The new era of point-of-care testing

The latest devices are very different from those of the past. The big question is: will physicians use them? • BY TRISTAN BRONCA

The most common point-of-care tests are the same as what you’re likely to see on a magazine cover: the take-home pregnancy test, for instance, or the humble blood-glucose monitor. But future devices promise to put far more diagnostic power in the hands of clinicians than the dipsticks and finger pricks of yore. Welcome to the era of hand-held DNA sequencers and Star Trek-style tricorders.

Determining which high-tech machines will rise to popular use, however, is another question. In 2014, researchers surveyed family physicians in five countries regarding which of the 50 most common lab tests they currently conduct at the point of care (POC) and which they most wanted to see there in the future (BMJ Open, online Aug. 8, 2014). According to study co-author Dr. Jochen Cals, a family physician and assistant professor at Maastricht University in the Netherlands, “GPs expressed the most need for tests that would affect the immediate management of that patient.” If a test could rule out a condition that would require an unnecessary course of antibiotics in the future (BMJ Open, online Aug. 8, 2014).

For tests that would affect the immediate management of that patient. If a test could rule out a condition that would require an unnecessary course of antibiotics in the future (BMJ Open, online Aug. 8, 2014). One of the POC testing applications enjoying the most investment is infectious disease. It was also identified as a priority for doctors surveyed for the BMJ Open study. Take, for instance, the MinION, a handheld genetic sequencer developed by Oxford Nanopore Technologies in the United Kingdom. Vancouver native Dr. Jared Simpson (PhD), now working out of the Ontario Institute for Cancer Research (OICR) in Toronto, has developed a way to detect genetic variation by carefully analyzing the electrical signals emitted by the device. He and his colleagues recently used it in Guinea to track the Ebola virus as it mutated and spread through the West African country.

Traditional, outbreak sequencing required sending viral samples to a lab. That meant results could take weeks (due to the massive number of calculations involved in the sequencing) and by then, it would have been too late to direct any sort of intervention. The handheld device changed that. It could sequence a sample in as little as 15 minutes.

The ultimate goal for Dr. Simpson at the OICR is to sequence cancer genomes, but such a calculation requires more data than the MinION can provide. Viral genomes, on the other hand, are about 150,000 times smaller and mutations can be detected accurately using Dr. Simpson’s software.

As a result, epidemiologists on the ground in Guinea were able to identify people in the path of the disease and direct resources accordingly. The findings were published in Nature (Feb. 11) and Dr. Simpson has released open-source software that would allow people unfamiliar with the technicalities of reading or analyzing sequencing data to use the device. With that, the MinION
could conceivably be used to track other viral outbreaks such as influenza or Zika.

**Wound care**

Other Canadian researchers are addressing less exotic forms of infection such as those found in chronic wounds.

Recently, Health Canada approved a device called Molecularight i:X, whose design was based on an unexpected observation made in 2007: bacteria glow. Dr. Ralph DaCosta (PhD), a scientist with the Princess Margaret Cancer Centre and the University Health Network’s Techna Institute in Toronto, was able to develop a sort of camera/flashlight out of technology no more complicated than that in a smartphone. It could detect “clinically significant” amounts of bacteria in wounds by calibrating out normal bacteria found on the skin. Without spraying any contrast agents or even touching the wound, infections lit up.

“The standard of care in wound care is you smell it, you look at it, you assess whether there’s pus or blood or other signs and symptoms,” explained Dr. DaCosta. “Clinicians use highly subjective methods to determine whether the wound is infected.” It was an area that he thought was “screaming for new methods and tools.”

Not only did the new device offer an objective measurement, it also affected patient outcomes. One study published in *PLoS One* (March 19, 2015) found that over a six-month trial, diabetic foot ulcers closed three times faster with the use of the light versus standard care. In a case study published in the *International Wound Journal* (April 2015), the device was used to detect a subsurface infection in an asymptomatic patient who was about to be discharged from hospital.

Earlier this year, Dr. DaCosta launched a company, Molecularight, to market fluorescence-guided wound imaging technologies, and currently about 20 practitioners in Ontario are using the first-generation device, which comes with a price tag of $6,750.

**Ultimate POC device**

The devices mentioned above offer just the tiniest peek into a few areas of POC testing. Acute conditions (especially cardiovascular) were another area pegged in the *BMJ* study that would stand to benefit most from new advances. But according to Dr. Cals, current POC tests for those conditions “aren’t quite there yet.” They aren’t accurate enough and it will likely be several years before rapid POC tests are introduced.

POC tests given the errors that might occur with untrained physicians or nurses. Even your run-of-the-mill blood-glucose test is often affected by human error, Dr. Isbell said. Extrapolate that for the public at large and the problem becomes much bigger.

“I think it’s a really cool idea,” Dr. Isbell said, adding that the tricorder is mentioned at the American Association for Clinical Chemistry’s conference all the time. “But will we have a bona fide device that we can use? Probably not for a while, but it gets us thinking about the future.” MP