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New Trends, Applications, and IVD Industry Analysis

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Companion Diagnostics Driving New Model for Pharma-Dx Partnerships

With a growing number of approvals for companion diagnostics, the pharmaceutical industry is taking keen interest in testing uptake and thinking about steps it can take to further drive testing.

A white paper by pharmaceutical advisor Diaceutics (Ireland) shows that a sizable percentage of U.S. oncology patients are missing out on targeted therapies due to a combination of testing "quality gaps" (e.g., turnaround time, test sensitivity, and sample management issues) and slow test diffusion. While this "lag" in testing adoption (driven by lack of physician awareness, reimbursement issues, and lack of inclusion in clinical guidelines) slows therapy demand (a concern for pharmaceutical companies), Diaceutics says it also prevents patients from receiving optimal therapy.

Diaceutics used real-world data from U.S. labs and claims databases to assess the patient and pharmaceutical financial impact resulting from nonideal integration of testing into the therapeutic business model. The assessment included only actual testing issues based on data for 13 oncology biomarkers (HER2, PD-L1, VEF, EGFR, MET, ALK, BRAF, BRCA, RAS, KRAS, IDH2, FLT3, JAK24) and did not include quantification of the number of patients who should or could be tested if there were faster test adoption at the physician and laboratory levels.

Peter Keeling, Diaceutics' CEO, reports that there is a "significant lost targeted treatment opportunity" estimated to be about 6,500

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FDA Approves First Companion Diagnostic Panel

The U.S. Food and Drug Administration (FDA) granted premarket approval to Thermo Fisher Scientific (Carlsbad, Calif.) for a next-generation sequencing (NGS)-based companion diagnostic that simultaneously screens for biomarkers associated with three FDA-approved therapies. The late-June approval marks the first NGS oncology panel approved for multiple therapies, the FDA says.

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oncology patients per month or 78,000 patients per year in the United States alone. These patients did not receive targeted treatment because the test results were incorrect, too late, or inconclusive due to sample issues. The actual number of patients not receiving therapy because of slow test adoption is likely much higher.

"In the real world clinical setting, achieving this synchronization of test and therapy is proving extremely difficult," Keeling says. He adds that testing and therapeutic adoption both will be enhanced when the diagnostics and pharmaceutical industries stop viewing these as two separate, parallel technologies, but rather as a single, integrated solution.

The Economics of Companion Diagnostics

Diaceutics previously estimated that for every dollar invested in diagnostics, the pharmaceutical industry could expect between $30 and $60 back in additional therapy revenue. Combining this estimate, with the recent findings that 30 percent to 50 percent of patients are not receiving targeted therapy due to testing issues and/or slow test uptake, Diaceutics suggests that further investment in test adoption could yield "rapid" returns through an increased share of patients receiving testing and, ultimately, the therapeutic product.

"Most of the top 10 pharma companies have a recognizable center of diagnostic planning and have awoken to the fact that their technology-centric diagnostic partners—whilst supporting their test development and regulatory goals—are ill-equipped to support the all-important clinical diffusion and laboratory adoption goals," Keeling writes in the white paper. "As a result, these therapy teams are having to learn how the diagnostic market can support their assets and fill the gaps in development infrastructure created by an underfunded diagnostic industry."

Keeling explains that pharmaceutical-diagnostic partnerships are typically split into two phases—the development portion, which is usually a fee-for-service payment to the diagnostics company, and a commercial agreement, often developed later in the process along with launch plans. The development payment, which can range from $5 million to $25 million per biomarker, is a "small" investment accounting for approximately six percent of the total spend for commercializing a therapeutic.

"We think this model is flawed since it leaves planning the critical commercial architecture much too late to stay in step with the needs of the therapy launch," Keeling says. He tells *DTET* that Diaceutics argues for "considerably more openness about the commercial bandwidth of diagnostic companies so the total partnership can then focus on what the gaps are and invest in those. Our experience is that our pharma clients are wakening to these commercial limitations and limiting the role of their diagnostic companies to what their known strengths are."

