





### **CADTH Horizon Scan**

# List of 2021 Health Technology Trends to Watch

A Compilation of Emerging Health Technology Trends and Devices to Watch in 2021



#### ISSN: 2563-6596

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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### **Key Messages**

Among others, the trends and technologies featured in this Watch List include:

- · developments in artificial intelligence within imaging technologies
- greater integration and connectedness of **wearables** to improving patient monitoring systems
- proliferation of transcatheter valve devices driving innovations for interventional cardiology
- increasing interest and development of non-pharmacological solutions for pain management
- rapid growth in technologies and digital services enabling virtual care.

The CADTH Horizon Scanning Service identifies and monitors new and emerging health technologies with the potential to have a significant impact on health care in Canada. This Watch List focuses on those categories of medical devices, clinical interventions, or other health technologies that are, or may become, important or disruptive to Canadian health care or decision-making in the next few years.

Summaries of information about the use, effectiveness, cost, and implementation of emerging technologies are published regularly in CADTH Horizon Scanning Issues in Emerging Technologies and Health Technology Updates.

### **About This Document**

The CADTH Horizon Scanning Service identified emerging trends among medical devices, clinical interventions, and other health technologies, as described by health and broader technology organizations from across the world. The search for new and emerging technologies involved a targeted search of websites and databases that described technologies that had either received an FDA Breakthrough Devices Designation or were considered to be innovations with potential health system impact now or over the next few years (typically within 2 to 5 years). These information sources included the scientific literature, media outlets, international health technology assessment institutions and forums, manufacturers, and government bodies. Information on technology trends to watch in 2021 is summarized according to broader categories that either align with overall Canadian health system priorities or were areas where innovation had been noted. Along with their forecasts, CADTH consulted with the Device Advisory Committee (consisting of federal and provincial health technology regulators, decision-makers, and health care professionals) to further contextualize and prioritize emerging technologies that may become disruptive to the Canadian health care system. The Watch List is not an exhaustive review of information about new technologies, but rather provides an overview of emerging health technologies that could change and impact Canadian health care within the coming years. The list is not an endorsement of any 1 of these technologies and is for information purposes only.

This Watch List covers a range of new and emerging technologies relevant to different conditions, models of health care delivery, and tools used to improve patient care. While some technologies have only recently been developed or received regulatory approval, others are further along in the product life cycle and are used in clinical practice. All technologies included, however, share the potential to make significant disruptions to the Canadian health



care system in the coming few years. Ten categories of specific trends, and devices within each, are presented and are listed alphabetically.

#### **3-D Printing and Bioprinting**

Additive manufacturing, or 3-D printing (3-DP), is the process of creating 3-D objects, layer by layer, from raw materials — such as plastics or powdered metals — guided by a digital design file. In health care, 3-D printing promises to disrupt procurement practices and supply chains by allowing health care facilities to produce needed equipment and supplies on-demand and onsite. 3-D printing may also benefit patients by allowing for the creation of customized implants and other personalized devices, like prosthetics, and by allowing clinicians to plan and practice complex procedures on 3-D printed models before surgery. Bioprinting is a 3-DP technique that uses living cells (e.g., stem cells) and supportive biocompatible materials (i.e., scaffolds) as living bio-inks to build living tissues such as cartilage or skin. Long-term goals of bioprinting include creating or regenerating organs and tissues, ultimately replacing the need for donor banks. Examples of 3-DP and bioprinting applications that have recently emerged include:

- Converting BiPAP machines into ventilators. Formlabs became the first manufacturer to use 3-DP to create small T-shaped adaptors made of plastic that allow BiPAP – bilevel positive airway pressure, which is typically used to treat conditions like obstructive sleep apnea – to be converted into mechanical ventilators in the event of a shortage; for example, due to COVID-19.
- Hand-held bioprinter for the treatment of severe burns. Developed by researchers in Toronto, this prototype device, now in its 10th iteration, applies a bio-ink of stem cells, stripe by stripe, forming a uniform layer over burn wounds to encourage tissue regeneration and reduce scarring.
- Low-cost ventilators. In response to the COVID-19 pandemic and the potential need for ventilators that could be quickly and inexpensively deployed in any location, a US-based team developed a ventilator that could be manufactured in-hospital from 3-D printed parts and low-cost springs in 8 to 10 hours. The cost is about US\$10.

#### **Artificial Intelligence**

Artificial intelligence (AI) and machine learning form, together, a branch of computer science concerned with the development of systems that can perform tasks that would usually require human intelligence, such as problem-solving, reasoning, and recognition. Because of factors such as advanced computing power, ability to understand and interpret algorithms, and ability to obtain large datasets sourced from medical records and wearable data, AI has the potential to transform the delivery of health care and address issues related to improving patient outcomes and health system sustainability. AI-based systems are already being used in all provinces and some territories in Canada to support patient care. In radiology, for example, AI tools are used clinically in imaging departments across Canada to reconstruct images, lower radiation dose, and to read and interpret imaging exams. Along with technical innovation in AI, there is a need to understand the ethical, legal, and equity-related issues

associated with the use of AI tools. AI applications are being used to support system efficiencies and patient care, and to advance clinical research. Examples of recent innovations in AI include:

- Al for brain CT exam analysis. This Al-enhanced software automatically detects and notifies health care professionals of critical brain abnormalities after analysis of CT scans, such as intracranial hemorrhage and large vessel occlusion in stroke.
- Al-enhanced breast cancer diagnosis. QuantX is a computer-aided breast cancer diagnostic system that uses Al-enhanced software to extract data from magnetic resonance images to detect breast lesions and diagnose and support biopsy procedures.
- Al sepsis predictor. An algorithm that uses an explainable Al model for the early prediction of sepsis risk in real time.
- Al-enhanced speech therapy (ST). The ST app combines Al and real-world data to provide cognitive, speech and language therapy to people who have had a stroke.
- Al-enhanced wheelchairs. The Wheelie uses facial recognition AI to improve user mobility by processing and translating facial expressions into real-time wheelchair commands.

#### Augmented Reality and Virtual Reality

Augmented reality (AR) technology involves modifying or enhancing the real-world environment in real time using computer-generated information such as text, images, or sounds that could be helpful or informative to clinicians or patients. In virtual reality (VR), users (typically patients) don a headset to enter computer-generated worlds and experiences designed to immerse, engage, or calm. AR and VR have the potential to alter how health care providers are trained and how patients are diagnosed and treated in fields ranging from pain medicine to physiotherapy, to ophthalmology. Examples of innovative applications of AR and VR include:

- Medical imaging and interventional radiology. AR and VR are emerging as potential tools for changing how images captured through CT and MRI can be used to support training, improve communication with patients or colleagues, and plan and execute clinical procedures.
- Smart contact lenses for low or impaired vision. Mojo Lens is a contact lens with a built-in display that uses AR to discreetly enhance the wearer's visual environment (e.g., enhancing contrast or brightness) and support activities of daily living such as navigation or reading.
- VR distraction therapy. Pain, anxiety, and distress are often experienced by people undergoing common medical procedures. An assessment by Health Technology Wales explored the potential of VR to deliver distraction therapy in these situations.
- VR for chronic pain. EaseVRx is a VR headset that combines audio and video programs to deliver cognitive behavioural therapy, mindfulness, relaxation, and other self-management skills. It is being developed for people with conditions such as fibromyalgia or chronic low back pain to reduce the need for opioid treatment and is intended for use in home or hospital settings.



