iAssay Developing Universal POC Instrument for Home Health Applications

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NEW YORK (360Dx) – Running point-of-care testing at the bedside of a home-bound patient is an ultimate distal site in a healthcare network, but to date the uptake of diagnostics in the home healthcare space has been limited.

A four-year-old startup, iAssay, hopes to change that by providing healthcare workers a single instrument that can run many different commercial tests. The company plans on partnering with commercial test makers to add assays to its universal assay reader.

While some makers of point-of-care diagnostics are strategizing for uptake of their products in emergency departments, physician offices, and retail pharmacy clinics, there hasn't been much public discussion of the home healthcare market. Home health workers served more than 3.5 million patients in 2016, making more than 110 billion visits, according to The Centers for Medicare & Medicaid Services. There are also more than 11,000 home healthcare agencies registered with CMS that offer nursing care.

Furthermore, in a recent article in Health Affairs the CMS Office of the Actuary estimated home health spending will grow at almost 7 percent annually between 2018 and 2027, and three quarters of the spending in home health is likely to be paid for by Medicare and Medicaid. The spending will account for about 3 percent of national health expenditures (NHE) during the projection period – with total NHE expected to reach $6 trillion in 2027.

There are more than 9,000 CLIA-waived diagnostics tests for different analytes. For example, to date the FDA has waived 31 different tests that measure prothrombin time (PT), a test often used to measure how quickly the blood clots in patients taking a blood thinner such as warfarin.

Yet, despite the large number of potential users with at least some medical training and access to patients in need of testing, and the tremendous menu of waived tests, by all currently available reports there is very little use of diagnostics in the home health market at the moment.

Lonnie Adelman, CEO and founder of iAssay, thinks that might be partly due to the fact that many tests typically require their own designated testing instruments. "A nurse would have to have an airline bag full of readers in order to effectively test a patient," Adelman said.

The key to iAssay's technology is an adapter module that the company has designed to run test cartridges from many different manufacturers on a single, universal instrument.

The company recently received a Notice of Allowance from the US Patent and Trademark Office for a patent covering adapting POC test cartridges of various formats and

technologies to one device, as well as wireless device communication, and the capability to guide care providers during sample collection and processing.

Test makers have already done all the hard work to develop test cartridges that produce a signal from a drop of blood, for example, as well as to get these tests cleared by the US Food and Drug Administration.

"What we do is we adapt already functioning, already cleared point-of-care test cartridges to our device," Adelman said. "The idea is to be able to provide the healthcare community with a single device that will effectively run any point-of-care test cartridges from any manufacturer," he added.

The adapter is designed to use the point-of-care test cartridges as they are, without changing anything, and "that way we've maintained the regulatory clearance of the device," Adelman said.

On the backend, the company also partners with a health IT cloud that can then do things with the test data from the system, he said, such as aggregate data from wireless blood pressure cuffs and stethoscopes, with that data also added into the patient's health record.

The sale of instruments and consumables is a razor/razorblade model, Adelman said, in which companies are perhaps more interested in consumable flow than in the instrument itself. "The more consumables they can sell, the better they like it," he said.

Adelman said that there is clearly a place for legacy instruments as well as the iAssay system. "I don't preach to any company to dump their single-use reader ... [but] they stand to gain from getting onto our platform by reaching new markets," he said.

In order to adapt a consumable to the iAssay instrument, the company must have an agreement with manufacturers, Adelman said, adding that he is not at liberty to disclose any partnerships at this time.

The iAssay system can run "a number of different types of cartridges [using] different formats and different technologies," he said. As an example of the multiformat capabilities, iAssay has validated a hemoglobin test that uses a cuvette format and photometric readout, as well as a lateral flow test on its second-generation prototype.

The firm has also run assay cartridges measuring hemoglobin, hematocrit, NT/pro-BNP, quantitative hCG, PSA, and other analytes, Adelman said.

It has concentrated development on lateral flow tests and cuvette photometric reads, but Adelman envisions doing molecular tests on the device as well. There isn't as much of a drive for molecular in home healthcare at the moment, he said, but he noted that "eventually molecular tests will be everywhere," and that the iAssay can be modified to do isothermal amplification and PCR. Indeed, Adelman's first company, Ericomp, was the first to market for a programmable PCR machine, he said, so he can bring his experience in thermal control to bear on future molecular testing developments.

iAssay will now have to show the FDA that its device can run a test the same as a predicate device, Adelman said. "The good news for us is that the whole clinical trial path is not part of our future," he added. The firm has already had some discussions with FDA and is currently raising $1.1 million in a seed round to finish building a production device, which it plans to follow with a $5 million Series A round.

Adelman said the marketing model involves working with cartridge manufacturers to sell through their existing channels, down to hospital systems who own the home health nursing groups.

iAssay has surveyed the market and also found a number of potential customers who have said they would use its universal reader. "Potential end users are all really excited about what we are doing," Adelman said.

For example, Novus Healthcare is a national service provider specializing in home-based comprehensive annual wellness visits. The company uses its practitioners as an extension of physician practices, visiting patients outside of a standard clinical setting in order to complete comprehensive patient assessments and assist with chronic care management so that doctors can focus on more skilled aspects of patient care.

"We are very interested in iAssay — the potential ability to receive results while still with the patient is the most intriguing aspect," Novus' CEO Damon Kenton said in an email.

Novus has tried to use some point-of-care testing in the past but did not find it to be a good fit, in part because results took too long. However, in the absence of POC testing, "Our only option is to send the patient in to get the screenings needed and hope the results get to their primary provider before the patient follow-up visit," Kenton said.

The capabilities of iAssay, on the other hand, would allow Novus to "organize the patient data in a timely manner, so providers have more information during regular patient visits and can use that information to improve the quality of care and patient outcomes," Kenton said.

In general, other end users of diagnostic testing also seem aware of the potential for POC in home health. For example, Diana Hernandez, the clinical research director for microbiology at Geisinger's Center for Infectious Disease Diagnostics and Research, said last year that her lab would consider the Cepheid Omni system when it becomes available, for use by the health systems' mobile phlebotomist team that makes home health visits.

In retail pharmacy clinics, companies like eTrueNorth are offering products that simplify administrative processes for CLIA-waived laboratory point-of-care testing, making it easier for end users to meet local regulations, for example, even as some proficiency testing providers have expressed concern over the level of oversight for such tests, specifically in a lab setting.

Indeed, the ultimate accuracy of POC diagnostics in the hands of users who may not be trained in standard lab techniques is an important variable.

Brenda Korte, a POC device consultant, noted that while convenience for the user is a criterion for a successful POC device, and having a single interface might reduce training requirements, it is also important to determine whether a device can deliver on the accuracy requirements for all the target assays in the home health context.

Korte, who previously oversaw POC device development as a program director for the National Institute of Biomedical Imaging and Bioengineering at the National Institutes of Health, cited recent concerns over PT monitors, and the recall of the Alere INRatio instruments over accuracy concerns, as an example of how hard it is to deliver accurate results at the point of care. She also noted that a comprehensive evaluation in procurement decisions would be needed, and pointed to a framework AdvaMed has developed to help decision-makers determine the value of diagnostic tests in their specific contexts.

Although it is difficult to say whether a particular device will lead to more uptake of POC testing, there does seem to be consensus among experts that decentralized testing is the way of the future.

"I do think the health care system is changing in ways that will increase adoption of point-of-care testing, with home health being a likely area of growth," Korte said.