

## Final Evaluation of the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project

Prepared for: Pharmacy Association of Nova Scotia

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# **Executive Summary**

#### Introduction

The Pharmacy Association of Nova Scotia (PANS) implemented the Community Pharmacist-led Anticoagulation Management Service (CPAMS) demonstration project in Nova Scotia, a new model of care delivery for patients that take warfarin for anticoagulation management. In the CPAMS model, community pharmacists provide point-of-care INR testing (with the device Coaguchek XS Pro) and adjust warfarin doses as needed using a decision support system (INR Online). Authority to perform testing, review results, and make dose adjustments is delegated to the pharmacist by the patient's primary care provider (PCP), with the PCP keeping overall responsibility for the patient's management. The project began with selection and training of pharmacies and pharmacists in fall 2017. Patients were enrolled in the study from February 1 to July 31, 2018 and participated in the project for at least 12 months (to July 31, 2019).

This report presents findings from the final evaluation of the CPAMS project. The evaluation builds on an interim evaluation conducted in October 2018 and draws from a variety of data sources, including a brief document review, focus groups with pharmacists and the CPAMS Working Group, interviews with PCPs whose patients participated in the project, surveys conducted with participating patients and pharmacists, and patient data collected from INR Online and the CPAMS online data portal.

#### **Findings**

#### **Project Participants and Activities**

Forty pharmacies participated in CPAMS, and a total of 106 pharmacists were trained and provided patient care over the course of the project. Pharmacies are distributed evenly between the Nova Scotia Health Authority's (NSHA) four health management zones across the province and almost half of the participating pharmacies are located in small towns (population of 1,000-10,000). A total of 946 patients were enrolled in CPAMS. At the end of the project (July 31, 2019), there were 746 active patients remaining, representing an attrition rate of 21%. The majority of active patients are taking warfarin for atrial fibrillation.

Over the whole course of the CPAMS project (February 2018 to July 2019) a total of 21,597 INR tests were conducted, representing an average of 1.7 tests per patient per month during the 12 months of the project (following completion of patient enrollment). For 66% of tests, pharmacists gave the warfarin dose that was recommended by INR Online, but were more likely to change the dose from that recommended by INR Online for tests with INR results outside the pharmacist's parameters for managing warfarin (INR below 1.5 or above 4.0). Tests with INR results outside of the pharmacist's parameters for management represented only 7% of all tests conducted in the pharmacy.

The average length of time pharmacy staff spent on patient appointments and follow up activities (e.g., scheduling appointments, phone calls with patients or PCPs) declined over the course of the project. The midpoint time of 11 minutes (7.1 minutes for patient appointments and 3.6 minutes for follow up) likely

represents the best estimate of an average time for appointments as this time data was gathered once pharmacists and patients gained some familiarity with the patient care process, but while new patients were still being enrolled in CPAMS. This time period provides a mix of appointments with both newer and more familiar patients, which is more reflective of the expected workload if new patients were being enrolled on a continuous basis. Based on the average number of tests conducted per patient per month (1.7), this represents a time requirement of approximately 19 minutes per patient per month.

#### Successes

The evaluation identified many successes resulting from the CPAMS project.

#### **Success for Patients**

- Increased patient satisfaction with care: The patient feedback provided through the patient survey was overwhelmingly positive and reported substantially higher satisfaction with the warfarin management provided through CPAMS compared to usual care. Almost all patients (98%) indicated they prefer to have their warfarin managed at the pharmacy. Key factors in patient satisfaction include access and convenience, the finger-prick blood test (vs. a venous blood draw), and the immediate test results and dosing adjustments.
- Improved access to and convenience of testing for patients: Most patients reported that having their blood test and warfarin management at the pharmacy was convenient and easier to schedule, saved them waiting and travel time (an average of 14 minutes for waiting/care and 13 minutes for travel in CPAMS compared to 90 minutes for waiting/care and 17 minutes for travel for usual care), and allowed them and family members/friends who accompany them to appointments to miss less time from work. The longer hours of service and greater accessibility of the pharmacy were important factors. CPAMS also improved access to care for unattached patients (i.e., patients without a current PCP).
- Increased adherence to testing and medications: Almost 80% of INR tests for CPAMS patients
  were completed on or before their due date. More patients reported that it was very easy for
  them to follow their required dosing schedule for warfarin in CPAMS compared to usual care, and
  some evaluation respondents also highlighted improved adherence as a project success.
- <u>Patient empowerment and improved understanding of their condition</u>: Some evaluation respondents (PCPs, pharmacists and patients) reported that patients had an improved understanding of their condition and their medication, empowering them to better manage their health.
- Improved health outcomes for patients: The main health outcome for patients was a high proportion of time in therapeutic range (TTR) of 71.4% across all patients and 75.7% for patients with tests in the most recent five months (March to July 2019). Almost three quarters of patients in this same time period (72.5%) had a TTR of 65% or greater in CPAMS. Other health benefits such as identifying and/or addressing other health conditions while at the pharmacy and reducing patient stress and anxiety related to warfarin testing were also reported by some evaluation respondents.

#### **Successes for Pharmacies and Pharmacists**

- <u>Increased awareness of the value of pharmacists/pharmacies:</u> Many patients and PCPs reported having a better awareness and understanding of the value that pharmacists provide for patients and the health system, and pharmacists also notice a change in perception in these groups.
- Improved knowledge, skills and confidence of pharmacists in anti-coagulation management: Most pharmacists reported that their knowledge, skills and confidence in managing patients on warfarin has increased as a result of participating in CPAMS. Pharmacists noted that by the end of the project they felt confident in using their clinical judgement to support patient management. PCPs also expressed confidence in the pharmacist's ability to appropriately manage patients.
- <u>Increased job satisfaction for pharmacists</u>: Some evaluation respondents said that pharmacists found participating in CPAMS professionally rewarding and enjoyed using their clinical skills and abilities and working more closely with patients.
- <u>Improved relationships with patients</u>: A few respondents indicated that pharmacists and patients were benefitting from closer relationships and increased trust as a result of CPAMS, better enabling pharmacists to assist patients with their health care needs.

#### **Successes for PCPs**

• <u>Saved PCP time</u>: Most PCPs reported that having their warfarin patients managed by the pharmacy saved them/their office time in having to communicate with patients about test results and warfarin dosing.

#### Successes for the Health System

- Improved collaboration and partnerships between providers and with other stakeholders: Many
  evaluation respondents identified improved collaboration and partnerships as a key project
  success, especially between pharmacists and PCPs. While many pharmacists and PCPs already
  have good relationships, participating in CPAMS helped to strengthen this. Most patients also
  reported that information was effectively communicated between the pharmacist and the PCP.
- Improved safety for patients taking warfarin: Many evaluation respondents felt that the CPAMS model increased the safety of anti-coagulation management because results and dose adjustments are provided right away and the pharmacist can check patient understanding of this information, and because the pharmacist can more easily monitor INRs when patients take a medication that may interact with warfarin. A smaller proportion of tests conducted in CPAMS had INR results more than 1.0 below the patient's INR target compared to the historical data for patients (3.3% of all tests in CPAMS and 4.8% of all tests in the historical data). This may reduce the likelihood of strokes as they occur more frequently when INR is low.
- <u>Increased efficiency in the system</u>: Some evaluation respondents suggested that CPAMS improves efficiency in the system by improving patient management, avoiding adverse outcomes (e.g., preventing hospitalizations or ER visits), and reducing the burden on PCPs and the laboratory system of managing INR testing

#### Key Learnings

This evaluation identified a number of key learnings for the implementation of CPAMS based on the enablers, challenges and suggestions for improvement discussed by evaluation respondents. The key learnings that were identified include:

#### **Patient Participation**

- <u>Open CPAMS to all patients</u> that have a Nova Scotia health card number (i.e., not just Pharmacare patients) to increase participation and facilitate enrollment.
- <u>Educate/inform PCPs about CPAMS</u> through various channels (e.g., colleges, associations, educational bodies) to support PCP engagement and buy-in.
- <u>Remove the requirement for a PCP to refer a patient</u> to CPAMS and allow patients to self-refer or be referred by another provider, which will also help to improve access and participation.

#### **Communication between Health Care Providers**

- <u>PANS could support work to integrate electronic information systems for patients</u> so that INR test results for CPAMS patients can be accessed easily by other health care providers.
- <u>Allow pharmacists to manage patients with a broader range of INR results</u> to reduce the communication requirements between providers (pharmacists can still notify PCPs of results but would not require PCP guidance for a wider range of INR results).
- <u>Reduce the length of INR test result notification forms</u> that are faxed to PCPs to minimize documentation clutter.
- <u>Facilitate pharmacist access to the PCP</u> in cases where they do need a PCP opinion to ensure they are able to obtain timely feedback on patient care (e.g. providing the PCP's cell phone number).
- <u>Notify other health care providers</u> such as emergency departments about CPAMS so that staff know where they can obtain recent INR results.

#### Patient Care Processes and Integrating CPAMS into Pharmacy Workflow

- Continue to provide patients with a variety of <u>reminders for appointments</u> including the INR Online calendar and follow up phone calls to patients that are late with their INR testing.
- Pharmacies can effectively <u>use a range of strategies for scheduling patient appointments</u> such as scheduling specific times or allowing patients to drop in. The best strategy for each pharmacy will be determined at the pharmacy level based on overall pharmacy workload and CPAMS patient numbers.
- <u>Home visits</u> could be provided for an additional fee to select patients, particularly those with mobility issues, to improve access and facilitate regular testing for these patients.

#### Pharmacy Supports

 <u>INR Online was a useful tool</u> for pharmacists that had helpful features to support compliance in addition to the dosing algorithm. It was useful especially at the beginning of the project as pharmacists were still gaining comfort and confidence with patient management. However, pharmacists did need to <u>adjust the warfarin dose</u> from that recommended by the INR Online algorithm at times, particularly in the case of patients with a target range of 2.5 to 3.5, and for patients just starting on warfarin.

- Pharmacists experienced some <u>errors and wasted test strips in using the POCT device</u>, particularly in relation to not collecting enough blood to obtain a result. An issue with <u>faulty test strips</u> provided by Roche was also a concern, though this has since been addressed.
- <u>Pharmacy compensation could be modified</u> to include an additional fee for patients that require more frequent testing than the standard 28 days to compensate pharmacies for the additional time and materials (i.e., test strips) required for this more frequent testing.
- <u>Fee-for-service physicians that currently charge a fee for warfarin management should continue</u> to receive this fee if they are still actively engaged in supporting patient warfarin management.
- <u>Supports provided by PANS</u> such as the discussion forum, Project Manager, and live day training were useful and <u>should be continued</u>.

#### **Expanding CPAMS**

The study portion of the CPAMS project officially ended July 31, 2019 (though service is continuing to be provided to patients until next steps are confirmed). Most evaluation respondents including many patients, almost all pharmacists (99%), and all the PCPs interviewed for this evaluation, said that they would like to see CPAMS continue as a service in Nova Scotia, and even be expanded to more patients and more pharmacies. Evaluation respondents noted that the CPAMS model is relatively easy for pharmacies to implement and scale up, and that the CPAMS model may even be a good service model for other types of POCT services that could be offered in pharmacies. Respondents noted that if the model is continued/expanded, additional pharmacies need to be selected with clear criteria in mind, and appropriate support and training needs to be in place for both current and new CPAMS pharmacies. While CPAMS patients were very appreciative of the service, the majority of patients indicated they could not afford to pay for the full costs of service out-of-pocket (\$54/month) and would have to return to the care of their PCP if patients were charged the full fee.

#### Conclusion

Overall, most of the evaluation feedback on CPAMS has been positive, with some key learnings and suggestions for improvement identified that could enhance project outcomes even further. The findings of this final evaluation will be used to inform next steps for anti-coagulation management by community pharmacists in Nova Scotia.

# Introduction

### **Project Overview**

The Pharmacy Association of Nova Scotia (PANS) implemented the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project in Nova Scotia, a new model of care delivery for patients that need anti-coagulant therapy. Anticoagulants are a type of drug that reduces the body's ability to form clots in the blood, and warfarin is the most common of these. Warfarin is typically prescribed to prevent stroke in patients with atrial fibrillation, for long-term secondary prevention of venous thromboembolism (VTE), and to prevent thrombosis or systemic embolization in patients with mechanical heart valves or with certain diseases of the native heart valves. Effective use of warfarin requires that patients are monitored through a blood clotting test called INR (international normalised ratio). A patient's INR should remain within +/- 0.5 units of their target INR; otherwise, the patient is at increased risk of a thromboembolic event such as a stroke (if the INR is too low), or increased risk of bleeding (if the INR is too high) (Pharmacy Association of Nova Scotia, 2018).

Traditionally, patients on warfarin are managed by their primary care provider (PCP, including family physicians and nurse practitioners) and complete the required blood testing through existing public or private blood collection clinics. In the CPAMS model, community pharmacists provide point-of-care INR testing (with a Coaguchek XS Pro device) using a capillary blood sample and adjust warfarin doses as needed using a decision support system, INR Online. INR Online is a web-based warfarin management tool that supports warfarin administration through a computerized dosing algorithm. Authority to perform testing, review results, and make dose adjustments is delegated to the pharmacist by the patient's PCP, with the PCP keeping overall responsibility for the patient's management.

CPAMS was modelled after a similar project that was implemented in New Zealand. The project in Nova Scotia has been funded through the Pharmacare Tariff Agreement Demonstration Project Fund and was approved by the Pharmacy Services Steering Committee. A Working Group was established to guide the development and implementation of CPAMS that included representatives from PANS, Doctors Nova Scotia (DNS), and the Department of Health and Wellness (DHW).

The development of this project began in the summer of 2017. In the fall of 2017, 40 pharmacies were recruited, and participating pharmacists completed training in anticoagulation therapy management. Patients were enrolled from February 1 to July 31, 2018 and participated in the study for a minimum of 12 months. The study portion of this project ended on July 31, 2019, but existing CPAMS patients are continuing to receive care through CPAMS at the time of this evaluation and PANS and DHW are working together to determine next steps in managing care for these patients.

A more detailed description of the CPAMS project, including project development and management, training and support for pharmacists, PCP and patient recruitment, and protocols for patient management and PCP-pharmacist communication are described in further detail in the interim evaluation report.

### **Purpose of this Evaluation**

This report presents findings from the final evaluation of CPAMS, conducted in June to August 2019. It builds on the interim evaluation of the project conducted in 2018. This report describes project participants (including pharmacies and pharmacists, PCPs, and patients) and key activities (testing and appointments, time spent by pharmacists), highlights the successes achieved by the project, and identifies key learnings for CPAMS going forward. The findings of this final evaluation will be used to inform next steps for anti-coagulation management by community pharmacists in Nova Scotia.

# **Evaluation Methodology**

### Overview

The final evaluation of CPAMS includes data from a variety of sources, including both qualitative and quantitative data. Sources of qualitative data include a brief document review, focus groups with pharmacists and the CPAMS Working Group, interviews with PCPs whose patients participated in the project, and open-ended responses to surveys conducted with participating patients and pharmacists. Quantitative data sources include patient data collected from INR Online and the CPAMS online data portal and responses to closed-ended questions from the two surveys. A more detailed description of each data source is provided below.

### **Document Review**

The interim evaluation included a detailed review of project documents such as protocols, recruitment materials, enrollment information, training programs, etc. to gather descriptive information about the project. During this final evaluation, documents were only reviewed in brief in order to assess whether any changes to project processes and activities were made since the interim evaluation.

### **Focus Groups and Interviews**

Three focus groups and eight interviews were conducted as part of the final evaluation:

- Two focus groups with a total of 11 participating pharmacists (one focus group was for managers/owners and one for staff pharmacists);
- One focus group with four members of the project Working Group; and
- Eight interviews with PCPs whose patients participated in the project (seven interviews with physicians and one with an NP).

Interview and focus group guides were developed to help ensure all areas of interest were addressed (see <u>Appendix A</u> for a copy of the guides). All focus groups and interviews were conducted by telephone. Focus groups were approximately 45-60 minutes and interviews were approximately 20-30 minutes. The three focus groups were audio-recorded and transcribed verbatim, with permission from participants, and detailed notes were taken during the interviews.

### **Surveys**

Two surveys were conducted at the end of this project, one with patients and one with pharmacists who participated in the project (copies of the surveys are provided in <u>Appendix A</u>).

#### Patient Survey

Patients completed two surveys, an initial survey on enrollment (February to July 2018), and a final survey at the end of the study period (June and July 2019). In both cases, pharmacists provided each of their participating patients with a paper copy of the survey to complete. Patients returned the completed surveys to the pharmacy in sealed envelopes and then the pharmacies mailed the survey to PANS for data entry. The patient's health card number was recorded on each survey so that survey results could be matched over time and with patient data from INR Online and the CPAMS online portal.

A total of 444 patients completed the enrollment survey (a response rate of 47% of the total 946 patients enrolled in the project), and 488 completed the final survey (a response rate of 65% of the total 746 patients that were still participating in CPAMS at the end of the project in July 2019). Surveys received by PANS that could not be matched to a patient in the project due to a missing or incorrect health card number, as well as surveys received from patients who were not part of the study (e.g., cash paying patients, unattached patients enrolled after the July 31, 2018 cut off date) are excluded from these totals and from the analysis presented in this report. In reporting results from the questions that were only asked on the final survey, all 488 survey responses are included. In the analysis of changes between the baseline (enrollment) and final surveys, only responses from the 254 patients who completed both the baseline and the final survey are included, to allow for comparison of the same patient data from baseline to the final survey.

#### Pharmacist Survey

All pharmacists participating in CPAMS were invited to complete a survey. The pharmacist survey was available online only. Of the 106 pharmacists that participated in CPAMS throughout the project, 72 completed the survey, a response rate of 68% (some pharmacists that no longer worked at CPAMS pharmacies were unable to be contacted to invite them to participate in the survey).

