which received the PT kits with the H2N2 virus. Laboratories participating in proficiency testing programs did not have the same level of concern. Many handle even deadlier pathogens on a daily basis. That fact was never mentioned by news reports.

I believe we all got a timely reminder about an important issue in laboratory management. Every laboratory and pathology group practice should have a contingency plan ready to deal with the media. It is the unexpected event, the sudden accident, which can thrust a laboratory into public scrutiny. When the flood of press calls inundates the laboratory, it is too late to develop a strategy and respond in a controlled, effective manner.

Public trust in local and national laboratories is essential. The "H2N2 Affair" is a reminder labs must be prepared to deal with negative publicity at the most unexpected moments and when such media questions are probably most unwelcome. TDR

"Coming Out" Party In Atlanta for IQLM

April meeting directly confronts issues of patient safety and quality

CEO SUMMARY: It was like a debutante ball for the fledgling Institute for Quality in Laboratory Medicine (IQLM). Over three days, thought leaders in healthcare and laboratory testing tackled the issue of how laboratory medicine can improve patient safety and contribute to higher-quality health outcomes. Key themes emerged with the potential to impact all laboratories and pathology group practices.

WHEN IT FIRST BECAME KNOWN a couple years back that, with the support of the **Centers for Disease Control and Prevention** (CDC), there was an effort to create an institute to address patient safety and quality in laboratory medicine, THE DARK REPORT considered this to be a significant development.

That prediction was validated in Atlanta on April 29-30, 2005 at the 2005 IQLM Conference "Recognizing Excellence in Practice." IQLM is the acronym for **Institute for Quality in Laboratory Medicine**. The April meeting was its "coming out" party.

One of the major goals of this conference was to introduce recommendations on specific ways to assess—from a national perspective—patient safety in labs and to develop indicators about the quality of laboratory practices. These recommendations are the product of almost two years of development effort by working teams within IQLM. *(See TDR, July 23, 2003.)*

This is not news for clients and regular readers of THE DARK REPORT. Besides coverage on these pages, we've hosted presentations by key IQLM leaders at the *Executive War College* in 2003, 2004, and 2005. THE DARK REPORT believes the creation of the IQLM, with the aid of the **Centers for Disease Control and Prevention** (CDC), to be a milestone event for the laboratory medicine community.

First, consider the source. The CDC, an initator of the effort, carries clout within the American healthcare system.

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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, $13.65 per week elsewhere (billed semi-annually).

Its decision to put considerable resources into creating the Institute for Quality in Laboratory Medicine is a strong statement of how the government health establishment views the importance of laboratory medicine and its ability to contribute to better healthcare outcomes in a cost-effective manner.

Credible, Powerful Force

Second, by launching a public/private partnership organization "formed to engage the healthcare community in improving the use of laboratory tests and services," the CDC is creating what it expects to be both a credible and powerful force. IQLM aims to drive change and improvement through three primary initiatives.

One initiative is to create an awards program that rewards laboratories which make demonstrable and exceptional gains in patient safety and quality of lab testing services. The second initiative is to issue a national "white paper" report which puts attention on the collective performance of laboratories in patient safety and quality from one year to the next.

The third initiative is the most ambitious. It is to develop national measures/indicators that reasonably gauge the performance of laboratories—and how well clinicians are using lab testing services to improve patient safety and healthcare outcomes.

First Recommendations

That is why the IQLM's 2005 conference is important to the laboratory industry and healthcare. Following two years of development efforts, IQLM's three work teams formally placed their findings and recommendations before the healthcare community. Over the three-day conference, participants engaged some of the keenest minds in healthcare and laboratory medicine in discussions about one topic: how laboratory medicine should be utilized to make its maximum contribution to solving the host of recognized problems and deficiencies in the American healthcare system.

"Keen minds" is not an understatement. The IQLM awards work group is tasked with developing some type of national laboratory awards process to recognize advances in patient safety and laboratory quality by individual labs. For the 2005 IQLM conference, it chose to recognize ten living individuals for their lifetime achievements in advancing quality in laboratory medicine.

These included James O. Westgard, M.D., Ph.D, Dennis O'Leary, M.D., Kenneth W. Kizer, M.D., and Michael LaPosata, M.D., just to name a few. The complete list of these awardees and their accomplishments can be found at *www.iqlm.org*. Their presence made this a laboratory industry summit that has no precedent in many years.

Indicators Work Group

Because laboratory testing is integrated into so many aspects of healthcare, it is particularly challenging to identify specific indicators/measures that accurately describe the state of laboratory testing services. That was the task of the indicators work group. It released its first draft of recommendations during the second day of the 2005 IQLM conference.

It has identified 12 promising measures to accomplish that goal. These 12 items are a first attempt to capture the full spectrum of pre-pre-analytical to post-post-analytical elements that play a role in the effective ordering, performing, reporting, and application of lab testing. The indicators work group's list of 12 measures and two explanatory slides is shown on the page opposite.

From the inception of the Institute for Quality in Laboratory Medicine, the guiding spirit has been Joe Boone,

First Look at IQLM's 12 Measures To Evaluate National Lab Quality

MEMBERS OF THE INDICATORS WORK GROUP probably had the toughest assignment within the Institute for Quality in Laboratory Medicine (IQLM).

Their charter was to identify a relevant "core set of indicators for laboratory practice." The workgroup framed this with a couple of questions: "If Congress wanted to quickly know about America's laboratories, what information should they have? How would indicators describe laboratory medicine's contribution to the nation's health? What indicators would measure what is important to the nation that should also be important to its laboratories?"

