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Special Strategic Alert!

Why a tsunami of millennials will soon be the dominant generation in every laboratory's workforce!

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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Houston Errors Are Every Clinical Pathologist's Fear

DUE TO MEDICAL ERRORS, THREE PATIENTS DIED in three Houston hospitals in a short period of time. Each adverse event led to inspections by the federal **Centers for Medicare and Medicaid Services** (CMS) and sanctions as tough as revocation of deemed status for participation in the Medicare program.

That these events came so closely together, at three prominent hospitals in the same city, is part of the unusual story you will read on pages 16-18. Significantly for our clients and readers, each hospital's clinical laboratory is reported to have had a role in the errors that caused the deaths of the three patients. In two cases, errors in how patients were transfused were the cause of death. In the third case, "an ineffective process in patient monitoring and communication of critical lab values" contributed to the death of a patient being treated in an emergency room.

Houston newspapers and television news programs have run headline stories about the deaths of these three patients at **Baylor St. Luke's Medical Center**, **University of Texas MD Anderson Cancer Center**, and **Ben Taub Hospital**. The news stories described the serious deficiencies identified during inspections by CMS and state officials.

Each of the three hospital laboratories had a role in the unfortunate deaths of the three patients, as described in CMS inspection reports. For this reason, clinical pathologists who are medical directors on the CLIA license of the labs they oversee should want to review these reports. The information can help them spot work practices in their own labs that could contribute to errors that cause severe patient harm.

Clinical pathologists will also want to follow how the three hospitals take corrective action to address the deficiencies identified by CMS—particularly those deficiencies that directly contributed to the deaths of the three patients. THE DARK REPORT has learned that one institution has already changed its pathology chair following recognition of the lab's role in the death of the patient at its hospital. Other changes in lab directorships and lab managers may result at the three hospitals.

Every pathologist, medical technologist, and laboratory scientist knows the potential for even a minor error in the lab to negatively affect a patient. It is a testament to their skills that such errors do not happen often. TDR

FDA Clears Aperio's Digital Pathology System

Agency says digital pathology whole-slide imaging system is substantially equivalent to Philips' device

CEO SUMMARY: In May, the FDA announced clearance for Leica Biosystems to market its Aperio AT2 DX System for clinical diagnosis in the United States. The Aperio AT2 DX System is intended for in vitro diagnostic use as an aid to pathologists reviewing and interpreting digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. U.S. pathologists now can choose between two FDA-cleared systems for digital pathology and whole-slide imaging.

PATHOLOGISTS INTERESTED IN USING DIGITAL PATHOLOGY AND WHOLE SLIDE IMAGING (WSI) for clinical diagnosis now have two systems to choose from after the **Food and Drug Administration** (FDA) cleared the **Leica Biosystems** Aperio AT2 DX System for clinical diagnosis in this country.

The agency's action ended **Philips'** two-year monopoly on the market for digital pathology and whole-slide imaging systems. In April 2017, the FDA authorized the marketing of the Philips IntelliSite Pathology Solutions (PIPS) whole-slide imaging system for the review and interpretation of digital surgical pathology slides prepared from biopsied tissue.

In May, Leica Biosystems of Vista, Calif., announced the FDA's clearance to market of the Aperio AT2 DX System. The AT2 DX is a scanning and viewing platform that will be launched commercially with clinical image management software, Leica said.

This second FDA clearance may accelerate the pathology profession's transition to digital images as the standard of care in anatomic pathology.

In February, Leica submitted a 510(K) premarket submission to the FDA. For such an application, Leica needed to show that the device—or system in this case—is at least as safe and effective as another legally-marketed device, meaning the previously-cleared whole-slide imaging system from Philips.

In its application, Leica compared the AT2 DX to what the FDA calls a predicate device, the Philips IntelliSite Pathology Solution (PIPS). In 2017, the FDA cleared the PIPS for marketing

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in the United States. *(See, "FDA Clears Digital Pathology for Primary Diagnosis," TDR, April 24, 2017.)*

In a two-page letter to Leica Biosystems Imaging on May 20, Yun-Fu Hu, PhD, Deputy Director of the FDA's Division of Molecular Genetics and Pathology, explained that after the FDA reviewed Aperio's application to market the device (the aforementioned Section 510(k) premarket notification of intent to market), it determined that the AT2 DX system is substantially equivalent to the PIPS.

FDA's Assessment

The AT2 DX system can create digital slides and allow pathologists to view those slides, the FDA said. "The system capabilities include digitizing microscope slides at diagnostic resolution, retrieving and displaying digital slides, including support for remote intranet access over computer networks, providing tools for annotating digital slides, entering data associated with digital slides, and displaying the scanned slide images for primary diagnoses by pathologists," Aperio said.

To support the application, Leica conducted a study with pathologists at the **University of California Davis, Pacific Rim Pathology, Dignity Health, TriCore Reference Laboratories,** and **Intermountain Healthcare**.

16,000 Slides in the Study

The study was, "One of the largest clinical concordance studies ever completed on digital whole slide images," Leica said in a news release. In the study, pathologists read approximately 16,000 cases and compared their reads of pathology slides under a microscope with on-screen digital reads, Leica added.

In reviewing Aperio's application, the FDA said, "The precision of the device was based on five reading pathologists' assessments and identification of specific histopathologic 'features' that are observed in FFPE hematoxylin and eosin (H&E) stained slides. Twenty-three (23) primary features were selected for the analytical studies. The selected primary features were evaluated at their relevant magnifications with twelve (12) primary features evaluated at 20x magnification level and eleven (11) primary features evaluated at 40x magnification level."

The application also compared the predicate device with what the FDA called the "candidate device," which was the Aperio AT2 DX system. The specimen types were the same for both: surgical pathology slides prepared from FFPE tissue.

