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Hidden Errors

Ellen Gabler

HIDDEN ERRORS A JOURNAL SENTINEL WATCHDOG REPORT

Weak oversight of labs puts patients at risk

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Leslie Falcon of California, shown with kids Jamie, 11, and Dylan Falcon, 8, was accused of cheating on boyfriend Michael Patterson after a paternity test showed Patterson was not Jamie's father. They learned years later that the lab had mixed up his sample with another man's.

Patterson (right) split from Falcon and ignored Jamie after the lab test showed he wasn't her father. Now he is trying to rebuild their relationship.

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From drug screens to vital medical tests, secretive system hides lab problems from public

By ELLEN GABLER
egabler@journalsentinel.com

Everyone assumes lab results are correct.

For Kenneth Drew, the results showed he had HIV in 2011. By the time he found out the lab was wrong, his relationship with his wife was badly damaged. The Alabama couple separated, both distraught about the diagnosis.

For Christine Simoneaud, the lab results seemed like good news. A routine blood screen from her 10-week pregnancy appointment came back clear in 2008. Seven months later, her son was born critically ill with a blood disorder that could have been treated during pregnancy. The baby died three weeks later at a Louisiana hospital.

The lab results crushed Michael Patterson: They showed he wasn't the father of the baby girl he had cuddled and fed for the first three months of her life. He split from the mother and ignored the child. She was 4 when they determined the California lab had switched his sample with another man's. Patterson is still trying to reconnect with his daughter, now 11. Wary after so many years apart, she calls him "Mike."

"It kills me that she doesn't call me 'Dad,' " Patterson said. "If the test was right the first time, I would be 'Dad' to her."

Lab tests influence about 70% of medical decisions, guiding treatments big and small: How much blood thinner should a heart-attack patient receive? Does the baby need antibiotics? Should you start taking cholesterol-lowering

KEY FINDINGS

A Milwaukee Journal Sentinel investigation into the nation's clinical laboratories found:

- Labs don't always follow basic policies and procedures meant to ensure accuracy of results.
- Accrediting organizations inspect many of the nation's labs, but the records are kept private.
- In their inspections, accrediting groups miss serious violations that put patients' health at risk.
- It's nearly impossible for patients to determine if their lab is doing a good job.

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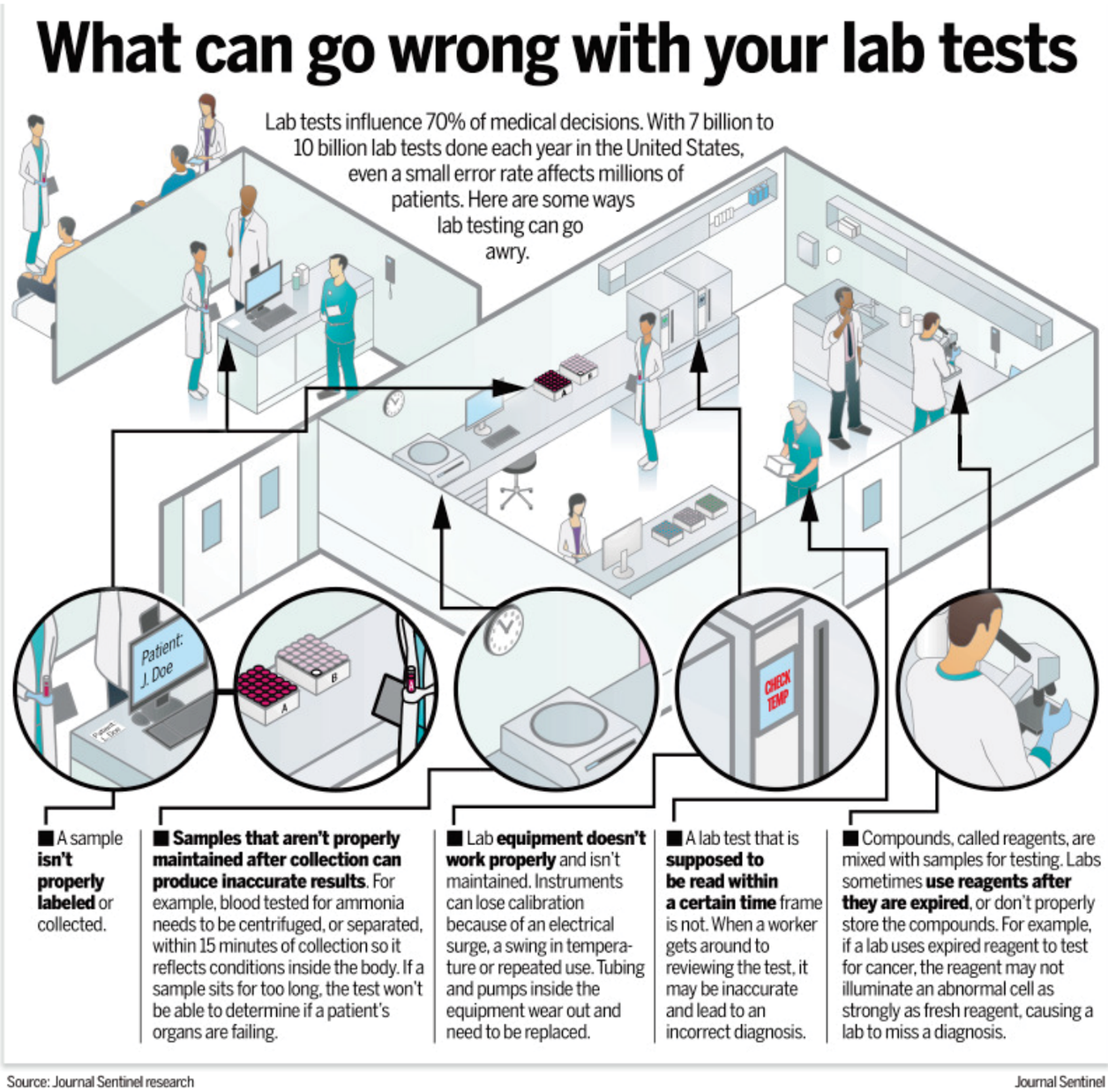


medication?

Even nonmedical tests can be life-changing: employment drug screening; blood work for life insurance, paternity testing.

The results need to be right.

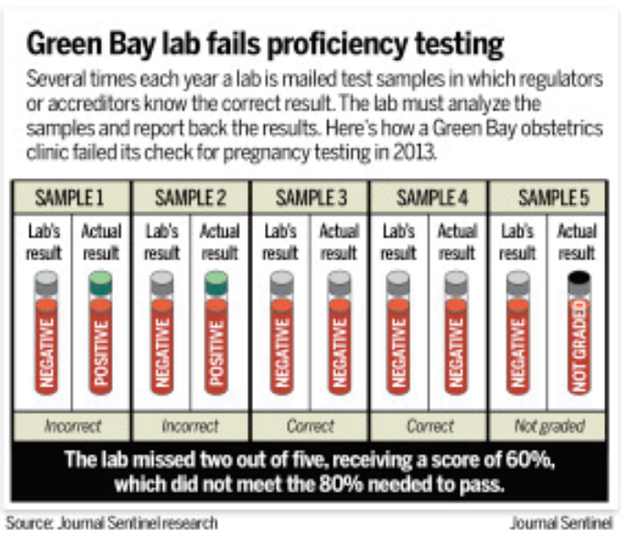
But laboratories across the nation aren't following basic policies and procedures designed to ensure the accuracy of test results. Patients have no way to know if their lab is taking shortcuts and private accrediting organizations that inspect labs fail to cite serious violations that put patients' health and lives at risk, an investigation by the Milwaukee Journal Sentinel has found. One of those main accreditors missed enough violations to require review by federal regulators last year.

Even when serious violations are identified, offending labs are rarely sanctioned except in the most extreme cases. In 2013, just 90 sanctions were issued — accounting for not even 1% of the 35,000 labs that do high-level lab testing in the United States.

Accrediting organizations that police labs on behalf of the federal government are allowed to keep their inspection reports private. In fact, federal law requires it in most cases. When state and federal inspection records exist, they can be difficult and time-consuming to get. The Journal Sentinel has spent months battling for records to ascertain what is happening in labs across the country.

Doctors and patients might never realize there was a mistake with a test result. Even if they do, labs often fight in court to avoid responsibility — or settle the case with strict confidentiality agreements that hide the specifics of how people were harmed and who was responsible.

The Simoneauds never found out why Christine's routine blood test didn't identify the condition that killed their son. Antibodies in her blood had been attacking the baby because their blood types were incompatible. Had the condition been identified by the lab test as it should have been, it could have been treated before Luke was born.



In 2011, Laboratory Corporation of America settled a lawsuit with the family. The Simoneauds and their attorney declined to comment because of a confidentiality agreement. LabCorp is one of the largest and fastest-growing commercial labs in the country, testing for more than 200,000 hospitals, doctors' offices and government agencies.

There is no way to quantify how many patients are being harmed by laboratory errors. Privacy laws prevent patient information from being disclosed in inspection reports and it's

up to the labs themselves to discover, and then report, if anyone was hurt or killed.