Presented here are three slides shown in Atlanta at the IQLM conference by Workgroup Co-Leader Lee Hilborne, M.D., Director, Patient Safety & Quality at **UCLA Medical Center** in Los Angeles, California. The full presentation can be found on the Internet at the IQLM Web site address of: *www.iqlm.org*.

The Following List Encompasses The Highest Priority Items

1.	Diabetes monitoring	(system)
2.	Hyperlipidemia screening	(system)
3.	Patient identification	(pre-analytic)
4.	Test order accuracy	(pre-analytic)
5.	Blood culture contamination	(pre-analytic)
6.	Adequacy of specimen information	(pre-analytic)
7.	Accuracy of Point of Care Testing	(analytic)
8.	Cervical Cytology/Biopsy Correlation	(analytic)
9.	Critical value reporting	(post-analytic)
10.	Turnaround time	(infrastructure)
11.	Clinician satisfaction	(infrastructure)
12.	Clinician follow up	(system/general)

The Indicators Group Was Given A Specific Agenda

Define a core indicator set for laboratory practice

- Institute of Medicine (IOM) quality domains
- Cover total testing process
- Practice settings

Be judicial in selection

- Perhaps 3-5 domains, 3-5 measures per domain

How should indicators be used?

- Surveillance for quality across organizations
- Identification of best practices for awards
- Ability to monitor through the IQLM Network

Review and incorporate existing evidence

- Identify evidence gaps related to core indicator set
- Determine strategies to fill the gaps

Some General Themes Emerge

System indicators likely are better supported by the evidence on health outcomes

- Selected because of their impact on patient outcome
- Results are linked to evidence-supported specific care interventions

Laboratory indicators are less frequently supported by ties to health outcomes

- Most of the work has been done by CAP
- Definitions for many are clear or could be standardized
- Linked to intermediate outcomes but links to health outcomes are generally inferential

Ph.D., Associate Director for Science at the Office of Public Health Partnerships at the CDC. In his address to the conference, Boone laid out the next phase in IQLM's development.

> ***"It is important to identify 'best practices' and spread that knowledge across not just the laboratory industry, but across the clinical community as well."***
> ***—Joe Boone, Ph.D.***

"Working in tandem with the **National Quality Forum** (NQF), we will produce a series of conferences in 2005 and 2006," he said. "The first conference will investigate what laboratory quality means to the 260 member organizations of NQF. Using information developed from that conference, a second conference will occur by the end of 2005 with the goal of determining measures that would be useful to access the quality of laboratory services.

"Building on that work, the first conference in 2006 will determine the utility of tests currently used in laboratories," continued Boone. "This will be followed by a conference later in 2006 to develop appropriate programs that encourage better utilization of laboratory tests across the healthcare system."

IQLM already has partner councils with over 65 partners that include healthcare organizations and healthcare vendors. "We intend to work with our partners to translate the results from these conferences into tangible programs," he stated. "In particular, IQLM wants to develop research and mentoring programs. It is important to identify 'best practices' and spread that knowledge across, not just the laboratory industry, but throughout the clinical community as well."

During the 2005 IQLM Conference, discussion and debate was sustained at an unusually high level. This was attributable to two factors. One was the breadth of excellence among the speakers. The other was a thoughtful and challenging audience of over 300 people. Included were laboratorians and participants from a broad cross-section of healthcare. Representatives from several foreign countries were in attendance.

THE DARK REPORT offers three key insights from this meeting. First, healthcare policy makers from several prominent organizations were in agreement on one point: the laboratory profession is failing to get its message across at the highest level of debate. Lacking a strong voice at the policy-setting table means that laboratory medicine will struggle to make a more effective contribution in efforts to reform the healthcare system.

Information Technology

Second, information technology (IT) remains the major obstacle in reforming the American healthcare system. Laboratories and providers which bring forth innovations in IT will thereby be best-positioned to add value.

Third, recognition that the American healthcare system currently fails to deliver the high quality of care necessary to meet needs and expectations of all stakeholders has triggered a fundamental change in healthcare. An inexorable march is under way to collect accurate information and use this information to drive improvements in the quality and cost of healthcare services.

Ultimately, the most important news is that the Institute for Quality in Laboratory Medicine is now a player on the national scene. Lab managers and pathologists can expect to see its influence grow during the next 24 months. **TDR**

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JCAHO, NQF CEOs Speak to Lab's Future Role

IQLM confab provides useful insights about evolving role of lab medicine

CEO SUMMARY: What an opportunity! On the same podium were the presidents of both the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Quality Forum (NQF), specifically to speak about laboratory medicine's role in the evolution of the nation's healthcare system. Their opinions and predictions provide useful clues to what lies ahead for all laboratories.

By Robert L. Michel

THERE ARE LOTS OF REASONS why healthcare leaders of national stature seldom deliver public speeches devoted to the subject of laboratory medicine and its role in the healthcare system.

Thus, when Kenneth W. Kizer, M.D. and Dennis O'Leary accepted an invitation by the **Institute for Quality in Laboratory Medicine** (IQLM) to speak on this subject, it was an important event. Kizer is President and CEO of the **National Quality Forum (NQF)** and O'Leary is President of the **Joint Commission on Accreditation of Healthcare Organizations**.

