Volume XVII, Number 5 Monday, March 29, 2010

Specialized Information Publishers Foundation
EDITORIAL EXCELLENCE AWARD WINNER

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

For Better or for Worse: Nation Has New Health Law

CONGRESS AND THE CURRENT ADMINISTRATION HAVE THEIR HEALTH LAW. Whether this new law serves the citizens of this country for the better or for the worse will not be known for several years into the future.

I suspect that many of our elected officials in the House and Senate do not fully understand the major elements of the health bill that has just become law. I believe I am also on safe ground to state the opinion that few of these "servants of the people" actually took the 2,700+ pages of the bill and perused them carefully before deciding how to cast their vote.

Therein lies the rub. First, these legislators have exempted themselves and their Congressional staffs from the health mandates that they are imposing on the remainder of the country. They know this insulates themselves and their families from whatever negative consequences develop from the parts of the new law which prove detrimental to the healthcare system. As an American citizen of good standing, I find it sad that our political leaders deliberately take themselves out of the legislative solution they consider best for the nation.

Second, in coming years, none of us should be surprised when various unintended consequences of this health law become obvious and troublesome. Expect these same senators and representatives to tell news reporters that "I didn't know that was in the bill," or "I didn't understand how this specific mandate would cause health providers to change the way they practiced medicine."

Forgive me for being skeptical about these developments. Like many of you, early last year I was hopeful that the goal of improving our nation's health system would include a robust exploration of innovative ways to organize healthcare. Healthcare's "best practices" examples, such as **Mayo Clinic**, **Cleveland Clinic**, **Kaiser Permanente**, and **Geisinger Health**, would be studied by policymakers and legislators. As part of the health bill, seed funding to encourage similar "health innovation incubators" would be authorized with the goal of covering more people at lower cost while achieving improved health outcomes.

On this point, I am not aware of any provision in the new law that financially encourages a health system, hospital, or physician group to experiment with innovative ways to organize and deliver healthcare. I am willing to be proven wrong on this point. If you know of such a provision, contact me at our editorial offices. In the meantime, like most of you, I am reserving judgement about whether this health law is good for our country. Like the residents of Missouri, I say "Show me." TDR

2.3% Medical Device Tax Hits Clinical Labs in 2013

Newly-enacted health reform bill requires medical device companies to pay excise tax

CEO SUMMARY: One aspect of the massive new health bill is that medical device companies will pay a 2.3% tax, effective January 1, 2013. Students of economics know that it is customers who invariably end up paying such direct taxes. Thus, clinical laboratories in the United States should prepare to see this 2.3% tax show up as a line item on sales contracts and in the form of higher prices for* in vitro *diagnostics analyzers, lab equipment, reagents, consumables, and even medical software.

BY SIGNING THE HEALTHCARE REFORM bill into law last week, President Obama started the clock on a 2.3% tax on medical devices that will go into effect on January 1, 2013. On that date, sales that close on any product classified as an FDA-approved medical device, including laboratory analyzers, laboratory equipment, reagents, and consumables, will be taxed at the 2.3% rate.

As currently structured, *in vitro* diagnostics (IVD) manufacturers, along with all medical device companies, will be required to pay this new 2.3% excise tax on almost all the products they sell to clinical laboratories and pathology groups. This makes it likely that clinical labs will pay this tax in one of two ways: either as an excise tax item of 2.3% that appears on the sales invoice from the manufacturer or in the form of higher prices, as medical device manufacturers use that method to recover the 2.3% they must pay to the federal government starting in 2013.

"It's a straightforward tax on the universe of medical device products and services as regulated by the FDA—regardless of class but with some exceptions," stated Brett Loper, Senior Executive Vice President and Director, Government Affairs, for the **Advanced Medical Technology Association** (AdvaMed), in Washington, D.C., in an interview with THE DARK REPORT. AdvaMed member companies produce about 90% of the medical devices, diagnostic products, and health information technology systems sold in the United States each year.

With passage of this bill, the clinic laboratory industry dodged the bullet of the proposed $750 million per year tax that was in an early draft of the Senate bill. In

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

that sense, lab industry efforts to educate Congress about the negative impact of such a direct tax on the revenues of clinical laboratories were successful. Now the laboratory industry needs to assess the financial impact of the 2.3% tax that will soon be paid by medical device companies.

Far-Reaching Effects

According to Loper, as currently written in the law, the tax would affect just about every purchase a laboratory would make. This includes analyzers, lab automation systems, lab equipment, information systems (including software), reagents, and consumable products. While the tax would apply to products and equipment a lab would purchase, it is not yet clear how the 2.3% tax would be administered for equipment a lab would lease or acquire on a reagent-rental basis, he added.

On questions regarding lease and reagent-rental arrangements that are commonly used by IVD companies and their clinical laboratory customers, Loper said that, "as with many of the details regarding this new legislation, we must wait for the U.S. Treasury Department to issue regulations that provide answers to these questions. There are rules that relate to rental payments and leasing payments. It could be some time before we learn how the 2.3% tax will be assessed on these types of medical device sales."

Questions Await An Answer

"As to whether the tax will be collected on consulting fees or equipment service contracts provided by IVD manufacturers, I think they would not be taxed under this new law," Loper added. "Consulting fees and service contracts are not FDA-approved products. Rather, these contracts ride alongside certain products. It may be that the answer to this question depends on how individual contracts for consulting and services are spelled out.

"If a medical device service contract is currently listed as being part of the price of the equipment, I would expect the buyer would see manufacturers wanting to unwind that connection in some way so that consulting fees and service fees would not be subject to the tax," explained Loper.

"At this point, it is impossible to accurately predict who will bear the economic imposition of the tax," he said. "I suspect that—depending on the company and the product involved—there will be varying degrees of absorption by the manufacturer versus the purchaser, and ultimately the consumer through Medicare or their insurance plan.

