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Warfarin Management in Patients with Atrial Fibrillation — Current Practice Study

Supporting Informed Decisions

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1 INTRODUCTION

The Canadian Agency for Drugs and Technologies in Health (CADTH) retained Vision Research to undertake a study into the prescription and management of anticoagulation therapy in Canada, with particular emphasis on warfarin treatment. The study investigated current practices as well as the perceived benefits and limitations of the treatment from the perspective of medical specialists, General Practitioners (GPs) and family physicians, allied health professionals, and patients. The research findings are based on the results of qualitative research in the form of focus groups and executive interviews. Vision Research sought to understand and explain the process of selecting between different anticoagulants and managing the therapy. This report of those findings will present a summary of the responses collected as well as the underlying themes that extend across the qualitative data from particular questions and respondents.

2 BACKGROUND

Optimizing drug-related health outcomes and cost-effective use of drugs by identifying and promoting optimal drug prescribing and use is a goal of CADTH. Where possible, CADTH builds on existing applicable Canadian and international initiatives and research. CADTH goals are achieved through three main approaches:

- identifying evidence-based optimal use in prescribing and use of specific drugs
- identifying gaps in clinical practice, then proposing evidence-based interventions to address these gaps
- supporting the implementation of these interventions.

Direction and advice are provided to CADTH through various channels, including the following:

- the Drug Policy Advisory Committee (DPAC), the DPAC Optimal Use Working Group (OUWG), and the Formulary Working Group (FWG),which include representatives from the federal, provincial, and territorial health ministries and related health organizations
- the COMPUS Expert Review Committee (CERC) (members are listed in Appendix A)
- stakeholder feedback.

2.1 COMPUS Expert Review Committee

CERC consists of eight Core Members appointed to serve for all topics under consideration during their term of office, and three or more Specialist Experts appointed to provide their expertise in recommending optimal use for one or more specific topics. For this project, five Specialist Experts were appointed; their expertise included cardiology, hematology, and thrombosis. Two of the Core Members are Public Members, who bring a lay perspective to the committee. The remaining six Core Members hold qualifications as physicians, pharmacists, or health economists, or have other relevant qualifications, with expertise in one or more areas such as, but not limited to, family practice, internal medicine, institutional or community clinical pharmacy, pharmacoeconomics, clinical epidemiology, drug utilization, methodology, affecting behaviour change (through health professional and/or patient and/or policy interventions), and critical appraisal. The Core Members, including Public Members, are appointed by the CADTH Board of Directors.

CERC's mandate is advisory in nature and consists of providing recommendations and advice to CADTH on assigned topics that relate to the identification, evaluation, and promotion of optimal practices in the prescribing and use of drugs across Canada. The overall perspective of CERC members in producing recommendations is that of public health care policy-makers in pursuit of optimizing the health of Canadians within available health care system resources.

3 ISSUE

The DPAC and its working groups, the OUWG and the FWG, have identified warfarin management for prevention of thromboembolic events in patients with atrial fibrillation (AF) as being a priority topic for optimal practice initiatives based on the following criteria:

- large deviations from optimal utilization (overuse or underuse)
- size of patient populations
- impact on health outcomes and cost-effectiveness
- benefit to multiple jurisdictions
- measurable outcomes
- potential to effect change in prescribing and use.

3.1 Atrial Fibrillation

Atrial fibrillation is the most common type of cardiac arrhythmia.[1] It has been estimated that 200,000 to 250,000 Canadians have AF.[2] This condition is associated with significant morbidity and mortality. Approximately 15% of all strokes are associated with AF; risk is strongly correlated with age, increasing from 6.7% of all strokes in patients aged 50 to 59 years to 36.2% of all strokes for patients aged 80 to 89 years.[3]

3.2 Technology Description

3.2.1 Vitamin K antagonist anticoagulants

Warfarin is part of the coumarin class of Vitamin K antagonists (Table 1). Vitamin K antagonists have been the mainstay of oral anticoagulant therapy for more than 60 years. Their effectiveness has been established by well-designed clinical trials for several thromboembolic indications.[4] Evidence from several randomized controlled trials (RCTs) shows that long-term anticoagulation therapy with warfarin reduces the risk of ischemic stroke by 68% in patients with non-valvular AF (NVAF).[3]

However, clinical use of Vitamin K antagonists requires vigilance because:

- they have complex pharmacokinetics and pharmacodynamics
- they have a narrow therapeutic window
- they require (and benefit from) regular laboratory monitoring through a standardized blood test [International Normalized Ratio (INR)]
- the dose response varies among patients
- they are subject to several drug and dietary interactions.[4]

Table 1: Vitamin K Antagonists Available in Canada		
Vitamin K Antagonist	**Manufacturer**	**Trade Name**
Acenocoumarol (nicoumalone)	Paladin Labs Inc.	Sintrom
Warfarin sodium	Apotex Inc.	Apo-Warfarin
Warfarin sodium	Bristol-Myers Squibb	Coumadin
Warfarin sodium	Mylan Pharmaceuticals ULC	Mylan-Warfarin
Warfarin sodium	Novopharm Limited	Novo-Warfarin
Warfarin sodium	Sanis Health Inc.	Warfarin
Warfarin sodium	Taro Pharmaceuticals Inc.	Taro-Warfarin

Source: Health Canada Drug Product Database.[5]

3.2.2 Vitamin K antagonist anticoagulant management models

The effectiveness and safety of warfarin therapy depend on maintaining the INR in the optimal therapeutic range[4] (between 2 and 3 for AF[6]). There is a relationship between the time in therapeutic INR range (TTR) and bleeding or thromboembolic events.[4] The percentage of TTR is used as a marker for the quality of warfarin management. Evidence (from international clinical trials and observational studies on cardiac and other indications) demonstrated a wide spectrum of TTRs, varying from a lower range of 32% to 68% for usual care, to a higher 55% to 92% range for patient self-management (PSM).[4]

Usual care is defined as warfarin dose adjustment, managed by a physician working in a private practice setting, that not only addresses anticoagulation management, but also other medical problems.[7] Physicians in this setting use their own judgment, without access to specialized anticoagulation tools or anticoagulation clinic staff and services.[7,8]

Approaches suggested by the literature[4] to improve anticoagulant therapy include:

- anticoagulant monitoring services
- the use of point-of-care (POC) INR testing that allows patient self-testing (PST) or PSM of dose adjustment (combines self-testing with patient adjustment of their own doses)
- specialized tools to guide warfarin dose adjustment.

Anticoagulation monitoring services include a number of alternatives to usual care, from tertiary or community hospital-based anticoagulation clinics to primary-care settings and POC testing and dose adjustment by community pharmacies.[9] Primary-care settings and hospital-based anticoagulation clinics may use computerized decision–support applications or other tools to guide warfarin dosing.[4,9] The primary-care anticoagulation setting involves a family practice group or family health team where nurses, pharmacists, or physicians are responsible for managing warfarin therapy.[9] Specialized anticoagulation tools refer to a broad range of products that can be used by clinicians to guide dosing of warfarin in their particular practice setting. These vary from a simple web-based or paper nomogram (e.g., University of Wisconsin dosing protocol[10]) to an online warfarin dose calculator (e.g., WarfarinDosing.org[11]**)** to a computer application (e.g., DAWN software[12]).

4 OBJECTIVE

The objective of this current practice study was to explore the views and experiences of health care professionals and patients with atrial fibrillation regarding the use of warfarin and management of warfarin therapy for the prevention of thromboembolic events.

5 PROJECT OVERVIEW

Once a topic is selected, CADTH undertakes activities related to key areas in the procedure. The OUWG and the FWG will provide advice and guidance throughout the process, through to supporting intervention and evaluation tools. CERC provides expert advice and recommendations on the topic area relating to the identification, evaluation, and promotion of optimal prescribing and use of drugs. A broad range of stakeholders are invited to provide feedback at key stages in the CADTH process.

6 METHODS

This study used a blended methodology, including focus groups (face-to-face and via teleconference) and individual telephone interviews. Table 2 summarizes the methods and participants.

Table 2: Study Methods and Participants

Participant Type	Location	Methodology
Medical specialists	Across Canada	Individual telephone interviews
Patients	Ottawa and Calgary	Face-to-face focus groups
Allied health professionals practising in anticoagulation clinics	Calgary	Face-to-face focus group
	Ottawa and Eastern Ontario	Teleconference focus group
GPs and family physicians	Ottawa and Calgary	Face-to-face focus groups
	Rural areas across Canada	Teleconference focus group

GPs = medical practitioners.

Health care practitioners were contacted using commercially available lists and screened before being invited to participate in the study. Patients were contacted using telephone directories and similarly screened before being invited to participate. All participants provided informed consent and were offered a monetary incentive to thank them for their time and effort.

In total, 15 medical specialists participated in executive phone interviews. The focus groups featured responses from 14 family physicians and general practitioners, 11 allied health professionals, and 7 patients.

The interviews lasted 20 to 30 minutes and were audio-recorded. Focus groups in Calgary and Ottawa were 60 minutes long. The audio recordings were transcribed and the transcripts used to inform this report.

Table 3: Participants and Demographics

Method	Profile	Ottawa	Calgary	Male	Female	Urban	Rural	Type of Practice
Executive Interview	Specialists (15)	NA	NA	14	1	14	1	Hospital outpatient clinic (10) Solo (3), Group (2)
Focus Groups	GPs and family physicians (14)	7	7	8	6	14	0	Group (7), Solo (4), Primary care (1), Hospital outpatient clinic (1), ER (1)
	Allied health professionals (11)	4	7	1	10	8	3	Nurse (4), Pharmacist (7)
	Patients (7)	5	2	3	4	5	2	
Totals	**47**	**16**	**16**	**26**	**21**	**41**	**6**	

ER = emergency room; GPs = general practitioners; NA = not available.

7 RESULTS

Interviews and focus groups were conducted in English during June and August of 2011. A total of 47 Canadian individuals participated, comprising 15 medical specialists, 14 GPs and family physicians, 11 allied health professionals, and 7 patients.

7.1 Findings from Interviews with Medical Specialists

7.1.1 Warfarin

A majority of medical specialists interviewed suggested that between 80% and 95% of their patients with NVAF are on warfarin treatment. The remaining medical specialists indicated that fewer of their patients with NVAF are undergoing warfarin therapy, with answers ranging as low as 15% to 25%. Most participants mentioned that a patient's CHADS score is a key determinant in deciding whether or not to initiate warfarin therapy. The $CHADS_2$ and CHA_2DS_2-VASc are simple and validated clinical prediction tools that predict the likelihood of someone with AF having a stroke. A high score corresponds to a greater risk of stroke, while a low score corresponds to a lower risk of stroke.

Medical specialists consider a wide range of factors when prescribing warfarin therapy for their patients. Most of these factors are centred on the risks of complication. Participants cited, for example:

- risk for stroke or transient ischemic attack (TIA)
- scores on assessments such as $CHADS_2$, CHA_2DS_2-VASc
- patient's age and their history of stroke and TIA
- patient's risk and history for falls and bleeds
- polypharmacy and the risk of drug interactions
- history of chronic alcoholism
- renal/hepatic impairment

As warfarin treatment requires frequent blood tests and monitoring, as well as diet restrictions, the likelihood of compliance is another significant factor respondents consider. This factor includes consideration of whether the patient is mobile enough and lives in close enough proximity to have access to labs and clinics. Participants also consider whether or not a patient can afford treatment.

7.1.2 Merits and limitations of warfarin

Table 4 lists the most commonly reported merits and limitations of warfarin, as described by medical specialists.

Table 4: Commonly Reported Merits and Limitations of Warfarin

Merits	Limitations
• Reduces the risk of stroke • Low cost • Well-known safety and side-effect profiles	• Frequency of blood testing • Risk of bleeding • Certain dietary restrictions • Difficult to manage fluctuating INRs • Keeping patients within therapeutic range • Risk associated with drug interactions with other medications

7.1.3 Unsuitable patients

Participants agreed that patients with NVAF, who are eligible for warfarin but are also at high risk of bleeding, would not be prescribed warfarin. Those with a risk of falling (e.g., the frail elderly) or injury (e.g., construction workers) and those with a history of bleeding (e.g., patients who have had recent major bleeding or bleeding disorders) would not be prescribed warfarin.

The inability to adequately monitor the patient's INR was also cited as a deterrent for prescription by a majority of medical specialists. Whether because of patient compliance, mental health, or mobility/accessibility issues, participants noted that they would not prescribe the treatment.

A number of respondents noted that ultimately the choice was up to the patient and they wouldn't prescribe the treatment if a patient was uncomfortable or refused to take the drug because of the risks.

7.1.4 Warfarin management

Many medical specialists indicated that their patients are managed with the help of anticoagulation clinics, especially where their hospitals or health care centres contain anticoagulation clinics.

In addition, many medical specialists suggested that the patient's therapy is largely managed by the patient's family physician. Patients are referred to them by the family physician either to initiate warfarin or to adjust the dosage when patients are not able to achieve therapeutic levels. Once those patients' INRs are stabilized, they are referred back to the family physician or GP for ongoing management.

7.1.5 Support tools

The majority of medical specialists reported that they do not make regular use of nomograms or other support tools. Most rely on clinical judgment and the patient's individual response. In addition, many are not involved in the regular adjustment of the dosage, leaving this to the family physician or anticoagulation clinic.

There were, however, a small number of medical specialists who indicated that these decision support tools are used in their practice setting.

7.1.6 Education

The majority of respondents suggested that the education patients received was presented verbally. Most said they discuss warfarin therapy with patients before initiating the treatment, taking the time to review the risks, the implications for the patient's diet, and the monitoring requirements.

A number of medical specialists highlighted the important role of nurses, family physicians, GPs, and pharmacists in patient education. Though much of the education was said to be delivered verbally, some participants did point out that publications are shared with patients as well.

7.1.7 Resources

The majority of medical specialists felt that they do not have the resources available to optimize warfarin management in their practice. Lack of proper staffing was among the biggest complaints, as many participants indicated that they have been requesting more funding or are low on funding that would be devoted to staffing. This, combined with the high number of patients, creates a significant challenge for practitioners and reduces patients' access.

A small number of respondents stated that they had the resources available to optimize warfarin management in their practices.

Participants identified a variety of factors that would help improve the management of warfarin in their practices. Specifically, increasing the availability of anticoagulation clinics was mentioned. Respondents also mentioned the importance of patient education and teamwork between clinics, hospitals, and pharmacies.

Many participants called for more human resources for educating patients as well as staffing clinics.

7.1.8 Well-managed versus difficult-to-manage therapy

Medical specialists painted a clear picture in contrasting well-managed to difficult-to-manage warfarin therapy. Table 5 best summarizes the most commonly identified characteristics of both.

Table 5: Warfarin Therapy Management Characteristics

Well-Managed Therapy	Difficult-to-Manage Therapy
• Educated patients • Patient compliance • Efficient INR management	• Lack of patient education • Lack of patient compliance • Inefficient INR management

INR = International Normalized Ratio.

A well-managed therapy was commonly described as involving an educated and compliant patient. On the other hand, patients who do not get their INRs checked regularly, are reluctant to get their blood tested, and do not keep a regular diet or lifestyle were commonly associated with a difficult-to-manage therapy.

Some factors outside patient control, notably medication interactions, the instability of INR levels, and the patient's metabolism, were also reported as factors contributing to difficult-to-manage therapy. Due to the high percentage of elderly warfarin patients, participants also identified complex medication interactions, lack of medical understanding, risks for falls and bleeding, and lack of mobility and access as factors determining if warfarin therapy will be effective.

Participants generally felt positive about being able to overcome the difficulties identified with warfarin management. For most participants, enhanced efforts to educate patients and reach out to them helped overcome difficulties in management. Enhanced collaboration and communication with other members of the health care team also made a difference for many participants.

For some medical specialists, the availability of alternatives to warfarin offered a solution to difficulties with warfarin management.

7.1.9 Adequate trial of warfarin therapy

Most medical specialists agreed that there is no specific time frame for an adequate trial of warfarin therapy. A small number of participants indicated a trial time of a month or less. Others indicated that though they can generally achieve therapeutic levels in a short period of time, more time is required to determine if the patient is compliant, stable, and if he or she is experiencing any adverse side effects.

7.1.10 Withdrawing warfarin

Only a small number of medical specialists indicated that they have recommended withdrawing a patient from warfarin treatment. In most cases, medical specialists who have withdrawn treatment did so because of bleeding. In addition, medical specialists who withdrew a patient from warfarin treatment recommended a newer anticoagulant, aspirin, or discontinuing anticoagulants entirely.

7.1.11 New anticoagulants

According to medical specialists, the main merit of the new oral anticoagulants is the reduced need for monitoring, blood testing, and INRs. A few mentioned the reduced risk of bleeding with these new drugs and others or the flexibility for the patients as other important merits.

Many participants pointed to the limitations of the new drugs. Most important, medical specialists felt that their lack of knowledge and experience with the new anticoagulants was a clear limitation. The irreversible nature of the new drugs compared with warfarin, the lack of a blood test to monitor levels, and the high cost were also mentioned as major limitations. In most provinces, warfarin is covered by health care and otherwise the cost is relatively low. Finally, a small number of medical specialists noted the side effects of the new drugs, such as acid reflux associated with dabigatran, as limitations.

7.1.12 Recommending newer anticoagulants

Respondents felt generally positive about recommending a new anticoagulant to a patient who had suffered a stroke while on warfarin. All specified the need to find out what caused the stroke, to make sure patients were within therapeutic range, and that the stroke was due to warfarin failure. If not, then they would most likely continue with warfarin.

Respondents generally indicated that these decisions are made on an individualized basis and are very dependent on what caused the stroke, not solely on the fact that patients happened to be on warfarin.

7.1.13 Quality of life on warfarin

A majority of respondents made it clear that warfarin does impose on patients and adversely affects their quality of life. Most pointed to the need for regular blood testing, as well as side effects and dietary restrictions. A small number of participants did suggest that the impact on quality of life for patients who are able to achieve stable INRs is less pronounced, because monitoring is less frequent.

7.1.14 Quality of life on newer anticoagulants

The majority of participants felt that the new anticoagulants have much less negative impact overall on their patients' quality of life. Some participants mentioned that their patients' anxiety levels were lower because they require less monitoring, have fewer dietary restrictions, and receive the same amount of stroke prevention.

7.1.15 Obtaining information

Participants generally indicated that they received or researched information through professional medical and academic sources. Many said that they got their information directly from the published medical trials or from drug representatives, while others rely on professional publications, conferences, continued education, colleagues, and the Internet.

7.2 Findings from GPs and Family Physicians

7.2.1 Warfarin

According to GPs and family physicians, a strong majority of patients with NVAF are prescribed warfarin. The group was largely split between those who initiate warfarin treatment and those who either refer patients to a specialist or whose patients were initiated at a hospital after a stroke.

7.2.2 Merits and limitations

GPs and family physicians discussed both the merits and limitations of warfarin therapy, though more comments focused on the limitations than the merits. The themes emerging from this discussion are presented in Table 6.

Table 6: Warfarin Therapy — Merits and Limitations Identified by Physicians

Merits	Limitations
• Physician's comfort and familiarity with the therapy • Low cost • Proven effectiveness • Reversible nature	• Complexity of treatment for physicians and patients • Risks of bleeding • Frequent blood tests • Difficulty to achieve stable INRs

INR = International Normalized Ratio.

The most common merits of warfarin identified by this group were the physician's familiarity and comfort with the therapy, its low cost, proven effectiveness in stroke risk reduction, and the fact that it can be reversed in emergency situations.

The most common limitations of warfarin mentioned by this group include the risk of bleeding that accompanies therapy, the need for frequent blood tests, the difficulty of achieving stable INRs, and the overall complexity of therapy for both physicians and patients.

7.2.3 Unsuitable candidates

When asked which patients would *not* be good candidates for warfarin therapy, participating physicians pointed to a number of groups:

- elderly at high risk of falls
- alcoholics
- people who refuse to have their INR monitored
- people with eating complications such as ulcers or GI bleeds
- those who can afford the newer alternatives to warfarin.

7.2.4 Warfarin management

Participating physicians reported that patients most often have blood work done in private or hospital labs. That information is then relayed to the physician, who decides on the course of treatment and works with other members of the team to relay the recommendations to the patient.

Some respondents felt that the anticoagulation clinics' approach to management was excessive and too complicated for elderly patients.

7.2.5 Support tools

Participants described that they have access to tools such as nomograms but choose not to use them on a regular basis. In rare cases when GPs and family physicians are unsure of a patient's INR results, tools such as nomograms are used occasionally.

7.2.6 Education

Most GPs and family physicians agreed that patient education is critical for effective warfarin therapy and highlighted the importance of interprofessional collaboration as an approach for providing that education. A number of participants singled out pharmacists as excellent sources of education for patients. In addition, anticoagulation clinics, where they are available, were cited as important partners in patient education.

7.2.7 Resources

GPs and family physicians were evenly split on whether or not they believe they have the resources necessary to provide optimal warfarin therapy to their patients. Those who felt they did have the necessary resources pointed to electronic medical records (EMR), new testing technology, and competent team members. Those who felt resources were lacking identified a need for more trained professionals and more effective monitoring systems.

When asked how to improve the management of warfarin therapy, participants came back to the same themes listed above: better use of technology (including self-monitoring), anticoagulation clinics, and more human resources to monitor and educate patients.

7.2.8 Well-managed versus difficult-to-manage therapy

GPs and medical specialists were quick to identify the traits of a well-managed patient and a difficult one. The most prevalent themes from conversation with this group are presented in Table 7.

Table 7: Traits of Well-Managed versus Difficult-to-Manage Patients on Warfarin Therapy*

Well-Managed Therapy	Difficult-to-Manage Therapy
• Self-managed • Educated • Compliant • Cognitively sound	• Not adequately educated • Cognitively impaired

* As observed by physicians and medical specialists.

Participants described difficult-to-manage patients as those who are not adequately educated about their condition and its treatment. Patients with cognitive disabilities were also identified as difficult to manage.

In addition to the characteristics mentioned above, patients whose diet and lifestyle is irregular were also cited as difficult to manage, as were patients with complex medication regimes, given the risk of adverse interactions with warfarin.

