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CADTH Horizon Scan

Single-Use Wearable Wireless Sensors for Vital Sign Monitoring

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Health Technology Update

Key Messages

What Is the Issue?

The monitoring of vital signs is a key component of patient care. Metrics such as heart rate, body temperature, respiratory rate, and oxygen saturation allow health care staff to monitor the well-being of their patients.

What Is the Technology?

Single-use, wearable devices for vital sign monitoring have a variety of designs that are embedded with sensors that allow for continuous monitoring. They transmit data wirelessly to a base unit within a health care setting or a home.

What Is the Potential Impact?

For patients in the hospital, single-use wearable monitors can allow for fewer interruptions to rest. For patients leaving the hospital, the wearable monitors can allow for peace of mind and earlier discharge because the individual continues to be monitored remotely. In out-of-hospital settings, vital sign monitoring can signal when a person should seek additional care. The potential impacts may extend to caring for older adults at home.

What Else Do We Need to Know?

This Horizon Scan summarizes information regarding the effectiveness, safety, cost, and other considerations should there be a broad implementation of emerging wearable devices for the remote measurement of vital signs.

Wearable Wireless Sensors May Allow for Early Discharge

Wearable devices can allow for vital sign monitoring without interruption from health care staff or can be carried out in the comfort of people's own homes with the capacity to continue to monitor their vital signs remotely allows an earlier discharge from the hospital after a procedure.

What Is the Technology?

There are a variety of designs of single-use wearable devices for vital signs and patient monitoring. These include wrist and arm bands, watches, Holter devices, and patches. Wearable wireless sensors include the BioSensor, Healthdot/HealthPatch, Sensium, and VitalPatch, among others. They are embedded with small sensors that allow for continuous patient monitoring. These devices can be medical grade (intended for use by trained health care providers only) or consumer grade (intended for use by the consumer without needing health care provider involvement). In this report, we are focused on single-use wearable devices that can be adhered to the skin, have an internal power source, and transmit information wirelessly to a base unit in the patient's home or with the health care provider. Notifications are sent to the health care provider when readings fall outside of preset thresholds to alert them to potential deterioration of the patient. The BioSensor, Healthdot/HealthPatch, Sensium, and VitalPatch that measure biometric data such as:

- physical activity level
- body posture
- sleep quality
- blood oxygen saturation
- heart rate (HR)
- respiratory rate (RR)
- skin temperature.

Who Might Benefit?

Single-use wearable wireless devices for continuous vital sign monitoring may benefit a variety of groups. When continuous monitoring is used for hospital inpatients, the ability to accurately monitor patient's vital signs remotely means minimizing disruptions to the patient to obtain these measurements manually. They also allow for health care providers to safely monitor patients hospitalized with an infectious disease while minimizing their own exposure to potential infection. Additionally, they have the potential to allow for simpler freedom of movement for people in hospital who are able to leave their beds and their rooms – reducing the number of wires and sensors that must be detached and reattached.

Out-of-hospital vital sign monitoring can allow for earlier discharge for surgical patients; they can return home sooner than without it, while still being monitored by a health care provider for signs of infection or

distress. It also allows for remote monitoring of people who have an infectious disease, such as COVID, in both hospital and out-of-hospital settings; protecting both the health care providers and their family caregivers from further exposure to infection. The benefits of such devices may also extend to caring for older adults at home.

Availability in Canada

The single-use wireless wearable vital sign monitoring devices identified in this report were not listed in the Health Canada Medical Devices Active Licence database as of the writing of this report. These devices have been available for use in the US and the UK since the early 2010s.

The VERDICT-2 trial is a research study that began in April 2023 by researchers at Population Health Research Institute of Hamilton Health Sciences and McMaster University assessing the accuracy of the Vitaliti, a new wearable patch developed by a Canadian company, Cloud Dx, compared to standard monitoring equipment.[1] The Vitaliti patch continuously tracks electrocardiogram (ECG) measurement, heart rate (HR), pulse rate, respiratory rate (RR), temperature, blood pressure, and oxygen saturation. When the accuracy study is complete, the researchers plan to study patient experience wearing the device at home. A large-scale effectiveness and usability study will follow this.[1]

What Does It Cost?

No Canadian prices for these devices were identified.

