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HIGHLIGHTS

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New Study IDs Income as Significant Barrier to Molecular Testing

Personalized medicine is considered a savior for both health care delivery and the laboratory sector. Patients receive guidance specific to them on how to attack their disease, and the lab sector would reap the benefits from marketing and distributing assays that often cost well into the four figures.

But a new study published in the journal *Health Affairs* by researchers at UCLA, UC San Francisco and Harvard University concludes that income is a barrier to many patients obtaining such testing, regardless of whether they have insurance to cover the procedure.

The study examined 1,847 women in 31 states who were treated for breast cancer. All had insurance from Aetna (the health plan provided de-identified data for the study).

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Labs Anxiously Await Pricing for Genome Sequencing Codes

The laboratory sector is awaiting how the Medicare program will price 21 codes for whole genome and exome sequencing procedures, providing some insight as to how much they will receive from both public and private payers for the often complex assays and panels.

The codes, which cover CPT numbers 81410 through 81471, include some highly esoteric tests, such as tests for Marfan syndrome, Loeys Dietz syndrome, and Ehlers-Danlos syndrome. However, it also includes tests for fetal chromosomal aneuploidy and circulating cell-free fetal DNA in maternal blood. The tests are currently being paid via the gapfill process, using previously priced codes for specific molecular tests.

It is up to the regional Medicare Administrative Contractors, or MACs, to price the codes. The MACs are supposed to submit their

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Labs Anxiously Await Pricing for Genome Sequencing Codes, *from page 1*

initial pricing this month, and the Centers for Medicare & Medicaid Services would likely release them later this spring. The prices would take effect next year.

Unlike the prior molecular codes whose prices were set two years ago, the MACs have the option of only submitting the codes they plan to cover for reimbursement in their respective regions. Codes for fetal testing are likely to be excluded by Medicare on statutory principles.

However, the stance the MACs take will likely influence the private payers as well. "It is still early in the process, and many private payers have not established how they expect labs to bill. There is some evidence of increased private payer denials when labs submit under the new codes, however, given increased visibility that the test is a genomic sequencing procedure," wrote Amanda Murphy, analyst with William Blair & Co., in a recent report.

The MACs' power over pricing—and the fact that they apparently have been tight-lipped about the direction they intend to take—has caused some anxiety among the laboratory sector, according to some observers.

"It has been so silent," said Rina Wolf, vice-president of commercialization strategies, consulting, and industry affairs at Xifin, the San Diego-based laboratory consulting firm. Wolf believes that the MACs may follow the course of MAC Palmetto GBA, whose MolDX coding system has drawn ire from the lab sector as a means to keep payments down.

Palmetto has already indicated analysis of multiple biomarkers would be considered a "panel" and will require each lab to submit them through a unique MolDX identifier. Palmetto said it would begin rejecting stacked CPT codes for panels on July 1.

William Blair's Murphy believes the pricing set by MACs will be conservative, noting that based on comments from Palmetto officials, "pricing for panels will be less than the pricing of the individual genes in aggregate."

Takeaway: The laboratory sector has experienced some anxiety over the planned pricing for whole sequencing tests.

New Sequencing CPT Codes

Code Number	Test Description
81410	Aortic dysfunction (minimum 9 gene sequence panel)
81411	Aortic dysfunction (duplication/deletion analysis panel)
81415	Exome sequence analysis
81416	Exome sequence/comparator exome
81417	Exome re-evaluation
81420	Fetal chromosomal aneuploidy
81425	Genome sequence analysis
81426	Genome sequence analysis/comparator

New Sequencing CPT Codes	
Code Number	Test Description
81427	Genome sequence re-evaluation
81430	Hearing loss, minimum 60 gene sequence
81431	Hearing loss duplication/deletion analysis
81435	Hereditary colon cancer syndrome (minimum 7 gene sequence)
81436	Hereditary colon cancer syndrome duplication/deletion analysis
81440	Nuclear encoded mitochondrial genes (minimum 100 gene sequence)
81445	Solid organ neoplasm 5-50 gene panel
81450	Hematolymphoid neoplasm 5-50 gene panel
81455	Solid organ or hematolymphoid neoplasm, 51 or greater genes
81460	Whole mitochondrial genome
81465	Whole mitochondrial genome large deletion analysis panel
81470	X-linked intellectual disability
81471	X-linked intellectual disability duplication/deletion analysis

Ambry Acquires Florida Lab Software Firm

California-based molecular laboratory Ambry Genetics has acquired Progeny Software for an undisclosed sum.