Given that launching diagnostics in tandem with therapeutics is more complex than launching either as a standalone, Keeling sees the evolution of a new type of partnership emerging that eliminates the learning curve for

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each launch and focusses on filling in the gaps associated with these dual launches. He sees companies like Diaceutics playing a future role in aligning testing and treatment commercialization.

Takeaway: Pharmaceutical-diagnostic partnerships are evolving to more fully align testing adoption and treatment commercialization to realize both maximal patient benefit and full return on investment.

Lessons from Ebola Can Enhance Future Diagnostic Preparedness

"Failures" in diagnostic preparedness, including testing capacity, led to delays in identifying the Ebola virus as the culprit of the 2014-2015 epidemic and contributed to the outbreak's spread, according to a viewpoint published online May 31 in *The Lancet*. The authors say that lessons learned from the Ebola outbreak led to the proposed development of a new partnership model that will speed new assay development and ensure their effective deployment in future outbreaks.

Post-episode reports, including those by the World Health Organization and the European Commission, showed that in the Ebola epidemic it took more than three months to identify that an outbreak was spreading in rural Guinea and it took a year for diagnostic capacity to be fully established. This delay in testing capacity was attributed to the complexity and cost of the technology used (The authors note that the fixed biocontainment laboratories using manual real-time polymerase chain reaction and staffed by those molecular experience cost more than $2 million to establish and operationalize) and contributed to the spread of the disease (Gerardo Chowell, from Arizona State University, previously estimated that diagnosing 60 percent of patients with Ebola within one day instead of five days could have dropped the population attack rate from 80 percent to nearly zero).

The Coalition for Epidemic Preparedness Innovations (CEPI), a multisector alliance between industry, academic, philanthropic, and government organizations, plus the World Health Organization and Médecins Sans Frontières, was officially launched in January with the goal of developing new vaccines to fight potential epidemics, including Ebola and Zika. Its next phase, CEPIdx, expands the focus to include diagnostics development through a partnership with the Foundation for Innovative New Diagnostics (FIND). The CEPIdx framework was explained in *The Lancet*.

The proposed framework for diagnostic preparedness and response includes four pillars—outbreak detection, research and development, manufacturing and distribution, and implementation of new diagnostic tools—and provides a unified, comprehensive vision for achieving better diagnostic preparedness and response.

"The diagnostic ecosystem for diagnostics research and development must be enabled by a number of cross-cutting systems, including ethically managed specimen repositories, platforms for data sharing and connectivity, sustained and targeted financing, and pre-agreed regulatory approaches," write the authors, led by Mark Perkins, M.D., from FIND (Switzerland).

Other key elements of the framework include:

- **Outbreak detection:** Pre-agreed logistical arrangements and financing for collection and shipping of samples to reference laboratories.
- **Research and development:** Focusing on pre-outbreak commercial test development using public investment to compensate for the lack of predictable return on investment associated with these tests. Additionally, efforts need to better define sample ownership, sharing of access to samples, and standardized agreements for ethical collection and use of specimens.
- **Implementation:** Addressing testing capacity requires diagnostics training, (including specimen collection, handling, and testing, and results reporting), as well as budgeting for laboratory and equipment maintenance.

Takeaway: Lessons learned from the 2014-2015 Ebola outbreak, including those elucidated in the CEPIdx framework, can improve diagnostic preparedness for potential future infectious disease outbreaks.

FDA Approves First Companion Diagnostic Panel, *from page 1*

The Oncomine Dx Target Test for non-small cell lung cancer (NSCLC) was approved to detect multiple gene mutations (BRAF, ROS1, and EGFR) from a single tissue specimen. The results of the test aid in selecting targeted therapies, including IRESSA (gefitinib) for EGFR L858R and Exon 19 deletions, Tafinlar + Mekinist (dabrafenib in combination with trametinib) for BRAF V600E, or XALKORI (crizotinib) for ROS1 fusion.

