

World leading journal Lancet Digital Health publishes PainChek® Infant validation study results

HIGHLIGHTS

- A study validating the use of PainChek® Infant to assess pain in infants aged under one year of age has been published in world's leading health informatics journal *Lancet Digital Health*
- The study found PainChek Infant's use of automated facial evaluation and analysis (AFEA) offered a valid and reliable means of assessing and monitoring procedural pain in infants
- A significantly large global market opportunity with 140 million children born per annum³
- PainChek® Infant recently received regulatory clearance in Australia, Europe, UK, Canada, Singapore and New Zealand
- PainChek is engaging with clinical partners to establish strategies for the implementation of PainChek® Infant in a range of clinical settings involving both healthcare professionals and parents

PainChek® Ltd (ASX: PCK) ("PainChek®" or "the Company"), developer of the world's first smart phone-based pain assessment and monitoring application, is pleased to announce a study validating its PainChek Infant pain assessment tool has been published in the *Lancet Digital Health* journal.

A paper entitled "Assessing procedural pain in infants: a feasibility study evaluating a point-of-care mobile solution based on automated facial analysis"¹ provides evidence on the validity and reliability of PainChek® Infant, which recently received regulatory clearance in regions including Australia and Europe.

PainChek® Infant, the first in a suite of pain assessment tools planned by PainChek, is a new unidimensional mobile device pain assessment application which utilises automated facial recognition and analysis via artificial intelligence (AI) to detect facial expressions indicative of pain.

Developed specifically to assess pain in infants (1 to 12 months), PainChek® Infant's validity and reliability was assessed against the paper-based Neonatal Facial Coding System Revised (NFCS-R), which can be used to assess pain in children up to 18 months of age, and the observer administered Visual Analogue Scale (ObsVAS). The study used video recordings of 40 infants aged 2 to 7 months of age, with more than 4,300 pain assessments completed in two separate evaluation sessions, four weeks apart.

¹ Hoti K, Chiivers PT, Hughes JD. *Assessing procedural pain in infants: a feasibility study evaluating a point-of-care mobile solution based on automated facial analysis*. Lancet Digital Health 2021

[https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(21\)00129-1/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(21)00129-1/fulltext)

All pain assessment tools showed significant changes in infants' pain undergoing immunisation across four phases of the procedure – baseline, during preparation, immediately post injection and during recovery. PainChek® Infant pain scores demonstrated excellent correlation with NFCS-R and ObsVAS scores ($r=0.82-0.88$; $p<0.001$). PainChek® Infant also demonstrated moderate to excellent inter-rater reliability ($ICC=0.81-0.97$, $p<0.001$) and high levels of internal consistency ($\alpha=0.82-0.97$).

Co-author and PainChek CSO Emeritus Professor Jeff Hughes said:

“PainChek® Infant pain assessments provide an automated means of translating infant’s facial expressions into a meaningful way to assess procedural pain in just three seconds. Procedural pain is very common in this cohort of children, and whilst considered short-lived, poorly managed, it can have significant long-term consequences including needle aversion and chronic pain.”

Undertreatment of childhood pain is a significant issue, and that Eccleston and colleagues (2020)² recommended four strategies to address this, namely 1) make pain matter, 2) make pain understood, 3) make pain visible, and 4) make pain better. PainChek® Infant addresses Strategy 3 by providing a rapid and reliable means of assessing pain.

PainChek CEO Phillip Daffas said:

“PainChek recently received regulatory clearances for PainChek Infant including CE Mark and UK MHRA, allowing sales and marketing of the Infant app in Australia, Europe, UK, Canada, Singapore and New Zealand.

The global market size for PainChek Infant is significant with more than 140 million children born each year³, with first time parents often struggling to assess when their child is in pain.

PainChek is now engaging with clinical partners for the introduction of its infant app within the hospital, primary care (e.g. GP surgeries) and home care settings. We have already identified a number of potential applications including post vaccination and post-surgical, and potential users include a combination of healthcare professionals, as well as parents in the home.”

The PainChek infant publication can be viewed at: [https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(21\)00129-1/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(21)00129-1/fulltext)

This release has been authorized for release by CEO Philip Daffas.

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² Eccleston C, Fisher E, F Howard RF, et al. *Delivering transformative action in paediatric pain: a Lancet Child & Adolescent Health Commission*. *Lancet Child & Adolescent Health* 2021; 5: 47-87.

³ https://ourworldindata.org/grapher/births-and-deaths-projected-to-2100?country=~OWID_WRL

About PainChek®

PainChek® Ltd is an Australian based company that develops pain assessment technologies.

PainChek® is a smart phone based medical device using artificial intelligence and smart automation to identify and quantify pain and update medical records in the cloud in real-time.

Firstly, PainChek® analyses in real-time images from a three second video capture for the presence of facial expressions indicative of pain and records those that are present.

Next, the caregiver uses PainChek® to record their observations of other pain related behaviours that complete the assessment. Finally, PainChek® calculates an overall pain score and stores the result allowing the caregiver to monitor the effect of medication and treatment over time.

PainChek® is being rolled out globally in two phases: first, PainChek® for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek® for Children who have not yet learnt to speak.

The PainChek® Shared Care Program is a PainChek® licensing model which enables a professional carer to share their resident or patient data securely with other healthcare professionals or designated homebased family carers for ongoing pain assessments or clinical data review.

To find out more, visit www.painchek.com