The Florida-based Progeny has created and distributes several software platforms, including a genotype data management system and a configurable inventory and sample tracking system. The companies had similar client lists and a deal was worked out not long after Ambry CEO Charles Dunlop and Progeny CEO Michael Brammer met for the first time, the companies said.

Ambry performs a variety of molecular tests for cancer and cardiology, as well as exome and genetic panels.

"The scientist and genetic counselor in me nearly jumped out of my skin thinking of all the ways we can improve the testing process, results interpretation, and patient follow-up with this partnership. This will be incredibly valuable not just for hereditary cancer testing, but for all specialties we focus on at Ambry," said product manager and genetic counselor Carin Espenschied in a statement.

Brammer will remain CEO of Progeny, which will operate as a subsidiary of Ambry.

"I wouldn't have made this deal with anyone but Ambry Genetics. Everything they do is for the betterment of the genetics community as a whole and they've shown that for the 15 years I've been watching them. We've tried to behave similarly at Progeny. Joining forces just made too much sense," he said in a statement.

Takeaway: Ambry Genetics has engaged in a transaction intended to make it into a complete genetics services company.

Inside The Lab Industry

Labs Quickly Move Toward Electronic Reporting of Public Health Information

When Patricia Quinlisk, M.D., joined the Iowa Department of Public Health (IDPH) two decades ago, laboratories reported their results in a time-honored fashion: paper forms filled out by hand or typewriter. Those forms could then be folded down to the size of an envelope and mailed in—only to require more manual inputting on the agency's side.

Quinlisk, who is the IDPH's medical director, admits that much has changed in the subsequent years. Virtually every laboratory of size now submits their data electronically—a change that has had a substantial impact on how the agency identifies and addresses potential health crises.

"If you go back to the late 1980s, everything was done by hand, and entered into logbooks," Quinlisk said. The process gradually morphed into manual entries into a computerized database, and then all-electronic submissions. That has cut substantial time from identifying and responding to potential epidemics and other public health crises, and the state of Indiana has benefited as a result.

But even in the private sector, labs have been changing how data is aggregated and reported. Quest Diagnostics recently used its billions of test results and the data it has generated over the years to publish an eyebrow-raising study about the nationwide state of diabetes diagnosis under the auspices of the Affordable Care Act (ACA).

Indeed, the ACA was highlighted in a recent study by the U.S. Centers for Disease Control and Prevention (CDC), which noted that funding made available from the health care reform law has also transformed the way labs transmit public data.

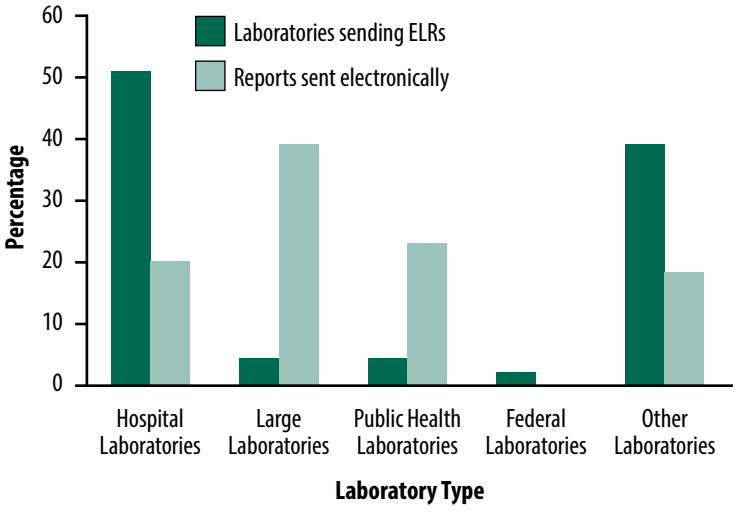
According to the CDC, 67 percent of the 20 million or so reportable conditions submitted by laboratories were sent electronically last year. That compares to 62 percent in 2013, an increase of about 8 percent in a single year. Although the proportion of hospital-based labs submitting electronically last year was only 20 percent, that's up from 14 percent in 2013—a nearly 50 percent increase in a single year. Large commercial laboratories still account for a large proportion of electronic transmissions—39 percent.