Thermo Fisher says that the test kit enables quicker matching for targeted therapies, through a single test rather than sequential testing. The company says the test will be available in the United States beginning in July 2017. LabCorp's Diagnostics and Covance Businesses, NeoGenomics Laboratories, and Cancer Genetics, are the first laboratories offering the test. The test is run on Thermo Fisher's Ion PGM Dx System, which received FDA 510(k) clearance in parallel for use on formalin-fixed, paraffin-embedded (FFPE) tissue samples.

"This first iteration of the test is just the beginning since the diagnostic claims of the Oncomine Dx Target Test may be expanded in the future based on the existing panel," said Joydeep Goswami, Thermo Fisher's president of clinical next-generation sequencing and oncology, in a statement. "Thermo Fisher has entered into discussions with several pharmaceutical companies looking to use the panel for FDA-approved targeted therapy applications beyond lung cancer."

The Oncomine Dx Target Test also currently targets an additional 20 NSCLC-associated gene variants currently being investigated in clinical trials that may be actionable in the future. The company expects that as other drugs are approved, the FDA will expand approvals on the panel.

Takeaway: FDA-approved NGS-based companion diagnostics are entering the commercial market both as kits and as laboratory-developed tests.

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At-Home Testing Options Expanding

There is a proliferation of companies offering at-home testing. In some cases these are mail-in tests where patients collect their own samples (blood, mouth swab, urine, or stool) and mail them into a laboratory for processing. In other cases, though, sample collection and testing is performed at the patients' home with results available in minutes.

These instant tests represent advancements in lateral flow technology (paper strips, much like easy-to-read pregnancy tests), as well as entirely new forms of testing, including portable analyzers intended for at-home use.

At-home testing offers many advantages for the consumer, including convenience, privacy (especially for sensitive tests like for sexually transmitted diseases [STDs]), increased access to care, especially for those without insurance, and reassurance from ongoing monitoring. But, some health care professionals are concerned that at-home testing, especially self-initiated, can result in false results, wasted resources for unneeded or unproven tests, or even worse, adjustments to treatment doses without clinician oversight.

For many analysts, at-home testing is the inevitable evolution of health care reflecting ongoing trends of consumerization of medicine, patient empowerment, and increased price awareness resulting from higher out-of-pocket medical expenditures. (Patient-initiated testing is entirely out-of-pocket, although in some cases health savings accounts can be used to pay for the tests.)

DTET examined some of the more popular at-home offerings currently available, as well as those expected to be commercially available soon. A sampling of at-home tests follows.

At-Home Sample Collection, Mail-In Testing

MyLabBox (Los Angeles, Calif.) offers a nationwide home-based STD testing service. The company says an estimated one-third of Americans may have an STD, but inconvenience, embarrassment, and lack of knowledge may hamper testing efforts. The company offers panels consisting of four, eight, or 14 conditions, including HIV, hepatitis C, herpes, syphilis, chlamydia, gonorrhea, trichomoniasis, mycoplasma genitalium, and human papilloma virus. The panels range from $189 to $399.

myLAbBox has partnered with Target, Walmart and Amazon to sell its "discreet" mail-in kits online. Samples (vaginal swab, urine, or finger prick) are mailed and testing is performed in CLIA-certified labs. The company says turnaround from order to results for all mail-in kits is estimated to be five to 11 days, including one to three days for customers to receive the kit and two to eight days for processing and posting of the results online. An email notification with a link to a secure portal is sent as soon as the results become available. All customers who test positive using the myLAB Box service are entitled to a complimentary

phone consultation with a myLAB Box physician affiliate, although availability of consultation and treatment services varies by the clients' state of residence and symptoms.

Everlywell (Austin, Texas) similarly offers STD panels, but also offers routine laboratory tests (such as cholesterol and HbA1c), as well as more niche offerings, including testosterone, thyroid, and heavy metals testing. The company says it works with a physician network to ensure that each individual's test requisition is authorized by a board-certified physician in the state of residence and that all results are reviewed and released by a physician prior to return to the individual.

The company currently does not offer services in New Jersey, Maryland, New York, or Rhode Island. In all other states kits are ordered online and delivered in two to five days.

