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OIG Report to Congress: 1 in 4 Medicare Patients Suffers Harm in Hospitals!

Latest OIG findings identify opportunity for clinical labs to add value.

See pages 10-15

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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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

1999's 'To Err Is Human' Still an Opportunity for Labs

NOT ONLY DID THE 1999 PUBLICATION OF "TO ERR IS HUMAN" trigger a wave of national news coverage about patient harm in hospitals, it also launched this nation's healthcare system on a multi-decade journey to boost the quality of care, reduce medical errors, and increase the transparency of both patient outcomes and prices.

"To Err Is Human" was published by the **Institute of Medicine** (IOM) and caught the public attention with its estimate that between 44,000 and 98,000 Americans died annually in hospitals due to medical errors. In 2001, the IOM published "Crossing the Quality Chasm: A New Health System for the 21st Century" and made a compelling case that the healthcare system needed to implement major reforms. At that time, THE DARK REPORT provided valuable intelligence about these developments. *(See TDR, "Provider Performance Ranking Now Hitting Healthcare System," Jan. 28, 2002.)*

I was reminded of these events last month when the **Office of the Inspector General** (OIG) issued its latest report to Congress, titled, "Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018," in which it concluded that "one in four hospitalized Medicare patients experienced harm during October 2018." Viewed with the perspective of the events above that happened 23 years ago, the fact that the OIG can document a rate of harm in hospitals today that affects 25% of Medicare patients is an important finding. Even more significant, this rate of harm to patients is consistent with the 17 annual reports the OIG has issued to Congress since 2008. On pages 10-15, you will find useful background on these developments.

As of today, it can be asserted that documented rates of harm to Medicare patients in hospitals are evidence that there is still the need for substantial improvement in the care of patients, whether they are treated in hospitals or ambulatory settings. This is an opportunity for clinical laboratories and anatomic pathology groups. Labs are perfectly positioned to identify patients who are undiagnosed, who have care gaps, or who may have challenging symptoms and where their providers may benefit from timely guidance on the appropriate lab tests. These are all opportunities for clinical labs to add value, support the goals of "Crossing the Quality Chasm," and be rewarded for these contributions—which also could generate a welcome source of new revenue. TDR

UHG's Optum to Offer Lab Test Management

New laboratory benefits management program may expand health plans' use of prior authorization

CEO SUMMARY: UnitedHealth Group subsidiary Optum announced a new laboratory benefits management program aimed at improving utilization of genetic/molecular clinical laboratory testing. The goal is to save health plans money while bringing genetic test validity data prominently into medical decision-making. Health plans buying this service from Optum can use its prior authorization features to manage genetic tests.

Prior authorization requirements instituted by health plans—particularly for expensive genetic tests—are considered to be cumbersome, time consuming, and unpopular by physicians and clinical laboratories alike.

Thus, last week's announcement by the nation's largest health insurer concerning a new clinical laboratory test utilization service may turn out to be a watershed event with unwelcome consequences for many genetic testing companies.

In a press release issued on June 22, **Optum**, owned by **UnitedHealth Group, Inc.**, declared that it is now launching "a comprehensive laboratory benefit management solution designed to help health plans reduce unnecessary lab testing and ensure their members receive appropriate, high-quality tests."

Essentially, Optum is taking the laboratory benefit management program it developed in collaboration with its sister division **UnitedHealthcare**, and will now offer it to any health plan in the United States wanting to improve utilization of expensive genetic tests, along with other clinical laboratory tests.

Genetic testing companies can expect Optum's laboratory benefit management program to have extra teeth, for a significant reason. Optum is working with **Palmetto GBA**, the Medicare Administrator Contractor (MAC) that oversees the MolDX Program, and **Avalon Healthcare Solutions** of Tampa.

The Dark Report is the only lab news source to alert its clients that the Optum laboratory benefit management program is partnering with these organizations. On its website, Optum states, "An absence of clinical efficacy data is making inappropriate utilization worse. This often leads to unnecessary interventions and

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costs. To address this, Optum is collaborating with Avalon Healthcare Solutions, a leader in laboratory benefit management. Optum also has an exclusive partnership with Palmetto GBA, the administrator of the MolDX Program, which identifies and establishes Medicare coverage and reimbursement for molecular diagnostic tests on behalf of the **Centers for Medicare and Medicaid Services** (CMS)."

Optum's Two Collaborators

Optum's relationships with Palmetto GBA and Avalon Healthcare Solutions are significant as they pertain to a laboratory benefit management program. Palmetto developed and manages the Medicare MolDX program. One of the early investors in Avalon is **BlueCross BlueShield of South Carolina** (BCBSSC), which has contracts with Avalon for laboratory benefit management services dating back to 2015.

Those lab executives that deal daily with prior-authorization requirements will recognize that UnitedHealth has created a winning trifecta in its development of a genetic test prior-authorization program:

- Optum supports the nation's largest health insurer in its lab test utilization efforts.
- Palmetto GBA administers Medicare's biggest program involving the coverage and reimbursement for molecular and genetic tests.
- Avalon Healthcare Solutions has a seven-year track record in managing lab test utilization with BCBSSC.

Prior Authorization at UHC

Optum's campaign to market a genetic test prior-authorization program to other health plans is probably based on its experience with UnitedHealthcare's existing prior-authorization program, instituted in the fall of 2017. At inception, there was a specific list of genetic tests that required prior authorization. More tests have been added over the years.

Coincidentally, **Anthem**, the nation's second largest health insurance company, instituted its own prior authorization in the summer of 2017. Thus, within the same year, the two largest health insurers in this country implemented prior-authorization programs in an effort to better manage the skyrocketing number of genetic test claims. *(See TDR, "Anthem Launches Program to Manage Genetic Tests" June, 26, 2017.)*

As reported over the past decade by THE DARK REPORT, one consequence of the explosion in genetic testing is that the Medicare program and private payers found themselves overwhelmed with claims for novel lab assays.