The principles of operation also were the same: "During review, the pathologist opens WSI images acquired with the WSI scanner from the image storage, performs further QC, and reads WSI images of the slides to make a diagnosis."

Intended Use of DP System

The intended use and indications for use were similar as well. In its application, Aperio described the intended use of the AT2 DX system and PIPS saying, both were "intended for *in vitro* diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue."

Aperio also said neither the AT2 DX system nor the PIPS is intended for use "with frozen section, cytology, or non-FFPE hematopathology specimens."

One significant difference was the Aperio AT2 DX scanner has a loading capacity of 400 slides, while the PIPS has a loading capacity of 300 slides. Aperio summarized the conclusions from the study, saying, "The clinical study results demonstrate that the AT2 DX system is substantially equivalent to the predicate device."

For this article, Leica said it was not prepared "to communicate further" given The Dark Report's deadline. Sources say that Leica may be developing a new strategy for how it will position the Aperio digital pathology system. **TDR**

—Joseph Burns

Outside US, Digital Path Moves Ahead Rapidly

Shortage of pathologists is one reason some countries moved quickly to adopt digital pathology

CEO SUMMARY: Implementation of digital pathology and whole-slide imaging systems in the United States lags behind that of other countries for two reasons. One is a more acute shortage of pathologists in those countries and the other is a less restrictive regulatory environment. In some locations outside the United States, pathologists have adopted fully-digital operations, eliminating the need for microscopes in their offices.

While the FDA has cleared a second digital pathology system with whole-slide imaging (WSI) for use in clinical diagnosis in the United States, pathologists outside of this country have adopted digital pathology and WSI systems at far greater rates.

The FDA's clearance in May for **Leica Biosystems** to market its Aperio AT2 DX whole-slide imaging system in the United States for clinical diagnosis will have a positive effect on the digital pathology marketplace, one researcher said. But the United States will continue to lag behind other countries in its adoption of these systems, added the researcher, Sylvia L. Asa, MD, PhD, a consultant at the **University Health Network** in Toronto.

Asa views the FDA clearance of the Aperio system as a positive step for pathologists in the United States. "The more options there are, the more market forces push competition and there will be more uptake of the technology," she said. From 2000 until 2015, Asa served as Pathologist-in-Chief and Medical Director of the Laboratory Medicine Program at the University Health Network in Toronto, where she oversaw the implementation of digital pathology systems that provided lab services to more than 20 hospitals in Ontario. She also is a member of Leica's medical advisory board.

Increased competition among vendors of digital pathology systems is not the only benefit of the FDA decision, Asa added. "The real driver for full adoption of digital pathology is being able to do something with whole-slide imaging that we cannot do with glass and microscopes," she explained.

Multiple Benefits of DP

At the University Health Network in Toronto, digital pathology systems have multiple benefits. "UHN had the ability to provide high-quality subspecialty diagnostics to multiple public institutions," she commented. "The same model will apply to multisite organizations in the United States.

"The ability to add image analysis is a driver," she continued. "And as artificial intelligence applications emerge, there will be a great push for pathology to digitize slides."

In Canada and other countries, the adoption of digital pathology systems has

progressed much faster than it has in the United States for two reasons, Asa commented. "First is the significant shortage of pathologists in many countries that created a need for access from remote locations," she said. "The second reason is the relative laxity of regulatory restrictions in other countries."

Used for Remote Diagnosis

In Toronto, Asa and other pathologists have at least 15 years of experience with digital pathology. "In 2004, **Health Canada** approved telepathology, allowing the University Health Network to initiate remote diagnosis, initially using a robotic microscope," she noted.

"By 2006, we moved to whole-slide imaging using the Aperio system that Leica subsequently acquired," she said. "UHN moved to full primary diagnosis in 2011 using the AT2 scanner fully integrated with our **Cerner** CoPath LIS."

"Other countries also have implemented digital pathology for primary diagnosis," Asa added. "The **LabPON** group in the Netherlands is well known for its use of the Philips IntelliSite Pathology System. In Kalmar, Sweden, Dr. Sten Thorstenson has been using WSI since 2006 and two years later expanded its use across his department in **University Hospital Linköping**. In 2014, Thorstenson went exclusively digital.

"On a recent visit to that department, I saw pathologists who no longer had microscopes in their offices because they use WSI with **Hamamatsu** scanners integrated with their **SymPathy** LIS for routine primary diagnosis," Asa continued. "An article on this development will be published soon.

"In Québec, a group has implemented WSI for consultation in remote parts of the province," she added. In 2014, Dr. Bernard Tetu and colleagues published an article about this effort in *Diagnostic Pathology*, titled, "The Eastern Québec Telepathology Network: a three-year experience of clinical diagnostic services.

"We can see from these few examples the effect of easier regulation in other countries versus that of the United States," Asa said. "But now that two DP systems have this approval in the United States, I expect other companies will follow. That means pathologists in the United State are sure to start investigating the advantages of digital pathology.

"Outside of the United States, regulators may have recognized the more significant need for pathologists because it is better to have access to a pathologist using WSI than to have no access to a pathologist at all," she added.

"Consider the initial position of Health Canada on this issue," Asa said. "Since pathologists examine whole-slide images just as they examine slides under a microscope, and since the microscope was never approved, regulators relied on the judgment of pathologists once the actual equipment was validated.

"By comparison, the FDA has been far more rigid, and in some ways perhaps too rigid," Asa remarked. "Being extremely cautious about the validity of WSI is appropriate, of course, because, as we have seen, there have been technical failures.

Variability in Different Labs

"On the other hand, every lab has variations in stain quality that result in different color patterns, and every pathologist has different preferences for light intensity," she said. "Yet the FDA has required validation of specific settings that do not affect diagnostic interpretation and may even get in the way of some pathologists.

"For example, the requirement for expensive medical grade monitors (as some vendors have proposed) creates a financial barrier," she concluded. "And, in my opinion, and in the opinion of others with fairly broad experience in Toronto and in Sweden, such monitors are not necessary." **TDR**

—Joseph Burns

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Bill Would Delay PAMA Reporting for One Year

Federal legislation has bipartisan support and would need to pass the House and Senate

CEO SUMMARY: For all laboratories that must report private payer price data under the Protecting Access to Medicare Act (PAMA), a new bill in congress would delay the next round of data reporting for one year and require the National Academy of Medicine to recommend ways to improve the data collection and market-rate setting processes under PAMA. Supporters consider the bill to be a first step toward more comprehensive reform of PAMA, which has resulted in deep cuts to Medicare lab test fees.

LATE LAST MONTH, members of both major parties co-sponsored a bill in Congress that supporters said could address two of the most significant problems labs face under the Protecting Access to Medicare Act (PAMA).

First, for all clinical laboratories that must report private payer lab test price data under the law, the bill would delay the next round of data reporting for one year. Instead of reporting payer data from private insurers in the first quarter of 2020, labs would not need to report those numbers until the first quarter of 2021.

Second, the bill would require the **National Academy of Medicine** to recommend to Congress less burdensome data collection methods and reimbursement rate calculations based on actual market rates, as Congress intended when it passed PAMA in 2014, according to the **American Clinical Laboratory Association** (ACLA).

In announcing its support for the billed, called the Laboratory Access for Beneficiaries Act (the LAB Act), ACLA said that when implementing PAMA, the Secretary of the federal **Department of Health and Human Services**, "deliberately disregarded Congress' instructions and cherry-picked payment data from less than 1% of laboratories nationwide." As a result, rates were much lower than if federal regulators collected data based on the entire clinical laboratory market.

The proposed bill has bipartisan support and the backing of the ACLA, the **National Independent Laboratory Association** (NILA), **AdvaMed**, and the **Point of Care Testing Association**. *(See sidebar on page 9, "About the LAB Act.")*

Deep Medicare Price Cuts

While much about the bill is positive for labs, it does not address the larger issue of the deep price cuts that labs have faced under PAMA since last year, said NILA Administrator Mark Birenbaum, PhD. Those Medicare price cuts total 10% in each of 2018, 2019, and 2020, and then 15% in each of the next three years: 2021, 2022, and 2023.

For labs struggling to meet the data requirements and facing ever-lower levels of payment under PAMA, the bill is a significant step in the right direction,

Birenbaum commented. "But it doesn't get to the heart of the problem: the cuts scheduled under PAMA and the fact that those price cuts are based on incomplete data," he said.

"The rates Medicare is paying are based on data from less than 1% of the lab marketplace," he said. "Those rates have been in place since last year and then they'll go even lower. If you cut most rates by up to 10% in each of the first three years, that's up to a 30% drop, and then you cut most rates by 15% the following year, that's a 45% drop in just four years for many rates.

Community Labs at Risk

"Such deep price cuts in high-volume tests mean very few community laboratories will be able to stay in business," Birenbaum predicted. "These reductions in payment are such a significant concern, that NILA has continuously advocated for a comprehensive fix for PAMA. That's why we believe additional reform will be needed after implementation of the LAB Act."

ACLA President Julie Khani agreed that such deep cuts in Medicare payments are a significant concern and that comprehensive reform is needed. Even without comprehensive reform, however, the LAB Act is a positive step, she added.

"ACLA recognizes that PAMA needs comprehensive reform and we see the LAB Act as an important first step toward that broader reform," she said in an interview with THE DARK REPORT. "One fundamental change we need now is to fix the data-collection process.

"In passing PAMA, lawmakers instructed the agency to set market-based rates, and you can't get to market-based rates when data is collected from less than 1% of all laboratories," she added.

The delay in reporting until 2021 is important not only because clinical labs need the extra time, but also because of changes the federal **Centers for Medicare and Medicaid Services** (CMS) made in defining which labs must report their private payer price data, Khani commented.

"In 2018, CMS amended the PAMA regulations to require more robust reporting, in particular for hospital labs," she said. "But awareness of that new data reporting requirement among hospital administrators is very low. Therefore, delaying the data reporting period is an important step toward broader reform of the PAMA law."

Even before CMS changed the reporting requirements last year, many hospitals were uninformed about PAMA and were unaware of how the Medicare price cuts would affect lab revenue, Khani added.

"The majority of hospitals were not aware of PAMA after it passed in 2014 and few hospitals are aware of the changes CMS made last year," she said. "That's why we're spreading the word to hospitals and to hospital lab directors about their obligation to report data to CMS on what private health insurers pay for lab tests."

To help spread the word to hospitals and hospital labs, ACLA partnered with one of its associate members, **Hologic**, to host a series of webinars last month about hospital reporting obligations under PAMA. An on-demand version of the last session is available on the ACLA website.

"The delay until 2021 would give us time to make more hospital labs aware of the requirements," Khani commented. "And, it would give labs the time they need to report private payer data to CMS."

Data Reporting Requirements

Birenbaum concurred, saying, "Many hospital outreach laboratories are unaware of this new requirement and had little time to build the necessary data systems and procedures to report the data.

"The one-year delay gives hospital laboratories more time to meet the new reporting requirement, but additional legislation or regulations will still be necessary to fix the data-collection and rate-setting processes," he added.

Fixing those processes is an important role for the National Academy of Medicine. "The LAB Act commis-

sions a study by the National Academy of Medicine (NAM) to assess how to improve PAMA implementation to better reflect Congress' original intent of a market-based fee schedule," Birenbaum said. "NAM was chosen because it's a neutral third party and has conducted previous studies related to the clinical laboratory fee schedule."