### **INR Online Data**

All pharmacies participating in CPAMS use INR Online, a web-based warfarin management tool and decision support system that supports warfarin administration through a computerized dosing algorithm. The INR Online database stores demographic data for each patient; health care provider information (PCP and pharmacist); treatment details including indication and target INR; and information collected at each visit, including test date and time, results, recommended and actual warfarin dose and details of adverse events (i.e., episodes of bleeding/bruising and thromboembolic events) and hospitalizations. Based on test results, INR Online also calculates the dose of warfarin and the optimal date of the next INR test. All of this data was used in this final evaluation.

### Comparison to Usual Care

For the purposes of evaluating CPAMS against usual care in Nova Scotia, it was not feasible to establish a matched control group of patients in usual care, nor was it possible to obtain historical INR testing history for CPAMS patients through laboratory data. As the next best option, PCPs were asked to provide the most recent five INR test results for patients on the patient enrollment form. This historical data was also entered manually into INR Online by pharmacists during the patient enrollment process. Over half of patients (56%) provided the requested five tests, and another 30% provided either four or six test results. About 8% (n=79) of patients were enrolled without sufficient historical data (three or fewer tests) and these patients are excluded from the analysis of historical INR data.

### **CPAMS Online Portal**

In addition to the patient data collected through INR Online, a separate CPAMS online data portal was also developed and implemented to allow pharmacists to record additional project information to support the evaluation. This information includes some patient data that could not be captured in INR Online (patient eligibility criteria, reasons for patient attrition). Pharmacists collected patient information as part of enrolling the patient and tracked attrition using the CPAMS portal, and patient survey data (baseline and final survey) was also captured via the portal. The portal was also used to capture data from pharmacists on project activities including meetings between pharmacists and PCPs at the start of the project, time spent on CPAMS activities by pharmacy staff, and a log of errors and test strip usage for the point-of-care-testing (POCT) device.

### **Data Analysis**

The qualitative information collected through the evaluation (i.e., focus group transcripts, interview notes, open-ended feedback from the patient and pharmacist surveys) was thematically analyzed, which involves identifying common themes across sources. Sources were first coded to reveal broader themes, as well as sub-categories that illuminate the data in ways not provided by the main themes. The themes and sub-categories were then compared and contrasted across data sources to further develop the themes and categories. Systematic comparisons and verifications ensure that important categories are not overlooked, and that emerging categories and concepts are properly identified. The analysis was completed using the qualitative software NVivo (version 10).

Verbatim quotes from transcripts, interview notes, and the surveys that illustrate a particular theme are included throughout the report and presented along with the theme description. The strength of response of a theme or finding is reflected in the order the themes are presented (except where otherwise noted), as well as through the use of descriptors such as "many", "some" and "a few".

Quantitative data from INR Online and the CPAMS portal was first cleaned (checked for errors and inconsistencies) and matched (patient health card number was used to match patient data between INR Online and the portal). This quantitative data was then analyzed and is integrated into the report along

with the qualitative findings. Descriptive statistics such as frequencies and means are reported for most indicators. Statistical tests of significance were also conducted to assess outcomes related to time in therapeutic range for patients. Detailed data tables for the quantitative information presented in the report are provided in <u>Appendix B</u>.

### Considerations

- Fifteen PCPs with patients participating in the CPAMS project were invited to participate in interviews and eight were able to participate. The purpose of these interviews is to provide more detailed insight into the PCP experience with the project, and this is not intended to be a representative sample (over 250 PCPs had patients participating in CPAMS). While qualitative findings provide detail and depth of understanding, they are not intended to be generalized to a broader population.
- Surveys were not completed by all pharmacists or all patients (response rates of 65% for patients and 68% for pharmacists). As we do not have information about the patients and pharmacists that did not complete a survey, it is possible that the lack of response by some participants created a positive bias in the survey results.
- As discussed above, to gather historical data on INR testing for all patients participating in CPAMS, PCPs enrolling their patients were asked to provide the five most recent INR test results for the patient prior to enrolling in CPAMS. Unfortunately, it was not possible to obtain a longer historical data series for INR results for participating patients from provincial health data, so requesting recent test results from the PCP was the best alternative to gathering this data. While this data provides some historical information for patients, there are some challenges in comparing these results to the CPAMS project results. First, historical data was not provided/available for all participating patients, and some patients reported more or fewer than the requested five results. Second, the time period covered by the historical data is an average of four months, though the range is large with many patients reporting only one month of data and a small number of patients reporting over two years of data. The limited number of observations for each patient in the historical data has the potential to create bias in the results. This issue is discussed in further detail later in this report.
- Historical data was transcribed by PCPs from patient charts, collected on CPAMS patient enrollment forms and then entered into INR Online. There is the possibility for data entry error in this process versus obtaining results directly from the lab data. Quality checks of the data entry by pharmacists did not indicate any significant errors in that process, but pharmacists were not able to verify the data provided by PCPs. Ideally, historical results would be obtained directly from lab data to ensure accuracy; however, this was not feasible for the CPAMS project.

# Findings

### **Organization of the Findings**

The findings in this section are organized into five main sub-sections:

- *Project Participants*: Describes the project participants including pharmacies/ pharmacists, PCPs, and patients.
- *Project Activities*: Describes INR testing, warfarin dosing adjustments, time spent on CPAMS activities, and pharmacy costs/compensation.
- *Successes*: Describes successes achieved through CPAMS for patients, pharmacists and pharmacies, PCPs, and the health system.
- *Key Learnings*: Describes the lessons learned during the CPAMS project, based on the helpful supports, challenges, and suggestions for improvement identified through the evaluation.
- *Expanding CPAMS*: The final section explores considerations for continuing and/or expanding the CPAMS project.

### **Project Participants**

#### Pharmacy and Pharmacist Participation

The process of recruiting pharmacies and pharmacists to participate in CPAMS is described in detail in the interim evaluation report. Between the time of the interim evaluation (fall 2018) and the final evaluation, there were no changes in the 40 pharmacies participating in CPAMS. However, there were changes in the individual pharmacists providing the service. To begin with, each pharmacy had at least two trained CPAMS pharmacists (and two pharmacies each trained four pharmacists). A few pharmacies later added more CPAMS pharmacists, and some pharmacies also trained new pharmacists due to staff leaves or turnover. A total of 22 additional pharmacists completed the required training and certification through the University of Waterloo's online Primary Care Certificate Program in the Management of Oral Anticoagulation Therapy (MOAT), for a total of 106 pharmacists trained over the course of the project.

The 40 participating CPAMS pharmacies are distributed evenly between the Nova Scotia Health Authority's (NSHA) four health management zones (see Figure 1). As seen in Figure 2, almost half of the participating pharmacies are located in small towns (population of 1,000-10,000), and another quarter in cities (population over 100,000).



Figure 1: Pharmacy Location by NSHA Health Zone





See Appendix B, Table 2, p. 65.



#### Primary Care Provider Participation

The process used to engage PCPs and encourage them to enroll their patients in CPAMS is described in detail in the interim evaluation report. A total of 237 PCPs (225 physicians and 12 NPs) enrolled patients in the project, and 217 PCPs (205 physicians and 12 NPs) had patients who were still actively participating in the project as of July 31, 2019. The majority of participating PCPs (78%) had five or fewer patients enrolled in CPAMS (median=2, maximum=39, minimum=1) (see Appendix B, Table 4, p. 65).

Each pharmacy is working with an average of 9 PCPs (median=8, maximum=32, minimum=1) (see Appendix B, Table 5, p. 66). The majority of PCPs (64%) are working with just one pharmacy, with a very small number (1.6%, n=4 of 237) working with between four and six different pharmacies (see Appendix B, Table 6, p. 67).

#### Patient Participation

A total of 946 patients were enrolled in the CPAMS study. The patient enrollment process for CPAMS is described in detail in the interim evaluation report. At the end of the study (July 31, 2019), there were 746 active patients remaining (see Appendix B, Table 7, p. 67), an attrition rate of 21.1%. As seen in Figure 3, the most common reasons for leaving the project were a change in the patient's treatment (recommended by either the pharmacist or PCP) (25%, n=48 of 200), discontinuation of warfarin (17%, n=34 of 200), or returning to the care of their PCP (12%, n=24 of 200).

#### **Figure 3: Reasons for Patient Attrition**



See Appendix B, Table 8, p. 68.

#### Patient Characteristics

The 746 patients still actively participating in CPAMS at the end of the project represent an average of 18 patients per pharmacy (median=14, maximum=61, minimum=0) (see Appendix B, Table 7, p. 67). As seen in Figure 4, the majority of patients (69%) are between the ages of 70 and 89. A little over half of the patients are males (56%).



Figure 4: Patient Age and Gender

See Appendix B, Table 9 and Table 10, p. 69.

Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project: Final Evaluation Pharmacy Association of Nova Scotia September 2019 – FINAL As seen in Figure 5, a greater proportion of patients are located in the Eastern and Western health zones of the NSHA than in the Central and Northern zones. The majority of patients (64%) are located in small towns (Figure 6).





See Appendix B, Table 11, p. 69.

See Appendix B, Table 12, p. 69.

\* Patient location was determined based on the location of the pharmacy where they were enrolled.

The majority of patients (76%) are taking warfarin for atrial fibrillation. Most patients (81%) had been on warfarin for at least 12 months (or more) at the time of enrolling in CPAMS.



#### **Figure 7: Patient Indication for Warfarin**

See Appendix B, Table 13, p. 70.

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### **Project Activities**

#### INR Testing Frequency

Over the whole course of the CPAMS project (February 2018 to July 2019) a total of 21,597 INR tests were conducted. Based on the 12 months of full patient enrollment (August 1, 2018 to July 31, 2019), CPAMS pharmacies conducted an average of 1,332 tests per month, 33 tests per pharmacy. The average number of tests per patient conducted each month was 1.7, and ranged between about 1.5 and 2 (see Figure 8).



Figure 8: Average Number of INR Tests Per Patient Per Month

See Appendix B, Table 15, p. 70.

#### Time Spent on CPAMS Activities

Pharmacies were asked to track the time pharmacists and pharmacy technicians/assistants spent on CPAMS activities at the beginning, middle, and end of the project. The average length of time pharmacy staff spent on patient appointments and follow up activities (e.g., scheduling appointments, phone calls with patients or PCPs) declined over the course of the project, from 15 minutes per patient at the beginning (10.5 minutes for an appointment and 4.4 minutes for follow up per patient) to 8 minutes at the end (6.2 minutes for an appointment and 1.7 minutes for follow up per patient). Unfortunately, the data collected at the final time point is limited (only five of forty pharmacies entered data), leaving the quality/accuracy of this data uncertain. The large reduction in time from the beginning to the end of the project could be due in part to the learning curve of pharmacists, but it is more likely due to increased patient familiarity, and also those patients that were more challenging (e.g., those that could not get a good finger-prick blood draw, those that could not maintain adherence and/or a TTR of 65% had left the project by the end).

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The midpoint time of 11 minutes (7.1 minutes for patient appointments and 3.6 minutes for follow up) likely represents the best estimate of an average time required for appointments on an ongoing basis as this time data was gathered once both pharmacists and patients gained some familiarity with the patient care process, but while new patients were still being enrolled in CPAMS. This time period provides a mix of appointments with both newer and more familiar patients, which is more reflective of the expected workload if new patients were being enrolled on a continuous basis. Based on the average number of tests conducted per patient per month (1.7), this represents a time requirement of approximately 19 minutes per patient per month (see Appendix B, Table 14, p. 70).

#### Pharmacy Costs

CPAMS pharmacies received a \$50.00 INR Management Fee monthly for each participating patient. While the project covered the cost to the pharmacy of the POCT device, initial staff training, and INR Online, pharmacies were responsible for the ongoing costs of test strips for the POCT device (\$7/strip). Going forward, pharmacies will also be responsible for the cost of INR Online themselves (\$4/patient/month). Data on test strip usage reported by pharmacists shows that approximately 16% of test strips were wasted (e.g., due to error codes, inability to obtain enough blood on the strip, etc.).

An average testing frequency of 1.7 tests per patient per month and an error rate of 16% results in an average of 2 test strips per patient per month (\$14), as well as the \$4 charge for INR Online, resulting in a total cost for supplies and resources of \$18 per patient per month.

# Results within Pharmacist Parameters for Management and Warfarin Dosage Adjustments

Of the total 21,597 tests conducted during CPAMS, about 7% of tests (n=1,501 of 21,597) had INR results that were outside of the parameters established in CPAMS for pharmacist management (i.e., if the INR result was below 1.5 or above 4.0 the pharmacist was to obtain input from the PCP on patient management). In terms of adjustments to warfarin dosages for patients, on 34% of tests (n=7,059 of 20,651) the patient's dose of warfarin was altered from the previous dose. In most cases (65.5% of tests), pharmacists gave the warfarin dose that was recommended by INR Online. The dose of warfarin was changed from the dose recommended by INR Online more frequently for tests with INR results outside the pharmacist's parameters for management (below 1.5 or above 4.0) than for those inside the parameters: 74% of tests outside the parameters were changed, compared to 34% of all tests and 32% of tests inside the parameters (see Appendix B, Table 16, p. 71).

### Successes

This section describes how successful the CPAMS project was at achieving its desired outcomes, as well as other unanticipated successes identified through the evaluation. The findings are organized into three

sections looking at successes for patients, for pharmacists and pharmacies, for PCPs, and for the health system as a whole.

#### Successes for Patients

Many positive outcomes for patients were identified in the evaluation, including increased satisfaction with care, improved access to and convenience of testing, increased adherence to testing and medications, patient empowerment and improved understanding of their condition, and improved health outcomes.

#### Increased Satisfaction with Care

Across all 488 patient surveys received during the final evaluation of the CPAMS project, the feedback provided by patients was overwhelmingly positive. No patients reported negative comments in the openended survey questions, and only a couple of patients provided suggestions for improvement. The vast majority were very positive about their experience as a CPAMS patient.

My blood INR remained at an excellent level and I had no problems maintaining an excellent INR level for the entire program while under the guidance of a very professional and caring pharmacist who devoted all the time I needed to get the best results possible. Very, very excellent program and I hope with all my heart it will continue.

- Patient

As seen in Figure 9 patients reported increased satisfaction with the warfarin management provided through CPAMS compared to usual care (their previous care process with their PCP), with a much higher proportion of patients reporting that they were completely satisfied with the care they received (89% in CPAMS vs. 46% in usual care).



#### Figure 9: Patient Satisfaction with Care\*, CPAMS vs. Usual Care

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See Appendix B, Table 28, p. 77.

\* Patients rated their satisfaction on a scale of 1 to 10 where 1 was completely unsatisfied and 10 was completely satisfied.

In addition, most patients responding to the survey agreed/strongly agreed that they prefer to have their warfarin managed by the pharmacy (98%), that they are confident that the pharmacist can manage their warfarin treatment safely (99%), and that they are able to communicate with the pharmacist as often as they needed (98%) (see Appendix B, Table 29, p. 77).

In terms of factors that contribute to increased satisfaction, accessibility and convenience (discussed in the next section) are important considerations. In addition, the finger-prick blood test and the immediate results from the CPAMS testing were both important considerations. Almost all patients (97%) agreed/strongly agreed that they preferred the finger-prick blood test, and that they like knowing the test result and warfarin dose immediately (99%) (see Appendix B, Table 29, p. 77). Many evaluation respondents also highlighted that patients liked receiving their results right away, and some indicated that patients preferred the finger-prick test.

Patients really like the idea that they get the result right away and know what they're doing. - PC	Ρ
I am pleased to have the results of my reading immediately and that they prick my finger not my arm. - Patien	nt
I know the day I go for testing what my level is. This is great. - Patien	nt
The finger prick, people seem to be pleased, a blood draw for some of my patients was very difficult, so they find the finger prick a lot easier.	0
- Pharmacis	st

#### Improved Access to and Convenience of Testing

Many evaluation respondents (pharmacists, PCPs, patients) highlighted the improved access to and convenience of INR testing as a major benefit for patients. As seen in Figure 10 below, the large majority of patients agreed/strongly agreed that having their blood test and warfarin management at the pharmacy was convenient and easier to schedule, saved them waiting and travel time, and allowed them to miss less time from work.



#### Figure 10: Patient Survey Responses on Access and Convenience of CPAMS

See Appendix B, Table 29, p. 77.

Evaluation respondents noted that patients benefitted from:

- Significantly less waiting time to have blood work completed at the pharmacy vs. the hospital blood collection clinic (many respondents);
- Improved accessibility of the pharmacy location including longer hours of service, a location that
  was closer/easier to travel to, and easier physical access (i.e., no stairs or long hallways) for those
  with mobility challenges (many respondents);
- Free parking at the pharmacy vs. having to pay for parking at a hospital blood collection clinic (a few respondents); and
- Improved ability to combine tasks (e.g., shopping) on the same trip as warfarin management (a few respondents).

Very convenient especially for working people because you can go at a time that is suitable for you. At the hospital you have to go at the time the lab is open.

- Patient

I am a senior and having my blood work done at the pharmacy is so convenient because I don't have to travel to the hospital and wait an hour or more to get blood taken.

- Patient

My experience with the participation in the CPAMS is extremely satisfying. I can park at the door and grab a cart to assist me to the counter. My mobility is limited so when I was going to the hospital lab for INR it was very inconvenient because of limited close parking.

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- Patient

It is more convenient for me to go to town to have my warfarin checked. I can go do my banking, shopping, etc. When I go to the hospital it was just for that and it was out of my way if I needed to go shopping. - Patient

It's better because the patients are more likely to have their blood tested, fewer barriers, more accessible hours (evenings, etc.).

- PCP

Comparison of baseline and final survey data provides data that supports the qualitative feedback from evaluation respondents (see Appendix B, Table 30, Table 29 and Table 31 p. 79):

- Visits to the pharmacy take much less time, including waiting time (an average of 14 minutes compared to 90 minutes for usual care).
- Travel time to the pharmacy is slightly less on average (13 minutes to the pharmacy compared to 17 minutes to the PCP office and 16 minutes to the blood collection location).
- Patients pay less for parking at the pharmacy (average of \$0 compared to \$3 for usual care).
- Fewer family members/friends had to take time off work to go with the patient to their warfarin management appointments during CPAMS (5% of patients in CPAMS compared to 10% of patients for PCP appointments and 11% for blood work).
- More patients are able to add another activity such as shopping or lunch with a friend when they go to the pharmacy for warfarin management (62% of patients in CPAMS compared to 35% of patients for PCP appointments and 28% for blood work).

