CADTH COVID-19 PANDEMIC

COVID-19 CADTH TECHNOLOGY REVIEW: FOCUSED CRITICAL APPRAISAL

Infrared Temperature Devices for Infectious Disease Screening During Outbreaks: Overview of an ECRI Evidence Assessment

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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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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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Table of Contents

Tables

Abbreviations

IR	infrared
SARS	severe acute respiratory syndrome

Key Findings

The evidence from the ECRI Clinical Evidence Assessment showed that non-contact infrared (IR) temperature screening methods were ineffective for detecting infected staff or visitors entering health care facilities or for screening travellers. Fever can result from conditions (including the absence of a specific illness) other than viral infections. Therefore, if temperature screening is used, provision of confirmatory tests to determine truly infected individuals may be necessarily, and, to prevent further spread of the infection, logistics to manage individuals confirmed to have infectious disease must be considered. Screening outcomes depend strongly on several factors, including pathogen natural history and epidemiological features, as well as human factors in implementation and compliance.

Background

During an infectious disease outbreak, there is an increased interest in the use of thermal and infrared temperature devices for mass screening. Earlier CADTH work on this subject may still be relevant but does not capture the latest literature.[1] However, ECRI reviewed the evidence on this subject in March 2020 and has captured the most recent information on the topic in its report and webinar.[2] Rather than duplicate ECRI's work, we are highlighting the findings of the ECRI review for Canadian decision-makers.

Fever, a significant elevation of body temperature beyond the normal range, can be an early indicator of illness, including infections.[3-6] Clinical thermometers placed in the armpit (axillary) or in the mouth (oral) are used to measure body temperature in clinical practice for children older than three years, and for adults. Oral readings, taken with the mouth closed while the thermometer is in place, are usually accurate, while axillary temperatures are usually the least accurate.[7] For infants, especially those three months or younger, as well as children up to three years of age, rectal temperatures provide the best readings. Digital ear thermometers, also called tympanic thermometers, are also available although they are less commonly used.[7]

Non-contact temperature screening devices may be used to measure the cutaneous temperature as a surrogate of core body temperature. For example, temporal artery thermometers (also known as forehead thermometers or "thermometer guns)" measure the temperature of the temporal artery in the forehead.[7] Non-contact temperature screening devices are equipped with infrared (IR) sensors that quickly measure surface temperature without making any contact with a person's skin. Their speed of measurement and the convenience of not having to sterilize them after each use before applying them to the next person makes them suitable for use in situations where mass temperature screening in many people is required.

As fever is a typical early sign of infection, there is interest in using non-contact temperature screening devices, including IR thermal cameras, as a way to detect and help contain viral outbreaks. They were widely used during outbreaks of severe acute respiratory syndrome (or SARS), H1N1 influenza (or the swine flu), and Ebola virus disease to identify persons with fevers who may be infected, and they have since been deployed in many countries as one of the measures to contain the spread of COVID-19.[8]

Many new technologies are in development, or in the early stages of use, for mass temperature screening. Examples of these technologies include:

- CrowdRx — provides high resolution, portable, thermal camera screening systems intended for mass screening at public events, facilities, and airports.[9]
- Scentech Medical — is assessing whether biomarkers for coronavirus can be detected using non-invasive breath tests.[10]
- Altoros Fever Screener — an automated system that combines artificial intelligence and dual thermal and video cameras, and can scan up to 30 people at a time from a distance of 10 ft. Additional features, such as cough detection, are expected to be available soon. The system includes facial recognition and is intended for use in detecting infectious respiratory diseases, including COVID-19, in various settings, including health care facilities, retail, and airports.[11]
- LifeSignals Patient Management Biosensor Patch 2A — a disposable, wearable sensor that may be worn for up to five days and could be used for the remote monitoring of various vital signs, including skin temperature.[11]

In March 2020, ECRI published a Clinical Evidence Assessment[2] focusing on the accuracy of external IR temperature screening devices for identifying visitors or staff entering health care facilities who may be potentially infected with an infectious disease. This review aims to summarize the findings in the ECRI paper and critically appraise its methodological and scientific rigour.

Objective

The objective of this CADTH overview is to examine the methodology, scientific rigour, and findings of a published study or evidence report.

Research Question

1. What is the evidence on the effectiveness and accuracy of non-contact thermal temperature/imaging screening systems for screening populations?
2. What are the guidelines on the use of non-contact thermal temperature/imaging screening systems? What are the risks and safety guidance compared to traditional approaches to temperature screening?

Study Under Review

This report includes a summary with a critical appraisal of the following: Clinical Evidence Assessment: ECRI. Review title: *Infrared Temperature Screening to Identify Potentially Infected Staff or Visitors Presenting to Healthcare Facilities during Infectious Disease Outbreaks*.[2] There is an accompanying webinar on this topic.[12]

Description of the Study

Objective

The objective of the ECRI Clinical Evidence Assessment was to review the literature on the accuracy of IR temperature screening devices for identifying visitors or staff entering health care facilities who may have potentially infectious diseases.

Research Design and Methods

Data Sources and Literature Search

The authors conducted literature searches in PubMed, Embase, and ECRI Guidelines Trust for relevant studies that examined the use of IR temperature screening devices at airports and health care facilities. Search dates were from January 1, 2008 through to March 13, 2020. Overall, 16 studies were included in the ECRI Clinical Evidence Assessment. They were made up of two systematic reviews[13,14] (one of them was a CADTH Rapid Response report[13]), three simulation studies,[15-17] six diagnostic cohort studies, [18-23] three case-control studies,[24-26] and two case series.[27,28] The ECRI Clinical Evidence Assessment was a narrative review that reported individual study-level findings and drew conclusions from a qualitative synthesis without calculating any combined estimates.

The characteristics of the studies included in the ECRI Clinical Evidence Assessment have been summarized in Table 1.

Summary of Findings

Clinical Effectiveness and Accuracy of Non-Contact Thermal Temperature/ Imaging Screening Systems for Temperature Measure Compared to Traditional for Screening Populations

Hand-Held Infrared Thermometers

One Rapid Response report[13]and one single-centre diagnostic cohort study[19] reported results about hand-held IR thermometers. The reported findings in the Rapid Response report[13] were inconclusive because favourable and unfavourable accuracy outcomes were reported by an equal number of included studies (three studies in each case). The settings of the included studies were hospitals and airports, and the reference standard was tympanic thermometers. The diagnostic cohort study[19] found that a hand-held IR thermoscope had a very low sensitivity (29.4%) but high specificity (96.8%). The low sensitivity means the device has a poor ability to detect people who have a fever and the high specificity shows that the device has a high ability to detect individuals without a fever. The study was conducted at a primary health care setting and the reference standard in the study was an oral thermometer.

Infrared Skin Thermometers

Four diagnostic cohort studies[18-20,22] reported sensitivity findings on IR skin thermometers without providing details about the mode of application of the devices (hand-held or otherwise). From these studies, the sensitivity of IR skin thermometers ranged from very low (24%) to high (93%), indicating poor-to-excellent ability to detect fever. However, the specificity data were not provided in the report to enable the assessment of how well the IR skin thermometers could correctly distinguish individuals without a fever. The studies were conducted in health care settings and the reference standards were oral[19-21] and tympanic[18,22,23] thermometers.

Infrared Thermal Cameras

Three diagnostic cohort studies,[19,21,23] three diagnostic case-control studies,[24-26] and two diagnostic case series[27,28] reported sensitivity outcomes for IR cameras. The sensitivity for

IR thermal cameras ranged from fair (57%) to good (91%) in the diagnostic cohort studies.[19,21,23] In contrast, all the diagnostic case-control studies reported high sensitivity ratings, ranging from 88% to 93%. It should be noted that diagnostic case-control studies or diagnostic case series generally overestimate the accuracy of diagnostic tests.[2]

One diagnostic case-series[28] assessed the effects of environmental temperature on the sensitivity and specificity of an IR thermal camera. It found that, in a warm environment, the camera's accuracy was much lower and did not correlate well with a tympanic thermometer compared to when used in a cold environment. A second diagnostic case-series[27] evaluating the sensitivity and specificity of an IR thermal camera showed that the operational distance between the device and the person undergoing screening should be 0.5 metres or less to get an accurate reading. All the diagnostic cohort,[19,21,23] case-control,[24-26] and case-series[27,28] studies were conducted in health care settings and the reference standards were oral,[19,21] tympanic,[23,26] or axillary.

Other

The findings of one systematic review[14] and three simulation studies[15-17] included in the ECRI Clinical Evidence Assessment were difficult to interpret in answer to the research question of this review. The reason was that the data from these studies, as reported in the Clinical Evidence Assessment, were incomplete, and time constraint precluded a follow-up effort to attempt searching for additional information. For example, the systematic review[14] was reported to have evaluated "screening programs" without mentioning any specified devices, and the included data about the simulation studies did not distinguish between screening methods. However, these studies had informative conclusions that aligned with the others. The systematic review[14] concluded that temperature screening measures alone are not effective in detecting imported cases at borders, but they may allow opportunities for raising awareness and educating the travelling public. One of the simulation studies[17] using preliminary estimates of COVID-19 epidemiology and natural history estimated that screening will detect less than half of infected travellers in a growing epidemic, with screening effectiveness increasing marginally as growth of the source epidemic decelerates. Another simulation study[15] concluded that "airport screening is unlikely to detect a sufficient proportion of 2019-nCoV infected travelers to avoid entry of infected travelers." Although the conclusion of the third simulation study[16] does not provide specific information about screening accuracy, it points out that screening outcomes depend strongly on pathogen natural history and epidemiological features, as well as human factors in implementation and compliance.

Guidelines on the Use of Non-Contact Thermal/Imaging Screening Systems

The authors of the ECRI Clinical Evidence Assessment[2] identified nine guidelines and guidance documents relevant to fever screening published between January 1, 2014 and April 20, 2020. However, only the guidance[29] from the US FDA provided specific guidance for using non-contact IR temperature devices. The objective of the FDA guidance[29] was to provide a "policy to help expand the availability of telethermographic systems used for body temperature measurements for triage use for the duration of the public health emergency" related to the COVID-19 outbreak in the US. The evaluation of the entire FDA guidance statement document (available online) is beyond the scope of this review. However, a few of the FDA guidance[29] statements regarding temperature screening systems are available in Table 2.

Critical Appraisal

Overall Strengths and Limitations

The main strength of the ECRI Clinical Evidence Assessment report was that its evidence was based on a large number of studies. Of the 16 studies that were included, two were systematic reviews with a total of 47 primary studies, while the remaining comprised three simulation studies, six diagnostic cohort studies, three case-control studies, and two case series. Furthermore, the reviewers used a structured search and the variety of the study designs of the individual studies they included suggest a broad eligibility criteria, although the actual rationale for selecting the study types was unclear. Also, the report is current, covering the literature up to March 2020. However, as noted earlier, the quality of the included studies were not assessed and included preprints, which have not gone through a peer-review process. Data from one systematic review[14] and three simulation studies,[15-17] as reported in the ECRI Clinical Evidence Assessment, were not independently interpretable because reported details were incomplete. However, these studies had informative conclusions that aligned with other studies. Furthermore, two included case-control studies[24,25] evaluated the effectiveness of IR camera systems enhanced to measure temperature, heart rate, and respiration rate to detected infected patients. Thus, it is difficult to separate the contribution of these enhanced features from the temperature screening function alone to the reported outcomes in these studies.

While the ECRI Clinical Evidence Assessment provided sensitivity and specificity of both hand-held thermometer guns and IR cameras separately, it did not identify any direct comparative effectiveness information for the different types of non-contact temperature screening devices.

Summary and Conclusions

The ECRI Clinical Evidence Assessment included sixteen studies,comprising two systematic reviews,[13,14] three simulation studies,[15-17] six diagnostic cohort studies, three case-control studies,[24-26] and two case series.[27,28] Overall, there was insufficient evidence to suggest that non-contact IR temperature screening methods were effective for detecting infected persons. Therefore, it may not be sufficient to identify infected staff or visitors entering health care facilities or for screening travellers. Limitations include generally low or inconsistent sensitivity for the devices examined. The ECRI review of the evidence identified several factors that affect the performance characteristics of non-contact IR temperature screening devices, including:

- the environmental temperature (environments that are too warm or too cold can affect the accuracy of the target temperature reading)
- the operating distance from individuals being tested (operators wielding the devices too close or not close enough to the person undergoing screening can produce false high- or unusually low-temperature readings)
- the use of medications that suppress a fever or elevate body temperature
- physical activity such as running.

The accuracy of the different temperature screening devices may also vary.

In addition, clinical characteristics and the prevalence of the disease affect the accuracy of temperature screening. These factors include:

- variation in periods of latency or incubation and the time-to-onset of clinical symptoms[2,30]
- the proportion of infected individuals who have no fever and otherwise mild or no symptoms of illness who will not be detected through temperature screening
- whether the epidemic is spreading or stable.[2,30]

It is important to note that fever is a symptom of many medical conditions other than infectious diseases. Therefore, detecting a fever is not a conclusive test for infection. Any plan to incorporate temperature screening should consider the many factors that may impact accuracy. At minimum, staff intending to operate non-contact temperature screening devices will require appropriate training. Also, provision for confirmatory tests to determine truly infected individuals may need to be available, as will the necessary logistics in place to manage individuals confirmed to have fever or infectious disease to prevent further spread of the infection. A cost-effectiveness analysis may also be warranted to determine the suitability of a device for mass screening.

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Appendix 1: Characteristics of Included Studies

Table 1: Characteristics of Studies Included in the ECRI Clinical Evidence Assessment[a]

Author, publication year	Number of participants	Settings	Device	Reference standard
Systematic Reviews				
Mouchtouri et al. (2019)[14]	Not reported	Airports	Screening programs with unspecified devices	Not reported
CADTH (2014)[13]	Not reported	Not defined	Non-contact IR thermometers (including both hand-held devices and cameras)	Tympanic thermometers
Diagnostic Cohort Studies				
Chen et al. (2020)[18] **Preprint**	528 (261 indoor and 267 outdoor participants)	Fever clinic and emergency department	Non-contact IR thermometer to measure wrist and forehead temperature (device type was not reported)	IR tympanic thermometer
Hogan et al. (2015)[20]	548	Emergency department	Cutaneous IR thermometry	Oral thermometer
Tay et al. (2015)[19]	430	Primary health care centre	Three brand-named IR thermal detection systems, including one hand-held device (device types were not described for the other two)	Oral thermometer
Nguyen et al. (2010)[21]	2,873	Emergency room	Three brand-named IR thermal detection systems (descriptions of devices were not provided)	Oral thermometer
Chiang et al. (2008)[23]	1,032	Medical centre	• Digital infrared thermal imaging of frontal or lateral views • A brand-named IR thermal detection device (no details provided)	Tympanic IR thermometer
Hausfater et al. (2008)[22]	2,026	Emergency department	IR thermometer to measure cutaneous temperature on the forehead	IR tympanic thermometer; systolic and diastolic arterial blood pressure and heart rate were also measured

Author, publication year	Number of participants	Settings	Device	Reference standard
Diagnostic Case-Control Studies				
Bardou et al. (2016)[26]	625 (246 in-patients and 379 healthy controls [i.e., health care workers])	Health care setting (details not reported)	IR thermal camera	Tympanic thermometer
Sun et al. (2017)[24]	38 (16 in-patients and 22 healthy controls)	Hospital	IR camera that produced thermal images and measure respiration rate and heart rate	Axillary temperature
Sun et al. (2016)[25]	87 (54 in-patients and 33 healthy controls)	International Airport Clinic	IR camera system that monitors facial skin temperature, heart rate, and respiration rate	Axillary temperature
Diagnostic Case-Series				
Sun et al. (2014)[27]	155 in-patients	Hospital	A brand-named IR thermal detection device (description of the device was not provided)	Axillary temperature
Suzuki et al. (2010)[28]	50 healthy participants	Not reported	IR thermal camera	Axillary thermometer
Simulation Studies				
Gostic et al. (2020)[17]	Assumed COVID-19 patients (number not provided)	Unclear	IR thermal image scanners (type not described)	None described
Quilty et al. (2020)[15]	Assumed 100 COVID-19 patients	Airport (assumed in simulation)	IR thermal image scanners (type not described) (assuming similar sensitivity as a device used in a single study published in 2011)	None described
Gostic et al. 2015[16]	Assumed patients with SARS, Ebola virus, and other disease outbreaks (number not provided)	Airport (assumed in simulation)	Non-contact IR thermometer applied to forehead (assuming similar performance efficacy as single study published in 2009)	None described

IR = infrared; SARS = severe acute respiratory syndrome.

[a] These characteristics are derived from information in the ECRI Clinical Evidence Assessment. The individual studies were not independently assessed.

Table 2: Guidance Statements From the FDA Regarding Telethermographic Systems

1	The advantage of using telethermographic systems for an initial temperature assessment in triage use is the potential use in high throughput areas (e.g., airports, businesses, warehouses, factories) and in settings where other temperature assessment products may be in short supply. The available scientific literature supports the use of telethermographic systems in the context of initial human temperature measurement during such a triage process.
2	Telethermographic systems are devices when they meet the definition of a device set forth in section 201(h) of the US *Food, Drug, and Cosmetic (FD&C) Act* 21, US Code 321(h). Under section 201(h) of the *FD&C Act* 21, US Code 321(h), these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.
3	The FDA believes devices included in this enforcement policy will not create such an undue risk where: • the performance and labelling elements in Section IV.D are met • an elevated body temperature measurement is confirmed in the context of use with secondary evaluation methods (e.g., non-contact infrared thermometer (i.e., NCIT) or clinical-grade contact thermometer).

4	The FDA recommends that the devices previously described use labelling that helps users better understand the device, such as:
	• The labelling includes a prominent notice that the measurement should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, or any other disease
	• The labelling includes a clear statement that:
	  ○ Elevated body temperature in the context of use should be confirmed with secondary evaluation methods (e.g., an NCIT or clinical-grade contact thermometer).
	  ○ Public health officials, through their experience with the device in the particular environment of use, should determine the significance of any fever or elevated temperature based on the skin telethermographic temperature measurement.
	  ○ The technology should be used to measure only one subject's temperature at a time.
	  ○ Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement.