How "digital therapeutics" differ from traditional health and wellness apps

Cite as: *CMAJ* 2019 October 28;191:E1200-1. doi: 10.1503/cmaj.1095801

Posted on cmajnews.com on Oct. 10, 2019

The term "digital therapeutics" may sound like Silicon Valley jargon for the wide array of health apps you can download onto a phone or tablet. Traditional health and wellness apps generally do little more than track activities such as sleep or exercise. Digital therapeutics, however, belong to a class of sophisticated, evidence-based software that can complement or even replace prescription drugs for managing certain health conditions.

A type 2 diabetes management program called BlueStar, for example, helps users address problems in real time, such as what action to take for a particular blood glucose reading or what they should order in a restaurant to maintain a healthy blood sugar balance.

Such capabilities elevate BlueStar, developed by Maryland-based Welldoc Inc., from being just another health app to one that is prescribed by physicians and meets Health Canada's requirements for a Class II medical device. These kinds of products are introducing new health care possibilities, according to Natalie Dakers, president and CEO of Vancouver-based Accel-Rx.

"We're not just compiling data but are actively engaging with the patient, gathering clinical evidence and directly affecting the treatment of the patient," she says. "That's the element that distinguishes digital therapeutics from other health and wellness apps."

Her organization serves as a business accelerator that helps companies tailor their commercial strategies and introduces them to prospective investors, who are becoming more interested in this sector. Dakers points to the creation of a US-based industry organization, Digital Therapeutics Alliance, as an indication of high expectations for the market and the medical potential of these technologies. She adds that the field is still in its infancy in Canada, where a few fledgling software firms fall into the category, which doesn't yet have a regulatory framework.

iStock.com/TARIK KIZILKAYA

Digital therapeutic products are more sophisticated than simple health tracking apps.

Health Canada is working on regulations, however, and recently circulated a draft guidance document on software as a medical device (SaMD). The document includes digital therapeutic products as part of its SaMD definition but acknowledges that innovation and advances may eventually necessitate specific regulations for such products.

In the meantime, well-established American digital therapeutic companies have been expanding into Canada. In 2015, Health Canada issued a medical device establishment licence to Wisconsin-based Propeller Health, allowing the company to sell its software for managing asthma and chronic obstructive pulmonary disease. Welldoc obtained clearance for BlueStar last year and is marketing its product to Canadian enterprises in hopes of the product being covered by health care plans for employees diagnosed with diabetes.

Anand Iyer, Welldoc's chief strategy officer, notes that SaMD products must not only meet Health Canada's requirements for quality and safety but also have a high degree of cybersecurity. Sensitive information can be shared through the software with a patient's physician, a pharmacist, a lab technician, and the company's physician support team, an

information flow he regards as the defining characteristic of digital therapeutics.

The emerging sector has caught the attention of the pharmaceutical industry, including the company Sanofi, which is exploring how digital therapeutics can complement prescription medications. "It's clear that through behaviour change, through education, through engagement and making the right choices, you can take steps to improve how you manage your disease," Rachel Sha, vice-president of digital business development and licensing for Sanofi, told an audience at the Biotechnology Innovation Organization's international convention earlier this year.

At the same time, a few dissenting voices have criticized SaMD products for occupying a regulatory grey area. Nathan Cortez, a law professor at Southern Methodist University in Dallas, Texas, argues that the US Food and Drug Administration relies on nonbinding guidance documents rather than strict regulations when it comes to software.

"Rarely does a class of technologies excite physicians, patients, financiers, gadgeteers, and policymakers alike," he wrote in *UC Davis Law*. "But for mobile health to begin to reach its immense potential — saving millions of lives, cutting billions in spending, and democratizing medicine — federal regulators will have to provide meaningful oversight, ensuring that these technologies are safe and effective."

The Canadian government, for its part, has been attempting to do just that, according to Health Canada communications advisor André Gagnon. For medical devices, Health Canada has requirements for labelling, quality management, safety and effectiveness. The SaMD draft guidance document has generated feedback that will shape revisions to the regulations that were applied to the products from Welldoc and Propeller Health. "The regulatory classification principles outlined in this document ultimately dictate the general application submission requirements for SaMD, which would include several digital therapeutic software products."

Tim Lougheed, Bath, Ont.