Exact Sciences (Madison, Wisconsin) offers Cologuard, the first and only FDA-approved stool DNA, noninvasive screening for colorectal cancer. The test assesses for 11 biomarkers, including seven DNA mutation markers, two DNA methylation markers, one hemoglobin marker, and Beta actin. Unlike the other tests mentioned above, Cologuard is available by prescription only. However, the company can assist individuals find a local doctor offering the test to individuals at routine risk of colorectal cancer. Kits are mailed directly to the individual and test results are returned to the prescribing physician within two weeks of the laboratory receiving a sample. Biomarker analysis provides a single positive or negative reportable result. Cologuard is also more expensive than many at-home tests, listing at $649, although some insurance carriers cover some or all of the cost.

At-home Testing With Instant Results

Pregnancy tests and blood glucose monitoring may be the best known, do-it-yourself tests, but innovation is expanding the potential for routine home monitoring for both wellness and chronic conditions.

In an article published earlier this year Consumer Reports medical advisers listed FDA-approved tests worth trying at home (blood glucose, fecal occult-blood tests, HIV, urinary tract infections, yeast infections) and those to avoid as do-it-yourself tests (allergy, c-reactive protein, prostate cancer, testosterone, thyroid disease, and vitamin D).

Scanadu's (Sunnyvale, Calif.) much hyped in-home consumer diagnostics for consumers have yet to make it to the commercial market. The company says it is awaiting FDA-approval for its urine test kit. The kit enables individuals to check for several health conditions by measuring markers in a urine sample. Scanadu Urine is a disposable paddle that consumers dip in a urine sample. Results can be read and analyzed using the Scanadu app and the camera on a smartphone. Results are displayed in a minute.

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Cor (San Francisco, Calif.) closed their Indiegogo crowdsourcing campaign in May 2016 and is still validating its hardware platform, which translates spectral data into quantitative chemistry insights. The single use Cor Cartridge is pressed anywhere against the user's arm to get a blood sample, using a fine needle that takes a surface-level blood sample, which the company says is completely painless. The cartridge is then placed in the Cor Reader. (Cartridges are available for a $10-per-month subscription.)

The company's patented vibrational spectroscopic technology analyzes the sample, with a report available in the Cor App in minutes. The report indicates overall health trends of key indicators like cholesterol (high-density lipoprotein, low-density lipoprotein, and total cholesterol), fasting blood glucose, inflammation (fibrinogen), and triglycerides. The Cor App gives "actionable insights," including diet and lifestyle recommendations. The company says that since they are only making only general wellness claims, they believe the regulatory timeframe will be "condensed."

Not only does the device save patients inconvenience and aggravation, but it reduces chemotherapy cancellations, saving treatment centers money, too.

Blood Test Before Chemotherapy - Patients undergoing chemotherapy receive a blood test at the treatment center before undergoing treatment. However, it is estimated that one in five are sent home without treatment because of low blood counts. Researchers at Royal Marsden Hospital (United Kingdom) developed Aptus, a handheld blood testing kit to monitor blood counts (hemoglobin and hematocrit) at home from a drop of blood from a finger prick. Results are available in a minute. The miniaturized optical technology is reagentless, meaning the cuvettes have a long shelf life and do not require special storage. A cloud-based communication system enables patient data to be transferred to electronic medical records for review by the clinical team. Not only does the device save patients inconvenience and aggravation, but it reduces chemotherapy cancellations, saving treatment centers money, too. Entia, a UK-based company that is validating and commercializing the technology, says it is likely two years before the device will be commercially available.

Paper-Based Monitoring of Heart Failure - A paper test strip can help doctors and patients with heart failure monitor the condition from home, according to a study published online May 8 in *ACS Nano*. Such monitoring allows for adjustments in treatment and prevention of emergency room visits. The platform is based on fluorescent lateral flow technology, which the authors say is highly sensitive and can provide simultaneous quantitative analysis for two target antigens associated with heart failure (brain natriuretic peptide [BTP] and suppression of tumorigenicity 2 [ST2]). The platform integrates a smartphone-based reader with the multiplexed fluorescent lateral flow strip (LFS). Colored dots glow on the strip if the antigen is present. The researchers report the platform achieved detection of BNP and ST2 antigens in spiked samples

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with detection limits of 5 pg/mL and 1 ng/mL, respectively, both of which are of one order lower than their clinical cutoff. The smartphone-based portable reader and analysis app can enable sharing of results with doctors remotely.

