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DIAGNOSTIC TESTING & Emerging Technologies

New Trends, Applications, and IVD Industry Analysis

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INSIDE THIS ISSUE

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Signs Point to Expansion of Provider-Initiated Personal Genomic Testing

Since 2013 when the U.S. Food and Drug Administration (FDA) effectively stopped direct-to-consumer personal genomic testing, there has been pent up demand among healthy individuals for testing options to learn about their DNA. Many believe this health-related genetic information has the potential to inform the long-term health care planning of healthy individuals.

In early April the FDA granted 23andMe (Mountain View, Calif.) the first authorization to market genetic reports on personal risk for 10 conditions, including late-onset Alzheimer's disease, Parkinson's disease, celiac disease, and hereditary thrombophilia (harmful blood clots).

"This is an important moment for people who want to know their genetic health risks and be more proactive about their health," declared 23andMe CEO and co-founder Anne Wojcicki in a statement. "The FDA has embraced innovation and has empowered individuals by authorizing direct access to this information. It is a significant step forward for 23andMe and for the adoption of personal genetics."

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FDA Reports Progress in Advancing Regulatory Science for Diagnostics

The U.S. Food and Drug Administration (FDA) recently unveiled its FY 2015-2016: Regulatory Science Progress Report. The report, the second of its kind under the Food and Drug Administration Safety and Innovation Act, says the agency has made "significant progress" in advancing the science of medical product development and evaluation, improving clinical evaluation, ensuring the safety and effectiveness of marketed products, and infrastructure/organizational development to advance regulatory science.

"FDA's regulatory responsibility to evaluate medical products drives our research agenda, but the outcomes of this research also directly foster and stimulate new medical product development," writes the agency in the report.

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Signs Point to Expansion of Provider-Initiated Personal Genomic Testing, *from page 1*

While DTC players are encouraged by the FDA's action there has been a marked uptick in activity in personal genomics testing ordered by health professionals, with several companies now having such tests commercially available. Some argue this approach will more effectively integrate healthy genome findings (e.g., disease risk and pharmacogenomic findings) into routine care (e.g., screening strategies and prescribing patterns).

"Interest in using genetic information to make better health decisions is growing among patients and physicians alike. Proactive genetic testing for healthy adults can be done responsibly if it is based on proven research and focuses on actionable, useful results delivered in a clinical context, with physician guidance throughout the process," said Robert Nussbaum, M.D., chief medical officer of Invitae, in a statement. "Genetic information can identify disease risk, impact screening decisions, and may lead to the earlier detection and prevention of disease. Our work with our pilot sites is showing how proactive screening can serve as a useful tool at the primary care level."

Healthy Genome Screening Can Detect Meaningful Variants

At the American College of Medical Genetics and Genomics (ACMG) annual meeting (Phoenix, Arizona; March 22-24) genomic information company Wuxi NextCODE presented findings from a pilot study of 190 customers (104 male) from the first whole-genome sequencing-based wellness program in China. Saliva or blood samples were tested with Illumina HiSeq X systems to achieve greater than 30X coverage in the company's CLIA-certified, CAP-accredited sequencing laboratory. Analysis focused on known pathogenic and expected pathogenic variants in genes recommended by ACMG for secondary finding reporting, carrier status for 402 genes of recessive diseases, and genetic risks for 28 common polygenic diseases. Findings were reported to the individuals through post-test counseling.

Two individuals had known pathogenic or expected pathogenic variants in ACMG secondary finding genes. For carrier status, 71 samples carried at least one pathogenic or likely pathogenic variant yielding an aggregate carrier frequency of 38.9 percent. On average, four common diseases were reported to each individual (defined as relative risks increased 50 percent above the average population).

Developing a Medically Actionable Genetic Screening Panel

Also at ACMG, the genetic testing firm Invitae reported on development of their expanded genetic screening panel for healthy individuals. The company's panel includes more than 120 clinically actionable genes derived from ACMG's 56 reportable genes plus additional genes that facilitate "more comprehensive testing" in specific clinical areas. The panel also includes 24 genes associated with increased risk for a cancer-related phenotype, 38 genes associated with increased risk for a cardiovascular-related phenotype, and six genes associated with increased risk for other medically actionable disorders. From this expanded list only likely pathogenic or known pathogenic variants are reported.