When the Journal Sentinel sought inspection records showing conditions at the lab that performed Simoneaud's blood test, federal regulators said they did not have any documents because the lab is monitored by an accrediting organization. Those records are private.

While occasional mistakes are inevitable in any field, the Journal Sentinel investigation identified problems in laboratories that are systemic and the result of attempts to cut costs and save money.

Expired products are used to screen for cancer and test children for lead poisoning. Blood that is supposed to be kept cold before a transfusion isn't. Samples are incorrectly labeled or swapped between patients. Basic quality control isn't done to ensure accuracy on tests for blood sugar, herpes and genetic defects.

"We have every right to assume that our safety, our health, is not being compromised by something stupid," said Sharon Ehrmeyer, a professor of pathology and laboratory medicine at the University of Wisconsin School of Medicine and Public Health. She is one of several laboratory and quality control experts who reviewed thousands of pages of inspection reports for the Journal Sentinel.

Federal regulations crafted over the past 25 years were meant to establish sound laboratory practices that would deliver accurate and reliable results. But when regulations are ignored, "the outcome of the testing has to really be questioned," Ehrmeyer said.

For example, in 2013, a Green Bay obstetrics clinic failed a check to see if employees were accurately testing for pregnancy — clearly a necessary and fundamental skill. After failing the proficiency testing in the first quarter of 2013, the lab simply didn't participate in an outside check of its pregnancy testing the following quarter.

It's unclear if any patients were incorrectly tested for pregnancy at the clinic, or if a fetus was harmed if a test indicated a mother wasn't pregnant when she actually was. For instance, if a woman who thinks she isn't pregnant takes certain medications, drinks alcohol or receives X-rays, the baby could be affected.

Robert DeMott, former owner of OB-GYN Associates of Green Bay, wouldn't answer questions about how and why his clinic failed the pregnancy test check. He sold the clinic later that year to Bellin Health System and is still employed by the company. A spokesman said the new clinic has passed its regulatory checks for pregnancy testing.

In Louisiana in 2013, a hospital was incorrectly handling blood being screened for ammonia and lactate. Such tests help doctors determine if a critically ill patient's organs are failing and if tissues aren't getting enough oxygen. To do these tests accurately, blood needs to be centrifuged — or separated — within 15 minutes of collection so the levels of ammonia or lactate reflect conditions inside the body.

At Byrd Regional Hospital, it took almost three hours to centrifuge the blood for one patient, and almost an hour and a half for another. Waits like that invalidate the samples.

"It's worthless," said Frederick A. Smith, who retired in March as director of quality for pathology and laboratory medicine at Lurie Children's Hospital of Chicago. "It's critical to be able to do this correctly if you're going to do it at all." Smith is another laboratory quality expert who reviewed inspection reports for the Journal Sentinel.

Dangerous problems at Byrd were uncovered when the facility was selected in a spot check by the federal government to review a laboratory accrediting organization.

The Joint Commission — a nonprofit that has long touted itself as a quality leader with rigorous performance standards — failed to identify nine major categories of violations at Byrd that could cause patients serious harm, according to federal records. After identifying problems that the Joint Commission missed, regulators forced Byrd to hire a technical director who still supervises the lab.

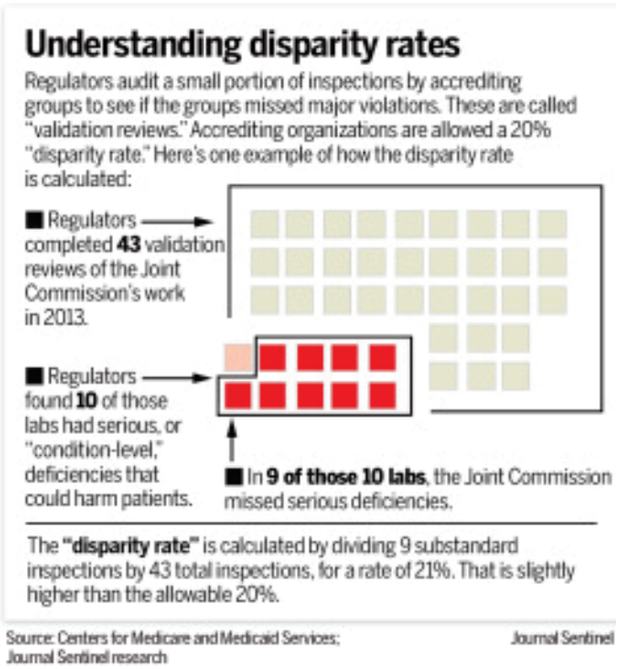
Hospital officials said in an email that they have since adopted new practices, including adding an alert system for time-sensitive specimens. They said their own "exhaustive investigation" determined that no patients were harmed by lab mistakes.

ABOUT THIS REPORT

To report this story, the Milwaukee Journal Sentinel reviewed thousands of pages of inspection reports, court documents and regulatory data. Dozens of record requests were filed for documents and data that covered complaints, proficiency testing and action taken against labs throughout the country. Details of conditions inside labs were taken from inspection reports. Laboratory and quality control experts helped the Journal Sentinel review and interpret inspection reports, proficiency testing and other regulatory records.

MIKE DE SISTI / MDESISTI@JOURNALSENTINEL.COM

A medical technologist creates control samples for blood coagulation in a hospital lab.



Regulators and accrediting groups insist that labs are closely monitored and forced to fix problems. Few are sanctioned, they say, because the goal isn't to punish labs or put them out of business, but to educate lab operators and encourage processes that minimize errors. However, sanctions provide one of the only clues to the public about which labs may be underperforming.

While not all testing mistakes will injure or kill, the precise nature of the work means labs must follow regulations and treat every potential risk as an "avoidable risk," said Paul Epner, past president of the Clinical Laboratories Management Association.

Though Epner believes laboratories are one of the highest quality parts of the nation's health care system, the sheer volume of tests means that even a defect rate of 0.1% will produce millions of problems each year.

"When you apply it to 7 to 10 billion tests, that's 7 to 10 million patients," he said.

Is he 'Dad' or not?

Without luck, fate and curious relatives, Michael Patterson

still wouldn't know that Jamie is his daughter.

A few years after Jamie was born — and a devastated Patterson left — he reconnected with the baby's mother. The couple was soon expecting another child.

Still believing his girlfriend had cheated on him years earlier, Patterson asked for a paternity test for the new baby boy about nine months after he was born. His girlfriend, Leslie Falcon, obliged, and a lab confirmed that Dylan was Patterson's son.

A few weeks later, Falcon's mother and aunt were looking over the two paternity tests. They immediately spotted that Patterson's genetic markers in the tests for each child didn't match. That would be impossible if the samples had been from the same man, since genetic markers don't change.

The lab eventually admitted it had mixed up Patterson's cheek swab with another man's in the first paternity test. Falcon felt vindicated, having endured years of snide remarks from disapproving family members despite her insistence that she had been faithful to Patterson all along.

John Taddie, who was director of Long Beach Genetics when the first test was done, said that while mistakes are extremely unfortunate, they are "just a fact of life."

"I think everyone who has a laboratory test done, unless they're not very bright, understands that people make mistakes and labs make mistakes," he said.

Taddie estimates a mistake is made with one of every 10,000 tests, meaning about two paternity tests each year had a problem when he was running the lab.

Michael Baird, chief science officer and laboratory director of DNA Diagnostics Center, a major testing lab in Ohio, doesn't share Taddie's mistakes-are-inevitable mentality.

"I will agree that mistakes are something that can happen with whatever you do," Baird said. "You just need to have the appropriate controls in place for when a mistake happens, (so) you can catch it before it goes out the door."

At Baird's lab, for example, two samples of each person's DNA are tested by two different lab technicians. Another safeguard requires that whenever a man is excluded as father of a child, the company double-checks to make sure the child's swab wasn't accidentally switched with the mother's swab, since the two often have their cheeks swabbed at the same time.

"We do everything possible to make sure we have gotten the right answer," Baird said. "I'm comfortable that we have accomplished that."

Two years after Patterson's first paternity test, LabCorp bought Long Beach Genetics. LabCorp missed an opportunity to right Patterson's situation when it did the paternity test for the second child. Had LabCorp properly integrated the purchased company's computer system with its own, the inconsistencies in Patterson's DNA between the two tests would have been caught. The couple's attorneys made that argument in court when Patterson and Falcon sued.

Although admitting the first test was wrong, LabCorp attorneys argued the company should not be held responsible because it was providing information for a court-supervised paternity test. The only duty owed to Patterson and Falcon was to "not injure them during DNA collection," the attorneys stated in court records.

The lab ultimately won but agreed to pay Patterson and Falcon settlements of less than $10,000 each under the condition that they would not appeal the decision to the state Supreme Court.

LabCorp declined to comment on its legal cases but said it has strict quality-control measures in place for the 500,000 specimens it processes daily.

During the lawsuit, LabCorp turned over documents that revealed additional mistakes. In 2007 and 2008, the lab issued corrected reports for at least three other significant mix-ups, affecting four children whose parents may have received incorrect paternity results. In one of the cases, the mistake was made by the child support agency collecting the sample.

"It's a scary thought to know there are other little kids out there who might not know who their dad is, " Falcon said.

