Chronic Pain MedsCheck Trial

The Pharmacy Guild of Australia are pleased to invite your pharmacy to register interest in participating in the Chronic Pain MedsCheck Trial.

Register your interest to participate in the Chronic Pain MedsCheck Pharmacy Trial program by:

- completing our online registration form, and
- emailing or faxing the two consent forms by Monday 17 September.

Please email chronicpain.ptp@6cpa.com.au for more information.

When registrations close, the list of community pharmacies that express interest to participate in the trial will be used in the selection process and will randomly allocated to either Group A or Group B of the "main trial". In addition, 50 pharmacies in each Group will be randomly selected to be "evaluation trial" sites. You will be notified in writing which Group you have been allocated to for the duration of the trial. We anticipate that patient recruitment to the trial will commence by October 2018. Mandatory training must be completed by all pharmacies prior to recruitment of any patients.

Participation in this trial is voluntary. By giving your consent to take part in this trial you are telling us that you understand what you have read; agree to take part in the trial as outlined below; and agree to the use of your personal information as described. You will be given a copy of this Participant Information Statement to keep. If you would like further information regarding any aspect of this trial, you are encouraged to contact the Pharmacy Guild of Australia via the phone number or email address listed above.

What is this trial about?

The Chronic Pain MedsCheck trial is funded by the Australian Department of Health 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 consumers and/or by progressing the role of pharmacists in the delivery of primary healthcare services through a community pharmacy.

The primary objective is to evaluate the efficacy of the Chronic Pain MedsCheck in preventing incorrect use and/or overuse of pain medication, increasing patients' pain medication health literacy, improving their ability to self-manage their chronic pain and improve their overall quality of life. In addition, pharmacists, patients and referred providers involved in the evaluation trial sites will be surveyed about the acceptance and satisfaction with the new service. In addition a cost-effectiveness/utility analysis will be undertaken using the data generated by the trial.

The Chronic Pain MedsCheck trial includes two randomly selected intervention groups:

- **Group A:** Involves an initial in-pharmacy face-to-face consultation between the pharmacist and the consumer that involves a review and assessment of the consumer's chronic pain experience and medication usage, including analgesics; and the collection of a set of data that needs to be entered directly into the trial software (as part of the consultation). This information will be used to identify the impact chronic pain is having on a patient's life and determine what information, education and/or referrals are to be provided. In consultation with the patient, the community pharmacist develops 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.

  At a three months post initial consultation you will be required to organise an in-pharmacy follow up consultation that involves a review and assessment against the written action plan, a collection of the same set of data that again needs to be entered directly into the trial software (as part of the consultation)) to assess whether the intervention has changed the impact chronic pain is having on a patient's life; ; update the written action plan, if required and provide follow up support (including referral) and advice as required.

- **Group B:** Involves an initial in-pharmacy face-to-face consultation between the pharmacist and the consumer that involves a review and assessment of the consumer's chronic pain experience and medication usage, including analgesics; a collection of a set of data that needs to be entered directly into the trial software (as part of the consultation). Like Group A, this data will be used to generate a score across six measures which will be used to identify the impact chronic pain is having on a patient's life and determine what information, education and/or referrals are to be provided. In consultation with the patient, the community pharmacist develops 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.

  At six weeks post initial consultation you will be required to organise a midpoint follow up consultation by telephone that involves a review and assessment against the written action plan, a collection of the data (i.e. same as collected at the initial consultation) that again needs to be entered directly into the trial software that will be used to assess whether the intervention has changed the impact chronic pain is having on a patient's life; update the written action plan, if required and provide follow up support (including referral) and advice as required.

  At three months post initial consultation you will be required to repeat the midpoint follow-up process in-pharmacy.

Funded by the Australian Government Department of Health as part of the Sixth Community Pharmacy Agreement Pharmacy Trial Program.

Why were you invited to participate in this trial?

All community pharmacies have been invited to participate in the Chronic Pain MedsCheck trial as per the statement made in the Minister of Health's press release on the 25 January 2018. To be eligible to participate in the Chronic Pain MedsCheck trial a community pharmacy must:

- Be 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)
- Ensure that services are delivered by a Registered Pharmacist face-to-face or over the telephone (midpoint consultation only for Group B) with the patient in the community pharmacy
- Provide evidence, if required, that there is an area of the community pharmacy that is physically separated from the retail trading floor so that privacy and confidentiality of the patient is protected
  - Be appropriately furnished with facilities (including a having a computer in the consultation room with the trial software loaded) to allow the patient and the pharmacist to sit down together
  - Allow the patient and pharmacist to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff)
- Obtain written patient consent in accordance with the Australian Privacy Principles (APP 3, APP5, APP6, APP 11 and APP 12)
- Be accredited by an approved Pharmacy Accreditation Program
- Follow the trial protocol (e.g. use the outputs of the mini-ePPOC tool (which will be 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 patient and guide the information included in their written action plan)
- Agree to provide the data you collect to the evaluation team (HealthConsult Pty Ltd) for both service delivery and evaluation of this trial

Pharmacists who take part in the trial will be required to complete mandatory online training modules to assist in the consistent delivery of interventions during the trial. In addition, pharmacies that are randomised to be an evaluation trial site pharmacy in either Group A or B will be required to attend an additional training session on the evaluation trial site specific requirements.

What will the trial involve for all trial sites?

If your pharmacy agrees to participate, all pharmacists participating in the trial will be required to complete a CPD accredited online Chronic Pain MedsCheck training program which will explain the trial design, requirements of pharmacies in each Group, types of patients that are suitable for invitation to the trial, suggested process for identifying patients that meet the trial criteria, intervention process including data collection requirements, and additional data collection requirements for evaluation trial sites only.

Once pharmacists have completed the training, the pharmacy will be asked to recruit up to about 40 patients between October 2018 and 1 June 2019 that meet the inclusion/exclusion criteria (described below).

Informed consent will need to be obtained from all patient trial participants. Data on invited patients who decline to participate in the trial, but meet the inclusion/exclusion criteria, will need to be collected and reported. In addition, regardless of which Group you are allocated to, you will be required to follow-up patients who do not attend scheduled consultations and either re-schedule the consultation appointments or report data that describes why the patient was "lost to follow-up".

Each pharmacy will be provided with the relevant trial software module for this trial. The software must be used as part of each consultation with the patient as data entered into the software will provide a score across six measures which will prescribe what information, education and/or referrals you need to provide. Trial software will provide all prompts and documentation required during the consultation.

The trial will also involve a number of surveys:

- At the beginning of the study, a survey to collect baseline data about the usual activities of your pharmacy will be conducted.
- On completion of the service delivery aspect of the trial, you will be invited to participate in a service satisfaction survey.

Inclusion criteria

- Adult who is greater than or equal to 18 years of age
- Is a holder of a valid Medicare and/or Department of Veterans' Affairs (DVA) card
- Living at home in a community setting
- Has not received a MedsCheck, Diabetes MedsCheck, Home Medicines Review (HMR) or Chronic Pain MedsCheck in the previous 12 months in the recruiting pharmacy
- Is taking medication (prescription or over the counter) for their chronic pain for three months or greater
- Identified by a community pharmacists as either experiencing self-management or dependency issues

Exclusion criteria

- Unable to give informed consent
- In-patients of public or private hospitals, day hospital facilities, transitional care facilities, residents of an Aged Care Facility or patients in a correctional facility.
- Chronic pain is due to cancer pain
- Based on patient's self-report:
  - they are active clients of a recognised Pain Management Service
  - they have received a MedsCheck, Diabetes MedsCheck, Home Medicines Review (HMR) or Chronic Pain MedsCheck in the previous 12 months from another community pharmacy

What additional work will the trial involve for evaluation trial sites?

For the purposes of a comprehensive evaluation, additional outcome measures are required. However statistical advice states that this data is only required from about 2,000 patients in each Group. In order to ensure this data can be collected, 50 pharmacies from Group A and 50 pharmacies from Group B will be randomly selected to be evaluation trial sites. The additional requirements of evaluation trial site pharmacies include:

- Administering of three additional patient survey tools at initial and three month follow-up consultation (estimated time to complete 10-15 minutes)
- Distribution of patient service satisfaction survey at follow-up intervention (i.e. provide paper survey to patient with sealed envelope for them to complete before leaving the pharmacy but without pharmacist present)
- In addition, 12 pharmacies from each evaluation Group will be visited by the evaluation team towards the end of the trial to conduct interviews with pharmacists involved in the trial in order to gather qualitative data on the satisfaction with intervention design, types of patients that pharmacists believe have benefited most from the intervention, issues identified etc.

What you need to know

Pharmacy/Pharmacist trial participants will receive approval to participate in the trial once they have completed the training requirements under the trial. Participants will then be able to access a secure portal (i.e. through the trial software) to enable the uploading of trial information.

Pharmacists who agree to take part will also be aware that there will potentially be a paper-based component of the trial, however we are doing our best to integrate it into the trial software.

If you have any queries regarding participation in the Chronic Pain MedsCheck Trial, please call the 6CPA helpline on 1300 555 262 or email chronicpain.ptp@6cpa.com.au

Risks and benefits to you

There are no perceived risks to participating in this trial. All participating pharmacists will be trained in the trial process which adheres to national guidelines and aligns with current activities of other primary care pain management services. You will be provided with all the resources, training and ongoing support to provide the Chronic Pain MedsCheck service to your patients.

Trial payment fees

The table below describes the trial payments that will be made for each trial service.