"Certainly manufacturers are responsible for remitting the tax," he added. "But economists generally agree that excise taxes are passed along—to be paid ultimately by the consumer.

Not Good Public Policy

"Medical device manufacturers certainly are not supportive of this tax," Loper noted. "We didn't want it and we don't think it is good public policy. There is some resignation that it will be in place in 2013. But if there is an opportunity to press for its repeal, I'm sure the industry would pursue that outcome. We have not yet developed a strategy related to repeal because these are all new developments.

"As it was, we worked very hard to get the device tax down to the rate that it is now," Loper continued. "There were suggestions that it should be much higher. In fact, the Senate bill had the tax structured differently and in such a way that it would have raised twice as much revenue. Also, in earlier versions of the health reform bill, the tax was going to become effective this year.

"As mentioned, there are exceptions in the bill that include eyeglasses, hearing aids, contact lenses, and a list to be determined by the Secretary of the Department of Treasury at a later date," Loper explained. "These exceptions cover products that are used by individuals and generally purchased in retail settings. The

exemptions cover simple products found, for example, at pharmacies, but not clinical laboratory equipment or supplies."

A Dampening of Innovation

Officials at the **Medical Device Manufacturers Association** (MDMA) believe the 2.3% federal tax will dampen innovation among companies that develop medical equipment. "MDMA is concerned that this $20 billion medical device tax will have a negative impact on patient care, innovation, and small business," said Mark Leahey, MDMA's President and CEO. "If eliminating the 2.3% tax is not possible, structuring it to provide relief for smaller companies is critical."

"Under the current structure, many companies will owe more in taxes than they generate in profits," predicted Leahy, "These companies will lay off employees, slash research and development budgets, and slow the development of new therapies that would have improved the quality of care for all Americans. Moving forward, these issues must be addressed before the tax takes effect."

Work To Repeal Tax

Because the effective date for this new tax is almost three years into the future, medical device manufacturers hope to eliminate or reduce the tax before then. In the meantime, the effect of the tax on pathologists and lab directors is likely to cause an increase the cost of all the equipment, reagents, consumables, and software that laboratories purchase as manufacturers take steps to offset that 2.3% tax.

THE DARK REPORT recommends that clinical laboratories and pathology groups assess the impact that the 2.3% federal tax on medical devices will have on their laboratories' finances. Although the effective date is not until January 1, 2013, lab industry suppliers will be looking for ways to recover that tax to minimize its negative impact on their own profits.

Two Senators Recognize Corrosive Effect of Tax

LAST WEDNESDAY, U.S. Senators Scott Brown (R-Massachusetts) and Pat Roberts (R-Kansas) co-sponsored an amendment to repeal the 2.3% medical device tax immediately.

"In Massachusetts, more than 200 medical device manufacturers—who employ tens of thousands of workers—would be impacted by this jobs-killing tax," predicted Brown. "Furthermore, this tax would ultimately be passed onto consumers, who will all pay more for their necessary medical equipment.

"With unemployment in my state near 10%, placing a tax on medical devices is the absolute last thing we should be doing right now," he stated. "This [2.3% medical device] tax will burden employers and cost jobs at a time we cannot afford one more job being lost."

Moreover, pathologists and laboratory administrators should keep a watchful eye as the Obama administration begins to implement the actions defined in the new legislation. With 2,700+ pages, the bill is a smorgasbord of action items. It includes the creation of almost 200 new health boards, review committees, and similar government departments.

As authorized by the new health law, many of these newly-formed departments will operate under the radar—until they issue directives and regulations that significantly alter existing aspects of the healthcare system. Because laboratory testing underpins a significant proportion of clinical activity, it is inevitable that a large number of these directives will have a direct and radical impact on how clinical laboratories provide testing services. TDR

Visit www.advamed.org for more information or call 202-783-8700.

Business Advantages From Whole Slide Imaging

➤WSI creates ways to significantly improve collaboration between pathologists and physicians

➤➤CEO SUMMARY: Whole slide imaging (WSI) is a niche product today, but it offers the potential to redefine the practice of pathology. That's the opinion of pathologists presenting at a digital pathology workshop last month. One pathologist explained how WSI significantly improves collaboration between pathologists and referring physicians. Another pathologist explained how regulators soon may require standards for WSI and why such standards are likely to result in a call for standards for light microscopes as well.

IN RESPONSE TO THE STEADY INCREASE in the number of anatomic pathology groups acquiring and using digital scanners and digital pathology systems, **Cerner Corporation** recently conducted a two-day workshop on the subject. Several innovative pathologists in this field were invited to speak.

"At this time, whole slide imaging (WSI) is a niche product," stated Susana M. Coelho, Director of Cerner CoPathPlus, in Waltham, Massachusetts. "However, the adoption rate of WSI by our clients makes it clear that WSI is here to stay.

"At this workshop, the consensus among the experts speaking and the pathologists in attendance was that whole slide imaging would only prove successful if it is well-integrated into the workflow of the laboratory and the individual pathologists," observed Coelho.

"Among other things, this will require seamless integration of the images and data with the information systems," she added. "We are not there yet, and so to hear the leaders in this field consistently reinforce this idea was significant."

During the conference, most presenters stressed this point and discussed how whole slide imaging can be used to increase the value pathologists deliver to referring physicians, their patients, and payers. For example, at **Pathology, Inc.**, in Torrance, California, whole slide imaging is dramatically improving collaboration between pathologists and referring physicians.

➤WSI's Business Advantage

In an interview with THE DARK REPORT after the conference, Eric F. Glassy, M.D., who is Medical Director at Pathology, Inc., discussed the early benefits derived from his pathology group's use of WSI. "Whole slide imaging offers several advantages for us in terms of presentations, as well as on the business side," he said.

"Take tumor boards, for example," noted Glassy. "Over the years, we tried different ways to present our cases. This ranged from presenting glass slides and showing 35 mm slides with a projector, to running a video feed and using digital still images. Hands down, use of whole slide images has proven the most effective.