The couple are no longer together but both are trying to help Jamie reconnect with her father.

Meeting requirements

About 35,000 labs in the United States perform "moderate-to-high-complexity" testing and are supposed to be inspected every two years to make sure they meet federal requirements.

The list of requirements to help ensure reliable and accurate testing is extensive but necessary for patient safety.

Highly technical machines must be cleaned, maintained and calibrated to ensure they produce proper results. A machine's calibration could be knocked out by an electrical surge, a swing in temperature or just repeated use over time, so lab technicians are required to run controls verifying accuracy before patients' samples are tested.

MISTAKES WITH LAB TESTS LEAD TO SECOND TRANSPLANT; CHILD DIES

A 5-year-old Massachusetts girl was diagnosed with a rare blood disorder that needed to be treated promptly or she would die. In 2012, the child underwent a bone marrow stem cell transplant at Boston Children's Hospital. The stem cells came from her twin sister.

At first, it seemed as if the transplant had been successful. But lab tests later suggested problems. The little girl would need a second transplant, doctors thought.

She got one, but doctors soon discovered there had been a mistake with the lab tests. The tests were meant to see if the donor cells had been accepted into the body and were generating new cells. For a test like this, it is important to know if a donor is related to the recipient so the cells can be properly analyzed.

The little girl's donor was listed as "unrelated," even though it was her fraternal twin sister.

In using that incorrect information to do the tests, the lab produced incorrect results, according to a summary of the case on the website for the family's attorneys.

Because siblings' cells are similar, it may have appeared as if the little girl was maintaining her own cells, instead of taking on those of her donor.

Attorneys for the girl's family contended the lab error led to an unnecessary second transplant and, ultimately, her death in the summer of 2012.

Two hospitals were involved, because a second hospital near Children's had done the lab work. Neither hospital spotted the error.

The child's family settled its lawsuit for $7.5 million.

Controls are samples with known values and can be expensive, so using them less often saves money — it's also against regulations. Controls frequently were not run, or were not documented, in lab inspection reports reviewed by the Journal Sentinel.

Compounds that are mixed with samples deteriorate over time, so they must be properly stored and used by expiration dates. This, too, was an issue noted in inspection reports. A lab may try to save money by using them past their expiration dates, which could compromise accuracy of tests.

Instruments get dirty if not routinely cleaned. Tubing wears inside machines. So do pumps that push testing compounds onto patient samples. Air bubbles fill lines that need to be flushed.

"Why do you have to change the oil in your car?" said Smith, from Lurie Children's Hospital of Chicago. "Nothing is forever."

Even fundamental procedures are sometimes overlooked.

When Kenneth Drew had his blood drawn for a routine military physical at Quest Diagnostics in Huntsville, Ala., he asked why his sample wasn't labeled. The phlebotomist told him "it would be done later," according to court records.

Five days later, Drew's primary care doctor told him he had tested positive for HIV. Drew had to notify the Army, where he worked as a systems control officer. And he had to tell his wife.

The couple separated for at least a month, but eventually reunited after counseling. It's unclear why Drew's test results were wrong, or how he found out he didn't have the virus. Neither Drew, his wife nor their attorney can talk about what happened.

The couple sued Quest Diagnostics and settled with the lab in March 2014.

Quest declined to comment and said the settlement is confidential.

Choosing inspectors

Lab officials are allowed to choose who inspects their facility. For most of the country, the choice is between state inspectors or private accrediting organizations, which both work on behalf of the federal government. State inspectors handle about 50% of labs, with accrediting organizations reviewing 46%, including most hospitals and large clinics where complex testing is done. New York and Washington run their own programs, accounting for the remaining 4%.

Three of seven accrediting organizations handle 97% of labs overseen by private groups. Accrediting groups have their own standards that are approved by federal regulators and are supposed to be at least as strict as federal regulations.

Yet records reviewed by the Journal Sentinel showed that the groups miss violations that could harm patients.

The Joint Commission accredits nearly 1,600 labs, most of which are in hospitals.

In an audit last year, federal regulators quietly flagged the Joint Commission because it missed too many significant problems that could harm patients.

In its audits, the U.S. Centers for Medicare and Medicaid

Services selects a sample of labs inspected by each accrediting group — about 2%. Government inspectors go in to see if any serious deficiencies were missed. A federal rule allows accrediting groups to have a 20% "disparity rate" in the audit before regulators must review the group's processes.

In 2013, the latest year available, the Joint Commission exceeded the 20% disparity rate by 1 percentage point. Nine of the 43 audited inspections were found to be substandard.

Officials with the Joint Commission said in an interview that they were unable to identify a common thread that knocked them over the threshold. They attributed some of the discrepancies to "differences in professional or clinical judgment" between their inspectors and government regulators.

Marco Villagrana, director of federal relations for the Joint Commission, said the group is improving its inspection process, including making sure inspectors are aware of new tests being done by labs so they remember to check any additional requirements for those tests.

The Centers for Medicare and Medicaid Services said it is reviewing the Joint Commission's plan for improvement and will monitor the group with hopes that its disparity rate decreases.

Conditions at Byrd Regional Hospital were bad enough that regulators found the place to be an "immediate jeopardy" to patients in their audits. The Joint Commission had missed nine major violations at the Louisiana hospital, including a glaring issue with how the lab was failing a common, yet critical, test to tell how quickly a patient's blood clots.

Often patients who have had a heart attack or stroke will have their blood analyzed so a doctor can determine how much blood thinner to give them. With too much blood thinner, patients can bleed to death. Too little and their blood can clot, causing another heart attack or stroke.

To run clotting tests, labs mix a compound, called reagent, with patient samples. Each batch of reagent varies substantially, so the testing machine needs to be recalibrated when a new batch is used. Otherwise, results reported to doctors can be off and the amount of blood thinner administered can be deadly. Byrd wasn't recalibrating the machine.

"It's fairly alarming that the Joint Commission missed this much slop-i-tude in the lab," said Smith of Lurie Children's Hospital, after reviewing the records.

But you would never know anything was wrong in Byrd's lab by looking at the Joint Commission's website. The site lists the hospital's name with a gold seal next to it and the simple word: accredited. You can download a report to get a closer look, but there's nothing about the lab's failure to follow regulations.

In an emailed response to the Journal Sentinel, the Joint Commission said it conducted an inspection of Byrd in response to patient safety concerns. The group said it identified various violations and gave the hospital the opportunity to fix the problems, so its accreditation was not affected. When accreditation is not affected, no changes are made on the website, which is the only way the public could learn something was amiss.

The Joint Commission would not respond directly to a question about why federal regulators cited the group for missing nine major categories of violations.

Another major accrediting group, the College of American Pathologists, or CAP, had a 17% disparity rate in 2013. The group accredits about 7,700 labs each year. Even the previous year, when CAP had a 11% disparity rate, labs it had accredited were found by federal auditors to be an "immediate jeopardy" to patients.

One of them was Davis Regional Medical Center in Statesville, N.C., where lab officials were improperly running the machine that tests blood clotting. Hospital officials said in a statement that they immediately fixed the problems, passed a follow-up inspection and are fully accredited by CAP.

CAP officials said "layers of problems" had been noted at Davis and acknowledged federal regulators found additional issues.

The same year, a North Carolina pediatrics clinic, Premiere Pediatrics, was running sloppy tests to screen children for viruses and infections. That included the test for strep A, a bacteria that can lead to heart problems and kill a child if not treated promptly. Premiere Pediatrics also was cited by federal regulators as an "immediate jeopardy" after CAP failed to identify the problems.

"These people could be missing diagnoses for real," said Smith, one of the experts the Journal Sentinel consulted. "They are clueless."

Premiere Pediatrics declined to discuss details of the inspection but said it didn't believe patients had been affected.

CAP officials said because similar issues were cited at a larger lab owned by the same company, inspectors assumed the problems would be fixed at the smaller lab next door.

LOOKING OUT FOR YOUR TESTS

While it's nearly impossible for you to know how a hospital or doctor's office operates its lab, here are some things you can do to guard against errors:

- Make sure your sample is labeled with your name and other identifying information when it's collected.
- If you know a test result is wrong, such as a positive drug test, go to a different lab for a second opinion.
- If you have a complaint about a lab, contact state health officials , who follow up on complaints for federal regulators.
- Patients can ask state health agencies if complaints have been filed against a particular lab and for a copy of inspection reports. However, many labs are inspected by accrediting groups, so there won't be any reports, as those records are private.

Both CAP and the Joint Commission say their accreditation and inspection processes are rigorous and designed to protect patients. Each said its requirements are more comprehensive than the standards set by the federal government.

In an interview, representatives for CAP said audits done by regulators might flag an issue the accrediting group's inspectors had already identified, using a slightly different standard to cite the same problem. But regulators said they take those different standards into account.

Denise Driscoll, CAP's director of accreditation and regulatory affairs, said regulators also may focus on issues that don't directly affect patient health, such as making sure the lab has diplomas proving employees meet education standards. While that is a violation regulators will cite, the Journal Sentinel review found dozens more violations where accreditors missed serious problems with testing equipment, procedures and other issues directly relating to patient health.

CAP also has a rigorous process for looking into complaints, Discroll said.