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Sampling of Companies Entering the Personal Genomics Market

WuXi NextCode (Cambridge, Mass. and China) has launched a whole-genome wellness scan for healthy individuals, called HealthCode, in China. The sequencing-based test is delivered in a clinical setting by partner health care institutions and detects rare disease variants and carrier status, as well as common disease risk factors. An online interface provides updated advice on how to stay healthy.

Invitae (San Francisco) recently expanded its menu of tests offered as part of its ongoing proactive genetic testing pilot program. The Invitae Genetic Health Screen tests are intended for use by patients who do not meet diagnostic criteria for genetic testing but who want genetic information to help guide their health decisions. The panel now provides information from 139 medically actionable genes, with available subpanels focused on cardiovascular conditions or cancer. The tests are ordered by a physician and provide diagnostic-grade genetic analysis from board-certified medical geneticists. The program has been available at select clinical pilot test sites for more than a year, but will be expanded in 2017.

HudsonAlpha Institute for Biotechnology (Huntsville, Alabama) is now offering via its Insight Genome clinical whole genome sequencing and pharmacogenomic testing for current and future health care planning. The test is offered through the Institute's Smith Family Clinic for Genomic Medicine. "Insight Genome was developed specifically to tell patients today about their risks for developing specific medical conditions—or passing them onto their children—and to help inform future health care decisions," explained Howard Jacob, Ph.D., HudsonAlpha executive vice president for genomic medicine, in a statement.

"Most of the data generated from whole-exome or whole-genome sequencing is not currently interpretable or applicable in the context of a healthy individual, but a focused gene panel presents an opportunity for these individuals to partner with their health care providers to support evidence-based personalized medical care," writes lead author Eden Haverfield, Ph.D., from Invitae, in the ACMG abstract. "Given the growing interest in and decreasing costs of obtaining this type of health-related genetic information, medically actionable genetic screening represents a notable paradigm shift in clinical genomics as it begins to integrate deeper into routine medical practice, and promotes risk assessment and prevention of serious heritable diseases."

Phone-Based Genetic Counseling Supports Healthy Genome Sequencing

Also at the ACMG meeting, researchers from Illumina (San Diego, Calif.) reported on a pilot project conducted at the San Diego Blood Bank where whole-genome sequencing was offered to a demographically diverse group of 70 blood donors. Certified genetic counselors from InformedDNA conducted post-test telephone genetic counseling sessions with the participating blood donors. Interviews included family and medical history collection, results disclosure, follow-up recommendations, and psychosocial assessment. Counseling metrics were calculated and compared to results from the 2016 National Society of Genetic Counselors Professional Status Survey (NSGC PSS).

The researchers found the average time spent counseling participants was 66 minutes, with 39 percent of counseling sessions taking less time—45 to 60 minutes. Counselors spent an average of 18 minutes preparing for patients and 35 minutes completing a consultation summary. These patient care metrics are comparable to results from the 2016 NSGC PSS.

"This pilot study demonstrates the feasibility of providing consistent genetic counseling services to a diverse healthy cohort with cWGS results," writes presenter Erica Ramos, from Illumina, in the abstract.

Motivation of Healthy Early Adopters

The PeopleSeq Consortium surveyed healthy individuals who underwent personal genome sequencing (PGS) through commercial or research avenues in order to understand their attitudes toward and expectations of PGS. Results were presented at the ACMG annual meeting.

Respondents had purchased PGS through Illumina's Understand Your Genome program, which provides participants with a clinically focused report through an ordering physician, followed by access to their raw genome sequence. This program was introduced at an educational symposium, which explains the fact that most survey respondents were highly educated (doctorate or professional degree).

The top three reasons cited for pursuing PGS were learning about disease risk (23 percent); learning about PGS for professional reasons (15 percent); and curiosity (14 percent). Most individuals reported consulted family members or colleagues, but not medical providers (primary care providers or genetic specialists) before undergoing testing. Additionally, most (62 percent) supported incorporating genomic information into the medical record.

Takeaway: While much public attention has focused on direct-to-consumer personal genome testing, there has been a lot of recent activity in the industry to bring physician-ordered PGS to the commercial market. Experts believe healthy individuals have unmet interest in learning about their disease risk and using a physician-involved model may drive greater integration of sequencing results into routine care.

TV Ads Driving Testosterone Testing

Televised direct-to-consumer advertising (DTCA) is associated with greater testosterone testing, according to a study published March 21 in the *Journal of the American Medical Association*. The advertising is also tied to new initiation of androgen replacement therapy with or without recent serum testosterone tests.

There has been a surge of men seeking testosterone for age-related reductions in testosterone levels without pathological hypogonadism. The U.S. Food and Drug Administration regulates brand-specific prescription testosterone advertisements, but nonbranded condition awareness advertisements ("low T") are not regulated.

The present study used MarketScan Commercial Claims and Encounters databases (Truven Health Analytics) to quantify population-level testosterone testing and initiation within designated market areas (DMA) based upon exposure to total monthly testosterone advertising. The researchers, led by J. Bradley Layton, Ph.D., from University of North Carolina at Chapel Hill, analyzed monthly television ratings data from Nielsen Media Research for televised testosterone advertisements in the largest 75 of 210 U.S. DMAs (2008 through 2013). The study found that DTCA exposure increased over the period, although there was substantial regional variation, ranging from months without any advertising to a mean of 13.6 monthly household exposures in December 2012. Cumulative exposures ranged from 154.9 to 203.5 advertisement exposures per DMA over the study period.

Of the more than 17 million commercially insured men in the 75 DMAs, more than one million men (mean age, 49.6 years) had new serum testosterone tests. In these 75 DMAs, each exposure to a testosterone advertisement was associated with monthly relative increases in rates of new testosterone testing of 0.6 percent or 0.14 new tests per 10,000 men. New initiation increased 0.7 percent, and initiation without a recent baseline test rose 0.8 percent. Initiation of therapy without a recent baseline test decreased slightly but consistently over the study period.

Takeaway: Television-based DTCA is associated with an increase in new testosterone testing and therapy initiation, even in the absence of testing.

INSIDE THE DIAGNOSTICS INDUSTRY

Genome Medical Bridges Genomic Testing, Medical Practice

Lisa Alderson, co-founder and CEO, Genome Medical

Many well-known barriers are slowing the integration of genomic testing into routine clinical practice, including workforce shortages and a lack of knowledge about genomic testing among many community-practicing primary care physicians. Genome Medical thinks it can fill in these current gaps.

Genome Medical is a newly launched medical genomics practice serving both patients and physicians through an online and telemedicine-type model. Founded by some big names in the molecular testing industry, including medical geneticist Robert Green, M.D., director of the Genome2People research program at Brigham and Women's Hospital, Broad Institute, and Harvard Medical School, and Randy Scott, Ph.D., chairman of genetic testing firm Invitae, Genome Medical has ambitious plans for growth this year.

DTET recently spoke to Lisa Alderson, Genome Medical's co-founder and CEO, to learn about the company's business model and its role in driving awareness of genomic testing.

What was the motivation for starting Genome Medical?

I envision a world where genomic information is fully accessible, easily understandable, and integrated into everyday health care. We think there is a critical opportunity to help patients and health care providers use genomic information and genetic services to ultimately improve health, decrease the cost of care, and potentially prevent disease.

The field of genomics is exploding. There are now great tools and technology more abundantly available and yet most clinicians are not knowledgeable about how to use this information for the benefit of patient care. This trend is creating the need for Genome Medical. There is an increasing gap between the technological advancements and medical care. We want to bridge that gap by making genetic experts more accessible and by focusing on actionable genetic insights to improve patient care.

How does the Genome Medical model mitigate workforce shortages?

