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Diagnostics Sector Saw Increased Investment, Exits in 2018

Life science and health care companies had a banner year in 2018, with a record-breaking year for venture capital investment, according to Silicon Valley Bank's Trends in Healthcare Investments and Exits annual 2019 report. While the largest gains were in biopharma, the diagnostics and tools sector (Dx/Tools) had a strong year with slight growth in investments, but a "rebound" in exits.

Overall, U.S. health care venture fundraising reached a record $9.6 billion, continuing a four-year upward trend. The Dx/Tools sector saw a modest increase in the U.S. fundraising, up from $4.3 billion in

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Newborn Sequencing Delivers Some Unanticipated Findings

Newborn genomic sequencing (NGS) can identify risk for a wide range of disorders that otherwise may not be detected, even in seemingly healthy babies, according to a study published Jan. 3 in the American Journal of Human Genetics. Additionally, this early knowledge can lead to surveillance, interventions, or avoidance of some medications that can improve health outcomes for newborns and their families.

"We were stunned by the number of babies with unanticipated genetic findings that could lead to disease prevention in the future," said **Robert Green**, M.D., co-director of the BabySeq Project study, in a statement.

BabySeq Project is a pilot randomized clinical trial that explores the medical, behavioral, and economic impacts of NGS. NGS has the potential to expand screening and clinical management, reduce the diagnostic odyssey for ill newborns, and provide information to guide future reproductive planning. Long-term, NGS can provide pharmacogenomic information that could be beneficial throughout the patient's lifespan and can provide a genetic dataset available for reanalysis, as indications arise. However, variant interpretation and

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2017 to $4.8 billion in 2018 spread over 211 deals.

Silicon Valley Bank (SVB) breaks down the Dx/Tools sector into three categories.

Device and Dx/tools sectors are expected to remain stable in 2019.

- Research and development tools companies saw total 2018 investment of $2.4 billion in 95 deals
- Diagnostic test companies (yes/no diagnostic tests) had $1.28 billion of investment in 64 deals
- Diagnostic tools and analytics (actionable data analytics) raised $1.11 billion in 51 deals

Despite modest growth in fundraising overall, the Dx/Tools sector attracted fewer series A deals (down from 70 in 2017 to 64 in 2018) and dollars (down from $845 million to $621 million). (Series A investments includes all first-round investments from institutional or corporate venture investment of $2 million or more.) Yet, the median series A round size remained stable at $6 million. Some of the biggest series A raises in the Dx/Tools sector in 2018 (over $20 million) included Glympse Bio (Cambridge, Mass.), Paige.AI (New York), Shine (Janesville, Wis.), Celsius Therapeutics (Cambridge, Mass.), ArcherDx (Boulder, Co.), Now Diagnostics (Springdale, Ark.), Mammoth Biosciences, and Alveo Technologies (Alameda, Calif.).

"Following multiple large Series A investments over the past two years, it is not surprising to see a slowdown in early-stage investment as investors wait for things to play out," write the report authors led by **Jonathan Norris**, managing director of the Life Science and Healthcare Practice at SVB. "As a result, most investments (85 percent) went to later-stage companies."

Over all Dx/Tools investments, there were 25 raises valued at over $50 million. Combined, these deals made up the majority of sector's financing. There were eight rounds over $100 million in 2018. These companies included: Tempus (Chicago, Ill.), Helix (San Carlos, Calif.), HeartFlow (Redwood City, Calif.), Synthego (Redwood City, Calif.), Twist Bioscience (San Francisco), Grail (Menlo Park, Calif.), 10x Genomics (Pleasanton, Calif.), and Zymergen (Emeryville, Calif.).

Six private Dx/Tools companies were valued at more than $1billion in the last two years—the largest number of any sector, SVB says, even exceeding biopharma unicorns. Companies included Grail, Tempus, 23andMe (Mountain View, Calif.), Human Longevity (San Diego, Calif.), 10x Genomics, and Ginkgo Bioworks (Boston).

After just one initial public offering (IPO) in 2017 and no mergers and acquisitions (M&A), Dx/Tools came back strong with 10 acquisitions and two successful IPOs in 2018. The sector's deal value set a six-year high, led by $1.9 billion in upfront M&A payments, which still substantially trailed other sectors, like biopharma. M&A was divided between diagnostic test companies (four deals) and research and development tools companies (six

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Study Showing PGx Testing Improves Depression Outcomes, Key to Myriad's Reimbursement Strategy

Pharmacogenomic testing (PGx) provides clinically meaningful improvement in response and remission rates for difficult-to-treat depression patients over standard of care, according to a study published Jan. 4 in Journal of Psychiatric Research. Although the study did not find significant improvement in symptoms, leadership at Myriad Genetics (Salt Lake City) are optimistic about the findings from the large randomized controlled trial and about reimbursement prospects.

Current antidepressant prescribing practices for major depressive disorder (MDD) are described as trial and error and previous studies have shown that more than half of patients with moderate-to-severe MDD do not respond adequately to their first medication, which foretells worsened long-term prognosis. Many in the field of psychiatry have been hopeful that PGx can better inform prescribing practices.

The first generation of PGx tests focused on single gene analysis. Even PGx panels interrogate single gene-drug interactions for each evaluated gene. Assurex Health, (Mason, Ohio; acquired by Myriad in 2016) developed the multigene PGx test GeneSight that evaluates 59 alleles and variants across eight genes using an algorithm. Genotypes for all measured variants are weighted and combined in order to categorize 38 psychotropic medications based on three levels of gene-drug interaction: "use as directed'" (no detected gene-drug interactions), "use with caution" (moderate interactions; medications may be effective with changes in dose), or "use with increased caution and with more frequent monitoring" (severe gene-drug interactions may significantly impact drug safety and/or efficacy).

In the Genomics Used to Improve DEpression Decisions (GUIDED) trial, 1,167 outpatients diagnosed with MDD and with an inadequate response to at least one antidepressant were randomized to treatment as usual (TAU) or a PGx-guided intervention arm (guided-care). Participants (70.6 percent female; mean age 47.5 years) were enrolled from 60 academic and community sites, assessed at weeks 0 (baseline), 4, 8, 12, and 24. Only 913 of the 1,167 completed the full 24 weeks.

> *"The overall impact of PGx testing in this trial may have been diluted by the large proportion of patients already taking genetically congruent medications"*
>
> — John Greden .

The researchers report that at enrollment, patients had failed a mean of 3.5 medications. Overall, at week 8, symptom improvement for guided-care was not significantly different than TAU (27.2 percent versus 24.4 percent). However, improvements in response and remission were statistically significant.

Prior to PGx-guided treatment change, at baseline, 79.4 percent of patients in the guided-care arm and 77.5 percent of patients in TAU were prescribed medications that were congruent with the PGx test report. The proportion of patients prescribed congruent medications at week 8 increased to 91.2 percent in the guided-care group

Study Showing PGx Testing Improves Depression Outcomes, *from page 3*

and remained relatively unchanged in TAU. Importantly, though, looking only at the subset of patients taking incongruent medications at baseline who switched to congruent medications by week 8, there were significant improvements in all three measures—symptoms, response, and remission—compared to those remaining on incongruent medications.

"The overall impact of PGx testing in this trial may have been diluted by the large proportion of patients already taking genetically congruent medications," write the authors led by **John Greden**, from University of Michigan in Ann Arbor. Further, when "the subset of patients taking incongruent medications at baseline were evaluated, side effect burden was significantly reduced when patients switched to congruent medications."

Several authors report financial ties to Assurex and/or the pharmaceutical industry.

