

Health Technology Update

CADTH

A newsletter on new and emerging health care technologies in Canada

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Rural and Remote Issue

This issue of *Health Technology Update* features brief summaries of information on a range of technologies with relevance to rural and remote health care settings — from medical drones to a teleoperated robotic ultrasound system. These technologies were identified through the CADTH Horizon Scanning Service as topics of potential interest to health care decision-makers in Canada.

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FEEDBACK

Have you heard of a new health technology you think will have an impact on health care in Canada?

Please let us know!

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New Technologies That Support the Delivery of Health Care in Rural and Remote Areas

Residents of rural and remote areas in Canada commonly have to contend with challenges when seeking access to health care. Geographic distance, limited availability of health care professionals, and logistical, economic, and sociocultural factors that can make medically related travel difficult are among the barriers to accessing health care in rural and remote areas.^{1,2} Leveraging technology to improve access to health care in rural and remote communities has been a longstanding and continuing pursuit in various jurisdictions across Canada.³⁻⁷ In this issue of *Health Technology Update*, we describe five emerging technologies that may be of interest to those looking to address health care access issues in rural and remote areas.

IMPROVING ACCESS TO HEALTH CARE USING TECHNOLOGY

In 2011, more than 6.3 million people, or 19% of the Canadian population, were living in rural and remote areas.⁸ Evidence indicates that people living in rural and remote communities in Canada tend to have poorer health status than those who live in urban areas.⁹ In these settings, access to physicians and other health care providers remains an issue. For example, it has been reported that less than 8% of Canadian physicians work in rural areas.¹⁰ Beyond this, residents of those communities can face considerable travel time and out-of-pocket costs to get to the places where they can obtain the medical services they need.¹

The technologies discussed in this issue may help enable better access to certain health care services in rural and remote areas of Canada. One of the technologies, the Intelligent Retinal Imaging Systems – IRIS – is a platform that may be used to facilitate the provision of diabetic retinopathy screening in areas that have limited access to eye care professionals. Another technology, unmanned aerial vehicles – or drones – may help to overcome challenges that affect conventional modes of transportation and enable the timely delivery of medical supplies to remote communities. For health care providers in rural and remote areas who are caring for patients with acute upper respiratory tract infections, a rapid, point-of-care test, FebriDx, may help to differentiate bacterial and viral infections and could enable the more judicious use of antibiotics. Video directly observed therapy (VDOT) enables patients to record themselves taking their medications at work or at home and send the video to their health care providers regardless of the time or distances involved. We discuss VDOT in the context of monitoring adherence to tuberculosis treatment in remote Canadian communities. Finally, a robotic arm that allows a clinician located at a distance to control an ultrasound system in a patient's home community may help improve access to ultrasound imaging for people living in communities without trained practitioners. It may also help improve access to specialized ultrasound imaging in smaller communities with low-volume clinics.

WHO MIGHT BENEFIT?

As noted, 19% of the Canadian population live in rural and remote areas and could benefit from technologies that facilitate access to health care services. Specifically, these technologies may help reduce the need for patients to travel far away from their communities to get medical care. In 2010, it is estimated that the provision of health care services through the telehealth approach helped residents of rural and remote communities in Canada to avoid 47 million km of travel and \$70 million in associated personal costs.³ Cost savings for the health care system and a more effective delivery of health care to the affected communities are often noted as potential advantages of initiatives that bring health care services closer to rural and remote populations.^{4,6,11,12}

Author: Bert Dolcine

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Intelligent Retinal Imaging Systems for the Telescreening of Diabetic Retinopathy

Evidence has shown that the early detection and treatment of diabetic retinopathy (DR) is effective at reducing the risk of the disease progressing to serious complications like visual impairment.^{1,2} This underscores the need for timely and regular DR screening in people with diabetes.



Photo: iStock/Rocky89

Teleophthalmology, the provision of eye care remotely using information and communications technology, is well-established in Canada. This approach has been piloted or implemented for screening and evaluation of eye diseases, such as DR, in several communities across the country.²⁻⁴ Available evidence indicates that the use of teleophthalmology may be a suitable alternative to conventional eye examination methods and may help to improve access to DR screening, reduce screening costs, and avoid visits and unnecessary referrals to eye care specialists.⁵⁻⁹ In this article, we describe the Intelligent Retinal Imaging Systems (IRIS) platform, which is one of the recent technologies that aim to facilitate and improve how screening for DR is conducted in the context of teleophthalmology.

HOW IT WORKS

The IRIS platform is a cloud-based software intended to be a comprehensive solution for screening and diagnosing DR, and coordinating related tasks such as patient referrals and billing.^{10,11} The software is compatible with cameras that take non-mydriatic (non-dilated pupils) fundus images of the retina.¹² DR screening with the IRIS platform can be integrated in the primary care setting and other care environments. To initiate the screening process, a primary

care professional or a trained individual captures images of the eye, along with the patient's information, which are then securely uploaded to the IRIS cloud-based application. The software also creates an enhanced version of the original image by highlighting the vessels and nerve fibre layer of the retina.¹² The company suggests that the enhanced image provides a better view of the retina and facilitates identification of potential abnormalities in the eye.^{12,13} After the necessary images and information are uploaded, the case is assigned to a licensed retina specialist or an ophthalmologist who can access the IRIS application via the Internet to review the images and provide a diagnosis.^{10,12} Screening results and, as needed, a plan for follow-up are entered into the system and transmitted to the provider who initiated the eye examination.^{10,12}

WHO MIGHT BENEFIT?

Based on the Canadian Chronic Disease Surveillance System data, about 3 million individuals (8.1% of the population) were diagnosed with diabetes in 2013-2014.¹⁴ The Canadian Diabetes Cost Model forecasts that this will rise to 11.4% by 2025.¹⁵ The same survey revealed that about 20% of all diabetes cases remain undiagnosed. DR is a common complication of diabetes and also a leading cause of vision loss and

blindness in Canada and worldwide.^{2,16}

The prevalence of DR is estimated at 23% among individuals with type 1 diabetes and 14% among those with type 2 diabetes on insulin therapy.¹⁶ However, it is thought that almost all people with type 1 diabetes and most with type 2 diabetes will be affected by some form of DR in the first 20 years of living with diabetes.^{2,17}

Thirty-two per cent of patients with type 2 diabetes received DR screening at the recommended frequency.² Lower rates of DR screening may be expected in rural and remote areas where access to conventional eye care may be limited because of having to travel long distances and because of the costs associated with visiting locations that offer screening services. Further, the prevalence of DR among diabetic patients from Indigenous communities is estimated to range between 28.5% to 40%.² Teleophthalmology programs built around technologies like the IRIS system may help improve access to DR screening in these communities.