"There is always a favorable reaction from the clinicians and surgeons who view these whole slide images," he noted. "It also

raised the profile and contribution of our pathologists who present these cases at tumor boards, during consultations, and in other interactions with colleagues.

"In our practice, the whole slide scanner is owned by the private laboratory that is Pathology, Inc.," said Glassy. "It provides images to the more than 30 pathologists who are part of our extended business family.

Business Benefits

"Besides use of WSI in tumor boards and in consultations with clinicians, we've enjoyed other significant business benefits," he said. "WSI allows us to compete against such national competitors as **Clarient** and **US Labs**. This is particularly true in virtual immunohistochemistry, breast marker analysis, and similar types of testing commonly offered by other national pathology labs."

Glassy says that Pathology, Inc., is using whole slide images as a way to open the door to more clinical interaction with the physicians who refer cases to his group. This improves client loyalty and fosters a professional relationship where the pathologist is a valued consultant.

"Remote viewing is one solid business case that argues in favor of local pathology groups using WSI," declared Glassy. "There are always clients who want to review slides directly with the pathologist.

"At Pathology, Inc., we set up a digital consultation system with remote viewing," he noted. "As the pathologist shows a slide, that same image appears and moves around on the client's computer desktop. This system allows the pathologist to discuss the finer points of a case.

"For example, when the client physician asks about the specifics of a lesion, our digital consultation system allows the pathologist to quickly respond to diagnostics issues and client concerns.

"This WSI remote viewing service has proven to be so popular that we've created a work flow arrangement to schedule consultation time," stated Glassy. "When a client calls services with a request to discuss a case with the pathologist, an appointment is scheduled.

"To start the consultation, the pathologist and the clinician log in to the web server with name and password, which keeps it private," he added. "Once they're logged in, they can talk over the phone while the case is being viewed on the monitor. The control is initiated by the pathologist. But control of the digital image can be passed to the clinician. That gives the clinician the ability to move to different areas of interest or to zoom in on specific areas.

"Use of whole slide imaging in this manner generates two benefits," explained Glassy. "One, if a clinician calls and wants to be reassured of a diagnosis, then this system is a powerful way to have the whole slide image viewed directly by the clinician.

"Second, there are a number of clinicians—such as gastrointerologists—who like looking at glass slides," he commented. "These physicians had good training in the basics of histology and they like to review these cases with the pathologists. The remote viewing application of WSI gives them an opportunity to discuss their case and focus in on any areas of concern.

"We've just opened up this service," he said. "We are still learning the different ways that this interaction encourages a new level of collaboration between pathologists and client physicians, particularly if the physician who referred the case is not nearby.

Remote Viewing By Clinician

"Pathologists know that, if the client is close by, he or she may come to the hospital and review a case," observed Glassy. "However, if the pathologist works at an off site laboratory—like Pathology, Inc.—remote viewing of the whole slide image provides a similar intimacy that occurs when a client and the pathologist review a slide together using a double-headed scope.

"By the way, it needs to be acknowledged that many physicians have never liked using

a microscope to view a glass slide," declared Glassy. "They pretend, but they just don't have a comfort level with using a microscope to view their case.

"It's been our experience that these physicians are much happier reviewing material on a computer monitor," he stated. "In fact, looking at a picture presented on a monitor is much more compelling and meaningful for them.

A More Compelling Story

"In our experience, there is great value for whole slide imaging," he added. "There is a certain level of novelty, of course, but beneath that there is an experience that can be quite compelling for both sides.

"From the pathologist's side, a digitized image now allows analysis with algorithms and computer scoring for breast markers, for example," commented Glassy. "The digital image can be manipulated and evaluated in ways that are not easily accomplished with a glass slide.

"From the referring clinician's side, the whole slide image creates immediacy and enables a more direct conversation with the pathologist," pointed out Glassy. "This can be seen at tumor board meetings, where the WSI allows the clinicians to get a better sense of what it is involved in analyzing a case.

Viewing Tumor Margins

"For example, surgeons and radiation therapists often are worried about margins," Glassy explained. "They ask 'How close is the tumor to the surgical margin?' The pathologist can show the area of concern on the whole slide image under very low power, allowing the clinician to see the ink on the surface where the margin of the tumor is. The pathologist can then zoom in at higher power to show the histologic details.

"Clinicians find this very useful," he continued. "They can see exactly why the pathologist described the margin as, say, only a millimeter away. They can see how close that is. The whole slide image tells a much better story, particularly when compared to reading the pathologist's findings on the paper report. In this way, clinicians have a greater appreciation for what pathologists do.

"Keep in mind that a tumor board is like telling a story," he said. "There is a patient who has a problem. Each individual physician brings part of the story to the conference. But it is the pathologists who tie all the pieces of the story together.

"It is the pathologists who explain what the tumor looked like, the degree of differentiation, margin involvement, and the like," continued Glassy. "The additional molecular tests or special stains add important details to that story.

"Whole slide imaging enables the pathologist to present all the information in a live—even dynamic—fashion as opposed to using static images," he said. "The pathologist becomes more of a storyteller, weaving the different facts together about how he or she arrived at the diagnosis. And that makes the whole conference much more beneficial to the patient and more interesting to the clinicians.

Pathology's Transformation

"At Pathology, Inc., our use of whole slide imaging has caused us to recognize how pathology is about to transform," continued Glassy. "Now, we are working hard to promote this idea of transformation so that pathologists are truly part of healthcare team and not just sitting off in a basement somewhere looking at glass slides.

"All of these advantages are obvious to us but we've only just scratched the surface," he said. "Digital pathology is going to get faster and better. The experience for the clinician and the pathologist will steadily improve as more digital pathology products come to the market." TDR

Contact Susana Coelho at 781-434-2230 or scoelho@cerner.com; Eric Glassy, M.D., at 310-225-3145 or efglassymd@pathologyinc.com; Michael Becich, M.D., at becich+@pitt.edu or 412-623-3941.