The Future of PGx Testing

In April 2018, the American Psychiatric Association said the evidence was "insufficient" to support widespread clinical use of PGx panels for personalizing antidepressant treatment. While failure to include such testing in clinical guidelines is a headwind, both Myriad leadership and Wall Street analysts are optimistic that publication of the GUIDED trial's results will meaningfully impact reimbursement prospects for the company.

> *"Fully reimbursed at our targeted average selling price, this GeneSight volume would represent greater than $600 million in revenue"*
>
> — Mark Capone .

Myriad CEO **Mark Capone** said on the company's Nov. 6, 2018 earnings call, "We are positioned to materially advance reimbursement for GeneSight." More recently, at the January J.P. Morgan Healthcare Conference (Jan. 7-10; San Francisco) Capone said that the test is the firm's "most important" for future growth.

On the earnings call, Capone said that for quarter 1 2019 GeneSight had 28 percent year-over-year volume growth, with 15,500 total ordering physicians and 2,500 new ordering physicians. "Fully reimbursed at our targeted average selling price, this GeneSight volume would represent greater than $600 million in revenue," Capone said.

The company is pursing additional GeneSight commercial coverage and expanded Medicare local coverage determinations to drive a "significant inflection in revenue." Following positive reimbursement decisions, the company plans to launch into the primary care market along with a campaign to raise awareness directly among patients with depression.

Takeaway: Myriad is optimistic that recent published results show that PGx can improve patient outcomes, while saving payers money. The company believes this evidence will be paramount in achieving improved reimbursement.

SPECIAL FOCUS

PGx Saves Payers Money

The use of PGx to guide medication treatment for psychiatric disorders can yield "material savings" for large commercial payers, according to a study published in September 2018 in Personalized Medicine.

The researchers used claims from a large payer database compiled by OptumInsight to evaluate payer costs associated with treating patients with psychiatric disorders (depression, anxiety, bipolar disorder, panic disorder, post traumatic stress disorder, obsessive compulsive disorder, and schizophrenia). Cost data were compared for patient care (inpatient, hospital-based outpatient, physician, and pharmacy) for 2,015 using the GeneSight test versus 478 patients with treatment-as-usual (TAU) over the 12-month period following PGx.

The analysis showed that, overall, the average total costs savings were $5,505 in the PGx group versus TAU ($17,627 versus $23,132). In subgroup analysis of patients with depression the costs savings were even larger, reaching $6,050 in the first year after testing ($18,741 versus $24,791).

"Since the test cost is a one-time investment, average savings are expected to increase as the duration is extended over the life cycle of psychiatric treatment," write the authors led by **Joachim Benitez**, from Weill Cornell Medical College in New York.

Sequencing Shows Promise in Care of Common Kidney Disease

Exome sequencing can yield a genetic diagnosis in almost 10 percent of patients with chronic kidney disease (CKD), according to a study published Jan. 10 in the New England Journal of Medicine. This yield, the authors say, is similar to what is seen for other conditions for which genomic diagnostics are used and establishes CKD as the most common adult disease, aside from cancer, for which sequencing has clinical utility.

"Our study shows that genetic testing can be used to personalize the diagnosis and management of kidney disease, and that nephrologists should consider incorporating it into the diagnostic workup for these patients," says coauthor **Ali Gharavi**, M.D., from Columbia University in New York.

Despite how common it is, the underlying mechanism of CKD remains poorly understood. Estimates show that more than 10 percent of adult cases of newly diagnosed end-stage renal disease may have an unknown diagnosis. This "diagnostic ambiguity" can negatively impact clinical management, the authors say.

The researchers conducted exome sequencing and diagnostic analysis in two cohorts totaling 3,315 patients with CKD (91.6 percent were over 21 years of

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age and 35.6 percent were self-identified as of non-European ancestry). The sequencing examined a manually curated list of 625 nephropathy-associated genes plus variants in other Mendelian disease–associated genes on Illumina platforms using in-house pipeline. In the cohort from the Columbia University Medical Center Genetic Studies of Chronic Kidney Disease biobank, 59 medically actionable genes recommended by the American College of Medical Genetics and Genomics (ACMG) were also assessed.

