

## December 2020 Quarterly Update

**PainChek delivers on sales growth during aged care lock down, while continuing market expansion and establishing partnerships to accelerate global growth**

### HIGHLIGHTS

Increases in all sales related KPI's across the business for the quarter ended 31 December 2020:

- **Residential Aged Care:** 884 Residential Aged Care (RAC) Facilities and 71,318 approved beds are under annual PainChek® license as at 31 December 2020, representing 133% and 123% growth over the previous year and 30%+ domestic market share. More than 260,000 PainChek clinical assessments have been conducted in aged care to date.
- **Annualised Recurring Revenue (ARR):** Contracted ARR increases 9% for the quarter to \$3.03M at 31<sup>st</sup> December 2020.
- **PainChek Universal Solution:** Product release as an App and system upgrade to all existing clients expected in Q1 C2021. The Universal App will broaden existing market size, accelerate new take up and support ongoing retention in all market segments.
- **PainChek Infants:** The PainChek Infant Face-Only clinical study successfully completed with excellent correlation to current manual children pain assessment tools used world-wide. PainChek on track for Q2 2021 TGA and CE Mark clearance and market launch into Australian and European markets.
- **Home Care market:** Australian Pilots coming to completion – domestic market and overseas market launches expected to commence in Q1 C2021.
- **Disability market:** Nulsen Group license and pilot study commenced for improving pain assessment and management of people with an intellectual disability. Six-month program is expected to lead to broader market release into NDIS/disabilities sector in 2021. Additional license agreement with the Disability Trust in Wollongong received in January 2021.
- **Hospital Market collaboration:** Ramsey Hospital and Cowan University Research study for hospitalised frail patient pain management commencing in Q1 2021.
- **Partnerships:** Philips HealthCare Europe-based collaboration for pain study related to reducing the risk of a delirium for hospital patients – to commence post COVID-19 vaccinations.
- **Overseas:** Canadian Home Care market launch with AlayaCare scheduled for late January 2021. UK market to re-open post COVID-19 vaccinations.
- **FDA clearance:** Awaiting internal FDA sign-off prior to commencing US based study work.
- **Cash Balance:** PainChek's consolidated cash balance at 31 December 2020 was \$12.4M.

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 report continued growth in aged care and initial entry into the hospital, home care and disability markets during the quarter ended 31 December 2020.

#### **Core Aged Care market:**

PainChek continued to deliver sales growth within Australian residential aged care in the past quarter. Sales growth in the quarter resulted in total global licenses covering 71,318 beds, which is 7% growth compared to the prior quarter and 123% growth year on year, and domestic sales reflects more than 30% of the Australian Residential Aged Care (RAC) market. PainChek now has 884 Aged care clients, which is 133% growth year on year, and the forward-looking revenue equates to more than \$3M Annualized Recurring Revenue post the government grant.

In the last quarter PainChek continued its growth contracting a net additional 4,431 Residential Aged Care beds. This is across 23 different Aged Care Providers who operate 89 Residential Aged Care Facilities. This included providers such as SA Health (45 RACs), Sundale (8 RAC's) and Uniting NSW/ACT (5 RAC's initially).

Several large provider agreements were delayed by the re-emergence of COVID outbreaks in late December and the Christmas shutdown period. These discussions have been picked up again in January, with senior stake holders of Aged Care Providers returning from leave. PainChek has an extremely strong pipeline of Aged Care beds to support continued growth in 2021.

In February 2021 the Department of Health, in line with the initiative, will conduct an email distribution to all aged care facilities in Australia to promote the further take up of the PainChek solution. This has been conducted previously and has resulted in a material uplift in inbound enquiries and sales leads for the Company.

During COVID-19 restrictions, the PainChek clinical team has successfully delivered training remotely, having conducted over 400 virtual workshops to Aged Care providers across Australia. Combined with the PainChek online learning curriculum, 3,198 aged care clinicians have been trained and conducted a PainChek assessment in the field. More than 260,000 PainChek clinical assessments have now been conducted in aged care, reflecting 190% growth year on year and the growing client acceptance and clinical utility.

The Company increased its partnerships program for broader distribution through new agreements with Ward Medication Management in Australia, Medi-Map in New Zealand and Medi-Care in the UK.

#### **Impact of COVID-19 and upcoming vaccine roll out on Aged Care business:**

This sales growth was achieved in very difficult circumstances as the impact of growing COVID-19 infection rates resulted in a government driven global lock down within residential aged care and restricting access to all except for essential workers to aged care facilities.

PainChek has continued to deliver its sales and service programs while respecting these restrictions and limitations placed on clients. This has been achieved through PainChek's fully digitized and remote sales and delivery business model.