AVAILABILITY IN CANADA

The IRIS platform is neither approved, nor available, in Canada at the moment. This product received approval in the US as a Class II device in 2015 and is reportedly being used in more than 250 clinics across that country.^{10,11} There are

no signs that the IRIS system has been implemented outside of the US and it is unknown if the manufacturer plans to expand to Canada in the future.

WHAT DOES IT COST?

Specific cost information for the IRIS platform could not be found in the various sources consulted, including the company's website and other documents published on the technology. The manufacturer did not provide this information upon request. Information available on the manufacturer's website suggests that IRIS implementation can be customized and the final cost may be based on the needs of the buyer.¹¹

Several studies have compared the costs of DR screening using teleophthalmology to the conventional screening method performed by an eye care professional.^{5,7,8}

CURRENT PRACTICE

The Canadian Ophthalmological Society published new evidence-based guidelines for the management of DR in 2017.² The guidelines recommend that DR screening be initiated five years after the diagnosis of type 1 diabetes if a person is diagnosed after puberty. Screening should start at puberty in the case of type 1 diabetes diagnosed before puberty. For type 2 diabetes, the guidelines state that DR screening should start when the disease is diagnosed. The frequency of screening is to be determined based on the severity of retinopathy. Otherwise, in patients who do not have retinopathy, recommended screening intervals are one year for type 1 diabetes and one to two years for type 2 diabetes. The guidelines also support the use of teleophthalmology programs for providing and improving access to DR screening, particularly in populations where cultural, economic, and geographic factors may prevent diabetes patients from getting regularly screened for DR.

WHAT IS THE EVIDENCE?

No published studies that evaluated the performance of the IRIS platform

in the specific context of DR screening were identified. Three case studies are available on the manufacturer's website regarding the implementation of the IRIS system in health care institutions in the US.¹⁸ It should be noted that performance data were not required for this product to be approved by the US FDA because it showed "substantial equivalence" to other licensed devices.¹⁰ Further, the IRIS system is not currently approved for diagnosing eye disease but rather for facilitating the administration of eye examinations and care within the health care system.¹⁹ This may help explain the lack of relevant evidence on performance.

SAFETY

No studies that assessed the safety of the IRIS system were identified.

ISSUES TO CONSIDER

The IRIS platform can be integrated into primary care facilities and various other care settings. Minimal training is purportedly required to perform the front-end part of the screening process — capturing the retinal images and patient information for uploading to the IRIS application.¹³ The ease of operation and availability of the system in the primary care setting allow providers to offer DR screening to patients at any suitable opportunity.

Implementation of the IRIS platform in a rural or remote setting does not appear to come with any considerations compared to other teleophthalmology systems. The provision of adequate training to local staff recruited from the community is noted as a key factor that can help in delivering effective teleophthalmology programs in rural and remote areas.^{3,5} Reliable Internet service is also an important consideration.

RELATED DEVELOPMENTS

The IRIS system is one of several options currently available to provide and manage screening for DR under the teleophthalmology approach.²⁰

Systems like the IRIS may be described as "assistive" in that they support and facilitate the work of eye care professionals in diagnosing eye disease. Of note, other products currently being developed or readied to enter the market are leveraging artificial intelligence to perform the automated diagnosis of DR and other eye diseases.^{19,21-23} These future systems would be autonomous and require no involvement of an eye care specialist in the diagnostic process.

LOOKING AHEAD

Technologies that support the teleophthalmology care approach are growing in numbers and rapidly evolving. There are reasons to believe that automated diagnostic systems, such as the recently FDA-cleared IDx-DR,²¹ may occupy an important place in DR screening in the future. Consideration of the IRIS system should take account of this context.

Author: Bert Dolcine

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MELODY: A Teleoperated Robotic Ultrasound System

Ultrasound — using sound waves to create images of organs, tissues, and blood flow — offers advantages for medical imaging, but access to trained clinicians in remote communities is often limited.¹ A device that allows experienced clinicians to remotely operate an ultrasound system located at a distant site using a robotic arm is emerging as an option for patients.



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HOW IT WORKS

The MELODY System (AdEchoTech, Naveil, France)² is a telerobotic ultrasound system — meaning that it's controlled at a distance by a human — comprised of separate “expert” and “patient” systems connected by land, satellite, or cellular Internet.³ It is designed to be used in combination with a conventional ultrasound system and video conferencing equipment.¹

At the patient site, an assistant places an ultrasound probe, held by the MELODY robotic arm, on the patient under the guidance of a remotely located clinician.³ The assistant is also responsible for moving the arm and probe to the correct anatomical location(s) and adjusting the initial pressure at the direction of the clinician.¹ At the expert site, the clinician uses a mock probe to control all the fine movements of the patient site probe through the robotic arm in real time; the clinician can also control all the ultrasound settings.^{1,3} Features of the mock probe allow the clinician to feel as though they are applying pressure to the patient, and for the patient system to maintain appropriate contact pressure.³ The clinician, patient, and assistant can interact with each other in real time through video conferencing equipment.³ For patient safety and comfort, the robotic arm is designed to apply a maximum force of 20 N and remain still at its last

set position in the event the network connection is lost.³

WHO MIGHT BENEFIT?

A network of telerobotic ultrasound clinics could serve patients in low-volume or underserved communities (where travel is often required to receive routine or specialty ultrasound exams) or help provide after-hours service.^{1,4} In larger communities, it could expand access to subspecialty ultrasound to low-volume clinics.¹

AVAILABILITY IN CANADA

The MELODY System is not currently licensed for use in Canada. The manufacturer anticipates approval in the summer of 2018 (Philippe Homs, Export Manager, AdEchoTech, Naveil, France: personal communication, 2 May 2018). It received 510(k) approval for use in the US in 2017.⁵

The province of Saskatchewan plans to develop a remote ultrasound clinic, using the MELODY System, with patient sites in remote communities throughout the province.¹ Two systems, one in La Loche and one in Stony Rapids, have been installed as part of the pilot project (Philippe Homs: personal communication, 30 2018 May).

WHAT DOES IT COST?

We did not find any studies evaluating the cost of implementing the MELODY System.

The manufacturer reports the purchase cost for a complete installation (MELODY System, ultrasound system, and videoconferencing system) is between C\$150,000 and C\$250,000, depending on the configuration, and includes a one-year warranty, maintenance, and training (Philippe Homs: personal communication, 2018 May). In Saskatchewan, a complete MELODY System installation was deployed using a grant of C\$300,000.⁶

A presentation by the manufacturer on a French study reported monthly leasing costs of €3,200 for the system.⁷ Other costs considered included patient site employees and payments to the operator at the expert site.⁷

CURRENT PRACTICE

Diagnostic ultrasound has wide applications including fetal imaging, cardiovascular disease, and soft-tissue injury.⁸ The use of ultrasound (i.e., number of examinations, devices, and locations) in Canada is not well-documented. Portable ultrasound systems that can be used at the point of care have emerged as a diagnostic tool in emergency departments and other out-of-hospital or remote locations.^{9,10} However, use in Canada may be limited by barriers such as lack of equipment, funding, and training; and the inability of clinicians to maintain ultrasound skills in low-volume settings.¹¹

WHAT IS THE EVIDENCE?

We found six observational studies of the MELODY System (or its predecessors)^{1,4,12-15} and six observational studies of telerobotic ultrasound systems in which the specific model used was unclear.¹⁶⁻²¹ Two presentations that included information on the use of the MELODY System were also identified.^{7,22} The studies were conducted in Saskatchewan^{1,4} (and also reported in a presentation²³), France,^{7,12,14,16,17,19-22} Cyprus,¹³ the UK,¹⁵ and Sweden.¹⁸ To date, the system has been used for a variety of ultrasound examinations including abdominal sonography,^{1,12,17,19,21,23} echocardiography,^{13,14,18} obstetrics,^{4,19,20} and other small structures.^{12,17} It has also been tested over cellular networks.^{13,15} To focus on the Canadian context, a more detailed discussion of Saskatchewan's implementation of the MELODY System follows.

Saskatchewan Studies

Researchers in Saskatchewan recruited adult patients scheduled for routine abdominal ultrasound examinations to assess the feasibility of deploying the MELODY System in the province.^{1,23} Image quality, duration of examination, and patient and clinician acceptance were compared with conventional ultrasound.^{1,23} Eighteen patients were included in the pilot study. The patient site was located at a Saskatoon imaging clinic 2.75 km away from the expert site at the city's academic health sciences centre.

A second study, published in 2018, evaluated the feasibility of using the MELODY System to perform routine prenatal ultrasound examinations. Thirty women received both a conventional and a telerobotic ultrasound exam. Image quality and acceptability of the system by patients and clinicians compared with conventional ultrasound was evaluated. The patient site was a clinic room next to the expert site.⁴

Safety

No studies about the safety of the MELODY System were identified.

ISSUES TO CONSIDER

Telecommunication Infrastructure

To function correctly, a telerobotic system relies on a telecommunications network of sufficient quality and bandwidth to allow real-time transmission of force feedback, video, and other data (e.g., device settings).³ Even then, most telerobotic systems operating over long distances will experience communications delays. As well, many rural and remote Canadian communities do not have access to broadband Internet, although efforts are being made to narrow this gap.^{3,24,25}

Training Requirements

Clinicians in Saskatchewan were provided with a 90-minute training session before using the ultrasound system and MELODY System.¹

Staffing Needs

An assistant is required to help operate the system at the patient site.³ This may exceed the usual number of staff required to perform an exam.¹ In Saskatchewan, an assistant with no prior health care experience was employed at the patient site.¹

Examination Time

Two studies observed a longer examination time for the MELODY System than conventional ultrasound.^{1,12} Researchers in Saskatchewan note that increased examination times should be accounted for in future cost studies.¹

Other Considerations

A 2016 review of medical telerobotic systems identified potential concerns including liability and responsibility should complications arise, network security, and patient privacy.³

RELATED DEVELOPMENTS

A trans-Atlantic telerobotic ultrasound system has been tested between Munich, Germany and Boston.²⁶ The state of its development and commercialization is unclear.

Hand-held ultrasound devices^{27,28} and novel ways of connecting clinicians

with distant experts using FaceTime and Skype^{29,30} have been explored and may offer solutions for rural and remote communities.

Telerobotic systems used over short distances are common in specialties such as surgery and ophthalmology.³ Long-distance telerobotic systems, like the MELODY, are also emerging in fields such as general surgery and orthopedics.³

LOOKING AHEAD

Improvements in our ability to transmit video and images over cellular networks are expected to expand the use of telerobotic systems.³ Currently, studies of the MELODY System have been limited to reported distances of under 50 km between sites.^{1,12,14} How longer distances, common in Canada, may affect the performance of the system is unknown.

Author: Jeff Mason

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Video Directly Observed Therapy of Tuberculosis Treatment

Medication adherence and completion of therapy is needed to cure tuberculosis (TB).^{1,2} Incomplete treatment may cause drug-resistant disease that entails longer, more costly, and more toxic treatment regimens, and that increases the risk of transmitting the disease to others.²⁻⁵

People with active TB have signs of illness, while those with latent TB have no symptoms and are not contagious but harbour latent infection that could develop into active disease.^{6,7} Many people have non-respiratory forms of TB that can affect the bones, joints, lymph nodes, or central nervous system.^{8,9}

Where possible, directly observed therapy (DOT) is recommended to improve medication adherence.^{1,8,10,11} Ideally, DOT involves a health care provider watching the patient take each dose of medication — typically, either at home or in a community clinic.² As TB treatment can take several months or more, DOT is resource-intensive, involving time and travel for staff and patients.^{3,4,12} This can be especially problematic for people living in remote areas.