"We investigate everything, no matter how tiny," she said. "We continue to bring the laboratories up to be the best we can."

Most hospitals and labs that perform complex tests choose to be accredited.

It's difficult to compare states' inspection performances with the accrediting groups because they are not audited in the same way. However state inspections do indicate how often serious violations are noted in labs they review. In 2013, about 5% of labs inspected by state agencies had at least one "condition-level," or serious, deficiency.

Machine malfunctions

Kristin Turner had warned her boss several times that the blood analyzer at Maryland General Hospital wasn't working properly. It would break down in the middle of testing; samples were cross-contaminated; lab technicians couldn't validate the machine to be confident it generated correct results. The machine was never fixed.

On March 12, 2003, Turner used the analyzer to run tests for HIV and hepatitis C. There were about 88 patient samples on the analyzer that day, she remembers. Many of the samples were being analyzed to confirm a previous positive HIV test.

She was standing next to the machine as it started to release chemicals onto the samples. Again, the machine malfunctioned. A movable arm above the samples crashed onto the plate that held them, causing the plate to flip. Liquid splashed onto her, seeping behind her protective goggles and dripping into her mouth.

It was blood serum — from infected patients.

Turner ran to the bathroom to rinse her eyes, nose and mouth. Then, she went to the hospital's emergency room, where she was immediately given drugs to try to prevent an infection.

Three months later, she got sick. She thought it was just the flu. When the doctor told her she had tested positive for both HIV and hepatitis C, she hoped he was joking.

"I was pretty devastated," Turner said. "Then to find out it was all preventable, that was the worst."

After the accident, she assumed her complaints about the broken equipment and other problems in the lab would finally be heeded. But lab officials didn't want to alert patients that their tests might have been wrong, she said. That summer, she went on medical leave. She realized she had been terminated when her dental insurance card was refused.

Turner felt she had to do something about the shoddy lab conditions. She sent a letter to health officials throughout Ma-

ryland. The case erupted into a national scandal after state investigators discovered that more than 400 patients may have received inaccurate HIV and hepatitis C results.

The College of American Pathologists had been accrediting the lab for years, but missed the problems. Federal and state regulators hadn't caught or corrected their errors.

Turner testified before Congress, explaining how lab staff prepared frantically for inspections, presenting a "cleaned-up, Sunday church version of the lab." Congressional leaders ordered a review of lab oversight by the Government Accountability Office.

The GAO's report, which came out in June 2006, concluded that oversight of labs was inadequate to ensure facilities were meeting federal regulations. Regulators were criticized for failing to issue sanctions to poor-performing labs, and for not having data available to identify the full extent of quality problems with labs and their accrediting organizations.

In the wake of the scandal, both CAP and the Joint Commission began conducting unannounced investigations for the first time. Labs were encouraged to more prominently display a phone number for employee complaints.

Yet nine years later, it remains difficult, if not impossible, to quantify problems with labs and accrediting organizations. Patients and medical professionals have little way of knowing if a lab is doing poor work.

Regulators say labs are required to fix problems when they are identified. Operators receive letters stating deadlines and can be required to submit "plans of correction," pay fines or limit their array of testing.

If labs can't or won't fix problems, they may receive *proposed* sanctions, which are not posted publicly. If they still refuse to address the issue, sanctions can be *imposed*.

Labs with imposed sanctions are put on the federal government's "laboratory registry," which includes facilities whose accreditation has been revoked or limited by the private groups.

In 2013, the accrediting organizations made public their decision to put on probation, deny or revoke accreditation for about two dozen labs. An additional 90 sanctions were imposed by federal regulators.

The list is the only place where patients could easily discover something wrong with a lab used by their doctor's office or hospital. It is located in an obscure spot, deep within a government website.

Even though regulators found that patients at both Premiere Pediatrics and Davis Regional Medical Center were in "immediate jeopardy," neither facility landed on that list.

Regulators said they would post a list of sanctioned labs from 2014 in mid-May — nearly a year and a half after serious problems were found at some facilities.

Thomas Hamilton, a director for the Centers for Medicare and Medicaid Services, which oversees laboratory regulation, said posting the list six months into the following year is a fairly "speedy response," given it is considered an "annual report" and labs are allowed 60 days to appeal a sanction.

Hamilton said patients aren't likely to choose a lab for testing anyway — a hospital or doctor's office determines which lab they use.

But even doctors, insurance companies and hospital officials don't have the information needed to determine how labs are performing, especially in a system that has been criticized as being too soft on violators.

In 2006, the Government Accountability Office analyzed seven years of regulatory data and found that sanctions were imposed on 501 of more than 9,000 labs that received proposed sanctions. The report warned that "without the threat of real consequences, labs may not be sufficiently motivated to comply" with inspection requirements.

The Journal Sentinel requested updated data, but federal regulators said they only track total sanctions — not the number of labs sanctioned. That makes a direct comparison impossible, as some labs are sanctioned more than once.

Yet the new data shows the number of proposed sanctions has dropped to 2,365 over the most recent seven-year period.

It's unclear how the number of labs sanctioned has changed, since the recent seven-year total of 725 includes multiple sanctions for some labs, meaning the actual number of labs sanctioned is lower.

CMS officials said in an email that the agency has not changed its approach to enforcement, but labs in the late 1990s and early 2000s may have been cited more often as they were adapting to stricter standards and inspections.

Hamilton said sanctions are just one way to motivate labs to comply with federal standards and said labs can be inspected by regulators at any time if there's a complaint or issue with an accrediting organization.

"The goal is not to impose sanctions," he said. "The goal is to improve laboratory performance, and quality and accuracy in testing."

With the data that's available, there is no way to verify any improvement has occurred.

Some labs dinged by regulators say the laws and inspections are too strict and focus on problems with paperwork and documentation — not genuine risk to patients. Others admit they could do better, but say it is challenging to manage frequent employee turnover and the high cost of testing chemicals and lab equipment.

"Some of the stuff slips through the cracks," said Jay Aswell, whose family owns Evangeline Diagnostic Center, a lab in rural Louisiana that was found to be an "immediate jeopardy" to patients in August 2012. "It's not easy when you're strapped for cash."

The risks are too great for inferior lab work to be tolerated, said Jason Jarzembowski, who directs the lab at Children's Hospital of Wisconsin.

"The question isn't, 'How much to do you save by cutting corners?' " he said. "The question is, 'How much would you lose if you got something wrong?' "

Turner, the worker who was exposed to HIV at Maryland General Hospital, agrees.

"We're not librarians where a book gets put in a wrong row," she said. "Every sample is a life."

HIDDEN ERRORS A JOURNAL SENTINEL WATCHDOG UPDATE

Problems at lab show lax regulation

Hospital demotes official, faces fines after spot check finds issues

By ELLEN GABLER
egabler@journalsentinel.com

The Cleveland Clinic has demoted a laboratory director, closed part of a testing lab and is facing hundreds of thousands of dollars in fines after government regulators found serious quality problems in one of its hospitals.

The problems only surfaced through a rare government spot check of one of the nation's most respected health systems, highlighting how lax regulation of laboratories puts patients at risk and allows mistakes to be hidden.

Disarray in the lab at Marymount Hospital dates back several years, records show. But just three months before regulators uncovered the problems this spring, the Ohio lab was inspected and approved by a private accrediting organization responsible for making sure labs are safe and in compliance with government regulations.

In May, a Milwaukee Journal Sentinel investigation found that these private accrediting organizations have failed to cite serious violations that put patients' health and lives at risk. The investigation also detailed the secretive way labs are regulated, which makes it virtually impossible for the public to know which labs are doing poor work.

The College of American Pathologists, or CAP, which did the inspection at Marymount, is one of three private accrediting organizations that inspect most hospitals and large clinics that do complex medical testing in the United States.

The conditions at Marymount bolster criticism within the industry that oversight of labs is insular and inspectors are too lax.

"If CAP does their job, they are supposed to catch egregious problems," said Jerry Hurst, a former regulator of labs in California, who now works as a consultant to advise labs on inspections and licensing. "I'd get them in a room and say, 'What the hell is going on? Why did you miss all of this?' "

Government regulators found dozens of violations in Marymount Hospital's lab, including six serious enough to be considered an "immediate jeopardy" to patients, which means the problems are likely to cause serious injury or death.

Lab workers were flouting basic quality and safety measures: They used expired chemicals to run tests, failed to calibrate machines, didn't run quality control checks and had poor procedures in one of the most critical departments of a lab — the blood bank.

Technicians weren't tracking the temperature of blood being returned to the lab from operating rooms — a violation that could cause another patient to receive blood that was no longer safe. The lab wasn't quickly investigating transfusion reactions, couldn't find records for patients who had received transfusions, and was using expired products to screen blood for compatibility with patients.

Throughout the lab, employees had not been properly trained and weren't following well-known rules for proficiency testing, a required program designed to make sure a lab and its employees are doing tests properly and getting accurate results. Some employees had not been evaluated on their ability to perform specific tests, and the lab couldn't provide documentation that they met the educational requirements for their jobs.