Overall, nephropathy of unknown origin was seen in 8.5 percent of the patient population. The researchers identified diagnostic variants across all clinically defined categories, including congenital or cystic renal disease (127 of 531 patients) and nephropathy of unknown origin (48 of 281 patients). Additionally, 1.6 percent of the Columbia cohort had genetic findings for ACMG medically actionable disorders that, although unrelated to their nephropathy, the authors say the secondary findings had implications for nephrologic care in all cases.

"Our study shows that genetic testing can be used to personalize the diagnosis and management of kidney disease, and that nephrologists should consider incorporating it into the diagnostic workup for these patients"

— Ali Gharavi .

More than one-fourth (28.3 percent) of the Columbia cohort had a family history of kidney disease. Diagnostic variants were found in 94 of these 619 patients (15.2 percent of patient with a family history of kidney disease versus findings in 4.8 percent without a family history).

Further, the researchers say that among the patients with a genetic diagnosis, it gave new clinical insights in nearly three-fourths of the cases, including estimation of the risk of nephropathy progression, guidance for family counseling, and donor selection for transplantation. The genetic information could inform therapy for half of patients receiving a genetic diagnosis (e.g., tailored therapies, clinical trial recommendation, or immunosuppression decision making). For just over one-third of patients, the genetic findings reclassified disease or provided a cause for undiagnosed nephropathy, emphasizing "the usefulness of the 'agnostic' approach" of exome sequencing, the authors say.

"We noted diagnostic variants in 48 of the 281 patients (17.1 percent) with nephropathy of unknown origin, a population that may comprise up to 15 percent of patients with newly diagnosed end-stage renal disease and for whom traditional diagnostic methods are often unrevealing or contraindicated," write the authors.

Takeaway: Sequencing shows promise for informing diagnosis and clinical management of CKD, particularly in patients with a family disease history and patients with unknown nephropathy.

Payer Medical Policies Can Promote Effective Use of Comprehensive Sequencing In Community Oncology Setting

Comprehensive genomic profiling (CGP) identifies clinically relevant genomic alterations that can be used to inform treatment decisions in community-based oncology practices that benefit both patients and payers, according to a study published in the *Journal of Managed Care & Specialty Pharmacy*. The authors say this real-world evidence supports covering CGP and integrating it into clinical practice.

"Given the recently released Centers for Medicare & Medicaid Services National Coverage Decision for next-generation sequencing in patients with advanced cancer (which includes coverage for tests used in this observational analysis…), this observational analysis provides timely evidence of the utility of CGP in a real-world setting," write the authors led by **Mitchell Reitsma**, from Priority Health in Grand Rapids, Mich. "The results presented here may provide insight into the clinical utility of broad CGP coverage for a commercial payer whose policy is in alignment with Medicare coverage of CGP in patients with advanced cancer."

CGP uses next-generation sequencing to detect genomic alterations, plus microsatellite instabilities and tumor mutational burden in order to guide treatment with targeted therapies. Despite emerging data demonstrating improved outcomes with targeted therapies, payers have been reluctant to cover CGP due to concerns about off-label drug use, test cost, and lack of professional guidelines including testing. Thus, many of these broad panel tests have been designated as experimental/investigational or medically unnecessary. Tissue insufficiency commonly precludes conventional gene-by-gene testing. Additionally, participation in clinical trials remains low outside of academic medical settings where CGP testing capabilities may be limited.

