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THE INFORMED PATIENT
By LAURA LANDRO



Hospitals Move to Cut Dangerous Lab Errors

Improved Specimen Collection And Efficiency Help Increase Accuracy of Medical Testing

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Diagnosed with a deadly neuroendocrine cancer at age 34, Kim Tutt was told she might have just months to live. After five surgeries to excise a cyst under her gum, remove her lower jaw and teeth, and reconstruct her face with bone taken from her lower leg, the Tyler, Texas, mother of two heard some shocking news: The slides from the biopsy of her cyst had been contaminated by cells from another patient, and she had never had cancer in the first place.

For patients, some of the most devastating medical mistakes can start in the lab, where studies show that 3% to 5% of the billions of specimens taken each year are defective, be it a biopsy that doesn't extract the tumor cells, blood that isn't drawn correctly or a mix-up with another patient's sample. The error rate is significantly higher and more dangerous in common tests for many cancers, where a false positive may lead to an unnecessary hysterectomy or a false negative can miss a deadly skin cancer.

Know Before You Go
Where to find more information about lab reports

- **College of American Pathologists**
www.cap.org
Consumer information about pathologists and help understanding test results
- **The Doctor's Doctor**
www.thedoctorsdoctor.com
How to interpret laboratory, surgical pathology and cytology reports
- **Lab Tests Online**
www.labtestsonline.org
Help understanding clinical terms and reliability of tests



Photo: Researchers

Now hospitals and health-care-quality groups around the

country are working on initiatives to bring more rigorous standards to pathology labs, with support from government and nonprofit groups including the federal Agency for Healthcare Research and Quality, the Centers for Disease Control and

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ABOUT THE INFORMED PATIENT

Laura Landro is an assistant managing editor of The Wall Street Journal, and writes frequently about health care. Her column, "The Informed Patient," runs on alternate Wednesdays. The column explains how to find information, evaluate the quality of medical services and aggressively manage your health care. Laura also occasionally writes the "Finicky Traveler" column for the Weekend Journal section. Laura joined the Wall Street Journal in 1981, and spent 20 years as a reporter and editor responsible for media, entertainment and marketing coverage. Her book, "Survivor: Taking Charge of Your Fight Against Cancer," was published in October 1998 by Simon & Schuster. She received a bachelor's degree in journalism from Ohio University.

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Prevention, the Jewish Healthcare Foundation and the Pittsburgh Regional Healthcare Initiative.

In the largest effort, a group of nine major academic medical centers is participating in a lab-safety collaborative to redesign the archaic and error-prone systems for collecting, labeling, handling and interpreting blood and tissue samples. The collective is finding success with quality-control methods -- such as checklists and automated specimen processing -- that were adapted from Toyota's production system and General Electric's Six Sigma principles for reducing manufacturing defects.

"Tests fail because things can go wrong at every step of the process, and there are no checks and balances in place in pathology to catch these errors," says Stephen Raab, director of the center for pathology quality and health-care research at the University of Pittsburgh Medical Center, who is leading the lab-safety collaborative. While only about 1% of errors lead to serious harm or delays in treatment, he says, "You wouldn't want to have 1% of all airlines crashing."

At stake is not only patient safety, but the huge costs of such mistakes and delays. False negatives or positives can lead to repeat tests and more expensive procedures. And while malpractice claims for pathology errors are relatively low in number, they are the second-most costly to hospitals after neurology payouts, says David Troxel, medical director of The Doctors Co., a Napa, Calif., company that insures 800 pathologists. In a study of 335 pathology-related malpractice claims, conducted by the company and published last month, 63% of these claims involved the false-negative diagnosis of cancer and 22% involved the false-positive diagnosis of cancer.

One of the most persistent problems is the poor quality of specimens to begin with. In diagnosing cervical cancer, for example, biopsies must be taken from a certain part of the cervix known as the "transformation zone," but gynecologists fail to collect cells from the zone often enough to miss lesions 30% to 40% of the time, says UPMC's Dr. Raab. Even though it is usually apparent if the proper cells aren't present, "the lab will just make a diagnosis on what it gets," Dr. Raab notes.

Missing tumor cells can lead to a false negative, but pathologists may also interpret sketchy results as positive to avoid error, leading to more expensive and painful cervical biopsies. In 2004, UPMC developed a new, more rigorous process for collecting the specimens, including checklists for gynecologists to follow that map out correct procedures; both false positives and negatives have been reduced, Dr. Raab says.

Likewise, in patients with thyroid nodules, 300,000 fine needle aspirations -- in which a doctor inserts a tiny needle into a growth to extract cells -- are done annually in the U.S. to rule out cancer, but 25% of the time the tests miss tumor cells and produce false negatives, studies show. In January 2005, UPMC began posting a pathologist at the bedside of patients undergoing a needle biopsy to evaluate the quality of samples. The hospital was able to drop the false-negative rate on malignant tumors to less than 5% and sharply reduce the number of patients who needed second biopsies.