It is an accepted fact that many of the genetic testing companies performing these new lab tests did not have sufficient documentation of analytic validity, clinical validity, and clinical utility of their assays. Therefore, health insurers found themselves reimbursing for sizeable volumes of genetic test claims—tests that might actually have little or no clinical value in patient care.

Genetic Test Claim Tsunami

How big a problem is the multi-year tsunami of genetic test claims for Medicare and private payers? One database of genetic tests maintained by **Concert Genetics** of Nashville, Tenn., catalogs more than 166,000 genetic tests offered by hundreds of companies in the United States. For comparison, around the year 2000, a complete lab test catalog offered by major national reference lab companies **ARUP Laboratories** and **Mayo Clinic Laboratories** listed not more than 2,000 diagnostic assays.

Seen from this perspective, growth over the past decade in the number of different genetic tests has been exponential. Payers were unprepared for the sheer volume of genetic test claims, often billed with between 10 and 40 Current Procedural Terminology (CPT) codes.

However, there is an unrecognized factor that is frustrating payers. The huge number of novel genetic tests and the mushrooming number of claims for these tests are easy to understand.

What gets much less attention is a remarkable fact: genetic testing companies are submitting huge volumes of genetic test claims that include multiple CPT codes. Concert Genetics has reported that the average genetic test claim involves 6.9 CPT codes! It also reports that the denial rate of these claims (full or partial denials) is 30% or more.

Claims Administration Costs

The reason prior authorization programs will appeal to most health plans is another statistic reported by Concert Genetics. It says there are avoidable administratives costs of $125 for every genetic test claim. Multiply that number by tens of thousands of genetic test claims, and the financial benefit to tighter management of these claims becomes significant.

Each of these factors motivates health plans to find better ways to manage genetic test utilization. To that end, Optum said it will achieve those goals by using clinical diagnostic data to guide physicians and patients to genetic/molecular tests that have high clinical validity.

"The offering will help health plans align lab testing with clinical, evidence-based guidelines and automate large parts of lab benefit administration," Optum stated.

Properly-Validated Tests

"We have the opportunity to accelerate the adoption of precision medicine if we track tests on a per-test, per-lab level and sort the ones that have been properly validated from those that have not," the Optum spokesperson noted. "That doesn't happen today, but the Optum lab benefit management solution will do that and push the field toward better clinical utility study designs, help payers and providers determine utility, and establish more transparent quality thresholds for laboratories."

If there is an elephant in the room when the topic of prior authorization of genetic tests is discussed, it is fraud associated with genetic test claims. Experts like pathologist Bruce Quinn, MD, PhD, of **Bruce Quinn Associates LLC**, have analyzed Medicare claims data for genetic tests and have identified tens of millions of dollars paid annually for certain genetic test CPT codes, such as 81408 (rare long genes, $2,000), that went from few claims in 2017 to $283,634,684 in payments in 2019!

This intelligence briefing summarizes why clinical laboratory managers and pathologists will want to pay close attention to the market acceptance of the Optum laboratory benefit management program by other payers. Because of Optum's collaborators, this offering may speed payers' adoption of prior authorization programs across the U.S. TDR

Prior Authorization for Genetic Testing

OPTUM'S ANNOUNCEMENT OF A NEW LABORATORY BENEFITS MANAGEMENT PROGRAM has roots that stretch back five years.

In 2017, UnitedHealthcare and Anthem grew concerned with both the number of novel genetic tests and the ever-increasing number of tests being ordered by physicians. Within months of each other, both insurers established policies calling for prior authorization for these tests. *(See TDR, "Two Largest Payers Start Lab Test Pre-Authorization," Aug. 28, 2017.)*

Beacon Laboratory Benefit Solutions, a lab services management company, worked with UnitedHealthcare to manage the prior-authorization system. UnitedHealthcare earlier had instituted a prior-authorization program in Florida that also involved BeaconLBS, a division of **Labcorp**.

Meanwhile, Anthem's **AIM Specialty Health** division managed that company's prior authorization program.

At the time, both BeaconLBS and Anthem's prior authorization efforts received criticism for being too cumbersome for physicians and for not integrating well with electronic health record systems.

Lab Market Update

Oracle's Plans for Cerner Might Increase Value of Lab Test Data

One major informatics player has ambitious plans that could make diagnostic data more accessible and, at the same time, more valuable for clinical laboratories. **Oracle**, the new owner of **Cerner Corporation**, is telling financial analysts that it wants to create a national repository of health records.

With the technology giant's acquisition of **Cerner** now complete, Oracle Chairman and Chief Technology Officer Larry Ellison said the company plans to build a cloud-based, national health records repository on top of existing electronic health record (EHR) systems.

"Each hospital system has its own patient electronic health records databases," Ellison said during a virtual presentation on June 9. "There are thousands of them in the United States."

With the amount of lab test results stored in EHRs and companion laboratory information systems (LIS), such data becomes very valuable in Oracle's scenario. Beyond patient treatment, a larger pool of anonymized testing data would benefit research and public health. *(See TDR, "Oracle's $28b Cerner Deal Shows Value of Health Data," Jan. 31, 2022.)*

A national database would allow greater interoperability and sharing of health records. "With that information, doctors can provide far better care," Ellison noted. Achieving interoperability of health records is a major challenge. Providers and patients recognize the value of having broad access to records, but health systems, software vendors, and others regularly stymie efforts to share that data.