#### **Connected Devices and Wearables**

Connected devices are physical objects that can connect to each other and other systems via the internet. The use of these types of devices in the medical context is often but not exclusively to provide health care in places outside of the hospital environment such as in homes or ambulances. A subcategory of connected devices are wearable devices, which are items embedded with small, inexpensive electronic sensors that can be comfortably worn and are typically used in patient monitoring. These technologies allow both patients and their health care providers to have up-to-date information about their health status. With the arrival of new delivery methods, such as the first smart pill approved in 2017 by the FDA, patients and practitioners will have decisions to make about balancing privacy with innovative and effective care. Examples of emerging connected devices and wearables include:

- **Digital prevention for sleep disturbance.** Nightware is an approved\_non-drug intervention for adults who have nightmare disorder or nightmares associated with post-traumatic stress syndrome. The device uses biometric data gathered from an Apple Watch to anticipate nightmares before they begin and interrupts the nightmare with a gentle vibration, without waking up the individual.
- **Respiratory sensor for depression**. Respiratory is a chest-worn wireless sensor that detects when the wearer is facing opioid-induced respiratory depression, or OIRD a common and often fatal side effect of using opioid drugs. The biosensor monitors and analyzes respiration and, when it detects OIRD in the wearer, the device sends an alert to first responders.
- Smartphone-connected ultrasound devices. This group of emerging devices are point-of-care ultrasound devices intended for use by trained clinicians at the bedside or in a clinical office setting. These devices are smaller, more compact, and less expensive than conventional ultrasound devices. The rationale for their use is allowing a clinician to answer a specific clinical question at the time of treatment without having to see an imaging specialist.
- Stroke rehabilitation sensor. The MedRhythms device uses music in conjunction with sensors to help people living with the effects of stroke improve their walking deficit. The sensors attach to an individual's shoes, calculate an individual's current stride, and begin to play music through headphones. The device can be used to support a change in the speed of walking by changing the tempo of the music.
- Wireless maternal and fetal monitoring. The Novii Wireless Patch System is a technology that measures the heart rates of a singleton fetus and the birthing person, as well as the activity of the uterus during labour. The system is attached to the lower abdomen of the birthing person with multiple adhesive patches and connects wirelessly to the monitoring unit. Because the device is wireless, it allows for the birthing person to move around during monitoring.

#### **COVID-19 Testing and Identification**

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, was first detected in late 2019. Since then, nearly 100 million cases of SARS-CoV-2 have been detected and more than 2 million people have died of the virus.



The approval and initial stages of the rollout of vaccines for COVID-19 began in December 2020 and are presumed to be the start of a reduction in transmission and thus a reduction in the number of cases of COVID-19 worldwide. With the volume of vaccine production, the number of people wanting to be vaccinated, and the uncertainty regarding the lasting immunity for COVID-19, testing will remain an important and evolving factor in the management of the pandemic. (See COVID-19 Testing: A Summary of Testing Methods – CADTH Covid-19 Evidence Portal). Rapid, accessible testing and sample collection may be of particular importance as access to vaccines and vaccination rates increase. Testing innovations and approvals are happening rapidly: at the time of this writing, the testing trends to watch include home testing, home sampling, and direct-to-consumer sampling. Examples of technologies to watch in 2021 include:

- Home sampling. The Switch Health home sampling kit for COVID-19 specimen sample collection at home has been approved in Canada. The company also offers step-by-step instructional support via videoconference to aid with specimen sample collection; samples are sent to the lab for polymerase chain reaction testing. Several manufacturers have received FDA Emergency Use Authorization, or EUA, for prescription-based self-collection kits. The IBX test uses saliva samples. The Pixel test kit allows consumers to take their own sample, send it to the lab, and receive test results via email or internet, without a prescription.
- Home testing kits. In the US, the Lucira all-in-one, COVID-19 prescription test kit and the Ellume test kit allow users to collect their own samples (via nasal swab), run their own tests, and receive results from home or from a location of choice.
- SARS-CoV-2 and influenza co-testing. Several manufacturers have received Health Canada authorization for lab-based COVID-19/influenza co-tests. As well, both Roche and Cepheid have developed co-tests that have been approved for point-of-care testing.
- Al decision support for radiology. XrAl is the first Al tool in radiology to receive Health Canada authorization as a Class III Medical Device. The decision support tool provides real-time X-ray data to aid in confirming the presence of pneumonia in those with suspected COVID-19.