The issues in Marymount Hospital's lab were first reported by The Plain Dealer, when the Cleveland newspaper discovered in early September the hospital was voluntarily shutting down part of its lab after an inspection by the U.S. Centers for Medicare and Medicaid Services.

But no attention has been paid — and no one will explain — how a lab with such serious problems received the stamp of approval from an accrediting organization that boasts strict quality requirements.

Little oversight

The federal government oversees regulation of clinical labs but grants authority to private accrediting organizations to police labs on its behalf. The accrediting groups have their own standards that are supposed to be at least as strict as federal regulations.

Labs pay the groups to do inspections and accredit them, with a stated goal of ensuring quality and keeping labs in compliance with government regulations. This arrangement makes the labs the clients and source of income for the accrediting groups that regulate them.

Each year, the government selects a small sample of labs that have been inspected by the accrediting organizations — up to 2% — and goes into the labs to see if inspectors for the accrediting organizations missed any serious deficiencies.

That's what happened at Marymount.

In March, regulators reviewed the work CAP inspectors had done at Marymount in December.

It's unclear exactly how the two inspections compare, because records from accrediting organizations are not public. In fact, a federal law requires that the reports are kept private in most cases.

Officials at Cleveland Clinic said they began making changes in the Marymount lab soon after federal regulators identified problems in the March inspection.

In addition to voluntarily closing part of the lab — which meant testing had to be done at other labs in the network — the clinic terminated about a dozen managers and lab technicians, and in July removed the lab director from her position.

Staff reviewed more than 11,000 patient records and determined that "patient care was not compromised" despite the problems, hospital officials said in a statement. It's unclear how the clinic could definitively know if anyone was harmed.

The health system has hired external consultants to audit all lab facilities in the network to make sure they meet federal regulations. When asked if the Cleveland Clinic would continue to use CAP as an accrediting organization, officials provided a statement that said they will first get Marymount compliant with government regulations and will then do a "full review of all accrediting agency regulations to determine our next steps."

CAP said in a statement that it takes seriously any discrepancies identified by federal regulators and investigates them. The group would not explain specifically how their inspectors appear to have overlooked so many serious problems at Marymount, and said they don't release their inspections because labs expect confidentiality.

Cleveland Clinic officials did not respond to a request to review the accrediting agency's inspection report.

Hurst, the lab consultant and former regulator, said that while it could be possible for a lab to hide some problems from inspectors, the extent of serious issues at Marymount should have been uncovered.

"It's incumbent upon the accrediting agency to look into that stuff," he said.

The Journal Sentinel investigation found that another accrediting organization, the Joint Commission, was quietly flagged last year after regulators found in an annual audit that inspectors for the group had missed too many significant problems that could harm patients.

A federal rule allows accrediting groups to have up to a 20% "disparity rate" between government spot inspections and those done by the accrediting organizations. A group that exceeds that mark can have its processes reviewed.

CAP said its most recent disparity rate was 14%, putting it below the requirement, which CAP said is meant to account for inherent differences in the way inspections are done.

But lab industry experts say that doesn't mitigate the unchecked problems at Marymount, or at other labs that have been approved by accrediting organizations but not double-checked by regulators.

"If I was a customer of CAP, I would say, 'You have sold us a shoddy product,' " said Frederick A. Smith, the former director of quality for pathology and laboratory medicine at Lurie Children's Hospital of Chicago.

Another concern is using teams of employees from other labs to inspect and accredit their peers. While CAP says it takes measures to avoid conflicts of interest — such as not having former colleagues or competitors inspect each other —

some lab professionals worry about how the process works.

It's a common discussion among pathologists and other lab professionals, said Robert Michel, a laboratory management expert and editor of The Dark Report, a publication about the lab industry.

"They recognize human nature would be for assessors in a peer lab to not be as tough as otherwise they might be, because they would want to maintain enough goodwill so that when their lab gets inspected at some future date, those peer assessors visiting their lab would be equally flexible," he said.

While Cleveland Clinic officials say no patients were injured as a result of problems in the Marymount lab, doctors and patients might never recognize when lab mistakes are made. Privacy laws prevent patient information from being disclosed in inspection reports, which often are not public anyway.

When the Journal Sentinel sought inspection records of a lab that performed a test on a pregnant woman whose infant later died, federal regulators said they did not have any documents because the lab is monitored by an accrediting organization. Those records are private.

HIDDEN ERRORS
A JOURNAL SENTINEL WATCHDOG REPORT

From glucose checks to drug tests, medical facilities perform thousands of tests without oversight. Health care decisions are increasingly based on tests anyone can do, yet are easy to fumble.

Is your lab test accurate?

By ELLEN GABLER
egabler@journalsentinel.com

A growing number of medical tests are considered so foolproof they can be done by anyone — no training required.

You've certainly had one. Maybe you suspected you had strep throat, got your glucose levels checked or needed blood thinners monitored.

These tests and thousands of others have been deemed so simple and accurate they are essentially waived from oversight.

The problem is, waived tests are often done incorrectly.

Last year, a government spot check of facilities that do the tests found not even 50% were in compliance with policies meant to ensure safe, quality care.

Directions aren't followed. Expired products are used. Chemicals aren't refrigerated. Labs run tests they're not authorized to do.

Incorrect results can have serious implications, even for seemingly foolproof tests.

In January, a baby died after doctors treated the wrong condition when a test misled them to think the child had influenza A. In April, a retiree suffered painful withdrawal after a clinic botched her routine drug screening and wrongly concluded she was abusing painkillers. In May, a woman received an unnecessary Cesarean section after a test flagged her as being HIV positive when she was not.

The rapid rise in waived testing means decisions about your health care are increasingly based on tests that are rarely scrutinized, easy to fumble, and sometimes simply inaccurate, a Milwaukee Journal Sentinel investigation has found.

Regulators and industry trade groups have worried about the tests for years, especially as their use spikes in doctor's offices, emergency rooms, nursing homes and retail clinics such as those at Walgreens and CVS.

The percentage of facilities dedicated to waived tests has gone from 20% in 1992 to more than 70% of the country's 250,000 labs today.

Regulators say they don't have the authority or resources to do more than urge labs to better train employees.

Medical facilities use the tests because they are quick, convenient and inexpensive; the lack of oversight and ability to hire untrained workers adds to their appeal.

By law, facilities licensed to do the tests cannot be routinely inspected by government regulators. A two-year license costs $150.

ANDREAS FUHRMANN / RECORD SEARCHLIGHT

Nancie Lucero, shown in her Redding, Calif., home last week, was cut off from her painkillers in April after a clinic botched a routine drug test. Clinic staff said Lucero tested positive for methadone and oxycodone, two drugs she had not been prescribed. Results from a second lab showed that first test was wrong.

The lab director and testing personnel don't need any formal education or training. Anyone — from a nurse practitioner to a receptionist to a drug store clerk — can do the tests. The only requirement is to follow the manufacturer's instructions.

"You know what's really hard for people? Following the manufacturer's instructions," said David Grenache, a professor of pathology at the University of Utah School of Medicine and a laboratory medical director.

Grenache remembers an experience early in his career as a lab director when a test done in an emergency room missed a pregnancy with complications that could have killed a woman. (The condition was discovered the next day at a different hospital. No one ever determined what went wrong with the first test.)

Because the industry is virtually unregulated, there isn't comprehensive data to quantify problems and mistakes. While some mistakes are inevitable in any field, a review of incident reports filed with federal health agencies and studies done by government officials over the years shows that people running the tests are often inadequately trained and lack an awareness of good laboratory practices.

That includes knowing how to properly collect and label a patient's sample; understanding why it is important to verify the accuracy of a test; and knowing how to properly interpret and report results.

Something as simple as incorrectly swabbing a child's nose, moving a device while a test is running, or failing to let a sample incubate long enough could lead to wrong results.

These problems were unforeseen in 1988 when Congress passed a series of laboratory-related laws, including one that allowed simple, low-risk tests to be performed without oversight from regulators.

According to the law, waived tests were supposed to be so simple and accurate that there was almost no likelihood of getting a wrong result. Or, if a result was wrong, a patient wouldn't be harmed because of it.

At the time, just eight tests met those requirements, including a standard urinalysis. Fueled by advancements in technology, the number of tests has since exploded to more than 3,000. While the availability of more tests is not inherently bad, laboratory experts say some tests that are now waived aren't as basic or low-stakes as lawmakers intended when the program began.

The tests are approved by the U.S. Food and Drug Administration. Once they're approved, responsibility for overseeing them shifts to the Centers for Medicare and Medicaid Services, although little monitoring is actually done.

The Journal Sentinel reviewed nearly 20 years of government reports, inspections, studies, meeting minutes and incident data from federal health regulators. Among the findings:

Nancie Lucero holds her daily dose of pain medication. She wound up in the emergency room, unable to deal with her back pain, after a clinic refused to treat her anymore because of a positive drug test.

"You know what's really hard for people? Following the manufacturer's instructions."

David Grenache, a professor of pathology at the University of Utah School of Medicine and a laboratory medical director

■ The quality of at least 98% of labs is unknown and depends solely on the competence of employees who do the tests. The federal government is allowed to visit up to 2% of labs each year for "educational visits," or if a complaint is lodged. Last year, only about 1,800 facilities — or 1% — were reviewed in such visits.

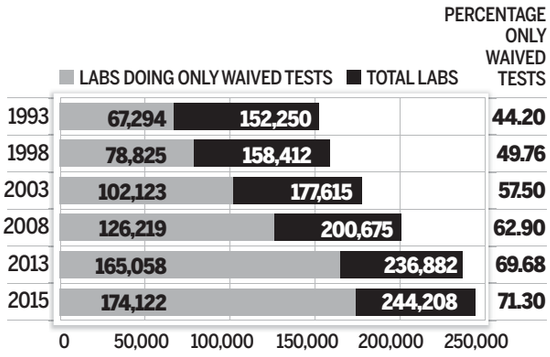
■ In 2011, the Centers for Medicare and Medicaid Services drafted a law that would have allowed routine oversight of waived laboratories, but the proposal never moved beyond that initial phase. Now, regulators won't discuss why it was never presented to Congress. Officials denied a Freedom of Information request seeking detailed information about the

Rise in lab tests with little oversight raises concern

Thousands of medical lab tests are considered so simple and accurate, they are essentially waived from regulation. Over the past 2 ½ decades, demand for the tests has skyrocketed, making them a bigger part of our health care.

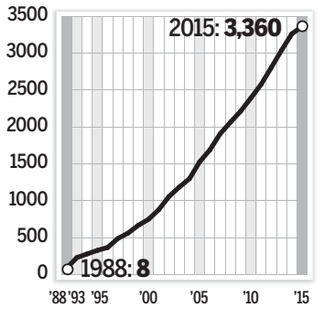
Large growth in labs dedicated to waived tests

The number of facilities dedicated to waived tests is increasing dramatically as more kinds of places do the tests – doctors' offices, emergency rooms, nursing homes and retail clinics such as those at Walgreens and CVS.



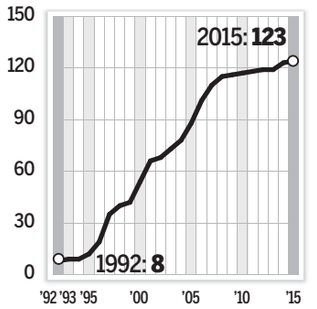
Number of tests skyrockets

In 1988, when Congress passed a law allowing simple, low-risk tests to be performed without oversight, just eight tests met the requirement. That number has since exploded to more than 3,000 test systems.



More conditions with available tests

Tests evaluate analytes, such as hemoglobin and glucose. The number of analytes that can be measured through waived tests has jumped from eight to 123.



Sources: U.S. Centers for Medicare and Medicaid Services, U.S. Food and Drug Administration data; Milwaukee Journal Sentinel analysis

Journal Sentinel

proposal.

■ Since the late 1990s, studies have shown the tests are highly susceptible to user error, and labs increasingly put patients at risk. A 2001 Office of Inspector General report identified "significant vulnerabilities" in oversight of labs that do the tests. Yet little has been done to address the problem beyond organizing a small campaign to better train and educate employees and asking manufacturers to provide more information and guidance with the tests they sell. For example, in 2008, manufacturers were asked to add "quick reference" instructions below an eighth-grade reading level — with pictures, if possible — for people who won't read directions.

■ Health regulators, trade organizations and manufacturers have talked for years about needing more comprehensive studies to quantify problems with waived tests. The groups say they can't take significant action to address problems until more data is gathered. There are no plans to gather such data.

■ The accuracy of some tests is questionable. Once the FDA OKs a manufacturer's new test, similar tests from other companies are essentially rubber-stamped. The agency doesn't require evidence of safety or effectiveness, according to a 2011 report from the Institute of Medicine, which called the process flawed. A common test used for diabetes has recently raised major concerns among laboratory experts because of the accuracy of results.

'The test doesn't lie'

Nancie Lucero wasn't worried as she sat in the doctor's office in Redding, Calif., in April, waiting for results of her drug test. The 68-year-old grandmother understood it was protocol to monitor patients on pain medication, which she had been taking since having surgery on two broken vertebrae more than a decade earlier.

Soon, she was called into an exam room where she was told by a medical assistant that her urine had tested positive for methadone and oxycodone — two drugs she had not been prescribed, and had not taken.

"That absolutely can't be," Lucero remembers telling the assistant, and later an office manager. "They said, 'The test doesn't lie.' "

While still in the exam room, Lucero was told to give back the prescription for pain pills she had just received. Her doctor at Pulse Urgent Care Clinic would no longer treat her because of the positive drug test.

Lucero started to panic: Taking those few pills each day allowed her to function — she needed them to go to the grocery store, make it to her grandkids' events and vacuum her house. Even with the pills, she had to take breaks after finishing each room.

Lucero asked the clinic staff to give her another drug test on the spot. But they refused. She then insisted that a sample from the same urine that had just tested positive be sent to a different lab. Lucero watched as the medical assistant packed it up. She signed her initials on the seal of the package.

HOW WE REPORTED THIS STORY

The Milwaukee Journal Sentinel reviewed nearly 20 years of government reports, inspections, studies, meeting minutes and incident data from federal health regulators. Databases from the U.S. Food and Drug Administration and the Centers for Medicare and Medicaid Services were used to analyze growth within the waived testing industry, and to find incidents where patients were harmed. Because of limitations in the data, it is impossible to quantify how many people are harmed by waived tests.

A week later, the second lab's results proved Lucero was taking only the medicine she had been prescribed. But the doctor wouldn't reconsider, leaving her without medical treatment and in extreme pain.

"It has just been a living hell," Lucero said a few weeks into the ordeal, having visited the emergency room at 3 a.m. that day because she was unable to deal with the pain.

Small mistakes, big problems

When done right, waived tests improve patient care and are considered essential to medicine.

Faster turnaround times mean patients can be treated quickly, instead of having to wait hours — or even days — for results from a larger laboratory. Doctors receive immediate information to help make treatment decisions and can talk with their patients in person.

Emergency rooms do waived tests to quickly assess a patient in crisis. The tests are used to screen for infection, check kidney function or determine if a patient is pregnant before administering drugs. There are waived tests for Lyme disease, Hepatitis C, HIV and influenza.

Proponents say the tests are critical to stem the spread of infectious diseases. They also offer more people access to inexpensive tests they otherwise might not receive.

While doctors and other health professionals consider many factors when treating a patient — medical history, physical symptoms, treatment options — lab tests influence about 70% of health care decisions.

"Testing is only as good as the person who is running the test or interpreting the test," said Brad Fedderly, a physician with Milwaukee-based Aurora Health Care who is on the board of directors for COLA, formerly the Commission on Office Laboratory Accreditation.

The group accredits nearly 8,000 labs that do higher-end tests. Some physician office labs, though, have been dropping accreditation by moving strictly to waived tests.

In 2013, COLA published a paper stating concerns about the rise in waived tests and the tendency for employees to do them incorrectly. The paper said the lack of requirements and training for employees — and lack of oversight for all the labs — could contribute to errors and patient harm.

Fedderly learned about problems with waived tests through his involvement with the accrediting group. He had used the tests frequently while working as a family physi-

cian for 23 years, but assumed they were simple to do, and therefore, accurate.

"How hard is it to put a drop of urine in a little window for a pregnancy test?" Fedderly said.

He decided to run an experiment in his own South Milwaukee office. He asked staffers to each run three waived tests — pregnancy, strep and a screening for mononucleosis. They drew from the same samples, so their results should match.

The testers included a registered nurse and medical assistants.

"It was stunning how variable the results were based on who was doing it," Fedderly said. "It should have been a no-brainer in how the test was done."

Even a small deviation from the instructions — or not understanding them— can make a big difference.

In July 2014, a premature baby, weighing less than 1 pound, was moved to an intensive care unit. While there, a nurse measured the baby's blood glucose levels with a waived testing device. The device displayed an error message: "extremely high blood glucose result or error detected during testing. Repeat the test using a new strip or verify symptoms."

The test was repeated at least three times. Staff in the intensive care unit misinterpreted the error message to mean that the baby had very high glucose levels, ignoring the possibility that something else was wrong. About 16 minutes after the last test, the infant was given an insulin infusion to lower glucose levels.

A lab test later revealed that the baby actually had very low blood glucose levels. To try to counteract the insulin, medical staff gave the baby an injection of dextrose, or sugar. The baby did not survive.

A report about the test and the child's death was submitted to the FDA, which releases only limited information for privacy reasons. While the infant faced obvious health challenges from being so premature, the staff's misinterpretation of the error caused unnecessary, and possibly harmful, treatment.

Late last year, a company recalled a monitoring system for patients on blood thinners, in part because people doing the test were not following instructions.

The devices, which measure how quickly a patient's blood clots, were generating results significantly lower than tests done in a regulated lab. That's dangerous because a patient with a low test result might be unnecessarily given more blood thinner to reduce the risk of blood clots and stroke. Too much medication can kill.

Alere Inc. had received reports of three deaths and six other serious problems.

The company offered two explanations: Either the patient had a medical condition that increased the risk of a false result, or directions weren't being followed.

A letter from the company to health care professionals said the monitor must be kept on a stable surface and not moved during testing. The device could also give an incorrect result if more than one drop of blood was added to the test strip after testing had begun.

