

Health Technology Update

CADTH

A newsletter on new and emerging health care technologies in Canada

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IN THIS ISSUE

Informing Decision-Makers About Emerging Medical Technologies

Health Technology Update presents brief articles about new, emerging, or innovative health technologies. As in our *Issues in Emerging Health Technologies*, readers will find information about the potential benefits and challenges of a cross-section of health care technologies in the *Updates*. Some of the technologies may be licensed only for use outside of Canada, while others are in their earliest stages of development or are being used only in clinical trials. Still others may be recently licensed for use in Canada but are not yet widely used.

We hope you find this issue informative and useful for your decision-making, and welcome your comments and suggestions for future issues.

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FEEDBACK

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

Let us know!

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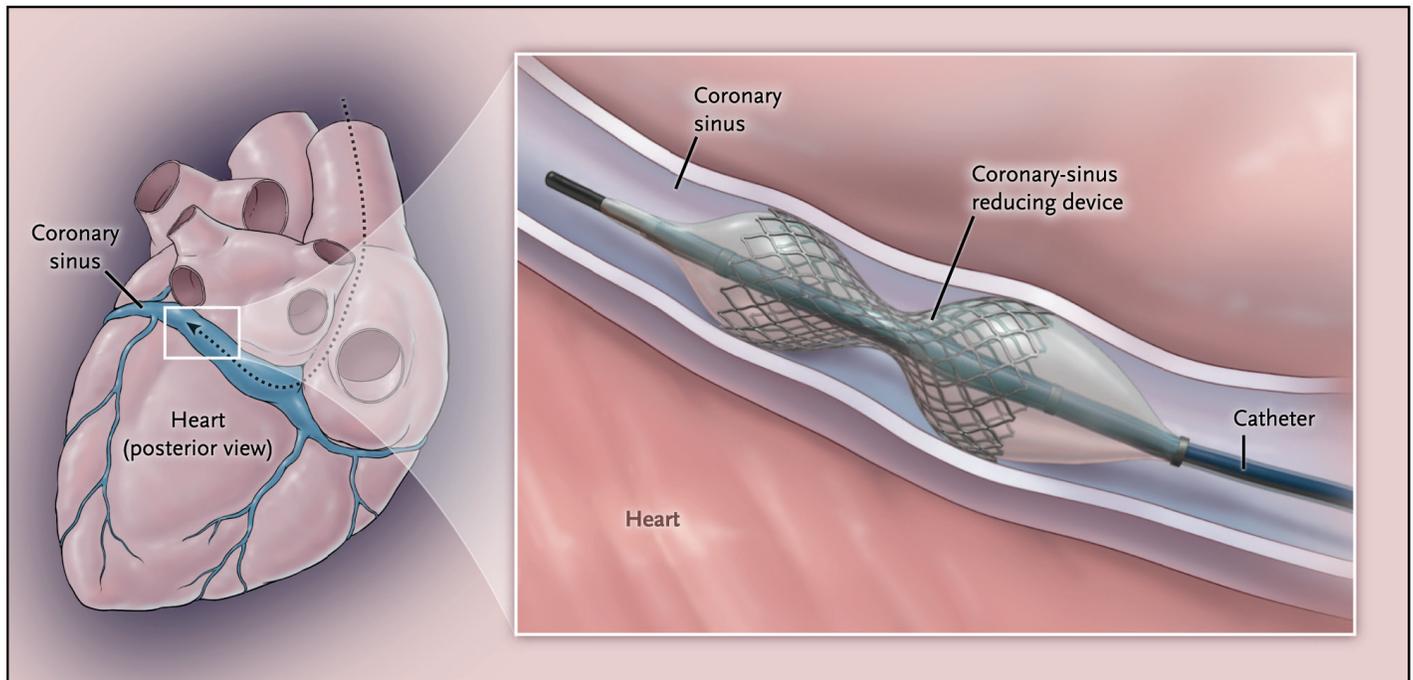
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The Reducer: A New Device for the Treatment of Refractory Angina



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Angina is a chronic condition that prevents adequate blood flow to the heart muscle (called ischemia). Symptoms include severe chest or upper body pain, nausea, fatigue, dizziness, and shortness of breath. Angina restricts the activities of daily living, which in turn affects quality of life.¹

Most people with angina find some symptom relief through medications. Others may also need cardiovascular interventions, such as coronary stents, angioplasty, or bypass surgery.² Despite these treatments, some patients have uncontrolled, or refractory, angina. The Reducer is intended for these patients.

