Drs. Andrew J. Steckl and Giovanni Pauletti recently produced a prototype of a low-cost, paper-based microfluidics diagnostic device which will allow patients to self-monitor their oral anticoagulation therapy.

Anticoagulants are drug molecules that interfere with normal blood clotting in order to prevent and treat potentially deadly blood clots. Doctors prescribe anticoagulants to patients to manage serious cardiovascular diseases such as venous thromboembolism, systemic embolism, and atrial fibrillation that can cause a stroke.

Since anticoagulation drugs like warfarin make the blood "thinner" to prevent the formation of blood clots, the effectiveness of anticoagulants must be regularly monitored in order to avoid excessive bleeding, a complication that could offset any benefits. Usually less than 50% of all patients are properly adjusted within the desired efficacy range. These patients are required to visit trained professionals to receive anticoagulation measurements in a hospital or lab setting that meets the federal regulatory requirements.

Recently, the US Food and Drug Administration (FDA) granted the use of portable point-of-care (POC) anticoagulation monitoring devices with the objective to improve clinical management of patients on oral anticoagulation therapy. Annual expenses associated with current commercial POC anticoagulation self-testing devices are expensive as they range between $3,000-4,000, including the purchase of the required optical reader.

The diagnostic testing device proposed by Drs. Steckl and Pauletti is made out of ultra-low-cost paper and does not require a battery-operated optical reader. Steckl predicts that successful implementation of the technology will allow patients adequate, rapid, self-monitoring of oral anticoagulation therapy at a fraction of the current cost. As opposed to monthly visits to the doctor at a hospital, the portable POC testing devices offer the advantage of convenient weekly
monitoring of patients in anticoagulation clinics, nursing homes, physician’s offices, or a patient’s home (self-testing).

Steckl and Pauletti’s paper-based microfluidic portable testing device comes in a diagnostic test kit. A small, oval cut-out in the plastic holder of the kit allows a small blood drop to be obtained after a fingerstick is applied. A rectangular window facilitates real-time visual monitoring of test progress on the paper strip that is completed within four minutes. The distance travelled by red blood cells on the paper strip depends on the overall viscosity, or consistency (the state of being thick, sticky, etc.), of the blood sample which is controlled by coagulation factors. Anticoagulants decrease blood viscosity and allow red blood cells to travel further on the paper strip within the same time.

Paper-based microfluidics create simple analytical devices that are easy to use anywhere and have inherently very low manufacturing costs. Steckl predicts that the combination of low-cost materials and the ability to efficiently mass produce very large quantities of this diagnostic test using advanced roll-to-roll printing press technology will translate into a very low cost of goods sold.

To date, the Bill & Melinda Gates Foundation has awarded Steckl and Pauletti a Grand Challenges Explorations Round 10 grant which has allowed the researchers to successfully create a prototype of their experimental paper-based microfluidics device. They are currently testing the device using animal blood samples. After successful clinical validation, commercialization will be possible within a year or so.

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