Formerly known as the **Institute of Medicine**, NAM is one of three academies that make up the **National Academies of Sciences, Engineering, and Medicine**. It is a private, nonprofit institution that works outside of government to provide objective advice.

Less Burdensome Reporting

If passed, the LAB Act would have NAM gather comments from clinical labs and other members of the lab community to recommend a less-burdensome way for CMS to collect the data it needs to set private market-based rates, Birenbaum explained. "CMS needs a data collection process that results in a representative and statistically valid sample," he said.

PAMA has frustrated clinical lab directors because it resulted in significantly lower Medicare payments and because many labs and lab associations have said the process CMS used to collect the payment data was flawed.

"In the first private payer price reporting cycle, CMS collected data from less than 1% of laboratories nationwide, resulting in a skewed and underrepresented sample of private payer market rate information," said Birenbaum, echoing ACLA's comment. "Congressional intent was to establish a market-based system, which CMS did not do. NILA believes that CMS should follow congressional intent and establish a data-collection process that represents the entire lab market."

On Jan. 1 of this year, CMS began the second round of data collection. That collection period ended June 30. If the LAB Act is not passed and signed into law, labs will need to report that data and test volume starting Jan. 1 and continuing through March 31 of next year. TDR

—Joseph Burns

Contact Mark Birenbaum at nila@nila-usa.org or Julie Khani at info@acla.com.

About the LAB Act

AS OF JUNE 27, when Representative Scott H. Peters (D-California) introduced HR 3584, the Laboratory Access for Beneficiaries Act, the bill had five co-sponsors: Gus Bilirakis (R-Florida), Bill Pascrell (D-New Jersey), Kurt Schrader (D-Oregon), Richard Hudson (R-North Carolina), and George Holding (R-North Carolina).

Four more cosponsors were added on July 11: Lisa Blunt Rochester (D-Delaware), Jackie Walorski (R-Indiana), Thomas R. Suozzi (D-New York), and Ken Calvert (R-California).

In addition to delaying the date for labs reporting private-payer rates to CMS for one year, the bill also would require CMS to have the National Academy of Medicine (NAM) review the methodology CMS used to implement the private payer rate-based clinical laboratory fee schedule.

Assuming the bill becomes law, the language in the bill directs CMS to contract with NAM within three months to consider how best to implement the least burdensome data-collection process required under PAMA. The bill states the goal would be to "result in a representative and statistically valid data sample of private market rates from all laboratory market segments, including hospital outreach laboratories, physician office laboratories, and independent laboratories."

Also, NAM would consider the variability of market segments by laboratory procedure code and appropriate statistical methods for estimating rates that are representative of the market.

After 18 months, NAM would report its conclusions to CMS and to Congress and recommend ways to improve the data-collection and reporting methodology under PAMA, the bill says.

Younger hires want guidance, latest tech, work-life balance

By 2025, Millennials Will Dominate Lab, Pathologist Workforce

CEO SUMMARY: Within five years, members of the millennial generation will make up 75% of the physician workforce in the United States, rising from about 24% in 2017. That three-fold increase represents a strong demographic trend that will require changes in the steps all clinical laboratories and pathology groups take when seeking to attract and retain clinical laboratory professionals and pathologists born between 1981 and 1996.

Second of Two Parts

Since members of the millennial generation entered the workforce, anatomic pathology groups and clinical laboratories have found that recruiting, hiring, and retaining these professionals can be much more challenging than hiring members of earlier generations.

"Demographic changes are bringing millennials into the healthcare workforce in greater numbers," said Rich Cornell, President and Founder of **Santé Consulting**, a recruitment firm in St. Louis that specializes in filling positions in anatomic and clinical laboratories at the director level and above.

"Members of the millennial generation—those born between 1981 and 1996—are not as focused on career planning or as driven by career goals as those in generation X—meaning 1965 to 1980—or as single-minded about work and their careers as were members of the baby boom generation—those born from 1946 to 1964," he added.

"Most leaders in the lab industry have yet to appreciate the effect millennials will have on the laboratory workforce," observed Cornell. "Many of them don't realize that by 2025, millennials will comprise 75% of the physician workforce in the United States, according to a recently published study in *JAMA*.

"To put that proportion into perspective, consider that less than 24% of all physicians with an active license in the United States were millennials in 2017, according to the **Federation of State Medical Boards**," he said. "Therefore, a physician workforce that is 75% millennials by 2025 represents a transformation in the laboratory workforce.

"This trend makes it imperative that the management of pathology groups and clinical laboratories understand how to attract, hire, and retain millennials," Cornell advised during a presentation at The Dark Report's *Executive War College* in New Orleans in May.

Part one of this series was based on Cornell's presentation and published in the June 10 issue of The Dark Report, as "Fewer Pathologists Means Tighter Market for Jobs." It covered the current market trends in pathologist hiring, compensation, and subspecialist demand.

Part two deals with how the millennial generation is about to have major influence on the staffing and operation of the nation's clinical labs and pathology groups.

"The demographic wave of millennials means that—to fill open positions—clinical lab directors and pathology groups will need to recognize that millennials have different career needs and interests than those of previous generations," commented Cornell.

"Generational differences are most visible in the fact that the younger millennial physicians aren't as interested in traditional partnership-type settings, compared with Gen Xers or baby boomers," he said. "Instead, they pay more attention to work-life balance, compensation, quality of life, and having access to the latest technology."

A strong interest in the latest technology extends to all forms of computers, reporting platforms, microscopes, digital pathology, and processors that they expect to find in clinical laboratories and pathology groups, Cornell explained.

Interest in Technology

"Because of their deep interest in technology, any lab or group making an offer to millennials will need to include a technology package," he said. That package should include at least a new computer, a laptop, and a new microscope. Those are all standard.

