

Point-of-care diagnostics is revolutionary

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In 2011, the Bill & Melinda Gates Foundation rolled out a new grant of \$31 million to fund innovation in point-of-care diagnostics (POCD) in the developing world. The initiative aimed to engage minds across scientific disciplines to work on solutions that could lead to breakthrough advances in diagnostic tool designs, making them more affordable and accessible. The idea behind the initiative is that new and improved diagnostics at point-of-care can help health workers provide affordable and easy-to-use tools. This will help in rapid disease diagnosis and more timely treatment, thereby reducing death, disability and transmission of infections in resource-poor communities.

Robust, inexpensive and simple diagnostic tests at point-of-care settings can greatly improve quality and efficacy of healthcare available to people living in developing countries, where the burden of disease is the highest.

The global point-of-care diagnostics market reached \$13.4 billion in 2010 and \$13.8 billion in 2011. Market analysis company TechNavio predicts that the market is poised to grow at a compound annual growth rate of 3.9 percent between 2011 and 2015 and will reach \$5.2 billion in 2014.

Multinational companies such as Roche Diagnostics, Beckman Coulter, Siemens Healthcare Diagnostics and Becton Dickinson have wide penetration in the point-of-care diagnostics market. The market for point-of-care testing can be widely divided into glucose monitoring, blood chemistry and electrolyte, pregnancy and fertility, cardiac markers, drug and alcohol, infectious disease, cholesterol, hemoglobin/hemostasis, urine chemistry and tumor marker.

Taking note of the trends in the healthcare sector, both multinationals and Asian medical device makers are giving investing to develop diagnostic tools that are simpler and easy-to-use to tap the market.

After the announcement of grant from the Gates Foundation, Qiagen started development of portable instruments based on its advanced molecular testing technologies for point of need applications. The company, a global provider of sample and

assay technologies, is developing easy-to-use, portable molecular testing devices that can perform diagnostic tests in the field, far from any hospital or laboratory infrastructure.

"The new low-cost portable testing devices currently under development are intended to enable reliable, quick diagnosis and timelier treatment of patients. We believe that modern diagnostic technologies can have a very significant positive impact on developing countries by helping to save lives, reducing economic impact (of diseases on patients) and curtailing the spread of infectious diseases," said Dr Ellen Sheets, chief medical officer of Qiagen.

Asian companies and researchers too have joined the bandwagon of innovation in this segment. A research team from Singapore Lipidomics Incubator under National University of Singapore is collaborating with the Foundation for Innovative New Diagnostics to identify novel target molecules to be employed as biomarkers for the detection of active tuberculosis. The aim is to translate these targets into a diagnostic test that is affordable, easy-to-use and produces rapid results, and that can be used by community health workers in poor countries.

Similarly, a new power-free microfluidic chip developed by researchers at the RIKEN Advanced Science Institute in Japan has enabled the detection of microRNA from extremely small sample volume in only 20 minutes. This is possible by drastically reducing the time and quantity of the sample required for detection. The chip lays the groundwork for early-stage point-of-care diagnosis of diseases, such as cancer and Alzheimer's disease.

Companies focus on disease management

Monitoring patients' vitals closely is crucial before and after surgery or some treatments. One example, patients with diabetes need constant monitoring. However, this is not always possible or convenient. Several medical devices companies are looking to address this challenge. Products and services that make patient monitoring easier go a long way in disease management. It allows healthcare professionals to deliver more efficient treatments in many cases.

For instance, diabetes management can enable people with diabetes to improve all aspects of self management and allow healthcare professionals to raise the efficiency of treatment. Diagnostic companies can play a major role in such situations by bringing out products and services to this end.

Speaking on the impact of point-of-care diagnostics in the healthcare sector, Mr Harish Nuggehalli, founder and chief technologist of Yethi Medical Systems, a Bangalore-based start-up, says it allows early detection of disease, helps in disease mapping and providing targeted drug delivery system. Devices developed by Yethi, which was founded in 2010, can measure ECG, SPO2, pulse, non-invasive blood pressure, blood sugar, temperature and weight. He mentioned that devices for haemoglobin, creatinine and other assay diagnostics are in the pipeline.