Ellison did not detail how Oracle will get competing EHR vendors to allow Oracle's proposed database to integrate with their products. It is likely that many health systems that use those EHR products also run Oracle systems, which may provide an avenue in for Oracle.

Voice-Enabled Feature

Oracle, based in Austin, Texas, announced on Dec. 21 that it would buy Cerner in Kansas City, Mo., for $28 billion. It was the largest acquisition in Oracle's history. *(See TDR, "LIS Market Will Change after Oracle, CliniSys Deals," Jan. 31, 2022.)*

Cerner is a top EHR vendor and many clinical labs and pathology groups are familiar with the company for its LIS products. Cerner had early success selling LIS solutions. However, in 2011, as federal incentives prompted hospitals to install EHRs, Cerner devoted more resources towards its Millennium EHR and ongoing investment in its LIS lagged.

Ellison said that big changes are coming to Millennium, some of which will be of interest to hundreds of hospital clinical laboratories that use Cerner.

For example, Oracle will add a voice-enabled interface to Millennium, which in theory would allow a lab employee or physician to say, "Give me all of Larry Ellison's lab test results," and then have those results immediately show up on the computer screen.

Also, all patient diagnostic results stored on Millennium will be fed into a machine learning algorithm, which will create an anonymized database of testing data and other patient information. The ability to aggregate and analyze large collections of clinical lab data is a cornerstone of population health efforts. TDR

Lab's Anemia Program Brings in New Revenue

Jefferson Health's lab team spurs anemia program, results: $11 million in cost savings, plus new earnings

Chris Tomlinson

***CEO SUMMARY:** In Philadelphia, Jefferson Health was looking for new revenue streams to help financial performance during the pandemic. It determined a strong opportunity existed by establishing a patient blood management program that included better anemia treatment options and utilized clinical lab test data.*

Joseph Thomas

By improving blood and anemia management, the opportunity exists to measurably improve patient care, cut costs by a meaningful amount and even generate a new source of revenue for the hospital. In Philadelphia, this was the strategy pursued by administration and the clinical laboratory team at 18-hospital **Jefferson Health**.

Since the outbreak began, Jefferson has struggled with high numbers of SARS-CoV-2 cases in the community and the financial consequences of the pandemic. Hospital executives knew financial recovery would be driven by several operating initiatives.

"Coming out of COVID-19, the health system is under pressure. Revenues are down, margins are tight," explained Chris Tomlinson, Enterprise Vice President of Clinical Lab/Pathology and Radiology/Imaging at Jefferson Health. "It's like getting punch drunk as an old boxer: You keep taking these hits; COVID-19 surges, blood shortages, staffing shortages, and supply chain disruptions.

"The health system was looking for opportunities that could drive revenue, cut costs, and decrease length of stay," he added. "As one of its key operating initiatives, Jefferson settled on blood and anemia management to improve the bottom line as well as clinical outcomes."

Successful patient blood management implementation requires a multidisciplinary effort within a hospital or health system. However, the hospital's clinical laboratory and the blood bank can act as the starting point for these projects, Tomlinson told The Dark Report.

Labs Can Help Their Hospitals

"Lab managers need to get out of their comfort zones as lab leaders if they are to positively impact length of stay and trigger cost savings coming out of the COVID-19 pandemic," he explained. "Blood utilization is not comfortable for all lab leaders. That's not really the discipline studied by these leaders. But the lab team can initiate clinical collaborations, start a project, engage resources from different parts of the organization—such as quality and safety or the medical staff—and position the lab as leading high-value change.

"Hospital and health system labs don't often get viewed that way," he added. "They get viewed as providing just lab

operations, but not providing additional value—such as impacting length of stay."

With its patient blood management program, Jefferson targeted two areas:

- Transfusion: The goal is to save $2.6 million in blood acquisition costs over three years by reducing unnecessary, excessive, or avoidable transfusions.
- Anemia: The goal is to achieve $8.3 million in additional revenue and savings by improving surgical outcomes, reducing hospital patient length of stay, and increasing outpatient anemia treatment revenue.

Project Launched in 2021

The project started in 2021 after some starts and stops due to the COVID-19 pandemic. The timing ironically ended up working well, because the nation's blood supply shortage made the transfusion and anemia projects more urgent.

"You need to change utilization quickly in the middle of blood shortage, and the shortage created a sense of urgency that definitely helped us," Tomlinson observed.

Jefferson Health—which has 18 hospitals within its system and performs 11 million diagnostic tests annually—rolled out a set of meaningful clinical metrics and scorecards to identify all areas of opportunity and measure progress with anemia management and blood utilization reform.

"Our strategy on blood was to create visibility across the health system and post the metrics of every division," Tomlinson said. "We wanted everybody accountable, we wanted every physician to be tracked among their peers, and every division to be tracked among its specialties and all of that against industry leading benchmarks."

The goal of a comprehensive patient blood management program—including anemia oversight—is to optimize care of the patients' own blood and only use transfusion when appropriate, said Joe Thomas, Vice President of Strategic Partnerships at **Accumen**, a healthcare consulting firm in Scottsdale, Ariz.

Accumen worked with Jefferson on its patient blood management initiative, including providing clinical analytics and anemia management software.

"It is expected that most organizations will probably see a combined 20% increase in the utilization and cost of blood over the next three years," Thomas noted. "That is what the national trends tell us. So, for many of those hospitals and health systems that already spend millions of dollars a year on blood, this will be a massive hit. The opportunity isn't price reduction, it is to improve utilization."

Thomas and Tomlinson spoke at the *Executive War College on Laboratory and Pathology Management* in April. Their session was titled, "Anemia as An Opportunity to Add Value."