Some states saw even more dramatic uptakes. In North Carolina in 2013, 76 percent of all laboratory reports were received electronically by the state's Division of Public Health. That's up from 56 percent in 2012. In Kansas, 29 laboratories were reporting electronically as of last fall, with nearly three-quarters of reports being submitted in that fashion. Those reports arrive nearly three days sooner than they did when labs fax them in—an average of 3.3 days versus six days.

Inside The Lab Industry

Not every lab is adopting so rapidly. Smaller laboratories, particularly those in rural areas, are far less likely to submit reports electronically, according to Quinlisk. Whether they will obtain the resources to do so in the near future remains to be seen.

States also have to remain on top of electronic submissions to make sure the data they contain is correct. The California Department of Public Health's CalREDIE submission system has to be monitored "to ensure that messages continue to flow correctly," said Gil Chavez, M.D., the department's deputy director and state epidemiologist.



Source: Centers for Disease Control and Prevention

Quest Study

Quest was able to use its own testing for diabetes to come to a stark conclusion as to how the ACA is unfolding in the United States. The New Jersey-based company analyzed the de-identified results of 434,288 of its patients who tested positive for diabetes throughout the country. Quest's conclusion: The rate of new diabetes diagnoses rose 23 percent in states that chose to expand their Medicaid eligibility under the ACA. By contrast, the rate of diagnoses in the non-expansion states—many of them with already below-average health trends—barely changed.

The conclusion was sobering: Not only is the disease in a nearly pandemic state in the U.S., but in the 20 states that have so far declined to expand their Medicaid programs, they will likely be facing a demographic time bomb in the coming years.

"Our study demonstrates the value of objective insights gleaned from aggregate diagnostic data for informing population health strategies that can promote better health outcomes," said Jay Wohlgemuth, M.D., a Quest senior vice president and chief scientific officer for research and development, in a press release. "If the lab (sector) wants to validate value of individual lab tests, we have to migrate to more health outcomes studies, and be involved with more health economics," said Harvey Kaufman, M.D., a Quest senior medical director. Kaufman said Quest has expanded funding and staff for future research.

Inside The Lab Industry

Iowa's Response

According to the CDC, Iowa was caught flat-footed in 2006, when there was a national outbreak of mumps. There were nearly 2,000 cases in Iowa, and handling the response required temporary reassignments of staff members and the hiring of temporary employees for data entry.

> *"We've always encouraged labs if they see something unusual, and that they pick up the telephone and call us. The bigger problem is if one lab sees three (cases of) salmonella, and another saw two, they might not have realized they were seeing a piece of an outbreak."*
>
> *— Patricia Quinlisk, M.D.*

"We've always encouraged labs if they see something unusual, and that they pick up the telephone and call us," Quinlisk said, referring to the pre-digital era. "The bigger problem is if one lab sees three (cases of) salmonella, and another saw two, they might not have realized they were seeing a piece of an outbreak."

That has changed in recent years. In 2012, the agency was able to handle sizable outbreaks of pertussis and the gastrointestinal condition cryptosporidiosis—more than 3,200 cases in total—without the need to divert any personnel or other resources. In the latter instance, the IDPH also used social media to urge the public to undergo stool testing after a sharp-eyed epidemiologist spotted a pattern in some slides that were submitted to the agency from area labs for inspection.

A Conflict Between Technology and Physical Collection

But as lab testing progresses, it does not necessarily mesh with more consistent physical collection of public health data. For example, the long-used stool test used to identify cryptosporidiosis allows for preservation of specimens on slides.

A 2012 article in the CDC publication *Morbidity and Mortality Weekly Report* noted that "cryptosporidiosis collection and molecular characterization of Cryptosporidium isolates would further the understanding of U.S. cryptosporidiosis epidemiology by revealing transmission patterns and potential risk factors." But that would also mean phasing out "the practice of preserving stool specimens with formalin," suggesting that public health labs would not have physical slides for inspection. Quinlisk noted that the lack of physical slides also impacts salmonella reporting. The recent molecular testing method for the bacteria—pulsed-field gel electrophoresis—excludes slides that can be sent to public health agencies for study.

"If the clinical lab does one of these platforms, they get a 'yes' or 'no' for salmonella, and we may never even find out," she said.