"When these younger physicians visit pathology practices, they sometimes express concerns that some groups have antiquated equipment," Cornell commented. "If the scopes are older, millennials may not give serious consideration to a job offer from that pathology group.

"They tell us, 'If I'm going to work for that pathology group, then I want the latest

and greatest microscope with digital technology,'" he said. "Millennial pathologists pay close attention to the tools they use and the technology behind those tools."

In placing millennial pathologists, Cornell identified other conditions of employment. "Physicians in the millennial generation want at least five to 10 days annually for continuing medical education, five paid sick days a year, and three personal days," he said.

"In addition, they want paid time off—including three to four weeks of vacation time," he added. "As a result, we see more pathology groups offer four weeks of vacation for new hires."

One factor that may hurt pathology groups when recruiting millennial pathologists is a conservative tendency toward paid time off. "Today, these millennial physicians are well aware of what physicians in other specialties get, in terms of paid time off," Cornell noted. "They know that pathology is fairly conservative with time off, as opposed to radiology or anesthesia. For example, I know an anesthesiologist who gets 12 weeks off every year."

Interview-to-Hire Ratio

While the first step when recruiting young pathologists is to understand what millennials want, the next step involves assessing how recruits react once they interview at your laboratory. That process starts with an assessment of a pathology group's interview-to-hire ratio to assess how many interviews it conducts before it gets one new hire.

"When a clinical laboratory or a pathology group wants to know how it can attract top talent, it first needs to understand its strategy for hiring," Cornell explained. "To do that, we track the number of candidates who interview and compare it to the number of successful hires. That's known as the interview-to-hire ratio.

"Next, the pathology group must know what it spends on interviewing," he added. "The average interview costs between $1,500 and $2,000 per candidate. And if you're hiring several physicians, you may need to budget at least $1,500 for each interview. For example, if it takes four interviews to hire one individual, you'll spend $6,000 for each open position, just on interviews.

Watch for Stress or Boredom

"In addition to accurate interview budgets, labs or path groups seeking to fill multiple positions must watch for stress or boredom among interviewers," he warned. "A pathology group is likely to have two or three people involved in the interview process. Over time, it's not unusual for the individuals interviewing candidates to get burned out.

"Those individuals can go to only so many dinners and interview only so many candidates before the process becomes mundane. When that happens, they could lose interest," he commented. "That factor alone will affect your group's ability to hire people and its interview-to-hire ratio.

"Another factor that affects the interview-to-hire ratio is whether the open position is for a specialist or a subspecialist," explained Cornell. "If it's for a subspecialist, does that mean the group wants a pathology fellow just coming out of training? If you want to hire a fellow, then you'll need to understand the recruitment cycle for fellows, which is synchronized to the academic calendar.

"We worked with a large single-specialty group that was struggling with their interview-to-hire ratio," Cornell recounted. "For three openings, they interviewed five individuals, made three offers, and got three rejections. That's a bad sign.

Facing Facts

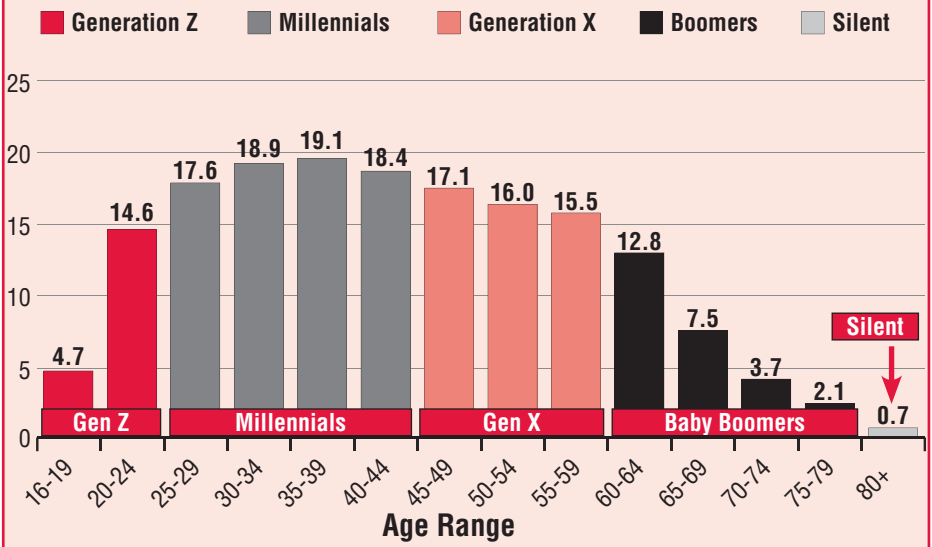
"When we were called in, we determined that the group was trying to recruit younger, early career physicians, but had old-school physicians as the face of the practice," he said. "Those older physicians

As Early as 2025, Millennials Will Represent 75% of Workforce Employed by Nation's Labs

IN JUST A FEW SHORT YEARS, A MAJOR DEMOGRAPHIC WAVE is poised to transform the workforce employed by anatomic pathology groups and clinical laboratories. In six years, by 2025, the millennial generation—with more than 74 million individuals—will represent 75% of the nation's workers. Because millennials have distinctly different characteristics than the earlier generations of Gen Xers and baby boomers, pathologists and lab administrators will need to recognize those differences with changes to how they attract, recruit, and retain millennials. The chart below shows the projected numbers for each of the five generations by the year 2025.

The Workforce in 2025

Projected size of U.S. labor force (in millions) by age, for the year 2025



Source: Dept. of Labor, Chart © The Wall Street Journal

were retiring but remained as part of the interview process. During the interviews, they would say things like, 'We've always done it this way.' Or, they'd say, 'When I was young, we did it this way and that's always worked for us.'