Thought Leaders' Insights

I am writing this at the IQLM meeting. My objective in this intelligence briefing is to share with you key insights which emerged from presentations given by these two thought leaders in healthcare policy. Each presentation is an uncommon opportunity to hear how such policymakers view the role of laboratory medicine in healthcare. More significantly, these thought leaders commented specifically on what the laboratory profession should be doing to establish its value proposition in ongoing health policy discussions.

IQLM's conference was kicked off by the keynote speech delivered by Dr. Kizer. His overview of increased healthcare cost and failure of the system to provide better quality care would be familiar to most healthcare professionals. That was the foundation for his observations and predictions about how various forces of change would reshape the American healthcare system in coming years.

Kizer observed that 1998 was the "watershed year for explicit recognition of healthcare's quality gap." He referenced such publications as *Quality First: Better Health Care for All Americans* (**President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry**) and the **Institute of Medicine's** (IOM) "The Urgent Need to Improve Health Care Quality" *(JAMA* 1998: 280: 1000-1005).

He next discussed employers and their response. "Certainly the double

digit increases in the cost of health benefits to employers is widely-known," stated Kizer. "This is motivating employers to take proactive steps to slow down the rate of such increases. Those initiatives can be seen in the support employers give to organizations like the **Leapfrog Group** and the **National Business Coalition on Health**.

"Further, employers see the health of their workers declining, even as the cost of their health benefits is climbing," noted Kizer. "This creates a powerful economic motive for employers to take proactive action to improve healthcare. Improvements in the overall health of their workforce reduces the cost of sick days and the lower productivity attributable to how the healthcare system fails to deliver the right quality of care."

Kizer is making a significant point. He has identified an often-unrecognized, but powerful, economic force that motivates employers to confront healthcare providers and demand improvement in the services they provide to patients. I view this as an opportunity for the laboratory profession. In coming years, we may find employers interested in working directly with laboratories to improve how clinicians use laboratory testing for early detection, diagnosis, prognosis, and patient monitoring.

Business Case For Quality

Kizer believes one way to improve existing deficiencies in the healthcare system is to use the vehicle of payment to change healthcare outcomes. "The problem with the business case for quality is that the existing payment system neither rewards nor incentivizes providers to improve current levels of clinical service," he declared, adding that the number of pay-for-performance programs was growing rapidly, but design flaws in many of them were likely to retard their ability to produce better quality healthcare outcomes in the near term.

One point made by Kizer succinctly captures a change in consumer attitudes. "Patients are shifting from blind trust in their healthcare providers to wanting transparency and collaboration in their interaction with their healthcare providers," he commented. "This is a paradigm shift which providers must recognize, or they will become irrelevant."

Important Consumer Shift

Lab administrators and pathologists should not let that observation go unaddressed within their laboratory. Kizer is describing a fundamental shift in the consumer mass market. His use of terms like transparency and collaboration describe traits not intrinsic among many physicians and healthcare providers. Consumers want an active role in the decisions made about their care, but many providers are not prepared to interact in such a fashion.

As he finished his presentation, Kizer made a bold statement which plays right to the strength of all laboratories. "Healthcare is the most information-intense activity in human history. All healthcare is driven by information, so progress in healthcare informatics is critical. Healthcare needs a Manhattan Project [to solve its information technology roadblocks]," stated Kizer.

Since all clinical laboratories are essentially information factories, Kizer's statement promises a key role for laboratory medicine in the future. However, Kizer qualified this point. "Laboratory medicine is not at the table today," he said when discussing how decisions to reform and evolve the healthcare system are now being made. "Without a place at the table, it is unlikely that such reforms will take full advantage of how laboratory medicine can contribute to higher quality healthcare outcomes."

Echoing this last opinion was another influential and respected healthcare leader. "Laboratories need to make their case with policy makers," stated Dennis O'Leary, President of JCAHO during a panel discussion. "Laboratory medicine has great potential to contribute in improving quality and outcomes while managing the cost of care. But in discussions on how to reform and improve our system, laboratories must make their case."

During his prepared remarks, O'Leary elaborated on this point. "Laboratories represent a link across many areas of healthcare," he stated. "For that reason, it is imperative that labs develop a systems approach in how they inter-relate with the healthcare system.

"Laboratory medicine is not a silo," he continued. "People in labs need to reach out and engage these other areas of the healthcare system. Much of the future of laboratory services rests upon good leadership and initiative from within your profession."

Labs Lose Accreditation

Having offered that advice, O'Leary next discussed a recent development. "During the past year, 12 to 14 hospital laboratories were found to have serious problems, to the point of withholding accreditation," he noted. "We don't yet fully understand why so many labs fell out of compliance. We need to go deeper. This may be an unusual 'blip,' or it may be an early sign that more laboratories are on 'on the edge'."

O'Leary then directly confronted the issue of the medical technologist (MT) shortage. "On the surface, I can see potential parallels to the nursing shortage. It may be that there are not enough trained technical staff to work in our laboratories," he explained.

"At that same time, the complexity of laboratory testing is increasing, and that only makes the labor situation worse," continued O'Leary. "This raises the stress levels in the working environment. Not only is there a lack of adequate med techs to perform the work, but the work itself is becoming more complex and detailed.

"At the same time, there is a trend where MTs with four years of training are supplemented with medical laboratory technicians (MLT), trained in a two-year program," he commented. "This shift in the balance of skills, combined with working in situations that are increasingly complex, may be causing laboratory staff to leave the laboratory profession."

Crisis In Lab Staff Shortage

O'Leary is making a significant point. It is a sign that, at the highest levels of JCAHO, there is recognition that the nation's hospitals face a serious crisis if their laboratories lack an adequate and trained staff to do the lab testing necessary to support their patient populations.

Moving to another point, O'Leary gave a big thumbs up to the use of quality management methods in laboratories. "Lean and Six Sigma are effective tools to fix [work] processes," he declared. "That favors patient safety and contributes to better healthcare outcomes."

In his own way, O'Leary also validated the important role of information technology and its link to laboratories. "In striving to improve outcomes, we need to know, with confidence, that laboratory test results are electronically delivered to referring physicians," he offered. "It is essential that accurate and timely information be in the hands of clinicians when they make the decisions which affect patient care."

These comments by Kizer and O'Leary provide useful insights about their views on the ongoing evolution of the healthcare system. Laboratories can use these insights to better focus their strategic thinking. TDR

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Managed Care Update

Horizon and Caremark Rx Put $3 Mil into E-Prescribing

Horizon BC/BS's 700 highest-prescribing docs are getting full e-prescribing capability

IT'S A $3 MILLION BET on the value of electronic prescribing by physicians. **Horizon Blue Cross/Blue Shield of New Jersey** and **Caremark Rx** are teaming up to subsidize the cost to convert 700 physicians onto electronic prescription systems.

The $3 million subsidy will cover the cost to provide a PDA (personal digital assistant), a printer, **iScribe's** prescribing software package, installation, and training. The program is targeting the 700 physicians who generate the largest volume of prescriptions in Horizon's provider network.

The new prescribing tools will support three primary functions. First, the prescription will be electronically transmitted to a printer in the physician's office and to selected pharmacies equipped to receive the transmission. Second, the software package enables the physician to check for drug interactions at the point of care. Third, the system will perform compliance checks.

Value of E-Prescribing

This is Horizon's second attempt to encourage physicians to prescribe through an electronic system. In 2000-01, it offered an e-prescribing initiative to which only 90 physicians responded. A lack of effective training of both physicians and office staff was one reason that participation was not better.

It will cost Horizon and Caremark Rx an average of about $43,000 per physician to provide the system and training. The willingness to subsidize costs of this magnitude to encourage e-prescribing by physicians demonstrates how much value will accrue from e-prescribing arrangements.

Savings Justify The Expense

Obviously Horizon and Caremark have calculated the savings. It is expected e-prescribing will reduce errors from illegible handwriting. There will be fewer adverse patient events caused by either the physician prescribing the wrong prescription or failing to anticipate negative drug interactions and negative side effects. Of course, another benefit is that the system is digitally capturing prescribing activity, which leads to more accurate clinical records and the ability to more precisely measure outcomes and conduct clinical studies.

Most lab managers and pathologists will make the obvious connection between e-prescribing and electronic ordering of laboratory tests. Horizon's initiative, and the growing numbers of physicians willing to use e-prescribing, are market forces which convert physicians away from paper Rx pads and lab requisitions and onto computer-based systems. The process of conversion from paper to computer screens is gathering momentum. TDR

Ramifications From The "H2N2 Virus Affair"

It was a "ho-hum" story to many laboratorians, and unreported details tell a different story

CEO SUMMARY: Here's the story, with new details, about how a patient sample, cross-contaminated with a "deadly" strain of influenza virus from a proficiency test kit, triggered alarm bells at the highest levels of public health in Canada, the United States, and the World Health Organization. It's story that has few heros and reveals the politics of public health. And this story has not been reported...until now!

BY NOW, MOST EVERYONE in the lab industry has heard about the brouhaha which followed the discovery that more than 4,000 laboratories in 18 countries were sent the "deadly" A/H2N2 strain of influenza virus by at least four laboratory proficiency testing programs.

It was an international story. Television and newspaper coverage was extensive. Government health officials acted swiftly to assure the public that there was little chance that a laboratory accident would introduce this virus into the environment and trigger a new influenza pandemic. For several days, the nation's clinical laboratory industry was in the media spotlight—and not necessarily in a complimentary way.

Yawns in Clinical Labs

But what went unreported in the national news was that, within the clinical laboratory industry, this story was a "yawner." Outside of the public health community, many individuals working in clinical laboratories considered the hubbub about live H2N2 virus going out in proficiency test kits to be a non-story.

On the surface, it is an inexplicable dichotomy. At one extreme, public health officials—and directors of public health laboratories—were telling reporters that live H2N2 flu virus was "deadly" and a lab accident had the potential to trigger a worldwide influenza pandemic. On the other extreme, individuals who worked in laboratories which received the H2N2 PT kits considered it no big deal.

It was this dichotomy which led THE DARK REPORT to a different story behind the "H2N2 Affair." Lab administrators and pathologists will find this alternative story instructive. It may explain the politics behind the decisions by various public health agencies to characterize the distribution of PT kits with live H2N2 flu virus as a significant threat with the potential to trigger an influenza pandemic. It also provides early warning about how an accident in a clinical lab with the potential to adversely affect public health might be used by public

health officials to shift public attention away from their own past performance.

The basic facts of the story are well-known. The virus was a strain of influenza known as A/H2N2. It had been included in virology proficiency test kits prepared by **Meridian Biosciences, Inc.**, then shipped to laboratories participating in the proficiency testing programs of the **College of American Pathologists** (CAP), **American College of Physicians** (ACP), the **American Association of Bioanalysts** (AAB), and the **American Association of Family Practitioners** (AAFP).