There are roughly 2,500 geneticists and 4,000 genetic counselors in the entire United States. They are not all clinicians seeing patients, so the number of genetic experts available to patients is even smaller. If you think of this in relation to a population of 330 million and the accelerating pace of genetic testing, it is very clear there is a shortage in the workforce. Genome Medical is really rethinking the service delivery model and trying to increase efficiency through the use of tools and technology. This will enable us to provide high-quality, medically appropriate service, but in a scalable manner. It is about evolving the present care model to enable clinicians to increase high-value patient interactions and remove a lot of the mundane processes by having care coordinators and technological solutions to support clinicians.

INSIDE THE DIAGNOSTICS INDUSTRY

"Our mission is to serve patients directly and to help health care professionals. On the professional side, we want to be a resource to help physicians bring genetics and genomics into their practice setting."

— Lisa Alderson, co-founder and CEO, Genome Medical

In some regions of the country, there are reported wait times of three months or longer to see a geneticist. Additionally, most geneticists are located at leading academic centers in major metropolitan areas. Whether for a patient in a rural area or a patient seeking shorter wait times or convenience, we think the online, telehealth service delivery model can increase availability and efficiency of genetic clinical care, complementing what is already available today.

Community-practicing physicians often report a lack of knowledge about genomics. How does Genome Medical's model help providers?

Our mission is to serve patients directly and to help health care professionals. On the professional side, we want to be a resource to help physicians bring genetics and genomics into their practice setting. We can do that in two ways. First, we are set up as a medical practice and can accept patient referrals. So for physicians who recognize the opportunity genomics provides and want to offer their patients genetic services, they can simply refer patients to us. We would see them, just as any specialist would, and would provide information back to the referring physician related to recommended clinical action for ongoing patient care.

The second pathway is to provide education, training, and support to physicians in order to enable them to become more familiar with genomics. This could be broad support or very limited in cases of high complexity or high acuity. We cue off the interests and needs of the physician. Part of our vision is that if we are working with a physician on a particular patient case, they are increasing their knowledge and as they do that across more and more cases, they eventually feel more comfortable integrating genetics into their practice. We see this as a path to accelerate adoption and appropriate use of genetic services and genetic testing over time.

Patients can also access Genome Medical directly, right?

Yes. For the direct patient approach, we are a navigator for the patient. As an expert navigator, we can help guide patients to determine whether testing is right for them. The answer may not always be to pursue testing. It is really about understanding the patient's likelihood of having a hereditary condition, risks and benefits of testing, and potential actionability of results. Then, if testing is indicated, we guide to the right test for that patient. Currently, we offer patient pay approaches so that patients can have easy access for questions regarding increased risk due to health history, family history, or ethnicity. In the future, we will accept insurance.

With growth of sequencing, there has been some discussion about the appropriateness of re-analysis as genomic knowledge increases. Does Genome Medical have a role to play in recontacting patients?

INSIDE THE DIAGNOSTICS INDUSTRY

As a navigator for patients, we want to ask the right questions at the right time and reveal the right information. It is about putting genomic information into the appropriate clinical context. For someone who has been sequenced, the interpretation of variants of unknown significance may change over time. Tracking, monitoring, and notifying patients about any change in the interpretation is an important part of making information clinically actionable. Part of our role as navigator is to help determine when science has advanced enough for it to make sense to re-examine the results or re-sequence the individual. There won't be a universal approach, but our support can help map a patient's journey.

How do regulatory issues impact your ability to expand?

We are currently in an early access program with services in select states due to regulatory requirements. Regulatory and compliance vary state by state for the corporate practice of medicine. As a physician practice, we are set up, including licensure and ownership by physicians, in the relevant states in which we practice. We are focused on a telehealth approach immediately. Our hope is to aggressively grow to full 50-state coverage.

We have two areas of service. The first is for genetic counseling, where we are further along. We can offer genetic counseling services in more than 40 states today. For physician services, we are in a very limited access program in a handful of states. We expect 50-state coverage by the end of 2017 in both lines of service.

What is your relationship with the laboratories you refer to?

Our responsibility and obligation is to the patient. We try to determine the best path—whether testing is appropriate, and if so, the best test for that patient. We are constantly evaluating the available testing options across multiple labs so that we can select those labs with the highest quality and great service for our patients. As a medical practice, we can order from any lab. We are truly independent, meaning that we are laboratory, technology, and platform agnostic.