All pharmacists surveyed (100%) agreed/strongly agreed that the project helped to improve access to care for participating patients (see Appendix B, Table 34, p. 81). This project also was particularly helpful in improving access for unattached patients (i.e., patients without a current PCP). While unattached patients were not the focus of the study portion of this project, a large number of unattached patients did participate in CPAMS (outside of the formal study), and a few evaluation respondents noted that this was a critical support for these patients in continuing their access to warfarin and regular INR testing when they did not have a regular PCP.

#### Increased Adherence to Testing and Medications

Some evaluation respondents highlighted improved adherence as a positive outcome for patients, including adherence to both INR testing and taking warfarin as instructed. Evaluation respondents noted that the improved convenience and accessibility of testing at the pharmacy was an important factor in supporting patient adherence, as well as some of the tools provided by the pharmacy such as the INR Online calendar with reminders about dosing and next appointments, and follow up phone calls to patients that are late with their blood testing.

I sense from talking to some of my patients that they're getting their INRs done on time more frequently. I had a couple of patients mention to me, they go down to the hospital sometimes and it'd be too busy, and there'd be sometimes a couple of weeks overtime before they ever got it done. Whereas, usually they're [at most] within a few days of their scheduled time [at the pharmacy]. - Pharmacist If not for this program my INRs would not be checked as regularly as it is with the program. Because of the several hours wait at the hospital I would often avoid going. - Patient I love that the pharmacist will call and remind me of my appointment. - Patient For patients that have trouble with adherence . . . this is a plus to having the pharmacist do the testing. - PCP

As seen in Figure 11, almost 80% of INR tests for CPAMS patients (78.4%) were completed on or before the date the patient should next have a test (this date is determined by the INR Online algorithm but can be overridden and manually entered by the pharmacist if required), and another 12% were completed within 1-3 days of the recommended test date (see Appendix B, Table 17, p. 71). There was also a small amount of early testing, with 5% of tests completed more than three days before the due date.





The average testing frequency for patients in CPAMS (1.7 tests per patient per month) appears to represent a significant increase over the testing frequency in usual care, suggesting improved adherence. Data provided to PANS on the frequency of INR tests conducted in Nova Scotia labs from April 1, 2016 to March 31, 2017 shows that patients had an average of eight test per year (less than once per month), while CPAMS patients had an average of 20 tests per year.

In terms of compliance with warfarin dosing, overall, more patients reported that it was very easy for them to follow their required dosing schedule for warfarin in CPAMS (95%) compared to usual care (66%) (see Appendix B, Table 33, p. 80).

#### Patient Empowerment and Improved Understanding of their Condition

Many evaluation respondents indicated that patients benefitted from the conversations with and support from the pharmacist they received as part of CPAMS. Respondents reported that patients learned more about their warfarin-related health conditions as well as about other aspects of their health. Patients with an improved understanding of their condition and their medication are more empowered and better equipped to self-manage their health. Almost all patients (99%) agreed/strongly agreed that they find it useful to discuss warfarin treatment with the pharmacist (see Appendix B, Table 29, p. 77).

 When they see the pharmacist, they are empowered by a program that gives them advice on top of the physician's experience.
 - PCP

 More than one patient has stated how much they have learned about their treatment as well as what the numbers mean, etc.
 - Pharmacist

 I like discussing reasons why results are out of range.
 - Patient

 I feel supported and assured by the level of [care] with my pharmacist who helps me understand more about my condition.
 - Patient

#### Improved Health Outcomes

The main health outcome for patients was a high proportion of time in therapeutic range (TTR). Other health benefits such as identifying and/or addressing other health conditions while at the pharmacy and reducing patient stress and anxiety were also reported.

#### Time in Therapeutic Range

The proportion of time the patient's INR is within the therapeutic range is a widely used measure of the quality of anti-coagulation control. International guidelines recommend maintaining a TTR of 60% or above in order to maximize the benefits of warfarin and limit adverse events. In the CPAMS project, the following results were observed (see Table 1):

 Overall, across all CPAMS patients the TTR was 71.4%. Thrombosis Canada defines TTR > 60% as "good control" (Thrombosis Canada, 2015). The overall TTR for CPAMS patients is well above this range, and a greater proportion of patients in CPAMS had a TTR above 60% compared to the historical data.

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- In assessing tightness of control (variation of INR results), patients with atrial fibrillation achieved a tightness of control of 78% tests within the range of 1.8 to 3.2. This result is similar to the tightness of control achieved for patients on warfarin in the Sportif III and V clinical trials (80%), which is noted as being "unquestionably better than in the typical practice setting that one would encounter" (Albers, 2004, p. S470; White et al., 2007).
- **TTR for CPAMS patients in the period March 1, 2019 to July 31, 2019 was even higher, at 75.7%.** This higher result for more recent INR testing is in line with expectations because patients have had more time to adapt to the management process at the pharmacy, and the patient population in the later months excludes those who left the project (e.g., due to health issues, return to PCP care, switch to a direct oral anti-coagulant (DOAC), etc.). TTR was measured for this time period to reflect a follow up interval similar to the historical data (where patients have an average of four months of testing data), and to exclude test results that could have been affected by a manufacturing error with the test strips CPAMS pharmacies use to test INR in the Coaguchek XS Pro that was not identified and corrected until October 2018.<sup>1</sup>
- Recent Canadian studies have revealed TTRs under usual care in the 50% to 60% range (Gateman et al., 2017; Liu et al., 2019), and another study showed that only 41% of patients in usual care achieved a TTR ≥ 65% (McAlister, Wiebe, & Hemmelgarn, 2018). In addition, the evaluation of the CPAMS pilot project in New Zealand identified a TTR in usual care of 60.4%. For the purposes of evaluating CPAMS against usual care in Nova Scotia, it was not feasible to establish a matched control group of patients in usual care, nor was it possible to obtain historical INR testing history for CPAMS patients through laboratory data. As the next best option, PCPs were asked to provide the five most recent INR test results for patients on the patient enrollment form. Based on this data, the historical TTR for all CPAMS patients with at least three historical test results was 71.6%. The historical data collected for patients represents an average of four months of data. At 71.6%, this data demonstrates a higher than expected TTR. There may be several reasons for this result compared with the usual care TTRs that have been identified in other research:
  - The historical data includes only a few observations for each patient, covering an average of four months of time. This may overestimate TTR as more fluctuation in results would naturally be expected over a longer time period.
  - A small number of patients have long periods of time between tests in the historical data. While this is only a few patients and would not have a large impact on the overall TTR across all patients, the TTR for these patients could be considerably higher than expected because the Rosendaal method of calculation assumes a linear movement between result A and result B, but this assumption does not hold as valid if patients have a long gap between tests.
  - It is possible that there is a positive selection bias in both participating PCPs and patients that is influencing historical results, i.e., PCPs that chose to participate and enrolled patients in the

<sup>&</sup>lt;sup>1</sup> In October 2018, Roche identified an error with the current batch of test strips for the Coagucheck XS Pro that could result in test values greater than 4.5 INR having an increasing positive bias (i.e., inflated results). These test strips may have been used by CPAMS pharmacies anytime between March 2018 and October 2018. Once CPAMS pharmacies were aware of this issue, they had patients with test values greater than 4.5 duplicate the test in a laboratory to confirm the results and provide them to the pharmacy to enter into INR Online until new test strips could be obtained.

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project already had better management practices for warfarin patients in place and therefore a higher TTR for their patients than is typically seen in usual care; and/or patients that chose to participate in CPAMS were less likely to have INRs out of range in usual care.

- TTR for patients that left the project (attrition) was lower at 62.1%.
- The TTR at the pharmacy level was also calculated and ranged from 64.4% to 87.9% (see Appendix B, Table 18, p. 72).

	Result			
	Time in	% of patients with	% of patients with	
	therapeutic	a TTR of 65% or	a TTR of 75% or	
Group	range (TTR)	greater	greater	
All CPAMS patients (N=930)	71.4%	67.3%	40.5%	
All CPAMS patients, most recent five				
months (N=785)	75.7%	72.5%	52.9%	
Historical data for CPAMS patients with				
at least 3 historical tests (N=867)	71.6%	63.3%	53.9%	
Usual care (as per research cited above)	50-60%	41%	Not available	
Attrition (CPAMS patients that left the				
project) (N=184)	62.1%	40.8%	21.7%	

Table I. The mesulus involution and method h All Fatients	Table 1: TTR Results	(Rosendaal Method <sup>2</sup> )	. All Patients
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Statistical tests were also conducted to assess whether the difference in TTR between CPAMS and historical data is statistically significant. Results show that the mean difference in patient mean TTR scores is statistically significant when considering all patients (t = 2.546, p < 0.05) and when considering results from the most recent five months of the project (March to July 2019) (t = -3.3798, p < 0.05) (i.e., TTR scores are different between CPAMS and historical data). See Appendix B (p. 75) for a more detailed discussion of the statistical testing process and the results tables.

From a qualitative perspective, some evaluation respondents reported that they felt patients participating in CPAMS better managed their INR levels and therefore had improved control and improved TTR. Most patients (96%) agreed/strongly agreed that they have the same or better control of their warfarin treatment now that they go to the pharmacy for testing (see Appendix B, Table 29, p. 77). A few evaluation respondents noted that the pharmacy was able to have more success controlling INR for some patients that were more challenging for the PCP to support.

I go more regularly than when I have an appointment at the hospital and therefore my warfarin is managed MUCH better than before!

- Patient

I have much better control using the pharmacy. Control is the answer to better health.

- Patient

<sup>&</sup>lt;sup>2</sup> TTR is calculated using the Rosendaal method. This method incorporates the value of INR and the frequency of measurement and assumes that changes between consecutive INR measurements are linear over time.

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*We've actually had people whose doctor couldn't get them in range, and we've gotten it done in a couple of months . . . the doctors were very happy with the results.* 

- Pharmacist

- PCP

Very rarely is the [CPAMS] patient ever out of range.

#### **Other Health Benefits**

Evaluation respondents also identified other health benefits for patients from participating in CPAMS:

- Most patients responding to the survey (88%) agreed/strongly agreed that the pharmacist has also been able to help them with other aspects of their health care (see Appendix B, Table 29, p. 77), and most pharmacists surveyed (90%) also agreed with this (see Appendix B, Table 34, p. 81). A few patients specifically mentioned that they had made other beneficial health changes on the advice of the pharmacist such as improving their eating habits or better managing other health conditions.
- Some patients reported feeling lower stress and anxiety about their health because they were
  getting their INR testing done at the pharmacy. These patients indicated that factors such as the
  immediate result and dose adjustments, reduced waiting time (i.e., not having a long wait to get
  bloodwork completed), and the feeling that the pharmacist cared about them and was monitoring
  their results closely contributed to lower stress.
- Some pharmacists described how they were able to identify and address other health conditions for patients as a result of the conversations they had as a part of CPAMS.
- A few patients noted that they reduced their chances of getting sick as they were not getting bloodwork done at the hospital, decreasing their exposure to people who may be ill and contagious.

I know what my results are the same time the test is taken. I am very anxious when I'm not aware as I only hear from the doctor/lab when it is abnormal... being able to do this at the drug store gives me a sense of calmness. I can't describe the pressure this has taken from me.

- Patient

My pharmacist also encouraged me to eat healthier as my INR could be closely monitored and I would know my results right away. Because of this I have lost weight as well!

- Patient

We have also been able to identify and address other health concerns for patients (discovered one patient had diabetes and were able to seek treatment and get patient to a target A1C despite not having a family doctor, helped a patient who struggled with depression for years but wasn't comfortable discussing it until now, discovered an early Alzheimer's patient . . . the list goes on . . .

- Pharmacist

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#### Successes for Pharmacists and Pharmacies

The evaluation identified several positive outcomes for participating pharmacies and pharmacists, including increased awareness of the value of pharmacists/pharmacies, improved knowledge, skills and confidence of pharmacists in anti-coagulation management, increased job satisfaction by providing a service that was highly professionally rewarding, and improved relationships with patients.

#### Increased Awareness of the Value of Pharmacists/Pharmacies

Many pharmacist and PCP evaluation respondents noted that the CPAMS project has increased awareness of the value of the work that pharmacists do and the services that pharmacies provide to patients among a range of stakeholders including patients, PCPs, and government. Most patients responding to the patient survey 97% agreed/strongly agreed that they are more aware of how pharmacists can help people with their healthcare as a result of participating in this project (see Appendix B, Table 29, p. 77), and all/most pharmacists also reported that understanding of the role of pharmacists and the value that pharmacists provide had improved among patients (100% of pharmacists) and PCPs (82% of pharmacists) over the course of the project (see Appendix B, Table 35, p. 83).

I think the project really impressed [a PCP] with how we could finally get someone like t manage] patient in range. I think it really impressed them and maybe gave them a little bu for us in what we do, and what our knowledge base is. I think it definitely improved that.	his [difficult to it more respect
	- Pharmacist
I felt the patients developed a greater trust in our abilities and knowledge.	- Pharmacist
I see the increased value of pharmacists.	
	- PCP

#### Improved Knowledge, Skills and Confidence

Most pharmacists reported that their knowledge, skills, and confidence related to anti-coagulation management had improved as a result of their participation in CPAMS. As seen in Figure 12, the proportion of pharmacists that agreed/strongly agreed that they have the knowledge and/or skills they need to manage anti-coagulation therapies for patients increased considerably from the beginning to the end of the CPAMS project. The majority of pharmacists (99%) also reported that their ability to support patient adherence to warfarin had improved (see Appendix B, Table 35, p. 83).





See Appendix B, Table 34, p. 81.

Most pharmacists in the focus groups also reported that their comfort and confidence in managing these patients had increased substantially over the course of the project.

Initially you depended on the INR online for all your recommendations, but as you got to know the patients and as you felt more comfortable in changing or not changing the dose . . . you've grown in your confidence.

- Pharmacist

[Confidence has] significantly increased. It's not only theoretical to know, but when you get in-depth, you feel that you are more confident. It significantly improved the skill, for sure, it's a big difference.

- Pharmacist

The level of comfort as we've gone along with being able to make adjustments when they needed to be made . . . being more comfortable, having confidence in the decision-making process.

- Pharmacist

The factors that contributed to this increased confidence, knowledge, and skill identified by pharmacists included the MOAT training at the beginning of the project, the opportunity to discuss patient care decisions with experienced providers especially early on in the project, and the hands on experience of providing care and getting to know patients and how they responded.

Most of the PCPs interviewed for this evaluation also indicated that they were confident in the pharmacist's ability to manage patients taking warfarin. A few indicated that pharmacist skill and ability had grown throughout the project, and one highlighted the depth of the training that pharmacists had to complete as a critical factor in enhancing their knowledge, skills and confidence.

Participating pharmacists have been conscientious and concerned about providing a quality service . . . they leaned towards being extra cautious and would consult with the doctor as needed.

- PCP

I am very confident, they are great. The pharmacists I deal with are very competent, I trust their judgement. - PCP

I am very confident in pharmacist ability. [Someone I know] went through the [MOAT] training and I know how in depth the knowledge is. No physicians have that much training in managing INRs – you learn on the job but not as much theoretical knowledge. The level of education that pharmacists have on this should be highlighted so that physicians are aware.

- PCP

#### Professionally Rewarding

Some evaluation respondents (pharmacists and working group members) noted that participating in CPAMS has been professionally rewarding for pharmacists. Pharmacists enjoyed using their clinical skills and abilities, working closely with and getting to know patients, and feeling that they were having a positive impact on individual patient care as well as on the health system overall.

... the professional satisfaction that I hear from pharmacists ... it speaks to the role of the pharmacist and that they feel they are capable, and they find it rewarding because they're helping people with their medication management.

- CPAMS working group member

CPAMS is the most rewarding project I have been involved in as a pharmacist thus far in my career. I truly enjoyed the collaboration, the patient experiences, and the [opportunity] to practice at a higher level. I always see the benefits to our patients and the cost savings to our health care system. It's a win for all. - Pharmacist

We really enjoyed the project and we feel that this is an ideal tool for community pharmacists to provide support to their warfarin patients. It improved patient adherence, time in therapeutic range and patient empowerment. It was an amazing experience to be able to make such an impact on patient health and satisfaction.

- Pharmacist

#### Improved Relationships with Patients

A few evaluation respondents highlighted improved relationships with patients participating in CPAMS as an important benefit of the project for both pharmacists and patients. Pharmacists noted that patient trust and confidence in the pharmacist increased over time and patients were more likely to share relevant health information with the pharmacist as a result. This helped to support anti-coagulation management, and also helped pharmacists identify other health issues for patients (as previously described). I found as we went along, patients were much more forthcoming with information when they began to realize how important it was to our making the right decision when their INRs were a little out of line of what we thought they would be.

- Pharmacist

Patients have more confidence now. This is totally outside of what a lot of them may have expected from the pharmacy. So, I think it's been a win and it's just improving . . .

- CPAMS working group member

#### Successes for Primary Care Providers

The PCPs interviewed as part of this evaluation were generally positive about their experience with CPAMS. All respondents emphasized the benefit and value for their patients and indicated that they had only heard positive feedback from their participating patients. Some PCPs indicated that they enjoyed collaborating with other health care providers and appreciated the opportunity to work with their local pharmacists. Most PCPs reported that having their warfarin patients managed by the pharmacy saved them/their office time in having to communicate with patients about test results and warfarin dosing. Only one respondent reported that they saw no strong benefit to themselves in the CPAMS program (though they did see benefits for patients).