HOW IT WORKS

Mobile technologies may alleviate some of the inconvenience and cost of DOT by allowing patients to record via video the ingestion of their medications at home and then relay the video to health care providers using a tablet, computer with a webcam, or smartphone.^{4,5,13} Various terms are used to describe this approach, including electronic DOT (eDOT), virtually observed therapy (VOT), wirelessly observed therapy (WOT), and video DOT (VDOT).¹³ In this article, we use the abbreviation VDOT.

The two main modes of VDOT are:

- **synchronous** — where the patient video is “live” and the health care provider monitors the treatment in real time
- **asynchronous** — or “store and forward,” where the patient video is saved and sent to be viewed by health care providers either immediately or at a later time.^{1,14}

WHO MIGHT BENEFIT?

TB disproportionately affects socioeconomically disadvantaged populations because of factors such as inadequate housing, malnutrition, higher rates of smoking, and comorbid diseases.^{7,15-17} The challenges of remote geography (e.g., lack of road access, dispersed populations, shortage of health care staff) impact the provision of TB care in Northern Canada.^{7,8,16} In Inuit communities, TB is a serious health problem, with rates of infection almost 300 times than elsewhere in Canada.^{7,9,16}

Canada had 1,737 reported cases of active TB in 2016.¹⁸ About 70% of cases were in immigrants to Canada, and 19% were in Indigenous people.¹⁸

Individuals with latent TB who are at higher risk for developing active TB also need drug treatment.⁸ Those at higher risk are infants, people who are immunocompromised, people with

diabetes, residents of prisons or long-term care facilities, health care workers, the homeless, and injection drug users.⁷⁻⁹

AVAILABILITY IN CANADA

Various mobile health products for providing VDOT are available, including videoconferencing programs, such as Skype and FaceTime, and specialized platforms to monitor drug adherence, such as SureAdhere VDOT (SureAdhere Mobile Technology), emocha (emocha Mobile Health), and AiCure.¹³

A Toronto Public Health pilot program of VDOT, initiated in 2011,¹⁹ has since been expanded and now uses the Ontario Telemedicine Network. Patients can use their own mobile devices (smartphones, tablets, or computers) to log into a secure video link with Toronto Public Health staff. The TB program currently supports up to 40 patients by VDOT, which constitutes about 20% of the total patients currently receiving DOT services. Health care staff providing VDOT can see an average of 18 stable patients per day, whereas staff seeing patients in the community can see an average of 10 patients per day depending on the complexity of the patient care (Theresa Samarita, Toronto Public Health, Toronto, ON: personal communication, 2018 Apr 11). Elsewhere in Ontario, the Region of Peel also uses the Ontario Telemedicine Network to

provide VDOT to some of their patients with TB (Sheryll Gordon, Region of Peel, Brampton, ON: personal communication, 2018 May 4) and the Middlesex-London Health Unit plans to use this network to do so in future (Jody Paget, Middlesex-London Health Unit, London, ON: personal communication, 2018 May 8).²⁰

WHAT DOES IT COST?

In a Maryland study using emocha, the costs of accessing the software were estimated at US\$50 per patient, per month.²¹ For developed countries, the cost of SureAdhere VDOT is US\$35 per patient, per month (Kelly Collins, SureAdhere Mobile Technology, San Diego, CA: personal communication, 2018 Apr 30).

CURRENT PRACTICE

TB treatment may require multiple drug therapies, usually taken for months, or longer for drug-resistant TB.^{2,8,22} DOT is recommended for monitoring compliance with therapy, particularly for patients at risk for not completing treatment.^{2,3,8,21}

WHAT IS THE EVIDENCE?

A systematic review²³ of digital technologies in the management of TB identified two observational studies that compared the effectiveness of VDOT to standard DOT.^{4,24} These studies reported on the adherence to scheduled treatment sessions,⁴ treatment completion,⁴ and the rate of missed observations.²⁴

Two additional observational studies were also identified^{21,25} that compared VDOT and in-person DOT, or evaluated VDOT with no comparator. The studies looked at medication adherence^{21,25} and user acceptance.²¹ In addition, a conference abstract was identified that reported on a UK randomized controlled trial.²⁶ It reported on adherence to scheduled treatment and treatment completion.

Cost Considerations

Several small US studies of cost considerations were identified,^{3-5,21,27-29} as well as one study from Australia²⁴ and the aforementioned UK conference abstract.²⁶

These studies assessed potential cost-savings with VDOT compared to DOT — considering factors such as staff travel and time. The New York City study found that, with VDOT, health care staff were able to observe up to 25 patients per day — similar to the number seen in a clinic but double the number seen using community visits.⁴ No Canadian cost studies were identified.

Safety

None of the studies reported any direct patient safety concerns with VDOT.

ISSUES TO CONSIDER

Technical Issues

In one study, over a one-year period, 95% of VDOT individual sessions were successfully completed. Technical problems included slow Internet connections, smartphone problems, and computer or software issues.⁴ In another study, more than half of the patients had at least one rejected video (2.1% of all videos), mainly because of poor quality of the video.²¹ A US/Mexico study found that most patients (89%) were able to record videos without problems, but lost, stolen, or broken phones were an issue for six patients (12%), and some patient videos were lost due to technical issues.²⁵

Connectivity

High bandwidth Internet access or smartphones with a data plan access are needed to ensure image quality and file transfer in VDOT.³⁰ Many remote Canadian communities do not have broadband Internet or cell phone network access.³¹ About half of the communities in Nunavut do not currently have cell phone service, although new satellite infrastructure to resolve this should be in place by 2019.³²

In the Puerto Rico study of VDOT for long-term care residents with cognitive impairments and TB, investigators noted that synchronous (live) VDOT was not feasible because of poor Internet reception but that asynchronous VDOT could be used.²⁷

Privacy and Data Security

Ensuring the security and confidentiality of health data in mobile health technologies that use cloud-based technology is complex.^{33,34} In the US, companies must meet the requirements of the *Health Insurance Portability and Accountability Act* (HIPAA). In Canada, health privacy regulations vary between jurisdictions and HIPAA compliance does not address all provincial health data privacy requirements, particularly when the data are stored outside of Canada.^{33,34}