Patients are finding laboratories and services online and essentially show up virtually to pursue testing. The lab can only say, 'Talk to your doctor.' But, if patients go to the average primary care physician and say they would like to pursue testing, it puts the physician in an uncomfortable position. They are being asked to act as a specialist in a field where they are not. We see this as an area of acute need. Through Genome Medical, patients can talk to a genetic counselor and can be guided to appropriate testing. This provides patients with easy access and a more rapid response. Particularly in cases with anxiety or concern triggered by an individual's or a family member's recent diagnosis, expert care delivered with speed, efficiency, and convenience are all critical.

Genome Medical By-the-Numbers

- **5-7x:** projected productivity increase of genetics professionals via Genome Medical's tele-genomics platform
- **40+:** number of states in which Genome Medical now offers telehealth genetic counseling
- **50:** number of states in which Genome Medical will offer telehealth genetic services by Q4 2017

Testing Guidelines *at a Glance*

Evidence Lacking to Evaluate Celiac Screening

The U.S. Preventive Services Task Force (USPSTF) found there is not enough evidence to advocate for or against screening asymptomatic adults, adolescents, and children for celiac disease, according to the recommendation, published March 28 in the *Journal of the American Medical Association*. The standard method of diagnosing celiac disease in symptomatic patients (older than 2 years) is the tissue transglutaminase IgA test, followed by intestinal biopsy for histologic confirmation.

The finding includes a lack of evidence for targeted screening of those that are asymptomatic, but at high risk for the disease due to family history or other autoimmune disorders. USPSTF reports inadequate evidence regarding the accuracy, effectiveness, and benefits/harms of screening with regard to morbidity, mortality, or quality of life. USPSTF suggests the need for future studies, particularly in high-risk populations, that randomly assign participants to screening or no screening to evaluate clinical outcomes.

Consensus Diagnosis Recommendations for Congenital Cytomegalovirus Infection

An informal International Congenital Cytomegalovirus Recommendations Group recently published consensus guidelines in *The Lancet Infectious Disease* against universal screening of mothers for primary infection. The group recommended "consideration" of universal neonatal screening for cytomegalovirus to facilitate early detection and intervention to minimize long-term, adverse outcomes. Given that congenital cytomegalovirus is a frequent, but under-recognized, infectious cause of newborn malformation in developed countries, the group made recommendations for testing in limited cases:

- When a pregnant woman develops an illness with influenza-like symptoms (fever, fatigue, and headache) not attributable to another specific infection, or when imaging findings suggest fetal cytomegalovirus infection, serology tests (cytomegalovirus-specific IgG, IgM, and IgG avidity) should be offered.
- In cytomegalovirus-seronegative pregnant women, the diagnostic assessment of primary cytomegalovirus infection should include cytomegalovirus-specific IgG in serum.
- If pre-pregnancy immune status is unknown, the diagnosis of maternal primary cytomegalovirus infection should be based on detection of both cytomegalovirus IgM and cytomegalovirus IgG antibodies of low-to-moderate avidity.
- Fetal cytomegalovirus infection can be made after 20–21 weeks of gestation, and at least 6 weeks from the time of maternal infection, through nucleic acid testing (e.g., real-time polymerase chain reaction [PCR]) of amniotic fluid.
- Diagnosis in neonates should include real-time PCR, preferably of saliva, within the first 3 weeks of life.

Validation of Next-Generation Sequencing–Based Oncology Panels

A joint consensus recommendation of the Association for Molecular Pathology and College of American Pathologists published in the *Journal of Molecular Diagnostics* provides assistance to clinical laboratories with the validation and ongoing monitoring of next-generation sequencing-based testing for detection of somatic variants. The guideline seeks to ensure high quality of sequencing results of targeted gene panels and their diagnostic use in solid tumors and hematological malignancies.