Strain Last Seen in 1957

A/H2N2 is the strain of virus which sparked a major influenza pandemic in 1957-58 and caused an estimated one million to four million deaths worldwide. In the United States, H2N2 caused about 70,000 deaths. This influenza strain was last seen in 1968. After that, H2N2 vanished with the emergence of influenza A/H3N2 viruses that caused the next pandemic.

Because it has not been seen since 1968, all persons born since that year have no immunity to H2N2. This is one reason why public health officials raised a public alarm upon discovering that live H2N2 flu virus had been distributed to 4,000 laboratories in PT kits. They emphasized, in their public statements, that a lab accident had the possibility of releasing the H2N2 influenza strain into the public, where it had the potential to trigger a serious outbreak of the disease.

Unreported Details

But that is not the full story about the "H2N2 Affair." From a variety of knowledgeable and well-placed sources, THE DARK REPORT has pieced together a tale which revolves around a victimized patient and the possible motives by some public health establishments to use this incident as an opportunity to trumpet their ability to protect global health. Even if there are some inaccuracies in the tale that follows, the collective picture offers alternative motives for different players involved in the "H2N2 Affair."

Our version of the story picks up in Vancouver, British Columbia in March 2005. A med tech in a hospital lab microbiology department was working with patient specimens and the virology PT kit with the H2N2 flu virus. This med tech cross-contaminated at least one patient specimen with the H2N2 virus.

There was a simple reason why this cross-contamination led to the discovery that H2N2 had been shipped in virology PT kits. The patient was a bone marrow transplant patient. When her specimen tested positive for influenza, protocol was for the patient to immediately start therapy for the influenza. Her specimen was also sent to the **National Microbiology Laboratory** (NML) in Winnipeg, Manitoba for identification of the influenza subtype.

Results Took Weeks

It took NML several weeks to culture the specimen and identify the subtype. It was Easter weekend when the results were ready. "We found this out in the middle of the night on Good Friday," recalled Frank Plummer, Scientific Director at NML. His lab had just identified a patient specimen containing a strain of live influenza virus considered virulent and not seen in the population in 37 years. "For several hours, we were very concerned," said an understated Plummer.

NML notified public health officials in British Columbia and the Canadian capitol on Sunday, March 26, 2005. Notification was sent to the **Centers for Disease Control and Preventio** (CDC) and the **World Health Organization** (WHO) on the same day.

From the start, health investigators suspected that the source of H2N2 in the patient specimen was contamination. The H2N2 specimen was a virtual DNA match for the H2N2 viruses that circu-

lated during the years 1957-58. It was as if it had been frozen in time.

"When we heard that it was virtually a genetic match to this 1957-58 isolate, a strain that might have been frozen down way back then, it seemed like this had to somehow be a contaminant of some sort. And that's what led to the more detailed analysis," stated Robert Brunham, MD., Director of the **British Columbia Center for Disease Control**.

Interview With Patient

Medical investigators first located the female patient. After determining that she was negative for the H2N2 virus, she was asked about recent travels, contacts with birds, and when she first felt sick. It was also determined that her respiratory symptoms were not due to influenza.

Investigators then shifted their attention to the hospital laboratory in Vancouver which had done the lab tests on the woman's specimen. According to Plummer, these investigators determined that a laboratory technician in that hospital "had somehow contaminated the woman's specimen while working under a protective flume hood on both her specimen and the proficiency test kit containing the 1957 A/H2N2 strain at the same time."

Cross-Contamination

Sources inside the public health establishment tell THE DARK REPORT that the med tech who worked with the specimens in question was known to have 'less than ideal" work habits. It was not difficult to rule out any other way that the patient's specimen could have become contaminated with H2N2 flu virus.

It took a number of days for this investigation to reach its conclusions. It was April 8 when Canadian health agencies notified the CDC of these findings. In turn, on the same day, the CDC contacted the College of American Pathologists and directed it to issue a "destruct the virus and confirm destruction" alert to the 3,747 lab-

"H2N2 Affair" Timeline

September 10, 2004: First virology proficiency kits containing influenza H2N2 virus are prepared for shipment.

March 2005: Hospital lab in Vancouver, BC has a specimen positive for influenza from a patient showing no flu symptoms. It refers the specimen to the National Microbiology Laboratory (NML) in Winnipeg, Manitoba for identification of subtype.

Easter Weekend 2005: NML identifies unknown flu virus as subtype A/H2N2, a strain not seen in the population since 1968. NML notifies Public Health Agency (PHA) of Canada.

March 26, 2005: PHA of Canada notifies the Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) of this discovery.

Late March 2005: Investigation determines that the Vancouver hospital lab contaminated the patient's specimen with live influenza A/H2N2 virus from a proficiency test kit provided by the College of American Pathologists (CAP).

April 8, 2005: NML reports the results of this investigation to PHA, the CDC, and WHO. CDC notifies the College of American Pathologists of the H2N2 issue. Directs CAP to alert labs with the virology proficiency test kits to immediately destroy the virus and report/attest to the fact.

April 9, 2005: CDC, WHO, and PHAC consult on course of action.

April 11, 2005: CDC sends CAP detailed instructions on how to destroy specimens and a process for reporting the destruction of specimens.

April 12, 2005: CDC learns at least three additional proficiency testing programs used PT kits with the H2N2 virus. CDC directs these programs to alert labs to the destruct and report requirements.