Anemia can be exacerbated by blood loss during surgery. In those situations, a transfusion is a common response. However, the journal *JAMA Internal Medicine* noted in January 2018 that transfusion was one of the five most overused procedures in U.S. hospitals. Unnecessary transfusions and related practices also expose patients to the threat of serious reactions and infections.

Lab's Role in Anemia Fixes

One noteworthy element in the Jefferson Health project to improve clinical services associated with blood products was to elevate the awareness of anemia as a factor in patient care. For example, when Jefferson Health looked at past cases of 32 non-emergency, high-blood-loss surgical procedures, it determined 39% of those patients were anemic prior to surgery.

By addressing anemic patients before a procedure, a health system can reduce the need for transfusions during or after a procedure while improving clinical recovery.

Laboratories play an important role in early anemia intervention via various blood-related tests; for example, to determine hemoglobin and iron levels.

Precautions for anemic patients prior to surgery include vitamin B12 supple-

Jefferson's COVID-19 Testing Success at Airport May Lead to Other Diagnostic Tests

IN OFFERING AIRPORT TESTING FOR SARS-CoV-2, Jefferson Health leaders made an assumption, only to discover the reality was different—in a good way.

In late 2020, **Philadelphia International Airport** asked the health system to set up a COVID-19 testing station onsite to aid with travelers who needed a test result before flying to meet destination requirements. This station also helped the airport open air routes with other countries where testing was a prerequisite.

"We thought it would be a boutique service," said Chris Tomlinson, Enterprise Vice President of Clinical Lab/Pathology and Radiology/Imaging at Jefferson Health.

Instead, far more people than expected took advantage of the service for the polymerase chain reaction tests (rapid antigen tests were also offered). Tomlinson played THE DARK REPORT a video clip showing the testing line extending down a corridor of a terminal. It resembled a throng of people waiting to get through airport security.

The testing volumes at Philadelphia International remain high. Jefferson's lab leaders are contemplating how to build on that success by offering additional diagnostic tests, telehealth, and other healthcare services at the airport as more of a permanent walk-through clinic for travelers.

That point should not be lost on other innovative clinical labs—if testing success occurs in one area, look at other options that use the same processes or locations, particularly if convenience is a factor.

ments and iron infusions offered on an outpatient basis. Both steps can improve red blood cell counts and reduce the risk of transfusion during a procedure.

A snapshot from one division within Jefferson Health—which includes a large academic medical center—showed the financial and length-of-stay impacts from an anemia management program from July 2021 through March 2022:

- Outpatient infusion revenue (after costs) earned $100,000.
- Reduced length-of-stay costs for anemic patients equaled $25,000 per month.
- Average hospital length-of-stay reduction for patients in the anemia management program was 1.08 days.
- The best reductions were seen in bowel, spine, and high-risk orthopedic surgery.

Tomlinson expects those figures to grow past their initial amounts once the patient blood management program is optimized in the coming two years. In addition, the entire health system achieved blood utilization savings (acquisition cost only) of $2.9 million in over 18 months.

"Payback from this clinical program comes with revenue from anemia infusions, as well as reducing length of stay on the back-end that saves additional costs—and these benefits are in addition to savings in blood costs," he said. "If length of stay is shortened by one day for an anemic patient prior to surgery, those are huge savings when multiplied over and over again."

Labs Leading Change

For lab directors and pathologists who want to lead change, whether with a blood management program or other endeavor, Tomlinson said to study benchmarks first.

"Find some benchmarks, either in your peer group or some of the larger lab or hospital associations," he suggested.

"Whatever benchmark your organization uses, see where you're at and determine the opportunity. Start with what the opportunity is and ask whether the effort will bring meaningful results." TDR

Contact Chris Tomlinson at Christopher.Tomlinson@jefferson.edu; Joe Thomas at joethomas@accumen.com.

CEO SUMMARY: This year's report to Congress on patient harm in hospitals—prepared by the Office of the Inspector General (OIG)—determined that one in four Medicare beneficiaries suffered harm while an inpatient in a hospital. The report garnered little attention outside the healthcare press. Moreover, the OIG's findings about the incidence of patient harm in hospitals for the study year of 2018 are consistent with its findings over the past 15 years. For clinical labs that want to add value, it would be useful to study these reports to develop solutions to that problem.

Is It the Institute of Medicine's 1999 pul

OIG: 25% of Med 'Harmed in Hosp

By Robert L. Michel

ONCE AGAIN, FEDERAL OFFICIALS have issued a report that concludes an unacceptable—and surprisingly high—proportion of Medicare patients are harmed as inpatients in the nation's hospitals. These findings are consistent with earlier federal studies on patient harm.

The report was issued on May 9, 2022, by the **U.S. Department of Health and Human Services** (HSS) **Office of Inspector General** (OIG). It was titled, "Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018," and it concluded that "one in four hospitalized Medicare patients experienced harm during October 2018."

These findings would certainly alarm the average American, were the national news media to splash headlines about how 25% of Medicare patients are harmed when receiving care as a hospital inpatient. But upon its release, the OIG's latest findings were mostly reported by various healthcare news sources and publications and not the mainstream press. Few Americans are aware of the OIG's report and the implications of its findings on themselves and their loved ones should they become Medicare inpatients.

Maybe one reason why this latest OIG report did not get more national attention

is that it is consistent with many earlier studies and findings published during the past 20 years. The rate of medical errors and patient harm in both hospital and ambulatory settings is often found to be significant.

As you will read later, there is a collective body of studies of medical errors over the past two decades. These studies determined that medical errors and/or patient harm (as defined by the researchers) happen to patients anywhere from 20% to almost 50% of the time, depending on the focus of the study.

Seen from this historical perspective, the OIG's May report simply affirms the status quo as it pertains to the rate of negative health events and medical errors that occur to patients within the U.S. healthcare system. THE DARK REPORT is not aware of credible published evidence that refutes the OIG's findings about the proportion of Medicare patients who experience a medical error or harm when in a hospital.