Topics covered in the consensus recommendations include: next-generation sequencing-based test development, optimization, and validation. Specifically, it includes recommendations on panel content selection, utilization of reference materials for evaluation of assay performance, determining of positive percentage agreement and positive predictive value for each variant type, and requirements for minimal depth of coverage and minimum number of samples that should be used to establish test performance characteristics. The recommendations also discuss quality control metrics.

Showing Test Prices May Not Change Ordering Behavior

Publishing testing prices in electronic ordering systems for inpatients may not lead to significant changes in clinician ordering behavior or associated fees, according to a study published April 21 in *JAMA Internal Medicine*. However, small changes were seen in ordering for patients in the intensive care unit and in higher fee tests. The authors say this suggests that more targeted price transparency interventions may have more impact.

"The price transparency intervention in this study was always displayed regardless of the clinical scenario," explain the authors led by Mina Sedrak, M.D., from the City of Hope Cancer Center in Duarte, Calif. "The presence of this information for appropriate tests may have diminished its impact when tests were inappropriate."

The study was conducted as part of the Pragmatic Randomized Introduction of Cost data through the Electronic health record (PRICE) trial. It assessed the effect of displaying Medicare allowable fees for 30 inpatient laboratory tests on clinician ordering behavior over a one-year period at three Philadelphia hospitals, representing 98,529 patients and 142,921 hospital admissions.

The 30 tests in the intervention were selected from a list of 30 high volume and 30 more expensive tests based on 2014 charges. Tests were then grouped by tests that could be ordered individually, as a panel, or as tests with similar alternatives in order to avoid situations where clinicians would have price transparency for only a part of a group. (For example, basic metabolic panels of varying sizes, as well as the individual tests they comprised, were grouped together.) Finally, stratified randomization occurred with the top quartile of higher volume tests followed by the top quartile of the more expensive tests followed by the remaining tests. At implementation, clinicians were told this was part of a health system-wide initiative to improve high value care and they were required to acknowledge a 1-time message within the electronic health record system.

The researchers found that there were no significant changes in overall test ordering behavior. In the intervention period, the mean number of tests ordered per patient-day was 2.34 in the control group and 4.01 in the intervention group versus 2.31 and 3.93, respectively in the one-year pre-intervention period. However, a small but significant decrease in test ordering was seen in patients with ICU stays and amongst the top quartile of the most expensive tests.

"Because health care decisions are changing more rapidly in this [ICU] setting, clinicians may be less likely to rely on repeating orders and therefore may have been exposed to the intervention more often," write the authors. "Future efforts might also consider pairing price transparency information with changing the default setting in the EHR so clinicians cannot order repeating laboratory testing for an extended duration."

Takeaway: Overall, studies examining price transparency's effect on test ordering remain inconclusive. This study suggests future efforts examine interventions without standing orders and targeting pricing information to clinical situations where a test may be unnecessary.

FDA Reports Progress in Advancing Regulatory Science for Diagnostics, *from page 1*

Improving Evaluation

The agency reports it has refined predictive models to support product evaluation by developing computational tools that now support nonclinical evaluation of medical products.

Over the past two years, the agency says it enhanced information technology tools that support scientific review of regulatory applications for complex, molecular diagnostics.

Importantly for the diagnostic industry, the FDA says it has carefully designed a pathway to foster biomarker development and adoption. Over this review period, the FDA reports it qualified three new biomarkers for use in clinical trials through the Biomarker Qualification Program.

Advancing Health Promotion

The FDA supported the regulatory public health response to the threats of Ebola virus and Zika virus through development of tools, reference materials, and publication of guidance to support rapid development of new medical products to diagnose, treat, and prevent spread of these diseases.

Infrastructure Development

Over the past two years, the agency says it enhanced information technology tools that support scientific review of regulatory applications for complex, molecular diagnostics. To make possible the secure deposition, retrieval, and analysis of the vast data needed to support next-generation sequencing-based testing, the FDA continued to enhance its high-performance, scientific computing environments.

Additionally, the FDA says it has expanded its ability to evaluate data from mass spectrometry for proteomics and glycomics.

Two other diagnostic-specific mentions in the report include the development of guidelines for reporting results of genetic tests in clinical pharmacology studies, as well as development of methods to analyze data from clinical validation studies for companion diagnostic assays.