HOW IT WORKS

Originally developed in Israel in the 1990s,³ the Reducer (Neovasc Inc., Richmond, British Columbia) is an hourglass-shaped, mesh stent made of stainless steel. To implant the Reducer device, an interventional cardiologist makes an incision in the right jugular vein in the neck. Next, a thin tube (catheter) is inserted through the incision and slid into the coronary sinus — a large vein in the heart that collects blood from smaller blood vessels. The Reducer is then passed through the catheter into position.

The device causes narrowing of the coronary sinus, resulting in a slight backwards

pressure to increase blood flow into the small vessels of the heart. The procedure takes about 20 minutes and patients are usually released from hospital the next day.⁴

Any effects of the intervention on blood flow are not obvious until several weeks or months post-implantation,^{4,5} and there is still some uncertainty about the mechanism of action.^{5,8}

MARKET AVAILABILITY

The Reducer does not have a medical device licence from Health Canada, nor is it yet approved by the US FDA. It does have European conformity (CE marking) that allows it to be marketed in Europe.⁹

WHAT DOES IT COST?

In 2010, Neovasc estimated the selling price of the Reducer to be anywhere from \$3,000 to \$5,000.¹⁰

WHO MIGHT BENEFIT?

More than 500,000 Canadians have refractory angina¹ and the number is expected to increase as Canadians live longer.

WHAT IS THE EVIDENCE?

The Canadian Cardiovascular Society (CCS) classifies angina severity into four broad categories, from mild grade I to severe grade IV. However, the placebo effect makes it difficult to assess angina treatments^{2,6,11} and applying the CCS categories is influenced by

a patient's activity level, pain tolerance, and ability to cope with the stress of angina.¹² Canadian guidelines conclude that only low- to moderate-quality evidence is available on most interventions for refractory angina.¹

The main evidence for the Reducer is from the COronary Sinus Reducer for Treatment of Refractory Angina (COSIRA) trial⁶ — a phase 2, randomized controlled trial sponsored by Neovasc that included 104 patients at 11 centres (including two in Canada). The treatment group received a Reducer stent implant and the control group underwent a sham procedure. In the treatment group, 18 of the 52 patients (35%) improved by at least two CCS grades at six months post-procedure compared with 8 of 52 patients (15%) in the control group. Most patients in both groups did not improve by more than one CCS grade, so the benefit for the treatment group was considered modest.⁶ There was no significant difference between the two groups for other outcome measures, such as improved exercise time. The Reducer was not implanted in two patients in the treatment group because of anatomical differences in their coronary sinuses.

During the six-month COSIRA trial, one patient in the Reducer group had a heart attack (around the time of the procedure), while three patients in the control group had heart attacks and one patient died.⁶ In total, 76 adverse events — 10 serious — were reported in the treatment group, and 93 — 24 serious — in the control group. Quality of life scores using the Seattle Angina Questionnaire improved by 17.6 points (on a scale of 100) in the Reducer group compared with 7.6 points in the control group.

A small observational study, also sponsored by Neovasc, reported experiences with the Reducer at two centres in Israel and Germany.¹³ The device was successfully implanted in 21 of 23 patients (91%), and the analysis was based on data from 20 patients.¹³ No device-related adverse events were reported during the follow-up and the

average CCS angina class score improved from 3.3 at baseline to 2.0 at six months.¹³

An earlier “first-in-man” safety study of the Reducer in 15 patients at one site in Germany and two sites in India reported that all implantations were successful and no device-related adverse events occurred.¹⁴ A follow-up on 14 of these patients noted that angina class improvements were sustained three years later.¹⁵ Three- and eight-year follow-up of 10 of the patients treated in India reported no patient deaths, and sustained improvement in CCS class.^{16,17} However, average ejection fraction (a measurement of heart functioning) and exercise duration were not significantly improved.¹⁸

SAFETY

The COSIRA study protocol lists potentially serious adverse events of the Reducer stent, including coronary sinus thrombosis, or blockage, and venous hypertension, or high blood pressure.¹¹ None of these events have been reported in the studies to date, but they could potentially occur in the future, beyond the current period of follow-up.

A patient registry, REDUCE-1, has been established to assess the safety and efficacy of the Reducer in patients who received the device through compassionate use outside of the clinical trials.¹⁹

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The Gastric Emptying Breath Test: A Tool to Assist the Diagnosis of Gastroparesis

The Gastric Emptying Breath Test (GEBT) (Advanced Breath Diagnostics, LLC, Brentwood, Tennessee) is a non-invasive test to determine how quickly solid food exits the stomach. It was approved by the US FDA in April 2015 as a tool to assist in diagnosing delayed emptying of the stomach, or gastroparesis, in adults.¹ The manufacturer is in the process of applying for CE marking for marketing the GEBT in Europe but does not have immediate plans to seek approval from Health Canada (Kerry Bush, Advanced Breath Diagnostics, Brentwood, TN: personal communication, 2015 Oct).

The GEBT is not to be used in people who are allergic to spirulina (an edible algae), eggs, milk, or wheat, or in people with known diseases of the liver, pancreas, small intestine, or lungs.¹

HOW IT WORKS

Patients who may have gastroparesis eat a small meal of eggs, crackers, and *Spirulina platensis*, a blue-green algae that is a food source in many places around the world.² The algae is grown under special conditions to increase the amount of Carbon-13 (¹³C) — a naturally occurring, non-radioactive isotope of carbon — in its cells.² When the algae leaves the stomach and is digested in the small intestine, Carbon-13 is released and exits the body through the lungs in a form of carbon dioxide (CO₂) that has a higher amount of Carbon-13 than normal.³ By comparing the amount of Carbon-13 to the amount of Carbon-12 (¹²C), which we usually get from our food, in the CO₂ we exhale, the GEBT provides an indirect estimate of how quickly solid food has left the stomach.³

After a patient fasts overnight, a health care provider collects two breath samples from the patient to determine a baseline level of ¹³CO₂ in the patient's breath. Six more breath samples are collected at 45 minutes, 90 minutes, 120 minutes, 150 minutes, 180 minutes, and 240 minutes (four hours) after the test meal is eaten. The samples are then sent to a central laboratory where gas isotope-ratio mass spectrometry is used to compare the amounts of ¹³CO₂ and ¹²CO₂ in the samples at the time points

collected.¹ The change in the amount of ¹³CO₂ compared with the amount of ¹²CO₂ over time is used to calculate how quickly the meal exited the stomach, and is then compared to measurements from healthy people to help diagnose delayed gastric emptying.²

WHO MIGHT BENEFIT?

Gastroparesis is a disorder in which food in the stomach takes a long time to move into the next part of the digestive tract. There is nothing blocking the exit of the stomach; rather, the muscles in the stomach do not work properly to push food along normally.⁴ People with gastroparesis often report symptoms such as nausea, vomiting, an unusual feeling of fullness after eating very little food, unusual fullness after a meal, bloating, and pain in their upper abdomen.⁴ Gastroparesis significantly reduces quality of life and is associated with higher health care costs due to additional visits to doctors and the emergency room, and increased hospitalization.⁴

The number of people in Canada who may suffer from gastroparesis is unknown.⁵ Research in the US estimates that gastroparesis affects about 0.2% of the population.⁴ The number of people affected is higher among those with diabetes mellitus (5% of people with type 1 diabetes and 1% of people with type 2 diabetes) and



Image courtesy of Advanced Breath Diagnostics

higher for those in hospital.^{4,5} Gastroparesis is also more common in women.⁴ While up to five million people in the US may experience delayed gastric emptying, only 17 to 35 people out of 100,000 (0.017% to 0.035%) suffer from severe gastroparesis.^{4,6}

WHAT DOES IT COST?

The commercial price of the GEBT is currently unavailable. However, breath samples can be collected in a clinic or at the bedside without special equipment, facilities, or specialized health care providers and then sent off-site for analysis. This may be more cost-effective than other methods of diagnosing gastroparesis, such as the gold standard, scintigraphy.^{2,7} In Canada, scintigraphy can cost between \$125 and \$150 for the specialist's time alone.⁸

The GEBT test meal has a three-year shelf-life.¹

CURRENT AND ALTERNATIVE PRACTICES

Alternatives to the GEBT include the gold standard for diagnosing gastroparesis, scintigraphy, and newer technologies, such as wireless capsules and other non-radioactive carbon isotope breath tests.⁴

For scintigraphy, patients eat a small meal labelled with the radioactive element technetium.⁴ Images are taken using a gamma camera after the meal and at

several additional times during the next four hours.⁹ Because the test meal is radioactively labelled, scintigraphy is not suitable for use in pregnant or breastfeeding woman, and care should be taken to reduce radioactive exposure when repeat testing or testing in children is required.⁷