"There are real, life-threatening issues going on here," Fedderly said.

He addressed the problem in his clinic by making sure instructions were prominently displayed, and followed.

As more tests are waived and more facilities use them, the opportunity for harm to patients increases. But it has been difficult to get anyone to research the issue in-depth and find solutions.

"Nobody's disagreeing that there's a problem here," Fedderly said. "But nobody is taking ownership over it."

$150 for a certificate

Nancie Lucero never found out what went wrong with that first drug test the clinic said she failed.

The emergency room doctor who treated her when she was in extreme pain wrote a note, asking the doctor at the clinic to reconsider cutting off her care. That doctor, Richard Musselman, declined to talk to the Milwaukee Journal Sentinel about what could have happened with Lucero's test. It took her three months to find a new doctor who would accept her as a patient.

Lucero said she called California's division of laboratory science and left a message to report that the lab had serious problems and needed to be checked out.

She never heard back. California state officials said they have not inspected any waived laboratories since 2013.

The nation's 180,000 waived labs have minimal contact with regulators. All someone needs to do before opening one is apply for the $150 "certificate of waiver" from the Centers for Medicare and Medicaid Services.

Although hospitals and big clinics do waived tests, too, they have a different certification because they also perform "moderate-to-high-complexity" tests in their labs.

They're required to comply with regulations for quality control, employee qualifications and proficiency tests to ensure accurate results. Those 35,000 labs are mostly overseen by private accrediting groups that are supposed to do inspections every two years.

A Milwaukee Journal Sentinel investigation in May showed how these private accrediting organizations have failed to cite serious violations that put patients' health and lives at risk. The investigation also detailed the secretive way labs are regulated, which makes it virtually impossible for the public to know which labs are doing poor work.

In the past, many tests that are now waived from regulation needed to be done by trained employees in these labs. In theory, the labs have more checks and balances given that they are inspected and must follow educational and technical requirements.

At the core of the system is what's being tested, such as hemoglobin and glucose. These are called analytes. Since 1992, the number of analytes with waived tests has jumped from eight to 123. That helps drive growth in the industry.

So does an increase in testing devices. Once the FDA approves a new type of test from a manufacturer, competitors can develop similar versions under their own brand. Those tests are generally assumed by the FDA to be safe and effective.

Even when there were half as many labs doing the tests, health officials were worried.

In 2001, the U.S. Office of Inspector General issued a report on the lab-related laws passed in 1988. While they hadn't planned on it, the reviewers ended up examining waived tests — then being done in 89,000 facilities — after discovering government studies that indicated "there may be widespread problems" at the labs, according to the report.

Two years earlier, state regulators in Colorado and Ohio had conducted random inspections of about 100 waived labs in their states. More than half were found to have "significant quality and certification problems."

The Inspector General's Office asked regulators to provide educational outreach to lab directors and continue to study the situation.

At the end of 2005, the U.S. Centers for Disease Control and Prevention issued a report on waived tests highlighting quality concerns that could "lead to errors in testing and poor patient outcomes." Problems were attributed to a variety of factors: High staff turnover; limited training; a lack of formal laboratory education.

The report, which examined several studies, found that employees at 21% of testing sites did not perform quality control measures outlined in the manufacturer's instructions.

Manufacturers sometimes change instructions for a test — for example, soak the test strip in urine for 10 minutes instead of 5 minutes.

The study found 12% of sites didn't have current instructions, and employees at 21% of facilities did not check to see if there were changes.

After the CDC published its report, the agency realized lab employees needed more training. The agency developed some educational products — a booklet, online training and some posters — to promote better laboratory practices.

Regulators distribute the products when they go to the 1% to 2% of labs that receive educational visits each year. Labs can also request materials or pick them up at professional conferences. While the intent is good, records show that only a few thousand of the country's 180,000 labs doing waived tests even receive the materials each year.

"You can't be interested in fixing a problem until you know a problem exists," said Marcia Zucker, a lab industry consultant who advises test manufacturers.

Zucker said manufacturers have been working hard to develop tests that "are as close to idiot-proof as possible."

For example, test strips are made so they won't generate a result if they're expired or improperly stored. A device with low battery power will signify the problem, instead of simply returning an incorrect result. But these safeguards often aren't enough.

"You can't make everything idiot-proof because you can always find a bigger idiot," Zucker said.

In one case, employees at an Indiana drug treatment center weren't following basic instructions for patient drug testing in 2013.

Directions on the test said the sample needed to incubate for 5 minutes until a result could be read. Employees told regulators during an educational visit that they read results after 10 seconds.

AdvaMed, the lobbying group that represents test manufacturers, says following directions is "critically important,"

and it supports the idea of educating employees.

The group says too much regulation would make tests inaccessible.

"We need to take care to not place undue burdens on physicians," said Khatereh Calleja, senior vice president of technology and regulatory affairs at AdvaMed.

Inaccurate tests

Most doctors assume the test they use to diagnose and monitor patients with diabetes is accurate, James Westgard says.

Westgard owns a lab consulting and training company, Westgard QC Inc., and developed a statistical quality control method for laboratories that is used around the globe. He is also an emeritus professor in the Department of Pathology and Laboratory Medicine at the University of Wisconsin Medical School and Public Health.

One of the waived tests he is most worried about is hemoglobin A1c, which measures blood glucose over an extended period of time. It helps doctors and patients know if treatments are working, and can help prevent organ damage from chronically elevated glucose levels. The waived test isn't supposed to be used to diagnose diabetes because studies have shown it's not accurate enough, but experts say it is commonly used to do just that.

The test requires a finger prick. Blood is typically sucked into a small tube. The tube is put into a cartridge, and the cartridge into a machine. Someone presses "start," and within 3 to 11 minutes — depending on the device — you have a result.

In 2009, a Dutch researcher published a study that found accuracy issues with six of the eight waived hemoglobin A1c tests examined. After the study, some manufacturers took their products off the market, while others made improvements.

Yet problems remained last year when the researcher, Erna Lenters-Westra, who works in the clinical chemistry department of Isala, a hospital in the Netherlands, published another study that found calibration and standardization issues with three of seven waived hemoglobin tests.

(The studies did not look at all tests on the market; some manufacturers declined to have their products involved.)

Lenters-Westra said that even though manufacturers are improving the tests, it is still problematic because there is no way to know if they are being used properly in the field.

She and Westgard stress the importance of training and believe any facility doing the test should be required to do proficiency testing to determine the accuracy of the results.

"The key message is quality, quality, quality, and education, education, education," Lenters-Westra said. "And when that is OK, you can use it."

Larger labs are required to do proficiency testing for many of their tests. Several times a year, each lab is mailed test samples from regulators or a private accrediting group. Employees must analyze the samples and report back results to show they know how to do the tests and can get accurate results.

In the United States, three major accrediting organizations that inspect larger labs on behalf of the federal government will review a lab's procedures for doing waived tests. One of the groups, the College of American Pathologists, even requires proficiency testing.

Proficiency testing is a huge boon to the accrediting organization's business.

But for labs, it costs money.

And the 180,000 facilities that aren't regulated — and manufacturers of waived tests — don't want additional scrutiny.

"Industry opposes any increase in new requirements," Westgard said. "It limits their ability to sell their products. It's no different than the drug industry. They have a pretty strong say in how things get done."

Many meetings, little action

Twice each year, a committee of about 20 people meets to review issues facing clinical laboratories. The group is supposed to provide technical and scientific guidance to the U.S. Department of Health and Human Services.

It's called the Clinical Laboratory Improvement Advisory Committee and is made up of doctors, lab professionals, scientists and regulators from federal and state health agencies.

Year after year, the discussion about waived testing is similar, just with updated statistics: More facilities are doing the tests; quality and patient safety remain a concern; can education or increased oversight help solve the problem?

In March 2014, the group met at the CDC in Atlanta. For the 28th time in 48 meetings, the topic of waived testing came up.

Judith Yost, who was director of laboratory services for the Centers for Medicare and Medicaid Services at the time, gave a presentation about the sector's growth, including findings from an annual government survey designed to help labs improve test quality.

While going through her PowerPoint slides, Yost explained how labs often showed improvement after being taught how to better train employees. Labs that don't have problems are given a "letter of congratulations."

In 2013, about 45% of the 900 labs surveyed didn't have any problems — an improvement from three years earlier when the percentage was just 18%.

Even the members of the committee seemed surprised by the statistics.

"Does that mean that 55% were not performing the tests correctly?" one member asked, according to meeting minutes.

Yes, Yost replied. Problems were identified in 55% of the labs.

The group meets again in 2½ weeks in Atlanta.

Here's what can go wrong with waived tests

Many of the medical tests you receive are considered so simple and accurate, they are essentially waived from oversight. Anyone is allowed to do them. When Congress approved the system, at least one of two key conditions was supposed to be met for a test to be waived: The test is so foolproof there is almost no likelihood of a wrong result, or if a result is wrong, a patient won't be harmed. But the tests are often done incorrectly — a Milwaukee Journal Sentinel investigation found — and that can lead to serious consequences. The Journal Sentinel identified specific incidents through complaints and reports made to the U.S. Food and Drug Administration. Because of privacy laws, individuals are not identified, and information on each case is limited.