Hospitals are also using efficiency methods to get labs to speed up the notoriously slow pace of processing specimens, which leads to unnecessary anxiety for patients. Richard Zarbo, senior vice president for pathology and laboratory medicine at Detroit's Henry Ford Health System, who developed quality measures used by the College of American Pathologists to certify labs, says that in 1993, 525 labs participating in one study completed 79% of routine biopsies in one day, but that turnaround time hasn't improved significantly since.

In January, after completing training in the Toyota production techniques, Dr. Zarbo and his team started a pilot to speed up specimen-processing time in the surgical pathology lab, moving racks that load slides on a machine nine feet closer so technicians didn't have to walk back and forth so often, and processing smaller batches of slides every 20 minutes instead of waiting for the 60 slides necessary to fill the machine.

In the main lab, blood samples were often unacceptable because phlebotomists (technicians who draw blood), nurses and other staffers incorrectly labeled blood tubes. Dr. Zarbo says labeling standards often weren't enforced because of a "quick and lazy culture" of tolerance to the detriment of patient safety. In 2001, the lab started an educational program and began rejecting inadequate blood samples through a strict specimen-labeling policy, reducing the number of defective specimens from 1,700 a month to just 30.

At another collaborative member, UCLA Medical Center, out of more than 4.29 million blood specimens taken in the 26-month period ended last August, there were about 16,000 errors. Most didn't cause harm, but about 12% were categorized as "critical," such as a requisition form with a specimen labeled with another patient's name or an unlabeled specimen. More infrequent but more dangerous to patients: "wrong blood in tube" mistakes, with one patient's name on another patient's blood.

Getting It Right

Questions to ask about your lab report

■ **How accurate is this type of test?**

Tests for gynecological, urinary-tract, lung and thyroid cancers can have high false negative or false positive rates.

■ **Was the sample taken of sufficient quality to make a diagnosis?**

Lab reports may indicate that the sample or specimen quality wasn't optimal.

■ **Was the slide or specimen reviewed by a second pathologist?**

Patients have the right to ask that their slides and pathology reports be released for a second opinion.

■ **Was my specimen labeled correctly?**

Ask to see labels on samples such as blood tubes to ensure your name is correct and matches requisition orders.

In 2003, UCLA reorganized its phlebotomy service to providing blood-drawing technicians around the clock, freeing nurses and other staff from having to draw blood in evening hours when they are distracted by other tasks. It

also automated some parts of its specimen processing and began using an electronic error-reporting system. The new systems helped reduce all errors, especially mislabeled specimens, which are the hardest to detect, says Elizabeth Wagar, director of the UCLA Clinical Laboratories.

Experts note that many mistakes are caught by doctors, nurses or other staffers in time to avoid patient harm. But often such mistakes slip through the cracks -- and even the best-trained pathologists may misread a slide because the specimen isn't good enough or they just don't see the cancer cells. David Novis, a pathologist with Chi Solutions, an Ann Arbor, Mich., health-care consulting firm that helps labs with quality improvement, says that when he was in practice, he once missed tumor cells on a slide of a patient who was found years later to have cancer. The error was later pointed out to him by another pathologist, which has haunted him ever since. "I know I'm not unique in my anguish when a patient gets hurt," Dr. Novis says.

Dr. Novis says double reading of pathology reports can reduce errors because a second pathologist usually catches the mistake the first made. At UPMC, for example, two pathologists will review

lung biopsies because of a high error rate in testing. But such policies are only starting to be adopted in hospital labs, Dr. Novis says, and pathologists strongly resist the idea because they are reluctant to question another's interpretation or have their own findings reviewed. Pathologists also protest that second viewings just add to health-care costs and delays. But Dr. Novis says, "if I were a patient and my biopsy said cancer, I would have a second pathologist look at it."

For patients like Ms. Tutt, a lack of checks and balances in the pathology lab can have devastating consequences. In the malpractice case she brought against the pathology lab and later settled, the medical-liability insurer noted that the mistake might have been avoided had the pathologist taken the extra time to review her own work from that day, when she would have discovered another patient with the same diagnosis whose slides had contaminated Ms. Tutt's slide. Because the cancer was unusual for a woman of her age, a surgeon recommended a second biopsy, but that was never documented or passed along, and the mass had been removed anyway, Ms. Tutt says.

"Someone just carelessly made a diagnosis, and no one took the time to check it," says Ms. Tutt, now 40, who has testified before Congress about medical-malpractice issues. Today, after more than 20 additional surgeries, she cannot feel anything in her lower face and struggles with frequently infected dental implants. "Ten minutes might have made a very big difference in my life," she says.

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