

## CHRONIC PAIN MEDSCHECK (CPMC) TRIAL CONSULTATION SUMMARY

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### CHRONIC PAIN MEDSCHECK TRIAL

The CPMC Trial was funded by the Australian Government Department of Health (the Department) as part of the Sixth Community Pharmacy Agreement (6CPA) Pharmacy Trial Program (PTP). The 6CPA PTP was established to trial new and expanded community pharmacy programs that seek to improve clinical outcomes for participants by progressing the role of community pharmacies in the delivery of primary healthcare services.

The Pharmacy Guild of Australia (the Guild) entered into a Grant Agreement with the Department to undertake this trial, and the Guild contracted HealthConsult to design and evaluate the effectiveness of the Trial. An Expert Panel was established by the Pharmacy Guild of Australia to oversee the Trial and evaluation design as well as the Trial implementation.

The primary objectives of the evaluation of the CPMC Trial were to determine:

- the efficacy of the CPMC intervention in preventing incorrect use and/or overuse of pain medication, increasing participant's pain medication health literacy, improving their ability to self-manage their chronic pain and improving their overall quality of life
- the acceptance of, and satisfaction with, the CPMC intervention by pharmacists, participants and referred providers
- the cost-effectiveness/utility of the CPMC intervention.

The CPMC intervention was an in-pharmacy, patient-centred service that focused on reviewing participant's medications and providing education and information to improve participant's self-management of chronic pain. The CPMC Trial was undertaken from November 2018 (commencement of patient recruitment) to February 2020 (last follow-up services conducted).

The CPMC Trial had two arms referred to as Group A and Group B:

- **Group A** pharmacies offered two face-to-face consultations with consenting eligible participants – an initial consultation and a follow-up consultation three months later.
- **Group B** offered two face-to-face consultations with consenting eligible participants – an initial consultation and a follow-up consultation three months later – in addition, a third contact point was at six weeks after the initial consultation, where a follow-up consultation was conducted by telephone.

The additional contact point was included in the CPMC Trial design based on expert advice which stated that patients with chronic pain are complex and require frequent contact with health professionals in order to

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enact change. This hypothesis was tested in a community pharmacy setting by the inclusion of Group B (three contact points) compared to Group A (two contact points).

Pharmacy recruitment to participate in the CPMC Trial occurred through an expression of interest (EOI) process issued by the Guild. All community pharmacies were invited to participate in the CPMC Trial, as per the Minister of Health’s announcement.

All pharmacies that expressed an interest to participate were randomised to either Group A or Group B on a ratio of 1:1 (i.e. equal number of pharmacies randomised to Group A and Group B). In addition, a subgroup of community pharmacies was then selected at random from Group A and Group B to be “evaluation trial” sites instead of “main trial” sites. There was no difference in the intervention conducted by “main trial” or “evaluation trial” sites. However, three additional measures were required to be collected from the evaluation trial site participants (quality of life, health literacy and self-management) to inform the evaluation.

### SUMMARY OF THE PICO

The Population, Intervention, Comparator and Outcomes (PICO) that guided the evaluation of the CPMC Trial is presented in Table 1. The PICO was considered and accepted by the Expert Panel.

**Table 1 Criteria for guiding the evaluation of the CPMC Trial in participants with chronic pain**

Component	Subgroup	Description
Population	Groups A and Group B	Individuals who: attended a community pharmacy; suffered from chronic pain for three months or longer; had not had a Home Medicines Review, MedsCheck, Diabetes MedsCheck or CPMC within the previous 12 months; were taking medication (prescription or over the counter) for their pain; were identified by a community pharmacist as either experiencing self-management or dependency issues; and were not active clients of a recognised Pain Management Service (to ensure the CPMC service did not duplicate existing services received by the trial participant).
Intervention	Group A	An <b>initial</b> in-pharmacy face-to-face consultation between the pharmacist and the trial participant which involves: a review and assessment of the trial participant’s chronic pain experience and medication usage, including analgesics; provision of information, education and/or referrals; development of a written action plan with a focus on medication management education (including medication safety and efficacy), and self-management strategies to reduce reliance on medication alone for pain management.  A <b>follow-up</b> in-pharmacy face-to-face consultation approximately <b>three months</b> after the initial consultation which involves a review and assessment against the written action plan, updating the action plan (if required) and providing follow-up support and referral as required.
	Group B	Same intervention as for Group A above, with additional <b>follow-up consultation</b> via telephone approximately 6 weeks after the initial

Component	Subgroup	Description
		consultation. The intervention carried out during the 6-week consultation was the same as the 3-month follow-up described for Group A.
Comparator/s	Group A (post-intervention)	The comparator groups for the Group A intervention are: <ul style="list-style-type: none"> <li>no service, with data collected on Group A participants prior to commencing the CPMC intervention and compared to data collected on Group A participants at the end of the CPMC intervention.</li> <li>the Group B intervention, with data collected from Group A participants post-intervention compared to data collected from Group B participants post-intervention.</li> </ul>
	Group B (post-intervention)	The comparator groups for the Group B intervention are: <ul style="list-style-type: none"> <li>no service, with data collected from Group B participants prior to commencing the CPMC intervention and compared to data collected from Group B participants at the end of the CPMC intervention.</li> <li>the Group A intervention, with data collected from Group B participants post-intervention compared to data collected from Group A participants post-intervention.</li> </ul>
Outcomes	Groups A and B	<p><b>Patient relevant outcomes</b></p> <ul style="list-style-type: none"> <li>Decrease in pain severity<sup>α</sup></li> <li>Decrease in pain interference<sup>α</sup></li> <li>Decrease in psychological distress, depression and/or anxiety<sup>α</sup></li> <li>Improvements in quality of life*</li> <li>Reduction in average daily morphine equivalent dose for participants taking opioid medication<sup>α</sup></li> <li>Improvements in self-management of pain*</li> <li>Improvements in health literacy*</li> <li>Patient acceptance/satisfaction with the service*</li> <li>Adherence to action plan*</li> </ul> <p><b>Cost-effectiveness outcomes</b></p> <ul style="list-style-type: none"> <li>Cost per participant involved in the CPMC Trial</li> <li>Cost per unit change in pain severity</li> <li>Cost per unit change in pain interference</li> <li>Cost per unit change in pain self-efficacy</li> <li>Cost per unit change in self-management*</li> </ul> <p><b>Cost-utility outcome</b></p> <ul style="list-style-type: none"> <li>Cost per Quality Adjust Life Years (QALY)*</li> </ul> <p><b>Healthcare system outcomes</b></p> <ul style="list-style-type: none"> <li>Pharmacist/Pharmacy acceptance/satisfaction</li> <li>Health care resource use (e.g. emergency department visits and/or admissions due to pain<sup>ε</sup>, PBS utilisation)</li> </ul>

<sup>α</sup> included in mini ePPOC (all sites) <sup>ε</sup> Derived from self-reported data collected in mini-ePPOC (all sites) and linked MBS/PBS data for participants that provided consent from evaluation sites only \*evaluation trial sites only

## DESCRIPTION OF THE CPMC

The CPMC intervention, is an in-pharmacy, patient-centred service that focused on reviewing participants' medications and providing education to improve participants' self-management of chronic pain. The trial design commenced in February 2018, and pharmacy recruitment began in September 2018 with participant recruitment beginning in November 2018.

The CPMC trial had two arms referred to as Group A and Group B. In summary:

- **Group A** pharmacies offered two face-to-face consultations with consenting eligible participants – an initial consultation and another three months later.
- **Group B** offered two face-to-face consultations with consenting eligible participants – an initial consultation and another three months later – the additional contact point was at six weeks after the initial consultation where a follow-up consultation was conducted by telephone.

Pharmacy recruitment to participate in the Trial occurred through an expression of interest (EOI) process issued by the Guild. The EOI included a description of the Trial as well as a description of the difference between participating as a Group A or Group B pharmacy. All community pharmacies were invited to participate in the trial, as per the Minister of Health's announcement at the time.

To be eligible to take part in the CPMC trial, pharmacies must have:

- been approved to dispense pharmaceutical benefits as part of the Pharmaceutical Benefits Scheme (PBS) defined in Section 90 of the National Health Act 1953 (Cth) (Section 90 pharmacy)
- been able to ensure that services are delivered by a Registered Pharmacist face-to-face with the participant in the community pharmacy or over the telephone (midpoint consultation only for Group B)
- provided evidence, if required, that there was an area of the community pharmacy that is physically separated from the retail trading floor so that privacy and confidentiality of the participant is protected
- been appropriately furnished with facilities (including a having a computer in the consultation room with the trial software loaded) to allow the participant and the pharmacist to sit down together
- been able to allow the participant and pharmacist to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff)
- been able to obtain written participant consent in accordance with the Australian Privacy Principles (APP 3, APP5, APP6, APP 11 and APP 12)
- been accredited by an approved Pharmacy Accreditation Program
- followed the trial protocol (e.g. used the outputs of the mini-ePPOC tool (which was the data collection process built into the trial software) and the associated flow charts which detail the type of education, information and/or referrals to provide to the participant and guide the information included in their written action plan); and
- agreed to providing the data collected to HealthConsult Pty Ltd for the purpose of evaluation.