When asked how they overcome the difficulties associated with a difficult-to-manage patient, participants pointed to effective collaboration with other members of the health care team and the possibility of switching to an alternative anticoagulation agent.

7.2.9 Adequate trial of warfarin therapy

Nearly all GPs and family physicians agreed that an adequate trial of warfarin is determined on a case-by-case basis. The deciding factor in most cases seemed to be the relationship between the physician and the patient, and the overall health of the patient. Participants were patient in allowing warfarin therapy enough time to achieve success. As one participant

concluded, the trial only ends when the physician and patient have "exhausted all their options."

7.2.10 Withdrawing warfarin

GPs and family physicians reported that they seldom recommend that patients withdraw from warfarin treatment. Of those participants who have made the recommendation, a small number said they had prescribed an alternate agent. However, this group also mentioned that their patients had experienced unpleasant side effects following the switch to the newer agent.

Those who indicated that they had not prescribed different agents said they hadn't done so because it wasn't right or necessary for the individual patient.

7.2.11 New anticoagulants

GPs and family physicians identified several key merits and limitations of the newly available anticoagulant agents. The most frequently discussed merits and limitations are presented in Table 9.

Table 8: Merits and Limitations with Newer Anticoagulant Agents

Merits	Limitations
• Do not require regular blood testing • Simple to dose • Efficacious	• Lack of clinical experience • High cost • Side effects

According to GPs and family physicians, the most positive aspect of the newly available anticoagulant agents stems from the fact they do not require regular blood monitoring and are simpler to dose. The efficacy of the newer agents was also cited by some.

However, the higher cost of dabigatran was cited by many as its chief limitation. Other limitations included lack of clinical experience and side effects such as GI bleeds. One participant also pointed to the inability to reverse the effects in emergencies, along with cost and a possible higher risk of myocardial infarctions.

7.2.12 Recommending newer anticoagulants

The majority of the GPs and family physicians expressed uncertainties about the new agents. Most cited costs, risk of side effects, lack of an antidote to reverse the effects in an emergency, and lack of knowledge and clinical experience with the agent as the chief reasons for their uncertainty.

A small number of participants discussed their approach to recommending a newer anticoagulant, stating that the decision was made on a case-by-case basis, considering the patient's individual condition and financial resources.

7.2.13 Obtaining information

Many GPs and family physicians singled out continuing medical education events as their preferred source for obtaining information about warfarin and newer anticoagulants. Participants also identified colleagues, specialists, and pharmaceutical representatives as

common sources of information. One participant also suggested reading journals as a way to gather information on anticoagulation therapy.

GPs and family physicians agreed more information is needed to raise their level of confidence in dabigatran. Information on long-term risks was uppermost in the minds of many. Others called for more clinical guidelines based on reliable evidence and from a reputable source.

7.2.14 Self-testing for patients as an option

GPs and family physicians felt that their patients have a limited understanding of their treatment, but know enough to contribute to effective management. For this reason, participants were mostly uncomfortable with the idea of patients doing self-testing. They questioned whether patients would be doing the tests accurately and with the right frequency, as well as the liability physicians might face if something goes wrong. One participant did suggest that having a detailed protocol in place might raise their level of comfort with self-testing.

7.3 Findings from Allied Health Professionals

7.3.1 Warfarin

Most participants (nurses and pharmacists) described their role in the anticoagulation clinics where they work as primarily centred around the management and administration of warfarin therapy, with less involvement in the initiation of warfarin therapy.

7.3.2 Merits and limitations

Allied health professionals discussed both the merits and limitations of warfarin therapy, though more comments focused on the merits rather than the limitations. The themes emerging from this discussion are presented in Table 9.

Table 9: Merits and Limitations of Warfarin Therapy According to Allied Professionals

Merits	Limitations
• Effectiveness of therapy • Low cost • Reversible nature	• Complications with other drug interactions • High risk of bleeding • Complexity of prescriptions

The majority of the allied health professionals focused on the effectiveness of warfarin therapy, especially when combined with patient education. The requirement for continual blood monitoring was not mentioned as a limitation by this group.

7.3.3 Unsuitable candidates

Allied health professionals widely agreed on the characteristics of patients they consider unsuitable for warfarin therapy. The chief characteristic is a complex medication regime, given the risk of adverse interaction with warfarin. Other characteristics that might be cause for concern include:

- lack of commitment to treatment and/or compliance with prescriptions
- poor cognitive ability
- poor quality of lifestyle choices
- compromising living conditions

- low level of mobility
- low Income
- limited access to blood testing laboratories.

On the other hand, and in keeping with the observations of other practitioners, suitable candidates were identified as compliant, informed, educated, and active in their warfarin treatment.

7.3.4 Warfarin management

The majority of allied health professionals expressed personal satisfaction with their work, especially as compared with other kinds of health care, delivered in different settings. Some did focus more on the challenges and frustrations that can accompany working in warfarin therapy, citing the need for continual patient education, a coordinated team approach, and great patience in the face of varying INRs.

The majority of participants described a very collaborative care process, involving close work with family physicians and medical specialists. Patients are typically referred to the clinic by a physician and communication with the referring physician is continual. Other participants reported working in clinics that are more pharmacist-run, though here too collaboration with physicians is ongoing.

7.3.5 Support tools

Many allied health professionals noted the importance of advanced technology, such as electronic medical records (EMR) and point-of-care testing in effective warfarin therapy.

Unlike the physicians who participated in the study, many also reported using nomograms and other decision-making support tools (e.g., Pharma-File). Others reported using clinical judgment and existing protocols instead.

7.3.6 Education

Participants agreed that patient education is a key contributor to successful warfarin therapy. They described a blend of verbal education and publications as being key tools for educating their patients about warfarin therapy.

7.3.7 Resources

Many respondents reported that a lack of funding limits the effectiveness of warfarin therapy at their clinic. In particular, many pointed to the lack of human resources that often accompanies shortages of funding as a key limiting factor.

7.3.8 Well-managed versus Difficult-to-manage patients

Allied health professionals identified the traits of both well-managed patients and those that are more difficult to manage.

Table 10: Traits of Well-Managed versus Difficult-to-Manage Patients on Warfarin Therapy*

Well-Managed Therapy	Difficult-to-Manage Therapy
• Compliance • Education	• Cognitive impairments • Poor mobility

* As observed by allied health professionals.

The issue of patient compliance was identified as an important characteristic of well-managed warfarin therapy. Allied health professionals indicated that the most common solution for overcoming difficulties with non-compliant patients is to engage and interact with them. More often than not, this interaction involves educating patients as well as motivating them. Elderly patients with cognitive impairments and patients with low levels of mobility were also considered by most allied health professionals to be difficult to manage.

7.3.9 Adequate trial of warfarin therapy

Allied health professionals described an individualized approach to care, as opposed to a particular guideline or protocol that calls for a specific period of time before switching to an alternate therapy. The decision to continue warfarin therapy or switch to another therapy is determined by the individual patient's condition, and his willingness and capacity to manage that therapy.

7.3.10 Withdrawing warfarin

Allied health professionals generally indicated that warfarin therapy continues except when patients are no longer willing, or the risks outweigh the benefits of remaining in treatment.

7.3.11 New anticoagulants

Allied health professionals who participated in this study were generally less enthusiastic about the new anticoagulants than their physician counterparts. Most focused their comments on the drawbacks or limitations they perceive with dabigatran, including the inability to measure levels in the blood and the lack of an antidote to counter the anticoagulant effects in the event of an emergency. Others cited the cost, the frequency of dosage, and the need to change a regime with which the patient has grown comfortable.

Some participants did point to the advantages of dabigatran, including its effectiveness and the likelihood that more patients would agree to anticoagulation therapy in the absence of a requirement for regular blood testing.

7.3.12 Recommending warfarin

Allied health professionals were generally in favour of considering a switch to dabigatran in the event that a patient in therapeutic range suffered a stroke. Their approach to such a switch was generally cautious. Respondents also indicated that they would still keep their patients on warfarin treatment in the event of a bleed, preferring warfarin's reversibility, the ability to monitor levels, and the ability to adjust dosage.

7.3.13 Obtaining information

Allied health professionals gather information on anticoagulation therapy from a variety of sources. The Internet, guidelines, conferences, colleagues, and trials were the sources most commonly identified.

7.4 Findings from Interviews with Patients

7.4.1 Warfarin

The patients who took part in the focus groups had been undergoing warfarin therapy for a minimum of two years. The majority of these patients had been receiving the treatment

between two and five years. One patient indicated over nine years of warfarin therapy. Most experienced the symptoms of atrial fibrillation, while others had suffered a stroke before being diagnosed.

Participants expressed a range of sentiments to describe how they feel about being on warfarin. Many focused on the health benefits of warfarin and expressed appreciation for the medicine. Some were concerned about taking what they perceive to be "a poison" on a regular and ongoing basis. One participant simply wished that she was healthy and did not have to take the medication at all.

7.4.2 Merits and limitations

Participants identified a number of drawbacks to warfarin therapy, with most focusing on fatigue and dietary restrictions. One participant also focused on the need for regular blood tests.

7.4.3 Warfarin management

The majority of patients indicated that the monitoring of their therapy is done through their family physician. In addition, they noted that they also use the help of a specialist, usually as an additional support, but much less frequently than their family physician. One participant also mentioned using an anticoagulation clinic.

Feedback from patients was generally quite positive in regard to the management process of their warfarin therapy. Patients described how warfarin management is now a part of their daily routine. Paradoxically, while one respondent expressed concern about her ability to "keep up" with her teenage children, another felt the treatment improved her energy levels dramatically.

Half of the patient participants indicated that their dosage has been stable and more or less unchanged in the past six months. The remaining half reported frequent changes in their dosage, with many expressing frustration with the frequent changes and the resulting need for even more frequent blood tests.

7.4.4 Education

Patients generally felt positive about the education they received and said that questions were answered for them in the initial phases of their warfarin treatment. Most mentioned that the information they received came directly from their doctor but was also supplemented by their own research. Online forums were most often cited as important sources. One participant did note that the initial education offered was not sufficient and that additional effort was required to answer questions.

Overall, participants felt that they knew what they needed and wanted to know about warfarin. Their discussion of why they were prescribed warfarin and how it functions, however, suggested that many were not fully educated. Few knew warfarin had been prescribed to them to prevent strokes, and there seemed to be a lack of understanding about the effects and complications associated with their treatment. Patients attributed benefits and side effects to warfarin treatment that were unlikely to be caused by warfarin. Similarly, many expressed the importance of having their blood tested, but were vague when trying to explain the reasoning.

7.4.5 Recommending warfarin

Participants agreed that they would recommend warfarin therapy to someone with the same condition as theirs. Most cited the fact that the medication is effective and not too onerous.

7.4.6 New anticoagulants

Patients were generally cautious when presented with the option to switch to a new anticoagulant, even when prompted by the advantages of fewer dietary restrictions and the elimination of the need for regular blood tests. Many indicated that they derive a sense of comfort and confidence from the blood tests and would want some testing done while on a new anticoagulant.

A few participants did show interest in changing to an alternate anticoagulant, drawn by both fewer dietary restrictions and the elimination of regular blood tests.

7.4.7 Self-Testing as an option

Some patients expressed openness to the idea of self-testing but only if supported by a health care professional. Others were more reluctant, citing lack of confidence, concerns about cost, and concern that self-testing would lessen contact with their family physician (lacking similar confidence in nurses and pharmacists).

7.4.8 Complexity of dosage

Patients reported a wide variety of doses, reflecting their individual conditions. Concern over the complexity of the dosage was only expressed by a small number of participants.

8 DISCUSSION

8.1 Key Themes

Four clear themes emerged from our thematic analysis of the transcripts from the focus groups and interviews. Interestingly, all four themes cut across the questions asked of the four different participant groups: medical specialists, family physicians and GPs, allied health professionals, and patients. The themes and supporting quotes are presented here in declining order of prevalence.

Comfort

The most prevalent theme in the transcripts, the desire for comfort, was expressed by members of all four groups. Practitioners want to be comfortable with the drugs they prescribe. They find comfort in the fact that blood tests exist to measure the level of warfarin in the blood and that antidotes exist in the event of an emergency. GPs, family physicians, and allied health professionals expressed reluctance to prescribe a course of medication in the absence of knowledge and clinical experience with that agent. Similarly, there is reluctance to prescribe drugs that are new and whose long-term side-effects profile is yet to be determined. Even among medical specialists — the group most receptive to the new agents — this lack of comfort was expressed.

> *Warfarin therapy has been a standby for a number of years now — since the 80s and 90s we have very strong evidence of anti-coagulants like warfarin to prevent stroke (medical specialist, Ontario).*

It has been time honoured and everybody is familiar with warfarin (medical specialist, Nova Scotia).

Your interactions are well known. You can adjust those interactions. It's reversible. It is annoying, but it provides a lot of people with jobs. There are a lot of people tied up in running it. It's onerous, but it's there and it's effective (allied health professional, Alberta.)

You're able to manoeuvre that way with warfarin and less with dabigatran. Dabigatran only has the one dose. If you do have a bleed there's nothing you can really do. With the warfarin the Vitamin K will help out. Dabigatran you're shooting blind, you really don't know what you're doing. At least with warfarin you have the INR that you can base your decisions on (allied health professional, Ontario).

You also have the reversal problem though because with Coumadin you can reverse it if they're bleeding (family physician/GP, Ontario).

Patients also worried about a lack of comfort from switching to new agents. They find comfort in blood tests that confirm they have achieved therapeutic levels. They find comfort in regular visits with a physician or other health care provider. Some allied health providers suggested patients also find comfort in a regimen to which they have grown accustomed.

I like to be monitored and know what is going on (patient, Ontario).

I'd be interested, but is it going to work as well for me? How often is it going to be checked? I'm wondering if anyone will be monitoring this for me. I'm used to testing and that for me is comfort. If I was a drinker I might be more interested, but because I'm not I don't care. I like to be tested rather than not. It goes back to comfort (patient, Alberta).

For me, having my blood drawn is a safety net — I know whether it's high or low and I know if it's working (patient, Ontario).

I wouldn't want to do it on my own. I like to see the doctors and talk to them. Even small things you say, for you it's small and to them they know (patient, Ontario).

Teaching helps them understand what warfarin is. It's working against the Vitamin K. It's all about balancing. What INR means? The reason why? Warfarin takes up to five days before you know what the full effect is. All of these teachings help the patient have comfort (allied health professional, Alberta).

Education

The importance of patients who are educated and have the cognitive ability to understand warfarin therapy was heard numerous times in this study. All practitioners agreed that knowledge is a prerequisite for successful warfarin management. Even when lack of compliance is deemed to be an issue, the response of many practitioners is to increase their efforts to educate patients on the risks of non-compliance and the health benefits of warfarin therapy.

I try whenever I recommend the medication to patients to give them information as well (medical specialist, Ontario).

I spend a lot of time educating my patient. If the patient is capable, without speaking to family, I probably spend 20 to 25 minutes of verbal education (medical specialist, Ontario).

Typically my nurse will talk to them as well as myself (medical specialist, Alberta).

Yet again, it is patient understanding and patient education and patient willingness. A lot of people just don't want to think about it (medical specialist, Nova Scotia).

Certainly the education helps out — if they know how important it is, they are more likely to follow up on getting their INRs testing (medical specialist, Ontario).

It is about careful assessment and education of the patient. And getting the pharmacists to see the patient as well to see if we could increase their likelihood of solving any manageable treatable problems that are interfering with the dosing and absorption (medical specialist, Ontario).

The other aspect we found a surprise, the educational aspect because once they understood what warfarin is and how it works they became very much involved in their own care and were able to be compliant (allied health professional, Ontario).

I think the best way to manage warfarin therapy is to do a lot of good teaching with the patient so they are aware of what the drug does. They have to have the commitment to doing the INRs (allied health professional, Alberta).

A patient who is more educated. I have a patient who never misses a dose. Every four weeks we check. She always makes sure she knows where the labs are. She makes sure she always follows up. She knows if there's a change in her medication she should go a little more frequently (family physician/GP, Alberta).

Patients appreciated the education they did receive and some described the efforts they went to to receive that education.

For me when I take medication, I like to know everything. And sometimes when you ask questions of doctors, their answers are different from other doctors or things that you can read up online on the medications (patient, Alberta).

In my case, what they did for me was they actually have little patient groups for certain things and we all got together with a practical nurse who sat down with us and gave us all of the information. She gave us about an hour's education on the drug and how it works and lots of handouts. Then they had a weekly follow-up for about six weeks. You could come once a week and mention any problems if you had any. They had a group for all different ailments. It is a long waiting list. From the time I was first diagnosed, it took me about 9 to 10 weeks to get into the weekly groups but I got the first part right away. I found that really helped me to have that little bit of support (patient, Ontario).

I would like more information about the side effects. I'm not seeing any that I'm aware of. I'd like to know if there are any side effects. What are some of the warning signs? On the INR, what do I have as an indicator? (patient, Alberta).

Well, the Heart Institute doctor was very busy. I asked the nurse at the anticoagulation clinic twice before she sat down with me and gave me the full story and she was a remarkable nurse. She was just called away to do more important work. They are busy but sometimes they think that less information is more as long as you keep taking it out because they don't want to freak you out (patient, Ontario).

Practitioners also recognized their own need for education, especially concerning new anticoagulants. Here, education links to comfort, as comfort levels grow with knowledge and experience.

You have to slow down just a little bit. This drug was approved amazingly fast through every regulatory body. I think faster than a lot of people would say is rational. It's a major thing. It seems very strange to rush through the process for a drug that is potentially one of the more dangerous on the market. It's not really stable. Why do the US and Canada have different guidelines? It's not as clear as it should be (allied health professional, Alberta).

Will there be more side effects that will come out in the years from now? Is anything being withheld? (family physician/GP, Alberta).

It seems like all the information you're getting is from the dabigatran drug rep. As much as you try not to be biased, what you really have to do is go to conferences. You have to make time to read non-biased sources and go to conferences and things like that (medical specialist, Alberta).

It's a newer medication so we don't know really what idiosyncratic effects might develop down the line although we can hope that the company manufacturing it took the lessons from some of the other inhibitors that were much hyped and turned out to have idiosyncratic effects such as liver failure. I think that in the clinical trials and then in post-marketing, people are being quite careful to look for these but I can tell a patient that it's been on the market in North America for maybe a year now so we don't know it as well. That is the major disadvantage (medical specialist, Ontario).

Cost

The final theme comes as no surprise, given the significant difference in price between warfarin and dabigatran. Cost is a chief advantage for warfarin and a chief disadvantage for dabigatran.

A merit is that it's cheap (medical specialist, Nova Scotia).

It's cheap. It's covered by Alberta Blue Cross (family physician/GP, Alberta).

It's an inexpensive product. It doesn't put a lot of financial burden on the patient (allied health professional, Alberta).

Another thing that I will be looking at is can they afford the drug? (medical specialist, Ontario).

The cost of it, if they can't afford to take anything else (medical specialist, New Brunswick).

One of the real challenges for us is the fact that none of this is funded by any government program so the strips are quite expensive. We use point of care and consequently the patients have to pay to participate in the clinic (allied health professional, Ontario).

I have some patients who have a difficult time affording it, but if their INRs are too low or too high I really push for it (family physician/GP, Ontario).

Most of our patients are seniors. I have had no chance to prescribe yet based on cost (family physician/GP, Alberta).

The negatives are the cost (family physician/GP, Alberta).
Cost also factors into the discussion as the various costs of warfarin therapy are considered. Management requires skilled staff and these individuals require funding.

No. I would rather do more. I would like to do a better job. I think we are doing the bare minimum job that is still acceptable. It could be better still but my boss hasn't been willing to fund us better. The funding is for staff. What we want is we want an anticoagulation nurse (Manitoba).

Definitely we need more resources for that. Warfarin is a kind of tedious work. You need to continuously monitor for their whole life, particularly for atrial fibrillation. We are talking about a lifelong treatment. It is very much a commitment. A patient needs constant attention from the medical personnel so a lot of resources are needed (Ontario).

Our major resource is humans. Staffing is always an issue so trying to find adequate staff. Having the resources to be able to hire those staff members (allied health professional, Ontario).

We can't access any anticoagulation clinics at all. If the patient comes in Friday, then I manage them Friday, Saturday, and Sunday until I can get them in on Monday. If this is such a great clinic, why can't they expand their mandate? (family physician/GP, Alberta).

We have to limit the number of patients that we can actually accept into the clinic. We have run into issues where we have had to hold the number of patients we were able to manage based on vacancies. We had a number of physicians that were ready to go to the media to make sure that adequate funding was put into the clinics that we'd be able to have a bit of a buffer (allied health professional, Ontario).

Even patients think of costs as they consider new options such as self-monitoring their INRs and switching to dabigatran.

I have heard about that (self-monitoring). The machine costs $5,000 so it's expensive but if you want to travel, in the past there was no way to get your blood tested. I would get it (patient, Ontario).

I believe here last time I checked, it [dabigatran] was $150 a month vs. warfarin which is $17. Right now, pharma care is not reimbursing yet so I pose the question, is the extra $130 worth it to you in convenience? And when I pose that question, so far none of mine have wanted to spend the money (medical specialist, Manitoba).

Risk

Given that we are dealing with therapy that helps prevent strokes, it is not surprising to find that the risks of AF and of warfarin therapy emerged so many times in the transcripts. The chief benefit of warfarin was deemed by most practitioners to be a reduced risk of stroke. Dabigatran is compared with warfarin in terms of its ability to reduce that risk.

Well for people who need to be on warfarin, there is a reduction in risk of stroke (medical specialist, Ontario).

You have to judge the patient and their risks for having a cardioembolic stroke — this is the most important thing (medical specialist, Ontario).

At lower doses of Pradax they're somewhat less at risk of a bleed compared to Coumadin. In fact higher doses there make them more at risk of a bleed (family physician/GP, Ontario).

The limitations of warfarin therapy were most often listed as risk of bleeding and risk of adverse drug interactions.

It's kind of a dirty drug, a lot of drug interactions, a lot of other problems with it, lab monitoring is always an issue, compliance to make sure they come in and to get their INR tested. Those are probably the major points (allied health professional, Alberta).

The bleeding risks and the risks to end back in hospital again (family physician/GP, Alberta).

The stakes in warfarin therapy are high and risk is often on the minds of participants. Many patients also understood that their condition places them at greater risk of stroke and appreciate the ability of warfarin to help them reduce that risk.

I know that if I don't take it, something could happen and I could keel over on the floor so I know that I don't have a choice. Either I take it or I croak (Ontario).

The notion of risk connects with the other themes. The high risk of living with AF and undergoing warfarin therapy renders comfort all the more valuable. Education is seen as a key means of reducing risk and, consequently, of increasing comfort. The high costs of warfarin therapy to the health care system are driven by the need to reduce the risk of stroke which, itself, brings with it significant treatment and rehabilitation costs. Together, these four themes — comfort, education, cost, and risk — constitute the backdrop against which discussions of warfarin therapy and its alternatives happen.

8.2 Results in Relation to Other Studies

The findings from this study align very well with findings from a number of published studies on the perceptions of patients and practitioners about warfarin therapy.

Regarding studies involving patients, such as the study by Wild et al.,[13] we found that patient interest in newer anticoagulants that do not require routine blood tests was not unanimous and that some expressed anxiety at the absence of monitoring.

Our findings also echo those of Dantas et al.[14] and Lip et al.,[15] in that we found that knowledge among patients about the risks and benefits of warfarin was low, especially regarding warfarin as a means of reducing the risk of stroke.

Our findings from focus groups and interviews with physicians (medical specialists, family physicians, and GPs) echo those of Bungard et al.,[3] and Pradhan et al.,[16] in that many of the physicians we spoke with focused on the risks of warfarin therapy to their patients, especially the risks of bleeding. Our study elicited perhaps fewer comments on the inconvenience of warfarin therapy to the physician than these two studies did, though certainly comments to this effect were heard.
Our findings also echo those of Partington et al.,[17] in that we heard from many physicians and allied health professionals that the age of the patient is an important consideration in the decision about whether to initiate warfarin therapy. Concerns about falling and cognitive impairment among the elderly were often expressed as reasons for opting out of warfarin therapy.

Like Gattellari et al.,[18] Deplanque et al.,[19] and Anderson et al.,[20] our focus groups and interviews yielded a number of comments by physicians that reveal clinical uncertainty about anticoagulation, especially for elderly patients who are deemed to be at greater risk of falling. Our findings also align with the findings of these studies in that clinical experience is often associated with lower levels of uncertainty and greater comfort.

Our findings from discussions with allied health professionals align well with those of Bajorek et al.[21] and their findings from interviews with nurses. Our focus groups with allied health professionals (and indeed all practitioners) revealed that patient knowledge was limited and that risk of falling was a major barrier to warfarin use, as were cognitive impairment and the risk of adverse interaction with other medications.

The Bajorek study aligns well with the findings of a systematic review by Pugh et al.[22] We also found that the patient's age and risk of falling are often considered by practitioners as they weigh the risks and benefits of warfarin therapy. Similarly, we also found that alcoholism, cognitive impairment, and patient compliance are all considered factors that could render a patient unsuitable for warfarin therapy.

Finally, like Bajorek et al.,[23] we found strong and broad support for greater education and information as a means of improving warfarin management in health care.

8.3 Strengths and Limitations

The strength of this study lies in the quality and richness of the comments offered by participants. Interview and focus group participants were engaged, informed, and willing to share their sentiments, experiences, and opinions with the moderator. The number and depth of discussions allowed us to achieve saturation on all the key points we set out to address.

The limitations to this study stem from the small number of participants (in particular, patients) and inherent self-selection bias. Participants were invited and remunerated to participate in the study. We also note that not all provinces and territories are represented in our sample. Because formularies and public insurance plans can vary from one jurisdiction to another, this is a limiting factor. Practice patterns may also vary across regions for other reasons.

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10 APPENDICES

APPENDIX A: MODERATOR GUIDES

The questions in the moderator guides were developed by CADTH in collaboration with Vision Research. They are based on the overarching research questions of the CADTH Optimal Use warfarin project:

1. What are the clinical benefits and harms associated with the use of individual specialized anticoagulation services, compared with usual care for adult patients receiving long-term warfarin therapy?

2. What are the clinical benefits and harms associated with the use of one type of specialized anticoagulation service compared with another type, for adult patients receiving long-term warfarin therapy?

3. What factors are considered by practitioners when determining likely candidates for warfarin treatment?

4. What are the perceived, relative merits and limitations of new anticoagulants?

A.1 Interviews with Medical Specialists

- Thank you joining us today
- The client is the Canadian Agency for Drugs and Technologies in Health or CADTH — an independent agency that is funded by Canada's provincial and federal governments. CADTH undertakes studies into the clinical and cost-effectiveness of different drugs and healthcare technologies and provides findings and advice to governments.
- Your participation today will remain strictly confidential at all times. Your identity will never be revealed to the client and any comments we cite will only ever be cited anonymously.
- I would like to audio record the session so that we can prepare a detailed report. The audio files will remain with our firm and be destroyed once a final report is submitted.
- The topic for the group is warfarin therapy for patients with non-valvular atrial fibrillation (AF).

Questions

1. In what proportion of your new patients with non-valvular atrial fibrillation do you initiate warfarin?
2. Describe the relative merits and limitations of warfarin therapy as you see them.
3. What factors do you consider when deciding whether to prescribe warfarin in a patient with atrial fibrillation? (Prompt if Required: Access to INR monitoring, Risk for stroke, Age, Stroke/TIA history, Fall risk/history, bleed history, Perceived compliance, expected patient refusal, cognitive ability, Polypharmacy/risk of drug interactions, History of chronic alcoholism, Renal/hepatic impairment, etc.)
4. Are there patients with AF who are eligible for warfarin, but for whom you would choose NOT to prescribe warfarin? If yes, please describe.

5. Describe how warfarin is managed at your practice.
6. Who reviews INRs and adjusts warfarin dosing at your practice?
7. Is patient referred back to family physician/primary care provider for warfarin management once INR stabilized, or does patient's warfarin management remain under your care?
8. What kind of decision support tools do you or your team employ for monitoring and adjusting warfarin doses? (e.g., nomogram, computerized decision support)
9. What type of warfarin education do you or your team provide to patients?
10. When is the education provided? By whom?
11. Do you believe you have the resources available to optimize warfarin management in your practice?
12. If not, what are you lacking? (Probe for barriers to optimizing warfarin management)
13. If yes, please describe what works well (Probe for enablers to optimizing warfarin management)
14. How could warfarin management be improved?
15. In your view, what constitutes well-managed warfarin therapy?
16. What are the key components that contribute to successful management of warfarin therapy?
17. Now consider some recent patients on warfarin in your practice who were more difficult for you to manage.
18. Why do you think managing their warfarin therapy was more difficult?
19. How did you attempt to deal with these difficulties?
20. Were you able to overcome these difficulties?
21. What do you consider an adequate trial of warfarin therapy?
22. How long would you stay with warfarin therapy if you weren't achieving the desired patient outcomes?
23. In what proportion of your AF patients have you recommended withdrawing warfarin treatment?
24. What were the reasons?
25. Were any of these patients prescribed an alternate agent? If yes, please indicate the choice of agent.
26. What is your opinion on the new oral anticoagulants as alternatives to warfarin treatment?
27. What do you consider the relative merits and limitations of new anticoagulants?
28. For what type of patient would you prescribe a new anticoagulant?
29. Would you recommend a new anticoagulant in a patient who experiences a stroke while taking warfarin? A bleed?
30. How do you feel a patient's quality of life is impacted by warfarin treatment? How would you expect the newer oral anticoagulants to impact a patient's quality of life? Please explain.
31. What are the best resources for obtaining information on new anticoagulants and on warfarin?

A.2 Interviews with GPs and Family Physicians

1. In what proportion of your patients with non-valvular atrial fibrillation do you prescribe warfarin?
2. With respect to prescribing practices in non-valvular atrial fibrillation, do you predominantly initiate, or continue warfarin therapy (started by another physician or specialist)?
3. Describe the relative merits and limitations of warfarin therapy.
4. Are there patients with AF who are eligible for warfarin, but for whom you would choose NOT to prescribe warfarin? If yes, please describe.
5. Describe how warfarin is managed at your practice.
6. Who reviews INRs and adjusts warfarin dosing at your practice?
7. Is patient referred back to family physician/primary care provider for warfarin management once INR stabilized, or does patient's warfarin management remain under your care?
8. What kind of decision support tools do you or your team employ for monitoring and adjusting warfarin doses? (e.g., nomogram, computerized decision support)
9. What type of warfarin education do you or your team provide to patients?
10. When is the education provided?
11. Do you believe you have the resources available to optimize warfarin management in your practice?
12. If not, what are you lacking? (Probe for barriers to optimizing warfarin management)
13. If yes, please describe what works well (Probe for enablers to optimizing warfarin management.)
14. How could warfarin management be improved?
15. Think of some recent patients on warfarin in your practice who you consider to be well-managed. In your view, what constitutes well-managed warfarin therapy?
16. What are the key components that contribute to successful management of warfarin therapy?
17. Now consider some recent patients on warfarin in your practice who were more difficult for you to manage.
18. Why do you think managing their warfarin therapy was more difficult? How did you attempt to deal with these difficulties?
19. Were you able to overcome these difficulties?
20. What do you consider an adequate trial of warfarin therapy?
21. What happens next?
22. In what proportion of your AF patients have you recommended withdrawing warfarin treatment?
23. What were the reasons?
24. Were any of these patients prescribed an alternate agent? If yes, please indicate the choice of agent.

25. What is your opinion on the new oral anticoagulants as alternatives to warfarin treatment?
26. What do you consider the relative merits and limitations of new anticoagulants?
27. Would you recommend a new anticoagulant in a patient who experiences a stroke while taking warfarin? A bleed?
28. Are/Would you be comfortable starting a new anticoagulant or do/would you rely on a specialist for this?
29. For what type of patient would you prescribe a new anticoagulant?
30. As compared to warfarin, how would you expect the newer oral anticoagulants to impact a patient's quality of life?
31. Would the new anticoagulant improve quality of life more or less than warfarin? How so?
32. What are the best resources for obtaining information on warfarin?
33. What are the best resources for obtaining information on new anticoagulants?

A.3 Interviews with Allied Health Professionals

1. How long have you been practicing?
2. How long have you been involved specifically in warfarin therapy?
3. Are you involved in warfarin therapy initiation, maintenance, or both?
4. How do you feel about managing warfarin?
5. How satisfied are you with the level of involvement in managing patients' warfarin therapy?
6. Are you and your fellow allied health professionals interested in playing a larger role?
7. Are there any barriers to their playing a larger role?
8. Describe the relative merits and limitations of warfarin therapy as you see them. Describe a good candidate for warfarin therapy.
9. What makes a patient a poor candidate for warfarin therapy? Describe how warfarin is managed at your practice or clinic.
10. Who reviews INRs and adjusts warfarin dosing at your practice?
11. What kind of decision support tools do you or your team employ for monitoring and adjusting warfarin doses? (e.g., nomogram, computerized decision support)
12. What type of warfarin education do you or your team provide to patients?
13. When is the education provided?
14. Do you believe you have the resources available to optimize warfarin management in your practice?
15. If not, what are you lacking?
16. Probe for barriers to optimizing warfarin management.
17. If yes, please describe what works well.
18. Probe for enablers to optimizing warfarin management.
19. How else could warfarin management be improved?
    Think of some recent patients on warfarin in your practice who you consider to be well-managed. In your view, what constitutes well-managed warfarin therapy?
20. What are the key components that contribute to successful management of warfarin therapy?
21. Now consider some recent patients on warfarin in your practice who were more difficult to manage. Why do you think managing their warfarin therapy was more difficult?
22. How did you attempt to deal with these difficulties?
23. Were you able to overcome these difficulties?
24. What do you consider an adequate trial of warfarin therapy? What happens next?
25. In what proportion of your AF patients have you recommended withdrawing warfarin treatment? What were the reasons? Were any of these patients prescribed an alternate agent? If yes, please indicate the choice of agent.
26. What are the best resources for obtaining information on warfarin?
27. What is your opinion on the new oral anticoagulants as alternatives to warfarin treatment?

28. What do you consider the relative merits and limitations of the new anticoagulants?
29. Have you recommended a new anticoagulant for any of your patients? If yes, please describe the circumstances.
30. Would you recommend a new anticoagulant in a patient who experiences a stroke while taking warfarin? A bleed?
31. What are the best resources for obtaining information on the new anticoagulants?
32. How do you feel a patient's quality of life is impacted by warfarin treatment?
33. How would you expect the newer oral anticoagulants to impact a patient's quality of life? Would it be improved or made worse? Why is that?

A.4 Interviews with Patients

1. What has been your experience taking warfarin?
2. How long have you been on warfarin therapy?
3. What or who influenced your decision to take warfarin?
4. How do you feel about taking warfarin?
5. What do you consider the relative advantages and disadvantages of warfarin therapy?
6. What do you consider the biggest challenge(s) with taking warfarin?
7. What do you like about taking warfarin?
8. Have you ever had a serious complication while taking warfarin? If yes, please explain.
9. Describe how your warfarin therapy is monitored and adjusted.
10. Who does the monitoring and where does the monitoring takes place?
11. Who adjusts the warfarin dosing
12. Does the warfarin therapy present any issues in terms of convenience, adherence or impact on your lifestyle? How so?
13. Are you satisfied with how your warfarin therapy is managed? If no, please explain.
14. What type of education did you receive when you first started taking warfarin? [Examples may include booklets, one-on-one or group education, verbal counselling, etc.]
15. Who provided the initial education?
16. Were any aspects of the initial education reviewed or revisited over time?
17. Do you feel you have all the information you need to be able to get the most benefit from taking warfarin? If not, please explain.
18. What have you found to be the best way to learn more about warfarin?
19. What are the best resources for obtaining information on warfarin?
20. What do you know about the reasons for having regular blood tests while on warfarin?
21. How do you feel about having to go for these regular blood tests?
22. How would you feel if you no longer had to go for regular blood tests?
23. How often is your warfarin dose changed?
24. How do you feel about the frequency of these dosage changes?
25. Would you recommend taking warfarin to other patients with atrial fibrillation? Why or why not?
26. Imagine a new anticoagulant (blood thinner) that did not require regular blood tests (INR monitoring), did not have any dietary or alcohol restrictions, and did not have many significant drug interactions.
27. Would you be interested in taking this new anticoagulant instead of warfarin? Please explain.
28. If yes, how do you think this new anticoagulant would affect your life?

APPENDIX B: QUOTATIONS FROM MEDICAL SPECIALISTS

The following quotations were selected from transcripts to represent all the opinions expressed by participants relating to this current practice study into the prescription and management of anticoagulation therapy in Canada. Duplicate and redundant comments, as well as those that were off topic, have been omitted.

Relative Merits of Warfarin Therapy

It is effective, well proven to reduce stroke and other cardio embolic complications (British Columbia).

The big benefit is in a select population who are looking at reducing their risk of stroke because that is our big issue — we want to reduce the risk of stroke. There are various ways we can look at that. There is a $CHADS_2$ score, CHA_2DS_2VASc score. But it's just basically ways that we can tell if we want to prevent stroke. Are we OK with something as simple as aspirin or do we want to use stronger agents like Coumadin or dabigatran to anticoagulate them to prevent the risk of stroke (Ontario)?

For the merits, it often works. It has been around for a long time and we are all familiar with it (New Brunswick).

It offers huge benefits. It does decrease your risk of stroke. So there is no question that it should be used (Nova Scotia).

The merit obviously is prevention of stroke. Not to be taken lightly. When people look at the complication of atrial fibrillation, if it was just the TIA it wouldn't be that big of a deal but it is the major debilitating stroke that you want to prevent. Clearly there are massive benefits if you can prevent that. So I think that is the benefit (Manitoba).

It is relatively cheap (British Columbia).

Warfarin therapy has been a standby for a number of years now — since the 80s and 90s we have very strong evidence of anticoagulants like warfarin to prevent stroke. Current guidelines from several different bodies basically suggest that as long as the patient has non-valvular atrial fibrillation plus essentially one other risk factor, most of the time it is suggested that patients should be anticoagulated. That will reduce the risk of stroke by up to 67% to 70% (Ontario).

Warfarin has been around forever so the drug profile has been known for a long time. It is a safe medication. We know the properties very well and the interaction with other meds very well (Alberta).

It is oral, it can be dosed for a wide variety of patients, including those who have renal failure, and it is usually well tolerated (Ontario).

Relative Limitations of Warfarin Therapy

The risk of bleeding is another one but of course as we are weighing the risk of stroke over bleeding, most of the time the risks outweigh the benefits in that respect (Ontario).

If you run a high INR increase, you are at risk for life-threatening bleeding (Ontario).

The main limitation as with all patients who are on Coumadin is the inconvenience of having their blood tests monitored (Ontario).

The monitoring is the big thing and trouble with use of coexisting medications or diet (New Brunswick).

First of all, for the patient most importantly, they have to do their blood work and adjust their dose. Two, for patient, and doctor as well, they have to follow it. They cannot move easily from one place to another although certainly within the country is possible. And with INR, it is easier to adjust doses. However, there is a little bit of a difference between warfarin and Coumadin (or certain brands of it) and then if someone goes outside of the country, it is very hard to follow up with that kind of patient in the US or Cuba or in Europe. Where you go, how you get information, how you adjust it. A lot of people don't like this concept that they cannot move outside of their familiar turf (Nova Scotia).

There is wide fluctuation in the INR — no more than 60% is in the therapeutic range so that is what makes it problematic (Ontario).

The therapeutic range is relatively narrow so in some patients, it is quite difficult to keep them within the therapeutic range. Even doing a lot of testing, sometimes they are under therapeutic — the patients that are at the highest risk of stroke (British Columbia).

The big limitation is that nobody knows how often patients are actually therapeutic. So monitoring their INRs is a big thing. Even when it's done well, we really don't know how often they are actually therapeutic (Ontario).

Interactions with other medications, food, and also if a patient has another medical condition. I see lots of cases where patients come in with an acute medical condition that affects the metabolization of the warfarin (Alberta).

Because there is a Vitamin K-dependent factor, diet is very important (Ontario)

Another issue from my personal perspective, to talk about warfarin, is diet. How do you explain to patients that they should be on a steady supply of Vitamin K and that their changes in INR volume with the same dose with warfarin maintained can occur because they changed diet (Nova Scotia).

Determining Whether to Prescribe Warfarin Therapy

I use the CHADS that predict the risk of stroke. Do they have heart failure? Hypertension? Age is a factor — are they age 75 or more? Diabetes? History of TIA or stroke? (Ontario).

We mainly use a classification score called the $CHADS_2$ score. The decision on whether we use an anticoagulant such as warfarin is mainly based on that $CHADS_2$ score, which determines individual risk of a stroke (British Columbia).

I use the CHADS scores but most of my patients have TIA strokes so they end up needing the warfarin. I manage secondary prevention more than primary prevention (Alberta).

It is an assessment of the risk of stroke. Like most people, I usually use the $CHADS_2$ score so if they have a risk of congestive heart failure, hypertension, diabetes or if they have had a previous stroke, those will all get them points and if they have a

moderate or high risk of stroke until recently, I have recommended warfarin for treatment. We now have other options of course that work to give consideration for (Ontario).

Well, we use the CHADS score and $CHADS_2$ score. Those should be things considered. I understand that $CHADS_2$ is more common in Europe and in Canada, we use CHADS and there is a little bit of a difference. If your risk is 1.9, that is higher than normal, then we consider that significant (Nova Scotia).

If their CHADS score is two or higher, I try to be very convincing that it's a good thing. I try to convince them that their benefit in terms of stroke prevention exceeds the risk of bleeding. If I get any people who don't buy that already, my next step is to say well even if it's not a huge difference, you have to remember that [you get] a 3% reduction in a major, debilitating life event vs. risk of the bleed. The bleed might be something that you need a transfusion for but it's not a life-threatening thing. So even if the risk is fairly close, the bleed in my mind is not as adverse a thing to happen as a stroke. That is usually my next step, is to tell them that numerically the benefit of stroke prevention outweighs the risk of bleed. If that isn't enough, then I talk about the quality of life with a stroke vs. a bleed that is treatable (Manitoba).

We have to take into account also the risk of the patient bleeding (British Columbia).

If they are having some risks from taking it like bleeding or unsteadiness (New Brunswick).

Also, potential side effects: patient having bleeds, patient having a history of adjusting for warfarin therapy, patient at high risk for falls (Nova Scotia).

The main thing is risk of bleeding. It depends on their occupation and depends on their past history. Most of these folks aren't doing dangerous things but I usually review their occupations and their hobbies just in case I have patients that do things that might not be the smartest things if you are fully anticoagulated. Typically that is for patients that are younger but by the time people have atrial fibrillation, typically I haven't found a lot of patients that are doing dangerous things but I'm nervous about doing that so I usually review for risk of bleeding. Not just hobbies and occupations but I also look at past history and whether they have had bleeding ulcers or ulcers for fear that I put them on anti-coagulants and suddenly they are going to start bleeding on me. And then risk of falls as well — I guess that's always an issue. If someone is falling multiple times a day, unless I can find a way of preventing that which is not typical, then I would be very nervous anticoagulating someone unless they had a very high CHADS score. A CHADS score of two and they are falling several times a day, I don't think that I would even approach that because I would look at it and say the benefit is going to be smaller and the risk is going to be high. The risk is no longer a fixed percent (Manitoba).

We also have to take into account the patient compliance with the product (British Columbia).

You factor in the patient preference. You basically give them a percentage — this is what your risk of a stroke over the course of a year is, this is what I could bring it down to with warfarin, this is what I could bring it down to with aspirin and they end up deciding (Ontario).

If they are old and having access by getting to the lab for monitoring can be a pain, if they have a supportive family or are cognitive enough to do it themselves (New Brunswick).

Another thing that I will be looking at is can they afford the drug? Currently here in Ontario, our province doesn't cover things like dabigatran so that is why the majority of my patients who are over 65, on [the] Ontario drug benefit plan, don't have other private insurance coverage, they are going to need to have warfarin rather than dabigatran (Ontario).

The cost of it, if they can't afford to take anything else (New Brunswick).

Certainly in this situation, cost, if it's covered by the government, will play a big role (Alberta).

There are other things that I factor such as how readily are we going to be able to monitor them? I have a number of patients who are from up north around Baffin Island and they are out hunting for months at a time, out somewhere where they know they can't get INR monitoring and they can't afford things like point-of-care testing that they could monitor their INR out in the middle of nowhere. Similarly, I have patients who do a lot of travelling all over and to third-world countries and they are not comfortable in getting their INRs monitored there. Also, sometimes elderly people can't get transportation to a laboratory to get blood testing and can't afford point-of-care INR testing (Ontario).

Also if the patient has clinical conditions or if they cannot get their INR checked as requested, it's not going to be a good medication (Alberta).

Patients Not Suited for Warfarin Therapy

People with history of frequent falls where the risk of bleeding is high. Number two is that I come across a lot of patients that is because of their occupation. Like carpenters — because of the risk of injury and bleeding. The very frail elderly, which ties into the risk of falling as well. As well as people with history of gastrointestinal bleeding (Ontario).

If the patients seem to be at too high of a risk of bleeding. There is an example of a gentleman who was in his 70s or so who had come in on aspirin, his $CHADS_2$ score was 5. He had been taken off Coumadin in April and he had been taken off not only because of falling but he had bruised so bad from the repeated falls that he ended up requiring a blood transfusion. At first, we calculated his $CHADS_2$ score and wondered why he wasn't on warfarin. Looking at the records, we saw that he was on warfarin and he got taken off of it in April and here is why. So this is one case where the risk of bleeding was deemed to be too high despite having a score that would classify him as a candidate for anticoagulation. So he was put on aspirin instead of another drug. The risk of anticoagulating him would have been too high (British Columbia).

There are the patients who have had clear histories of severe hemorrhaging either on or off of warfarin. If someone has been on anticoagulation before and has had unpredicted hemorrhage, most of the time people would say, look, we assume that you might be at risk for another such hemorrhage and you might not be a candidate. A patient who is known to have some other bleeding disorder or an active source of bleeding (such as an out of control gastric ulcer or a bleeding tumour somewhere in the body) then they wouldn't be a candidate (Ontario).

Yes — the elderly, frequent falls, risk of hemorrhage, any bleeding problems or difficulties, if they have had a hemorrhage before, previous GIT's (Alberta).

Typically it is going to be someone who has a massive risk of bleeding. Someone who is extremely unstable, falling several times a day, landing on their head. I would look at that person and say even with a high CHADS score, it's not going to do you much good to have full anticoagulation. People like that I would rather just say you are at higher risk of stroke but maybe we should just use ASA instead. That is not an uncommon thing to do. Hopefully you don't have to do that in a lot of people but it does happen (Manitoba).

Sure, there are lots of them. The most commonly are patients who refuse to take warfarin. Despite being told what it could do for them, they just refuse to take it. So that's the main reason I won't (Ontario).

Because they are unreliable or they don't have someone who can help them administer it or are not monitoring it (New Brunswick).

Somebody who does have dementia or someone who does have some other disease that would affect their life expectancy, like lung cancer, it doesn't really matter that they have atrial fibrillation. That is for the patient to decide. I say if you are having trouble with cognitive functions, miserable quality of life, they end up requiring more care, the future doesn't look good and they won't get better — do you really want to give them the curse of an agent? You will make them survive longer but to what effect? (Nova Scotia).

Actually, in the part of the city where I work there are a lot of people with alcohol problems, for example, they have had frequent falls and they are not going to comply in monitoring their INR, I would definitely not prescribe it to them. Some of the patients just don't want to bother with the INRs in which case I said ok, I won't prescribe it then (Ontario).

How Warfarin Therapy Is Managed

It's a bit of a unique situation because I run an outpatient community practice that is also affiliated with the hospital. At the hospital, we have an anticoagulation clinic and it's run by a nurse. She has medical directives and she works with the pharmacy. So what I do when I see a patient in the office is that typically I refer them to the anticoagulation clinic, which I technically supervise. If there is an anticoagulation issue that the nurse or the pharmacist has a question with, they call me and we have a call schedule set up for it. They will bring the patient in, draw their blood, then the patient typically goes home. In the afternoon, the pharmacist and the nurse review all of the INR tests and then they call the patients back individually and tell them how much Coumadin to take and when to come back for the next INR (Ontario).

It's kind of interesting in that I am the director of the anticoagulation clinic here. So not only do I monitor my own INRs but many of the cardiologists at my centre refer patients to me for INR monitoring. So in conjunction with some nurses that I have, we run an anticoagulation clinic so we tend to do it based on pre-determined values (Ontario).

Those that don't have a family doctor have a makeshift anticoagulation clinic here that they can be referred to (Ontario).

There is a very small number of my patients that I can get into the anticoagulation clinic, which is run by a pharmacist in our hospital. The number of patients that are

on warfarin and the greater number of patients that should be on it but aren't because they don't want to take it because of the blood tests, far exceeds the number that I can get into the anticoagulation clinic. I can really only get patients in there that really have compelling reasons why they need to be looked after in the anticoagulation clinic and even then, they are full most of the time (Alberta),

We have an anticoagulation clinic affiliated with the hospital that I work at. There are physicians that provide weekly monitoring in conjunction with their family physician as well. If I am overseeing it, most of my practice is in the hospital so it is usually to initiate therapy (Ontario),

I do also work in ICU in Dartmouth. Patients there are often to be warfarinized or who are on warfarin. They are followed either by the family doctor or in Halifax, there is a warfarin clinic available. I see a lot of atrial fibrillation. People from Dartmouth can be enrolled in the anticoagulation clinic in Halifax (Nova Scotia),

We send them to the lab for INR blood tests. In my office, one of my colleagues does the point of care so some patients come for that as well. This is where they prick their finger and check the INR (Ontario),

I prefer doing it myself. I just find that I don't have a lot of confidence in other people doing it. I'm hospital based. A lot of the work that I do is dealing with people that come in through emergency and I see far too many people come in with INRs that are too high or too low so I don't have a lot of confidence in leaving it in other people's hands. I know a lot of family doctors do it and I see a lot of the people outside of the therapeutic range. I know a lot of people will delegate that to a nurse or to a computer program or to a pharmacist. I'm not averse to that but personally I don't feel comfortable doing it. Luckily I have a pretty good setup at work where we don't have a lot of problems because I have staff that hunts down INRs for me and keeps flow sheets so when I'm not here, any of my colleagues that are covering, my nurse will page them and say Mr. so and so's INR is 2.1 today and they will say and the indication is atrial fibrillation, strength tablet is 5 mg, farct is two to three so it becomes a 10-second page to my colleague if they are covering (Manitoba),

We have an outpatient program out of the hospital that bridges patients with heparin while we get them anticoagulated with warfarin. Our pharmacists look after the INRs and dosing without contacting us for the most part (British Columbia),

Once a patient is discharged or if it is an outpatient, I give the responsibility of dosing and monitoring the INR to the primary care doctor (British Columbia),

Because I am at a tertiary referral centre, the patients are referred to me by either a general practitioner or sometimes even by neurologists where I do see stroke patients. So there is going to be, in terms of referral, back to the general practitioner or interaction with some of the local anticoagulation clinics at other hospitals. My hospital is a geriatric care centre — we don't have hematologists who have anticoagulation clinics but some of the nearby hospitals do so I will either refer the patients back to their GP if the GP is comfortable monitoring INRs, or I will refer them to the hospital (Ontario).

The family doctor does it (New Brunswick).

In most patients, I don't have to track down the INRs by myself. Most people go to their family doctor and they feel comfortable to give advice. But I always mention that I will be there for them if they have any questions or concerns (Alberta).

The family doctor. I am working in different places. I have my office in Windsor, Nova Scotia, which is rural where patients are referred to me by family doctors for consultation. Patients like that would usually be followed by a family doctor (Nova Scotia).

I initiate the treatment and I might check it once but the rest is for the family doctors (Alberta).

It depends. If somebody is away, then I would follow up with them. Sometimes quite honestly it is a weekend or long weekend but sometimes that is the reason to actually keep patients in the hospital for a day or two longer. Some people may not have family doctors so they have to get someone first. Sometimes, the doctor is on holidays so someone else has to follow up with that. I would send them to the anticoagulation clinic if they are in Dartmouth and they don't have a family doctor (Nova Scotia).

Decision Support Tools

Once the physician, whether it's myself of another physician, says here is our target, 2 to 3, or 2.5 to 3.5 depending on what the indication is, we have a nomogram that we can follow and say if the INR is a little above or a little below, we make subtle changes (10% changes). So we tend to follow in the majority of patients, a previously prescribed nomogram that we can follow. There are some patients however that really don't fit the nomogram — their INRs are consistently varied, going all over the place. Then it tends to be an individual decision where the nurse, rather than just going by the nomogram, will call me and say here is their INR today, what do we do? And that is an individual decision based on getting a feel of, overall, how has their flow been, have we made certain changes before and so maybe I won't make that same change this time and so it has to be done on an individual basis. But that tends to be a minority of the patients. For most people, just following the nomogram works quite well (Ontario).

I have played around with some of them. The only one that I continually use is for initiating warfarin for outpatients with DVT and pulmonary embolism. So I use a Kovacs nomogram for that. Other than that, for atrial fibrillation, I have not found one that I would like to use. Whereas for acute DVT and PE, I find Kovacs works very well. In our anticoagulation clinic, we have chopped about a day and a half off of our bridging since we switched over to the Kovacs nomogram, so we like that. But $150 a week times we do about 120 DVTs and PEs in our outpatient clinic per year. For a day and a half per patient, that's a lot of money (Manitoba).

We don't have any tools. It is just an INR result and then we use our judgment (Ontario).

Personally I don't. It's the anticoagulation clinic that adjusts the dose. So on initiation to warfarin, I will generally give depending on the size of the patient 5 or 10 mg for three days and monitor the INR daily and then pick a dose — it's trial and error in the beginning (Ontario).

I just want to know where their blood work is and what doses they were taking. I don't use nomograms. It is in a controlled setting, mostly in the hospital (Nova Scotia).

In hospitals, we have warfarin dosing protocol. So basically, we fill out the protocol and the pharmacists are the ones that check the INRs and call the patient to advise them of what dosage to take. This goes for the in-patients as well. The pharmacists are the ones who check up on it and are responsible for dosing the warfarin as part of

our protocol. The protocol is a daily INR for both the in-patient as well as the out-patients (British Columbia).

Providing Warfarin Education

We physically tell them the risks and the benefits. The benefits being reduction in stroke. We also tell them about risk of bleeding and we tell them to avoid significant contact sports. They have to be very careful with instruments. It is more of a verbal education (Ontario).

There is some information and part of it is a brief counselling session with the pharmacist. I briefly go over how it works and to avoid other potential blood thinners but the bulk of it is done by the pharmacists (British Columbia).

There is a half-hour session that our nurse does for every patient that starts warfarin for the first time. She goes through education content, she gives them a booklet, she goes through the dos and don'ts, the diet, and the alcohol and Vitamin K-dependent foods and basically prepares them for what to expect while they are on warfarin treatment (Ontario).

We discuss the risks and what they should avoid. It is more verbal (Alberta).

When we were setting up the anticoagulation clinic, the nurses and I sat down and thought about what the messages were that we wanted to get across to patients. Other than that, it's just education on other stuff like alcohol and how it can affect their levels, the importance of having close monitoring and monitoring these INRs because a lot of people see it as a pain and they were supposed to go in and get their INRs tested but they are kind of busy so they put it off down the road. So they need to know the importance of that, including that they need to know the risks associated with it. The risks of not taking it (the risk of stroke) and the risks of taking it, which can include bleeding. They need to know what are the potential side effects that they need to watch out for, especially when it comes to bleeding such as are they noticing any blood in their urine, are they having any dark stools, things that suggest they are having bleeding side effects related to the anticoagulation therapy (Ontario).

Again I usually leave it up to the family doctor. Warfarin has been around for a long time, I'm pretty sure that they can manage. I don't give any literature or anything like that (New Brunswick).

... Neither myself nor any family doctors I'm aware of or the anticoagulation clinic has any kind of instructional videos or anything like that. We probably talk to them for about five minutes and intermittently a minute or two after that in subsequent visits (Ontario).

If it is a new medicine to a patient, I always give them details on why they are on that medication, how it works, what are the benefits and the potential risk that you have to watch on this medication. We do that verbally (Alberta).

I spend a lot of time educating my patient. If the patient is capable, without speaking to family, I probably spend 20 to 25 minutes of verbal education. I tell them that their non-valvular atrial fibrillation places them at a high risk of stroke and I tell them the consequences of a stroke. I give them all of the potential options to decrease that risk including risk factor reduction such as high blood pressure, diabetes, cholesterol. I tell them the rates of stroke with the different anticoagulants (Aspirin, Pradax, warfarin) and I outline the benefits of the different anticoagulation regiments and the risks. I tell them how warfarin works, the potential adverse effects and then I get their

opinion and I counsel them on what to do in case they bleed or start an antibiotic or another drug that could interact with the warfarin or in case they are going for surgery. Then we take it from there depending on what their reaction is and what they feel that their risk is (Ontario).

No, I don't have any literature. But I have a computer at my desk and I try and show them and encourage them to research the issue with the help of the Internet. We have long waiting times for dieticians, which is not very practical. Sometimes I do refer them but it's just not practical. There are a number of websites that give you examples of meals from one day to another for weeks at a time. You can check types of vegetables that you should or should not eat.
After I talked to them, they understand that they should not touch any broccoli or Swiss chard or any other leafy greens. I do it but I know that nobody else does it. When I talk with patients pretty much across the board, they have almost never heard about the warfarin diet (Nova Scotia).

Typically my nurse will talk to them as well as myself (Alberta).

In addition to a verbal education, patients also get a written pamphlet on what to watch out for, etc. (British Columbia).

In many cases, I use a company called Lexi drugs and they have copies of the different pharmaceutical profiles for physicians to look at but they also have versions for the public so I can print them something from that. Another source that I use sometimes is eMedicine. Those are primarily the two sources I go to for information (Ontario).

We provide them with a pamphlet about the type of food to take on Coumadin; that is number one (Alberta).

The maker (I think it's Dupont) that made the Coumadin brand warfarin, they used to have a nice teaching package that we used to give them so now that warfarin is available generically, we aren't getting the Dupont ones but there are other pamphlets that we hand out. I figure they will remember about one-tenth or one-quarter of what I said so we give them teaching and reading material just to reinforce it (Manitoba).

Whether Resources Suffice for Optimal Warfarin Management

I don't think so. To be able to do this effectively, one needs a lot of staff so human resources is a big drawback. Because some of the problems at times are that one is out of town so that becomes difficult (Ontario),

The only limitation we have is logistics — it's numbers. We have way too many patients to refer to this clinic. It's funded by the hospital and with the shortages in funding, we are not able to get an extra pharmacist or an extra nurse. We are trying to get point of care so that we can have the INRs checked so that we don't have to wait the afternoon. I shouldn't say wait but we are using up most of the afternoon calling back the patients we saw in the morning. If we had point of care, we could essentially double the number of patients we see in the clinic (Ontario).

No. We have the Coumadin clinic and they are dedicated to warfarin management, but they don't accept patients easily. There is an overload (Alberta).

There are still a lot of patients who do not have a family physician. There are some family physicians who are reluctant to monitor it or aren't very good at it although the majority are very good at it (those that run a large practice). The big problem is

our anticoagulation clinic. I said earlier that we have a makeshift one and I do mean that. It's not a formal clinic in a formal space. It is being run all part-time by people who have other things to do as well. At the present, they have reached their capacity and they are no longer willing to accept new patients except in a dire circumstance so it has become a big problem (Ontario).

No, absolutely not. We are lacking time. If we had a full time nurse available to monitor, that would be the best. I don't know of any enablers per se (Ontario).

No. I would rather do more. I would like to do a better job. I think we are doing the bare minimum job that is still acceptable. It could be better still but my boss hasn't been willing to fund us better. The funding is for staff. What we want is we want an anticoagulation nurse (Manitoba).

I think access to education is very important to be able to send them somewhere where they can learn more about their diet but access to this is quite inhibited... I think a basic understanding works well. Even yesterday, I had a patient who commented to me that he had been adjusting his warfarin and so far no doctor has gotten it better than he has and he knows how to adjust it. Empowering them is important (Nova Scotia).

I believe we do. The clinic works very well. The staff, the pharmacists, the nurses all work well together; the patients appreciate that personal phone call and the education around it (Ontario).

Yes. To me, I think atrial fibrillation is a very common disease and anticoagulation is also very common. I think the key is to have a clinic that can do that job. I have had patients from out of town and I find in those cases, a lot of times there is a grey area for who is responsible for monitoring the INR. In lots of cases, it is the family doctor but for lots of reasons — the doctor is on vacation etc., they leave out the patient management. That is, INR testing as frequently as possible (Alberta).

With the anticoagulation clinic, yes. As a solo practitioner, I think it would be suboptimal. But the anticoagulation clinic is very helpful (Ontario).

Improving Warfarin Therapy

Really there is no question that anticoagulation clinics improve time in therapeutic range in patients on warfarin so it really would be helpful if we could beef up our anticoagulation clinic, have more of a dedicated space, more of a dedicated laboratory. Actually they do have point-of-care testing for INR for patients. But just more capacity in our anticoagulation clinic would be extremely helpful (Ontario).

Definitely we need more resources for that. Warfarin is a kind of tedious work. You need to continuously monitor for their whole life, particularly for atrial fibrillation... A patient needs constant attention from the medical personnel so a lot of resources are needed (Ontario).

I guess it would be an independent person taking full responsibility for this so that I don't have to. A trained nurse or pharmacist — someone that would just act independently (Ontario).

I think that one of the most important things is to educate patients and make sure they understand why they are taking warfarin, what the risks are and the interaction with other medications. Once a patient is well educated, the patient can be kind of a backup to prevent something from happening (Alberta).

Essentially the face time with all of the information available would be helpful. And then a booklet or educational materials for the patient. Using the clinic nurse or clinic coordinator or pharmacists to review or assist with the education and procotolize dose administration would also be helpful (Ontario).

... it is patient understanding, patient education, and patient willingness (Nova Scotia).

... Another thing that I think is extremely important, at least for most people, some of those who do not want to participate in it is one story but people should be aware or should have an option of being aware in having their blood work reported to them. It's like if you go to the doctor and the doctor sends you for blood work and you have to go back to find out what is your cholesterol level. It is the most infuriating thing as a patient because after all, it is your cholesterol level and it is for you to know what it is. That's like the doctor saying, oh, it's good and you are thinking, OK, that's good but what is it? Give me the number. Doctor's notes about the patient is part of privileged notes to myself. But that patient's blood work results should be shared. If you want to know, why shouldn't you be able to have that information? (Nova Scotia).

I think one of the biggest things is having immediate INR results. Point of care testing.. (Ontario).

I think like insulin administration and some other medications, the patient should be the one for the most part to take the responsibility. There are products available for the at-home monitoring of the INRs for patients. They have been on the market for about 10 years. I think there are a lot of patients who are more than capable to monitor their own and adjust their own warfarin better than we do. I think as far as the home monitors, I think it comes down to cost. The cost to the patient is too great for them to do that (British Columbia).

I think there needs to be a formulation that doesn't require INR monitoring. That would be the most important thing but that it is also reversible like warfarin (Ontario).

Defining the Well-managed Patient

I guess the ultimate is to have them within therapeutic range. Their INR falls within the two to three range at least 70% of the time. I talked about age before because warfarin is a medication that has the potential for a lot of drug interaction. Part of the education is telling the patients what to avoid and to let your pharmacist know anytime you are going on any new medication that may enhance your interaction with Coumadin (Ontario).

If the patient is educated, they will know what to look for and if they can watch that, that is the most important (Alberta).

It is compliance that the patients show up for INR testing. It is vigilance on the part of whoever is managing the INRs. If they are in the anticoagulation clinic, they are getting their INRs checked as frequently as necessary. So if their INRs fluctuate a lot, then they are in there weekly or even twice weekly (Alberta).

Frequent blood testing and a family doctor who is following up on that. It is a compliance issue. It's the patients and family doctors who make the treatment successful (Alberta).

If nothing changes and they keep their INRs stable, then hopefully they can even check it every three months or six months and it's not a problem. The INR is the key component. The ability and the condition for whatever it is given for (New Brunswick).

For instance, I have some people who have INRs exactly where you want it and there is very little fluctuation. You look at their TTR and they are 100%. I have never had to adjust their doses of warfarin. I presume they eat the same thing every day and that's why there is no fluctuation. But I have some people like that and you back their INRs down to once a month. Every four weeks, they come on the dot and their INR is always in the therapeutic range. They don't have complications with the treatment. I would say that is the ideal patient and I have a few like that. Unfortunately, not as many as I would like (Manitoba).

Well-managed is that the INR is therapeutic for — 80% to 90% would be really good. We need a systematic approach so if the INRs are subtherapeutic, there is a process to facilitate making a prompt change (British Columbia).

Defining Patients Who Are Difficult to Manage

I think compliance is a big factor in it. A lot of these patients are on many different medications so if the medications are constantly changing or the patient's food intake or lifestyle is changing and the INRs are going up and down, up and down, that is the type of patient that makes things really challenging. Often that is the patient that doesn't come regularly for follow up as well. That would be a patient that would be a good candidate to switch to something else as long as they are taking it. As far as somebody that is requiring very frequent INR checks because the dosing is changing and their INRs are sub-therapeutic 30% to 40% of the time — that would be a very good candidate to be switching to something that you can get a more standard response (British Columbia).

We have had patients in the past where compliance was an issue. They just did not want to have their blood tests done and they thought that they could just take the same dose once it was stable and not worry about having an INR. And then you have patients whose compliance is an issue with any medication, regardless of whether it is warfarin or not. One in particular takes their medication on and off depending on their symptoms. If they feel like they might have high blood pressure, they will start taking their blood pressure medication (Ontario).

The big ones tend to be patients with alcoholism because they are not drinking, then they are suddenly binge drinking and the levels are all over the map so alcoholic patients are patients that we are having a bugger of a time with. Another patient population tends to be the patients with psychiatric illnesses. They have difficulty understanding the importance of it. They are difficult in following up on when they are going to get their next INR measured, do they actually go and get the blood testing and that tends to be another population where we feel we aren't managing them as well as could be done (Ontario).

Usually they are elderly, they have lots of different other medications that are involved or they don't speak English, which is a challenge. There are usually other factors besides the drug itself (New Brunswick).

Patients who are cognitively impaired or forget their medications or if they have complex medical regiments don't necessarily understand what the drugs are for or why they have to take them. I have countless patients who forget to take their medication or they do well and then over the years, they start to forget to take it. So

they need supervision to ensure monitoring and ensure adequate compliance (Ontario).

You will also see things like drug interactions where I will manage their anticoagulation and they get a UTI or something like that, go to a walk in clinic and someone puts them on Cipro. Next thing you know, their INR shoots up because of the drug interaction. So things like that happen frequently (Manitoba).

It is definitely a metabolic issue. It is metabolized through the liver. So for some patients, their INR will be steady, some are up and down and really, you cannot get it to work (Alberta).

Those people who have general complications with anticoagulation treatment like bleeders, those who fall a lot, etc. Those people who bleed a lot or fall a lot should not be on warfarin. I talk with them about it (Nova Scotia).

I trained in another city and in that city, access to primary care physicians and anticoagulation clinics was somewhat more problematic than here and I can recall patients there that weren't well managed because their blood tests got lost or the referral to the anticoagulation clinic wasn't made seamlessly from discharge from hospital. Fortunately since being in Toronto, I haven't had that kind of experience. But that is certainly one of the ways that patients can be improperly managed — if there is delays in getting access to the tests that they need and access to the clinics (Ontario).

Whether Difficulties Were Overcome

Communication among physicians and their patients is very important. One doctor could start you on a new medication that could have an interaction with warfarin but that physician didn't even know that patient was on warfarin. Communication among physicians can help. For example, in Alberta, we have a provincial wide computer database. We can log in to check patients' blood work, imaging studies, etc. Or the primary care physician or specialist can get access to it. I think this is one way to go (Alberta).

Honestly, due to the presence of dabigatran, I move them to dabigatran. I am hoping that Coumadin will be an old drug which we will never use again (Alberta).

Yes. There have been several recently where I have been able to put them on Pradax. That has nothing to do with warfarin but it certainly made the patients a lot easier to manage. I can probably think of one or two patients who initially started off being unreliable with their INRs and once they were reminded or continually reminded of the importance of getting their INRs done and following up with the person who is managing their warfarin. There are some people that do improve after that (Ontario).

Certainly. For example, to improve patient communication. With my practice, when a patient is discharged from the hospital, we always do a paper copy of the discharge summary for the physician as well as an electronic copy. In some patients, if I think that the patient may get lost during this transition, I will give their family doctor a call. If they are on warfarin and it is a new medication, the INR needs to be followed and I ask them to follow up (Alberta).

Yes. I talk with them and they usually choose aspirin or the family chooses to give them aspirin if they are incoherent (Nova Scotia).

I would love to say that we have overcome them but all I can say is that there is things that we do that help. Certainly the education helps out — if they know how important it is, they are more likely to follow up on getting their INRs testing. For the elderly with confusion, use of pre-filled dosettes can help out with that. They just know that they take their pills but the difficulty with that is that if you need to change a dosage, you are contacting the pharmacy and it won't happen until the next time. We have contacted family members saying, "You know, he's not getting his blood tests, you have to help them and push them to do that." We have contacted family physicians to try and encourage the patient (Ontario).

First we try to involve more people. Like in the past, we are the one who make the dosing instructions, the nurse will execute it and implement the dosing. Nowadays, we include family physicians and try to shift the burden to them (Ontario).

It is about careful assessment and education of the patient. And getting the pharmacists to see the patient as well to see if we could increase their likelihood of solving any manageable treatable problems that are interfering with the dosing and absorption. No, they didn't overcome them but they did increase our confidence (Ontario).

A lot of it is just education. People will forget their warfarin and we remind them that they have to take it. Other things as far as diet goes, I recognize that you aren't doing the same thing all the time so we just remind them to be as consistent and practical in terms of diet. I tell them that I don't expect them to eat the same thing every day but to try and avoid major fluctuations in diet from one week to the next (Manitoba).

Adequate Trial Period

I would say three weeks (Ontario).

It's quite confusing because how long does it take to level warfarin therapy? Probably about 10 days to arrive at a desirable level. Desirable outcome means that the patient doesn't bleed or doesn't have a stroke. There is no real side effect (Nova Scotia).

I would probably say if we can achieve compliance and adequate control and reasonable INRs in a couple of months (Ontario).

When you are talking about not working, I guess you are talking about INRs that don't reach therapeutic levels or that bounce around too much of if someone fails and has a stroke on warfarin. But in terms of reaching therapeutic values, I would say a month (Ontario).

Three months (British Columbia).

We would generally give it a good honest try — at least three months (Alberta).

I don't have an exact pattern on that but roughly speaking, if someone has been unable to get good INR control within six months, they are probably never going to. So six months is about as long as I would wait before suggesting to do something else (Ontario).

At least three to six months (Alberta).

... Usually it takes me about one to two weeks minimum to test how much warfarin they need. Then I need three to six months to see how the patient is doing because a

warfarin dose can shift from week to week. Then I need a little bit longer to tell me if the patient is taking warfarin, how stable the INR will be (Ontario).

I have never suggested discontinuing warfarin because it has been an inadequate trial because this is a preventative medication (Ontario).

A trial — what is the definition of that because of course this is a preventative therapy. We generally give patients several months on therapy. It's only when we see they are not following up on their INRs, they aren't getting them tested, something like that where despite repeated requests and education on how dangerous it is not to have monitoring. It is usually after several months where we say, we gave it a shot, the patient obviously isn't following directions, it's dangerous to have them on this therapy without appropriate monitoring, that's when we would be recommending that they come off this therapy (Ontario).

Withdrawing Warfarin Therapy

As time goes on, if patients get bleeds or develop conditions where the risk of bleeding is considered to be too high, as time goes on there is an increasing percentage that are intolerant or their risk of continuing is too high. I would say about 10% to 15% (British Columbia).

That would be a minority — less than 5%. And bleeding would be the only reason I would have done it. Generally I go to aspirin. At least until the bleeding episode is over (Ontario).

Very few. Probably 10%. Either because of intercranial hemorrhage or we are unable to safely monitor (Ontario).

A minority. Recently there was an elderly lady who came to me with a second episode of bleeding and the source was never identified but nevertheless, she could not be on warfarin. Probably 3% of patients I recommend withdrawing. I often recommend they switch to aspirin (Nova Scotia).

Five per cent to ten per cent. This was for sometimes bleeding and sometimes unexplained falls that I thought were dangerous, sometimes severe, uncontrolled hypertension (Ontario).

The times it has happened are typically when people come into emergency with a GI bleed or something like that and, if that's the case, then another anticoagulant is not likely to be any better anyway. Whether it's warfarin or something else, they are going to need the problem fixed or treated before they can be anticoagulated again. It is treating the underlying problem. Typically when I withdraw, it is going to be for a short period of time until the cause goes away (Manitoba).

Oh definitely. There would be even a consideration of going to aspirin or aspirin plus Pradax. Because at least you were getting some benefit and maybe similar benefit to what you were getting from warfarin if you were subtherapeutic for such a significant period of time (British Columbia).

I am withdrawing more and more. I leave it up to the patients but more are leaning towards dabigatran. There is less risk of bleeding, no need for blood tests. The only issue is the expense (Alberta).

Not that many — maybe 5%. Because they had a recurrent relapse despite an optimal management in their INR (New Brunswick).

Very minimal. Probably 5% to 10%. Some of them were prescribed an alternate agent. The majority of my patients who have AF will be anticoagulated on warfarin. A few patients if they are looking for some alternatives, I give them a new agent medication. Pradax for example (Alberta).

This was for non-compliance in monitoring the INRs, sometimes unexplained high INRs (Ontario).

In a specific patient that has had a subtherapeutic INR and an ischemic stroke, the old practice was we have learned our lesson, I will write a scolding letter to your GP telling them to be more careful with your INRs, I'm going to give you a speech and ask you to take ownership and be more careful with what you eat in terms of Vitamin K foods or I can give you dabigatran which if you take twice daily, we can avoid all of that and improve your chances and you can get on with your life. Most people, if you have the money and can afford the $115 to 125 a month, they will go for that (Alberta).

Relative Merits of New Anticoagulants

I'm all for it. Like I said, it doesn't require the blood tests (Ontario).

Long time coming. I think they are an excellent option. I think they will overtake warfarin as the standard anticoagulants. I think warfarin will be used in a very select group of patients in the future and I think they will be the anticoagulant of choice. The merit is that you get a prompt, reliable anticoagulant response without need of monitoring, without any significant increase in risk of bleeding. There are some caveats in there with the one that is out there already — it increases risk of upper GI bleeding because it has an acid in it to help dissolve it. So I think they have a lot of advantages vs. few disadvantages (British Columbia).

... I think drugs like the dabigatran do have a clear advantage over warfarin in not having to monitor because the monitoring is difficult and we know that even in clinical trial circumstances, which is essentially the best monitoring you can do, patients on warfarin will spend up to a third of the time not in the therapeutic window (Ontario).

There is less risk of bleeding, no need for blood testing, it is very convenient (Alberta).

I think it's a very good choice. The monitoring factor is definitely an advantage (New Brunswick).

Pradax in the clinical trial is equally effective. It is easier for patients. If their lifestyle is travelling around to more than one place, it is impossible for them to check their INRs. For those patients, Pradax is an excellent agent (Alberta).

The by far most important merit is that you don't have to do blood work or adjust the dose. And that is worth every penny to a lot of patients. But a lot of people choose to pay out of pocket because of those merits. Because they don't want to be bothered with blood work every week or every other week (Nova Scotia).

One is that they are more effective. Pradax at a higher dose is more effective at preventing stroke. In some ways it's safer, not for overall bleeding but there is less risk of inter-cerebral hemorrhage (Ontario).

I love it. I love it because it is so stable, you just ask the patient to take two pills and then they will be protected from having stroke or a blood clot problem. It is so easy, it's almost like telling people to take high blood pressure pills (Ontario).

Relative Limitations of New Anticoagulants

It's a newer medication so we don't know really what idiosyncratic effects might develop down the line although we can hope that the company manufacturing it took the lessons from some of the other inhibitors that were much hyped and turned out to have idiosyncratic effects such as liver failure (Ontario).

This agent is new so we don't know the long-term data. Some side effects for new medications are being found in the post audit. Since this medication just started, we don't have any long-term data so that is the major limitation (Alberta).

Also, in the event of a major hemorrhage, that we couldn't really reverse it (Ontario).

For limitations, other than the no reversing should a bleed occur (Nova Scotia).

The problem though, and this is my slant as somebody who works in the hospital, there are going to be those that bleed (that 1% risk per year roughly) and they are not going to be able to be reversed. So I don't know how that is going to play out in terms of will it affect my prescribing (Ontario).

The other concern that I have with dabigatran is I tell them if you have to go for surgery, none of us as of right now really know how many doses you are supposed to skip before your surgery, and none of us know how to check to see if you are safe for surgery (Manitoba).

The current big limiting factor right now is the provincial formulary coverage where currently, it's currently not on our provincial formulary so most of our patients who are over 65 and on Ontario drug benefit formulary don't have coverage for this. So that is why we are still using warfarin as our first-line agent. But we are getting more and more of our patients on these second-line agents and we are looking forward to using those more frequently — especially in those that have erratic INRs so we are hoping that provincial coverage occurs sooner so that we can get them on a safer medication (Ontario).

Cost is the main limitation (New Brunswick).

In Nova Scotia, it is not covered by Pharmacare so people say that it's not covered so they can't take it but I'm not quite sure that's the case (Nova Scotia).

I believe here last time I checked, it was $150 a month vs. warfarin, which is $17. Right now, Pharmacare is not reimbursing yet so I pose the question, is the extra $130 worth it to you in convenience? (Manitoba)

The most common side effect, which they saw in trials, is acid reflux because of the tartaric acid component. Three of my patients have had to stop because of it because it was so significant (Ontario).

So what I tell them is roughly 10% of people in the study get dyspepsia and I can't imagine that is going to go away because that is part of how the drug is made, 10% will always get dyspepsia unless they find another way to formulate the medication (Manitoba).

We also have a number of patients who have severe renal dysfunction and so these available alternative agents aren't an option for them (Ontario).

A limitation is if a patient has a liver dysfunction, you have to be careful in prescribing this medication (Alberta).

Optimal Patients for New Anticoagulants

Anybody with atrial fibrillation with a CHADS score of one or higher and normal or only mildly impaired renal function. For any patient like that, to me the new anticoagulants are a better choice. Only for patients who do not have coverage, will not pay for it or a creatinine clearance less than 30 will I accept the fact that warfarin is the only thing they can take (Ontario).

If a patient is doing too well but their lifestyle is affected, warfarin can be trouble for them. Either inconvenient or potential dangerous if they aren't tracking it (Alberta).

Atrial fibrillation so far only. I have had patients who had other conditions and I spoke to a hematologist and I understand that dabigatran is to be approved in those cases momentarily but in my understanding, it's still not approved for DET yet. But I understand that studies were done and approval is pending (Nova Scotia).

I would offer it to everybody because it is so much easier than having to go for these INRs so if cost wasn't an issue — I guess cost is the one thing that would lead me to not offer it (Ontario).

I think if the patient expressed interest in it because they didn't want their INR monitored and they didn't have renal dysfunction or coronary artery disease, I would consider it.
There was an increased incident in cardiac event with a higher dose (Ontario).

Newer Anticoagulants for Patients Who Experience Stroke or Bleeding on Warfarin

I think at that point, yes you do have to try something else, as long as you were sure that they were therapeutic. Going back to what I was talking about earlier, sometimes they will show up in the emergency room with a stroke, their INR will be 1 or 1.2 and people would call that a Coumadin failure which is not technically true. If you show up and their INRs have been monitored and they were between a 2 and 3 and they had a stroke and their INR is 2.4, then yes that would be deemed a Coumadin failure. You would have to do a bit of a medical workup to make sure that there was nothing else causing it but I think you need to try something else at that point whether it is Heparin or one of these newer agents (Ontario).

Yes, of course. If they failed the Coumadin and there is no reason why they had another stroke, then certainly I would try a different medication to try and prevent another relapse (New Brunswick).

If someone comes in and they are 85 years old, they have a history of hypertension, they are on warfarin and their INR is therapeutic which most of them are we can't say that you had a bleed because you are on warfarin because lots of 85 year olds have bleeds. So it's an anticoagulant associated bleed. Certainly being on warfarin is a risk factor for it. The main predictors of bleeds on warfarin are age, blood pressure control and INR control. So if someone comes in with a very high INR and after some time, has made a reasonable recovery, re-challenging them on warfarin and being very careful. So that is the type of patient I have no trouble re-challenging again with

Pradax because dabigatran is associated with much lower of intercranial bleeding (Alberta).

It depends on what type of stroke. Were they subtherapeutic on warfarin? If they were, why were they subtherapeutic? It's really dependent. There are a lot of different factors. Not necessarily everyone who has a bleed, even if it's an ischemic non hemorrhagic bleed. If the patient has been on warfarin and have been therapeutic for 90% of the time and they come in and they are subtherapeutic and they have a stroke, that is someone that you may want to consider continuing on the warfarin. But you may also want to consider avoiding any subtherapeutic events (British Columbia).

I guess it depends on the situation and their overall medical condition. There are some things in people that have had a hemorrhagic stroke that you have to consider and be cautious about. Usually in this situation, I would sit down and go over with the patient what is the pros and the cons with anticoagulation (Alberta).

Were they therapeutic or were they subtherapeutic? If they were subtherapeutic, I would consider that the warfarin failure is a good question. Why were they sub-therapeutic? If that could be remedied, I might persist with warfarin. Otherwise, I would consider it. Not in the acute stage but in the long term prevention I would consider it. I think the problem right now is that there have only been 9,000 to 10,000 patients studied on this medication so post-market surveillance, safety, and efficiency is yet unknown (Ontario).

Usually not. For most of our patients, if they were subtherapeutic at the time of the stroke, then it would just be a matter of that that they were not being adequately treated. For our patients who were at therapeutic range or supratherapeutic, the short answer is that I would leave it up to their neurologist but for the most part, I have never changed a patient because of that, and I am not aware of any neurologist having done that as well too. We will sometimes change their target. So let's say they had a stroke and they were within target with their INR at 2.2, we might say let's increase your target and aim for 2.5 to 3.5. So in general, we have changed the therapeutic range that we are aiming for but we haven't stopped it for a stroke. Except if it's a large stroke, we might stop it because of risk of hemorrhaging, if it was a hemorrhagic stroke, we may have to consider that and stopping it for that reason but we wouldn't be switching it to another agent unless it was something less so, something along the lines of aspirin (Ontario).

Patient Quality of Life: Warfarin Therapy

I think having to have blood tests all the time is a bad thing. Most patients will have to go every two weeks or every week. It impacts travel and just the nuisance of having to go to a lab and just getting poked for a blood test is not a pleasant thing (British Columbia).

Then I have a lot of patients who like to travel to Florida for six months out of the year and one in particular gets the prescription for Pradax which he pays for six months while he is in Florida and then when he comes back here, he switches back to Coumadin. So every six months, he switches oral agents depending on the convenience factor (Ontario).

But for other people, it's a massive impact. That's where you get into the issues where they have difficulty trying to get INR monitoring, their medications are being changed left right and centre and that is a source of anxiety for them. They are having side effects such as bleeding and bruising. Some of our patients get all excited about bruising and we just try to reassure them that it's more of a cosmetic issue. So for the

majority, it's not a major issue but for some, it's a significant problem for them with respect to their quality of life (Ontario).

The monitoring is very difficult, especially if they are elderly. We are all familiar with Coumadin, it has been around a long time so that is a big plus for us but sometimes, if there is a problem with the INR, then that is always a pain to sort out (New Brunswick).

Blood work, limitations, a lot of anxiety wondering where their INR is. I'm not quite sure if quality of life is worse because of warfarin, or would it be improved with Pradax or not. In self-published studies, some people say people with atrial fibrillation have a worse quality of life and some people say there is no difference (Nova Scotia).

There are patients that don't have problems with achieving the therapeutic level as far as the INR. There are patients who go for blood tests once a month and they are just fine with that (Ontario).

There are some patients that their INR is therapeutic most of the time and they can go to the lab once a month or once every two months even. That is someone whose quality of life is not badly impacted but that is a rare patient (British Columbia).

Most people handle it pretty well when they are on warfarin. For most people, I don't see a big impact on their lifestyle or their quality of life (Alberta).

Patient Quality of Life: Newer Anticoagulants

I think overall in comparison to warfarin, it will actually improve the patient's quality of life (British Columbia).

There should be less impact. Less risk of bleeding and they are not requiring blood testing. There would probably be a 20% impact (Alberta).

With the new ones, it's going to be a lot easier because it's a fixed set dose so they aren't constantly being called and told to take more or take less. They aren't having to run out and get testing on a regular basis so that's where there is going to be a significant improvement in people's quality of life. People don't want to be reminded that they have a condition like a heart condition and knowing that they have to run out and get blood tests and they are being told to adjust things, it's a constant reminder that you have a heart problem. Patients like to say, just give me my medication, I will take it every day and I can kind of forget that I have a heart problem. It actually decreases their anxiety level significantly (Ontario).

The new ones should help. No monitoring, less worry about other drugs and diet (New Brunswick).

People are willing to pay out of pocket for new anticoagulants just so they don't have to travel to get their blood work done and trying to call the doctor and the doctor isn't there so they leave a message and then the doctor calls them back and has to leave them a message — it's a weekly ritual. Many want to pay out of pocket and forget it (Nova Scotia).

I have seen a few patients with whom the reflux symptoms are bothersome (Ontario).

At this point, the cost can be prohibitive or almost prohibitive to a lot of patients (British Columbia).

The only drawback to the new anticoagulants is that it has to be taken twice a day (Ontario).

With the new ones, you still have to avoid putting yourself in situations where there is a risk of trauma. If you have to be on an anti-coagulant, you are never going to be able to avoid that (British Columbia)

Preferred Sources for Information on New Anticoagulants

You can always go back to the individual trials (British Columbia).

Medical trials. I do some CME talks about this so I have to stay up to date on it so I end up getting most of my information from the trials and the researchers themselves (Ontario).

I usually read the original paper — the published studies and clinical trials (Alberta).

I went to the trials. The original was published in the New England Journal so I have the trial (Alberta).

Well-constructed, reliable clinical studies. As you know, I am in the academic unit and I trust the good academic resources (Ontario).

For warfarin now that several trials have been done, I will go to meta-analysis data and sometimes the original trials themselves (Ontario).

The RE-LY study (Manitoba).

I think the stuff that is put out there by the pharmaceutical industry is good in some ways but it amplifies the good and doesn't concentrate on the potential negative or drawbacks of the product (British Columbia).

Drug reps are always good and resources seem to come through my email all the time (New Brunswick).

I have also attended a lot of advisory board meetings in person for the makers of Pradax so I get a lot of education from the trials here in Canada so I get a lot of information from those types of meetings (Ontario).

There is usually somebody who gives rounds at the hospital. The hematologists give rounds a couple of times a year and reviewed this several months ago (Ontario).

I think probably the guidelines. For example, the Canadian guidelines recently came out at the beginning of this year and I think that is very reliable and trustworthy and based on evidence. They don't come out every year but if they are available and relatively new, I think that's the best source (British Columbia).

I went to the American Academy of Neurology in Hawaii in the spring (New Brunswick).

I go to two international stroke meetings a year. Even though they don't present these primary papers at these meetings, they present them at the cardiology meetings. They do the presentations within a couple of months of the paper release which is another place I get educated (Alberta).

I try to continue my education — the most useful publication to me is the continuum published by the American Academy of Neurology. And then I try as much as possible

to keep up with primary literature — at least the summaries of primary articles (Ontario).

There is a lot of stuff that is in the New England Journal of Medicine *(Manitoba).*

Two websites I use for most of my information are CardioSource and theheart.org. I do most of my CMA online now (Ontario).

APPENDIX C: QUOTATIONS FROM GPS AND FAMILY PHYSICIANS

Relative Merits of Warfarin Therapy

It's cheap, but the cost associated with the stroke or the mobility is associated with someone who is easily treated and prevented from having that stroke. I can't say there are too many patients that shouldn't be on it. We all recognize that there are side effects. But the ones who have strokes are the ones who don't stay on it. And even the subgroup that go on to have a second stroke, 80% still don't stay on their warfarin. Although the costs are quite substantial, I think it's well worth the benefit of stroke prevention (Alberta).

Coverage is cheap and it works (Ontario).

You can monitor. You can reverse it (Ontario).

It's cheap. It's covered by Alberta Blue Cross (Alberta).

The debate really is the cost: The drug is cheap, monitoring is relatively expensive (Alberta).

Familiarity. Many of us are familiar with the prescribing of it and aware of its side effects. It breeds a sense of confidence (Alberta).

Relative Limitations of Warfarin Therapy

Frequent INR checking (Alberta).

The tediousness of patients having to be tested again. Many patients are immobile. It can be quite difficult to arrange (Alberta).

Another term I would use for it is "tedious." A lot of my patients would fine tune it to the point where they would stay within the proper INR range. They would flip back and forth on a tedious cycle or otherwise they'll end up in the hospital before long (Alberta).

A lot of these patients are old and talk in terms of pills instead of milligrams. You wonder how well they're really taking it (Alberta).

The bleeding risks and the risks to end back in hospital again (Alberta).

Patients Not Suited to Warfarin Therapy

I have a big problem with patients who go south and run into a lot of problems with their INRs over the winter. They aren't so interested in having their INRs monitored (Ontario).

Patients who vary on their diet. It's very hard to give counsel in terms of their dietary intake (Ontario).

People who are a little bit confused affects their compliance. They're often not steady in their diets or their other medications (Ontario).

Elderly with frequent falls (Ontario).

People who refuse to have their INR monitored (Ontario).

Alcoholics (Ontario).

People with eating complications like ulcers or GI bleed patients. Up until we had Pradax we used to not have much of a choice but to cross our fingers and keep their INRs closer to the twos and threes. We would load them up on EPIs and see how they do (Ontario).

How Warfarin Therapy Is Managed

If we started the patient (most of them are seniors) we load them on five mg for two days, then cut back to 2.5 mg and at the end of the week the nurse can draw blood to check what the number is. We don't have a lab, but we can draw blood and send it to the lab (Alberta).

On weekends we have no anticoagulation. We have admitted patients staying for extended periods of time. We end up going 10/10 and 5/5. We do blood work every day and I'm excited and refreshed to hear that some people take a moderate approach. We take care of them. Every day they get blood work. I never do blood work the first two days of initiation because there is no point, but there are many people who do it thoughtlessly. I think we over investigate in a hospital setting. It's 10 or 5 depending on who trained and who likes it and then aggressive monitoring (Alberta).

I'm not actually sure of the anticoagulation clinic protocol, but it does seem to be at times excessive from my point of view. Once I get the patient and I send them off far less often for INRs. I know I've seen them stable. They come back on quite complicated machines (Alberta).

If they come from the anticoagulation clinic they'll be like two mg on Monday, Wednesday, Friday and three mg on Thursday and Saturday and Sundays are something else. I find over time they end up being on a much simpler dose (Alberta).

We do INRs ourselves. We have a machine in the office that tells us the INRs. The nurses tell me what the INR is right then and there and if we need to adjust it. If we go to the lab we get the results from the lab and tell the nurse to call the patient. Generally it's done with the doctors and the nurses (Ontario).

My patients do their INRs in the lab. The report comes and I would make the decision and my secretary would make the accommodation. It takes up to a day if the INRs are really out of whack (Ontario).

The patients go to the lab. The message goes out to the staff and the staff calls the patient. We had a pharmacist. Unfortunately we don't have her anymore (Ontario).

I call the patients myself. Usually, I speak to the family members. Most of my patients are older. I don't initiate too much. It's one of those things the way my practice developed. Most of my patients I respect and just I carry on. I have some patients with DVTs where I'm dealing with at the clinic (Ontario).

I'm lucky to work in the hospital so I see the results within an hour or two of it being done. I call the patient and tell them what to do and record it. Some of the more complicated ones. They are out patients who come in to the clinic at the hospital. The clinic runs the management themselves. The thrombosis unit sees the people with DVTs — not so much the people with atrial fibrillation. They see the cardiologist or a neurologist perhaps if they've had a stroke (Ontario).

My walk-in patients that have nowhere else to go, I'll send them to a colleague who follows a lot of INRs and he will follow them. I monitor and follow and call and direct my own patients at my retirement home. Nurses do the tests. They call me and I direct them and tell them what to do (Ontario).

Decision Support Tools

Sometimes I refer to a nomogram, but on a day to day basis, never (Alberta).

Nomograms are a lazy way out. They don't know the patient or the patient history. I never use them (Alberta).

We use CHAD to access the score and get it between two and three (Ontario).

I have a tool in the filing cabinet. I have to say I haven't looked at it yet. If I had an INR that really confused me, I'd have access to the tools, but usually you kind of wing it and it looks ok. We don't call it "winging it" to the patients (Ontario).

Providing Warfarin Education

Most of them get very good information from the pharmacist (Ontario).

The thrombosis interest group website has great handouts for patients. They have the protocol on there too (Ontario).

We are working with a health educator team (Ontario).

Most of my patients have been on it for a long time. They're coming from cardiologists and neurologists. I rely on them for providing a lot of the education. I have a lot of ethnic patients too. It's not that easy to explain (Ontario).

The pharmacists are quite good I find (Ontario).

One good thing with regards to the anticoagulation clinics is that they do a decent job in that aspect. They provide the patients with hand outs and detail what to watch for, what are good fruits and vegetables and what to watch for. You get a pretty good bang for your buck... Oftentimes I'll get a phone call from the pharmacist after the patient comes in to pick up their prescriptions. It's a good cooperation (Alberta).

In my clinic we have a pharmacist who comes on site once a week and is available for consultation. I usually get my patients to see the pharmacist at least once. There is a nurse there too for more educating (Alberta).

At my practice we don't have a PCN pharmacist connected to our clinic. I don't find community pharmacists play much of a role for providing education. It's mostly anticoagulation clinics initially and then more as we go along. You always have patients you need to constantly remind to get an INR. You kind of have to do it on the fly. We don't have anything structured in terms of providing education (Alberta).

We use the clinics and the nurses help a lot. They are always teaching (Alberta).

Whether Resources Suffice for Optimal Warfarin Management

I like the machines at my retirement home. I know the results right away. For me the biggest limitation is knowing the result right away (Ontario).

Nurses are trained. They come to me and ask the right questions and everything gets done very fast (Alberta).

I had the resource but she left. She had two roles as a pharmacist and an educator: she established the protocol of when your INR is at a certain level you go up or down by a certain mg. The next step was that all the INR was going to be managed by her. The recall system is already in there so that was done by our own staff. She helped with education (Ontario).

It's staff, realistically. If you don't have a good number of allied health care professionals in the area, there's no way you'll have time to look after all these patients (Alberta).

In my practice, I am the one making phone calls. We have a medical receptionist taking calls, but I can't expect that person to ask the right questions. They can handle tasks on the computer, but they don't know what questions to ask. I would trust a nurse, but a medical receptionist isn't trained to know what to ask. They are more reading a script (Alberta).

Improving Warfarin Therapy

If I had something set in place to flag which people were on it, I would have known which people are supposed to be monitoring their INRs or not. Some of my patients are put off by cardiologists. There needs to be a system telling us who is currently on and off treatment (Ontario).

Self-monitoring devices could be improved. That's an obvious answer (Alberta).

I think we need more education. We still have patients missing doses and thinking nothing of it. They don't know how it will affect their INR. We could improve education. It's not about educating once. It needs to be a continuing process (Alberta).

Also, maybe having a fall back of primary care networks where you can allocate resources within your own group to actually have the resources to deal with INR management, and the risks of bleeds on the weekend to have the after-hours clinics available at that time. It works great for a city (Alberta).

We can't access any anticoagulation clinics at all. If the patient comes in Friday, then I manage them Friday, Saturday, and Sunday until I can get them in on Monday. If this is such a great clinic, why can't they expand their mandate? Why can't they support this process and free up time for other important medical things? They could be managing the abnormal tests at night time. They could be managing those patients and continue to take care of them. It would be less resource intense for everyone if that group of trained specialists or nurses were managing that (Alberta).

A PCM pharmacist could come in and do everyone's INRs once a week. Maybe you wouldn't see so much micromanaging that we've all come to complain about from anticoagulation clinics. Maybe they would get to know the patients better and it would save time (Alberta).

Defining the Well-managed Patient

Someone who lives in a retirement or nursing home, who has the ability to get their tests done and monitored, outside of their control, is a well-managed patient. They are easily well-managed because someone else is taking their blood. There is no

responsibility on the patient to have to do it so that immediately takes care of that problem (Ontario).

If you have immediate feedback from the patient's perspective, that's a big help (Ontario).

If a patient has their marbles in their head! (Ontario).

If patients are compliant (Ontario).

Someone who is self-managed (Alberta).

The patient needs to have initiative and be self-managed and have an interest and concern for their own health (Alberta).

A patient who is more educated. I have a patient who never misses a dose. Every four weeks we check. She always makes sure she knows where the labs are. She makes sure she always follows up. She knows if there's a change in her medication she should go a little more frequently (Alberta).

I had one patient have a stroke and he got his licence revoked for three months. He's the most compliant guy now! He wasn't before that (Ontario).

You get a responsible family member to help you and to be the go-to person. They can help you make sure the doses are in the right cases and that they're the right doses (Ontario).

Defining Patients Who Are Difficult to Manage

A patient who doesn't care or a patient who chooses not to realize the importance of their condition is a difficult patient to manage. Sometimes, you feel bad for the patients who don't have the resources available to them. That can be difficult as well (Alberta).

Patients who don't understand the risks associated with poor management in terms of taking the right doses (Alberta).

Lack of compliance (Alberta).

Younger patients are much more difficult to control because they're trying to lose weight and they're exercising some days and not (Alberta).

Patients who drink or take other medication, like Tylenol. We tell them all the time that taking drugs like Tylenol can increase your risk of bleeding (Alberta).

There are patients with learning disabilities or who are on other medications (Alberta)

I think of patients with cognitive issues or who don't understand. I have a couple patients who come to mind who had families who weren't involved. I've had a couple instances where language barriers were a problem (Alberta).

Patients with lots of pills and forget to take doses or are easily confused (Alberta).

Patients with irregular diets are harder to monitor. It takes a remarkable amount of insight to have to understand you have to keep your life predictable (Alberta).

Adequate Trial Period

If the patient is doing well, we don't need to stop. Most times there is nothing there (Alberta).

It comes down to the individual and their relationship with the physician (Alberta).

If you've exhausted all your resources (Alberta).

Withdrawing Warfarin Therapy

Thus far, I've never had to do it (Alberta).

I would say 5% (Alberta).

I've stopped one person. I've stopped more people on Pradax, with Pradax complications from hemorrhaging and bruising and tumours than I have on warfarin (Alberta).

It's always related to identifiable complications related to Coumadin therapy. It's always the person who has massive subdurals on both sides from falls. They're older and demented and you know they're going to do it again. Largely, it's those identifiable patients with major complications who are the ones we stop therapy (Alberta).

Prescribing A Newer Anticoagulant

I did, but it didn't last long. He was a very informed man. He read up on it and said the chances of me hemorrhaging are very similar. I tried him on dabigatran and I think he developed a head ache or some other side effect and he couldn't take it (Alberta).

I stopped one patient. Her INRs were all over the map. I talked to her about it. She thought she could afford it. It was difficult. I had taken her licence away. She couldn't drive anymore so it was a hassle to get to the lab. I talked to her about it and switched her. Then she came back two weeks later and complained about black stool (Alberta).

I had to put three or four patients on dabigatran. One of the guys had full coverage so he was initiated. He had taken Coumadin. I have a patient who went to Hawaii for holidays and he had atrial fibrillation. He called. He was seeing the doctor in Hawaii. They put him on dabigatran. When he came back he continued to take it. I initiated another patient because he had poor INR. He had full coverage so I talked to him about another medication and he jumped on board. He hasn't come back to tell me about any side effects (Alberta).

Most of our patients are seniors. I have had no chance to prescribe yet based on cost (Alberta).

I've discussed it and many patients do not seem interested in making a switch for any reason. The ones who would seem interested have had DBT's and I guess it's not yet indicated. Perhaps that might be reasonable down the road. They are young and they can afford it (Alberta).

I had another guy I was going to switch, but he was a young guy. He's also on [inaudible]. He has coverage so that wasn't an issue. And he's one of these guys that only has to go every three months so I thought he was a perfect candidate for it. But

then the cardiologist said you can't put him on it with amiodarone. She said there could be some sort of interaction there (Alberta).

I've had patients with constant bleeding and we've had to switch to a different agent. Like nose bleeds and gums and tongue and fingers, despite not a bad INR (Ontario).

Pradax. In the past before Pradax, we may have used aspirin, but those are rare patients (Inaudible) we would give up and go to that agent (Ontario).

Relative Merits of New Anticoagulants

It's one dose. It's independent of food and age I guess. In most cases, you don't really have to adjust the dose. That's really easy (Alberta).

It's supposed to be more effective. More GIP's apparently. They're minor, but less life threatening (Alberta).

The plusses are obviously the monitoring (Alberta).

The side effects are very limited. Experience will find us more other people to go on it and we might have more of a practice (Alberta).

It would be interesting to look at the cost of Coumadin to the system. If you have the cost of a mobile lab, the cost of an INR and the cost of monitoring. So this patient will average, any independent person who rides the lab will cost the government of Alberta 80 to 100 bucks a month or a choice of 150 bucks compared to warfarin. Now you have relative rationale which would skew my decision differently. I never think about mobile labs costing money but each call out will cost 150 bucks (Ontario).

My one patient who is on it [Pradax] is valvulated. She desperately wanted off her Coumadin. She hated it. She had wicked heartburn despite being on a PBI now. She's muddling through, but she knows if she can't get over it she's going back to Coumadin. She doesn't want to go back though (Ontario).

You don't have to wait ten days or whatever to get back to speed and you don't have to do INRs (Ontario).

No one has come off of it who has been on it. I gave them their first dose and they recovered in two hours without needles (Ontario).

I have 12 patients on Pradax. Some of them asked for it because they had heard about it. They didn't want to have INRs done. Some of them go to Florida. It's hard to get INRs down there. I have two people who get epidurals every few months for back pain and they have to go on a fragment if they come off of Coumadin so it was more of a hassle. It was more my urging to get them to go on Pradax (Ontario).

As a practitioner, you can stop worrying about all these INRs (Ontario).

Relative Limitations of New Anticoagulants

My one concern with Pradax, why I haven't been using it more often, is I'm worried about reversing it. With Pradax you really can't reverse it. The other thing is the cost. The advantages are the diet doesn't matter. There aren't as many drug interactions with Pradax. Patients on multiple medications or have urinary infections, in most cases I'd put them on Pradax. There's a higher risk of MIs with Pradax in some of the

studies. I guess those are the main merits and limitations (Ontario).

Coverage costs money. I think cost is a huge issue. There's a select few this would be quite good for, but it's going to be useless anyway. I'm not going to put people on it because of the monitoring. If warfarin costs 20 bucks a month, this costs 150 bucks a month (Alberta).

I don't think people understand it (Alberta).

If you take the management of atrial fibrillation out of their hands or the anticoagulation, and you get a large majority of people covered for anticoagulation with little effort other than prescribing medication, we can down major morbidity and mortality from stroke in Calgary alone. Frankly all of us work hard and are good at our jobs, but there's a lot out there who maybe aren't so diligent with their patients and this might remove some of the ambiguity with all the patients who are cared for in Calgary (Alberta).

I've been asked about it by different patients who were interested until they heard that it's not covered. Then they retracted their interest (Ontario).

It is expensive and I hear it causes heartburn (Ontario).

I had one patient who should be on Coumadin but he has absolutely terrible vessels so it's impossible to get his blood tests done. He couldn't tolerate Pradax because of GI upset. So he's basically just desperate (Ontario).

My population isn't going to pay for it. It's not covered. It's interesting that even though the academia is there and the evidence is there to do all that, people don't want to do it because of the cost (Ontario).

I'd be much more inclined to try the Pradax if it had coverage (Ontario).

Most of the patients on Coumadin do very well. There's no need to change it (Ontario).

This is a new medication. If the patient is worried about starting a new medication, I'm worried about starting a new medication (Ontario).

Newer Anticoagulants for Patients Who Experience Stroke or Bleeding on Warfarin

Assuming they had coverage, oh yes (Alberta).

It depends on what their level is at the time (Ontario).

If they're therapeutic and they've always been that way, and they're quite stable, there's no real benefit to Pradax. If they're not being well controlled they shouldn't be on Pradax (Ontario).

At lower doses of Pradax they're somewhat less at risk of a bleed compared to Coumadin. In fact higher doses there make them more at risk of a bleed (Ontario).

You also have the reversal problem though because with Coumadin you can reverse it if they're bleeding (Ontario).

It depends what the INR is. If they're sitting at six, yeah, of course (Ontario).

If their INR is fluctuating a lot and you're having trouble controlling it, they'd certainly be a good candidate for Pradax. If they're having a bleed on a higher level or they're on other medication that caused it, I'd probably keep them on Coumadin (Ontario).

Stroke with A-Fib is a massive event. GI bleeds is not a big deal. We can fix the bleed. We can't fix the stroke. Stroke is devastating (Ontario).

Preferred Sources for Information on New Anticoagulants

When Pradax came out they put out this big fantastic talk and with cardiology and the GI and it was incredibly informative (Ontario).

Reading journals (Ontario).

I see specialists and the occasional pharmaceutical rep (Ontario).

I would call my friend in cardiology. It's much easier to obtain the information that way than to do a bunch of research (Alberta).

Where I live there's a yearly conference geared towards family docs. I've been the last couple of years. It's really good. They have an entire two hours devoted to anticoagulation and atrial fibrillation. If that's a consensus forum for cardiology opinion on this I think this is where you're going to get it. I don't think you'll get it from journals or this and that, but I think when they're together presenting in front of their peers, that is pretty much a consensus opinion for Calgary (Alberta).

A conference where cardiology and stroke prevention presented together would be helpful (Ontario).

Information Gaps

Better evidence-based guidelines. We were talking about the guidelines coming out for stroke prevention, but you don't necessarily go across all the domains for what you're actually preventing. Is it just due to A-Fib? Is it just due to a valvular abnormality? If they could separate out the individual diagnosis and give us at least some ballpark idea based on what some evidence guidelines of what to do in those circumstances. Are patients who are subtherapeutic gaining benefit compared to being on nothing at all? Are they gaining the exact same benefit as they were when their INRs were in the two to three range all the time? (Alberta).

Will there be more side effects that will come out in the years from now? Is anything being withheld? (Alberta).

It seems like all the information you're getting is from the dabigatran drug rep. As much as you try not to be biased, what you really have to do is go to conferences. You have to make time to read non-biased sources and go to conferences and things like that (Alberta).

Is there something from the Alberta Chapter of Family Physicians where somebody has said there's a group and this is what we recommend? Like we've sat down and we've looked at these two groups and this is what we really recommend (Alberta).

I think TOP's will do it, but they haven't done it yet (Alberta).

Thoughts on Patient Self-Testing

I guess it comes down to whether or not you can trust the patient to do the test correctly (Ontario).

I'm not so comfortable with it. My concern is they'd be checking too often. They're going to be constantly playing catch up and not doing it right. There's too much education needed (Ontario).

I see the liability in that. If they have a stroke and some lawyer says it's your fault or you're making it up (Ontario).

I don't think I'd trust the idea (Ontario).

You may if it was the standard of care. As long as you have the documentation to support that they are doing everything correctly. That needs to be the protocol (Ontario).

Patient Understanding of Warfarin Therapy

I think it is like religion (Ontario).

I think they know what numbers are too high and what is too low. It's like diabetes. How well do they understand the numbers? They know enough to stay at the number that is safe (Ontario)

They understand the goal of 2.5 to 3.5 (Ontario).

I think the only patients who need to know more are the ones who aren't being compliant and that would tell them why they should be. Otherwise, I don't think they care (Ontario).

My nursing home patients don't have a clue — and they can't have a clue. They're demented. But young 50 year olds absolutely have a clue (Ontario).

APPENDIX D: QUOTATIONS FROM ALLIED HEALTH PROFESSIONALS

Satisfaction With Role in Warfarin Management

In a primary retail setting, it's very nerve-racking for someone who likes to play with a lot of patient care as a pharmacist to get a warfarin patient in, and they're in a hurry and you can't get your materials through to them. There are all these things impeding on your education to the patient. Now, it's easier. It's not as stressful because we have the protocol that we follow. We are very able to get ahold of doctors and nurses and all of the players in the group. We are much more team approached. It's a lot less stressful. [Long-term care as opposed to retail.] (Alberta).

It's a very frustrating drug because of the variability in INRs and because patients have to be tested. I have patients who have been on warfarin for 20 years. That's very tough (Alberta).

I love it. I'm in management. So this is really my clinical component as opposed to my job. We have prescriptive authority in the province so it gives me the capability to utilize that. The educational component; the patient contact; the working with the physicians. All of it, it's very rewarding (Ontario).

Certainly it is rewarding and in terms of how other professionals view you too, I mean, there is more of a collaborative care process. Again I'm speaking from a community perspective, and in the hospital it tends to be different with pharmacists, but in the community the pharmacist's role hasn't gone into that area except for the family health team where they're directly involved with that team (Ontario).

It's great. We have over 600 patients. The clinic has been running for five years. I just find it rewarding to be able to communicate with the patients. We have a lot of patients that we may be the only people they see and pick up things and communicate with the doctors (Ontario).

We work under medical directive so we do prescribe warfarin as well. You're actually putting your hands on the patient which is a little bit different for pharmacists. For pharmacists, we generally don't do that and that gives you a totally different relationship with that patient and them with you (Ontario).

Working in the hospital you gain a lot of independence. So in our clinics the pharmacists do all the dosing and the physicians are just there if problems arise. In comparison to community pharmacy, I have a lot more opportunity to interact with the patients and really get to know them. And to be able to make decisions about their care. In community, you are kind of just told what to do and you carry it out. I feel like I'm more involved (Ontario).

I did visiting nursing before so I was comfortable with the patients and being a nurse we are comfortable with putting your hands on them. We are used to that. Them managing their warfarin and them being so involved. We also found too that patients coming in we're also catching other health concerns (Ontario).

Relative Merits of Warfarin Therapy

Your interactions are well-known. You can adjust those interactions. It's reversible. It is annoying, but it provides a lot of people with jobs. There are a lot of people tied up in running it. It's onerous, but it's there and it's effective (Alberta).

Some of the merits are in the indications. It certainly does reduce the risk of stroke and heart attack. We also administer warfarin for patients that have poor function of the left ventricle, or a part of it, after heart attack. It could develop clots. There are merits to preventing that. I think a great thing that's happened is all these anticoagulation clinics that are now in place. They certainly keep right on top of the INR's (Alberta).

And actually it becomes something that they [patients] become more invested in their healthcare period, not just the anticoagulation. Whatever their issues are, now they know that they can get information (Ontario).

It's an inexpensive product. It doesn't put a lot of financial burden on the patient (Alberta).

The advantage is there is a pretty good window. So it will accommodate the patient that forgets the dose and that type of thing. It's all about the monitoring. Ultimately if you have good monitoring you can manage that patient quite well (Ontario).

Relative Limitations of Warfarin Therapy

With our patients, probably falls is a huge thing — especially with the geriatric population. Worrying about bleeding out. We are dealing with patients at risk of falling (Alberta).

Adverse drug interaction is huge. That's where they like to challenge us. Every time they get to be on an antibiotic or antidrug that is high codeine we have to closely monitor it (Alberta).

It's kind of a dirty drug, a lot of drug interactions, a lot of other problems with it; lab monitoring is always an issue, compliance to make sure they come in and to get their INR tested. Those are probably the major points (Alberta).

Some physicians tend to apply their doses too exactly. I don't think a small quarter of a milligram change in dose is going to make too much of a difference. They do things like splitting the tablets which makes the dose even more inaccurate. There's more intervention time. There's more discussing with the doctor. Related to that is unstable INRs. You try to figure out why, but you can't figure it out. They just fall off the chart. Nothing has changed but for some reason it's off. So you always question if the INR result is accurate (Alberta).

There are a lot of pharmacists out there who are not familiar enough. That is a real challenge (Alberta).

On the downside, the fact it often takes a couple days to start working and it's not as quick is also a factor too. Patients need instant relief (Alberta).

Optimal Candidates for Warfarin Therapy

The risk has to be lower than the benefits. If someone has one arrhythmia, it's not appropriate. You can manage that guy on Aspirin. Or if you have someone at a high risk of stroke, or they fall or they're demented and can't take their pills. You have to weigh those risks. It's all related to how much a person will benefit from trying it (Alberta).

I would say compliance. You have to be willing to get tested. Willing to get INRs taken. You have to draw blood on a regular basis. There are clients who don't want anything to do with getting tested (Alberta).

The cognitive ability to understand those changes. A good family support structure (Alberta).

Patients Not Suited for Warfarin Therapy

Yeah for sure there are poor candidates. But then you know it's also about the ability to communicate with that patient. You can't do it with everyone. In terms of some people just do not respond well. And that patient is generally not invested in the therapy and that's the patient where you run into problems. And we've had that situation with younger patients for example. Where they are not that compliant because they're going to go out and party on the weekend. That type of thing (Ontario).

The other patient that is not a particularly good candidate are patients that are really difficult to control. That's because of other things going on in their medical lives, or their own genetic makeup. Those people are a huge challenge because it's not about their unwillingness, its more about just that they're up and down and disease states are taking control and the levels go everywhere. That's also the type of patient where there are concerns (Ontario).

The challenges of other medical considerations, those are going to be there. The young. The middle aged and the old. Sometimes it's actually kind of fun to work with physicians to find a solution to the problems. Those adjustments of other meds or changing them to something totally different if there are issues. That kind of adds to the fun working through this clinic (Ontario).

Oncology patients have a difficult time managing their INR as well. Because they're on and off chemo therapy they have nausea, vomiting — just a lot of other factors interacting. Cancer itself will throw off the anticoagulation cycle. So that's problematic on all kinds of levels (Ontario).

Cognitive ability. With a number of elderly patients, depending on if they have additional caregivers that can help them or if they're on their own cognitive ability can do even simply things like remember to take their pills is an issue (Ontario).

... Some of them have unstable lifestyles; we sometimes have patients that are living in and out of shelters. Don't have money to cover their medications. Sometimes with those patients we have to try and figure out alternative arrangements (Ontario).

They might decide to never go on warfarin at all. Some people are very much against it (Alberta).

If they are hypersensitive to the drug for some reason. Perhaps they have an allergy or they are on other medications that conflict with warfarin. Then we'd have to move them off as well (Alberta).

How Warfarin Therapy Is Managed

I use nomograms mixed with your knowledge and experience with that person (Alberta).

We rely on physicians to direct us as to what orders we're supposed to do and what we're supposed to look for as well (Alberta).

When patients are in the hospital, an INR is drawn from the lab. We get the results back and either phone it in or show the physician. We get a direct order as to what the dose of Coumadin is. That gets sent to the pharmacy. The pharmacy processes the order and brings it up and we dispense it. It's fairly regimented. There are always conversations going on between the pharmacy and the physicians (Alberta).

Where I work, some patients come into the lab every day to get their blood work done or get their medication. It's stabilized where the doctor wants it to be. Then we get a print-out and show the doctor, who decides if they want to change the dose (Alberta).

We do meds for long-term care facilities or retirement homes. They're controlled dose packaging. We have some of our homes take care of their warfarin protocols on their own. And we have our own warfarin protocols as well, that we get permission from the physician to administer the protocol. We're adjusting doses when we get the INR readings of either Net Care or the lab... We're very involved in the adjustment of doses as well. We don't see our patients as much because most of the ones that are getting really controlled doses have some nursing care as well. We don't get out to the homes as much. We do have consultant practices who speak with the patients. It's more the nursing staff and the dietary departments (Alberta).

I'm with the family health team so our clinic is by doctor referral and they have to be patients of the doctors that are in the family health team. So currently we have about 60 doctors in the family health team and 30 more coming on shortly. Their first appointment is they try set up with the pharmacist but sometimes that doesn't work and they have to come in sooner, so the nurses in the clinic will do the first visit. We do the point of care with the machine and what we do is we give them a calendar and we write the dose in calendar and when they need to come back. So then they just bring that calendar every time they come. Because we get their INR right away and we do their doses. We also go right into their medical chart. Because we have access to all the doctors that are on the family health team and we have access to their charts, so we can go right in and can look up everything (Ontario).

In our practice, patients are referred to the clinic. So it could be referrals from physicians that are discharging them from hospital, or from community physicians. So then on their first appointment they come to the clinic, get a point of care INR test and meet with a physician for 10 to 20 minutes to gather their history. Each visit after that they have their INR testing done, then meet with the pharmacist (Ontario).

They only meet with the physician on the initial appointment. And then if any problems develop that the pharmacists don't feel like they can deal with. But in most cases the pharmacist feels like they can deal with it. We have point of care testing. We have lab technicians that take a finger prick and put it in the machine and it reads a value within 20 to 30 seconds so. We're able to dose it right away (Ontario).

We are strictly a pharmacist-run clinic. We have no nursing involvement whatsoever. We basically bring the patient in after we receive the physician's referral form which gives us a diagnosis. We check with the family physician to see if there are any other pertinent health issues that we should be concerned with. We bring the patient in for the initial hour and a half education component and bring them back in about three days to whatever lab facility they wish to go to. We have arrangements with all lab facilities within the city and then also the surrounding towns that they will fax or phone results if critical. At that point we'll determine warfarin doses for the next

number of days and we do phone follow-up with patients. So an initial one on one and then subsequent to that we do phone follow-up. If there are other issues we'll bring them back to hospital and basically go through further education or answer questions (Ontario).

By referral because we do work under community pharmacy setting but it's in a medical building so we do have a number of family doctors that do use our clinic, but a lot of our referrals do come from the cardiologists or people who are being discharged from hospital because either the family physician isn't available or they don't have one, whatever it is (Ontario).

One of the real challenges for us is the fact that none of this is funded by any government program so the strips are quite expensive. We use point of care and consequently the patients have to pay to participate in the clinic. So far it's been as I say, we have very committed patients and it's quite interesting to see why they do use our clinic. But they do. We do hold them at some occasion as well where it's appropriate (Ontario).

The only other thing I might mention is because we are in this particular medical clinic we do have access to the INR and it becomes very important for us to have that information because a lot of patients really don't know what their medical conditions are all about. We find that extremely useful. Plus we enter the results right into the patient's record for the physician to see as well as whatever we're doing in terms of dosing (Ontario).

We have a physician who has agreed to be our medical director. So if there is any patient where we need a medical opinion specific to the warfarin or the therapy than we can contact him. As far as nurses, because it's point of care it's very simple, and we do have technicians who can assist us with drawing samples where necessary. Other than that it's strictly pharmacists (Ontario).

Right now, physicians are struggling. There's no way physicians have time to ever teach. They are juggling the INR. They cut it by way over 10% or they'll increase it by too high and the INR will take weeks before it settles down again. Ideally, it would be nice if we could really look at who's the best person to deal with warfarin properly. I would think the pharmacist should rise up to it (Alberta).

Warfarin is being managed by pharmacists, nurses, physicians, and practitioners, and if there's three or four on the same patient, you're going to get messes. You're going to mess up. I think she's right. It needs to be accountable to one person. Physicians were historically the ones dosing and setting up INRs and now they have too much on their plate. So they head out to the warfarin clinics (Alberta).

Decision-making Support Tools

We're using Pharma-file out of Quebec. It's a support system, so basically for warfarin. We can put the dose right in and calculate how much we're changing it in percentage. We can also do a printout of the pills for the patient. So if they have two different doses we actually give a printout in colour of what doses they take every day. So that does it right through Pharma-file (Ontario).

We use Pharma-file as well. They do have two in their program — two mg groups. You know, there's a lot of clinical decision-making that goes into dosing warfarin (Ontario).

We don't. We just rely on clinical judgment (Ontario).

We don't have a computer system. We do have a protocol set but we don't necessarily follow it. There's sort of a mathematical way you can do it but we don't often do that, we just use more clinical judgement (Ontario).

We look at the CHADS guidelines, which I hear they are coming out with a new one in January (Ontario).

Providing Warfarin Education

First visit and every time they come in basically because they don't get everything at first. And in the calendar we give them it has information in it as well. It's just the size of a chequebook and has the information all about warfarin and about food interactions and stuff like that (Ontario).

We've come up with a very comprehensive guide to taking warfarin including list of foods with the high Vitamin K and number of micrograms of that type of food so it gives you a very clear idea of how much of something they can consume. On top of which we recommend they have at least 100 mg of Vitamin K daily in their diet. And we found a lot of patients wouldn't touch anything that looked green, so we found it quite helpful. As I said it's very comprehensive. It gives a patient something to refer to if it's three in the morning (Ontario).

We do face-to face but we do supply a written material for them as well. We put together a booklet with basically the same type of information. A calendar we prepared so it gives them a place to record their dose and their next INR. It's too bad that sites do not have the capability to share the information we have put together because it sounds like we have all tried to reinvent the same wheel when a lot of us have put a lot of time and effort into it and anybody that wants to use this information is more than happy to have it (Ontario).

It's ongoing every time they come into the clinic; we ask them how they're doing, ask if they have any questions and they often ask questions. Like if their INR is high, why is it going high? We do give them a calendar that does have warfarin information in the front, we tell them to refer to that and not the information sheet they get from their pharmacy because we found that there's a lot of misinformation in the pharmacy handout sheet (Ontario).

I think the best way to manage warfarin therapy is to do a lot of good teaching with the patient so they are aware of what the drug does. They have to have the commitment to doing the INRs. They have to be at low risk for bleeding so you have to do patient history to figure that out. I have some patients that manage their own INRs and the ability to take home that responsibility. They do great. The lab will give them their INRs with permission from their physician and they just manage their dosing and they just seem to sail along very well. In some ways, I think that works the best. A lot of patients aren't appropriate for that because their family doctor isn't there or hasn't seen their INR. I think a lot of good teaching and awareness of effects (Alberta).

Teaching helps them understand what warfarin is. It's working against the Vitamin K. It's all about balancing. What INR means? The reason why? Warfarin takes up to five days before you know what the full effect is. All of these teachings help the patient have comfort (Alberta).

We try to use education as much as possible. We will reinforce the importance of making sure they are compliant not only to their medication taking, but also to their

INR draws. We have used everything from one-on-one education, to having somebody else talk to them as far as one of our other staff. We will have the family come in, we will see if we can work with the family to make it easier to a point of, I guess you could call it threatening, basically, that if compliance is going to continue to be an issue and it is nothing more than an issue of non-compliance by the patient themselves, then we tell them that these are the consequences that you are going to face as far as the possibility of increased percentage and we may have to discharge you from our clinic. And refer you back to our family physician. A lot of times that seems to work for the really non-compliant patients, so those are kind of the ways we approach it (Ontario).

Whether Resources Suffice for Optimal Warfarin Management

Every time you go to give a Coumadin dose, you need someone to co-sign with you. And when you're running around trying to get everything done it makes it really difficult to find someone (Alberta).

If there was enough staff there would be no issue (Alberta).

We talked to the branch doctor, who has no idea about his patients and they have to go through the chart and look through what they have to order (Alberta).

Our major resource is humans. Staffing is always an issue so trying to find adequate staff. Having the resources to be able to hire those staff members (Ontario).

We have to limit the number of patients that we can actually accept into the clinic. We have run into issues where we have had to hold the number of patients we were able to manage based on vacancies. We had a number of physicians that were ready to go to the media to make sure that adequate funding was put into the clinics that we'd be able to have a bit of a buffer (Ontario).

For us, because we are in the community and we don't have funding sources, the strips are very expensive and I think this is an issue for certain patients, they just can't afford the service (Ontario).

It would be nice for us to go into the community. Right now we aren't able to do that. Because we belong to the family health team unfortunately we can only service the people who are with the family health team. So that's kind of hard. It's hard when some of our patients end up going into nursing homes, so they can't come into our clinic. Those are the patients that it's really hard to draw blood [from] and it would be nice if we could go in there and do the point of care clinic for them. As well as people that have surgery or can't make it into the clinic or are sick, unfortunately those patients, if they can't make it in, we have to get a lab to go in and they draw it and it costs 30 bucks for that. We are free. They don't pay for our service. The patient has to pay for it if they can't make it into us and they can't make it into a regular lab, so that's what they have to do. To have a community, if we were able to go out, I think we need more staffing and more funding. We're funded through the government, but that would be something we'd like to be able to do — more outreach (Ontario).

One of our limitations is that our clinic is only open a half day once a week. Only Thursday morning, so that can be somewhat inconvenient for people who are working. So it would be nice if we had funding to have maybe an evening clinic or a late afternoon clinic to accommodate more people. Another limitation we have is that we're still using old-fashioned cards for each patient. We're not computerized at all. It's just written on a card so if that card gets lost or misplaced we've completely lost

the records; there's no computerized records. We have the hospital files of the patient but none of their INRs are linked to that and none of our information is linked to that. So if they're seeing other physicians in the hospital, none of their INR results will be recorded in the computer system (Ontario).

Where I practise now, yes, but not when I was practising in retail. It depends on who your employer is and what your ratio is to free up your time from this dispensing... That's the biggest downfall to retail. If you're in a fill-and-bill type environment, you're slinging those pills out and it's like "Go, go, go!" A lot of pharmacists just don't have the time. Even if they had a simple procedure where the INR would pop up magically, and they had a nomogram they could follow, they'd still need the time to sit and think about it. It's a real problem. Retail is struggling with regulated technicians. If retail pharmacy jumps on board with it, it certainly would free up time for pharmacists to have more responsibilities (Alberta).

Technicians are on call on the weekends and have designated hours where they get called in on nights. A majority of our blood work is drawn on Mondays and Fridays. Well, if you get an abnormal INR result back on Fridays, a doctor will have to come in and have to reorder on Saturday. Normally, they wouldn't come in unless they're called in (Alberta).

We have to make it viable. We can't operate at a loss. The patients we have certainly are willing to pay that. It's unfortunate. One woman we saw this afternoon had to be a home visit because she had a leg amputation. So that type of patient, they're very concerned about their warfarin levels and they're willing to pay, but it's not easy for them. So there should be some mechanism to make the process a little easier. The argument could be made, is it cheaper to pay for that strip versus having her admitted into an ER facility because of a bleed or a stroke (Ontario).

Defining A Well-managed Patient

They haven't had any events (Alberta).

They're usually the kind of person that is compliant with their health care, like diet and taking their medications. One that has stabilized for a few months, only has to go in for blood work once a month, and tries to stay on a fairly regular diet. They are patients who know their dose and are cautious. They are aware of what to look for and when to go in for blood work (Ontario).

When they start up with the anticoagulation clinic there is a letter of consent that they sign as part of documentation. In that letter of consent they agree to attend their appointment and all of the compliance issues. That's part of their consent letter and it's stated there as well that if it's not working out for them that they're not being compliant they'd be referred back. We have only had one case like that (Ontario).

Defining Patients Who Are Difficult to Manage

Patients with dementia (Alberta).

I deal with patients with chronic heart problems and a lot of them are quite elderly. I had a man who seemed very lucid and together and always said he was doing this and that. He'd come in and I would check on him and he didn't have his INRs done and he went into a complete crisis with dementia and had a really high INR result and nobody could get ahold of him. That's very scary (Alberta).

Our hospital is quite close to a reserve that doesn't always have transportation to get to the hospital. Therefore if they can't get to the hospital they can't get their INR or their medication (Alberta).

Someone who still drinks alcohol and goes on binges is also a huge risk (Alberta).

It's not very expensive, but some people still can't afford it (Alberta).

We try to determine why they're having difficulties. We provide education talk about the consequences and identify why there is a problem. Sometimes it could be they can't afford the medications or they just cannot remember to take it. So then we'll work with them. We also have free supply available for some patients that are non-compliant. There are still some that are a problem. Some people are just not motivated to take their medication. Our clinic assistant will call people who are late for their testing and encourage them to come back to make sure they realize they are late and encourage them to come back to make sure there are no issues (Ontario).

We do the same thing. We call them. First we make sure they're not in hospital — we check their chart. We call them about a week or so after if they miss their visit. We call them twice and then we send the message to the family doctor and then the doctor will look at that. We do have some patients that will come whenever they want. It could be three months between visits and they come in and then they're therapeutic so they don't see why they need to change, so we educate them and let them know (Ontario).

We have some patients that just seem to forget a dose. So we do fill dosettes as well. We have them come in weekly if they need to, to just keep a closer eye on them to make sure they're taking the right dose. We really try and keep our patients just to one strength of warfarin if we can because we don't want them to get mixed up with the different strengths (Ontario).

We do a consistent dose as well if we can and we also don't like it when we have to split the pills. We do try to work with the pills the patients have but unfortunately it doesn't work all the time. And you have to try to work around it but for some patients we try to get the families involved if there's a problem and the patients themselves, because of cognitive abilities or what, can't manage it (Ontario).

Adequate Trial Period

My setting is geriatrics. It really depends on the client's quality of life and the family. Do we want to treat Mom as aggressively as we did or do we let her go naturally? After discussions of the risks with the physician, we may keep it going slower, lower, and lower, and then just stop (Alberta).

You try until they tell you not to. If they still want to try we're also being paid to be there. Even if they keep forgetting to take it, if they keep wanting to try, it's our job to be there. Unless it's dangerous for the patient (Alberta).

For us it would be on a case-by-case basis. We have carried patients for a number of months based on the best interest for that patient, some of them based on their lifestyle, their inability to get to labs. We have a number of oil workers out in the boonies and they're not always able to get in the exact time their therapy should be and we've carried them for a while. Others are very young and their lifestyle, they think they're invincible. We will work with them as long as we think we can. I guess when you get to a point of absolute frustration that's when we say it's enough. We

also have them sign a patient responsibility form and we use that as a basis to discharge them from our clinic (Ontario).

I guess it depends on how erratic they really are. There are patients that are difficult to control but they'll be in range for two or three visits and then go out of range. There are usually good reasons for why that's happening so you try to work with it and tweak it as you go along, so the answer to that is that you just need to see them more frequently (Ontario).

We do a sort of case by case. Right now we have a patient who's 99 on warfarin, she's only a two score and one of them is because her age. We kind of look at that because, for some reason, we don't know what's going on but we can't seem to get her INR down. In the past week, she's had 0.5 mg and her INR was 3.1. We've slowly been holding doses and she's not coming down. Finally we decided to speak with the family physician and they put her on a low dose Aspirin. So in situations like that we look at where their score is and their compliance and their risk of bleeding and in the best interest of the patient we look at other options. For her, she's just on the Aspirin until they can figure out what is going on. And we explain to her the risks of that. As well as patients who drink quite a bit. We look at their risk of falling and stuff like that. We've had patients who have fallen and bled and we look at their risk and they're just not a good candidate for warfarin in that situation (Ontario).

We mainly go on a case-by-case basis as well. We have had a couple of cases where we have given the patient a low dose of Vitamin K on a daily basis to try and stabilize their INR. It hasn't been all that successful. We've also tried — especially for younger patients — for them to have their own machine at home to check it themselves. It depends on their financial situation. It works for some patients and not for others. Some can't afford it. So sometimes that helps, especially for younger patients. They don't have to come into the clinic as often. They check their INR and call it in and they know how to dose it. They might only come in once every three months (Ontario).

Relative Merits of the New Anticoagulants

If used properly, the lack of lab requirements, the point of testing or having to go in for blood draws, especially if they're in rural sites and have to travel into labs (Ontario).

Relative Limitations of the New Anticoagulants

It's a little too much hype, truthfully. It's probably a great product. People are excited about not having to get INRs. They don't want to deal with all these interactions. You have to slow down just a little bit. This drug was approved amazingly fast through every regulatory body. I think faster than a lot of people would say is rational. It's a major thing. It seems very strange to rush through the process for a drug that is potentially one of the more dangerous on the market. It's not really stable. Why do the US and Canada have different guidelines? It's not as clear as it should be. You can't modify the pill in any way. There are a few things about how exciting it is, but I think everyone needs to chill a little bit (Alberta).

One other thing that we've found is that it's twice a day. Some of our patients find it hard enough to remember once a day (Ontario).
Also they want to know what their INR is. There is no test for that. They don't monitor that like that. So they just say how do I know where I am? And I think that's the advantage of going to a point of care clinic you're so involved in their health and now they don't have that (Ontario).

I think one of the minuses is that no one is checking up on them, so if they're taking dabigatran twice a day you kind of question what their compliance will be (Ontario).

Another concern that we've heard is that I guess they're in a foil package so the pill itself can't be in a blister pack. So that's one concern with patients (Ontario)

Also, the issue of pretty much one dose for people of all weights and all sizes. You really don't know if it's going to work the same for someone whose 150 kg vs. 40 kg. A lot of variability there and we really don't know (Alberta).

They're saying 150 mg is superior to warfarin, yet the 110 people over the age of 70 so that is comparable to warfarin. So you look at those people and think, what's the point of changing everything when you're going to something they say isn't necessarily superior to warfarin? (Ontario).

I think one other issue is that there are patients who are well controlled for whom there doesn't seem to be any reason. There's also the patient that is in range so rather than raising the warfarin dose and increasing bleeding risks, physicians would then consider a product like dabigatran. There are patients who will refuse to take warfarin and there are physicians who are reluctant to prescribe warfarin. So I am hoping that there will be a few more patients who should be anticoagulated and are not because there are a number of different issues. Because some of these are reluctant to take that type of agent, perhaps some of the newer agents will capture some of that population (Ontario).

Newer Anticoagulants for Patients Who Experience Stroke or Bleeding on Warfarin

I'm recommending for someone to go on it. The person was already on warfarin and stroke within the therapeutic range at 2.6. He was being put on. He was on top of it. He's quite well. Everything is going good for him. He's quite young — in his seventies. In his case, that was what we recommended (Alberta).

I think that certainly you have to look for the hemorrhagic risk and see which way to go with that (Ontario)

I guess it would be dependent on the control of that patient. Each patient is going to be slightly different, if they were consistent within the therapeutic range then I would consider. If we were having problems with the patients and they were outside the therapeutic range then I would have to look specifically at that patient then discuss with the physician first (Ontario).

I would keep them on warfarin. A lot of times it is easier to control a bleed than it is a clot (Ontario).

And you can reverse the warfarin quickly if you need to (Ontario).

You're able to manoeuvre that way with warfarin and less with dabigatran. Dabigatran only has the one dose. If you do have a bleed there's nothing you can really do. With the warfarin the Vitamin K will help out. Dabigatran you're shooting blind you really don't know what you're doing. At least with warfarin you have the INR that you can base your decisions on (Ontario).

We've done with some people, say we have a young girl who has factor 5 so she has clotting problems, so she is on warfarin but her menstrual cycles are very heavy so we've lowered her dose a little. Lower their dose and we've done that with other

patients who are on a higher risk of bleeding, we try and keep them on lower therapeutic. So we try and work with that (Ontario).

Preferred Sources for Information

We attended the conference in Hamilton and in Boston. As well as new information that comes out it's really helpful the pharmacists are usually the first to get the information and pass it along. We have INR meetings every two months and everything new we research and discuss it (Ontario).

I like the Internet: Clotconnect and Anticoagulation forums. Because of all the new agents there's a lot with Medscape and so on where they're doing various reviews. A lot would come from that source (Ontario).

Conferences would be my primary [source] but unfortunately haven't been to many in a long time. So the Internet would probably be my most utilized source of information (Ontario).

Also, specialists that I know, I would run things by with them (Ontario).

A lot of clinical trials. We have a pretty good relationship with a lot of the drug reps from different companies so they will let us know about their new products and any trials that are going on (Ontario).

Thoughts on Self-testing

We have a number of patients who have gotten monitors for themselves because they travel or are away for six months or whatever (Ontario).

We have some physicians who have been quite worried about it because they're afraid they're going to overtest. We have some patients who come in monthly to see us but they've tested themselves twice a week and adjust their warfarin accordingly. We don't want them to test it that frequently and they end up changing their dose. We'd rather them just do it on a weekly basis and just call us and let us know. But even if they're range is two to three and they're 3.1, sometimes they'll change their dose. And it could be just where they are that day. We'd rather just see the whole picture. So you have some people that you just worry that they're going to change things and worry so much about it (Ontario).

Cost impact is probably going to be a negative impact to them because they don't pay for their lab services in our province anyhow. The only cost they have for us is the actual cost of the drug. Warfarin being a lot cheaper than dabigatran is (Alberta).

No reversal agents is probably one of my major concerns (Ontario).

APPENDIX E: QUOTATIONS FROM PATIENTS

Reason for Warfarin Therapy

What prompted me to go on warfarin is that I had a round of atrial fibrillation at the general hospital and the doctor at that time took me in and left me on monitors for eight hours and then he said I had a virus. So I went home for about a year and got another one and I went to the Heart Institute. I was referred there by a resident. So I saw a doctor who put me on warfarin and I go to the clinic there now for INR monitoring every month. If something happens like stress or whatever and the INR goes off, I have to go back more often so I have had to go back twice in the last two weeks. To stay between the target of 2-3 is really hard. I like to stay at the low end of 2 actually because my complexion goes weird and I will get kind of bubbles in my face just from too much being at the surface so I try and keep my INR at 2 or 2.5. (Ontario).

I started having some weird feelings in my chest and a really fast heartbeat and I went to the emergency room a couple of times and they always just dismissed it because I was so young. Then I went back one time and the doctor actually gave me warfarin through an IV and that helped and then I went back and saw a cardiologist who did an electro-cardiogram (Ontario).

I had a fast heartbeat too and at first I went to the emergency room and they did the same thing. They told me it was panic attacks. I had to go home with the monitor for 24 hours to see how regular my heart was. Because it would come in a bout and it would be really bad and then it would go. They started figuring out what it could be and started me on the warfarin. So at least they figured out what it was (Ontario).

For me, I had been going through a little bit of a hard time. My grandmother was sick and I was taking care of her so they thought that it was a panic attack when I went in. So I let it go for another two or three months and then I found out I was pregnant and it just kept happening so I went back and they did scans and ended up crossing other things out and came to a conclusion. So I couldn't start warfarin because I was pregnant so we were trying to find other medicines that were safe and then the second trimester, they put me on it. They thought that the health risks that I was going through would be better if I was on the warfarin (Ontario).

They gave it to me because my heart was going crazy. I was born with a heart defect of a hole in my heart. They sewed it up when I was a kid and they thought that I would be fine. I was fine and then about four years ago, I was walking and my heart just started racing and I went to the emergency room and they said that I was just having a panic attack. So they kept dismissing it and finally I told my doctor to get me a specialist... So I went to Toronto and I saw the cardiologist and he took one look at me and sent me to get a pacemaker. So I got that and then I went on warfarin because occasionally my heart still goes wonky. I don't take as much as I used to now because I have the pacemaker which kicks in and helps a lot. They are weaning me off of it slowly (Ontario).

I had a stroke. I was in the hospital. I couldn't talk or write for 18 days. It was like being trapped in my own body. I couldn't communicate. The decision to start was made in the hospital. I was seeing a specialist. Basically, my blood pressure was too high. They wanted to control my heart (Alberta).

Feelings About Warfarin Therapy

I would rather not take it. I would rather be healthy — it would be nice not to have to take it (Ontario).

Aside from the fact that it's rat poison, it works. It's hard to get over that sometimes. It does drift through your mind (Ontario).

When I was reading up on it, they said it's used in grass killing stuff too, I was thinking oh my god! I'm taking something that is going to kill me! (Ontario).

You do wonder, if it kills rats, they are pretty sturdy creatures (Ontario).

I wouldn't dare not take it (Ontario).

I know that if I don't take it, something could happen and I could keel over on the floor so I know that I don't have a choice. Either I take it or I croak (Ontario).

Basically, they figured from birth I had a heart defect that made me predisposed to having strokes. They explained numerous things at the time, but I couldn't communicate back to them. I got put on this medication to control my condition and it turned out great. I have no complications. I'm 95% back in terms of communication skills (Alberta).

If I am late taking it, especially lately, I have noticed that my heart starts racing. Your heart starts galloping and that's when you really have to sit and get normalized. Lately what I have been doing is just sitting down, taking an hour all by myself and really breathe. It's still dangerous, I recognize that. My INRs are ok but I think I am actually getting worse (Ontario).

It's not convenient but it's part of life. For me, it's kind of hard to answer the question because I'm used to it now. At the beginning, I wasn't happy but at the same time, I was happy because they knew what was wrong so I was getting help. Now it's just like a routine — you take your pills and go where you have to go. You just know how you feel and communicate with the doctor (Ontario).

For me, I found that it was hard sometimes having to constantly go back and forth to Toronto but it's well managed now (Ontario).

It works for me (Alberta).

I want to do things with my kids who are teenagers now but sometimes you are just worried about yourself. I really worry that I can't keep up with them and be as much fun as you want to be. Like we are going to volunteer at Country Hoedown and I'm wondering if I can stand up for five hours and take care of kids (Ontario).

When I got my warfarin, it dramatically improved my energy level (Ontario).

I would recommend it because I remember what it was like to be not on it. You always want to help someone else that you care about so you know that if they are going through the same thing, you always want to suggest something (Ontario).

I would recommend it because a lot of people that have the same condition are on Aspirin or baby Aspirin and people have actually passed out or their heart has stopped briefly. I know someone on baby Aspirin that should be on warfarin (Ontario).

It depends on how serious it is. If it was identical to me, then I would recommend it but if it is a little different, then I would tell them to talk their doctor. I would say yes if the question was identical to me but I would tell them to make sure they know that they get monitored properly and communicate with your doctor (Ontario).

I would because it's worked for me. I haven't had an issue with it at all (Alberta).

Drawbacks to Warfarin Therapy

I find it makes me tired. It wears me out after a while. After I take it, I'm just exhausted. I take 10 mgs a day (Ontario).

I'm not taking that much but I find that when I do take it, I will be on the computer and I know I have things to do but I just can't find the energy (Ontario).

It's worse when you have a kid because that is 24/7. You can't take an hour out (Ontario).

You are tired and you want something like a coffee to pick you up but you are scared and you don't want to counteract it (Ontario).

I find if I eat certain things, like if it has a lot of sugar in it or a high acid level like orange juice, I start shaking. This happens with fast foods too (Ontario).

My doctor told me not to drink a lot of cranberry juice or eat cranberries and other acidic fruits (Ontario).

The disadvantages are just going in and getting tested. It's a pain in the butt. I put it off sometimes. The wait at the clinic is incredibly long. I've waited up to two hours. That throws off your whole day. I found if I go late in the day it's a little bit quieter and they're more inclined to get you done (Alberta).

Frequency of Changes to Dosage

The past couple of weeks, it has changed a lot but other than that, it was stable (Ontario).

They are lowering mine because the pacemaker is helping so they are slowly weaning me off of it. I will be on it forever but they are taking my dose down a lot (Ontario).

Mine is very stable. We found a dose that is good and I am responding to it so I am happier than I was before (Ontario).

During the pregnancy and after, there was a bit of fluctuation but the last six months have been good (Ontario).

Probably about three times a year and in that year span it'll change up or down. It's not a huge amount, but it does happen from time to time. Usually, I have a step up or down and then the next time it's back to normal. After they change the dose, I have to be retested a week or 10 days later (Alberta).

How Therapy Is Monitored

I have a specialist here in Ottawa now which just switched over about a week and a half ago but before that, I was still with Toronto. Every three to three and a half weeks, I would go down and do blood work and see my heart specialist. I just got

transferred back. The reason why I had to go to Toronto was because they kept saying well you are so young and even though I had previous heart problems, they would just say oh you are fixed, you're fine. And when your heart is beating out of your chest and you can't breathe, you are not "fine." So my doctor finally had enough. Thankfully I have a really good family physician who transferred me to Toronto to get the help. I went to Toronto Women's Sunnybrook Hospital and they were great there. It has been my specialist who has been adjusting my dose — my family doctor doesn't deal with that (Ontario).

During my pregnancy, it was done at the general hospital with those doctors that were on there and there was a specialist there as well. But that was mostly just through my pregnancy and delivery. A couple of months after, my family doctor then took on my case again and said that my INRs were great and my blood work was good. She is on top of it. I usually go every two to three weeks to a lab and my family doctor adjusts the medication (Ontario).

My family doctor is the one who monitors it but she sends me once in a while to see the specialist. She gives me the requisition and I go to a private lab and she calls me after if there is anything I need to know. It has been pretty level so the dose I have been taking is pretty good. Before, I would get the racing and I would have to lay down and breathe. I get tested about once a month when it is pretty level. We have talked about going in more when it fluctuates (Ontario).

I also go to my family doctor and I go every two months to see my specialist at the hospital. At the beginning, it was pretty level but now some months it's higher and some months it's lower so I have been going more to see how it's doing. Once they see that it's too high or it's too low, they change my medication and have me come back in a week or two (Ontario).

I go in and get my testing done. Then the doctor calls me back within a couple days. I'll have a message on my machine telling me to stay at this level or change. Like stay on the nine mg or change to eight mg and we'll retest in 10 days. I don't have to go back to see the doctor. My family doctor dictates how much has to be changed: higher or lower (Alberta).

The anticoagulation clinic at the [name of hospital] is pretty good. I usually go about once a month but I have been twice in the last two weeks because the level was low — it was around 1.4 because I had gotten a prescription for a respiratory infection and it thins your blood. The medication made me really sick so I had to go off of warfarin completely for three days (Ontario).

Effectiveness of Patient Education

For me when I take medication, I like to know everything. And sometimes when you ask questions of doctors, their answers are different from other doctors or things that you can read up online on the medications. They put me on it and then I wasn't sure if I was going to stay on it so they wanted to make sure that I really knew this drug and what it was going to do to me and how I would have to change my life around. My doctor is good at answering questions but you can't always get everything that you want out of the doctor. They just want to assure you that it's safe and nothing is going to happen but you know there are other risks. I knew that the benefit was greater than the risk. I read a lot online and that was the extent of my research but I read case studies and forums, etc (Ontario).

My doctor explained it to me and I was kind of worried and did some research online and was even more worried but she told me that I had a choice of whether I wanted to

go forward and it was most likely to help me. I was feeling terrible at the time and I always had to sleep on one side and the fear of not knowing was awful. Especially when I was in the ambulance a couple of times and they put the monitor on me and you hear them talking and saying they don't know why your heart is beating so fast. After I did get all of my questions answered, I just had to make the choice about whether or not to be scared. Any drug you take has a long list of side effects and risks. I did some reading online but people usually go online to complain so you read the bad experiences (Ontario).

In my case, what they did for me was they actually have little patient groups for certain things and we all got together with a practical nurse who sat down with us and gave us all of the information. She gave us about an hour of education on the drug and how it works and lots of handouts. Then they had a weekly follow up for about six weeks. You could come once a week and mention any problems if you had any. They had a group for all different ailments. It is a long waiting list. From the time I was first diagnosed, it took me about 9 to 10 weeks to get into the weekly groups but I got the first part right away. I found that really helped me to have that little bit of support (Ontario).

Probably in the initial information session they did, but I can't remember it. Initially, the wife was taking care of all my meds because they weren't sure if I was "there" because I couldn't communicate (Alberta).

Well the [name of hospital] doctor was very busy. I asked the nurse at the anticoagulation clinic twice before she sat down with me and gave me the full story and she was a remarkable nurse. She was just called away to do more important work. They are busy but sometimes they think that less information is more as long as you keep taking it out because they don't want to freak you out (Ontario).

We have been on it long enough that we know the ups and downs and how it affects us. As first you don't so you are more closely monitored (Ontario).

I think there is more that you can always know about something and it would be nice to not to have to take it but it is beneficial to me and I kind of got upset about how you want to do more things with your children and you can't and it's hard because I'm so young and I wish that wasn't the case. But I try and fight it and warfarin does work for me and keeps me on a steady level where I can enjoy my life more (Ontario).

Understanding of Blood-testing Requirement

Yes, to make sure that my levels are not too high or not too low (Ontario).

When the blood is thinner, it is easier on your heart and puts less stress on your body. If the levels are too low though, it is harder on your heart (Ontario).

My doctor told me that we don't want your levels too high or too low and be at risk for those complications. Once you get the hang of it, it levels out (Ontario).

My doctor told me to watch on the weeks the levels are too high, to watch for blood in my urine or if I get a small cut and it won't stop bleeding. Just to watch for that stuff and make sure that I'm monitoring myself and nothing bad happens to me on the weeks that my levels are too high (Ontario).

I know that my doctor just wants to make sure that the levels are OK and that the medication is in my system and it's working because she says there is no point in giving medication if it's not going to work or it's not in your system (Ontario).

Basically, they want to check my level of my warfarin. They want to make sure it's not too high or too low. If it's too high, I don't talk well. I have to be very careful. I'm a mechanic and a diabetic. If I cut myself all of a sudden, it's not clotting well. Sometimes I can't stop the bleeding. Maybe, if I've changed my diet and it's affected it, I'll go in and get tested because it's time anyway. I can't remember if my dosages were ever too low. I started at 12 and so I'm down to 8 (Alberta).

Thoughts on Newer Anticoagulants

Give it to me now! (Ontario).

I think that no blood tests would be good but I like the fact that there are less eating restrictions. If they gave you the same outcome of what warfarin does with less other restrictions then definitely (Ontario).

I would ask why (Ontario).

Yeah, I would be nervous too. I like to know (Ontario).

I like to be monitored and know what is going on (Ontario).

I'd be interested, but is it going to work as well for me? How often is it going to be checked? I'm wondering if anyone will be monitoring this for me. I'm used to testing and that for me is comfort. If I was a drinker I might be more interested, but because I'm not I don't care. I like to be tested rather than not. It goes back to comfort (Alberta).

I want to know why they are not monitoring me, what is in this drug that causes no need to be monitored, what is the difference between this and warfarin. It is a whole different drug so I would want to know my research and know why (Ontario).

I would want to compare the facts between warfarin and this other drug. If I don't need the blood tests and there is no dietary restrictions, then it is a different drug so how is that going to help me? It's not the same as warfarin so where is the magical ingredient in this new pill. I would want a comparison because I'm very cautious with new drugs I'm taking (Ontario).

I would feel insecure and I would want some testing done to make sure your blood is OK. We have had our blood tested forever and we feel safe knowing (Ontario).

I would rather have my blood tested for a couple of months on the new one until it is proven that there is no change at all and then I would feel better about it. But I wouldn't like to do that without knowing because with warfarin, it is closely monitored and it makes me feel more secure. It's your heart — you don't want to play around with it (Ontario).

For me, having my blood drawn is a safety net — I know whether it's high or low and I know if it's working (Ontario).

Thoughts on Self-testing

I have heard about that. The machine costs $5,000 so it's expensive but if you want to travel, in the past there was no way to get your blood tested. I would get it (Ontario).

The doctor is putting a lot of their faith and trust onto you so it's kind of like they are

putting their job onto you. So if you make a mistake, you are not the expert. You would kind of be afraid to do that yourself because you have all of these experts doing it and now you are doing it (Ontario).

Machines don't always work all the time. That would be a concern there (Ontario).

I think it would be good as long as it's a cooperative thing where the doctor is working with you. If you are a little low, rather than adjusting the medication yourself, which for me, I would never do because that would just be plain dangerous, I would like to have an option where I could call my doctor and let them know what the home test did and ask what they recommend. Doing it on my own, I would be very scared. If I suggested wrong, it would land me in emergency or worse (Ontario).

I wouldn't want to do it on my own. I like to see the doctors and talk to them. Even small things you say, for you it's small and to them they know. Even if it was something where you could call up your doctor or if it was online and you submit and they tell you but I prefer to talk to my doctor. As long as there was somebody handy to help me monitor, I would maybe like it a bit. But I would rather leave it in the hands of the professional (Ontario).

A lot of medical companies probably wouldn't cover it. I know for me, my pacemaker was hard to get covered so I can only imagine. It is coming out of your pocket (Ontario).

I would be ok as long as they were adjusting the medication (Ontario).

I would be about 80% sure. I would always prefer the top hand come from the doctor to make the judgement call. If the pharmacist makes the judgment call, that's ok but he hasn't had as much experience as the doctor so I would just prefer the doctor be doing it (Ontario).

If the pharmacists seem like they care, then I would be more trusting. Doctors are busy so it is hard for them to be as open and concerned as a pharmacist. I need that trust. If I had trust in what they are telling me, I would be more open to monitoring it but I do like to talk to the doctor (Ontario).

I find they change the nurses often because the really good nurses go off to higher jobs. We have had nurses with poor language skills and I had less faith in them. The nurses are varied in care. You need to feel that they care and are committed to what they are doing and not just a job they are rotating through on the way to something else (Ontario).

I actually changed pharmacists for that reason because I had a pharmacist that wouldn't explain anything to me and just gave me my medication. Like you, I was taking cold medicine just over the counter and asked the pharmacist, mentioned what I was on, she never said anything and I took it and two days later I was in my doctor's office with a 105 degree temperature. From that point forward, I was very cautious with pharmacists. If you don't have the trust in them, it's a battle. There is nothing worse than having to battle for your health care (Ontario).