Hemoglobin: In July 2009, a patient went to the doctor's office complaining of shortness of breath and exhaustion. The patient's hemoglobin levels were checked. Hemoglobin is a protein in your red blood cells that carries oxygen to organs and tissues and transports carbon dioxide back to your lungs. The waived test showed an "acceptable" level of hemoglobin at 10 gm/dl. The next day, additional results came back from a test done in a laboratory: The levels were half of what the first test had found — an amount considered critically low. The patient was called back in for a blood transfusion. Had the patient had a complicating illness or sudden loss of blood, the delay could have been life-threatening.

HIV: In late May, a pregnant woman received a waived HIV test before giving birth. Hospitals often do the tests when a woman goes into labor to determine if a vaginal birth is safe, as a newborn is more likely to contract the virus that way. The test was positive for HIV, so the woman underwent an emergency C-section. After delivery, the woman and newborn were given anti-HIV medications and the woman was not allowed to breastfeed the child. Testing done by a lab after the C-section showed that the woman was not HIV positive.

Flu: Early this year, a hospital was treating a baby for influenza A based on a positive waived test result. The baby was transported to a different facility where a new sample was collected and tested. That result came back negative, meaning something else was wrong. The baby did not have influenza A.

Because of privacy laws and limited information available, it's difficult to determine exactly what happened to the child and why. However, it is clear the baby did not survive. The baby was removed from life support, according to a report submitted to the FDA in January.

In response to the report, the manufacturer said that the test should be used to help diagnose the flu, along with clinical history and other information gathered by the person treating the patient.

Potassium: In July, nurses at an infusion center noticed patients' potassium results from a waived testing machine seemed unusually low, so they sent blood samples to the hospital lab and discovered a large discrepancy in results.

Potassium is an important electrolyte that keeps muscles functioning properly — high levels can cause irregular, and deadly, heart rhythms. It is critical to have an accurate reading before patients are treated or given new medication because many medications can affect potassium levels.

Although the report to the FDA did not specify why the patients were receiving infusions, they're often given for chemotherapy drugs or antibiotics to treat serious conditions.

Dozens of errors for multiple patients were discovered, even after the infusion center got a new waived testing machine. At least one patient received an extra dose of potassium that was unnecessary. The report to the FDA said patients weren't harmed, but had the nurses not suspected something was wrong, someone could have been killed.

It's unclear why the machine was not providing accurate results. The manufacturer said it appeared to meet its "product release specifications."

Creatinine: In December 2011, a doctor checked a patient's kidney function using a waived test for creatinine, which is a chemical waste product produced by muscles. Healthy kidneys filter creatinine out of the body. After getting a high result for creatinine, the doctor did a biopsy on the patient's kidneys.

But the patient had been taking a drug that is known to interfere with the test. The interaction between the drug and the test is listed in the test's instructions, but the doctor was apparently unaware of this and performed the unnecessary procedure.

Blood glucose: In July 2014, a premature baby, weighing less than 1 pound, was moved to an intensive care unit. There a nurse tested the baby's blood glucose levels with a waived device. The device displayed an error message: "extremely high blood glucose result or error detected during testing. Repeat the test using a new strip or verify symptoms."

The test was repeated at least three times. Staff in the intensive care unit misinterpreted the error message to mean that the baby had very high glucose levels, ignoring the possibility that something else was wrong. About 16 minutes after the last test, the infant was given an insulin infusion to lower glucose levels.

A lab test later revealed that the baby actually had very low blood glucose levels. To try to counteract the insulin, the medical staff gave the baby an injection of dextrose, or sugar. The baby did not survive.

While the infant faced obvious health challenges from being so premature, the staff's misinterpretation of the error caused unnecessary, and possibly harmful, treatment.

Blood clotting: In June 2014, a nurse practitioner misinterpreted an error on a device that checks how quickly a patient's blood is clotting. The nurse thought an error came about because the value was too high for the device to measure. A high number means blood is taking longer to clot than usual. As a result, the patient wasn't given blood thinner that night, even though a more in-depth lab test reported low levels. The patient was later reported to be "OK," but the situation shows how a medical professional did not understand the intricacies of the test and made a treatment decision based on an incorrect result.

In response to similar reports made to the FDA, the manufacturer said instructions for the device explain that this type of error message is designed as a quality control measure, signaling several potential issues including problems with a sample, improper storage or improper technique.

Source: *U.S. Food and Drug Administration, MAUDE database (Manufacturer and User Facility Device Experience), Journal Sentinel reporting*

HIDDEN ERRORS A JOURNAL SENTINEL WATCHDOG REPORT

Inaction on medical test flaws persists

Lack of oversight frustrates CDC advisory panel

By ELLEN GABLER
egabler@journalsentinel.com

Atlanta — A federal advisory committee at the U.S. Centers for Disease Control and Prevention has again taken no action after discussing concerns about a growing category of medical tests described by one member as the "Wild West" of lab testing.

Federal regulators said during a meeting last week they don't have the authority or resources to address the tests that have long-standing quality issues, yet are increasingly used in doctor's offices, emergency rooms and retail clinics across the country.

Health care decisions are frequently based on medical tests that are essentially waived from oversight and regulation. Thousands of the "waived tests" have been developed to quickly and cheaply detect conditions including influenza, Hepatitis C, HIV and Lyme disease, among others.

The tests are supposed to be foolproof — no training or qualifications are required for those who do them — but the tests are often done incorrectly, which can lead to wrong results and serious harm to patients, a Milwaukee Journal Sentinel investigation found this month.

"(Waived testing) does fall through the cracks. I think we all agree," Karen Dyer, director of the division of laboratory services for the U.S. Centers for Medicare and Medicaid Services, which oversees clinical laboratory testing, said at the meeting.

A director with the U.S. Food and Drug Administration, Alberto Gutierrez, acknowledged a "weakness in the system" that prevents regulators from being able to track how many patients are harmed.

Some members of the advisory committee — which is made up of 20 doctors, lab professionals, scientists and public health regulators from around the country — also expressed frustration at their collective inability to make well-thought-out recommendations on any issue, including the ever-expanding sector of waived tests.

The percentage of facilities dedicated to waived tests has gone from 20% in 1992 to more than 70% of the country's 250,000 labs. A two-year license costs $150.

By law, facilities that do the tests cannot be routinely inspected by government regulators. Up to 2% can be scheduled for "educational visits" each year.

"That's basically all we can do," Dyer told the advisory group. "We would really like to look at doing more. We are limited by law."

The advisory group — which meets twice a year and is supposed to provide guidance on clinical laboratory issues to the U.S. Department of Health and Human Services — has discussed waived testing during at least 30 of its past 50 meetings.

"When the topic keeps coming up, you feel like you aren't doing the job," said Qian-Yun Zhang, a member of the advisory group, and laboratory medical director at the University of New Mexico's University Hospital. "I don't think we have a solution."

Zhang was concerned at the dismal performance of labs doing waived tests. Dyer's presentation to the committee showed 52% of labs in a government spot check last year were not in compliance with policies meant to ensure safe, quality care.

Dyer said the Centers for Medicare and Medicaid will now send education and training material to all labs that apply for the $150 license to do waived tests.

The Journal Sentinel investigation found that only a few thousand of those 180,000 labs had received materials. Even when more do, it's unclear if that will address the problem.

"Education just gives you the potential for doing the right thing. It doesn't monitor actual practice," said Barbara Zehnbauer, director of the CDC's division of laboratory systems, which is also involved with the advisory group.

No action taken

The only requirement for doing waived tests is to follow the manufacturer's instructions. But studies have shown that often doesn't happen.

The Journal Sentinel found that health regulators, trade organizations and manufacturers have talked for years about needing more comprehensive studies to quantify problems with waived tests. The groups say they can't take significant action to address problems until more data is gathered. Yet there are no plans to gather the data.

Gutierrez, the director of the FDA's center for devices and radiological health, said during the meeting that the only data that is gathered is "passively" collected by the FDA, which accepts complaints and problems from manufacturers and health care professionals, many of whom would not think to report problems.

"We don't get a lot of information," he said.

The advisory group discussed having the FDA improve its post-market surveillance of waived tests, or requiring manufacturers to develop measurable performance standards for people using their tests.

But no specific action was taken and committee members seemed unclear as to what regulators could do about the problem.

"It would appear that there is no authority vested in any federal authority to do what you are asking to be done," said Burton Wilcke, the chairman of the committee and an assistant professor in the department of medical and radiation sciences at the University of Vermont.

"I think that may be the problem: Nobody actually owns the problem," said Hardeep Singh, another committee member, who runs the quality and informatics program at the Veterans Affairs Medical Center in Houston.

On a broader scale, members of the committee who have grown frustrated with its lack of action asked regulators to rethink the two-day meeting, where members often seem confused about what they are asked to vote on after quick discussions, and uninformed about various topics.

"It just seems like it's not working in 15-minute aliquots, twice a year," said Richard D. Press, a professor and director of molecular pathology at Oregon Health & Sciences University.

Regulators from the CDC who help coordinate the meeting said they would try to address the problems.