Opportunity for Clinical Labs?

Along with confirming the status quo, the OIG's findings validate an opportunity available to the nation's clinical laboratories and anatomic pathology groups. That opportunity is for clinical lab executives and pathologists to think strategically as to how their lab organizations can contribute to the reduction of medical errors, particularly those that harm patients.

This opportunity is consistent with the Clinical Lab 2.0 model of delivering value and actionable intelligence to physicians that improves patient care and positions the laboratory to be paid for the value of this intelligence. *(See TDR, "Clinical Lab 2.0's Message to Labs: Improve Outcomes, Get Paid More Money!" June 5, 2017.)*

Healthcare's 20-Year Journey

For those pathologists and clinical lab managers interested in the opportunities and benefits that might result from organizing lab testing services that effectively address and reduce medical errors, it is essential for them to understand the U.S. healthcare system's 20-year journey involving medical errors and patient harm.

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For example, the findings of Medicare patient harm in hospitals from this latest OIG study is consistent with its earlier findings over the past 10 years. The May 2022 OIG report is the most recent in a series of reports mandated by the Tax Relief and Health Care Act of 2006.

The 2006 law also requires HHS and OIG to report to Congress the number of "never events" involving Medicare patients. In these reports, OIG describes never events as "a subset of adverse events that should never occur, such as surgery on the wrong patient, among Medicare patients."

In response to this action, THE DARK REPORT described several of the never

events, writing "after implementation of the new rules, Medicare will no longer reimburse hospitals for treatment that resulted from nosocomial infections, surgeries performed to retrieve objects—including sponges or instruments—left in a patient, reactions when transfusion patients get the wrong blood type, bedsores that develop during hospitalization, and injuries from a fall sustained in the hospital."

In that 2006 law, Congress further directed that Medicare officials stop paying hospitals for never events that affected Medicare beneficiaries. The law also forbids hospitals from billing Medicare beneficiaries directly for care related to medical errors. *(See TDR, "Medicare Soon Won't Pay Hospitals for Errors" Oct. 8, 2007.)*

In compliance with the 2006 law, the OIG annually reports to Congress regarding the incidence of never events. Since 2008, OIG has issued 17 reports that focus on adverse events in hospitals and other healthcare settings.

Patient Harm Study in 2010

For example, in its "First National Study of Adverse Events" issued in 2010, the OIG "provided the first nationwide estimate of patient harm." In the section "In Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries," the OIG reported the following:

- 27% of hospitalized Medicare patients experienced adverse events and temporary harm events in October 2008.
- 44% of harm events were preventable.
- Care associated with adverse events cost Medicare and patients an estimated $324 million in that single month.
- For that same period, OIG estimated that adverse events contributed to approximately 15,000 deaths among hospitalized Medicare patients.

Some of the OIG's findings are remarkable. In this most recent report, the OIG said, "Subsequent OIG reports [after 2010] on adverse events have focused on incident reporting and incidence rates in different healthcare settings. In a 2012 followup report, OIG found that *only 14% of patient harm events were reported to hospitals' incident reporting systems or other internal surveillance systems.* [Italics by TDR.]

Incidence of Harm Events

This statement continued: "In a series of reports regarding the incidence of harm events in post-acute settings, OIG found that 32% of Medicare residents in skilled nursing facilities, 29% of Medicare patients in rehabilitation hospitals, and 46% of Medicare patients in long-term care hospitals experienced harm."

The OIG, using accepted methodology, is documenting a rate of medical errors and patient harm that seems consistent in the series of reports it has issued since Congress tasked it with reporting on patient harm in the 2006 legislation.

Pathologists and clinical lab managers who started their careers in recent years will find it helpful to understand that the campaign to publicize medical errors and patient harm goes back almost three decades. A key starting point on the story about medical errors in the United States starts in 1999. That's when the **Institute of Medicine** (IOM) published "To Err Is Human."

Up to 96,000 Deaths

In that report, the IOM estimated that 44,000 to 96,000 Americans die in any given year from medical errors that occur in hospitals. This assessment triggered news headlines and caught the full attention of the American public. The study authors gave context to this estimate, noting, "that's more [people] than die from motor vehicle accidents, breast cancer, or AIDS—three causes that receive far more public attention. Indeed, more people die annually from medication errors than from workplace injuries."

Publication of "To Err Is Human" was the trigger that caused a group of business

It's been a Multi-Decade Journey to Improve Quality of Patient Care in the U.S. Health System

PUBLICATION IN 1999 OF A MAJOR STUDY OF MEDICAL ERRORS AND PATIENT HARM by a respected healthcare institution caught the attention of Congress and set the nation's healthcare system on the path: first to increase the transparency of medical errors and healthcare outcomes, and second to trigger greater attention by hospitals and physicians to improving the quality of care they provide. Milestones in the decade following release of that study include the following:

- **1999** "To Err is Human" is issued by the Institute of Medicine (IOM). It estimates that between 44,000 and 98,000 Americans die from medical errors in hospitals in a year. This document generates national headlines.
- **2000** Leapfrog Group formed with the stated goal of improving transparency of healthcare outcomes and the cost of care. Initial membership includes 96 corporations that collectively represented 28 million people who were spending $52 billion annually on healthcare.
- **2001** "Crossing the Quality Chasm" is the follow-up report by the IOM. It was a thorough review of the overall quality of the healthcare system, included an assessment of the healthcare industry's safety and effectiveness, and made recommendations for a comprehensive strategy for improvement.
- **2002** Peer-reviewed journal *Quality Management in Healthcare* published a study with this abstract:

  This article compares seven non-federal general hospital performance measures derived from Medicare against Joint Commission scores. Joint Commission measures are generally not correlated with outcome measures. The few significant correlations that appear are often counterintuitive. We conclude that a potentially serious disjuncture exists between the outcomes measures and Joint Commission evaluations. ("Structural versus Outcomes Measures in Hospitals: A Comparison of Joint Commission and Medicare Outcomes Scores in Hospitals;" Griffith, John R.; Knutzen, Steven R.; Alexander, Jeffrey A.; QMHC 10(2):29-38, Winter 2002.)
- **2002** Leapfrog issues its first hospital quality rankings.
- **2002** The Joint Commission (then known as The Joint Commission on Accreditation of Healthcare Organizations [JCAHO]) joins Leapfrog Group.
- **2002** **NCQA** begins to expand the data reported by health plans via the Healthcare Effectiveness Data and Information Set (HEDIS). This includes adding utilization of a larger number of screening tests, along with the tests scores and associated patient outcomes that health plans provided to their beneficiaries.
- **2006** Congress passed the Tax Relief and Health Care Act of 2006.
- **2008** OIG issued the first annual report on quality of care and patient harm experienced by Medicare beneficiaries in hospitals.
- **2009** CMS grants **Det Norske Veritas** (DNV) deeming authority for hospital accreditation to the Medicare Conditions of Participation (COP). DNV offers ISO 9001 certification and Medicare accreditation for one price.

leaders to come together and create an organization specifically to help employers assess the quality of healthcare while also enabling their employees to shop for care. One way to achieve this was to improve transparency in patient outcomes, medical errors, and provider quality.

These efforts led to the formation of the **Leapfrog Group**, now based in Washington, DC. It launched in 2000, only months after the publication of "To Err Is Human." Initial membership was 96 corporations and organizations. Included were **General Motors**, **AT&T**, **General Electric**, **IBM**, and **Boeing**. Collectively, these members were spending $52 billion annually on healthcare and represented 28 million people.

The next development in this progression toward today's quality and transparency movement in healthcare came March, 2001. That is when the IOM published a companion document in support of "To Err is Human." It was "Crossing the Quality Chasm: A New Health System for the 21st Century."

Emphasis on Quality

In a user's guide he prepared for acting on "Crossing the Quality Chasm," Donald M. Berwick, MD, then a member of the IOM, described how that document was a call for providers to pay more attention to:

- Overuse (using medical resources and treatments with insufficient evidence that they improve patient outcomes),
- Underuse (failing to deliver resources or treatments known to be of benefit), and
- Misuse (failing to execute care safely and correctly) of healthcare resources and treatments.

Within months of this second IOM report, Leapfrog acted in support of its mission to improve transparency in healthcare quality and patient outcomes, and reduce medical errors.

In January, 2002, the Leapfrog Group made public its findings on how 241 hospitals in six regions measured up in three performance areas.

"To Err Is Human" and "Crossing the Quality Chasm" also influenced developments at **The Joint Commission** (then known as **The Joint Commission on Accreditation of Healthcare Organizations** [JCAHO]).

One day before the Leapfrog Group unveiled its survey of hospital responses to the three performance areas at a Jan. 17, 2002, press conference, The Joint Commission announced it had accepted an invitation from the Leapfrog Group to become a formal partner.

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Pathologists and clinical lab managers who started their careers in recent years will find it helpful to understand that the campaign to publicize medical errors and patient harm goes back almost three decades.

THE DARK REPORT considered the timing of The Joint Commission's (TJC) announcement that it was becoming a member of the Leapfrog Group—just days before the release of the survey of hospital performance measures—not serendipity. At that time, we observed how just weeks earlier, the journal *Quality Management in Healthcare* had published a peer-reviewed study that investigated if a hospital's accreditation status statistically correlated to better quality and safety of patient care. (This study was itself influenced by the two earlier publications issued by the IOM.)

In assessing this situation, THE DARK REPORT wrote the following:

The findings of the study revealed that a hospital's accreditation status did not correlate to better quality and safety of patient care. The study specifically noted that hospitals with higher-than-average

rates of deaths and complications often received favorable scores from JCAHO.

One observation by study co-author John R. Griffith, from the University of ***Michigan School of Public Health****, is that the accreditation process relies almost exclusively on surveying the hospital's organizational structure and process. He noted that little weight is given to objective performance measures, such as the rates of death and unexpected complications, as well as whether the hospital is adaptable and incorporating the latest clinical procedures and new technologies.*

That is why JCAHO's willingness to partner with the Leapfrog Group is a significant event. The timing of JCAHO's announcement, one day before Leapfrog made its hospital data available to the public, demonstrates that it will become more responsive to the quality concerns of employers. (See TDR, "Provider Performance Ranking Now Hitting Healthcare System," Jan. 28, 2002.)

Two Consequences

This study in *Quality Management in Healthcare* had two immediate and long term consequences for quality in healthcare in general, and at The Joint Commission specifically.

First, the study's conclusions that data on patient quality and patient safety could not be correlated to a hospital's choice of accreditation organization caught the full attention of executives at TJC. They recognized that this was a situation that needed to be rectified. Joining the Leapfrog Group and supporting the drive for more transparency in quality and patient outcomes was one way to demonstrate that commitment to the public.

The second consequence was more profound. As noted in the quote by John R. Griffith reproduced above, the study team recognized that [as of 2002] the hospital "accreditation process relies almost exclusively on surveying the hospital's organizational structure and process."

Researchers were recognizing that hospital accreditation standards at that time were heavily weighted to check compliance with regulations, how staff followed requirements, and how all of these organizational tasks were documented. Essentially, the primary objective of these hospital inspections was to assess compliance with processes. Measuring improvement in patient care, patient outcomes, and reduction in errors received much less emphasis.