Takeaway: The Affordable Care Act and the expansion of digital technology has played a significant role in the way laboratories, collect sort and report test data. G2

New Study IDs Income as Significant Barrier to Molecular Testing, *from page 1*

According to the study, 12.5 percent of the women underwent the Oncotype DX assay, developed and distributed by California-based molecular laboratory Genomic Health to help target chemotherapy and other treatments. A Genomic Health spokesperson said the test retails for $4,000, but that the lab also offers financial assistance programs to ensure patients have access to the assay.

Overall, 12.5 percent of the women in the study used the Oncotype assay, but there was wide divergence of its use among income levels. A total of 16.2 percent of women who earned more than $100,000 a year underwent the test. But only 12.4 percent of women who earned between $50,000 and $100,000 used it. And among those who earned below $50,000, it dropped to 9.5 percent. Moreover, women who resided in regions with high income inequality were 8.4 percent more likely to undergo testing than those who resided in regions with a smaller income gap.

There were also testing gaps by ethnicity. Only 8.6 percent of African-Americans underwent the test, and just 1.5 percent of Hispanic women.

"Income inequality is at an all-time high right now," said Jennifer Haas, M.D., a study co-author and associate professor at Harvard Medical School's Brigham and Women's Hospital, in a statement issued by UCLA. "That it should have a bearing on who gets an innovative test and who doesn't could lead to more social disparities in cancer care."

Ninez Ponce, the study's lead author and associate director of the UCLA Center for Health Policy Research, believes that education may play a role in who uses the test.

"Patients who are higher in socioeconomic status tend to have higher education levels ... and there is more access and wherewithal to research the tools that are available, and I think that's what is at play there," Ponce said, although she added that the insurance data does not include education levels.

There were other caveats: The study included data from 2006 and 2007—a long time ago in the molecular testing space, according to Ponce. The impact of deductibles and co-payments were not factored into the study. The Oncotype DX test retails for $4,000, according to a Genomic Health spokesperson. She did not immediately respond to a request seeking further comment.

Ponce believes that there are other drivers at work behind the test utilization gap. Many more academic medical centers operate in areas with higher income, and doctors are in fiercer competition for patients. That may prompt more doctors to offer such testing as part of the services they provide.

"Of those women who do have access, this is shedding light on early diffusion of use," Ponce said. "The next question is, among those who have access, is it used in a way where decisionmaking is optimized by the test?" She added that a study addressing that question would be published in the near future.

Takeaway: Socioeconomic issues could create unintended barriers to precision medicine—and potentially impact the laboratory sector.

INDUSTRY BUZZ

Quest, Quintiles Will Create Clinical Trials Joint Venture

Quest Diagnostics and Quintiles have joined forces to create a clinical trials laboratory services arm with a global reach.

The New Jersey-based Quest, the nation's largest national laboratory, and the North Carolina-based Quintiles, one of the world's largest drug development firms, said they would leverage the former's 20 billion test results, and the latter's electronic health records for some 60 million lives and a network of 250,000 clinical investigators. The venture will have some 3,500 physicians, doctorates and biostatisticians on staff, officials said. It will be managed by executives from both Quest and Quintiles.

The decision by Quest to team with Quintiles comes just a few months after its primary rival, LabCorp, moved to acquire pharmaceutical firm Covance in a deal worth nearly $6 billion. That transaction is expected to push LabCorp in front of Quest in terms of total annual revenue.

"We view this arrangement as a capital-efficient means of duplicating some of the strategic merits behind the LabCorp/Covance combination, although clearly a joint venture structure is less direct than an outright acquisition," said Ross Muken and Michael Cherny, analysts with EverCore ISI, in a recent report. "So both companies must ensure that goals are fully aligned in order to achieve maximum results."

Quintiles will own 60 percent of the joint venture, with Quest owning the remaining 40 percent. The joint venture deal is expected to be closed by the third quarter of this year.

Although the financial details of the joint venture were not disclosed, the companies said the combined revenue from the business would be about $575 million per year—about 5 percent of the companies' overall revenues.

"It will join together the scale, expertise and end-to-end capabilities of the broader Quintiles and Quest Diagnostics organizations with a laser-like focus on providing world-class laboratory services that will help improve customers' probability of success," said Quintiles Chief Executive Officer Tom Pike in a press release.

Takeaway: Quest and Quintiles are trying to expand their capabilities in clinical trials by combining their existing resources. G2

References

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