#### Interventional Cardiology

Advances in cardiac medical devices and procedures may offer new therapeutic options for people living with atrial fibrillation and heart failure, and assist with preventing associated infections. Technological innovations in Al and wearables are driving many of the therapeutic developments in interventional cardiology. Examples of innovations in this category include:

- Cardiac venous pressure reliever. The preCARDIA device is a balloon catheter with a pump controller intended to quickly reduce congestion in the venous system via intermittent superior vena cava occlusion. By managing the blood flow in the superior vena cava, the device may help improve overall cardio-renal function in patients with acutely decompensated heart failure.
- Implant for pulmonary arteries. The Aria CV PH System is an implanted balloon intended to treat pulmonary hypertension and reduce cardiac workload. The device aims to restore damaged arteries in the lungs by inflating and deflating in unison with the heart and facilitating appropriate blood flow.

- **Portable blood-clotting sensor**. <u>ClotChip</u> is a hand-held sensor that measures bleeding risk by a finger prick blood test in people at risk of excessive bleeding. The device can provide rapid and point-of-care testing for people being treated in emergency or trauma situations, people with hemophilia, or individuals using anticoagulants.
- **Temporary IV catheter**. The DORAYA catheter device relieves congestion in patients with acute heart failure for up to 12 hours. The device can reduce venous pressure and improve the efficacy of diuretic therapy, which is the most common treatment for hospitalized patients with acute heart failure.
- Transcatheter valves. Several emerging devices like the Cardiovalve, Harpoon, TriClip, among several others, are valve repair systems that can be used to treat a spectrum of heart valve@related diseases. These devices can be delivered via minimally invasive surgical procedures, removing the need for performing open-heart surgery.

#### **Minimally and Less-Invasive Diagnostics**

Diagnostic tests are essential to the delivery of safe, high-quality, and affordable health care, and have become indispensable for diagnosing and monitoring disease, for providing prognoses, and for predicting treatment responses. Technological advances in minimally and less-invasive diagnostic tests facilitate faster and more accurate testing, can be less painful to the patient, may be more cost-effective, and can provide insight that guides decisions on patient care. Recent innovations in diagnostics include:

#### **General Diagnostics**

- **Microscopic needle tests.** Tiny microneedles (less than the width of a human hair) are attached to a syringe or patch and can reach the epidermis without contacting (or barely contacting) the nerve endings in the dermis. This technology may deliver painless injections and may allow for rapid blood testing without any finger-pricks.
- Point-of-care antibiotics suitability tests. C-reactive protein PoC tests can rapidly assess specific blood C-reactive protein levels that are elevated in bacterial infections but not in viral infections. Several trials show that these tests may help guide antibiotic prescribing in patients with respiratory tract infections in primary care settings and improve antibiotic stewardship.
- Sepsis diagnosis. LiDia-SEQ is an assay that performs DNA sequencing on a microchip at the point of care to provide rapid sepsis diagnosis. Prototypes of the device indicate that it may detect over 1,000 different bacteria and 35 different antimicrobial resistance markers.

#### **Oncology Diagnostics**

- Cancer treatment companion diagnostics. ArcherDX and Oncotype DX are next-generation sequencing tests that can detect neurotrophic receptor tyrosine kinase gene fusions that lead to cancer cell growth. These emerging tests may help inform cancer therapy decisions by ensuring treatments are effective for patients' specific tumour profiles.
- Early detection tests for liver cancers. Next-generation sequencing test <u>HCCscreen</u> and biomarker-based algorithmic model <u>Elecsys GALAD</u> score rely on minimally invasive serum samples to detect hepatocellular carcinoma.
- Liquid biopsies. This is an emerging, minimally invasive approach to detect cancer within plasma and other fluids. (See An Overview of Liquid Biopsy for Screening and

Early Detection of Cancer – CADTH Issues in Emerging Health Technologies). Ongoing developments in genomics technology provide a promising outlook on devices that may allow for rapidly detecting, diagnosing, and monitoring cancer growth for several cancers including breast, lung, and colon cancers, without the need for invasive tumour biopsies. For example, the Guardant360 CDx device uses next-generation sequencing to guide radiotherapy treatment decisions for metastatic non-small cell lung cancer and has been recently approved in the US.

