CADTH COVID-19 PANDEMIC

COVID-19 CADTH HORIZON SCAN

Wearable Devices for Monitoring and Detecting COVID-19 Symptoms

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To produce this report, CADTH used a modified approach to the selection, appraisal, and synthesis of the evidence to meet decision-making needs during the COVID-19 pandemic. Care has been taken to ensure the information is accurate and complete, but it should be noted that international scientific evidence about COVID-19 is changing and growing rapidly.

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Author: Kendra Brett

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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Context

Coronavirus disease (COVID-19) is associated with numerous symptoms, including new or worsening cough, difficulty breathing, fever and fatigue, and in severe cases, death.[1] COVID-19 is very contagious and is spread primarily from an infected person through respiratory droplets and close, prolonged contact. One of the strategies to reduce the transmission of COVID-19 is to minimize close contact with others (i.e., physical distancing).[2] Physical distancing, in order to reduce the exposure of health care workers (and other patients) to the virus, can create challenges in monitoring and detecting COVID-19 symptoms.

Canada's COVID-19 pandemic guidance recommends that innovative technologies, such as remote monitoring tools and digital devices, are used in order to divert patients from health care facilities.[3] Medical devices that facilitate remote monitoring of patients with COVID-19 (e.g., from home, or from a distance within a health care facility) could help limit the spread of COVID-19 and help reduce the strain on the health care system. As COVID-19 symptoms can take up to 14 days to appear,[4] wearable devices could be used to monitor people who have been exposed to COVID-19 for the development of symptoms, and to monitor individuals who have tested positive for COVID-19 and are pre-symptomatic.

Wearable devices that can assist with early detection of symptoms and facilitate safer monitoring of patients could play a role in addressing the COVID-19 pandemic.

How It Works

Wearable technologies are devices such as wrist or arm bands, patches, or watches, that are embedded with small, inexpensive sensors that allow for continuous monitoring. Various types of wearable devices are available that monitor activities or vital signs such as:

- physical activity level
- sleep quality
- blood oxygen saturation
- heart rate
- respiratory rate
- skin temperature.

Some of these devices operate independently, while others are paired with an app on a smart phone or computer. Wearable devices can be consumer grade (i.e., widely available to the public) or medical grade (i.e., require prescription or supervision by a health care provider). The focus of this article is on wearable devices that have the potential to be used to monitor symptoms and warning signs of COVID-19.

Consumer-grade wearable devices

The Oura Ring[5] is worn on the finger and is paired with a smart phone app. It measures physical activity during the day and heart rate, temperature, respiratory rate, and sleep quality overnight. It is lightweight and water-resistant, and offers wireless charging with a battery that lasts up to seven days.

The WHOOP strap[6] is a heart rate monitor, worn on the wrist that is paired with a smart phone or computer app. It monitors heart rate 24 hours a day that is used to calculate respiratory rate, sleep quality, and physical activity. It is lightweight, waterproof, and has up to five days of battery life.

The Fitbit tracker[7] is worn on the wrist and is used in conjunction with an app (smart phone or computer based). It monitors physical activity and sleep quality, and also measures heart rate 24 hours a day that it uses to calculate heart rate variability, resting heart rate, and breathing rate. The app can also be used to conduct surveys (e.g., symptoms). The battery lasts up to seven days.

The Apple Watch Series 5[8] continuously measures heart rate and physical activity, and it connects to an electrocardiogram (ECG) app on an iPhone. To measure heart rhythm with the ECG app, the user must intentionally touch the screen with their finger for 30 seconds. Apple released the Apple Watch Series 6 on September 18, 2020, and it is similar to the Series 5 device but with the addition of a sensor to measure blood oxygen level.[9]

Medical-grade wearable devices

The Shirley Ryan AbilityLab[10] wearable is a wireless biosensor that sits at the base of the throat to monitor cough intensity, temperature, respiratory activity (e.g., sounds, difficulty), and heart rate 24 hours a day. Data are transmitted to a protected cloud where it can be accessed by health care professionals. It is a soft, flexible silicone patch about the size of a postage stamp. This wearable was specifically designed for COVID-19.

The Philips Biosensor BX100[11] is an electronic, single-use wearable skin patch that is used by health care professionals to monitor patients who are isolated but who do not require ventilation. It is placed on the chest and measures respiratory rate and heart rate every minute; the data are transmitted to a hub that is used to monitor multiple patients across multiple rooms. The biosensor also measures, posture, activity level, and ambulation. It is lightweight, disposable, requires no cleaning or charging, and can be worn for five days.