With wireless capsules, patients swallow a small pill with a sensor that measures the time it takes for it to travel from the stomach to the small intestine. The sensor detects changes in acid levels, temperature, and pressure.^{4,10} As the pill moves through the patient's digestive tract, data are wirelessly sent to a receiver worn by the patient. The data on this receiver are then analyzed to give an estimate of how quickly the stomach emptied. Both the cost of the wireless capsule and the time needed to complete the test are possible limitations to the use of this technology.^{1,7}

Breath tests for gastric emptying were first proposed more than 20 years ago and are often used in pharmaceutical testing and other research settings.^{11,12} Since their introduction, a number of stable carbon isotope breath tests have been developed, including EXPIROGer (Sofar Farm S.r.l., Bucharest, Romania)¹³ and the Gastric Motility Octanoate Breath Test (Metabolic Solutions, Nashua, New Hampshire).¹⁴ Both these tests use Carbon-13-labelled octanoic acid mixed into a muffin meal.^{15,16} Both tests have reported similar results to the GEBT.^{15,16} Exalenz Bioscience Ltd. (Modiin, Israel) is also working to adapt its BreathID Hp technology, currently used for diagnosing *Helicobacter pylori* infections, for a similar purpose.^{17,18} Because breath tests for gastroparesis indirectly measure gastric emptying, questions remain about how to standardize the testing process and how to calculate and interpret the results.^{19,20}

WHAT IS THE EVIDENCE?

The FDA approval of the GEBT was primarily based on the results of two studies.¹ In the first study, Szarka et al.³ provided a standardized, shelf-stable test

meal to 124 adult patients suspected of having abnormal gastric emptying, and to five healthy adult volunteers who were given atropine to delay gastric emptying. The test meal contained egg labelled with technetium and Carbon-13-labelled *Spirulina platensis* to compare scintigraphy and GEBT results at the same time, in the same patient.³ A total of 115 patients completed the study. Compared with scintigraphy, the GEBT was found to be good at detecting patients without gastroparesis (high specificity) but was not good at detecting patients with the disease (low sensitivity). A subsequent study validating a slightly different way of mixing the Carbon-13-labelled algae and egg because of a change in the test meal supplier found similar results with the new test meal.²

SAFETY

Over the course of its development, the GEBT has been given to 321 adults.¹ According to the manufacturer, the test has now been used in more than 2,000 patients participating in pharmaceutical research studies (Kerry Bush: personal communication, 2015 Oct). No serious adverse events have been reported and other adverse events (e.g., nausea, heartburn, dizziness) were considered minor by the FDA.¹

As of 2013, US guidelines for the management of gastroparesis provide a conditional recommendation (pending further validation) for using breath tests, including the GEBT, to diagnose gastroparesis.⁴ With the additional validation^{2,3} now available, the GEBT may soon be a clinical alternative to more invasive diagnostic tests currently used for people with suspected gastroparesis, particularly in patients or settings where scintigraphy may not be appropriate or available.

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Granulox Hemoglobin Spray for Non-Healing (Chronic) Wounds

Chronic wounds that don't heal are a burden for patients and a substantial health care cost.¹⁻³

More than 4,000 wound care products are estimated to be commercially available, but their availability and use varies between programs and jurisdictions. Also, good-quality evidence on the clinical- and cost-effectiveness of most wound treatments is lacking.⁴

HOW IT WORKS

Oxygen is essential to wound healing: it helps wounds close and it reduces infection.⁵⁻⁷ Many different therapies to promote wound oxygenation have been investigated, including hyperbaric oxygen and topical oxygen gas.¹

Granulox (infirst Healthcare/SastoMed) is a spray-on oxygen treatment for chronic wounds.⁵ The spray is made of 10% hemoglobin (derived from pigs' blood), 0.7% phenoxyethanol, 0.9% sodium chloride, 0.05% N-acetylcysteine (an antioxidant), and water.^{5,8} The hemoglobin helps bind oxygen from the air and improves oxygenation of the wound.^{3,5} Granulox is sprayed directly onto the wound at every dressing change (at least once every three days).² It is intended as an add-on treatment for non-healing wounds in addition to standard wound care.

WHO MIGHT BENEFIT?