Training

Patients may need training on using the smartphone or other videoconferencing platforms. A US study that used Skype on patients' personal smartphones or computers estimated that nursing staff spent about one hour on training for each patient.⁵ Maryland study patients all reported VDOT was "easy to use."²¹

Patient Perspectives

The relationship between the health providers and the patient is an important part of medication adherence, but some evidence suggests this can be maintained with VDOT.^{2,4,5,24}

Patients have reported that VDOT is more convenient and this contributes to patient-centred care.^{4,5,21,23,24,35,36} Patients have also reported that VDOT offered greater privacy than in-home DOT,^{24,25} and that they prefer VDOT to in-person DOT.^{5,21,25,35} However, other investigators caution that patient acceptability of mobile health should not be assumed^{2,14} — not all patients are able to use the technology, and this option is not suitable for all patients with TB.^{5,13,25}

Ethical Considerations

Two US researchers have outlined four elements of an ethical framework for assessing mobile health technologies in managing TB therapy adherence.² These elements include accuracy of the technology in monitoring compliance, stigmatization and intrusiveness of monitoring, use of incentives, and

balancing the good of the individual with that of the public.²

RELATED DEVELOPMENTS

Another smartphone development for VDOT incorporates artificial intelligence for the automated assessment of medication adherence — alleviating the need for the DOT of each patient.^{37,38} The smartphone app sends patients reminders for each dosage and walks them through the steps involved. Each dose is recorded by video and the data transmitted to a central, cloud-based dashboard. Software algorithms detect missed or incorrect doses and send reminders to nursing staff for follow-up.³⁷ The technology AiCure was used in a pilot study of patients with active and latent TB patients in Los Angeles³⁷ and is now in use in TB programs in California and Illinois (Ted Kirby, AiCure, New York, NY: personal communication, 2018 Apr 24). The AiCure technology is currently being used to monitor medication adherence in drug trials in Canada but has not yet been used for TB patients here (Ted Kirby: personal communication, 2018 Apr 24).

Digitized medications for WOT incorporate ingestible sensors into drug capsules.^{12,39} The ingestible component transmits data to a wearable sensor and mobile device to monitor and support adherence.^{2,12} Technology platforms for digitized medications include the Proteus (Proteus Digital Health) and ID-Cap (etectRx).²

Earlier innovations, such as electronic medication monitors or “smart pill boxes,” use sensors to detect the opening of the pill container by the patient and relay this information to a remote server — although this may not accurately reflect drug ingestion.^{12,23} At-home urine testing to measure drug levels is another method of assessing adherence to therapy.²

LOOKING AHEAD

In both urban and rural areas, VDOT achieved similar treatment adherence to standard DOT, and with cost-savings in staff time and travel costs.^{2,23} Possibly,

VDOT may improve treatment adherence where DOT is not currently effectively delivered.²³ For patients in rural and remote areas, VDOT may remove some of the geographic barriers to receiving TB care.² It may also be useful in managing treatment for patients with latent TB, where treatments are not usually monitored with DOT.^{23,25}

Mobile health technologies, including new ways of providing DOT, are expected to facilitate the World Health Organization's End TB Strategy.^{22,23} These technologies could also be used to help manage other health concerns for people with TB, such as the promotion of smoking cessation or compliance with HIV or hepatitis treatments.^{5,22}

Indigenous Services Canada and the Inuit Tapiriit Kanatami non-profit organization are developing a framework for eliminating TB in Inuit populations,¹⁶ and earlier this year the Public Health Agency of Canada released a report calling for collaborative efforts to eliminate TB in Canada.⁷

For more information, the US Centers for Disease Control and Prevention (CDC) has produced a [free toolkit](#) to help implement VDOT into clinical practice in different settings.¹³

Author: Leigh-Ann Topfer

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A Rapid Point-of-Care Test to Differentiate Bacterial From Viral Acute Upper Respiratory Infections

Acute upper respiratory infections – which include the common cold, rhinosinusitis, pharyngitis, and bronchitis – are a common reason for primary care visits.^{1,2} Patients with bacterial and viral upper respiratory infections may have similar symptoms (for example, fever, sore throat, or cough), making clinical diagnosis and management difficult.^{3,4}



FebriDx: Reproduced with permission from RPS Diagnostics

Most upper respiratory infections are caused by viruses, and most will resolve without treatment. But for some patients with bacterial infections, such as group A *Streptococcus*, antibiotics may be needed.^{1,5-7} Antibiotics are not recommended for viral infections, yet these are often prescribed for respiratory infections for various reasons, including the difficulty in making a diagnosis based on clinical symptoms alone and the delay in getting the results of more definitive laboratory tests.^{3,7-10}

A point-of-care blood test, FebriDx, may help health care providers identify clinically significant infections, distinguish bacterial from viral infections during the initial primary care office visit, and prescribe antibiotics more judiciously.^{3,10}

HOW IT WORKS

FebriDx is an add-on test and is not intended to be used as a stand-alone diagnostic test, or to replace other tests. Rather, it is to be used in combination with clinical assessments and other diagnostic assessments, as needed.¹¹

FebriDx is a single-use, finger stick blood test that provides results in 10 minutes.^{7,12} The immunoassay identifies two proteins (biomarkers) in the blood that are elevated as part of the body's immune response to infection.¹⁰

- C-reactive protein (CRP), a biomarker of **bacterial infection** (CRP \geq 20 mg/L is used as the threshold)⁷
- myxovirus resistance protein A (MxA), a biomarker of **viral infection** (MxA \geq 40 ng/mL is used as the threshold).¹⁰

Combining the two biomarkers increases the clinical utility of the test compared to using a single biomarker, such as CRP.^{13,14} Results appear as lines on the test card (black for elevated CRP, red for elevated MxA, and blue for negative results when neither biomarker is elevated).¹¹ Elevated MxA, with or without an elevated CRP, is considered a viral infection. Elevated CRP with no elevation of MxA is considered a bacterial infection. Coinfections, where both viral and bacterial acute respiratory infections are present, are estimated to occur in less than 2% of cases.²

WHO MIGHT BENEFIT?