The LifeSignals Biosensor 2A*[12] is a wireless, single-use biosensor patch that monitors oxygen saturation, heart rate, respiration rate, skin temperature, and has a two-lead ECG. Data are continuously sent to the cloud, allowing patients to be monitored remotely. This self-applied sensor is showerproof, lightweight, and can be worn up to five days. The LifeSignals Biosensor 1AX* is similar to the 2A* model, but the 1AX* does not measure oxygen saturation.[12]

The Spry Health Loop System[13] is a wireless wrist-worn device that measures heart rate, pulse oximetry, and breathing. The system remotely monitors patients and transmits the information to health care teams. It does not require a smartphone, WiFi, or Bluetooth.

The VitalConnect VitalPatch[14] is a biosensor patch, with a single-lead ECG, that measures heart rate, heart rate variability, respiratory rate, body temperature, body posture, and activity. It is a single-use, water-resistant, disposable patch that can be placed in multiple positions and can be worn for up to seven days. It is intended to be used in hospital or for remote monitoring of patients. The data are sent wirelessly to a mobile device or a server.

Who Might Benefit?

Wearable devices might be beneficial for early detection of COVID-19 symptoms, which could benefit people with known exposure to COVID-19, or the general public (to help identify spread in the community). For people with mild or moderate COVID-19 who are not hospitalized, wearable devices could help with early detection of worsening symptoms, which could prompt people to seek health care before their health status deteriorates substantially. Populations that are more vulnerable to COVID-19 (e.g., those with compromised immune systems) might also benefit from remote monitoring using wearable devices, as it could allow for early detection of symptoms.

Wearable devices can also facilitate safer monitoring of hospitalized patients with COVID-19 by allowing patients to be monitored from a distance, which could help protect health care workers by minimizing patient contact and protect other non-COVID-19 patients who do not have COVID-19 from infection. Wearable devices could also allow for safer monitoring of individuals who are isolated at home, and protect their families or care givers by reducing the need for contact.

Availability in Canada

None of the medical-grade wearables identified in this report are currently licensed for use in Canada,[15] but some are available in the US. The Spry Health Loop System received premarket notification by the FDA in March 2019,[16] and the Philips Biosensor BX100,[17] the LifeSignals Biosensor ECG remote monitoring patch platform,[18] and the VitalConnect VitalPatch[19] all received premarket notification by the FDA in the first half of 2020. The consumer-grade Fitbit, Apple Watch, Oura Ring, and WHOOP strap are all available in Canada.

In April 2020, the National Research Council of Canada (NRC) put out a call for a wearable device that can be used for remote monitoring of patients with COVID-19 at home or within a health care facility.[20] The requirements for the device include the ability to continuously measure temperature, oxygen saturation, blood pressure, pulse and respiration rate, and it must be able to transmit information wirelessly to a base station.[20] The device also needs to be inexpensive (cost less than $25 per unit), disposable, water-resistant, and last 24 hours on a single charge.[20] Two Canadian companies (Cloud Diagnostics, Kitchener, Ontario; Braebon Medical Corporation, Kanata, Ontario) were awarded phase I research and development funding to prove the feasibility of their proposed device for monitoring patients with COVID-19.[21] The phase II award recipients have yet to be announced.

What Does It Cost?

The NRC has challenged manufacturers to develop a wearable device for monitoring COVID-19 symptoms that costs less than $25 per unit.[20] No cost information was identified for the medical-grade devices that have received premarket notification with the FDA.

For the consumer-grade devices, the Fitbit trackers cost around CAD$200[7] and the Apple Watch Series 5 and Series 6 devices start at CAD$529.[8,9] The Oura Ring[5] costs $299 USD, and the WHOOP strap costs US$39 plus a US$30 monthly membership.[6]

Current Practice

No evidence was found that medical-grade wearable devices are being used in Canada for monitoring or detecting COVID-19. It is unknown whether individuals are using consumer-grade wearable devices to monitor or detect COVID-19 symptoms. For people exposed to COVID-19 or those who have mild COVID-19 symptoms, the current guidance from the Government of Canada is to isolate at home and self-monitor symptoms.[1] Individuals with severe or worsening COVID-19 symptoms are advised to seek emergency medical help.[1,22] Patients who are hospitalized with moderate or severe COVID-19 should be closely monitored following standard procedure (e.g., pulse oximeters to measure blood oxygen saturation).[22]

What is the Evidence?

No peer-reviewed, published evidence was identified regarding medical-grade or consumer-grade wearable devices for monitoring or detecting COVID-19 symptoms. Numerous preprints, letters to the editor, and protocols were identified suggesting that there may be evidence published on this topic in the future. The preprints summarized in this report have not been peer-reviewed and the evidence should be interpreted with caution as it may change upon publication of the final manuscript.