"What the candidates heard was that the practice environment was stifling and no younger physicians would want to join that pathology group," Cornell recounted. "We suggested that the practice change its messaging so that everyone was talking about the benefits of working there.

"To do that, you have to coach your staff about how to interview and what each one's role is during each interview," he recommended. "If you don't coach your team on their roles and how to interview, then it's likely that everyone doing the interviews will ask the same questions and your messaging will be confusing.

"The key is to assign different roles to different members of the group," he said. "The president of the group, for example, should talk about the practice's vision and the business dynamics of the group. If

possible, have a sub-specialist similar to the person you want to hire talk about the community and how to fit in within the practice and the area.

"Once we got everyone's support for these ideas, this group filled its three positions and did so with a good interview-to-hire ratio," he commented.

Assessing Experience

"In the case where the pathology group wants to find a practicing physician, does it want someone who's worked for only two to five years?" he asked. "That's actually the time when most physicians are considering new job opportunities. Also, if the goal is to hire more experienced pathologists, then the group may need to pay more compensation to attract physicians with the desired experience.

"Another consideration is whether a lab or pathology group is open to recruiting physicians who are exiting the military for private practice," Cornell commented. "If so, these people can be great hires. Because of their experience in the military, these candidates interview well, they dress well, and interact well with others."

Networking Success

One question many clinical laboratory and pathology group directors ask is how to find new candidates for job openings. About 39% of positions in pathology are filled through networking with other professionals in the field.

"That means word-of-mouth is effective much of the time," Cornell commented. "After that, about 25% of pathologist positions are filled by using a physician recruiter. About 13% of pathology jobs are filled directly through a residency program, and 5% of open positions are filled from listings on an internet job board." Pathology positions also are filled through journal advertising (5%) and through a specialty society (2%), he added.

When seeking to recruit a millennial, pathology groups and clinical laboratories may want to consider the advice sales managers offer to their staff members. "In sales, managers recommend that salespeople should, 'always be closing,'" Cornell suggested. "That means continually asking the prospect if he or she has what's needed to make a decision about buying or not.

"This principle also applies when interviewing candidates for your pathology group or clinical lab," he added. "When hiring millennials, keep in mind that they expect you to work quickly and efficiently. Millennials expect a direct, focused interview, and an instant feedback and offer process.

Move Expeditiously

"Therefore, work fast or at least proceed with deliberate speed," he said. "Groups should recognize that millennial physicians expect everything to happen in real time—meaning as quickly as possible. When dealing with millennials, you may find that they do not operate with an hour clock. Instead, they're working with a stopwatch.

"Old-line pathology groups and clinical laboratories and, in particular, academic pathology programs, need to be aware of this imperative," noted Cornell. "Therefore, it's best to do everything possible to ensure that the interview and offer process goes quickly and smoothly.

"This is equally true for those pathology groups that have a mentality of 'if we built it, they will come'—meaning that the group expects that whenever it has a job opening, everyone will want to work there," he explained. "That's not true anymore, particularly in academic settings and in large pathology groups.

"Labs and pathology groups fail to move quickly for many reasons, but chief among them are two factors that could cause the loss of a desired candidate," he advised. "The first reason why a lab loses a top prospect is because the hiring process took too long.

"The second reason is the need for the pathology group and clinical labs to have

multiple committees review candidates, and decide on each potential hire which prolongs the process," he said.

Meeting Younger Candidates

"In addition to moving quickly, another way to help top candidates feel comfortable with your lab is to ask a millennial on your staff to meet with younger candidates whenever possible," Cornell said. "As mentioned earlier, millennials may relate to others in the same age and be more willing to ask about the work environment and how younger physicians fit in with others on staff.

"Also, I recommend that everyone in the lab who meets with job candidates should be able to explain the groups' hiring process and the group or lab's expectations for all new hires," he added.

"In fact, many younger physicians require having the contract terms printed out and ready for review when the time is right," Cornell suggested.

Offer Plenty of Guidance

"Once a group or lab hires a millennial, it will want to retain that individual, of course," he advised. "Keep in mind that hiring and retention go hand-in-hand in every successful practice.

"To that point, millennials expect guidance from their new colleagues, particularly in the beginning," he said. "Therefore, it's important for your lab's key staff members to meet with each new hire regularly and set appropriate expectations for improvement. Also, give plenty of guidance and consider having a more experienced physician serve as a mentor."

As leaders in both clinical laboratories and anatomic pathology groups develop staffing strategies for their respective labs in coming years, it will be important to keep focused on the fact that, in less than six years, 75% of physicians and lab staff will be members of the millennial generation. That fact will have significant ramifications in how labs hire and retain staff.

What Millennials Seek in a New Job

WHEN MILLENNIAL PATHOLOGISTS LOOK for positions in anatomic pathology groups and clinical laboratories, they have at least six concerns about any new position, said recruiter Rich Cornell, President and Founder of the recruitment firm Santé Consulting.

1) **Competitive compensation:** Salary is particularly important because they have substantial debt from medical school.
2) **Competitive benefits:** Studies show that millennials want good benefits so that they can start saving money early in their careers.
3) **Leadership opportunities:** They tend to be team-oriented and are looking for a future career path.
4) **Technology:** Millennials want the latest technology, including cellphones, laptop computers, and microscopes. Such technology is important because they want instant gratification and ease of reporting results.
5) **Mentorship:** They value a feel-good environment that comes from teamwork and having a trustworthy confidant within the group.
6 **Work-life balance:** Life outside of work is important, including paid time off for family.