FebriDx is intended for use in patients over the age of two, within three days of the onset of fever and within seven days of the onset of respiratory symptoms.^{11,15} Test results should be considered in clinical context; for example, the results may be affected by altered immune responses in people taking immunosuppressants or antibiotics, trauma patients, or those with chronic health conditions that affect their immune response.^{10,11,16}

Acute respiratory infections are the main reason for antibiotic prescriptions in primary care.⁴ Rates of respiratory tract infections and related hospitalizations are higher in Indigenous populations than in non-Indigenous populations in Canada.¹⁷

AVAILABILITY IN CANADA

FebriDx (RPS Diagnostics, Sarasota, Florida) received a Health Canada licence in December 2015.¹⁸ The manufacturer is seeking Canadian distributors and the test is not currently in clinical use here (Dr. Robert Sambursky, RPS Diagnostics, Sarasota, FL: personal communication, 2018 April 6).

WHAT DOES IT COST?

FebriDx comes in a box of 25 disposable test kits. Each individual test includes an all-in-one retractable lancet, blood collection and transfer tube, and push-button buffer delivery mechanism (Dr. Robert Sambursky: personal communication, 2018 May).¹² Each test costs approximately US\$15 to US\$18 (Dr. Robert Sambursky: personal communication, 2018 April). This would be an additional cost to current practice.

CURRENT PRACTICE

Depending on the patient's symptoms and clinical assessment, the diagnosis of upper respiratory infection may involve throat swab and culture, point-of-care rapid antigen detection tests, chest X-ray, or other diagnostic tests.^{10,14,19}

Table 1: FebriDx Studies

Study	Patients Setting Study Type	Intervention Comparator	Results				
			Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Other
Shapiro et al. (2018) ⁷ US	<ul style="list-style-type: none"> convenience sample of n = 220 children (age > 1 year) and adults with fever and signs of upper respiratory infections at 10 centres^a multi-centre cross-sectional diagnostic test accuracy study (prospective enrolment) 	FebriDx compared with clinical algorithm of standard tests ^b	Full population Bacterial: 85% Viral: 90% Confirmed febrile (n = 121) Bacterial: 95% Viral: 90%	Full population Bacterial: 93% Viral: 76% Confirmed febrile (n = 121) Bacterial: 94% Viral: 78%	Full population Bacterial: 69% Viral: 83% Confirmed febrile (n = 121) Bacterial: 76% Viral: 89%	Full population Bacterial: 97% Viral: 85% Confirmed febrile (n = 121) Bacterial: 99% Viral: 80%	
Self et al. (2017) ¹⁰ US	<ul style="list-style-type: none"> convenience sample of n = 205 children (n = 61) and adults (n = 144) with upper respiratory infections multi-centre cross-sectional diagnostic test accuracy study (prospective enrolment) 	FebriDx compared with clinical algorithm of standard reference tests ^c	Bacterial: 80% Viral: 87%	Bacterial: 93% Viral: 83%	Bacterial: 63% Viral: 64%	Bacterial: 97% Viral: 95%	
Davidson (2017) ³ UK	<ul style="list-style-type: none"> n = 21 children and adults with upper or lower respiratory infections retrospective chart review 	FebriDx with clinical assessment versus clinical assessment alone (within subject)					Change in clinical management = 10/21 (48%); Reduced antibiotics = 8/10 (80%)
Sambursky and Shapiro (2015) ¹³ US	<ul style="list-style-type: none"> n = 60 adults with sore throat (n = 19) or lower respiratory tract infection (n = 41)^d single-centre, diagnostic, case-control study (prospective enrolment) 	[FebriDx] immunoassay compared with standard reference tests ^d	Bacterial: 80% Viral: 70% ^f	92% ^f			

^a Three patients excluded (two because of incomplete reference standard tests and one because of an invalid FebriDx test).

^b Reference tests include: bacterial cultures, respiratory polymerase chain reaction panels, procalcitonin, white blood cell count, with expert physician override in patients presenting with confirmed fever (55%) versus history of fever (45%) within the prior three days.

^c Reference tests include: bacterial cultures, polymerase chain reaction test using the FilmArray Respiratory Panel, Epstein-Barr virus testing, polymerase chain reaction panels, white blood cell count, with MxA protein enzyme-linked immunosorbent assay & CRP immunoassay testing) with expert physician override.

^d Results available for 54 patients; 6 invalid/indeterminate tests because of sample problems.

^e For example: viral PCR, bacterial cell culture, ELISA measurement of C-reactive protein and MxA, urine samples, and white blood cell count.

^f Results for pharyngitis and lower respiratory tract infection combined.

WHAT IS THE EVIDENCE

Four studies of the FebriDx test were identified.^{3,7,10,13} This includes three US diagnostic test accuracy studies that looked at the agreement between FebriDx and various reference standard tests, and test sensitivity, specificity, and positive and negative predictive value.^{7,10,13} One UK retrospective chart review studied the impact of using FebriDx on patient management and antibiotic prescribing.³ There is currently no gold standard test for differentiating between bacterial and viral respiratory infections.¹⁰ Consequently, the comparator reference standard tests used in the studies varied. Study characteristics and findings are presented in Table 1.

In addition, a July 2017 briefing by the UK National Institute for Health and Care Excellence (NICE) concluded that “... there was very limited evidence in terms of quantity and quality to assess the FebriDx test.”¹⁴ This brief was published before the 2018 US,⁷ and the 2017 US¹⁰ and UK,³ study results were available.