European companies such as Roche and CeQur are developing devices that combine diagnostics and insulin delivery pumps, which not only remove the need for multiple daily injections of insulin but also mimic the role of pancreas.

Roche's recently launched Accu-Chek Combo insulin interactive pump combines a blood glucose meter with an insulin pump. In the system, the meter and the pump exchange data via bluetooth wireless technology. So, the meter not only enables the user to quickly test blood glucose levels, but also allows remote operation of the insulin pump. Then, with the help of an easy-to-handle bolus advisor, it provides support in defining the right amount of insulin.

The Accu-Chek Combo system therefore supports a more targeted therapy management, while also allowing discreet insulin administration without the need to touch the pump. The product has been successfully launched in several European and Asia Pacific countries.

The 2008 swiss start-up CeQur developed the CeQur system, which is a small, wearable insulin delivery device that delivers both basal and bolus doses subcutaneously. The simple and discrete design enables patients to easily comply with the insulin regimens and experience the benefits of intensive insulin therapy. The CeQur insulin infuser includes a disposable insulin reservoir that attaches to a reusable electronic messenger. The device easily attaches to the patient's abdominal area with a safe and secure adhesive backing. Once in place, insulin is delivered subcutaneously through a fine, soft tube or cannula from the reservoir that is changed by the patient every few days.

Asian companies join the bandwagon

Similar developments are taking place on the Asian soil as well and Indian companies are taking a lead in the field. Indian company Bigtec's TrueLab is a point-of-care, hand-held, real time quantitative mini PCR that is battery operated. This device can be lifted in one hand, and detects the disease organism by a polymerase chain reaction carried out on a chip designed using microelectromechanical systems (MEMS) technology and is specific to each disease. Bigtec Labs has also developed

chips for other diseases, such as H1N1, with the support of the Indian Council of Medical Research.

Australian company Universal Biosensors has developed OneTouch Verio, a blood glucose monitoring product for diabetes patients. The company, which spends roughly \$10 million annually on research and development, is also developing a number of other clinically relevant point-of-care diagnostic tests, such as Prothrombin Time test (PT-INR test), which will be used to monitor blood thinning anticoagulant warfarin, which is a treatment for patients at risk of blood clot or stroke.

"POCD would lead to more frequent testing or monitoring, improved health economics (reduced costs of healthcare) driven by better health management, increased efficiencies in testing at the point of care (lower costs of logistics, administration, health professional time), and POCD products will help relieve pressure on the healthcare system by increasing use of self-monitoring tests at home (e.g. diabetes care)," says Mr Paul Wright, CEO, Universal Biosensors.

India-based TATA Elxsi has also developed a device to monitor blood glucose level. The device is targeted at diabetes patients who require to continuously monitor their blood glucose level, multiple times a day and accordingly take insulin shots. Typically, the user needs to carry a set of three devices - the lancet, a glucose monitoring device and an insulin-delivery device. The research team at Tata Elxsi has developed a device that combines the features of these three devices and integrates them into a single convenient lifestyle accessory that is compact and easy-to-use.

Similarly, Wipro is developing remote fetal monitoring solution for high risk pregnancies. It is a wireless cardiotograph (CTG) for antenatal care and labor or delivery that uses a small wearable wireless fetal-maternal monitoring device. The solution offers ambulatory belt-less monitoring solution that needs minimal user intervention. Accurate surveillance of fetal heart rate, maternal heart rate and uterine activities is additionally supported by electronic storage of clinical data and decision support software that acts as aid to the doctors. Currently, two pilot studies are taking place in India.

Yethi Medical System offers a multi-parameter measuring device with cloud connectivity. "We are the only portable multi-parameter measurement device that has cloud connectivity. We are significantly lower in cost compared to other devices that can measure the same parameters, but do not have connectivity. This does not include the cost of sales or marketing cycles," says Mr Harish Nuggehally of Yethi Medical Systems. He added that developing a good solution in 18-24 months required around \$750,000.