Over the past 15 years, both clinical laboratories and anatomic pathology groups regularly anticipated the retirement of baby boomers—for decades, the dominant generation in the workforce. Now, the next six years will see the youngest baby boomers retire. This will give Gen Xers the opportunity to take up the prime leadership positions in labs until they reach retirement age. TDR

—Joseph Burns

Contact Rich Cornell at 636-777-7885 or rcornell@santellc.com.

CMS Sanctioned Three Houston Hospitals, Labs

Each hospital had a patient death following mistakes in handling blood products or lab tests

CEO SUMMARY: At MD Anderson Cancer Center and Baylor St. Luke's Medical Center, blood transfusion errors led to two patients' deaths in separate incidents last fall. Then, this spring, a patient died in the emergency department of Ben Taub Hospital following "an ineffective process in patient monitoring and communication of critical lab values." State and federal inspectors found deficiencies at all three hospitals.

Three prominent Houston hospitals were sanctioned in different ways by the federal **Centers for Medicare and Medicaid Services** (CMS)following patient deaths at each hospital. CMS identified the clinical laboratories as having a role in each patient's death.

It's unusual for CMS to identify such serious deficiencies in patient care at three major hospitals in such a short period of time. News reporting identified each hospital where a patient died as:

- **Baylor St. Luke's Medical Center,**
- **Ben Taub Hospital, and**
- **University of Texas MD Anderson Cancer Center.**

All three health systems were placed under state and federal authority as a result of CMS revoking their "deemed status," *The Houston Chronicle* reported.

Labeling Error Causes Death

The first reported patient death happened at 661-bed Baylor St. Luke's Medical Center in November. A 75-year-old female died in the emergency room when a labeling error caused her to be transfused with the wrong type of blood, the *Chronicle* reported. *(See sidebar on next page.)*

Then, in December, a 23-year-old female patient with leukemia died at 681-bed MD Anderson Cancer Center as a result of being transfused with blood tainted with a bacterial infection.

Her death led to increased oversight by CMS and the **Texas Department of State Health Services**. Following its inspections of the hospital, CMS revoked the cancer center's deemed status.

Critical Lab Values

In April, at 650-bed Ben Taub Hospital, a third patient died due to a failure to communicate critical lab values, according to reporting in the *Chronicle*.

On June 27, the *Chronicle* reported that Ben Taub Hospital was placed under federal and state authority after a patient at the Ben Taub Emergency Center died when staff failed to follow federal patient care and safety requirements.

Ben Taub Hospital is part of **Harris Health System**, a public safety net hospital network in the Texas Medical Center where MD Anderson and Baylor St. Luke's also are located.

Having two deaths due to similar patient-safety deficiencies related to

CMS Investigators Identified 122 Incidents of Mislabeled Blood at Baylor St. Luke's

OVER FOUR MONTHS LAST YEAR, inspectors from the federal Centers for Medicare and Medicaid Services (CMS) found 122 incidents in which the staff at Baylor St. Luke's Medical Center in Houston labeled blood incorrectly, according to *The Houston Chronicle*.

In a report CMS issued in February, CMS investigators found that in November, the medical center's clinical laboratory failed to notice that a blood sample had arrived with another patient's blood in it.

As a result of that failure, a 75-year-old woman was mistaken for a patient who had been in the emergency room just before her and was given the wrong blood, according to the *Chronicle*.

The 75-year-old ER patient died the next day due to cardiac arrest."That fatal mistake followed a pattern of blood labeling errors at St. Luke's Medical Center last year," the *Chronicle* reported.

Pattern of Labeling Errors

CMS cut off funding for heart transplants at St. Luke's following a yearlong joint investigation by the *Chronicle* and *ProPublica* which documented numerous errors that led to patient deaths and surgical complications following heart surgery.

The recent patients' deaths occurred at about the same time the *Chronicle-ProPublica* reports were published. The medical center made the CMS report public in March and has since worked to fix those errors and eliminate the deficiencies, CMS cited.

In its review of the 75-year-old patient's death, CMS found that an internal hospital committee had previously identified problems with the way staff labeled blood samples, but the unsafe practices continued, the *Chronicle* reported.

The hospital also had a "short-staffed nursing crew that lacked training in how to detect adverse reactions during transfusions and a hospital laboratory with too few workers on staff to always catch potentially fatal labeling mistakes," the CMS report showed.

In May, Baylor St. Luke's Medical Center President Doug Lawson, PhD, posted a letter on the hospital's website explaining the steps staff were taking to correct the deficiencies. "Over the next few weeks, we will meet with CMS in a full-scale review of our hospital, our organization, and our operations, painstakingly reviewing every policy and practice we have. I expect the CMS reviews to reveal additional areas of improvement," he wrote.

Along with the letter, Lawson posted the CLIA deficiencies reports and the medical center's correction plan. The hospital is accredited by **DNV GL Healthcare**.

transfusions in two large hospitals in the same city is extremely unusual.

"One **Harvard** expert said he hasn't seen any national data but couldn't imagine that adverse events prompting Centers for Medicare and Medicaid Services reports happen more than half a dozen times a year in the nation's more than 5,000 hospitals," the *Chronicle* reported.

On June 14, *Modern Healthcare* reported that surveys by CMS and the Texas Department of State Health Services found MD Anderson wasn't complying with CMS' conditions of participation regarding its governing body; quality assessment and performance improvement program; patient rights; and nursing and laboratory services.

Tragic Consequences

The CMS survey showed that the female patient had experienced serious compli-

cations and then died on Dec. 8, two days after receiving a transfusion tainted with the bacteria *Serratia marcescens*, the *Chronicle* reported. *S. marcescens* is a gram-negative bacillus that occurs naturally in soil and water. It is associated with common infections, septicemia, and meningitis, *Science Direct* reported. It is commonly acquired in hospitals but rarely found in blood transfusions.