The authors of a cost-utility analysis of continuous and intermittent versus intermittent vital signs monitoring in patients admitted to surgical wards in the UK using the SensiumVitals device for continuous monitoring found that continuous vital sign monitoring with additional intermittent monitoring was less costly than intermittent monitoring alone.[2] The cost of the Sensium patch was reported as £150 and the cost per patient to use the patch (including installation, annual licensing fees, staff training, and system maintenance) was estimated to be £350 per patient.[2] Over a 30-day time horizon, the total cost per patient was £6,329 for intermittent monitoring versus £5,863 for the combined monitoring group.[2] Reduced costs of hospital readmissions and length of stays in hospital drove the estimated cost savings.

Current Practice

Depending on the setting and facility, vital signs are monitored either manually (using stethoscopes, blood pressure cuffs, thermometers, etc.) or via wired digital vital sign monitors (where wired sensors such as blood pressure cuffs are attached to both the patient and the monitor).[3,4] Measurements from both methods can be charted with pen and paper or transferred to an electronic record; however, as long as the systems

are compatible, wired digital monitors allow for the transfer of vital sign data digitally – without the risk of transcription error.[5]

No Canadian guidelines recommending the appropriate frequency of vital sign monitoring or guidelines specifically related to the use of single-use wearable vital sign monitoring devices, at home or in hospital, were identified. In a July 2022 CADTH summary of abstracts report, Assessment of Postoperative Vital Signs Frequency, 2 evidence-based guidelines were identified.[6] It was recommended that general postoperative patients should have their oxygenation monitored continuously until they are no longer at risk for hypoxemia or respiratory depression and ventilation and circulation could be monitored at regular intervals (e.g., every 5 to 15 minutes) until patients are suitable for discharge. For patients who have undergone bariatric surgery, continuous monitoring of vital signs during the early postoperative period was recommended until patients were no longer at risk for respiratory depression.[6]

An observational study of vital sign measurement on the general medical ward of a hospital in the US found that vital signs were most often measured 6 times per day or about once every 4 hours.[7] The frequency of measurement ranged from 1 to 24 times per day.

What Is the Evidence?

Clinical studies were identified regarding 4 wearable vital sign monitoring devices: the BioSensor, Healthdot/HealthPatch, Sensium, and VitalPatch. The characteristics and results of these studies are summarized in Table 1, Appendix 2.

As reported in the studies, the BioSensor measured HR, RR, skin temperature, posture and can detect patient falls.[8] The Healthdot measured HR every 8 seconds and RR measurements every second.[9] The Sensium Vital Sign Sensor measured HR, RR, and temperature[10,] and the VitalPatch measured HR, HR variability, RR, skin temperature, body posture, and steps taken.[11]

In Hospital

BioSensor

Kant and colleagues (2022) found that all HR measurements from the BioSensor were within the limits of agreement with the reference monitor of 8 beats per minute. The RR measurements exceeded the 2 respirations per minute limit of agreement in 58% of compared measurements. A data loss of 4.5% was observed.[8]

Healthdot and HealthPatch

Three studies were identified examining the use of the Healthdot and HealthPatch.[9,12,13] All 3 were based on subsets of the TRICA study, a prospective, single-centre observational study of postsurgical patients.

- For adult patients recovering from major abdominal cancer surgery, the authors found that the wearable patch detected the same number of true clinical deteriorations as vital sign monitoring with manual spot checks.[9]

- Another study of the same population determined that 97% of HR measurements were within the 5 beats per minute limit of the gold standard measurement and 87% of RR measurements were within the 3 respirations per minute limit.[12]
- For adults undergoing bariatric procedures, 87.5% of the HR data met the 5 beats per minute limit and 92.3% of RR data met the limit of 5 respirations per minute.[13]

Sensium Vital Sign Monitor

The Sensium Vital Sign Monitor was assessed in 3 publications and used for adults hospitalized following surgery.[14-16]

- For abdominal surgery, the algorithm sent 972 alerts (90.3% system alerts, 9.7% vital sign alerts). It was determined that only 35% of the vital sign alerts were true positives.[14]
- Patients who had undergone major elective surgery were randomized to receive either remote monitoring plus National Early Warning Score (NEWS) monitoring or manual monitoring using NEWS alone.[15,16]
  - The authors found there was no clinically meaningful bias in HR but the precision of the patch was poor. Overall agreement was poor for RR and temperature.[16]
  - A second study assessed the ability of continuous monitoring to detect sepsis.[15] On average, the patients who were continuously monitored received antibiotics for sepsis sooner and had a shorter average hospital stay and were less likely to require readmission within 30 days of discharge; however, the differences between groups were not statistically significant.

