No Longer "Out of Sight, Out of Mind":
Laboratory Errors Attract Headlines and Public Concern

ROBERT L. MICHEL
Editor In Chief

THE DARK REPORT
Spicewood, Texas

Lab Quality Confab
Atlanta, Georgia
October 29, 2009

rmichel@darkreport.com
ph: 512-264-7103
fax: 512-264-0969

My Premise…

- **Laboratory errors now receive wider press coverage than ever before.**
- Public pays attention to issues of lab test accuracy and lab test integrity.
- Lab Industry is behind on improving its acceptable level of lab test accuracy and laboratory operations—when gauged against current expectations of patients and their families.

Listing Public Lab Errors by Decade

- 1980s:
  Pap smear sink test scandal.
- 1990s:
  Chem-Bio Labs and SmithKline Beecham (needle reuse).
- 2000s:
  explosion of lab errors during this decade; national media coverage!

Lab Error Events Since 2000

- 2000-06: Nichols Institute Diagnostics (NID) manufactures and distributes inaccurate test kits, per DOJ.
- 2004: Maryland General Hospital Lab
- 2005: ER/PR Testing in Newfoundland and Labrador
- 2007-08: Pap testing issues in Ireland
- 2008: Pathology testing problems in Ontario, Manitoba, New Brunswick

Lab Error Events Since 2000

- 2007-2008: Inaccurate Vitamin D results at Quest Diagnostics Incorporated.
- 2009: Breast Cancer problems in Quebec
- 2009: Serious deficiencies in start-up of Labtests in Auckland, New Zealand

What Caused These Lab Testing Problems?

- **Proposal:** as a group, let's look at some of the public statements about problems with these events.
- **Help to answer the question:** might use of modern quality management systems (QMS) have prevented these situations?

"Lab Breakdowns" in 1980s

- In the 1980s, it was the "sink test" scandals in Pap testing labs.
- News reports impelled Congress to enact "Clinical Laboratory Improvement Act" (CLIA) in 1988.
- However, this was simple fraud.
- No effort was made to perform the test according to protocols.

ChemBio Case-1993

- Chem-Bio Corp., of Oak Creek, Wisconsin
- Pap testing laboratory
- Indicted for reckless homicide in the death of Dolores Geary, 40, and second-degree reckless homicide in the death of Karin Smith, 29.
- Smith asked before she died that prosecutors pursue criminal charges.
- Chem-Bio pled "no contest." Had been acquired by Damon Clinical Labs.

Chem-Bio

- *Karin Smith said the H.M.O. performed three biopsies and three Pap smears, but the laboratory misread all but one of them. Had her cervical cancer been properly diagnosed in 1988, when the first Pap smear was misread, she would have had a 95 percent chance of survival, she said. Instead, her cancer was not diagnosed until 1991, when she saw a doctor who was not affiliated with the H.M.O.* NY Times, Thursday, April 13, 1995

Chem-Bio

- *Mr. McCann, the prosecutor, said grave errors had been made because the laboratory's director, Dr. Robert Lipo, had paid its technician, June Fricano, on a piecework basis for reading Pap smears. As a consequence, Ms. Fricano in 1989 read 31,000 slides for Chem-Bio and 16,000 slides for another laboratory. In contrast, Mr. McCann said, the American Society of Cytology had recommended that for the sake of quality control, technicians read no more than 12,000 slides a year.* NY Times, Thursday, April 13, 1995

SmithKline Beecham Clinical Laboratories-1999

- Phlebotomist discovered to reusing needles in a PSC in Palo Alto, CA.
- “More than 3,600 patients who had their blood drawn at the Palo Alto facility were notified in April, and 11,700 individuals seen at other locations began to receive notification in May.”

SmithKline Beecham Clinical Laboratories-1999

- "These were the actions of one person acting outside of company policy and outside of medical standards of practice who made the conscious decision to reuse needles," the (SBCL) spokesman continued. If an individual makes that decision, "...there's really no way to supervise adequately to keep [it] from happening."

SmithKline Beecham Clinical Laboratories-1999

- Former phlebotomist Elaine M. Giorgi, 53, could face 12 years, eight months in prison if convicted on all counts. In addition to the five felony assault counts, she faces seven felony counts of improper disposal of medical waste and one misdemeanor count of falsifying medical records.

San Francisco Chronicle, October 4, 2000

SmithKline Beecham Clinical Laboratories-1999

- Officials for Quest Diagnostics, SmithKline's parent company, testified yesterday that the curve-tipped butterfly needles cost 80 cents each, compared to five cents each for larger, “straight needles.” Although officials would track excessive use of butterfly needles because of the “cost factor,” supply manager Michael Carney said clinic employees were allowed to order whatever supplies they needed to serve patients' needs.

San Francisco Chronicle, October 4, 2000

SmithKline Beecham Clinical Laboratories-1999

- Yesterday, Dvorsky, who was a temporary blood-drawing technician at the clinic, described Giorgi as a woman obsessed with saving SmithKline money by reusing the more expensive butterfly syringes that she favored because they were easier to use and less painful for patients.
- In late February 1999, Dvorsky testified, she asked Giorgi why the technician kept a brown sack of "dirty needles"` in a white plastic basket in a blood-draw room.

San Francisco Chronicle, October 4, 2000

SmithKline Beecham Clinical Laboratories-1999

- "She said, 'Don't you touch them. Those needles have to be used two or three times,'" Dvorsky recounted. When Dvorsky asked why, Giorgi allegedly said "because she would get in trouble with SmithKline because the butterfly needles are very expensive."

San Francisco Chronicle, October 4, 2000

SmithKline Beecham Clinical Laboratories-1999

- Elaine Giorgi… on Thursday received a one-year prison term after pleading no contest to a misdemeanor charge of falsifying medical records, the *San Jose Mercury News* reports. She also plead no contest to a felony charge of illegally disposing of medical waste, for which she received four years probation (*San Jose Mercury News*, 8/16/2000).

Maryland General Hospital Laboratory-2004

- Acting on a complaint apparently filed by a former hospital employee, state health officials discovered in January that the Baltimore hospital's laboratory personnel overrode controls in the testing equipment that showed the results might be in error, then mailed them to patients anyway.

Baltimore Sun, March 11, 2004

Maryland General Hospital Laboratory-2004

- Labotech Open Microplate Blood Testing System was used to do HIV, HCV; manufactured by Adaltis, Inc.
- Put into operation June, 2002. Ceased using this instrument in August 2003.
- Lab staff alerted lab administrator.
- Lab staff went to hospital HR department to notify them about unacceptable results.

Maryland General Hospital Laboratory-2004

- One med tech was infected by HIV and HCV while operating the instrument.
- She tested positive for both infections six months later.
- She was the whistleblower who got attention of the Maryland Department of Health in January 2004.

Maryland General Hospital Laboratory-2004

- Lab administrator fired.
- Pathologist medical director cited.
- Hospital CEO resigned.
- Approximately 4,500 patients needed to be found and retested for HIV and HVC.
- CAP inspection process and Maryland Dept. of Health inspection criticized.
- Events triggered Congressional hearing.

Newfoundland, Labrador 2005

- In May 2005 Eastern Health discovered errors in hormone receptor breast cancer test results from a histology lab in St. Johns, Newfoundland.
- Affected patients had been tested between 1997 and 2005.
- Up to 1,500 patients authorized for retesting based on indications of errors in original test result report.

Newfoundland, Labrador 2005

- After retesting, Eastern Health concluded that 383 patients had received erroneous results, of whom 117 required a change to their treatment programs.
- More than 100 of the women whose lab results were reviewed had died prior to this review.

Newfoundland, Labrador 2005

- A judicial enquiry, on Tuesday [March 2, 2009], reported that the protocols and procedures at the health authority at the centre of a breast-cancer-testing scandal in Newfoundland and Labrador were "so deficient as to be practically non-existent."

Pathology Testing-Ontario

- May, 2008, Owen Sound, Ontario: After routine quality control testing identified an error by pathologist Barry Sawka, M.D., at Owen Sound Hospital, a more detailed review of 600 of his cases was launched. Grey Bruce Health Services, the local health authority, determined that the error rate was 6%, which health officials stated was six times the “the normal error rate for pathologists.” These misdiagnoses lead to errors in treating patients.

Testing Problems-Manitoba

- ● May, 2008, Winnipeg, Manitoba: Pathologist Robert Stark, M.D., was put on leave from his position as head of the pathology department at St. Boniface Hospital.
- The outside pathology review of this lab, including approximately 822 of the cases diagnosed from February 2008 and complex cancer cases dating back to March 2007, determined that errors were made in at least 42 cases and two patients received the wrong cancer diagnosis due to error.

Testing Problems-New Brunswick

- February 2008, Miramichi, New Brunswick:
- Pathologist Rajgopal Menon, M.D., left his position as head of pathology at Miramichi Regional Hospital following a review of 227 cases of prostate and breast cancer biopsies from 2004-2005.