The event has tainted MD Anderson's stellar reputation for patient care and safety. In a letter to CMS on June 21, MD Anderson President Peter Pisters, MD, said *U.S. News & World Report* ranked the hospital as the top cancer center in 2018, and that it has been ranked first in 14 of the publication's 17 annual surveys.

'Swift and Decisive Actions'

In the same letter, Pisters noted that MD Anderson has taken "swift and decisive actions" in an effort to ensure compliance with Medicare's conditions of participation and to address CMS' statement of deficiencies.

MD Anderson included a corrective plan of action and asked for reinstatement of its deemed status. Inspectors are expected to return to the hospital this month before making a decision on the reinstatement. **The Joint Commission** accredits MD Anderson.

In a statement MD Anderson issued June 25, the cancer center said it reported late last year to the **Food and Drug Administration** (FDA) an incident involving contaminated platelets that contributed to a patient's death.

The FDA conducted a review of the lab and did not issue any citations, but under its policies FDA referred the case to CMS.

"CMS in conjunction with the Texas Department of State Health Services conducted surveys of MD Anderson from March 29 to April 5 and from May 13 to 17," the statement said. MD Anderson cooperated with CMS and has submitted improvement plans.

"It is important to note that there have been no changes to our participation in Medicare and Medicaid programs. MD Anderson transfuses as many as 200,000 blood products each year," the statement added. "Those transfusions carry inherent risks, and, for our patients, many who are very sick with weakened immune systems, those risks are more significant."

'An Ineffective Process'

In an e-mail to staff about the problems at Ben Taub Hospital, Harris Health CEO George Masi disclosed the death, explaining that the patient died as a result of "an ineffective process in patient monitoring and communication of critical lab values." No other details were available at the time THE DARK REPORT went to press.

Harris Health did not report the death to CMS. Instead, the federal agency learned about the death through a complaint, the *Chronicle* reported.

On June 4 and 5, the Texas Health and Human Services Commission investigated the complaint and found deficiencies in patient rights and emergency services, CMS said in a letter to Harris Health. **DNV GL Healthcare** accredits the Harris Health System.

Loss of Deemed Status

Each hospital is still feeling the effects of the deaths and is responding to deficiencies cited in reports that CMS issued after investigations into all three events.

The entire Harris Health System, Baylor St. Luke's Medical Center, and MD Anderson Cancer Center, were all placed under state and federal authority as a result of CMS revoking the deemed status for each one, the *Chronicle* reported.

Even though all three health systems will continue as participants in the Medicare and Medicaid programs, all three also will remain under government authority until they demonstrate compliance with CMS' conditions of participation, the *Chronicle* stated. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Another clinical laboratory company disclosed a major breach of its patients' protected health information (PHI). On July 15, **Clinical Pathology Laboratories** (CPL), a division of **Sonic Healthcare**, issued a press release and disclosed that it estimated as many as 2.2 million of its patients may have had their data exposed in a breach at **Retrieval Masters Credit Bureau d/b/a/ American Medical Collection Agency** (AMCA). CPL said, "The impact of this incident is limited to patients whose accounts were referred for debt collection and who reside in the United States." CPL is providing information to those of its patients whose PHI may have been exposed during this breach.

MORE ON: *Data Breach*

AMCA is the same billing company that, earlier this year, revealed that it had been breached, exposing the data of more than 20 million patients of lab companies **BioReference Laboratories**, **LabCorp**, and **Quest Diagnostics**. *(See TDR, June 10, 2019.)* AMCA filed a bankruptcy action earlier this spring, after it disclosed the PHI breaches involving the patients at the above-named three national lab companies.

NEOGENOMICS TO BUILD NEW LAB

Neogenomics of Ft. Myers, Fla., is the latest lab company to announce that it will construct a new, state-of-the-art laboratory facility for cancer diagnostics. The lab will be 150,000 square feet and will include corporate headquarters. It will be located in Ft. Myers. The estimated construction cost is $50 million to $60 million, with a target opening date of 2021.

TRANSITIONS

- **Sonora Quest Laboratories** of Tempe, Ariz. appointed Sonya Engle as COO. Engle previously worked at **LabCorp**, **Quest Diagnostics**, and **Specialty Laboratories**.

- Joyce Santis retired from Sonora Quest Laboratories, effective June 28. She was COO and joined Sonora Quest in 1997. She formerly held management positions at **Tempe St. Luke's Hospital** and **Baptist Memorial Hospital**.

- **Deep Lens, Inc.,** of Columbus, Ohio, named Kevin Whiteley as Vice President of Provider Sales. Whiteley previously held positions at **Danaher-Leica BioSystems**, **Aperio**, **Xoft**, **Skylight Healthcare Systems**, **R2 Technology**, **Alaris Medical Systems**, and **American Hospital Supply Corporation**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 12, 2019.

New This Year!
Smart Ways to Cut Costs

★SPECIAL SESSION!★

Eliminating Paper in Our Lab! Harnessing Staff Creativity with Lean Tools and Culture

Jean Hammelev

Vice President, Operational Excellence, Sonora Quest Laboratories

Lessons from Our Successful Journey to Automate Everything Everywhere to Get Rid of Paper, Improve Productivity, and Reduce Errors

Paper in its many forms and uses is expensive, gets misplaced, and meets the Lean definition of waste (any activity that does not add value to the customer). That is why a laboratory-wide initiative to eliminate paper is now underway at Sonora Quest Laboratories.

One surprisingly effective approach to eliminating paper is to "think automation!" Sonora's lab team is using a variety of tools to accomplish this. In some cases, a process redesign can make it possible to have instruments and automated systems interface directly to digitally move the data they produce. Another approach is to use the lab's existing CRM (customer relationship management) software to digitally capture data that comes into the lab as paper, then manage that data in ways that are easy for the staff to access. These successes can be duplicated in your lab or pathology group!

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