Medical Electronics Systems (Los Angeles) has received much attention for its FDA-approved, YO Home Sperm Test, the first home male fertility test kit powered by a smartphone platform and supported by an interactive app experience. The company also manufacturers commercial-grade semen analyzers. The at-home test allows users to view and measure the number of motile (moving) sperm in their sample, which the company says is a key measure of assessing male fertility.

For $49.95, two YO fertility tests are supplied with each kit. The YO Clip (mini-microscope) is placed over the camera of the smartphone, then a YO slide is prepared and inserted into the YO Clip. The smartphone camera records and YO displays an actual video of your sperm, and the YO app "reads" this video and delivers immediate, easy-to-understand and accurate results.

Takeaway: There are an expanding number of options for consumers to conduct at-home testing. The commercial market is growing for tests mailed in to CLIA-certified laboratories and is expected to see a number of new entrants for instant tests capable of providing results at home, as well.

IgE Testing May Be Underused in Dermatology

Allergists have long used immunoglobulin E quantitative assaying of allergens (IgEQAA) to determine reactivates for allergies associated with a runny nose and asthma. However, the test is not widely used for other dermatologic conditions. Now, new research shows the test may be useful in identifying antigens associated with atopic dermatitis (AD). Test results can help patients avoid sources of some specific environmental allergens and lessen disease severity, according to a study published June 20 in the *International Journal of Dermatology*.

The researchers retrospectively assessed affected AD severity based on body surface area (BSA) at first presentation, IgEQAA classes, and total IgE concentration (Immunocap; Thermo Scientific) for 54 patients (average age of 42.9 years) with AD, seen in a private dermatology practice. The panel included the most common respiratory allergen antigens.

The researchers found that 41 of the 54 patients had an abnormally high total IgE concentration (defined as greater than 150 IU/ml) with an average IgE concentration of 2682.7 IU/ml. Additionally, nine patients (17 percent) had significant improvements in AD symptoms after making lifestyle changes to avoid allergens (such as dog, cat, Bermuda grass, and rabbit) that patients had been in contact with. No patients had repeat IgEQAA levels drawn, as results would not be expected to be significantly different from pre-lifestyle change levels.

"From our data it appears that IgEQAA testing can have a significant impact on treatment outcomes in selected patients with AD," writes senior author Douglas Johnson, M.D., from University of Hawaii. "IgEQAA is easy to perform, compared to skin prick testing, and may be helpful in some patients who are not responding to conservative treatment."

Yet, Johnson tells *DTET*, IgE testing is not routinely ordered as part of AD care.

"I think that ordering the test and sharing the results with the patient and family can play a significant role in some patients," Johnson says. " It saved them from immunosuppressive therapy, biologics, topical treatments and phototherapy."

Yet, Johnson cautions that some aeroallergens, such as dust mites, may be unavoidable.

Takeaway: IgE testing may enhance care for AD by identifying avoidable allergens associated with worsening disease severity.

Lab-Pharmacy Partnerships Expand Retail Lab Testing Trend

Another undeniable sign that commercialization of health care is making meaningful inroads on Main Street with the late June partnership announcement between the laboratory chain Quest Diagnostics (Madison, N.J.) and retail giant Walmart (Bentonville, Ark.), as well as the subsequent announcement between LabCorp (Burlington, N.C.) and Walgreens (Deerfield, Ill.). The co-branded testing sites expand the presence of alternative health care delivery settings with the stated goals of increasing access, improving outcomes, and, potentially, lowering costs.

The collaboration will launch with 15 locations in Walmart stores in Florida and Texas by the end of 2017. Initially, these sites will just provide testing services, but over time are expected to expand to include other basic health care services.

Retail-lab partnerships have been viewed as a potential win-win opportunity for both partners—driving foot traffic in both pharmacy and front-end retail and generating incremental volumes for labs through greater retail real estate exposure for their patient service centers (PSCs), with the added benefit of increasing convenience and access for consumers.