April 12, 2005: CDC, WHO, PHAC hold press conferences to alert the public to the situation. News stories begin appearing in the national press.

April 13, 2005: CAP and Meridian Biosciences both issue press releases on the subject.

April 20, 2005: Last CAP proficiency test specimen is located in Beirut, Lebanon and is prepared for destruction.

oratories which had received its virology proficiency test kit containing the B/H2N2 strain of influenza virus.

On April 12, 2005, the CDC conducted a press conference which sparked news headlines around the world. The CDC downplayed the risk that the H2N2 virus might get back into the population because of an accident in a laboratory working with the virology PT kits. Despite such assurances, the press interpreted developments to mean that a major error had occurred within the clinical laboratory industry.

Reporters hyped the statements given by public health officials. "I was certainly disturbed that it happened," said Danuta Skronski, an influenza expert at the **British Columbia Center for Disease Control**. "H2N2 is one of the top five pandemic candidates. There's no doubt of that. And this should be a strong warning to labs that you do not mess around with pandemic candidates."

Potential Global Emergency

"I think it's fair to say that, if many bad-luck things had come together, it could have caused a global health emergency," declared Klaus Stohr, M.D., who directs the WHO's global pandemic program, based in Geneva, Switzerland. "We all know that laboratory technicians are very well-trained and take care with what they're doing. But we have seen SARS slipping out in laboratories which belong to national virologic institutions."

Stohr was making a reference to the fact that, of the last six cases of SARS known in the world, three were directly caused by accidents in laboratories handling the SARS virus.

"We are very concerned that this particular strain of virus was used for proficiency testing," stated Julie Gerberding, answering a question at a press briefing as to why the A/H2N2 strain of virus had been included in PT kits. Gerberding, Director of the CDC, said, "It's impossible to believe that they [CAP, Meridian, etc.] did not know they were dealing with H2N2."

4,271 Labs Got H2N2 Kits

Four proficiency testing programs sent PT kits with H2N2 to participating laboratories. CAP sent out 3,747 kits. The American Association of Bioanalysts sent PT kits to 343 laboratories and the American Association of Family Practitioners sent kits to 144 physician office labs (POLs). The American College of Physicians sent out PT kits to 173 POLs. Meridian Biosciences produced the virology PT kits with H2N2 virus for each of these programs.

The quotes above, pulled from various news sources, provide good examples of how various public health communities beat their drums. A potential pandemic had been averted. It was a close call, and the world was lucky because a blunder in choosing the "wrong bug" for a laboratory proficiency test program had not led to the inadvertent introduction of a virulent virus into the environment.

Several sources helped THE DARK REPORT understand why clinical laboratories which had received the virology PT kits with H2N2 virus were not concerned, but that the story still made international news.

Their informed speculation is that certain public health agencies had a motive to improve their public image by the way they characterized this event—and their response to it. First is the National Microbiology Laboratory in Winnipeg. It was observed to THE DARK REPORT that, following the outbreak of SARS in Toronto in the winter of 2003, NML had come under some criticism for not being fast enough to identify the new disease and to institute procedures to control its transmission.

Under this scenario, NML, upon discovering H2N2, a virulent influen-

za virus not seen since 1967, could go public with news that it had discovered the virus was floating around in some clinical laboratories and it was now taking proactive steps to prevent the possibility of lab accidents involving proficiency kits from introducing H2N2 virus into the environment.

Sources speculate that the Centers for Disease Control and Prevention also had some recent "egg on the face" and thus found the "H2N2 Affair" a convenient opportunity to get favorable publicity. After all, during the past 12 months, the CDC was criticized for not having selected the "right" strains of influenza for this season's vaccines. Then, a few months later, a major manufacturer of influenza vaccines was shut down for quality control issues. This left the United States critically short of flu vaccines just as the flu season was building.

Way To Increase Credibility

One pathologist working in a public health agency, suggested to THE DARK REPORT that some individuals within the CDC would thus have a motive to consider the "H2N2 Affair" as a way to restore some luster and credibility with the public and government officials. It was a flu-related issue that could demonstrate how the agency was alert, effective, and pro-active in protecting the public health from the threat of an inadvertent introduction of H2N2 into the environment.

Thus, the "H2N2 Affair" may be a story of the public health establishment seizing an opportunity to generate favorable public—and political attention—on an issue that was considered much less of a threat by professionals working inside clinical laboratories handling virology PT kits with live H2N2 Virus.

That may also help explain why there was no mention, by either public health officials or the international media, that POLs, lacking bio-safety level 2 protections, had received live H2N2 virus in their PT kits.

Thus, it is likely that the real victim in this affair has yet to be recognized. That is the female transplant patient in a Vancouver hospital who received therapy for an influenza infection she didn't have, because a med tech cross-contaminated her specimen with live H2N2 virus. That seems to be the only lab accident involving H2N2 virus which has harmed a patient. TDR

H2N2 in POL PT Kits? Why It Was No Problem

CONCERNS THAT H2N2 INFLUENZA VIRUS in bio-safely level two (BSL-2) labs might escape into the environment and trigger an influenza pandemic eclipsed the fact that hundreds of physician office laboratories (POLs) got H2N2 in their proficiency test kits.

This is another dichotomy in the story about the "H2N2 Affair." THE DARK REPORT can find no newspaper or major media story that addresses the fact that POLs, lacking BSL-2 protections, received PT kits with H2N2. This may be evidence that that publicity about the threat of a global pandemic was overblown.