During CPAMS, fee-for-service (FFS) physicians continued to bill in the same way they have done in the past for long term management of anticoagulation therapy as they were still involved in patient management (e.g., maintaining documentation of CPAMS test results in the range of 1.5 to 4.0 in their patient records; addressing test results outside of this range and determining the best course of action for these patients). A few PCPs noted that maintaining this fee was helpful to gain physician buy in and support for the project, and that the fee should continue to be maintained going forward.

I'm extremely satisfied overall. From my perspective working as a primary care provider, anytime we can find ways to delegate the multitude of patient care tasks we need to juggle and manage, that can be delegated to someone with expertise to manage, we can then focus on other things.

- PCP

We had doctors that just wanted to keep adding and adding and adding, and they were disappointed to have it closed to them [when enrollment ended] because they just wanted us to take many more patients. - Pharmacist

I really like it. I have heard a lot of positive feedback from my patients.

- PCP

It helps take some of the load off of us in terms of the constant INRs and tracking patients down.

- PCP

#### Successes for the Health System

Evaluation respondents discussed several benefits for the health system resulting from CPAMS, including improved collaboration and partnerships between providers and with other stakeholders; improved safety for patients taking warfarin; and increased efficiency in the system.

#### Improved Collaboration and Partnerships

Many evaluation respondents spoke about improved collaboration and partnerships that occurred as a result of this project. In some cases, relationships between PCPs and pharmacists were strengthened (many of the PCPs interviewed for this evaluation indicated that they already had a very strong relationship with the pharmacist prior to participating in CPAMS). On the survey, 72% of pharmacists reported that collaboration between themselves and the participating PCPs had improved (see Appendix B, Table 35, p. 83). In other instances, new relationships and partnerships were formed. For example, pharmacies collaborated with new providers (e.g., hematologists and internists, emergency department (ED) physicians) and with other pharmacies (to manage patients moving between pharmacies); and PANS expanded their relationships with other organizations such as Roche, INR Online, and health system stakeholders such as DHW and DNS.

I think it's extremely helpful and I feel our relationship has strengthened because there is that competency part of things. I don't question what they're doing because I feel they are competent enough to do it. - PCP

I think our relationship with our general physician population just got stronger, and we certainly developed new relationships with the anti-coagulation clinic and the physicians there. I think it's probably been a plus all the way around.

#### - Pharmacist

In terms of communication between pharmacists and PCPs to support delivery of patient care, most evaluation respondents reported that the processes in place as part of CPAMS generally worked well to keep the PCP informed about patient care (lessons learned around communication are discussed in a subsequent section). As seen in Figure 13, most pharmacists felt that roles and responsibilities of pharmacists and PCPs were clear and that communication about patient care generally worked well.



#### Figure 13: Pharmacist Responses to Statements about Communication with Physicians

Most patients responding to the patient survey agreed/strongly agreed that the information provided to them about their warfarin management is consistent and does not conflict between the PCP and pharmacist (98%), and that their PCP knows what is happening with their warfarin dose when they attend regular appointments (96%) (see Appendix B, Table 29, p. 77).

The communication was great. They faxed me a sheet that summarized what they were doing with the patient. They would call with any issues or problems.

- PCP

*Great communication between the pharmacist and my GP! Helps me maintain the proper INR numbers.* - Patient

#### Improved Safety

Many evaluation respondents noted that the anti-coagulation management provided through CPAMS helped to support improved safety of care. Respondents indicated that CPAMS patients were getting their results right away and communicating in-person with the pharmacist about any dose changes, which helped to ensure patient understanding and reduce any delays in required dose changes. Pharmacists are also better able to manage the introduction of new medications that could interact with warfarin. Most (97%) pharmacists reported that their ability to help patients on warfarin manage all of their medications (e.g., drug interactions with warfarin) had improved as result of CPAMS (see Appendix B, Table 35, p. 83).

This project offers a better way to do something . . . there is tremendous potential with the technology to spot check INRs and give immediate feedback to patients. This is a much superior way to do this kind of business vs. the old model of care . . . there is so much room for error the way we've historically been doing

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See Appendix B, Table 34, p. 81

it . . . This easy access for patients to immediate feedback and adjustments is much safer and more efficient.

- PCP

Whenever you saw interactions with warfarin before this project, you'd be really nervous about the patient taking it [and wondering] whether they're going to be getting their INR checked. But now you can say . . . drop in [in a few days] and we'll check it and make sure [the new medication] is not affecting [the INR], or if it is, we can adjust it right away. So, less concern about the interactions because you know you can manage it a lot better.

- Pharmacist

Physicians usually work on the phone with the patient [to communicate INR results and dosing changes] or their secretary does. Sometimes it's hard to make sure the patient understands the change to the dosage.

- PCP

The safety and efficacy results for CPAMS patients (see Figure 14) in the last five months of the project are better than or comparable to the results seen in the historical data for CPAMS patients, and better than the results achieved in the CPAMS pilot project in New Zealand. As seen in the figure, a smaller proportion of tests conducted in CPAMS had INR results more than 1.0 below the patient's INR target compared to the historical data for patients (3.3% of all tests in CPAMS and 4.8% of all tests in the historical data). This may reduce the likelihood of strokes as they occur more frequently when INR is low.

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	INR > 1.0					
	below target	INR >5.0	INR ≥8.0			
CPAMS NS*						
% of test results	3.3%	0.6%	0.1%			
% of patients	14.7%	3.9%	0.5%			
Historical Results						
% of test results	4.8%	0.5%	0.1%			
% of patients	16.0%	2.5%	0.5%			
CPAMS New Zealand						
% of test results	3.9%	0.8%	0.1%			
% of patients	33.8%	10.4%	0.7%			

See Appendix B, Table 19, p. 73.

\* Safety and efficacy results for CPAMS were measured with a subset of results from March 1 to July 31, 2019 in order to use a similar time period to the historical data (4 months) and also to remove data that could have been affected by a manufacturing error with the test strips used by CPAMS pharmacies to test INR in the Coaguchek XS Pro that was not identified until October 2018. The error could result in test values greater than 4.5 INR having an increasing positive bias (i.e., inflated results). These test strips may have been used by pharmacies anytime between March 2018 and October 2018. Once CPAMS pharmacies were aware of this issue, they had patients with test values
greater than 4.5 duplicate the test in a laboratory to confirm the results and provide them to the pharmacy to enter into INR Online until new test strips could be provided.

In terms of adverse events, this study was not designed to compare the frequency of adverse events with other studies. Overall, adverse events are associated with patient TTR and fewer adverse events would be expected in a patient population with a better managed/higher TTR. From a descriptive perspective, in CPAMS:

- Patients reported bleeding or bruising on 2.0% (430) of the 21,597 tests (see Appendix B, Table 20 and Table 21, p. 73).<sup>3</sup>
- 24% of patients (n=227 of 946) reported at least one instance of bleeding, including:
  - 0.6% of patients reported a major bleed (n=6 of 946)
  - 1.8% (n=17 of 946) that reported bleeding on five or more occasions.
- Patients reported hospitalizations on 1.1% (238) of the 21,597 tests completed during CPAMS (see Appendix B, Table 22 and Table 23, p. 74).
- The vast majority of these hospitalizations were for other reasons unrelated to warfarin (71%, n=169 of 238) or for scheduled visits/procedures (19%, n=44 of 238).
  - $\circ~$  Three hospitalizations were related to clotting (1.3% of 238) and 13 were related to bleeding (6% of 238).<sup>4</sup>
  - Overall, 19% of patients (n=176 of 946) reported at least one hospitalization, but only 1.7% of patients (n=16 of 946) reported hospitalizations related to bleeding or clotting.

As previously discussed (see Figure 3 and Table 8, p. 68), six patient deaths due to either bleeding or thromboembolic events were reported, two due to bleeding events (0.2% of all 946 patients) and four due to thromboembolic events (0.4% of all 946 patients). Two patients (0.2%) also left the project due to bleeding-related hospitalizations.

#### Increased Efficiency

Some evaluation respondents highlighted the ability of the CPAMS model to improve efficiency in the health care system. Respondents suggested that efficiency is improved by improving patient management, avoiding adverse outcomes (e.g., preventing hospitalizations), and reducing the burden on PCPs and the laboratory system of managing INR testing.

<sup>&</sup>lt;sup>3</sup> Minor bleeds are defined as gum bleeding, spotting from the nose and minor bruising. Moderate bleeds are defined as blood in bowel movements or urine, prolonged nosebleed, or large bruises (bigger than 4 cm in diameter). Major bleeds are defined as bleeds that required attention in hospital (intracranial bleeds, bleeding from the gastrointestinal tract, major urinary tract bleeding, and any bleeding that requires a blood transfusion).

<sup>&</sup>lt;sup>4</sup> Bleeding-related hospitalizations are defined as hospitalizations for a bleed around the brain (intracranial bleed, haemorrhagic stroke, subdural haematoma, extradural haematoma, subarachnoid haemorrhage), bleeding from the gastrointestinal tract (bleeding peptic ulcer or rectal bleeding from a polyp or tumour), haematuria (blood in the urine), servere menorrhagia or other gynaecological causes of bleeding, and a massive haematoma (retroperitoneal or perinenal). Clotting-related hospitalizations are defined as embolic stroke, transient ischaemic attack (TIA), cerebral sinus thrombosis, deep vein thrombosis, pulmonary embolus, myocardial infarction, or thrombosis in another major vessel.

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We had a few successful [instances of] keeping people out of the emergency department . . . we had a few very high, out of range INRs that were able to be managed with some follow up tests, and administration of vitamin K in the pharmacy, after speaking with the physician as opposed to having to refer the patient to the emergency department.

- Pharmacist

## **Key Learnings**

This section of the report describes the key lessons learned throughout the implementation of the CPAMS project. They address the areas of patient participation and enrollment into CPAMS; communication between health care providers (PCPs and pharmacists); patient care processes and integrating CPAMS work into the pharmacy workflow; and pharmacy supports.

Within each area of focus, the context of the project and the issues is first discussed, followed by a list of key learnings in that area that reflect the enablers, challenges and suggestions for improvement from the evaluation findings. Quotes from evaluation participants are highlighted in text boxes throughout.

## Patient Participation

#### Context

At the beginning of the CPAMS project, pharmacists worked with PCPs and patients to identify patients that were eligible and interested in participating in CPAMS and enrolling them in the study. This process is discussed in greater detail in the interim evaluation report, but most pharmacists overall reported that the process was clear (87%) and it was easy to enroll identified patients (71%) (See Appendix B, Table 34, p. 81).

The main challenges with this process were that some PCPs were not aware of the project and/or did not want their patients to participate in CPAMS, and it was also quite difficult initially for unattached patients with no PCP to be enrolled. A little less than half of pharmacists (44%) disagreed with the statement that most PCPs they met with during initial recruitment were willing to participate in the project (See Appendix B, Table 34, p. 81). Also, some PCPs did initially agree to participate, but then did not complete the patient enrollment form on time to have their patients participate in the project or did not provide all the required data for patient enrollment. From the patient perspective, a few pharmacists reported that patients having to enroll in Pharmacare (and then re-enroll again a year later) was a barrier to participation for some patients. A few respondents noted that patients had concerns about sharing confidential information (e.g., their income levels) through the application process and/or were concerned about how this would impact their private health insurance.

#### **Key Learnings**

- Open access to CPAMS to all patients: Some evaluation respondents suggested that any patient with a Nova Scotia health card number should be able to participate in CPAMS regardless of their coverage under Nova Scotia Pharmacare.
- Ensure PCPs are informed about the project: Many pharmacists and PCPs noted that the initial communication process where pharmacists met in person with PCPs to tell them about the project was

I think the benefits of this project are plenty and in order to see it utilized to its full potential, all [appropriate] patients receiving warfarin should be able to participate and it should not require Pharmacare enrollment and renewal every year.

- Pharmacist

very helpful in ensuring that PCPs understood the project and the potential benefits for patients and for PCPs. Some respondents also said that it was/would be helpful to have communication informing PCPs about CPAMS from their relevant colleges and associations (i.e., Doctors Nova Scotia, Nova Scotia College of Nursing, etc.), and as part of their educational curriculum.

• Remove the requirement for a PCP referral to participate in the project: Many respondents highlighted that removing the need for a PCP referral for patients to participate in CPAMS would improve access to the service. This would ensure unattached patients could access ongoing warfarin management at the pharmacy without a referral, and would give all patients more choice in determining where they preferred to have their warfarin managed. A patient's PCP would still be notified that patients were having their warfarin managed at the pharmacy and receive notification of results as required.

#### Communication between Health Care Providers

#### Context

Communication between pharmacists and PCPs to support patient care was a critical aspect of the CPAMS project, particularly in handling patients with out of range INR test results. As discussed previously, in general, the communication between providers worked well. However, evaluation respondents did identify a few challenges related to communication between health care providers. The main challenge identified by many respondents is that the patient's INR test results from testing at the pharmacy are not integrated with other electronic health systems in the province (i.e., public laboratory results reported through SHARE) and other providers therefore do not have easy access to this data (e.g., ED physicians, PCPs, etc.). Evaluation respondents also identified communication challenges in the following areas:

It appears that communication was a challenge with some PCPs. Some pharmacists noted that it
was not easy to communicate with the PCP about the patient's warfarin treatment (17% of those
responding to the pharmacy survey), and that they did not get timely feedback from the PCP when
a patient's INR was outside the pharmacist's management range of 1.5 to 4.0 (23% of those
responding to the pharmacy survey) (See Appendix B, Table 34, p. 81). A few pharmacists in the
focus groups noted that it was difficult to reach the PCP outside of regular office hours, though
others also indicated that they had access to the PCP's personal cell phone for such situations.

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- A few pharmacists mentioned that they experienced occasional differences of opinion with the PCP about dosing for a patient with an out-of-range INR, and there were a few instances where PCPs changed the patient's dose without communicating with the pharmacist about the change.
- A few PCPs indicated that the faxed results were too long and difficult to handle. It created a lot
  of documentation to be added to the patient's chart and was not a functional way to access
  information in an electronic medical record (EMR).

#### **Key Learnings**

- Support work to integrate electronic information systems for patients: Many respondents noted that in an ideal world, INR results from point-of-care testing at the pharmacy would be automatically integrated with the provincial laboratory system and be accessible to any other health care provider that needed this information (e.g., PCP, ED staff, anti-coagulation clinics, etc.). Although this is a broader health system issue that is outside the scope of CPAMS specifically, PANS and other project stakeholders may wish to explore how they can best contribute to work at the system level that will support eventual electronic integration of results from health care provided at pharmacies.
- Allow pharmacists to manage patients with a broader range of INR results: Many respondents (PCPs and pharmacists) suggested that pharmacists are capable of managing a wider range of INR results (the pharmacist's range for CPAMS was INRs from 1.5 to 4.0). Respondents noted that the protocol in place for how pharmacists should handle out of range results was generally appropriate and the majority of PCPs did not make any changes to this process. A few respondents suggested that the PCP may only need to be contacted in the case of a high result (INR>6 or 7), or that the pharmacist could use their

When the doctors figured out we knew what we were doing in adjusting INR they really depended on us to figure out the issues and provide the patient with the proper care.

- Pharmacist

With tests that were outside of range, I felt comfortable with the protocol pharmacists followed, I was fine with what they were doing.

- PCP

clinical judgement as to when they needed guidance from the PCP. This would help to address difficulties in reaching the PCP to get their feedback on patient results and could also reduce situations where there was a difference of opinion between the PCP and pharmacist about the actions to take to address an out of range result for a particular patient as PCPs would not need to be contacted as much with an expanded range (in CPAMS only 0.6% of all tests conducted were below 1.0 or above 6.0 compared to 7% of tests that were below 1.5 or above 4.0). Most pharmacists (87%) agreed/strongly agreed that they would feel comfortable managing patients with INR results outside of the range of 1.5 to 4.0 using their professional judgement and referring to other providers as needed (See Appendix B, Table 34, p. 81). As discussed previously, the PCPs interviewed as part of this evaluation seemed to be confident in the pharmacist's ability to use their clinical judgement to manage the patient appropriately.

- Minimize paper files: A few respondents recommended that the forms for notification of INR
  results that pharmacists fax to PCPs be shortened. As other PCPs indicated they appreciated
  seeing the detailed results, this is potentially something that could be tailored to the needs of the
  PCP.
- Facilitate access to the PCP: In cases where pharmacists do need to contact the PCP regarding a patient with an out of range result, a few respondents noted that it was helpful to make specific arrangements for handling issues outside of office hours, and that pharmacists appreciated having the PCP's cell phone number for ease of communication in these circumstances.
- Notify other health care providers about the project: A few respondents noted that until there is automatic electronic sharing of information/test results, pharmacies with patients in CPAMS should notify other health care providers in their local area about the project (e.g., ED physicians, anti-coagulation clinics) so that other providers know where to get INR results if a CPAMS patient comes into the ED.

#### Patient Care Processes and Integrating CPAMS into Pharmacy Workflow

#### Context

Most evaluation respondents reported that it was relatively easy to manage patient care and integrate the work involved in the CPAMS project into the pharmacy workflow. Once the initial work of meeting with physicians, enrolling patients, and getting patients established with warfarin management at the pharmacy was over, pharmacists reported that processes for managing patient appointments worked smoothly. Almost all pharmacists surveyed (99%) agreed/strongly agreed that it was easy to arrange for patients to come to the pharmacy for their warfarin management and that it was easy to integrate the work involved in CPAMS into the pharmacy workflow (94%) (see Appendix B, Table 34, p. 81). As seen in Figure 15, pharmacies generally reported providing flexible options for scheduling appointments, used various strategies to remind patients about upcoming appointments (e.g., phone call, INR Online calendar), and reminded patients who had missed an appointment to come to the pharmacy for testing. Pharmacists noted that the feature in INR Online that shows the patients that have upcoming test dates or who are overdue for their next test was useful in identifying patients that require follow up. The majority of patients on the survey reported receiving reminder phone calls and the INR Online calendar and indicated that these tools were very helpful (see Appendix B, Table 32, p. 79).



Figure 15: Use of Patient Appointment Scheduling (solid bar) and Reminder (patterned bar) Strategies

See Appendix B, Table 36, p. 83.

#### **Key Learnings**

- **Reminders for appointments:** As discussed previously, some patients and pharmacists reported that it was helpful to have reminders from the pharmacy such as the INR Online calendar with reminders about dosing and next appointments, or follow up phone calls to patients that were late with their INR testing.
- Range of strategies for scheduling patient appointments: Pharmacies used a range of strategies
  for scheduling patient appointments based on their pharmacy context and patient needs. For
  example, some very busy pharmacies scheduled a pharmacist specifically to conduct CPAMS work
  and booked patients at a specific time for this purpose, while other pharmacies with a smaller
  workload and/or fewer CPAMS patients allowed patients to drop in any time a CPAMS pharmacist
  was working on the day of their test, and pharmacist overlap was not always required.
- Strategies for efficiency: A few pharmacists reported different strategies that they used to
  manage the workload and make processes in the pharmacy more efficient, such as having all the
  CPAMS materials and paperwork prepared in advance, or faxing all the testing results at one time
  at the end of the day.
- Home visits: A few pharmacists and patients mentioned that home visits to complete the blood test were conducted for a small number of patients with mobility issues. These patients benefitted greatly from the support and increased access provided through these home visits. A few pharmacists suggested that home visits could be

We had two people specifically that we ended up doing home visits . . . they're both quite elderly and unable to travel . . . the appreciation that they had . . . has been really great.

- Pharmacist

provided to select patients going forward for an additional fee.

#### Pharmacy Supports

#### Context

Pharmacies had a number of supports to assist them with CPAMS project activities:

- **POCT device:** Each CPAMS pharmacy was equipped with a hospital grade point-of-care testing (POCT) device, the Coaguchek XS Pro, manufactured by Roche Diagnostics. Pharmacists were trained to use the POCT device as part of the project's live day training. Each pharmacy regularly performs quality control tests on the device as per manufacturer recommendations.
- INR Online: Pharmacists have access to INR Online, a web-based warfarin management tool that supports warfarin administration through a computerized dosing algorithm. Pharmacists enter patient information and test results, and INR Online provides a recommended dose of warfarin, which pharmacists can modify if required based on their knowledge of the patient and using their own clinical judgement.
- Other supports from PANS: PANS provided support to all participating pharmacies, including an
  initial project orientation and a range of project documentation (e.g., CPAMS operational manual,
  consent and communication materials, outreach materials for meeting with PCPs, etc.).
  Pharmacists also have access to an online discussion forum where they can share
  questions/comments with each other and the PANS Project Manager is available to assist
  pharmacies as needed.

In general, pharmacists reported that the resources and supports provided as part of the project were

useful (see Figure 16). Most pharmacists agreed/strongly agreed that they had all the resources and supports needed to participate in the project (96%) and that it was easy to address any questions or concerns throughout the project (94%) (see Appendix B, Table 34, p. 81). A few pharmacists also noted that overall the CPAMS project was well planned and executed.

It went extremely well. It was rolled out well by PANS, I think. The communication was good; our support was good. Everything from my point-of-view was well done, and although it was quite an undertaking. - Pharmacist



#### Figure 16: Helpfulness of Training, Resources and Supports for Pharmacists

See Appendix B, Table 37, p. 84.

#### **Key Learnings**

Regarding the specific supports provided through the project, the following key learnings are identified:

- INR Online:
  - Most pharmacists agreed/strongly agreed that INR Online was easy to use (97%) and helpful in identifying patients who were overdue for appointments (89%) (see Appendix B, Table 34, p. 81).
  - $\circ~$  A few evaluation respondents noted that in some cases, they disagreed with the dosing

recommendations provided by INR Online and altered the dose based on their professional judgement, and only 76% of pharmacists agreed/strongly agreed that they were confident in the warfarin dosing recommendations provided by INR Online (see Appendix B, Table 34, p. 81). The challenges with dosing were highlighted

I think [INR Online] was really helpful and it still is when you first start, but . . . as it went on, we felt more comfortable not agreeing with INR because we just knew [our patients].

- Pharmacist

particularly in relation to new warfarin starts for patients and patients with a therapeutic range of 2.5 to 3.5 (vs. the usual 2 to 3 range). As previously discussed, the dose recommended by INR Online was more likely to be altered by the health care provider for tests that were particularly high or low (below 1.5 or above 4.0), suggesting that the dosing algorithm may be less accurate in these situations.

 A few pharmacists indicated that the dosing algorithm was very helpful to have in the beginning, but once they gained more skill and confidence in managing warfarin, they depended less on the algorithm's results to support their clinical decision-making. A few

Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project: Final Evaluation Pharmacy Association of Nova Scotia September 2019 – FINAL PCPs also indicated they felt the dosing algorithm was an important support to have in place for pharmacists.

#### • Coaguchek XS Pro POCT Device:

- Pharmacies were asked to report monthly on their test strip usage. Although not all pharmacies reported this data consistently, the data shows that approximately 16% of test strips used were wasted (i.e., pharmacists had to use 16% more test strips than the number of patient visits reported). In addition, pharmacies reported an average of 5 error codes per month received from the Coagucheck XS POCT device. This is also reflected on the results from the pharmacist survey as only 76% of pharmacists agreed/strongly agreed that it is usually easy to obtain a blood sample from the poCT device was easy to use) (see Appendix B, Table 34, p. 81). A few pharmacists highlighted problems with test strips, in particular ensuring there was enough blood on the strip, and trouble-shooting error messages received from the device.
- A few respondents noted that the connection between the POCT device and INR Online did not work and the results had to be entered manually into INR Online. This was a widespread problem across all pharmacies. However, respondents noted that this was not a major challenge and manually entering the data worked well.
- A few evaluation respondents noted that there were some concerns with accuracy,

particularly for patients with high out of range results. This was likely related to the issue of faulty test strips from Roche that led to inflated results. which was identified and corrected in October 2018. However, this did not seem to affect overall confidence in the results from the POCT device. (99%) Almost all pharmacists agreed/strongly agreed that they were confident that the INR results obtained through the POCT device at the pharmacy are reliable (see Appendix B, Table 34, p. 81). Some evaluation

I've actually had people that have had other blood work done and they get their INR done at the lab at the hospital, and the results are almost identical [to the POCT device] . . . So, I'm pretty confident that it's pretty accurate. - Pharmacist

I am quite confident in the POCT machines, I wasn't at the beginning when they first came out, but much better now. I have compared lab test results with results from the pharmacy in the past and they were spot on. - Pharmacist

respondents (PCPs and pharmacists) also noted that when they had CPAMS patients with INR testing done in a lab and compared the results to the POCT device, the results were very similar (the same or within 0.1).

#### • Pharmacy Compensation:

CPAMS pharmacies bill a \$50.00 INR Management Fee monthly for each participating patient. Only 58% of pharmacists agreed/strongly agreed that the amount of compensation the pharmacy received for the work involved in this project was sufficient (see Appendix B, Table 34, p. 81). In the qualitative feedback provided in the survey and

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in focus groups, pharmacists noted that the \$50 monthly fee was sufficient for the standard stable patient that is tested every 28 days, but was not enough to cover more frequent testing (e.g., a new warfarin start, a patient starting a new medication that interacts with warfarin or returning to pharmacy care after surgery, etc.). The mean interval between tests across all patients was 17.6 days, which suggests that on average patients were being tested more frequently than the standard 28 days. Only 5% of tests were completed three or more days before their due date, suggesting that there were valid clinical reasons why patients may need to be tested more frequently. Creating an additional fee billable by pharmacies in situations where a patient needed more than two tests per month could help to address compensation for patients that require more frequent testing.

#### • Other pharmacy supports:

- A few respondents said that the discussion portal was a useful tool for pharmacists to share information and have questions answered.
- A few respondents suggested that having occasional live day training sessions to support pharmacists that are newly trained in warfarin management would be helpful.
- A few respondents indicated that it was very helpful to have a Project Manager at PANS that could provide support and guidance to pharmacies, particularly at the beginning of the project when pharmacies were getting established with the service.

## **Expanding CPAMS**

Most evaluation respondents including many patients, almost all pharmacists, and all the PCPs interviewed for this evaluation said that they would like to see CPAMS continue beyond the formal end date of the evaluation period (July 2019) and even expand to provide services in more locations and to more patients. Almost all pharmacists surveyed (99%) agreed/strongly agreed that they would like to continue to offer a warfarin management service at their pharmacy (see Appendix B, Table 34, p. 81). PCPs were also supportive of the project continuing/expanding, though a few noted caveats such as ensuring interested pharmacies/pharmacists were involved, assessing the cost-effectiveness of the CPAMS model, and maintaining the fee provided to PCPs for warfarin management for their continued role in the care process.

I really appreciate this service - hope this continues for a long time.
- Patient
I think it would be terrific for every community to have at least one pharmacy that offers this [service] right across the province
- Pharmacist
I really want to keep this program and expand upon it for an unlimited number of patients. Pharmacy- dependent, but if they have the staff trained to do this, that would be fantastic.
- PCP

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### Considerations for Expansion

Evaluation respondents identified a number of considerations for expanding the CPAMS service:

- Model for other services: A few evaluation respondents noted that the CPAMS model could also serve as a model for other services that could be provided in pharmacies (e.g., to support testing and management of other chronic conditions such as diabetes or hypertension).
- Easy to scale up: A few respondents indicated that CPAMS is a service that is easy to scale up as you can start with a smaller number of patients and add more as the pharmacists become more comfortable and confident with patient management, and based on the resources available in the pharmacy to support the project.

As discussed previously, the time required to

complete project activities (patient appointments and follow up) appears to have declined over

You could do it at your own pace, really. You could offer it to these many patients at first, see how you do and then gradually increase the number of patients, according to what you can handle.

- Pharmacist

time, indicating increased efficiency as pharmacists become more comfortable with the service and get to know their enrolled patients.

- Pharmacy recruitment: A few respondents said that if the CPAMS service is expanded, a clear plan must be in place to select pharmacies in the right communities in order to improve access to care for patients (e.g., places that have no pharmacies currently participating in CPAMS or where there are many unattached patients using warfarin).
- Pharmacist training and support: A few evaluation participants highlighted the importance of having an appropriate plan in place for training and support of new pharmacies and pharmacists that join CPAMS, taking into consideration the key learnings identified in this evaluation process. If the service is expanded to new pharmacies, the existing CPAMS pharmacies can also be an important source of support and guidance to the new pharmacies in terms of how best to establish and manage the service.

### ✤ Willingness to Pay

Because the future of CPAMS is unknown at the time of this evaluation, patients responding to the patient survey were asked if they would be willing to pay a fee for the service going forward. Approximately a quarter of patients (22%) agreed that they would continue to use CPAMS even if they had to pay a monthly fee of \$54. However, most patients (61%) indicated that they would not continue to use the service if this fee was charged (see Appendix B, Table 29, p. 77). In the open-ended survey feedback, many patients said that they could not afford this cost, even though they felt the service was of value (e.g., seniors on a fixed income). A few patients indicated they would be willing to pay a smaller fee (those that mentioned amounts indicated amounts in the range of \$5-\$25 per month).

I think its being done perfect at the pharmacy. I would pay a fee but not \$54/month. Maybe \$25/month - Patient

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The pharmacist is very helpful and it has been a positive experience. However, I am a senior on a fixed income and if I had to pay \$54 a month I would not be able to do so!

- Patient

## Conclusion

This evaluation of CPAMS has demonstrated many successes for patients, pharmacies/pharmacists, PCPs, and the health system. Patients appear to be extremely satisfied with the service, access to care has been enhanced, and there seems to be better patient adherence to testing and medications. Patient TTR demonstrates good control, and the project has also helped patients with other aspects of their health care. Benefits for pharmacists have included a greater awareness of the value of pharmacists among stakeholders (patients, PCPs, etc.), improvements in knowledge, skills and confidence in warfarin management, and improved relationships with patients. PCPs report that CPAMS has helped to save them time in managing warfarin for their patients. Across the health system, there have been improvements to collaboration (particularly between pharmacists and PCPs), as well as improved safety for warfarin patients and more efficient use of health care resources.

The evaluation also identified key learnings that can be used to support a service like CPAMS going forward. Many aspects of the project worked well and should continue (e.g., strategies for integrating the work into pharmacy workflow, managing patient appointments and supporting adherence, and communicating results to PCPs). Most of the key areas that were identified for potential change are related to improving access to the service (e.g., expanding the service to all patients with a Nova Scotia health card number, removing the requirement for a PCP referral, expanding the number of pharmacies where the service is offered) and ensuring communication processes are efficient and work smoothly (e.g., expanding the range of INR results that a pharmacist can manage without requiring a consultation with the PCP, working with other stakeholders to support electronic integration of INR results from POCT devices, etc.), as well as a few adjustment to improve the tools that support CPAMS work such as the POCT devices and INR Online.

Overall, the majority of the feedback on this project was positive, and many patients, pharmacists and PCPs reported that they want CPAMS to continue into the future. PANS and other stakeholders will use the findings from this evaluation to determine the next steps for the community pharmacist anticoagulation management service in Nova Scotia.

## **Appendix A: Data Collection Tools**

## Pharmacist and Pharmacy Owners Focus Group Guide

#### Prior to the Meeting

• As participants join the focus group call, the facilitator will welcome them individually.

#### Welcome and Introductions

- The facilitator will introduce herself and ask participants to introduce themselves.
- The facilitator will explain the purpose of the focus group as follows:

#### Purpose

Thank you for participating in the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project. Your participation has helped the Pharmacy Association of Nova Scotia (PANS) to evaluate the benefits of providing anticoagulation management to patients through community pharmacies. An important part of the project evaluation is gathering feedback from pharmacists about your experiences with the project

To help with the analysis of the information, I would like to audio record and transcribe this focus group. The transcript of the focus group will be kept confidential (i.e., only consultants from RPI will see it), and any identifying information (names, places, etc.) will be removed. The responses that you provide will only be reported in aggregate (summed together), and although individual responses may be used as quotations in the final report, you will not be personally identified.

Do you have any questions?

Do you consent to participate in the focus group? \_\_\_Yes \_\_\_No

Do I have your permission to record the focus group? \_\_\_\_Yes \_\_\_\_No

#### Questions

1. What were the greatest accomplishments or successes of the CPAMS project?

Sub-questions:

- [*Owners only*] How, if at all, has your pharmacy benefitted from participating in the CPAMS Project?
- What helped you to achieve these successes/accomplishments?
- 2. What were the greatest challenges?

#### Sub-questions:

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- How were the challenges addressed, or how could they be addressed?
- 3. How easy or difficult has it been to integrate the work required for the CPAMS Project into the daily work flow?

Sub-questions:

- What has helped support integrating anticoagulation management into your daily work flow?
- What has been challenging about integrating anticoagulation management into your daily work flow?
- What resources or supports has your pharmacy provided (e.g., time, management support, team support, etc.) to integrate CPAMS work into daily work flow?
- 4. Thinking of the communication and review processes that were established with physicians for communicating patient INR results (both routine results and results that were outside of the pharmacist's scope of practice), how effective were these processes in supporting patient care?

Sub-questions:

- Were there any challenges related to communicating INR results and related care? How were the challenges addressed, or how could they be addressed?
- How could communication of INR results to physicians be improved?
- 5. Were new partnerships developed or existing partnerships strengthened as a result of this project (e.g., with physicians, with other pharmacies, with PANS, etc.)? If yes, please describe. If no, why not?
- 6. How satisfied are you with the anticoagulation management provided to patients through this project?

Sub-questions:

- How confident are you in the accuracy of the point-of-care testing system?
- How confident are you in the dosing recommendations provided by INR Online?
- Have there been any challenges to providing patient care? How were the challenges addressed, or how could they be addressed?
- 7. How, if at all, has your participation in the CPAMS Project affected your level of confidence in providing anticoagulation management?

Sub-questions:

- Has there been a change in your level of knowledge or skills in anticoagulation management? Please describe.
- What was the most important influencer in any changes to your confidence, skills or knowledge?
- Going forward, how comfortable do you feel managing patients with INR results outside of the range of 1.5 to 4.0 using your professional judgement?
- 8. How, if at all, has your participation in the CPAMS Project affected your ability to manage other medications for patients on warfarin (e.g., drug interactions with warfarin)?
- 9. How, if at all, has your participation in the CPAMS Project affected your ability to support patient adherence to warfarin?

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- 10. [*Owners only*] Do you plan to continue offering anticoagulation management services at your pharmacy? Why or why not?
- 11. [*Owners only*] From your perspective, are anticoagulation management services an adequate revenue stream for pharmacies? Why or why not?
- 12. From your perspective, could the CPAMS model be scaled up to pharmacies across Nova Scotia? Why or why not?

Sub-questions:

- What other supports do pharmacies need to provide anticoagulation management services?
- 13. Do you have any additional feedback you would like to share?

Thank you very much for your participation and input.

## Working Group Focus Group Guide

#### **Prior to the Meeting**

• As participants join the focus group, the facilitator will welcome them individually.

#### Welcome and Introductions

- The facilitator will introduce herself and ask participants to introduce themselves.
- The facilitator will explain the purpose of the focus group as follows:

#### Purpose

As you know, an important part of the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project is evaluation. This focus group will gather your input on project processes and outcomes.

To help with the analysis of the information, I would like to audio record and transcribe this focus group. The transcript of the focus group will be kept confidential (i.e., only consultants from RPI will see it), and any identifying information (names, places, etc.) will be removed. The responses that you provide will only be reported in aggregate (summed together), and although individual responses may be used as quotations in the final report, you will not be personally identified.

Do you have any questions?

Do you consent to participate in the focus group? \_\_\_\_Yes \_\_\_\_No

Do I have your permission to record the focus group? Yes No

#### Questions

1. Overall, how satisfied are you with the CPAMS project? Please explain.

#### Sub-questions:

- What were the greatest accomplishments or successes of the project?
- What were the greatest challenges? How were the challenges addressed, or how could they be addressed?
- How satisfied are you with the supports that were provided to pharmacies and physicians during the project, including the training and orientation (Management of Oral Anticoagulation Therapy (MOAT) online training and live day training on INR Online, MOAT, point-of-care testing, and project orientation), project and procedural documentation, INR Online support, project online forum, Project Manager, etc.?

Sub-questions:

- Were there any challenges related to any of these supports [facilitator can prompt with the list above]? How were the challenges addressed, or how could they be addressed?
- Are any other supports needed to ensure successful anticoagulation management at community pharmacies?
- 3. How effective were the quality control processes put in place throughout the project?
- 4. Overall, how satisfied are you with the communication and collaboration between physicians and pharmacists during this project?

Sub-questions:

- Were there any challenges to communicating/collaborating between pharmacists and physicians? How were the challenges addressed, or how could they be addressed?
- How could communication and collaboration be improved?
- 5. Were new partnerships developed or existing partnerships strengthened as a result of this project (e.g., with physicians, with other pharmacies, with PANS, with DHW, etc.)? If yes, please describe. If no, why not?

Sub-questions:

- What other supports could help to develop strong partnerships between stakeholders?
- 6. How satisfied are you with the evaluation strategy for this project?

Sub-questions:

- Were the databases and data collection tools used in the evaluation appropriate? Why or why not?
- 7. Do you feel there have been changes in how stakeholders (e.g., physicians, patients, DHW) see the role of pharmacists or the value that pharmacists can provide? Please describe.

8. From your perspective, could the CPAMS model be scaled up to pharmacies across Nova Scotia? Why or why not?

Sub-questions:

- What other supports do pharmacies need to provide anticoagulation management services?
- 9. Do you have any additional feedback you would like to share?

Thank you very much for your participation and input.

## **PCP Interview Guide**

#### **Introduction and Purpose**

Thank you for participating in the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Project. Your participation has helped the Pharmacy Association of Nova Scotia (PANS) to evaluate the benefits of providing anticoagulation management to patients through community pharmacies. An important part of the project evaluation is gathering feedback from physicians and NPs about your experiences with having your patients' warfarin managed at a community pharmacy.

To help with analysis of the information, I would like to take notes during this interview. With your permission, I will also audio-record the interview. The audio-recording will only be used to refine the interview notes and will be destroyed once the interview notes are finalized. You will have an opportunity to review the notes from your interview to ensure accuracy and validate the information provided (if you wish to do so). The notes from your interview will be kept confidential (i.e., only consultants from RPI will see them). The responses that you provide will only be reported in aggregate (summed together) in the evaluation report, and although individual responses may be used as quotations in the final report, you will not be personally identified.

Do you have any questions?

Do you consent to participate in the interview? \_\_\_\_Yes \_\_\_\_No

Do I have your permission to record the interview? \_\_\_\_Yes \_\_\_\_No

#### Questions

1. Overall, how satisfied are you with the CPAMS project? Please explain.

Sub-questions:

- Why did you choose to participate in this project?
- 2. How satisfied are you with the communication between yourself and the pharmacist(s) participating in this project?

Sub-questions:

- How satisfied are you with the methods pharmacist(s) used to inform you about INR test results? How could this communication be improved?
- Were there any challenges to communicating/collaborating with pharmacists to provide patient care? How were the challenges addressed, or how could they be addressed?
- 3. How satisfied are you with the anticoagulation management provided to your patients through this project?

Sub-questions:

- How confident do you feel in the pharmacist's ability to manage warfarin treatment with the supports in place (e.g., INR Online, point-of-care testing device)?
- Is there anything you would about how care is provided? Please describe.
- Have there been any challenges to providing patient care? How were the challenges addressed, or how could they be addressed?
- 4. Has this project resulted in any benefits for you as a physician/NP? Please describe.
- 5. Has this project changed your views of the value that pharmacists provide to primary care providers or patients? Please describe.
- 6. In your opinion, should the CPAMS service be provided in pharmacies across Nova Scotia? Why or why not?
- 7. Do you have any additional feedback you would like to share?

Thank you very much for your participation and input.

## **Pharmacist Survey**

#### <u>Purpose</u>

Thank you for participating in the Community Pharmacist-led Anticoagulation Management Service (CPAMS) project. Your participation has helped the Pharmacy Association of Nova Scotia (PANS) to evaluate the benefits of providing anticoagulation management to patients through community pharmacies. An important part of the project evaluation is gathering feedback from pharmacists about your experiences with managing patients' warfarin at your pharmacy.

#### Who Should Complete this Survey?

Any pharmacist participating in the CPAMS project should complete this survey.

The survey will take approximately 15 minutes to complete.

#### **Confidentiality**

Because completion of this survey is a project requirement, you will be asked to provide your name and the name and location of your pharmacy on the survey. However, your responses will not be associated with you personally and all responses will be kept confidential – only the consultant hired to do the survey will have access to the raw survey data (i.e., individual responses), and the survey data will be stored securely on a password protected server. Other stakeholders (e.g., PANS, patients, physicians/nurse

practitioners (NPs), pharmacies) will only have access to the compiled data, summed together across all respondents.

There are no right or wrong answers, and you are free to skip any questions you do not wish to answer.

By completing the survey, you indicate that you have reviewed the information provided above and give your consent to participate.

#### Thank you for your input!

1. I am a (please select the option that best fits your main role in the pharmacy):

Pharmacy owner Pharmacy manager		Staff pharmacist
---------------------------------	--	------------------

2. Thinking back to the **training** provided to you at the beginning of this project, please indicate how helpful each part of the training has been, where 1 is not helpful at all and 5 is very helpful:

	Training	Not Helpful at All 1	2	3	4	Very Helpful 5	Did Not Use
a)	Management of Oral Anticoagulation Therapy (MOAT) online training						
b)	MOAT live day training						
c)	INR Online training						
d)	Point-of-care testing training						
e)	Project information/orientation						

3. Thinking of the **project resources and supports** provided to you throughout this project, please indicate how helpful each has been, where 1 is not helpful at all and 5 is very helpful:

	Resources/Supports	Not Helpful at All 1	2	3	4	Very Helpful 5	Did Not Use
a)	Project Manager						
b)	Discussion board						
c)	INR Online						
d)	Procedural documentation (i.e., CPAMS Operational Guidelines)						
e)	Information to support communication (e.g., patient and physician/nurse practitioner (NP) information and consent forms)						

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4. Thinking of the **project resources and supports** that were provided to you over the course of the CPAMS project, please rate your level of agreement for each statement:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	It was easy to address any questions or concerns I had throughout the project.					
b)	The amount of compensation the pharmacy received for the work involved in this project was sufficient.					
c)	I had all the resources and supports I needed to participate in the project.					

5. Thinking of the process of **identifying and recruiting physicians/NPs and patients** to participate in the CPAMS project, please rate your level of agreement for each statement:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	The process for identifying patients who might participate in the project was clear.					
b)	It was helpful to meet face-to-face with potential participating physicians/NPs at the beginning of the project.					
c)	Most physicians/NPs I spoke with during initial recruitment were willing to participate in the project.					
d)	It was easy to enroll identified patients in the project.					

6. You answered "Disagree", "Strongly Disagree", or "Neutral" to the statement "It was easy to enroll identified patients in the project" in the previous question. Please explain any challenges you experienced enrolling patients in the project:

7. Thinking of the **communication and collaboration** that has taken place between yourself and the physician(s)/NP(s) involved in the CPAMS project, please rate your level of agreement for each statement:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	The roles and responsibilities of physicians/NPs in managing the patient's warfarin were clearly defined.					
b)	The roles and responsibilities of pharmacists in managing the patient's warfarin were clearly defined.					
c)	It was easy to communicate with <u>the</u> <u>majority</u> of physicians/NPs about patients' warfarin treatment when needed.					
d)	When a patient had an INR result that was too high or too low (outside the range of 1.5 to 4.0), <u>the majority</u> of physicians/NPs					
e)	Going forward, I would feel comfortable managing patients with INR results outside of the range of 1.5 to 4.0 using my professional judgement and referring to other providers as needed.					

8. Given your experience with this project, do you have any other feedback on collaboration and communication between physicians/NPs and pharmacists for anticoagulation management?

9. Thinking about processes for **arranging for patients to come to the pharmacy for warfarin management** during the CPAMS project, please rate your level of agreement for each statement:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	It was easy to arrange for patients to come to the pharmacy for their warfarin management.					
b)	INR Online was helpful in identifying patients who were overdue for appointments.					

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- 10. Which of the following strategies did you use to **schedule** patients for warfarin management appointments? (check all that apply)
  - Booked specific appointment days and times (e.g., Wednesday at 9:30 am)
  - Booked specific dates with a time window (e.g., Wednesday in the morning, Wednesday
  - between 9 am and 5 pm)
  - □ Walk in appointments (the patient decided when to come in)
  - Other (please explain): \_\_\_\_\_\_
- 11. Which of the following strategies did you use to **remind** patients about their warfarin management appointments? (check all that apply)
  - □ Called patients to remind them prior to the appointment
  - □ Used an appointment reminder app
  - Called patients to follow up in an appointment was missed
  - Other (please explain): \_\_\_\_\_\_
- 12. Thinking about the **point-of-care testing unit** you used during the CPAMS project, please rate your level of agreement for each statement:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	The point-of care testing unit was easy to use.					
b)	It is usually easy to obtain a blood sample from the patient using the point-of care testing unit.					
c)	I am confident that the INR results obtained through point-of-care testing at the pharmacy are reliable.					

13. Thinking about how you used **INR Online and made adjustments to warfarin doses** during the CPAMS project, please rate your level of agreement for each statement:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	INR Online was easy to use.					
b)	I am confident in the warfarin dosing recommendations provided by INR Online.					

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14. Thinking about your overall experience with the CPAMS project, please rate your level of agreement for each statement:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	It was easy to integrate the work involved in CPAMS into our pharmacy workflow.					
b)	I have been able to help patients participating in this project with other aspects of their health care (not related to warfarin management).					
c)	The project helped to improve access to care for participating patients.					
d)	I would like to continue to offer a warfarin management service at our pharmacy.					

15. Thinking about where you are **NOW**, after your participation in the CPAMS project, please rate your level of agreement for each statement:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	I have the knowledge I need to manage anticoagulation therapies for patients.					
b)	I have the skills I need to manage anticoagulation therapies for patients.					

16. Now, **THINK BACK** to **before** you participated in the CPAMS project. Using the scale below, please select the option that best corresponds to where you were **BEFORE** the project:

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	I had the knowledge I need to manage anticoagulation therapies for patients.					
b)	I had the skills I need to manage anticoagulation therapies for patients.					

17. To what extent have the following elements changed over the course of the CPAMS project?

		Deteriorated	No Change	Improved
a)	Collaboration between myself and the participating physicians/NPs.			
b)	My ability to support patient adherence to warfarin.			
c)	My ability to help patients on warfarin manage all of their medications (e.g., drug interactions with warfarin).			
d)	Physician/NP understanding of the role of pharmacists and the value that pharmacists provide.			
e)	Patient understanding of the role of pharmacists and the value that pharmacists provide.			

18. Do you have any other feedback or suggestions for how warfarin management at the community pharmacy could be improved?

Thank you for taking the time to complete this survey.

## **Patient Enrollment Survey**

Thank you for participating in the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project. Your participation will help the Pharmacy Association of Nova Scotia (PANS) to evaluate the patient benefits of providing anticoagulation management through community pharmacies. As you start your care through this project, we would like to gather some information to help with the evaluation of the project. You will be asked for more input in another survey at the end of the project.

All your responses to this survey will be kept confidential. Only the consultant hired to conduct the survey will have access to the raw survey data (i.e., individual patient responses), and the survey data will be stored securely on a password protected server. PANS and the participating pharmacies will only have access to the compiled data, summed together across all patients.

There are no right or wrong answers, and you are free to skip any questions you do not wish to answer.

By completing the survey, you indicate that you have reviewed the information provided above and give your consent to participate.

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Once you have completed the survey, please place it in the envelope provided, seal the envelope, and return it to the pharmacist.

#### Thank you for your time and helping us to understand the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project.

Patient Health Card Number: \_\_\_\_\_\_

#### **SECTION 1: Demographics**

Please answer a few demographic questions about yourself.

#### 1. What is your marital status?

- □ Single (never married) □ Widowed
- □ Married/Common-law □ Separated/Divorced

#### 2. Where do you live?

□ Urban area □ Rural area

#### 3. What is the highest level of education you have completed?

- □ Less than secondary (high) school diploma
- □ Secondary (high) school diploma or equivalent
- □ Some post-secondary education (college/university/trade school)
- Post-secondary degree (college or university)
- □ Graduate degree (Masters, PhD)
- 4. Please indicate your ethnic background: \_\_\_\_\_
- 5. Did you use this pharmacy before starting the CPAMS Project?

🗆 No

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#### SECTION 2: Your Current Warfarin Management

Please think about how you currently manage your warfarin dose (i.e., by completing bloodwork and visiting your family doctor) to answer the questions in this section.

6. Please answer the following questions for your trips to your <u>family doctor or nurse</u> <u>practitioner (NP)</u> for warfarin management in the past year:

- a) How do you usually travel to the doctor or NP's office?
- □ Private vehicle (myself or □ Taxi □ Public □ Walk or someone else driving) transit bike
- b) How long does it usually take to get there (one way)?

\_\_\_\_\_ minutes

c) If you pay for parking at the doctor or NP's office, how much do you usually pay on each visit?

\_\_\_\_\_dollars

d) How long does your appointment at the doctor/NP usually take, including waiting time?

\_\_\_\_\_ minutes

e) How long do you usually spend with the doctor/NP at each visit to manage your warfarin?

\_\_\_\_\_ minutes

- f) Does someone usually go with you to your doctor/NP appointments?
  - Yes friend, family member, or
     Yes paid
     No
     other unpaid person (e.g.,
     support person
     volunteer)

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g) Thinking about the time you spend visiting the doctor/NP for your warfarin management, does anyone usually have to take this time off work?

Person	Yes	No
Me		
Family member/friend		

h) Do you usually add another activity (e.g., shopping, lunch with a friend, etc.) when you go to the doctor/NP for your warfarin management?

🗆 Yes 🗆 No

- 7. Please answer the following questions for your trips to get <u>bloodwork</u> for warfarin management in the past year:
  - a) How do you usually travel there to the blood collection location?
  - □ Private vehicle (myself or □ Taxi □ Public □ Walk or someone else driving) transit bike
  - b) How long does it usually take to get there (one way)?

\_\_\_\_\_ minutes

c) If you pay for parking at the blood collection location, how much do you usually pay on each visit?

\_\_\_\_\_dollars

d) How long does your appointment for bloodwork usually take, including waiting time?

\_\_\_\_\_ minutes

e) How long do you usually spend actually getting blood drawn?

\_\_\_\_\_ minutes
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- f) Does someone usually go with you to get your bloodwork completed?
  - Yes friend, family member, or
     Yes paid
     No
     other unpaid person (e.g.,
     volunteer)
- g) Thinking about the time you spend getting bloodwork for your warfarin management, does anyone usually have to take this time off work?

Person	Yes	No
Me		
Family member/friend		

h) Do you usually add another activity (e.g., shopping, lunch with a friend, etc.) when you go to get bloodwork for your warfarin management?

🗆 Yes 🗆 No

#### 8. How easy is it for you to follow your required dosing schedule for warfarin?

Very	Somewhat	Neither	Somewhat	Very
easy	easy	easy nor	difficult	difficult
		difficult		

9. On a scale of 1 to 10, where 10 is completely satisfied and 1 is completely unsatisfied, please circle the number that reflects how satisfied you are with the care you receive now to help you manage your warfarin.

Completely Unsatisfied							Со	mpletely Satisfied	
1	2	3	4	5	6	7	8	9	10

#### Thank you for taking the time to complete this survey.

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## **Patient Final Survey**

Thank you for participating in the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project. Your participation is helping the Pharmacy Association of Nova Scotia (PANS) evaluate the patient benefits of providing anticoagulation management through community pharmacies. An important part of this evaluation is gathering feedback from patients about your experiences with the management of your warfarin at your community pharmacy.

As the study portion of this service is now coming to an end, we are asking you to complete this short survey to provide your feedback. The survey will take approximately 15 minutes to complete.

All your responses to this survey will be kept confidential. Only the consultant hired to conduct the survey will have access to the raw survey data (i.e., individual patient responses), and the survey data will be stored securely on a password protected server. PANS and the participating pharmacies will only have access to the compiled data, summed together across all patients. Quotations from the surveys may be used in evaluation reporting but will not be linked to any specific individual.

There are no right or wrong answers, and you are free to skip any questions you do not wish to answer.

By completing the survey, you indicate that you have reviewed the information provided above and give your consent to participate.

Once you have completed the survey, please place it in the envelope provided, seal the envelope, and return it to the pharmacist.

#### Thank you for your time and helping us to understand the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project.

TO BE COMPLETED BY PHARMACY:	
Patient Health Card Number:	
Pharmacy Name and Location:	

# 1. Thinking about booking appointments for your warfarin management, please select your level of agreement with each statement (select one option for each statement):

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	I was able to visit the pharmacy to					
	receive my warfarin management at					
	times that were convenient for me.					

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	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
<ul> <li>b) It is easier to get an appointment for warfarin management at the pharmacy than with my doctor or nurse practitioner (NP).</li> </ul>					

# 2. Did you receive either of the following services to help you remember your warfarin management appointments and/or your warfarin dose?

	Yes	No
Reminders about my upcoming appointments from the pharmacy.		
A calendar showing me what dose of warfarin to take.		

#### a) If Yes, How Helpful Was this Support?

	Not Helpful	Somewhat Helpful	Very Helpful
Reminders about my upcoming appointments from the pharmacy.			
A calendar showing me what dose of warfarin to take.			

# **3.** Please answer the following questions for your trips to the <u>pharmacy</u> for warfarin management in the past year:

#### i) How do you usually travel to the pharmacy?

□ Private vehicle (myself or □ Taxi □ Public □ Walk or someone else driving) transit bike

### j) How long does it usually take to get there (one way)?

\_\_\_\_\_ minutes

k) If you pay for parking at the pharmacy, how much do you usually pay on each visit?

\_\_\_\_\_dollars

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I) How long does your appointment at the pharmacy usually take, including waiting time?

\_\_\_\_\_ minutes

m) How long do you usually spend with the pharmacist to manage your warfarin at each appointment (blood test, adjustments to your warfarin dose, etc.)?

\_\_\_\_\_ minutes

- n) Does someone usually go with you to the pharmacy for warfarin management?
  - □ Yes friend, family member, or
     □ Yes paid
     □ No
     other unpaid person (e.g., support person
     volunteer)
- o) Thinking about your warfarin management visits to the pharmacy, does anyone usually take time off work for these visits?

Person	Yes	No
Me		
Family member/friend		

p) Do you usually add another activity (e.g., shopping, lunch with a friend, etc.) when you go to the pharmacy for your warfarin management?

□ Yes □ No

4. Thinking about the convenience of the pharmacy warfarin management service, please select your level of agreement with each statement (select one option for each statement):

		Strongly				Strongly
		Disagree	Disagree	Neutral	Agree	Agree
a)	It is more convenient to have my blood test at the pharmacy.					
b)	I do not have to travel as far to have my warfarin managed at the pharmacy.					

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		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
c)	It saves me time having my warfarin managed by the pharmacist.					
d)	I miss less time at work for my warfarin management now.					

5. Thinking about the communication and support you received from the pharmacist during this project, please select your level of agreement with each statement (select one option for each statement):

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	I was able to communicate with the pharmacist as often as I needed.					
b)	I find it useful to be able to discuss my warfarin treatment with the pharmacist when I go for my test.					
c)	Using the warfarin service at the pharmacy has meant that the pharmacist has also been able to help me with other aspects of my health care.					

6. Thinking about the process for collecting your blood and adjusting your warfarin dose used by the pharmacist, please select your level of agreement with each statement (select one option for each statement):

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	I prefer the finger-prick blood test to having blood taken from my arm using a needle.					
b)	I like knowing my test result and dose immediately.					

7. Thinking about how well your doctor/nurse practitioner (NP) and pharmacist communicated about your warfarin management, please select your level of agreement with each statement (select one option for each statement):

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a)	Information provided to me about my warfarin management is consistent and does not conflict between the doctor/NP and pharmacist.					
b)	My doctor/NP knows what is happening with my warfarin dose when I attend regular appointments.					

#### 8. How easy is it for you to follow your required dosing schedule for warfarin?

- Very
   easy
- Somewhat
   easy
- Neither easy nor difficult
- Somewhat
   difficult
- Very difficult
- 9. Please describe any changes in your health, positive or negative, that occurred as a result of your participation in the Community Pharmacist-led Anticoagulation Management Service (CPAMS) Canada Project:

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10. Thinking about your overall experience with the Community Pharmacist-led Anticoagulation Management Project, please rate your level of agreement for each statement (select one option for each statement):

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
e)	I am confident that the pharmacist can manage my warfarin treatment safely.					
f)	I have the same or better control of my warfarin treatment now that I go to the pharmacy for testing.					
g)	I prefer to have my warfarin managed by the pharmacy.					
h)	I am more aware of how pharmacists can help people with their healthcare as a result of participating in this project.					
i)	I would still use the warfarin service at the pharmacy even if I had to pay a monthly fee of \$54.					

11. On a scale of 1 to 10, where 10 is completely satisfied and 1 is completely unsatisfied, please <u>circle</u> the number that reflects how satisfied you are with the care you received through this project to help you manage your warfarin.

Complet Unsatisf	ely ied					Complete Satisfie					
1	2	3	4	5	6	7	8	9	10		

**12.** Do you have any other feedback or suggestions for how your warfarin management at the community pharmacy could be improved?

#### Thank you for taking the time to complete this survey.

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## **Appendix B: Data Tables**

This Appendix provides the detailed data tables that support the figures that are included in the body of the report.

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# Patient Data from INR Online and the CPAMS Online Portal

Zone	#	%
Central	11	28%
Eastern	10	25%
Northern	10	25%
Western	9	23%
Total	40	100%

## **Table 2: Participating Pharmacies by Provincial Health Zone**

### Table 3: Participating Pharmacies by Community Size

Size of Location	#	%
Small town	19	48%
City	9	23%
Medium town	7	18%
Rural	3	8%
Large town	2	5%
Total	40	100%

Definitions of city size adapted from Stats Canada (<u>https://www.statcan.gc.ca/eng/subjects/</u> <u>standard/pcrac/2016/introduction#s3</u>):

- Small town: 1,000-10,000
- Medium town: 10,001-30,000
- Large town: 30,000-100,000
- City: Over 100,000

### Table 4: Number of Patients in CPAMS per PCP (all enrolled patients)

# of Patients	# of PCPs with this many	% of PCPs with this
enrolled in CPAMS	Patients Enrolled	many Patients Enrolled
1	81	34%
2	41	17%
3	23	10%
4	28	12%
5	13	5%
6 to 10	33	14%
11 to 20	13	5%
More than 20	5	2%
Total	237	100%

Pharmacy	# of PCPs Referring Patients
Pharmacy 06	0
Pharmacy 12	1
Pharmacy 07	3
Pharmacy 18	3
Pharmacy 35	4
Pharmacy 38	4
Pharmacy 10	5
Pharmacy 05	5
Pharmacy 03	5
Pharmacy 19	5
Pharmacy 01	6
Pharmacy 11	6
Pharmacy 04	6
Pharmacy 08	6
Pharmacy 15	7
Pharmacy 25	7
Pharmacy 09	7
Pharmacy 34	8
Pharmacy 40	8
Pharmacy 26	8
Pharmacy 27	8
Pharmacy 24	8
Pharmacy 33	9
Pharmacy 21	9
Pharmacy 13	9
Pharmacy 37	9
Pharmacy 02	10
Pharmacy 16	10
Pharmacy 39	11
Pharmacy 20	11
Pharmacy 28	12
Pharmacy 17	12
Pharmacy 22	12
Pharmacy 23	12
Pharmacy 14	14
Pharmacy 36	14
Pharmacy 32	15
Pharmacy 29	18
Pharmacy 31	20
Pharmacy 30	32

Table 5: PCPs Referring Patients (all enrolled patients)

# of Pharmacies	# of PCPs	%
1	151	63.7%
2	56	23.6%
3	26	11.0%
4	2	0.8%
5	1	0.4%
6	1	0.4%
Total	237	100.0%

# Table 6: Number of Pharmacies each PCP is Working With

#### Table 7: Patient Attrition, Overall and by Pharmacy

Pharmacy	# of Patients Initially	# of Patients that	% of Patients
	Enrolled	Left	that Left
Pharmacy 06	0	0	
Pharmacy 12	1	0	0.0%
Pharmacy 26	21	0	0.0%
Pharmacy 01	7	0	0.0%
Pharmacy 28	21	1	4.8%
Pharmacy 14	22	2	9.1%
Pharmacy 05	10	1	10.0%
Pharmacy 15	10	1	10.0%
Pharmacy 34	9	1	11.1%
Pharmacy 30	57	8	14.0%
Pharmacy 18	49	7	14.3%
Pharmacy 40	14	2	14.3%
Pharmacy 08	39	6	15.4%
Pharmacy 09	19	3	15.8%
Pharmacy 27	36	6	16.7%
Pharmacy 04	17	3	17.6%
Pharmacy 02	17	3	17.6%
Pharmacy 33	10	2	20.0%
Pharmacy 38	10	2	20.0%
Pharmacy 39	19	4	21.1%
Pharmacy 13	23	5	21.7%
Pharmacy 37	79	18	22.8%
Pharmacy 20	35	8	22.9%
Pharmacy 29	43	10	23.3%
Pharmacy 16	17	4	23.5%
Pharmacy 17	29	7	24.1%
Pharmacy 24	33	8	24.2%
Pharmacy 36	62	15	24.2%

Pharmacy	# of Patients Initially	# of Patients that	% of Patients
	Enrolled	Left	that Left
Pharmacy 03	12	3	25.0%
Pharmacy 22	36	9	25.0%
Pharmacy 35	4	1	25.0%
Pharmacy 23	51	14	27.5%
Pharmacy 32	17	5	29.4%
Pharmacy 25	10	3	30.0%
Pharmacy 31	42	13	31.0%
Pharmacy 21	19	6	31.6%
Pharmacy 19	25	8	32.0%
Pharmacy 07	5	2	40.0%
Pharmacy 10	6	3	50.0%
Pharmacy 11	10	6	60.0%
Total	946	200	21.1%

### **Table 8: Reasons for Patient Attrition**

		% of patients reporting	% of all patients
Reason	#	attrition (N=200)	(N=946)
Hospitalization, bleeding-related	2	1.0%	0.2%
Death, bleeding event	2	1.0%	0.2%
Death, thromboembolic event	4	2.0%	0.4%
Hospitalization, not warfarin related	5	2.5%	0.5%
Treatment changed - pharmacist			
recommended switch to DOAC	7	3.5%	0.7%
Moved away or changed physician	7	3.5%	0.7%
Long term care or rehabilitation,			
unrelated to warfarin	12	6.0%	1.3%
Death, unrelated to warfarin	18	9.0%	1.9%
Death, unknown cause	21	10.5%	2.2%
Unknown/unspecified	23	11.5%	2.4%
Returned to physician care	24	12.0%	2.5%
Warfarin discontinued	34	17.0%	3.6%
Treatment changed	41	20.5%	4.3%
Total	200	100.0%	21.1%

### Table 9: Patient Age

	All Enrolled Patients (n=946)		Active Pati	ents (n=746)
Age	#	%	#	%
Under 30	2	0.2%	1	0.1%
30-39	6	0.6%	5	0.7%
40-49	13	1.4%	13	1.7%
50-59	37	3.9%	30	4.0%
60-69	173	18.3%	143	19.2%
70-79	379	40.1%	303	40.6%
80-89	283	29.9%	221	29.6%
90+	53	5.6%	30	4.0%
Total	946	100.0%	746	100.0%

## Table 10: Patient Gender

	All Enrolled Patients (n=946)		All Enrolled Patients (n=		Active Pati	ents (n=746)
Gender	#	%	#	%		
Male	411	43.4%	332	44.5%		
Female	535	56.6%	414	55.5%		
Total	946	100.0%	746	100.0%		

# Table 11: Patient Location by Provincial Health Zone

	All Enrolled Patients (n=946)		Active Patients (n=746)	
Zone	#	%	#	%
Eastern	343	36.3%	268	35.9%
Western	294	31.1%	233	31.2%
Northern	175	18.5%	136	18.2%
Central	134	14.2%	109	14.6%
Total	946	100.0%	746	100.0%

#### Table 12: Patient Location by Community Size

	All Enrolled Patients (n=946)		Active Patients (n=746)	
Size of Location	#	%	#	%
Small town	599	63.3%	474	63.5%
Medium town	146	15.4%	115	15.4%
City	84	8.9%	70	9.4%
Large town	61	6.4%	42	5.6%
Rural	56	5.9%	45	6.0%
Total	946	100.0%	746	100.0%

\* See definitions of community size following Table 3.

Table	13:	Indication	for	Warfarin
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	All Enrolled Pa	atients (n=946)	Active Patients (n=746)		
Indication	#	%	#	%	
Atrial fibrillation	731	77.3%	569	76.3%	
Deep vein thrombosis	57	6.0%	49	6.6%	
Pulmonary embolus	58	6.1%	45	6.0%	
Mechanical heart valve	50	5.3%	43	5.8%	
Other	27	2.9%	19	2.5%	
TIA	8	0.8%	8	1.1%	
Post myocardial infarction	7	0.7%	7	0.9%	
Tissue heart valve	5	0.5%	4	0.5%	
Mural thrombus	3	0.3%	2	0.3%	
Total	946	100.0%	746	100.0%	

#### Table 14: Pharmacist/Tech/Assistant Time Spent on CPAMS Activities

	Patient Appts		Follow Up			Total			
	Avg	Min	Max	Avg	Min	Max	Avg	Min	Max
Beginning	10.5	2	50	4.4	1.2	15.0	15.4	6.2	43.3
Middle	7.1	4.7	15.0	3.6	1.2	7.7	10.6	6.0	20.0
End	6.2	5.0	9.9	1.7	0.5	5.3	7.9	5.5	12.7

Time is reported in minutes.

The quality of this time data is poor and should be used with caution. While most pharmacies reported data at the beginning of the project (30 of 40 pharmacies), only 19 pharmacies reported at the middle of the project (less than half), and only five pharmacies at the end. Only a few stores reported time spent by pharmacy technicians or assistants (five in the beginning, four in the middle, and none at the end).

Month	#	% of all tests	Average Tests per Patient per Month
August 2018	1,796	11.2%	2.07
September	1,496	9.4%	1.75
October	1,634	10.2%	1.94
November	1,449	9.1%	1.76
December	1,274	8.0%	1.64
January 2019	1,421	8.9%	1.78
February	1,178	7.4%	1.54
March	1,120	7.0%	1.49
April	1,152	7.2%	1.54
May	1,186	7.4%	1.59
June	1,079	6.7%	1.49
July	1,201	7.5%	1.68
Total	15,986	100.0%	1.69

### Table 15: Patient INR Tests per Month\*

\* Tests reported only for study months once enrollment was completed. Tests included for all patients (active and attrition).

Was the Warfarin Dose	All Te	ests	Tests with INR Pharmacist's N Parameters	Results in the Management (1.5 to 4.0)	Tests Outside the Pharmacist's Management Parameters (<1.5 and >4.0)		
Changed?	#	%	#	%	#	%	
No	14,148	66%	13,758	68%	390	26%	
Yes, decrease	4,006	19%	3,186	16%	820	55%	
Yes, increase	3,443	16%	3,152	16%	291	19%	
Total	21,597	100%	20,096	100%	1,501	100%	

Table 16: Tests When the Warfarin Dose was Changed from the Dose Recommended by INR Online

### **Table 17: Compliance with Appointments**

Actual vs. Expected Testing Date	#	% of all tests (N=20,651*)
Tests performed on/before the due date	16,196	78.4%
Tests 1-3 days overdue	2,545	12.3%
Tests 4-7 days overdue	1,022	5.0%
Tests more than 7 days overdue	888	4.3%
Tests more than 3 days before the due date	1,025	5.0%

\* The total number of tests for which the variable of actual vs. expected test date can be measured is less than the total number of tests in the database as this variable cannot be calculated for the first test for each of the 946 CPAMS patients in the INR Online database (therefore total number of tests = 21,597 – 946 = 20,651).

Pharmacy	TTR - CPAMS
Pharmacy 12	87.9%
Pharmacy 38	82.4%
Pharmacy 01	78.1%
Pharmacy 16	76.9%
Pharmacy 27	76.2%
Pharmacy 40	76.0%
Pharmacy 04	74.9%
Pharmacy 09	74.9%
Pharmacy 39	74.5%
Pharmacy 02	74.1%
Pharmacy 15	73.0%
Pharmacy 08	72.9%
Pharmacy 30	72.9%
Pharmacy 26	72.8%
Pharmacy 28	72.6%
Pharmacy 11	72.4%
Pharmacy 37	72.4%
Pharmacy 25	72.3%
Pharmacy 10	72.1%
Pharmacy 21	72.1%
Pharmacy 29	71.8%
Pharmacy 31	71.7%
Pharmacy 23	71.3%
Pharmacy 33	71.2%
Pharmacy 24	70.7%
Pharmacy 35	70.6%
Pharmacy 34	70.5%
Pharmacy 18	69.7%
Pharmacy 36	69.6%
Pharmacy 05	69.3%
Pharmacy 20	69.1%
Pharmacy 14	68.2%
Pharmacy 22	68.0%
Pharmacy 32	67.9%
Pharmacy 19	66.7%
Pharmacy 17	66.5%
Pharmacy 13	66.0%
Pharmacy 07	65.0%
Pharmacy 03	64.4%

Table 18: TTR by Pharmacy, all patients (Rosendaal method)

	Historical Results			CPAMS NS*			CPAMS New Zealand			
<b>Total Patients</b>		867			797			154		
Total Tests		4,516			5,738			2,637		
<b>Results Outside of</b>	INR >			INR >			INR >			
Safety and	1.0			1.0			1.0			
Efficacy	below	INR	INR	below	INR	INR	below	INR	INR	
Thresholds	target	>5.0	≥8.0	target	>5.0	≥8.0	target	>5.0	≥8.0	
# of test results	216	22	4	187	37	4	103	21	2	
% of test results	4.8%	0.5%	0.1%	3.3%	0.6%	0.1%	3.9%	0.8%	0.1%	
# of patients with										
one or more										
result	139	22	4	117	31	4	52	16	1	
% of patients with										
one or more										
result	16.0%	2.5%	0.5%	14.7%	3.9%	0.5%	33.8%	10.4%	0.7%	

Table 19: Safety and Efficacy Results

\* Safety and efficacy results for CPAMS were measured with a subset of results from March 1 to July 31, 2019 in order to use a similar time period to the historical data (4 months) and also to remove data that could have been affected by a manufacturing error with the test strips used by CPAMS pharmacies to test INR in the Coaguchek XS Pro that was not identified until October 2018. The error could result in test values greater than 4.5 INR having an increasing positive bias (i.e., inflated results). These test strips may have been used by pharmacies anytime between March 2018 and October 2018. Once CPAMS pharmacies were aware of this issue, they had patients with test values greater than 4.5 duplicate the test in a laboratory to confirm the results and provide them to the pharmacy to enter into INR Online until new test strips could be provided.

### **Table 20: Patients Reporting Bleeding**

# of Reports of Bleeds	#	% of patients reporting a bleed (N=227)	% of all patients (N=946)
10 or more bleeds reported	1	0.4%	0.1%
7-9 bleeds reported	8	3.5%	0.8%
4-6 bleeds reported	21	9.3%	2.2%
2-3 bleeds reported	53	23.3%	5.6%
1 bleed reported	144	63.4%	15.2%
Total	227	100.0%	24.0%
Major bleed reported	10*	4.4%	1.1%

\* In order to get an accurate incidence of major bleeding, the four patients that were reported in the attrition data as leaving the project due to either a bleeding-related death or hospitalization (considered major bleeds) were added to the six patients with one major bleed reported in the INR Online data. However, these four patients are not reflected in the next table as it is based on number of tests.

### Table 21: Type of Bleed

	# of	% of tests where a bleed was	% of all tests
Type of Bleed	tests	reported (N=430)	(N=21,597)
Major Bleed	6	1.4%	0.1%
Moderate Bleed	74	17.2%	0.3%
Minor Bleed	350	81.4%	1.6%
	430	100.0%	2.0%

### **Table 22: Patients Reporting a Hospitalization**

# of Reports of Hospitalizations	#	% of patients reporting a hospitalization (N=176)	% of all patients (N=1,010)
Four hospitalizations reported	4	2.3%	0.4%
Three hospitalizations reported	6	3.4%	0.6%
Two hospitalizations reported	38	21.6%	3.8%
One hospitalization reported	128	72.7%	12.7%
Total	176	100.0%	17.4%
One bleeding-related			
hospitalization reported	12	6.8%	1.3%
Two bleeding-related			
hospitalizations reported	1	0.6%	0.1%
One clotting-related			
hospitalization reported	3	1.7%	0.3%
Total	16	9.1%	1.7%

### **Table 23: Hospitalization Reasons**

	# of	% of tests where a hospitalization	% of all tests
Reason for Hospitalization	tests	was reported (N=238)	(N=21,597)
Other	169	71.0%	0.78%
Scheduled	44	18.5%	0.20%
Bleeding	13	5.5%	0.06%
Unknown Reason	9	3.8%	0.04%
Clotting	3	1.3%	0.01%
Total	238	100.0%	1.10%

# Table 24: Strip Usage and Error Codes

Number of months of data across all pharmacies	416
Total errors reported	2,072
Average errors reported per pharmacy per month	4.98
Total number of patient visits reported across all pharmacies	14,468
Total test strips used	16,799
Total number of test strips wasted	2,331
% of strips wasted	16%

# ✤ Results of Statistical Testing

When testing the significance of the difference between means in the case of a "before and after" comparison, it must be recognized that the observations at each time period (before, after) are not independent, so a paired t-test is recommended. To perform a paired t-test, you would match patient observations between time periods, calculate the difference in means between the before and after time periods, and test if the difference between the means is significant. Certain conditions need to be met in order to run such an analysis, namely that the data points must be approximately normally distributed and that each patient observation has a matching data point in the before and after time periods. Both of these conditions are not met in when examining the individual TTR patient reports: the data is not normally distributed, with high 0s and 1s making a bimodal distribution (U-shape), and there are not matching observations on each individual before and after (most individuals have many more observations in the after period). We could alternatively do a two-sample means difference test by group (gr 1= before, gr 2 = after), but conditions of independence and normality are not held so results would be biased.

As an alternative, we calculate the mean TTR for each individual in the before and after time periods, creating one mean TTR score per individual. The mean TTR score before and after are then matched. We see that the distributions are approximately normally distributed in each time period, as well as the difference in means. When matching historical and study data, the sample does become smaller as some individuals do not have historical data and some individuals attritioned. With such data, we can now appropriately run a paired t-test. Statistical significance of the mean difference is determined by the p-value assuming a 95% confidence interval (i.e., p-value < 0.05 determines statistical significance). Robustness checks with the the non-parametric Wilcoxon t-test uphold the results from the paired t-tests reported below.

	Vars	Count	Mean	Std Dev	St Err				
Mean difference between TTR	Before	852	0.677	0.279	0.010	Confidence intervals			
(mean per patient) before and									
after	After	852	0.651	0.162	0.006	Lower	Upper	t	2-tailed sig
	Difference	852	0.026	0.295	0.010	0.006	0.046	2.546	0.0111*

### Table 25: Mean difference between TTR (mean per patient) before and after

p = 0.05\*

Wilcoxon rank-sum t-test (Non-parametric method for non normal distributions) z = 3.497 Prob > |z| = 0.0005\*

### Table 26: Mean difference between TTR (mean per patient) before and after (last 5 months - March 1 2019-July 31 2019)

	Vars	Count	Mean	Std Dev	St Err				
Mean difference between TTR	Before	732	0.688	0.284	0.010	Confidenc	e intervals		
(mean per patient) before and									
after (last 5 months)	After	732	0.729	0.219	0.008	Lower	Upper	t	2-tailed sig
	Difference	732	-0.042	0.332	0.012	-0.066	-0.017	-3.380	0.0008*

p = 0.05\*

Wilcoxon rank-sum t-test (Non-parametric method for non normal distributions)  $z = -2.726 \text{ Prob} > |z| = 0.0064^*$ 

|--|

	Vars	Count	Mean	Std Dev	St Err				
Mean difference between TTR	Before	697	0.691	0.281	0.011	Confidenc	e intervals		
(mean per patient) before and									
after (last 5 months)	After	697	0.675	0.136	0.005	Lower	Upper	t	2-tailed sig
	Difference	697	0.016	0.285	0.011	-0.005	0.038	1.514	0.131

p = 0.05\*

Wilcoxon rank-sum t-test (Non-parametric method for non normal distributions) z = 2.629 Prob > |z| = 0.086

# Patient Survey Results

#### Table 28: Patient Satisfaction with Care\*

	Usual	Care	CPAMS			
Rating	#	%	#	%		
1 to 5	44	17.9%	0	0.0%		
6 to 8	58	23.6%	9	3.7%		
9 or 10	144	58.5%	235	96.3%		
Total	246	100.0%	244	100.0%		

Patients rated their satisfaction on a scale of 1 to 10 where 1 was completely unsatisfied and 10 was completely satisfied.

### Table 29: Patient Responses to Agree/Disagree Statements

	Disagree + Strongly Agree		Neu	utral	Agree + Ag	Total	
Statement	#	%	#	%	#	%	
Satisfaction with Care							
I prefer the finger-prick blood test to having blood taken from my	2	0.6%	12	2 7%	161	06.6%	477
arm using a needle.	5	0.0%	15	2.770	401	90.0%	4//
I like knowing my test result and dose immediately.	2	0.4%	3	0.6%	474	99.0%	479
I am confident that the pharmacist can manage my warfarin	5	1.1%	0	0.0%	467	98.9%	472
treatment sately.							
I was able to communicate with the pharmacist as often as I needed.	3	0.6%	6	1.3%	467	98.1%	476
I prefer to have my warfarin managed by the pharmacy.	4	0.9%	5	1.1%	460	98.1%	469
Convenience							
I miss less time at work for my warfarin management now.	10	4.2%	96	40.3%	132	55.5%	238
I do not have to travel as far to have my warfarin managed at the pharmacy.	20	4.3%	92	19.7%	354	76.0%	466
It is easier to get an appointment for warfarin management at the pharmacy than with my doctor or NP.	8	1.7%	10	2.1%	457	96.2%	475
It saves me time having my warfarin managed by the pharmacist.	6	1.3%	4	0.8%	461	97.9%	471

	Disagree + Strongly Agree		Neu	utral	Agree + Ag	Total	
Statement	#	%	#	%	#	%	
I was able to visit the pharmacy to receive my warfarin management at times that were convenient for me.	9	1.9%	0	0.0%	474	98.1%	483
It is more convenient to have my blood test at the pharmacy.	3	0.6%	2	0.4%	471	98.9%	476
Patient Education							
I find it useful to be able to discuss my warfarin treatment with the pharmacist when I go for my test.	3	0.6%	2	0.4%	472	99.0%	477
Health Improvements							
Using the warfarin service at the pharmacy has meant that the pharmacist has also been able to help me with other aspects of my health care.	9	1.9%	46	9.8%	415	88.3%	470
I have the same or better control of my warfarin treatment now that I go to the pharmacy for testing.	6	1.3%	12	2.6%	450	96.2%	468
Value of Pharmacists							
I am more aware of how pharmacists can help people with their healthcare as a result of participating in this project.	5	1.1%	9	1.9%	455	97.0%	469
Willingness to Pay							
I would still use the warfarin service at the pharmacy even if I had to pay a monthly fee of \$54.	279	60.8%	77	16.8%	103	22.4%	459
Communication							
Information provided to me about my warfarin management is consistent and does not conflict between the doctor/NP and pharmacist.	3	0.6%	6	1.3%	459	98.1%	468
My doctor/NP knows what is happening with my warfarin dose when I attend regular appointments.	7	1.5%	12	2.6%	443	95.9%	462

#### Table 30: Patient-reported Time and Costs for Warfarin Management

	Usua	al Care - PCP	Visit	Usual Ca	re - Blood C	ollection	CPAMS		
	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min
Appointment length, including waiting time	40 mins	120 mins	2 mins	50 mins	150 mins	4 mins	14 mins	60 mins	3 mins
Cost for parking	\$0.80	\$20.00	\$0.00	\$2.10	\$20.00	\$0.00	\$0.00	\$3.00	\$0.00
Travel time	17 mins	150 mins	0 mins*	16 mins	80 mins	2 mins	13 mins	50 mins	2 mins

\* Some patients reported a travel time of 0 for PCP appointments as their provider would notify them over the phone.

### Table 31: Patient-reported Time Off from Work and Coordination of Visits with Other Activities

	Usual Care - PCP Visit			Usual Care - Blood Collection			CPAMS		
	#	%	Total Responses	#	%	Total Responses	#	%	Total Responses
I usually take time off work for my warfarin management appointments.	14	6.0%	234	13	5.5%	238	4	1.7%	241
A friend/family member usually takes time off work for my warfarin management appointments.	9	10.3%	87	8	10.8%	74	9	4.5%	201
I usually add another activity (e.g., shopping, lunch with a friend, etc.) when I go to my warfarin management appointments.	82	34.9%	235	69	28.3%	244	155	61.8%	251

### Table 32: Use of Reminders and INR Online Calendar

	Yes, rece	eived this	Received and it was Very Helpful		
Reminder Action	#	%	#	%	
	399	0.2%	381	06%	
Reminders about upcoming appointments from the pharmacy.	(of 431)	95%	(of 399)	90%	
	432	05%	406	0.49/	
A calendar showing me what dose of warfarin to take.	(of 453)	95%	(of 432)	94%	

### Table 33: Ease of Dosing

	Usua	l Care	CPAMS			
Ease	#	%	#	%		
Very difficult	1	0.4%	0	0.0%		
Somewhat Difficult	6	2.4%	1	0.4%		
Neither easy nor difficult	19	7.7%	4	1.6%		
Somewhat Easy	58	23.4%	7	2.8%		
Very Easy	164	66.1%	236	95.2%		
Total	248	100.0%	248	100.0%		

# Pharmacist Survey Results

# Table 34: Pharmacist Responses to Agree/Disagree Statements

	Disagree + Strongly Agree		Neutral		Agree + Strongly Agree		Total
Statement	#	%	#	%	#	%	
Patient Appointments and Integration into Workflow							
It was easy to arrange for patients to come to the pharmacy for their warfarin management.	0	0.0%	1	1.4%	70	98.6%	71
It was easy to integrate the work involved in CPAMS into our pharmacy workflow.	1	1.4%	3	4.2%	67	94.4%	71
Project Technology and Supports							
INR Online was helpful in identifying patients who were overdue for appointments.	1	1.4%	7	9.9%	63	88.7%	71
The point-of care testing unit was easy to use.	1	1.4%	5	7.0%	65	91.5%	71
It is usually easy to obtain a blood sample from the patient using the point-of care testing unit.	2	2.8%	15	21.1%	54	76.1%	71
I am confident that the INR results obtained through point-of-care testing at the pharmacy are reliable.	0	0.0%	1	1.4%	70	98.6%	71
INR Online was easy to use.	1	1.4%	1	1.4%	69	97.2%	71
I am confident in the warfarin dosing recommendations provided by INR Online.	5	7.0%	12	16.9%	54	76.1%	71
It was easy to address any questions or concerns I had throughout the project.	0	0.0%	4	5.6%	68	94.4%	72
The amount of compensation the pharmacy received for the work involved in this project was sufficient.	14	19.4%	16	22.2%	42	58.3%	72
I had all the resources and supports I needed to participate in the project.	1	1.4%	2	2.8%	68	95.8%	71
Patient Outcomes							
I have been able to help patients participating in this project with other aspects of their health care (not related to warfarin management).	0	0.0%	7	9.9%	64	90.1%	71

	Disagree + Strongly Agree		Neutral		Agree + Strongly Agree		Total
Statement	#	%	#	%	#	%	
The project helped to improve access to care for participating	0	0.0%	0	0.0%	71	100.0%	71
patients.	0	0.0%	0	0.0%	/1	100.0%	/1
Knowledge and Skills							
BEFORE CPAMS, I had the knowledge I need to manage	50	70.4%	12	16.0%	0	12 7%	71
anticoagulation therapies for patients.	50	70.470	12	10.570	5	12.770	/1
NOW, I have the knowledge I need to manage anticoagulation	0	0.0%	1	1 4%	70	98.6%	71
therapies for patients.	Ŭ	0.070	-	1.470	,0	50.070	/1
BEFORE CPAMS, I had the skills I need to manage anticoagulation	51	71 8%	12	16.9%	8	11 3%	71
therapies for patients.	51	71.070	12	10.570	0	11.570	/1
NOW, I have the skills I need to manage anticoagulation therapies	0	0.0%	1	1 4%	70	98.6%	71
for patients.	l .	0.070	-	1.170		50.070	/ <del>-</del>
Patient Recruitment/Enrollment							
The process for identifying patients who might participate in the	1	1.4%	8	11.4%	61	87.1%	70
project was clear.		1.170		11170		07.1270	
It was helpful to meet face-to-face with potential participating	8	11.4%	17	24.3%	45	64.3%	70
physicians/NPs at the beginning of the project.	, in the second			2.1107/0		0 110/0	
Most physicians/NPs I spoke with during initial recruitment were	14	20.0%	17	24.3%	39	55.7%	70
willing to participate in the project.	<u> </u>	2010/0		2.1107/0		551770	
It was easy to enroll identified patients in the project.	8	11.4%	12	17.1%	50	71.4%	70
Communication							
The roles and responsibilities of physicians/NPs in managing the	1	1.4%	5	7.0%	65	91.5%	71
patient's warfarin were clearly defined.		1.170				511570	
The roles and responsibilities of pharmacists in managing the	0	0.0%	1	1.4%	70	98.6%	71
patient's warfarin were clearly defined.	, in the second	0.070		1.170	,,,	50.070	· -
It was easy to communicate with the majority of physicians/NPs	2	2.8%	10	14.1%	59	83.1%	71
about patients' warfarin treatment when needed.		2.070		1 111/0		0011/0	
When a patient had an INR result that was too high or too low							
(outside the range of 1.5 to 4.0), the majority of physicians/NPs	8	11.3%	8	11.3%	55	77.5%	71
addressed this in a timely manner.							
Next Steps							

	Disagree + Strongly Agree		Neutral		Agree + Strongly Agree		Total
Statement	#	%	#	%	#	%	
I would like to continue to offer a warfarin management service at our pharmacy.	0	0.0%	1	1.4%	70	98.6%	71
Going forward, I would feel comfortable managing patients with INR results outside of the range of 1.5 to 4.0 using my professional judgement and referring to other providers as needed.	4	5.6%	5	7.0%	62	87.3%	71

### Table 35: Pharmacist Responses to Statements about Changes Over Time

To what extent have the following elements changed over the course of the CPAMS		oved	No C	Total	
project?	#	%	#	%	TOLAT
Collaboration between myself and the participating physicians/NPs.	51	71.8%	20	28.2%	71
My ability to support patient adherence to warfarin.	70	98.6%	1	1.4%	71
My ability to help patients on warfarin manage all of their medications (e.g., drug					71
interactions with warfarin).	69	97.2%	2	2.8%	/1
Physician/NP understanding of the role of pharmacists and the value that pharmacists					71
provide.	58	81.7%	13	18.3%	/1
Patient understanding of the role of pharmacists and the value that pharmacists provide.	71	100.0%	0	0.0%	71

## Table 36: Use of Patient Appointment Scheduling and Reminder Strategies

	Pharmacists that Report Using the Strategy (n=71)				
Strategy	#	%			
Appointment Scheduling Strategies					
Using specific appointment days and times (e.g., Wednesday at 9:30 am)	35	49.3%			
Using specific dates with a time window (e.g., Wednesday from 9 am to 5					
pm)	43	60.6%			
Walk-in any time	26	36.6%			
Other	9	12.7%			
Appointment Reminder Strategies					

Called patients PRIOR to their appointment to remind them	33	46.5%
Used an appointment reminder app	3	4.2%
Called patients AFTER to follow up if an appointment was missed	53	74.6%
Gave patients the INR Online calendar and/or an appointment card with		
their next appointment	12	16.9%
Other	4	5.6%

### Table 37: Helpfulness of Training, Resources and Supports for Pharmacists

	Not Useful		Neutral		Useful		Total
Statement	#	%	#	%	#	%	Total
Management of Oral Anticoagulation Therapy (MOAT) online training	4	5.6%	9	12.5%	59	81.9%	72
MOAT live day training	0	0.0%	2	3.1%	63	96.9%	65
INR Online training	6	9.1%	14	21.2%	46	69.7%	66
Point-of-care testing unit training	1	1.5%	9	13.8%	55	84.6%	65
Project information/orientation	0	0.0%	9	13.4%	58	86.6%	67
Project Manager	0	0.0%	3	4.5%	63	95.5%	66
Discussion board	0	0.0%	10	15.6%	54	84.4%	64
INR Online	0	0.0%	8	11.1%	64	88.9%	72
Procedural documentation (i.e., CPAMS Operational Guidelines)	1	1.4%	12	16.9%	58	81.7%	71
Information to support communication (e.g., patient and physician/							
NP information and consent forms)	1	1.4%	4	5.6%	66	93.0%	71

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