The researchers evaluated medical records of 96 patients undergoing testing with CGP assays (FoundationOne or FoundationOne Heme; Foundation Medicine, Cambridge, Mass.) at Cancer and Hematology Centers of West Michigan, a community oncology practice, after Priority Health, a regional health plan, implemented a medical policy that enabled coverage of CGP for patients with advanced solid or hematologic cancers (November 2013 to January 2017) meeting seven indications. The researchers examined all previous and current molecular test results, matched therapy or clinical trial enrollment, and clinical outcomes (clinical benefit or disease progression), as well as potential cost diversion for patients who enrolled in clinical trials. (Two local programs enabled enrollment in clinical trials.)

The majority of patients (89.6 percent) had clinically relevant genomic alterations.

Testing occurred before completion of first-line therapy in 51 of 96 patients, while 34 patients had CGP testing following either first- or second-line treatment, and 11 patients had CGP testing following three or more lines of treatment.

Payer Medical Policies Can Promote Effective Use of Comprehensive Sequencing In Community Oncology Setting, *from page 7*

Of the 70 patients who were treated following receipt of CGP results, 15 received targeted therapy or immunotherapy and six patients enrolled in clinical trials based on CGP results. In total, roughly one-third of patients (21 of 64) with actionable genomic alterations and who continued treatment following CGP testing, had treatment informed by CGP. Among patients treated with CGP-matched targeted therapy or immunotherapy, 10 patients experienced clinical benefit, while five experienced disease progression.

Thirty-two patients previously underwent conventional testing (BRAF, EGFR, ERBB2, and KRAS), but for most (84 percent), CGP detected clinically relevant genomic alterations that conventional testing did not identify. A portion of these patients subsequently received treatment based on the CGP results.

Eighty of the 96 patients met the requirements stated in the health plan CGP medical policy. In the cost diversion analysis, 20 patients enrolled in phase 1 clinical trials, with an estimated $25,000 per-patient cost-benefit accrued to the payer (or $500,000 annually).

"The high proportion of tested patients who met the health plan's medical policy clinical and disease requirements also suggests that CGP will be used in accordance with commercial payer medical policies if covered," the authors write.

Authors include employees of the health plan and Foundation Medicine.

Takeaway: This study, based on real-world data, indicates that CGP testing offers clinical benefits to patients and cost benefits for payers.

Newborn Sequencing Delivers Some Unanticipated Findings, *from page 1*

appropriate reporting of findings remain challenges.

The researchers report on findings from NGS in 159 newborns (127 healthy newborns in well nurseries and 32 ill newborns in an intensive care unit [NICU]). Babies in the NICU were not preselected on the basis of having a suspected genetic disorder. Half of the newborns in each cohort were randomized to receive standard care, including state-mandated newborn screening and genetic counseling based on their family histories. The others received NGS in addition to standard care.

Only pathogenic and likely pathogenic variants were returned. Results fell into four groups: monogenic disease risk that is highly penetrant and present or manageable during childhood; carrier status for any gene meeting the monogenic disease risk reporting criteria; pharmacogenomic genes associated with drugs that might be used in the pediatric population; and actionable, adult-onset disease-associated gene. These included five of 59 American College of Medical Genetics and Genomics (ACMG) actionable genes (BRCA1,

BRCA2, MLH1, MSH2, and MSH6. The other 53 ACMG genes were already being returned on the basis of being childhood-onset or childhood-actionable conditions.

Some patients underwent indication-based analysis (IBA). For these analyses, all variants with evidence of a possible contribution to the infant's indication, including variants of uncertain significance were returned. Sanger sequencing was used to confirm all reported variants.

The researchers report that NGS identified a risk of childhood-onset disease in 9.4 percent newborns (n = 15), but none of the disease risks were anticipated based on the infants' clinical or family history. Of these identified newborns, 10 were healthy.

Eleven newborns had variants expected to have moderate penetrance or variable expressivity based on the literature, but the variants were considered as medically actionable during childhood (e.g., cardiomyopathies for which surveillance with regular echocardiograms and electrocardiograph could significantly reduce the risk for sudden cardiac death). NGS identified risk for newborn screening-targeted conditions (e.g., hearing loss, biotinidase deficiency) in three newborns that passed newborn screening.