Outpatient

VitalPatch

Outpatient and out-of-hospital use of the VitalPatch was assessed in 3 clinical studies.[11,17,18]

- Patients discharged early after esophagectomy were provided with the VitalPatch device to allow health care providers to check on their vital signs remotely following surgery.[11] Overall data loss of vital sign measurements at home was 25%. Clinical decision-making was not altered based on the trends observed in the remotely obtained vital sign measurements.[11]
- Stehlik et al.[17] aimed to determine the accuracy of machine learning analytics of a remote patient monitoring system in predicting heart failure (HF) hospital readmission. The remote vital sign monitors provided data sufficient to predict 87% of hospitalizations and 87.5% of unplanned nontrauma hospitalizations.[17] Patient compliance with the device was high with 87 of 100 participants completing 30 days of monitoring and 74 completing 90 days of monitoring.[17]
- Tonino et al.[18] assessed the wearability, usability, and safety of use of the VitalPatch system for adults with a confirmed hematological disorder who were monitored during transfusion therapy. Patient-reported outcomes were not dependent on whether the patient or a nurse applied the patch. The devices were generally well tolerated and remained in place during use.

Safety

No patient safety concerns were described in the clinical studies aside from adhesive reactions. For the VitalPatch, no reports of skin irritation were reported in 1 clinical study;[11] however, 3 patients withdrew from another study due to skin irritation related to the device's adhesive.[18]

Issues to Consider

The hope is that these types of devices will help to lessen burden on the health care system by reducing the number of required patient and/or provider interactions. Continuous remote monitoring of vital signs saves time for providers and lessens bother and disruption to the patient. The use of these devices may free up hospital rooms through earlier discharge paired with safe and appropriate postsurgical monitoring done remotely. There is a need to ensure the devices strike the balance between adequate measurement accuracy and overreaction to changes in vital signs, resulting in excessive notifications sent to health care providers.

Patients' Perspectives and Experiences

Sensium Patch

For adults following abdominal surgery, the majority of patients rated the Sensium patch as comfortable.[14] More than half of patients said they felt safer knowing they were wearing the monitoring patch and 89% said they would like to wear 1 if they were in hospital again.[14] Downey et al.[15] similarly found that patients found the device to be acceptable in terms of comfort and perceived an enhanced sense of safety knowing the device provided continuous monitoring. Joshi et al.[10] conducted a study of patient's perspectives related to the use of the Sensium monitor while in hospital. Of the 500 patients who wore the sensor, 453 completed the questionnaire. The respondents generally agreed that the patch was comfortable to wear (94.3%) and that they would agree to wear it again when in hospital (94.7%) and 87.9% agreed that they would wear the patch at home.[10] As was found in other studies, the patients said the patches improved their sense of safety and they felt they could help to relieve pressure on health care staff.[10]

VitalPatch

In the outpatient setting, patients who were discharged early with the VitalPatch following esophagectomy were happy to have the ability to have their vital signs monitored remotely. They appreciated the daily check-ins from their health care providers during the postoperative period.[11]

Health Care Provider Experience

Nurses were neutral about the usefulness and satisfaction with the Sensium Vital Sign Monitoring Patch but generally agreed that the system was easy to use.[14] In 1 study of the VitalPatch, nurses reported the device was easy to use, and they were comfortable relying on the data it measured.[18]

Related Developments

In 2018, an invention from Canada, the Bio-Monitor, was launched into space to record the vital sign data of astronauts at the International Space Station.[19] The Bio-Monitor combines multiple devices into a smart shirt worn by the astronauts during sleep and exercise. Information is sent to earth so the astronauts can be continuously monitored. The manufacturer suggested the technology could monitor people in their homes including remote or rural areas.

Looking Ahead

The field of wireless wearable medical devices is developing very quickly and in Canada, is still in the early days of implementation. The US market for vital sign monitoring devices is projected to be valued at more than US$11 billion by 2028.[20] The increase in the percentage of the population that lives with chronic diseases that require continuous monitoring will likely impact the demand for these kinds of devices.[20] The overall evidence base evaluating the accuracy and effectiveness of these devices remains relatively small. More work is needed to appropriately compare the outputs of wearables to the gold standard vital sign monitoring equipment, particularly those for consumer wearables and for remote monitoring outside of a clinical setting.

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Appendix 1: Methods

Note that this appendix has not been copy-edited.

Literature Search Strategy

An information specialist conducted a literature search on key resources including MEDLINE, Embase, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were the BioSticker as well as wearable devices and vital signs monitoring. The search was completed on April 26, 2023 and limited to English-language documents published since January 1, 2018.

Selection Criteria

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the intervention was single-use wireless wearable vital sign monitoring devices. Conference abstracts and grey literature were included when they provided additional information to that available in the published studies.

Appendix 2: Additional Information

Note that this appendix has not been copy-edited.

Table 1: Summary of Clinical Studies of Wearable Monitoring Devices

Authors, year	Study design and setting	Population and comparator(s)	Outcomes	Results
BioSensor				
Kant et al. (2022)[8]	Prospective observational study Hospital	Severely obese adult patients during and after bariatric surgery (n = 94) Reference monitor	• Mean absolute difference in HR and RR measurements by the wearable Biosensor in comparison to the reference monitor in the operating room and the recovery room • Percentage of data that fell outside the predefined limits of agreement, as well as the duration and causes of data loss, and delay in transmission between the Biosensor and the relay device until hospital discharge	• All HR measurements of both the original and the averaged dataset were within the limits of agreement of 8 bpm • The mean absolute difference for RR was 1.78 bpm during surgery and 4.24 rpm during recovery • The Biosensor's RR measurements exceeded the 2 rpm limit of agreement in 58% of the compared measurements • Data loss was limited to 4.5% of the total duration of measurements for RR. No clear causes for data loss were found
Healthdot and HealthPatch				
van der Stam (2023)[9]	Prospective, single-centre observational study Tertiary hospital	Adult patients undergoing major abdominal cancer surgery (n = 120) REWS measured with Healthdot vs. MEWS spot checks measured by nursing staff	Prediction of deterioration toward a complication graded Clavien-Dindo of 2 or higher	• 103 participants were included in the analysis • 28% experienced clinically meaningful deterioration during the study • The number of false positives was higher for REWS than for MEWS (72 vs. 65 spot checks) • The wearable patch detected the same number of true deteriorations without requiring manual spot checks

Authors, year	Study design and setting	Population and comparator(s)	Outcomes	Results
van der Stam (2022)[12]	Prospective, single-centre observational study (subset of the TRICA study) Tertiary hospital	Adult patients undergoing major abdominal cancer surgery • HR (n = 26) • RR (n = 21)	Agreement between HR and RR measured by the Healthdot vs. the gold standard patient monitor in the intensive and postanesthesia care unit	• 97% of HR measurements were within 5 bpm of the gold standard measurement • 87% of the RR measurements were within 3 rpm of the gold standard measurement
Jacobs et al. (2021)[13]	Prospective, single-centre observational study (subset of the TRICA study) Tertiary hospital	Adult patients undergoing bariatric procedures (n = 30) Gold standard patient monitors	Agreement between HR and RR measured by the Healthdot vs. the gold standard patient monitor in the intensive and postanesthesia care unit	• 87.5% of the data met the predefined bias of 5 bpm for HR • 92.3% of the data met the predefined bias of 5 rpm for RR
Sensium Vital Sign Sensor				
Leenen et al. (2021)[14]	Prospective observational cohort study Tertiary hospital	Adult patients who had undergone abdominal surgery (n = 30) No comparator	• System fidelity was measured by analysis of the monitoring data • Acceptability by patients and nurses was assessed using questionnaires	• 19% of HR, 51% of RR, and 9% of temperature measurements showed artifacts • The system algorithm sent 972 alerts (median alert rate of 4.5 per patient per day), of which 90.3% (n = 878) were system alerts and 9.7% (n = 94) were vital sign alerts • 35% (n = 33) of vital sign alerts were true positives • 93% (n = 25) of patients rated the patch as comfortable, 67% felt safer and 89% would like to wear it next time in the hospital • Nurses were neutral about usefulness, ease of use and satisfaction but agreed the system was easy to use
Downey et al. (2019)[16]	Trial of Remote vs. Continuous Intermittent monitoring (TRaCINg) study Single-centre,	Adult patients who had undergone major elective general surgery (n = 51) Participants were individually	• 95% limits of agreement between manual nurse observations and wearable vital sign patch recordings of HR, RR, and temperature	• There was no clinically meaningful bias in HR, but precision was poor • Agreement was poor for RR and temperature • Vital sign patch data

Authors, year	Study design and setting	Population and comparator(s)	Outcomes	Results
	feasibility, randomized, controlled, parallel-group trial	randomized on a 1 to 1 basis to receive either remote monitoring plus NEWS or monitoring by NEWS alone	• Average percentage completeness of continuous patch data	completeness was 72.8% for temperature, 59.2% for HR and 34.1% for RR
Downey et al. (2018)[15]	Prospective, cluster-randomized, parallel-group, unblinded, controlled pilot study	Adult patients admitted to 2 surgical wards at a large tertiary hospital Continuous and intermittent vital signs monitoring (n = 140) or intermittent monitoring alone (n = 86) using an early warning score system	• Time to administration of antibiotics in sepsis • Length of hospital stay, 30-day readmission rate, mortality, and patient acceptability	• On average, patients receiving continuous monitoring received antibiotics for sepsis sooner and had a shorter average hospital stay and were less likely to require readmission within 30 days of discharge • The differences between groups were not statistically significant • Patients found the monitoring device to be acceptable in terms of comfort and perceived an enhanced sense of safety
VitalPatch and VitalConnect				
Breteler et al. (2020)[11]	Observational feasibility study Outpatient setting in the Netherlands	Patients discharged early after esophagectomy (n = 20) No comparator	• Patient experience • Technical feasibility based on daily percentage of data loss and gap durations over 7 days • Number of patients for whom a change in clinical decision was made based on the results of remote vital signs monitoring at home	• Patients appreciated the daily check in from the surgical team and were happy to have their vital signs checked each day • No reports of skin irritation from the patch were recorded • Overall data loss of vital signs measurements at home was 25% • Remotely observed vital signs trends did not alter clinical decision-making
Stehlik et al. (2020)[17]	LINK-HF study (Multisensor Non-invasive Remote Monitoring for Prediction of Heart Failure Exacerbation) Multicenter,	Adult subjects (≥ 18 years) with a history of HF and New York Heart Association functional class II-IV symptoms who were hospitalized for acute HF exacerbation enrolled at discharge	• Determining the accuracy of machine learning analytics of a remote patient monitoring system in predicting HF readmission to the hospital	• The sensors provided sufficient data to predict 89% of hospitalizations for HF and 87.5% of unplanned nontrauma hospitalizations. • The platform was able to detect the

Authors, year	Study design and setting	Population and comparator(s)	Outcomes	Results
	observational study Outpatient setting	(n = 100) No comparator	• Assessment of subject compliance with the study procedures	risk of hospitalization for worsening of HF with 76.0% to 87.5% sensitivity and 85% specificity • Compliance was high with 87 of 100 participants completing 30 days of monitoring and 74 completed 90 days
Tonino et al. (2020)[18]	3-arm, parallel, single-centre, observational, nonrandomized, open-label feasibility study Outpatient setting	Adult participants with a confirmed hematological disorder (n = 12): • 4 patients receiving red blood cell transfusions • 4 patients receiving IV proteasome inhibitors • 4 patients receiving IV Immunotherapy • No comparator	Wearability, usability, and safety of use of the accelerateIQ and VitalPatch system	• No difference in PROs was observed when either the nurses or the patients applied the patch • Patients were generally satisfied with the comfort of the patch and reported it remained in place • 3 participants withdrew from the study due to skin irritation • Nurses reported ease of use and comfort with relying on data measured by the VitalPatch

bpm = beats per minute; HF = heart failure; HR = heart rate; MEWS = Modified Early Warning Score; NEWS = National Early Warning Score; PRO = patient-reported outcome; REWS = Remote Early Warning Score; rpm = respirations per minute; RR = respiratory rate.

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