Imaging Expert Predicts Standards Will Be Developed for Whole Slide Images and Light Microscopes

AS WHOLE SLIDE IMAGING (WSI) technology improves, it is likely to trigger a reassessment of light microscopes. That's the opinion of Michael J. Becich, M.D., Ph.D., Chairman, Department of Biomedical Informatics, at the **University of Pittsburgh Medical School** in Pittsburgh, Pennsylvania.

"In the near term, WSI will make its way into practice as an adjunctive tool to the light microscope," predicted Becich. "There will still be a need for light microscopes in pathology departments. But the real issue is that no standards have ever been established for the light microscope.

"A dizzying variety of choices of light microscopes exists in the market today," he observed. "In some cases, limited budgets dictate the type of light microscopes that are acquired and used. These are often not of the highest quality.

"In my view, patient care would improve if there was more standardization in light microscopes," stated Becich. "For example, quality would improve if high-quality, wide-field microscopes—with focusing objectives to account for cover slip thickness and other aberrations—were the standard in pathology.

Quality of Light Microscope

"There is lots of variability in the quality of the light microscopes used across the country, particularly in some community practices," he added. "By that, I mean microscopes that medical students would not be allowed to use in their laboratory training can be found in regular use at some local pathology labs.

"The pathology profession needs higher quality microscopes," noted Becich. "It needs to adopt useful standards to ensure that microscopes deliver optimum viewing performance. That would help us all.

"I anticipate that the FDA will look at whole slide imaging as a new instrument," he continued. "The FDA will insist upon standards for WSI. In turn, that will have a positive effect on the standardization of light microscopes in laboratories.

"The impact of developing standards for WSHI will ensure and verify performance of whole slide imaging systems, as well as light microscopes. In turn, these standards will require such instruments to be appropriately centered, to have the proper light sources, and to have the correct objective so that they are optimized for quality viewing.

Using The Best Tool

"Today's reality is that the pathologist who works with a high quality microscope that includes wide-field correcting, focusing objectives, and quality optics, has a better tool than the pathologist who is forced to use a microscope that's been in use for over 40 years—and probably was not manufactured to today's highest standards," Becich said.

"Fortunately, I expect that FDA scrutiny of WSI will raise the standards for pathology viewing via microscope in a manner that will be very helpful to patient care," he added. "However, until that happens, this country has many pathology practices where substandard microscopes are used. Why? Because the pathology profession has no practice standard concerning light microscopes that address these important issues.

"At the end of the day, we should have standards for diagnostic pathologists using microscopes," he said. "They should be binocular scopes and have aberration-correcting lenses above 40x. They should also have focusing objectives and Kohler-illumination corrected light sources. Many in pathology know this and realize its just a matter of time. That's my prediction."

CEO Summary: In a thinly-populated region the size of Texas and New Mexico combined, an integrated clinical care program based on point-of-care testing (POCT) has delivered impressive gains in health outcomes. For rural residents, mortality rates from cardiovascular disease have fallen by 50%. There were comparable declines in hospital length of stay and the rate of readmissions. A reliable test result and speed to answer from POC testing is a major factor in these improved outcomes.

Use of Point-of-Care Testing Reduces Mortality by 50%

IS POINT-OF-CARE TESTING (POCT) ready for prime time as a front line tool for the diagnosis of patients—whether in physicians' offices or in hospitals? A compelling case study in the state of South Australia suggests that the answer is "yes"!

One visionary clinician (not a pathologist, by the way) saw the potential for point-of-care testing to be a game-changer in both hospital and clinic settings, but only if the POCT program was well organized and tightly managed.

Over the past decade, the deliberate placement and use of POC testing devices has contributed to a 50% reduction in mortality from acute coronary disease for rural patients in South Australia.

The story starts in the late-1990s, when Phillip Tideman, M.D., a cardiologist at **Flinders Medical Centre** in Adelaide, Australia, was wrestling with two important issues in cardiac care in South Australia. He saw that point-of-care testing could be the answer for both dilemmas.

The first dilemma Tideman faced was how to switch the emergency center at his tertiary-care hospital in Adelaide to troponin assays in place of the then-standard CK-MB assay for detecting myocardial necrosis. "By the late 1990s, troponin assays had become the gold standard," said Tideman. "But at that time, the hospital laboratory could only run troponin assays on a dedicated machine that was not part of the express laboratory service, and the lab staff ran the assays only once a day.

"When dealing with acute coronary syndromes, results are needed immediately," he added. Faced with waiting for the once-a-day troponin run, most physicians continued to rely on the CK-MB assay.

At the same time that Tideman was pondering how to make the switch to troponins at this Adelaide hospital, he was also consulting with rural hospitals in an effort to improve survival rates for their cardiac patients. "Most of the data would suggest that an individual had twice the risk of dying from coronary heart disease if he or she lived in country areas compared with metropolitan areas," observed Tideman.

Tideman explained that South Australia has a highly centralized population, with two-thirds of its 1.6 million people located in Adelaide. The other 500,000 people are scattered across the 985,000 square kilometers of farming and pastoral areas.

The size of this rural area is immense. In the United States, it would take the combined area of Texas and New Mexico to equal the geography encompassed by the state of South Australia. Only 11 of the 66 hospitals serving these rural areas had an on-site laboratory. These labs mostly operate on a Monday-Friday schedule, with on-call staff for nights and weekends.

Not Every Hospital Had A Lab

For the hospitals without laboratories, the only way to get blood chemistry tests done was to send specimens to the tertiary care centers in Adelaide or to a lab at one of the 11 laboratory-equipped peripheral hospitals.

"At this time, it was typical to transport blood specimens 200 kilometers (124 miles) or more—sometimes a lot more," recalled Tideman. "Some remote centers were transporting a sample as much as 1,000 kilometers (620 miles)! The specimens traveled overland by bus, taxi, or private car.

"If the specimens arrived at a peripheral hospital at night or on the weekend, laboratory staff would have to be called in," commented Tideman. "Turnaround times were at best six hours, but often as long as 24 hours. With so much time between the blood draw and running the test, some routine laboratory test results, such as potassium levels, were unreliable."

Tideman recognized how point-of-care testing could contribute to improved outcomes for cardiac patients. He enlisted laboratory scientist Rosy Tirimacco, B.Sc., to help him develop a cardiac network to improve patient care in the rural areas.

They created **iCCnet SA**, or **Integrated Cardiovascular Clinical Network for South Australia**. Tideman was Clinical Director and Tirimacco became Operations and Research Manager.

"When we talked to the doctors about what services they needed, they identified better and faster pathology laboratory testing as one of the main things required to improve patient care," said Tirimacco.

As part of the cardiac network protocols, Tideman and Tirimacco introduced a point-of-care platform to do troponin assays in the

rural hospitals. With a troponin assay result in hand, a physician could more definitively determine which patients were high risk and immediately transport those patients to tertiary hospitals in Adelaide for advanced care.

POC Testing In The ER

Further, Tideman and Tirimacco recognized that the same POC test platform could be used to introduce troponin assays in the emergency room at the tertiary hospitals. Instead of waiting for the daily troponin assay run, ER physicians could have results in 12 minutes, allowing them to quickly distinguish a heart attack from other sources of chest pain.

They began their work in mid-2000. The first of the point-of-care devices, the **Roche** Cardiac Reader, was placed in rural hospitals in 2001. "This device is an optical reader that measures troponin-T in a blood drop on a disposable strip. It takes away the interpretive error and gives the clinician a negative result, a borderline result, or a semi-quantitative positive result," explained Tirimacco.

"When dealing with acute cardiac syndromes, clinicians need results immediately, 24 hours a day, seven days a week," said Tideman. "Point-of-care testing was the answer to that clinical need."

Tideman and Tirimacco traveled around South Australia, training nursing staff to use the devices. An interactive consulting service was established that allowed rural medical providers to contact network staff by phone and fax, and more recently, through video-conference. If a nurse had a problem with the testing device, a laboratory scientist could help troubleshoot; if a physician had questions about cardiac patient care, a cardiologist could consult.

The team met some resistance when they placed the point-of-care devices in hospitals that had on-site laboratories. "We got a fair bit of angst from traditional laboratory professionals," stated Tideman, "although they did admit that they couldn't provide the turnaround time that a POC test device could. There was irritation expressed, but they had no will or motivation to solve the problem that we were asking these laboratory professionals to solve. So we solved it ourselves."

Back in Adelaide, the team used the point-of-care device to introduce troponin assays in the emergency department at Flinders Medical Center. To make an effective business case for using troponin assays instead of the CK-MB assay, Tideman says he had to offer the physicians a way to get the results as quickly as the CK-MB results.

"When dealing with acute cardiac syndromes, clinicians need results immediately, 24 hours a day, seven days a week," said Tideman. "Point-of-care testing was the answer to that clinical need."

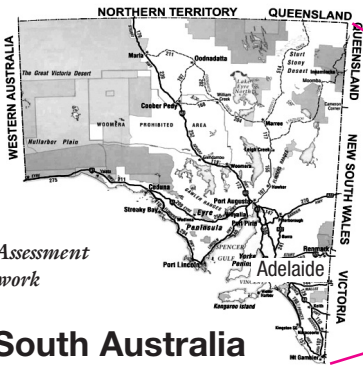
Knowing that quality control would be a concern, Tirimacco was careful to establish high standards at the outset of the point-of-care testing program. "Being a laboratory scientist, I was aware of the quality issues around this type of testing," says Tirimacco. "We insisted on internal and external quality controls. We essentially transposed the protocols that happen in the laboratory to the ward areas of our hospitals."

POC Testing Succeeded

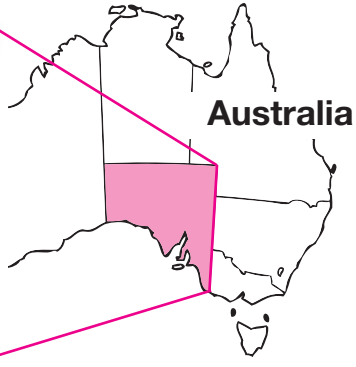
Within the central hospital, use of the point-of-care platform for troponin testing proved successful. Physicians regularly rely on the troponin test as part of their diagnostic protocols. The central laboratory now offers troponin assay runs as needed, rather than just once a day, although the point-of-care devices are still used when physicians evaluate a chest-pain presentation and need fast results.

Use of POC Testing in South Australia Improves Cardiology Patient Outcomes

Integrated Cardiac Assessment Regional Newtwork



State of South Australia



COMBINING POINT-OF-CARE TESTING (POCT) with evidence-based medicine protocols helped the Integrated Cardiovascular Clinical Network for South Australia (iCCnet SA) achieve substantial improvements in patient outcomes.

Recognizing that the risk of death from cardiovascular disease was almost twice as much for rural residents compared to city dwellers, iCCnet SA deployed POCT, accompanied by training and access to cardiovascular care consultants. During the life of this program, mortality from cardiovascular disease for rural residents has fallen dramatically. It now is comparable to that of urban dwellers in South Australia.

How POCT Produced Cost Savings

- Approximately 6% total reduction in 30 days readmissions for ACS
- Reduced length of stay in rural hospital
- Reduce cost of unnecessary RFDS transfers (approximately A$1,500 to A$2,500 per transfer)
- Evidence-based cardiac care reduces progression of Coronary Artery Disease thereby lowering the cost of healthcare to the community
- Reduced clinical laboratory on-call costs

iCCnet SA Clinical Audit

	Pre-iCARnet	Post-iCARnet	P value
Number of Patients	397	212	
Males	237 (60%)	138 (54%)	
Average Age (yr)	63	65	
Number of Admissions	495	255	
Readmissions	60 (15%)	33 (13%)	0.58
ACS readmissions	16 (4.0%)	3 (1.4%)	
Time to Angio (days)	6.3 (n=34)	2.5 (n=13)	0.0002

It is in South Australia's rural areas where the impact of iCCnet SA has been most significant. In rural hospitals, the combination of point-of-care troponin assays and 24-hour interactive consultation services dramatically improved outcomes. For rural cardiac patients, there were substantial reductions in mortality rates, as well as length of stay and re-admittance rates.

"In our rural hospitals there is both the demand and the need for point-of-care testing," noted Tideman. "Without point-of-care testing, in our country areas we could never deliver evidence-based acute cardiology."

"The inpatient mortality rate in our study population is now half what it used to be!" stated Tideman. "Currently it is the same in country and metropolitan areas, whereas previously it was double in country areas versus city.

"As a consequence of using POCT testing, the number of transports has doubled," he continued, "but now all of the patients who are transported are high risk. We see a reduced length of stay and reduced time to angiography."

Expansion of POCT Menu

iCCnet SA's point-of-care testing progam has proven so effective that the test menu was expanded. Increasingly, rural hospitals in South Australia have a set of four or five POC devices that can do a range of cardiac markers, basic hematology, biochemistry, and blood gasses, as well as coagulation studies. Results are reported in a format similar to results from the hospital labs, or are reported in a format that gives the normal ranges for the test as performed on the point-of-care device.

Quality control has not been a problem, Tirimacco says. In addition to internal quality controls and calibration, the rural hospitals periodically send matched samples to the peripheral hospital labs or labs in the Adelaide hospitals to check for accuracy of their devices. So far, the devices have performed extremely well, with only minor variations in results.

Demand for POC Testing

"In our rural hospitals there is both the demand and the need for point-of-care testing," noted Tideman. "Without point-of-care testing, in our country areas we could never deliver evidence-based acute cardiology."

"I think we'll see more and more acute care tests move into the point-of-care arena," says Tirimacco, "mostly because of the faster turnaround times that support better patient outcomes. POCT supplements those tests that will always be performed in the central laboratory."

THE DARK REPORT notes that iCCnet SA's successful use of point-of-care testing has several insights and useful lessons for the laboratory medicine profession. First, it provides an invaluable case study, since this program now has almost 10 years of operational and clinical history. It offers a well-documented road map on how to design, deploy, and sustain an effective point-of-care testing program.

Second, the lower mortality rates from cardiovascular disease for rural residents living in South Australia resulted from how iCCnet SA encouraged adoption of evidence-based medicine guidelines in tandem with use of point-of-care testing for cardiology patients. It shows the importance of pathologists and laboratory scientists taking a more interactive and collaborative role with clinicians as a way to deliver more value from laboratory medicine.

Third, this case study provides a reminder of why champions and innovators are important. It was Phillip Tideman, M.D.'s vision that led to the creation of the iCCnet SA program. It was the commitment and enthusiam shared by

Successful Use of Point-of-Care Testing Earns Funds from Government Health Program

DURING THE FIRST FIVE YEARS that the Integrated Cardiac Care Network for South Australia (iCCnet SA) operated, funding for point-of-care testing was a struggle. The project was launched with A$40,000 scavenged from leftovers in the Cardiology Department's budget. It kept going with a grant from the commonwealth that the team secured 18 months later.

"It took a long time to get anyone in the health service sufficiently interested in what we were doing to fund us," noted Phillip Tideman, M.D., the cardiologist who organized iCCnet SA. "They weren't prepared to come onboard until we had some results. About five years ago, when it became clear that project was saving lives and reducing costs, funding came easier, allowing the team to expand the program.

Establishing A Budget

"iCCnet SA now operates on a yearly administrative budget of about A$500,000, which covers network staff and office expenses," he explained. "Testing costs come out of the individual hospitals' budgets."

This year, the South Australian health department decided that it wanted a single, state-wide pathology/lab testing service. That might have spelled disaster for the carefully-constructed POCT program that Tideman and Tirimacco had nurtured. But Tideman was able to negotiate an agreement to integrate his project with the new statewide service as part of a state-wide point-of-care service.

Tideman sees this as a major victory. Though the state government runs both the pathology service and the cardiac network, competition between the two was as fierce as if they were for-profit entities. "We have been told in the past that, because we are not pathologists, we have no role in expanding POCT services. We enjoy proving them wrong and letting the outcomes speak for themselves," he said.

POCT Is Feasible

"What happened over the last ten years is that the laboratory-based biochemists and pathologists have seen that what we've accomplished with POCT is feasible," observed Tideman. "On the business side of things, there has always been resistance and a great deal of angst from the central laboratories about whether we are stepping on their territory."

"We overcame that because we deliver a POCT service that they can't match since they are no longer clinically integrated," he continued. "The force of consumer and clinician demand has brought them to the table, and we were able to negotiate this new agreement from a position of strength. We had the support of the clinicians and they didn't.

View POC Test Results

A major advantage of the integrated arrangement, he adds, is that they will have an interface able to upload the results from their point-of-care testing instruments to the central clinical and laboratory information systems operated by the state health service. This will allow physicians anywhere in the system to view the point-of-care test results just as they would the test results performed by the central labs. Previously, the results were only available through the cardiac network database.

Making POCT Work In Clinical Settings

TO WORK WELL, the point-of-care testing platform must be utilized as one part of an integrated system that oversees quality control and provides consultation about results.