Measuring Patient Outcomes

With the benefit of 20 years of hindsight, one can look back to this moment in 2002 and recognize that the second consequence of the *Quality Management in Healthcare's* study—in tandem with the two reports published by the IOM—was to launch a drive to expand the role of measuring outcomes and performance in delivering patient care during the accreditation and certification of healthcare providers.

From 2002 forward, U.S. healthcare began a long-term shift in two dimensions. One dimension was to shift the basis of accreditation and certification activities to primarily the assessment of how quality, patient outcomes, and patient safety were measured and improved from one inspection period to the next.

The other dimension was to increase the transparency of this same data to buyers—be they employers selecting the best performing health insurance plans or patients choosing a hospital or doctor.

This review of seminal events in healthcare quality during the decade of the 2000s was followed by equally significant developments in the next decade in how providers improved quality and patient outcomes. A future issue of THE DARK REPORT will advance this retrospective on the quality movement in healthcare. **TDR**

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How to Better Recruit Millennial Pathologists

Anatomic pathology practices need to update their recruiting techniques to stay competitive

Rich Cornell

CEO SUMMARY: With the Great Resignation taking its toll on existing pathology rosters and only a small pool of talent to replace the retirees, competition is intense to fill open roles. Pathology groups and clinical laboratories must adjust their hiring methods to better attract Millennial candidates, a group with professional and personal priorities different from those of Baby Boomer and Gen X pathologists.

MILLENNIAL PATHOLOGISTS LEAVING RESIDENCY TO BEGIN THEIR PROFESSIONAL CAREERS have different needs and priorities compared with older generations. This presents unique new challenges for pathology groups and clinical laboratories competing to recruit the best and brightest young pathologists.

Exacerbating this new dynamic in pathologist employment is the one-two punch of a historically-low pathology talent pool combined with the Great Resignation, which saw older pathologists retire in large waves during the pandemic.

Reality of Today's Job Market

One expert in the field urges pathology groups wanting to fill open positions to recognize the reality of the current job market for pathologists, where the scales are tipped in favor of candidate pathologists and against labs seeking to fill open positions.

"What I tell labs and pathology groups is that they have to change their mindset in recruiting talent today," said Rich Cornell, President and Founder of **Santé Consulting**, a pathologist and laboratory medicine recruiting firm in Chesterfield, Mo. "Their old methodologies don't work in today's market."

Cornell pointed to job listings on *PathologyOutlines.com* and the **College of American Pathologists** website as one indicator of the challenge. These days, he explained, there are more listed openings for pathologists than at any time in the past 20 years, and this only tells part of the story. *(See TDR, "Record 600 Pathologist Jobs Open Nationwide," Aug. 16, 2021.)*

"I would say two-thirds of the jobs are actually posted in one of those two websites, and one-third are not," he noted.

So how does a lab adapt its recruiting practices to this new job market? Cornell offered suggestions in an interview with THE DARK REPORT and during a session at April's *Executive War College Conference on Laboratory and Pathology Management*, titled, "Pathology's Hottest Job Market in Two Decades: Proven Ways to Make Your Practice Competitive When Recruiting."

"When attempting to recruit a senior pathologist or medical director with, let's say, 15 years of experience, that process is going to look a lot different when the recruit is a Generation X candidate versus a

Millennial," Cornell said. "It's essential that the lab or pathology group know the candidate pool from which it wants to recruit and adjust its process. Cookie cutter approaches won't succeed in today's job market. It is essential to have a strategy tailored to attract the most talented candidates."

For many pathology practices, this means gaining a greater understanding of the Millennial generation, loosely defined as people born from 1980 through the mid-1990s. Within the next four years, "up to 75% of the workforce is going to be Millennials," Cornell noted, and pathologists who are Baby Boomers or Gen Xers need to be aware that Millennials have different workplace and lifestyle priorities.

"They don't like a competitive environment," he said of the younger generation. "They like to collaborate. They like inclusion. They thrive when they have a purpose. They love technology."

Gearing Up for Millennials

Cornell recommends that forward-thinking pathology practices should take the following eight actions to attract more Millennial candidates:

One: Accelerate the hiring pace. Younger physicians make decisions quickly, Cornell said, which means practices should speed up the interview process. He advised conducting the initial interviews virtually, and "the closing sequence of that candidate needs to be weeks, if not days," instead of months.

Two: Once a pathology group completes the onsite interview, "give candidates immediate feedback within two to three days on how you're going to proceed in that process. Don't wait, especially if they're an A-list candidate."

Three: Don't forget the family. "Practices are not just recruiting the clinician, they're recruiting the family," Cornell advised, noting that "60% of a candidate's decision, if not more, is going to be based on spousal needs, family needs, and lifestyle. So, make sure that the recruitment process encompasses that."

Avoiding Pathologist Retention Headaches

AS COMPENSATION GOES UP FOR NEW HIRES, pathology practices face an age-old dilemma: Do they also adjust the pay scales for the currently-employed pathologists? The impact of the hiring crunch on existing staff is an important consideration for observant pathologists, said Rich Cornell, President and Founder of Santé Consulting.

"Assume your group recruited a pathologist in the last three or four years at X salary. Today your group will pay X+ salary to hire a new pathologist. What's going to happen?" Cornell asked. "The current employees will go out and have a couple drinks or a watercooler conversation and talk about the compensation."

As a result, pathology groups may have to create more parity for existing staff compensation as it compares with new hires. Another approach is to consider other measures, such as enhancing benefit packages. "Otherwise, you're going to have employee retention issues down the road, because current pathologists are going to be upset," he warned.

