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# **CADTH Horizon Scan**

# Facial Analysis Technology for Pain Detection: A Potentially Useful Tool for People Living With Dementia





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#### **Key Messages**

- Pain is a common symptom for people living with dementia; however, older adults with cognitive impairments or dementia are less likely to be diagnosed with pain or receive appropriate pain management, which may lead to misdiagnosis and unnecessary treatments.
- PainChek is a point-of-care app that aims to support care providers with the detection of pain for those who cannot reliably communicate their pain, including adults living with dementia.
- This Horizon Scan summarizes information regarding effectiveness, cost, availability, and some of the issues to consider should PainChek or other artificial intelligence–enabled pain detection apps be widely implemented.

## PainChek Can Automate and Digitize the Detection of Pain

Traditional tools for pain assessment in those who cannot communicate their pain require observers to identify and evaluate the pain. The PainChek app is a point-of-care tool that uses artificial intelligence (AI) analysis of facial expressions to automate part of the pain assessment process for people who are unable to communicate their pain.

#### How It Works

PainChek combines AI and smart automation with a series of digital pain checklists that are completed by a caregiver to provide an overall pain score.<sup>1-3</sup> PainChek is a clinical decision support tool that can assist care providers — it does not provide recommendations for pain management.

The PainChek system combines the mobile PainChek App, which is used to conduct the pain assessment, and the PainChek Portal, which is a secure system for managing data and real-time documentation of results.<sup>4</sup> The Portal includes PainChek Analytics, which provides pain assessment information at the individual and institutional level.<sup>5</sup> The complete details of how to use the app and web portal are available online.<sup>6</sup> The PainChek app is compatible with Apple and Android smartphones or tablets.<sup>4,5</sup>

PainChek was initially designed for people who cannot self-report their pain, such as people living with dementia,<sup>1,4</sup> but it was expanded to include a numerical rating scale for those who can reliably self-report their pain (i.e., PainChek Universal).<sup>1,3</sup> This report will focus on the use of PainChek for those who cannot reliably self-report their pain.

The PainChek app is a hybrid tool that combines AI facial recognition with other nonfacial pain cues to calculate an overall pain score from 42 items across 6 domains: Face, Voice, Movement, Behaviour, Activity, and Body.<sup>1,4,5</sup>

The Face domain is fully automated. Using the device's camera, a caregiver takes a 3-second video of the person's face, and PainChek uses AI to automatically analyze the images to identify facial muscle



movements and determine the presence pain (refer to <u>Figure 1</u>). The other 5 domains in the app include a series of binary questions about pain-related indicators that are completed manually by the caregiver.<sup>4,5</sup>

Once the assessment is complete, the app automatically provides an overall pain score (ranging from 0 to 42) and a pain intensity level (i.e., no pain, mild, moderate, severe).<sup>4,5</sup> This pain score can be used and interpreted by care providers to make decisions about pain management.

Figure 1: PainChek Photo Interface



Source: Reprinted with permission from PainChek, Sydney, Australia: personal communication, May 2, 2023.

## Who Might Benefit?

PainChek can be used in long-term care facilities with adults who cannot reliably report their pain, such as those living with dementia or other cognitive impairments.<sup>1,2,7,8</sup> Dementia is a general term that refers to a set of signs and symptoms associated with the progressive decline in physical and cognitive functions that results in impaired everyday activities.<sup>9</sup> Symptoms of dementia include memory loss, changes in mood and behaviour, and altered communication ability.<sup>9</sup> In 2020, the number of people in Canada living with dementia was 597,000,<sup>10</sup> and it is expected that the number of people living with dementia will continue to rise in Canada due to growth in the population of older adults.<sup>11</sup>



Pain is a common symptom for people living with dementia;<sup>12</sup> however, older adults with cognitive impairments or dementia are less likely to be diagnosed with pain or receive appropriate pain management,<sup>9,13,14</sup> which may lead to misdiagnosis (e.g., aggression) and unnecessary treatments.<sup>15</sup>

Although there are observational tools to assist care providers in assessing pain in those living with dementia, these tools rely on subjective observations from care providers, which may be subject to user bias, such as gender bias in the recognition of the facial expression of pain<sup>16</sup> and/or result in pain being improperly diagnosed. By automating the face domain in pain assessment, PainChek could provide a more objective pain assessment, and may help reduce biases in pain assessment, such as those due to gender or age.<sup>2</sup>

In addition to the point-of-care pain assessments through the app, the documentation of each person's results in the PainChek Portal facilitates communication of the results of the pain assessments across caregivers.<sup>3</sup>

## Availability in Canada

PainChek received regulatory clearance from Health Canada in November 2020 as a Class I device.<sup>17</sup> PainChek is being implemented by 2 long-term care providers in Edmonton, Alberta (PainChek, Sydney, Australia: personal communication, May 2, 2023).

PainChek has Therapeutic Goods Administration (TGA) clearance in Australia<sup>18</sup> and received CE Mark clearance in Europe and the UK.<sup>19</sup> In Australia, PainChek is used in routine pain assessments for adults with dementia living in long-term care facilities.<sup>2,7,8</sup>

## What Does It Cost?

The Canadian price for PainChek is \$50 per bed per year in long-term care, which includes use of the tool, training, all upgrades and updates, and ongoing support (PainChek, Sydney, Australia: personal communication, May 2, 2023). The price is negotiable for community, disability, and acute care settings, and discounts may be available (e.g., introductory rates, length of term) (PainChek, Sydney, Australia: personal communication, May 2, 2023).

In addition to the cost of the app, other cost considerations include the devices needed to use the app (e.g., smart phone or tablet), maintenance of these devices and other IT infrastructure (e.g., Wi-Fi), and time for staff to complete the training to use PainChek.

No peer-reviewed economic evaluations of PainChek were identified. An Australian benefits analysis case study was identified that assumed that PainChek would reduce the years lost to disability by 5% in people living with dementia experiencing moderate pain.<sup>20</sup> Based on this assumption, the case study reported that "the present value of the total health benefits of PainChek for Australians living with dementia with moderate to severe pain between 2018 and 2027 is estimated to be \$1.4 billion in 2019 dollars under a 7 per cent real discount rate" (p. 10).<sup>20</sup>



#### **Current Practice**

Pain assessment is a necessary step for pain management but can be challenging in adults with cognitive impairment.<sup>21</sup> It is recommended to use disease-specific pain assessment tools that evaluate pain-related behaviours (e.g., facial expressions, vocalizations, body movements, activities).<sup>12</sup> Identifying an individual's pain behaviours requires both clinical judgment and familiarity with the individual, and it is recommended that a family member or caregiver be involved with the assessment.<sup>22</sup>

In Canada, recommended observational tools for assessing pain in adults who cannot communicate their pain include the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC), the Pain Assessment Advanced Dementia scale (PAINAD), and the Abbey Pain Scale.<sup>22</sup> In the UK National Guidelines, the PAINAD scale and the Doloplus-2 are recommended for people with severe cognitive impairment because these scales are shown to be reliable and valid.<sup>23</sup> These UK guidelines also note that the Abbey Pain Scale is widely used in the UK, but did not recommend this scale.<sup>23</sup>

#### What Is the Evidence?

PainChek pain scores correlate with Abbey Pain Scale scores in adults living with dementia (3 studies).<sup>24-26</sup> PainChek also appears to correctly detect the presence of pain or the absence of pain in residents in longterm care who have moderate to severe dementia.<sup>27</sup> This means that PainChek may provide a digital point-ofcare tool to assist with pain assessment in people who are unable to reliably communicate their pain.

When comparing pain scores between observers, PainChek appears to have good to very good agreement (i.e., interrater reliability),<sup>24-26,28</sup> and moderate to good reliability (i.e., intraclass correlation),<sup>24,26</sup> PainChek also has good internal consistency,<sup>24-26,28</sup> (i.e., scores are consistent across items that measure the similar characteristics). This suggests that PainChek has a good level of reliability (i.e., pain scores measured through PainChek can be consistently replicated) and, when used by different people, adequately consistent measures of pain will be produced (4 studies). Additional details of the studies that compared PainChek to the Abbey Pain Scale are provided in <u>Appendix 2</u>.

In 1 long-term care facility, residents with dementia, family members, and formal caregivers reported that they found PainChek helpful, easy to use, and useful for decision-making in pain management (1 qualitative study).<sup>29</sup> Privacy concerns with using the PainChek app and the importance of experienced staff conducting the PainChek assessments (i.e., accuracy concerns) were also expressed by family members of people living with dementia and caregivers (1 qualitative study).<sup>29</sup>

#### Gaps in the Available Evidence

The available evidence for PainChek is limited to studies that were funded by or conducted by individuals within the PainChek company, with small sample sizes (i.e., fewer than 40 participants per study) and populations that are primarily white (90% to 100% white).<sup>24-28</sup> In addition, the PainChek app was only evaluated against the Abbey Pain Scale, and was not validated against other pain assessment tools for this population, such as PAINAD or PACSLAC.



There is limited information on provider outcomes (e.g., satisfaction, ease of use, feasibility), and none of the studies included outcomes about the effectiveness of PainChek to improve pain management, nor did they report safety outcomes or information on the cost-effectiveness of incorporating the PainChek app into routine clinical practice.

## Safety

No evidence was identified regarding safety issues related to the use of PainChek.

#### **Issues to Consider**

As a pain detection tool, PainChek can assist care providers by automating part of a pain assessment (for adults); however, a care provider is still required to interpret the pain assessment and to provide pain relief as appropriate. The PainChek app for adults who cannot self-report their pain is not fully automated and still requires manual entry by a care provider.

To use PainChek, care providers are required to complete an online learning module and a training session (1.5 to 2 hours, online or in-person).<sup>2,26</sup> The PainChek app and related resources (e.g., user guides, training videos) are all available in English,<sup>6</sup> and it is unknown whether the app is available or validated in other languages, such as French, which may limit its usability in Canada.

Although PainChek employs multiple security controls, (PainChek, Sydney, Australia: personal communication, May 19, 2023), patient data, including facial images, are stored on the web portal, which presents patient privacy and security implications if there is a data breach on the PainChek Portal.<sup>30</sup> Given the privacy considerations, and that people with dementia may not have the capacity to provide informed consent, it will be important to obtain informed consent from the appropriate legal guardian.

Providers should consider that PainChek may not be appropriate for all populations if the app has not been validated in those populations. For instance, PainChek was only evaluated in adults with dementia, and it is not known whether PainChek should be used in adults with cognitive impairments other than dementia because the type of cognitive impairment may affect facial expression of pain.<sup>31</sup> There were also specific populations that were excluded from PainChek studies, such as patients with underlying medical conditions that affect the ability to exhibit facial expression (e.g., Parkinson disease, facial palsy, facial deformities, or stroke) and for whom communication about pain can be difficult.<sup>26</sup>

There is evidence of racial bias in identifying pain in racialized populations,<sup>32</sup> and both the adult and infant versions of the PainChek app were evaluated in predominantly white populations, with no evidence that the app has been validated in other racial or ethnic groups. Given that PainChek combines AI facial recognition with user input to calculate the total pain score, it is possible that the app may also be subject to racial bias in pain perception. In 1 study using the PainChek app with adults with cognitive impairments in long-term care, Aboriginal and Torres Strait Islander residents had lower total pain scores compared with adults with cognitive impairments from non-Indigenous backgrounds when the total pain score was used, but



this difference disappeared when only the automatic facial recognition domain of the app was used.<sup>7</sup> This suggests the total pain score (which combines the automated Face domain and the 5 user input domains) may be impacted by user bias or a lack of culturally specific training on how to score the other domains.

## **Related Developments**

Many of the studies of PainChek have been limited by small sample sizes and the reported outcomes. A clinical trial in Australia has recruited 45 people with dementia and is testing the feasibility of using the PainChek app and a social robot to improve pain management, including training, costs, completion rates, and clinical benefits.<sup>33,34</sup>

While initially designed for people who cannot self-report their pain, PainChek was expanded to include a numerical rating scale for those who can reliably self-report their pain and for those whose ability to self-report fluctuates.<sup>1,3</sup> A clinical trial using PainChek Universal with an estimated recruitment of 200 adults admitted to geriatric hospital wards is currently under way in Australia, which will measure hospital length of stay and other clinical outcomes (e.g., falls, pressure injuries, analgesic use, behavioural incidents, delirium).<sup>35</sup>

Following the adoption in long-term care facilities in Australia, PainChek is expanding into hospitals, including integration with electronic medical record systems.<sup>36</sup> PainChek may also explore the feasibility of using their app to assist caregivers in the community setting to assess and monitor pain for their family members with severe dementia, as there is a clinical trial from Australia registered in 2019, although it has yet to start recruiting.<sup>37</sup>