All pharmacies that expressed an interest to participate in the CPMC Trial were randomised to either Group A or Group B on a ratio of 1:1 (i.e. equal number of pharmacies randomised to Group A and Group B). After completing the required continuing professional development (CPD) accredited online training, pharmacists in each group recruited participants that met the inclusion/exclusion criteria. Pharmacists then provided their designated Group services according to the Trial protocol.

The CPMC service model for Group A was largely based on the Diabetes MedsCheck service model delivered by community pharmacies under the 6CPA. Hence, the Group A intervention included two consultations.

The Group B intervention built on literature and expert advice which suggested participants suffering from chronic pain are complex participants who need additional support. Therefore, an additional consultation was added. The initial consultation and final consultation for Group A and B were identical. The only difference between Group A and Group B was the additional consultation which occurred at midpoint of the intervention (i.e. six weeks after the initial consultation).

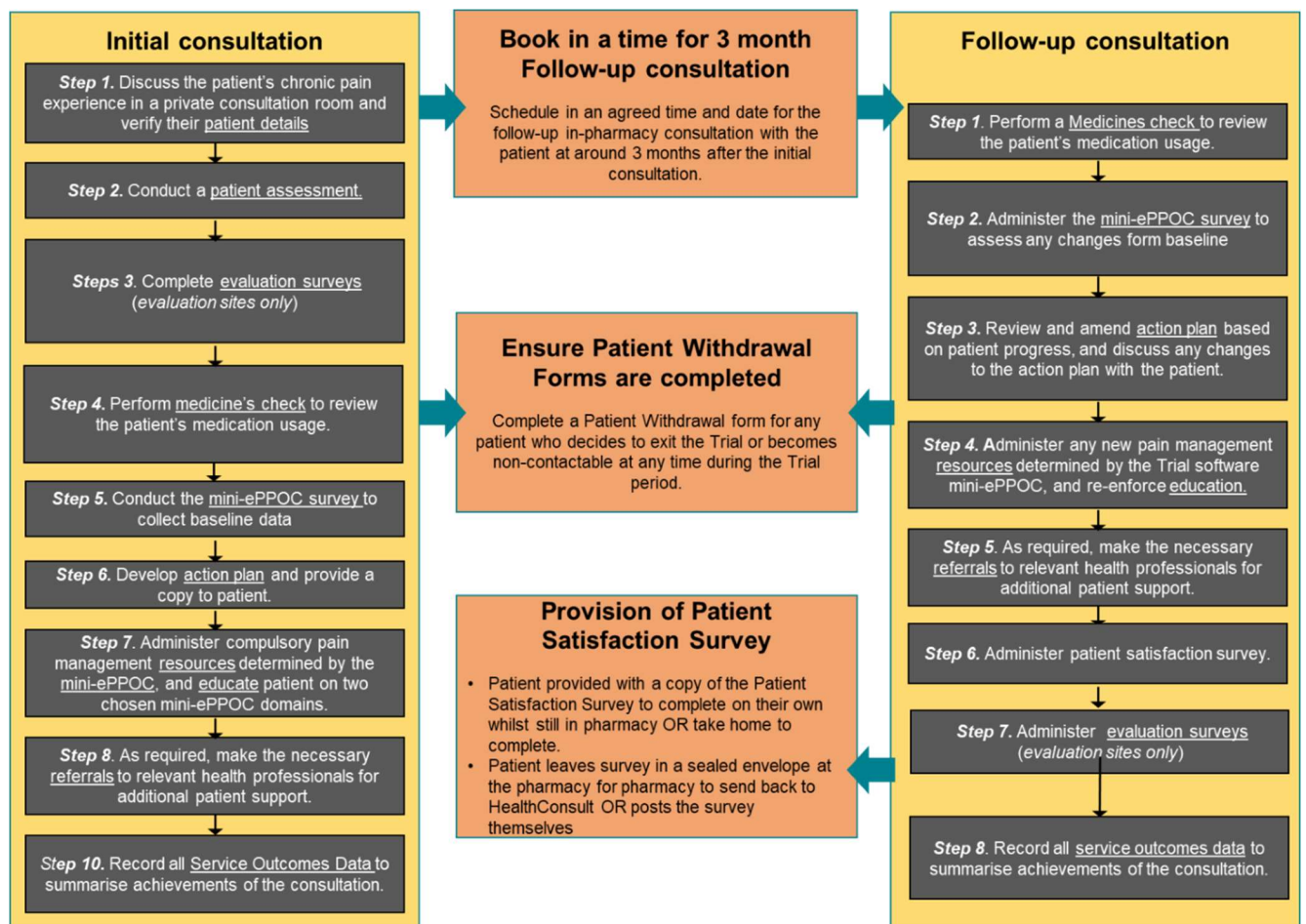
The population eligible for the Trial were participants who:

- attended a community pharmacy
- over the age of 18
- holder of a valid Medicare card and/or DVA card
- living at home in a community setting
- suffered from chronic pain for three months or longer
- had not had a Home Medicines Review, MedsCheck, Diabetes MedsCheck or Chronic Pain MedsCheck within the previous 12 months
- had been taking medication (prescription or over the counter) for their pain
- were identified by a community pharmacist as either experiencing self-management or dependency issues, and
- not a current client of a recognised Pain Management Service.

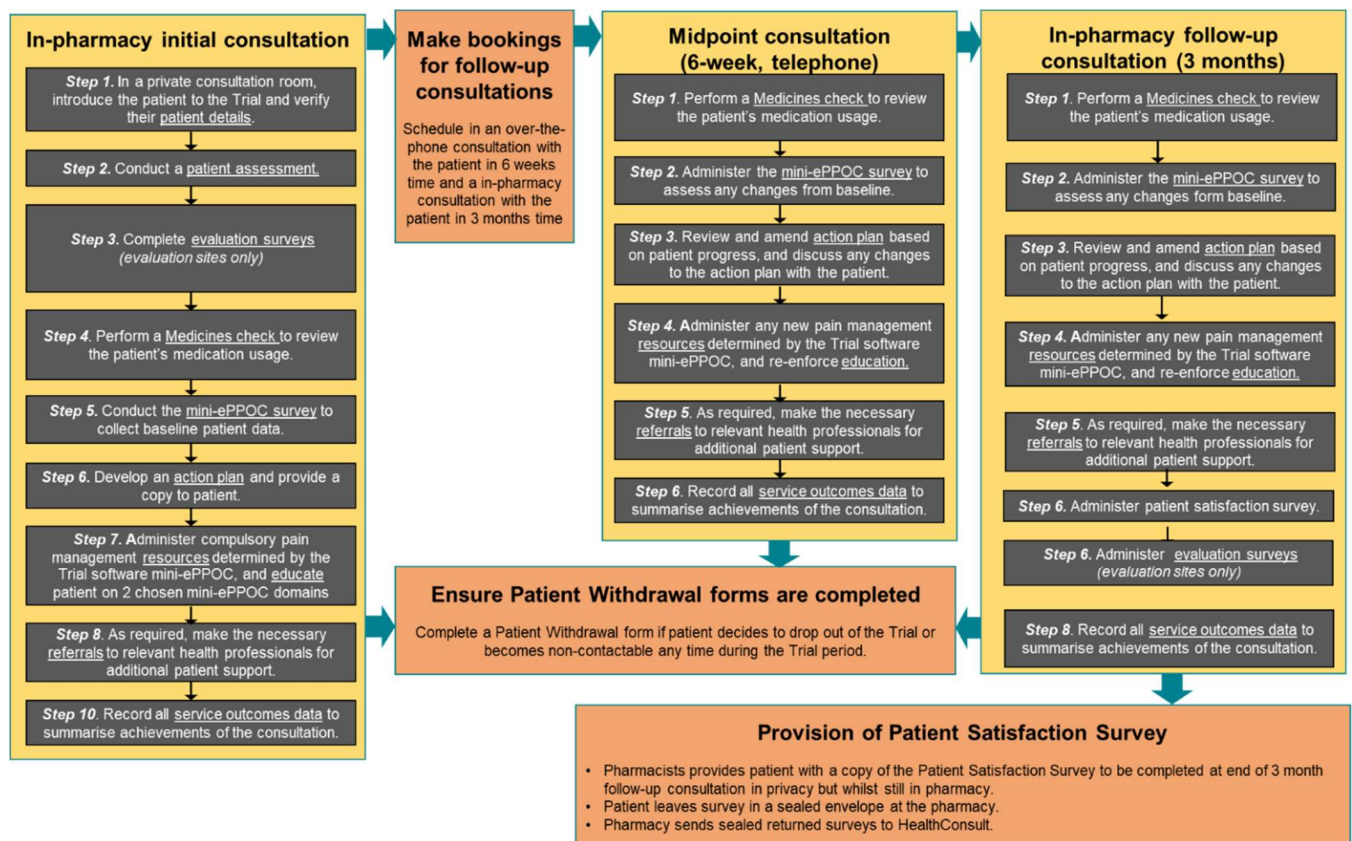
#### **Overview of CPMC services offered by Group A and Group B pharmacies**

Details about the intervention implemented at Group A and Group B pharmacies are provided below, respectively.

Detailed overview of the intervention implemented at Group A pharmacies



## Detailed overview of the intervention implemented at Group B pharmacies



## PHARMACY NUMBERS AND CHARACTERISTICS

From October 2018 to December 2019, 1,630 pharmacies registered for the CPMC Trial. Of these, 1,042 (63.9%) completed the training. Only 550 pharmacies (33.7%) had at least one participant commence the CPMC Trial and complete their initial consultation. In total, 1,080 pharmacies (66.3%) either withdrew and provided notification, were lost to follow up, or did not have anyone commence the CPMC intervention and complete their initial consultation.

Pharmacy characteristic data including the type of pharmacy, location and dispensing model was collected from the 550 participating pharmacies, with participation defined as pharmacies that had at least one individual start the CPMC Trial and complete their initial consultation.

Overall, pharmacies in all States and Territories were represented in the CPMC Trial with the exception of Northern Territory. Most of the pharmacies were located in major cities (64.1%), with around a third located in inner and outer regional areas (32.8%) and only a very small proportion of pharmacies located in remote and very remote areas (3.1%).

In total, 452 (82.2%) of the participating pharmacies were main trial sites and 98 (17.8%) were evaluation trial sites. Group A and Group B had similar proportions of main and evaluation sites and spread of

pharmacies across the different Pharmacy Accessibility and Remoteness Index for Australia (PhARIA) categories. The PhARIA was used to determine the accessibility of participating pharmacies. Most of the participating pharmacies were highly accessible (86.2%). Much smaller proportions of participating pharmacies were accessible (9.3%), moderately accessible (2.2%), remote (1.1%) and very remote (1.3%).

#### **PARTICIPANT NUMBERS AND CHARACTERISTICS**

A total of 8,239 individuals (termed ‘participants’) enrolled in the CPMC Trial and completed their initial consultation. Around two thirds of them participated in the trial at a main trial site (68.5%) and almost a third participated in the trial at an evaluation trial site (31.5%). Table 2 presents the number of participants that completed their initial, midpoint (Group B only) and follow-up consultations. In summary:

- Group A had a total of 4,316 participants (52% of the total number of participants) commence the CPMC Trial. Of these, 2,853 (66%) completed their follow-up consultation.
- Group B had 3,923 participants (48% of the total number of participants) commence the CPMC Trial. Over half of these participants (60%) completed their midpoint consultation and around a third (39%) completed their follow-up consultation.

**Table 2: Number of CPMC Trial participants who completed initial, midpoint and follow-up consultations**

Group	Consultation		
	Initial	Midpoint	Follow-up
Group A	4,316	-	2,853
Group B	3,923	2,335	1,521
<b>TOTAL</b>	<b>8,239</b>	<b>2,335</b>	<b>4,374</b>

*Source: Participant data collected using Trial GuildLink software*

There was no follow-up data for 3,865 of the 8,239 participants that commenced the Trial and completed their initial consultation. These participants represent 46.9% of the total initial sample and are considered to be lost to follow up.

The distribution of participants across the different age groups was comparable between the main trial and evaluation trial sites, with largest proportion of participants in the 70-74 year age range in both types of trial sites.

Across all pharmacies, 62.6% of participants were female and 37.4% of participants were male. There were similar differences in gender between participants at main and evaluation sites and between participants in Group A and Group B. The gender characteristics of participants across all trial sites were similar at the initial and follow-up timepoints.

To be eligible for the CPMC Trial, participants needed to have been experiencing pain for more than three months. Around half of them (47% in Group A and 50% in Group B) had experienced pain for more than five years, and most (85% in Group A and 82% in Group B) had experienced pain for over 12 months.



The most common reason pharmacists invited individuals to participate in the CPMC Trial across all pharmacies was suboptimal chronic pain management (26.9%), followed by taking analgesics including non-prescription and complementary medicines (20.0%), difficulties in maintaining activities of daily living due to pain (10.8%), and taking opioids (<50 OME) (10.8%).

The number of pain sites reported by participants at their initial consultation was similar between Groups A and B, with the largest proportion of participants experiencing pain at 2-3 sites. The site of pain most commonly reported by participants at their initial consultation across all pharmacies was the back (24.6%), followed by leg (11.1%), knee (10.4%) and arm/shoulder (10.3%).

Prior to commencement of the CPMC intervention, around three quarters of the participants in both Group A and Group B reported experiencing pain all the time, either at varying levels of intensity or the pain was always present at the same intensity. Participants were also asked to rate the severity of their pain in the past week. At the start of the intervention, 22% reported experiencing mild pain, 31% reported experiencing moderate pain and 47% reported experiencing severe pain.

The key characteristics of participants who were lost to follow-up were comparable to those of participants that completed their follow-up consultation, except participants that attended their follow-up consultation had slightly higher proportions belonging in the older age categories, defined as 65 years and above, and living in a major city. The frequency and severity of the pain experienced by participants prior to commencing the intervention were also comparable between those that completed their follow-up consultation and those who were lost to follow-up.

#### IMPACT ON PARTICIPANT OUTCOMES

Overall, the CPMC intervention delivered by both Group A and Group B pharmacies has been shown to be effective in improving a number of participant health outcomes, including pain severity, pain interference and overall level of psychological distress. Participation in the CPMC intervention also helped individuals improve their pain self-efficacy and self-management, which suggests they are better equipped to manage their chronic pain and are more confident in performing daily activities despite their pain. Group B demonstrated greater improvements, in terms of the effect size, in most of these participant outcomes from initial to follow-up compared to Group A. Table 3 provides a summary of the changes in key participant outcomes by Group A and Group B sites.

**Table 3: Summary of the changes in the key outcomes from initial to follow-up in Groups A and B**

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
<b><i>Pain severity</i></b>										
<b>Group A</b>	4,316	6.09 (2.08)	6	2,853	5.20 (2.24)	5	-0.89	-0.79	-0.99	0.00
<b>Group B</b>	3,923	6.15 (2.20)	6	1,521	4.60 (2.54)	5	-1.55	-1.41	-1.69	0.00

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
<b><i>Pain interference (general activities)</i></b>										
Group A	4,316	5.72 (2.62)	6	2,853	4.81 (2.58)	5	-0.91	-0.78	-1.03	0.00
Group B	3,923	5.80 (2.73)	6	1,521	4.15 (2.79)	4	-1.65	-1.49	-1.82	0.00
<b><i>Pain interference (sleep)</i></b>										
Group A	4,316	5.27 (3.04)	6	2,853	4.38 (2.86)	5	-0.88	-0.74	-1.03	0.00
Group B	3,923	5.25 (3.15)	5	1,521	3.56 (2.91)	3	-1.69	-1.51	-1.88	0.00
<b><i>Psychological distress</i></b>										
Group A	4,316	3.35 (3.38)	2	2,853	2.62 (2.96)	2	-0.73	-0.58	-0.88	0.00
Group B	3,923	3.47 (3.60)	2	1,521	2.33 (3.20)	1	-1.13	-0.93	-1.34	0.00
<b><i>Pain self-efficacy</i></b>										
Group A	4,316	7.37 (3.08)	8	2,853	8.14 (2.80)	8	0.77	0.91	0.63	0.00
Group B	3,923	7.22 (3.31)	7	1,521	8.60 (3.19)	9	1.38	1.57	1.18	0.00
<b><i>Self-management total score</i></b>										
Group A	1,452	71.08 (14.35)	72	725	76.69 (13.41)	78	5.61	6.86	4.36	0.00
Group B	565	72.82 (15.71)	76	239	73.98 (15.00)	76	1.16	3.51	1.18	0.00
<b><i>AQoL utility score</i></b>										
Group A	1,443	0.58 (0.26)	0.61	725	0.63 (0.25)	0.68	0.05	0.07	0.03	0.00
Group B	562	0.53 (0.28)	0.54	234	0.70 (0.24)	0.75	0.17	0.21	0.13	0.00
<b><i>Average morphine equivalent dose</i></b>										
Group A	2,161	50.84 (63.90)	30	1,359	49.87 (62.35)	30	-0.97	3.33	-5.26	0.07
Group B	1,809	47.74 (54.30)	30	700	47.82 (54.52)	30	0.08	4.82	-4.67	0.60
<b><i>Healthy literacy total score</i></b>										
Group A	1,450	39.05 (11.3)	39	725	45.71 (9.52)	46	6.66	7.63	5.71	0.00
Group B	565	44.11 (12.27)	46	238	44.60 (12.01)	47	0.49	2.34	1.36	0.60
<b><i>ED presentations</i></b>										
Group A	4,316	0.16 (0.65)	0	2,853	0.15 (0.62)	0	-0.01	0.01	-0.04	0.67
Group B	3,923	0.16 (0.69)	0	1,521	0.14 (0.65)	0	-0.02	0.01	-0.03	0.40
<b><i>Hospital admissions</i></b>										

	Initial measure			Follow-up measure			Change from initial to follow-up			
	n	Mean (SD)	Median	n	Mean (SD)	Median	Mean	95% CI		P value
								Upper	Lower	
<b>Group A</b>	4,316	0.10 (0.47)	0	2,853	0.09 (0.48)	0	-0.00	0.00	-0.01	0.26
<b>Group B</b>	3,923	0.10 (0.43)	0	1,521	0.09 (0.46)	0	-0.00	0.00	-0.01	0.50
<b>Vegetable intake</b>										
<b>Group A</b>	4,316	2.51 (1.36)	2	2,853	2.74 (1.30)	3	0.23	0.17	0.29	0.00
<b>Group B</b>	3,923	2.63 (1.43)	2	1,521	3.31 (1.35)	3	0.68	0.59	0.76	0.00

Abbreviations: AQoL, The Assessment of quality of life instrument; CI, Confidence interval; ED, Emergency department; SD, Standard deviation

There were improvements in the severity of pain experienced by participants from initial to follow-up in both Groups and these changes were statistically significant. On average, Group B participants demonstrated a greater improvement in their pain severity over time from initial to follow-up compared to Group A participants.

There were also improvements in the degree of interference the participant's pain had on both their general activities and sleep from initial to follow-up in both Groups, and these changes were also statistically significant. On average, Group B participants demonstrated greater improvements in the degree of pain interference compared to Group A participants from initial to follow-up on both their general activities and sleep from initial to follow-up.

The average level of psychological distress experienced by participants at the initial consultation were similar in Groups A and B and both Groups demonstrated statistically significant improvements from initial to follow-up.

Pain self-efficacy scores were similar in Groups A and B at the start of the intervention. There were improvements in the participant's levels of self-efficacy from initial to follow-up in both Groups A and B, and these changes were statistically significant. On average, Group B participants demonstrated a greater improvement in their self-efficacy in managing their pain from initial to follow-up compared to Group A participants.

Group A participants improved their average self-management and health literacy total scores from initial to follow-up and both increases were statistically significant. Group B participants also had a statistically significantly higher average self-management score at follow-up compared to initial but the increase in their average health literacy total score was not statistically significant.

There was a statistically significant improvement in the average AQoL utility score from initial to follow-up in Group A participants that was almost clinically important (i.e. change of 0.06 units or more).<sup>1</sup> Group B

participants also demonstrated a statistically significant improvement in their average AQL utility score from initial to follow-up and this change was clinically important.

There was no change in the average daily morphine equivalent dose in Group A or Group B participants from initial to follow-up. Given the intervention was only over a three-month period, advice from Expert Panel membership suggests this is not unexpected in the short timeframe.

Less than 10% of participants in both Groups reported at the initial and follow-up timepoints that they had visited the hospital, either as a presentation to an Emergency Department (ED) or hospital admission, in the last month as a result of their pain. On average, participants in both Group A and Group B reported fewer ED presentations due to their chronic pain at follow-up compared to the initial timepoint (0.15 c.f. 0.16 times in Group A and 0.14 c.f. 0.16 times in Group B) but these changes were not statistically significant. Participants also reported fewer hospital admissions because of their pain, on average, at follow-up compared to the initial timepoint. Again, this change was not statistically significant.

Participants were asked two questions on vegetable intake and consumption of sugar sweetened drinks because it was hypothesised by members of the Australian Pain Society, that optimising diet with healthy food allows gut bacteria to thrive, which results in a reduction in inflammation and pain. Vegetable intake and consumption of sugar sweetened drinks were similar in Groups A and B at the start of the intervention and there were statistically significant improvements in both measures from initial to follow-up in both Groups. On average, Group B participants demonstrated greater improvements in these two nutritional measures.

At the start of the intervention, 22% of participants (n=1,813) reported experiencing mild pain, 31% (n=2,591) reported experiencing moderate pain and 47% (n=3,835) reported experiencing severe pain. Subgroup analyses using data combined from both Groups A and B showed that, on average, participants' pain severity (Table 4) decreased from initial to follow-up regardless of whether their pain was mild (3.02 to 2.82), moderate (5.55 to 4.71) or severe (7.97 to 6.23) prior to commencing the intervention. However, participants that had moderate or severe pain at the initial timepoint benefited more from the intervention, demonstrating significantly larger improvements to their average pain severity scores, with reductions of 15.3% and 21.5% respectively, compared to those that had mild pain, with a reduction of 8.3%, from the start of the intervention.

**Table 4: Changes to average pain severity scores for different categories of pain severity**

Pain severity experienced at initial	Pain severity score at initial			Pain severity score at follow-up			Change in pain severity score from initial to follow-up (using only matched data)			
	n	Mean (SD)	Median	n	Mean (SD)	Median	n	Mean (SD)	% change	P value*
Mild pain	1,813	3.02 (1.03)	3	961	2.82 (1.77)	3	961	-0.25 (1.69)	-8.28	N/A#

<b>Moderate pain</b>	2,591	5.55 (0.50)	6	1,407	4.71 (1.81)	5	1,407	-0.85 (1.81)	-15.3	0.00
<b>Severe pain</b>	3,835	7.97 (1.00)	8	2,006	6.23 (2.13)	7	2,006	-1.71 (2.09)	-21.5	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

\*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Mild pain category was used as the comparison group in this regression modelling

Similarly, subgroup analyses using data combined from both Groups A and B showed that, on average, participants' pain interference to general activities (Table 5) also decreased from initial to follow-up regardless of whether their pain was mild (3.17 to 2.58), moderate (5.33 to 4.33) or severe (7.30 to 5.72) prior to commencing the intervention. However, participants who had moderate or severe pain at the initial timepoint benefited more from the intervention, demonstrating statistically significantly larger improvements to their average pain interference scores, with reductions of 17.6% and 21.8% respectively, compared to those that had mild pain, with a reduction of 16.7%, at the start of the intervention.

**Table 5: Changes to pain interference (to general activities) levels for different categories of pain severity**

Pain severity experienced at initial	Pain interference score at initial			Pain interference score at follow-up			Change in pain interference score from initial to follow-up (using only matched data)			
	N	Mean (SD)	Median	n	Mean (SD)	Median	n	Mean (SD)	% change	P value*
<b>Mild pain</b>	1,813	3.17 (2.10)	3	961	2.58 (2.07)	2	961	-0.53 (1.85)	-16.72	N/A#
<b>Moderate pain</b>	2,591	5.33 (2.06)	5	1,407	4.33 (2.29)	5	1,407	-0.94 (2.14)	-17.64	0.00
<b>Severe pain</b>	3,835	7.30 (2.16)	8	2,006	5.72 (2.57)	6	2,006	-1.59 (2.35)	-21.78	0.00

Source: Participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

\*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Mild pain category was used as the comparison group in this regression modelling

Further subgroup analyses using data combined from Group A and B Group showed the average AqoL utility scores increased the most for participants whose pain severity and pain interference to general activities improved and, conversely, became worse for participants whose pain severity and interference became worse (

Table 6). There were also slight improvements in the average AQL utility score, pain self-efficacy and self-management for participants whose pain severity and pain interference to general activities were unchanged from initial to follow-up. This suggests those that were more confident and able to manage their pain and perform their daily activities despite their ongoing chronic pain experienced improved quality of life.

Table 6: Average change in AQoL utility scores depending on whether participants' pain severity and interference (to general activities) changed from initial to follow-up

	AQoL utility score at initial			AQoL utility score at follow-up			Change in AQoL utility score from initial to follow-up (using only matched data)			
	n	Mean (SD)	Median	n	Mean (SD)	Median	n	Mean (SD)	% change	P value*
<b>Changes in pain severity from initial to follow-up</b>										
Pain severity improved	755	0.57 (0.26)	0.60	560	0.70 (0.24)	0.75	382	0.10 (0.22)	0.27	0.00
Pain severity unchanged	313	0.52 (0.29)	0.56	239	0.58 (0.26)	0.62	155	0.03 (0.26)	0.10	N/A#
Pain severity became worse	194	0.59 (0.25)	0.64	160	0.57 (0.24)	0.56	109	-0.02 (0.24)	-0.07	0.22
<b>Changes in pain interference (general activities) from initial to follow-up</b>										
Interference improved	703	0.56 (0.26)	0.59	537	0.70 (0.23)	0.75	366	0.10 (0.22)	0.24	0.00
Interference unchanged	362	0.55 (0.28)	0.59	275	0.60 (0.27)	0.65	176	0.04 (0.25)	0.10	N/A#
Interference became worse	197	0.59 (0.25)	0.64	147	0.54 (0.25)	0.55	104	-0.04 (0.26)	-0.10	0.05

Source: Evaluation data collected via Survey Monkey at the initial (n=1,443) and follow-up (n=565) timepoints, and participant data collected using GuildLink at the initial (n=8,239) and follow-up (n=4,374) timepoints

Note: AQoL questionnaire was administered only at the evaluation sites during the initial and follow-up consultations. Not all participants who responded to questions about their pain severity and interference completed the AQoL questionnaire.

\*Regression modelling using matched data and with pain severity treated as an ordinal variable, adjusted for clustering by pharmacy

#Unchanged pain severity and pain interference categories were used as the comparison groups in this regression modelling

## TRANSLATION ISSUES

The economic model used CPMC Trial intervention data, CPMC evaluation data which included linked MBS and PBS data. The key translation issues are summarised below in Table 7.

Table 7: Translation issues

Type	Issue	Comments
Applicability	<p>Generalisability of the evidence</p> <ul style="list-style-type: none"> <li>• Comparability of trial population vs. general Australian population <ul style="list-style-type: none"> <li>- Baseline characteristics</li> </ul> </li> <li>• Determination of the cost of the pharmacy intervention by trial arm</li> </ul>	<p>In general, the population in the CPMC Trial was comparable to the Australian population with chronic pain.</p> <p>HealthConsult conducted an activity-based costing study to determine costs of the interventions. However, to align with standard practice for MSAC assessment, the trial fees and not the representative cost of the interventions have been used in the economic model.</p>
Extrapolation	<ul style="list-style-type: none"> <li>• Time horizon of the model</li> </ul>	<p>The time horizon in the model was considered conservative as the condition does not lead to a reduction in survival. A pre vs post model was used</p>

Type	Issue	Comments
		with results after six months before and after trial initiation evaluated.
Transformation	<ul style="list-style-type: none"> <li>• Derivation of reduction in PBS and MBS services and hospital costs data</li> <li>• Utilities applied in the economic evaluation</li> <li>• Application of participant reported outcomes using an unvalidated questionnaire in this population</li> <li>• Morphine equivalent units</li> </ul>	<p>Analysis on the reduction in PBS and MBS services undertaken from data requested from Services Australia. Self-reported emergency department presentation and hospitalisation data used. The utilities were calculated directly from the trial utilities</p> <p>The use of the mini-ePPOC tool and analysis of morphine units is discussed in Section C</p>

Abbreviations: CPMC, Chronic pain MedsCheck; MBS, Medicare Benefits Schedule; mini-ePPOC, mini- electronic Persistent Pain Outcomes Collaboration; MSAC, Medical services advisory committee; PBS, Pharmaceutical Benefits Schedule

#### DURATION OF THE CHRONIC PAIN MEDSCHECK CONSULTATION AND TRIAL FEE

The Group B intervention is the recommended intervention model (a face-to-face initial consultation and follow-up consultation with a telephone consultation at midpoint) if CPMC is to be implemented as an ongoing program. This is due to the Group B intervention resulting in greater improvements in most of the participant health outcomes at three months and was shown to be more cost-effective compared to Group A. The total fees paid to Group B Trial Site pharmacies was \$164.03. This is the fee recommended for the intervention.

**Table 8: Consultation duration and trial fee**

##### Initial consultation

	Minutes	Trial Fee
<b>Group B Trial Site</b> – for the completion of the initial 45-minute face-to-face consultation between the pharmacist and the patient	45 mins	\$98.41

Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019. Please note that numbers in this table may not add due to rounding.

##### Midpoint consultation

The midpoint consultation was only performed by Group B trial site pharmacies.

	Minutes	Trial Fee
<b>Group B Trial Site</b> – for the completion of midpoint telephone 15-minute face-to-face consultations between the pharmacist and the patient	15 mins	\$32.81

Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019. Please note that numbers in this table may not add due to rounding.

##### Three-month follow-up consultation

	Minutes	Trial Fee
<b>Group B Trial Site</b> – for the completion of the 3-month follow-up in-pharmacy 15-minute	15 mins	\$32.81



face-to-face consultation between the pharmacist and the patient.		
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Source: Chronic Pain MedsCheck Trial Pack – Group B Main Sites; October 2018 and HealthConsult activity-based costing study undertaken from August to September 2019. Please note that numbers in this table may not add due to rounding

## ECONOMIC EVALUATION

A stepped economic evaluation of the CPMC Trial was not possible. Instead, a pragmatic pre vs post analysis was undertaken. Costs and outcomes at baseline were assumed to be reflective of Treatment-As-Usual (TAU). Results at the 3-month follow up were analysed to determine whether the interventions were effective in providing benefits to CPMC Trial participants. A summary of the key characteristics of the economic evaluation is provided in Table 98. A total of 24 analyses were conducted.

**Table 98: Summary of the economic evaluation**

<b>Perspective</b>	Healthcare system
<b>Comparator</b>	Treatment-As-Usual (TAU)
<b>Type of economic evaluation</b>	Cost utility analysis (CUA) and cost effectiveness analysis (CEA)
<b>Sources of evidence</b>	CPMC Trial
<b>Time horizon</b>	Six months
<b>Outcomes</b>	<p><b>Primary outcome:</b> Cost per QALY</p> <p><b>Secondary Outcomes:</b> Cost per unit reduction in pain interference measured using the BPI as part of the mini-ePPOC Cost per unit reduction in pain severity measured using the BPI as part of the mini-ePPOC Cost per unit reduction in pain self-efficacy measured using the PSEQ-2 as part of the mini-ePPOC Cost per unit increase in self-management measured using the PIH Cost per unit reduction in morphine equivalent units Cost per PBS script reduction Cost per MBS service reduction</p>
<b>Methods used to generate results</b>	Trial based. A quasi-experiment of pre vs post intervention
<b>Discount rate</b>	Not applicable as the model duration is less than one year
<b>Software packages used</b>	Microsoft Excel 2016

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; mini-ePPOC, The miniature electronic persistent pain outcomes collaboration questionnaire; PBS, Pharmaceutical benefits scheme; PIH, The Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire

Key structural assumption of the model are: analyses assume that baseline results obtained prior to (or at the start of) the initial intervention are indicative of TAU.

The overall costs and outcomes, and incremental costs and outcomes as calculated for the intervention and comparative intervention in the model, and using the base case assumptions, are shown by groups analysed (Group A and Group B in Table 10 and Table 9, respectively). For the primary analysis, ICERs showed that

Groups A and B are dominant to TAU (i.e. lower costs and greater outcomes). For morphine units, pain interference, pain severity, MBS services and PBS scripts – lower outcome values are more desirable. For calculation purposes, the incremental gain in outcomes was inversed. Group B has a cost saving ICER of \$2,578.43 per unit of morphine lost.

Table 10: Results of the economic evaluation: Group A

<b>Incremental cost per QALY</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,378.46	\$1,513.57	-\$135.11
QALYs	0.63	0.58	0.05
Cost per QALY	DOMINANT		
<b>Incremental cost per unit change for self-management assessed using the PIH scale</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,378.46	\$1,513.57	-\$135.11
Units	76.69	71.08	5.61
Cost per unit change	DOMINANT		
<b>Incremental cost per unit change in morphine equivalent units</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,378.46	\$1,513.57	-\$135.11
Units	49.87	50.84	0.97
Cost per unit change	DOMINANT		
<b>Incremental cost per reduction change in moderate-severe pain interference in participants assessed using the BPI</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,378.46	\$1,513.57	-\$135.11
Proportion moderate-severe	0.65	0.79	0.14
Cost per reduction in moderate-severe participants	DOMINANT		
<b>Incremental cost per reduction change in moderate-severe pain severity in participants assessed using the BPI</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,378.46	\$1,513.57	-\$135.11
Proportion moderate-severe	0.58	0.70	0.11*
Cost per reduction in moderate-severe participants	DOMINANT		
<b>Incremental cost per unit change in participants achieving meaningful functional outcomes assessed using the PSEQ-2</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,378.46	\$1,513.57	-\$135.11
Change	0.65	0.53	0.12
Cost per unit change	DOMINANT		
<b>Incremental cost per unit change in PBS script usage</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,378.46	\$1,513.57	-\$135.11
Units	8.10	9.78	1.68
Cost per unit change	DOMINANT		
<b>Incremental cost per unit change in MBS service usage</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,378.46	\$1,513.57	-\$135.11
Units	7.85	10.49	2.64
Cost per unit change	DOMINANT		

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; QALY, Quality adjusted life years; PBS, Pharmaceutical benefits scheme; PIH, Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire; TAU, Treatment as usual

Note: For morphine units, pain interference, pain severity, MBS services and PBS scripts – lower outcome values are more desirable. For calculation purposes, the incremental gain in outcomes were inversed.  
 Note \* rounding error

**Table 9: Results of the economic evaluation: Group B**

<b>Incremental cost per QALY</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,386.27	-\$206.27
QALYs	0.70	0.53	0.17
Cost per QALY	DOMINANT		
<b>Incremental cost per unit change for self-management assessed using the PIH scale</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,386.27	-\$206.27
Units	73.98	72.82	1.16
Cost per unit change	DOMINANT		
<b>Incremental cost per unit change in morphine equivalent units</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,386.27	-\$206.27
Units	47.82	47.74	-0.08
Cost per unit change	\$2,578.43		
<b>Incremental cost per reduction change in moderate-severe pain interference in participants assessed using the BPI</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,386.27	-\$206.27
Proportion moderate-severe	0.52	0.77	0.26
Cost per reduction in moderate-severe participants	DOMINANT		
<b>Incremental cost per reduction change in moderate-severe pain severity in participants assessed using the BPI</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,386.27	-\$206.27
Proportion moderate-severe	0.58	0.69	0.11
Cost per reduction in moderate-severe participants	DOMINANT		
<b>Incremental cost per unit change in participants achieving meaningful functional outcomes assessed using the PSEQ-2</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,386.27	-\$206.27
Change	0.62	0.50	0.13
Cost per unit change	DOMINANT		
<b>Incremental cost per unit change in PBS script usage</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,386.27	-\$206.27
Units	5.69	7.84	2.15
Cost per unit change	DOMINANT		
<b>Incremental cost per change in MBS service usage</b>			
	<b>CPMC intervention</b>	<b>TAU</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,386.27	-\$206.27

Units	5.88	10.33	4.44
Cost per unit change	DOMINANT		

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; QALY, Quality adjusted life years; PBS, Pharmaceutical benefits scheme; PIH, Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire; TAU, Treatment as usual

Note: For morphine units, pain interference, pain severity, MBS services and PBS scripts – lower outcome values are more desirable. For calculation purposes, the incremental gain in outcomes were inverted.

Group B is dominant to Group A, for the primary outcome of cost/QALY. When comparing results for three secondary outcomes (pain self-management, morphine equivalence and pain severity) for Group B vs A, cost saving ICERs per unit lost were obtained (~\$45, ~189 and ~\$99,000 per outcome, respectively, Table 10).<sup>ii</sup> As there are no published ‘willingness to pay’ thresholds for these outcomes, it is difficult to determine if these cost savings are acceptable. Group B is dominant (i.e. lower costs and greater outcomes) to Group A in other analyses. For the pain-severity analysis, three decimal places have intentionally been shown to provide clarity behind the ICER presented.

**Table 10: Results of the economic evaluation: Group B vs A**

<b>Incremental cost per QALY</b>			
	<b>Group B</b>	<b>Group A</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,378.46	-\$198.46
Incremental QALYs	0.17	0.05	0.12
Cost per QALY	DOMINANT		
<b>Incremental cost per unit change for self-management assessed using the PIH scale</b>			
	<b>Group B</b>	<b>Group A</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,378.46	-\$198.46
Incremental units	1.16	5.61	-4.45
Cost per unit change	\$44.57		
<b>Incremental cost per unit change in morphine equivalent units</b>			
	<b>Group B</b>	<b>Group A</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,378.46	-\$198.46
Incremental units	-0.08	0.97	-1.05
Cost per unit change	\$189.42		
<b>Incremental cost per reduction change in moderate-severe pain interference in participants assessed using the BPI</b>			
	<b>Group B</b>	<b>Group A</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,378.46	-\$198.46
Incremental change in proportion moderate-severe	0.26	0.14	0.12
Cost per reduction in moderate-severe participants	DOMINANT		
<b>Incremental cost per reduction change in moderate-severe pain severity in participants assessed using the BPI</b>			
	<b>Group B</b>	<b>Group A</b>	<b>Increment</b>
Costs	\$1,180.00	\$1,378.46	-\$198.46
Incremental change in proportion moderate-severe	0.109*	0.111*	-0.002*
Cost per reduction in moderate-severe participants	\$99,231.13		

Incremental cost per unit change in participants achieving meaningful functional outcomes assessed using the PSEQ-2			
	Group B	Group A	Increment
Costs	\$1,180.00	\$1,378.46	-\$198.46
Incremental change	0.13	0.12	0.01
Cost per unit change	DOMINANT		
Incremental cost per unit change in PBS script usage			
	Group B	Group A	Increment
Costs	\$1,180.00	\$1,378.46	-\$198.46
Incremental units	3.40	2.56	0.84
Cost per unit change	DOMINANT		
Incremental cost per unit change in MBS service usage			
	Group B	Group A	Increment
Costs	\$1,180.00	\$1,378.46	-\$198.46
Incremental units	4.44	2.64	1.80
Cost per unit change	DOMINANT		

Abbreviations: BPI: Brief pain inventory; CPMC, Chronic Pain MedsCheck; MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme; QALY, Quality adjusted life years; PIH, Partners in health scale; PSEQ-2, Pain self-efficacy questionnaire; TAU, Treatment as usual

Note: For morphine units, pain interference, pain severity, MBS services and PBS scripts – lower outcome values are more desirable. For calculation purposes, the incremental gain in outcomes were inversed. Dominant has been used to indicate that the intervention is cheaper and provides greater outcomes compared to the comparator. Numbers calculated are indicative of the SW quadrant whereby the intervention is cheaper but has worse outcomes than the comparator.

\* Three decimal places shown to demonstrate the difference between both groups

For brevity, results of the primary analysis (cost/QALY) are presented in Table 11. Modelled results were most sensitive to hospitalisation and MBS costs in Groups A and B as well as B vs A. As with Groups A and B vs TAU, in all sensitivity analyses Group B is dominant (i.e. greater outcomes and lower costs) over Group A for cost per QALY. Consequently, individual ICERs calculated for each sensitivity analysis was not produced in Table 11.

**Table 11: Key drivers of the economic model**

Description	ICER
<b>Group A</b>	
Base case	DOMINANT
Intervention hospitalisation costs increased from \$438.16 to \$514.40 (Upper bound of 95% CI)	DOMINANT
Intervention hospitalisation costs decreased from \$438.16 to \$361.93 (Lower bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from \$109.15 to \$125.92 (Upper bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from \$109.15 to \$92.39 (Lower bound of 95% CI)	DOMINANT
Intervention CPMC Trial costs increased from \$131.22 to \$157.46 (20% relative increase)	DOMINANT
Intervention CPMC Trial costs decreased from \$131.22 to \$104.98 (20% relative decrease)	DOMINANT
Intervention PBS costs increased from \$250.91 to \$279.04 (Upper bound of 95% CI)	DOMINANT
Intervention PBS costs decreased from \$250.91 to \$222.77 (Lower bound of 95% CI)	DOMINANT

Intervention MBS costs increased from \$449.01 to \$515.29 (Upper bound of 95% CI)	DOMINANT
Intervention MBS costs decreased from \$449.01 to \$382.73 (Lower bound of 95% CI)	DOMINANT
Intervention QALYs increased from 0.63 to 0.65 (Upper bound of 95% CI)	DOMINANT
Intervention QALYs decreased from 0.65 to 0.61 (Lower bound of 95% CI)	DOMINANT
TAU hospitalisation costs increased from \$498.13 to \$565.98 (Upper bound of 95% CI)	DOMINANT
TAU hospitalisation costs decreased from \$498.13 to \$430.29 (Lower bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from \$114.43 to \$128.55 (Upper bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from \$114.43 to \$100.30 (Lower bound of 95% CI)	DOMINANT
TAU PBS costs increased from \$310.94 to \$345.80 (Upper bound of 95% CI)	DOMINANT
TAU PBS costs decreased from \$310.94 to \$276.07 (Lower bound of 95% CI)	DOMINANT
TAU MBS costs increased from \$590.07 to \$631.78 (Upper bound of 95% CI)	DOMINANT
TAU MBS costs decreased from \$590.07 to \$548.36 (Lower bound of 95% CI)	DOMINANT
TAU QALYs increased from 0.59 to 0.60 (Upper bound of 95% CI)	DOMINANT
TAU QALYs decreased from 0.59 to 0.57 (Lower bound of 95% CI)	DOMINANT
<b>Group B</b>	
Base case	DOMINANT
Intervention hospitalisation costs increased from \$457.31 to \$568.78 (Upper bound of 95% CI)	DOMINANT
Intervention hospitalisation costs decreased from \$457.31 to \$345.84 (Lower bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from \$101.65 to \$125.67 (Upper bound of 95% CI)	DOMINANT
Intervention emergency department presentation costs from \$101.65 to \$77.63 (Lower bound of 95% CI)	DOMINANT
Intervention CPMC Trial costs increased from \$164.03 to \$196.84 (20% relative increase)	DOMINANT
Intervention CPMC Trial costs decreased from \$164.03 to \$131.22 (20% relative decrease)	DOMINANT
Intervention PBS costs increased from \$145.94 to \$172.42 (Upper bound of 95% CI)	DOMINANT
Intervention PBS costs decreased from \$145.94 to \$119.45 (Lower bound of 95% CI)	DOMINANT
Intervention MBS costs increased from \$311.07 to \$367.11 (Upper bound of 95% CI)	DOMINANT
Intervention MBS costs decreased from \$311.07 to \$255.03 (Lower bound of 95% CI)	DOMINANT
Intervention CPMC Trial QALYs increased from 0.70 to 0.73 (Upper bound of 95% CI)	DOMINANT
Intervention CPMC Trial QALYs decreased from 0.70 to 0.67 (Lower bound of 95% CI)	DOMINANT
TAU hospitalisation costs increased from \$495.91 to \$568.47 (Upper bound of 95% CI)	DOMINANT
TAU hospitalisation costs decreased from \$495.91 to \$423.35 (Lower bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from \$101.87 to \$125.94 (Upper bound of 95% CI)	DOMINANT
TAU emergency department presentation costs from \$101.87 to \$77.79 (Lower bound of 95% CI)	DOMINANT

TAU PBS costs increased from \$216.92 to \$256.28 (Upper bound of 95% CI)	DOMINANT
TAU PBS costs decreased from \$216.92 to \$177.55 (Lower bound of 95% CI)	DOMINANT
TAU MBS costs increased from \$560.16 to \$599.89 (Upper bound of 95% CI)	DOMINANT
TAU MBS costs decreased from \$560.16 to \$520.44 (Lower bound of 95% CI)	DOMINANT
TAU QALYs increased from 0.53 to 0.55 (Upper bound of 95% CI)	DOMINANT
TAU QALYs decreased from 0.53 to 0.51 (Lower bound of 95% CI)	DOMINANT
<b>Group B vs A</b>	
Base case	DOMINANT
Group B hospitalisation costs increased from \$457.31 to \$568.78 (Upper bound of 95% CI)	DOMINANT
Group B hospitalisation costs decreased from \$457.31 to \$345.84 (Lower bound of 95% CI)	DOMINANT
Group B emergency department presentation costs from \$101.65 to \$125.67 (Upper bound of 95% CI)	DOMINANT
Group B emergency department presentation costs from \$101.65 to \$77.63 (Lower bound of 95% CI)	DOMINANT
Group B CPMC Trial costs increased from \$164.03 to \$196.84 (20% relative increase)	DOMINANT
Group B CPMC Trial costs decreased from \$164.03 to \$131.22 (20% relative decrease)	DOMINANT
Group B PBS costs increased from \$145.94 to \$172.42 (Upper bound of 95% CI)	DOMINANT
Group B PBS costs decreased from \$145.94 to \$119.45 (Lower bound of 95% CI)	DOMINANT
Group B MBS costs increased from \$311.07 to \$367.11 (Upper bound of 95% CI)	DOMINANT
Group B MBS costs decreased from \$311.07 to \$255.03 (Lower bound of 95% CI)	DOMINANT
Group B trial incremental QALYs increased from 0.17 to 0.20 (Arbitrary 20% increase)	DOMINANT
Group B CPMC Trial QALYs decreased from 0.17 to 0.14 (Arbitrary 20% decrease)	DOMINANT
Group A hospitalisation costs increased from \$438.16 to \$514.40 (Upper bound of 95% CI)	DOMINANT
Group A hospitalisation costs decreased from \$438.16 to \$361.93 (Lower bound of 95% CI)	DOMINANT
Group A emergency department presentation costs from \$109.15 to \$125.92 (Upper bound of 95% CI)	DOMINANT
Group A emergency department presentation costs from \$109.15 to \$92.39 (Lower bound of 95% CI)	DOMINANT
Group A CPMC Trial costs increased from \$131.22 to \$157.46 (20% relative increase)	DOMINANT
Group A CPMC Trial costs decreased from \$131.22 to \$104.98 (20% relative decrease)	DOMINANT
Group A PBS costs increased from \$250.91 to \$279.04 (Upper bound of 95% CI)	DOMINANT
Group A PBS costs decreased from \$250.91 to \$222.77 (Lower bound of 95% CI)	DOMINANT
Group A MBS costs increased from \$449.01 to \$515.29 (Upper bound of 95% CI)	DOMINANT
Group A MBS costs decreased from \$449.01 to \$382.73 (Lower bound of 95% CI)	DOMINANT
Group A CPMC Trial QALYs increased from 0.05 to 0.06 (arbitrary 20% increase)	DOMINANT
Group A CPMC Trial QALYs decreased from 0.05 to 0.04 (arbitrary 20% decrease)	DOMINANT

Abbreviations: CI, confidence intervals; ICER, Incremental cost effectiveness ratio; MBS, Medicare benefits schedule; PBS, Pharmaceutical benefits scheme QALY, Quality adjusted life year.

There is a strong association between chronic pain and mental health conditions such as depression, anxiety or mental health problems in general. Pain is also associated with sleep disorders.<sup>iii</sup> Consequently, additional



codes analysed under system groups N03, N05 and N06 were included in the analysis (originally codes for N02A N02B, N02C, M01A and M02A were analysed which cover for opioids, anti-neuropathic, migraine medications and NSAIDs). These additional codes cover for anticonvulsants, benzodiazepines and antidepressants, respectively. When analysing results by system groups, every group (excluding NSAIDs) saw a decrease in scripts per patient in both Groups A and B. NSAID usage slightly increased by an average of 0.09 and 0.08 scripts per patient in Group A and B, respectively, but this gain was not statistically significant.

An increase in Allied Health usage was observed in Group A (8.2% increase, 0.21 services), while service usage significantly declined in Group B (31.3% decrease, 0.76 services). This could be due to the additional contact with the pharmacist but smaller participant numbers in Group B at follow up may have meant any increase in service usage were unable to be detected.

#### **ESTIMATED EXTENT OF USE AND FINANCIAL IMPLICATIONS**

An epidemiological approach was used to estimate the financial implications of the introduction of the CPMC intervention for chronic pain.

Group B resulted in greater cost savings than Group A due to a greater number of MBS services averted. When comparing Group B to A, a cost to States and Territories is calculated. This is due to a greater number of hospitalisations avoided in Group A compared to Group B, which results in greater savings to States and Territories.

#### **CONSUMER IMPACT SUMMARY**

In a participant survey, undertaken as part of the evaluation, that had a total of 186 completed responses, participants were asked at the conclusion of their CPMC intervention to reflect on whether they felt their knowledge and understanding of their chronic pain medications had changed as a result of the intervention. A large majority of the participants (81.7%) responded that they felt their overall knowledge and understanding of their chronic pain medication had improved as a result of the intervention and around a fifth reported noticing a definite improvement that has made a real and worthwhile difference.

Overall, participants described the CPMC intervention as “great”, “worthwhile” and “an excellent opportunity”. Other qualitative feedback obtained from participants indicated that participating in the CPMC Trial had helped improved their knowledge about the causes of their chronic pain, medications they were taking and their effects, pain management techniques other than medication, and the importance of a healthy diet and regular physical activity.