Good data on the prevalence of chronic wounds in Canada are not available. European estimates are that 1% of the population is affected by chronic wounds and 2% of health care budgets are spent on their treatment.¹ In Canada, one-third to one-half of the more than 1.5 million Canadians receiving home care need wound care.⁴

People most likely to benefit from Granulox therapy are those with non-healing wounds associated with peripheral artery disease or diabetes; for example, leg and foot ulcers caused by poor blood flow.^{1,9} The elderly and those confined to wheelchairs or beds are also at risk for non-healing pressure ulcers.

MARKET AVAILABILITY

Granulox is commercially available in Europe¹⁰ but not yet in Canada or the US; infirst Healthcare has applied for an investigational device exemption (IDE) with the US FDA and has also indicated it will start licensing applications in Canada in late 2015 or early 2016 (Manfred Scheske, infirst Healthcare, London, UK: personal communication, 21 September 2015).

WHAT IS THE EVIDENCE?

The largest trial of Granulox to date included 72 patients with chronic venous leg ulcers at a single centre in the Czech Republic.⁹ Patients were randomly assigned to receive standard wound care plus daily Granulox spray, or standard wound care alone. After 13 weeks, patients in the Granulox group had an average reduction in wound size of 53%; patients who received only standard wound care had an average enlargement in wound size of 21%.^{9,10}

A small, randomized trial of Granulox conducted in Mexico included 28 patients with chronic leg ulcers.⁸ In the trial, 13 of the 14 patients in the Granulox treatment group (93%) had wound healing at six months compared with one of the 14 patients (7%) in the standard care group. Subsequently, these patients, along with additional patients with chronic wounds, also received Granulox treatment for a total of 42 treated patients. Thirty-nine of the 42 patients had complete wound healing.

In the UK, several small, non-randomized studies of Granulox treatment have been conducted. A single-centre study of 20

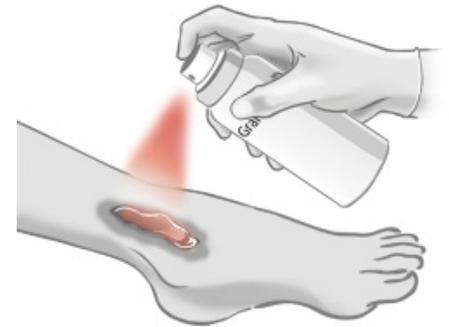


Image courtesy of infirst Healthcare/SastoMed

patients with non-healing diabetic foot ulcers assessed the percentage of wound reduction after four weeks of treatment with Granulox.² Granulox was administered twice weekly with dressing changes but patient care was otherwise unchanged. Most patients (75%) applied the Granulox spray themselves. All 18 health care providers reported that the product was extremely easy to use, and the 15 patients who administered Granulox themselves rated it as either "extremely easy" or "easy" to use. All wounds were free of slough (dead tissue) at the end of the study. Average wound size reduction was 62% (ranging from 18% to 100%).²

A second UK study reported on 25 patients with various sloughy (not necessarily non-healing) wounds in community care who were treated with Granulox twice weekly at dressing changes for a period of four weeks.¹¹ With the exception of one pediatric patient, all patients applied Granulox themselves. By the third week, all wounds were free of slough and 76% of patients had complete healing within either the four-week treatment or five-week follow-up period.

In another small UK study, 17 patients with non-healing venous leg ulcers were treated with Granulox.⁵ Three patients were withdrawn from the study, and the results were based on the remaining 14 patients. Granulox, applied on average twice weekly in addition to standard wound care, reduced wound size by an average of 68% (range: 15.5% to 96%) by the end of the four-week study.⁵

A study of 18 patients at four UK sites examined the effect of treatment with Granulox on pressure ulcer healing in addition to standard care.³ At four weeks, the study found an improvement in wound healing in all 18 wounds and a reduction in the size of the wounds in 17 wounds. The average wound size after Granulox treatment was reduced to 3.39 cm² from 11.23 cm² and all patients reported pain reduction.³ More frequent applications of Granulox did not appear to affect the outcomes.

SAFETY

Most studies reported no adverse events with the use of Granulox, but case reports from Mexico reported nine adverse events in two patients, including local inflammation, skin irritation, burning sensations, and pain.⁸

A recent UK consensus statement funded by Infirst Healthcare includes a treatment pathway that incorporates Granulox therapy and highlights gaps in the evidence where further research on this treatment is needed.⁷

WHAT DOES IT COST?