With the availability of the COVID 19 vaccines, governments have now prioritized aged care and disability staff and residents and front-line healthcare workers as the primary recipients for vaccination in early 2021.

This will result in the re-opening of aged care centers and hospitals and form the basis for re-accelerating global sales, support and research programs, continuing to deliver on the Australian government funded initiative up to June 2021.

### New Market Expansion developments:

PainChek has also taken the opportunity to work with existing clients in the development of new PainChek initiatives including entering new larger healthcare market segments and the development of new PainChek products. These are core to the Company's business growth over the next 12 months. These new initiatives include;

#### 1. Home Care and Disabilities market - market entry:

- Four PainChek pilots with Home Care providers in Australia – these pilots are coming to a close in early 2021 and will provide the basis for entering the market locally.
- Canadian market Home Care launch in partnership with AlayaCare on 27 January 2021.
- UK market negotiations ongoing with Home Care providers.
- Initial disability license agreements with the Nulsen Group in Western Australia and the Disability Trust in Wollongong to assess pain for people living with disabilities. These pilot programs are expected to provide the basis for expansion into the disability sector in 2021.

#### 2. Hospital Market - new applications and market entry:

- Ramsay Hospital Research Foundation research agreements now in place to assess pain management for frail patients. This study commences in Western Australia in Q1 2021 and results will be used to review hospital patient pain management within the Ramsay Hospital Group.
- Philips Healthcare – European research collaboration on pain management for patients at risk of a delirium. This is being finalised and is expected to commence post vaccine roll out for healthcare professionals in Europe.
- Ongoing partner negotiations in place in multiple markets for hospital distribution.

#### 3. PainChek Universal Pain Assessment Solution:

Based on market feedback and client demand, PainChek has expanded the utility of the PainChek App to include the Numeric Rating Scale (NRS). The combination of PainChek and the NRS in one point-of-care PainChek application allows carers to assess pain for both those who cannot verbalise their pain and to document the pain score of those who can self-report their pain. PainChek is evolving to become the **Universal Pain Assessment Solution** for all people in all environments.

This means PainChek can now become the sole solution for multiple healthcare professionals in assessing and documenting pain across all their patients, making PainChek even stickier with existing clients and attracting new clients.

PainChek Universal App has been developed and is being tested now and is expected to be available globally during Q1 calendar 2021. More information can be found in the attachment and at <https://painchek.com/latest-publications/>.

#### **4. PainChek Infant:**

The Company is pleased to report that the PainChek Infant Face-Only study has been successfully completed and a publication has been written and submitted to a scientific journal for peer review. The findings support the use of PainChek Infant for procedural pain assessment with infants.

The findings showed that PainChek Infant (Face Only) has excellent correlation with Neonatal Facing Coding System and other similar tools currently in clinical use worldwide. Detailed results of the study will be made available following the peer-review and publication in a scientific journal.

PainChek is on schedule to achieve Australian (TGA) and European (CE mark) regulatory clearance for the Infants App in Q2 C2021. The results of this study will support the subsequent market launch in these markets.

PainChek expects to broaden the applications of PainChek Infant, through additional clinical studies in 2021 at the Royal Children's Hospital (RCH) in Melbourne, which is currently on hold due to COVID-19.

#### **PainChek CEO Philip Daffas commented:**

"PainChek is so much more than an Australian Aged Care App. It will be a Universal Pain Assessment Solution for all people – adults and kids – useable by every healthcare professional in all locations. We are on our way to becoming a new healthcare vital sign.

While 2020 was challenging for many businesses, we successfully continued to deliver with significant sales growth. This included pivoting to a fully digital sales and delivery model that met the immediate needs of our clients, as well as establishing a new cost-effective global go-to-market model.

We've now reached the point where the earliest RAC adopters of the Government initiative are coming off the 12-month trial period. We remain very confident of the vast majority of RACs continuing as fully paying clients of PainChek, and currently this is estimated to translate into \$3m of annual recurring revenue, a number we expect to continue to grow as we move forward.

We have listened to client feedback to continually improve our product and service delivery and commenced entry into new larger markets including home care, hospitals and the disability sector – growing our partnerships in these markets. We also continued the development of new products including the PainChek Universal pain assessment solution and the Infants App both of which will further expand our global market opportunities in 2021.

We also believe the worldwide COVID-19 vaccine roll out in early 2021 will underpin and support the re-acceleration of our global business opportunities."

Below is a summary of key measures for the past year on a quarterly basis.

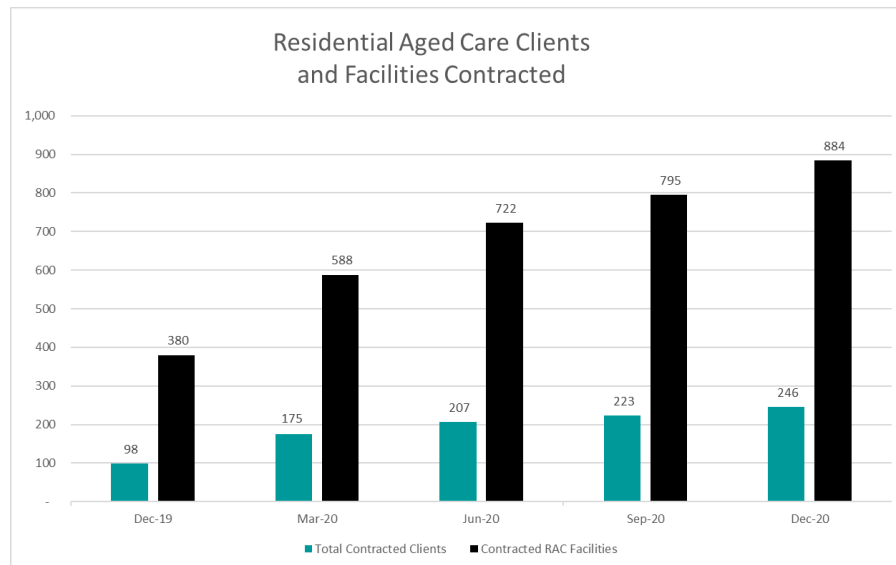


Table 1 above reflects PainChek's total contracted Residential Aged Care (RAC) clients and RAC facilities globally as at the end of each quarter. Contracted clients and RACs have grown to 246 and 884 respectively at 31 December 2020, an 10% and 11% increase respectively over the previous quarter.

In the last quarter PainChek continued its growth contracting a net additional 4,431 Residential Aged Care beds. The net increase (after non-renewals and adjustments) is 23 Aged Care providers who operate 89 Residential Aged Care facilities. This included providers such as SA Health (45 RAC's), Sundale (8 RAC's) and Uniting NSW/ACT (5 RAC's initially).

Several large provider agreements were delayed by the re-emergence of COVID outbreaks in late December and the Christmas period. These discussions have been picked up again in January, as senior stake holders of Aged Care providers return from leave. PainChek has a strong sales pipeline to support further growth in 2021.

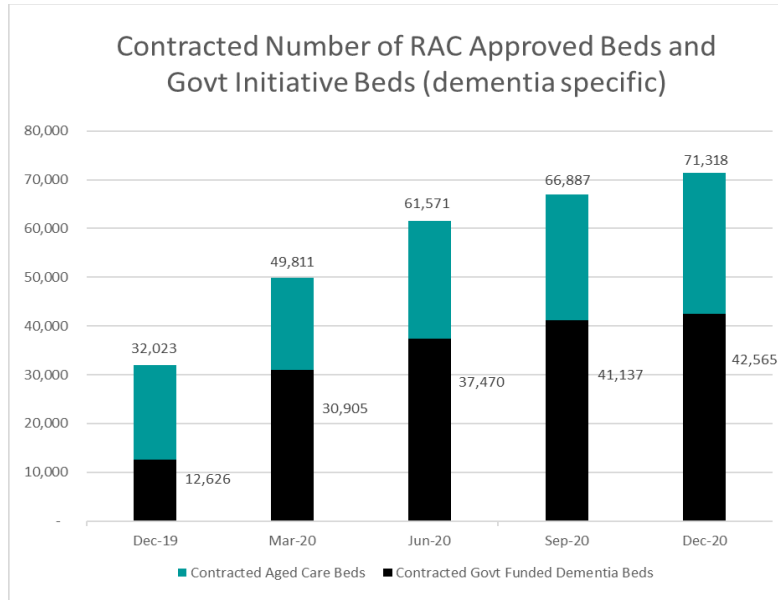


Table 2 above reflects the total approved beds contracted in all markets at the end of each quarter, including the dementia specific beds signed and funded under the government initiative.

- Total approved beds contracted have increased from 66,887 at 30 September 2020 to 71,318 at 31 December 2020, a 7% increase for the quarter.
- Under the government funded initiative, the Federal Government is funding a subset of the total approved contracted beds, in that the grant is funding the use of PainChek for those people living with dementia or cognitive impairment. The data gathered from the RAC participants to date supports that this subgroup is on average 62% of the total approved beds. On this basis, PainChek had achieved a total of 42,565 contracted dementia specific beds as at 31 December 2020, representing a 4% increase for the quarter.

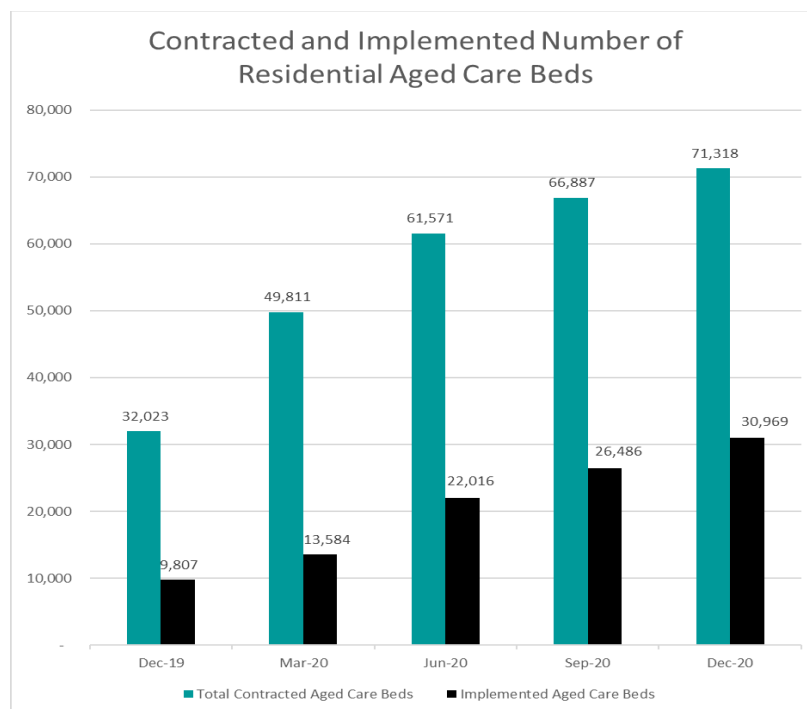


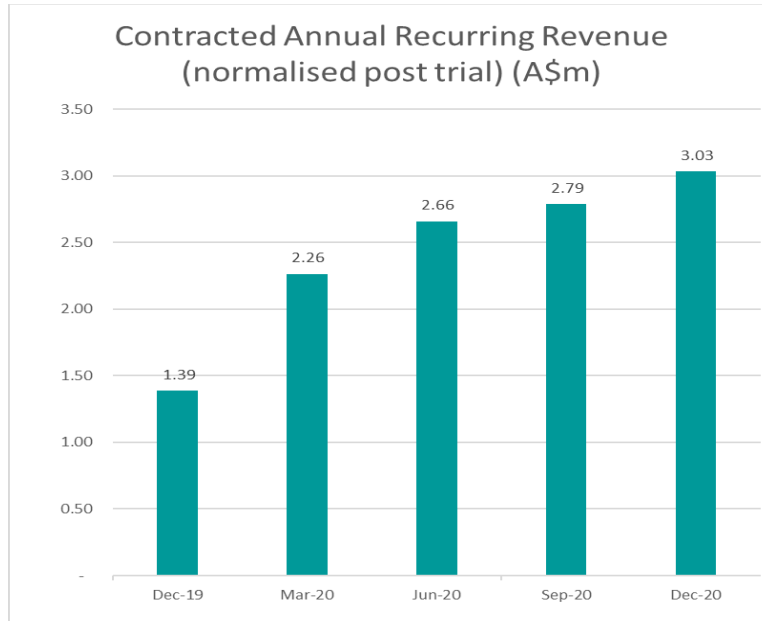
Table 3 above reflects total contracted and implemented beds at each quarter end across all markets. Implemented beds increased to 43.4% of total contracted beds at 31 December 2020, an increase on the comparative percentage of 39.6% at 30 September 2020.

There is a lag in implementing the bed licenses for the following reasons:

- There is a time differential between signing up the client and scheduling implementation of PainChek® across a client's multiple aged care facilities, which has been exacerbated by the pandemic and the issues it created in aged care.
- Large clients can take a number of months to implement due to the large number of facilities to be covered in the roll out.
- The continuing impact of COVID-19 in terms of staff availability to attend training and implement change in clinical practices.

To improve implementation rates the Company has significantly improved the quality and quantity of the on-line training and successfully transitioned to provide this service to clients through the remote digital delivery platform.

The Company has a plan in place to accelerate the implementation of PainChek® when the aged care sector's management of the COVID-19 impact and staff availability improve post the vaccine roll out.



\* Contracted ARR figures for the quarters to 30 September 2019 were calculated on the basis of contracted MRR x 12 months, as subscription contracts were on PainChek's normal commercial terms to that point in time. Contracted ARR figures for the quarters ending 31 December 2019 and later are presented on a normalized basis post completion of the Government grant reflecting contracted pricing on completion of the trial, and assumes the contracts are not terminated after the initial 12-month grant period.

Table 4 above reflects the increase in contracted Annualized Recurring Revenue (ARR) for the quarters ended 31 December 2019 through to 31 December 2020.

- ARR measured on this basis provides an indication of the Company's future revenue, as PainChek's normal commercial pricing will apply to total approved beds across all existing RAC's in year two of the contract, on the assumption that the clients do not terminate their contracts after the initial 12-month grant period.
- For the 71,318 approved beds contracted as at 31 December 2020, the contracted Annualized Recurring Revenue on a normalized basis in year 2 of the contract is \$3.03M, a 9% increase for the quarter.



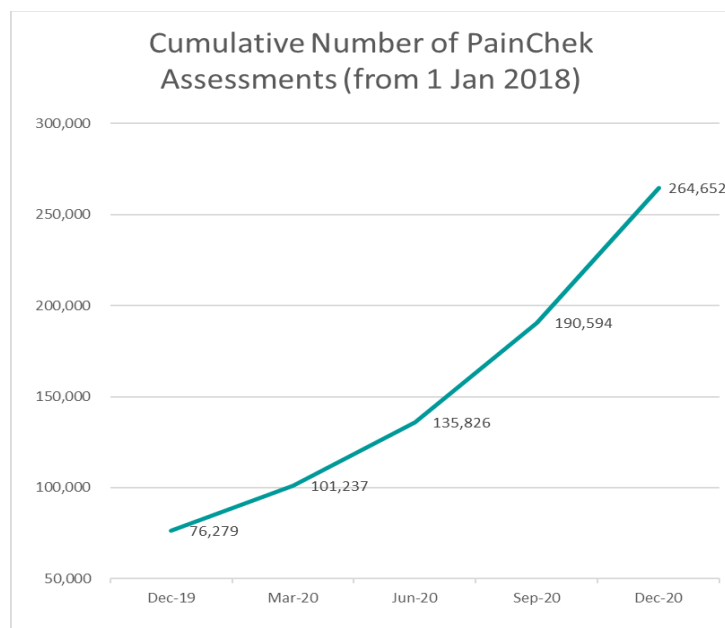


Table 6 above reflects the cumulative number of PainChek assessments up to 31 December 2020. There have now been more than 264,000 clinical pain assessments conducted by clients, demonstrating the App's strong clinical utility and uptake in the residential aged care market.

As a consequence, PainChek now has a comprehensive and growing database of pain assessments for people living with dementia. This database represents a significant asset to the company, PainChek users at an organisational, facility and patient level, and for researchers. The data collected is being used to:

- Develop business intelligence tools
- Promote and monitor best practice
- Facilitate future App and web admin portal development
- Further the understanding of how pain is manifested in those living with dementia

#### ***Australian Government funded sales activity this quarter***

In the quarter ended 31 December 2020, the Company signed 29 new clients to the government trial, representing an additional 105 RACs and 5,638 approved beds. These figures represent the gross number of new contracts, and are not net of non-renewals or adjustments during the quarter.

With the first tranche of 12-month trials ending, a small cohort of early adopters of the National trial were due to transition to paid subscriptions during the quarter. Some of these clients have successfully embedded PainChek as their pain assessment practice and have continued as contracted PainChek customers on standard commercial terms. There is also a cohort of Aged Care providers who undertook training, however due to COVID-19 outbreaks were unable to make use of PainChek during their 12-month trial period. This group mostly comprises small providers who do not have the same infrastructure or resources as larger organisations. After consultation with the Department of Health, PainChek granted a short extension of their trial to provide an opportunity for staff to experience the benefits of the PainChek technology. A few small clients have not renewed at this stage but we remain in contact and we have the opportunity to re-engage with them post COVID pandemic.

As of 31 December 2020, the Company has delivered and fully implemented PainChek into 152 of the clients signed or who opted into the government trial, covering 397 residential aged care facilities.

**Federal Government / Department of Health Grant milestones**

The following are the next milestones and related dates for which payments will be made under the contract terms to PainChek as part of the Federal Government initiative:

Milestone	Payment Amount (excl. GST)
Received prior to 30 June 2020	\$3,000,000
Provision of 75,000 cumulative licenses during FY2021 (Milestone 3: March 2021 or later)	\$950,000
Provision of 100,000 cumulative licenses during FY2021 (Milestone 4: May 2021 or later)	\$950,000
Provision of evaluation report during FY2021	\$100,000
Total funding	\$5,000,000

**Australian Home Care Market Expansion:**

Whilst competitive and operational pressures continue to constrain margins in the home care sector, the increased demand for evidence and value-based services positions PainChek well to support innovative and digital improvements for home care providers in the effective and consistent measurement of pain.

There are currently four PainChek home care Australian trials underway comprising three private providers and a not-for-profit home care provider. These trials are targeted for completion at the end of January 2021. Early indications are that there is an unmet need for standardized, documented and reproducible pain assessments in this market for clients with dementia and cognitive impairment and the point of care and continuity of care delivery of PainChek provides an effective solution to address this need. The overall trial goal is to collect user acceptance, provider and client clinical data as a basis for the broader home care market launch in Australia and overseas market in early 2021. PainChek has identified the top tier targets in the domestic market to underpin the subsequent local market roll out, directed at providers with density and scale.

Initial market development activity is also underway in the adjacent disability (NDIS) sector, targeted towards the assessment and management of people with an intellectual disability. With challenging behaviors 3–5 times more common in the intellectually disabled population than in the general population, a critical aspect of assessment is to screen for physical causes and look for unrecognized pain.

PainChek has successfully secured a first commercial agreements with NDIS disability services provider Nulsen Group and the Disability Trust in Wollongong, to further validate the application in this market and the use of PainChek to determine pain assessment indicators in people with intellectual disability and trials are underway. People with

cognitive impairment are eligible for the NDIS if they meet the age and residence requirements and either of the disability or early intervention criteria. The NDIS is a potentially high value market for PainChek with 392,000 active participants and \$16.1 billion paid by the NDIS for participant support in FY20.

### **PainChek infant's App development**

There are 400 Million pre-verbal children<sup>1</sup> in the world of which it is estimated a 100 Million are born to first time parents each year. This is a significantly large new market opportunity.

PainChek is pleased to report that the PainChek Infant Face-Only clinical study has been successfully completed and publication has been written and submitted to a scientific journal for peer review.

PainChek remains on schedule for Australian and European regulatory clearance of the PainChek® Infant product, with submission planned for Q2 calendar 2021 followed by market launch in these territories.

The PainChek Infant Face-Only study was developed to test the feasibility of using PainChek® Infant's face domain alone as an indicator of pain, and to evaluate it using video recordings of infants undergoing painful procedures. This study received ethics approval from Curtin University. The study involved PainChek infant face domain scores being compared with assessments conducted using the Revised Neonatal Facial Coding System (NFCS-R)<sup>3</sup> and the Observer Visual Analogue Scale (ObsVAS). Both NFCS-R and ObsVAS are well known and validated scales used in assessing procedural pain in infants, such as vaccinations, finger and heel pricks, dressing changes or more invasive procedures such as biopsies. Assessment of procedural pain occurs in various settings, from hospitals to home care environments.

Findings from the study support the use of PainChek Infant for procedural pain assessment. This was achieved by using the face only automatic assessment of infants' faces. Comparison against the NFCS-R and ObsVAS demonstrated the psychometric properties of PainChek Infant (Face Only) i.e. validity, reliability and internal consistency. The findings showed that PainChek Infant (Face Only) has excellent correlation with NFCS-R and ObsVAS. Detailed results of the study will be made available following the peer-review and publication in a scientific journal.

PainChek continues with next steps to broaden the clinical applications of PainChek Infant, including research at the Royal Children's Hospital (RCH) in Melbourne, which was put on hold due to COVID-19.

### **FDA regulatory clearance progress**

PainChek has been made aware that the assigned reviewer has completed their assessment of its pre-submission Supplement application, and it is awaiting internal FDA sign-off before it can be released.

In the meantime, PainChek already has TGA, CE mark, HSA Singapore and Health Canada clearances that covers approximately 40% of the global market. With FDA clearance the Company will effectively have access to more than 70% of the global medical device market.

## UK market progress

The UK market progress has been significantly impacted by COVID-19 during 2020 and the range of lock downs through the country. The UK team continue to operate digitally whilst visitation to residential aged care facilities remains restricted. Medium sized aged care groups are in a more stable position, enabling them to engage and consider larger scale technology implementations.

COVID-19 vaccinations commenced in December for UK care home staff and residents which concluded mid-January. This significant event will provide much comfort for operators of care homes and is likely to translate into purchasing confidence.

The sales pipeline continues to grow in the small and medium tiers, in particular where facilities have a speciality in dementia care and recent new license agreements have been finalised with aged care facilities Notwen House (Scotland), Grosvenor House, Meadows Sands and a large operator, Orchard Care, during October 2020.