#### **OTHER RELEVANT CONSIDERATIONS**

The pharmacist’s experience of providing CPMC services was examined via a Pharmacist Satisfaction Survey, which had a low response rate of 43 completed responses. This explored the impact of completing training, assessing the consistency of service delivery and by determining pharmacists’ perception of the ease and usefulness of the CPMC Trial resources. In summary:

- Only just over half of the participants (n=24) reported that the CPMC Trial had a moderate to very high impact on improving their job satisfaction.
- The perceived ease of the CPMC Trial was mixed. 'Following the intervention protocol' and 'using the mini-ePPOC tool' were rated to be the easiest tools to use, and 'developing an action plan' was rated as being harder to perform.
- Nearly two thirds of pharmacists reported that the participant education resources were useful (26 of 43, or 60%).
- Pharmacists reported that the most substantial perceived benefits as a result of the CPMC Trial were seen in participants with mild to moderate pain and with mild depression, anxiety, or stress. They perceived that participants with severe pain and mild to severe depression, anxiety or stress were less likely to experience any benefits from this service.

Pharmacists were interviewed as part of the 24 case studies that were randomly selected from all pharmacies enrolled in the CPMC Trial. These pharmacists reported that the intervention changed their scope of practice in a mostly rewarding way. The intervention and its associated remuneration encouraged more in-depth patient assessments resulting in holistic treatment and care, and provided pharmacists with the opportunity to delve deeper into the various aspects of chronic pain (quality of life, pain severity, diet, exercise) which they felt helped them provide better advice to their patients.

## **CONCLUSION**

The CPMC intervention was shown to be effective in improving a number of participant health outcomes, including pain severity, pain interference and overall level of psychological distress. Participation in the CPMC intervention also helped individuals improve their pain self-efficacy and management, which means they were better equipped to manage their chronic pain and were more confident in performing daily activities despite their pain.

The Group B intervention (i.e. three consultations) showed greater improvements in most of the participant health outcomes from initial to follow-up compared to Group A (i.e. two consultations).

The value of the midpoint telephone consultation in the Group B intervention was highlighted by pharmacists who were interviewed as part of the case studies as it provided them with an earlier opportunity to assess compliance to recommendations made during the initial consultation, reinforce key information and address any questions or issues the participants had. The usefulness of telephone follow-up of patients as part of pharmacy interventions has also been demonstrated in the literature, providing further support that the telephone consultation provided at midpoint may have been key to the achievement of the greater outcomes experienced by Group B participants.

Overall, participants that experienced all levels of pain severity and interference to general activities (mild, moderate or severe) at the start of the intervention benefited from completing the CPMC intervention. However, participants with moderate or severe pain or experienced moderate or severe pain interference at the initial timepoint appeared to have benefited more from the intervention.

For the primary analysis, Groups A and B are dominant to TAU (i.e. lower cost and greater outcomes). When comparing Group B to Group A, three secondary outcomes (morphine equivalence, self-management and pain severity scores) for Group B vs A, cost saving ICERs per unit lost were obtained (~\$45 and ~\$189 and ~\$99,000 per outcome, respectively).<sup>iv</sup> As there are no published '*willingness to pay*' values for these outcomes, it is difficult to determine whether these ICERs are acceptable. Group B is dominant to Group A in other analyses.

Overall, the CPMC intervention was deemed to provide greater value for money for those with moderate and severe levels of pain at the start of the intervention.

## RECOMMENDATIONS

The Group B intervention is the recommended intervention model (i.e. face-to-face initial consultation and follow-up consultation with a telephone consultation at midpoint) if CPMC is to be implemented as an ongoing program. This is due to the Group B intervention resulting in greater improvements in most of the participant health outcomes at three months and was shown to be more cost-effective compared to Group A.

A number of aspects of the intervention have shown to be particularly effective in improving health outcomes, and in any future iterations of the intervention the recommendation is to continue the following:

- focus on improving the participants' pain self-efficacy levels and enabling them to manage their own pain effectively regardless of their pain severity and interference at the initial consultation
- motivate participants to adhere to the action plan provided as much as possible, and
- provide written referrals for participants to bring to their GP and/or an allied health professional where appropriate.

A number of changes are suggested, based on the feedback received during the CPMC Trial, to further improve participants' and pharmacists' experiences of the CPMC intervention if CPMC is implemented as a future program.

1. While the action plans were tailored for the individual based on their responses to the initial assessment questions, in the CPMC Trial they included all the recommended actions which was found to be overwhelming for the participants. Although it is important to allow individuals flexibility in which action/s to implement, it may be more helpful if a 'staged approach' is adopted where the pharmacist outlines the overall plan but works with the participant on implementing a few agreed actions. Progress should continue to be reviewed at each contact point and once the participant feels they are able to implement another action, it is added progressively to the action plan. Individuals' attempts to implement the recommended actions could also be better supported in between consultations through automated prompts and advice provided via email or SMS.
2. Additional work is needed to further improve pharmacists' use of technology to facilitate the delivery of the CPMC intervention. Pharmacists involved in the CPMC Trial found it challenging to

work with the trial software including the assessment tools they needed to administer with the participant. The software was developed specifically for the CPMC Trial within a very short timeframe. A number of fixes were made during the CPMC Trial period but further enhancements are still required. The initial focus should be on automating the patient's results from their assessment and tailoring of the action plan, streamlining how the medication record is populated and reviewed by the pharmacist whilst with the patient, and facilitating the GP and/or allied health professional referral process.

3. More targeted training and professional development opportunities may be helpful in supporting an ongoing high quality of care provided to participants as well as maintaining or increasing the pharmacists' motivation to deliver the CPMC intervention particularly during periods of less activity.
4. Pharmacists valued the patient assessments conducted at the consultations, as they provided them with an understanding of the participant's health and pain experience and were useful prompts for considering the key factors impacting on their pain and quality of life. A number of the outcome measures were, however, collected for the purposes of the evaluation only (i.e. assessment of QoL (AQoL-4D), PIH Scale and the health literacy questions) and are not required as part of an ongoing future delivery of the CPMC intervention. It is recommended that a monitoring process is set up if the CPMC program is delivered as part of routine practice and the intervention is evaluated periodically. Monitoring should involve the use of the mini ePPOC as a tool for pharmacists to assess the participants, guide treatment options and measure their outcomes. Future evaluations will benefit from the use of the AQoL-4D and PIH Scale but it is not recommended that the health literacy tool is used as it is not validated (no suitable tool was identified for the CPMC Trial and so an unvalidated one was used) and may therefore add to the participant burden unnecessarily.
5. Given the short duration of the CPMC Trial (i.e. three months), it would benefit from some additional research to understand participants' experiences of the service and the longer-term effectiveness (i.e. post three months) of the CPMC intervention. One potential way to do this would be to follow up with participants six months after they complete the CPMC intervention to assess whether any behavioural changes and outcomes are sustained and gain insight into the key enabling factors. Future research efforts may also include interviewing or surveying individuals who do not continue with the service and pharmacists who are unable to recruit individuals to further improve the intervention delivery. In addition, because some positive outcomes of the CPMC Trial were demonstrated at the midpoint consultation, it may be worthwhile conducting more evaluation activities for a subgroup of participants at that timepoint, such as administering the additional evaluation questions at the midpoint consultation, to explore this further.

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<sup>1</sup> Hawthorne, Graeme & Osborne, Richard. (2005). Population norms and meaningful differences for the Assessment of Quality of Life (AQoL) Measure. *Australian and New Zealand Journal of Public Health*. 29. 136-42. [10.1111/j.1467-842X.2005.tb00063.x](https://doi.org/10.1111/j.1467-842X.2005.tb00063.x).

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- ii Vos T, Carter R, Barendregt J, Mihalopoulos C, Veerman JL, Magnus A, Cobiac L, Bertram MY, Wallace AL, ACE–Prevention Team (2010). Assessing Cost-Effectiveness in Prevention (ACE–Prevention): Final Report. University of Queensland, Brisbane and Deakin University, Melbourne.
- iii Davis JA, Robinson RL, Le TK, Xie J. Incidence and impact of pain conditions and comorbid illnesses. *J Pain Res.* 2011;4:331-45. doi: 10.2147/JPR.S24170. Epub 2011 Oct 10. PMID: 22090802; PMCID: PMC3215513.
- iv Vos T, Carter R, Barendregt J, Mihalopoulos C, Veerman JL, Magnus A, Cobiac L, Bertram MY, Wallace AL, ACE–Prevention Team (2010). Assessing Cost-Effectiveness in Prevention (ACE–Prevention): Final Report. University of Queensland, Brisbane and Deakin University, Melbourne.