#### **Neuromodulation and Neurostimulation**

Neuromodulation involves the alteration of nerve activity through the targeted delivery of a chemical, electrical, or other stimulus to specific neurologic sites in the body. Neurostimulation devices deliver electrical stimulation to sites in the brain, spine, or peripheral nerves via transcranial or transdermal techniques, or implanted electrodes. These therapies are used to manage and treat a range of health conditions, with some common indications being chronic neuropathic pain, Parkinson disease, essential tremor, and mental health issues. The diverse application of neuromodulation in health care continues to foster broad interest in the field, innovation, and significant activity in research and development of new devices for various conditions. These technologies seek to provide relief or help people recover from conditions that have a neurologic basis and may bring improvement in quality of life. Some examples of emerging devices include:

- Chronic migraine therapy. The Salvia BioElectronics company is developing a neurostimulation system as a treatment for refractory chronic migraine. A highlighted characteristic of this system lies in its use of thin and conforming bioelectronic foils that the company says uniquely adapt to the anatomy of the head. The technology, which is about to enter the clinical trial stage, aspires to be the first approved, commercially available neurostimulation option for migraine care.
- Home-based therapy for Alzheimer disease. MemorEM delivers transcranial electromagnetic stimulation to the brain via a head cap equipped with 8 bioengineered emitters. The neurostimulator seeks to act on and decrease the accumulation of the protein beta-amyloid in the brain to treat Alzheimer disease. A pivotal clinical trial is being planned and is expected to start in mid-2021.
- Implantable pulse generator. SetPoint Medical is a neurostimulation platform being developed for the treatment of chronic inflammatory autoimmune diseases, with an initial focus on rheumatoid arthritis. By stimulating the vagus nerve to activate the inflammatory reflex, the device aims to achieve a beneficial immune response that contributes to reduce inflammation and provide relief to affected individuals. The company is currently preparing a pivotal clinical trial to evaluate the technology.
- Magnetic brain stimulation. NeuroStar is an emerging therapy that uses transcranial magnetic stimulation to target and activate areas of the brain that may be involved in depression and other psychiatric disorders. It is under consideration by the US FDA as a potential treatment for people living with bipolar depression.
- Pharyngeal stimulation. The Phagenyx neurostimulation device, which is approved in Europe, aims to restore the neurologic control of swallowing and help affected people overcome dysphagia a common side effect of stroke and traumatic brain injury. A treatment catheter incorporating 2 electrodes and connected to a portable base station



is inserted in the pharynx through the nose and delivers electrical stimulation to the pharyngeal area.

#### Pain Management

Chronic pain is estimated to affect approximately 19% of adults in Canada resulting in substantial physical and psychological morbidity and cost to the health care system. Current guidelines recommend the use of non-opioid pharmacotherapy and non-pharmacological interventions in caring for chronic non-cancer pain. The ability to deliver this type of care partly rests on the availability of effective and reliable non-pharmacological solutions designed to treat and manage different pain-related conditions. Amid a range of unmet needs in chronic pain care, new and innovative medical devices are proposed on a regular basis to address this challenge and help individuals affected by this condition. Two emerging devices are:

- Laser treatment for lower back pain. The Erchonia FX-635 system offers a non-invasive, laser-based option for the treatment of chronic lower back pain. It involves pinpoint delivery of light therapy to the pain sites with the use of a low-level (non-thermal) laser, which aims to reduce inflammation and trigger beneficial bio-stimulation of cells at the musculoskeletal spot that generates the pain.
- **Spinal implant**. Barricaid\_is designed to correct lumbar disc hernia with large annular defects. The device, which consists of a titanium anchor connected to a polymer component for filling in the annular defect, is meant to be fitted to the spine during initial surgery. The potential benefits of this implant include reducing the risk of reherniation and reducing the risk of further surgery.