PainChek UK entered into an integration agreement with Med e-Care, a leading provider of Electronic Medication Management and Care Management Software in both the UK and Canada. Further collaborations are planned for the next quarter. The collaboration with Person Centred Software UK has also seen the addition of new residential aged care clients (Rathgar Care and The Old Vicarage) and this demonstrates the strength in creating integrations with established technology providers.

The UK market has adapted to the presence of COVID-19 and whilst there are regional concerns, the social care sector is better prepared this time around. Additional funding for residential aged care facilities for pandemic support from the UK Government has been provided.

The next quarter should see an increase in pipeline that should lead to spending decisions increasing into Q1 CY2021. A key focus is establishing and capitalising on further integrations and partner working.

## Philips Healthcare collaboration:

The PainChek and Philips Europe-based research study plan is still delayed due to the COVID-19 impact in the Netherlands. The focus of the study is around combining PainChek facial pain indicators with other patient vital sign measures to proactively assess the risk of a delirium for a patient in hospital care.

Communications between the two parties around the fit of PainChek pain assessment technology within the Philips vital signs monitoring platform and its global pain management strategy continues. The collective aim of the parties' is to progress and finalize these collaborations so that they are ready to jointly execute immediately following the easing of COVID-19 related measures.

In accordance with ASX Listing Rule 4.7C.3, the amount of \$103,000 stated in section 6.1 of the Appendix 4C paid to related parties and their associates related to director fees and salaries for the quarter.

This release has been authorized for release by the Company's board.

**Philip Daffas**

**CEO – PainChek Limited**

**22<sup>nd</sup> January 2021**

## References

1. See PainChek ASX release Company presentation 28<sup>th</sup> November 2019

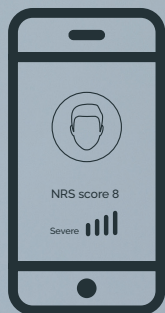


## The Universal Pain Assessment Solution for best-practice pain management

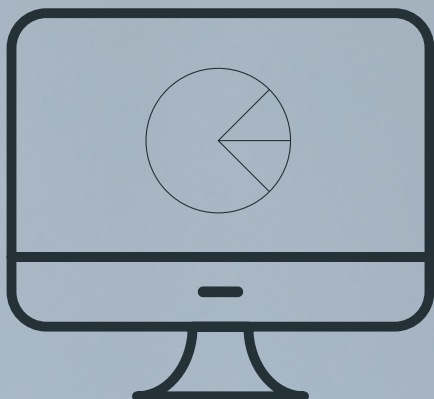
PainChek®  
App



Numerical  
Rating Scale



PainChek® Analytics



↓  
Enabling best-practice  
pain management





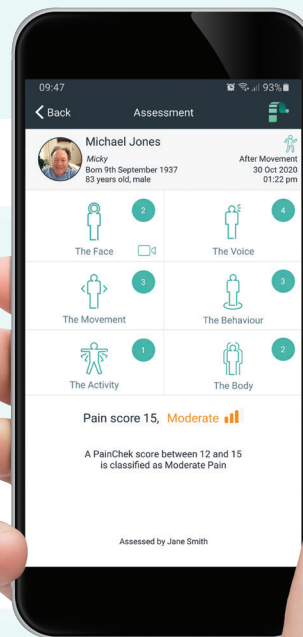


# The universal pain assessment solution for all residents in all situations

## PainChek® – giving a voice to those who cannot verbalise their pain.

PainChek® is now the gold-standard for pain assessment – providing a voice for those who cannot verbalise their pain. PainChek® has become the established standard of care within Residential Aged Care facilities, helping carers to accurately and rapidly assess pain severity levels at the point of care, for those residents living with dementia or cognitive impairment.

The PainChek® App's assessment framework includes the use of artificial intelligence to automatically assess the micro-facial features of pain for aged care residents, driving objectivity and consistency in all assessments.

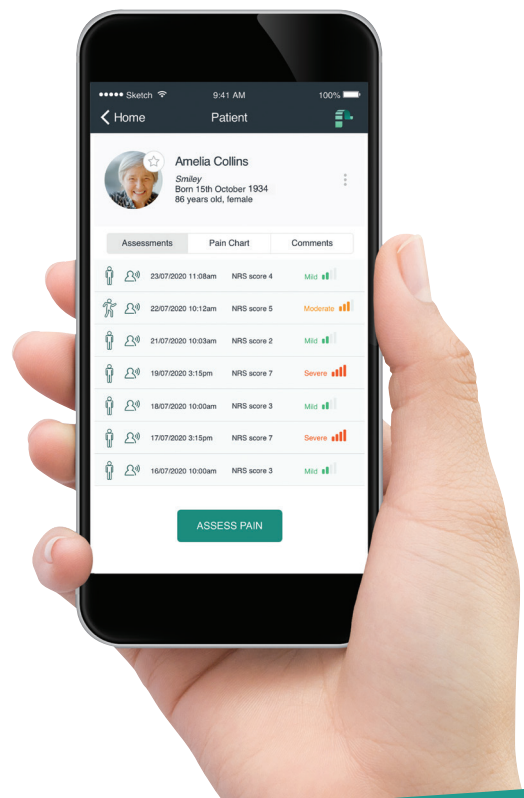




## Numeric Rating Scale (NRS) – documenting the pain scores of those who can.

Across all Residential Aged Care facilities, many residents are able to reliably verbalise their pain. The Numerical Rating Scale (NRS) is an established standard used to document self-reported pain levels, the results of which are typically manually transcribed by the assessor.

Historically, PainChek® and NRS have been separate pain assessment processes in terms of function and documentation. We have now improved the process by bringing the NRS into the PainChek® app, combining the benefits of the two pain scales into one universal pain assessment solution, simplifying and streamlining your pain assessment procedures.





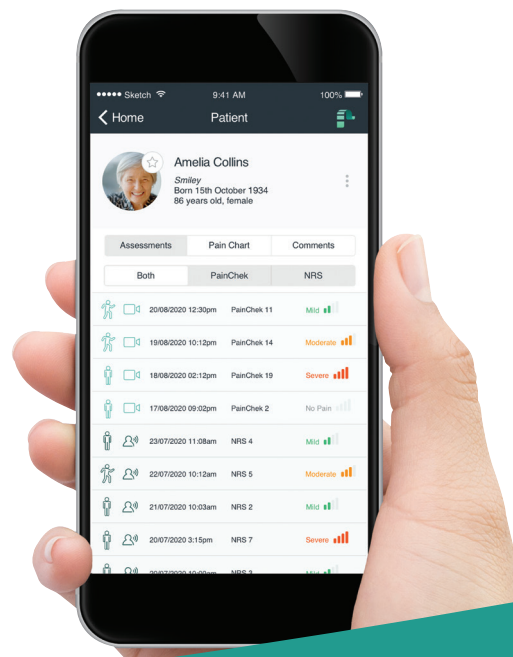


## The universal solution for those who fluctuate between the two.

There are times when an aged care resident's ability to reliably communicate the severity of their pain will fluctuate, with causes ranging from acute delirium brought on by a urinary tract infection, to the impacts of psychotropic medications.

In these, and other scenarios, residents may require access to both PainChek® and NRS over the course of a day, or even an hour.

PainChek® is the universal pain assessment solution, capturing pain scores for all residents regardless of their condition or ability to communicate their pain. Pain scores which are documented in real time, are seamlessly sent to your CMS and PainChek® Analytics within seconds of completion at the point of care. Through this, PainChek® ensures accurate pain assessment and enables best-practice pain management regardless of the situation.







## PainChek® Analytics supporting best-practice pain management

The updated PainChek® App which now includes NRS, generates significant data on pain assessment outcomes and activity at individual, facility and group levels. This data is presented through tailored dashboards to inform and empower

clinicians as they make crucial medical decisions on pain management. This unique and powerful dataset is created and reported through PainChek® Analytics and is available online through the PainChek® portal for all PainChek® clients.



## **The Universal Pain Assessment Solution enabling best-practice pain management**

The new Universal Pain Assessment Solution combines the unique PainChek® App with the NRS pain scale and PainChek® Analytics. This combination enables best-practice pain management for all residents, patients and people living with pain in any environment. It improves clinical processes through a fully digital product, training and documentation system. Benefits include:

- A complete Point of Care pain assessment solution
- Automated documentation - time saving for staff with no duplication of effort, double handling, or paperwork
- Fully digitised delivery, training and storage, with CMS integration across leading providers, including: AlayaCare, AutumnCare, CareLynx, Leecare, Management Advantage, Person Centred Software, Sarah Systems, TelstraHealth, Medi-Map (NZ)
- PainChek® Analytics – to monitor and improve assessment practices, and pain outcomes by resident, facility and across the group.

## **Free Federal Government 12-month PainChek license now available for Australian Residential Aged Care**

More than 900 aged care facilities have accessed a PainChek® license and more than 250,000 assessments have been completed with multiple reported clinical benefits.

If you're interested in finding out more and accessing the Federal Government funded PainChek® license, don't delay - this is a time-sensitive offer and spaces are limited.

Call or register online today.

Call **1800 098 809** or go online and visit **[www.painchek.com/free](http://www.painchek.com/free)**