Testing Problems-New Brunswick

These independent reviews determined:

- 18% of the cases had incomplete results.
- 3% were misdiagnosed.
- 41 cases included incomplete protocols or examinations and or miscalculated the stage of the cancer.
- Compared to the original diagnosis, there were seven cases of undetected cancer, and four additional cases that were possibly cancerous.

Testing Problems-New Brunswick

- Health officials announced they would review as many as 24,000 cases.
- Menon characterized this review as “unjustified and unfair.”
- He filed a civil suit against the regional health authority.

Testing Problems-Quebec

- The province's health department has ordered 2,100 new tests after a tiny pathology study exploded on the Quebec scene last week, suggesting that 15 to 30 per cent of breast-cancer tests were botched, throwing patients into a panic about the reliability of their tests and health status.

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- Not only are Quebec's ill-equipped, underfunded and short-staffed laboratories under a microscope, but the government was forced to revise its standards and is now setting up a universal quality control program.
- Effective immediately, all provincial labs will be required to have external audits of their tests. Some labs are already doing that.

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- Gaetan Barrette, head of Quebec's federation of medical specialists, said problems in the labs are long-term and systemic. It's not just breast cancer tests that are at risk, but all cancer testing, Barrette said.

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- In 20 to 30 per cent of cases, there are disagreements between labs and individuals on whether a result is negative or positive, because of variables in technique and interpretation, said Jared Schwartz, president of the College of American Pathologists (CAP), a world authority on lab quality control and accreditation.

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- "The problem is that there is no gold standard anywhere on how you call a specific test positive or negative," Schwartz said, also co-chair of an international team that's developing universal guidelines on process and criteria that pathologists will use. "We are trying to get rid of the variables to get it down to 10 per cent discordance."

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- St. Mary's Hospital Centre is the only Quebec facility to have a CAP accreditation, and it took a decade to achieve, said chief pathologist Ron Onerheim. Having no quality control program is a red flag, he said.

Montreal Gazette, June 6, 2009

Vitamin D-Quest Diagnostics

- *The Dark Report*, December 22, 2008:
- "Quest Diagnostics has recognized that, starting in early 2007 and into 2008, for some periods of time for a small percentage of tests, there were potentially inaccurate results at certain of our testing sites," acknowledged Richard Reitz, M.D. "A thorough review of Vitamin D results reported throughout this time was conducted."

Vitamin D-Quest Diagnostics

- *New York Times*, January 8, 2009
- Quest's problems with the vitamin D analysis arose after it shifted in 2006 and 2007 to a new test of its own design, replacing an older F.D.A.-approved test. The new test promised to be more accurate and offer more detailed information, Quest executives said. But the test relied on a sophisticated instrument called a mass spectrometer, which can be tricky to use, especially for high-volume testing.

Vitamin D-Quest Diagnostics

New York Times, January 8, 2009

- Dr. Wael A. Salameh, the medical director for endocrinology at Quest's most sophisticated laboratory, which is in San Juan Capistrano, Calif., said some materials used to calibrate test results had been faulty. And four of the seven Quest testing laboratories around the country did not always follow proper procedures, he said.

Vitamin D-Quest Diagnostics

New York Times, January 8, 2009

- Quest would not say how many patients were affected. But a spokesman did not deny that thousands of doctors were sent letters in October. Each doctor had at least one patient, and in many cases dozens of patients, who had a possibly inaccurate test result.
- Dr. Salameh said the inaccurate results represented less than 10 percent of all the vitamin D tests done by Quest from early 2007 to mid-2008.

Vitamin D-Quest Diagnostics

Dark Daily, January 8, 2009

- Take Salameh's statement [in the *New York Times*] that “fewer than 10% of all the Vitamin D tests” were inaccurate, and assume a 9% rate of inaccurate tests. Next, combine that with a rough estimate that Quest Diagnostics performed between 5 million and 7 million Vitamin D results during 2007-2008, and one comes up with a possible range of between 450,000 to 630,000 inaccurate Vitamin D test results.

Ireland Outsources Pap Tests

- In Ireland, Irish labs were averaging six months turnaround time to report Pap test results.
- Starting July 1, 2008, Ireland outsourced all of its Pap testing to Quest Diagnostics.
- Government health service was promised a 10-day TAT by Quest.
- Quest Diagnostics bid one-third less money than any Irish lab that bid.

DOJ Settlement with Quest and Nichols Institute Diagnostics

- Announced on April 15, 2009, it had several components, as described by the Department of Justice Press Release:
- "As part of the criminal resolution, NID pled guilty this morning…to a felony misbranding charge in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.
- "The charge relates to NID's Nichols Advantage Chemiluminescence Intact Parathyroid Hormone Immunoassay (the "Advantage Intact PTH Assay"), a test that was used by laboratories throughout the country to measure parathyroid hormone ("PTH") levels in patients.
- "As part of the plea, NID will pay a criminal fine of $40 million."

DOJ Settlement with Quest and Nichols Institute Diagnostics

- Next, as described by the Department of Justice Press Release:
- "Quest and NID have also entered into a civil settlement agreement with the United States pursuant to which Quest will pay $262 million plus interest to resolve federal False Claims Act allegations relating to the Advantage Intact PTH assay and four other assays manufactured by NID that allegedly provided inaccurate and unreliable results.
- "Quest has agreed to pay various state Medicaid programs approximately $6.2 million to resolve similar civil claims. Quest has also entered into a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services."

What was the problem?

- Dept of Justice Press Release:
- "The civil settlement resolves allegations that NID manufactured, marketed and sold the Intact PTH and Bio-Intact PTH test kits, despite knowing that between May 1, 2000 and April 30, 2006, some of these kits produced results that were materially inaccurate and unreliable, thereby causing: (a) some clinical laboratories that purchased and used the Intact PTH and Bio-Intact PTH test kits to submit false claims for reimbursement to federal health programs; and (b) some medical providers to submit false claims for reimbursement to federal health programs for unnecessarily prescribed treatments. "

Case Study of Quality Issues

- What might have caused these failures?
- Science and design of the assays?
- Manufacturing of the assays?
- Quality Control/Quality Assurance?
- Systemic issues or management failures to recognize problems and take corrective action?

Auckland, New Zealand

- In 2006, District Health Boards in Auckland awarded monopoly, six-year contract to new laboratory.
- Contract is to provide testing for 12,000 patients per day; approximately 30,000 tests per day.
- Problem: Labtests, the winning lab firm, had neither a lab facility nor staff in Auckland.

Auckland, New Zealand

- Effective September 7, 2009, the new Labtest lab facility become operational to serve the 12,000 patients per day.
- Problems were immediate.
- Wait times in collection centers
- Patients reported getting other patient's lab test results.
- Excessive delays in lab test reports.

Auckland, New Zealand

- In just 10 days, on September 17, District Health Boards put Labtests on notice of violation of its contract.
- District Health Boards put seven employees into Labtests to watch operations.
- New Zealand Medical Association has complained publicly of unacceptable lab test result quality and poor overall lab services.

Root Cause Analysis

- What factors contributed to the range of laboratory problems that have become public news?
- Money may be a common element.
- In some cases, motivation to maximize profit, influenced lab leadership.
- In some cases, inadequate reimbursement or payment for lab testing is a reason why inadequacies in staffing, service infrastructure, and handling of the specimen came to be.

ONE MORE THING!

Diagnostic Errors by Doctors

- It was in 1999 that the Institute of Medicine issued “To Err is Human.”
- IOM estimated that between 44,000 and 96,000 patients died in hospitals due to medical errors.
- That launched the modern patient safety movement.
- Now, attention is shifting outside hospitals to office-based physicians.

Attention on Docs' Errors

- March 11, 2009, issue of *Journal of the America Medical Association* (JAMA).
- From Johns Hopkins School of Medicine, David Newman-Toker, M.D., Ph.D., and Peter Pronovost, M.D., Ph.D.
- They wrote that the problems caused by errors in diagnosis are much bigger in terms of deaths than more popular targets, like medication errors and wrong-site surgeries.

More on Docs' Errors

Newman-Toker and Pronovost wrote that:

- Diagnostic errors—including missed, wrong, or delayed diagnoses—account for an estimated 40,000 to 90,000 deaths a year.
- Diagnostic errors trigger nearly twice as many tort claims as medication errors and also subject patients to medical complications, as well as the discomfort and cost of medical tests they don't need.

Clear Message for Labs

- Publicity about lab errors is increasing.
- Patients and consumers are savvy and understand the consequences of errors in laboratory testing.
- Labs should be proactive at using quality management methods to continuously improve all aspects of their testing performance and operational execution.

There's Good News…

- Quality Management Systems are a proven way for labs to "error proof" their activities.
- Progress is incremental, which is why continuous improvement is one new paradigm in laboratory management.
- This *Lab Quality Confab* offers you more than 40 speakers and sessions to help you advance the cause of quality in your lab or hospital.

-30-