The UK price of Granulox is £125 (C\$254) per can. Each can contains 30 applications, at a cost of £4.17 per application (approximately C\$8.55) (Manfred Scheske, Infirst Healthcare, London, UK: personal communication, 21 September 2015). Treatment may last up to three months, and Granulox should be applied at every wound-dressing change.⁷ The optimal application schedule is not yet known.⁶

The Scottish Health Technologies Group assessed Granulox in a 2014 *Innovative Medical Technology Overview*.¹⁰ The overview included a German economic evaluation which found that, although using Granulox adds an additional cost to each dressing change, if using it shortens healing time (i.e., fewer dressing changes overall), it will offer cost savings.¹² However, the overview concluded that this evaluation was not of sufficient quality to inform policy in Scotland.¹⁰

ISSUES TO CONSIDER

Granulox contains hemoglobin derived from pigs' blood. This may pose challenges for patients whose religious beliefs forbid the use of treatments derived from pigs or other animals.¹³

Because it is easy to apply, Granulox may allow greater patient self-care and reduce nursing staff time.^{2,11}

If further studies find that Granulox improves the healing of other types of wounds — such as burns, surgical wounds, and other non-chronic wounds — a much larger patient population could be eligible for this treatment.

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Closed-Loop Insulin Systems: The Artificial Pancreas

In type 1 diabetes, the immune system destroys the cells in the pancreas that produce insulin and glucagon (hormones that help the body regulate blood sugar and convert food to energy). Most people with type 1 diabetes are diagnosed at a young age, and there is currently no way to prevent or cure this disease.¹ Individuals with type 1 diabetes need to monitor their blood sugar levels and take external insulin multiple times a day by injection, insulin pen, or insulin pump.

Diabetes can lead to hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar), and may eventually cause serious complications, including kidney and cardiovascular disease, blindness, and nerve damage. Health care use and costs are substantially higher for those with diabetes due to more frequent physician visits and increased hospitalizations.^{1,2}

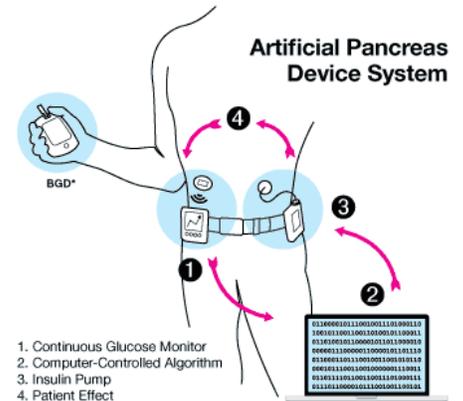


Image reprinted from US FDA³

HOW IT WORKS

A closed-loop insulin system (or artificial pancreas) mimics the body's ability to produce and regulate insulin. By using continuous blood sugar (or glucose) readings from a monitor, computer software determines the amount of insulin a pump delivers based on a patient's target levels. The artificial pancreas is called "closed-loop" because the system regulates itself, like a loop, with the final readings affecting how the cycle begins again. This system alleviates most of the need for a patient to monitor blood sugar levels and to calculate and deliver the insulin he or she needs throughout the day and night.

As defined by the US FDA, an artificial pancreas system is made up of four components:³

1. A continuous glucose monitor — a sensor implanted beneath the skin to provide continuous measurement of glucose in the fluid around the cells. The monitor is calibrated with readings from finger prick testing and a blood glucose meter.
2. An insulin infusion pump — a device that delivers insulin subcutaneously.
3. A control algorithm — a computer program that uses the readings from

the glucose monitor to determine how much insulin is needed and sends this information to the insulin pump.

4. The individual patient — whose blood sugar levels change depending on diet, level of activity, and individual metabolism.

Although the terms "artificial pancreas" and "bionic pancreas" are often used in the media, current systems are not yet completely closed-loop. With current open-loop systems — which use continuous glucose monitors and insulin pumps — patients or caregivers must still check blood sugar readings and determine how much insulin they need.

WHO MIGHT BENEFIT?

Of the 2.4 million Canadians with diabetes, between 5% and 10% have type 1 diabetes. By 2019, the total number of Canadians with diabetes may increase to 3.4 million.² Some of these individuals are already using parts of a closed-loop insulin delivery system — continuous glucose monitors that measure blood sugar levels, and insulin pumps that deliver insulin without the need for injections (without the computer program that connects the two). These patients will most likely be the early users of closed-loop insulin systems.⁴ Some people with type 2 diabetes may also benefit from artificial pancreas systems in the future.