Table 1: Consumer-Grade Wearable Devices

Device	Evidence for monitoring or detecting COVID-19 symptoms
WHOOP Strap	A 2020 preprint reported that respiratory rates measured with the WHOOP strap were used as part of a model that correctly identified 20% of individuals with COVID-19 infections before the onset of symptoms, and correctly identified 80% of those infected with COVID-19 by the third day of symptoms.[23]
Fitbit Tracker	Preprints of two observational studies (with 41[24] and 31[25] people who tested positive for COVID-19) that used the Fitbit and self-reported symptoms and symptom onset, reported that elevated resting heart rate[24,25] and altered sleep and step measurements[25] could usually be detected before the onset of COVID-19 symptoms. The authors of both studies suggested that data collected by the Fitbit may be useful for identifying a possible COVID-19 infection before the onset of symptoms. A preprint using Fitbit data collected from 1,181 individuals who tested positive for COVID-19 and who self-reported their symptoms, found that heart rate and respiration rate were useful indicators for the onset of illness.[26] A preprint of the DETECT[a] study in which 78% of the participants used the Fitbit, reported that a model that combined data from the wearable devices (i.e., resting heart rate, sleep, activity) and self-reported symptoms improved the ability differentiate between participants who tested positive for COVID-19 and those who tested negative for COVID-19, compared to a symptoms-only based model.[27]
Apple Watch	A letter to the editor[28] reported a validation study of the ECG app for the Apple Watch when used in nonstandard watch positions (e.g., left lateral chest) to monitor for a specific type of heart rhythm abnormality that is a potential side effect of some of the treatments for COVID-19 (i.e., prolonged QT interval). The authors of the letter hypothesize that this alternative use of the Apple Watch ECG could facilitate remote monitoring of COVID-19 treatment side effects in isolated patients.[28]
Others	A brief letter to the editor reported on the use of the HEARThermo, a watch-like wearable device, to monitor temperature and heart rate in people at risk of COVID-19 infection in Taiwan.[29] The rate of data

Device	Evidence for monitoring or detecting COVID-19 symptoms
	retrieval by the HEARThermo ranged from 33% to 70%, and the authors speculate that this device could be used for early detection of COVID-19 symptoms.[29] A protocol for a randomized controlled trial in Hong Kong was identified that reported on a wearable arm band biosensor for the early detection of COVID-19 symptoms in asymptomatic individuals quarantined after close contact with someone with COVID-19.[30] This biosensor, called Everion, monitors heart rate, oxygen saturation, pulse, respiration rate, temperature and activity, and is linked to a smartphone app (Biovitals Sentinel) that measures symptoms and cough sounds.[30]

DETECT = Digital Engagement & Tracking for Early Control & Treatment; ECG = electrocardiogram.

[a] The DETECT study is an ongoing study that recruits individuals currently using wearable devices that measure resting heart rate (e.g., Fitbit, Apple Watch) and uses an app to track symptoms such as coughing or fever.[31]

Table 2: Medical-Grade Wearable Devices

Device	Evidence for monitoring or detecting COVID-19 symptoms
LifeSignals Biosensor	A protocol for a randomized controlled trial was identified that will compare remote monitoring of COVID-19 patients using the LifeSignals Biosensor 1AX* to patients without wearable monitoring technology undergoing standard care at the hospital.[32] The study is not yet recruiting.
VitalPatch	A 2020 clinical evidence assessment by ECRI found no evidence regarding the use of the VitalConnect VitalPatch Biosensor for continuously vital sign monitoring in patients with COVID-19, or any other group of patients.[33] The evidence review found one conference abstract that reported on the accuracy of the VitalPatch for monitoring artificially reproduced ECG waveforms (but did not assess the accuracy in patients).[33]

ECG = electrocardiogram.

Safety

No safety issues were identified in the FDA premarket notifications for the VitalConnect VitalPatch,[19] the Spry Health Loop System,[16] the Philips Biosensor BX100,[17] and the LifeSignals Biosensor ECG remote monitoring patch platform.[18]

Issues to Consider

There are a number of issues to consider with regard to the use of wearable devices for monitoring COVID-19 symptoms, including:[34,35]

- data privacy and security of health data — many of these devices rely on an app, an online platform, or data that is sent wirelessly to a server, there is a possibly of data breaches
- the accuracy of the devices — evidence is needed that these devices can accurately monitor and detect COVID-19 symptoms
- where the devices should be used — at home or in a health care setting, or both
- who are appropriate candidates for wearable devices — consider if the use of such a device depends on access to the internet or a smartphone, or technical knowledge to use it properly

- device design — the devices need to have an unobtrusive design to encourage continuous wearing, and they must fit properly in order to function properly
- cost-effectiveness — it is unknown whether using wearables for monitoring or detecting COVID-19 symptoms is cost-effective, and the consumer-grade devices may be prohibitively expensive for some individuals.

Looking Ahead

Currently, there is limited evidence on the use of consumer or medical-grade wearable devices for monitoring and detecting COVID-19 symptoms, and the role of wearable devices to help manage the COVID-19 pandemic is not fully understood. Hopefully, evidence from future trials and those that are now under way will help address these evidence gaps.

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