Quest has been adding to its consumer-facing offerings in recent years including through its 100-plus company-branded PSCs at Albertsons companies' grocery stores (Safeway, Vons, Randalls, and Tom Thumb) in California, Colorado, Maryland, Oregon, Texas, Virginia and Washington; patient-initiated testing in Colorado and Missouri (QuestDirect) and Sonora Quest Laboratories in Arizona; and direct-to-consumer genotype testing through AncestryDNA. Walmart, too, has been extending its health care offerings with free health screenings, like blood pressure readings at all U.S. stores, and vaccines in select stores.

The co-branded LabCorp-Walgreens centers will provide specimen collection sites for the LabCorp network. The companies say that seven locations will begin seeing patients in 2017. This summer five patient service centers in Denver and one in Morrisville, N.C. will open. A site in Deerfield, Ill. will open later in the year.

Expansion of laboratory services in the retail environment is a natural extension of pharmacy diversification, says Morgan Stanley analyst Ricky Goldwasser, and she expects such diversification to accelerate with Amazon's "anticipated" entry into the pharmacy space.

Goldwasser's analysis shows that CVS's 1,081 MinuteClinics and Walgreen's 374 in-store clinics offer laboratories a "premier" retail footprint, while sharing overhead expenses could yield incremental savings, if laboratories relocate PSCs from other sites, like medical office buildings. Goldwasser says that in addition to the potential overhead savings, relocation to more consumer-friendly sites can also drive increases in testing volume. She highlighted in a recent research note that an estimated 10 percent to 20 percent of laboratory requisitions go unfilled. Goldwasser's analysis shows that if retail PSCs can capture 10 percent of the unfilled requisitions it would yield a 150 bps pickup in test volumes, or an incremental increase in earnings per share growth of one percent to two percent.

Takeaway: Look for future announcements from large national laboratories about further expansions of retail PSCs, as part of a strengthening trend towards increasing consumerization in alternative health care delivery sites.

Utility of Whole-Genome Sequencing in Primary Care Uncertain

Adding whole-genome sequencing (WGS) to standardized family history assessment of healthy patients in the primary care setting uncovers new molecular findings, although the findings prompt additional clinical investigation and their clinical utility remains uncertain, according to a study published June 26 in the *Annals of Internal Medicine*. Additionally, the study found that the majority of primary care providers (PCPs) are able to manage WGS results appropriately without causing patients undue distress, both of which had been previous concerns about employing WGS technology in nonspecialist settings and among healthy patients.

The researchers retrospectively assessed affected AD severity based on As part of the MedSeq Project at Brigham and Women's Hospital, the researchers conducted a pilot in which 100 generally healthy patients (aged 40 to 65 years and free of cardiovascular disease or diabetes mellitus) were randomly assigned to receive a family history report alone (FH) or in combination with an interpreted WGS report (FH + WGS). The report included a summary of variant interpretation (monogenic disease risk [MDR] associated with Mendelian disorders, carrier variants, pharmacogenomic associations, and polygenic risk estimates for cardiometabolic traits), disease information, and familial risk, but did not include recommendations for clinical management.

Prior to patient enrollment nine PCP participants received an educational intervention (four hours of case-based online modules and two one-hour, in-person group classes, including an orientation to the genome report). During the study, PCPs could contact a genome resource center staffed by medical geneticists and genetic counselors to ask questions about test result interpretation. Patients received their results from their PCP. These sessions were recorded and a panel of clinician-geneticists rated the appropriateness of PCP management of MDR results. Additionally, downstream outcomes (health care utilization, cost, and outcomes) were assessed for 6 months following return of results.

The researchers found that 11 of 50 FH + WGS patients had new MDR results. However, only two had phenotypic evidence by the MDR result (one ophthalmic condition and one dermatologic condition). Two of the 12 MDR variants were in medically actionable genes (KCNQ1 and TNNT2), as defined by the American College of Medical Genetics and Genomics, but were classified as likely pathogenic and as a variant of uncertain significance favoring pathogenic in the report. Six variants in five patients prompted additional clinical evaluation, including electrocardiograms, referrals to specialists, or a laboratory test. The external panel of geneticists judged that eight of the 11 cases had been managed appropriately and two cases inappropriately (one due to underevaluation of a pathogenic variant and one because of miscommunication about inheritance).

Overall, 96 percent of patients received a pharmacogenomic result indicating atypical or nonstandard response to at least one medication and six of these patients were receiving at least one of these medications at baseline. However, no prescription change or adverse effect was seen during the 6-month observation period.

It should be noted that even in these established PCP–patient dyads, discussion of FH alone prompted additional actions, such as a specialist referral and laboratory testing.

Total costs for the immediately attributable recommended actions averaged $41 in the FH group and $68 in the FH + WGS group. Six-month costs averaged $1,142 in the FH group and $1,490 in the FH + WGS group, overall and $2,526 for 11 patients with new MDR results. No patients with a new molecular diagnoses showed clearly improved short-term health outcomes or harm from WGS.

"The results of this pilot study do not support the use of WGS in primary care but suggest that, if a healthy adult has WGS, some of the resulting increased health care use may be clinically appropriate, write the authors, led by Jason Vassy, M.D. "Furthermore, they challenge the common notion that PCPs are unprepared to make appropriate medical decisions about complex sequencing results."

Takeaway: The clinical utility of incorporating WGS results into routine primary care remains uncertain, although this study shows that with a little preparation, PCPs are able to appropriately manage clinical sequencing data.

HIV Testing Remains Low in Young Adults

The United States is falling behind national goals to identify patients unaware of their positive HIV status and link them to care. New analysis from the U.S. Centers for Disease Control and Prevention (CDC) shows that testing among sexually active teens and young adults remains low and the CDC suggests a multipronged strategy to increase testing.

The June 23 report in MMWR includes analysis of CDC-funded program data for youths submitted by 61 health departments (state and local) and 123 community-based organizations providing HIV testing and related services in 2015.

"Increasing the number of youths at risk for HIV infection who are tested for HIV on a regular basis and ensuring that youths who receive positive test results for HIV are rapidly linked to and retained in appropriate medical care, including early initiation of antiretroviral therapy, are essential steps for reducing HIV infection in this vulnerable population," writes Renee Stein, Ph.D., from the CDC's Division of HIV/AIDS Prevention in Morbidity and Mortality Weekly Report (MMWR). "Including HIV testing as part of routine medical care for youths is key to increasing early diagnosis, and a health care provider's testing recommendation is the most important predictor of testing among adolescents at risk for HIV infection."

In 2015 more than 3 million CDC-funded tests were run with 28 percent provided to youths—primarily those aged 20–24 years (74 percent), female (55 percent), and black (50 percent). More than three-quarter of tests were provided in health care facilities and in medium and high prevalence areas

(97 percent). Tests in health care facilities were less likely to yield new diagnoses than tests performed in non-health care facilities.

An average of 22 percent of high school students who had sexual intercourse and 33 percent of young adults (persons aged 18 to 24 years) reported ever receiving an HIV test. Among the nearly 4,900 HIV infections identified among youths, 39 percent had been previously diagnosed, but 92 percent of these youths with previously diagnosed infection were not in HIV medical care at the time of testing. Young men who have sex with men accounted for 83 percent of new diagnoses among all youths in non–health care facilities and received 28 percent of HIV tests in those settings.

Increasing HIV testing and regular retesting among youths at risk for HIV is of "high importance." The CDC suggests this could be accomplished through a combined strategy of routine HIV testing among youths, especially young men, in health care settings, and targeted testing in settings where youths at risk for HIV infection congregate. Additionally, the CDC calls for measures to encourage health care providers to include HIV testing as a routine part of health care for youth and suggests schools can also play an important role in facilitating access to HIV testing.

Takeaway: Strategies are needed to increase HIV testing among young adults, including measures to make HIV testing routine in the health care setting and expand nontraditional settings where at-risk youth may congregate.