One reason might be that the difference in the threat would be recognized quickly by reporters. VR1 kits, which test proficiency for live culture of the virus in laboratories running at BSL-2, actually increase the quantity of live virus over the course of the procedure. In contrast, PT kits like VR4 and M21, which test proficiency in antigen detection and are more commonly used in POLs, start with a finite quantity of live virus which diminishes as the test is conducted.

Several hundred POLs got live H2N2 virus in their virology PT kits. Yet none of the officials at agencies like the CDC and WHO mentioned POLs in their press briefings. Nor did reporters pick up this facet of the story.

Why Is There Crime In the Lab Industry?

Indictments of Ex-IMPATH executives are one more example of bad lab leadership

CEO SUMMARY: Since 1991, there have been criminal indictments or criminal convictions of four former CEOs of public lab companies. Given the limited number of public lab companies active in the market at any moment in time, this is a remarkably high rate of criminal behavior. Moreover, the "bad behavior" of such lab firms puts the entire laboratory industry in a bad light and invites federal scrutiny of abusive business practices.

By Robert L. Michel

CRIME IN THE LAB INDUSTRY is a difficult topic for all of us. News that federal prosecutors indicted six ex-executives from **IMPATH, Inc.** is an event which dishonors a profession which deserves better.

Unfortunately, the indictments of these former IMPATH executives are not an exceptional event for the laboratory industry. Just eight months ago, three ex-**UroCor** executives were indicted for violating Medicare anti-kickback laws and **Securities and Exchange** (SEC) statutes. *(See TDR, July 19, 2005.)*

Lab Industry Misdeeds

The shameful list of lab industry criminal misdeeds goes back many years. Remember the "sink-testing" laboratories during the 1980s? This scandal caused Congress to pass the Clinical Laboratory Improvement Act (CLIA) as a way to stop the most egregious actions of unscrupulous laboratory operators, some who never performed tests, but poured specimens down the drain and sent the referring physician an invented lab test result.

Following declines in Medicare reimbursement in 1987 and 1988, certain executives at some public lab companies decided to "game" the Medicare system. Their goal was to offset lower Medicare fees by manipulating test ordering, coding, and billing techniques on certain laboratory tests in ways that would generate additional Medicare reimbursement to their lab company.

There was a bad harvest from these actions. When federal healthcare investigators finally took action in the early 1990s, **National Health Laboratories** (NHL) was the first to feel the sting of federal prosecution. The company agreed to pay $112 million to settle charges of Medicare Fraud and Abuse. Robert E. Draper, CEO of NHL, pled guilty to two felony counts and served prison time. Joseph Isola, former CEO of **Damon Clinical Laboratories**, and Robert Thurston, formerly a Vice President at Damon Labs, earned criminal convictions for similar actions.

During the 1990s, the so-called "Lab Scam" investigation by the **Office of the Inspector General**

(OIG) generated more than $1 billion in restitution and fines from laboratories accused of violating Medicare Fraud and Abuse statutes, along with the criminal convictions noted above.

Criminal Behavior In Labs

Why does the laboratory industry find itself dogged by episodes of criminal behavior? What motivates some among us to institute and sustain business practices which, at their worst, are outright violations of regulations and statutes, and, at best, certainly violate the intent and spirit of such laws?

I would like to speak candidly on a number of points. Throughout my 15 years of service within the laboratory industry, I have heard and overheard many comments and opinions by all types of laboratorians. Generally, those in the profession of laboratory medicine abhor this criminal behavior and the mindset which encourages it.

During the past 25 years, it could be said that two "types" of laboratory companies can be linked to business behavior which violates state and federal regulations and statutes. The first type, loosely, is made up of privately-held laboratory companies where the owners brazenly defraud the healthcare system with obvious criminal behavior.

"Old Country" Mindset

"Sink testers" of the 1980s are one example. Another example are labs which bill for services never performed and/or collude with referring physicians to initiate unnecessary claims. These types of labs have been a somewhat common phenomenon, particularly in California and Florida. Often such labs companies are quite small, tied to specific ethnic communities, and are operated with an "old country" mindset.

The other "type" is more troubling to the entire laboratory profession. It is publicly-traded laboratory companies which "go bad." Essentially, at certain times and for certain reasons, there are executives within these types of lab companies who make decisions which are just plain criminal. Indictments in the UroCor and IMPATH cases allege precisely this type of behavior.

However, there is another dimension to the ethical decisions made in some public lab companies. It is certainly true that, across the laboratory industry, there is a broadly-held perception that executives in some public companies are willing to push the boundaries of Medicare/Medicaid compliance up to, and past, the point of violation.

What motivates some among us to institute and sustain business practices which, at their worst, are outright violations of regulations and statutes, and, at best, certainly violate the intent and spirit of such laws?

This is certainly a widely-held belief by pathologists and lab managers working in hospital labs and other not-for-profit laboratory settings. In fairness to their bias, they do have good reason to hold this belief. For many years, they have watched several generations of public lab companies institute sales, marketing, pricing, and coding/billing/collection practices which caused great damage to the reputation of the laboratory industry.

Further, lab administrators and pathologists running independent laboratories and hospital outreach programs have first-hand knowledge of the sales, marketing, and billing practices used by their public laboratory competitors. They collect the documents provided by competing laboratories from physicians. They show these documents to their legal counsel and discuss how and why such practices might violate compliance laws.

Too often their legal counsel advises them that the business practice in question either crosses the line into outright violation, or skirts that boundary so close that it is not a risk they advise their local laboratory client to take.

High-Priced Lab Firms

In contrast, because of the potential for economic advantage that accrues from aggressively pushing compliance boundaries, public laboratory companies often use high-priced Washington and New York law firms to give them legal opinions which they feel gives them the justification to engage in this activity in the marketplace.

What allows this situation to continue is the lack of clear and consistent guidance—and enforcement action—by the **Centers for Medicare and Medicaid Services** (CMS) and the **Office of the Inspector General** (OIG). Laboratory companies willing to push compliance boundaries take advantage of the lack of detailed guidance on key points of Medicare compliance and paucity of specific enforcement by the OIG on laboratory business practices which do cross over the compliance line.

This creates an unlevel playing field in the laboratory services marketplace. Hospital lab outreach programs and local pathology group practices—advised by their attorneys to adopt a conservative legal interpretation of Medicare statutes and OIG guidance—find themselves at a competitive disadvantage to certain public lab companies willing to be more aggressive in their sales and marketing practices.

THE DARK REPORT has spotlighted some of these issues. One is the use of the "Waiver of Charges to Managed Care Patients." *(See TDR, August 26, 2002.)* Another is the decision to not back-charge client-billed accounts for physicians' failure to provide the lab with the diagnosis information required to file a Medicare claim. *(See TDR, June 16, 2003.)*

Certainly each of these two business practices has an appropriate use in the marketplace, per guidance from the OIG. However, too often a local laboratory will see a public lab competitor use these techniques in an aggressive manner—one which crosses the line from compliant practice to violation.

Local labs have reason to believe this to be true. The physician office receiving the benefits from the competing laboratory often discusses the details of the business arrangement. It may even pass over copies of documents supporting the "non-compliant" or "abusive" marketing practice.

This is a dichotomy in the lab marketplace between the compliance practices of hospital outreach programs and certain publicly-traded lab companies. In specific years, it seems to be the source of the worst criminal behavior in the laboratory profession.

First To Be Investigated

Evidence bears that out. It is seldom a hospital lab outreach program which is the first target by federal investigators and prosecutors. To the contrary, it is usually a public lab company which undergoes a federal investigation for specific laboratory business practices viewed as violations of compliance statutes.

The incessant pressure to produce ever-greater profits—and the lure of great personal financial reward—are the key factors which motivate individuals working in these settings to push the law as far as it allows. In the absence of more effective regulatory enforcement, our industry can expect to see more Drapers, Isolas, Hagstroms, and Saads—all indicted or convicted former CEOs of public laboratory companies. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Tight-lipped executives at **Meridian Bioscience, Inc.** have yet to speak in public on any aspect of how live H2N2 influenza virus found its way into the virology proficiency test kits it shipped to thousands of labs on behalf of four lab proficiency testing organizations. Meridian, based in Cincinnati, Ohio, may be reluctant to speak publicly because it has a history of problems with the **Food and Drug Administration** (FDA). In 2001, FDA criticized Meridian for failings in the company's manufacturing process for medical test kits. Meridian pulled 30 products from the market. It laid off 52 workers and absorbed a net revenue loss of $9 million from that incident. In March 2004, Meridian responded to an FDA finding by recalling certain production lots of a diagnostic test kit that was generating false results.

ADD TO: *Meridian*

Meridian's revenues total about $80 million annually. It "manufactures and distributes...diagnostic test kits, purified reagents and related products." Last year it sold about $3 million of products to the **College of American Pathologists**. Its stock symbol is "VIVO."

CANON PREPARES TO ENTER MEDICAL DNA CHIP MARKET

Canon, Inc., the world's largest manufacturer of office machines, announced plans to commercialize DNA chips for applications in medical diagnostics. Canon believes it can incorporate the bubble-jet technology it uses in printers to the mass production of DNA chips. It is targeting oncology and infectious disease testing. It believes it can apply its expertise in manufacturing to reduce the cost of DNA chips and make them more cost-effective to use in both research and clinical diagnostics.

ADD TO: *Canon, Inc.*

Canon becomes the latest company to announce major investments in bio-medical products. Currently the leader in "lab on a chip" production is **Affymetrix, Inc.**, based in Santa Clara, California. The lure of the medical marketplace has encouraged companies like **Toshiba Corp.** and **Toppan Printing Co.** to develop similar types of DNA chips for use in drug development and similar medical applications. Canon's interest in developing a "lab on a chip" business is more evidence that the market for molecular diagnostics is expected to be huge, fueled by new technologies in genetic medicine.

Microbiologists are seeing a growing proportion of drug-resistant staff infections occurring outside hospitals and nursing homes. CDC researchers reported their findings in a study published in the *Journal of the American Medical Association* (JAMA) recently. In communities studied, which included Baltimore, Atlanta, and parts of Minnesota, up to 17% of all drug-resistant staph infections were transmitted in the community and had no apparent links to healthcare settings like hospitals and skilled nursing facilities. The more resistant strains showed up among inmates, children, and athletes.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, May 30, 2005.

Audio Conference: June 21, 2005

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- ***SCC Soft Computer's CEO Talks About How Lab Info Systems Must Change to Support Molecular Diagnostic Testing.***

- ***Surprising Reasons Why Urologists Urgently Want a Piece of the Anatomic Pathology Pie.***

- ***California Requires Phlebotomist Certification: Will Other States Do the Same?***

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