#### PainChek for Infants

PainChek has expanded to include PainChek Infant, which is intended to assess procedural pain (e.g., immunizations, blood draws) in infants aged 1 to 12 months.<sup>38</sup> The PainChek Infant app is fully automated and does not require the user to input their interpretation of the infant's facial expression.<sup>38,39</sup> Caregivers use the PainChek Infant app to take a 3-second video of the infant's face via the device's camera, and the app automatically completes the pain assessment using facial recognition and AI analysis to detect the presence of pain.<sup>38</sup> PainChek Infant appears to correctly detect the presence of pain or the absence of pain in infants undergoing immunization (1 study)<sup>39</sup> The app was also reported to be easy and quick to use.<sup>39</sup> PainChek Infant scores correlated with scores from 2 separate pain assessment scales for infants, and has had very good internal consistency (1 study).<sup>40</sup> Additional details of the studies that evaluated PainChek Infant are provided <u>Appendix 2</u>. In May 2021, the PainChek Infant app received regulatory clearance, which enables PainChek Infant to be marketed in Canada, Australia, Europe, the UK, Singapore, and New Zealand.<sup>38,41</sup> PainChek Infant could be used by health care providers, in hospital or in general practice, or by parents or other care providers.<sup>38</sup>



#### **Canadian Developments**

There are other AI technologies exploring automatic analysis of facial expression of pain, such as OpenFace, which in an open-source algorithm that looks at facial action units from the facial action coding system (FACS) in adults and children.<sup>42,43</sup> The OpenFace algorithm was trained using a Canadian pain dataset that is reported to be predominantly "young, healthy Caucasian persons."<sup>43</sup> It may be at risk of some of the same challenges experienced by PainChek when used in different ethnic and cultural groups. For instance, OpenFace pain assessments were not correlated to PAINAD pain assessments in older Asian patients.<sup>43</sup>

Researchers in Saskatchewan and Ontario have received a grant to develop technologies to help staff in long-term care homes monitor and record pain behaviour in older adults with dementia.<sup>15</sup> These technologies will detect facial expressions while residents are in their rooms, and alert staff if pain is detected in an individual. As part of this grant, the researchers have developed a fully automated computer model to detect pain level using facial expression.<sup>44</sup> This model was trained and evaluated using video data from 2 datasets, including both healthy, young adults and older adults with dementia.<sup>44</sup>

## **Looking Ahead**

PainChek is currently being implemented by 2 long-term care providers in Alberta, and it has the potential to change the way pain is assessed in Canada for adults who cannot reliably communicate their pain. This simple, point-of-care app can facilitate fast pain assessments without the need for care providers to have extensive training in recognizing and interpreting facial expressions of pain. PainChek Infant has the potential to support parents and care providers in detecting whether pain is present during routine medical procedures, such as immunization. By automating part of the pain assessment process, PainChek can support care providers in making pain management decisions in people who cannot communicate their pain. However, users should consider that PainChek is not without limitations, including the limitations of AI, such as the potential for racial bias if the AI algorithm was not trained on a racially diverse population, and potential bias from caregivers when answering the manual questions.



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## **Appendix 1: Methods**

#### Literature Search Strategy

An information specialist conducted a literature search on key resources including MEDLINE, Embase, Scopus, 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 PainChek as well as facial analysis technology for pain assessment. <u>CADTH-developed search filters</u> were applied to limit retrieval to the human population. The search was completed on April 13, 2023, and limited to English-language documents published since January 1, 2017.

#### **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 PainChek or another technology for the automatic analysis of facial expressions to detect pain. Conference abstracts and grey literature were included when they provided additional information to that available in the published studies.



## **Appendix 2: Tables**

#### Table 1: Evaluation of PainChek for the Detection of Pain in Adults With Dementia

Study citation, country	Number of participants and assessments	Intervention and comparator(s)	Pain scores	Correlation
Babicova et al. (2021) <sup>26</sup> UK	N = 22ª 302 paired assessments (179 at rest, 123 post-movement)	PainChek (Apple OS) Abbey Pain Scale	Overall	r = 0.82, P < 0.001
			Post-movement	r = 0.81, P < 0.001
			At rest	r = 0.79, P < 0.001
Atee et al. (2018) <sup>24</sup> Australia	N = 34 <sup>b</sup> 400 paired assessments (204 at rest, 196 post- movement)	ePAT (Android OS) Abbey Pain Scale	Overall	r = 0.911
			Post-movement	r = 0.904
			At rest	r = 0.896
Atee et al. (2017)25N = 40dAustralia353 paired asso at rest, 144 post	N = 40 <sup>d</sup> 353 paired assessments (209	ePAT (Android OS) Abbey Pain Scale	Overall	r = 0.882 (95% Cl, 0.857 to 0.903)
	at rest, 144 post-movement)		Post-movement	r = 0.894 (95% Cl, 0.855 to 0.922)
			At rest	r = 0.880 (95% Cl, 0.845 to 0.907)

CI = confidence interval; ePAT = electronic Pain Assessment Tool; OS = operating system.

Note: PainChek was previously called ePAT, and the initial studies are published using the name ePAT.

<sup>a</sup>Sex: 23% female, 77% male; Ethnicity: 95.5% White British, 4.5% Black British

<sup>b</sup>Sex: 58.8% female, 41.2% male; Ethnicity: 97.1% Caucasian, 2.9% other (not further described)

°Sex: 70% female, 30% male; Ethnicity: 97.5% Caucasian, 2.5% Asian

#### Table 2: Predictive Validity of PainChek for the Detection of Pain in Adults With Dementia

	Number of		Detection of pain vs. no pain		
Study citation, country	participants and assessments	Intervention and comparator	Sensitivity	Specificity	Accuracy
Hoti et al. (2018) <sup>27</sup> Australia	N = 34ª 400 paired assessments	ePAT (Android OS) Abbey Pain Scale	96.1% (95% Cl, 93.9% to 98.3%)	91.4% (95% Cl, 85.7% to 97.1%)	95.0% (95% Cl, 92.9% to 97.1%)

CI = confidence interval; ePAT = electronic Pain Assessment Tool; OS = operating system.

Note: PainChek was previously called ePAT, and the initial studies are published using the name ePAT.

<sup>a</sup>Sex: 58.8% female, 41.2% male; race or ethnicity: 97.1% white, 2.9% other (not further described).

#### Table 3: Evaluation of PainChek for the Detection of Pain in Infants

Publication, country	Number of participants and assessments	Outcome	PainChek Infant standard	PainChek Infant adaptive
Hughes et al. (2023) <sup>39</sup> Australia and Kosovo	Pre-recorded videos from 40 infants <sup>a</sup> undergoing immunization from a digital library	Sensitivity	0.904	0.912



Publication, country	Number of participants and assessments	Outcome	PainChek Infant standard	PainChek Infant adaptive
	4,303 total pain assessments			
		Specificity	0.911	0.895
		Accuracy	0.908	0.912
		Precision	0.912	0.897
Hoti et al. (2021) <sup>40</sup> Australia and Kosovo		Correlation, r		
		With ObsVAS	0.88 (95% Cl, 0.86 to 0.90)	0.88 (95% Cl, 0.85 to 0.90)
		With NFCS-R single	0.82 (95% Cl, 0.79 to 0.85)	0.83 (95% Cl, 0.79 to 0.86)
		With NFCS-R multiple	0.83 (95% Cl, 0.79 to 0.85)	0.82 (95% Cl, 0.78 to 0.85)
		Internal consistency, alpha	From 0.84 (preparation) to 0.97 (during vaccination)	From 0.82 (baseline) to 0.97 (during vaccination)

CCC = concordance correlation coefficient; CI = confidence interval; ICC = interclass correlation coefficient; NFCS-R = neonatal facia coding system-revised; ObsVAS = observer administered visual analogue scale.

Notes: PainChek Infant was tested with on an Apple operating system with 2 modes of analysis: Adaptive, which used a predetermined number of valid images (i.e., 1 image), and Standard, which used a predetermined duration of the video (i.e., 3 seconds). One study was reported across 2 publications. Hughes et at. (2023)<sup>39</sup> examined the ability of PainChek Infant to detect the presence or absence of painful stimuli. Hoti et al. (2021)<sup>40</sup> compared PainChek Infant to 2 separate pain assessments scales – the ObsVAS and the NFCS-R (multiple and single).

<sup>a</sup>Sex: 60% female, 40% male; race or ethnicity: 100% white.