"You could put point-of-care testing out there and make no difference whatsoever," says Phillip Tideman, M.D., Clinical Director of iCCnet SA. "Point-of-care testing has to be part of an integrated clinical network, in which the POC instruments are part of a unified system that ensures evidence-based care, quality results and constant monitoring. That system must be collaborative, so users in the field feel free to offer feedback and suggestions on how to improve performance.

"If you tried to impose this from above, it wouldn't work. It's hard to get engagement from the doctors and the nurses unless they feel they own it too," concluded Tideman.

iCCnet SA @-a-glance

Point of Care Test Instruments

Roche Ccardiac Reader, Cobas h232, Coaguchek XS, Coaguchek XS Plus, Roche Inform 11 (soon to be implemented)

Abbott Diagnostics i-STAT

Abaxis Piccolo

Haemocue – Hb and WCC

Menu-of-Point of Care Tests

Troponin T, NT-proBNP, D-Dimer, CK-MB, INR, Sodium, Potassium, Chloride, Glucose, Lactate, Creatinine, pH, pCO2, PO2, Ionised Calcium, Urea, Haematocrit, Haemoglobin, TCO2, HCO3, Base Excess, Anion Gap, sO2, Cholesterol, HDL, TRIG, ALB, ALP, ALT, Amylase, AST, Bilirubin, GGT, TP, White Cell Count, Glucose

Number of POC Testing Sites

- 66 Hospital sites currently running POCT through ICCnet
- 3 Aboriginal Health Centres
- 33 Clinic Sites
- 1,800 Operators Trained (estimate)

Tideman and Tirimacco that inspired other clinicians to participate in a new way of assessing cardiology patients—even though it required clinicians to change long-standing clinical practices and embrace the use of point-of-care testing.

➤Adoption Of POCT

While the unique geography of South Australia encouraged the adoption of point-of-care testing there, use of the technology elsewhere will follow as the cost of POCT comes down. Pathology labs can choose to see POCT as a threat to business as usual, or they can see it as an opportunity to promote, manage and profit from adoption of this rapidly-improving diagnostics testing technology.

With a 10-year track record and a documented ability to improve patient outcomes in a cost-effective manner, ICCnet SA's successful use of point-of-care testing provides a useful template. It demonstrates one way that laboratory testing can be leveraged to boost outcomes and add value to the healthcare system.

For example, both the United States and Canada have large regions that are thinly-populated. It is likely that ICCnet SA's approach to using point-of-care testing to support an integrated clinical care program could deliver similar improvements to patient care in these regions as was achieved in South Australia.

➤Fast, Accurate Answer

Because the capabilities of POC testing devices are improving continually, it can be expected that use of POCT will expand in coming years. Both physicians and patients welcome a fast, accurate answer at the point of care, because it improves the accuracy of the physicians' diagnosis while allowing the patient to start therapy without having to wait overnight or longer for a central laboratory to report back all the test results. **TDR**

–K. Branz | Contact Phillip Tideman, M.D., at Phil.Tideman@health.sa.gov.au; and Rosy Tirimacco at Rosy.Tirimacco@health.sa.gov.au.

Serious Problems Plague Newfoundland Laboratory

Inaccurate cyclosporine test results trigger lab director resignations and more media scrutiny

CEO SUMMARY: Newfoundland's St. John laboratory was rocked by revelations in February that its cyclosporine testing was flawed, exposing patients to the harmful affects from inappropriately high doses of the immunosuppressant drug. Within weeks of this news, the Chief of Laboratory Medicine resigned. Now a team from Toronto's University Health Network (UHN) is at the laboratory to conduct a review of operations and make recommendations to the health authority.

THERE IS MORE TROUBLE with laboratory testing services at **Eastern Health**, the largest health authority in the Newfoundland-Labrador health system. New disclosures of laboratory test errors and an unflattering outside review of the laboratory again generated national news headlines in Canada.

It was 2005 when it was discovered that this same laboratory had reported inaccurate breast cancer test results. Between 1997 and 2005, almost 500 women were given inaccurate breast cancer test results. Even today, the consequences from this failure in laboratory test accuracy continue to reverberate throughout Canada today. *(See TDR, May 18, 2009.)*

Over the past four to six weeks, the St. John laboratory has been rocked by a new series of events. First, in mid-February, it was disclosed that the laboratory had reported inaccurate cyclosporine testing since June 2009 and these problems went undetected until just days earlier.

Next, within weeks of this disclosure, the Chief of Laboratory Medicine, pathologist Dr. Nash Denic, was asked by Eastern Health President Vickie Kaminski to either resign or be terminated. Just days later, it was learned that Denic had tendered a resignation back in December and—at that time—Eastern Health officials had asked him to stay on.

More Resignations

Following Denic's resignation, two more pathologists resigned from their laboratory directorships. They were Dr. Ford Elms at **Health Sciences Center** and Dr. Don Cook, at **St. Clare's Hospital**. Both pathologists continue to handle clinical duties. Another chief of laboratory service resigned days later. These resignations were in support of Denic.

Days later, Dr. Jim Hutchinson resigned his management position, but did not mention support of Denic as a reason for his decision. He remained on staff in the microbiology department at Health Sciences Center.

The next grenade that exploded in this story was public release of an outside study of the St. John laboratory. On Monday, March 15, Kaminiski and Health Minister Jerome Kennedy told the press about the findings of the study.

It was conducted by the **Institute of Quality Management in Healthcare** (IQMH), based in Toronto, Ontario. The report was signed by pathologist Gregory J. Flynn, M.D., who is IQMH's CEO.

Lab Work Environment

The study was based on interviews with staff at the St. John laboratory. The interviews were conducted in the months between Denic's attempt to resign in December and the March 12 submission of the findings to Eastern Health officials. In its report, the IQMH described the work environment in the St. John laboratory as "dysfunctional", "autocratic", "toxic", and "hostile."

All of these events were extensively covered by the press. In defense of Denic, the President of the **Newfoundland and Laboratory Association of Pathologists**, Dr. Barry Gallagher, wrote a letter to the *St. John Telegram*, commending Denic for "remarkable improvements" made during his tenure at the laboratory. "How he managed such a heavy workload for so long is a mystery to us all," said Gallagher.

On March 20, Kaminiski told reporters that seven of the authority's 24 pathologists were on sick leave. She admitted that a work backlog was building within the Eastern Health laboratories.

In response to these developments, Health Minister Jerome Kennedy announced that a team from **University Health Network** (UHN) of Toronto, Ontario, would come in and review laboratory work flow within Eastern Health.

All of these events were widely-reported by the Canadian press. It was just last year when Judge Margaret Cameron released the findings of her commission, which investigated the reasons for the failure of the St. John laboratory's breast cancer testing program during the years 1997-2005. Not surprisingly, disclosure of more lab testing failures at the St. John lab was a major story.

In fact, officials at Eastern Health were caught off guard by the discovery of problems with cyclosporine testing. A critically-ill 14-year-old boy was admitted to intensive care in early February. He had received an excessive amount of cyclosporine.

That's when it was determined that the laboratory test results underreported his cyclosporine level. The faulty cyclosporine test results were caused by a new mass spectrometer which was brought into service last June and it was not properly calibrated.

In February, after this discovery, Kaminiski confirmed to reporters that problems with cyclosporine testing had been identified at Eastern Health's St. John laboratory. Beginning in June 2009, 235 patients had received inaccurate test results, mostly underreporting the patient's actual level of cyclosporine. At least 13 of these patients had died. If administered in high doses, this immunosuppressant drug can cause kidney damage.

THE DARK REPORT believes the ongoing story of Newfoundland's St. John laboratory is an early and important example of what happens when a parent health system underfunds its laboratories over a sustained period of time.

If the parent health system fails to provide adequate capital for expansion and modernization of testing systems, then at some point the laboratory cannot accommodate the increase in specimens required to support clinical services. Similarly, failure to fund competitive salaries and benefits prevents the laboratory from recruiting and retaining the needed number of skilled laboratory scientists.

Inadequate Lab Funding

Thus, the problems now visible at the St. John lab are probably not of recent origin. Rather, they are mostly likely the consequence of inadequate budgets going back 10 years or longer. The truth of this will become more obvious with each passing year. However, it costs much more to "restore" an underperforming lab than to maintain it as a start-of-the-art testing service. In the meantime, patients will pay the ultimate cost of a poorly-funded lab testing service. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

News sources are reporting a rumor that President Barack Obama intends to appoint Donald Berwick, M.D., as Director of the Centers for **Medicare and Medicaid Services** (CMS). Berwick is currently Director of the **Institute for Healthcare Improvement** in Boston, Massachusetts. He has been outspoken about the need for healthcare to devote more effort to improving quality. CMS has not had a permanent director since the departure of Mark McClellan, M.D., in 2006.

JUAN ROSAI, MD'S CASES TO BE PUT IN DIGITAL ARCHIVE

It's another milestone on the road to full adoption of digital pathology. On March 22, the **United States and Canadian Academy of Pathologists** (USCAP) and **Aperio Technologies, Inc.**, announced a partnership that will "digitize, archive, and make publicly available online, at no cost to the pathology community, the Dr. Juan Rosai Collection of Surgical Pathology Seminars." This comprehensive collection consists of about 20,000 cases. The archive will include digital images of the original slides, along with clinical history and the diagnostic summary. Also included will be "present day commentary by Rosai and other experts." Both Aperio and USCAP will make the digital information available through their respective web sites. The goal is to complete the archiving by early 2011.

ADD To: *ROSAI*

This partnership is an early example of how the combination of digital pathology technology and the Internet will change pathology education. In this case, once USCAP and Aperio finish with archiving Dr. Rosai's collection, it will be possible for any pathologist anywhere in the world to use the Internet and access these cases. That allows anyone to learn from Dr. Rosai on a 24/7 basis. Going forward, entrepreneurial schools of medicine are likely to engage world-class pathologists and create similar learning and lecture modules in their particular subspecialty of laboratory medicine. In turn, that makes it easy for any medical student to access and learn from the lectures of the world's foremost pathologists.

PHLEBOTOMIST GETS LUCKY, WINS $111,250

One lucky phlebotomist from Camas, Washington, became this season's first $100,000 winner on television's *Wheel of Fortune* game show. In a show aired in March, Barry Williams, who works at a family practice clinic, won a total of $111,250 after solving the $100,000 round puzzle.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...the new requirements of the HITECH ACT that laboratories must follow when a breach of protected health information (PHI) occurs. This can include notifying media of the lab's PHI breach.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 19, 2010.

Make plans Now!

EXECUTIVE WAR COLLEGE

April 27-28, 2010 • Sheraton Hotel • New Orleans

Preview–Alan Mertz, American Clinical Lab Assoc.

What the New Health Law Means to Future of Clinical Labs and Pathology Groups!

Join us for the first detailed assessment of the new health law. Learn how it will recast laboratory testing, along with the negative consequences to reimbursement and coverage guidelines for routine and genetic testing. Alan Mertz participated in many of the discussions with Senate and House leaders as this far-reaching health legislation was crafted. This guarantees you an inside perspective on the design of the health law. Get the knowledge you need to prepare your lab for the far-reaching changes soon to come!

Check for program details and to register!
visit www.executivewarcollege.com

UPCOMING...

- ***How HIPAA Breach Caused Community Hospital to Terminate Contract with Its Pathology Group***
- ***Practical Steps Laboratories Should Take to Prepare for Accreditation to ISO 15189.***
- ***Advertising Experts Discuss Social Networking and How Clinical Labs Can Use It to Build Revenue.***

For more information, visit:

www.darkreport.com

Sign Up for our FREE News Service!

Delivered directly to your desktop,
DARK Daily is news, analysis, and more.

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends