Clinical pharmacists and nurses' perceptions on implementing anticoagulation therapy recommendations for the frail elderly: An exploratory study based on psychological theory

by

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AUTHOR'S DECLARATION

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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ABSTRACT

Background: Stroke is a leading cause of mortality and disability in Canada. Persons with atrial fibrillation (AF) have a five-fold increased risk of developing a stroke. AF occurs when there are ineffective rapid contractions of the atrium, which leads to stagnant blood flow and promotes the formation of thrombi. AF is a significant contributor to stroke at all ages and the prevalence of AF is rising with age. In Canada, the treatment for persons with chronic non-valvular AF is to provide long-term oral anticoagulation therapy (OAT) with warfarin, which has been shown to reduce the risk of stroke by two-thirds. Routine care administered by physicians is often inconvenient because it requires regular doctor visits, a time lag between laboratory testing and follow ups, and frequent ad-hoc dose adjustments to prevent adverse outcomes. These challenges often contribute to poor OAT management to result in an increased risk of bleeding and clotting. These risks are further complicated for people with AF who are older, frail, have multiple co-morbidities and polypharmacy. The solution is to offset these complications through optimizing delivery of OAT using anticoagulation management services (AMS). Research has shown that pharmacist or nurse-led AMS are comparable or better than physician-led care in terms of cost-effectiveness and patient outcomes. Despite this, AMS clinics need to establish a more integrated approach for the optimal delivery of OAT management. Published and available in the literature are clinical recommendations by Garcia et al. (2008) on how to optimize OAT delivery in outpatient AMS settings; however, the deliberate implementation of the guideline remains an issue. To address the problem, this thesis explores the pharmacists and nurses' perception of implementing the guideline in community-based AMS clinics, especially for older and frail patients with AF.

Objectives: In the context of a frail, aging population, this study explores the pharmacists and nurses' perceptions of implementing Garcia et al.'s (2008) clinical guideline for optimal OAT

management in existing specialized AMS clinics within the Waterloo-Wellington Local Health Integration Network (WWLHIN) community. Specifically, this study uses Michie et al.'s (2005) psychological theory to explore **(1)** how existing intrinsic and extrinsic factors hindered or supported; and **(2)** how behavioural changes facilitate the implementation of Garcia et al.'s (2008) clinical guideline for optimal OAT management. In essence, this study investigated the clinicians' perceptions on *how* different factors hindered, supported or facilitate the implementation of clinical recommendations to inform a coordinated, regional approach to OAT management.

Methods: This study used a qualitative, explorative design with a purposive sample of clinicians (key informants) working in AMS clinics within the WWLHIN community: Waterloo-Kitchener, Cambridge and Guelph. Key informants were recruited from family health teams (FHTs) and community pharmacies, and sampled until the point of saturation. Semi-structured interview questions covered 12 domains under a theoretical lens, Michie et al.'s (2005) psychological theory: (1) Knowledge, (2) Skills, (3) Social/professional role and identity, (4) Beliefs about capabilities, (5) Beliefs about consequences, (6) Motivation and goals, (7) Memory, attention and decision processes, (8) Environmental context and resources, (9) Social influences, (10) Emotion, (11) Behavioural regulation, and (12) Nature of the behaviours. These 12 domains represent the relevant factors that influence the implementation of clinical guidelines. Garcia et al. (2008) published a clinical guideline with 9 key recommendations for optimal delivery of OAT management in outpatient AMS settings: (1) Qualifications of Personnel, (2) Supervision, (3) Care Management and Coordination, (4) Documentation, (5) Patient Education, (6) Patient Selection and Assessment, (7) Laboratory Monitoring, (8) Initiation and Stabilization of Warfarin Therapy, and (9) Maintenance of Therapy. Interviews averaged 40 minutes per key informant and produced

a total of 108 pages of transcript. Data were coded and analyzed using NVIVO Pro 11 based on the theoretical framework, and summarized into key findings to address the research objectives.

Results: There were six clinics that participated in the study: three family health teams and three community pharmacies with AMS clinics. Within these six clinics, there were a total of eight key informants: six pharmacists and two registered nurses. The majority of key informants were from the Kitchener-Waterloo region with more than one-year experience in OAT in the community setting. There were five salient themes in the results: (1) Inadequate reimbursement for logistical operation of AMS clinics; (2) Clinicians' awareness of how to apply knowledge to support practices; (3) Tailored organizational supports for the frail elderly; (4) Engagement of efforts to improve interprofessional communication and collaboration; and (5) Use of compatible software platforms for documentation. Theme 1 hindered, theme 2 and 3 supported, and theme 4 and 5 facilitate the implementation of Garcia et al.'s (2008) clinical guideline for the optimal delivery of OAT management in participating AMS clinics.

Discussion: In determining that inadequate funding was a key barrier to implementation, the finding suggests that if key informants cannot cover their costs, they cannot offer optimal OAT management per the clinical guideline. There is currently no coverage of services and materials for OAT management by pharmacists and nurses in Canada, except for Quebec. Instead, Ontario's pharmacists in community AMS clinics use other means to recover costs for OAT management services. In light of these findings, there needs to be appropriate funding for community AMS to continue their valuable services, otherwise OAT management may fall back to usual care and block optimal practices. Other factors affecting implementation are awareness of how to apply each recommendation of the clinical guideline to support practice and tailored organizational supports for the frail elderly. Although there was general awareness of the recommendations, one exception

was the finding that suggests that key informants relied on an incomplete frailty assessment; this finding reflected other work showing that clinicians tend to diagnose frailty syndrome based on chronological age rather than biological age. Furthermore, other work corroborated the finding that tailored organizational supports for the frail elderly, such as physical tools, face-to-face interactions and home visits, enabled the implementation of the clinical guideline via improving medication adherence and monitoring of other health issues.

In addition, other studies supported the finding that clinicians should engage in interprofessional communication and collaboration, especially during care transitions to facilitate optimal practices. One strategy was for nurse navigators to act as the focal point of contact for seamless care transitions, but existing pharmacists and nurses can also expand their scope of practice to methodically provide continuity of care and coordination of services in community-based AMS settings. Other work also supported the finding that social networking with experts in the local and wider regions facilitated optimal practices through maintaining competencies and gaining new knowledge. Another facilitator of optimal OAT management was to use compatible software platforms for standardized OAT documentation to integrate a systematic approach to management. However, the selection of an anticoagulation software program is complicated with many considerations, depending on individual clinic's needs. There needs to be further investigation on the limited literature on the implications of using compatible software platforms for standardized documentation of OAT management.

Conclusion: Linking key themes to the domains of Michie et al.'s (2005) psychological theory that influenced the implementation of the clinical guideline: (1) Inadequate reimbursement for logistical operation of AMS clinics was an environmental constraint (domain #8); (2) Clinicians' awareness of how to apply knowledge to support practices was having the knowledge and skills

(domains #1 and 2); (3) Tailored organizational supports for the frail elderly were environmental resources within their context (domain #8); (4) Engagement of efforts to improve interprofessional communication and collaboration was using social influences to prompt behavioural changes (domains #9 and 12); and (5) Use of compatible software platforms for documentation was a proposed system to change the nature of behaviours related to tracking and recording anticoagulation data (domain #12). Using the underlying theory, these key themes represent important factors for the deliberate implementation of the clinical guideline for optimizing delivery of OAT management.

Significance: Few studies use specific theories to understand the reasons underlying the uptake or not of clinical guidelines. This study contributes to the literature because it uses Michie et al.'s (2005) psychological theory to explore clinicians' perceptions on the deliberate implementation of clinical recommendations for optimized OAT delivery in practice. These data can help the Waterloo-Wellington Local Health Integration Network (WWLHIN) focus on factors that are important to improving systems of OAT delivery in outpatient settings that serve a frail population. In turn, there can be improvements in the quality and consistency of patient care, government funding, and the lessons learned can be portable to other LHINs. Ultimately, this study brought insight on how various factors affect the implementation the clinical guideline and can help key stakeholders scale up efforts for a broader, more uniform approach to optimal OAT management.

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LIST OF ABBREVIATIONS

Abbreviation	Full Text
ACCP	American College of Chest Physicians
AF	Atrial fibrillation
AMS	Anticoagulation management service(s)
CCS	Canadian Cardiovascular Society
CDM	Chronic disease management
CHADS	**C**ongestive Heart Failure, **H**ypertension, **A**ge, **D**iabetes, **S**troke/Transient Ischemic Attack
Clinical guideline	Garcia et al.'s clinical guideline for the optimal delivery of OAT management (9 key recommendations)
CMC	Care management and coordination
CP	Clinical pharmacist
EBP	Evidence-based practice(s)
EMR	Electronic medical record(s)
FHT	Family health team(s)
GP	General practitioner(s)
HAS-BLED	**H**ypertension, **A**bnormal liver or kidney function, **S**troke, **B**leeding, **L**abile INRs, **E**lderly, **D**rugs
HCP	Health Care Professional(s)
INR	International normalized ratio
IP	Inter-professional
NOAC	New oral anticoagulant(s)

OAC	Oral anticoagulant
OAT	Oral anticoagulation therapy
POC	Point-of-care
POCT	Point-of-care testing
RN	Registered nurse(s)
SAMeTT2R2	**S**ex, **A**ge, **Me**dical history, **T**reatment, **T**obacco use, **R**ace
TTR	Time in therapeutic range
VKA	Vitamin K antagonist
VTE	Venous thromboembolism
WWLHIN	Waterloo-Wellington Local Health Integration Network (includes Waterloo-Kitchener, Cambridge and Guelph)

CHAPTER 1: INTRODUCTION

1.1 **Overview**

Stroke is a leading cause of mortality and disability in Canada (Statistics Canada, 2014). It is characterized by an impairment in the function of the brain due to an insufficient amount of blood supply caused by a clot (ischemic stroke), or by a ruptured blood vessel (Heart and Stroke Foundation of Canada, 2014). Persons with atrial fibrillation (AF), a common cardiac arrhythmia, are characterized by an abnormal heart rhythm and may be classified as having non-valvular, or valvular AF, which links to rheumatic valvular disease or prosthetic heart valves (Hobbs, Taylor, Geersing, Rutten, & Brouwer, 2016). AF is a significant contributor to stroke at all ages (Wolf, Abbott, & Kannel, 1987). In the Framingham study, persons with AF have a five-fold increased risk of having a stroke (Ciervo, Granger, & Schaller, 2012; Fang, Panguluri, Machtinger, & Schillinger, 2009; Go et al., 2014; McKelvie et al., 2013; Wolf et al., 1987). The risk of stroke is increased with AF because a fibrillating atrium can produce stagnant blood that can potentially form thrombi to block cerebral circulation, thereby restricting blood flow through the arteries (Bereznicki, Peterson, Jackson, & Jeffrey, 2006; Ciervo et al., 2012; McKelvie et al., 2013). AF is a morbid cardiovascular condition with negative implications on the quality of life, work productivity and health resource utilization.

More specifically, AF causes more than 529,000 hospitalizations each year in the United States, costing approximately $6.65 billion to manage and treat AF-related stroke (Ciervo et al., 2012). In North America, 6% of all health and social services expenditures are used for stroke related causes (Quinn & Dawson, 2009). AF-related strokes are more severe with a 12% rate of recurrence that causes longer hospitalizations and greater morbidity, thus requiring a higher need for outpatient care (Ciervo et al., 2012). Stroke also has negative psychological effects such as depression (Chemerinski, Robinson, & Kosier, 2001), where the frequency of a major depression

following a stroke is between 10-25% (Chemerinski et al., 2001). A stroke event can affect the patient, as well as their family members, particularly spouses and adult children, who are prone to anxiety and depression following a relative's stroke event (Chow, Wong, & Poon, 2007). Persons with AF also have a major independent risk factor for cognitive decline, which is commonly associated with increased age and greater vascular events (Cao, Pokorney, Hayden, Welsh-Bohmer, & Newby, 2015; Flaker et al., 2010; Hui, Morley, & Mikolajczak, 2015).

In Canada, AF affects approximately 1 to 2% of the population, and about 6% of older adults aged 65 and over (Canadian Stroke Prevention Intervention Network, 2014; Franken, Rosa, & Santos, 2012; Ganz, 2015). The prevalence of AF is rising with age, indicating that the elderly population has the greatest risk of AF-related stroke (Bereznicki et al., 2006; Ciervo et al., 2012; Wolf et al., 1987). The proportion of AF-related stroke steadily increased from 6.7% for ages 50-59, to 36.2% for ages 80-89 (Wolf et al., 1987). The median age of AF occurrence is 75 years, and it affects about 10% of the population that is more than 80 years of age, a cohort that is expected to double by 2026. Notably, aging results in greater vulnerability to health stressors, making older persons more vulnerable to AF, thromboembolic events and bleeding risks (Foody, 2017; Lubitz et al., 2013). Not only that, but older age is often associated with frailty syndrome which ensues a myriad of complex issues, such as comorbidities, polypharmacy, non-adherence, risk of falls, cognitive impairment, mobility issues, nutritional status, swallowing disorders, and so on (Granziera, Cohen, Nante, Manzato, & Sergi, 2015). An epidemiological study published that 5% of older persons over the age of 65 had AF and at least three chronic conditions (Barnett et al., 2012). A recent review of the literature found significant physical and mental impairments affecting quality of life in older adults with AF compared to the general population (Zhang, Gallagher, & Neubeck, 2015). The complexity of health issues in older adults increases their risk

from AF, morbidity and mortality compared to their younger counterparts (Bereznicki et al., 2006; Hobbs et al., 2016). Based on these needs, chronic AF management programs should specifically target the frail elderly as a population to reduce their higher risk of preventable stroke as compared to the general population (Barnett et al., 2012; Bereznicki et al., 2006; Ciervo et al., 2012).

The long-standing standard of care in Canada for persons with chronic non-valvular AF is to provide long term oral anticoagulation therapy (OAT) with an inexpensive drug called warfarin, a vitamin K antagonist (VKA) to reduce blood clots and prevent stroke (Bereznicki et al., 2006; Skanes et al., 2012; Young et al., 2011) . Warfarin has been used as the main therapeutic option for its widespread availability and long-term efficacy in stroke prevention for persons with non-valvular AF, reducing the risk of stroke by two-thirds (Bereznicki et al., 2006; Ciervo et al., 2012; Phillips & Ansell, 2008). Warfarin use has been steadily increasing up to about 10% per year due to an aging population and the increasing prevalence of AF (Bereznicki et al., 2006; Ciervo et al., 2012). Typically, older persons with AF have a higher risk of stroke and bleeding, and when coupled with frailty, geriatric assessments are required before prescribing warfarin therapy (Uchmanowicz et al., 2015). Studies have shown that frail elderly persons were less likely to receive anticoagulation therapy despite the clear indication of AF (Chen et al., 2012; Maes et al., 2014; Perera, Bajorek, Matthews, & Hilmer, 2009). Chen et al. (2012) identified that frail older adults who had difficulty obtaining necessary health care were less likely to receive anticoagulant therapy. Maes et al. (2014) discovered that the use of aspirin by frail older adults with AF was the strongest predictor of warfarin underuse, regardless of the risk of stroke and bleeding. The authors suspected that patients were using aspirin to prevent AF-related stroke or "underlying cardiovascular ischemic disease," despite the evidence that long-term OAT was more effective. This was because clinicians feared that the risk of bleeding on warfarin offset the benefits of OAT

therapy in older adults (Maes et al., 2014). Perera et al. (2009) speculated that OACs were not recommended to frail older persons with AF because of potential issues with cognition and daily activities to control INR values (Perera et al., 2009).

Another study revealed that poor compliance and suboptimal clinical condition, such as a history of hemorrhages, a risk of falls, physical disabilities and dementia, contributed to the decreased use of oral anticoagulation (OAC) as a treatment option in the very elderly (Lotze et al., 2010). This high risk population, as seen in one study, had a 70% rate for the use of anticoagulants, compared to other studies that ranged from 35-65%; it also revealed potential barriers of prescribing OAC to elderly patients aged 80 years and older, including risk of stroke, bleeding and frailty (Lefebvre et al., 2015). A recent observational study further reported that the myriad of medical and functional disabilities in the frail elderly with AF was a negative predictor of adherence to anticoagulation therapy, rather than mild cognitive impairment (Horstmann et al., 2015). However, a position paper by an expert panel for optimal stroke prevention in the geriatric patient agreed that OAT should be recommended, despite the fear of adverse events due to the complex patient profile, such as comorbidities, polypharmacy and bleeding events from falls (Bahrmann et al., 2015). The risk of falls in elderly people is usually perceived as a contraindication to warfarin therapy, despite evidence that the benefits outweigh the risks (Cheng & Fung, 2007; Heckman & Braceland, 2015). Persons aged 65 and older would have to fall 295 times per year to make OAT riskier than beneficial to this high-risk population (Cheng & Fung, 2007). In determining treatment for older people, clinicians should do comprehensive assessments, such as the $CHADS_2$ and HAS-BLED scores for stroke and bleeding risks, as well as the Mini Mental State Examination for cognitive decline to determine appropriateness of warfarin therapy (Uchmanowicz et al., 2015).

Comprehensive assessments for therapy are important because of warfarin's high risk-benefit profile. Warfarin is difficult to manage because of its variable dosing regimen to meet a narrow therapeutic range; its complications arising from interactions with diet, co-morbidities, age, and other factors; and poor patient-provider communication during therapy (Ciervo et al., 2012; Fang et al., 2009; Phillips & Ansell, 2008). A recent study revealed further risks for older patients with AF treated with long-term warfarin therapy because of their higher rates of all dementia types, including Alzheimer's disease than older patients with other indications (Bunch et al., 2016). Having high quality OAT management makes the difference in reducing these risks. In routine medical care, OAT management is led by physicians, and often described as inconvenient and time-consuming. Usual care requires regular doctor visits, a time lag between INR laboratory testing and follow-ups, and frequent ad-hoc dose adjustments to prevent adverse outcomes. These are challenges that can affect older patients more often than their younger counterparts (Bereznicki et al., 2006; Decker et al., 2012; Young et al., 2011). As a result, such relatively disjointed management leads to INR levels that deviate from the therapeutic range, suboptimal anticoagulation and an increased risk of hemorrhage and stroke (Ciervo et al., 2012; Fang et al., 2009).

As a result of these complications, new oral anticoagulants (NOACs) with fixed doses have been developed and appear to offer more convenience than warfarin with similar efficacy in reducing clinical outcomes for older adults with AF (Grander & Armaganijan, 2012; Hart et al., 2012). NOACs require significantly less monitoring because they have fewer interactions with other drugs, a faster mechanism of action, and more predictable pharmacokinetics and pharmacodynamics than warfarin (Bauer, 2013). However, questions remain about whether NOACs are non-inferior to warfarin when the Time in Therapeutic Range (TTR) of 70 to 75% is

achieved during high quality anticoagulation management (Trusler, 2014). NOACs are costly and clinically proven antidotes for overdose are still difficult to access, which may cause major hemorrhages, whereas warfarin overdose is easily reversed with Vitamin K (Bauer, 2013; Trusler, 2014). Recently, the U.S. Food and Drug Administration approved Praxbind as the first reversal agent for Dabigatran, a NOAC which acts as a direct thrombin inhibitor (FDA, 2015); however, that still brings into question the safety of using other NOACs, i.e., direct factor Xa inhibitors: Rivaroxaban, Apixaban and Edoxaban, that were approved for therapeutic use without clinically proven antidotes (Project On Government Oversight, 2015). There is currently no effective antidote to reverse the effects of anticoagulation by direct factor Xa inhibitors because studies have not yet found a reliable pathway to neutralize the anticoagulant activity of these NOACs (Sarich et al., 2015).

Although clinical studies on reversal agents for the remaining NOACs are underway, the current use of NOACs without an effective reversal agent can increase morbidity and possibly mortality, especially if there is an expected risk of bleeding (Bauer, 2013; Harper, 2012). A cohort study showed that dabigatran use was associated with a higher risk of major lower gastrointestinal bleeding than warfarin use in clinical care (Villines et al., 2015). Other concerns for NOAC use in elderly persons with AF include the unknown interactions with foods and drugs (Stollberger & Finsterer, 2013). Further concerns for NOAC dosing are in special populations, such as frail persons with multiple conditions such as renal dysfunction, causing drug accumulation; persons with extremes of body weights, such as morbid obesity or very low body weight; and medication non-adherence, especially in the absence of routine coagulation monitoring (Bauer, 2013; Bauersachs, 2012). As a result, Granziera et al. (2015) suggested an algorithm that focused on frailty aspects for tailoring anticoagulation for the elderly to use either NOACs or VKAs. For

example, frail elderly patients with AF who have high adherence and severe renal/liver impairment would benefit from VKAs, whereas those with a risk of falls, mobility issues and polypharmacy would benefit from NOAC use (Granziera et al., 2015). A recent retrospective study showed that dabigatran use in elderly patients with non-valvular AF and a history of fractures had a significantly lower risk of osteoporotic fractures than warfarin (Lau et al., 2017). However, this significant risk of osteoporotic fractures was not true for older adults with AF and without a history of fractures (Lau et al., 2017; Misra et al., 2014). Dependent on the clinical situation, tailored oral anticoagulation regimens using either VKAs or NOACs can prevent stroke and bleeding risks in the frail elderly population. However, there are still concerns over the long-term effects of NOAC use because they are not as well studied as warfarin,, which have been widely prescribed over 50 years with an approved reversal agent and little long term effects on organs and physiological systems (Bauer, 2013).

Despite warfarin's high risk-benefit ratio, the complications are mitigated by optimal management and delivery of OAT (J. E. Ansell, 2009) . Optimal management of OAT can be provided to patients through specialized anticoagulation management services (AMS) in outpatient settings, such as FHTs and community pharmacies (J. E. Ansell, 2009). It has been shown that pharmacist-led AMS clinics were as effective or better than usual care led by GPs (Canadian Agency for Drugs and Technologies in Health, 2012). AMS programs in primary care settings follow a multi-disciplinary and collaborative approach, which has been shown to improve health outcomes for patients with chronic diseases such as AF (Wagner et al., 2001). Wider implementation across community-based AMS settings requires a coordinated, systematic approach to OAT management to balance efficacy and risks of warfarin therapy.

Specifically, Garcia et al. (2008) established a practical consensus-based guideline of 9 key recommendations to optimize delivery of OAT in all outpatient settings: (1) Qualifications of Personnel, (2) Supervision, (3) Care Management and Coordination, (4) Documentation, (5) Patient Education, (6) Patient Selection and Assessment, (7) Laboratory Monitoring, (8) Initiation and Stabilization of Warfarin Therapy, and (9) Maintenance of Therapy. Garcia et al.'s (2008) recommendations for optimal OAT delivery can provide more consistent care for patients with AF, particularly the elderly who have specific characteristics that make them more vulnerable to adverse events and complications (Bereznicki et al., 2006; Heckman & Braceland, 2015). The elderly are at higher risk for AF-related stroke, bleeding, but also of frailty syndrome, the latter of which in turn reduces their likelihood of receiving OAT (Lefebvre et al., 2015). Therefore, chronic OAT management should be delivered systematically in wider community settings and target frail elderly with AF to make services accessible, coordinated and consistent.

Although these recommendations are identified in the literature, their implementation in community practice remains a challenge. In order to inform future implementation research, this study will first explore the clinicians' perceptions on implementing such recommendations in community practice. Then other studies may use this assessment of how various factors affect implementation and consider intervention in actual practice. To date, there is limited qualitative research on these perceptions for implementation, especially in the community and in the context of a frail elderly population. This study will, therefore, use a theoretical framework to explore the clinicians' perceptions on how different factors influence the implementation of the recommendations (Michie et al., 2005). This study will bridge the gap in the research by focusing

on a theory-based assessment of clinicians' perceptions of the implementation process, which will help inform future studies on interventions of a wider and more uniform approach to OAT.

1.2 **Research Objectives**

This qualitative, exploratory study aims to explore and describe the perceptions of pharmacists and nurses on the uptake or not of Garcia et al.'s (2008) nine key recommendations in AMS clinics within the WWLHIN community for a frail elderly population. Specifically, the research objective is to use Michie et al.'s psychological theory:

(1) To explore and describe how existing **intrinsic and extrinsic factors hindered or supported** the delivery of optimal OAT management, per the Garcia et al.'s (2008) clinical guideline, in a frail elderly population.

(2) To discover, describe and identify how **behavioural changes facilitate** the delivery of optimal OAT management in a frail elderly population

CHAPTER 2: LITERATURE REVIEW

2.1 Oral Anticoagulation Therapy

Vitamin K antagonists (VKAs) were discovered in 1939 by Schofield after examining spoiled sweet clover consumed by cattle with hemorrhagic disease. In the 1900s, several scientists revealed the link between VKAs and oral anticoagulation, and described the prothrombin time assay for measuring how blood clots in vitamin K deficient animals; this assay became the mainstream method for tracking oral anticoagulation therapy (OAT). Vitamin K was known to aid the synthesis of coagulation factors, in which VKAs opposed clotting of the blood (J. E. Ansell, 2009). In the 1940's, a biochemist named Link investigated the cause of bleeding disorders in these cows and then synthesized a class of VKAs called coumarin compounds, specifically dicumarol for its first use in humans at the Mayo Clinic. Dicumarol's pharmacokinetic and pharmacodynamic properties could then form a related coumarin compound called warfarin sodium. At this time, warfarin became an effective widespread rodenticide. It was not until the 1950s that scientists started to perform experiments with warfarin as a suitable oral anticoagulant in humans. After President Dwight D. Eisenhower's heart attack in the mid-1950s, warfarin became a more widespread human oral anticoagulant in North America to treat thromboembolism in the cardiovascular system (J. E. Ansell, 2009).

2.1.1 Cardiovascular Indications for OAT with Warfarin

The most common cardiovascular indications for OAT with warfarin are chronic atrial fibrillation (AF), prosthetic heart valves, venous thromboembolism (VTE), and acute myocardial infarction (Bereznicki et al., 2006; Canadian Agency for Drugs and Technologies in Health, 2014; Hirsh, Fuster, Ansell, & Halperin, 2003). AF is the most common cardiac rhythm disorder, and it poses a significant risk factor for stroke. There is extensive evidence supporting that long term

OAT reduces the risk of thromboembolism related to AF as a primary and secondary prevention (Bereznicki et al., 2006; Hirsh et al., 2003). High risk patients with AF show a larger absolute risk reduction in stroke rates using adjusted-dose warfarin than aspirin. High risk patients are generally defined as those with prior thromboembolism or stroke, hypertension, diabetes mellitus, aged > 65 years, coronary arterial disease, and poor ventricular function (Bereznicki et al., 2006; Hart & Halperin, 1999; Hirsh et al., 2003) . According to the Canadian Cardiovascular Society (CCS) guidelines, the $CHADS_2$ scoring schema should be used to estimate stroke risk: **C**ongestive Heart Failure, **H**ypertension, **A**ge, **D**iabetes, **S**troke/Transient Ischemic Attack (2014). Generally, the CCS recommends that patients with AF should receive OAT if ≥ 65 years of age or $CHADS_2$ score of ≥1 (Verma et al., 2014). Typically, warfarin is adjusted to achieve an optimal INR of 2.0 to 3.0 for most patients with AF, although low initiation dosing, careful monitoring and education are particularly important for elderly patients (Canadian Agency for Drugs and Technologies in Health, 2012; Hirsh et al., 2003). Clinical OAT systems should improve to provide patients access to better care and health outcomes to balance the high risk/benefit profile of warfarin (J. E. Ansell, 2009). VTE and AMI are two other cardiac indications for the therapeutic use of warfarin to prevent embolic events, and stroke, recurrent infarction or mortality, respectively (Bereznicki et al., 2006).

Although clinicians prescribe OAT for these cardiovascular indications, they need to balance the benefits with the risks by administering the appropriate drug intensity to stay within the therapeutic range. Warfarin is characterized with a high risk-benefit profile because of these characteristics: (1) a narrow therapeutic index, making it difficult to precisely manage medication dosage for an accurate therapeutic response; (2) OAT complications influenced by user characteristics, ranging from age, diet, co-morbidities, etc.; and (3) fluctuating therapeutic

intensity due to poor provider-patient communication during therapy (J. E. Ansell, 2009). For these reasons, health care professionals need to reduce the risk/benefit profile by ensuring the quality of OAT and its optimal management for patients.

2.1.2 Quality of Oral Anticoagulation Therapy

A study by Phillips and Ansell describes that parameters of high-quality anticoagulation management must achieve, and measure efficacy and safety of warfarin therapy. Elements that measure efficacy of stroke prevention include appropriate therapy initiation and maintenance of therapeutic anticoagulation as measured by time in therapeutic range (TTR); management of suboptimal INR scores; and management of peri-operative dosing. A major parameter used to assess the efficacy of OAT management is the time in which the international normalized ratio (INR) is in the therapeutic range (Phillips & Ansell, 2008). INR scores are based on prothrombin time that measures the time that blood takes to clot when added to a mixture of thromboplastin and calcium (Medical Advisory Secretariat, 2009). Health care professionals in a variety of settings, such as private practice, family health teams or hospitals, need to manage OAC dosages through regular blood tests to keep INR scores within the therapeutic range (Trusler, 2014). Patients within the INR range of 2.0 to 3.0, for example, takes 2 to 3 times longer for their blood to clot than the average healthy person, resulting in less clotting when blood is stagnant in the fibrillating atrium. Therefore, the time that a patient is within this target range is ideal in determining anticoagulation adequacy, which becomes important because it is inversely related to major patient outcomes of hemorrhage, stroke and mortality (Dlott et al., 2014; Trusler, 2014). TTR is calculated using the Rosendaal method to measure the percentage of the time that a patient's INR is within the target therapeutic range (Medical Advisory Secretariat, 2009). As well, the tightness of control measures

how close these INR values cluster within the target range, in which a smaller variation results in fewer strokes and hemorrhages (Trusler, 2014).

Furthermore, the safety of warfarin therapy is achieved by proper management of suboptimal INR scores and patient education with competent and qualified staff (Phillips & Ansell, 2008). INR scores outside the therapeutic index may lead to adverse events, such as hemorrhages or strokes; therefore, therapeutic intensity must be precisely maintained to accommodate the patient characteristics that affect OAT and management (J. E. Ansell, 2009). Another aspect of OAT safety is to ensure adequate patient education. Patient education is supported by Fang et al., a study that encourages clinicians to have clear public health communication strategies while counseling patients who are taking warfarin for stroke prevention; this priority for communication can engage and support patients on long-term warfarin therapy to recognize the early signs and symptoms of stroke to prevent adverse events (2009). As well, using scales such as the SAMeTT2R2 score to measure the likelihood of successful warfarin therapy, along with medical details from updated records, and in a setting that promotes inter-professional communication and collaboration, can help determine if a patient should start oral anticoagulation therapy (J. E. Ansell, 2009; Apostolakis, Sullivan, Olshansky, & Lip, 2013). Ultimately, incorporating elements of high-quality anticoagulation management is important in achieving efficacy and safety during OAT.

2.1.3 Optimal Oral Anticoagulation Therapy using AMS vs. Usual Care

The routine medical care for patients on OAT is usually managed by primary care physicians who also attend to other patients in their clinical practices (J. E. Ansell, 2009). Optimal management of OAT can be provided to patients through specialized anticoagulation management services (AMS), such as anticoagulation clinics in hospitals, primary care settings and community pharmacies with dedicated health care professionals focused on warfarin dosing and management.

This structure provides a practical and coordinated approach with a specialized system to track, follow up and educate patients about their care (J. E. Ansell, 2009). Nurses (practical and registered), pharmacists and/or physician assistants usually manage OAT under the direction of a single physician in the program or a referring primary physician. The basic characteristics of an AMS include (1) active management, (2) high competency in OAT as the primary responsibility, (3) organized follow-up system, (4) rapid and reliable monitoring of INR scores, and (5) ongoing patient education and communication with the provider (J. E. Ansell, 2009).

These characteristics of an AMS are similar to the principles of a chronic disease management (CDM) model. A CDM model comprises of patient-centered care that is multi-disciplinary, sustainable by the patient, coordinated across networks and providers, and rooted in evidence-based care. It relies on the physician's expertise and leadership in chronic disease care (Scott, 2008). Therefore, it thrives in primary care settings, such as family health teams (FHTs) because the success is attributed to the fact that majority of patients with chronic diseases receive care from their primary care physicians (e.g. 90% of diabetic patients are cared for by their GPs) (Rothman & Wagner, 2003). In FHTs, family physicians or pharmacists can provide warfarin therapy to patients with AF through usual care (laboratory testing) or a point-of-care testing (POCT) model, which is as effective for anticoagulation control as usual care (see section 1.2). Clinical pharmacists in FHTs work closely with family physicians to act as the front-line staff to the patient's health issues, providing an opportunity to build rapport with patients. Especially with older adults who have more health complexities, there is much to gain with personalized knowledge of their social and health patterns to help address potential risk factors that might exacerbate warfarin therapy. Evidently, there is the link between the importance of chronic disease management and frailty because CDM components help evade poor prognoses especially in a

vulnerable population such as the frail elderly. This is a population that needs the most care due to potential for quick decline if a health problem occurs. AMS clinics are essentially applying components of the CDM framework which have been tailored for OAT management of patients with the chronic disease, AF.

A systematic review indicates that specialized AMS yield higher TTR than usual care by physicians in their practice (Canadian Agency for Drugs and Technologies in Health, 2012). Even with the CHEST guidelines for warfarin management, patients managed by usual care were found to be sub-optimally treated in a study (Samsa et al., 2000). Therefore, several studies supported that a pharmacist-led anticoagulation clinic with evidence-based protocols and venipuncture had significantly better INR control than usual care (Young et al., 2011). Another study goes further to mention that an interdisciplinary approach between pharmacists and physicians in a primary care setting can improve INR control and reduce thromboembolism rates as compared to usual care (Bungard et al., 2009). Ansell (2009) presents evidence on the rates of major hemorrhage and thromboembolism from several retrospective and prospective trials of usual care vs. AMS, reporting that OAT managed by AMS had better patient outcomes than usual care by physicians. Although there were variable results for INR control between pharmacists and physician-led anticoagulation management (Young et al., 2011), the advent of technology with a POCT model can improve anticoagulation therapy management via convenience for INR testing, follow-up and dose adjustments. This model of care enhances patient satisfaction, allows clinicians to make timely decisions for care, provides savings to the health care system, and improve clinical outcomes (Canadian Agency for Drugs and Technologies in Health, 2014; Davidson, Lindelof, Wallen, Lindahl, & Hallert, 2015; Franke, Dickerson, & Carek, 2008; Mifsude, Azzopardi, & Serracino-Inglott, 2014; Shaw, Harrison, & Harrison, 2014).

A POCT model typically includes a hand-held device such as the Coaguchek XS™ for rapid and reliable diagnostic testing via a finger prick sample (Medical Advisory Secretariat, 2009; Trusler, 2014; Wurster, 2009). INR results are obtained shortly afterward on the device for health care provider to manage warfarin dosing; therefore, helping patients to stay within their ideal INR range and reduce the onset of hemorrhages or strokes. POCT can also include computerized decision support software, such as INR Online™ and Posologic™ that can tabulate INR results and calculate TTR to help keep records of patient information and INR readings for future assessments and accurate follow-ups (Medical Advisory Secretariat, 2009; Trusler, 2014). INR Online™ also has a built-in dosing algorithm for warfarin for clinicians to adjust suboptimal INR scores. In a recent audit, it has been shown that clinicians who closely followed the algorithm had better anticoagulation control than those who overrode the decision-support software (Harper, Harper, & Hill, 2014). Furthermore, the use of a simple algorithm to adjust warfarin dosages in the Randomized Evaluation of Long-term Anticoagulation Therapy (RE-LY) trial predicted better TTR and accounted for TTR variations between comparison centers and countries (Spall et al., 2012).

It has been shown that POCT is a viable model for improving INR scores in the therapeutic range when managed by physicians (Franke et al., 2008). Other studies have shown nurse-led anticoagulation management is similar to physician-led care (Davidson et al., 2015; Levine, Shao, & Klein, 2012) and slightly better control when led by pharmacists who act under the authorization of physicians (Bungard et al., 2009; Young et al., 2011). Shaw et al. demonstrated a strong support by patients and primary care practitioners for a pharmacist-led POC-testing anticoagulation management program that requires strong interprofessional relationships in the community for wider implementation (2014). Bajorek et al. further supported this collaboration and

communication between health care professionals as a significant contributor to improving warfarin management in the community (2007).

2.1.4 Cost-Effectiveness of Oral Anticoagulation Management Services

Experts from the American College of Chest Physicians (ACCP) advise that the delivery of OAT be systematic and coordinated with procedures for patient education, communication and the INR testing process (J. Ansell et al., 2008). Anticoagulation management services (AMS) allow this type of approach to happen in clinical settings because they are specialized in providing oral anticoagulation with key functional features. The literature reveals that the cost-effectiveness of AMS vs. usual care is rooted in the cost savings from reduced number of adverse events and reduced hospitalizations. Eckman and colleagues estimated that the average annual cost of hospitalizations for patients using AMS versus usual care was due to a lower incidence of adverse events, such as thromboembolism and major bleeding (Eckman, Levine, & Pauker, 1995). Similarly, another study performed an economic analysis for 1000 patients of atrial fibrillation on warfarin therapy, estimating a cost savings of $0.8 million for patients using AMS compared to usual care; the majority of the cost difference was accounted for by the reduced incidence of adverse events in the AMS model of care (Campbell, Radensky, & Denham, 2000). J. E. Ansell also revealed four studies that showed the cost/benefit ratios of AMS vs. usual care, favoring the former model of care (2009). On average, a significant cost saving $1000 per patient-year could be achieved from reduced hospital admissions for major complications through coordinated care in AMS (J. E. Ansell, 2009).

2.1.5 Oral Anticoagulation Therapy in Community-Dwelling Frail Elderly

Frailty is a multidimensional term with no consensus on its definition, but it usually occurs in older adults aged 65 years and over with conditions that increases their vulnerability to health

stressors to affect physiological systems (Heckman & Braceland, 2015). Frailty is usually associated with a higher risk for adverse outcomes, hospitalization and death. The clinical frailty scale is commonly used to identify frailty syndrome (Uchmanowicz et al., 2015). As well, frailty in older adults with AF is known to reduce the likelihood of being prescribed OAT (Uchmanowicz et al., 2015). In an article by Lefebvre et al., octogenarians that received the highest probability of anticoagulation therapy were characterized with higher thromboembolism risk, lower bleeding risk, and a lower frailty score (2015). Studies have shown the appropriate initiation protocol for warfarin therapy in an inpatient and outpatient geriatric population; however, a study reports that frailty was a major negative predictor of OAC to AF patients over 70 years of age (Perera et al., 2009; Uchmanowicz et al., 2015). However, there seems to be a misconception that confounds frailty with increased chronological age, which may lead some health care providers to believe that all older adults have a complex profile. This confusion about frailty may contribute to OAC under-prescription to older adults over the age of 75 (Heckman & Braceland, 2015). A review of the quality indicators for the care of vulnerable elders for stroke and atrial fibrillation supported evidence that those with medium to high risk, according to the $CHADS_2$ score of 2 or more, and without any contraindications should be recommended warfarin to reduce the risk of thromboembolism and bleeding with the INR range of 2.0 to 3.0 (Cheng & Fung, 2007). Although intracerebral bleeds after a fall was a long-standing major concern for older adults taking OAC, eventually, there was evidence supporting that the risk of falls was not a contraindication for OAC use (Heckman & Braceland, 2015). Essentially, there is a disproportionate incidence of AF-related stroke for frail elderly persons due to their complex patient profile: increasing age, comorbidities, polypharmacy, risk of falls, etc. These aspects make frail older adults more prone to poor oral anticoagulation management, resulting in a higher risk of thromboembolism or major bleeding. As

such, chronic disease management interventions, such as coordinated long-term AMS, should be tailored for the frail elderly because they need intensive intervention for meaningful outcomes.

2.2 **Preliminary Environmental Scan of Local AMS Clinics**

A preliminary environmental scan (see Appendix A) of AMS clinics in the WWLHIN area during the Summer of 2015 revealed three possible areas of improvement in coordinated anticoagulation care: (1) the perceived knowledge gaps in the use of clinical tools to optimize care for the frail population, i.e., POCT and dosing algorithms (2) the need for IP relationships, collaboration, and communication between health care providers of AMS and primary physicians to optimize OAT delivery and management; and (2) the need for system integration.

The perceived knowledge gaps in the use of clinical tools in AMS vs. usual care for warfarin therapy management was also mentioned in the literature. A New Zealand survey revealed that patients were more concerned with the pharmacist's knowledge of POC technology to manage warfarin therapy than with the physician's knowledge to make ad-hoc adjustments (Shaw et al., 2014). Despite all pharmacists receiving accreditation prior to the study, patients still felt that the pharmacists should have more qualifications. The study revealed that only 60% of pharmacists were confident with the computerized decision support system's dose recommendations, whereas 20% were unsure, and 15% were indifferent. This variation in confidence showed that not all pharmacists are experienced in warfarin dosing adjustments using POCT, thereby creating gaps in perceived knowledge. Pharmacists' training qualifications should be standardized for OAT management by a single regulatory body. This way, patients will be able to trust AMS led by pharmacists with the accreditation because they will have the same standard of knowledge and training on the use of POCT for OAT management. Despite the absence of such qualifications, majority of pharmacists in this study still expressed confidence in their knowledge

on using POCT to offer OAT management. In a controlled study by Wilson et al. (2004), pharmacists were trained to provide high quality warfarin therapy management using POCT, and received satisfied responses from patients and pharmacists; however, as the study mentioned, not all comparisons using uncontrolled studies had the same quality of care. This aspect makes it more likely that pharmacists without the proper certifications will create distrust or dissatisfaction from their patients. Therefore, this knowledge gap on the use of clinical tools for OAT management should be addressed.

Furthermore, inter-professional (IP) relationships and communication were improved with a pharmacist-led anticoagulation program as shown in Shaw et al. included relationships between providers and patients (2014). Patients felt that pharmacists were communicating with their primary physicians on a regular basis to keep their care up to date. However, this IP relationship had to be built on the physician's confidence in the pharmacist's skills; if not, physicians were hesitant to give up their patients to be managed by pharmacists. General practitioners (GPs) were concerned with the accountability and uncertainty of responsibility for their patients' OAT. All GPs mentioned that a good relationship with the pharmacists prior to the study is key to entrusting them with their anticoagulation patients (Shaw et al., 2014).

Lastly, it is speculated that a system-integrated approach is necessary for anticoagulation management to have a seamless transition between institutions (e.g. hospitals and convalescence homes), and between community clinics (e.g. family health teams, private family doctor offices and specialized AMS). A review showed that communication and coordination of care between various health care settings (e.g. outpatient to emergency; or acute to long-term care) was essential for reducing the risk of stroke or bleeds in patients with AF taking anticoagulants (Deitelzweig, 2013). Fragmented care remains an issue unless patient data is clearly communicated and

documented for appropriate care in transition between health care settings. OAT management relies on parameters associated with high-quality anticoagulation management as described by Phillips & Ansell (2008). In order to accomplish this high quality management in the clinical setting, a set of recommendations was developed to optimize delivery of OAT (Garcia et al., 2008). Hence, the investigators will explore the perceptions of clinicians who work in AMS clinics on the effective implementation of these recommendations to improve the delivery of OAT in outpatient settings.

2.3 **Recommendations for Delivery of Optimized OAT in all Outpatient Settings**

Garcia and colleagues provides a practical consensus-based guideline for delivering optimized OAT in all outpatient settings, which comprises of health care professionals proficient in AMS. The guideline describes 9 key recommendations as a guideline for delivery optimized OAT in all outpatient settings, including (1) Qualifications of Personnel, (2) Supervision, (3) Care Management and Coordination, (4) Documentation, (5) Patient Education, (6) Patient Selection and Assessment, (7) Laboratory Monitoring, (8) Initiation and Stabilization of Warfarin Therapy, and (9) Maintenance of Therapy. The following will describe each recommendation in detail.

(1) Qualifications of Personnel

Licensed health care professionals (e.g. pharmacist, nurse) who are trained in patient-oriented care should receive additional certification from formal anticoagulation management training programs (Garcia et al., 2008) . In the United States, the National Certification Board of Anticoagulation Providers certifies US health care professionals with expertise in OAT based on the core competencies in the following domains: applied physiology and pathophysiology of thromboembolic disorders; patient assessment and management; patient education; and

applied pharmacology of antithrombotic agents (NCBAP, 2014). Garcia et al. lists 4 other US training programs (2008).

On the contrary, Canada does not have a national board to certify anticoagulation providers; however, there are organizations such as the Canadian Council On Continuing Education in Pharmacy that provide OAT management for Pharmacists (CCCEP, 2008). University of Waterloo in partnership with the School of Pharmacy and the Centre for Family Medicine also offers a professional Management of Oral Anticoagulation Therapy (MOAT) Primary Care Certification Program for pharmacists, registered nurses and nurse practitioners to gain effective competency and management under a medical directive. This program has an online component and three site visits with evaluations of the participants by the instructor, a pharmacist named Dr. Jeff Nagge (University of Waterloo, 2015).

(2) Supervision

A "collaborative practice agreement" outlining administrative details, such as job duties, daily responsibilities and accountability is imperative (Garcia et al., 2008). AMS practice guidelines are published to guide staffing of AMS providers (Nutescu, Earl, & Oertel, 2009).

(3) Care Management and Coordination

Timely care management and coordination with all stakeholders of ACM is dependent on clearly established and up-to-date policies and procedures in the organization. The individual in charge of the AMS should widely disseminate these approved policies and procedures to all individuals involved in the patient's therapy. These written protocols to deal with typical issues during routine visits in the clinic should be available for review by all personnel. Clear communication between stakeholders in anticoagulation management can ensure better patient outcomes and reduce fragmented care in the health care system. AMS policies and

procedures are currently available to all clinicians (Nutescu et al., 2009). CHEST guidelines also provide policies and procedures on managing OAT for practical dosing, non-therapeutic INRs, invasive procedures, adverse events, models of care and special situations (J. Ansell et al., 2001)

(4) Documentation

Documentation in a standardized way is vital for improving quality of data. Computer software programs, such as INROnline™ and PharmaFile™ can document, analyze and retrieve patient data. There are other software products, such as DAWN AC, CoagCare, CoagClinic, CoaguTrak, etc. There are many benefits of computerized databases: improved data storage, tools for data analysis, dosing algorithms, automated interventions, and data transfer via electronic interfaces(Oertel, 2009). This record-keeping system tracks patients' information, such as demographic, treatment, communication processes, and miscellaneous data (e.g. complications, missed appointments, other laboratory values and invasive procedures) (Garcia et al., 2008).

(5) Patient Education

Enhancing individualized patient and caregiver education can improve patient safety while on warfarin therapy. There are various ways to impart knowledge: audio-visual resources, face-to-face interactions and written materials. Knowledge assessment tools can help make these sources of knowledge more appropriate for individual patients, e.g. assess written materials at the correct reading level, or materials in native language, etc. (Garcia et al., 2008). Effective patient education needs to be tailored to the diverse patients receiving warfarin, giving considerations to potentially low health literacy, limitations from cognitive and physical impairments, and reluctance to learn after being newly diagnosed with a disease

requiring OAT. Examples of patient educational materials are published to improve patient understanding of their therapy at baseline visits. These components include knowing the medication, importance of adherence, common adverse reactions (i.e. minor bleeding) and interactions (e.g. with acute illnesses), diet restrictions (i.e. to avoid foods high in vitamin K content and excessive alcohol intake), and disease management of symptoms (Shapiro, 2009).

(6) Patient Selection and Assessment

Clinicians should consider the appropriateness of OAT based on patients' individual risk and benefit profiles. Evidence-based guidelines are published for clinicians to assess and periodically reassess the patient's suitability for OAT (January et al., 2014; Nishimura et al., 2014; Verma et al., 2014; You et al., 2012). For example, the Canadian Cardiovascular Guideline reports that OAT should be recommended to older patients with an appropriate indication such as AF. The $CHADS_2$ (**C**ongestive Heart Failure, **H**ypertension, **A**ge, **D**iabetes, **S**troke/Transient Ischemic Attack) score assesses the yearly risk of thromboembolism related to AF, whereas the HAS-BLED (**H**ypertension, **A**bnormal liver or kidney function, **S**troke, **B**leeding, **L**abile INRs, **E**lderly, **D**rugs) score assesses the risk of bleeding (Verma et al., 2014). Frailty should also be considered in warfarin therapy using assessment tools, such as the clinical frailty scale, because older adults with frailty syndrome have an increased chance of scoring higher on the $CHADS_2$ and HAS-BLED scales that interfere with INR monitoring and thus require closer monitoring (Uchmanowicz et al., 2015). A comprehensive medical history should also be taken into account at the initial visit to assess all risk factors that influence the patient's therapy: medical, social, psychological, etc. (Garcia et al., 2008).

(7) Laboratory Monitoring

Regular monitoring of anticoagulation therapy should be done using prothrombin time testing of laboratory plasma samples (venipuncture), or whole blood samples (finger prick) on point-of-care devices (Garcia et al., 2008). Both methods of testing are shown to be equally acceptable for reporting INR scores (Plesch et al., 2008; Yelland et al., 2010). A list of point-of-care devices available in the market for INR testing is published (Wurster, 2009).

(8) Initiation and Stabilization of Warfarin Therapy

Initiation of anticoagulation therapy aims at reaching the lower limit of the therapeutic INR range in a timely manner (Wittkowsky, 2009). Initial dosing should be based on evidence-based guidelines to reach this range within an appropriate timeframe (ACCP, 2012; J. Ansell et al., 2008; Holbrook et al., 2012; Lastoria et al., 2014; Sridhar, Leung, Seymour, & Nagge, 2014). Patient-specific factors, such as age, weight, height, comorbidities and drug-drug interactions should be considered by clinicians who determine starting doses of warfarin therapy (Garcia et al., 2008). The recommended initial dose is between 5mg and 10mg daily for the first 1-2 days for patients without sensitivity to warfarin, but more recent guidelines favors 10mg daily for the first 2 days (J. Ansell et al., 2008; Holbrook et al., 2012). Otherwise, it is recommended that initial doses are less than 5mg if there are factors to increase sensitivity to warfarin (J. Ansell et al., 2008). Sridhar et al. reported that a safe initiation dose of 4mg daily for 3 days could achieve a therapeutic INR range in a timely matter (2014). Regardless of the loading dose, INR monitoring should be done after 2 to 3 initial doses at least 2 to 3 times weekly until INR stabilization (J. Ansell et al., 2004; J. Ansell et al., 2008; Wittkowsky, 2009). Depending on the INR response, subsequent dose adjustments are made to predict the maintenance dose at which the INR value is stable at the

lower limit of the therapeutic range. These dose adjustments can be done empirically or through published dosing nomograms (Wittkowsky, 2009).

(9) Maintenance of Therapy

Maintenance therapy aims at stabilizing the long term dosage (Wittkowsky, 2009). A systematic approach using evidence-based guidelines should be used for the maintenance of therapy (J. Ansell et al., 2008; CADTH, 2016; Holbrook et al., 2012). CADTH outlines a structured management plan that considers ongoing patient assessment, dose adjustments and follow-up testing (2016). Patients with consistently stable INRs, i.e., stable for at least 3 months, are recommended to receive follow-up testing every 4 weeks, but recent guidelines recommend patient follow up can occur every 12 weeks instead (Holbrook et al., 2012). Validated algorithms for dose adjustments to improve delivery of OAT (Harper et al., 2014), but evidence-based guidelines should be used to deal with extreme INR values (Garcia et al., 2008).

2.4 Research Addresses Gap in Literature

The literature depicts limited qualitative research on anticoagulation management as seen in table 1 (see Appendix B). The majority of these studies performed interviews without an underlying framework, using inductive data analysis to probe health care providers on anticoagulation management, patient-provider satisfaction and perceived barriers/ facilitators. This type of analysis is useful in obtaining emerging themes from the participants to learn more about a less known problem, but it has limitations on exploring a more comprehensive list of factors that, for example, are detailed in theories to influence implementation research. For example, Shaw et al.'s study on examining the attitudes of a community pharmacist-led anticoagulation management service in New Zealand has similar features as this study: a collaborative model of AMS using

POCT based on many of Garcia et al.'s key recommendations in a community setting (2014). However, Shaw et al. used inductive methods to create the data collection tools and to analyze the data, whereas this study used a deductive method under a theoretical lens to guide systematic data collection and analysis. Michie et al.'s psychological theory has 12 domains of behavior change that influences implementation of evidence-based practices, which provided a comprehensive guide on topic-specific probes during data collection, and influenced data analysis.

Shaw et al. (2014) also focused on AMS clinics that incorporated many of Garcia et al.'s components, but not for a frail elderly population. Chronic disease interventions, such as AMS clinics are expensive and thus, should be run efficiently to be cost-effective. This means that AMS clinics should be standardized to follow key components for optimal OAT delivery and tailored for those, like the frail, who need intensive intervention to achieve meaningful clinical outcomes. As such, this study can contribute knowledge to a limited literature of implementation research using theory. Specifically, this study will report the perceptions of pharmacists and nurses on the implementation of Garcia et al.'s consensus-based guideline for optimized OAT delivery using a theoretical framework, such as psychological theory to systematically understand the factors for implementation in practice. These data can contribute to the knowledge of theory-based implementation interview techniques to understand the influences on health care professional behaviour. The key themes that result from this study can be used to inform further development of implementation research by helping clinicians identify, address and improve any issues upon wider implementation in outpatient settings.

2.5 **Significance of Research**

The literature shows that AMS is a coordinated, cost effective approach that can reduce hospitalizations and other medical expenses related to complications of warfarin therapy (J. E. Ansell, 2009). Despite its success, there is limited research on how to integrate a wider and systematic approach to OAT management in community AMS clinics. This study sought to understand how various factors affected the uptake or not of a clinical guideline to optimize OAT management within the WWLHIN community. The region can use this data to consider how to develop or refine the components of AMS clinics across the community to successfully integrate a wider and more systematic approach to OAT management.

Wider implementation of standardized AMS clinics can make the government realize the potential health care savings on a larger scale, especially for managing chronic AF in vulnerable populations like the frail elderly. Cost savings may be gauged through measuring anticoagulation benchmarks, such as adverse events and hospitalizations, to show as evidence to secure reliable funding. As a result, these AMS clinics may gain more consistent funding from the government to continue services in the future. In 2012, the Ontario Ministry of Health and Long Term Care recognized the potential benefits of POC INR-testing and funded the one-time cost of POC-monitoring devices in some Family Health Teams in Ontario; however, medical supplies, education and training on how to use the device and the support software were excluded (Ministry of Health and Long Term Care, 2012). Hence, funding opportunities could improve with more research on how to systematically apply AMS clinics to its full potential for cost savings to the health care system. By leveraging existing resources, reducing barriers and recognizing factors that facilitate the implementation of a wider approach to OAT management in AMS clinics, this study is contributing to this area of research. In the end, the hope is for patients with AF to

ultimately benefit from improved quality of life via positive health outcomes, and the reduction in adverse outcomes and complications through coordinated and timely care. Conducting this study is a stepping stone toward achieving the aim of wider implementation and consistent funding for community AMS clinics serving frail older persons with AF. In the next chapter, the methods on how this study was conducted are described.

CHAPTER 3: METHODS & STUDY DESIGN

3.1 **Introduction**

This chapter presents the objectives of the research and how they are addressed by a research approach. In this study, the qualitative research approach to address the research objectives in this particular context with several assumptions that guide the collection, analysis and interpretations of data (Creswell, 2009). The investigator made the following assumptions in the study: (1) Garcia et al.'s (2008) work is a recent clinical guideline for optimizing the delivery of OAT management therapy in community AMS settings; therefore, when the guideline is applied in practice, a more systematic approach results; (2) Michie et al.'s (2005) psychological theory domains affect the behaviour of clinicians to implement the clinical guideline in practice (see section 3.3); and (3) a constructivist worldview because the implementation of the clinical guideline is dependent on the particular social context in which it is implemented (see section 3.4). The research objectives aimed to explore the clinicians' perceptions of how various factors affected the implementation of a clinical guideline for optimal OAT management a community-dwelling frail elderly population. A detailed account of the research objectives, theoretical lens and the philosophical world view are described in this chapter, as well as the study design and data analysis. To ensure the trustworthiness of the data, potential biases of the analysis and ethical considerations are also discussed.

3.2 **Research Purpose & Objectives**

The purpose of this qualitative, explorative study was to explore and describe the pharmacists and nurses' perceptions of the implementation of Garcia et al.'s (2008) guideline for optimal OAT management in the WWLHIN community, with a particular lens for a frail elderly population. This clinical guideline includes nine key recommendations for the optimal delivery

of OAT management in outpatient AMS settings (see section 2.3). These recommendations are available in the literature, yet their implementation in community practice remains a challenge. Therefore, this study sought to address the following research objectives using the theoretical lens of Michie et al.'s (2005) psychological theory (see section 3.3):

(1) To explore and describe how existing **intrinsic and extrinsic factors hindered or supported** the delivery of optimal OAT management, according to Garcia et al.'s (2008) guideline, with specific emphasis on frail seniors.

(2) To discover, describe and identify how **behavioural changes facilitate** the delivery of optimal OAT management, with specific emphasis on frail seniors.

A qualitative approach using an exploratory design was selected to study meanings in a particular context using emerging methods to collect data and interpret underlying patterns (Creswell, 2009). In contrast, a quantitative approach, including mixed methods were not suitable for addressing the objectives because quantitative research tests theories by examining relationships among variables. Instead, the objectives of this study was to gain insights from clinicians on how various factors from Michie et al.'s (2005) psychological theory influenced the implementation of Garcia et al.'s (2008) clinical guideline to inform future investigations. Therefore, a qualitative, exploratory approach guided by an underlying theoretical lens was selected to address the research objectives. The next section describes how Michie et al.'s (2005) psychological theory was used as the theoretical lens to guide this research.

3.3 Theoretical Lens: Michie et al.'s Psychological Theory

In a qualitative study, a theoretical perspective generally helps the investigator orient the research in terms of the questions asked and how data is collected, analyzed and interpreted

(Creswell, 2009). Michie et al.'s (2005) psychological theory was the theoretical lens that shaped the research objectives and the questions asked (see section 3.5.3) for this study. Michie and colleagues (2005) from the Center for Outcomes Research and Effectiveness in the Department of Psychology at the University College London, U.K. adapted psychological theories relevant to behaviour and behaviour change to optimize implementation research of evidence-based practices (EBPs). These authors conducted a consensus-based approach of a theoretical framework among health psychology theorists, health services researchers and health psychologists. This group of experts consolidated psychological constructs and theories in three areas (motivational, action and organizational) to identify a list of 12 domainsand corresponding interview questions for an "integrative framework for studying the implementation of EBP" (Michie et al., 2005). EBP guidelines need to be effectively implemented in practice to achieve the best health outcomes. The implementation process largely depends on these 12 domains, comprising of intrinsic and extrinsic factors that modify clinician's behaviours (Michie et al., 2005). Underlined texts represented the necessary and sufficient pre-requisites for the performance of a behavior by the health care provider aiming to effectively implement EBPs (Michie et al., 2005):

(1) **Knowledge:** Implementer's schemas or procedural knowledge of EBP guidelines

(2) **Skills:** Implementer's competency or skills to provide components of EBP guidelines

(3) **Social/professional role and identity**: Compatibility of EBP guidelines with implementer's social or professional standards

(4) **Beliefs about capabilities (self-efficacy):** Implementer's self-empowerment or self-esteem to deliver EBP guidelines

(5) **Beliefs about consequences (anticipated outcomes/ attitude):** Implementer's outcome expectancies for applying EBP guidelines

(6) **Motivation and goals (intention):** Implementer's commitment or goal priority to applying EBP guidelines

(7) **Memory, attention and decision processes**: Implementer's cognitive processes (memory, attention and decision) to delivering components of EBP guidelines

(8) **Environmental context and resources (environmental constraints):** Physical resources and context available (or lacking) for implementer to apply EBP guidelines

(9) **Social influences (norms)**: Social effects, including group dynamics, support and conflict that influences the implementer to apply EBP guidelines

(10) **Emotion**: Implementer's positive or negative affect of implementing EBP guidelines

(11) **Behavioural regulation**: Implementer's perception of what preparatory steps or procedures were needed to encourage the application of EBP guidelines

(12) **Nature of behaviours**: Implementer's perception of potential behavioural changes that facilitates the application of EBP guidelines in the future

This framework largely reflected Fishbein et al.'s (2001) approach to studying the implementation of HIV best practice guidelines. Fishbein and colleagues (2001) created their framework through an informal exercise of consolidating psychological theories by leading psychologists to promote preventative behaviours for HIV. Michie and colleagues (2005) also conducted expert consensus of psychological theories and constructs, but included three expert groups using recent literature, resulting in a more comprehensive framework with a total of 12 domains, compared to the 8 domains by Fishbein et al. (2001).

Therefore, this study applied these 12 domains by Michie et al. (2005) with component constructs and eliciting questions to investigate how these factors affected the implementation of Garcia et al.'s (2008) clinical guideline for optimizing OAT delivery (see table 2, Appendix C). For research objective 1, exploring the clinicians' thoughts on *how* existing intrinsic factors (i.e., explanatory behaviours) and extrinsic factors (i.e., context) supported or countered the implementation of the clinical guideline. This inquiry was guided by the constructs from domains #1 to 11 of Michie et al.'s (2005) psychological theory, with domains #8 and 9 as extrinsic factors, and the remaining as intrinsic factors. For research objective 2, exploring the clinicians' perceptions on how proposed behavioural changes facilitate the implementation of the clinical guideline was guided by domain # 12 (Michie et al., 2005).

Rationale for Theoretical Lens Guiding Research

Michie et al.'s (2005) psychological theory was the ideal framework to guide the development of data collection tools and the data analysis process in this study. The data collection tool was a semi-structured interview guide with questions based on Michie et al.'s (2005) psychological theory (see Appendix C). The interview guide covered all 12 domains of this theory as factors affecting implementation, shaping the types of questions asked. These deductive questions also had eliciting probes for inductive themes to emerge from the data, such as frailty. This would be an emerging theme because the majority of patients in community-based AMS clinics were older adults with intensive needs. Therefore, semi-structured interviews have both the structure and flexibility to explore existing and emerging themes (Creswell, 2009; Sliverman, 2013).

In contrast, other research methods such as surveys, open-ended interviews and focus groups were often used in research with limitations. Surveys employed close-ended questions to

collect deductive data in a quantitative approach, whereas focus groups and open- ended interviews collect emerging data using qualitative methods. Both focus groups and open-ended interviews encourage participants to talk openly about an issue without structure, allowing inductive data to emerge naturally from the interviews (Creswell, 2009). Conversely, semi-structure interviews conducted without an underlying theory was not as structured as with one. As selected for this study, semi-structure interviews guided by theory allows the investigator to develop and ask questions to cover all theoretical domains for comprehensiveness, yet the flexibility for participants to provide their own input and expand upon their responses (Creswell, 2009). Limited studies used theory-based implementation interviews to guide the research process, which was a strength of this study.

Firstly, a surveys and open-ended interviews were widely used in previous studies to explore factors affecting anticoagulation therapy. Prior research on anticoagulation management described data on health care providers' perception on anticoagulation management, satisfaction on patient-provider relationships and barriers or facilitators for OAT delivery (see Appendix B). For example, one study by Bishiop and colleagues described satisfaction of patients and physicians with a pharmacist-managed anticoagulation program in a family medicine clinic in St. John's, Newfoundland and Labrador using a self-administered survey (2015). Other studies also used surveys as the data collection tool for examining factors that impacted warfarin management services, such as Frankel et al. (2015), Lee et al. (2013), and Peterson & Jackson (2002). These are examples of a few studies already using surveys to identify barriers and facilitators for anticoagulation management, but surveys are limited in that participants cannot expand on their responses.

Other studies such as Shaw et al. (2014) in New Zealand examined pharmacists, nurses, practitioners and patients in the community about their attitudes toward a community pharmacist-led AMS using both surveys and telephone interviews so that clinicians could expand on their responses. Other work also conducted focus groups and semi-structured interviews to explore issues related to OAT delivery. For example, Kountz et al. (2015) used focus group interviews to explore multiple perspectives on strategies for improving anticoagulation management for patients with AF. As well, Bajorek et al. (2007) conducted focus group interviews of clinicians, patients and their carers to identify strategies for warfarin management in Australia. Chang & Pizzey (2013) used both focus groups and semi-structured interviews to collect data from pharmacists and physicians for warfarin management in primary care settings in the Kitchener/Waterloo area . Additionally, Decker et al. conducted semi-structured interviews to determine the clinicians' perceptions of barriers for optimal AF management in the United States (2012). These studies explored aspects of anticoagulation management for AF in an inductive manner, allowing themes to emerge from the participants rather than deductively.

There are limited studies using theory to guide their research methods. A qualitative study by Michie et al. (2007) was useful for this research because it modeled the use of Michie et al.'s (2005) psychological theory to explore and measure the implementation process in the community. Michie and colleagues (2007) investigated the effectiveness of implementing a mental health guideline by identifying barriers influencing its implementation. In semi-structure interviews, 20 participants from mental health teams across the United Kingdom were asked questions based on 11 theoretical domains of Michie et al.'s (2005) psychological theory to explore thoughts, opinions and attitudes. These interviewees' responses were analyzed based on how much the content reflected each of the 11 domains: 0= none (definite difficulty), 0.5= partial

evidence (possible difficulty), and 1=full evidence (no difficulty). This coding system allowed the authors to calculate an implementation score in each domain for each participant. Each domain was a potential explanatory factor of implementation, so if participants scored low on the knowledge domain, the poor application of the mental health guideline could be due to difficulty in understanding the guideline. An overall score organized by profession and mental health trust location was also calculated; a lower implementation score indicated poor application of the mental health guideline as a whole (Michie et al., 2007). Therefore, Michie et al.'s (2007) study and this study were similar in studying the factors that affected the implementation of clinical guidelines, yet this study additionally explored *how* these factors hindered, supported or facilitate the delivery of optimal OAT management, as outlined in Garcia et al.'s (2008) clinical guideline.

After examining the facts, semi-structured interviews guided by theory was the ideal research method for this study because it allowed a rigorous process to develop, ask and analyze data, while still allowing for new patterns to emerge from guided probes. Therefore, semi-structured interviews based on theory was more effective in gathering both deductive and inductive data than surveys, focus groups and open ended interviews. This qualitative study was also guided by the assumptions of a philosophical world view of the investigator as discussed below.

3.4 **Philosophical World View**

The underlying philosophical world view of this research is constructivism. A constructivist approach takes into account how reality is fallible and facts are socially constructed in particular contexts (Creswell, 2009; Sliverman, 2013). The implementation of an EBP is dependent on the particular social context in which it is implemented. Prior to this study, the investigator visited community AMS clinics as a part of an environmental scan to better understand the context in

which clinicians were working. This environmental scan allowed the investigator to better interpret the data collected within the context of community-based AMS settings, which fits into a constructivist approach of understanding contexts for interpretation of data. This philosophical world view recognizes that the working context influences clinicians' circumstances and thus, their perceptions of what affects the implementation process.

In detail, this world view that the investigator endorses was used to interpret the data from semi-structured interviews through her life experiences. The investigator acknowledged that she used her own background and experiences to interpret meanings in that specific context. The investigator came from a health studies background, studying at the University of Waterloo, and is a volunteer at the Hospital Elder Life Program who has connected with many patients who used anticoagulation services. She also has a personal connection with a close friend who experienced difficulties from poor anticoagulation management in the community to understand better understand the patient's perspective. She has also met and spoken with experts in the field, and observed OAT delivery from the clinician's perspective. Keeping in mind both perspectives, it helped the investigator describe her interpretation of the clinicians' responses; for example, when clinicians talked about the convenience of AMS for patients, the investigator understood the impact on patients. This is especially important in the constructivist approach because the interpretation is dependent on the context in which clinicians were working and in which the investigator was doing research about how existing factors affected the implementation of the clinical recommendations.

3.5 **Study Design**

This section describes the study design, including the study population, setting, and the methods for recruitment and data collection. Clinicians who met the inclusion and exclusion

criteria (see section 3.5.1) were key informants of this study. They were interviewed in semi-structured interviews because it had both the structure and flexibility to guide purposeful interactions (Creswell, 2009; Sliverman, 2013). The semi-structured interview guide was based on the eliciting questions from Michie et al.'s (2005) psychological theory framework (see Appendix C), shaping deductive questions that covered all12 domains as factors affecting the implementation of the clinical guideline. There were also probes to direct key informants to elaborate upon their responses, allowing inductive themes to emerge from the data.

During the process of interviewing, key informants chose to speak about the recommendations from the clinical guideline that resonated with them the most.. The investigator acknowledged that the interview guide was not a "one-size fits all" data collection tool, so a flexible approach was adopted to guide a purposeful interaction. Not all questions in the interview guide were asked of every key informant. As stated by the constructivist approach, as long as the same broad questions were asked in each interview, then every key informant had the chance to construct responses relevant to their experience and context (Creswell, 2009). All key informants were asked the same general questions related to skills, intention and environmental resources, all of which were necessary for health care providers to implement clinical guidelines in practice (Michie et al., 2005).

The investigator's role was to collect this information and interpret the key informant's meanings (Creswell, 2009). When needed, further explorative questions were asked if (a) the questions were relevant to the selected recommendations; and (b) the key informant had additional insight on the topic being asked. Overall, the flexibility of a semi-structured interview approach helped to focus the conversation, but allowed adaptability to gather new information (inductive themes) (Creswell, 2009). Key informants were selected for interviews through a

purposive sample. Interviews lasted approximately 30-40 minutes and were audio-recorded, transcribed and analyzed for data analysis. The results of this analysis addressed the research objectives of this study. These components are described in detailed in the section below.

3.5.1 Study Population & Setting

The study population included pharmacists and trained registered nurses who worked in outpatient AMS clinics in family health teams and community pharmacies within the WWLHIN community: Waterloo-Kitchener, Cambridge and Guelph. Only pharmacists and nurses were chosen in the purposive sample because they represented care providers in community-based AMS clinics (more details in section 3.5.2). The study sample consisted of key informants who met the following inclusion criteria: (1) Registered as a pharmacist with the Ontario College of Pharmacists, or nurse (RPN or BScN with the College of Nurses of Ontario); (2) Aged 18 and over; (3) Employed at an AMS clinic using POCT, i.e., INR testing devices and software, for at least 6 months to arbitrarily represent "experienced" clinics; and (4) Be located within the WWLHIN community. The 6-month mark was chosen arbitrarily as the cut-off for the length of time that a clinician working in an AMS clinic; this study sought to study the perspectives of relatively experienced key informants. Key informants were not qualified if they met any of these exclusion criteria: (1) Provided laboratory testing in routine medical care; and (2) Employed at AMS clinics within hospitals. Clinicians who were employed in hospital-based AMS clinics were excluded because the research interest was in a regional, not hospital-based model.

3.5.2 Recruitment

Key informants were primarily identified during the prior environmental scan of AMS clinics (see Appendix A). During this scan, seven pharmacists working at AMS clinics within the

WWLHIN community expressed an interest in participation. In purposive sampling, the investigator aimed to recruit key informants of each profession from different study sites. The investigator sent a recruitment email (see Appendix G) to these seven pharmacists and additional eligible key informants. The email explained the details of the study and how to participate. A follow up email was sent within one week of the initial recruitment email for non-respondents (see Appendix I).

Upon expressing interest, the investigator sent a confirmation email to key informants to confirm time, date and location of the interview (see Appendix H), and attached two documents for the participant to read in advance: the information and consent form (see Appendix D), and Garcia et al.'s (2008) clinical guidelines. The information and consent form explained the research, interview process and how confidential information will be handled, asking for the key informant's permission to proceed with the interview. Key informants completed the interviews either during normal working hours of the clinic or after hours. During working hours, the investigator conducted the interview during a 30-minute slot when no patients were scheduled in. The alternative was to conduct the interview after hours if the clinic was fully booked. The investigator collected the data following the procedures outlined below.

Recruitment resulted in one pharmacist from each study site and two nurses from one site. This small sample size affected the transferability because it generated a non-probability sample that cannot claim generalizability to the study population. The point of saturation may be prematurely reached if key informants provided only 'status-quo' responses. This could be resolved if the sampling frame was widened and included at least one or more key informant of each profession to capture a variety of new information. In this study, the sampling frame was still too narrow since only two nurses were available to participate, so there might not be enough

data to capture more diverse information. This narrow sampling frame reduced transferability of the data to a larger population, but this study can still add value to a larger project, which can include more nurses for a richer study.

3.5.3 Data Collection

The data collection instruments included the information and consent forms (see Appendix D) for a key informant semi-structured interview guide (see Appendix E). Justification of the questions with probes is found in table 3 (see Appendix F). Outlined below was the procedure for conducting semi-structured interviews:

1. At the start of the interview, the key informant was given the information and consent form to sign, as well as Garcia et al.'s recommendation guidelines to reference during the interview.
2. The investigator prompted the key informant for any questions or concerns, then proceeded to collect the consent form and set up the audio recorder on the table if the key informant had fully consented.
3. Closing remarks were made and the audio recorder was turned off with all materials being re-collected and placed into a secure filing cabinet in an office. The feedback letter (see Appendix J) was subsequently emailed to thank the participant for their time.
4. At the end of each interview, the investigator immediately made field notes in a reflexive journal to reduce interviewer bias, since no note taker was present.

Field notes were kept by the investigator on overall impressions and thoughts about the key informant's responses and the interview, including any strategies to improve the interview process. These notes helped to optimize the process of subsequent interviews. For instance, in the first few interviews, the investigator noticed that key informants tended to go off topic, so the

investigator learnt to re-direct questions. As well, the investigator needed to provide more prompts without leading key informants to a particular answer.

Additionally, the investigator noticed that the interview went more smoothly when the key informants were asked to discuss topics based on a case study. All relevant factors related to Michie et al.'s (2005) 12 domains came up when the key informant discussed how the clinic was run, or what happened in a specific patient case. During the interviews, the investigator modified the semi-structured interview guides to ask about examples in the form of patient cases. For instance, the question about care management and coordination was framed as a patient case example: "If a frail older adult with atrial fibrillation was a patient in the family health team, how would they be referred into the anti-coagulation clinic?" As key informants answered this question, the investigator probed about any existing policies and procedures for Warfarin therapy management and coordination in the clinic. After these interviews were completed, data analysis was performed on the transcripts as outlined below.

3.4 Qualitative Data Analysis

Interviews were transcribed verbatim onto Microsoft Word. Transcripts were de-identified using a code and uploaded on NVIVO Pro 11 software. The transcribed data were first characterized as cases based on the type of clinic and profession (tables 5-6 in Chapter 4). Next, the investigator performed a thematic analysis of each transcript using both deductive and inductive codes. The investigator started by deductively identifying data that fit into the appropriate domain from Michie et al.'s (2005) psychological theory. Deductive coding used the investigator's interpretation of the definitions from Michie et al. (2005). Codes were also attached to Garcia et al.'s (2008) recommendations to put the domains into context when the investigator interpreted the data. Since semi-structured interviews allowed for inductive themes

to emerge from the data, the investigator looked for recurrent patterns in the data to code, such as frailty. As thematic analyses were being conducted, the nodes were compared, contrasted and condensed into a codebook to code all interviews.

After this round of coding, the coded data and codebook was sent to a second coder with qualitative data analysis experience. She performed the second coding analysis and compared nodes and consolidated them into a single codebook in a manual comparison to refine the themes line-by-line (see Appendix K). Conflict in themes were refined either by coding to additional nodes or un-coding unnecessary nodes. This review and refinement was done using NVIVO Pro 11's side-by-side view of the nodes coded to each line. A list of coding issues and assumptions discussed between the investigator and the second coder is available (see Appendix L).

Next in the data analysis, the investigator created a compilation of similarly coded blocks of texts across all interviews. After all texts were coded, this analysis provided the investigator with the number of references to particular nodes from all key informants. The 'query wizard' function in NVIVO Pro 11 was used to 'search for content based on how it is coded' by selecting 'search for content coded at all of these nodes' using terms seen in the rows of table 4 (see Appendix M). Each row consists of the *emergent concept or the Garcia et al.'s recommendation* AND *Michie et al.'s domain* AND *benefit or barrier to* further differentiate how each domain contributed to the implementation. For example, there was one reference coded at all these nodes: *Qualifications* AND *Knowledge* AND *Barrier* to help interpret coded data as a lack of knowledge about the qualifications of personnel. This output (i.e. block of text) was saved as a query result with the actual quote in NVIVO and the number of references (i.e., in this case, one) was recorded in table 4 (see Appendix M). The compilation of the output of similarly coded texts showed which combination of nodes were referenced the most or the least for a rough idea of

themes mentioned in the study. For example, there were 32 references related to the nodes: *Care management and coordination* AND *Environmental Context and Resources* AND *Barriers* suggesting that the environment was mentioned as a barrier 32 times for optimizing the care management and coordination recommendation in warfarin therapy.

3.5 **Trustworthiness of Data**

Generally, the trustworthiness of a qualitative study is assessed by looking at the dependability (reliability), credibility (internal validity), transferability (external validity), and confirmability (objectivity) of the study (Shenton, 2004). Dependability is the reliability of the study design, demonstrating the consistency in which other investigators are able to repeat the study. In this study, the data collection tool was a semi-structured interview guided by an underlying theory. This theory-guided approach allowed the investigator to ask general questions about Garcia et al.'s (2008) clinical recommendations based on the 12 domains of Michie et al.'s (2005) psychological theory. These theory-guided questions allowed for some consistency in responses between interviewees (i.e. similar themes to come up with each question) for potentially reliable data if other investigators choose to repeat the study. However, there could be variations in the data collected since the investigator conducted a semi-structured interview where new information emerged from the data. Therefore, in this qualitative inquiry, it was important to verify meanings, interpretations and assumptions between key informants and within key informants, then explain the thinking process. A reflexive journal (see Appendix N) was kept to document the investigator's thought processes and decisions, which enables other investigators to repeat the study more reliably (Shenton, 2004). In this journal, the investigator kept a record of the activities and thought processes done during data collection, transcription

and analysis to explain the way interpretations were reached. This reflexive journaling allowed other investigators to review the activities taken by the investigator during the study.

Secondly, credibility of data is the process of demonstrating that a true representation of the phenomenon is being presented (i.e. the data analysis actually captures the key informant's responses on how various factors affected the implementation of the clinical guideline). In this study, the investigator strived to obtain accurate details of the interview based on the participant's responses by recognizing any assumptions when interpreting the meanings of data. The investigator also employed techniques to establish internal validity to verify data, including triangulation of different sources by comparing the transcripts with audio files and field notes (Corbett, 2015; Creswell, 2009; Shenton, 2004). The investigator re-listened to the audio files before categorizing and coding the text in the transcripts. Then, a peer reviewed and compared the transcripts with the audio files to doubled check the interpretation of the raw data during transcription and coding. This process was done to confirm what was said and how it was said (inflection and tone) to improve credibility of the data.

Furthermore, thick descriptions of the context of the fieldwork provide sufficient details for other investigators to determine if the findings are applicable to other settings for to improve transferability standards (Corbett, 2015; Shenton, 2004). Elaborate descriptions of the key informants' behaviours in the study's context were noted after each interview, such as personal impressions, characteristics and thoughts. For example, the majority of key informants in this study were pharmacists who were knowledgeable and keen to participate in the study. Most of them wanted to provide quality data for this research and asked several times if they provided enough information. They had clear knowledge about AMS and were all formally trained at the School of Pharmacy in the anti-coagulation course. They all prepared for the interview by

reading the guidelines and usually elaborated on their responses without prompts. In comparison, the sample of nurses in the study was small, so their responses may be biased. Both nurses had extensive clinical experience in the community AMS clinics, which was involved in ongoing research and learning. They tend to provide rich data when given a case or example to explain a concept. Complex or multiple questions were difficult for them to elaborate more on, so interpretative probes helped to guide the conversation.

Finally, confirmability of the study was demonstrated when findings emerged from the data and not from the investigator's predisposed ideas to bias the study. Since the data collection tools and procedure were dependent on human skills, there was a possibility of bias. The investigator improved objectivity by emphasizing triangulation to reduce interviewer bias, which used different sources to verify the data, as stated earlier, to trace the course by which the results were drawn from the data (Shenton, 2004).

3.6 **Ethical Considerations**

This study received ethics clearance through a University of Waterloo Research Ethics Committee. All key informants voluntarily agreed to participate in the study without remuneration, and after fully understanding the purpose of the study via information and consent forms (see Appendix D) and verbal clarifications. All confidential information obtained from the interviews, including all field notes and audio-tapes, was kept in a securely locked cabinet in the investigator's office. All information identifying the participant was removed upon transcription and stored separately. The transcription files were de-identified using a code.

3.7 **Practical Insights**

Overall, there is practical insight on exploring how various existing factors hindered or supported, and how behavioural factors can facilitate the implementation of the clinical guideline. Lessons learned from this study may be portable to other LHINs that plan, integrate and fund local health care in communities for improved access to patients (Ontario's LHIN, 2016). Additionally, acknowledgement of this existing work may also promote the usefulness and validity of psychological explanations to behaviour change for the implementation for EBP. This qualitative study guided by theory can help shape future research and development of best-practice guidelines for the optimal delivery of OAT in a frail elderly population. Therefore, the next chapter examines the results of this study to address the research objectives and inform the discussion.

CHAPTER 4: RESULTS

4.1 Introduction

This chapter presents the results of the study, including the characteristics of the study sites and key informants. Although there was a wide range of themes (see Appendix M), the investigator focused on those that addressed the research objectives. For the purpose of this Master's thesis, the key results reported here are how existing intrinsic and extrinsic factors hindered or supported, and how behavioural changes facilitate the delivery of optimal OAT management, according to Garcia et al. (2008), in AMS clinics within the WWLHIN community: Kitchener-Waterloo, Cambridge and Guelph.

4.2 Characteristics of Study Sites

Firstly, the results were gathered from six AMS clinics or study sites that participated in the study with the same proportion of family health teams and community pharmacies. Table 5 shows the characteristics of these study sites. The majority of clinics had a sizable patient base of 50 or more patients, either only for only rostered members in family health teams or community members in pharmacies. In family health teams, there was a mix of registered nurses and pharmacists providing care, compared to just pharmacists in pharmacies. Regardless, all OAT management in these clinics was headed by pharmacists, per the inclusion criteria for this study.

Table 5. Characteristics of Study Sites

Type of Outpatient Setting	Type of Patients	Type of Trained Staff
Family Health Team	Rostered in community	RNs & CPs
Community Pharmacy	Any in community	CPs only

4.3 **Characteristics of Key Informants**

In these clinics, there were a total of eight key informants: six pharmacists and two registered nurses (see table 6). Key informants had at least one-year of experience in OAT management within a community setting , and met inclusion and exclusion criteria of this study (see section 3.5.1). All key informants received some type of formal training, either through a course at University of Waterloo (School of Pharmacy) or a workshop from Roche CoaguChek™. After examining these characteristics, the most salient themes are presented to address research objectives 1 and 2.

Table 6**. Characteristics of Key Informants**

Key Informant Code	Job Title	Years of OAT experience (# years)
KI 1	Pharmacists & Registered Nurses	1.5
KI 2		5
KI 3		2
KI 4		1.5
KI 5		6
KI 6		8
KI 7		3
KI 8		3

4.4 **Themes for Research Objective 1**

In order to address research objective 1, key informants revealed three important themes that described how existing intrinsic and extrinsic factors counteracted or supported the implementation of the clinical guideline for optimal OAT management in community AMS clinics (see table 7).

Table 7. Themes for Research Objective 1

Research Objective 1: To explore how existing intrinsic or extrinsic factors hindered or supported the implementation of Garcia et al.'s (2008) clinical guideline for optimal OAT management.	
Hindered implementation	**Theme 1:** Inadequate reimbursement for logistical operation of AMS clinics
Supported implementation	**Theme 2:** Clinicians' awareness of how to apply knowledge to support practice
	Theme 3: Tailored organizational supports for the frail elderly

In table 7, theme 1 shows how inadequate reimbursement for operating AMS clinics (extrinsic factor of environment) counteracted the implementation of the clinical guideline. The clinical guideline portrayed key recommendations for the optimal delivery of OAT management, so there needed to be an infrastructure to support this practice. Clinicians in these AMS clinics were not sufficiently compensated for their resources and services rendered, which jeopardized the long-term sustainability of the infrastructure of AMS clinics. As a result, consistent funding was needed to support AMS clinics for clinicians to apply the recommendations. On the contrary, themes 2 and 3 were about how existing intrinsic and extrinsic factors supported the implementation in practice. Theme 2 showed how the implementation of the clinical guideline depended on the clinicians' awareness to apply the knowledge of the recommendations to support practice (intrinsic factors of knowledge and skills). Clinicians generally knew how each element in the clinical guideline was applied to start a community AMS clinic; however, there were some issues related to an incomplete frailty assessment among key informants. Whereas, theme 3 described how tailored organizational supports for the frail elderly, such as physical tools, face-to-face interactions and home visits (extrinsic factor of environment) helped with the implementation of the clinical guideline for the optimal delivery of OAT management in the community. Below, each theme is described in more detail:

Theme 1: Inadequate Reimbursement for Logistical Operation of AMS Clinics

For the first of three themes, the most prominent was how inadequate reimbursement for logistical operation of AMS clinics hindered the delivery of optimal OAT management. Because of funding issues, there was insufficient compensation for materials and services rendered for therapeutic activities in AMS clinics. AMS clinics procured overhead costs related to equipment (hand-held POC-INR testing device and strips) and salary. An inadequate reimbursement model compromised the delivery of optimal OAT management within AMS clinics in both FHTs and community pharmacies. For example, it seemed that FHTs had a problem with the allocation of funds for AMS clinics when this key informant said:

> *"Funding for any type of clinic like this is difficult. Um...within the family health team model, it has been especially difficult to get the Ministry to specifically fund the INR clinics so every single year we're worried about whether or not we're able to continue with the program because other priorities within the family health team may take away funding from our program."*- KI 6

As funding was unpredictable from year-to-year, it threatened the long-term sustainability of the clinic, which was the infrastructure supporting the delivery of optimal OAT management. These clinics continued to operate as long as FHTs funded them. Funding issues were more severe in community pharmacies with inadequate funding from the government:

> *"Actually, it'll be awesome if ODB* [Ontario Drug Benefit] *initiated the MedsCheck program that was seventeen to eighteen dollars that was meant specifically for management of a disease. So they have one for diabetes, it's seventy-five bucks for the first one and twenty-five dollars thereafter. Why can't they do one for Warfarin that's just 18 bucks per INR tests with certain criteria of when you can bill it and when you can't. You're maintaining somebody at therapeutic dose, you do their INR monitoring, you don't get reimbursed. If you have to make a change in therapy, that would make sense to be reimbursed as a follow up MedChek in any regard or as a pharmaceutical opinion, but most of the Warfarin clinics that are run by pharmacists are done by medical directives, which therefore excludes you from billing for a pharmaceutical opinion. In order for a pharmaceutical opinion, you need to have a doctor sign off on your dose recommendation. Well, that's done through the medical directive.""* –KI 4

As demonstrated, community pharmacists were not paid for the majority of therapeutic activities, such as maintaining and monitoring INR values. The only way for reimbursement was through a physician-signed pharmaceutical opinion during therapeutic dose changes. This reimbursement model jeopardized the long-term sustainability of AMS clinics because it meant pharmacists were not being paid unless there was a therapeutic change approved by a physician. Without the means to keep up with overhead costs over the long term, clinicians were not well supported to deliver the clinical guideline. Instead, community pharmacies had to compensate for the cost of operating AMS clinics in other ways:

> *"....there's really no billing, there's no good billing way in the community, for pharmacists in the community. I think that they justify it by the patient being a client in other ways, so they spend money in the pharmacy and their other prescriptions come to them. Um, so that's how they balance it." – KI 3*

Since patients were using other services in the pharmacies, these AMS clinics were able to stay in operation; however, this was not a viable long-term solution for reimbursing AMS clinics that were expected to provide chronic disease management. This inadequate funding issue caused a dilemma for pharmacists who wanted to stay in operation and manage optimal standards, but struggled to do so:

> *"...I mean I can cancel my clinics and let them go back to labs if I wanted to, but it's just not something we're prepared to do at this time. But it is scary, you know, when we hear about other pharmacies that have been billing for the service. To me personal opinion, it's reasonable to bill but then you hear that they've been audited and you're like okay well, why am I putting myself out there for these potential repercussions if all I'm trying to do is taking care of my patients?" – KI 1*

As seen above, this key informant had financial concerns to continue operating and could not effectively focus on delivering optimal OAT management for patients. There were concerns about how to balance the optimal delivery of OAT management using limited financial resources. This funding concern clearly conflicted with the clinician's ability to provide optimal

services. An advocacy letter by a community pharmacist to the government showed how important funding was to the operation of AMS clinics to support OAT:

> *"Well, we proposed that a nominal fee be set up specifically for this work. Like this activity that you're doing, we should be reimbursed for it, we said between $10-$15. Right now, you know we're doing a lot of other things in these INR appointments as well which helps cover some of the funding, but you should be paid for what you do and it's ...so hopefully [laughs]… And we calculate how much drug therapy problems we saw on top of Warfarin issues during our clinic appointments and we had about 15 a month. So if you think of how much money that saves the government if each drug therapy problem is, you know the x amount of dollars. So, hm...we're including all of this in our advocacy letter!"* -KI 5

They advocated for the government to set up a reasonable fee to help sustain the foundation of the AMS clinic. There was inadequate funding for FHTs and community pharmacies to maintain the infrastructures of these AMS clinics, which counteracted the implementation of the clinical guideline for the optimal delivery of OAT management in the community. Yet, for those AMS clinics that stayed in operation despite the inadequate funding, there were other existing factors that supported the delivery of optimal OAT management.

Theme 2: Awareness of how to apply knowledge to support practice

In order for clinicians to apply the clinical guidelines, there should be knowledge and skills to do so. In sum, there should be an awareness of how to use that knowledge to support practice. That is what was portrayed in theme 2, which showed how recommendations from the clinical guideline were well known and applied by the majority of key informants. The awareness of the clinical guideline as a whole was apparent for pharmacists in both FHTs and community pharmacies. An example of this is described here:

> *"So if like first you would need* ***medical directives*** *and* ***everyone to buy in*** *to whoever's managing it. Everyone would have to have a comfort level of the people who have been* ***trained t****o do it and I think it works the best when the people managing it are the* ***only ones managing it*** *and they have the* ***medical directives to make the changes on the spot*** *instead of getting the result,* ***double checking with the physician*** *and then giving a*

> *response because there is sometimes urgency to making a decision and managing it. So I think it's good if* ***full medical directive*** *is in place to give that person a full scope of managing. Um...and then once that step is in place, I think if you've been trained, you should have the* ***knowledge of what patient education is necessarily****, ho****w to monitor, how to start, what influences or impacts INRs and what barriers patients have to maintaining INRs, including older age and frailty and where extra support is needed."*** *– KI 3*

There was a general understanding of how to apply the key elements for optimal OAT management in participating AMS clinics. As shown above, the key informant identified the need for qualified individuals who understood the terms for supervision of team, care coordination with physicians, OAT management and patient education, as well as the concept of frailty for care in this context. Having this awareness of how to apply knowledge is the first step to the implementation of these recommendations in practice. Clinicians were also aware of how to apply their knowledge of each recommendation in this clinical guideline to support practice. These results did not report on the fourth and seventh recommendations of documentation and laboratory monitoring of the clinical guideline because they were in the inclusion criteria; AMS clinics had to use computerized software for documentation, and POCT to test whole blood capillary samples for INR values.

Among the nine recommendations of the clinical guideline, the first two were qualifications of personnel and supervision of team. These recommendations were implemented to support how different professions involved in OAT management organized themselves to ensure that patients' needs were met:

> *"Um, no, I think we are very fortunate that um we had been given such free reign […] we go to the docs when we are over 4, if we have an issue we, you know, we let the docs know this is what we are doing […]. But other than that, that's you know, we have our outline of what our protocols are, we follow them and we are very fortunate that we have a physician who overlooks us if they're not here"* – KI 7

As this key informant described, the team dynamics of qualified team members in the clinic showed how this awareness supported the delivery of optimal OAT management. This

understanding was also foundational to the delivery of other recommendations in the clinical guideline.

Among the other recommendations, the third is care management and coordination. Clinicians knew how to apply the procedures for managing and coordinating care processes, such as those expressed by this key informant:

> "*We have templates. Yeah, of specific letters, like for the first INR appointment, we use the same thing every time. We have a checklist for that. When a patient discharges from the hospital, we can't really use a template for that, but we have a template in terms of discharges for all patients that we send the providers what was changed, what was new, same would apply to our Warfarin patients when there's a surgery again, we have a template for requesting or denying bridging like we talk about discussing bridging and duration of anti-coagulation, when it should be started or stopped, and when it should be restarted. We kind of have all the same format."* – KI 5

Having these templates and checklists for initial appointments, follow ups and bridging showed that this key informant understood how to apply established care procedures to support practice. The awareness to apply knowledge of care management and coordination protocols allowed key informants to implement this component of the clinical guideline. Note that documentation, the fourth recommendation of Garcia et al.'s (2008) clinical guideline, was not reported because it was an inclusion criterion for key informants to know how to use computerized software for OAT management documentation.

Furthermore, the fifth recommendation is patient education. Clinicians were aware of how to provide tailored education to individual patients, as this key informant portrayed:

> *"[…]spread[ing] out our education in some ways because it can be information overload, so we try and provide the necessary information upfront and then education along the way, like you said, as issues come up. We try and explain how important adherence is for this medication because it will tend to, you'll see it in the INRs. We explain things like if you, if they have a low INR today, like for example they had a 1.8, letting them know that if you've missed a dose in the last week or the last few days, that could be an indication of why it's low today. So they can kind of connect that and then they understand what missing a dose means. And then they kind of learn that if that*

> *happens then we will probably want to see them back sooner so it kind of gives them more reason to try and be diligent with their medications"* –KI 3

As demonstrated, this key informant explained the information in "chunks" and guided patients through the practical aspects of therapy, the lows and highs of the INR value and what the changes in values meant. The key informant was delivering the information to meet the patient's educational needs, showing that clinicians' awareness of how to apply this knowledge supported the implementation of the clinical guideline for optimal OAT management.

Subsequently, the sixth recommendation of this guideline refers to the patient selection and assessment for therapy. It recommended that clinicians need to have a comprehensive history of medical, social, lifestyle, psychological and employment profiles to determine the appropriateness of therapy for patients. In this study, clinicians were aware of how to select and assess patients for OAT management to support practice, as shown when this key informant described:

> ***"****I can't again stress the importance of getting a good clinical history and doing a proper cardiovascular risk assessment in terms of clot assessment, bleed assessment, frailty assessment, nutritional status assessment, compliance assessment. Is this person a good candidate for anti-coagulation, period? Does the benefit outweigh the risk? And compliance needs to be part of that initial assessment, it's absolutely key, and it's not say that if there's poor compliance that Warfarin is not a good option, what I'm saying is that if the initial assessment is done." – KI 2*

In considering these elements, it showed that awareness of how to apply the knowledge of a comprehensive selection and assessment process supported the uptake of this recommendation. Although key informants had a comprehensive list of elements to assess and select patients on, there were issues with the frailty assessment. Despite having an adequate understanding of the concept of frailty, the frailty assessment was incomplete, as described by this participant:

> *"It's usually everyone that's seventy-five and older, we screen them using gait, grip strength, um...falls and we screen nutrition, and then based on a combination of those things we would go and define them as frail. So, some of our patients are frail and some aren't but many of them have multiple comorbidities for sure."* –KI 3

As shown, patients who were older often received a frailty assessment using the gait, grip strength and nutritional status evaluations. Screening by chronological age showed that this frailty assessment was ad-hoc and not standardized based on evidence. It has been shown that chronological age is not a good indicator of frailty (Heckman & Braceland, 2015), but at least the key informant considered frailty in the assessment and selection for warfarin therapy. Even though the assessment of frailty was not standardized, the general awareness of how to apply knowledge of a comprehensive patient assessment and selection for therapy supported the uptake of this recommendation in the clinical guideline.

Another aspect of the clinical guideline for optimal OAT management is initiation and stabilization of therapy. The majority of key informants knew how to apply a systematic, validated process for the initiation and stabilization of therapy, as shown when this key informant expressed:

> *"So using dosing nomograms for initiation that have been validated are very important. But what's equally and arguable more important is frequent testing in that first month." – KI 2*

> *"Well, there's a nomogram for 4mg that's well studied with Dr. X who published it, 4 mgs in elderly people, then there's a 5 and 10mg start."* – KI 5

Validated dosing nomograms were used to start and stabilize a patient's therapy to reach the lower limit of the therapeutic range in a timely fashion, as recommended by the clinical guideline (Garcia et al., 2008). When therapy was initiated and stabilized promptly following evidence-based guidelines, such as the 4 mg initiation for older persons with AF (Siguret et al., 2005; Sridhar et al., 2014), the clinicians' awareness of how to apply this knowledge supported the uptake of the clinical guideline to optimize OAT management.

Finally, the ninth and last therapeutic recommendation is maintenance of therapy. Clinicians knew how to systematically maintain longitudinal therapy, as shown when this key informant revealed:

> *"In our older population, the four milligram initiation nomogram has had good predictability for maintenance dosing. I believe it's about 72 or about 75% predictive of the maintenance dosage so that's a very useful tool if it's followed correctly." –KI 2*

As shown above, the maintenance dosage was determined by the previously established evidence-based initiation dosing nomogram. When INR values are fluctuating, there was also a systematic process to determine the issues during longitudinal follow-ups:

> *"Yeah! So if there's a low dose, we ask them a list of questions that I can give you about why the dose is low. We review all these things: Is there a med change? Is there a change in their diet? Is there a change to their medical conditions? How are you feeling today? Did you miss any meds? There's a list of questions we ask."* – KI 5

As shown above, this key informant knew how to use a standard procedure for long-term follow up assessments, dose adjustments and monitoring of adverse events. All of these activities using standardized protocols helped to optimize OAT management per the clinical guideline. Overall, the awareness of how to apply this knowledge supported the implementation of the clinical guideline, but there were also external factors that supported this implementation in practice.

Theme 3: Tailored organizational supports for the frail elderly

Theme 3 described how tailored organizational supports for the frail elderly supported the optimal delivery of OAT management. This theme illustrated how the environmental resources such as blister packs, calendars and written reminders; the context of face-to-face interactions; and home visits tailored for the frail elderly supported the uptake of the clinical guideline as a whole. Patients who are frail, elderly and have AF are vulnerable, requiring vigilant care and attention from clinicians in AMS clinics to optimize OAT management. One of these initiatives included the organizational support of physical tools such as blister packs, which were used to

support the optimal delivery of OAT management by reducing non-adherence to therapy. This helped the frail elderly population as portrayed by this key informant:

> *"And if it's an adherence issue, we deal with that by introducing the idea of blister packs. Sometimes we need to dispense one at a time. We actually have one guy, he's frail and he has a language barrier and we actually fill up the dosettes with him with just Warfarin every time he comes."* – KI 5

As seen above, the use of blister packs was a physical tool used to support the delivery of optimal OAT management in the frail elderly. Additionally, the use of other resources was also useful to improve adherence in this population:

> *"We have seen trends that there's been unidentified cognitive impairment but then once they have started on Warfarin, which is a complex medication that requires strict adherence, cognitive issues will come out, so ...and then steps have to be taken to manage that too. But we'll just put in place lots of support initially for the patient and back up support so that we know that there are some safeguards if there are difficulties. But we use lots of tools to help all of our patients, not just our frail older patients, but written calendars, verbal instructions, written instructions and reminders, um..."* –KI 3

As detailed above, written calendars and instructions were used as reminders particularly for the frail elderly with cognitive issues. The use of these resources helped clinicians to deliver OAT for this population that would otherwise not be able to receive care if these tools did not exist. The clinical guideline recommended having standardized protocols for delivering therapy, so the systematic use of these physical tools to manage compliance in the frail elderly was one way that organizational supports encouraged the implementation of the clinical guideline as a whole.

As with these physical tools, the environmental context of AMS clinics also provided support for optimal OAT management, such as face-to-face interactions and home visits. In face-to-face interactions, clinicians did longitudinal patient assessments, dose adjustments and health monitoring for other conditions such as frailty. The benefits of a face-to-face interaction were described by this key informant:

> *"However, what tends to happen is, I would say that offering an in-person point of care anti-coagulation service has far reaching benefits beyond INR monitoring itself,*

> *especially in your older, more frail populations, right? Because what it is, is a face-to-face opportunity to address and screen and monitor all the other co-morbidities that they are currently dealing with. When you've got that face-to-face contact with them routinely, whether it be once a month or once every six weeks, you know in that neighbourhood, in terms of that time frame, you have a very unique and valuable opportunity to address everything else right? You can see if they are becoming more frail."- KI 2*

This key informant had the opportunity to monitor adverse events and frailty markers to promptly resolve any interacting conditions during these face-to-face interactions. This context allowed for face-to-face interactions in AMS clinics, which enabled key informants to deliver therapeutic activities as recommended by the clinical guideline.

In addition, another organizational support was having home visits for patients who were frailer and who notably needed the service the most. Having home visits reduced the complexity of therapy and supported the ability for clinicians to provide optimal OAT, as stated by this key informant:

> *"We do home visits. We take as much out of their hands as we can without taking away the sense of empowerment just to make it simple and easier for them. Just a way of simplifying regimens… If that's what's needed, yeahh... You do whatever's gotta be done. (laughs)"* – KI 4

The point of organizing these home visits was to support the delivery of OAT management for this specific population who tend to be more frail, which was typically characterized as having multiple co-morbidities, polypharmacy and loss of independence (Heckman & Braceland, 2015). Essentially, the AMS approach provides tailored organizational supports, such as blister packs, written calendars, face-to-face interactions and home visits for the frail elderly to monitor adherence and complete follow-up assessments and measurements in a more systematic manner. Therefore, these tailored organizational supports allowed key informants to deliver optimal OAT management through the deliberate implementation of the clinical guideline.

Summary: Themes for Research Objective 1

Ultimately, three themes illustrated how existing intrinsic and extrinsic factors played a role in the uptake of the clinical guideline for optimal OAT management in community AMS clinics. Firstly, theme 1 showed inadequate reimbursement for logistical operation of AMS clinics as an environmental constraint (Michie et al.'s (2005) domain #8) that hindered the delivery of optimal OAT management recommendations. There was an unstable reimbursement model for sustaining the infrastructure of AMS clinics in the long term so the recommendations were not effectively implemented in practice. For clinics with unstable financial support, clinicians' awareness of how to apply the knowledge of key recommendations of the clinical guideline (domains #1 and 2) supported practice. Key informants generally knew about how to apply these recommendations as a whole for the optimal delivery of OAT in practice. Despite that, there were concerns for specific recommendations of the clinical guideline, specifically with ad-hoc assessments of frailty based on chronological age, rather than standardized methods using evidence. Furthermore, the environmental resources of tailored organizational supports for the frail elderly, such as blister packs, reminders, and the context of face-to-face interactions and home visits helped key informants to deliver optimal OAT management by moving toward a systematic method of adherence monitoring and follow up assessments in this context. All in all, these three themes addressed how existing intrinsic and extrinsic factors counteracted or supported the implementation of the clinical guideline (**Objective 1)**.

4.5 **Themes for Research Objective 2**

Themes 4 and 5 described how behavioural changes can facilitate the implementation of Garcia et al.'s clinical guideline for the optimal delivery of OAT management in community AMS clinics (see table 8).

Table 8. Themes for Research Objective 2

Research Objective 2: To discover, describe and identify how behavioural changes facilitate the implementation of Garcia et al.'s (2008) clinical guideline for optimal OAT management.	
Facilitates Implementation	**Theme 4:** Engage efforts to improve interprofessional communication and collaboration
	Theme 5: Use compatible software platforms for OAT documentation

As seen in table 8, theme 4 showed how clinicians can engage in efforts to improve interprofessional communication and collaboration to facilitate the optimal delivery of OAT via hiring a nurse navigator and social networking with other clinicians. These opportunities can help change clinicians' behaviours from working in isolation to working together. Furthermore, theme 2 described another behavioural change, showing how clinicians can take action to use compatible software platforms for documentation of OAT management. In essence, both themes described how behavioural changes can facilitate the implementation of the clinical guideline for optimal OAT management in the WWLHIN community. Each theme is elaborated below.

Theme 4: Engage Efforts to Improve Interprofessional Communication and Collaboration

The fourth theme was for clinicians to engage in opportunities to improve interprofessional communication and collaboration efforts. The clinical guideline for optimal OAT management had recommendations that advised how care procedures and protocols should enable communication between all providers (Garcia et al., 2008). When clinicians change their

behaviours from working in isolation to effectively communicating and collaborating in teams, this change can facilitate the implementation of the clinical guideline. There was a need for pharmacists and nurses to develop these strong interprofessional communication and collaboration skills to facilitate care processes, especially during transitions of care. This was reinforced by this key informant:

> *"It's gotta be about collaboration. Um...nobody's doing this in a silo and you can't fully function without that integration […] So it's true collaboration, it's building those relationships so that there's trust amongst different practitioners. And building bridges with other community partners like the hospitals and making sure that people are doing things in a similar fashion [...]"*-KI 6

As a pre-requisite for building trust and efficiency, true communication and collaboration between providers was a necessary factor to facilitate the implementation of the clinical guideline for optimal OAT management. Firstly, the opportunity to connect with others was limited in community pharmacies compared to family health teams, as described by this key informant:

> *"[…] it takes a lot of collaboration and coordination between professionals. […]So I don't know if I would consider it easy in our system if you're outside a family health team because you can probably tell we have a lot of people that are helping us maintain all these standards including our nursing team, our physician buy-in and the support of experts. "* –KI 3

In this situation, it was easier for key informants to communicate and work with other providers in family health teams than community pharmacies because of the dedicated nursing team, trust from physicians and so on. Even with these available resources, clinicians in family health teams struggled with communication with other providers outside the organization such as hospitals. The following scenario illustrated the need for improvements in interprofessional communication and collaboration between providers in institutions and the community to improve OAT management:

> "*There was so many things that could go wrong, so if any one of them has taken a moment picked up the phone and said "please keep an eye on this person" you know, thankfully, Person X noted the end review when she got the discharge summary and thankfully the surgeon sent off a quick discharge summary of all you know, not all discharge summaries come quickly um disaster was adverted. But some discharge summaries don't come until like weeks or two later um there could've been some serious problems […]" –KI 7*

As demonstrated, this key informant revealed that provide interprofessional communication was not always consistent during transitions of care. Since interprofessional practice was not consistent, providers clearly needed to engage their efforts to improve communication to prevent disastrous consequences during therapy. One such effort could be to institute a new position as a contextual prompt to behaviour change, as suggested by this key informant:

> *"The-there needs to be a nurse navigator that sort of works through that either at the hospital end or at the doctor's office or maybe at the booking office or something like that."* – KI 7

This "nurse navigator" could be the channel of communication to connect health care providers for seamless transitions. Having a "nurse navigator" could be a prompt for behaviour change in this context, allowing for clinicians to improve interprofessional communication and collaboration efforts. As a result of improved communication, health care providers could facilitate improvements of all aspects of therapy as recommended by the clinical guideline, facilitating its implementation in practice. However, financial considerations for an additional health care role of a "nurse navigator" were not considered.

Another effort for clinicians to improve interprofessional collaboration was to create more opportunities for social networking with experts and other clinicians. The clinical guideline for optimal OAT management recommended having a systematic approach to therapy. Clinicians who engage in interprofessional collaboration efforts could promote this systematic approach and facilitate the implementation of the clinical guideline. Firstly, pharmacists and nurses can

connect with experts in the local region to learn more about and improve anticoagulation systems, as suggested by this key informant:

> *"And we're very lucky to have the McMaster so close. They do a thrombosis and hemostasis conference every year so we go to that and the physicians there are remarkably approachable so you just walk up and ask them a question, they're happy to help! Send them emails, they always respond pretty darn quickly so that's another bridge that's making sure you're maintaining that competency is key!"* – KI 6

As clinicians network, this opportunity would maintain competencies in OAT management, help clinicians connect to experts in the field and start a conversation on how to create a broader approach to therapy. Secondly, creating connections with clinicians in other regions can facilitate the implementation of the clinical guideline, as was suggested by this key informant:

> *"[…] looking to other regions that are already doing this and doing this very, very well. And so the folks in Edmonton are doing this very, very well. The Germans, the Swedes, they are doing this very, very well. And we need to be looking more broadly to apply those successes here. And it's about system integration, that's what it boils down to. The systems need to be integrated, the communication needs to be seamless and the patients need to be well-informed and move towards becoming self-managers when appropriate." –KI 2*

Interprofessional collaboration between clinicians can help generate ideas and broaden their perspectives on how to have an integrated and systematic approach to therapy. In turn, this social networking opportunity can facilitate the systemic implementation of the clinical guideline for the optimal delivery of OAT management. Ultimately, creating the new position of a "nurse navigator" and social networking opportunities are two ways to engage clinicians to improve interprofessional communication and collaboration, a behavioural change which ultimately facilitates the uptake of the clinical guideline in community-based AMS clinics. The next theme describes the other behavioural change that clinicians can make to facilitate the implementation of the clinical guideline.

Theme 5: Use of Compatible Software Platforms for OAT documentation

The fifth and last theme illustrated how clinicians can use compatible software platforms for OAT documentation to facilitate the implementation of the clinical guideline for optimal OAT management. The clinical guideline generally recommended that documentation of OAT should be done on a computer software program for timely record-keeping, tracking and retrieval of "accurate and easily accessible" information (Garcia et al., 2008). All participating clinics used computer software programs, albeit not on the same platform, as this key informant described:

> *"Um, no, only that where we need to move more broadly is connecting the INR clinics together. So right now they seem to operate as silos which is hard to overcome but we need to address that and put in strategies of communication to kind of break down those silo barriers. It seems a bit counterproductive for such as large population being managed in community pharmacies, Family Health Teams, by their solo practice physicians and then of course our self-managers, it seems a bit strange that this patient population is not more well connected and the clinicians managing them are not more well connected. So I think we need to think more broadly about creating databases, right?" –KI 2*

As demonstrated, clinicians in the community were operating in silos (isolation) rather than in unity. An integrative approach via compatible for OAT management was one way to facilitate the implementation of documentation standards. This standardized, integrated approach via compatible systems would make the same patient information, such as demographics, treatment details, patient education materials and so on, more accessible to all clinicians in the community for enhanced patient safety, as was suggested by this key informant:

> *" […]So perhaps it makes more sense for everyone to pick a tool, whether it'd be INROnline or DonAC or PharmaFile or whatever it may be, there are different tools out there and they are online based. It would make more sense that we all use the same one so that the databases could be combined, the information could be shared, the INR clinic leads could collaborate with each other much more easily and patients could get more support, patient education materials and then with that, we can get a much better sense of are we actually do a good job to manage these patients or what could we be doing to*

> *improve their outcomes and improve safety and move towards patients becoming self-managers." –KI 2*

Patient information and therapy elements can be streamlined across the community AMS clinics if clinicians change their behaviour to adopt compatible software platforms for documentation of OAT. All software platforms should be interoperable to combine standardized patient information for anticoagulation management. For example, the key informant mentioned that a combined system can provide shared information, such as patient educational materials to support them in therapy. Clinicians can then make informed decisions about OAT management with the use compatible software platforms because documented information would be up-to-date and available to all of those involved. .

Furthermore, the use compatible software platforms for documentation was already implemented in one region with much success, although it was not widespread in the WWLHIN community. As this key informant said:

> *"[…] So everybody is working on a very similar system and with the plans to integrate all the physicians who are not part of the [organization], that's gonna make it that much better. So the ability for system integration has really been helpful for us but I could see where it could be a huge barrier in community where they don't have the processes set up for that to happen."* KI 6

From this case, other clinicians can learn about the benefits of a compatible software platform, although there was still much to do to create a truly integrative system. These key informants made it clear that a behavioural change to using a compatible software platform can facilitate the implementation of the clinical guideline in other regions of the WWLHIN community. This behavioural change would not only encourage the documentation standards in the clinical guideline, but it can also facilitate the uptake of other recommendations that focus on having a standardized protocol to therapy. Documentation on compatible software platforms would make

all patient information accessible to other clinicians in different care settings for an integrated and systematic approach to OAT management.

Summary: Themes for Research Objective 2

Ultimately, themes 4 and 5 addressed research objective 2 by depicting how behavioural changes facilitate the implementation of the clinical guideline for optimal OAT management. This clinical guideline recommended a systematic approach to OAT management in all aspects, so when clinicians change their behaviours to promote this approach, it would lead to the optimal delivery of OAT management. The first behavioural change was described in theme 4, which showed how clinicians can engage in efforts to improve interprofessional communication and collaboration to facilitate the optimal delivery of OAT management. A "nurse navigator" could act as a contextual prompt to behavioural change of clinicians working in isolation to effectively communicating with one another. In addition, social networking with experts and clinicians in other regions can prompt interprofessional collaboration. So, when clinicians engage in these two efforts to improve inter-professional communication and communication, this behavioural change facilitates the uptake of the clinical guideline as a whole. Furthermore, theme 5 illustrated how using compatible software platforms to document OAT can encourage the uptake of the clinical guideline. Clinicians who change their behaviour to uniformly document elements of OAT management in a compatible software platform can promote the standardized approach to therapy and encourage the uptake of the clinical guideline in practice. Essentially, these two themes showed how behavioural changes could facilitate the optimal delivery of OAT management in the WWLHIN community.

4.6 **Conclusion**

This chapter summarizes the key findings of the data analysis. The study had six AMS clinics with a total of eight key informants. The most salient themes addressing research objectives 1 and 2 sought to explore how existing intrinsic and extrinsic factors hindered or supported, and how behavioural changes facilitate the implementation of the clinical guideline for optimal OAT management. The end of sections 4.4 and 4.5 summarized these themes for research objectives 1 and 2 respectively. The next chapter presents the discussion of these key findings within the context of other work or gaps in the literature.

CHAPTER 5: DISCUSSION

5.1 **Introduction**

Community-based AMS clinics offer a practical and coordinated approach for chronic OAT management, particularly for frail older persons with AF (J. E. Ansell, 2009; Heckman & Braceland, 2015). AMS clinics are more cost-effective than usual care, because of improved patient outcomes and reduced hospitalizations (J. E. Ansell, 2009; Campbell et al., 2000; Eckman et al., 1995). There are, however, challenges for an integrative and systematic approach to OAT management in AMS clinics. To address this need, clinicians can apply Garcia et al.'s (2008) clinical guideline to deliver optimal OAT management in outpatient AMS settings, but there is limited research on how to go about implementing a regional program. The findings of this study provide insight on how various factors counteract, support and facilitate the potential uptake of the clinical guideline in community AMS clinics for a frail elderly population. This chapter compares the findings with existing work in order to highlight the contributions of this study to the literature. In closing, limitations of qualitative studies and directions for further research are also outlined.

5.2 **Key Themes for Research Objective 1**

The findings of the study revealed three key themes related to research objective 1, which described how various factors counteracted or supported the implementation of Garcia et al.'s (2008) clinical guideline in AMS settings for a frail elderly population.

Theme 1: Inadequate Reimbursement for Logistical Operation of AMS Clinics

In determining that inadequate funding was a key barrier to implementation, the finding suggests that if key informants cannot cover their costs, they cannot offer optimal OAT

management per the clinical guideline. This sentiment was shared by more than half of the community pharmacists providing INR monitoring for older people in a New Zealand study, who claimed that services could not continue without appropriate funding (Tordoff, Chang, & Norris, 2012). There is currently no coverage of services and materials for OAT management by pharmacists and nurses in Canada, except for Quebec (Coaguchek, 2016).

Starting in 2014, Quebec has been covering test strips for patient self-testing and management using a POC INR device, and allowing pharmacists to bill for OAT management services (Coaguchek, 2016; Régie de l'assurance maladie du Québec (RAMQ), 2014). Medicare Part B in the United States of America also covers the cost of test strips, as well as devices for patient self-testing and management, but still does not allow pharmacists to bill for OAT management services (Medicare, 2017). In contrast, Ontario's Ministry of Health and Long Term Care does not allow the billing of POC-INR devices, test strips or OAT management services by both patients and non-physicians. Instead, community-based pharmacists previously relied on the Pharmaceutical Opinion Program to partially recover costs for OAT management services, but only when INR values change sufficiently to require a change in OAC dose and this change is approved by a physician (Ontario Ministry of Health and Long Term Care, 2008). In comparison, FHTs receive funding from the Ministry of Health and Long Term Care to sustain initiatives of interprofessional primary care, such as chronic disease management programs. Specifically in 2016, the Government of Ontario invested $85 million to recruit and retain non-physician health care staff in FHTs (Association of Family Health Teams of Ontario, 2017), but even so the allocation of funds to AMS programs are not guaranteed. The findings suggest that the allocation of funds to AMS programs within FHTs are not consistent and remains a challenge

from year to year. Therefore, such inequitable funding goes against principals of care delivery elaborated by the Ministry of Health and Long-Term Care.

In light of these findings, there needs to be appropriate and assured funding for community AMS to continue their valuable services. Pharmacist-led AMS clinics have been shown to be superior and safer than usual care (Bungard et al., 2009; Canadian Agency for Drugs and Technologies in Health, 2012; Poon, Brown, & Braun, 2007). These services are especially important for the frail elderly who may benefit the most from pharmacist-led AMS (Heckman & Braceland, 2015; Poon et al., 2007). Poon *et al.* (2007) found that older veterans had reduced thromboembolic events from pharmacist-led OAT management compared to usual care. Targeting frail seniors can potentially be cost-saving because they have the most to lose from poor care, although the benefits of well-managed AMS also extend to a variety of other stakeholders, including physicians, pharmacists and caregivers (Bishop, Young, Twells, Dilon, & Hawboldt, 2015; Shaw et al., 2014; Thompson, Ragucci, Fermo, & Whitley, 2009).

Despite many benefits, a study by Schulman *et al.* (2010) revealed the Ministry of Health's perspective on the high costs of long-term warfarin therapy management in Canada. It showed that OAT management using warfarin was 10 times the lowest cost of the drug. However, the cost analysis was based on only three models of care: hospital-based sites (physician-led and pharmacist-led) and community sites led by physicians. The cost analysis was incomplete because the authors did not have enough data to analyze the cost for a pharmacist-led community site and the potential benefits on the management of other conditions, especially for frail seniors in this setting. Despite that, the study still suggested that the cost analysis be used to compare with newer anticoagulants (Schulman et al., 2010). There were potential conflicts of interest from the majority of authors working with pharmaceutical companies (Schulman et al., 2010).

In light of the evidence, the Ministry of Health should consider how to optimize warfarin therapy instead of replacing it. Warfarin is not as expensive as NOACs and has a more reliable history of use, efficacy and safety (Bauer, 2013). Analyses have shown that clinic-based POC INR testing is more cost-effective than usual care led by physicians (J. E. Ansell, 2009; Campbell et al., 2000; Eckman et al., 1995). The government should focus their funding on community pharmacist-led AMS that aim to optimize OAT management. However, laboratory INR testing for usual care continues to be covered by the Ministry of Health (Ontario Health Insurance Plan, 1999). If inadequate billing models for pharmacist-led AMS persist, OAT management may fall back to usual care, causing negative effects to patients. A study established a significant decline in the quality and satisfaction of OAT management for patients transitioning from pharmacist to physician-managed care (Garwood, Dumno, Baringhaus, & Laban, 2008). Therefore, the finding suggests that it is important for community AMS clinics to receive consistent funding for logistical operation. That way, clinicians can cover costs for their services and work toward optimizing OAT management in the community, especially for frail older persons.

Theme 2: Awareness of how to apply knowledge to support practice

The finding that key informants knew how to apply general knowledge of the clinical guideline to support practice is consistent with other findings. An Albertan study developed a three-phase approach to establish community-based AMS clinics for optimal OAT management (Bungard, Hamilton, & Tymcak, 2006). In phase one, they developed a core AMS program to create, test and establish key components for the anticoagulation program, such as policies and procedures, and teaching modules. In the second year, phase two proceeded to teach these key components to pharmacists through three ways: (i) a web-based educational module to provide the fundamental knowledge; (ii) a 4-week experiential component at the core clinic; and (iii) a

self-directed component with therapeutic discussions to integrate knowledge with practice. These modules were created to teach pharmacists about OAT management in AMS settings. Finally, in the third phase, they successfully applied their knowledge and skills to establish AMS clinics at their own practices (Bungard et al., 2006). As a result, it showed that pharmacists understood how to implement key components to run AMS clinics, which was consistent with the finding of this study that being aware of the general knowledge and skills supported the implementation of the clinical guideline for optimal OAT management.

This finding is also consistent with a review that highlighted key features to consider to implement anticoagulation clinics (Bounda, Ngarambe, Hong, & Feng, 2013). The review found strategies for delivering effective OAT management in anticoagulation clinics, including the importance of team composition, pharmacist education and competencies for OAT management (Bounda et al., 2013). It showed the importance of learning how to apply components for optimal OAT management, which further supports the finding that awareness of the knowledge and skills were important for delivering optimal OAT management per Garcia et al.'s (2008) clinical guideline.

Furthermore, the finding that it was important for key informants to be aware of how to organize themselves to meet patients' needs to deliver optimal OAT management is consistent with other work. A New Zealand study of community pharmacists who provided a range of services, including INR monitoring, revealed that working cooperatively with other health care providers, such as nursing staff, was important for developing programs (Tordoff et al., 2012). These community pharmacists knew that working cooperatively within their roles supported the delivery of services, further endorsing the finding that awareness of applying the knowledge of

the qualifications of personnel and supervision supported the implementation of the clinical guideline for optimal OAT management.

Secondly, the finding that it was important for key informants to know about care management and coordination standards to support practice is also seen in other studies. Bungard *et al.'s* (2006) core AMS clinic developed and refined policies and procedures that adhered to national and local standards, which helped to engage physicians and pharmacists to run the clinic efficiently. Later, pharmacists in that study successfully adapted these policies and procedures to their own practices (Bungard et al., 2006). As such, those results endorsed the finding of this study that clinicians' awareness of established policies and procedures supported the delivery of optimal OAT management.

Thirdly, the finding that key informants were aware of tailoring patient education to support practice is consistent with other studies. One review article found that the pharmacist's ability to communicate, provide patient education and counseling was important to developing an anticoagulation clinic (Bounda et al., 2013), and to optimizing patient outcomes (Burke et al., 2008). One German study showed that standardized patient education was effective for improving knowledge and patient safety during anticoagulation (Vormfelde et al., 2014). Reports also indicated that strategies such as standardizing educational content, focusing on topics of patient safety, and using effective delivery methods optimized OAT management (Wofford, Wells, & Singh, 2008). As shown in that study key informants of this study utilized some of these methods, such as delivering relevant information in small "chunks" to accommodate for individual patients' educational needs. Hence, key informants showed an awareness to apply patient education standards to support practices of optimal OAT management, according to Garcia et al. (2008).

Fourthly, the findings suggest that key informants were aware of the standards for patient selection and assessment of therapy and were applying them to practice as best as they can. This finding supported implementation of the clinical guideline and is consistent with other findings. One study showed health professionals, including pharmacists and nurses, viewed comprehensive assessment as necessary for stroke prevention in AF (Wang & Bajorek, 2016). Experienced pharmacists and nurses who managed OAT emphasized the medication safety and management aspects of antithrombotic use, such as the cognitive function, lifestyle factors, polypharmacy issues and adherence in patients (Wang & Bajorek, 2016). This closely resembled the finding of this study where the majority of key informants in this study knew how to select and assess patients using these same factors, except for some discrepancies in the frailty assessment.

Other work supported the finding that key informants had an incomplete assessment of frailty. One review reported that the diagnosis of frailty syndrome was often based on chronological age, leading to an inadequate risk assessment (Uchmanowicz et al., 2015). Instead, clinicians should focus on frailty, which is reflects biological age better than chronological age (Heckman & Braceland, 2015). Despite that, the findings indicate that key informants knew which components of frailty to assess in patients. A recent study on stroke prevention in frail elderly patients proposed a practical algorithm for tailored anticoagulation therapy to guide clinicians on selecting appropriate VKAs or NOACs (Granziera et al., 2015). Granziera et al. (2015) created a diagram to show all aspects of frailty, which were components mentioned by key informants in this study. The finding showed that key informants were aware that assessment and selection of frail older patients with AF depended on their nutritional status, cognitive issues, risk of falls, adherence and gait tests. In turn, the awareness to apply these frailty components in

the assessment and selection process supported the implementation of the clinical guideline in practice. However, the currently ad-hoc assessment of frailty needs to be more standardized and rigorous to systematically determine who in particular is frail and needs additional intervention or supports.

Moreover, the finding that key informants' awareness of how to systematically apply therapeutic knowledge during initiation, stabilization and maintenance of therapy supported implementation is consistent with other findings. Studies have shown that the 4mg regimen was effective for initiating elderly patients with non-valvular AF on warfarin therapy to stabilize them in the therapeutic range (Siguret et al., 2005; Sridhar et al., 2014). This evidence has been established for optimal OAT management for the frail elderly with AF and was used by key informants in this study to support optimal practices of OAT management, as outlined by Garcia et al. (2008).

Lastly, in determining that key informants were aware of how to apply a systematic process for maintenance dosing and follow-ups, the finding supported the implementation of the clinical guideline and is consistent with other studies. CADTH endorsed a systematic plan for managing long-term assessment, dose adjustments and follow-up testing for optimal OAT management (2016), a conclusion that resonated with Garcia et al.'s (2008) clinical guideline. Other work also supported a systematic approach to maintenance therapy using evidence-based guidelines (J. Ansell et al., 2008; CADTH, 2016; Holbrook et al., 2012), and validated algorithms for dose adjustments to improve delivery of OAT management (Harper et al., 2014). This systematic approach was used by key informants to maintain therapy showing that they were aware of the knowledge to support practice. Furthermore, one implementation study showed that high clinical skills supported implementation of a mental health guideline, which is

consistent with the finding of this study that key informants had the knowledge and skills to maintain therapy and thus, supported the implementation of the clinical guideline for optimal OAT management.

Theme 3: Tailored organizational supports for the frail elderly

Although there needs to be a more rigorous way to assess for frailty, key informants knew how to apply an ad-hoc assessment of frailty to determine who in particular needs additional attention. Once identified, the findings suggest that tailored organizational resources for the frail elderly supported the delivery of optimal OAT management in community AMS clinics. Organizational supports, such as physical tools, face to face interactions, and home visits optimized therapeutic activities in AMS clinics by improving medication adherence and health monitoring. A study of pharmacists in New Zealand demonstrated that compliance packaging, repeat prescription reminder services, home deliveries and home visits improved medication adherence and safety for older patients, especially with cognitive issues in a range of services including INR monitoring in community pharmacies (Tordoff et al., 2012). Patients also felt more involved in their treatment when they had printouts to remind them of their next dose and test date, as shown in a pilot study of a pharmacist-led AMS clinic (Shaw et al., 2014). New warfarin patients were also empowered to adhere to treatment in post-discharge home visitations (Stafford et al., 2011). For patients who can attend clinics, pharmacists in a study by Tordoff *et al.* (2012) found that face-to-face counseling were helpful for improving patients' knowledge or understanding of their medications (Tordoff et al., 2012). In person counseling was particularly important for medication adherence in older adults who tend to take on average seven prescriptions per day (Tordoff et al., 2012).

Another study also showed that frequent face-to-face counseling in pharmacist-managed anticoagulation clinics helped patients (mean age of 58.2) to improve their overall health by monitoring health issues not related to anticoagulation management (Hicho, Rybarczyk, & Boros, 2016). Pharmacists managed the majority of older patient's overall health through interventions, such as promoting continuity of care, assessing and triaging health concerns to other providers, acquiring necessary diagnostic tests, reconciling medications, modifying therapy and providing drug information and counseling (Hicho et al., 2016). Similar findings were found in another study of pharmacists in Veterans Health Administration (VHA) anticoagulation clinics (McCullough et al., 2016). This study further supported the value of frequent face-to-face interactions, point-of-care or telephone visits in the pharmacist-patient relationship, helping pharmacists to manage warfarin therapy more effectively. Pharmacists took a more active role to identify unmet needs, such as underlying mental and health conditions, then connected them to appropriate health care providers as needed (McCullough et al., 2016). These studies corroborated the finding that tailored organizational supports for the frail elderly, such as physical tools (blister packaging and verbal or written reminders), face-to-face interactions and home visits, supported the implementation of the clinical guideline through improving medication adherence and monitoring of other health issues.

5.3 **Key Themes for Research Objective 2**

The findings of the study revealed two major themes related to research objective 2, which described how various factors facilitate the delivery of optimal OAT management, according to Garcia et al.'s (2008) clinical guideline, in community AMS settings for a frail elderly population.

Theme 4: Engage Efforts to Improve Interprofessional Communication and Collaboration

The finding that clinicians' engagement in interprofessional communication and collaboration facilitates implementation of optimal OAT management is consistent with other work. Bounda et al. (2013) found that effective communication with other health care providers was vital for establishing successful anticoagulation clinics. A pilot study of a community pharmacist-led AMS clinic in New Zealand showed the importance of strong collaboration between health care professionals in wider implementation, especially with general practitioners to support the role of community pharmacists and nurses (Shaw et al., 2014). Although general practitioners (GPs) were hesitant about pharmacists taking on clinical activities, studies showed that the pharmacist-GP relationship improved through building trust and confidence in the pharmacist as a 'warfarin expert' who communicated with and worked closely with GPs (Hatah, Braund, Duffull, & Tordoff, 2012; Shaw et al., 2014). In a later study by Bishop et al. (2015), pharmacists were shown to be supported in their role in OAT management within a multi-family medicine clinic.

One particular area of interest is during transitions of care between the community and hospitals. A study of clinicians' perceptions further confirmed that a breakdown in communication between health care providers in primary care and hospitals was perceived as a key barrier to optimal anticoagulation (Decker et al., 2012). This corroborates the finding that interprofessional communication and collaboration during care transitions facilitates optimal OAT management. One American study emphasized effective communication and collaboration between clinicians for safe care transitions of anticoagulated patients with AF, particularly for elderly patients moving from the hospital back into the community (Deitelzweig, 2013). Clinicians in hospitals and anticoagulation clinics should work closely with one another, but the

findings suggest that community pharmacies had limited opportunity to connect with other providers compared to family health teams. One study found that post-discharge communication between hospitals and pharmacies for medication reconciliation was inconsistent and jeopardized patient safety (Urban, Paloumpi, Rana, & Morgan, 2013). Although FHTs function on a collaborative model of multidisciplinary teams of providers (Ontario Ministry of Health and Long Term Care, 2016) with commitments to patient-centered care, a qualitative study showed that there were still challenges for patient's transition of care when FHTs were not notified (Brown, Ryan, & Thorpe, 2016). This was consistent with the finding that FHTs still faced challenges during patient discharges when there was a lack of communication and close collaboration between providers in the community and hospitals. With this care transition issue, the finding suggests that having the additional role of a 'nurse navigator' can prompt interprofessional communication and collaboration. However, the financial implications of introducing this additional role needs to be considered.

One report outlined that nurse navigators were advocates who educated, guided and coordinated services for patients, families and care providers (McMurray & Cooper, 2016). Like studies have shown, nurse navigators can act as liaisons to multidisciplinary teams of care providers while they manage patient cases, functioning as both case managers and care coordinators (McMurray & Cooper, 2016; Watts & Lucatorto, 2014). One report showed that nurse navigators in primary care settings were instrumental to service integration and interprofessional collaboration during transitions of acute, post-acute and community care , especially for underserved populations who experience fragmented care (McMurray & Cooper, 2016). Another review of a chronic disease management program for diabetes revealed that registered nurse case managers were vital to improving patient outcomes and satisfaction in the

program (Watts & Lucatorto, 2014). This review showed that there were cost savings and benefits from nurse contact with patients and clinicians that still have to be examined. However, several of these reviewed studies did not have a formal cost analysis of having registered case managers in a chronic disease management program for diabetes (Watts & Lucatorto, 2014). Additional costs are expected when introducing "nurse navigators" to the health care system.

Another solution could be to significantly redesign the role of nurses in primary care settings (Anderson, St. Hilaire, & Flinter, 2012). Existing nurses could either take on the role of a "pod nurse" who would attend to the daily medical and administrative needs of the primary care clinic, or a "coordination nurse" who would work as a case manager, helping primary care providers manage care for complex patients. They proposed that sufficient funding would still be required to support the redesign of nursing roles and incentivize coordination of complex patients. (Anderson et al., 2012). There needs to be further investigation on whether or not redesigning staff roles are effective in prompting care coordination.

An alternative to introducing a new role is for existing pharmacists and nurses to expand their scope of practice to methodically provide care coordination in community-based AMS settings. Anderson et al. (2012) reported that care coordination was often done "as needed" rather than deliberately. McMaster University provides busy clinicians with educational modules to integrate interprofessional education in practice (2013). One module outlined how guided discussion of case studies can become real life opportunities for teaching and learning interprofessional education. Going through this series of modules can help clinicians reach the goals of working and communicating better with other providers to reach patient-centered goals (McMaster University, 2013). As a result, pharmacists and nurses can develop interprofessional knowledge, attitudes and skills to deliberately apply these concepts in practice for a more

systematic and coordinated approach to OAT management, facilitating the delivery of optimal OAT management in AMS settings. In turn, integrating interprofessional education in practice appears to be a more feasible effort than introducing an additional nurse navigator in the health care system to prompt better interprofessional communication and coordination.

Lastly, the finding that social networking among anticoagulation experts in the local and wider regions provides the opportunity for interprofessional collaboration is consistent with other work. The World Health Organization's work on transforming education in health professionals included interprofessional education as one of six themes. The Canadian Interprofessional Collaborative connects world leaders on interprofessional practice and education through hosting conferences and events (2010). Providers, researchers and students exhibit proposals and abstracts to further interprofessional practice and opportunities (Canadian Interprofessional Health Collaborative, 2010). A New Zealand study of community pharmacists providing services, such as INR monitoring to older people, presented peer support from other pharmacists across the country and professional institutions as integral to facilitating services in their clinics (Tordoff et al., 2012). Care providers, such as pharmacists have the responsibility to share their knowledge with students and other colleagues (World Health Organization, 1997), which helps existing and new pharmacists to maintain competencies and gain new knowledge (Bounda et al., 2013). Therefore, other work is consistent with the finding that suggests collaborative efforts from social networking with experts can facilitate the adoption of an integrated and coordinated approach to OAT management, facilitating the implementation of the clinical guideline.

Theme 5: Use of Compatible Software Platforms for OAT documentation

Last but not least, the finding that a compatible software for OAT documentation was a facilitator for implementation is consistent with other work. Optimal OAT management is rooted in evidence-based care, requiring standardized and integrative documentation practices to ensure patient-centered care, a practice that prioritizes continuity and coordination of care. Standardization of the data collection and retrieval process is also necessary for consistent documentation over time during wider implementation of optimal OAT management (Oertel, 2009).

With the advent of dedicated computerized software for anticoagulation management, there are various applications available to collect vast amount of data. However, there are inherent disadvantages with the use of multiple software applications across community AMS clinics, including interface incompatibility, and unorganized, non-standardized data. Efficiency of data collection and retrieval is compromised with incompatible software applications across clinics, making performance reviews of benchmarks and the implementation of coordinated and timely care more difficult (Oertel, 2009). Therefore, clinicians should select software that are interoperable with other data systems, especially hospital-based information systems to create opportunities for information exchange. Benefits in timely care for AMS patients during care transitions, such as admittance and discharge from hospitals can foster continuity and coordination of care. AMS software should also create interfaces with laboratory databases for INR values to be readily available to clinicians not using POC technology (Oertel, 2009).

Another solution is to use web-based software applications, which make it possible to achieve systematic documentation standards across care settings. However, the reality is that the selection of an anticoagulation software program is complicated with many considerations,

including the compatibility of the software's basic features, functionality, interoperability, user support and financial implications to the AMS clinic. There are a variety of dedicated software applications for OAT management created by different vendors with varying needs (Oertel, 2009). Depending on individual clinic's needs, it may be difficult for all community AMS to have interoperable software to be a part of a compatible platform for OAT management. Literature on the implications of using compatible software platforms for OAT management is limited and needs further investigation.

5.4 **Limitations**

Selection bias may influence the findings of the study. Only interested pharmacists and nurses participated in the interviews, and may not have captured implementation difficulties seen in smaller clinics that are not as well run or have closed down. As well, the sampling frame of this study may not be wide enough to capture diverse information because only two nurses were interviewed. Although sampling until the point of saturation was achieved from six interviews with pharmacists, there may be incomplete data from the small sample of nurses. However, it was feasible to combine the perceptions of pharmacists and nurses because they were both care providers in AMS community-based settings who provided the same underlying OAT management. Rather than claim generalizability, it is more important for this research to contribute to a larger project that may include more nurses and pharmacists in its sample. A larger sample size of pharmacists, nurses, doctors and patients in the WWLHIN community, including those in institutional settings should also be investigated to understand care transitions better.

Another limitation was that the kappa coefficient was not calculated due to coding software incompatibility, but the percent agreement between the two coders should be calculated for inter-coder reliability. Since each coder performed a line-by-line comparison of themes for each

transcript, the investigator could have recorded the percent agreement in coding from each transcript. A simple chart to document the coder's agreement could be done for each variable of interest (McHugh, 2012). The chart would have column one as variable (line), two as coder's themes, and three as agreement (Yes= 0; No= 1) to calculate the percent agreement for each transcript (number of zeros/total lines), aiming for an 80% agreement (Lombard, Snyder-Duch, & Bracken, 2002).

However, reaching consensus in coding may be difficult if the second coder does not have an understanding of the context. For example, a quote could clearly be related to environmental constraints as a barrier, but regardless of these difficulties, the circumstances may suggest that key informants may still have the intention to continue services to support implementation. However, that element would be missed by a second coder who does not know the context well. There are more difficulties in coding because Michie et al.'s (2005) psychology theory domains represent distinct factors, rather than an interconnected model. From the underlying theory, Michie and colleagues (2005) mentioned that not all factors were required for successful implementation, but mainly three factors: skills, intention, and environmental resources for the performance of a behaviour. The investigator acknowledged that environmental factors and skills explicitly showed up as key themes in this study, but not intention. Although it was not a key theme, it was interpreted implicitly through inflection and tone of speech during interviews. Intention to continue services was strongly present in key informants who participated in the study hoping to standardize and rigorously advance OAT management systems. In order to prevent isolating factors that affect implementation, Michie et al. (2005) could work toward a dynamic model to interconnect these three factors necessary for the performance of a behaviour.

5.5 **Directions for Further Research**

OAT management for persons with AF needs to be optimized especially for vulnerable populations, such as the frail elderly who tend to move in and out from the community. There should be a broad and uniform approach to managing OAT across facilities in the region to maintain the quality of care. There needs to be continued research to validate optimal practices of OAT management across community AMS settings. In the following section, directions for further research related to each key finding are presented. For each area of focus, further exploratory studies would help gain insights on the problems for further investigation. A summary of research questions for further studies that expand on the study's key findings are shown below in table 9.

Table 9. Summary of further studies

Key Findings	**Research Questions**
1. Inadequate reimbursement for logistical operation of AMS clinics	Before looking at the cost-effectiveness of long-term warfarin therapy, what are the perceptions of other stakeholders in adopting a regional approach to therapy in pharmacist-managed AMS settings in Canada?
2. Awareness of how to apply the knowledge to support optimal delivery of OAT management	What are clinicians' perceptions of adopting clinical tools for frailty assessment of patients with AF during OAT management in community-based AMS settings?
3. Tailored organizational supports for the frail elderly	What are the additional benefits and barriers that could exist by having a pharmacist or nurse regularly review patients with chronic non-valvular AF?
4. Create new opportunities for interprofessional communication and collaboration to facilitate efficient care processes	Instead of adding an additional role in the health care system, further studies should focus on how physicians, pharmacists and nurses can collaborate more effectively? What are the implications of improved interprofessional communication and collaboration for integrating documentation standards?

5. Use of compatible software platform for documentation of OAT to facilitate an integrated, systematic approach to management	What are the perceived benefits and barriers for transitioning to compatible software platforms for OAT management?

Further studies should focus on gathering more qualitative data using the study's methods, but from other stakeholders on their perceptions of adopting optimal practices across a wider community setting. Other stakeholders include general practitioners, specialists, nurses, physician assistants, caregivers, frail elderly patients, and so on. To expand upon the finding of incomplete frailty assessments, one area of focus could be on stakeholders' perceptions of adopting clinical frailty tools for selection and assessment for therapy. Conducting an exploratory study would help stakeholders, including policy makers and clinicians, gain insights on the issues around frailty tools and their use in practice. Secondly, to further explore the finding that tailored organizational supports for the frail elderly supported practice, another area of focus could be on exploring the additional benefits and barriers of regular review of patients with AF. As corroborated by McCullough et al. (2016), there were many additional supports such as face-to-face counselling to help pharmacists to manage warfarin therapy more effectively at the Veterans Health Administration anticoagulation clinics, but there still needs to be further studies in the Canadian context. The pharmacist-patient relationship in community AMS settings was important to delivering optimal OAT management, and for patient compliance.

Not only that, but gaining interprofessional opportunities was a key finding to facilitate optimal practices in this study. Further work should also focus on how pharmacists, nurses and physicians can make a community-wide effort to work better together, especially during care transitions for patients with chronic AF. Then, further studies could look at the implications of improved interprofessional opportunities in the community, including safer transitions of care and better patient outcomes. As well, interprofessional education and competencies may lead to

improved documentation standards on interoperable software. Then, research on the clinicians' perceptions of compatible software platforms for documentation of OAT management should be further explored.

After acquiring deeper insights and community-wide recognition on these research problems, future studies could then focus on the cost-effectiveness of long-term warfarin therapy in pharmacist-managed AMS settings to compare upfront costs with long-term benefits. A cost-effectiveness analysis will not only consider the immediate costs and benefits, but also the long-term outputs of the program such as cost per case prevented. This is why it is important to first gather more qualitative data on the benefits offered in community-wide AMS clinics, such as additional supports for the frail elderly during regular therapeutic reviews. As such, a systems approach will be useful in considering all these elements influencing patient care and health in pharmacist-managed AMS settings. With these studies, the Ministry of Health can make informed decisions to fund community AMS clinics or not. However, this is a considerably long path without ongoing evidence to show support from several stakeholders in the community for a regional approach to OAT management in the community.

In conclusion, further studies inspired by key findings in this study can help optimize OAT management for efficient and quality care across the community to improve health outcomes. As Bungard et al. (2006) conducted a province wide study in Alberta using the health innovation fund for early adoption of community AMS clinics, a similar study should be conducted in Ontario. Further studies on validating optimal practices across community networks can lead to a more complete understanding of the benefits of pharmacist-managed AMS clinics. Initiatives to achieve a wider, integrative approach to OAT management in the community can improve the quality of care and patient outcomes.

5.6 **Implications of Study**

As a theory-based assessment of factors affecting implementation, this study provides strategies for interventions working toward an integrative, regional approach to OAT systems. Insights into how intrinsic and extrinsic factors help, hinder or facilitate the implementation of optimal OAT management in community AMS settings can be useful for clinicians and policymakers. Clinicians can start to bridge gaps within their own clinics by applying these strategies, such as adding tailored organizational supports, improving awareness of the clinical guideline components, or taking initiatives for interprofessional communication and collaboration. Policy makers can consider issues systematic issues of funding and documentation software as logistical barriers to optimal practices of OAT management in community AMS settings. A warfarin registry, like the one conducted by Quebec, could be created for Ontario to assess the optimization of use (Quebec Drug Research Network, 2017). Pharmacist-led AMS clinics in communities across Ontario could join in the initiative to standardize documentation of patient data, as outlined by Garcia et al.'s (2008) clinical guideline. Then, make a combined effort to collate standardized data into a warfarin registry, which can be useful to clinicians and policymakers for monitoring clinical outcomes and performance measures.

5.7 **Conclusion**

This chapter summarizes the key findings in comparison with other work and gaps in the literature, as well as the limitations, directions for further research and implications of the study. In essence, the key findings addressed the research objectives 1 and 2 (see section 3.2), which was guided by the underlying theoretical lens, Michie et al.'s (2005) psychological theory. Table 10 shows how the research objectives were addressed by the key themes and linked to the key

domains (i.e. factors) in the underlying theory that affected implementation of the clinical guideline in this study.

Table 10. Linking key themes with research objectives and domains

Research Objectives	Key Themes	Domains of psychological theory
(1) To explore and describe how existing **intrinsic and extrinsic factors hindered or supported** the delivery of optimal OAT management, according to Garcia et al.'s (2008) guideline, with specific emphasis on frail seniors.	1. Inadequate reimbursement for logistical operation of AMS clinics	(8) Environmental Constraints
	2. Awareness of how to apply the knowledge to support optimal delivery of OAT management	(1) Knowledge (2) Skills
	3. Tailored organizational supports for the frail elderly	(8) Environmental Resources and Context
(2) To discover, describe and identify how **behavioural changes facilitate** the delivery of optimal OAT management, with specific emphasis on frail seniors	4. Create new opportunities for interprofessional communication and collaboration to facilitate efficient care processes	(9) Social Influences (12) Nature of Behaviours
	5. Use of compatible software platforms for documentation of OAT to facilitate an integrated, systematic approach to management	(12) Nature of Behaviours

In conclusion, linking key themes to the domains of Michie et al.'s (2005) psychological that influenced the implementation of the clinical guideline: (1) Inadequate reimbursement for logistical operation of AMS clinics was an environmental constraint; (2) Clinicians' awareness of how to apply knowledge to support practices was having the knowledge and skills; (3) Tailored organizational supports for the frail elderly were environmental resources within their context; (4) Engagement of efforts to improve interprofessional communication and

collaboration was using social influences to prompt behavioural changes; and (5) Use of compatible software platforms for documentation was a proposed system to change the nature of behaviours related to tracking and recording anticoagulation data.

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APPENDICES

APPENDIX A- Environmental Scan Report

Field Visits

A list of 12 potential clinics, including family health teams (FHTs) and community pharmacies within the WWLHIN were compiled with the help of key stakeholders, such as pharmacists in the community for the field visits. I contacted the pharmacists at each of the 12 clinics to explain the purpose of my visit, but in the end, only 7 clinics were appropriate for observations (i.e. regular flow of anticoagulation patients).

I also created a worksheet titled "Practicum Observations" as an observation/interview guideline to use at each visit in order to compare the similarities and differences later on. This worksheet was created out of the brainstorming of "Questions/Topics to Explore" (see appendix Figure 2) to include final questions about the POCT, feasibility in operating the INR-testing site, quality control, barriers/challenges and facilitators.

List of Clinics Visited

- **Family Health Teams**
    - FHT 1, Clinical Pharmacist
    - FHT 2, Clinical Pharmacist
    - FHT 3, Clinical Pharmacist
    - FHT 4, Clinical Pharmacist

- **Community Pharmacies**
    - Community Pharmacy 1, Clinical Pharmacist
    - Community Pharmacy 2, Clinical Pharmacists
    - Community Pharmacy 3, Clinical Pharmacist

Practicum Observations

1. FHT

G.HECKMAN | HSG 641 | SPRING 2015

Name of HCP: Clinical Pharmacist Date: June 1st, 2015

OBJECTIVE: To understand the current processes of INR testing and to identify gaps in real life practice within different health care settings as compared to the literature.

TASK	DONE
POC TECHNOLOGY **POC Device**: CoaguChek XS (Roche Canada) **Software to track**? Posologic (formerly PharmaFile) includes data on… - Name of patient and physician - CHADs Score, diagnosis, other medications, tablet strength - INR range, history of INR scores and notes on adjustments, current period for new dosage (mg), next appointment date - TTR (+/- 10% range, Rosendaal method) and point-prevalence (% days within INR range = days within INR range/ total days that INR scores were taken) **Patient base**? FHT patients only. Drop-in basis M/R mornings at Location 1; alternate W afternoons at Location 2. Patient has a calendar booklet with dosage to take for each day until the next INR test. **Adjustments**? Clinical judgement based on principle taught in Jeff Nagge's Pharmacist-led anti-coagulation course (i.e. considering all risk factors, including CHADs score) - 5-10% increase on their maintenance dose if patient has low INR not due to missed dosages -diet interactions: 1 mg of kale, parsley, and cooked spinach to get to antidote level to affect warfarin -medication interactions, i.e. Tylenol 1300mg for 3 or more days on average will affect INR reading -questions on medical/non-medical factors to assess any further adjustments -principle taught based on validated McMaster's nomogram; but pharmacists don't use algorithm during clinic. **TTR Calculation**? >75% via Rosendaal method for average TTR every quarter for reporting to MoHLTC **Cost/ Billing**? Software covered by the FHT discretionary funding for operation of clinic; device covered by research funding. INR strips covered by physician code billed to OHIP.	☒
FEASIBILITY IN OPERATING INR **TESTING SITE How you started?** Program History started 9y ago using DON AC software (English program costing $8/patient) -patient management system is imperative -English dosing system where daily dosage was the same, so needed to override system if days altered in doses -device needed to be checked for quality at the start of every clinic session Trust in technology?	☒

TASK	DONE
How do you get a medical directive? **- Procedure** o Doctor from the FHT issues a medical directive from the doctor to manage warfarin therapy; initiate, maintain and adjust the dosage. o Nurse performs the test using the device and strips o An INR reading is inputted into the software, and adjustments are made based on the pharmacist's knowledge based on past history of INR scores and follow-up medical/ non-medical questions to determine why INR is low or high (i.e. interactions with other medications or with lifestyle factors –diet, exercise, stress, etc.) o Nurses sometimes cover for the pharmacist in-charge o Pharmacist fill in the calendar booklet for the patient, advise them of the maintenance dosage if changed and make next appointment based on their judgement based on training/experience ▪ Dosage in booklets are written in mg or tabs depending on patient's preference **Trust in technology by MDs?** Yes, due to evidence in the literature. Also trusts Jeff as the pharmacist managing their patients. **Networks within Community? How do you deal with special cases? "Go-to" Resources?** **-**Physician or other colleagues such as the local hematologist -Course material from training program -Encouraged to make links in the community on their own; there is no platform for communication between HCPs offering clinics in the area.	
QUALITY CONTROL **Device:** Quality of device tested every year by One World Accuracy (formerly Digital PT) o Otherwise, no need to match to lab-test because they are not the gold standard o Over-estimates INR between 3 and 4 **INR Training/Mentorship**:Training program at UW School of Pharmacy and trained nurses at the FHT to cover his shifts. - *Pharmacy school anticoagulation program* o 6 weeks online + 40 readings with 60h coursework + 5 case studies + online exam o Mentorship includes 3 clinics o Trained 165-170 people- including pharmacists, nurses, residents and other HCPs **Availability of trained staff:** Clinical pharmacist, several trained nurses	☒
CHALLENGES/ BARRIERS? -**Why do you think POC technology is limited in use in Canada**? Funding issues with the INR strips. Need trained and experienced HCPs running the clinic. -**Trust issues between Doctor-Pharmacist?** Minimal in FHT because Jeff is a well-known advocate and professor for INR testing clinic. Doctor trusts his management skills. -**Collaboration with other HCPs for continuity of patient care (i.e. past INR reading, meds, if patient moves, etc)**? Cardiologist, Hematologist, other colleagues including pharmacists in other cities/ regions in case patient moves.	☒
WHAT WORKS? **-**Rapport with patients -Asking the right questions (medical and non-medical) to adjust warfarin -Experience and mentorship of pharmacists to run an anticoagulation clinic	☒

2. Community Pharmacy

G.HECKMAN | HSG 641 | SPRING 2015

Name of HCP: Clinical Pharmacist Date: June 11, 2015

TASK	DONE
POC TECHNOLOGY **POC Device**: CoaguChek XS (Roche Canada) **Software to track**? Posologic (formerly PharmaFile) includes questions/prompts on the program **Patient base**? Patients in the community; 60-70% of patient base is valve; # patients. Does home visits for non-mobile patients. **Adjustments**? Manual based on clinical judgement based on Jeff Nagge's principle of +/- 10% **TTR Calculation**? 70% skewed down because of new patients who are not yet stable; 80% for long-term patients. **Cost/ Billing**? MedsCheck ($25 follow up); Site pays for program and device.	☒
FEASIBILITY IN OPERATING INR TESTING SITE **How you started?** January 2015 after taking Jeff's program. **Trust in technology**? Yes. **How do you get a medical directive**? Authorization per patient; fax with information sheet and fax every result and follow up plan to MD. **Trust in technology by MDs**? Cardiologists prefer NOACs; Pharmacist has to explain and reassure MDs of his program and skills. **Networks within Community? How do you deal with special cases? "Go-to"** **Resources**? Colleagues, Jeff Nagge, Course notes, physicians	☒
QUALITY CONTROL **Device**? Quality Control done at initiation of program; still too new to consider another quality test. **INR Training/Mentorship**: Anticoagulation Course **Availability of trained staff**: Pharmacy Student and Clinical Pharmacist	☒

TASK	DONE
CHALLENGES/ BARRIERS? -**Why do you think POC technology is limited in use in Canada?** o unawareness o billing issue o pharmacist: cost of being trained in the anticoagulation course o MDs are conservative and don't trust pharmacists that they don't know to manage their patients just in case an adverse event occurs, which would be the responsibility of the primary physician **-Any perverse billing incentives?** X community pharmacy was being audited for the MEDSCHECK program by the ODB -**Trust issues between HCPs? Doc-pharm? Pharm-patient? Pharm-pharm (transfers)?** If the doctor doesn't know the pharmacist, they don't give their authorization. Through other services provided by the pharmacist, the doctor can come to trust the pharmacist's abilities. Patients are on board and trust the pharmacist.	☒
WHAT WORKS? Rapport with patients Trust from MDs Training and experience from anticoagulation program Initiative from pharmacist IP communication and collaboration	☒

3. FHT

G.HECKMAN | HSG 641 | SPRING 2015

Name of HCP: Clinical Pharmacist Date: June 15, 2015

TASK	DONE
POC TECHNOLOGY **POC Device**: CoaguChek XS (Roche Canada) **Software to track**? INROnline and Telus EMR (documents on separate spreadsheet) **Patient base**? Patients; majority 65+ **Adjustments**? Clinical judgement based on principle taught in Jeff's program: +/- 10%. Claims that INROnline adjustments are overestimations of the actual INR so they use clinical judgement first, then refer to program's adjustment as support **TTR Calculation**? Average TTR = 70% ; no individual TTR's **Cost/ Billing**? OHIP service	☒
FEASIBILITY IN OPERATING INR TESTING SITE **How you started**? Person X started the anticoagulation clinic after training with Jeff. **Trust in technology**? Yes, literature to support it. **How do you get a medical directive**? FHT physicians authorize pharmacists to see all their warfarin patients. **Trust in technology by MDs**? Yes, because doctor knows/ trust FHT pharmacist **Networks within Community? How do you deal with special cases? "Go-to" Resources**? Physicians in FHT, Jeff Nagge, referral to emergency if cannot reach physician	☒
QUALITY CONTROL **Device:** Calibrated 3x/year for quality control **INR Training/Mentorship**: Jeff's anticoagulation course **Availability of trained staff**: Nurses and Clinical Pharmacist	☒
CHALLENGES/ BARRIERS? -**Why do you think POC technology is limited in use in Canada**? Funding, billing -**Any perverse billing incentives**? None for FHT because they allocate the funds to the program. Not billed directly to OHIP or ODB. -**Collaboration with other HCPs for continuity of patient care (i.e. past INR reading, meds, if patient moves, etc**)? Jeff Nagge, course notes, physician, nurses, community pharmacist if need to clarify other medications, other colleagues (not so much the cardiologist)	☒

4. Community Pharmacy

G.HECKMAN | HSG 641 | SPRING 2015

Name of HCP: Clinical Pharmacists Date: June 25, 2015

TASK	DONE
POC TECHNOLOGY **POC Device**: CoaguChek XS (Roche Canada) **Software to track**? Posologic (formerly PharmaFile) **Patient base**? Patients in the community and from the adjacent doctor's offices; drop-in basis; majority of their patients fill their prescriptions here. **Adjustments**? Clinical judgement based on Jeff's principles and teachings. INROnline doesn't adjust for special situations, so clinical judgement is used first. **TTR Calculation**? 78% built in TTR calculator. **Cost/ Billing**? Medscheck; government is not allowing pharmacists to bill if INR adjustments are stable and needs no changes. Need to do an annual meds review, papers to sign by patient to submit to ODB.	☒
FEASIBILITY IN OPERATING INR TESTING SITE How you started? 5-6y ago after training in Jeff's anticoagulation program Trust in technology? Assessed variability between lab and POCT device How do you get a medical directive? Dr. offices surrounding the pharmacy. Knowing the doctors and having a good relationship with them so they can trust their skills. **Trust in technology by MDs**? At first, it was new, but as they started using them, the doctors warmed up and started becoming familiar with the new technology. Although Cardiologists prefer NOACs because there is no need to monitor their patients— sometimes they have no time. It was actually protocol to offer NOACS e.g. Xarelto at one clinic but no evidence it's effective, and apixaban at another which is the best NOAC with 62% TTR. Doctors usually gave authorization if their patient's INR is equal to or less than 5. **Networks within Community? How do you deal with special cases? "Go-to" Resources**? Jeff Nagge, Physicians , Other Colleagues	☒
QUALITY CONTROL INR Training/Mentorship: Anticoagulation program Availability of trained staff: 2 pharmacists on site in a separate room used for drop-in INR-testing	☒

TASK	DONE
CHALLENGES/ BARRIERS? -**Why do you think POC technology is limited in use in Canada?** Billing Medscheck only if INR needs adjustment. Cost of POCT ($25test, $7 strips) vs. lab-test ($18) but without the long wait and pharmacists can provide patient counselling. Patient interaction about missed dosages, mixed up tablet strengths and catch any mistakes before they get worse at consistent meetings. **-Any perverse billing incentives**? ODB Medscheck: requirements are narrow (seniors/social assistance are eligible but need >3 medications) -skills-set of pharmacy; "counter" medscheck is trying to capitalize on the reimbursement -But it is meant to incentivize the pharmacist to provide service to patients -**Trust issues between HCPs? Doc-pharm? Pharm-patient? Pharm-pharm (transfers)?** Not a problem for those who know the doctor well enough. Patient doesn't always disclose all medications if not a client at the pharmacy → unnecessary liability for both parties Switching pharmacists- dispensing all medications to prevent drug-drug interactions but it may cause friction between pharmacists in the community if they think Pharmacy is "stealing their business" -**Collaboration with other HCPs for continuity of patient care (i.e. past INR reading, meds, if patient moves, etc**)? Dispense all medications at Pharmacy so they know other medications patients are taking Doctor next door or have contact via phone/fax	☒
WHAT WORKS? -Rapport with patients, trust and easy access to pharmacists -Professional Opinion and Intervention for patient advocacy -Urge and engage patients for treatment to manage co-morbidities -Privacy in professional setting -Time for patients to express concerns -Clinician to question and give advice to patients	☒

5. Community Pharmacy

G.HECKMAN | HSG 641 | SPRING 2015

Name of HCP: Clinical Pharmacist Date: July 13th, 2015

TASK	DONE
POC TECHNOLOGY **POC Device**: CoaguChek XS (Roche Canada) **Software to track**? Posologic (formerly PharmaFile) **Patient base**? Referral based from the community; total of # patients with # doctors on board. Patients mostly 65+ **Adjustments**? Clinical judgement based on Jeff's principle. **TTR Calculation**? 71% two years ago. **Cost/ Billing**? Medscheck requested by Physician. Some patients don't qualify so it's $20/test. Narrow requirements by ODB: check out website to see.	☒
FEASIBILITY IN OPERATING INR TESTING SITE **How you started**? 3 years ago; introduced to anticoagulation clinic by Clinical Pharmacist at FHT **Trust in technology?** Yes, validated by studies in the literature **How do you get a medical directive?** Community doctors, referral based. 40 doctors authorized by doctor to treat all their anticoagulation patients. **Trust in technology by MDs**? Yes, via successful clinical studies for CoaguChek XS and additional references. **Networks within Community?** How do you deal with special cases? "Go-to" Resources?	☒
QUALITY CONTROL **Device:** Quality check yearly **INR Training/Mentorship**: Anticoagulation Program **Availability of trained staff**: 2 pharmacists on site	☒
CHALLENGES/ BARRIERS? -Why do you think POC technology is limited in use in Canada? Funding issues. -Any perverse billing incentives? FHTs controversy with billing.	☒

TASK	DONE
-Trust issues between HCPs? Doc-pharm? Pharm-patient? Pharm-pharm (transfers)? 1.Minimal trust issues if rapport with doctors and have other doctors backing the program up. 2. Don't want to mess with patient's relationship with their current pharmacist so patients do not need to switch to their pharmacy to access the clinic; however, they are required to pay $100 to start. 3. Pharmacist has rapport with doctors and there are some doctors advocating for the program 4.Hospital referrals too. 5. Patients sometimes do not disclose all meds used such as antibiotics, which is especially difficult if it's due to memory issues/cognitive issues → need to refer to CCAC -**Collaboration with other HCPs for continuity of patient care (i.e. past INR reading, meds, if patient moves, etc)**? Collaborate with doctors advocating for program, other pharmacists for up-to-date meds for patients, physicians giving authorization if INRs are too high or low, other colleagues **-Others** If pharmacist working for FHT and own pharmacy, there could be a conflict of interest if sharing EMRs and patient info.	
WHAT WORKS? - Close rapport with doctors and patients -Long-standing relationships - M/W INR clinic days by appointment in the office -Medscheck at the same time -Patient advocacy and help counsel patients to get right health service by noticing first signs through visits	☒

6. FHT

G.HECKMAN | HSG 641 | SPRING 2015

Name of HCP: Clinical Pharmacist Date: July 22nd, 2015

TASK	DONE
POC TECHNOLOGY **POC Device**: CoaguChek XS (Roche Canada) **Software to track**? Practice Solutions - Telus EMR only system includes INR score range (In/out of therapeutic range) **Patient base**? FHT patients ~# total; 60% are older adults with AF; all physicians sign one directive for all their patients. **Adjustments**? University of Wisconsin- validated algorithm (nomogram) **TTR Calculation**? Point prevalence **Cost/ Billing**? FHT discretionary funds for POCT (device and all program related costs)	☒
FEASIBILITY IN OPERATING INR TESTING SITE **How you started?** Pharmacist initiated through "gap analysis" to see who would benefit from one-on-one staff attention. **Trust in technology**? Yes. Studies to show effectiveness. **How do you get a medical directive**? Authorization from FHT doctors. Program in the FHT so doctors get involved. **Trust in technology by MDs**? Yes. Studies to show effectiveness. **Networks within Community? How do you deal with special cases? "Go-to" Resources?** Doctor in the FHT, course notes, nurses etc for DVT duration	☒
QUALITY CONTROL **INR Training/Mentorship:** BC anticoagulation program for 5 days then it became outdated so they still use the philosophy to train other nurses **Availability of trained staff**: Three; Clinical pharmacist, nurses	☒
CHALLENGES/ BARRIERS? **-Why do you think POC technology is limited in use in Canada?** 1.Managers- accountability issues in the FHT 2.No comparison for POC vs. lab? [Shows gap in knowledge to action! That's why there's trouble with funding!] 3.Scheduling barriers with HCPs- time for other programs	☒

TASK	DONE
4.Cost of strips - unsure about funding each fiscal year **-Any perverse billing incentives?** None since FHT funds them. Controversy if funds not used efficiently. -**Trust issues between HCPs? Doc-pharm? Pharm-patient? Pharm-pharm (transfers)?** All involved in FHT so there is minimal issue as long as it's a FHT pharmacist doing a program. **-Collaboration with other HCPs for continuity of patient care (i.e. past INR reading, meds, if patient moves, etc)?** *EMR messaging system with doctors or face-face interaction; barely contact Cardiologist. *Community pharmacies have no communication with FHTs if they don't fill a prescription 1.Need documentation 2.Infers with trust of pharmacies with the FHTs 3.Nurse education to document properly but also workload issues * Assess bridging for patients into surgery → heparin needles **Others:** -Each FHT operates differently and has its own work routines and related issues -Low risk guidelines for bridging warfarin before surgery not available? [gap in knowledge: need to see CHESS guidelines!] -Not using software for adjustments and using their own clinical judgement based on the nomogram; but not standardized protocol each time.	
WHAT WORKS? **-**Education sessions for nurses for critical thinking when receiving INR form lab (to ask questions before dose adjustments on the phone when doing it the usual care way) -MedsReview; check blood pressure and address other patient concerns such as dizzy spells, fall risks and surgery bridging	☒

7. FHT

G.HECKMAN | HSG 641 | SPRING 2015

Name of HCP: Clinical Pharmacist Date: August 13, 2015

TASK	DONE
POC TECHNOLOGY **POC Device**: CoaguChek XS (Roche Canada) **Software to track**? Posologic (formerly PharmaFile) + EMR (Telus) **Patient base**? # patients (~# physicians in the FHT) **Adjustments**? Clinical judgment using algorithm based on a combination of CHESS guidelines, Jeff's prinicple, PharmaLearn at University of AB **TTR Calculation**? Pharmacy co-op students make a excel worksheet to calculate TTR every 4 months. TTR= 70-75% all patients **Cost/ Billing**? FHT Global budget (L/G physician codes ceased); report #counts to MoLTC but they aren't really checking so they stopped doing it.	☒
FEASIBILITY IN OPERATING INR TESTING SITE **How you started?** August 200# first project to start this clinic; first clinic in Jan 2008 **Trust in technology?** Yes, there are clinical studies on the device. **How do you get a medical directive?** Pharmacist goes around and recruits doctors from the FHT. Every 2 years, pharmacist renews the directive. **Trust in technology by MDs?** Ok--there are many physicians on board. **Networks within Community? How do you deal with special cases? "Go-to" Resources?** -Physicians -Bridging letter for surgeons; oral surgeon will automatically refer patients to the clinic and GI surgeons write note for patients to be managed in clinic -CCAC now trusts them for home care, injection and clinic without doctor' signature	☒

QUALITY CONTROL **Device**: Quality control yearly with 3 samples from 1WorldAccuracy **INR Training/Mentorship:** * Pharmacist and Nurse initially took Anticoagulation Course with 1-2d mentorship (longer if needed), then other nurses would get the PharmaLearn certification with case presentations - valid up to 2012 since CHESS guidelines changed since then. They still use the thought process to guide HCPs. *As of June 2015: reading package, INR clinic time with certified HCP, 11 cases to present and discuss before they are qualified	☒
Availability of trained staff: Two HCPs (pharmacist/student and nurse) always present in 2 rooms for INR clinic.	
CHALLENGES/ BARRIERS? -**Why do you think POC technology is limited in use in Canada?** *Documentation and communication -difficulty faxing lots of information -access to all information including new meds, conditions, lifestyle -in order to run it on this level, you need to collaborate and communicate *****Funding to buy strips is the biggest expense *Expenses for full time nurse, point nurse and pharmacist for 2 full days is expensive (POCT is $18 vs. lab is $21 per test) *Hospital cannot do just POCT because they need to take blood to test for other conditions as well. So it's not efficient to use POCT for just warfarin management. **-Any perverse billing incentives?** **-Trust issues between HCPs? Doc-pharm? Pharm-patient? Pharm-pharm (transfers)?** **-Collaboration with other HCPs for continuity of patient care (i.e. past INR reading, meds, if patient moves, etc)?** -Communication with specialists is frustrating -Close communication with community pharmacist **-Others:** -Does Roche give away devices to FHTs willing to buy strips from them? They do replace devices for free…check this out! -Wants to turn program into an anticoagulation clinic for all anticoagulants including NOACs (should	☒

WHAT WORKS? **-I**mplement CHAD2 scores and ECHO especially if patient is older -Seamless EMR between all sites involved with the FHT -Clinical pharmacist allowed to refill and plan warfarin dosing regime -3.6 pharmacists per FHT site; so they work closely with doctors and build a rapport/trust with them **-**Patients bring up other issues besides anticoagulation such as issues with physician relationship, other conditions, compliance issues -Patient was in hospital and had to wait in frustration for hospital to do lab testing and result so patients really like the convenience	☒

Potential Gaps Identified during Environmental Scan

Reflecting on this practicum course, I observed 7 clinics within the WWLHIN that are operating anticoagulation clinics for warfarin management. I met key stakeholders in the community, such as pharmacists at FHTs, Grand River Hospital and UW's School of Pharmacy as additional supports for my thesis research. As such, we began to discuss and compare what was shown in the literature and reality to identify potential gaps for my thesis research.

In the literature, there are data to suggest that pharmacist-led anticoagulation clinics are superior to physician or nurse-led anticoagulation in terms of reducing clinical outcomes and improving INR control. The implementation of POC-INR clinics in local FHTs and community pharmacists reflect this knowledge in the literature. The data also suggests that using validated algorithms for warfarin dosing adjustments resulted in a better time in therapeutic range (TTR), a surrogate outcome for anticoagulation adequacy, and a reduction in total bleeds. Despite what's shown in the literature, a gap exists between this knowledge and action in reality because clinics using validated algorithms for dose adjustments varied. Although most of them were certified through the anticoagulation program at the School of Pharmacy, they were using their experience, clinical judgement and the principle taught in the program rather than a validated nomogram for initiation and maintenance dose adjustments.

Furthermore, quality control of the CoaguChek XS device and collection of data such as TTRs also varied between the clinics. This poses as another barrier to make it difficult to compare and contrast the anticoagulation adequacy. There needs to be improvement in the standardization of protocols for anticoagulation clinics, as well as the making it more available to all patients requiring warfarin management. Currently, an eligible patient would have to either find a participating community pharmacy or be enrolled in a FHT to receive anticoagulation services. This may be due to barriers such as a lack of inter-professional communication and collaboration between pharmacists and physicians, especially in community pharmacies. Accountability of patient outcomes is another issue because the primary physician has the defaulted responsibility of the managing the patient care; therefore, pharmacists must gain the trust of physicians to manage their patients. This is often difficult for most physicians who are more conservative and/or who don't know the pharmacist well enough to assess their clinical skills to manage their patients. Ultimately, through conducting the preliminary scoping review and field visits, I believe this environmental scan has steered me into the right direction to determining the potential gaps for my thesis research question.

APPENDIX B- Summary of Articles on AMS

Table 1. Research and review articles on anticoagulation management services (n=16)

Study	Purpose	Methods	Conclusions
(Bishop et al., 2015)	To describe the satisfaction of patients and physicians with a pharmacist-managed anticoagulation program in a family medicine clinic in St. John's, Newfoundland and Labrador	A self-administered survey of 94 patients and 9 physicians on patient demographics, satisfaction with warfarin education and daily anticoagulation management by the pharmacist	Patients and family physicians were satisfied with the competency of pharmacists in managing the anticoagulation program with clear instructions on dosing and INR testing. All physicians recommended the program continue to other clinics.
(Kountz et al., 2015)	To explore multiple perspectives on strategies for improved management of AF	Focus groups of health care stakeholders were conducted by a moderator and note taker on topics such as preliminary data on the prevalence of AF, treatment patterns, adherence with anticoagulants and their impact on clinical and economic outcomes, and strategies for optimizing treatment.	Short and long term recommendations to improving AF management targeted three groups: patients/ caregivers, physicians and payers. They recognized the need to understand the reasons for under-prescription and non-adherence for anticoagulation therapy. As well, a concerted effort between the three stakeholders using evidence and outcome based data are required to address the gaps and optimize anticoagulation therapy and management.
(Frankel, Parker, Rosenfeld, & Gorelick, 2015)	To examine the impact of stroke on patients with AF and caregivers, knowledge gaps, perceptions of physicians	A survey of patients with AF, caregivers and physicians were conducted online or via telephone	The impact of stroke on patients with AF can be improved with better decision making strategies for the

	and patients, and barriers to optimal anticoagulation therapy management		management of care, which may be achieved with increased education, communication and knowledge of stroke between all stakeholders. Patients and caregivers expressed the desire to learn, receive more information and take action to reduce their risk of stroke, despite overwhelmed and socially isolated. In spite of this, physicians underestimate the patient compliance and willingness to take anticoagulants.
(Barra & Fynn, 2015)	To examine the barriers of prescribing anticoagulation in patients with atrial fibrillation (AF) and how to overcome them in the United Kingdom	Review article of the epidemiology of AF, economic analysis of AF, the use of warfarin in managing AF and barriers to anticoagulation	Barriers to anticoagulation include patient age, multiple conditions, insufficient risk stratification based on the $CHADS_2$ or CHA_2DS_2-VASc scores, perceived falls and bleeding risk, and complexity of achieving a stable INR for patients using warfarin
(Nicholls et al., 2014)	To survey Canadian physicians on the treatment of patients with AF and barriers to the prescription of anticoagulants	A cross-sectional survey of 1149 Canadian physicians, geriatricians and internal medicine specialists had 1032 who were contactable and 335 who completed the survey about the frequency of patients with AF	Physician groups had similar prescribing practices and reported seeing at least 1 patient with AF. Cited barriers of prescription were falls risk, hemorrhage risk, and poor patient adherence. Physicians were more likely to prescribe warfarin to

		seen, treatment practices and barriers to prescription of warfarin. The survey was developed through a narrative review of the literature for previously identified data on the topics asked in this study.	patients with prior stroke while not on warfarin, even with a risk of falls.
(Shaw et al., 2014)	To examine attitudes of a community pharmacist-led anticoagulation management service (CPAMS) in New Zealand	15 community pharmacies with participants (patients, GPs, practice nurses, pharmacists) who were all surveyed and some of which were also interviewed on the telephone about their attitudes on a variety of attributes related to CPAMS, such as accessibility, convenience, etc.	Patients and primary care physicians positively supported CPAMS; however, pharmacists and general practitioners had pre-existing relationships for effective implementation. Widespread implementation was strongly encouraged. CPAMS followed some of Garcia et al.'s key components for optimized OAT, but program was for general population.
(Lee, Tam, Yan, Yu, & Yat, 2013)	To explore the perceptions of doctors and patients on stroke prevention management in Hong Kong	A prospective survey of 62 physicians and 114 warfarin users examined their perceptions of warfarin management for stroke prophylaxis, patients' knowledge of AF and warfarin therapy	Barriers of stroke prevention management were related to physicians and patients' knowledge, which were lower than their international comparison groups. Majority of physicians in Hong Kong did not comply to recommendations for stroke management, and patients had low

			knowledge on AF and warfarin therapy.
(Chang, Sayavong, & Pizzey, 2013)	To describe the perceptions of pharmacists and physicians for warfarin management in primary care settings in Kitchener/Waterloo area	Focus groups and semi-structured interviews held with pharmacists with respondents with identical response rate from pharmacists and physicians (42, 16.8%). Basic demographics were also collected.	Pharmacists favoured POCT in community pharmacies more than physicians, who were more hesitant about inaccurate results even with more training. Both practitioners suggest that additional training, funding for costs and changes as a profession were required for implementation. No theory-based data collection.
(Decker et al., 2012)	To determine the clinicians' perceptions of barriers for optimal atrial fibrillation (AF) management in warfarin treatment at Kansas City, Missouri (United States)	Clinicians were identified as cardiology specialists and internal medicine physicians who are responsible for anticoagulation management for AF. Semi-structured interviews were conducted on 27 clinicians from two different clinics until point of saturation	Many challenges to warfarin treatment were identified by clinicians. 5 major themes of barriers emerged from the study: treatment decisions and non-clinical characteristics; patient knowledge; real-world problems; breakdown in communication; and clinician reluctance. These social and lifestyle factors were pertinent to warfarin treatment. This exploratory, qualitative study has limitations in non-generalizability and differences in other clinicians' perspectives on optimal treatment experiences.
(Pugh, Pugh, & Mead, 2011)	To determine the attitudes of physicians	A systematic review of 1375 citations	Physicians are reluctant to prescribe

	and identify the reasons for the under-prescription of warfarin for patients with AF	from 5 databases from an electronic search of MEDLINE, EMBASE, CINAHL, PsycINFO and Web of Knowledge	warfarin therapy to elderly patients with AF with risk of falls and hemorrhaging as highly cited barriers to warfarin prescription. Despite the greater benefits of anticoagulation in the elderly over younger patients, these perceived barriers were seen by physicians. Further investigation into strategies to overcome these perceptions for appropriate warfarin therapy.
(Thompson et al., 2009)	To examine the clinical outcomes and views of patients using warfarin and managed by a pharmacist in an anticoagulation clinic using point-of-care testing (POCT) device vs. venipuncture in outpatient care clinics in the United States	Enrolled 145 patients using warfarin who had anticoagulation services managed by clinical pharmacists at the MUSC Family Medicine Centre and University Diagnostic Center. Patients were asked to fill out a satisfaction survey, and had these data collected via an electronic database: emergency department visits, hospitalizations and % of time in the INR therapeutic range for 6 months before and after the use of POCT device	41% of patients were taking warfarin for atrial fibrillation. 59% of patients completed satisfaction surveys, which revealed preference of POCT device over venipuncture due to more face-to-face interaction, shorter wait time, more convenience in INR testing and faster results. No significant differences were found in the clinical outcomes before and after the use of POCT device. Concluded that patients were more satisfied with POCT than venipuncture but difference in clinical outcomes were limited.
(Garwood et al., 2008)	To assess the changes in the quality and	Enrolled 40 patients stabilized on warfarin	Transition to physician-managed

	satisfaction of anticoagulation care for patients in a transition from a pharmacist-managed anticoagulation clinic to a physician-managed care clinic after stabilization of warfarin in Detroit, Michigan	therapy to measure the outcomes for determining the quality of anticoagulation care, including % of INR in target range, anticoagulation-related health care visits, and responses to satisfaction surveys	services resulted in a significant decrease in the quality and satisfaction of anticoagulation care after the stabilization of warfarin therapy.
(Bajorek, Ogle, Duguid, Shenfield, & Krass, 2007)	To identify perspectives of clinicians, allied health professionals, older patients and their carers on the strategies for the use and management of warfarin in Australia	Focus group interviews of 14 patients with atrial fibrillation aged 65 and older taking warfarin, 3 carers, 12 specialists, 8 general practitioners (GPs), 6 community pharmacists and 11 nurses recruited in the hospital and local community	Customized information was required to support the use and management of warfarin by health care professionals and patients. Several issues were identified in the study, such as ways to improve decision making processes, and dissemination of practical information to apply trial evidence to treatment recommendations. GPs and pharmacists recognized that allied health professionals need to take responsibility in warfarin therapy as a major step to improving the service in the community.
(Ford & Close, 2007) Editorial	To criticize Bajorek et al. on the time of dose and point-of-care testing that may affect compliance for the management of patients with atrial fibrillation taking warfarin in the community	To the editor: Criticizes that warfarin dosing in the evening is a practice to allow dose adjustment on the day of testing in a hospital that flowed into community	In reply: Time of warfarin dosing is due to medication safety protocol in the hospital so that the main treatment team can review the patient's blood test and adjust the dose accordingly.

		practice; however, taking warfarin as morning doses with other medications would improve compliance. Point-of-care testing by a registered nurse would improve management of warfarin therapy.	The authors recognized that this timing may not be optimal for patients discharged in the community, and should be at a time that is most convenient for patients to comply to warfarin therapy. Point-of-care testing was not expanded in the study due to word limits, but it was recognized as a service in outpatient settings. The authors claimed to currently be investigating GPs' preferences for frameworks of care, including mobile services.
(Wilson et al., 2004)	To assess the quality of anticoagulation using a pharmacist-led point-of-care testing model of care under the supervision of an Anticoagulation clinic at a specialized hospital in Halifax, Nova Scotia.	Enrolled 19 patients receiving long-term warfarin therapy for at least 3 months in the hospital anticoagulation clinic or the designated pharmacy. The primary outcome measured was the proportion of time for INR within the therapeutic range for 2 groups (patients managed in the community pharmacy and historical controls managed in the hospital clinic). Secondary outcomes were the rates of thromboembolic and major bleeding	The two groups had similar warfarin management measured by the primary endpoint of INR level in the therapeutic range. No adverse events occurred in any participants, and there was no difference in the patient satisfaction surveys between the two groups.

		events, and patient satisfaction	
(Peterson, Boom, Jackson, & Vial, 2002)	To investigate doctors' attitudes on the use and lack-of prescription of warfarin therapy for stroke prophylaxis in patients with AF in Australia.	An anonymous questionnaire was mailed to 711 practitioners (general practitioners, cardiologists and physicians) to examine their knowledge on current guidelines of therapeutic management of AF and attitudes on potential barriers on the prescription and use of warfarin.	There is room for improvement of doctors' knowledge about the suitable use of warfarin therapy and the results of recent clinical trials. Major barriers to warfarin use in patients with AF were identified. Strategies were listed to target these barriers to improve warfarin prescription: (1) create and disseminate clear guidelines on whether to anticoagulated patients or not, (2) education on other risk factors in patients with AF, etc.

APPENDIX C- Michie et al.'s Psychological Theory Domains

Table 2. Theoretical domains adapted from Michie et al. (2005) to investigating clinicians' perceptions of implementing the recommendations for optimized OAT

Domains*	**Constructs**	**Interview questions**
(1) Knowledge	Knowledge about components of the guidelines for optimized OAT Schemas+mindsets+illness representations Procedural knowledge	Do they know about the guideline? What do they think the guideline says? What do they think the evidence is? Do they know they should be doing x? Do they know why they should be doing x?
(2) Skills	Skills to provide components for optimized OAT Competence/ability/ skill assessment of personnel Practice/ skills development Interpersonal skills Coping strategies	Do they know how to do x? How easy or difficult do they find performing x to the required standard in the required context?
(3) Social/ Professional role and identity	Identity Professional identity/boundaries/ role Group/social identity Social/group norms Alienation/organizational commitment	What is the purpose of the guidelines? What do they think about the credibility of the source, e.g. consensus-based on the anticoagulation forum? Do they think guidelines should determine their behaviour? Is doing x compatible or in conflict with professional standards/ identity? (prompts: moral/ ethical issues, limits to autonomy) Would this be true for all professional groups involved (e.g. GPs, cardiologists)
(4) Beliefs about capabilities (self-efficacy)	Self-efficacy Control—of behaviour and material and social environment Perceived competence Self-confidence/ professional confidence Empowerment Self-esteem Perceived behavioural control Optimism/ pessimism	How difficult or easy is it for them to do x? (prompt re. internal and external capabilities/ constraints) What problems have they encountered? What would help them? How confident are they that they can do x despite the difficulties? How capable are they of maintaining x? How well equipped/ comfortable do they feel to do x?
(5) Beliefs about consequences (anticipated outcomes/ attitude)	Outcome expectancies Anticipated regret Appraisal evaluation/review Consequents	What do they think will happen if they do x? (prompt re themselves, patients, colleagues, and the organization; positive

	Attitudes Contingencies Reinforcement/punishment/consequences Incentives/rewards Beliefs Unrealistic optimism Salient events/ sensitisation/critical incidents Characteristics of outcome expectancies—physical, social, emotional Sanctions/rewards, proximal/distal, valued/not valued, probable/improbable, salient/not salient, perceived risk/threat	and negative, short term and long term consequences) What are the costs of x and what are the costs of the consequences of x? What do they think will happen if they do not do x? (prompts) Do benefits of doing x outweigh the costs? How will they feel if they do/don't do x? (prompts) Does the evidence suggest that doing x is a good thing?
(6) Motivation and goals (intention)	Intention; stability of intention/ certainty of intention Goals (autonomous, controlled) Goal target/ setting Goal priority Intrinsic motivation Commitment Distal and proximal goals Transtheoretical model and stages of change	How much do they want to do x? How much do they feel they need to do x? Are there other things they want to do or achieve that might interfere with x? Does the guideline conflict with others? Are there incentives to do x?
(7) Memory, attention and decision processes	Memory Attention Attention control Decision making	Is x something they usually do? Will they think to do x? How much attention will they have to pay to do x? Will they remember to do x? How? Might they decide not to do x? Why? (prompt: competing tasks, time constraints)
(8) Environmental context and resources (environmental constraints)	Resources/ material resources (availability and management) Environmental stressors Person x environment interaction Knowledge of task environment	To what extent do physical or resource factors facilitate or hinder x? Are there competing tasks and time constraints? Are the necessary resources available to those expected to undertake x?
(9) Social influences (norms)	Social support Social/group norms Organizational development Leadership Team working Group conformity Organization climate/culture Social pressure Power/hierarchy Professional boundaries/roles Management commitment Supervision Inter-group conflict Champions Social comparisons Identity; group/social identity	To what extent do social influences facilitate or hinder x? (prompts: peers, managers, other professional groups, patients, relatives) Will they observe others doing x (i.e. have role models)?

	Organization commitment/alienation Feedback Conflict—competing demands, conflicting roles Change management Crew resource management Negotiation Social support: personal/ professional/ organizational, intra/interpersonal, society/community Social/group norms: subjective, descriptive, injunctive norms Learning and modelling	
(10) Emotion (emotion)	Affect Stress Anticipated regret Fear Burn-out Cognitive overload/tiredness Threat Positive/negative affect Anxiety/depression	Does doing x evoke an emotional response? If so, what? To what extent do emotional factors facilitate or hinder x? How does emotion affect x?
(11) Behavioural regulation	Goal/target setting Implementation intention Action planning Self-monitoring Goal priority Generating alternatives Feedback Moderators of intention-behaviour gap Project management Barriers and facilitators of delivery of optimized OAT	What preparatory steps are needed to do x? (prompt re individual and organizational) Are there procedures or ways of working that encourage x?
(12) Nature of the behaviours	Routine/automatic/habit Breaking habit Direct experience/past behaviour Representation of tasks Stages of change model	What is the proposed behaviour? (e.g. systematic approach in patient selection, initiation and management of OAT; provider education and training; etc.) Who needs to do what differently when, where, how, how often and with whom? How do they know whether the behaviour has happened? What do they currently do? Is this a new behaviour or an existing behaviour that needs to become a habit? Can the context be used to prompt the new behaviour? (prompts: layout, reminders,

		equipment) e.g. reminder posters on the wall How long are changes going to take? Are there systems for maintaining long term change?

*Corresponding constructs from Fishbein et al. (2001) shown in parentheses

APPENDIX D- Information and Consent Forms

Key Informant Information Sheet

Faculty Supervisor: Dr. George Heckman (ggheckma@uwaterloo.ca)
Student Investigator: Brenda Trinh (b2trinh@uwaterloo.ca)
Organization: University of Waterloo, School of Public Health and Health Systems
Study: "Clinical pharmacists and nurses' perceptions on implementing anticoagulation therapy recommendations for the frail elderly: An exploratory study based on psychological theory**"**

Introduction

My name is Brenda Trinh, a MSc. student at the University of Waterloo working under the supervision of Dr. George Heckman in the School of Public Health and Health Systems Department in the faculty of Applied Health Sciences. This information letter will explain my research and your involvement in this study as a participant. Our research focuses on understanding the perceptions of pharmacists and nurses on the implementation of the guideline recommendations for the delivery of optimized oral anticoagulation therapy (OAT) by Garcia et al. (2008). The target population is the frail elderly with atrial fibrillation (AF) who live in the community.

As a participant, you will be interviewed as a key informant to help us understand your *perceptions* on why the guideline for optimal OAT delivery is implemented or not. These interviews will help us create a list of the benefits, barriers and facilitators for effective implementation. We hope that this information will be a vital for informing how a coordinated, regional approach to OAT is possible in the Waterloo-Wellington LHIN (WWLHIN) community. You do not have to make a decision to participate or not today, but before you decide, you can feel free to talk about this research with anyone. I encourage you to ask any questions or express any concerns that you may have after reading this information sheet.

Background & Aim of Research

AF is a significant contributor to stroke at all ages and the prevalence of AF rises with age. In Canada, stroke is the leading cause of mortality and disability. The standard of care for persons with chronic non-valvular AF is to provide long term oral anticoagulation therapy (OAT) with warfarin, which reduces blood clots and the risk of stroke by two-thirds. Research has shown that pharmacist or nurse-led anticoagulation management service (AMS) clinics are comparable or better than routine medical care by physicians, in terms of cost-effectiveness and patient outcomes. Poor OAT management often results in an increased risk of major hemorrhage and stroke. These risks are further complicated for people with AF who are older, frail, and have multiple co-morbidities and polypharmacy. Hence, a coordinated, regional approach is required to optimize OAT management for the frail elderly to offset complications and improve outcomes.

The first step to achieving this goal is to understand why implementation of key elements in a systematic approach to OAT delivery are implemented or not. Then, a list of the benefits, barriers and facilitators can be generated from this data to help inform the wider implementation of an integrated OAT system within the WWLHIN region. The investigator will conduct this research by first inquiring the clinician on which of the 9 guideline recommendations he or she feels requires the most improvement in practice. Then, the clinician will be asked several questions about the knowledge,

skills and other factors that influence the uptake or not of the selected guideline recommendations. This way, clinicians and policymakers in the region can start a conversation about what worked, didn't work and will work in the wider implementation of a coordinated approach to OAT.

Participant Selection

You are being invited to take part in this research because we feel that you are a key informant for this study. Key informants are pharmacists and nurses with the following criteria:

- Possess the proper certifications to work at AMS clinics within the WWLHIN community: Waterloo-Kitchener, Cambridge and Guelph;
- Involved in a AMS clinic using point-of-care technology (i.e., hand-held INR testing device and software) within a Family Health Team or community pharmacy; and
- Have worked for at least 6 months.

Excluded key informants are clinicians who work in hospitals; provide laboratory testing for routine medical care in the community (e.g. physicians who provide venipuncture INR testing); and/or have worked less than 6 months at AMS clinics.

Voluntary Participation

Your participation in this research through key informant interviews is completely voluntary. It is your choice on whether or not to participate. If you choose not to participate, there are **no consequences**. You can choose not to answer any questions that you feel uncomfortable with. You may choose to participate now and still be able to change your mind later, ending the interview at any time.

Procedures/Duration

We are inviting you to participate in a 30-minute key informant interview to learn more about your perceptions on how different influences affect the uptake or not of the guideline recommendations for optimal OAT delivery. The target population we will be talking about is a frail elderly population. If you accept, you will be asked **ahead of time** to review the 9 guideline recommendations by Garcia et al. and identify 1 or 2 key recommendations that require improvement in practice. This 7-page journal article will typically take less than 30 minutes to read, and will be provided again for your reference during the interview. During the interview, questions about your knowledge, opinions and attitudes that affect your selected guideline recommendation(s) will be asked. With your permission, the interview will be audio-recorded to help facilitate the collection of information and later be transcribed for analysis.

Confidential Information

The interview will be conducted by the investigator, Brenda Trinh, and interviewer notes will be taken by a research assistant for the purpose of data triangulation to ensure accuracy during qualitative coding and analysis. Your information and the interview you provide, including all notes and audio-tapes, will remain confidential and only identified by a code. Nothing will be attributed to your name. All information that could identify you, except for your profession and the city in which you work, will be removed from the data immediately after transcription by the student investigator or the research assistant, and stored separately. All recordings and notes will be maintained for a minimum of seven years. You can withdraw consent to participate and have your data destroyed by contacting us within

this time period. Only those associated with this study will have access to these records which are password protected. It is not possible to withdraw your consent once papers have been submitted to publishers. All records will be destroyed according to the University of Waterloo policy.

Risks and Benefits

There may be sensitive or uncomfortable topics about your knowledge, opinions and attitudes that you may choose not to answer. You do not have to provide any explanations for questions left unanswered. There will be no direct benefit to you, the participant, but your help in answering the interview questions is likely to help us identify the clinicians' perspective on implementing guidelines for optimal OAT

Sharing the Results

The knowledge we gain from this research will be made available to you before it is made public for other interested people to learn from the research. A summary of the results will be emailed to all key informants before we publish it.

Right to Refuse or Withdraw

You do not have to participate in the interview if you choose not to. There are no consequences to withdrawing your consent, even if you agreed to participate earlier. You may choose not to participate by saying you want to stop the interview.

Who to Contact

If you have any further questions or concerns, please ask them now or anytime during the interview. If you have further questions after the interview, please contact any of the following people: Student Investigator-- Brenda Trinh, b2trinh@uwaterloo.ca; Faculty Supervisor – George Heckman, ggheckman@uwaterloo.ca

Ethics Statement

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee. However, the final decision about participation is yours. If you have any comments or concerns resulting from your participation in this study, please contact the Chief Ethics Officer, Office of Research Ethics, at 1-519-888-4567, ext. 36005 or ore-ceo@uwaterloo.ca.

Key Informant Consent Form

Study: "Clinical pharmacists and nurses' perceptions on implementing anticoagulation therapy recommendations for the frail elderly: An exploratory study based on psychological theory**"**
Project context: A Masters of Science thesis

I have read and fully understood the information sheet provided about this study, so I agree to voluntarily participate in this project as shown below:

- The aim of the research is to identify pharmacists and nurses' perceptions on what behaviours influence the implementation of selected guideline recommendations for optimal OAT delivery in AMS clinics. The population of interest is the frail elderly in the WWLHIN community.

- I am a pharmacist or nurse working at a Family Health Team or community pharmacy that uses point-of-care technology (i.e., hand-held device to check INR and computerized software) for at least 6 months.

- I will be asked to review the 7-page journal article with guideline recommendations and select 1-2 key areas that I feel require improvement in clinical practice before I meet the investigator. Then, I will be asked to do a 30-minute interview.

- Questions will be about my knowledge, opinions and attitudes on why different factors influence the uptake or not of the selected guideline recommendation(s). I understand that my perceptions will contribute a collective list of benefits, barriers, and facilitators for effective implementation across community clinics. This study will be a small but vital step to informing the region how we can achieve a broader, more uniform approach to OAT.

- At any time, I can refuse to answer or discuss certain questions/ topics, or even end the interview without any problems.

- With your permission, the interview will be recorded to facilitate collection of information and later transcribed for analysis.

- The interview that I give with its information will be used solely for the purposes defined by the project and will remain confidential using a number code to protect my identity. All data will be maintained for a minimum of seven years. You can withdraw consent to participate and have your data destroyed according to the University of Waterloo policy by contacting us within this time period. Only those associated with this study will have access to these records which are password protected.

- For any information about the project, I can contact the investigator, Brenda Trinh at b2trinh@uwaterloo.ca or her academic supervisor: George Heckman, ggheckman@uwaterloo.ca

- By indicating my consent, I am not waiving my legal rights or releasing the investigators or involved institution from their legal and professional responsibilities.

- This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee. I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact the Chief Ethics Officer, Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

Respondent's signature: _____ Date: _____

Interviewer's signature: _____ Date: _____

APPENDIX E- Key Informant Interview Guide

Welcome Message

Thank-you for meeting with me today to discuss your perceptions as a pharmacist or nurse on implementing the recommendations for optimal oral anticoagulation therapy (OAT).

The big picture is to understand how we can go from the status quo to an integrated, regional approach to OAT. But first, we must understand why the guidelines, being a systematic approach for optimal delivery, are being implemented or not in community clinics.

Before we begin, I want to make sure that you understand what this study involves.

[**Review the forms handed out**:

- *Garcia et al. provides us with these 9 key elements or recommendations for optimal OAT delivery: You have chosen* _____ (insert 1 or 2 selected recommendations) *to focus on in detail.*
- *The information and consent forms explain the research and how we are conducting it. The purpose is to help you decide whether you want to be interviewed or not.*
- *The interview will last about 30 minutes and it will be audio recorded with your permission. We will talk about what you think are current behaviours or lack of behavioural change, and prompts for future changes that influence the uptake or not of the selected guideline recommendations within the general scope of community practice.*
- *You don't need to answer any question and you can stop the interview at any time.*
- *We will be using the information from the interview to help us identify a list of benefits, barriers and facilitators for effective implementation of the guideline recommendations. This will help inform the WWLHIN on the steps to take for a broader and more uniform OAT system.*
- *Information from this interview will remain confidential.*

Collect the Informed Consent Form at the end.]

[Investigator has these general probes for each question:

- Watch tone of voice and facial expressions
- Silence
- Clarification of ambiguous terms (e.g. *Can you give me an example of 'term?'*)
- Encourage more information by asking neutral prompts: *What else? Can you give me an example of 'term?* **]**

1.0 Key Informant Characteristics

(1) *Tell me a little about yourself and the clinic.*

- **Specific Probes:**
  - *What is your…*
    - *Job title (e.g. pharmacist or nurse)?*
    - *Professional degree designation (PharmD, BScN, etc.)?*
    - *Employment Status (full time, part time, sessional, etc.)?*
    - *Experience with anticoagulation?*
      - *# years working with anticoagulation management*
      - *POC technology training/experience*
    - *POCT device and software used?*
    - *# of active patients in the database?*
    - *Availability of trained staff in clinic*

2.0 Frailty Consideration in Patient Selection and Assessment for OAT

(2) *As we are targeting a vulnerable older population, we tend to see frailty. What is your take on frailty and how it influences patient selection and assessment for anticoagulation therapy?*

- **Reiterate question** for clarification:
  - *So in other words, what is frailty?*
  - *Do you know if frailty is assessed in patients with OAT?*
  - *If so, what is the frailty assessment based on?*
  - *Do you think it has an effect on anticoagulation therapy management?*
  - *If so, why or why not? How so?*

3.0 Internal Influences on the Implementation of Selected Recommendation(s)

Looking at the optimized OAT guidelines, we will ask the following questions in regards to your selected recommendation(s): _____ (1 or 2 chosen). *Keep in mind that OAT is in the context of a frail elderly population.*

(3) Knowledge: [Highlight selected recommendations and ask those ones]

- **1. Qualifications of Personnel**
  - *What certifications are required to work in this AMS clinic?*
    - If formal training: *Can you describe what the program entails?*
    - If informal training*: Do you think it necessary to obtain formal anticoagulation management training programs? Why or why not?*
  - *What do you think the guideline says about optimizing qualifications of personnel? Why is that?*

- **2. Supervision**
  - *What kind of supervisory agreement is required by referring physicians to transfer patient care to AMS clinics?*
    - *Who is accountable for the patient during therapy?*
  - *What do you think the guideline says about optimizing practice guidelines for AMS providers, in terms of daily job duties, responsibilities and accountability?*
  - *Why do you think it is necessary to obtain a "collaborative practice agreement"?*
- **3. Care Management and Coordination**
  - *What policies and procedures are followed for care management and coordination for routine visits and continuity of care across institutions?*
  - *What do you think the guideline says about optimal care management and coordination?*
  - *Why is it recommended? How does it affect the patient?*
- **4. Documentation**
  - *What kind of documentation system do you use?*
  - *What do you think the evidence says about optimizing documentation in practice?*
  - *Why do you think it was recommended?*
- **5. Patient Education**
  - *During a typical visit, how do patients learn more about their condition?*
  - *What do you think the guideline says about optimizing patient education?*
  - *Why do you think the evidence suggests this?*
- **6. Patient Selection and Assessment**
  - *How are patients currently selected and assessed for OAT?*
  - *What do you think the guideline says about optimizing patient selection and assessment procedures?*
  - *Why do you think this should be done?*
- **7. Laboratory Monitoring**
  - *Based on the POC device you use for regular monitoring; how would you describe your trust in the technology?*
  - *What do you think the evidence is for optimizing laboratory monitoring for warfarin therapy?*
  - *Why do you think this is recommended?*
- **8. Initiation and Stabilization of Warfarin Therapy**
  - *What is initial dosing based on?*
    - *Is it based on a nomogram?*
    - *Where from? E.g. CHEST guidelines*
  - *What do you think the evidence is for optimizing initiation and stabilization of warfarin therapy?*
  - *Why do you think this should be done?*

- **9. Maintenance of Warfarin Therapy:**
    - *What is the approach for maintenance therapy to stabilize the long term dosage?*
        - *Is it based on a nomogram?*
        - *Where from? E.g. CHEST guidelines*
    - *What do you think the evidence is for optimizing maintenance?*
    - *Why do you think this should be done?*

(4) Skills- *How easy or difficult do you find implementing the recommendation(s) to the required standard in the context of a frail elderly population?*

- **Specific probes** if topic not mentioned:
    - **Reason for difficulty:**
        - *Why is it easy or difficult for you?*
    - **Interpersonal skills:**
        - *How about your experience when collaborating or communicating with physicians and other health care providers involved in your patient's therapy?*
    - **Skills Training & Development**
        - *If a PD (professional development) workshop such as OAT training or mentorship were available, what would you want to learn more about?*
    - **Skills Assessment:**
        - *What qualifies a clinician to work in the AMS clinic?*

(5) Social/Professional role and identity- *Is applying the guideline recommendation(s) compatible or in conflict with professional standards/identity?*

- **Specific probes** if topics not mentioned:
    - **Professional Role:**
        - *What do you think about the credibility of the source, i.e. consensus-based anticoagulation forum?*
        - *Do you think these recommendation(s) should determine your behaviour in practice?*
        - *Are there moral/ethical issues?*
        - *Are there limits to autonomy?*
    - **Social norm:**
        - *Would this be true for all health care professionals involved?*

(6) Beliefs about capabilities (self-efficacy)- *How comfortable do you feel about following the selected recommendation(s)?*

- **Specific probes** if topics not mentioned:
    - *What problems have you encountered?*

- *What would help you?*
- *Despite these difficulties, how confident are you that you can follow the recommendation(s)?*

(7) Beliefs about consequences (anticipated outcomes/ attitudes) – *What do you think will happen if you follow the guideline recommendation(s)?*

- **Reiterate the question** if clarification required:
  - *What do you think will happen if you <u>do not</u> follow the guideline recommendation(s)?*
  - *Do benefits of following the guideline outweigh the costs?*
- **Specific probes:**
  - *Regarding patients, colleagues, and the organization*
  - *Short term and long term consequences*
  - *How will you feel if you do/don't follow the guideline(s)?*

(8) Motivation and goals (intention)- *Do you feel that the implementation of the selected recommendation(s) is a goal priority for this clinic? Why or why not?*

- **Specific probes:**
  - *Are there incentives to do so?*
  - *Or does it conflict with others, i.e. colleagues in the same field (nurse or pharmacist), physicians, specialists, etc.?*
  - *If so, do you feel that it is harder to commit to the implementation?*

(9) Memory, attention and decision processes – *Might you decide not to follow the selected recommendation(s)? Why?*

- **Specific Probes:**
  - *Will you usually think to implement the recommendation(s)?*
  - *How much attention will you have to pay to do it?*
  - *What if there are competing tasks, or time constraints?*

4.0 External Influences on Implementation of Selected Recommendation(s)

(10) Environmental context and resources- *How does the physical environment or resources facilitate or hinder implementation?*

- **Specific Probes:**
  - **1. Qualifications of Personnel**
    - *Are there available formal training programs in Canada?*
    - *How well are these programs managed for students?*
    - *Are there any competing tasks and/or time constraints to obtaining a certification?*
    - *How would a new trainee sign up?*

- *How do they facilitate or hinder implementation of this recommendation?*

- **2. Supervision**
  - *Are there AMS practice guidelines available?*
  - *Are trained personnel familiar with the AMS practice guidelines?*
  - *How are AMS staffing guidelines managed for accountability of patient care?*
    - ***i.*** *Are there times when staffing was short?*
    - ***ii.*** *What happens if the main staff take temporary leave, i.e. vacation?*
    - ***iii.*** *How would the pharmacist or nurse ensure that the terms of supervision are satisfied?*
  - *How would these resources influence the implementation of a collaborative practice agreement?*
- **3. Care Management and Coordination**
  - *Are there opportunities for inter-professional communication and collaboration with all involved stakeholders?*
    - ***i.*** *Physicians*
    - ***ii.*** *Cardiologists/ specialists*
    - ***iii.*** *Relatives/ Family Members*
    - ***iv.*** *Other pharmacists*
    - ***v.*** *Health care providers in long-term, hospitals, etc.*
  - *How are these inter-professional relationships initiated and managed?*
  - *Are there any time constraints or competing tasks that interfere with communication and collaboration processes?*
  - *How would having this input affect the continuity of care?*
- **4. Documentation:**
  - *Is there access to information technology (IT), software, and the relevant patient data?*
  - *How is the patient data managed in the system on a regular basis?*
  - *Is there access to shared patient data between health care providers?*
    - ***i.*** *During transfers into/out of institutions*
    - ***ii.*** *Between community providers*
    - ***iii.*** *How are paper based records handled?*
  - *Do you know how to access help from the supplier or other resources during IT errors?*
  - *Is there a competing documentation system?*
  - *How would these resources influence the implementation of documentation software into practice?*
- **5. Patient Education**

- *Is there access to educational resources for providers to give to patients? What are they about?*
    - ***i.*** *Prompt: In case of a warfarin dosing error (over/underdose), how do patients know what to do?*
- *Are AMS providers available for face-face interactions if patients have questions? How is this done?*
- *Is there availability to the knowledge assessment tools to customize education materials to the patient population?*
    - ***i.*** *What is being done for the frail elderly?*
- *How are these resources managed to keep the education materials up-to-date? E.g. which data source is used?*
- *What strategy do you use to disseminate educational materials to patients? Individualized or general? Why?*
- *How would these resources influence the implementation of patient education?*

- **6. Patient Selection and Assessment**
    - *From your experience, how long does it take for family physicians to assess patients and refer them to your clinic?*
        - ***i.*** *Is there a time lag? Why is that?*
        - ***ii.*** *What happens to the patient's condition when there is a long wait time?*
        - ***iii.*** *How are patients usually selected and assessed by the referring physician to go to your clinic? Does it differ for high risk patients?*
    - *Do AMS providers have resources providing up-to-date comprehensive exam tools:*
        - ***i.*** *Evidence-based guidelines: $CHADS_2$, HAS-BLED to assess appropriateness for OAT?*
        - ***ii.*** *Clinical frailty tools?*
    - *How do these resources (or the lack of) influence the implementation of patient selection and assessment for appropriate OAT?*
- **7. Laboratory Monitoring**
    - *Is there access to point-of-care devices? How many?*
    - *Is there access to testing strips? How often do you have to order?*
    - *Is there adequate management and quality control of the point-of-care devices?*
    - *If there are issues with the device or strips, who do you contact to troubleshoot? Is help available and managed properly?*
    - *How will these resources influence the implementation of regular laboratory monitoring? How is this important in the context of a frail elderly population?*

i. *Prompt re: special characteristics that make it difficult for them to come out for regular testing, so the resources need to be available and working at clinic*

- **8. Initiation and Stabilization of Warfarin Therapy & 9. Maintenance of Therapy**
  - *Are there AMS providers available who are knowledgeable about their patients to provide appropriate advice?*
  - *What resources are available for AMS providers to start or maintain warfarin dosing to the required standard?*
    i. *Prompt: Are evidence-based nomograms available?*
  - *What available resources do you find are useful for patients to reduce dosing errors?*
    i. *Prompt: What are used to keep track of dosing schedule for patients?*
      - *A calendar booklet, electronic reminders, relatives, pill box, tablet strength (1mg vs. breaking tablets), etc.?*
  - *How else do resources influence initiation, stabilization and maintenance of therapy?*

(11) Social influences (norm)- *To what extent do social influences facilitate or hinder following the selected recommendation(s)?*

- ***S*pecific Probes**
  - **1. Qualifications of Personnel**
    - *Who influenced or will influence you to get additional anticoagulation training or mentorship? Why?*
    - *E.g. managers, peers, other health care professionals, etc.?*
  - **2. Supervision, ask:**
    - *Who is primarily responsible or accountable for patient outcomes during OAT?*
    - *How do you go about obtaining a medical directive from referring physicians?*
      i. *Are there strategies learned from other people?*
      ii. *Is there any reluctance to provide medical directives to pharmacists? Why?*
      iii. *Does it differ between physicians, specialists and surgeons? Why do you think that happens?*
    - *How do you think inter-professional relationships can play a role to influence trust between health care professionals?*
  - **3. Care Management and Coordination, ask:**
    - *Who are your "go-to" resources or networks in the community for questions or consultation for special cases?*
    - *Are there internship opportunities for others to observe successful AMS clinics?*

- *Additionally, what happens to the patient's OAT management when they enter another institution, such as a hospital, long-term care, retirement home, another pharmacy, etc.?*

- **5. Patient Education, ask*:***
  - *How does social support facilitate patient education?*
    - *i. Social support such as personal, professional, organizational, interpersonal or community structures*
    - *ii. Particularly, how does the interpersonal relationship between patient-provider influence the uptake or not of patient education?*
    - *iii. Are there any conflicting messages provided to patients by different health care providers? If so, how do you see that affecting the patient?*
- **6. Patient Selection and Assessment**
  - *What social influence will influence appropriate patient selection and assessment for OAT, especially for frail elderly patients?*
    - ***i.*** *In other words, what social support will help this process?*
      - ***Prompt:*** *having trust from patients and their relatives, or the physicians?*
    - ***ii.*** *What social pressures, processes or relationships will hinder it?*
      - ***Prompt:*** *reluctant physicians or specialists, conflict with other pharmacists in business, etc.*
- **7. Laboratory Monitoring**
  - *How does the social context influence regular monitoring of INR in patients?*
    - *i. How does social support from managers, organization, and community play a role?*
    - ii. *Inter-professionalism between pharmacist-physician?*
    - iii. *Social support from family/ relatives?*

- **8. Initiation and Stabilization of Warfarin Therapy &**
  9. Maintenance of Therapy, *ask:*
  - *What social supports are in place to ensure appropriate initial dosing and stabilization, or maintenance therapy for your patients?*
    - *i. How do inter-professional relationships with the referring physician, specialists, pharmacists and other health care professionals play a role?*
    - ***ii.*** *How about with patients and their families?*
  - *What are social pressures that hinder the implementation processes? How so?*

i. *How do conflicts—such as competing demands, roles or change in management—interfere with implementation?*
ii. *How about conflicts with the organization commitment to the program?*
iii. *Are there other social groups?*

(12) Emotion- To what extent do emotional factors facilitate or hinder following the selected recommendation(s)?

- **Specific probes:**
  - *How about emotions such as stress, burn-out, anticipated regret, cognitive tiredness, threat, positive/negative affect, anxiety/depression?*

5.0 Ways for improving implementation of the selected guideline recommendation(s)

(13) Behavioural regulation – *What preparatory steps do you think are required to implement the guideline recommendation(s), especially in a frail elderly population?*

- **Reiterate question** for clarification:
  - *Are there ways of working that encourage following the selected recommendation(s)? Why?*
  - *What are the action plans to implement the recommendation(s)?*
- **Specific Probes** to prompt topics not mentioned:
  - *Preparatory steps such as goal/target setting, action planning, self-monitoring, prioritizing goals, generating alternatives, obtaining feedback, etc.?*
  - *Explain how these action steps are facilitators for applying the selected recommendation(s) in practice?*

(14) Behavourial Change- *What behaviour do you think should become a habit for improving the implementation of the recommendation(s)?*

- **Topic specific probes***:*
  - *Think of a situation involving your selected recommendation(s) that was handled well by yourself or a colleague. What is the behaviour that should be exemplified here?*
  - *Is this a new behaviour or an existing behaviour?*
  - *Who needs to do what differently?*

(15) *What do you think can prompt the new behaviour as a long term change?*

- **Specific Probes:**
  - *When would you do it? Where? How often? With whom? Why would it work as a long term prompt?*

- *How about clinic layout, reminder systems or equipment as prompts?*
- *Are there current systems for maintaining this long term change? Why or why not?*

4.0 Closing

Is there any other information that you think we should know about what else influences the delivery of the selected guideline recommendation(s) to a frail, elderly population?

Do you have any questions about this interview, or what we talked about?

Thank you for sharing your time and insights with me today, and I hoped you enjoyed our discussion.

APPENDIX F- Justification of Questions

Table 3. Justification of Interview Guide Questions for Key Informants

Question #		**Reasoning (To answer research question)**
General Probes	Caution: Watch tone of voice and facial expressions	To avoid criticism when talking about sensitive topics, such as a respected individual's skills or knowledge
	Probe 1. Silence	To give time for the participant to think and process
	Probe 2. Clarification of vague terms before using more probes	e.g. "Can you give me an example of the 'term?' To clarify ambiguous terms to probe for more information
	Probe 3. Encourage more information	Asking neutral prompts just in case the participant does not have anymore things to say
1. *Tell me a little about yourself and the clinic.*		**To know the characteristics of the participant to identify the individual or personal factors that affect perceptions**
Specific Probes	Type 1. Employment details	The specific probes will enable investigators to create a frequency table of the characteristics to describe the key informants and the AMS clinic.
	Type 2. POCT device and software	
	Type 3. Clinic details (# patients & staff)	
2. *As we are targeting a vulnerable older population, we tend to see frailty. What is your take on frailty and how it influences patient selection and assessment for anticoagulation therapy?*		**To assess the baseline understanding of frailty and its implications on patient selection and assessment for OAT.**
Probes	Reiterate Question in other words	To stay on topic by reiterating the question to remind the participant of what is being asked
3. **Knowledge** (Generic version): *What is currently being done? What do you think the guideline says about the recommendation(s)? Why do you think it was necessary?*		**To identify the status quo and clinicians' knowledge of the selected guideline recommendation(s), guided by the component constructs of (1) Knowledge from Michie et al.'s psychological theory**
4. **Skills**- *How easy or difficult do you find implementing the recommendation(s) to the required standard in the context of a frail elderly population?*		**To identify the clinicians' view on personnel competence/skills that may affect the implementation of the selected guideline recommendation(s). This question is guided by the component constructs of (2) Skills from Michie et al.**
Specific Probes	Type 1. Reason for difficulty	Because question asks the level of difficulty, we want to probe the reason why it is easy or difficult to implement in the context
	Type 2. Interpersonal skills	If interpersonal skills does not come up as a reason, this probe will ask for the clinicians' experience working with others to find out if this

		specific skill influences the implementation process
	Type 3. Skills Training & Development	To find out about what skills need to be developed
	Type 4. Skills Assessment	To find out how AMS providers are qualified to work in the clinic
5. **Social/Professional role and identity**- Is apply the guideline recommendation(s) compatible or in conflict with professional standards/identity?		**To identify the clinicians' views on how the social/professional role and identity influences the implementation of guideline recommendation(s), guided by the component constructs of (3) from Michie et al.**
Specific Probes	Type 1. Professional Role	To identify whether the implementation of the selected recommendation(s) align with professional identity
	Type 2. Social norm	To identify group norms of implementing the recommendation(s)
6. **Beliefs about capabilities (self-efficacy**)- *How comfortable do you feel about following the selected recommendation(s)?*		**To identify the clinician's views on how the beliefs about capabilities influence the implementation of guideline recommendation(s), guided by component constructs of (4) from Michie et al.**
Specific Probes	Type 1. Problems Encountered	To identify any issues that interfere with professional confidence
	Type 2. Initiatives to Help	To identify any initiatives that would help empower self-efficacy
	Type 3. Optimism/ Pessimism	To identify perceived behavioural control over task
7. **Beliefs about consequences (anticipated outcomes/ attitudes)** – *What do you think will happen if you follow the guideline recommendation(s)?*		**To identify the clinicians' view on how the benefits about consequences influence the implementation of guideline recommendation(s), guided by component (5) from Michie et al.**
Probes	Probe 1. Reiterate Question in other words	To stay on topic by reiterating the question to remind the participant of what is being asked
	Specific Probe Type 1. Outcome expectancies to stakeholders	To prompt participant on consequences to different stakeholders to jog their memory
	Specific Probe Type 2. Timeline consequences	To prompt key informants on the short and long term consequences
	Specific Probe Type 3. Resulting Emotion Consequences	To prompt the key informants on how they feel if they follow or do not follow the selected recommendations
8. **Motivation and goals (intention)**- *Do you feel that the implementation of the selected recommendation(s) is a goal priority for this clinic? Why or why not?*		**To identify how the clinicians' motivation and goals influence the implementation of the guideline recommendation(s), guided by the construct components of (6) from Michie et al.**
Specific Probes	Type 1. Incentives	To identify if there are positive incentives for implementation
	Type 2. Conflicts with others	To identify if there are negative conflicts with others for implementation

	Type 3. Conflict leading to commitment issues	To identify if commitment issues stem from lack of intrinsic motivation due to conflict with other professionals
9. Memory, attention and decision processes – *Might you decide not to follow the selected recommendation(s)? Why?*		**To identify how the memory, attention and decision processes of clinicians influence the implementation of guideline recommendation(s), guided by (7) from Michie et al.**
Specific Probes	Probe 1. Memory	To identify if participant remembers to do the task
	Probe 2. Attention	To identify if participant pays attention to the task
	Probe 3. Decision making factors	To identify if participant makes a decision not to follow it due to time or task constraints
10. Environmental context and resources- *How does the physical environment or resources facilitate or hinder implementation?*		**To identify the view of clinicians on how environmental context and resources influence the implementation of guideline recommendation(s), guided by (8) from Michie et al.**
Possible Specific Probes for each question (Generic Verison)	Type 1. Availability of resource	To identify if that resource is available, and does it facilitate or hinder implementation
	Type 2. Management of resource	To identify if the available resource is managed properly, and if not, does it hinder implementation?
	Type 3. Environmental stressors	To identify if there are time or task constraints on obtaining the resource
	Type 4. Knowledge of task environment	To identify if AMS providers know how to reach implementation goals with the resources available to them
11. Social influences (norm)- *To what extent do social influences facilitate or hinder following the guideline recommendation(s)?*		**To identify the clinicians' view on how the social influences, affect the implementation of the guideline recommendation(s), guided by component constructs of (9) from Michie et al.**
Specific Probes (Generic)	Type 1. Who influences the uptake or not of the selected recommendation(s)?	To identify the stakeholders who are influential in the implementation process
	Type 2. Inter-professionalism and team working	To identify how interpersonal relationships between health care professionals, and/or patient-providers play a social support role in the implementation process
	Type 3. Professional roles, power/hierarchy and group conformity	To identify how professional roles, hierarchy and group conformity of referring doctors, specialists, surgeons, or other health care providers may hinder the implementation of the guidelines by pharmacists.
	Type 4. Learning and modelling	To identify if mentorship or internship programs influence the implementation process
	Type 5. Social pressures	To identify conflicts at different social levels that may influence the implementation process
12. Emotion- *To what extent do emotional factors facilitate or hinder*		**To identify the clinicians' view on how emotions influence the implementation of the**

following the guideline recommendation(s)?		**guideline recommendation(s), guided by (10) from Michie et al.**
Specific Probes	Type 1. Examples of Emotional factors	To bring up the specific emotions such as stress, burn out, etc. to probe participant on the extent of emotional influence
13. Behavioural regulation – *What preparatory steps do you think are required to implement the guideline recommendation(s)? Why?*		**To identify the clinicians' view on how behavioural regulation influences the implementation of the guideline recommendation(s), guided by (11) from Michie et al.**
Probes	Probe 1. Reiterate Question	To keep participant on track and clarify question in other words
	Specific probe type 1. Preparatory steps examples	To bring up examples of preparatory steps to jog the participant's memory for a response
	Specific probe type 2. Reason that action steps are facilitators	To probe the reason that these action steps are required if not mentioned
14. Behavourial Change- *What behaviour do you think should become a habit for improving the implementation of the recommendation(s)*		**To identify the clinicians' view on how behavioural change influences the improvement of implementing the guideline recommendation(s), guided by (12) from Michie et al.**
Specific Probes	Type 1. Situational Probe	To help the participant think of a proposed behaviour by directing them to a particular situation where an ideal behaviour was displayed to implement the selected recommendation(s).
	Type 2. Novel or Existing Behaviour	To identify if the behaviour is new or existing?
	Type 3. Who needs to change?	To identify the stakeholders involved in the behaviour change
15. *What do you think can prompt the new behaviour as a long term change?*		**To identify the clinicians' view on what prompts are required for long-term behaviour change for implementing the selected guideline recommendation(s), guided by (12) from Michie et al.**
Specific Probes	Type 1. Freestyle 5W's	To probe the participant's idea on how to maintain the new behaviour in the long-term through answering the 5W's
	Type 2. Examples	To bring up examples if the participant does not have ideas
	Type 3. Pragmatic question	To probe the participant on how realistic it is to maintain long term changes with the current systems in place

APPENDIX G- Recruitment Email Correspondence

Dear (insert participant's name),

My name is Brenda Trinh and I am a MSc. student working under the supervision of Dr. George Heckman in the School of Public Health and Health Systems at the University of Waterloo. I am contacting you because we are conducting a study that will be a stepping stone for the implementation of a coordinated, regional approach to oral anticoagulation therapy (OAT). Our study aims to understand the clinician's perceptions on the uptake of a systematic approach to key elements for optimal OAT practices. This research will generate a list of benefits, barriers and facilitators for effective implementation. We are currently seeking key informants for this study who are pharmacists and nurses with certifications to work in specialized anticoagulation management service (AMS) clinics using point-of-care technology (i.e., CoaguChek XS^{TM} and computerized software) for at least 6 months within the WWLHIN community (Waterloo-Kitchener, Cambridge and Guelph).

Participation in this study involves a 30-minute interview at a time and place convenient to you. I hope to book your time in advance when there are no patients scheduled to come in at the AMS clinic. Interviews will be between October and November 2016, but if a later date is necessary, I would be pleased to coordinate with you. Before the interview, I will send you an information sheet about the study and a short article to read ahead of time: *Delivery of Optimized Anticoagulation Therapy* by Garcia et al. (2008). I would like to assure you that our study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee. However, the final decision about participation is yours.

If you are interested in participating, please contact me at b2trinh@uwaterloo.ca and list your top two availabilities. I will then send a confirmation email indicating that you've been signed up for an interview time slot and discuss further details.

I look forward to your reply!

Sincerely,

Brenda Trinh
MSc. candidate
University of Waterloo
School of Public Health and Health Systems

APPENDIX H- Confirmation Email to Respondents

Subject: Confirmation of Participation in Study

Hi **(insert participant's name):**

You have recently responded to our invitation to participate in the study entitled "*"Clinical pharmacists and nurses' perceptions on implementing anticoagulation therapy recommendations for the frail elderly: An exploratory study based on psychological theory."*

This is an email to confirm that our interview is scheduled at **(insert time)** at the **(insert location).**

As a reminder, please find attached the information sheet and a short article by Garcia et al. (2008) on the 9 key recommendations for the delivery of optimized anticoagulant therapy.

I would like you to select 1 or 2 out of the 9 key recommendations by Garcia et al. for our interview: (1) Qualifications of Personnel, (2) Supervision, (3) Care Management and Coordination, (4) Documentation, (5) Patient Education, (6) Patient Selection and Assessment, (7) Laboratory Monitoring, (8) Initiation and Stabilization of Warfarin Therapy, and (9) Maintenance of Therapy.

If you require more information or have any questions, please do not hesitate to email me at b2trinh@uwaterloo.ca. Otherwise, please reply to this email with your 1-2 selected recommendations so that I may prepare accordingly for our interview. If you have to reschedule or cancel for any reason, please notify me at the email address above.

Sincerely,
Brenda Trinh
MSc. candidate
University of Waterloo
School of Public Health and Health Systems

APPENDIX I- Non Response Follow Up Email

Subject: Follow-up for Study

Hi (insert participant's name):

I recently sent an email message to invite you to participate in a study. This study aims to understand how we can implement a broader, more uniform approach to oral anticoagulation therapy (OAT). Since I have not heard back from you, I wanted to inquire as to whether you've made a decision. If we are still under consideration, I would like to again express my interest in conducting an interview with you for this study. I believe that your expertise and knowledge would be a valuable contribution for this research.

If you are looking for more flexible timing, I would be happy to coordinate with you to find a time and place convenient to you.

Again, I would like to assure you that our study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee. However, the final decision about participation is yours.

If you are still interested in participating, please contact me at b2trinh@uwaterloo.ca and list your top two availabilities. I will then send a confirmation email indicating that you've been signed up for an interview time slot and discuss further details on the location.

I look forward to your reply!

Sincerely,
Brenda Trinh
MSc. candidate
University of Waterloo
School of Public Health and Health Systems

APPENDIX J- Participant Feedback/Appreciation Letter

University of Waterloo

(Insert Date)

Dear ***(Insert Name of Participant),***

I would like to thank you for your participation in this study entitled *"Clinical pharmacists and nurses' perceptions on implementing anticoagulation therapy recommendations for the frail elderly: An exploratory study based on psychological theory."* As a reminder, the purpose of this study is to explore perceptions of pharmacists and nurses about the uptake or not of a systematic approach to key recommendations for optimal oral anticoagulation therapy (OAT). The larger goal is to aid in the implementation process of an integrated regional approach to OAT.

Please remember that any data pertaining to you as an individual participant will be kept confidential. Once all the data are collected and analyzed for this project, I plan on sharing this information with the research community through seminars, conferences, presentations, and journal articles. If you are interested in receiving more information regarding the results of this study, or would like a summary of the results, please provide your email address, and when the study is completed, anticipated by January 2017, I will send you the information. In the meantime, if you have any questions about the study or findings, please do not hesitate to contact any of the following people: Student Investigator- Brenda Trinh, b2trinh@uwaterloo.ca; or Faculty Supervisor in the School of Public Health and Health Systems Department– George Heckman, ggheckman@uwaterloo.ca.

As with all University of Waterloo projects involving human participants, this study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee. Should you have any comments or concerns resulting from your participation in this study, please contact the Chief Ethics Officer, Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

Brenda Trinh
Student Researcher

University of Waterloo
School of Public Health and Health Systems

519-729-2819

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APPENDIX K- Codebook using Nodes from NVIVO

Name of Node (inductive or deductive)
Guideline Recommendations
Care Management and Coordination
Transition of Care
Documentation
About software
Clinical Connect
Initiation and Stabilization of Warfarin Therapy
Lab Monitoring
Maintenance of Therapy
Patient Education
Patient Selection and Assessment
Qualifications of Personnel
Supervision
Medical Directive
Role Confusion
Staffing
List of...
Barriers
Benefits
Facilitators
Accessibility
Communication & Collaboration
Continuing Education
Importance of Clinical Experience
Reimbursement
Software Upgrades
Standardizing protocols
System Integration
Older Population with AF
Adherence issues
Frailty
Psychological Theory 12 Domains
Anticipated Outcomes & Attitudes
Behavioural Regulation
Emotion
Environmental Context & Resources
Intention
Knowledge
Memory, Attention & Decision Processes
Professional Role and Identity
Self-Efficacy
Skills
Social Influences
Family & Caregiver
Other allied HCPs
Other pharmacists
Patients
Physicians
Third Party Dispenser
Selected Recommendation(s)
Sentiment
Negative
Neutral
Positive

APPENDIX L- Coding Issues & Assumptions

During the data coding process, the researcher noticed the following issues and/or assumptions:

1. There was overlap in the data on software used for dosing adjustments so there was conflict on whether or not it should be coded as *documentation, care management/coordination* or *maintenance therapy*:
   "Like the dosing recommendations are a bit blunt, so big dosing recommendation changes when it's not, the computer of course can't look at the patient and can't see the whole picture as to explaining why an INR might be out of range. And it might be much better to do a very small one-time dose adjustment, whether it'd be a boost or a reduction one time and then continue the maintenance dose and recheck, right? Whereas dosing algorithms tend to be quick to make broad sweeping adjustments to the maintenance dose with a bit of over testing. So the clinical experience with Warfarin comes to say yes but the patient in front of me has these characteristics, this is the clinical scenario and no I don't agree with the dosage algorithm suggestion because I know that we'd be better off to make a very small adjustment or none at all, and simply recheck."

   So, the investigator and second coder went through the process of elimination while consulting the definitions from the guidelines. At first, *documentation* was considered as the main recommendation because the participant spoke about the computerized software, but it was not coded as such because it did not talk about the documentation process. *Care management and coordination* was also considered but not coded because the focus was not on the policies and procedures as a clinical tool for managing warfarin therapy. The content was more about the maintenance therapy aspect because the focus was on the uptake or not of the dosing algorithm for longitudinal adjustment of Warfarin. So, after re-analyzing the participant's quote in its context, the second coder and the researcher came to the consensus that the main recommendation was maintenance of therapy. The next step was to determine what factor from Michie et al. influenced the implementation or not of this recommendation. The credibility of this systematic process for long-term dose adjustments was critiqued as being too blunt and as such, the participant said that it should not be used as a 'tell-all' to guide their practice, so it was clearly in conflict with the professional standards. Therefore, it was coded as *maintenance therapy* as the key recommendation and *professional/social role or identity* as the factor from the psychological theory. This process of re-analysis and discussion was done by the researcher and second coder for each transcript to ensure that all themes were coded as closely to the definitions in the documents for deductive themes.
2. Difficulty categorizing the data content as *maintenance of therapy* or *care management/coordination* because of overlap in concepts. It is coded as *maintenance of therapy* if it talks about the systematic process for longitudinal Warfarin management. This would include using checklists for follow-ups, and validated algorithms as a systematic approach to stable dosing, dealing with extreme INR values, interrupting and restarting for invasive procedures, and managing adverse or interacting events (e.g. number of days between INR testing). *CMC* is referring to the procedures or policies as a clinical tool to resolve issues of Warfarin management and coordination, or in other words, <u>how</u> they run the clinic.

3. There were coding conflicts with the second coder due to subjective interpretations. For example, the researcher coded the data based on the participant's point-of-view and context in the community. FHTs have mixed clinicians so the researcher considered the perspective of the nurses and pharmacists, but there are just pharmacists in community pharmacies.
    - A community pharmacist successfully receives patient referrals to his clinic from nurses because they know the pharmacist is knowledgeable and has a good inter-professional relationship with the nurses. This content was coded as care management/coordination, positive, benefit, knowledge, social influence (other allied professionals).
    - The second coder interpreted it in the community nurse's perspective because they did not have knowledge for Warfarin management, so she coded it as care management/coordination, negative, barrier, knowledge
    - In the end, the researcher and second coder agreed to code all transcripts based on the participant's point of view.
4. The researcher and second coder assumed that from the interview's introduction that subsequent questions were about the target population: older adult with frailty and AF
5. Patient selection and assessment refers to any content related to the systematic approach of assessing the risk and benefits for patients to initiate OAT. E.g. Require relevant patient history (medical, family, social, employment, beliefs, health literacy, resources)

APPENDIX M-Output of Similarly Coded Text

Table 4. Output of Similarly Coded Text where all the terms in each row applies. E.g. 'Frailty' AND 'BARRIER' yields 13 references of similarly coded blocks of text

Garcia et al. Recommendation or Concept	Factor from Michie et al.'s Psychological Theory	Barrier, Benefit or Facilitator?	# references
Frailty	-	Barrier	13
		Benefit	20
Older Population	-	Barrier	0
		Benefit	4
Adherence Issues	-	Barrier	6
		Benefit	5
Guideline Recommendations (General)	Any	Any	6
For each of the 9 key reccommendation: 1. Qualifications 2. Supervision 3. Care Management/ Coordination 4. Documentation 5. Patient education 6. Patient Selection/ Assessment 7. Lab Monitoring 8. Initiation/ Stabilization 9. Maintenance Therapy	Knowledge	Barrier (15)	1 (Qualification) 1 (Superv)/ 1 (MD)/ 3 (role confusion)/ 0 (staffing) 4 (CMC)/ 0 (transition) 0 (doc)/ 1 (soft)/ 1 (CC) 0 (pt education) 2 (pt SA) 0 (lab monitor) 2 (initiation/stab) 1 (maintenance)
		Benefit (82)	3 (Qualifications) 3 (Supervision)/ 6 (MD) /4 (role confusion)/ 0 (staffing) 18 (CMC)/ 4 (transition) 4 (doc)/ 2 (soft)/0 (CC) 10 (Pt Education) 5 (pt SA) 2 (lab monitor) 5 (initiation/stab) 16 (maintenance)
	Skills	Barrier (7)	0 (Qual) 0 (Supervision)/ 0 (MD)/ 1 (role confusion)/ 0 (staffing) 2 (CMC)/ 0 (transition) 1 (doc)/ 0 (soft)/ 0 (CC) 1 (pt edu) 0 (ptSA) 0 (lab monitor) 0 (initi/stab)

			2 (maintenance)
		Benefit (30)	1 (Qual) 1 (Superv)/ 0 (MD) / 0 (RC)/ 0 (staffing) 9 (CMC)/ 1 (transition) 7 (doc)/ 5 (soft) / 0(CC) 4 (pt edu) 0 (PtSA) 0 (lab) 1 (initi/stab) 1 (maintenance)
	Social/Professional role and identity	Barrier (27)	0 (Qual) 1 (Superv)/ 2 (MD)/ 0 (Staffing) 9 (CMC)/ 1 (transition) 1 (doc)/ 4 (soft)/ 1 (CC) 0 (pt edu) 1 (pt SA) 0 (lab) 0(Initi/Stab) 7 (maintenance)
		Benefit (16)	2 (Qual) 1 (Superv)/ 3 (MD)/ 0 (RC)/ 0 (Staffing) 5 (CMC)/ 1 (transition) 1 (doc)/ 0 (soft)/ 1 (CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (initi/stab) 2 (maintenance)
	Self-efficacy	Barrier (4)	0 (Qual) 0 (Superv)/ 0 (MD)/ 0 (RC)/ 0 (Staffing) 3 (CMC)/ 0 (transition) 0 (doc)/ 0(soft)/0 (CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 1 (maintanence)
		Benefit (8)	0 (Qual) 0 (Superv)/ 0 (MD)/ 1 (RC)/ 0 (Staffing) 3 (CMC)/ 3 (transition) 0 (doc)/ 1 (soft)/ 1 (CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 0 (maintenance)
	Anticipated Outcomes/Attitudes	Barrier (7)	0 (Qual) 0 (Superv)/ 0 (MD)/ 1 (RC)/ 0 (Staffing) 4 (CMC)/ 0 (Transition) 1 (doc)/ 0 (soft)/ 0 (CC)

			0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 1 (maintenance)
		Benefit (16)	1 (Qual) 1 (Superv)/ 0 (MD)/ 0 (RC)/ 0 (Staffing) 5 (CMC)/ 1 (Transition) 1 (doc)/ 1 (soft)/ 1 (CC) 3 (pt edu) 1 (pt SA) 0 (lab) 1 (init/stab) 0 (maintenance)
	Intention	Barrier (12)	0 (Qual) 0 (Superv)/ 2 (MD)/ 0 (RC)/ 0 (Staffing) 5 (CMC)/ 0 (Transition) 0 (doc)/ 4 (soft)/ 0 (CC) 0 (pt edu) 1 (pt SA) 0 (lab) 0 (init/stab) 0 (maintenance)
		Benefit (12)	2 (Qual) 0 (Superv)/ 0 (MD)/ 0 (RC)/ 0 (Staffing) 7 (CMC)/ 2 (Transition) 0 (doc)/ 1 (soft)/ 0 (CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 0 (maintanence)
	Memory, attention and decision processes	Barrier (3)	0 (qual) 0 (superv)/ 0 (MD)/ 0 (RC)/ 0 (Staffing) 0 (CMC)/0 (Transition) 2 (doc)/ 1 (soft)/ 0 (CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 0 (maintanence)
		Benefit (1)	0 (qual) 0 (superv)/ 0 (MD)/ 0 (RC)/ 0 (Staffing) 0 (CMC)/ 0(Transition) 0 (doc)/ 0(soft)/ 0 (CC) 0 (pt edu) 1 (pt SA) 0 (lab) 0 (init/stab) 0 (maintenance)

	Environmental Context and Resources	Barrier (66)	3 (qual) 0 (superv)/2 (MD)/ 1 (RC)/ 5 (Staffing) 32 (CMC)/ 5 (Transition) 5 (doc)/ 9 (soft)/ 2 (CC) 1 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 1 (maintenance)
		Benefit (56)	3 (qual) 1(superv)/ 1 (MD)/ 0 (RC)/2 (Staffing) 21 (CMC)/ 2 (Transition) 8 (doc)/ 2 (soft)/ 3(CC) 5 (pt edu) 1 (pt SA) 0 (lab) 0 (init/stab) 7 (maintenance)
	Social Influences	Barrier (44)	0 (qual) 0 (superv)/ 2 (MD)-physicians/ 1 (RC)-Family/0 (Staffing) 1 (CMC)/ 1 (CMC)-Family/ 1 (CMC) –Other Allied HCPs/ 3 (CMC)-Other Pharmacists/ 3 (CMC)- patients/ 11(CMC)- physicians/ 1 (CMC)-3rd party 2 (Transition)/ 1 (Transition)- Family/3 (Transition)- Other HCPs/ 4 (Transition)- Patients/ 1 (CMC)-Physicians/ 1 (CMC)- 3rd party 0 (doc)/2 (doc)-physician 0 (soft)/ 1 (soft)-patients/ 2 (soft)-physicians 0 (CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab)/ 0 (maintenance)/ 1(main)-other HCPs/ 1 (main)-patients/1 (main)-physicians
		Benefit (62)	0 (qual) 1(superv)- physicians/ 2 (MD)- physicians/ 1

			(MD)- patients/ 0 (RC)/ 0 (Staffing) 3 (CMC)/ 2 (CMC)- other HCPs/ 3 (CMC)- other pharmacists/ 8 (CMC)- patients/ 18 (CMC)- physicians 5 (Transition)/ 2 (Transition)-Other HCPs/ 2 (Transition)- Other Pharmacists/ 2 (Transition)-Physicians 0 (doc)/ 1 (doc)-other pharmacists/2 (doc)- patients/ 2 (doc)- physicians 0 (soft) 0 (CC) 0 (pt edu)/1 (pt edu)- family/ 2 (pt edu)-patients 0 (pt SA)/1 (pt SA)-family 0 (lab) 0 (init/stab)/ 1 (init/stab)- patients 0 (maintenance)/ 2 (main)- patients/ 1 (main) - physicians
	Emotion	Barrier (6)	0 (Qual) 0 (Superv)/ 0(MD)/1 (RC)/0(Staffing) 4 (CMC)/ 0 (Transition) 1 (Doc)/ 0 (Soft)/0 (CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 0 (maintenance)
		Benefit (2)	1 (Qual) 0 (Superv)/ 0 (MD)/0 (RC)/0 (Staffing) 1 (CMC)/ 0 (Transition) 0 (Doc)/ 0 (Soft)/0 (CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 0 (maintenance)
	Behavioural Regulation	Barrier (0)	0 (Qual)

				0 (Superv)/ 0 (MD)/ 0 (RC)/0 (Staffing) 0 (CMC)/ 0 (Transition) 0 (Doc)/0 (Soft)/ 0(CC) 0 (pt edu) 0 (pt SA) 0 (lab) 0 (init/stab) 0 (maintenance)
		Benefit (6)		0 (Qual) 1 (Superv)/ 0 (MD)/0 (RC)/0 (Staffing) 3 (CMC)/ 0 (Transition) 0 (Doc)/ 2 (Soft)/0 (CC) 0 (pt edu) 0 (pt SA) 0(lab) 0 (init/stab) 0 (maintenance)
	Nature of Behaviour (theme coded as facilitator – what will change?)	Facilitators (41 total)	Accessibility	1
			Communication & Collaboration	17
			Continuing Education	3
			Clinical Experience	2
			Reimbursement	8
			Software Upgrades	4
			Standardizing Protocols	9
			System integration	8

APPENDIX N- Reflexive Journaling

Data Collection Process

- I emailed a pharmacist in the community who was willing to do a dry run to practice my interview questions. The pharmacist was helpful in providing feedback to adjust my interview questions so that they are more applicable to the key informants. I also contacted my committee member with extensive qualitative experience to review and provide feedback on the interview guide and tips on interviewing key informants. I had a phone conference with that expert and then jotted the notes down: ask a few (not all) questions during one interview to yield quality data, form a relationship with the interviewer and keep time at the end for additional comments/ questions. This is where I learned that I would yield the most valuable answers.
- I changed the way the questions were asked to make it more "on the ground" or applicable to pharmacists and nurses. I did this by making sure I had other ways of re-iterating the same point. I also formatted the interview guide in a chart form because I found it easier to read.
- Then, I proceeded to recruit and set up an interview time with the first pharmacist as outlined in the proposal. Once I received the reply that the selected recommendations were initiation/stabilization of warfarin therapy and care management/coordination, I simplified the interview guide to include questions about the selected recommendations only. I did this modification in order to focus on the topics rather than have the entire interview guide in front of me, which was too long to print and have a paper copy of.
- During the interview, I met the pharmacist in the AMS clinic office and went through the interview questions one by one and provided positive feedback as the participant answered each question. The interview was audio recorded and I felt the first interview was a success even though I had much to improve on. I wrote down my first impressions about the participant and clinic right after on the back of the interview guide; there is a physical copy for reference. I also wrote down how to improve my interviewing skills and the content to focus more on in the next interview. The participant was very knowledgeable and provided all the necessary information without many prompts. I felt that I was confused about the care management/coordination recommendation after transcribing the audio file and that might have affected the quality of the data. So, I reviewed the recommendations again and made sure to create a checklist of the main points to hit during my next interview.
- I asked the pharmacist to refer me to some nurses as a snowball sample. Soon after, I received correspondence from two nurses in the same family health team who were interested in my study. I sent the recruitment email and set up times to conduct the interview.
- Again, I modified the interview based on their selected recommendations (supervision and documentation) and simplified it into a chart form with clear topic headings. I found that I needed more prompts in this interview compared to the first interview with the pharmacist. I made a lot of notes beside the topic headings after the interview about my impressions about the lack of knowledge on frailty and the clear chain of duty, as well as how the documentation process was done very well. I noted that the participant chose documentation even when it was already done well so this was a great feat for my benefit list. I wondered why it was chosen —maybe because it was the most comfortable aspect for her to talk about. However, I did ask the participant to choose recommendations based on what needed the most improvement, but the participant ended up picking documentation. This is interesting.
- I interviewed the next nurse on the next day. Since the last interview was fresh in my mind, I decided to not use the table format and stick to the original guide in the proposal. I deleted irrelevant questions not related to the selected recommendation. I ended up choosing care management and coordination since the nurse did not reply to my email on which recommendation he/she wanted to focus on. The nurse was fine talking about care management and coordination, although there was some initial hesitation. The nurse was unsure because the participant thought he/she did not know much about the policies and procedures. However, as I probed the nurse with questions on how they managed and dealt with management issues, more information arose. It was clear that written policies were not explicitly available and communicated to the staff, although they were learned through experience and informal learning in the clinic. I noticed nurses did not have the formal training course at the School of Pharmacy, but they did have training from the pharmacist and Roche. This nurse was knowledgeable about frailty and raised a lot of issues about inter-professional relationships. I noticed the nurse was younger than the head nurse (previous participant) and that nurse also knew more about the policies to follow for risk assessment, initiation and etc. The nurse knew a lot about transition of care, especially describing the relationship between nurses in different

institutions and providers outside the family health team. The transitions are very choppy, unlike in the family health team where physicians are now all on board (although they weren't before). I noticed a conversation style interview brought out more issues and themes than asking question after question.

- I decided to make the next interview more like a case study or ask them to describe an example and then probe for the concepts. The next interview was not until a week later because I was sick, so I had to review all the concepts while transcribing my first three interviews.
- My first interview with a community pharmacist (CP) was quite different than those at the family health team. The CP chose care management and coordination; documentation; and qualifications of personnel. There was more self-efficacy and intention to run the AMS clinic since it was managed entirely by him. I stuck with the original interview guide and highlighted the questions to ask. I noticed it was more difficult to schedule and sit down for the interview. We were interrupted once at 30 minutes because he was the only one who could do flu shots. There seems to be a staffing issue. This could mean that patients do not have the luxury to talk to the community pharmacists for as long as the pharmacists in family health teams. I was not interrupted once in those interviews. The scheduling in family health teams is more organized and they have more time with patients. At the end of the interview, I jotted down themes related to coordination, intention, and general impressions. Answers were short and quick because it seemed to me that it was all intuitive and common sense. CP asked "why isn't it already being done across clinics?" All the recommendations were claimed to be followed in this community clinic and the concern was more about reimbursement procurement. CP wanted to make sure I had all the information I needed and offered to clarify anything if needed; I just need to call or email.
- Reimbursement seems to be a recurring theme in all my interviews so far.
- My next interview is at a family health team. This pharmacist read the entire guideline and told me it was okay to focus on all of them, although the participant originally chose patient education and initiation/stabilization of warfarin therapy. As a matter of fact, the responses focused a lot of the education aspect! With this participant, I wanted to try a narrative approach where I gave a scenario: "An older patient is suspected to have an indication for warfarin therapy by the family physician, what do you think the guideline says about the next steps for the patient to get started in the clinic?" This way we were able to tell the story of a patient going through the system and at the same time, we discussed all the recommendations and I probed about the factors that might have affected their implementation. I found that the information came more easily to the participant when framed as a case study or example, than straight up question after question. The participant gave hypothetical responses (opinions and feelings) about the barriers that other pharmacists in the community might have compared to family health team clinicians. Participant really understood that the guideline implementation was in the general scope of the community and not just this clinic. Although I said this in previous interviews, this pharmacist was the first one to consider that point when answering all questions.
- Asking about all the recommendations was overwhelming in even 40 minutes because there is A LOT of information, so in the next interview I want to re-focus on specific recommendations.
- Next interview with a community pharmacist selected care management and coordination; and initiation and stabilization of warfarin therapy. Again, I noticed the trend that community pharmacies have less time than family health teams for the interview. CP provided clear and concise answers to my questions. My interview guide had a mix of just questions and case examples to clarify concepts. It worked very well, the best by far. I added a clear list of prompts for myself in case the participant wanted me to re-iterate or give examples. I had clear transitions between questions and the interview flowed much better. My interview skills improved since the first interview and I understood all the recommendations really well by now so I felt like I could probe and ask for clarifications from the participant much better. In 30 minutes, I was able to get through 10 questions since I was clear in my questions and CP was concise in replying. CP mentioned that a pharmacy technician was important to free up time for pharmacists to do therapeutic activities. CP was enthusiastic and excited to be the first community pharmacy to have access to Clinical Connect and is drafting an advocate letter to the government for reimbursement for anti-coagulation clinics!
- The last two interviews and phone conference with a missing voice (pharmacist at a hospital but previously had extensive experience in the community and family health teams) occurred on the same day.
- In the morning, I had an interview a pharmacist in a community pharmacy. We met at a coffee shop because CP did not have an office. CP showed me the documentation software and we focused on all the recommendations because CP did not respond to my request to select 1-2 recommendations. I tried an

informal approach to starting the interaction with this pharmacist instead of recording the demographic information. As CP showed me the documentation system, I asked about the job title, training and experience in the clinic, as well as the patient base and trained staff. I noticed that I built a better rapport with the participant when the conversation was not recorded. Then we proceeded to the coffee shop and CP talked freely about how his clinic had a medical directive that followed a New Zealand guideline but it was quickly abolished. Before CP went on any more, I suggested we recorded the interview staring with the frailty questions. CP was happy to oblige and we continued our talk. This interview felt more like a conversation and he brought up many issues with strict medical directives. This participant had trouble identifying frailty and how it affected assessment. Initiation of warfarin therapy was not done in this clinic since they have a very small patient base and never had to start therapy for any of them; they just continued warfarin therapy that was initiated by other providers. Social networks and supports played a large role in this clinic; a lot was informal because there was no time or resources to formalize policies especially with independent physician offices.

- In the afternoon, I had input from the pharmacist over the phone. This person was not an official participant because he/she no longer worked for a AMS clinic in the community, however he/she is the missing voice due to their experience and knowledge of the benefits, barriers and facilitators. We spoke on the phone without recordings, but I took extensive notes. We discussed what works, what doesn't and what will help in the context of the community anti-coagulation clinics. Many themes emerged from our conversation: social influences, intention/empowerment, issues with system integration of documentation processes, non-standardized patient education materials and needing a reliable systematic approach to clinical support. Bridging was also discussed as a huge issue because of environmental constraints (a logistics problem). Then we closed with how the frail older with AF is a labour-intensive population to manage.
- The last interview was with a pharmacist from a family health team that manages a huge patient base. We had the interview after her office hours in a coffee shop; he/she was busy during work and didn't have space.
- Since I had redundancy in the themes mentioned, and time was limited, the participant above talked about the main benefits, barriers and facilitators of the guidelines in general. I thought we could learn about what they have to offer since they were a deviant case. I was correct because when we were talking about the general benefits, barriers and facilitators, many factors influencing the uptake or not of specific recommendations also came up. Although the interview was still semi-structured and guided by the theory domains, the flow of the interview was more natural when the participant was not forced to talk about a certain concept via questioning. I started out with the most important question that is simple to understand: "Currently what's the factors affecting how well anti-coagulation clinics are run in the community?" Once participant talked about what worked, what didn't and what helped, many of Michie et al.'s psychological theory domains came up in the conversation.
- The participant talked about how the clinic got started, its barriers and how they were overcome, and the benefits of having one clinic managing Warfarin therapy and also what they were working on. This was a unique perspective that none of the other clinicians had because they were not in this environment. Participant talked about a whole host of different factors influencing the implementation of different recommendations. Frailty was a big topic and he/she replied keeping this population in mind.
- I gained a lot of insight about the themes and concepts on how these factors influenced the uptake or not of the 9 key recommendations in the community. I was ready to analyse the transcripts and draw inferences from the data.

Transcription Process

- I used an audio recorder to record the interviews.
- I transcribed the audio files right after I conducted the interviews to keep it fresh in my mind. I consulted the field notes during transcription if things were unclear. This triangulation of various data sources ensures the credibility of my data.
- If any information was unclear in the transcript and audio files, I sent the participant a quick clarification email and received a prompt reply. Member checking was useful when I did not probe or clarified in the interview. For example, I saw that the participant was unsure of the response about the number of patients in her clinic, so I confirmed the number through an email. Participant replied and confirmed that number.
- In each transcript, the heading has the relevant information: location, type of clinician, date, audio file name and my name as the transcriber.

- I made sure to include non-verbal impressions (tone, laughs, hesitations, long pauses, etc.) in order to code for emotion and intention later.
- I cleaned up the transcript of the umm's if I said them too much but kept the integrity of the key informants' responses.
- When there was overlap of voices, I made sure include that in to show that the participant was keen to answer my questions.
- I used an online program called "transcribe really" to simultaneously type and listen to the audio in one window. It had features to automatically play for 5 seconds and then pause for 3 seconds, then re-play for 3 seconds. That feature helped to transcribe the audio file word-for-word more accurately. It would take 3-4 hours to transcribe each audio file of about 30-40 minutes.

Data Analysis Process

- I have experience from a qualitative data course and a previous research assistant position on how to code interview content in Word.
- I used NVIVO Pro 11 and watched the tutorials and read the HELP section on how to analyze interview transcripts. They suggested using single nodes and then using the query function to search multiple nodes during data analysis.
- I categorized the hierarchy of the nodes as such:
    - Garcia et al. recommendations (9 elements)
    - Michie et al. psychological theory domains (11 domains)
    - List of …
        - Benefits
        - Barriers
        - Facilitators
    - Sentiment
        - Positive
        - Negative
        - Neutral
    - Older Population with AF
        - Frailty
- Then I started to code the transcripts in order of when they were conducted. I used these deductive nodes to code the data, then I added nodes as emergent themes appeared.
- The codebook above grew as I noticed recurrent themes in the data, such as adherence issues, different facilitators (reimbursement, continuing education, system integration, etc.)
- After categorization and coding all the data, I asked a colleague with qualitative data analysis experience. She coded my transcripts on NVIVO 8 and we did not notice until she tried using the data comparison function to generate a kappa score. It was not compatible so due to time and resource constraints, we did the second coding to refine the codes in the transcripts. We sat together and had the program opened with my coding scheme, and we discussed what was meant by the data. We noticed more recurrent themes, re-coded and un-coded strings of text from multiple sources. After our discussions, I noticed that the qualitative data can be organized in many different ways and I needed solid criteria to code the text. We did content analysis and made sure to code the main ideas of each string or block of text. It took us two full days (19 hours) to go through second analysis coding. As we were second coding, I noted conflicts in coding, why we had the discretions and how we resolved it. As we were analysing and discussing the themes, I revised my coding and how it fit into the themes.
- I had a list of interesting findings as I was second coding and as I grouped recurrent themes with headings in the analysis, I noticed that some themes were still not coded properly since I had difficulty categorizing care management and coordination, and maintenance therapy. I reflected on the difference and made it clear what criteria made it one or the other. See analysis for clear descriptions.
- I went through the coding a third time to fix the mistakes in the coding confusion above.
- I decided to read more about qualitative data analysis online in order to write about all the points in my thesis. I found this website with a slide show talking about how to conduct qualitative studies by a Masters of Public Health employee: http://www.slideshare.net/tilahunigatu/qualitative-data-analysis-11895136
- The slides were comprehensive of all the features in qualitative data collection and analysis, so I took a few notes and included main points that I had previously left out.