Trial subset	Payment Number	Reason for payment	Payment amount ($) ex GST
Patient recruited to participate in Group A	Trial Payment 1	For the completion of the initial in-pharmacy 45 minute face-to-face consultation between the pharmacist and the patient	$98.41
	Trial Payment 2	For the completion of the 3 month follow-up in-pharmacy 15 minute face-to-face consultation between the pharmacist and the patient	$32.81
	Trial Payment 3	For the completion of the initial in-pharmacy 45 minute face-to-face consultation between the pharmacist and the patient AND submission of the required data (**Group A evaluation site pharmacies ONLY**)	$162.21
	Trial Payment 4	For the completion of the 3 month follow-up in-pharmacy 15 minute face-to-face consultation between the pharmacist and the patient AND submission of the required data (**Group A evaluation site pharmacies ONLY**)	$96.61
Patient recruited to participate in Group B	Trial Payment 5	For the completion of the initial in-pharmacy 45 minute face-to-face consultation between the pharmacist and the patient	$98.41
	Trial Payment 6	For the completion of midpoint telephone 15 minute consultation between the pharmacist and the patient	$32.81
	Trial Payment 7	For the completion of the 3 month follow-up in-pharmacy 15 minute face-to-face consultation between the pharmacist and the patient	$32.81
	Trial Payment 8	For the completion of the initial in-pharmacy 45 minute face-to-face consultation between the pharmacist and the patient AND submission of the required data (**Group B evaluation site pharmacies ONLY**)	$162.21
	Trial Payment 9	For the completion of midpoint telephone 15 minute consultation between the pharmacist and the patient AND submission of the required data (**Group B evaluation site pharmacies ONLY**)	$64.71
	Trial Payment 10	For the completion of the 3 month follow-up in-pharmacy 15 minute face-to-face consultation between the pharmacist and the patient AND submission of the required data (**Group B evaluation site pharmacies ONLY**)	$96.61
Group A and B Evaluation Sites	Trial Payment 11	Training fee per 100 evaluation sites for intensive service data collection	$500.00
	Trial Payment 12	Case study interview fee per 24 evaluation sites for qualitative data collection	$250.00

Confidentiality and security of the data

All individual information collected will be kept strictly confidential and will not be published or communicated in a way that makes individuals identifiable. All data collected by trial sites will be entered by participating pharmacists via a password protected interface on the trial software. Data will be retained for a minimum of 15 years. All electronic data will be stored securely in compliance with the Pharmacy Guild of Australia and/or HealthConsult's Data Privacy Policies. Any hardcopy data will be stored in a locked file in HealthConsult offices in Sydney. Only members of the evaluation team will have access to the trial data.

Results

The results of the trial need to be provided to the Medical Services Advisory Committee (MSAC) in a report that meets the Technical Guidelines for preparing assessment reports for the MSAC– Service Type: Investigative. These guidelines for investigative services require applicants to prove that both the proposed service (i.e. the Chronic Pain MedsCheck) provides accurate, meaningful information and also that the information improves the subsequent treatment (and health outcomes) of patients. Data presented in the MSAC report will only be in aggregate form. No individuals or organisations will be identified to maintain confidentiality of all trial participants. The overall results for this study will be available on the websites of the Department of Health and the Pharmacy Guild of Australia.

Do you have to be involved in the trial? Can you withdraw from the trial once you've started?

Your decision about your pharmacy's involvement in this trial is completely voluntary as is that of individual pharmacists who are involved in delivering the Chronic Pain MedsCheck trial services. You do not have to take part. In addition, your decision whether to participate is not anticipated to affect your current or future relationship with local GPs, other service providers or the Pharmacy Guild of Australia.

If you decide to take part in the trial, and then change your mind later, you are free to withdraw at any time. You can do this by contacting a member of the Pharmacy Guild of Australia. If you decide to withdraw from the trial, and inform the Pharmacy Guild of Australia, we will not collect any more information about your pharmacy or pharmacists and all data collected up to the point of withdrawal will be kept by the independent evaluation team as specified and included unless expressly asked not to do so by you.

As we are using an "intention to treat" approach, pharmacists will be required to follow up any trial participants that fail to show up for scheduled appointments to try and retain them for the full duration of the trial.

What if you have a complaint or any concerns about the trial?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this trial have been approved by the Bellberry HREC (ABN 16 109 019 730) in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at May 2015). This statement has been developed to protect people who agree to take part in the trial.

If you are concerned about the way this trial is being conducted or you wish to make a complaint to someone independent from the trial, please contact Bellberry using the details outlined below. Please quote the trial title [Chronic Pain MedsCheck Trial in Community Pharmacies] and protocol number [2018-05-369].

The Operations Manager, Bellberry:
Address: 129 Glen Osmond Road, Eastwood SA 5061
Email: Bellberry@bellberry.com.au
Phone: 08 8361 3222
Fax: 08 8361 3322