WHAT IS THE EVIDENCE?

There are three recent evaluations of closed-loop insulin systems:

- A 2015 report from the United Kingdom's National Institute for Health Research Horizon Scanning Research & Intelligence Centre (NIHR-HSRIC) identified 18 different artificial pancreas device systems, most in the early stages of development.⁵ The review describes the different types of systems and includes the perspectives on these devices from both health care experts and patients.⁵
- A 2015 alert, also from NIHR-HSRIC, reviewed the evidence on the Inreda artificial pancreas — one of the devices closest to being ready for commercial marketing.⁶ The Inreda system has a dual pump set up for delivery of both insulin and glucagon. According to the manufacturer, Inreda Diabetic BV, the system may be available in Europe in the latter half of 2016.⁶
- A 2014 assessment from the US Blue Cross Blue Shield Technology Evaluation Center looked at a low-glucose suspend system — a possible step toward a true artificial pancreas.⁷ Intended to prevent episodes of hypoglycemia, this system automatically stops insulin delivery for two hours if glucose levels are low

and the patient has not responded to a warning alarm. The review concluded that there was insufficient evidence to determine health outcomes or potential benefits of low-glucose suspend systems compared with established alternatives.⁷

WHAT DOES IT COST?

No totally automated closed-loop systems are commercially available. Some companies anticipate their systems may be on the market in Europe by late 2016.⁵ Others believe these systems are further off on the horizon — up to seven or eight years away from being commercially available.^{4,8,9}

The ECRI Institute noted that closed-loop insulin systems will cost more than continuous glucose monitors and insulin pumps combined (more than US\$10,000, with annual maintenance and supply costs of US\$1,500 to \$2,000).¹⁰ In Canada, insulin pumps cost from \$6,500 to \$7,500,¹¹ and the estimated annual costs of insulin pump accessories and supplies is about \$7,000.¹² Continuous glucose monitors cost approximately \$2,000, with additional costs for batteries, chargers, and replacement sensors.¹³ Evidence is needed to determine if the higher costs of closed-loop systems will be offset by reduced costs in treating complications from diabetes.

WHAT ELSE IS HAPPENING?

The artificial pancreas is one of the Cochrane Collaboration's priority topics for review.¹⁴ In Canada, researchers at the IRCM — Institut de recherches cliniques de Montréal — are comparing the effectiveness of an artificial pancreas using insulin alone to a dual-hormone (both insulin and glucagon) system and to standard insulin pump therapy.⁹ Google has also entered the field of diabetes care through commercial partnerships with Sanofi and Dexcom to develop smaller and less expensive continuous glucose monitors, and better ways to collect and use patient data.¹⁵

This is an important area of research and development, and one CADTH will continue to watch closely.

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Focus On: Wearable Health Technologies

Wearable technologies (or wearables) are items embedded with small, inexpensive electronic sensors that can be comfortably worn — such as clothing, watches, and jewellery.¹ These devices can monitor heart rate, sleep patterns, or physical activity.² Because wearables can easily collect and share health information, they are becoming increasingly popular with several emerging health movements. They are favoured by the personal health movement because they can be worn for self-care or monitoring, with or without health care provider supervision.³ They are also an essential part of the mobile health (or mHealth) movement because of the ability of these small devices, with their built-in sensors, to send information from patients' homes to health care providers at a distance.⁴ And the ability of wearables to track, collect, and share many different pieces of data about their users makes them an ideal fit for the quantified self movement and its focus on collecting data on all aspects of our daily lives — what we do, feel, use, and consume.⁵

HOW BIG IS THE MARKET?

Many companies sell wearables designed with personal or research use in mind.^{6,9} By the end of June, 2015 Fitbit led the world in shipments of such devices, followed by Apple, Xiaomi, Garmin, and Samsung.¹⁰

In 2013, Forbes² estimated the wearables market would bring in revenues of US\$8 billion, with growth projections to US\$20 billion by 2017. More recently, the International Data Corporation reported that, during the second quarter of 2015, manufacturers of wearables had shipped 18.1 billion units worldwide up from 5.6 million units in the same quarter of 2014, or a 223.2% increase.¹⁰ In Canada, a total of 1.4 million wearable devices, with an average price of \$257, are expected to be shipped by the end of 2015.¹¹

WHAT KIND OF RESEARCH IS UNDERWAY?

Because of their potential uses in health care, it is not surprising to find a great deal of available published research on wearables. Recent studies include their use in tracking physical activity and weight loss,¹²⁻¹⁷ sleeping patterns,¹⁸⁻²¹ mobility,²² and blood pressure,²³ as well as evaluating the accuracy of the data captured by different devices.²⁴⁻³¹

A search of clinical trial registries found many additional studies of wearables that are recruiting participants.³²⁻³⁶

ISSUES TO CONSIDER

Accuracy of data

One of the current areas of wearables research is the accuracy of the data these devices collect. Studies comparing commercial wearables with research wearables have found that the data collected by commercial wearables vary by device and activity being measured.^{8,30,37} This means that health care providers and researchers must ensure they select the right device for their purposes.

Too much data

The proliferation of wearable technologies means that users could be constantly collecting many types of data, and from more than one device.⁵ How quickly large amounts of data can be accumulated is illustrated by Apple's claim that its fitness lab has already collected more than 33,000 hours of data to develop its Apple Watch health features — possibly more than any other organization, public or private, in the world.³⁸ The ability of any single person to generate extremely large amounts of health data presents questions about how and if it will be possible to interpret and use this information to achieve better health outcomes.⁵

Fragmented data

People are free to choose the wearable device or devices that best suit their needs. For consumers, health care providers, and researchers to get the most out of any device, the manufacturer must allow the data their products collect to be interpreted and used by other platforms and devices, even those of competitors.^{39,40} Not all manufacturers are willing to share data and this has begun to lead to health data silos, as well as questions about data ownership and use.^{39,41} Lack of cooperation among manufacturers may further complicate the already complex process of collecting, storing, and interpreting data, and poses a barrier to achieving useful health information and outcomes.^{5,42}



Privacy of data

As wearable devices collect and transmit health data, protecting individual privacy is a concern.³ Unfortunately, the responsibility for regulating the collection and sharing of this data is unclear.⁴³ For example, in the US, this type of health data collection isn't regulated by the FDA, and the Federal Trade Commission has indicated it intends to play a larger role.⁴³ People who use wearables may unwittingly give control of their personal health information to manufacturers – many of whom are not bound by health privacy legislation.^{42,43} Although there is much excitement about the potential for these devices to improve one's health, users must also be aware that their self-monitoring may add another layer of surveillance to their lives.³

Self-diagnosis

Wearables have created a perhaps unintended way for patients to diagnose themselves.^{44,45} Increasing patient involvement in their own health management through the use of wearables is not a bad thing. However, as more people collect large amounts of data about themselves, health care providers will need to evaluate how useful this additional information is, particularly as it compares to standard health tests.^{4,45}

Need for better evidence

Whether wearables actually help people achieve healthier lifestyles is still uncertain. While there are currently many small studies available, there is a lack of reliable evidence to help consumers and health care providers determine if wearables are beneficial.⁴⁶ A Rapid Review conducted by CADTH in 2015⁴⁷ found a lack of evidence supporting the use of wearables to measure heart rate in hospital and rehabilitation settings. Similarly, a recent systematic review of activity trackers as an intervention for improving physical activity found that wearables are being used as an intervention, but that there is a lack of high-quality studies assessing the impact of these devices on health outcomes.⁶

WHAT DOES THE FUTURE HOLD?

We have seen wearables evolve from basic devices that do not run third-party software (e.g., fitness trackers) to "smart" wearables that support applications developed by third parties.¹⁰ This trend toward "smart" devices is expected to pose significant challenges to manufacturers of basic devices, as they try to stay relevant in the face of increasing competition.^{10,48}

Given Fitbit's position in the global market, it is not surprising to see that much of the existing and planned research focuses on Fitbit technology.^{12,14,22,32,35,49} What future research will look like now that Google and Apple have declared their intent to support research on wearables remains to be seen.^{9,43,50}

As sensors become smaller and use less power, wearables may move from our wrists and ankles to our ears and eyes, and even inside our bodies.⁵¹ While the current focus is on physical activity and general health, the potential for wearables to help improve the quality of life for people with specific health conditions or disabilities might transform health care in the future.⁵²

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Mini-Roundup

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ENROUTE Transcarotid Neuroprotection and Stent Systems (HSRIC)

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