Staff Pharmacist Information and Consent Letter

Title of Project: Opioid and Pain Management in Pharmacies Program (OPMPP)

Primary Investigator:
Ashley Cid, BSc PharmD PhD(c) RPh
Ontario Pharmacists Association
University of Waterloo, School of Pharmacy
P: 1-877-341-0788
Opmpp@opatoday.com

Faculty Investigator:
Feng Chang, BScPhm PharmD RPh
University of Waterloo, School of Pharmacy
P: 519-888-4567 ext: 21321
feng.chang@uwaterloo.ca

Summary of Project:
There is a need to develop and implement new strategies to address the opioid crisis as it continues to worsen and contribute to death and hospitalizations in Canada. Although illicit opioids are known for being a contributor to the Canadian opioid crisis, prescription opioids also play a role as they are commonly prescribed to treat pain, but their long-term use can lead to physical dependence, addiction, and an increased risk for developing opioid use disorder. Pharmacists, being medication experts and educators, play an important role in the circle of care as opioid stewards where they can collaborate with prescribers and patients to identify drug therapy problems and ways to safely optimize a patient's therapy. The role that pharmacists can play in addressing the opioid crisis is valuable and should be better leveraged in the community setting.

This research project involves the implementation and evaluation of an opioid and pain management program in Ontario community pharmacies. The purpose of this research project is to demonstrate the program's feasible application of a medication consultation service that focuses on the appropriate prescribing and dispensing of opioids, as well as their safe and appropriate use in chronic non-cancer pain patients. This research study is being conducted by the Ontario Pharmacists Association (OPA) in conjunction with the University of Waterloo School of Pharmacy and is funded by the Ontario Health Mental Health and Addictions Centre of Excellence.

Procedure:
Only pharmacists who are providing services from an approved Ontario community pharmacy to participate in this study should complete this form. If you are unsure about whether your pharmacy is eligible to participate, please speak to your pharmacy owner/designated manager.

As a staff pharmacist enrolled in this study, you will be invited to complete a free, accredited, online continuing education program developed by the OPA (approximately 3 hours to complete). You will be given one month to complete this course to supplement and support your knowledge in providing an opioid and chronic pain focused medication consultation. You will also receive reminder emails during

this time to remind you to complete the continuing education program by the deadline. Please note that you have the option to withdraw from the study or not take the continuing education course, however, this would make you ineligible to participate in the rest of the study. Following completion of this course, you will be given the opportunity to attend an online webinar (approximately 1 hour) hosted by the OPA to understand the process for appropriate implementation of the OPMPP medication consultation in your pharmacy and have the opportunity to ask questions. This webinar will be recorded and will be available to you throughout the study period.

The OPMPP medication consultation consists of three components, an initial consult and up to two follow-ups per patient. Providing both follow-up consultations are not mandatory but can be provided based on professional judgement and patient need. The OPA has developed worksheets to help guide you and your team with these processes. The purpose of the initial consult will be to collect the patient's medical history and work with the patient to identify drug therapy problems, the goals of therapy, and an action plan. You will be responsible for contacting the patient's primary care provider to address and implement any recommendations for changes to the patient's therapy. Each follow-up appointment will allow for a reassessment of any changes to the patient's therapy plan.

You and any other staff also enrolled from your pharmacy location(s) will be responsible for identifying and recruiting eligible patients to complete the OPMPP medication consultation intervention. Your pharmacy will have a goal to recruit a target of 10 patients over a period of 6 months to complete the OPMPP intervention (initial consult and up to 2 follow-ups) with each patient. Following each step of the OPMPP intervention, the pharmacist who provided the consultation will be responsible for submitting an online outcome measures survey to report on items identified during each interaction, such as the types of drug therapy problems, education provided to the patient, etc. Additionally, at the end of the study period, you will be invited to complete an anonymous satisfaction survey. The pharmacist will also invite patients to complete an anonymous online satisfaction survey after each consultation. If they require a paper version, one will be made available with a pre-paid envelope for the patient to mail their survey directly to the research team. Finally, at the end of the study period, all pharmacist participants will be invited to complete an anonymous satisfaction survey. Note: patient health information must not be shared in any of the surveys.

Confidentiality and Data Security:
Participation in this study will require an e-mail address and phone number to be shared with the research team to be enrolled in the online continuing education program and webinar and to also receive information regarding reminders about the study. If you wish to withdraw from the study, you may contact the research team to request the removal of the information you submitted from your pharmacy location as part of the outcomes survey data or your continuing education program online profile, up until publication of the study results which is expected to occur in March 2025. (Note: If you start any of the surveys and close the browser before completing them, your data will not be collected and therefore your data will not be collected by the research team.) You are able to stop participating in any of the surveys at any time. It will not be possible to remove data from the satisfaction survey once it is submitted since the survey is anonymous.

Any data collected during the study will be de-identified before data analysis and publication. As well, the researchers completing the data analysis will only be given de-identified data, blinding researchers from bias. Please note that anonymous quotations from any open-ended survey responses may be used with permission in papers and publications resulting from this study, but participants will only be referred to by code such as Participant 1, Participant 2, etc. (or P1, P2, etc.). Collected data will be securely stored in an encrypted file on a password-protected computer and internet storage for a minimum of 7 years.

Risks and Benefits:
You will be completing the consent and contact information survey, outcome measures survey and satisfaction survey via Qualtrics. Qualtrics has implemented technical, administrative, and physical safeguards to protect the information from loss, misuse, and unauthorized access, disclosure, alteration, or destruction. However, no internet transmission is ever fully secure or error free. Please Note: We do not collect or use internet protocol (IP) addresses or other information which could link your participation to your computer or electronic device.
Participation in this study may provide some benefits to you, such as the ability to increase your knowledge about management of opioid use and supporting patients living with chronic pain. Completion of the online continuing education program will allow you to report continuing education credits for your learning portfolio as required by the Ontario College of Pharmacists. In addition, your intent to offer the OPMPP intervention in your pharmacy may result in improved health outcomes and quality of life for your patients.

In appreciation for the time spent to carry out this study, the pharmacy will receive $75 for each initial patient consultation and $25 for each follow-up (up to a maximum of two follow-ups per patient) upon completion of the online outcome measures survey for each component. Any information collected to send the pharmacy payment will be stored separately and will not be linked to the study data in any way. Any payment-related information will then be destroyed after the remuneration has been provided. The amount received is taxable and it is the pharmacy's responsibility to report this amount for income tax purposes.

Research Ethics Clearance:

This study has been reviewed and received ethics clearance through the University of Waterloo Research Ethics Board (REB #45514). If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or reb@uwaterloo.ca. For all other questions regarding this project, please contact Ashley Cid at the email or phone number listed at the beginning of this letter. Thank you for your interest and assistance in this study.

Sincerely,

Ashley Cid
Ontario Pharmacists Association
University of Waterloo, School of Pharmacy