There are other ways to mitigate the impact, he suggested. "For example, many physicians have $300,000 to $400,000 in student loan debt before they go into practice," he noted. "Pathology groups could create a student loan repayment program and make this part of the compensation package."

Four: In cases where candidates bring their families to an onsite visit, "have a separate itinerary for the family and spouse. Have a welcoming basket in the hotel room with snacks and things that are local to the area," Cornell suggested. "Include a handwritten note from the practice or group welcoming them to the community."

Five: Ask younger pathologists on staff to take the lead. "A practice may have a

Boomer who is nearing retirement trying to recruit into the practice, because they've always done that function," Cornell said. "But for pathology groups that want to be successful, the face of the practice should be somebody who's maybe Gen X or a Millennial."

Six: Assign roles to job interviewers. Cornell pointed to a common—yet counterproductive—scenario in many interview processes. "What happens if a pathologist interviews the candidate and hasn't been coached on their role?" Cornell asked. "The first thing they say is, 'Tell me about yourself.' Then the candidate goes to the next interview, and again the first question is, 'Tell me about yourself.' It's the same conversation over and over. Instead, each interviewer should have an assigned role. For example, the head of the group might discuss business dynamics, whereas another interviewer can discuss caseloads or call schedules."

Seven: Point to work/life balance benefits. Flexible schedules and paid time off can be just as enticing as high salaries for some candidates, especially those with young families or aging parents. The pandemic reset many Millennials' expectations on how they balance work duties and their personal lives.

Eight: Offer a mentorship program. "This is where the Gen X, mid-career person comes into play," Cornell noted. "Most residency and fellowship programs don't address the business aspects of pathology and community practice in their training, so this is one area where mentorship can be especially helpful."

Rethinking Compensation

With more demand for job candidates, salaries and bonuses are also on the rise, Cornell observed. Hiring budgets need to reflect this fact at the risk of falling behind competitors. For example, first-year pathologists at academic medical centers were making an average of $200,000 to $220,000 before the pandemic. Today, that compensation is now up to $230,000 to $240,000.

"These numbers are relevant because many academic centers are aggressively recruiting subspecialty pathologists," he continued. "Private pathology labs must recognize this reality and be prepared to offer competitive compensation and benefits packages to the most desirable candidates."

Among Cornell's placements, the highest compensation for a first-year recruit was $350,000 for a gastrointestinal pathologist in California. "Pathologists who have been in practice for a number of years cringe when they see these numbers," he said. "They remember what they got paid when they first came out of fellowship. Today's higher compensation reflects the high demand for qualified pathologists."

Practices are also beefing up other forms of compensation, including relocation assistance, signing bonuses, retirement plans, and paid health insurance.

Bigger Signing Bonuses

"We see signing bonuses in the $20,000 to $25,000 range," Cornell noted. "In previous years, we did not often see signing bonuses for candidates. If they did get one, it might have been in the $5,000 to $10,000 range."

The cost and effort to hire new pathologists points to a related and growing need for practices to control costs more efficiently and seek new ways to generate additional revenue. These initiatives will lead to a more financially-sustainable pathology practice that is prepared for future staffing needs.

Although this is a challenging time for recruitment, Cornell sees positive signs on the horizon. "There is a lot of technology advancing in lab medicine, digital pathology, informatics, and molecular and genome testing," he added. "This has special appeal for Millennials. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Efforts to revise the much-criticized methods Medicare officials use to establish prices the government pays clinical laboratories under the Protecting Access to Medicare Act (PAMA) of 2014 got a boost last week. On June 22, a bipartisan bill to accomplish that was introduced in the U.S. Senate. The new Saving Access to Laboratory Services Act will adjust lab reporting of private sector payer rates to "create a more representative, sustainable, and market-based [clinical laboratory fee schedule]," according to the bill's authors. This legislation would also reduce reporting periods from every three years to every four years.

MORE ON: *Laboratory Data Reporting*

Under PAMA, labs are required to regularly collect and report data on what private insurers paid for lab tests. **The Centers for Medicare and Medicaid Services** used that data to lower prices for lab tests in 2018, 2019, and 2020. Another payment cut was scheduled for Jan. 1, 2021, but it has been delayed until next year. Lawmakers behind the proposed Saving Access to Laboratory Services Act said data collection under PAMA has been flawed, with independent labs overrepresented and hospital labs underrepresented.

BECTON DICKINSON, MAYO CLINIC ENTER DATA-SHARE DEAL

In another example of *in vitro* diagnostics companies having interest in clinical data, **Becton, Dickinson and Company** in Franklin Lakes, N.J., announced a new collaboration with **Mayo Clinic Platform** in Rochester, Minn., to access deidentified patient records. This information includes 1.2 billion laboratory test results.

INTERMOUNTAIN ENTERS NEW DIGITAL PATHOLOGY DEAL

Digital pathology capabilities at **Intermountain Healthcare** are getting a boost. The respected integrated delivery network (IDN) has teamed up with **Gestalt Diagnostics** in Spokane, Wash., and **Hamamatsu Photonics K.K.** in Japan. Pathologists will be using Hamamatsu's whole-slide imaging technology with Gestalt's image management system. Intermountain, based in Salt Lake City, said the deal will help advance its use of digital pathology in patient care.

TRANSITIONS

- Ken Bloom, MD, was named Head of Pathology at **Nucleai** in San Clemente, Calif., which develops a machine learning platform for pathologists. He was most recently Chief Medical Officer of Advanced Pathology and Genomic Services at **Invicro** and **Ambry Genetics**. Bloom also served at **Clarient**.

- **Baptist Health** in Boynton Beach, Fla., announced that Rachel Scott is the new lab director. Previously, she served at **HCA Healthcare** and **Trinity Hospital** in Ohio.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 18, 2022.

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