SAFETY

The main concern with any diagnostic test is the impact on patient care as a result of a missed, delayed, or incorrect test result.²⁰ Untreated bacterial infections may be self-limiting or may cause serious illness, while the ineffective treatment of viral infections with antibiotics can cause adverse reactions, as well as contributing to antimicrobial resistance.¹³ No clinical adverse events were reported in the studies of FebriDx.³

ISSUES TO CONSIDER

The cost of the FebriDx test, and staff time providing the test, may be offset by the reduced use of unnecessary antibiotics and their associated adverse effects.¹⁴ One UK specialist commented that it could reduce hospital stays through the more timely administration of antibiotics to patients with pneumonia.¹⁴ A recent US review speculated that using FebriDx in primary care may decrease the need for

point-of-care streptococcus and flu tests and reduce these costs.⁴

A European commentary on point-of-care tests for respiratory tract infections suggested that incentives to primary care physicians may be needed to encourage the adoption of these first-generation technologies.⁸

Unlike other rapid tests for bacterial infection, the FebriDx does not require laboratory access or equipment, such as a benchtop analyzer.^{4,14}

The FebriDx test cannot identify which particular bacteria or virus is causing the infection.^{4,13} FebriDx is not intended to provide a final diagnosis but is rather an additional decision aid for the primary care practitioner. One UK specialist comment in the NICE briefing was that C-reactive protein testing had been shown to reduce prescriptions for antibiotics, but that the benefit of adding MxA still needed to be demonstrated.¹⁴

Most of the evidence to date has been in adult populations and more studies in children are needed.⁷

In the UK, where the FebriDx test is available, training is provided by the distributor.¹⁴ One specialist commentator for the UK NICE briefing noted that the FebriDx test is “... simpler than benchtop analyser tests and can therefore be used by health care assistants with minimal training.”¹⁴ The use of the test may lengthen the patient-health provider consult time (to accommodate the wait for test results); however, unlike with benchtop analyzers, multiple tests could be run concurrently.¹⁴

RELATED DEVELOPMENTS

Other studies of FebriDx are planned or underway. One UK study, expected to be completed in July 2018, is assessing its use in urgent care. A UK health technology assessment, which will compare FebriDx to stand-alone CRP testing, is planned to

start in the summer of 2018 (Dr. Robert Sambursky: personal communication, 2018 April). A further study, using a new quantitative version of FebriDx, will begin in the fall of 2019 (Dr. Robert Sambursky: personal communication, 2018 May 15).

Other investigators and manufacturers are assessing single biomarkers (such as CRP or procalcitonin) or different combinations of biomarkers to differentiate bacterial and viral respiratory infections.^{4,21} Other rapid point-of-care tests for respiratory infections are also entering primary care practice; for example, the cobas Liat System (Roche Molecular Diagnostics) and Alere i (Abbott) tests for influenza.²²

LOOKING AHEAD

Using point-of-care tests to differentiate between bacterial and viral respiratory infections may improve the appropriate prescribing of antibiotics in primary care and contribute to antibiotic stewardship.¹⁴ A recent US study found that the majority of patients with respiratory tract infections in six primary care clinics would be willing to have a blood test to help determine whether antibiotic treatment could be avoided.²³

Author: Leigh-Ann Topfer

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Focus On: Drone Applications in Health Care

Unmanned aerial vehicles (UAVs), commonly known as drones, originated in the military.¹ Today, commercial drones are readily available to businesses and individuals.¹ As drone technology evolves, it may offer solutions for expanding the delivery of health services to Canadians living in communities where access is restricted by long distances and limited or seasonal road access.

DRONE TECHNOLOGY

A drone is any vehicle that can be operated without a person on board – in some cases, autonomously.^{1,2} Most people are familiar with airborne drones used recreationally, or for research or commercial purposes (such as aerial photography).¹ Although drones vary in shape, size, speed, and other features, a general distinction can be made in the way they fly: fixed-wing (like a small airplane) or rotor-wing (like small helicopters).¹ They can be launched by being thrown, catapulted, launched from pneumatic (compressed air or gas-powered) launchers, or using conventional runway systems.² Drones can often fly longer than traditional human-piloted aircraft and can be customized with sensors and equipment (such as cameras and storage compartments), making them appealing for research and commercial purposes.¹

In Canada, the number of drones being used for non-recreational purposes was expected to exceed 87,000 in 2017.¹ Globally, companies such as Zipline,³ Drone Delivery Canada,⁴ Matternet,⁵ and Vayu⁶ all currently deploy drones to deliver medical supplies and laboratory samples.

POTENTIAL USES IN HEALTH CARE

Research into health care applications of drones abounds; however, the literature we identified is currently limited to simulations, feasibility studies, and theoretical models, and does not evaluate health outcomes.⁷⁻²⁰ Reports of organizations using drones to provide health care services are also plentiful.²¹⁻²⁵

Real-World and Simulated Uses

Transporting Medical Equipment, Supplies, and Biological Samples

In Canada, paramedics in Renfrew County just outside Ottawa have been testing multi-rotor



Photo: iStock/sarawuth702

drones to deliver automated external defibrillators (AEDs) to rural residents since 2016.²¹ In Sweden, researchers have conducted real-world simulations using drones to deliver AEDs to bystanders who have witnessed an out-of-hospital cardiac arrest.^{7,8}

Moose Cree First Nation in northern Ontario is experimenting with drone delivery for key supplies, including medical supplies, over the 2.5 km stretch of water separating the island community from the mainland.²²

Elsewhere, fixed-wing drones have been used in Rwanda since 2011 to deliver blood supplies over mountainous terrain without paved roads,²³ while in Madagascar and Malawi, drones are being tested and used to deliver patient samples to central labs.^{24,25} In a series of feasibility and proof-of-concept studies, researchers at Johns Hopkins University in Baltimore have studied how drone delivery affects routine laboratory tests,⁹ blood

samples,¹⁰ blood products,¹¹ and microbes in blood and sputum samples.¹²

Mass Casualty and Disaster Medicine

Researchers in Prince Edward Island compared the time taken to identify seven hazards in a simulated mass casualty incident in groups of paramedic students who surveyed the scene using a drone or by approaching it on foot.¹³ Similarly, the feasibility of using drones to facilitate information-sharing in a simulated motor vehicle accident has been studied in Norway.¹⁴

Researchers in Italy have also explored the feasibility of using drones for aerial mapping in response to a natural disaster.¹⁵

Theoretical Work

Researchers in Toronto¹⁶ and Salt Lake City¹⁷ have created models to help optimize the placement of drones in urban and rural settings with the goal of minimizing response times for delivering AEDs to bystanders who have witnessed an out-of-hospital cardiac arrest.

Models have also been created to explore how drones could assist in the distribution of blood products,¹⁸ complement existing medical transportation networks,¹⁹ and pick up and drop off supplies for people with chronic diseases living in rural areas.²⁰

REGULATION OF DRONES IN CANADA

Transport Canada is responsible for commercial drone operation under the *Canadian Aviation Regulations*.²⁶ Canadians wishing to use a drone for non-recreational purposes must first acquire a Special Flight Operations Certificate from Transport Canada.²⁷ In order to operate a drone beyond the visual line of sight, Canadian drone pilots must also obtain a Compliant UAV Operator Special Flight Operations Certificate.²⁷

Since 2014, Transport Canada has provided exemptions that allow some non-recreational drones to be operated without a Special Flight Operations Certificate.¹ However, these exemptions generally require the drone be flown within the visual line of sight of the operator.¹ In 2018, new regulations for drone operation are expected to eliminate the distinction between recreational and non-recreational use, replacing it with a risk-based approach that depends on drone size and operating environment (for example, rural versus urban).^{1,28}

WHAT DOES IT COST?

The costs of using and maintaining a drone or network of drones to transport medical supplies are not well-understood.²⁹ Early research modelling potential costs has been conducted.^{20,30} In these studies, costs considered included initial drone purchases, the set-up of deployment centres, operation, maintenance, labour, and replacement purchases. A formal cost-effectiveness study is underway in Toronto (Dr. Timothy Chan, Associate Professor, University of Toronto, Toronto, ON: personal communication, 2018 May 7).

IMPLEMENTATION ISSUES

Were a drone or a network of drones to be implemented and used for health care purposes in Canada, decision-makers would have to consider a number of issues including safe operation, effects on biological samples, infrastructure, training, practitioner acceptance, and privacy.

Safe Operation

Transport Canada's regulation of drones exist largely to ensure public safety.¹ Risks posed by drones include collisions with other aircraft or obstacles, crashes, and injury to bystanders retrieving items from a landed drone.^{1,7,14}

Compared to conventional aircraft, the small size and light weight of drones makes them more vulnerable to turbulence, icing, and extreme cold, which can lead to loss of control and crashes.³¹

Effects on Biological Samples

How conditions such as altitude, acceleration, and temperature changes associated with flight affect biological samples must be considered and has been explored in early research, including how these samples can be best packaged for delivery.⁹⁻¹²

Infrastructure

One study that considered how best to implement an AED drone delivery network identified specific infrastructure considerations.¹⁷ For example, in order for a drone network to provide maximum coverage, new launch locations may need to be built; existing buildings, such paramedic or ambulance stations, could be retrofitted; or some combination of both approaches may make sense.¹⁷

Training

While exceptions can be made, it is likely the proposed drone applications in health care

discussed earlier would require a Special Flight Operations Certificate or Compliant UAV Operator Special Flight Operations Certificate.^{1,27} Obtaining these certificates requires the operator to meet a number of skill and knowledge requirements.³²

Practitioner Acceptance

Buy-in from practitioners may also be necessary before deploying drones. A pilot study by researchers in the Boston area evaluated the acceptability of using drones to provide real-time support to mass critical incident commanders using qualitative interviews after a simulated incident.³³ Participants were asked to consider how the technology affected the overall management of the scene, resource allocation, and patient triage.

Privacy

Using drones to deliver medical supplies or patient lab samples, or take pictures or record videos, may have implications for patient privacy if operators are not a part of the circle of care.^{14,29,34} Caution must be taken to prevent unauthorized access to live or recorded video, and picture or other health information contained within or transmitted by the drone.^{14,34} Clear ownership of data captured by drones must also be established to ensure that secondary use of the content (e.g., for research) is used ethically.¹⁴

LOOKING AHEAD

Other proposed health care applications include military medical evacuation,³⁵ patient transportation,³⁶⁻³⁸ locating potential drowning victims,³⁹ delivery of portable DNA sequencing equipment for infectious diseases,⁴⁰ remote detection and monitoring of vital signs,⁴¹ and mapping infectious disease areas.⁴²

A systematic review to identify real-life and simulated applications of drones in health care is currently underway.⁴³

Author: Jeff Mason

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Mini-Roundup:

Recent Reports From CADTH and Other Agencies

CADTH Resources on Rural and Remote Health Care

- [Detection and Diagnosis of Sepsis in Rural and Remote Areas: An Environmental Scan](#) (project in progress)
- CADTH reports relevant to rural and remote health care are listed within a new Evidence Bundle: [CADTH Evidence Bundle: Evidence Related to Rural and Remote Health](#)

CADTH Horizon Scan Roundup 2017

- Part 2 of the [Horizon Scan Roundup 2017](#) is now available. This list reports on new and emerging technologies published by CADTH and other agencies in the second half of 2017.

Recent Horizon Scanning Reports From Other Agencies

Agencies Included in the Mini-Roundup That Follows:

- [Agency for Healthcare Research and Quality \(AHRQ\)](#), US
- [Cleveland Clinic](#), US
- [National Institute for Health and Care Excellence \(NICE\)](#), UK
- [The Medical Futurist](#)
- [Sax Institute](#), Australia
- [ECRI Institute \(ECRI\)](#), US

Endocrine, Nutrition, and Metabolic

- [Mobile Health Applications for Self-Management of Diabetes](#) (AHRQ)

Infectious Disease and Infection Control

- [Point-of-Care Diagnostic Testing in Primary Care for Strep A Infection in Sore Throat](#) (NICE)

Palliative and Long-Term Care

- [The Patient Centred Medical Home: Barriers and Enablers to Implementation](#) (Sax Institute)

Other

- [Rating Portable Diagnostic Devices That Make Patients the Point-Of-Care](#) (The Medical Futurist)
- [The Future of Emergency Medicine: Innovations Making Patients the Point-of-Care](#) (The Medical Futurist)

Trends and Forecasts

- [Top 10 Medical Innovations for 2018](#) (Cleveland Clinic)
(See: #5, The Emergence of Distance Health.)
- [2018 Top 10 Hospital C-Suite Watch List](#) (ECRI)

Strategic Initiatives

- [Final Report: Summit to Improve Health Care Access and Equity for Rural Communities in Canada](#) (The College of Family Physicians of Canada; Society of Rural Physicians of Canada)
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