#### **Regenerative Medicine**

Regenerative medicine involves restoring or establishing normal functioning by replacing, repairing, or regenerating body organs, tissues, and cells that have been damaged by disease, trauma, or congenital issues. The 3 main strategies used in regenerative medicine include cell-based therapy, the use of biologic or synthetic material to lead repair processes and cell growth, and the implantation of scaffolds seeded with cells. Canada's stem cell and regenerative medicine research network supports projects that address health challenges including type 1 diabetes, cancer, blood disorders, heart disease, multiple sclerosis, cystic fibrosis, and muscular dystrophy. Recent innovations in regenerative medicine may provide potential cures or improve the quality of life of people living with these conditions. Examples of recent innovations include:

- Autologous hematopoietic stem-cell transplantation. This is a one-time procedure for relapsing-remitting multiple sclerosis intended to end the reliance on disease-modifying drugs and reduce episodes of relapse and disability progression.
- Spinal cord regeneration. CelluBridge is a cellulose scaffold implant that regenerates healthy spinal cord tissue to restore motor function. It was granted an FDA Breakthrough Device Designation in November of 2020.



#### **Technologies to Support Virtual Care**

Virtual care is a model of care facilitated by a range of technologies that aim to help health care providers deliver care remotely to their patients. Some of these technologies include audio and video conferencing, secure messaging, and patient monitoring systems. These technologies offer many benefits to patients such as improved access to services, convenience, and a greater involvement of patients and caregivers. (See CADTH Policy Insights – Enablers for Virtual Visits.) While virtual care has existed in Canada for many years, 2020 and the COVID-19 pandemic ushered in a new wave of rapid expansion and uptake. Virtual care is expected to see increased investment from public and private institutions, spurring further development to enhance integration with patient records, contribute to more robust AI prediction models, and improve access to high-demand services. Questions about what services return to being in-person and what services continue to expand within virtual care, and about how best to structure the care that remains virtual (such as privacy legislation, scope of practice, and interjurisdictional licensing), will be pertinent in 2021 and beyond. Some examples of emerging innovations in virtual care include:

- **Digital pharmacy**. Pillway is an online digital pharmacy that, in addition to preparing and delivering prescriptions, connects patients to pharmacists, integrates data with electronic medical records, and uses AI to send personalized reminders.
- **Physician consultation applications**. Babylon, Maple, and Tia Health are digital health applications and online services that connect patients to licensed primary care physicians through video consultations. Physicians can remotely obtain medical histories of patients, provide referrals, order tests or imaging, and write prescriptions.
- **Remote monitoring devices**. Cloud DX and TytoHome are just 2 example of emerging remote monitoring devices that connect with a smartphone or use smartphone cameras to assess various biophysical markers, including blood pressure, oxygen levels, temperature, and heart rate. These devices may especially help facilitate follow-up of remote patients; for example, after surgery.
- Self-management applications. The myCOPD digital application is for patients with chronic obstructive pulmonary disease, or COPD, to support in the self-management of symptoms remotely with resources and guides for pulmonary rehabilitation. It may help improve outcomes and provide an alternative for patients who face challenges in making in-person health care visits.
- Virtual therapies for substance use disorders. reSET-0 and CHESS Health are examples
  of emerging digital applications that provide patients affected by substance use disorders
  with virtual therapeutic sessions to support their recovery. In particular, patients with opioid
  use disorder who are unable to access face-to-face care may benefit from having ongoing
  access to clinicians and therapists through their smartphone.