NGS also identified actionable adult-onset disease risk in three of 85 newborns whose parents consented to receive this information (e.g., pathogenic variants conferring risk for hereditary breast and ovarian cancer and Lynch syndrome). Further, these variants were also identified in the mothers of the three children.

"Our findings suggest that thoroughly sequencing newborns reveals potentially life-saving information in both infants and their parents far more commonly than was previously thought and should encourage our entire field to re-evaluate the value of comprehensively analyzing and disclosing genomic information at any age," said Green in a statement.

Carrier status for recessive childhood-onset disorder was reported in 88 percent of infants and pharmacogenomics variants were in 5 percent. While variants for carrier status were frequently identified, nearly three-quarters of variants were identified only once in throughout the cohort.

IBA were performed in 29 of 32 NICU newborns and six of 127 healthy newborns who later had presentations prompting analysis. However, analysis did not reveal any variants that sufficiently explained the indication, although however, suspicious but uncertain results were reported in five newborns.

Testing parental samples contributed to the interpretation and reporting of results in eight percent of newborns overall, including both variants of disease risk and carrier status variants for which adult carriers could present symptoms.

Takeaway: NGS can identify risk for many conditions that would otherwise not be detected through family history or usual care. However, many reporting issues still need to be further researched, including age of onset and penetrance, as well as downstream costs for the system and psychosocial impacts for families.

Point-of-Care PCR Tests Better Diagnosis, Rx for Kids' Sore Throats

Given we are still in the midst of cold and flu season, a new study highlights the benefit of point-of-care (POC) polymerase chain reaction (PCR) testing among pediatric patients presenting to the doctor's office with sore throats. Under real-world conditions, rapid antigen detection tests (RADTs) and culture were less accurate than in the published literature and led to increased rates of inappropriate antibiotic use, compared to POC PCR, according to a study published Jan. 16 in *BMC Pediatrics*.

Current clinical guidelines encourage the use of antibiotics only for confirmed cases of group A Streptococcus (GAS), however some studies suggest that antibiotics may be prescribed in as many as 60 percent of patient visits for sore throat. The growing threat of antibiotic resistance is leading to increasing urgency to find rapid, onsite diagnosis of the pathogenic source of respiratory-related infections.

While RADTs offer the benefit of efficiency, the overall sensitivity of the test is low. When combined with culture, the results are highly accurate, but the two-step testing strategy is time and labor intensive, delaying results by up to three days. More recently approved POC PCR tests have reported sensitivity closer to that of cultures, but with the added benefit of more rapid turnaround times.

The researchers compared the sensitivity and specificity of the recommended two-step RADT plus confirmatory culture testing strategy versus the Roche cobas Liat Strep A POC PCR test for detection of GAS in 255 pediatric patients (aged 3 to 18 years) with pharyngitis. Throat swab specimens were obtained from patients seen in a large, pediatric, outpatient clinic in the fall/winter of 2016-2017. The RADT or POC PCR result was provided to clinicians on alternating weeks to compare the impact on antibiotic use.

The researchers found that 43.1 percent of samples were positive for GAS. Sensitivity for POC PCR was 95.5 percent versus 85.5 percent for RADT and71.8 percent for culture. Specificities were 99.3 percent, 93.7 percent, and 100 percent, respectively. Culture results took a median of two days. POC PCR results took five to 10 minutes longer RADT. Compared with RADT plus culture, POC PCR resulted in significantly greater appropriate antibiotic use (97.1 percent versus 87.5 percent).

"POC PCR can provide highly accurate results for patients at the time of the office visit, eliminating the need for follow-up confirmatory testing of negative results and for empiric treatment," write the authors led by **Arundhati Rao**, from the Scott and White Medical Center–Temple in Texas. "Providers in this busy pediatric clinic believed that the increased wait time and decreased room availability were offset by more appropriate antibiotic use, the potential for fewer missed days of school/work for patients and their parents, and less staff and provider time and resources while awaiting confirmatory culture results."

Takeaway: POC PCR testing appears to speed accurate diagnosis of Strep A-related sore throats in kids and drive more appropriate antibiotic use.

Diagnostics Sector Saw Increased Investment, Exits in 2018, *from page 1*

deals). Three of the four diagnostic companies were commercial. Of the companies with exists, the median years to exit was 9.1 years, the highest reported in the past six years.

"Nine of 10 deals were at a commercial stage and acquired by traditional lab instrument, research and diagnostic companies," writes Norris. "We are surprised to see no new acquirers, especially tech players, emerge."

In 2018, both Guardant Health (Redwood City, Calif.) and Twist biosciences had successful IPOs.

> *"Nine of 10 deals were at a commercial stage and acquired by traditional lab instrument, research and diagnostic companies. We are surprised to see no new acquirers, especially tech players, emerge"*
>
> — Jonathan Norris.

Geographically, California still dominates in the Dx/Tools space with 65 deals valued at $2.09 billion in Northern California and 17 deals valued at $362 million in Southern California. Massachusetts had 31 deals in 2018 valued at $579 million. Other deals occurred in New York (11 deals valued at $148 million) and Pennsylvania (7 deals valued at $36 million).

So what is in store for the coming year? Norris and colleagues predict investment will continue at a "healthy pace" overall in the life science and health care space. For the Dx/Tools sector, SVB predicts

- Series A deals will "likely climb" in 2019, although overall investment dollars could shrink following multiple larger 2017 and 2018 financings
- Tech acquirers will likely scoop up a few diagnostic test, tools, and analytics companies, which could drive an uptick in M&A deal value.
- There could be two to four IPOs among revenue-generating, R&D tools companies

Takeaway: The diagnostics sector, like the broader life sciences and health care sector, had a strong 2018, with upticks in investment and a rebound in exits.

PreOp Point-of-Care HbA1c Screening May Cut Complications

Point-of-care (POC) HbA1c measurements show a high level of agreement with central laboratory test in the outpatient setting, according to a small study published Jan. 18 in the Journal of Clinical Monitoring and Computing. Implementing broad preoperative screening may improve risk profiling in overweight and obese patients, who are prone to surgical cardiometabolic complications.

The authors say nondiabetic patients who are overweight are not routinely screened for metabolic abnormalities during their visit to the preoperative outpatient clinic. Yet, prior research has shown that impaired glucose tolerance or undiagnosed diabetes preoperatively is relatively common in patients undergoing surgery and may be associated with postoperative complications. POC HbA1c screening may enable implementation of broader preoperative screening, given that fasting is not necessary.

The researchers evaluated the level of agreement between a POC HbA1c test (Siemens DCA Vantage HbA1c analyzer) and laboratory values in nondiabetic patients visiting the outpatient clinic for preoperative risk profiling (between November 2013 and February 2014) before elective surgery. POC HbA1c levels were measured in whole blood samples using a finger prick, as well as a venipuncture sample collected in the central laboratory on the same day.

"We consider the use of the point-of-care HbA1c test valid and feasible to implement in the preoperative evaluation of patients scheduled for elective surgery," write the authors led by Floris van Raalten, from Amsterdam University Medical Center in the Netherlands. "Our findings suggest that point-of-care HbA1c measurements might be valuable in identifying modifiable risk factors in patients undergoing surgery visiting the preoperative outpatient clinic, and may facilitate the promotion of preoperative prehabilitation and patient optimization programs by anesthetists."

Takeaway: Given the potential risk for postoperative complications in patients with undiagnosed diabetes, and possibly impaired glucose control, broad screening using a POC HbA1c test during the preoperative anesthesia visit may be beneficial. POC HbA1c and central laboratory testing results are within acceptable agreement.