Takeaway: Much of the progress the FDA notes in its recent report highlight how advances in diagnostic technology are driving advances regulatory science.

Role of Healthcare AI in the Lab: Today & Tomorrow

By Jason Bhan, MD

Laboratories have traditionally directed their information technology (IT) focus to support their main business of testing. The IT infrastructure they have invested in allows them to address key business issues such as quality, turnaround times, and reimbursement.

Laboratories also excel at logistics, clinical operations, and point-to-point connections on the IT front. This focus on the operational aspects makes sense for laboratories, as many operate on single-digit margins and face pressure to maintain profitability.

Diagnostic data is critical in the early detection of disease, and yet, most decisions made around population health management or patient care are based on medical claims or prescription information.

Despite having significant amounts of data playing a vital role in clinical decision-making, most laboratories (with a few notable exceptions) have neither invested in data strategy nor leveraged their individual data assets. Meanwhile, the rest of the healthcare industry has made great strides in exploring the potential and harnessing the power of big data, advanced analytics, and Artificial Intelligence (AI) to grow business and improve patient outcomes.

Welcoming Healthcare AI in the Lab

Fortunately, the situation has recently begun to change. Several leading laboratories such as Quest Diagnostics and LabCorp now recognize the value of their data and have partnered with AI experts to leverage it and grow their businesses. Other laboratories are taking notice of this aggregated AI data strategy, which can have an immediate impact.

Diagnostic data is critical in the early detection of disease, and yet, most decisions made around population health management or patient care are based on medical claims or prescription information. Both are transactional in nature and both only indicate decisions already made. When combined with advanced analytics and AI, diagnostic information can be used to identify or predict events well before the claim or prescription. This means that laboratories can put their data to work to help various healthcare stakeholders make better treatment decisions, earlier.

Multiple Beneficiaries of Lab Data Insights

Physicians, patients, therapy developers, and health plans all can benefit from diagnostic data insights.

Payers require more clinical specificity to effectively identify and manage patients. The timely and clinically insightful data of laboratory test results can predict patients who need attention. Such early detection enables payers to better design interventions to improve patient outcomes and lower cost of care.

The benefits to patients and healthcare research communities include the ability to better understand disease patterns and positively impact people's lives. By having large clinical datasets that can longitudinally track patients across different laboratories, payers and providers will be able to better understand health outcomes and identify areas for improvement.

Labs Cannot Go It Alone

When it comes to gaining actionable insights from diagnostic data using healthcare AI, laboratories cannot go it alone. Among the approximately 5,000 community hospital, reference, and academic laboratories in the U.S., no single laboratory has the necessary amount of data to provide meaningful insights using AI. Actionable insights are possible only when large amounts of data are available, aggregated from hundreds of laboratories, then analyzed to identify patterns that can be used to predict risk or outcomes.

Healthcare AI companies use techniques such as machine learning and natural language processing, coupled with massive computational power,

on these big data sets to make sense out of reams of non-standard, complex, and heterogeneous data.

Collaborating with other healthcare solution providers eliminates the need for laboratories to invest into building up the informatics infrastructure necessary to capture value from their own data. In order for a laboratory to establish a footprint in the AI space, it would need to invest in hiring expert staff, invest in new technology, and acquire a broader set of data. These are things not within the core capabilities of the typical lab. Laboratories can also benefit financially from sharing their data as well as gain a definitive sense of the markets that they serve and their market share.

What's Next?

While AI is no silver bullet for laboratory industry challenges, it has great potential to highlight the tremendous value of lab testing in the care of patients. Laboratory data is most valuable when it is integrated into larger clinical datasets, which enable AI to work and deliver impactful insights. Healthcare AI will further understanding of clinical patterns, highlight treatment opportunities, and help predict disease earlier.

***Jason Bhan, MD**, is Co-Founder and Chief Medical Officer at Prognos, www.prognos.ai, an innovative healthcare AI company. He is an expert in the applications of technology to healthcare and medicine. Dr. Bhan obtained his medical degree at the University of Miami School of Medicine.*