Singapore-based Veredus Laboratories developed the VereChip technology that allows point-of-need testing and is suited to a wide range of clinical diagnostics applications. The VereChip platform combines microelectro mechanical systems (MEMS) with micro-fluidics to automate and integrate multiplexed DNA amplification with microarray detection.

Similarly, Singapore's Clearbridge BioLoc developed AssayQuest, an innovative and affordable analysis platform that can facilitate quantitative point-of-care-testing (POCT) from a small amount of patient sample. The AssayQuest system comprises a reader and a disposable test card, which is the size of a credit card. A roller-pump mechanism processes the test card that constitutes of a microfluidic matrix of reagent-filled blisters that are ruptured in an automated and programmable sequence. The AssayQuest platform allows the test card to be customized with different reagent combinations and assay formats to provide professional and reproducible laboratory-quality results within minutes.

Taiwan-based Rossmax and Microlife and Korean company Allmedicus are also engaged in development and manufacturing of medical diagnostic equipment for home monitoring and institutional use. Blood pressure monitors, digital thermometers, asthma monitors and flexible heating are their core products. Australian company Tyrian Diagnostics developed point-of-care and point-of-need diagnostic tests for clinical and non-clinical applications. The company engages in developing its DiagnostIQ platform, a patented disposable test device, which utilizes an antibody or antigen printed membrane to create a multi-analyte test, suitable for use with crude samples such as whole blood, sputum, saliva or plant materials.

Roadblocks in growth path

Getting diagnostics to patients in the developing world is a challenge. There are many obstacles, including issues of remote locations, extreme temperatures, access to cold chain and lack of trained personnel. The key stumbling block, however, is mostly the cost of the product.

US-based QuantuMDx is tackling these problems by developing hand-held and portable low-cost devices for diagnosis, genomic sequencing and proteomic profiling for both developed and developing nations. These are designed to be simple and user-friendly.

The company is developing the Q-POC point-of-care device for multi-drug-resistant infectious disease testing, including tuberculosis, HIV/AIDS and other sexually transmitted infections, and also as a companion diagnostic. According to the company, it will deliver results that are as accurate as those from state-of-the-art laboratories, but in less than 20 minutes and at a fraction of the cost of tests done at labs. A similar device could both diagnose and stage in less than 20 minutes. This will

mean patients getting diagnosed of a disease and starting treatment in one clinic visit, which is especially important in remote and rural areas.

Besides, there are roadblocks in leveraging the point-of-care market. Though the target users are primarily in developing countries where delivering fast healthcare is a challenge, patients may find discomfort in using point-of-care devices due to lack of technical know-how. "It is important to educate the market about the product, what it does, why it is needed, and how to integrate it into the established work practices. In terms of obtaining regulatory approvals, the US market is typically the most challenging and time consuming but represents over 40 percent of the world market," said Mr Wright of Universal Biosensors.

What the future holds

Technology and scale will bring down costs related to development and production of devices and, therefore, their prices over time.

However, more important is the overall cost to the healthcare system in using point-of-care diagnostics rather than alternatives (either via centralised lab testing or avoiding diagnosis). According to Universal Biosensors, point-of-care diagnostic solutions are effective where they reduce overall cost to the economy through better health outcomes (due to frequent monitoring or more rapid clinical intervention) and reduced treatment costs.

Mr Nitin Sawant, general manager, diagnostics, Trivitron Healthcare, points out that the point-of-care segment will show the highest growth in the near future due to demand for tests that can give faster results and can be performed near the patients and without the lab infrastructure and trained personnel.

"Lifestyle diseases such as diabetes and cardiac diseases are increasing and they require immediate diagnosis and self-monitoring. This is possible with point-of-care testing. In India, currently most of the quality devices and consumables are imported and have 29 percent import duty on them. The government can cut down on this duty. In addition, the government can encourage local manufacturing and usage of point-of-care in public hospitals," he said.